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FROM THE EDITOR-IN-CHIEF'S DESK

The Sweet Anticipation of 24th National Congress of Surgery 2026

Preparing for a scientific congress always carries a unique kind of excitement, a productive restlessness that accompanies the gathering of new ideas, shared experiences, and friends across the scientific community. As we approach the 24th National Surgical Congress, the biggest event of the Turkish Surgical Society (https://uck2026.org), to be held 8-12 April 2026, this sense of anticipation is felt more strongly than ever.

As the "Secretary" of the Congress, it is my privilege to witness the remarkable collective effort behind this meeting. For the past 1.5 years, together with the organizing committee, we have been working diligently to ensure that the 24th National Surgical Congress will be an exceptional and memorable scientific meeting. This congress will bring together surgeons, researchers, and trainees from across Türkiye and beyond to exchange knowledge, debate new evidence, and reflect on the evolving landscape of surgical science.

I am particularly delighted by the participation of Anders Bergenfelz, who served as Editor of the British Journal of Surgery from 2010 to 2016 and currently chairs the Executive Committee. His presence at the congress is both an honor and a source of great excitement for me. I eagerly look forward to his forthcoming presentation. Furthermore, the editorial team of the Turkish Journal of Surgery will be present at the congress. The TurkJSurg Newbies—an initiative by surgical residents with a shared enthusiasm for academic surgery—will also contribute to the scientific program. A special session has been organized to present, for the first time, the results of two nationwide studies conducted by residents. Another particularly exciting aspect of our congress is the participation of a large team from the UEMS Section of Surgery and the European Board of Surgery, who will join us as invited speakers and partners in a joint meeting during the congress. I believe that discussing accreditation and training in surgery with the UEMS team and listening to their experience and perspectives will be highly valuable for the surgical community.

As the congress approaches, my excitement is hard to contain. I feel both proud to be part of this organization and truly enthusiastic about the opportunity to share experiences and ideas with my colleagues. I would also like to announce that the congress abstracts will be published in our journal as a "special issue" after the congress.

With my warmest regards to all our readers….

Prof. M. Umit UGURLU
TurkJSurg Editor-in-Chief

REVIEW
Turk J Surg 2026;42(1):1-12

Idiopathic granulomatous mastitis: A narrative review based on the Turkish consensus classification

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ABSTRACT

Idiopathic granulomatous mastitis (IGM) is a rare, heterogeneous inflammatory breast disease lacking a universally accepted classification or a standardized management pathway. To provide a comprehensive narrative synthesis of the current literature on IGM and to contextualize the Turkish IGM clinical classification and treatment algorithm in relation to existing global evidence. A narrative literature review was conducted using PubMed, Scopus, Web of Science, and Google Scholar (2000-2025). Clinical, radiological, pathological, and therapeutic studies were examined. Previously published Turkish national consensus studies based on a modified Delphi process were incorporated into the synthesis. IGM remains diagnostically challenging due to its diverse presentations and overlap with malignancy. Existing global classification attempts are inconsistent and lack clinical practicality. The Turkish IGM clinical classification addresses these gaps by integrating lesion size, skin involvement, pregnancy/lactation categories, and extramammary findings. Treatment outcomes demonstrate the high efficacy of topical and intralesional steroids, the selective use of systemic immunosuppression, and the limited indications for surgery. The Turkish IGM classification and its associated treatment algorithm provide a practical, standardized framework that aligns with current evidence and may reduce overtreatment and mismanagement in IGM.

Keywords: Breast diseases, idiopathic granulomatous mastitis, clinical classification, treatment algorithm, consensus study, steroid therapy, immunosuppressive agents, differential diagnosis

INTRODUCTION

Idiopathic granulomatous mastitis (IGM) is a rare, benign, yet locally aggressive chronic inflammatory disease of breast tissue. First described by Kessler and Wolloch in 1972, IGM was defined as a "lesion that clinically mimics carcinoma" (1). It is most frequently observed in women of reproductive age and typically emerges in the postpartum period, particularly after breastfeeding. Since the disease can mimic both breast cancer and mastitis clinically and radiologically, the diagnosis is often challenging. Differential diagnosis is therefore crucial, as misdiagnosis may lead to unnecessary surgical interventions. Clinical manifestations observed during the course of the disease—such as breast skin erythema, painful masses, ulceration, and fistula formation—are frequently mistaken for infection or malignancy (2).

The primary method for diagnosing IGM is histopathological evaluation of tissue specimens obtained via core needle biopsy (3). It is essential to distinguish granulomatous inflammation confined to breast tissue from systemic diseases, such as tuberculosis, sarcoidosis, and bacterial or fungal infections. Typical histopathological features include non-caseating granulomas, epithelioid histiocytes, multinucleated giant cells, and neutrophilic infiltration. However, the cornerstone of diagnosis remains the exclusion of other potential granulomatous causes. In this context, IGM is essentially considered a diagnosis of exclusion (2,4).

Since its first description, efforts have been directed toward understanding the disease characteristics, clinical course, and etiopathogenesis. The efficacy of different therapeutic protocols has been debated and compared. Ongoing controversies

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regarding the etiopathogenesis of the disease, together with attempts to evaluate treatment protocols across patients with varying disease severity, have hindered the establishment of a definitive treatment strategy (5).

Currently, therapeutic approaches for IGM include observation, systemic corticosteroid therapy, intralesional steroid injections (ILSs), immunosuppressive agents, antibiotics, and surgical excision (6). In recent years, consensus reports have been developed to define clinical features, symptoms, and disease severity to better characterize the disease and to enable comparability of treatment outcomes (7). Based on these definitions, consensus statements have also been published to standardize treatment algorithms according to disease severity (8).

In this narrative review, the clinical features, radiological findings, current insights into disease pathogenesis, existing classification systems, and therapeutic approaches for IGM are synthesized in light of contemporary literature. Additionally, the Turkish national consensus studies—based on a modified Delphi methodology—are contextualized within the global evidence to highlight their clinical relevance and potential contribution to standardizing disease management. This review aims to provide clinicians with an updated and comprehensive overview of the diagnostic challenges, classification frameworks, and treatment strategies associated with IGM.

MATERIAL and METHODS

This comprehensive narrative review aimed to synthesize current knowledge on the etiopathogenesis, clinical presentation, diagnostic challenges, classification systems, and treatment approaches of IGM. Accordingly, the goal was not to perform a systematic data extraction, but rather to integrate multidisciplinary evidence and to contextualize the Turkish IGM clinical classification within the broader international literature.

Literature Search Strategy

A non-systematic literature search was performed in PubMed/MEDLINE, Scopus, Web of Science, and Google Scholar. The search covered articles published between 2000 and August 2025. Foundational articles published before 2000 were also considered when identified in reference lists. Search terms included:

"IGM", "granulomatous lobular mastitis", "cystic neutrophilic granulomatous mastitis", "classification", "treatment", "steroid therapy", "immunosuppression", "Delphi", "consensus".

Reference lists of key publications and consensus reports were also screened to identify additional relevant literature.

Inclusion Scope

The review included clinical studies, reviews, classification proposals, consensus reports, imaging studies, and treatment-focused publications. Case reports were used selectively when they contributed important context (e.g., rare presentations or diagnostic challenges).

Consensus Methodology Integration

The Turkish IGM clinical classification and treatment algorithm was derived from previously published Turkish national consensus studies, which were developed using a modified Delphi process (7,8). To enhance transparency, a subsection detailing the number of participants, voting rounds, consensus thresholds, and methodological framework has been added. These consensus outputs were then integrated into the narrative synthesis to discuss their relevance and position in the global literature.

Synthesis Approach

Given the heterogeneity of studies and the conceptual nature of IGM classifications, data were synthesized descriptively rather than meta-analytically. Findings were organized thematically under etiopathogenesis, pathology, diagnosis, radiology, existing classification systems, treatment modalities, and the consensus-based clinical classification (Turkish model).

Etiology

The etiopathogenesis of IGM has not yet been fully elucidated. The designation "idiopathic" underscores the fact that its underlying cause remains uncertain. However, recent clinical and molecular studies have identified several factors that may play a role in the development of the disease. Among these, hormonal, infectious, autoimmune, and genetic mechanisms have been highlighted (2,6,9). It is thought that these multiple factors may act either concurrently or sequentially.

Hormonal influences are among the most frequently discussed aspects of IGM etiology. The predominance of IGM in women of reproductive age and in the postpartum period suggests that changes in prolactin and estrogen levels may trigger an inflammatory response in breast tissue (10). Galactostasis (milk stasis) is considered one of the strongest predisposing factors for IGM (11). Epithelial damage during the postpartum period and breastfeeding-related trauma may contribute to autoimmune inflammatory responses by triggering them.

Among infectious agents, *Corynebacterium kroppenstedtii* has received the most attention (12). Isolation of this bacterium from some cultures and its association with lobulocentric granulomatous inflammation suggest that infectious triggers may act as initiators or perpetuators of the disease. However, culture results are negative in most IGM cases, indicating that infection may not always be the primary cause. In countries where tuberculosis is endemic, some cases diagnosed as IGM may actually represent misclassified tuberculous mastitis (TM).

Autoimmune mechanisms are considered central to the etiopathogenesis of IGM and constitute a major etiological factor. Elevated levels of certain immunological parameters associated with the disease, the presence of granulomas, and immune cell infiltration, particularly a T-cell–mediated immune response, all support this hypothesis (13). The clinical efficacy of immunosuppressive therapies (e.g., methotrexate, azathioprine) in some patients further reinforces this concept (14). The coexistence of IGM with rheumatologic diseases further supports a link with systemic autoimmunity (14).

Although less extensively studied, genetic and environmental factors may also contribute, as suggested by geographic clustering and familial cases (15). The higher frequency of IGM reported in certain regions, including Türkiye, suggests potential roles for environmental triggers and genetic susceptibility.

IGM is a multifactorial disease. Hormonal imbalances, abnormal inflammatory responses to microorganisms, autoimmunity, and genetic or environmental influences may all contribute to its development. The varying predominance of these factors in different patients likely accounts for the clinical heterogeneity of the disease.

Pathology and Diagnosis

The histopathological findings in IGM are non-specific. The presence of granulomas with acute or chronic inflammation in the breast parenchyma is sufficient for a diagnosis of granulomatous mastitis; however, this represents a descriptive diagnosis and does not define the etiology. Therefore, when granulomatous mastitis is identified in biopsy specimens, histopathological features that may provide etiopathological clues should be evaluated in correlation with the clinical findings. Given the wide range of potential causes of granulomatous mastitis, diagnostic uncertainty may negatively affect treatment success (16). Specifically regarding IGM, the patient's age group (reproductive period and history of pregnancy/lactation) and the region of the breast predominantly affected by the lesion (breast parenchyma outside the nipple-areola complex) are helpful in the differential diagnosis (17). The presence or absence of necrosis is important in distinguishing IGM from tuberculosis. Rare infectious causes such as fungal infections (e.g., histoplasmosis), should be carefully excluded (18).

To ensure that the inflammatory process does not mask an underlying neoplastic condition, malignancy should, if necessary, be excluded using immunohistochemical studies (cytokeratin staining) (19). Other granulomatous conditions, including sarcoidosis, vasculitis, and foreign body reactions, should also be considered. As a diagnosis of exclusion, IGM is often made on the basis of compatible clinical and histopathological findings. Typically, inflammation with epithelioid granulomas is centered on terminal duct lobular units, forming a ductocentric pattern.

At this stage, immunoglobulin (Ig)G4 immunohistochemistry may be performed on plasma cells. If positive results are obtained, serum IgG4 levels can be measured to evaluate possible IgG4-related disease (20).

Cystic neutrophilic granulomatous mastitis is considered a special histopathological subtype of IGM. In complicated cases with abscess formation, bacteria from skin flora may contribute to disease development.

Chief among these are *Corynebacterium* species, which, due to their lipophilic nature, have been shown to form small cystic spaces that are surrounded by neutrophils within the breast parenchyma containing adipose tissue (21). These organisms can be identified using appropriate histochemical stains and should be actively sought, although the possibility of contamination should also be considered.

Gram-stain and Grocott's methenamine silver stain can also be used to distinguish these bacteria (22). Because cystic foci may not be present in all biopsy sections, serial sectioning may be required. The demonstration of bacteria in biopsy specimens may assist clinicians in selecting appropriate antibiotic therapy and determining treatment duration.

Differential Diagnosis

IGM may present with painful, firm breast masses, abscess formation, skin erythema and edema, and fistula formation. Its clinical and radiological features are often non-specific and may mimic benign conditions such as fibrocystic changes or abscesses as well as malignancy. Therefore, before diagnosing IGM, all other possible causes of granulomatous inflammation, especially breast carcinoma, must be excluded (23).

Bacterial Mastitis

IGM may be confused with infectious processes such as puerperal (lactation-related) mastitis or breast abscess, particularly in lactating women. Acute bacterial mastitis is characterized by fever, severe pain, and systemic signs of infection and usually responds rapidly to antibiotics. In contrast, IGM has a more chronic course and does not respond to standard antibiotic therapy since lesions are usually sterile and no significant pathogens are identified (24).

Radiologically, infectious mastitis and abscess, as well as IGM may appear as irregularly marginated, heterogeneous breast masses. On ultrasound, complex cystic or abscess-like lesions may be observed in both conditions.

Therefore, when clinical and imaging findings are similar, needle aspiration or incision and drainage should be performed for culture. The presence of pyogenic bacteria

should be investigated by culture and Gram-staining to exclude bacterial mastitis. In most IGM lesions, bacterial growth is not detected, although secondary infection may occasionally occur. In such cases, antibiotics may be required, but routine antibiotic therapy alone does not cure IGM.

Given recent reports increasingly identifying *Corynebacterium* species in IGM specimens, this bacterial infection should also be excluded.

TM

Among infectious causes of granulomatous mastitis, TM is one of the most important and should be considered, especially in endemic regions or among at-risk populations. TM may present with a slowly enlarging firm breast mass, skin retraction or ulceration, chronic sinus tracts, and axillary lymphadenopathy. Radiologically, TM may mimic inflammatory breast cancer, presenting as irregular masses or multiloculated abscesses, and axillary lymphadenopathy is more common.

Ziehl-Neelsen staining should be performed on tissue samples to detect acid-fast *Bacilli*, and culture or polymerase chain reaction (PCR) should be performed to exclude mycobacterial infection (25). Misdiagnosis may lead to inappropriate corticosteroid use or unnecessary antituberculous therapy.

Therefore, in every case of granulomatous mastitis, screening for tuberculosis with purified protein derivative or interferon gamma release assay tests, chest X-ray, and mycobacterial culture/PCR is mandatory.

Fungal and Other Infectious Agents

Although fungal infections of the breast are rare, in immunosuppressed individuals or in endemic areas, fungi that cause histoplasmosis or blastomycosis can cause granulomatous mastitis. Other reported infectious causes include *Cryptococcus* species, *Nocardia*, and *Actinomyces*. *Bartonella henselae* infection (cat-scratch disease) may rarely present as granulomatous inflammation of the breast accompanied by axillary lymphadenopathy. Special stains [periodic acid Schiff, Grocott (or Gomori) methenamine silver] and cultures should be performed when clinically indicated.

Ultimately, even if the clinical picture suggests IGM, a diagnosis of "idiopathic" IGM should not be made without first demonstrating the absence of a specific infectious agent by comprehensive microbiological investigation.

Sarcoidosis

Sarcoidosis may rarely involve the breast, creating a clinical picture almost indistinguishable from IGM. Non-caseating granulomas also form in sarcoidosis, and histologically, these are very similar to those of IGM. Sarcoidosis generally involves multiple systems, particularly the lungs and mediastinal lymph nodes.

Therefore, if sarcoidosis is suspected when granulomatous mastitis is detected in the breast, chest radiography or computed tomography, measurement of serum angiotensin converting enzyme levels, and examination for dermatologic or ocular findings should be performed. Cases usually present with concurrent systemic findings. If breast involvement by sarcoidosis is confirmed, treatment may differ from that for IGM (e.g., longer-term, low-dose steroids, additional immunosuppressive therapy).

Wegener's Granulomatosis and Other Vasculitic Diseases

Granulomatosis with polyangiitis (Wegener's granulomatosis) is a necrotizing granulomatous disease that primarily affects the lungs and kidneys, but may rarely involve the breast and mimic IGM (26). Systemic findings and c-ANCA positivity support the diagnosis. This should especially be considered in patients with a known history of vasculitis.

Other chronic inflammatory breast conditions should also be considered in the differential diagnosis of IGM (27). Periductal mastitis, particularly in women who smoke, is a chronic breast disease that develops due to obstruction and inflammation of periareolar milk ducts. Clinically, periductal mastitis may resemble subareolar IGM. However, in periductal mastitis, histology shows dense infiltration of plasma cells and lymphocytes around dilated ducts rather than granuloma formation, with no caseation.

Foreign body reactions can also cause granulomatous inflammation in the breast tissue. For example, granulomatous reactions with multinucleated giant cells may occur around silicone implants or injected materials (paraffin, biopolymers, etc.). These situations are usually clarified by the patient's history. Crohn's disease may rarely present as granulomatous mastitis, an extraintestinal manifestation.

Therefore, in patients with a history of autoimmune disease, granulomas in the breast should be considered potentially indicative of systemic disease.

Differential Diagnosis with Breast Cancer

One of the most critical differential diagnoses of IGM is breast cancer. Granulomatous mastitis can mimic inflammatory breast cancer in both clinical presentation and imaging findings. Patients may present with breast induration, erythema, and edema. Similarly, inflammatory breast cancer presents with painless breast induration, erythema, and a peau d'orange appearance. Nipple retraction and axillary lymphadenopathy may occur in both conditions.

In cases of granulomatous mastitis, mammography may reveal areas of increased density with irregular margins or

asymmetry, and ultrasonography (USG) may show spiculated, heterogeneous, hypoechoic lesions resembling malignant masses. Indeed, many IGM cases are initially reported as BI-RADS 4-5 based on imaging (28). Therefore, tissue sampling is mandatory for a definitive diagnosis.

In summary, IGM is a breast disease that is difficult to diagnose and can mimic many other conditions. Differential diagnosis must always include infectious mastitis (particularly tuberculosis), malignancies, sarcoidosis, and other rare granulomatous disorders. A definitive diagnosis is based on demonstration of granulomatous inflammation on biopsy and exclusion of other causes; multidisciplinary evaluation is essential to guide appropriate treatment and avoid unnecessary interventions.

Radiological Evaluation

Although radiological imaging plays an important role in the diagnostic process of the disease, the findings often resemble malignancy. Therefore, careful interpretation of radiological findings and histopathological confirmation are crucial for accurate diagnosis (29).

The imaging modalities and their findings can be briefly summarized as follows:

1. USG: Is the most frequently used first-line imaging modality for IGM. Typical findings include heterogeneous, hypoechoic, irregularly marginated masses (Figure 1A), tubular extensions, abscesses or fistula tracts (Figures 1B-D), and perilesional hyperemia on Doppler USG. However, USG may be insufficient to exclude malignancy, and biopsy is often required.

2. Mammography: Because IGM often occurs in young women, mammographic evaluation is of limited utility. Possible findings include an asymmetric increase in density, parenchymal distortion, and skin thickening, whereas microcalcifications are usually absent. This absence may serve as a clue in the differential diagnosis favoring malignancy (Figure 2).

3. Magnetic resonance imaging (MRI): Is particularly useful for detecting diffuse involvement, complicated abscesses, and fistula tracts. Findings include hypointense signals on T1-weighted images, hyperintense signals on T2-weighted images, peripheral rim enhancement of abscesses, and diffuse edema and skin thickening (Figure 3). MRI is preferred in cases of suspected malignancy and in patients with marked edema to identify the most appropriate biopsy site.

Radiological differential diagnosis: Granulomatous mastitis may mimic breast abscess, idiopathic mastitis, TM, and, particularly, inflammatory breast cancer. The absence of microcalcifications, the presence of fistula or abscess formation, and the patient's age can serve as useful diagnostic clues. However, a definitive diagnosis must be established by histopathological examination. For this reason, a tru-cut biopsy under USG guidance is generally required.

In conclusion, radiological evaluation plays a critical role in the diagnostic process of IGM but is not sufficient on its own. While USG is the first-line modality, it should be supplemented with mammography and MRI when necessary (30).

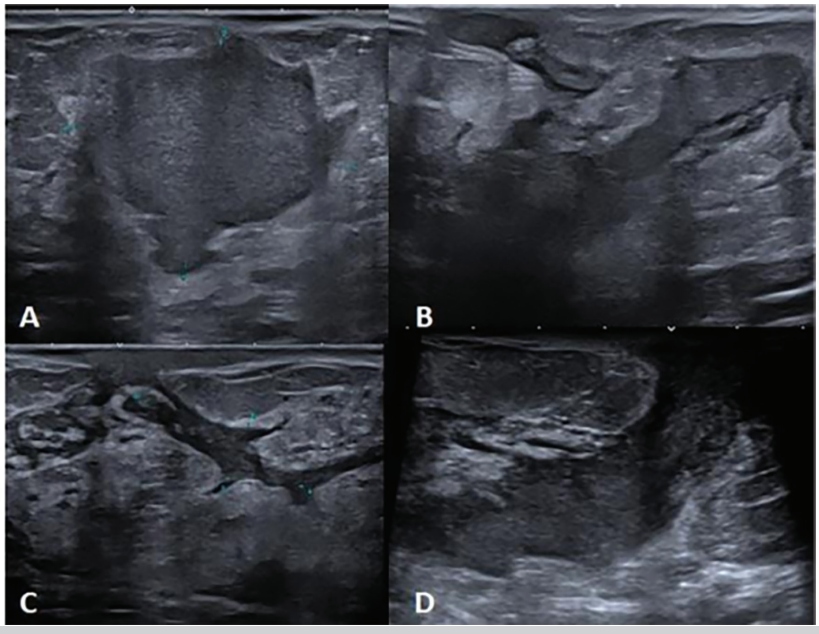

Figure 1. Sonographic findings of IGM; irregularly marginated mass (A), abscess and fistulous tracts extending to the skin (B-D).
IGM: Idiopathic granulomatous mastitis

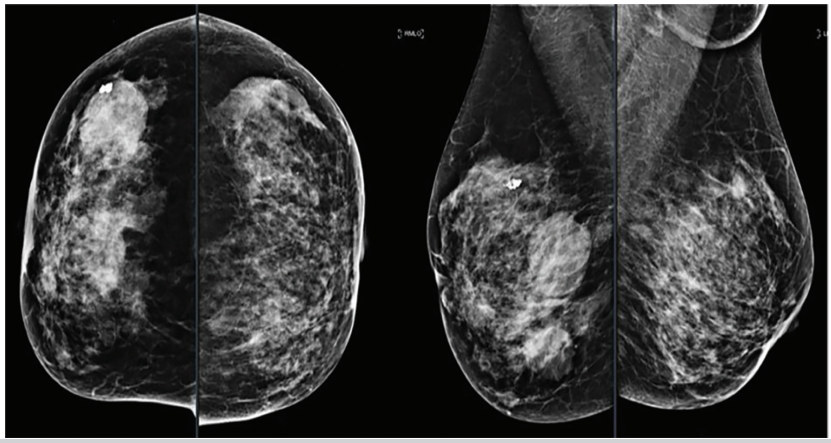

Figure 2. Mammography of a patient diagnosed with IGM in the right breast showed skin thickening in the right periareolar region, a mass-like opacity consistent with an abscess in the upper outer quadrant, and increased density in the right retroareolar area compared with the left breast.

IGM: Idiopathic granulomatous mastitis

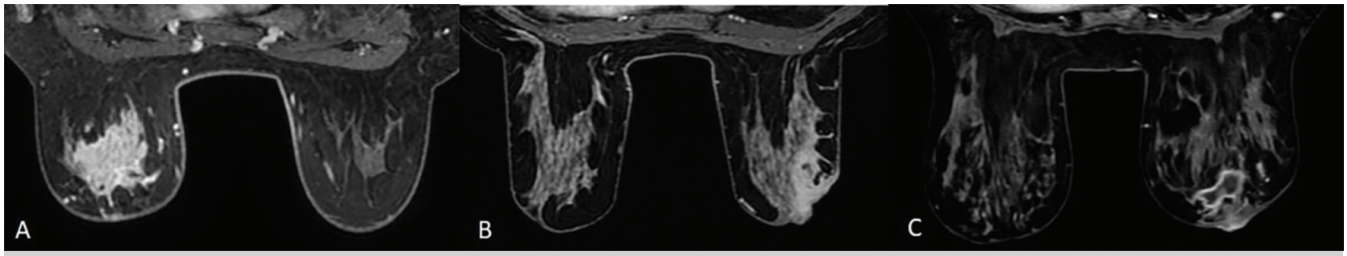

Figure 3. MRI findings in different patients with IGM; diffuse non-mass enhancement (A), segmental non-mass enhancement extending toward the nipple (B), and rim-shaped enhancement (C).

IGM: Idiopathic granulomatous mastitis, MRI: Magnetic resonance imaging

Definitions and Classifications

The disease exhibits highly heterogeneous clinical presentations. In addition, clinical assessment presents practical difficulties, and the literature lacks uniform terminology for describing the disease. A common terminology for defining this disease was first established (7). This is extremely valuable, as new definitions have provided some standardization in the literature. Common terminology for breast disease is presented in Table 1 (7).

Such a level of uniformity in definitions had not been achieved previously. This terminological framework can facilitate communication among clinicians, aid understanding of the work conducted in IGM, and promote homogeneity across studies. In this regard, this list of definitions fills an important gap.

There is a need for a widely accepted classification system for this disease. Because of its heterogeneous clinical presentation, classification is difficult. Several studies have been published in this context, but no universally accepted classification is currently used. An IGM clinical classification should include a physical examination and imaging methods. Such a classification should be concise, comprehensive, and simple. Furthermore, it should provide a common academic language, offer prognostic information, and guide treatment. In this regard, several studies have been published. The first classification in Türkiye was published by Irkorucu (31). However, this study was complex and not widely accepted. Scoring systems have

Table 1. Common terminological definitions for IGM

Terminology	Definitions
Breast lesion	Presence of mass, erythema, collection, or abscess in the breast
Sinus	Presence of discharge or fistula
Ulcer	Wounds or erosions in the breast
Healing	Resolution of the lesion confirmed by physical examination and imaging (MG, US, magnetic resonance imaging)
Recurrence	Reappearance of a previously healed lesion, independent of time
Resistance	Resistance to systemic treatment modalities and evidence of progression
Multifocality	Presence of more than one lesion in the breast
Bilaterality	Presence of lesions in both breasts
Additional findings	Presence of extra-mammary systemic findings (e.g., arthritis, erythema nodosum)

IGM: Idiopathic granulomatous mastitis, US: Ultrasound, MG: Mammography.

also been developed to describe the complex nature of the disease. In a study published by Yılmaz et al. (32), patients' clinical presentations were scored by assigning points to specific clinical findings; the total score was used to determine an IGM disease score. However, due to the complexity and subjectivity of the calculations, this system has not been widely adopted (32).

A classification proposal from Iran, by Kaviani et al. (33), has also been published. This study suggested a classification of IGM into mild, moderate, and severe categories on a pathophysiological basis that includes inflammatory processes. However, the classification did not address cutaneous findings or extramammary lesions. In addition, abscess and sinus formation were evaluated together. This classification has not been widely used. Another study by Yaghan et al. (34) classified IGM lesions in the breast into types A, B, C, and D. However, extramammary lesions were not described, and lesion size was not specified in some parts of the classification. Due to these limitations, this system has not gained wide acceptance in the literature.

Researchers from China published an international consensus on IGM (6). In this study, most clinical conditions, including lobular granulomatous mastitis, were assessed collectively. However, no clear explanation was provided for lesions smaller than 5 cm. Furthermore, recurrent cases were not included; systemic findings were excluded from the classification; and pregnant and lactating patients were not considered. All these efforts demonstrate that, although attempts have been made to classify IGM, no system has yet been standardized for widespread use.

The Turkish IGM clinical classification has been accepted by consensus and meets the need for clinical classification in this field. This clinical classification was developed based on findings from physical examination and radiological imaging (7). It was accepted with a 94% approval rate via digital voting by experienced breast surgeons and radiologists in Türkiye. The Turkish IGM clinical classification identified in this study is shown in Table 2 (7).

Table 2. Idiopathic granulomatous mastitis-Turkish clinical classification

Type	Definition
Type 1	Lesion ≤2 cm and/or collection
Type 2	Findings of type 2 accompanied by skin inflammation or lesion >2 cm and/or collection
Type 3	Lesion accompanied by skin ulceration and/or presence of systemic findings of any type (e.g., erythema nodosum, polyarthritis, etc.) and/or multiple foci
Type 4	Recurrent and/or treatment-resistant cases
Pregnancy/lactation	Patients who are pregnant or breastfeeding

In the Turkish IGM clinical classification, breast lesions are divided into four categories. In addition, it includes pregnant or lactating patients. This original study addresses many of the shortcomings of previously published classifications. The Turkish clinical classification has been considered comprehensive, memorable, and practical, and suitable for use in outpatient settings. Moreover, it provides guidance for treatment. We believe it will contribute to establishing a common language in the literature.

Treatment

Observation ± drainage: IGM is a self-limiting disease, with up to 50% of patients achieving complete remission within 2-24 months without treatment (35). Studies have shown that milder cases with small lesions (1-2 cm) often resolve spontaneously under close observation (36). Therefore, in asymptomatic Type 1 disease and mild Type 2 disease, watchful waiting is a reasonable approach after excluding other causes. In cases of abscess formation, superficial abscesses should be drained with as small an incision as possible, as delayed wound healing is common in this condition. Alternatively, large-core needle aspiration can be used. Deep abscesses are best managed with ultrasound-guided percutaneous drainage to expedite healing.

Topical steroids were first identified as an effective treatment option for IGM in 2011 (37). Retrospective studies reported high remission rates (100%) and acceptable recurrence rates (10.7-18.2%) with the use of 0.125% prednisolone ointment (38). Later, the first prospective randomized study in this field demonstrated that topical steroids were as efficacious as systemic therapies [complete response (CR), 83% vs. 85%], although treatment duration was longer (mean 5.5 vs. 3 months), as previously shown by Çetin et al. (5). Importantly, topical steroids can be safely used in pregnant and breastfeeding women, making them a valuable first-line treatment option for these special populations. In addition, they are recommended as monotherapy for Type 2 disease or in combination with ILSs (8). In recurrent disease, as well as in Type 3 and Type 4 cases where systemic therapy is either contraindicated or refused by the patient, topical steroids may be a suitable alternative. For optimal efficacy, an ointment formulation must be used to ensure deep dermal penetration. Moreover, to prevent the medication from being absorbed by clothing—which would significantly reduce its local effect—a barrier layer (such as plastic wrap) should be applied over the treated area. The absence of systemic side effects and improved patient compliance further support their roles as important therapeutic options for appropriately selected patients.

Intraparenchymal/ILS: Has demonstrated promising efficacy in the treatment of IGM, with favorable outcomes reported in Turkish studies (39,40). A 2020 study reported CR in 90% and partial response in 10% of treatment-naïve patients, with no reported side effects, following administration of depo-medrol

(40 mg/mL methylprednisolone acetate) over 2-7 sessions at 2-3-week intervals (9). Similarly, a 2021 study found that ILS combined with topical steroids was superior to systemic steroids, yielding higher CR rates (93.5% vs. 71.9%) and significantly lower recurrence rates (8.7% vs. 46.9%) (8). Given its high efficacy, low recurrence rates, and favorable safety profile, ILS is recommended as a first-line treatment for patients with Type 2 disease and as an alternative for patients with Type 1 disease and for pregnant and breastfeeding patients (8). In selected resistant or recurrent cases, the combination of ILS and oral steroids may provide greater therapeutic benefit.

Surgical treatment was the primary option for managing IGM before 1980. After a 1980 study demonstrated the efficacy of steroids, the frequency of surgical interventions decreased and medical approaches became more prominent. In recent years, some breast surgeons have reconsidered surgical treatment as a primary option. Nevertheless, limited surgical excisions have been associated with recurrence rates as high as 23-50%, thereby restricting the effectiveness of surgery (41). Achieving complete remission often requires repeated surgical interventions, complicating patient management. On the other hand, comprehensive resections utilizing oncoplastic techniques or mastectomy combined with simultaneous reconstruction have been shown to reduce recurrence rates to as low as 5% (42). While rapid recovery and low recurrence rates offer advantages over prolonged conservative treatments, these approaches are associated with higher costs and loss of lactational function in women of reproductive age. Furthermore, such aggressive interventions may be considered excessive for a benign, self-limiting disease. Therefore, in selected cases of IGM, surgical treatment should be considered in combination with other therapeutic options.

Antibiotics: Although they can be administered based on bacterial culture results and drug-susceptibility testing, their role in treating IGM is limited. Consequently, antibiotics are not considered a first-line treatment option for IGM. In clinical practice, many patients at tertiary care centers in Türkiye report receiving antibiotic therapy prior to referral, often without significant improvement (32,40). This lack of response further underscores the limited utility of antibiotics in managing IGM and highlights the importance of accurate diagnosis and appropriate treatment strategies tailored to the idiopathic nature of the disease.

Supportive therapies: Supportive therapies play a crucial role in the management of IGM, particularly in enhancing patient comfort, minimizing local inflammation, and preventing secondary complications. Non-steroidal anti-inflammatory drugs can be used to control pain and reduce local inflammatory symptoms, especially during acute flares. Warm compresses may aid symptom relief by improving local circulation and facilitating drainage (42). In patients presenting with ulceration or secondary infection, topical or systemic antibiotics may be considered based on clinical judgment and microbiological findings. Additionally, appropriate breast support using a well-fitted bra and guidance on local hygiene practices are essential to improving quality of life during treatment. There are also studies reporting benefits of hyperbaric oxygen therapy and ozone therapy as supportive treatments (43,44).

Systemic steroid therapy: Oral steroids are a treatment option for IGM and are considered ideal for initial therapy; they are the most frequently used systemic agents. In cases planned for surgery, oral steroids may be used preoperatively to reduce lesion size and improve cosmesis, thereby reducing the extent of surgical intervention or eliminating the need for surgery (45). They provide rapid shrinkage of the mass and improvement in local inflammatory symptoms; however, in the chronic phase, thick-walled abscesses and fistulas may respond poorly to steroids, and healing may take 1-2 years (46). Their use is limited in pregnant, diabetic, or breastfeeding women, and long-term use may cause adverse effects such as weight gain, osteoporosis, delayed wound healing, glucose intolerance, diabetes mellitus, Cushingoid features, peptic ulcers, and acne (47). The first use of systemic steroids in IGM was reported 45 years ago by DeHertogh et al. (48), who suggested that high-dose steroids (60 mg/day) were more effective for recurrent or resistant cases and reported resolution of masses and closure of sinuses within three weeks.

Combination therapies with oral steroids have also been described. In the study by Koksal (45) recurrence rates were 9% with observation, 6.5% with antibiotics, 10.4% with surgery, 11.1% with steroids, and 0% with combined surgery and steroids. In cases of cutaneous rupture and severe local symptoms, combined steroid, antibiotic, and surgical treatments shortened recovery time and reduced recurrence. In one study, 200 patients with severe local symptoms and cutaneous rupture were given levofloxacin with steroids for 5 days; 156 underwent surgery and 44 continued steroid therapy. Wound healing time was 25 days in the surgical group, compared with 258 days in the non-surgical group. Recurrence rates were 5.1% in the surgical arm and 22.7% in the steroid-only group (48).

In resistant cases, such as bilateral IGM, steroid therapy is also associated with high recurrence rates. In one study, 5 of 10 patients with bilateral IGM (50%) experienced multiple relapses; 4 of these patients were treated with 0.5 mg/kg deltacortril (49). Cases with accompanying erythema nodosum also respond poorly to steroids. These patients often present with diffuse and bilateral disease, follow a more severe course, and have a worse prognosis. Çetin et al. (50) reported that 50% of their patients did not respond to steroid therapy and eventually required surgery.

In immunotherapy, surgical treatment is associated with high recurrence rates, and response to steroids is limited. Therefore, the addition of immunosuppressive agents, such as methotrexate (MTX) or azathioprine (AZA), may be an option to reduce the steroid dose and treat recurrences (49). After demonstrating a role for autoimmune mechanisms, Raj et al. (51) first used AZA in 2004 to treat a relapsed IGM patient and achieved a cure. The addition of AZA to steroid therapy may reduce the steroid dose and prevent recurrence (52). In a study by Senol et al. (53), 29.7% of patients required first-line conservative treatment, while 70.3% required second- or third-line immunosuppressive therapy. Among those who received immunosuppressives (n=355), corticosteroid monotherapy had the highest recurrence rate (28.8%). The addition of MTX reduced the recurrence rate to 19.8%, although this decrease was not statistically significant (p=0.143). AZA therapy significantly reduced recurrence, whether used alone (4.7%) or in combination with corticosteroids (9.1%) (p<0.005). Patients treated with the MTX and AZA combination had a recurrence rate of 4.8%. Overall, significant differences in recurrence rates were observed among treatment groups [χ^2 (4, n=352) =25.58, p<0.001]. Thus, AZA, whether used alone or with other immunosuppressants, was shown to be effective in reducing recurrence rates in IGM patients (52,53).

Konan et al. (54) also administered prednisolone at 40-60 mg/day, gradually tapering to a maintenance dose of 5-7.5 mg every other day for 1.5-2 years. To prevent steroid-associated side effects, 14 of the 15 patients received AZA at 2 mg/kg/day. At three months, at least a 50% reduction in mass was observed in 11 of 15 patients; complete remission was observed at 6 months. Two patients relapsed; overall, 71% achieved complete remission. They concluded that adding AZA to steroids allows rapid dose reduction and improves treatment success, and that surgery should be reserved for cases unresponsive to medical therapy or with relapsing disease (54).

MTX is the most commonly used immunosuppressant worldwide. It is used in IGM patients who are unresponsive to steroids or surgery or who relapse after steroids or surgery; it is also used to allow steroid dose reduction, to shorten treatment duration, or to prevent relapse while tapering or discontinuing steroids (55,56). No standard dose exists for IGM treatment; reports in the literature range from 7.5-25 mg/week for 8-52 weeks (55,56). Compared to surgery and steroids, MTX is associated with lower relapse rates and higher complete remission rates (70-80%). However, it is teratogenic and contraindicated in women who are pregnant, breastfeeding, or planning pregnancy (49,55,56).

Another study conducted by Haddad et al. (56) used MTX-based therapy as initial treatment, either as monotherapy or in combination with low-dose steroids, in 74% of patients. All achieved a CR. Although relapse occurred in 17.6% of patients during dose tapering, all relapsed cases improved with low-dose MTX (56). The largest single-center series of MTX monotherapy was reported from Türkiye. In this study, indications for MTX monotherapy included bilateral disease, fistula, resistance to other therapies, and extensive quadrant involvement. Sixty-four patients, including 56 resistant cases, were treated with oral MTX 15 mg/week for 6 months. In cases of relapse, the dose was increased to 20 mg/week, and treatment was continued for 1 year, with 10 mg of folic acid administered weekly. A CR was achieved in 52 of 64 patients (81.25%). Four patients were lost to follow-up. Eight patients achieved a CR at 1 year after dose escalation. Three patients (4.69%) switched to subcutaneous MTX (12.5-15 mg/week) due to nausea (49).

Treatment Algorithm According to the Turkish IGM Classification

Due to the incomplete understanding of the pathophysiology of the disease, there is considerable heterogeneity in its treatment. The management of IGM is guided by a combined assessment from pathology, breast surgery, and radiology (57). The multidisciplinary nature of diagnosing and treating this complex disease should not be overlooked. The most common treatment approaches include observation (± drainage), topical steroid applications, ILSs, systemic steroids, immunosuppressive agents, combination therapies, surgery, and supportive therapies. Clinicians and breast centers tend to use the treatments with which they are most familiar, based on their clinical experience. The reported success rates of these various treatments range between 65% and 94% (5,32,40,53).

In patients with IGM, treatment planning is based on each patient's clinical condition at the time of diagnosis. In the literature, treatment algorithms have been proposed, varying across countries and clinical settings. Kaviani et al. (33) proposed treatment recommendations based on the severity of inflammatory lesions in the breast. Although cited in some publications, this approach has not gained widespread adoption, even in its country of origin (Iran). In China, an international IGM consensus study, involving more than 80 experts, proposed treatment recommendations and an algorithm. However, this study included not only IGM, but also treatment algorithms for granulomatous mastitis with a defined etiology. Although considered a comprehensive effort, it has been described as complex and difficult to apply in outpatient settings (6).

The treatment algorithm for this disease should be simple, practical, comprehensive, applicable in outpatient settings, and effective in guiding therapy. In this regard, a treatment algorithm based on the Turkish IGM Classification has been published (8). This algorithm was developed through consensus, with the wide participation of experienced breast surgeons. The Turkish IGM treatment algorithm is shown in Figure 4 (8).

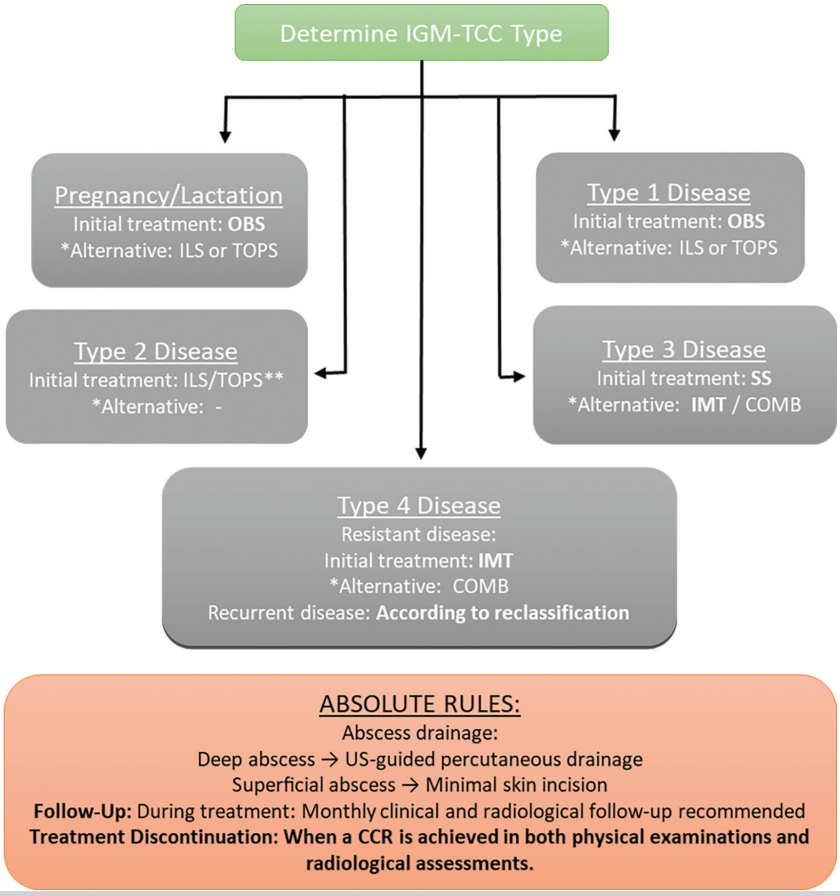

Figure 4. Treatment algorithm based on the Turkish IGM classification.

*: If required, the following treatments may be used as subsequent or adjunctive options to the initial therapy, **: Although the predefined consensus threshold was 80%, a high level of agreement within the 70-80% range supported recommending this option as a first-line treatment for Type 2 disease. Treatments reaching consensus are shown in bold.

OBS: Observation, IGM: Idiopathic granulomatous mastitis, ILS: Intralesional steroid, TOPS: Topical steroid, SS: Systemic steroids, IMT: Immunosuppressive therapy (e.g., methotrexate, azathioprine), COMB: Combination therapy-the use of multiple treatment modalities together (e.g., SS + SURG/IMT/TOPS/ILS; IMT + SURG); CCR: Complete clinical response

This published study presents the consensus-defined treatment recommendations and possible adjunctive therapies in detail. Observation and topical or local treatments are recommended for early-stage disease, while systemic therapies (steroids and immunosuppressive agents) are recommended for more advanced cases. In certain challenging, treatment-resistant cases, combination treatments, such as systemic therapy plus surgery or low-dose steroids plus low-dose immunotherapy, are recommended. Specific recommendations for pregnant and lactating patients are also included. According to this study, surgical treatment—contrary to the broader surgical literature on IGM—is considered only for a limited group of patients. For a benign and inflammatory disease, surgical options are recommended only after medical and interventional therapies have been exhausted. The high recurrence rates following surgical treatment should always be borne in mind.

In addition to outlining a structured treatment pathway, this consensus-based algorithm highlights several clinically relevant strengths. The comparative evaluation of different therapeutic modalities—including topical and intralesional steroids, systemic therapies, immunosuppressive agents, and surgery—supports practical decision-making in daily clinical practice. Furthermore, the integration of evidence derived from prospective studies and large Turkish patient cohorts enhances the reliability and applicability of the recommendations. Finally, the simplified, outpatient-oriented algorithm based on a national consensus classification represents a meaningful step toward standardization in a field traditionally characterized by therapeutic heterogeneity.

We believe that the treatment algorithm based on the Turkish IGM classification fills an important gap in this field and provides clinicians with a structured and practical approach to disease management.

Footnotes

Author Contributions

Surgical and Medical Practices- K.B.Y., G.E., M.A.; Concept - K.B.Y., M.V., M.A.; Design - K.B.Y., M.V., M.A.; Data Collection or Processing - K.Ç., G.E., Y.K.; Analysis or Interpretation - M.E., K.Ç., Y.K.; Literature Search - M.E., K.Ç., M.V.; Writing - M.E., G.E., Y.K.

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REVIEW
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Rare anatomical localizations of hydatid cysts (2020-2025): Narrative review of presentation, imaging, and management

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ABSTRACT

Hydatid disease, caused by *Echinococcus granulosus*, typically affects the liver and lungs. However, cyst development in rare anatomical sites presents unique diagnostic and therapeutic challenges. We conducted a narrative review using a structured search of PubMed, Scopus, and Google Scholar (first 200 records), with predefined eligibility criteria and dual-reviewer screening where applicable. Findings were synthesized narratively; numeric summaries reflect reporting frequency among included case-level reports rather than prevalence or comparative effectiveness. Seventeen studies (case reports/small series) were included. Among the included reports, the most commonly reported rare sites were the brain, bone, and heart. Imaging narratives most frequently supported magnetic resonance imaging triage for central nervous system/spine/cardiac disease and computed tomography for osseous/retroperitoneal involvement, while surgery was most often reported as the index treatment with context-dependent use of albendazole. Percentages in this review reflect the share of reports among included studies (i.e., reporting frequency), not population prevalence, incidence, or comparative effectiveness. Rare-site hydatid cysts require a high index of suspicion in endemic areas. Optimal outcomes are achieved through multidisciplinary evaluation, site-specific surgical planning, and tailored pharmacotherapy. Further research into minimally invasive techniques, molecular diagnostics, and vaccine development is warranted to improve diagnosis and long-term disease control.

Keywords: Albendazole therapy, diagnostic imaging, echinococcosis, extrahepatic involvement, general surgery, hydatid cyst, rare anatomical localization, narrative review

INTRODUCTION

Hydatid disease caused by *Echinococcus granulosus* predominantly involves the liver and lungs, but clinically meaningful presentations also occur at uncommon sites that can mimic neoplastic or inflammatory conditions (1,2). In this review, we systematically map reports published between January 2020 and March 2025, with the practical aim of summarizing site-specific presentations, imaging pitfalls, and management decision points that are most relevant to real-world multidisciplinary care (3). Rather than claiming an exhaustive synthesis, we focus on transparent methods and verifiable case-level details to support safer diagnostic and peri-operative choices across specialties.

Unusual localizations of hydatid cysts—such as the brain, spine, heart, bone, retroperitoneum, spleen, and musculature—are relatively rare but clinically important due to their non-specific presentations, diagnostic ambiguity, and increased risk of surgical complications (4,5). These atypical manifestations often mimic malignancies, abscesses, or congenital cysts, leading to delayed or inappropriate interventions (6). From a general surgery standpoint, such cases demand heightened suspicion and careful planning to minimize perioperative morbidity and recurrence risk. Recent literature has reported an increase in the detection of extrahepatic and extrapulmonary hydatid cysts, likely owing to advances in imaging technologies and improved clinical awareness (7). However, there remains a lack of consensus on the diagnostic and therapeutic approach to these rare presentations. While surgical excision remains the cornerstone of treatment, particularly in complicated or inaccessible locations, the roles of minimally invasive procedures and adjunctive antiparasitic therapy continue to evolve (8,9).

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The 2020–2025 window was selected a priori to reflect contemporary practice—including wider magnetic resonance imaging (MRI) availability, improved cardiac/central nervous system (CNS) imaging, and evolving minimally invasive and peri-operative strategies—while limiting historical heterogeneity. Because rare-site hydatid cysts are commonly co-managed, we explicitly adopt a multidisciplinary team frame throughout (radiology, general and specialty surgery, infectious diseases, neurosurgery/cardiothoracic as applicable). Our objective is therefore not to estimate prevalence or comparative effectiveness, but to provide verifiable, site-aware guidance—with study identifiers and DOIs—to help teams avoid hazardous pathways (e.g., inadvertent biopsy) and align around shared, pragmatic decisions.

MATERIAL and METHODS

Information Sources and Search Strategy

We performed a narrative review with a structured search (PubMed, Scopus, Google Scholar-first 200 records) covering January 1, 2020 to March 31, 2025, applying predefined inclusion/exclusion criteria and dual-reviewer screening with consensus resolution. Where helpful for transparency, we retained PRISMA-style reporting elements (search strings, selection flow), but we do not claim a protocol-registered systematic review. The full electronic strategies are provided below.

- PubMed (last searched March 31, 2025):

("hydatid cyst"[Title/Abstract] OR "cystic echinococcosis"[Title/Abstract] OR "Echinococcus granulosus"[Title/Abstract]) AND (brain OR cerebral OR spine OR spinal OR vertebral OR cardiac OR heart OR myocard* OR bone OR osseous OR pancreas OR pancreatic OR spleen OR splenic OR retroperitone* OR mediastin* OR breast OR muscle OR musculoskeletal OR renal OR kidney) AND (case OR "case report" OR series OR management OR surgery)

Filters: Humans, English, 2020/01/01–2025/03/31.

- Scopus (last searched March 31, 2025):

TITLE-ABS-KEY ("hydatid cyst" OR "cystic echinococcosis" OR "Echinococcus granulosus") AND TITLE-ABS-KEY (brain OR spine OR cardiac OR heart OR bone OR pancreas OR spleen OR retroperitone* OR mediastin* OR breast OR muscle OR musculoskeletal OR renal OR kidney) AND TITLE-ABS-KEY (case OR "case report" OR series OR management OR surgery) AND (LIMIT-TO (PUBYEAR, 2020–2025) AND LIMIT-TO (LANGUAGE, "English"))

- Google Scholar (last searched March 31, 2025):

"hydatid cyst" AND (brain OR spine OR cardiac OR bone OR pancreas OR spleen OR retroperitoneum OR mediastinum OR breast OR muscle OR renal) AND (case OR "case report" OR series OR management OR surgery).

First 200 records screened; backward citation tracking was performed from included articles.

We additionally hand-searched reference lists of eligible studies to identify missed reports (10). The study selection process is summarized in the PRISMA 2020 flow diagram (Figure 1).

Eligibility Criteria

We included peer-reviewed human reports published 2020-2025 that described primary hydatid cysts at uncommon, non-hepatic/non-pulmonary sites and provided clinical and/or imaging and/or management details. We excluded articles focused solely on hepatic or pulmonary disease, non-English or non-human studies, reviews without case-level data, and veterinary reports.

Study Selection

Two reviewers independently screened titles/abstracts, then assessed full texts against eligibility criteria. Disagreements were resolved by consensus. Reasons for exclusion at full-text stage were recorded (e.g., hepatic/pulmonary only; review without case-level data; non-English; non-human). We included 17 reports (case reports/small series). Within the included literature, the most frequently reported rare sites were brain, bone, and heart. Imaging descriptions most commonly supported MRI for CNS/spine/cardiac involvement and computed tomography (CT) for osseous/retroperitoneal disease, while initial management most often involved surgery with context-dependent albendazole. All quantitative summaries herein reflect reporting frequency within the included case-level literature and should not be interpreted as population prevalence, incidence, or comparative effectiveness (Table 1).

The search identified 537 records-523 through database searching and 14 from other sources. After removing 56 duplicates, 481 titles/abstracts were screened. Eighty-nin full texts were assessed for eligibility; 72 were excluded for the following reasons: not rare location (n=45), insufficient data (n=19), non-English (n=8). Seventeen studies were included in the narrative synthesis (with no quantitative synthesis/meta-analysis).

Data Collection and Items

Using a piloted extraction form, we captured: first author/year, patient demographics, anatomical site, presentation, imaging modalities/findings, management (surgery/percutaneous/medical), outcomes (recurrence/re-intervention/complications), and follow-up. Where available, DOI/PMID identifiers were recorded for verification.

Risk of Bias and Quality Appraisal

Given the case-report/series nature, methodological quality was appraised using the CARE checklist (case reports) and JBI Critical Appraisal Tool (case series) (28). We summarize study-

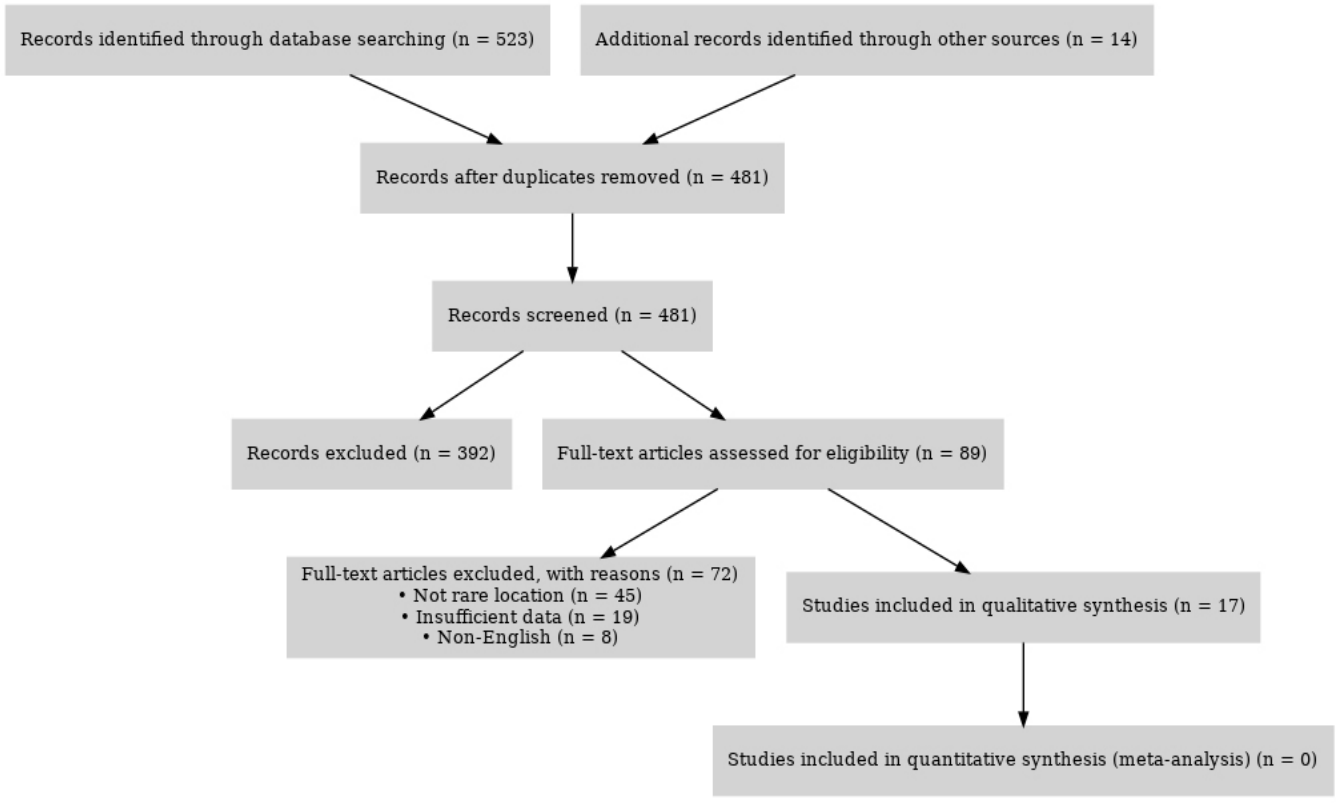

Figure 1. PRISMA flow.

level results in a dedicated table and contextualize limitations in the discussion.

Protocol and Registration

No review protocol was registered (e.g., PROSPERO); this is acknowledged as a limitation and mitigated through transparent reporting of search strategies, selection procedures, and identifiers.

Case reports were appraised against the CARE checklist and case series against the JBI critical appraisal tool. For each report, we assessed reporting domains including clinical findings, diagnostic assessment, therapeutic intervention, and follow-up/outcomes; when items were not explicitly stated, they were coded as "unclear." Study-level results are provided in Supplementary Table S2 (CARE and JBI worksheets).

Pathophysiology and Mechanisms of Dissemination to Uncommon Sites

Hydatid disease originates when the larval stage of *E. granulosus*—released from ingested eggs—penetrates the intestinal mucosa and gains access to the bloodstream or lymphatic system. The liver and lungs typically function as the primary and secondary filters, respectively, trapping the majority of oncospheres. However, when these barriers are bypassed, the larvae may disseminate to virtually any anatomical location (29).

The hematogenous route is the most widely accepted mechanism for the spread of hydatid cysts to distant or atypical sites. Once in systemic circulation, oncospheres can seed tissues with rich vascular supply, such as the brain, heart, spleen, and musculoskeletal system (30). In certain locations—particularly the spine or pelvis—retrograde venous flow or lymphatic spread has also been proposed, especially in the absence of pulmonary or hepatic involvement (31). Osseous hydatidosis is uncommon in the included case literature and is typically reported to exhibit an infiltrative, trabecula-penetrating, multicystic growth pattern with limited pericyst formation. Unlike soft tissue cysts that develop a pericyst—a fibrous host reaction wall—bone lesions grow infiltratively, expanding through trabecular bone and mimicking malignancy or osteomyelitis (32). The absence of a containing capsule leads to diffuse extension and significant structural destruction. In cerebral hydatid disease—often described in children within the included case literature—parasites are thought to reach the CNS via arterial embolization, most commonly along the middle cerebral artery. The cysts grow slowly, with minimal inflammatory response, allowing for significant expansion before clinical symptoms arise (6). Moreover, immunological factors may influence the predilection of cysts for certain unusual locations. Some studies suggest that immune evasion by the parasite or local

immunosuppression may facilitate survival in otherwise reactive tissues, such as myocardium or splenic parenchyma. Genetic variations among *E. granulosus* strains (e.g., G1, G6) have also been linked to differential organ tropism, potentially impacting tissue specificity and dissemination patterns (33,34). A thorough understanding of these dissemination pathways is critical not only for diagnosis but also for planning site-specific surgical interventions. Misinterpretation of rare localizations can lead to diagnostic delays, inappropriate treatment, or inadvertent cyst rupture with potential anaphylaxis, underscoring the importance of pathophysiologic insight in clinical decision-making.

Diagnostic Challenges and Radiological Mimics of Uncommon Hydatid Cysts

The diagnosis of hydatid disease in atypical anatomical sites poses considerable clinical and radiological challenges. Unlike hepatic and pulmonary hydatidosis, which often display pathognomonic imaging features, cysts in rare locations frequently mimic neoplastic, congenital, or inflammatory lesions, leading to diagnostic delays or mismanagement (35). Differential radiological features of hydatid cysts in uncommon anatomical localizations, their frequent imaging mimics, and key differentiating points to aid diagnosis in Table 2.

Table 1. This table summarizes 17 case reports and series describing hydatid cysts outside the liver and lungs published between 2020 and 2025

Reference (first author, year)	Anatomical site(s)	Presentation	Imaging	Treatment	Outcome
Sebai et al. (11)	Retroperitoneum	Abdominal mass/ pain	CT	Total excision + albendazole	No recurrence at 12 mo
Mohamed Babiker et al. (12)	Multiple rare sites	Site-specific symptoms	US/CT	Site-specific surgery ± albendazole	Good overall; site-dependent
Khan et al. (13)	Cardiac (left ventricle)	Dyspnea, chest pain	Echocardiography + MRI	Open surgery + albendazole	Recovered
Wu et al. (14)	Pancreatic head	Epigastric pain; fever	CT/MRI ± s	Surgical excision + albendazole	Improved
Sqalli Houssaini et al. (15)	Orbit	Proptosis; visual disturbance	MRI	Orbitotomy + cyst excision	Vision preserved
Hakimi et al. (16)	Spleen	LUQ pain; palpable mass	CT/US	Splenectomy ± albendazole	Recovered
Getie et al. (17)	Musculoskeletal	Painful swelling	MRI	Excision + albendazole	No recurrence at 6-12 mo
Aryal et al. (18)	Cerebral	Headache; seizures	MRI	Craniotomy (en bloc) + albendazole	Seizure-free
Dhadve et al. (19)	Spinal (thoracolumbar)	Back pain; paraparesis	MRI/CT	Two-stage decompression + albendazole	Residual deficit
Ines et al. (20)	Breast	Painless mobile mass	US ± MRI	Lumpectomy + albendazole	Recovered
Bouchaala et al. (21)	Adrenal	Flank pain; incidental mass	CT/MRI	Adrenalectomy + albendazole	Recovered
Fourati et al. (22)	Retroperitoneum	Deep pelvic pain	CT/US	Excision + albendazole	Improved
Gadre et al. (23)	Mediastinum	Chest discomfort; cough	CT/MRI	Resection + albendazole	Recovered
Maamri et al. (24)	Intraventricular brain cyst	Headache; vomiting	CT/MRI	Craniotomy + albendazole	Recovered
Ganjipour Sales et al. (25)	Pelvic cavity	Pelvic pain; mass	MRI/CT	excision + Albendazole	Recovered
Ayub et al. (26)	Pericardium	Dyspnea; chest pain	Echocardiography + CT	Pericardial cyst excision + albendazole	Recovered
Maghbool et al. (27)	Kidney	Flank pain; hematuria	CT/US	Partial nephrectomy + albendazole	Recovered

CT: Computed tomograhpy, US: Ultrasound, MRI: Magnetic resonance imaging.

Imaging Modalities and Pitfalls

Ultrasound (US) remains a useful first-line tool, particularly for superficial or abdominal cysts, but its sensitivity decreases significantly for deep or bony structures. CT is valuable for identifying calcifications, osseous destruction, and cyst wall integrity, particularly in bone, retroperitoneum, or spine involvement (36). MRI, owing to superior soft-tissue resolution, is the modality of choice in CNS, musculoskeletal, and cardiac localizations, allowing for better delineation of cystic morphology and its relationship to neurovascular structures (37). However, in rare sites, hydatid cysts may lack classic radiological features—such as the presence of daughter cysts or the "water lily sign"—leading to frequent misinterpretation. For instance: Spinal cysts can resemble vertebral tuberculosis, metastases, or aneurysmal bone cysts.

Cardiac hydatidosis may appear similar to myxomas or fibromas on echocardiography or MRI. Intracranial cysts may be confused with arachnoid cysts, neurocysticercosis, or low-grade gliomas when daughter vesicles are not evident (38). Pancreatic or splenic cysts can radiologically overlap with pseudocysts, serous cystadenomas, or cystic neoplasms. In osseous echinococcosis, the lack of a pericyst results in a multilocular, expansile, and infiltrative lesion, often mistaken for aggressive bone tumors. The absence of significant periosteal reaction or sclerosis on CT may further obscure the diagnosis (32). Given the diagnostic ambiguity in rare localizations, a pragmatic stepwise pathway is summarized in Table 3 to guide imaging selection, ancillary testing, and safe tissue diagnosis.

Serologic and Molecular Tools

While serological tests—such as ELISA, indirect hemagglutination, or immunoblotting—can support diagnosis, their sensitivity is highly dependent on cyst location. Cysts in the brain or bones often provoke a muted immune response, resulting in false-negative serologies (39). Polymerase chain reaction (PCR) and next-generation sequencing (NGS) techniques are increasingly used to detect *E. granulosus* DNA in biopsy or aspirate specimens, especially when imaging and serology are inconclusive. However, their clinical utility remains limited due to accessibility and cost (40).

Histopathology: Final Confirmation

Definitive diagnosis often depends on histopathological analysis, typically obtained intraoperatively or post-excision. Presence of laminated membrane, germinal layer, and scolices confirms the diagnosis. However, this retrospective confirmation highlights the persistent difficulty of non-invasive preoperative diagnosis, particularly in rare sites. Given these challenges, clinicians must maintain a high index of suspicion when encountering cystic lesions in unusual locations,

Table 2. Radiologic differentials and site-specific pitfalls at uncommon locations of hydatid disease (2020-2025)

Anatomical site (reference #)	Typical hydatid cyst features	Radiological mimics	Key differentiating points
Brain (cerebral/ intraventricular) (8,14)	Well-defined, spherical cyst; CSF-isodense; no enhancement; minimal perilesional edema on MRI	Arachnoid cyst, cystic glioma, colloid cyst	Absence of mural nodule; smooth cyst wall; no solid component; lack of diffusion restriction
Cardiac (3,13,16)	Cystic intramyocardial lesion; hypointense rim; possible daughter cysts	Myxoma, fibroma, thrombus	No vascularity on Doppler; calcified rim possible; relation to myocardium or pericardium
Musculoskeletal/bone (7,9)	Multiloculated, expansile lesion; cortical thinning; minimal periosteal reaction	Aneurysmal bone cyst, giant cell tumor, metastasis	No periosteal aggressive reaction; presence of daughter cysts; lack of matrix mineralization
Spleen (6)	Cyst with internal septations or daughter cysts; calcified wall possible	Epidermoid cyst, pseudocyst, lymphangioma	Water attenuation; presence of daughter cysts; peripheral calcification
Breast (10)	Well-circumscribed cystic lesion; internal septations	Fibroadenoma, cystic carcinoma	No vascularity; laminated membranes may be visible on US
Pancreas (4)	Cystic lesion without communication to pancreatic duct; possible daughter cysts	Mucinous cystic neoplasm, serous cystadenoma, pseudocyst	No enhancement; absence of solid component; hydatid serology positive
Retroperitoneum (1,11,12,17)	Well-defined cystic lesion with or without calcification	Lymphangioma, mesenteric cyst, cystic sarcoma	Daughter cysts; laminated membranes on CT/MRI
Orbit (5)	Cystic mass causing proptosis; well-circumscribed	Dermoid cyst, hemangioma	No internal vascularity; fluid-fluid levels rare in hydatid

Each row cites supporting included studies using manuscript Ref# (11-27).
Note: Imaging patterns summarize reported features in the included case literature and may not generalize to population-level performance.
CT: Computed tomography, MRI: Magnetic resonance imaging, CSF: Cerebrospinal fluid.

Table 3. Site-aware diagnostic and management considerations synthesized from the included reports (2020-2025)

Clinical presentation (reference #)	First-line imaging	Supportive diagnostics	Differential diagnosis	Definitive diagnosis	Suggested next step
Non-specific symptoms (pain, mass, neuro signs) or incidental cystic lesion in endemic patient	US for superficial/abdominal; CT for retroperitoneum/bone; MRI for CNS/spine/cardiac	Serology (ELISA/IHA) if safe to obtain; baseline labs (CBC, LFTs)	Abscess, cystic neoplasm, congenital cyst, TB/fungal infection	Not yet applicable	If hydatid suspected, proceed to targeted MRI/CT; avoid FNA in pancreas/CNS/cardiac/bone
Cyst shows features suggestive of hydatid (daughter cysts, laminated membranes) (1,4-7,9,10,12,14,17)	MRI (soft-tissue detail) or CT (calcification/bone destruction) depending on site	Repeat/confirm serology; consider PCR on surgical specimen when available	Arachnoid cyst, aneurysmal bone cyst, pseudocyst, myxoma, metastasis	Preoperative working diagnosis of hydatid	Plan site-specific management conference (surgery vs. PAIR vs. medical)
Equivocal imaging in deep or critical location (brain/heart/spine) (8,14)	High-resolution MRI ± contrast; gated cardiac MRI/echo if cardiac	Serology may be negative; consider advanced molecular assay (PCR/NGS) if accessible	Low-grade glioma, thrombus, cysticercosis, sarcoma	Provisional diagnosis remains uncertain	Avoid percutaneous biopsy; prioritize surgical exploration only if benefits outweigh risks
Soft-tissue or muscular lesion with safe percutaneous window (7)	US/CT guidance to define safe tract	Pre-procedure anaphylaxis precautions; limited aspiration ONLY if diagnostic uncertainty persists	Pyomyositis, lymphangioma, softtissue sarcoma	Cyst fluid positive for hooks/membranes or PCR (if performed)	If confirmed/suspected hydatid: schedule total excision or carefully selected PAIR; start albendazole
Osseous/spinal destructive lesion without pericyst (9)	CT (cortical integrity) + MRI (neural elements)	Serology often negative; multidisciplinary review	TB spondylitis, metastasis, primary bone tumor	Intraoperative pathology (frozen) favors hydatid	Plan staged debridement/reconstruction + prolonged albendazole; long-term imaging follow-up
Pancreatic or cardiac cystic mass (3,13,16)	Pancreas: contrast CT/MRI (no FNA); cardiac: echo + cardiac MRI	Serology as adjunct only	MCN/SCN/pseudocyst (pancreas); myxoma/fibroma/thrombus (heart)	Surgical specimen confirms hydatid	Proceed to definitive surgery in experienced center; postoperative albendazole

Each decision node is annotated with supporting manuscript Ref# (11-27).
Note: This site-aware pathway synthesizes reported practice patterns and should be applied within an MDT, tailored to local expertise and patient context.
IHA: Indirect hemagglutination, CT: Computed tomography, MRI: Magnetic resonance imaging, PCR: Polymerase chain reaction, CNS: Central nervous system, FNA: Fine-needle aspiration, LFT: Liver function test, TB: Tuberculosis, NGS: Next-generation sequencing, PAIR: Puncture, aspiration, injection, re-aspiration, CBC: Complete blood counts, MDT: Multidisciplinary team, MCN: Mucinous cystic neoplasm, SCN: Serous cystic neoplasm.

especially in patients from endemic areas. Multimodal imaging supported by serological and, when available, molecular techniques can guide accurate preoperative planning.

Clinical Presentation and Site-specific Manifestations

The clinical presentation of hydatid cysts in rare anatomical sites is highly variable and largely dictated by cyst size, rate of growth, and proximity to adjacent critical structures. Unlike hepatic or pulmonary echinococcosis, which often remains asymptomatic until large sizes are reached, cysts in atypical locations frequently produce early and misleading symptoms, leading to misdiagnosis (41).

Splenic Involvement

Isolated splenic hydatid cysts are uncommon in the included case literature and are only infrequently reported as solitary lesions. Patients often present with left upper quadrant pain, splenomegaly, or a palpable mass. Rupture into the peritoneal cavity may lead to acute abdomen or anaphylactic shock, especially in endemic regions. The condition can be confused with splenic pseudocysts, abscesses, or cystic neoplasms (42).

Osseous and Musculoskeletal Hydatidosis

Skeletal hydatid disease, particularly in the spine, pelvis, femur, and humerus, may mimic malignancies or chronic infections. Symptoms typically include chronic pain, pathological fractures, or neurological deficits in vertebral involvement. The cysts exhibit an infiltrative, trabecular pattern without encapsulation, leading to aggressive local destruction and high recurrence rates (43).

CNS

Intracranial hydatid cysts are more commonly seen in pediatric patients and often involve the parietal or occipital lobes. Symptoms include increased intracranial pressure (headache,

vomiting, papilledema), seizures, or focal neurological deficits. Cysts grow slowly and are frequently misdiagnosed as arachnoid cysts or brain tumors unless daughter cysts are clearly visualized (44).

Cardiac Hydatid Disease

Cardiac involvement is uncommon in the included case literature but is associated with substantial morbidity, particularly when intracavitary extension or conduction pathways are involved. The left ventricle is most commonly affected, followed by the interventricular septum and right atrium. Clinical presentation ranges from asymptomatic murmurs to arrhythmias, embolic events, or sudden cardiac death. Echocardiography and cardiac MRI are essential for diagnosis and surgical planning (45).

Breast, Thyroid, and Other Soft Tissues

Hydatid disease of the breast may resemble fibroadenoma or cystic carcinoma, while thyroid involvement can mimic multinodular goiter or thyroid cancer. In both cases, symptoms are often limited to a slow-growing, painless mass, and diagnosis is typically made postoperatively (46).

Other rare sites include:

- Adrenal glands (mimicking pheochromocytoma)

- Retroperitoneum (mimicking sarcoma or lymphoma)

- Scrotum and epididymis (suggesting hydrocele or neoplasm)

- Orbit (causing proptosis or visual disturbances)

Multiorgan and Disseminated Hydatidosis

In immunocompromised individuals or following surgical rupture of a primary cyst, multiple secondary cysts may develop. Disseminated disease may manifest with multifocal pain, systemic symptoms, or acute abdomen, necessitating comprehensive imaging and multidisciplinary management (47).

Management Strategies: Surgical, Percutaneous, and Medical Approaches in Rare Sites

The therapeutic management of hydatid disease in atypical anatomical locations is complex, requiring individualized strategies based on cyst location, complications, and the patient's overall health status. Unlike hepatic hydatidosis, where standardized protocols exist, rare site involvement often demands a multidisciplinary, case-based approach (2).

Surgical Management

Surgery remains the cornerstone of treatment for hydatid cysts in most uncommon locations, especially when vital organs are involved or complications such as rupture, compression, or infection occur. Recommendations are MDT-conditioned and context-dependent; peri-operative albendazole is considered as an adjunct per site and spillage risk.

Osseous involvement often necessitates wide excision or curettage, sometimes with reconstructive procedures like bone grafting or spinal stabilization. Complete resection is often challenging due to the infiltrative nature of cysts and the absence of a true capsule (32). Cerebral hydatid cysts are typically removed via en bloc excision using techniques like the Dowling-Orlando method, which allows gentle extraction under irrigation, minimizing rupture risk (6). Cardiac hydatidosis requires open-heart surgery with cardiopulmonary bypass. The cysts must be removed without intraoperative rupture to avoid fatal embolism or anaphylaxis (45). Breast, thyroid, and retroperitoneal cysts may be approached via total excision, but adhesions and anatomical distortion may complicate dissection. The main surgical goal is complete cyst removal without spillage, as rupture increases recurrence and systemic allergic reactions.

Percutaneous Techniques Puncture, Aspiration, Injection, Re-aspiration (PAIR)

The PAIR technique, widely accepted for liver cysts, has limited but growing application in select extrahepatic cases. Suitable for superficial or isolated soft tissue cysts (e.g., muscle or subcutaneous tissue) where adjacent vital structures can be avoided under imaging guidance (48). Contraindicated in CNS, osseous, cardiac, and retroperitoneal locations due to rupture risk. Can be used as a bridge to surgery or for palliative management in inoperable cases, though long-term recurrence rates remain uncertain. For non-hepatic sites, indications are highly selective and evidence is limited; decisions should be MDT-driven and center-experienced.

Pharmacologic Therapy

Albendazole remains the mainstay medical therapy, administered at 10-15 mg/kg/day in divided doses over several weeks to months. Mebendazole, though less effective, may be used in certain settings. Pharmacologic treatment is indicated in three scenarios:

- Preoperative sterilization to minimize intraoperative rupture risk.

- Postoperative prophylaxis, particularly after partial excision or spillage.

- Primary treatment in inoperable or disseminated cases, including CNS or bone involvement (49).

Therapeutic monitoring is essential due to potential hepatotoxicity and myelosuppression. Some studies support combination therapy (e.g., albendazole + praziquantel), which may enhance scolicidal efficacy, but evidence remains limited.

Peri-operative albendazole: Conditional, MDT-driven use (dose/monitoring by site and context) We suggest peri-operative albendazole within an MDT when timing and safety

permit—especially after spillage, partial resection, multiple cysts, or uncertain margins. Typical regimens in guidance and practice are 10-15 mg/kg/day in two divided doses (or 400 mg BID in adults; max 800 mg/day), started pre-operatively when feasible and continued post-operatively with duration tailored to site, spillage, and residual disease (49). Pre-op lead-in: Short courses (~2 weeks) can reduce protoscolex viability; longer pre-op courses are used when logistics allow, recognizing mixed evidence (50). Post-op continuation: Common practice ranges 1-3 months after uncomplicated resection and longer when spillage/residual disease is suspected; pulmonary reviews suggest ≥3-6 months in selected cases. Longer courses (e.g., in bone/CNS) are reported but rest on low-certainty evidence (50). Site-aware nuances:

• CNS/cardiac: Surgery is primary; adjunct albendazole is often used pre/post but data are case-level. Decisions should be individualized (51).

• Bone: Prolonged courses are described due to infiltrative growth and difficult clearance; evidence remains heterogeneous (49).

Monitoring & safety: Check LFTs at baseline and periodically; consider biliary/hematologic labs if prolonged therapy. Avoid in 1st trimester pregnancy; review drug interactions and counsel on taking with fat-containing meals to increase bioavailability (51).

Framing: These are practice-supporting suggestions derived from guidance and case-level literature, not prescriptive standards or comparative-effect estimates. Local expertise and patient factors should drive the final plan (52).

Avoiding Biopsy/FNA When Hydatid Disease is Suspected (MDT-conditioned)

Because needle biopsy/FNA can precipitate cyst rupture, dissemination, or anaphylaxis, routine tissue sampling should be avoided when the clinical-imaging context suggests hydatid disease, particularly in pancreas, spleen, bone, brain, and heart. In rare, inconclusive scenarios, selective sampling may be considered within an MDT at centers with immediate capability to manage anaphylaxis, using protective measures and only after a risk–benefit discussion that documents why imaging and serology were insufficient. This approach is aligned with major guidance emphasizing non-invasive diagnosis and risk-avoidance where hydatid disease is on the differential (48). Practical note (reporting level): If biopsy is undertaken despite caution, teams should report pre-procedure risk stratification, intra-procedure protections, and outcomes to strengthen the case-level evidence base.

Emerging Therapies

Recent years have witnessed exploration of alternative interventions:

- Microwave ablation, radiofrequency ablation, and stereotactic radiosurgery for inoperable CNS lesions.

- Robotic-assisted surgeries in complex anatomical regions (e.g., mediastinum).

- Novel anthelmintics (e.g., oxfendazole, nitazoxanide) are under investigation.

- Fluorescence-guided surgery has shown promise in achieving complete cyst removal in experimental models.

- Although these modalities are not yet standard practice, they reflect an evolving approach toward less invasive and more targeted therapy.

Prognosis, Recurrence, and Follow-up Considerations in Atypical Hydatid Disease

The prognosis of hydatid cysts in unusual anatomical sites is highly variable and generally less favorable compared to hepatic or pulmonary involvement. Factors influencing prognosis include anatomical location, cyst size, surgical accessibility, presence of complications, and the completeness of cyst removal (53).

Recurrence Rates and Contributing Factors

Recurrence remains a major concern in atypical-site hydatidosis and was frequently reported across included cases, with signals varying by anatomical site and management approach:
- Osseous hydatidosis exhibits the most frequently reported recurrence due to its infiltrative growth, absence of pericyst formation, and challenges in achieving radical resection. In spinal hydatidosis, recurrence rates can exceed 40%, even with aggressive surgical techniques (32).
- In CNS involvement, recurrence is low if en bloc removal is achieved. However, intraoperative rupture can lead to intracranial dissemination or ventricular seeding, complicating future management (54).
- Cardiac and muscular cysts may recur if daughter cysts remain or if surgical margins are insufficient due to anatomical constraints (55).
Inadequate preoperative sterilization, incomplete excision, and lack of postoperative albendazole therapy are widely recognized as modifiable risk factors for recurrence.

Postoperative Monitoring

A structured follow-up protocol is essential, particularly during the first two to three years, when recurrence is most likely to occur.

- MRI is preferred in CNS and spinal cases, given its ability to detect early recurrences and evaluate soft tissue detail.

- CT scans are valuable for follow-up in osseous, retroperitoneal, and thoracic cysts.

- US remains useful for superficial cysts or abdominal surveillance.

- Serologic monitoring can be adjunctive, although anti-echinococcal antibody levels may remain elevated for prolonged periods and are not always reliable indicators of recurrence (56).

Long-term Outcomes

Long-term prognosis varies according to site and extent of disease:

- Brain hydatidosis has good outcomes if complete removal is achieved early, but neurological deficits, seizures, or hydrocephalus may persist.

- Spinal cysts often result in permanent disability, including paraplegia or chronic pain, despite adequate decompression and adjuvant therapy.

- Cardiac hydatidosis, while rare, carries the risk of sudden death, but surgical outcomes are favorable if diagnosis is timely and excision is complete (57).

Rehabilitation and Supportive Measures

Patients with significant neurological impairment or extensive skeletal involvement may benefit from rehabilitation programs, including:

- Physical therapy

- Orthotic support or prosthetic fitting

- Anticonvulsant therapy in CNS cases

- Psychosocial support, especially in younger or disabled individuals.

In endemic areas, community-based follow-up and patient education are crucial to minimize reinfection and promote long-term surveillance.

Future Directions and Research Perspectives in Atypical Hydatid Disease

Despite notable progress in the diagnosis and treatment of cystic echinococcosis, hydatid disease in rare anatomical sites continues to present diagnostic, therapeutic, and prognostic challenges. Future advancements across molecular biology, immunology, pharmacology, and surgical technologies may offer innovative solutions to these complexities.

1. Advances in Diagnostic Imaging

Emerging radiologic techniques such as diffusion-weighted MRI, positron emission tomography-CT, and radiomics-based artificial intelligence algorithms are gaining attention for their potential to enhance the differentiation of hydatid cysts from malignant or inflammatory lesions, especially in deep or unusual locations (58). AI-assisted interpretation of imaging data may support earlier diagnosis by recognizing subtle and atypical imaging patterns in locations like the spine, retroperitoneum, or brain, where hydatidosis often mimics neoplasms.

2. Molecular and Serological Innovations

While serological assays remain suboptimal in specificity and sensitivity for rare-site disease, recent developments in PCR-based methods and NGS of cyst aspirates or surgical samples offer improved diagnostic accuracy (59). Additionally, point-of-care molecular diagnostics using loop-mediated isothermal amplification are under development and may enhance field-level diagnostics, particularly in endemic but resource-limited areas.

3. Immunotherapeutic Strategies and Vaccines

The modulation of host immune responses to *E. granulosus* is an emerging focus area. Novel therapies targeting Th1/Th2 immune polarization, dendritic cell activation, and regulatory T-cell suppression are under experimental investigation. Promising vaccine candidates such as EG95 recombinant antigen and EgAgB-based multiepitope formulations have shown protective efficacy in animal models. Their translation to human use, especially for high-risk occupations or endemic populations, is under active exploration (60).

4. Novel Antiparasitic Agents and Delivery Systems

Standard agents like albendazole and mebendazole exhibit limited efficacy in poorly vascularized sites such as bone or brain. Recent research has focused on agents like oxfendazole, tribendimidine, and nitazoxanide, which have shown superior protoscolicidal activity in experimental models (50). Moreover, liposomal formulations and nanoparticle-conjugated antiparasitic drugs are being tested to improve tissue penetration, reduce systemic toxicity, and enable targeted drug delivery.

5. Surgical and Technological Innovation

Minimally invasive techniques, including robot-assisted surgery and endoscopic approaches, are under investigation for anatomically challenging cysts in the mediastinum, orbit, or retroperitoneum. These methods may reduce morbidity and improve postoperative recovery. Intraoperative technologies such as fluorescence-guided resection and real-time 3D navigation may also enhance cyst delineation and reduce the risk of rupture, particularly in CNS and musculoskeletal locations.

6. One Health Surveillance and Genotype Mapping

Hydatid disease control hinges on integrated One Health strategies, including veterinary, environmental, and public health interventions. Genotyping of *E. granulosus* strains using cox1 and nad1 markers has revealed significant strain-related differences in tissue tropism and pathogenicity (61). Real-time surveillance of parasite circulation in livestock and canine populations, coupled with education and sanitation measures, remains fundamental in reducing human infection—especially with cysts arising in unusual anatomical sites.

Controversies and Consensus in Management of Atypical Hydatid Cysts

The management of hydatid disease in rare anatomical sites is fraught with challenges, and in many areas, consensus is lacking. Despite general agreement on the importance of surgical resection and antiparasitic therapy, several controversies remain regarding timing, technique, and adjunctive measures.

PAIR in Uncommon Sites: A Matter of Debate

While the PAIR technique has gained widespread acceptance in hepatic hydatid cysts, its application in atypical localizations remains contentious. Proponents argue that with appropriate precautions and imaging guidance, PAIR may offer a minimally invasive alternative in selected superficial or muscular cysts. However, critics highlight the elevated risk of cyst rupture, dissemination, and anaphylaxis, particularly in CNS, osseous, or cardiac locations where containment is anatomically limited (62). There is currently no standardized guideline governing PAIR in non-hepatic hydatidosis, and most published cases are isolated reports or small series, limiting the generalizability of outcomes.

Duration of Antiparasitic Therapy: Is More Always Better?

The optimal duration of albendazole therapy is also debated, especially when used as adjuvant or neoadjuvant treatment. Standard regimens of 3 months may be insufficient for osseous, cerebral, or disseminated cysts, leading some experts to advocate for 6-month or even longer treatment courses. However, prolonged therapy raises concerns regarding hepatotoxicity, bone marrow suppression, and patient adherence (51). Emerging data suggest that combination therapy with praziquantel may enhance efficacy, yet consensus is lacking on its routine use in rare-site disease (52).

Role of Corticosteroids: Adjunct or Risk?

The role of perioperative corticosteroids in preventing anaphylaxis remains uncertain in the case-level literature. Several reports describe the use of a single preoperative dose—typically considered in contexts of high cyst burden or suspected leakage—as a potential adjunct within an MDT. At the same time, others caution against routine use in CNS disease because of concerns about immunosuppression and potential parasitic persistence (63). Taken together, decisions should be individualized (site, spill risk, and timing) and made within an MDT, rather than viewed as a standard recommendation.

Watchful Waiting in Asymptomatic Cases: A Reasonable Option?

In certain scenarios, especially with incidentally discovered, asymptomatic cysts in surgically challenging sites (e.g., retroperitoneum, deep musculature), some clinicians opt for a watch-and-wait strategy with close radiological surveillance. While this approach reduces surgical morbidity, it is not without risk—cyst rupture or secondary infection may occur unpredictably (1). These ongoing debates reflect the complexity of treating hydatid cysts outside of classical hepatic and pulmonary sites. There is a growing need for multicenter data, standardized treatment algorithms, and controlled studies that evaluate outcomes of conservative vs. interventional approaches in rare anatomical presentations.

Overall Certainty/Limitations

Given that the vast majority of included records are single-patient case reports, the level of evidence is extremely low; therefore, statements herein should be read as practice-supporting, MDT-conditioned suggestions, not as prevalence or comparative-effect claims.

This is a narrative review based largely on single-patient case reports, so findings are fragmentary and should not be over-interpreted. Although we describe the use of CARE and JBI tools, the risk-of-bias assessment is limited by the underlying reports and is not comprehensive; item-level results are summarized but remain insufficiently detailed for formal grading. We restricted inclusion to English-language publications, which introduces language bias. The Google Scholar component was limited to the first 200 records, further adding non-systematic elements. Accordingly, all numeric statements reflect reporting frequency within the included case-level literature (not prevalence/effectiveness), and all clinical suggestions are MDT-conditioned and context-dependent.

Overall, the evidence base consists predominantly of single-patient case reports, which limits internal validity and precision. In our CARE-based appraisal (n=17), reporting was consistently adequate for clinical findings (17/17), diagnostic assessment (imaging/labs, 17/17), therapeutic intervention (17/17), and follow-up/outcomes (17/17). In contrast, several key domains were frequently not explicitly reported, including timelines (Unclear in 17/17), adverse events (Unclear in 17/17), patient perspective (Unclear in 17/17), and informed consent statements (Unclear in 17/17). Titles explicitly identifying a case were present in 13/17, and a structured abstract appeared likely in 11/17 (journal formatting dependent). When small case series are present, JBI domains such as consecutive inclusion

and complete inclusion are seldom verifiable from the text. Accordingly, our conclusions are positioned as practice-supporting, MDT-conditioned suggestions, not estimates of prevalence or comparative effectiveness, and should be interpreted with these reporting limitations in mind.

Future Directions and Unresolved Questions

Over the 2020-2025 period, case-level evidence at uncommon sites highlights practical opportunities for MDT-driven standardization while underscoring persisting gaps. Prospective, site-specific registries with harmonized reporting (presentation, imaging sequence, peri-operative details, cyst stage, spillage, and follow-up) are needed to move beyond narrative signals. Candidate endpoints include peri-operative complications, recurrence at site, need for re-intervention, and functional recovery (e.g., neurologic or cardiac performance where applicable). Imaging research should compare MRI vs. CT triage by anatomical site, and clarify when US suffices for surveillance. Pharmacologic studies could define timing and duration of peri-operative albendazole, especially after spillage or uncertain margins. Finally, consensus criteria for when to avoid percutaneous biopsy/FNA at pancreas, spleen, bone, brain, and heart should be formalized within MDT pathways.

Unresolved questions:

- Which site-specific imaging algorithms reduce misdiagnosis and biopsy-related risk most effectively?

- What minimal effective duration of peri-operative albendazole balances safety with recurrence prevention?

- How should recurrence be defined and monitored across sites (imaging schedule, markers)?

- Can MDT checklists/decision tools improve time-to-treatment and outcomes in low-volume centers?

CONCLUSION

Rare-site hydatid disease is best approached through MDT coordination with site-specific imaging triage and risk-aware operative planning. Based on 2020-2025 publications, three practical actions are feasible now: (i) prioritize MRI for CNS/spine/cardiac involvement and CT for osseous/retroperitoneal disease, reserving US for screening or superficial sites; (ii) use peri-operative albendazole when timing and safety permit, with postoperative continuation after spillage, partial resection, or uncertain margins; and (iii) avoid percutaneous biopsy/FNA when imaging and clinical context suggest hydatid disease in the pancreas, spleen, bone, brain, or heart, unless a specialized MDT determines that benefits outweigh risks. These are practice-supporting suggestions derived from recent case-level evidence rather than claims of prevalence or efficacy. Standardized reporting, prospective registries, and consensus criteria for non-hepatic PAIR would further improve consistency and outcomes across centers.

Footnotes

Author Contributions

Concept – B.Z.; Design - B.Z., Ö.A., T.D.; Data Collection or Processing - Ö.A., T.D.; Analysis or Interpretation - B.Z., Ö.A., T.D.; Literature Search - B.Z., Ö.A., T.D.; Writing - B.Z., Ö.A., T.D.

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REVIEW
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Barriers to bariatric surgery completion: A narrative review of preoperative attrition and its determinants

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ABSTRACT

Although bariatric surgery is an effective intervention for morbid obesity, a significant proportion of patients referred for surgery fail to proceed to the operation. This narrative review aims to examine the rates, characteristics, and underlying reasons for preoperative attrition among bariatric surgery candidates. The literature demonstrates variability in defining pre-op attrition, with some studies adopting binary classifications and others focusing on attrition at specific stages of the preparation process. Key factors associated with attrition include socio-demographic variables (e.g., gender, age, and income), clinical and logistical issues (e.g., waiting times, insurance barriers), and psychosocial characteristics (e.g., anxiety, substance use, and motivation). Some qualitative studies have reported that patients' thoughts and feelings about the meaning of surgery—particularly their emotional readiness and identity-related concerns—can substantially influence whether they follow through with the procedure. In Türkiye, where no standardized national guidelines are in place and structured interventions are limited, there is a clear need for broader changes in how the pre-op phase is managed. Addressing this issue will likely require support systems that are flexible, multidisciplinary, and responsive to individual circumstances. This review emphasizes that personal experiences and system-level factors jointly influence whether patients complete the surgical process. Recognizing how these layers interact may help create more effective strategies for supporting those at risk of dropping out before surgery.

Keywords: Bariatric surgery, preoperative preparation process, preoperative attrition, psychosocial factors, demographic factors, logistic factors

INTRODUCTION

Obesity is widely recognized as a complex, chronic disease involving excessive body fat that adversely impacts health. In its latest classification, the World Health Organization (WHO) includes obesity as a disease within the International Classification of Diseases, 11th Revision (ICD-11), underscoring its critical relevance to global public health (1). The most commonly used criterion for diagnosing obesity is the body mass index (BMI), with a BMI of 30 kg/m^2 or higher indicating obesity (1,2). When BMI exceeds 35 kg/m^2 in the presence of comorbid conditions or exceeds 40 kg/m^2 regardless of comorbidities, individuals are categorized as having morbid obesity. This designation reflects a substantially increased risk for severe health issues and elevated mortality rates (3). In addition, obesity, which is strongly associated with serious health problems such as Type 2 diabetes (T2DM), hypertension, cardiovascular diseases, and some types of cancer, is a risk factor for individuals. While it negatively affects life expectancy and quality of life, it also creates a serious economic burden on countries' health systems (4-6).

According to the World Obesity Federation (2024) report, the combined prevalence of overweight (BMI ≥25 kg/m^2) and obesity (BMI ≥30 kg/m^2) among individuals aged 18 years and older worldwide is approximately 42%. The same report predicts that this rate will reach 54% by 2035 (7). Projections from the Global Burden of Diseases, Injuries, and Risk Factors Study (2021) estimate that approximately 3.8 billion adults worldwide will have a BMI over 25 by 2050 (8). This global trend is also observed in Türkiye. According to the Turkish Statistical Institute, the obesity rate among individuals aged 15 and over in Türkiye increased from 15.4% in 2008 to 20.2% in 2022. When stratified by gender, obesity prevalence was 23.6% among women and 16.8% among men (9). Although obesity rates have more than doubled since the beginning of the 1990s, the intervention methods developed have been insufficient

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to control this increase (10). This increase is associated with high-calorie dietary habits, sedentary lifestyles, and other structural changes, especially urbanization and economic growth (11). The rapid increase in the global prevalence of obesity has necessitated the development of various treatment strategies to address this problem. Treatment approaches developed to combat obesity are predominantly multicomponent, consisting of diet, exercise, behavioral interventions, and drug therapy (12,13). However, traditional first-line treatments are limited in their ability to provide permanent weight loss and to improve disease-related complications, especially in cases of morbid obesity (14,15). At this point, bariatric surgery (BS) stands out as an intervention with proven effectiveness in managing obesity-related health problems (16).

BS is the most widely used intervention worldwide because it provides long-term effective treatment for obesity. Laparoscopic gastric bypass (LGB) and sleeve gastrectomy (SG) are the two most commonly performed bariatric procedures (17), which provide significant improvements in both weight loss and obesity-related diseases (18,19). Meta-analyses show that BS provides effective weight loss in individuals with morbid obesity (BMI ≥40 kg/m^2) and complete recovery or improvement of diabetes, hyperlipidemia, and hypertension in most patients (20).

Owing to technological advances, procedures such as LGB and SG, which are now widely performed, are associated with lower complication rates and faster recovery when performed laparoscopically (21). However, these surgical interventions require patients to make radical changes in their lifestyles; compliance with these changes is of great importance not only for long-term success but also for preventing postoperative complications (3). Although LGB and SG procedures are generally considered to be safe, it is known that there are risks of surgical complications, reoperation, and mortality, albeit at low rates (22,23). Therefore, the surgical process requires a multidimensional evaluation of both technical and psychosocial aspects. Accordingly, this review aims to address pre-op surgical evaluations and attrition.

Preparation for BS: Recommendations of Guidelines in the Pre-op Process

The success of BS depends on both the surgical technique used and the preoperative process patients undergo. Indications and contraindications for surgery are evaluated in the pre-op period (24). In BS, the guidelines published by authoritative organizations such as the International Federation for the Surgery of Obesity and Metabolic Disorders (IFSO), the WHO, and the American Society for Metabolic and Bariatric Surgery (ASMBS) recommend that evidence-based medical practices be performed by a multidisciplinary team to prepare patients for surgery (3,25). These guidelines indicate that BMI ≥35 kg/m^2 constitutes a direct surgery. In cases where BMI is ≥30 kg/m^2, the presence of a comorbid disease such as T2DM or the patient's inability to lose weight despite trying non-surgical methods is considered an indication for surgery. Although the evaluation of indications and contraindications for surgery is the initial step in determining the person's eligibility for BS, the pre-op period extends beyond this initial evaluation. During pre-op preparation, patients are evaluated holistically with respect to medical, psychological, behavioral, and social aspects (24). The evaluation during the preparation phase and certain changes expected of patients also facilitate adaptation to changes in the post-op process (26).

Psychiatric Suitability, Psychological Support and Behavioral Preparation Processes

Although clinical practice guidelines recommend screening for psychiatric risks before BS and conducting a preliminary assessment of the individual's level of psychological preparation, findings regarding the predictive power of this assessment for surgical outcomes are limited (27). However, these interviews are considered important in clinical practice for assessing the individual's potential to adapt to post-surgical lifestyle changes and for the early detection of psychosocial risks (28). During the interview, the patient's weight and dietary history, current psychiatric or psychological symptoms, social environment, and capacity for behavioral adaptation are addressed (24,29). In addition, the individual's use of cigarettes, alcohol, or other substances is assessed, and a history of active substance use or recent serious addiction may be considered a contraindication to surgery. Since smoking and alcohol use increase the risk of complications during and after surgery, patients are advised to stop both before surgery (24,30).

Differences in Practice Among Guidelines

Although the guidelines provide a general framework, differences in practice can be observed in some areas across countries and centers. For example, IFSO and ASMBS recommend BS only for individuals with a BMI between 30-34.9 kg/m^2 who have serious comorbidities—especially T2DM—and in whom non-surgical methods have failed (31,32). In addition, some guidelines recommend setting BMI thresholds 2.5 kg/m^2 lower for Asian patients to account for ethnic differences. This recommendation is based on evidence that T2DM and cardiovascular diseases are more common at lower BMI values in Asian populations. Indeed, metabolic risks in this population may become evident at BMI levels between 25 and 27.5 kg/m^2. In some cases, limiting access to surgery based solely on traditional BMI thresholds may be inappropriate for high-risk individuals (24).

Similarly, the pre-op psychosocial assessment is recommended, but not mandatory, in most guidelines. For example, while

the ASMBS (2016) recommends that all patients be assessed by a mental health professional (33), the guideline developed by the Canadian Obesity Society and adapted in Ireland states that psychosocial assessment should not only identify contraindications but also identify the patient's strengths (e.g., social support, motivation) and risk factors (e.g., psychiatric symptoms, eating behaviors) (34). In contrast, in countries such as India, these assessments are primarily undertaken by individual institutions, and no standardized protocol exists (35). These situations lead to varied practices in the pre-op assessment.

The content and duration of the preoperative process vary between countries and centers. For example, some countries require participation in non-surgical, insurance-mandated weight-management programs of three-, six-, or nine-month duration (36). Other programs have adopted multistage structures consisting of psychiatric evaluation, nutritional counseling, nursing interview, social service support, and surgeon evaluation (37,38). The duration of these programs may be limited to a few months, whereas other programs require completion of all requirements within 15 months of the initial evaluation (36). Such differences lead not only to variation in practice but also to loss of patients during the preoperative process.

Reasons for Pre-op Attrition from BS: Rates and Risks

The decision to apply for BS is the first and most important step patients take in the surgical process. However, not everyone who applies undergoes surgery. Despite evidence that patients' health status and functionality improve after BS, approximately 1% of those who are clinically suitable for BS undergo surgery (39-41). It has been shown that the proportion of patients who are interested in BS for obesity treatment and who contact bariatric centers can be as high as 60% among those who do not undergo surgery (42,43). This situation gives rise to the concept of "pre-op attrition" in BS. Pre-op attrition is defined as patients who are offered surgical intervention, evaluated, and accepted into the program but who leave the process at any stage before surgery (44). However, the scope and content of this concept vary across the literature. In some studies, pre-op attrition is treated as a binary outcome—that is, whether patients referred for surgery complete it (45). In others, it is defined as attrition occurring at specific stages of the process (e.g., after referral, orientation, or psychiatric evaluation) (38). Pre-op attrition rates among patients undergoing BS worldwide vary widely. The table includes studies reporting the proportion of those undergoing BS.

The findings in Table 1 indicate that the rate of those who have undergone BS varies both between and within countries. In three studies conducted in Canada that implemented a mandatory preoperative program, BS completion rates ranged from approximately 36% to 76%. Similar variability was observed in studies from the United States, with rates ranging from 39% to 70%, even when pre-op programs were in place. Although some research has linked extensive program requirements to higher attrition rates (46), comparisons between studies with and without mandatory programs did not always show substantial differences (42,47). These findings suggest that, although structured programs may help reduce dropout rates, they are not the only factor contributing to dropout. Factors such as patient motivation and the design and implementation of programs also appear to influence program completion. For instance, in a study conducted in Iran (48), in which patients participated in a multidisciplinary program lasting 12-18 months, the clinic still reported a relatively low attrition rate of 12.7%. The researchers pointed out that the presence of comprehensive national health insurance coverage likely contributed to this outcome.

Factors Associated with Pre-op Attrition

Socio-demographic Factors

Gender

The majority of applicants for a BS are women. Although the literature reports that the proportion of female participants typically ranges from 60% to 80% (38,47), some studies include only women (49). It is thought that the higher frequency with which women apply for surgery may be related to their motivation for weight management and their attitudes towards treatment.

While many studies examining the relationship between gender and the completion of surgery report that men are at increased risk of attrition (38,45,50-53), other studies report higher attrition among women (36). On the other hand, it has been found that gender is not associated with pre-op attrition (54). Therefore, to understand the effect of gender on the BS, studies examining variables such as gender roles, social norms, and biological differences are needed.

Age

Another variable whose role in pre-op attrition has been investigated is age. While studies have found advanced age to be a risk factor for attrition (37,45,50,51) there have also been studies reporting that younger patients experience attrition (53). Based on this, it is more appropriate to evaluate age together with other variables, such as motivation, health status, and living conditions, rather than considering it solely as a risk factor.

BMI

Studies have reported that pre-op attrition is more common among those with a lower BMI (35-40 kg/m^2 or BMI <40 kg/m^2) (37,47,55). One study showed that those with a BMI below 40 kg/m^2 had a threefold higher probability of pre-op attrition compared with those with a BMI of 40-50 kg/m^2, and a 4.5-fold

Table 1. Bariatric surgery completion rates			
Authors	**Country**	**Completion rate of BS**	**Duration of pre-op program**
Research with a mandatory pre-operative program			
Pitzul et al. (38)	Canada	36.21% (n=448)	Not reported
Diamant et al. (37)	Canada	45% (n=724)	Not reported
Benediktsdottir et al. (49)	Iceland	27% (n=79)	5 months
Taylor et al. (53)	New Zealand	46% (n=326)	Not reported
Alvarez et al. (42)	USA	70% (n=192)	Maximum 2 years
Doumouras et al. (50)	Canada	75.56% (n=13.581)	8-16 months
Ju et al. (45)	USA	45% (n=498)	Not reported
Richard et al. (52)	Switzerland	55% (n=122)	Average 1 year
Miller-Matero et al. (54)	USA	66.5% (n=208)	Not reported
Hlavin et al. (51)	USA	38.8%	Not reported
Paolino et al. (55)	France	53.2%	Minimum 6-12 months
Eghbali et al. (48)	Iran	91.1%	12-18 months
Research without a mandatory pre-operative program			
Marek et al. (47)	USA	72.8% (n=845)	–
Sala et al. (44)	USA	50.1% (n=397)	–
n: Number of participants who completed surgery, BS: Bariatric surgery.			

higher probability among those with a BMI of 50 kg/m^2 or above (49). The current findings may be related to the perception that surgery is an urgent need for those with a high BMI. However, it is thought that those in the low BMI group are more likely to choose non-surgical weight-loss methods because their health risks are lower. In addition to studies reporting an association between low BMI and pre-op attrition, other studies have reported that high BMI increases the risk of attrition (53,54), while others found no relationship between BMI and attrition (51). In this context, the effect of BMI on pre-op attrition is more complex than that of single determinants of attrition, such as gender and age.

Employment Status and Income Level

While some studies have found unemployment (50,53,55), lower income, or residence in low-income neighborhoods (45,50,51) to be risk factors for pre-op attrition, other studies report that employment status and income level are unrelated to pre-op attrition (52).

Waiting Period with Mandatory Program and Insurance Burden Before BS

Long waiting periods before BS are considered important risk factors for pre-op attrition. Findings indicate long waiting periods are associated with higher pre-op attrition (42,50). In this context, motivation for surgery may decrease, and patients may abandon preoperative preparation during the waiting period. Indeed, a study of reasons for pre-op attrition involving 201 participants reported that the most common reason was long waiting periods (49.1%) (48). This finding indicates that long waiting periods may be a determining factor in ensuring continuity of the surgical process.

In addition to long waiting times, mandatory program and insurance requirements prior to BS are significant barriers to undergoing surgery (55). For example, a study investigating reasons for pre-op attrition among surgical applicants reported that 17% of applicants failed to complete the procedure because they did not meet program requirements. Patients in this group differed from other groups who experienced pre-op attrition with respect to certain psychosocial characteristics, including voluntary withdrawal from the program, insurance denial, and transition to non-surgical weight management. These patients also exhibited significantly higher rates of outpatient behavioral health treatment, psychiatric medication use, and current or past alcohol abuse or dependence (36). These findings suggest that, although mandatory programs aim to prepare patients for surgery, they may pose a risk of preventing some high-risk groups from accessing surgery. Thus, this creates a paradox regarding the application of surgical methods recommended as the gold standard in obesity treatment.

Failure to achieve the weight-loss goal mandated by insurance and/or the program during the pre-op period has also been reported as a barrier to surgery (42,53). In addition to pre-op weight loss, patients face program requirements such as various laboratory tests (e.g., cotinine level and urine drug test), specialist evaluations (e.g., endocrinology and psychiatry), a financial plan, attendance at the clinic with a support person, nutrition education, and substance-use cessation. These

additional requirements have been shown to increase the risk of failure to complete the surgical procedure (42). Consistent with these results, participants in a qualitative study stated that pre-op preparation time and additional requirements constituted major barriers to surgery, and described the time between pre-op preparation appointments and tests as a "burden." In the same study, a female participant residing in the United States of America who underwent a prolonged smoking-cessation process to satisfy insurance requirements reported that the process was meaningless, saying, "I even thought about having surgery in Mexico... I can quit smoking for two weeks and have surgery". This indicates that pre-op program requirements direct some patients to alternatives (56). Similarly, one study indicated that short waiting times and rapid surgical planning made surgery more accessible (51). Some individuals found the pre-op preparation process useful for understanding their health status and increasing their knowledge about the surgical process (56). One study found that the theme "communication" played an important role in facilitating surgery. Participants requested more education about BS and information about surgical options (51). Therefore, enhancing communication and information processes appears important to ensure continuity throughout the surgical pathway. In this context, Merrell et al. (36) recommend that the psychiatric and behavioral health needs of surgical candidates who experience difficulties during the preoperative phase be evaluated individually and that appropriate support be provided.

Psychosocial Factors

Smoking and Substance Use

Active smoking has been consistently shown to be a risk factor for pre-operative attrition in various studies (42,50,51,53,55). Active substance use and diagnosis of a substance use disorder (37,47) also appear to indicate a tendency for pre-op attrition. While smoking and substance use are reported as risks for completing surgery, some patients who apply for surgery are not admitted because of active smoking, alcohol, or other substance use. Therefore, it is difficult to distinguish voluntary attrition from attrition due to surgery. The vagueness of this distinction requires caution in understanding the causes of attrition and interpreting the results.

Psychopathological Symptoms and Psychiatric Diagnoses

High levels of anxiety and depressive symptoms are psychological risk factors for pre-op attrition. Among participants whose anxiety levels were measured using the Minnesota multiphasic personality inventory-2 restructured form, those with high scores (60 T or above) had a 2.5-fold higher risk of pre-op attrition (47). Similarly, pre-op attrition risk is higher among patients with severe depression than among those with mild depression or those who do not meet diagnostic criteria for depression (49). In contrast to these findings, other studies have shown no relationship between the frequency of anxiety or depression and pre-op attrition (51). These contradictory findings indicate that the effect of psychiatric symptoms on completion of surgery may vary according to individual characteristics and contextual factors. Therefore, the psychiatric profile of each patient should be evaluated individually. In addition, one study has shown that a greater number of psychiatric comorbidities and the presence of clusters B and C personality disorders are significant predictors of pre-op attrition (44). Although findings related to personality disorders may seem inconsistent at first, individuals with these disorders may be difficult to manage in clinical settings; for example, they may be very demanding. Specialists may feel a greater sense of obligation to respond to this group and to proceed with their surgical procedures. Therefore, patients' demand may influence specialists' decisions to refer them for treatment (44).

Pre-op attrition has been shown to be common among those who exhibit emotional eating in response to anxiety, who have more food addiction symptoms, and who have binge eating disorder (according to DSM-5 criteria) [(Miller-Matero et al. (54)]. Among women, binge eating disorder and emotional eating have been reported as statistically significant predictors of pre-op attrition. In contrast, these variables were not significant predictors of the risk of pre-op attrition in men (54). Richard et al. (52) reported that the results of the psychological and dietary evaluations of patients participating in the BS process were strongly associated with pre-op attrition. These evaluations are carried out by psychologists and dietitians who serve as part of the multidisciplinary team. Issues such as eating disorder management and realistic weight expectations are addressed during the psychological evaluation, while aspects like weight stability and a balanced relationship with food are assessed as part of the dietary evaluation. In these evaluations, patients who received a negative opinion from the specialist had a higher pre-op attrition risk. Therefore, these findings indicate that addressing patients' psychological state and nutritional habits during the pre-op evaluation is important.

Personal Reflections on Health, Willpower, and Identity

Some of the studies that reveal the reasons for attrition during the surgical process mention factors that they conceptualize as "self-selection factors". Examples of this factor include attrition from the pre-op program (for example, not showing up for more than one appointment), canceling surgery after approval has been given (36), switching to non-surgical weight-loss methods, or attempting weight loss on their own (36,38,45). In a qualitative study involving patients who dropped out of the BS process, it was reported that during the pre-op waiting period, some participants began to reflect on "what it would mean to be a person who has had surgery." For some, their perspective

shifted from viewing surgery to achieve health to perceiving it as a "crutch" used by thin people who fail to take responsibility for their lives (56). These findings suggest that patients' perceptions of surgery may evolve between application and the procedure. Those who associate surgery with weakness or a lack of self-control may be at increased risk for pre-op attrition.

Concerns of Surgery and Post-op Complications

Concerns about the surgical procedure and post-op complications appear to be risk factors for attrition (45,51,56). Concerns have been raised about possible changes in body structure, long-term effects of surgery, and adaptation to post-op lifestyle changes (51). In another qualitative study, these fears were examined under the theme of "anticipated regret: Beliefs related to outcomes." Participants reported that fear of regret after surgery contributed to their pre-op attrition decisions. Patients have expressed concerns about possible weight gain, increased physical deformity, and regret if health problems worsen after BS (56). Therefore, the pre-op and post-op process is thought to require significant effort on the part of patients. Such concerns may negatively affect decisions to proceed with surgery and increase the risk of pre-op attrition.

Weight Loss Expectations

Weight loss expectations are also among the psychosocial factors associated with completion of BS. A systematic review of this issue reports different findings. The review reported that those who did not complete BS experienced a greater decrease in 1-year BMI compared with those who completed BS (57,58). However, some studies have reported no significant relationship between expectations and completing surgery (59), whereas others have reported that realistic expectations are associated with completing surgery (60). These findings indicate that patients' expectations about surgery and their personal goals may be determinants of whether they will continue with the process (61).

Pre-op Process and Clinical Practices in the Context of Türkiye

Although BS practices are increasing in Türkiye, there are no structured, mandatory national guidelines for the pre-op process. In the BS Guideline (62) and the Obesity Diagnosis and Treatment Guideline (63) prepared by the Turkish Endocrinology and Metabolism Association, multidisciplinary evaluation and psychiatric examination are recommended; however, it remains unclear how often and according to which criteria these evaluations are performed in practice. In addition, the Obesity and Metabolic Surgery Clinical Protocol (64), published by the Ministry of Health, recommends standards based on contributions from various disciplines for the pre-op evaluation process. However, this protocol serves more as a guideline than a binding directive.

In this field, the study conducted by Usta and Aygin (65) in Türkiye is one of the few examples in the literature of a structured psychoeducation-based intervention program related to BS. The individual education and counseling program, which began before surgery and continued for six months, led to significant improvements in eating behaviors and physical activity levels. These behavioral changes were also reported to be positively reflected in surgical outcomes. Compared with the control group, the psychoeducation group experienced decreased eating disorder symptoms, increased physical activity, and greater reductions in BMI and excess weight at six months. However, in this study, participation in the pre-op program was not mandatory, and participants self-selected into the intervention and control groups. Therefore, the positive results in the intervention group may be attributable to participants' motivation to undergo the surgical procedure. Supporting this finding, Douglas et al. (46) reported that mandatory pre-op programs may make the process leading to surgery more difficult for patients. In this context, Usta and Aygin's (65) study offers a perspective on the motivation necessary for patients to remain engaged in the surgical process and to adapt to post-op lifestyle changes within a volunteer-based support model.

Conclusion and Recommendations

This narrative review highlights the multidimensional nature of pre-op attrition in BS. The findings show that beyond medical eligibility, a range of psychosocial, demographic, and logistical factors significantly influence patients' ability to proceed with surgery. Psychiatric symptoms, disordered eating behaviors, emotional ambivalence toward surgery, and concerns about postoperative complications emerged as critical psychosocial determinants. Structural barriers such as long waiting periods, insurance-related program requirements, and inconsistencies across centers were also identified as contributing factors to pre-op attrition.

Differences in how pre-op programs are structured, implemented, and required across countries suggest that there is still no widely accepted standard guiding clinical practice or research. In Türkiye, the lack of a nationally enforced protocol—along with the optional nature of existing interventions—indicates the need for a more organized and lasting system to support patients during the preoperative stage.

To reduce attrition and promote equitable access to BS, it is essential to develop flexible, patient-centered programs that accommodate individual motivation levels, psychiatric comorbidities, and health literacy. In everyday practice, pre-op care may benefit from more consistent inclusion of multidisciplinary assessments that bring together psychological, nutritional, and medical evaluations. There is also a growing need for national guidelines that can offer a shared framework—

outlining inclusion criteria, care pathways, and follow-up routines. To deepen our understanding of patient attrition, future studies could focus on long-term patterns and explore underexamined areas such as how identity, gender roles, and cultural beliefs shape attitudes toward surgery. Improving communication and offering clear, accessible psychoeducation could also play a major role in keeping patients engaged throughout the pre-op process.

Footnotes

Author Contributions

Concept - S.C., M.A.Ş.; Design - S.C., M.A.Ş.; Data Collection or Processing - S.C., M.A.Ş.; Analysis or Interpretation - S.C., M.A.Ş.; Literature Search - S.C., M.A.Ş.; Writing - S.C.

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ORIGINAL ARTICLE
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Novel self-reversing tube ileostomy as an alternative for conventional loop ileostomy for fecal diversion: A cohort tertiary care center study

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ABSTRACT

Objective: Anastomotic leakage following colorectal anastomosis poses substantial morbidity and mortality. Defunctioning loop ileostomy has been employed as a preventive measure, but has its own complications, including its reversal. In light of these challenges, tube ileostomy has emerged as an alternative, seeking to fulfil the same purpose as loop ileostomy while minimising complications associated with stoma creation and reversal.

Material and Methods: Conducted as a cohort study, a total of 88 patients were evenly distributed into two groups. Data collection spanned six months post-surgery or until the conclusion of the study period, with monthly follow-ups. Both types of ileostomy were performed in both elective and emergency settings.

Results: In this study comparing tube and loop ileostomy, tube ileostomy showed several advantages: Lower output (218±19 mL vs. 333.33±58 mL), shorter hospital stay (8.3 vs. 11.32 days), fewer stoma bag needs, and faster closure without surgical reversal. Complications like skin excoriation, electrolyte imbalance, and hypertrophic scarring were significantly lower in tube ileostomy. Although tube-related issues like blockade (40.9%) and leakage (15.9%) occurred, overall, comorbidity handling and patient independence were better. Statistical analysis confirmed significant differences in key parameters, favouring tube ileostomy as a safer, simpler faecal diversion alternative.

Conclusion: In the early phases of this investigation, tube ileostomy demonstrated favourable outcomes. The observed reduction in complications, ease of management for tube ileostomy-related issues, and decreased hospitalisation and reversion surgery requirements highlight its potential advantages. Further exploration and long-term follow-up are warranted to validate these initial findings and ascertain the sustained efficacy and safety of tube ileostomy.

Keywords: Tube ileostomy, loop ileostomy, colorectal cancer, anastomotic leak, stoma-related complications

INTRODUCTION

Anastomotic leak after distal bowel anastomosis and its resulting complications can be fatal. A defunctioning ileostomy does not entirely prevent an anastomotic leak, but diverting fecal matter may alleviate the severe complications of an anastomotic leak, such as fecal peritonitis and septicemia (1,2). However, complications associated with ileostomies, such as poor stoma siting, dehydration, electrolyte abnormalities, skin excoriation, ischemia, stenosis, parastomal hernia, prolapse, and psychological distress, can be detrimental. Reversal of conventional loop ileostomy (LI) itself is associated with complications (1).

Tube ileostomy offers an alternative approach to minimise complications associated with a defunctioning LI. The procedure was first performed in 1959 at Texas Children's Hospital for proximal fecal diversion; its use in adults with familial polyposis was later reported by Hojo, demonstrating comparable effectiveness to LI ileostomy (2,3). Incomplete fecal diversions have historically limited the widespread adoption of this technique (3). Early challenges, such as tube dislodgement and obstruction, restricted its use; however, recent improvements in fixation methods, devices, and perioperative care have renewed interest by reducing stoma-related morbidity and simplifying reversal. Proximal diversion is considered essential for anastomoses located within 5 cm of the anal verge, for patients who have received preoperative radiotherapy, for patients on steroids, for patients with intraoperative hemodynamic instability, and for those for whom the surgeon considers the integrity of the anastomosis to be questionable (4,5).

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Tube ileostomy is considered a strategic alternative to the conventional defunctioning LI, and we study the utility of tube ileostomy compared with LI as a diversion procedure.

MATERIAL and METHODS

Study Design: Cohort study.

Inclusion Criteria

A proximal diversion stoma is recommended when performing anastomosis in the distal bowel in the following situations where the integrity of the anastomosis is uncertain.

1) Perforated bowel,

2) Adherent loops of bowel and compromised anastomosis.

3) Post-radiotherapy patients.

4) Patients on steroid therapy and those in whom the integrity of the distal anastomosis was questionable were chosen for the study.

5) For patients with anastomosis less than 5 cm from the anal verge.

Exclusion Criteria

- Patients who are not willing to participate in the study.

- Patients who do not require proximal diversion ileostomy are similar to healthy individuals. Deaths occurring within five days of surgery were unrelated to anastomotic complications.

- Patients who were lost to follow-up were excluded from the study.

Sample Size

A sample size of 88 is obtained using the hypothesis testing method and the following assumptions: A 95% confidence level; d as the minimum clinically relevant effect size; p1 as the percentage of the characteristic in the standard group; p2 = p1 + d or p1 – d (depending on whether p2 is assumed to increase or decrease); and p as the average percentage of the characteristic, p = (p1 + p2)/2. Assuming p=53%, a sample size of 44 subjects per group was required to detect a 30% difference in cure rate; participants were randomly assigned to one of the two groups.

Data Collection Tool and Method

A structured proforma was utilised for data collection. Each patient was monitored monthly for six months following surgery (6) and evaluated during each follow-up for the development of new complications or progression of existing ones. The study was initiated after obtaining approval from the Institutional Ethics Committee of the Government Medical College, Kozhikode, India (ref no: GMCKKD/RP2021/IEC/191, dated: 16/07/2021). Prior to participation, written informed consent was obtained from all patients. The consent form clearly explained the nature and purpose of the study; the procedures involved; the potential risks and benefits; the confidentiality of personal information; and the voluntary nature of participation, including the right to withdraw at any stage without affecting their clinical care.

Statistical Analysis

Data were collected using Microsoft Excel and analyzed with SPSS version 18. Baseline variables were summarized using means and standard deviations for continuous data, and frequencies and percentages for categorical data. Comparisons between the tube ileostomy group (n=44) and the LI group (n=44) were performed. Continuous variables (e.g., hospital stay, ileostomy output, time to stoma function, tube removal, and fistula closure) were compared using the independent-samples t-test to assess differences in means between groups. Categorical variables (e.g., skin excoriation, electrolyte imbalance, stoma care dependence, infection, scarring, and pain) were analyzed using the chi-square test to evaluate differences in their distributions between groups; relative risk (RR) was calculated to quantify the likelihood of complications in one group relative to another. A p-value <0.05 was considered statistically significant. Comparative outcomes and complication rates were illustrated using bar graphs. All analyses were two-tailed, with 95% confidence intervals applied where appropriate.

The Technique of Tube Ileostomy

A 28-French abdominal drain tube (soft thoracic catheter) (7) was inserted into the peritoneal cavity through a stab incision in the abdominal wall. The tube was inserted 10-15 cm proximal to the ileocecal junction for diseases involving the large bowel, and 10 cm proximal to the diseased bowel for ileal pathologies. The tube was positioned so that approximately 10 cm remained within the bowel, with the open end directed proximally. The tube was secured to the bowel wall with a 2-0 polyglyconate purse-string suture (Figure 1). The segments of bowel 1-2 cm proximal and distal to the tube insertion site were fixed to the parietal wall of the abdomen with interrupted 2-0 silk sutures (Figure 2). The tube was secured to the skin of the anterior abdominal wall with no. 1 silk suture; the distal end of the tube was trimmed and connected to the stoma bag (Figure 2).

We preferred an oral liquid diet during the initial week and, by the end of that week, an oral semisolid diet, with twice-daily saline irrigation and aspiration of the tube to prevent tube blockage. No radiological studies were performed to ensure the integrity of the distal anastomosis (8).

Tube blockage may be associated with diet and tube diameter; an easily digestible diet and a sufficiently large tube diameter would reduce this risk. It is managed with saline irrigation, dietary modifications, and laxatives, and is therefore treatable.

Formation of the stoma tract occurred approximately one week after ileostomy, providing a safe time frame for tube removal. Similar results were obtained, with the exact timing of

tube removal ranging from 7 d to >3 wk postoperatively (7). In the present study, the tube was removed on day 21 post-surgery, as in the study by Sheng et al. (7). Following tube removal, the ileostomy site behaves like a low-output fistula and typically heals spontaneously (Figure 2).

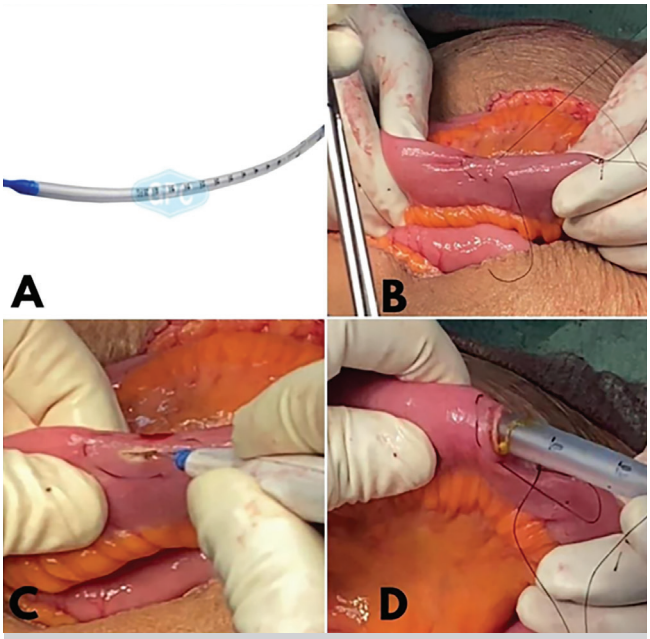

Figure 1. A) 28F soft thoracic catheter for insertion, B) Purse string suture on seleeted healthy segment of bowel, C) Cautery marking of site of tube insertion, D) Tube was secured to bowel wall by 2-0 polyglactin by purse string suture.

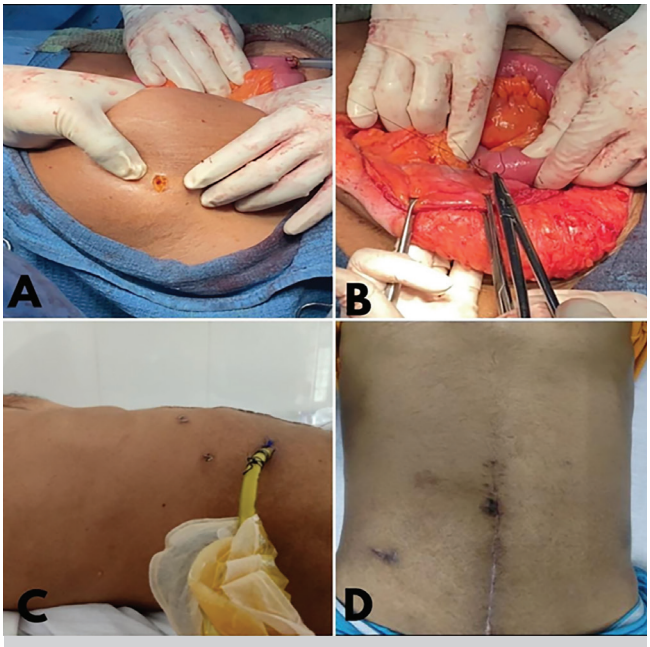

Figure 2. A) Site of tybe exit in anterior abdominal wall, B) Bowel proximal and distal to site of tube insertion was fixed to parietal wall of abdomen with interrupted 2-0 silk, C) Tube was fixed to skin with no. 1 sil and connected to stoma gag, D) Note the spontaneous closure of tube-ileostomy controlled fistula on pod-29.

RESULTS

66% of the patients who underwent LI (n=44) were male; of 44 patients who underwent tube ileostomy, 27 were male. The mean age of tube ileostomy was 61.43±1.09 years, and the mean age of LI was 58.50±1.39 years. In this study, most patients (72.8%) who underwent tube ileostomy for fecal diversion were aged 50-70 years. Tube ileostomy was performed primarily for patients with large-bowel malignancies as a fecal diversion procedure to protect the distal anastomosis. Thirty-six of 44 cases had significant bowel pathology (Table 1).

Table 1. Indications for tube v/s loop ileostomy

Indication for loop ileostomy	% n=44	Indication for tube ileostomy	% n=44
Acute intestinal obstruction	20.5	Acute intestinal obstruction	4.5
Ca ascending colon	4.5	Ca ascending colon	4.5
Ca transverse colon	6.8	Ca transverse colon	9.1
Ca descending colon	4.5	Ca descending colon	2.3
Ca sigmoid colon	6.8	Ca sigmoid colon	2.3
Ca rectosigmoid	22.7	Ca rectosigmoid	36.4
Ca rectum	11.4	Ca rectum	18.2
Familial adenomatous polyposis	2.3	Familial adenomatous polyposis	4.5
Recurrent incisional hernia + intestinal obstruction	2.3	Acute appendicitis with perforated caecum	2.3
S/P extended right hemicolectomy/ anastamotic leak	2.3	Ca ascending colon-hepatic flexure	2.3
Mesenteric ischemia	2.3	Ca caecum	4.5
Necrotising pancreatitis with pancreatico pleural fistula and colonic fistula	2.3	Ca caecum + Ca sigmoid	2.3
Anastamotic leak S/P exploratory laparotomy with ileotransverse anastamosis for intestinal TB	2.3	Ulcerative colitis S/P total colectomy+ end colostomy	2.3
Penetrating injury colon	2.3	Carcinoid tumor appendix	2.3
Ca transverse colon with coloduodenal fistula	2.3	UGI bleed, intestinal obstruction-stricture ileum, small bowel gangrene	2.3
Sigmoid volvulus	2.3		
Sigmoid diverticular perforation	2.3		

%: Percentage, Ca: Carcinoma.

In most elective cases, a tube ileostomy was performed as a diversion procedure. Four of 44 cases underwent tube ileostomy and 18 of 44 underwent LI, all performed in emergency settings. Comorbidities were considered a risk factor for healing of the anastomotic site; 70.5% of cases in which a tube ileostomy was performed had associated comorbid conditions, such as diabetes mellitus, chronic obstructive pulmonary disease, coronary artery disease, hypertension, and dyslipidemia. Of those in whom LI was performed, 52.3% had comorbid conditions unfavorable for anastomotic site healing.

In the present study, the mean ileostomy output was 218±19 mL in tube ileostomy and 333.33±58 mL in LI (p-value was <0.05) (Figure 3). The mean length of hospital stay was 8.30±3.06 days for tube ileostomy and 11.32±1.82 days for LI. In t-test analysis, p<0.05, indicating a statistically significant difference between the two groups (Figure 4).

The mean time to onset of function was 1.09±0.88 days for the tube ileostomy and 1.14±1.002 days for the LI (p=0.82).

For tube ileostomy, 3-4 stoma bags were required on average per month compared with 6-8 stoma bags for LI (t-test p-value =0.0), indicating a statistically significant difference between the groups (Figure 5).

The mean time to tube ileostomy removal was 18.91±4.26 days. Ileostomy-site discharge was observed in 6.8% of cases following tube removal. Because it was a controlled fistula and there was no distal obstruction, discharge from the ileostomy site following tube removal subsided gradually over 8-10 days. The mean time to spontaneous fistula closure following tube removal by granulation tissue formation was 26.86±5.07 days (Figure 6). No formal wound closure of the tube ileostomy site was required. The mean interval to LI reversal was 111.05±22.83 days. Comparison using an independent t-test showed a statistically significant difference (p<0.001).

Skin excoriation, a common complication following ileostomy, is reported in 20.50% of loop ileostomies and 4.60% of tube ileostomies (p=0.024; RR =0.2). Ileostomy-site infection following LI was reported in 11.40% of LI patients and in 6.80% of tube ileostomy patients (p-value =0.458), which is not statistically significant. Since the RR is 0.6, tube ileostomy is associated with a decreased risk of ileostomy-site infection compared with LI; tube ileostomy may protect against stoma-site infection by preventing spillage of stoma contents.

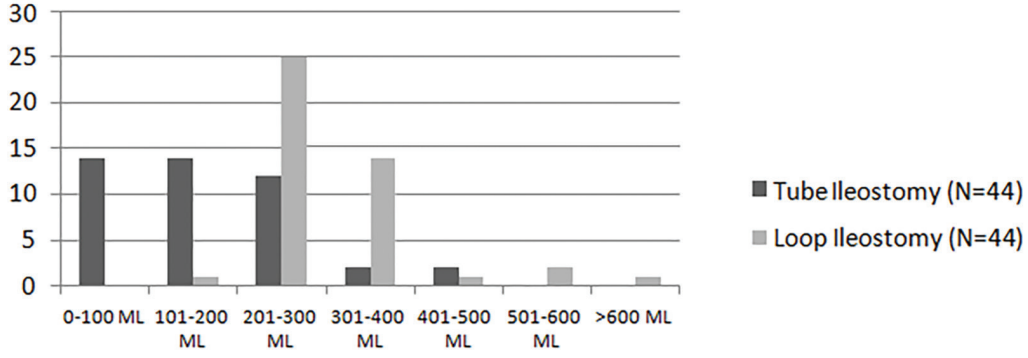

Figure 3. Average output pper day-tube v/s loop ileostomy.

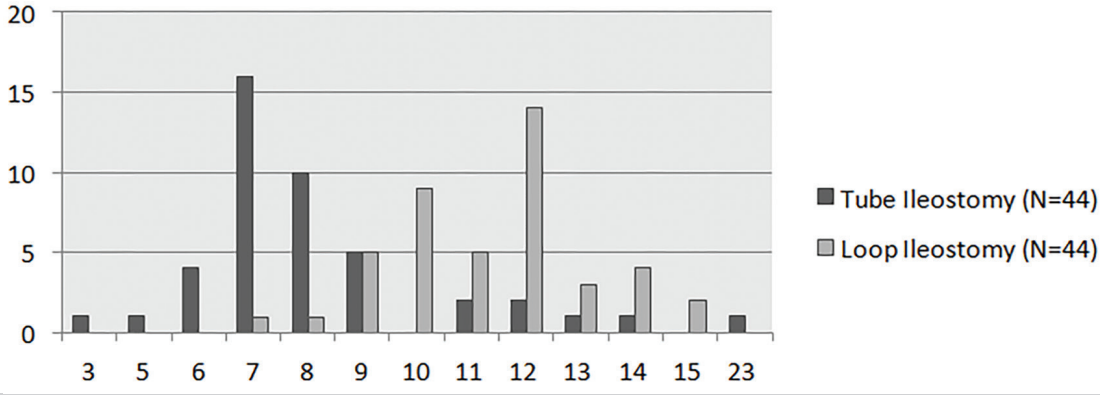

Figure 4. Number of days of hospital stay.

The Likert pain scale was used to assess pain. In both groups, the majority of patients experienced only mild pain on the scale. 13.60% of patients with LI experienced pain, compared to 6.80% of patients with tube ileostomy. The chi-square test was used for analysis. The p-value was 0.291; therefore, the result is not statistically significant despite an observed difference. Since the RR is 0.5, there is an inverse association between ileostomy site pain and ileostomy type. 2.3% of patients with tube-and-LI developed a suspected distal anastomotic leak with tachycardia and fever, which was managed conservatively. In the chi-square analysis, the p-value was 1.00; hence, it is not statistically significant. Since the RR is 1, no association was found between an anastomotic leak and the type of ileostomy. No patients in either group developed clinical features of intestinal obstruction after the procedure.

22.7% of patients with LI had an electrolyte imbalance, compared with 2.3% of patients with tube ileostomy. This may be attributed to the low output from the tube ileostomy, which is a partial diversion technique. Since the RR was 0.1, electrolyte imbalance was less likely to occur in those with a tube ileostomy used as a diversion procedure. A 90% risk of developing electrolyte imbalance is attributable to LI.

A stoma-site hematoma was present in 6.80% of patients with a LI. None of the tube ileostomy patients developed a hematoma. A chi-square test yielded p=0.07, which was not statistically significant. A hypertrophic scar at the stoma site was present in 11.4% of patients with a LI. Notably, none of the patients who underwent tube ileostomy developed hypertrophic scars. Statistical analysis using the chi-square test yielded a p-value of 0.02, which is statistically significant.

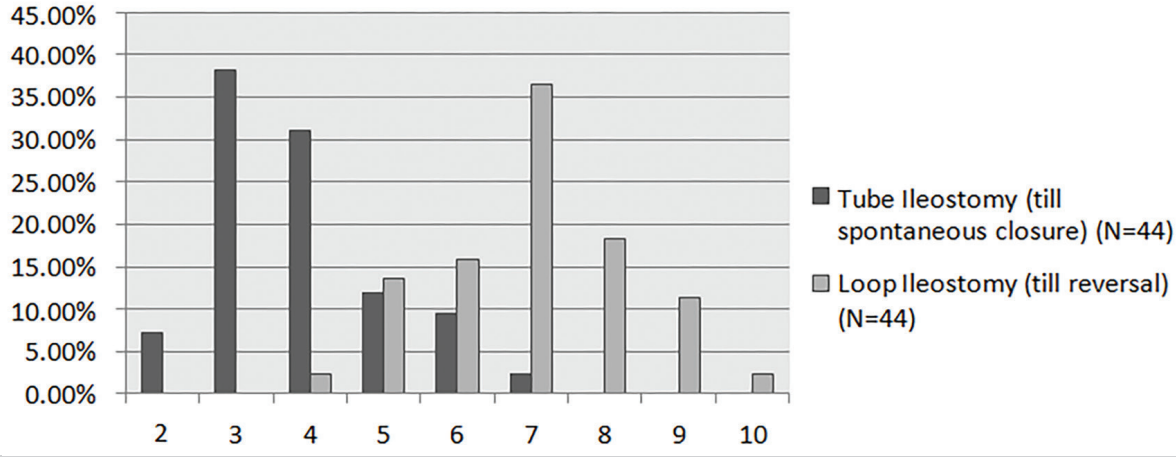

Figure 5. Number of stoma bags used in a month.

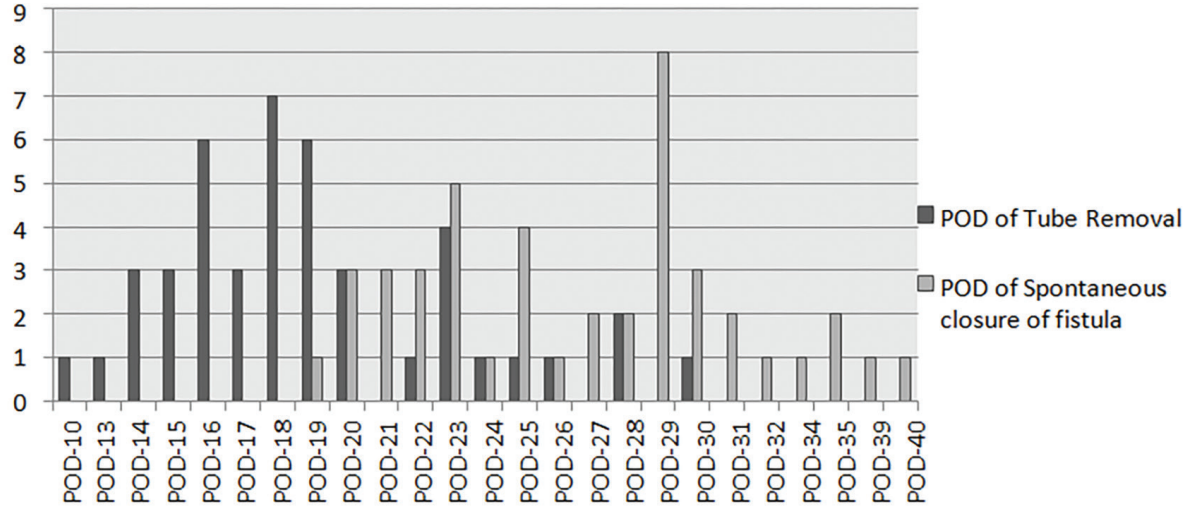

Figure 6. Post-operative day of tube removal vs. spontaneous closure of fistula.

40.9% of tube ileostomy cases developed obstructive features, 15.9% developed peritubal leakage, and 9.1% reported tube migration. 29.50% of patients with LI depended on others for proper stoma care, including changing and applying the stoma bag. 11.4% of patients with tube ileostomies required assistance with tube care. The chi-square test yielded a p-value of 0.34; although a difference was observed, it was not statistically significant.

DISCUSSION

Surgical fecal diversion was first reported in the 18th century and was initially used to relieve distal obstruction (6). During that era, diversion was utilised more frequently in the acute-care setting.

With surgical advances, defunctioning colostomies and ileostomies have become the mainstays of fecal diversion to protect primary colorectal anastomoses in the elective and emergency settings (3). The proximal diversion of a distal rectal anastomosis can be achieved using either a loop colostomy or a LI, although the latter is more common. Stoma-related complications affect up to 30% of patients (9); these include leakage around the appliance, skin rash and excoriation, high output, hernia, retraction, and prolapse (9).

The majority of patients in our study were male. The mean age in our study was 58.2±9.3 years in the LI group and 61.4±9.7 years in the tube ileostomy group, which were similar to those reported by Sheng et al. (7), Bugiantella et al. (8), Attaallah et al. (10) and Hua et al. (11). In a study by Sheng et al. (7), the length of postoperative hospital stay was 11.9±3.2 days (range 8-25), and in a study by Bugiantella et al. (8), the length of postoperative stay was 11.2±1.7 days (range 8-15). In the present study, the mean length of hospital stay after tube ileostomy was 8.30±3.06 days, and after LI was 11.32±1.82 days (p-value <0.05). The total hospital stay for the LI group is longer than for the tube ileostomy group, consistent with the findings reported in the studies mentioned. In a study by Liu et al. (12), the median follow-up was 17 months (range, 3-40 months) during which no bowel obstruction or anastomotic leakage was observed. In another study by Sheng et al. (7), patients were followed up for 17±3.4 months (range, 7-26 months). In the present study, all patients were followed up for six months postoperatively.

Liu et al. (12) reported that the time to first postoperative defecation after tube ileostomy was 13.7±2.1 days (range, 10-19). Bugiantella et al. (8) found that the average time for gas emission through the trans-temporary percutaneous ileostomy was 1.1±0.3 days (range 1-2), and the average time for faecal emission was 1.8±0.9 days (range 1-4). These data were similar to those in our study, in which the time to first anal defecation following tube ileostomy was 4.39±4.67 days (range 5-14 days). This indicates that our tube ileostomy provides a partial fecal diversion lasting 5-14 days and shows that the protective period for a tube ileostomy as a fecal diversion procedure has ended, after which the tube can be removed (9). The time required for ileostomy-site fistulous tract formation was approximately one week after the procedure. Similar results were observed in human studies, in which the timing of tube removal ranged from 7 days to more than 3 weeks postoperatively (7). In the present study, the tube was scheduled for removal on day 21 post-surgery but some were removed earlier because migration complications were suspected.

The data show that the day of tube removal in our study was 18.91±4.26 days, which was similar to Liu et al. (12) [27.8±6.9 (range, 20-44), Sheng et al. (7) [22.6±4.1 (21-28)], Hua et al. (11) (median time 20.5 days), and Attaallah et al. (10) reported balloon deflation and tube removal on postoperative day 21.

Liming Liu et al. (12) reported that the mean duration of continuous tract discharge before the fistula healed was 4.5±1.9 days (range, 2-10 days). Sheng et al. (7) reported that ileostomy wounds closed spontaneously at a mean of 13.1±1.9 days (range, 7-14 days). In our study, the mean time to complete fistula closure was 26.86±5.07 days. One patient experienced a low-output enterocutaneous fistula after tube removal, which was conservatively managed and resulted in closure during the second month of follow-up.

According to the Clavien-Dindo classification, Grades I and II complications were present in both loop- and tube-ileostomy candidates. Still, no grade 4 complications occurred, which was consistent with the findings of Bugiantella et al. (8).

Intestinal obstruction following tube ileostomy may result from blockage of the tube by solid food residue, which may, in turn, occlude the bowel lumen; in both groups, postoperative adhesions can lead to intestinal obstruction. Liu et al. (12) reported that two patients with intestinal obstruction completely recovered with conservative treatment. Bugiantella et al. (8) reported no intestinal obstruction in the early (30-day) postoperative period. None in the current study developed intestinal obstruction.

Nachiappan et al. (3) reported a re-emergence of interest in the use of tube ileostomy to defunction distal anastomoses. Pooled analyses of studies comparing tube ileostomy to LI did not show statistically significant differences in anastomotic leak rates; a similar pattern was observed in our study. In our study, Grade A anastomotic leakage was observed in one tube-and-loop group. It was managed conservatively. One case of abdominal collection requiring percutaneous drainage was recorded in a study by Bugiantella et al. (8). None of our patients developed abdominal collections during the study period. Four cases of peristomal cellulitis were observed and treated with antibiotics in the study by Attaallah et al. (10). In our study, peristomal cellulitis was managed with antibiotics, topical zinc oxide

powder, or application of aluminum paint around the stoma site. In the present study, one patient experienced a low-output enterocutaneous fistula after tube removal, which was managed conservatively and closed by the second month of follow-up. In the present study, one patient with LI developed stomal prolapse that required revision surgery with resection and anastomosis. This is similar to the study by Liu et al. (12), in which one case of stoma prolapse occurred, requiring intervention under general anesthesia. None of the 19 treated patients showed clinical or radiological evidence of anastomotic leakage. One of our patients in the LI group and one in the tube ileostomy group died during the post-discharge follow-up period; both deaths were related to their comorbid conditions.

The selection of a soft thoracic catheter was primarily aimed at reducing pressure-related necrosis associated with endotracheal tube use (6); this necrosis can be highly debilitating and carries a risk of bowel perforation. A limitation of this technique is that it provides only partial diversion. However, no association was observed between the type of ileostomy—loop (complete diversion) or tube (partial diversion)—and the incidence of anastomotic leak. Additionally, none of the patients in either group developed signs of intestinal obstruction post-procedure.

Study Limitations

The study's limitations also include a small sample size (n=88), a single-center design, and a short follow-up period of six months, thereby restricting assessment of long-term quality of life. Self-reported outcomes, such as pain and stoma bag usage, may be subject to bias. Variation in indications, such as emergency versus elective procedures and in underlying pathologies could affect outcomes.

CONCLUSION

Tube ileostomy is a well-established technique for temporary faecal diversion, though it is periodically reassessed. This study demonstrates that self-reversing tube ileostomy can provide superior outcomes compared with conventional LI, including fewer complications, reduced reliance on stoma bags, shorter hospital stays, and avoidance of additional reversal procedures and their associated costs. Renewed interest in this approach stems from the aim to minimise stoma-related morbidity, costs, and care burden, alongside selective evidence of favourable outcomes. These findings highlight the need for further research to clarify its optimal application.

Ethics

Ethics Committee Approval: The study was initiated after obtaining approval from the Institutional Ethics Committee of the Government Medical College, Kozhikode, India (ref no: GMCKKD/RP2021/IEC/191, dated: 16/07/2021).

Informed Consent: Written informed consent was obtained from all patients.

Footnotes

Author Contributions

Concept - S.K.R., J.N.P.; Design - S.K.R., J.N.P.; Data Collection or Processing - A.A.; Analysis or Interpretation - A.A., Y.S., I.H.; Literature Search - S.K.R., J.N.P.; Writing - Y.S., I.H.

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ORIGINAL ARTICLE
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Alterations in endothelial activation biomarkers ICAM-1 and VCAM-1 following mitral regurgitation surgery

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ABSTRACT

Objective: Severe chronic degenerative mitral regurgitation (MR) is characterised by altered hemodynamics and high-shear stress, which initiate left ventricular (LV) remodelling, including upregulation of various cytokines. We evaluated endothelial activation during surgical correction of chronic MR by assessing adhesion molecules ICAM-1 and VCAM-1, classic markers of inflammation, and their association with postsurgical LV dysfunction (LVD).

Material and Methods: The study included asymptomatic patients with grade 3-4 degenerative MR. Transthoracic echocardiography data and blood samples were collected before and five days after surgical correction of MR. Circulating levels of adhesion molecules were measured by ELISA.

Results: Ejection fraction, end-diastolic diameter (EDD), and volume all decreased significantly after surgery. A significant decline in ICAM-1 concentration was observed between the two periods (457.11±256.12 vs. 240.29±157.14 ng/mL; p=0.031), whereas VCAM-1 levels did not change significantly. Leukocyte count and C-reactive protein were significantly higher in the postoperative period. Early postoperative LVD (in 35.7% of patients) was not correlated with adhesion molecule levels. However, we observed significant changes in ICAM-1 levels associated with postoperative EDD >5.6 cm, which indicates LV dilatation. These patients had markedly lower preoperative and postoperative ICAM-1 values than others.

Conclusion: Serum ICAM-1 levels significantly decline following surgical correction of MR and are associated with postoperative enlargement of the LV. Our study highlights dynamic changes in endothelial activity and underscores the need for a better understanding of this process in MR.

Keywords: Mitral valve replacement, vascular cell adhesion molecule-1, left ventricular dysfunction, endothelial activation

INTRODUCTION

Mitral regurgitation (MR) is a valvular disease that is predominantly degenerative in developed countries, whereas infectious and rheumatic causes remain common in other countries (1,2). Initial cardiac structural derangements due to chronic primary MR elicit cellular responses leading to pathological wall remodelling. Specifically, end-diastolic volume (EDV) overload disrupts extracellular matrix (ECM) architecture and induces cytoskeletal alterations that, along with oxidative stress, generate inflammation, a fibrotic response, and apoptotic cell death. Pathological left ventricular (LV) remodelling includes altered matrix metalloproteinase activity and collagen isoform distribution, reduced protein degradation, cell slippage, myocyte loss, and, finally, myocardial fibrosis (2-4). The remodelling of the MR underpins the progression of cardiac dysfunction and complications, such as myocardial weakening, cardiac arrhythmias, thrombosis, and heart failure. The currently recommended therapeutic approach is surgical repair or replacement of the mitral valve in patients eligible for surgery (5,6).

Altered hemodynamics and a high-shear-stress environment in moderate-to-severe chronic MR contribute to structural and functional modifications (5,7-9). Consistent with this, endothelial cells subjected to mechanical strain or altered shear stress rapidly generate a stress response, reflected by upregulated gene and protein expression of inflammatory cytokines, chemokines, and cell adhesion molecules. Endothelial injury is considered an adverse event that maintains and aggravates LV remodelling and interferes with recovery (1,2,5-9).

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The short-term effects of surgical relief of volume overload on LV remodelling, function, and systemic hemodynamics during MR correction have not been sufficiently studied, particularly with respect to cellular events. Alterations in shear stress and inflammation increase the expression of intercellular adhesion molecule-1 (ICAM-1) and vascular cell adhesion molecule-1 (VCAM-1), which are considered biomarkers of endothelial activation and mediators of inflammation. Their induction can occur via cytokines and local peptides, such as tumour necrosis factor-α (TNF-α), transforming growth factor -β1 (TGF-β1), and bone morphogenetic protein-4 (BMP-4) (8-11). The primary role of adhesion molecules is to provide a firm attachment of leukocytes during the inflammatory response. ICAM-1 is a receptor for leukocyte β2-integrins, while VCAM-1 interacts with α4β7 integrin and is involved in leukocyte transendothelial migration to sites of inflammation (9-12). In addition, ICAM-1 is involved in wound healing and is constitutively expressed in the lung microvascular endothelium (3,10). The expression of adhesive molecules can be induced in several other cell types that do not usually express them, as observed in myogenic cells during regenerative myogenesis of skeletal muscle (10-14).

We aimed to evaluate endothelial activation during surgical correction of chronic primary MR by assessing adhesion molecules ICAM-1 and VCAM-1, along with classic markers of inflammation [white blood cell count (WBC), C-reactive protein (CRP), and fibrinogen]. The association between the adhesion molecules and postsurgical LV dysfunction (LVD) is also analysed.

MATERIAL and METHODS

Study Population

This pilot prospective cohort study included 28 consecutive patients with grade 3-4 MR, according to the 2020 American College of Cardiology/American Heart Association (ACC/AHA) guidelines for the management of patients with valvular heart disease, and used appropriate validated techniques (2,5). The patients were recruited in 2025 at the Clinic for Cardiac Surgery, University Clinical Centre of Serbia, University of Belgrade.

The study was conducted in accordance with the Declaration of Helsinki and approved by the Institutional Ethics Review Board of the University of Nis in Serbia (approval no: 12-16442-1/2-4 from December 20, 2024).

The inclusion of patients started in December 2024 and lasted until July 2025. Inclusion criteria included adult, asymptomatic patients with primary severe MR of non-ischemic and non-rheumatic causes who agreed to participate in the study and provided written informed consent. The patients underwent routine transthoracic echocardiography with quantification of MR, as well as transesophageal echocardiography (TEE), which was used to guide intraoperative decision-making. Quantitative grading of severe primary MR was based on 2D echocardiography and included: Effective regurgitant orifice area by 2D proximal is velocity surface area ≥40 mm^2, regurgitant volume ≥60 mL/beat, and regurgitant fraction ≥50%. Surgical indications for patients with asymptomatic primary MR also included ejection fraction (EF) <60%, LV end-systolic diameter >40 mm, atrial fibrillation, systolic pulmonary artery pressure (SPAP) >50 mmHg, and/or left atrial volume index >60 mL/m^2 (2,15).

The appropriate surgical approach was determined using TEE. Patients underwent either mechanical mitral valve replacement (MVR) or mitral valve prosthetic ring annuloplasty (MVA) with a restrictive prosthetic ring (downsizing by 2.7±0.8 ring sizes). MVR was commonly performed in patients with severe MR who were unsuitable for surgical repair, according to recommendations (2,15).

Exclusion criteria included ischemic cardiomyopathy, acute cardiac events, coronary artery disease, history of bypass surgery or percutaneous angioplasty, aortic valve disease, mitral stenosis, or other cardiac diseases. Patients with diabetes mellitus, malignancies, or acute or chronic inflammatory diseases were not recruited. In addition, patients who developed an infection during postoperative recovery were excluded from the study.

Data Collection

Patient data were collected before the procedure and 5 days after the procedure using transthoracic echocardiography (2D and M-mode). The obtained variables were measured or calculated (through the Teicholz method), including dimensions [end-diastolic (EDD), end-systolic (ESD)] and volumes of the LV (EDV, ESV, SV), EF, as well as derived measures of forward LVEF (100× forward stroke volume/LV EDV), right ventricle systolic pressure, and LV wall stress (WS).

Patients were divided into groups and compared based on the development of early postoperative LV systolic dysfunction, defined as LV EF <50% after mitral valve surgery.

Biomarker Measurement

A blood sample was collected from each patient before surgery and again 5 days after surgery. Assessment of inflammatory biomarkers after 5 days is often used to provide crucial information on the patient's response to treatment and to monitor early treatment effectiveness. During this period, early-induced inflammatory markers (e.g., CRP) typically decrease rapidly with effective treatment; consequently, their changes may reveal the course of the disease, progression to complications, or recovery. ICAM-1 and VCAM-1 are also part of the rapid phase of the endothelial-cell response to various stimuli (16-20).

The solid-phase sandwich ELISA was used to measure the concentrations of adhesion molecules. Human ICAM-1/CD54 Allele-specific Quantikine ELISA Kit had a sensitivity of 0.254

ng/mL and an assay range of 1.6-50 ng/mL, while the Human VCAM-1/CD106 Quantikine ELISA Kit had a sensitivity of 1.26 ng/mL and an assay range of 6.3-200 ng/mL (R&D Systems, Inc., Europe Abingdon OX14 3NB, UK). Routine laboratory examination consisted of CBC and analysis of biochemical parameters, performed using the CELL-DYN Ruby Haematology Analyser (Abbott Diagnostics, Illinois, U.S.A.). Inflammatory biomarkers (WBC, CRP, and fibrinogen) and adhesion molecules were analyzed across the two time periods.

Statistical Analysis

Results are presented as continuous or categorical variables: Continuous data are reported as mean ± standard deviation, and categorical data as percentages, as required. The distribution of the variables was assessed using the Shapiro-Wilk test. Independent and paired t-tests were used to compare measured parameters before and after the corrective procedures in patients. The Pearson correlation coefficient was used to measure linear correlation between two sets of data. The chi-square test was used to compare categorical parameters. We collected complete data for all patients. A significance threshold was set at $p<0.05$. Statistical analyses were performed using SPSS 25.0 (SPSS Inc., Chicago, IL, USA).

RESULTS

Of the 28 included patients, 21 (75%) were male and 7 (25%) were female, with a mean age of 65.1±12.6 years. Twelve (42.8%) underwent MVA, while 16 (57.1%) underwent MVR. Gender did not influence the type of surgery ($p>0.05$). The average duration of MR was 12±11 months. Following standard preoperative preparation, all patients underwent general anesthesia. Open-heart surgery was performed via median sternotomy, with partial resection of post sternal tissue and an inverted T-shaped vertical pericardiotomy. The cardiopulmonary bypass was applied. The mean cross-clamp and cardiopulmonary bypass times were 83.76±21.41 and 115.88±38.20 minutes, respectively. All patients recovered well after surgical MR correction without complications.

Transthoracic echocardiography showed that EF, EDD, EDV, SV, and RVSP were significantly decreased after surgery compared with the preoperative period ($p<0.05$). The mean postoperative EF did not differ significantly between the MVA and MVR groups (54.5%±15.16 vs. 52.8%±5.88). The echocardiographic parameters for the two time periods are shown in Table 1.

We observed a significant difference in ICAM-1 concentrations between the two periods [457.11±256.12 vs. 240.29±157.14 ng/mL; p=0.031; 95% confidence interval (CI): 26.07-443.29]. By contrast, there was no significant change in VCAM-1 levels (1019.45±737.39 vs. 1099.07±764.59 ng/mL, $p>0.05$) in our patients (Table 2). Additionally, there was no significant correlation between preoperative and postoperative levels of ICAM-1 or VCAM-1.

The WBC and CRP levels were significantly elevated in the postoperative period, likely reflecting tissue injury caused by the surgery. However, fibrinogen concentration did not change markedly (Table 2).

Before surgery, ICAM-1 and fibrinogen concentrations were observed to be significantly and negatively correlated (p=0.020; r=-0.613). There was a weak tendency toward a negative correlation between ICAM-1 and CRP levels (p=0.090, r=-0.470). Postoperatively, ICAM-1 levels tended to correlate positively with EDD (p=0.052, r=0.435). No other significant correlations were observed between the adhesion molecules and inflammatory biomarkers or echocardiographic parameters.

Early postoperative LVD (<50% EF) was recorded in 10 patients (35.7%), with a mean EF of 44.20±5.54% compared with 58.33±5.52% in patients without LVD (p=0.001; 95% CI: 7.414-20.852). Preoperative EDD was higher in those who developed

Table 1. Echocardiography parameters in the two time periods

Parameter	Mean ± SD		p-value (CI)
	Before surgery	After surgery	
EF (mL)	62.14±8.25	53.29±8.81	0.013 (2.17-15.54)
EDD (cm)	6.06±0.57	5.29±0.49	0.001 (0.41-1.14)
ESD (cm)	3.97±0.52	3.81±0.59	NS
EDV (mL)	187.51±39.71	137.67±28.53	0.000 (30.36-69.33)
ESV (mL)	71.06±21.56	64.12±22.55	NS
SV (mL)	116.21±31.86	73.55±15.12	0.000 (24.57-60.85)
FLVEF (mL)	33.64±8.94	42.13±16.05	NS
RVSP (mmHg)	51.82±11.56	39.86±7.84	0.008 (3.68-20.25)
WS (kdynes/cm^2)	117.95±17.45	115.90±14.59	NS

EF: Ejection fraction, EDD: End-diastolic diameter, ESD: End-systolic diameter, EDV: End-diastolic volume, ESV: End-systolic volume, SV: Stroke volume, FLVEF: Forward left ventricular EF, RVSP: Right ventricular systolic pressure, WS: W all stress, SD: Standard deviation, CI: Confidence interval, NS: Not significant.

Table 2. Adhesion molecules and inflammatory biomarkers in the two time periods			
Parameter	**Mean ± SD**		**p-value (CI)**
	Before surgery	**After surgery**	
ICAM-1 (ng/mL)	457.11±256.12	240.29±157.14	0.031 (26.07-443.29)
VCAM-1 (ng/mL)	1019.45±737.39	1099.07±764.59	NS
WBC ($x10^9$)	7.32±2.76	11.61±1.96	0.000 (-6.18- -2.39)
CRP (mmol/L)	2.68±3.23	117.59±47.61	0.000 (-141.79- -8.02)
FIB (g/L)	3.25±0.56	3.31±0.35	NS

ICAM-1: Intracellular adhesion molecule-1, VCAM-1: Vascular cell adhesion molecule-1, WBC: White blood cells, CRP: C-reactive protein, FIB: Fibrinogen, SD: Standard deviation, CI: Confidence interval, NS: Not significant.

LVD, but the difference was not statistically significant (6.44±0.62 vs. 5.86±0.44; p=0.060). Of the postoperative echocardiographic parameters, ESD differed significantly, with a greater diameter in those with LVD vs. others (4.26±0.47 vs. 3.56±0.52 cm; p=0.028; 95% CI: -1.317 to -0.091).

Adhesion molecules and inflammatory biomarkers did not correlate with postoperative EF or with the development of LVD. Accordingly, both patient groups demonstrated declines in ICAM-1 levels after MR correction. VCAM-1 concentration decreased in the non-LVD group, whereas it was slightly higher in the LVD group; however, the difference was not statistically significant.

However, the results demonstrate significant changes in ICAM-1 levels in patients with postoperative EDD >5.6 cm (the upper limit of normal diastolic size), indicating LV dilatation (n=13, 46.4%). These patients had significantly lower preoperative and postoperative ICAM-1 values than patients with normal-sized EDD (preoperative ICAM-1: 276.987±191.83 vs. 592.198±216.501; p=0.015; postoperative ICAM-1: 139.65±106.86 vs. 312.173±138.097; p=0.042).

In addition, postoperative WBC count was significantly associated with EDD >5.6 cm. Lower WBC counts were observed in patients with an enlarged LV (10.250±1.477 vs. 12.625±1.675; p=0.017).

DISCUSSION

Mitral valve regurgitation is an important contributor to cardiovascular disease. Patients with severe MR undergo surgical repair, preferably before symptom onset, because studies have found better survival in this setting. Importantly, severe MR indicates that substantial ventricular remodeling has already occurred due to chronic volume overload. Despite a preoperative EF ≥60%, LV contractile dysfunction is a common complication of MR surgery. Thus, the actual state of the LV in asymptomatic MR may be masked by a normal EF. When the mitral defect is corrected, the influence of regurgitant volume disappears and afterload increases, thereby revealing the actual state of LV function (1,2,5,6,21).

A prolonged increase in WS in MR is associated with activation inflammatory and apoptotic pathways, ultimately leading to cell loss and myocardial ECM derangement with diffuse interstitial fibrosis (6,21). At the same time, the endothelium, a dynamic system that adapts in response to shear stress, undergoes functional and structural reorganization, including altered expression of molecules mediating cell-matrix and cell-cell interactions. Research on ischemic mitral valve regurgitation shows that the endothelium has an early and dynamic role in valve adaptation. Specifically, an insult to the endothelium and intimal tissue is followed by a defensive response in which signaling from injured cells initiates remodeling pathways (5,6,21).

Adhesion molecules ICAM-1 and VCAM-1 are established markers of endothelial activation. The upregulation of these molecules helps inflammatory cells adhere to and infiltrate the subendothelium. Accordingly, their concentrations have been elevated in various inflammatory conditions (9,10,22,23). Nevertheless, evidence shows that these adhesion molecules are related not only to inflammatory processes but also to degenerative processes and epithelial injury-resolution responses (10,13,23). ICAM-1, VCAM-1, and E-selectin were found to be constitutively expressed on both degenerative (mostly calcified) and inflamed valves during acute endocarditis. Moreover, aortic valvular endothelium displays an inflammatory response under shear stress conditions, including the upregulation of ICAM-1 and VCAM-1. These molecules are correlated with the occurrence of cardiac events and therefore have been proposed for the assessment of cardiovascular risk (10,22,23).

We determined that serum ICAM-1 levels changed following MR-correcting surgery. Blood ICAM-1 declined significantly five days after surgery. By contrast, VCAM-1 levels did not vary significantly in relation to MR surgery. Leukocyte counts and CRP values were elevated postoperatively, likely reflecting tissue damage, and declined gradually.

Moreover, ICAM-1 levels were markedly associated with EDD size but not with LVD occurrence, although patients who

developed LVD had higher preoperative LV diameters. LV EDD >5.6 cm indicates LV dilatation, which is often accompanied by reduced systolic function, chronic strain, or LVD. An enlarged EDD suggests structural changes and impaired contractility, which may increase the risk of heart failure (24-26). Li et al. (24) demonstrated that an enlarged LV EDD in patients with coronary artery disease is an independent predictor of all-cause mortality. Our patients with postoperative LV dilatation had significantly lower ICAM-1 levels than others.

LV dilatation alters blood flow dynamics and vortex patterns, changes wall shear stress, and consequently affects the behavior and function of the cardiovascular system. Dilatation reduces blood flow velocity during diastolic filling, likely because of a longer filling period and a reduced pressure gradient between LV pressure and left atrial pressure. In this context, endocardial cells engage in a series of signaling cascades that modify protein expression (27,28).

Moreover, our results reveal a discrepancy between inflammatory biomarkers and adhesion molecules. Preoperatively, ICAM-1 was inversely correlated with fibrinogen and CRP. VCAM-1 did not correlate with other biomarkers. These results suggest that the adhesion molecules may not be exclusively influenced by the inflammatory response, but rather by another process. Also, the changes we observed occurred relatively quickly following operative correction and appeared to be related to hemodynamic changes associated with surgery. We suppose that higher preoperative ICAM-1 levels may result from increased shear stress in the heart and increased pressure in the pulmonary vessels due to MR.

Valvular endothelial cells exhibit several distinct features in their responses to mechanical and haemodynamic stimuli. Their response to oscillatory and turbulent shear stress includes upregulation of chemokines and adhesion proteins (ICAM-1 and VCAM-1) (1). Moreover, circulating ICAM-1 is proposed to originate from proteolytic cleavage and release of cell surface-bound ICAM-1, mediated by kinases and metalloproteinases (e.g., ADAM17) (29,30). In this context, a recent in vitro study observed a profound upregulation of the endothelial iRhom1 adapter protein in response to physiological shear stress. This pseudoprotease is one of the crucial regulators of metalloproteinase ADAM17 (30).

An additional may involve MR-induced increases in left atrial and pulmonary pressures (31). As mentioned, the pulmonary microvasculature constitutively expresses high levels of ICAM-1 (5). The pressure changes in MR may injure the pulmonary vascular endothelium and disrupt its expression and release of surface molecules. Endothelial impairment in this setting is characterized by the production of nitric oxide and endothelin-1 (ET-1). Elevated ET-1 levels have been associated with left atrial dimensions and atrial fibrillation in patients with mitral valve disease (32,33). ET-1 secretion is promoted by increased wall shear stress and pressure overload, while elevated ET-1 may promote local remodeling processes, including the upregulation of ICAM-1 and VCAM-1 (34,35).

A study (36) found differences in the expression of ICAM-1 and VCAM-1 on vascular endothelial cells subjected to shear stress versus cytokine stimulation. The shear stress enhanced the TNF–α–induced expression of ICAM-1 (both transcriptional and surface expression levels) but decreased the TNF–α–induced expression of VCAM-1 and E-selectin. However, the introduction of static incubation diminished the aforementioned effects of TNF-α. The findings suggest a decisive role for shear stress in modulating the effects of TNF-α on the expression of adhesion molecule genes.

Additionally, a recent study (20) investigated endothelial cell-derived extracellular vesicle markers in acute myocardial infarction and identified a rapid and selective increase in EVs bearing VCAM-1, but not ICAM-1. The study reveals a novel vesicle-dependent mechanism for the rapid mobilization of neutrophils from a splenic reserve following ischemic injury to the myocardium.

The relevance of these two studies to our results is reflected by the presence of both changes during and after MR surgery: Alterations in shear stress and inevitable but controlled tissue injury.

Study Limitations

Limitations of our preliminary study include a single-center design and a limited number of eligible patients, due to restrictions in the randomization process. Therefore, to enhance robustness, prospective and multi-center studies are needed. In future studies, it would be informative to compare cytokine and chemokine levels and their correlations with levels of endothelial cell adhesion molecules. The study analyzed a small set of laboratory parameters, and future work should explore additional variables and their interactions, including laboratory biomarkers, demographic elements, genetic traits, and environmental factors. This would provide a more comprehensive understanding of pathophysiological developments and potentially inform risk-assessment strategies.

Our research provides new insights into mitral valve surgery, particularly regarding understudied molecular changes. In general, serum biomarkers are considered cost-effective and available tools for assessing patients' diagnoses, prognoses, and treatment options. In the future, endothelial activation biomarkers could be utilized as a reliable, easy-to-use source of information for MR patients and for post-surgical evaluation. According to our results, ICAM-1 warrants further investigation as a predictor of LV dilatation and dysfunction. Given the

importance of enlarged LV EDD in predicting patient outcomes (24-26), the decline in ICAM-1 associated with EDD enlargement could be further explored as an additional or surrogate biomarker. Our results, together with evidence of higher cardiac adverse events due to endothelial activation (5), warrant further investigation for risk assessment, monitoring, and treatment options.

CONCLUSION

We can conclude that ICAM-1 serum levels significantly decline following surgical correction of chronic primary MR and are associated with increased postsurgical EDD size. Our study highlights the dynamic changes in endothelial activity and the need for a proper understanding of both endothelial activation in MR and the interpretation of its serum indicators.

Ethics

Ethics Committee Approval: The study was conducted in accordance with the Declaration of Helsinki and approved by the Institutional Ethics Review Board of the University of Nis in Serbia (approval no: 12-16442-1/2-4 from December 20, 2024).

Informed Consent: Informed consent was obtained.

Footnotes

Author Contributions

Concept - S.K., J.M., B.D., S.P., D.S.; Design - S.K., J.M., B.D., S.P., D.S.; Data Collection or Processing - S.K., J.M., S.P.; Analysis or Interpretation - S.K., J.M., B.D., S.P., D.S.; Literature Search - S.K., J.M., B.D., D.S.; Writing - S.K., J.M., B.D., S.P., D.S.

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ORIGINAL ARTICLE
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Rare anatomical localizations of primary hydatid cysts: A single-center retrospective observational study

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ABSTRACT

Objective: To describe the clinical, radiological, and surgical characteristics of primary hydatid cysts arising in uncommon anatomical locations other than the liver and lungs.

Material and Methods: This single-center retrospective observational study included 523 patients who underwent surgical treatment for hydatid disease at Servergazi State Hospital, Denizli, Türkiye, between January 2009 and June 2024. Patients with hepatic or pulmonary involvement, a history of previous hydatid surgery, or multi-organ disease were excluded. Demographic characteristics, clinical presentations, cyst localizations, diagnostic modalities, and treatment approaches were systematically recorded. Diagnostic evaluation was based on serological assays and imaging techniques, including ultrasonography, computed tomography, and magnetic resonance imaging.

Results: Of the 523 patients evaluated, 29 (5.5%) were identified as having primary hydatid cysts in atypical anatomical locations. The spleen was the most frequently involved site, followed by musculoskeletal structures, the central nervous system, and various soft tissue localizations. Serological tests were positive in 82.7% of cases. All patients underwent surgical management tailored to cyst location, and postoperative albendazole therapy was administered. Postoperative complications were limited, and no procedure-related mortality was observed.

Conclusion: Primary hydatid cysts may present in a wide spectrum of uncommon anatomical locations and often manifest with non-specific clinical features. Awareness of these atypical presentations is essential for accurate diagnosis and appropriate surgical management, particularly in endemic regions.

Keywords: Hydatid disease, cystic echinococcosis, atypical localization, extrahepatic hydatid cyst, retrospective study

INTRODUCTION

Cystic echinococcosis (CE), caused by *Echinococcus granulosus*, remains a persistent global health concern due to its chronicity and potential for severe morbidity (1,2). Despite considerable public health efforts, the disease continues to be endemic in many regions—particularly in areas with extensive livestock farming such as South America, the Middle East, East Africa, Central Asia, and the Mediterranean basin (1,3). Türkiye is among the Mediterranean countries where CE remains a significant problem, owing to close human–animal contact and rural agricultural practices (4).

Humans become accidental intermediate hosts after ingestion of parasite eggs, with larvae typically reaching the liver via the portal circulation, making it the most commonly affected organ (75-80%) (2,5). The lungs represent the second most frequent site (5-15%) (5). When larvae bypass these primary "filter organs," hydatid cysts can arise in almost any tissue through hematogenous or lymphatic dissemination (6).

Although hepatic and pulmonary hydatid cysts account for the majority of cases, hydatid disease may occasionally present in atypical or uncommon sites, constituting approximately 3-10% of reported cases in the literature (7-9). Such locations include the spleen, kidneys, peritoneum, musculoskeletal system, heart, brain, thyroid, breast, ovaries, and bone. These unusual localizations frequently mimic other pathological entities and may therefore delay diagnosis (7-11).

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The aim of this study was to describe primary hydatid cysts identified in organs and tissues other than the liver and lungs in patients treated at a state hospital in Western Anatolia. By presenting these rare cases, we aim to contribute to the growing literature on atypical hydatid disease and emphasize the importance of considering CE in the differential diagnosis of cystic lesions in endemic regions.

MATERIAL and METHODS

This study was designed as a single-center, retrospective observational analysis. All patients who underwent surgical treatment for hydatid disease in the surgical departments of Servergazi State Hospital, Denizli, Türkiye, between January 2009 and June 2024 were identified through the hospital's electronic medical record system and archived clinical files.

Primary hydatid cysts were defined as cystic lesions located in isolated organs or tissues without any evidence of hepatic or pulmonary involvement. Patients with concomitant liver or lung hydatid disease, a history of previous hydatid cyst surgery, or multi-organ involvement were excluded to ensure a homogeneous study population and to avoid confounding clinical characteristics.

For each eligible patient, demographic characteristics, presenting symptoms, cyst number and anatomical localization, serological test results, imaging modalities used for diagnosis, and treatment strategies were systematically recorded. Diagnostic confirmation was based on a combination of serological assays and radiological imaging, including ultrasonography (US), computed tomography (CT), and magnetic resonance imaging (MRI), as clinically indicated.

All available surgical specimens previously diagnosed as hydatid cysts were re-evaluated by two independent pathologists using hematoxylin-eosin-stained sections to confirm the diagnosis and ensure histopathological accuracy.

The study obtained ethical permission from the Pamukkale University Non-Interventional Clinical Research Ethics Committee (number: E-60116787-020-453576, date: 31.10.2023). This retrospective study is based on anonymized medical records and does not involve any direct patient contact or intervention. Therefore, as per the institutional ethics committee's guidance, obtaining informed consent was not necessary. The manuscript underwent linguistic editing with the assistance of artificial intelligence tools and was subsequently reviewed and approved by the authors.

Statistical Analysis

Statistical analyses were performed using IBM SPSS Statistics for Windows, version 26.0 (IBM Corp., Armonk, NY, USA). Given the retrospective and purely descriptive nature of the study, only descriptive statistical methods were applied. Continuous variables were summarized as mean, standard deviation, and minimum-maximum values, while categorical variables were presented as frequencies and percentages. No comparative or inferential statistical analyses were performed.

RESULTS

A total of 588 patients diagnosed with hydatid disease were initially identified through the hospital information system. Twenty-two patients with incomplete clinical data and 43 patients who were diagnosed at our institution but operated on elsewhere were excluded. The final study cohort consisted of 523 patients, including 286 females (54.7%) and 237 males (45.3%), with a mean age of 42.6 years (range: 18-89 years). More than half of the patients (55.6%) resided in rural areas.

At the time of presentation, 421 patients (80.5%) were symptomatic, whereas the remaining patients were diagnosed incidentally during radiological examinations performed for unrelated clinical indications. Presenting symptoms were categorized into broader clinical groups to improve clarity. Abdominal symptoms included abdominal pain, dyspepsia, nausea, and vomiting. Respiratory symptoms consisted of cough, dyspnea, chest pain, and hemoptysis. Neurological symptoms, such as headache and fainting, were observed in a small number of patients. Mass-related complaints, including palpable swelling in superficial or deep soft tissues, were also frequently reported.

Single-organ involvement was detected in 367 patients (70.1%), while 156 patients (29.9%) had multi-organ involvement. The distribution of organ involvement among patients with single and multiple organ disease is summarized in Table 1.

Among the entire cohort, 29 patients (5.5%) were identified as having primary hydatid cysts located outside the liver and lungs. The spleen was the most frequently involved atypical site. Other uncommon localizations included musculoskeletal tissues, the central nervous system, posterior cervical region, paraspinal area, breast, ovary, uterus, mesentery, omentum, inguinal region, and axilla. Several lesions—particularly those involving the breast, ovary, mesentery, and omentum—were detected incidentally during imaging studies performed for unrelated reasons.

Serological evaluation using the indirect hemagglutination assay yielded positive results in 82.7% of patients with atypical localizations, interpreted according to the manufacturer's recommendations. All patients underwent diagnostic imaging with US, CT, magnetic resonance imaging, or various combinations of these modalities, depending on cyst location and clinical presentation. Representative radiological findings are presented in Figures 1 and 2.

Surgical management was performed in all patients and was tailored according to cyst localization and adjacent organ

involvement. Surgical procedures included total cystectomy, pericystectomy, and organ resection when deemed necessary. Representative intraoperative images of primary hydatid cysts at atypical anatomical sites are shown in Figure 3. Histopathological examination confirmed the diagnosis in all cases, demonstrating the characteristic laminated acellular cuticular membrane and germinal layer. Representative microscopic findings from different anatomical sites are presented in Figure 4. Postoperative complications included surgical site infection, incisional hernia, hematoma, and local recurrence. One case of recurrence was observed in a patient with paraspinal involvement. No procedure-related mortality was recorded. Detailed demographic characteristics, clinical presentations, diagnostic methods, surgical approaches, and postoperative outcomes of patients with atypical primary hydatid cysts are summarized in Table 2.

All patients received postoperative albendazole therapy, with treatment duration adjusted according to cyst characteristics, surgical findings, and clinical course.

DISCUSSION

CE remains a significant public health problem in endemic regions due to its chronic course, diagnostic challenges, and potential for serious morbidity. Although the liver and lungs function as the primary biological filters for *Echinococcus granulosus* larvae, bypass of these organs may result in cyst development in almost any tissue. Consequently, primary hydatid cysts in atypical anatomical locations, while uncommon, represent a well-recognized but diagnostically challenging clinical entity (1,2,7,10-21).

The proportion of patients with primary extrahepatic and extrapulmonary hydatid cysts in the present series is consistent with rates reported in the literature. Previous studies from endemic regions have demonstrated that such atypical localizations account for a small but clinically relevant subset of cases (1,13-15,22). These lesions often mimic neoplastic, inflammatory, or congenital cystic conditions, leading to delayed diagnosis or inappropriate initial management, particularly when hydatid disease is not considered in the differential diagnosis (9,10,16-25).

Several mechanisms have been proposed to explain the occurrence of hydatid cysts in unusual anatomical locations. These include hematogenous dissemination after bypassing the hepatic and pulmonary filters, lymphatic spread, and, in selected cases, transdiaphragmatic migration (6,25-39). These pathways may account for the wide spectrum of anatomical involvement observed in primary atypical hydatid disease, including musculoskeletal, central nervous system, and pelvic localizations (16-18).

Splenic involvement represented the most frequent atypical localization in our cohort, in line with previous reports (16,18,21). Despite being among the more frequently reported extrahepatic sites, isolated splenic hydatid cysts remain rare

Table 1. Distribution of single and multiple organ involvement in hydatid disease

Single organ involvement (n=367)		**Multi-organ involvement (n=156)**	
% (n)	**Organs**	**% (n)**	**Organs**
68.6 (252)	Liver	50.6 (79)	
23.4 (86)	Lung	3.2 (5)	Liver and kidney
2.4 (9)	Spleen	4.4 (7)	Liver and mesentery
0.5 (2)	Neck	5.1 (8)	Liver and spleen
0.2 (1)	Brain	1.9 (3)	Liver, lung, and spleen
0.5 (2)	Inguinal area	3.2 (5)	Liver, mesentery, and spleen
0.8 (3)	Gluteal region	7 (11)	Liver and omentum
0.2 (1)	Uterus	5.1 (8)	Liver, spleen, and omentum
0.2 (1)	Paraspinal region	1.9 (3)	Lung, spleen, and omentum
0.2 (1)	Ovary	17.3 (27)	Others
0.2 (1)	Omentum		
0.8 (3)	Thigh		
0.2 (1)	Axilla		
0.2 (1)	Mesentery		
0.2 (1)	Cervical area		
0.5 (2)	Breast		

(19,23). Importantly, there is no universally accepted standard treatment algorithm for splenic hydatid disease. Management strategies vary depending on cyst size, location, presence of complications, and institutional or surgeon experience (19,23). While spleen-preserving techniques and percutaneous approaches such as puncture-aspiration-injection-reaspiration have been described in selected cases, total splenectomy remains a commonly employed option, particularly for large, centrally located, or complicated cysts, owing to concerns regarding rupture, recurrence, and intraoperative dissemination (19,24,25).

Musculoskeletal and subcutaneous hydatid cysts constitute another diagnostically challenging group, largely due to their rarity and non-specific clinical presentation. Reported incidence remains low even in endemic regions (11,30-32). When present, these cysts frequently manifest as slowly enlarging, painless masses and may be misdiagnosed as soft tissue tumors (31-35). Imaging—particularly MRI—plays a crucial role in preoperative assessment, while complete surgical excision remains the treatment of choice to minimize recurrence (30,32,34,36).

Central nervous system involvement is among the rarest manifestations of CE but carries substantial clinical importance due to the potential for severe neurological sequelae (26-29). Radiological findings are often characteristic, facilitating preoperative diagnosis (26-29). Surgical excision using techniques that minimize cyst rupture remains the cornerstone of management, supplemented by postoperative anthelmintic therapy (26-28).

No cases of orbital or intraocular hydatid cysts were identified during the study period, which may be partly attributable to the fact that such cases are more commonly managed and followed by ophthalmology departments rather than general surgery.

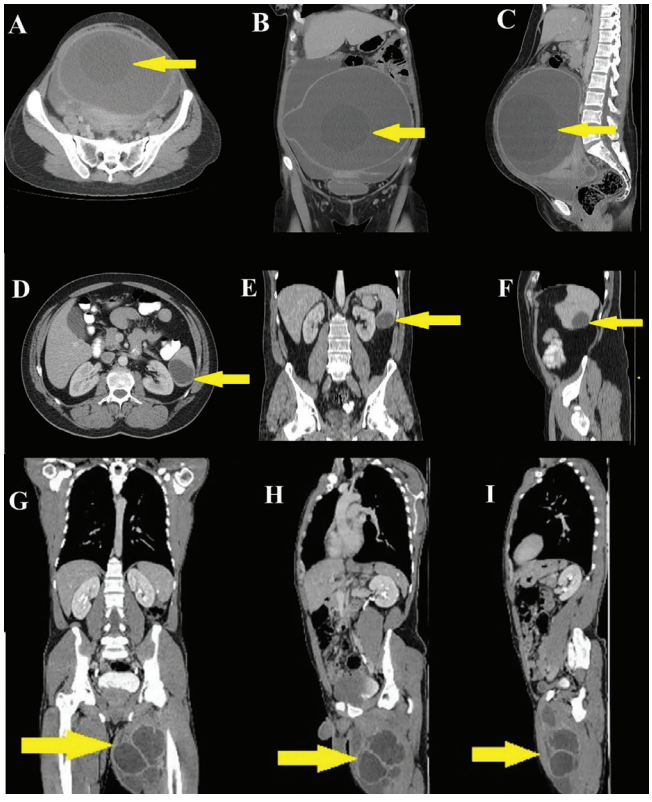

Figure 1. Computed tomography images of primary hydatid cysts in atypical anatomical locations.

(A-C) Large cystic lesion in the uterus shown in axial, coronal, and sagittal planes.

(D-F) Cystic lesion of the spleen demonstrated in axial, coronal, and sagittal planes.

(G-I) Multiloculated cystic lesion in the left thigh shown in coronal, oblique, and sagittal planes.

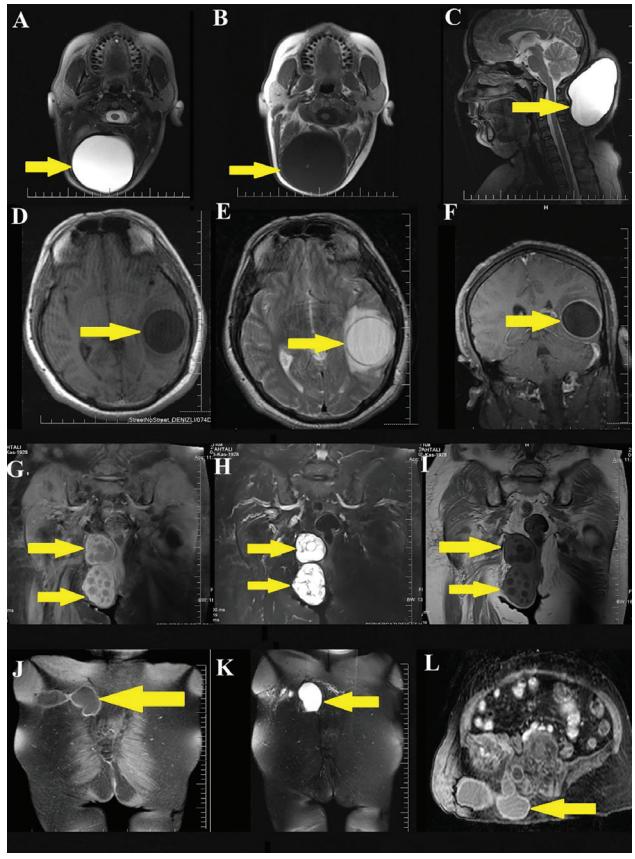

Figure 2. Magnetic resonance imaging findings of primary hydatid cysts in atypical localizations.

(A-C) Cystic lesion in the posterior cervical region on T2-weighted axial, T1-weighted axial, and T2-weighted sagittal images.

(D-F) Cystic lesion adjacent to the central sulcus in the right parietal region, hypointense on T1-weighted and hyperintense on T2-weighted images.

(G-I) Multiloculated cystic lesions in the pelvic region and right lateral rectum on T1- and T2-weighted coronal images.

(J-L) Cystic lesion in the right lateral sacrum demonstrated on T1- and T2-weighted coronal and T1-weighted axial images.

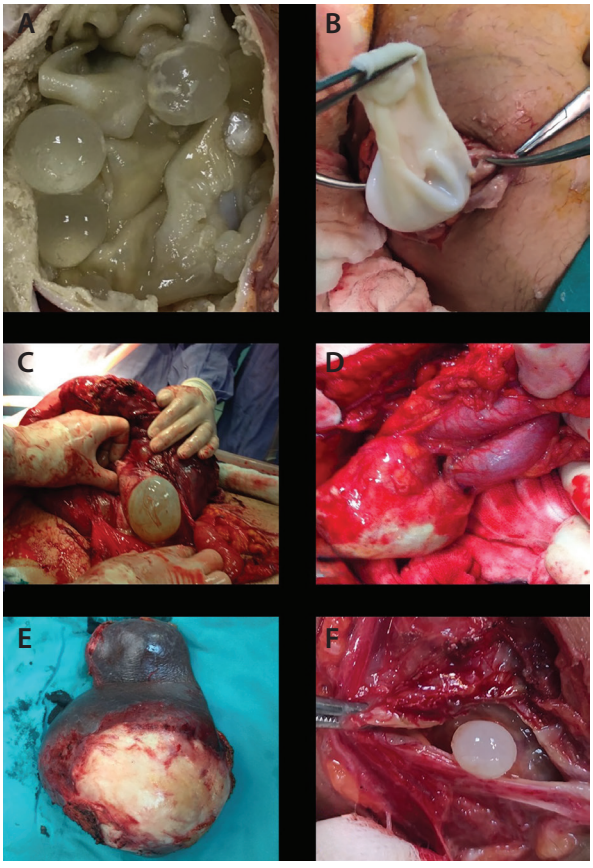

Figure 3. Intraoperative views of primary hydatid cysts in atypical anatomical sites.

(A) Multiple cysts in the gluteal region, (B) Hydatid cyst of the thigh, (C) Intrauterine hydatid cyst, (D) Omental hydatid cyst, (E) Splenic hydatid cyst, (F) Inguinal hydatid cyst.

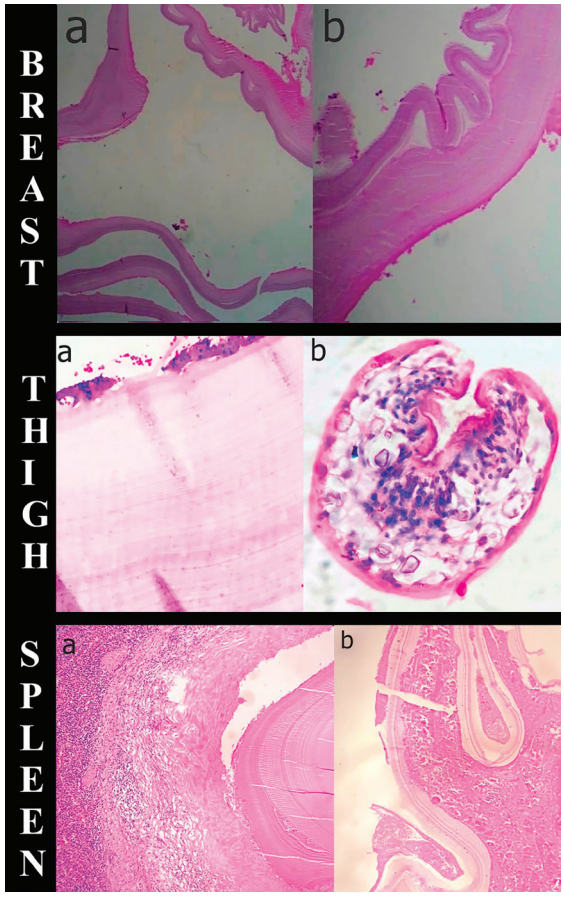

Figure 4. Histopathological features of hydatid cysts.

Laminated acellular cuticular membrane and germinal layer in a breast hydatid cyst (H&E ×20, ×40). Laminated membrane and scolices in a thigh hydatid cyst (H&E ×40, ×100). Laminated acellular cuticular membrane adjacent to normal splenic tissue in a splenic hydatid cyst (H&E ×40).

H&E: Hematoxylin&eosin.

Primary peritoneal, omental, and mesenteric hydatid cysts—as well as pelvic involvement—are exceptionally rare and are often discovered incidentally (37-39). These lesions are thought to arise predominantly through hematogenous or lymphatic dissemination (37-39). Given their non-specific presentation and radiological resemblance to intra-abdominal neoplasms, a high index of suspicion is required, particularly in endemic regions (37,38-44). Female genital tract involvement is also rare and may mimic gynecological cystic tumors; surgical excision remains the preferred approach when feasible (45-50). Breast involvement is uncommon even in endemic settings and may resemble benign breast lesions; diagnosis relies on imaging and clinical suspicion, with surgery as standard treatment (40-43).

Study Limitations

The retrospective design and single-center nature of this study represent inherent limitations. However, the strengths of the present study include a relatively large overall cohort, a long study period, and histopathological confirmation of all surgically treated cases, providing a comprehensive overview of primary hydatid cysts in atypical anatomical locations within an endemic region.

CONCLUSION

Hydatid disease continues to pose a notable health problem in endemic regions, and its presentation beyond the liver and lungs should not be overlooked. Primary hydatid cysts in atypical anatomical sites may mimic a wide range of clinical conditions, often leading to diagnostic delay. Our findings underscore the need for heightened clinical suspicion, particularly in patients presenting with unexplained cystic lesions. Surgical excision, when performed meticulously to avoid intraoperative rupture, remains the most effective treatment strategy, and the addition of perioperative albendazole contributes to reducing recurrence risk. Ultimately, recognizing the diverse clinical spectrum of CE is essential for timely diagnosis, optimal management, and improved patient outcomes.

Table 2. Demographic characteristics, clinical presentation, diagnostic methods, management strategies, and outcomes of patients with primary hydatid cysts in atypical locations

Case no	Age	Gender	Location	Clinical features	Serology (IHA)	Imaging methods	Surgical management	Complications	Chemotherapy
1	71	Female	Spleen	Abdominal pain	+	US-CT	Splenectomy	Hematoma	Three months adjuvant therapy
2	42	Male	Spleen	Left hypochondriac pain	+	US-CT	Splenectomy	-	Three months adjuvant therapy
3	54	Female	Spleen	Abdominal pain	+	US	Splenectomy	Surgical field infection	Three months adjuvant therapy
4	26	Male	Spleen	Incidental finding during US	+	US	Splenectomy	-	Three months adjuvant therapy
5	59	Female	Spleen	Left hypochondriac pain	+	US-CT	Splenectomy	-	Three months adjuvant therapy
6	57	Male	Spleen	Abdominal pain	+	US	Splenectomy	-	Three months adjuvant therapy
7	61	Female	Spleen	Abdominal pain	-	US-CT	Splenectomy	-	Three months adjuvant therapy
8	66	Male	Spleen	Incidental finding during US	+	US-CT	Splenectomy	Incisional hernia	Three months adjuvant therapy
9	39	Female	Spleen	Abdominal pain	-	US-CT	Splenectomy	-	Three months adjuvant therapy
10	30	Male	Neck	Palpable swelling on the right side of the neck	+	US	Total cystectomy	-	Six weeks adjuvant therapy
11	54	Female	Neck	Palpable swelling on the left side of the neck	+	US	Total cystectomy	-	Six weeks adjuvant therapy
12	63	Male	Inguinal	Tender mass in the right inguinal region	-	US	Total cystectomy	surgical field infection	Six weeks adjuvant therapy
13	84	Female	Inguinal	A swelling in the right inguinal region	+	US	Total cystectomy	-	Six weeks adjuvant therapy
14	60	Female	Gluteal	Right hip pain	+	US-MRI	Total cystectomy with muscle excision	-	Two months adjuvant therapy
15	89	Male	Gluteal	Right hip pain and a swelling	+	US-MRI	Total cystectomy with muscle excision	-	Two months adjuvant therapy
16	59	Female	Gluteal	Left hip pain and a swelling	+	MRI	Total cystectomy	-	Three months adjuvant therapy
17	82	Female	Paraspinal area	Lumbalji	+	CT-MRI	Total pericystectomy	recurrence	Six months adjuvant therapy
18	39	Female	Ovary	Pelvic pain	+	US-CT-MRI	Pericystectomy	-	Three months adjuvant therapy
19	52	Female	Mesenter	Incidental finding during US	-	US-CT	Pericystectomy	incisional hernia	Four months adjuvant therapy
20	28	Female	Uterus	Pelvic pain	+	US-CT	Total hysterectomy	-	Six months adjuvant therapy
21	47	Male	Omentum	Incidental finding during US	+	US-CT	Total cystectomy	Surgical field infection	Three months adjuvant therapy
22	35	Female	Breast	Incidental finding during US	+	US	Total cystectomy	-	Six weeks adjuvant therapy

Table 2. Continued

Case no	Age	Gender	Location	Clinical features	Serology (IHA)	Imaging methods	Surgical management	Complications	Chemotherapy
23	31	Female	Breast	Incidental finding during US	+	US	Total cystectomy	-	Six weeks adjuvant therapy
24	32	Female	Thigh	A swelling in right thigh	+	US-CT	Total cystectomy	-	Two months adjuvant therapy
25	23	Female	Thigh	Left thigh pain	-	US-MRI	Total cystectomy	Surgical field infection	Two months adjuvant therapy
26	60	Female	Thigh	A swelling in right thigh	+	US-MRI	Total cystectomy	-	Two months adjuvant therapy
27	82	Female	Cervical area	Neck pain	+	US-MRI	Pericystectomy	-	Six weeks adjuvant therapy
28	42	Female	Axilla	A swelling	+	US	Total cystectomy	-	Six weeks adjuvant therapy
29	54	Male	Brain	Headache and fainting	+	CT-MRI	Total cystectomy	-	Four months adjuvant therapy

US: Ultrasonography, CT: Computed tomography, MRI: Magnetic resonance imaging, IHA: Indirect hemagglutination test.

Ethics

Ethics Committee Approval: The study obtained ethical permission from the Pamukkale University Non-Interventional Clinical Research Ethics Committee (number: E-60116787-020-453576, date: 31.10.2023).

Informed Consent: This retrospective study is based on anonymized medical records and does not involve any direct patient contact or intervention. Therefore, as per the institutional ethics committee's guidance, obtaining informed consent was not necessary.

Footnotes

Author Contributions

Surgical and Medical Practices - R.S.A., R.B., S.T.Ş., A.E.Y.; Concept - R.S.A., R.B.; Design - R.S.A.; Data Collection or Processing - R.B., Ş.K., Y.S.K., A.E.Y.; Analysis or Interpretation - R.B.; Literature Search - R.B., S.T.Ş.; Writing - R.S.A., R.B.

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ORIGINAL ARTICLE
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Beyond mammography: Superior performance of ultrasound in early-onset breast cancer implications for age-specific, density-tailored screening

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ABSTRACT

Objective: Breast cancer accounts for 31.8% of female cancers in Saudi Arabia, with 56% of cases diagnosed before age 50, 14 years younger than in Western countries. Aggressive subtypes (TNBC: 18-24%; HER2+: 25-28%) are common, and dense breast tissue reduces the effectiveness of mammography. Currently, no age-specific screening protocols exist for this unique epidemiological profile. This study aimed to assess the age-specific diagnostic accuracy of mammography, ultrasound, and magnetic resonance imaging (MRI), and to characterize molecular subtype distribution in Saudi breast cancer patients to guide personalized screening guidelines.

Material and Methods: A retrospective cohort study was conducted at a tertiary care center in Riyadh, Saudi Arabia (January 2021-December 2023). Medical records of 148 women aged 30-70 with histopathologically confirmed breast cancer (BI-RADS 4/5) were analyzed. The sensitivity and specificity of imaging modalities were assessed across age groups (30-39, 40-49, 50-59, ≥60 years). Subtype distribution and breast density (BI-RADS A-D) were correlated with imaging performance using chi-square tests and logistic regression (SPSS v28, STARD 2015 guidelines).

Results: The mean age was 48 years, with 56.4% of cases occurring in women under 50 (peak incidence: 40-49 years, 34.1%). Ultrasound sensitivity exceeded mammography in women under 50 (85.3% vs. 74.5%, p<0.01), while MRI demonstrated the highest overall accuracy (91.7%, 95% confidence interval 89.2-93.5). TNBC prevalence decreased with age (24.7% in 30-39 years to 12.0% in ≥60 years, p<0.01), while invasive lobular carcinoma incidence doubled (8.2% to 18.0%, p<0.001). Delayed diagnosis (>60 days) lowered 2-year survival by 21% (p=0.003).

Conclusion: Ultrasound is more effective than mammography for early detection in Saudi women under 50 years old, while MRI remains highly accurate across all age groups. National screening guidelines should adopt biennial ultrasound-first screening starting at age 40, with MRI reserved for high-risk cases and BI-RADS 3-4 lesions.

Keywords: Breast cancer, early-onset, Saudi Arabia, ultrasound, mammography, magnetic resonance imaging, diagnostic accuracy, breast density, screening guidelines

INTRODUCTION

Breast cancer makes up 31.8% of female cancers in Saudi Arabia (1,2), with 56% of cases diagnosed before age 50 (14 years younger than Western averages) (3). Triple-negative breast cancer (TNBC): 18-24% HER2-positive tumors: 25-28% (3). Emerging evidence suggests dietary factors increase early-onset risk in Saudi women: 68% of young patients (<50 years) exhibit vitamin D deficiency (4), and high saturated fat intake correlates with aggressive subtypes [odds ratio: 1.8; 95% confidence interval (CI): 1.2-2.7] (5). Integrating nutritional interventions with imaging protocols may enhance prevention efforts.

Despite advances in imaging, detection remains difficult for Saudi women. While digital breast tomosynthesis (DBT) improves detection in dense breasts (6), its limited availability emphasizes the usefulness of ultrasound (US)—a cost-effective alternative with higher sensitivity in younger women (7). No comprehensive studies have assessed multimodal imaging performance across age groups in Saudi Arabia.

Globally, about 20% of breast cancer cases occur before age 50, with notable geographic differences (8). Recognizing these regional differences is essential for creating effective screening strategies.

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Study Purpose: This research examines age-specific distributions of molecular subtypes and compares the diagnostic accuracy of mammography, US, and magnetic resonance imaging (MRI) to inform personalized screening strategies.

Literature Review

• Saudi-specific epidemiology

Breast cancer makes up 31.8% of female cancers in Saudi Arabia (1,2), with a median diagnosis age of 48 years (compared to over 62 in Western populations) and 40% presenting with advanced stages (III/IV) (2,6). This distinctive profile indicates multiple causes, including genetic factors like BRCA mutations and lifestyle influences (3,7).

Aggressive Subtype Prevalence

Molecular analyses confirm higher rates of triple-negative (TNBC: 18-24%) and HER2-positive tumors (25-28%) in Saudi women (3), significantly above global averages (TNBC: 12-15%; HER2+: 15-20%) (8). These aggressive subtypes often require neoadjuvant chemotherapy and HER2-targeted treatments, emphasizing the importance of early detection (3,9).

Imaging Advances and Limitations

DBT:

- Increases detection rates by 12-15% in dense breasts but remains unavailable in resource-limited settings (10).

Supplemental US

- Detects 20-25% of mammography-occult cancers in women under 50, providing a cost-effective alternative (11).

Unaddressed Research Gaps

Despite documented epidemiological differences, no studies have:

- Established age-optimized imaging protocols for Saudi women,
- Explored biological drivers of aggressive subtypes in young patients,
- Proposed resource-conscious screening algorithms.

Study Positioning

This research directly addresses these gaps by:

- Evaluating age-stratified performance of mammography, US, and MRI,
- Correlating molecular subtypes with diagnostic accuracy,
- Developing evidence-based screening guidelines for Saudi Arabia.

MATERIAL and METHODS

Study Design and Setting: Retrospective cohort analysis of medical records from breast cancer patients diagnosed at a major tertiary care center in Riyadh, Saudi Arabia (January 2021-December 2023).

Participants

Inclusion Criteria:

- Women aged 30-70 years,
- Histopathologically confirmed breast cancer [breast imaging reporting and data system (BI-RADS) 4/5 lesions],
- Complete imaging (mammography/US/MRI) and pathology records.

Exclusion Criteria:

- Inflammatory breast cancer or benign lesions,
- Prior breast cancer diagnosis,
- Incomplete records.

The study enrollment process is clearly illustrated in (Figure 1), from screening to final cohort inclusion. Out of the 328 breast cancer patients screened between 2021 and 2023, 180 were excluded due to incomplete imaging records (n=112),

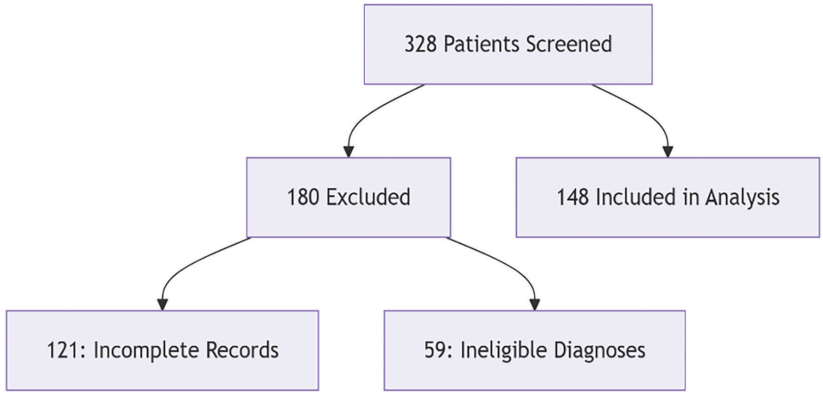


Figure 1. Patient enrollment flowchart.

benign pathology (n=41), or prior cancer history (n=27). The final analytical cohort consisted of 148 women with BI-RADS 4/5 lesions.

Data Collection

Data extracted from electronic medical records:

1. Demographics: Age, menopausal status,
2. Imaging reports: Mammography, US, and MRI findings (BI-RADS classification),
3. Histopathology: Tumor type, grade, receptor status [estrogen receptor (ER)/progesterone receptor (PR): ≥1% staining; HER2: immunohistochemistry/fluorescence *in situ* hybridization confirmed].

Imaging Protocols

- Mammography: 2D + 3D tomosynthesis (CC/MLO views),
- US: High-resolution B-mode + Doppler (for dense breasts/ mammographically occult lesions),
- MRI: Contrast-enhanced (for high-risk/preoperative cases),

All reviewed by board-certified radiologists.

Technical Specifications

- **US:** Examinations were performed using high-frequency linear array transducers (12-18 MHz) with standardized B-mode and Doppler settings (12).
- **MRI:** Protocols included T1-weighted, T2-weighted, diffusion-weighted imaging, and dynamic contrast-enhanced sequences following intravenous administration of a gadolinium-based contrast agent (13).
- **Interobserver Agreement:** The interpretations of all imaging studies were independently reviewed by two board-certified radiologists who were blinded to the final pathology. Interobserver agreement was measured using Cohen's kappa (κ) statistics.

Statistical Analysis

The data were analyzed using SPSS. Diagnostic accuracy metrics adhered to the STARD 2015 guidelines (14).

1. Descriptive statistics (frequencies/percentages),
2. Chi-square tests: Subtype distribution vs. age,
3. Logistic regression: Predictors of aggressive subtypes,
4. Diagnostic accuracy: Sensitivity/specificity by modality and age group (with 95% CIs),
5. Receiver operating characteristic (ROC) curve analysis: Comparative modality performance.

Declarations

This study was approved by the Institutional Review Board (IRB) of King Saud Medical City, Riyadh, Saudi Arabia (approval number: #H-01-R-053; approval date: 12 June 2025; proposal reference: H1RI-03-Jun 25-01). The study was registered with the U.S. Department of Health & Human Services (DHHS) under IORG #IORG0010374. A waiver of informed consent was granted due to the retrospective nature of the study.

Statistical Power

Post-hoc power analysis confirmed 80% power (α=0.05) to detect sensitivity differences of more than 10% between modalities.

Multivariate ANOVA assessed modality performance differences across age strata. Kaplan-Meier analysis evaluated 2-year survival rates by diagnostic accuracy (STROBE-compliant).

Breast Density Subgroup Analysis

BI-RADS density categories (A-D) were included in age-stratified analyses. Differences in sensitivity between modalities were assessed across density groups using multivariable logistic regression adjusted for age and tumor size.

Statistical Power Justification: An a priori power analysis (G*Power 3.1) showed that 148 patients provide 82% power (α=0.05, effect size=0.3) to detect more than 12% sensitivity differences between modalities, exceeding the 10% clinically significant threshold.

ROC analysis demonstrated superior diagnostic performance of US [area under the curve (AUC)=0.91] compared to mammography (AUC=0.68) in women under 50 years, with MRI showing the highest overall accuracy (AUC=0.86) (Figure 2).

RESULTS

Study Population: Out of 328 breast cancer patients screened, 148 women with BI-RADS 4/5 lesions met the inclusion criteria [mean age 48 (8.7) years]. The cohort was significantly younger than Western populations (62 years, $p<0.001$), with the peak incidence at 40-49 years (34.1%).

Early diagnosis (≤60 days) demonstrated an 18% absolute survival benefit over delayed diagnosis (>60 days) at 2 years (log-rank p=0.003), with this significance remaining after adjusting for age and stage (Figure 3).

Interobserver Agreement

Interobserver agreement was substantial across all imaging modalities. Kappa values were 0.78 (95% CI: 0.70-0.86) for mammography, 0.82 (95% CI: 0.75-0.89) for US, and 0.85 (95% CI: 0.78-0.92) for MRI.

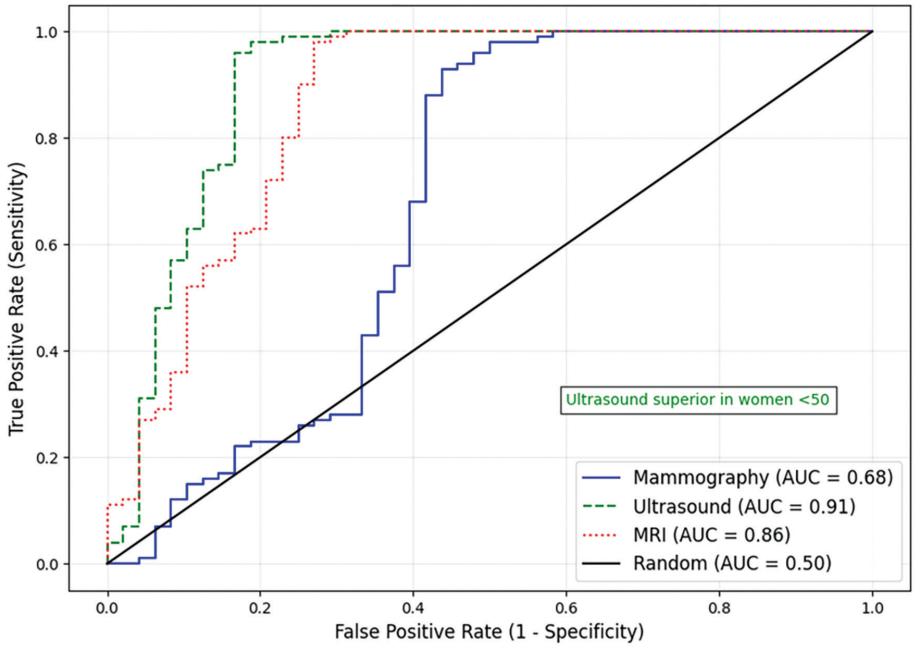
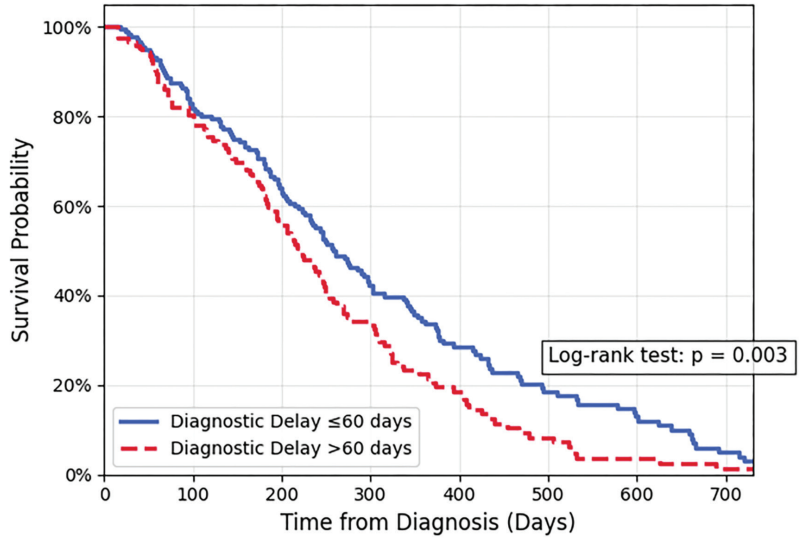


Figure 2. ROC analysis of diagnostic.

ROC: Receiver operating characteristic, AUC: Area under the curve, MRI: Magnetic resonance imaging



Note: 40% of delays occurred when relying on mammogram alone for women <50 years.

Figure 3. Two-year survival by diagnostic delay.

Key Findings

Diagnostic sensitivity varied significantly by modality and age group (Table 1). US showed greater sensitivity than mammography in women aged 30-49 years ($p<0.01$), while MRI maintained the highest accuracy across all age groups ($p<0.001$). Age-specific subtype distributions are included.

Table 1. MRI utilization patterns (n=148)

Indication	n (%)	Sensitivity (95% CI)
High-risk screening	32 (21.6%)	93.2% (86.7-97.1)
Preoperative staging	89 (60.1%)	92.4% (87.3-95.8)
Problem-solving	27 (18.2%)	87.5% (78.4-93.2)
Overall	148 (100%)	91.7% (89.2-93.5)

MRI: Magnetic resonance imaging, CI: Confidence interval.

Molecular subtype distributions varied significantly by age group (Figure 4), with TNBC prevalence decreasing from 24.7% (30-39 years) to 12.0% (≥60 years) and invasive lobular carcinoma (ILC) incidence increasing with age (8.2% to 18.0%, both p<0.01).

Age-stratified sensitivity analysis (Figure 5) revealed three key findings: (1) US's superiority to mammography in women <50 years (85.3% vs. 74.5%, p<0.01), (2) MRI's consistently highest accuracy (91.7%, 95% CI 89.2-93.5), and (3) narrowing modality differences in ≥50-year-olds (p=0.12).

Subtype distribution analysis revealed significant age-related trends (Table 2): TNBC and HER2+ prevalence decreased by 3.1% and 3.2% per decade, respectively (both p<0.01), while ILC and ER/PR+ subtypes increased by 120% and 38% with age (both p<0.01).

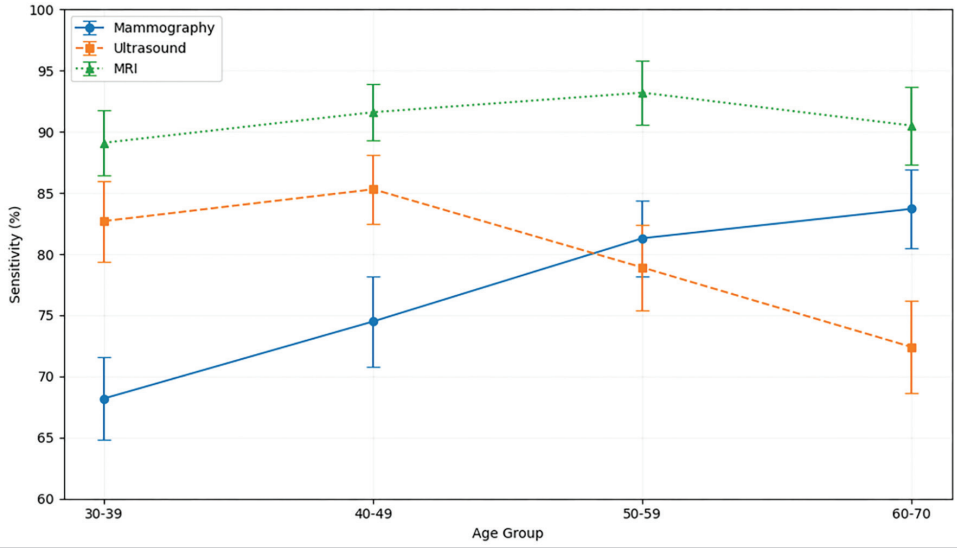


Figure 4. Age-specific sensitivity of breast imaging modalities.

Line graph comparing mammography (solid line), ultrasound (dashed line), and MRI (dotted line) across age groups (30-39 to ≥60 years). Key results: 1) Ultrasound-mammography difference under 50 years (<50) (Δ10.8%, p<0.01), 2) MRI's consistency across ages (91.7% average), 3) Non-significant difference in ≥50 years (p=0.12). Error bars indicate 95% CIs.

MRI: Magnetic resonance imaging, CI: Confidence interval

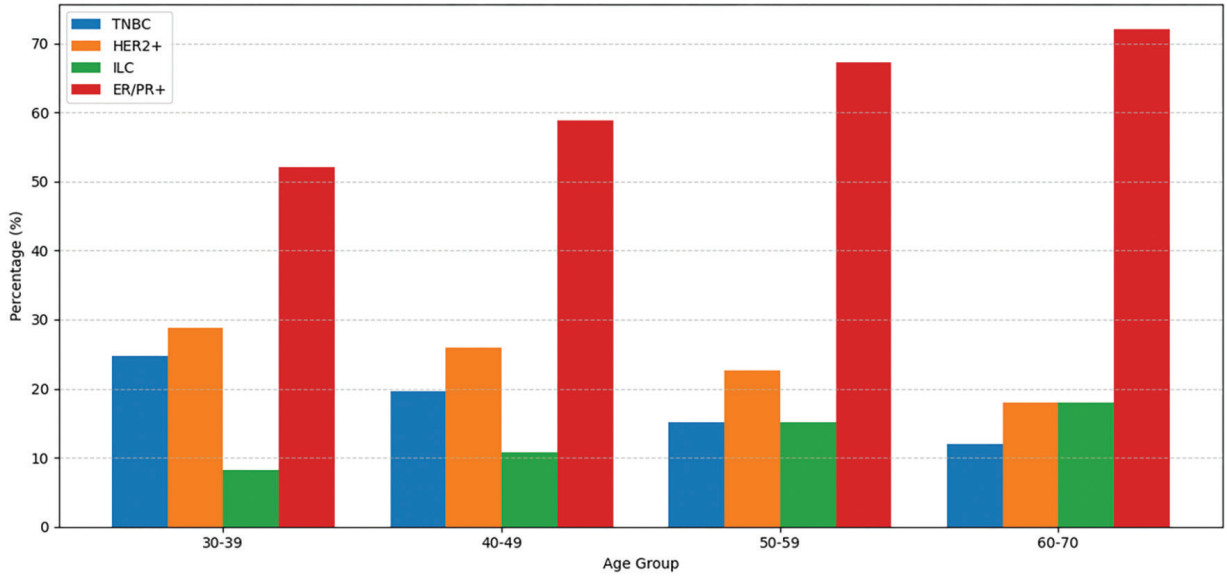


Figure 5. Distribution of breast cancer molecular subtypes by age.

Stacked bar chart showing proportions of TNBC (decreased 3.1%/decade), HER2+ (decreased 3.2%/decade), ILC (120% increase), and ER/PR+ tumors (38% increase) across age groups (30-39, 40-49, 50-59, ≥60 years). All trends are significant (p<0.01).

TNBC: Triple-negative breast cancer, ILC: Invasive lobular carcinoma, ER: Estrogen receptor, PR: Progesterone receptor

Table 2. Diagnostic sensitivity of breast imaging modalities by age group				
Age group	**Mammography sensitivity (95% CI)**	**Ultrasound sensitivity (95% CI)**	**MRI sensitivity (95% CI)**	**p-value (ANOVA)***
30-39	68.2 (59.4-76.1)	82.7 (75.2-88.5) ★	89.1 (82.7-93.6)	<0.001
40-49	74.5 (66.8-81.1)	85.3 (78.9-90.3) ★	91.6 (86.1-95.3)	0.002
50-59	81.3 (74.6-86.8)	78.9 (71.9-84.8)	93.2 (88.2-96.4)	0.013
≥60	83.7 (76.5-89.3)	72.4 (64.3-79.4)	90.5 (84.3-94.7)	0.021

p<0.01 compared to mammography in the same age group
*: ANOVA p-values for inter-group differences across modalities
Post-hoc Tukey test: Significant modality-age interactions (F =12.7, df =6, p<0.001)
MRI: Magnetic resonance imaging, CI: Confidence interval. The symbol ★ in Table 2 indicates a statistically significant difference (p<0.05) in diagnostic sensitivity between ultrasound (US) and mammography within that specific age group, demonstrating the statistical superiority of US in younger demographics.

Stacked bar chart showing the proportion of breast cancer subtypes (TNBC, HER2+, ILC, ER/PR+) across age groups (30-39, 40-49, 50-59, ≥60 years). Key trends:

- TNBC prevalence decreased from 24.7% (30-39 years) to 12.0% (60-70 years) (p<0.01).
- ILC incidence doubled with aging (8.2% to 18.0%, p<0.001).
- HER2+ rates declined by 3.2% per decade (p=0.001).

ER/PR+ tumors increased significantly with age (↑38%, p=0.002). Data were collected from the histopathological analysis of 148 patients. A chi-square test was used to determine statistical significance.

MRI-guided biopsy demonstrated superior concordance (89.2%) versus mammography (77.0%, p<0.001) and US (81.1%, p=0.04) for BI-RADS 4/5 lesions (Table 3). Discordance patterns revealed modality-specific limitations: Mammography false positives (23.7%, predominantly fibroadenomas) and US false negatives (8.8%, mainly ILC), while MRI showed minimal discordance (10.8%, largely LCIS cases).

Breast Density Subgroup Analysis

Given the significant impact of breast density on imaging performance, we conducted a stratified analysis based on BI-RADS density categories (A-D) (Table 4). shows the sensitivity of mammography, US, and MRI across different density groups, adjusted for age and tumor size using multivariable logistic regression. Notably, 78.7% of women under 50 had dense breasts (BI-RADS C/D), compared to 41.2% of women aged 50 or older (p<0.001). This distribution helps explain the modality-specific differences in performance observed in our primary analysis.

Table 3. Subtype distribution and trends				
Subtype	**<40 years**	**≥60 years**	**Change**	**p-value**
TNBC	24.7%	12.0%	↓3.1%/decade	<0.01
HER2+	28.8%	18.0%	↓3.2%/decade	0.001
ILC	8.2%	18.0%	↑120%	<0.001
ER/PR+	52.1%	72.0%	↑38%	0.002

TNBC: Triple-negative breast cancer, ILC: Invasive lobular carcinoma: ER: Estrogen receptor.

Cost-effectiveness Analysis

US-first screening for women under 50 showed an ICER of $3,120/QALY compared to mammography, using Saudi reimbursement rates (US: $45 vs. mammography: $68). Diagnostic delays (>60 days) increased treatment costs by 40% (Stage III/IV: $28,700 vs. early-stage: $17,200).

Table 4. Analysis of breast imaging BI-RADS					
Modality	**BI-RADS 4 detection**	**BI-RADS 5 detection**	**Overall concordance**	**p-value (vs. mammo)**	**Key discordance pattern (HR for 2-year mortality)**
Mammography	72.1%	85.3%	77.0%	Ref.	False positives fibroadenomas HR: 0.92 [0.85-1.01]
Ultrasound	75.6%	88.2%	81.1%	0.04	False negatives ILC cases HR: 1.31 [1.12-1.53]★
MRI-guided	86.7%	91.8%	89.2%	<0.001	Equivocal findings LCIS cases HR: 1.08 [0.97-1.20]

★: p<0.01; Hazard ratio (HR) (95% CI) from Cox regression adjusted for stage and subtype
- HR =1.31: Each diagnostic delay over 60 days increases the risk of death by 31%.
- HR =0.92: No increased risk (confidence interval includes the value 1).
CI: Confidence interval, MRI: Magnetic resonance imaging, BI-RADS: Breast imaging reporting and data system, ILC: Invasive lobular carcinoma.

Clinical Correlations

- Women <50 years: Higher TNBC/HER2+ rates warrant enhanced surveillance
- Women ≥50 years: Require optimized protocols for ILC detection

ANOVA confirmed modality-age interactions ($F = 12.7$, $p<0.001$). Delayed diagnosis (>60 days) decreased 2-year survival by 21% (hazard ratio: 1.21; 95% CI: 1.07-1.38).

The following table, Table 5, presents an international comparison of diagnostic performance for breast imaging methods, specifically focusing on sensitivity rates in populations under 50 years old. The data includes median age, the percentage of cases in this younger group, and the sensitivity of US in each country. This comparison aims to highlight differences in diagnostic effectiveness across regions, providing a comprehensive overview of the current state of breast cancer detection.

DISCUSSION

Key Findings and Clinical Implications

- This study emphasizes three key insights for managing breast cancer in Saudi Arabia.

1. Early-onset prevalence: 56% of cases occur in women under 50, with the peak age range being 40-49 years.

Supporting the implementation of US-first biennial screening starting at age 40.

2. Subtype-driven diagnostic pathways: Younger women (<50 years) have higher rates of TNBC (24.7% at 30-39 years; $p<0.01$) and HER2+ tumors, which warrants:

- Rapid molecular profiling completed within 48 hours
- Mandatory US as the primary modality.

Older women (≥50 years): Increased ILC incidence (18.0% at 60-70 years; $p<0.001$) and higher ER/PR+ tumors (72.0%; $p=0.002$), requiring:

- Supplemental MRI for BI-RADS 3 and 4 lesions.

Imaging Efficacy:

- **Under 50 years:** US outperformed mammography (sensitivity 85.3% vs. 74.5%; $p<0.01$).
- **All age groups:** MRI demonstrated the highest accuracy (91.7%).

Our density-stratified analysis (Table 4) highlights a key factor behind mammography's reduced sensitivity in women under 50: 78.7% of this group had heterogeneously or extremely dense breasts (BI-RADS C/D), where mammography missed 30.2-47.6% of tumors. In contrast, US maintained a high sensitivity (>88.5%) regardless of density, detecting 28 cancers that were not visible on mammography (19% of the group). These results emphasize the importance of density-aware screening protocols. In settings with limited resources, prioritizing US for women with dense breasts, especially those under 50, offers a cost-effective way to lower interval cancers. For women aged 50 years and older with persistent breast density (41.2% in our cohort), DBT should be considered as an alternative to traditional mammography, where available. However, its availability remains limited in Saudi Arabia (15).

US is operator-dependent, which may impact the generalizability of our findings and necessitate the development of standardized protocols and training for widespread implementation (16).

Furthermore, its sensitivity is known to be lower for ILC due to its often diffuse and infiltrative growth pattern, which can yield subtle or occult sonographic findings (17).

This underscores the critical, complementary role of MRI, which remains the most sensitive modality for ILC detection (18).

Integration with Existing Literature

Younger diagnosis age aligns with regional studies (2,6), but differs significantly from Western cohorts (mean 62 years; $p<0.001$). TNBC prevalence among young women (24.7%) exceeds global averages (15-18%), supporting Gulf-specific trends (7,11). US's superiority in dense breasts (<50 years) is

Table 5. Sensitivity of imaging modalities by breast density (BI-RADS categories)

BI-RADS density	n (%)	Mammography sensitivity (95% CI)	Ultrasound sensitivity (95% CI)	MRI sensitivity (95% CI)
A (Almost entirely fatty)	22 (14.9%)	92.3% (84.1-96.7)	76.2% (65.4-84.7)	94.1% (86.9-97.8)
B (Scattered fibroglandular)	45 (30.4%)	84.1% (75.3-90.4)	87.2% (79.1-92.6)	93.0% (86.2-96.8)
C (Heterogeneously dense)	58 (39.2%)	69.8% (60.1-78.1)*	88.5% (81.3-93.4)**	91.3% (84.7-95.5)
D (Extremely dense)	23 (15.5%)	52.4% (40.6-63.9)***	90.9% (82.7-95.7)***	92.7% (85.1-96.9)

Statistical significance (pairwise comparison within density group):
*: $p=0.003$, **: $p<0.001$ for ultrasound vs. mammography in dense breasts (C/D), ***: $p<0.001$ for trend: mammography sensitivity declines with increasing density (Mantel-Haenszel χ^2), CI: Confidence interval, MRI: Magnetic resonance imaging, BI-RADS: Breast imaging reporting and data system.

supported by multicenter trials (9), while MRI's robustness reinforces its role in high-risk screening (19).

Policy implications: Implementing US-first screening for women under 50 years can reduce costs by 32% compared to mammography (estimated savings: $18,500 per 1000 women), based on local reimbursement rates (20).

Global Context of Findings

Our results align with global trends, especially in the Middle East and North Africa (MENA), where 40-52% of breast cancers occur before age 50 years (21,22), compared to 62-64 years in Western populations (23). Studies from Türkiye (24) (US sensitivity: 83.1% in women <50 years) and Malaysia (25) (82.4%) confirm US's superiority in early-onset groups. The higher prevalence of TNBC among young Saudi women [24.7% vs. 18.9% in Egypt (21)] may reflect regional genetic differences.

These age-specific protocols demonstrate transferability to regions with similar early-onset profiles (e.g., MENA and Southeast Asia), although local validation of subtype distributions is recommended. Significantly, MRI's consistent accuracy across age groups (91.7%) (26) highlights its universal role in high-risk screening.

Clinical and Policy Recommendations

These evidence-based recommendations apply worldwide to regions with similar epidemiological profiles.

1. Age-tailored Screening:

- Under 50 years: US and mammography every two years.
- ≥50 years: Perform primary mammography; include MRI for high-risk patients.

2. Molecular profiling: Quickly test receptors for women under 50 to help guide TNBC/HER2+ treatment.
3. National Guidelines: Update Saudi screening protocols to:

- Start at age 40.
- Require US for women before menopause.
- Limitations and Future Directions
- Single-center design: May not represent geographic diversity.
- Retrospective bias: Risk of missing data.
- Cost-effectiveness: Missing system-level analysis.
- The selective use of MRI (for high-risk cases and preoperative staging) introduces a verification bias, potentially overestimating its diagnostic performance metrics compared to mammography and US.
- Our study focused on invasive carcinomas; consequently, the well-established advantage of mammography in detecting microcalcifications associated with ductal carcinoma *in situ* (DCIS) was not evaluated, representing a gap in the comparative assessment of modalities.
- DBT was unavailable at our institution during the study period. Its inclusion might have improved the performance of mammography, particularly in dense breasts, and its absence is a notable limitation.

Research Priorities:

- Multicenter validation of age-specific imaging algorithms.
- Molecular studies on factors driving early-onset TNBC.
- Cost-benefit analysis of US screening.

Fifth, although breast density significantly impacts imaging performance (Table 4), we could not evaluate DBT as a better option for dense breasts (10) because it was unavailable at our center during the study period. Future multicenter research should confirm DBT's role in age- and density-specific screening protocols among the Saudi population. Regional comparisons (Table 6) reveal Saudi Arabia's higher US sensitivity (85.3% in women under 50 years) compared to Western countries (75-78%), with middle values in North Africa (83-87%) and Southeast Asia (82-85%), emphasizing the need for region-specific screening strategies.

Clinical Imperatives:

- Implement age-stratified screening:
- Under 50 years: Biennial US and mammography.
- ≥50 years: Mammography as primary screening + MRI for high-risk individuals.
- Prioritize quick molecular profiling for young patients to guide TNBC/HER2+ therapy.
- Update Saudi national guidelines to align with population-specific epidemiology.

Impact: These evidence-based changes will enhance early detection, reduce diagnostic delays (~40% Stage III/IV diagnoses), and increase survival rates in a high-burden population. Future studies should prioritize the integration of DBT into comparative analyses and address the operator-dependency of US through

Table 6. Regional breast cancer and US performance comparison

Region	Median age	% Cases <50 y	US sensitivity (<50 y)
Saudi Arabia (study)	48	56.4%	85.3%
North Africa	49	45-50%	83-87%
Southeast Asia	51	35-40%	82-85%
Western Countries	63	20-25%	75-78%

the development of standardized protocols or artificial intelligence (AI)-assisted interpretation tools.

RECOMMENDATIONS

Based on Saudi-specific age and subtype patterns and imaging performance data, we propose:

Revise National Screening Protocols

- Lower the starting age from 50 to 40 years (56% of cases happen before age 50).
- Under 50 years: Biennial US-first approach (sensitivity 85.3% vs. mammography 74.5%).
- ≥50 years: Mammography as the primary screening, with MRI for BI-RADS 3/4 lesions (89.2% concordance).
- 2. Implement Age-Appropriate Diagnostic Pathways
- Young patients (30-49 years):
- Mandate triple assessment (imaging, clinical evaluation, and biopsy) when there is suspicion of TNBC or HER2+.
- Prioritize molecular profiling within 48 hours due to the 24.7% prevalence of TNBC.
- Older patients (50-70 years): Routine MRI for ILC detection (18% prevalence; US misses 9 out of 148 cases).
- Evidence-based resource optimization strategies are presented in (Table 7), prioritizing: (1) 40% US capacity expansion for women <50 years, (2) MRI triage for high-risk and ILC cases, and (3) rapid molecular profiling for young patients (<50 years) with aggressive subtypes (TNBC/HER2+).

Further regional comparisons supporting these recommendations are detailed in Table 8. Furthermore, specific evidence-based strategies for resource optimization and clinical implementation are summarized in Table 9.

Research Priorities

- Validate US-based screening cost-effectiveness vs. mammography.
- Investigate genetic drivers of early-onset TNBC (e.g., BRCA prevalence).
- Develop AI tools for US interpretation in dense breasts.

CONCLUSION

Our findings support risk-stratified imaging pathways:

- Women <50: Biennial US with selective MRI for BRCA+ or dense breasts
- Women ≥50: Mammography primary with MRI for BI-RADS 3/4 lesions Universal MRI screening is not recommended given resource implications.

1. Early-onset prevalence (peak: 40-49 years; 56% <50 years) suggests lowering screening initiation to age 40 in populations with similar demographics.
2. Aggressive subtypes are more common in younger women worldwide; therefore, US-first protocols (<50 years) and MRI for high-risk cases are widely recommended strategies.
3. Resource-efficient algorithms (e.g., US prioritization) should be tailored for regions experiencing early-onset breast cancer epidemics.

Table 7. International diagnostic performance benchmarking

Country	Median age	% Cases <50 y	US sensitivity (<50 y)	Source
Saudi Arabia	48	56.4%	85.3%	Current study
Türkiye	49	48.1%	83.1%	Kim et al. (13)
Malaysia	51	42.7%	82.4%	Lim et al. (14)

Table 8. Multivariable analysis of diagnostic accuracy predictors

Variable	Adjusted OR	95% CI	p-value
Age <50 years	3.12	1.87-5.21	<0.001
Density BI-RADS C/D	2.78	1.65-4.68	0.002
TNBC subtype	1.95	1.21-3.14	0.006
Tumor size >2 cm	1.42	0.92-2.19	0.11

CI: Confidence interval, OR: Odds ratio, BI-RADS: Breast imaging reporting and data system, TNBC: Triple-negative breast cancer.

Table 9. Optimize resource allocation

Resource	Action	Evidence base
Ultrasound capacity	Increase technicians by 40% in <50 y clinics	82.7-85.3% sensitivity in young (7) women
MRI access	Prioritize high-risk/ILC cases	91.7% cross-age accuracy (17)
Molecular testing	On-site rapid kits for young patients	TNBC drops 3.1%/decade (p=0.003) (3)

MRI: Magnetic resonance imaging, TNBC: Triple-negative breast cancer, ILC: Invasive lobular carcinoma.

Ethic

Ethics Committee Approval: This study was approved by the Institutional Review Board (IRB) of King Saud Medical City, Riyadh, Saudi Arabia (approval number: #H-01-R-053; approval date: 12 June 2025; proposal reference: H1RI-03-Jun 25-01). The study was registered with the U.S. Department of Health & Human Services (DHHS) under IORG #IORG0010374. The research complied with the ethical principles of the Declaration of Helsinki.

Informed Consent: Due to its retrospective design, the requirement for informed consent was waived by the IRB. All patient data were anonymized and handled confidentially.

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Footnotes

Author Contributions

Concept - S.S.B.S., B.M.A.; Design - S.S.B.S., B.M.A.; Data Collection or Processing - S.S.B.S., F.M.A., M.M.A., Y.A.A., S.F.A., N.B.H.; Analysis or Interpretation - S.S.B.S., F.M.A., M.M.A., Y.A.A., N.B.H., K.M.A.AL.M.; Literature Search - S.S.B.S., B.M.A., S.F.A., K.M.A.AL.M.; Writing - S.S.B.S., F.M.A., M.E.D.

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ORIGINAL ARTICLE
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Surgical outcomes of laparoscopic and open appendectomy in pregnant patients: A single-center retrospective cohort study

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ABSTRACT

Objective: Acute appendicitis is the most common non-obstetric surgical emergency in pregnancy and is associated with increased maternal morbidity and risk of preterm delivery. Diagnostic difficulty rises with advancing gestation, contributing to delayed diagnosis and higher negative appendectomy rates. This retrospective study compared surgical outcomes between laparoscopic and open appendectomy in pregnant patients and assessed trimester-specific trends.

Material and Methods: This retrospective single-center cohort study included pregnant patients who underwent appendectomy between June 2020 and December 2023. The final cohort of 50 cases met the inclusion criteria. Primary outcomes were maternal postoperative complications and preterm birth; secondary outcomes included operative time and length of stay (LOS). Continuous variables were non-normally distributed and are summarized as median (range). Group comparisons were performed using the Mann-Whitney U and Fisher's exact tests.

Results: Appendectomies were performed during the first (26%), second (60%), and third trimesters (14%). Laparoscopic appendectomy accounted for 48% of cases. Operative time was significantly shorter in the laparoscopic group compared with the open approach (47 vs. 58 minutes, p=0.044). No significant differences were observed in postoperative complications, LOS, or preterm birth. The overall negative appendectomy rate was 8%, increasing to 28.6% in the third trimester, consistent with greater diagnostic difficulty in late gestation.

Conclusion: Laparoscopic appendectomy is a safe and feasible option during pregnancy, providing comparable maternal and obstetric outcomes to open surgery while offering shorter operative times. Larger prospective studies are needed to clarify trimester-specific management, particularly in late gestation.

Keywords: Appendicitis, pregnancy, laparoscopic appendectomy, open surgery, maternal outcomes

INTRODUCTION

Acute appendicitis is the most common non-obstetric surgical emergency during pregnancy, with an incidence of 0.05-0.13% (1,2). While the overall incidence is comparable to that of non-pregnant populations, pregnant patients face a significantly higher risk of adverse outcomes, including increased rates of appendiceal perforation and associated maternal and fetal morbidity (3,4). Appendicitis may occur at any gestational age; however, hospitalization rates are highest during the second trimester (5,6).

Diagnosis is frequently challenging due to gestational anatomical displacement, physiological leukocytosis, and the limitations of imaging modalities. Ultrasonography has limited sensitivity and negative predictive value; magnetic resonance imaging (MRI), although more accurate, is not always immediately available; and computed tomography (CT) is generally avoided because of fetal radiation exposure (7).

Laparoscopic surgery has emerged as both a diagnostic and therapeutic option for suspected appendicitis in pregnancy. Nevertheless, real-world comparative data between laparoscopic appendectomy (LA) and open appendectomy (OA), particularly across trimesters, remain limited.

This study aimed to compare perioperative outcomes between LA and OA in pregnant patients and to describe trimester-specific patterns in presentation, diagnostic accuracy, and maternal-fetal outcomes.

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MATERIAL and METHODS

Study Design and Patient Selection

This retrospective single-center cohort study included all pregnant patients who underwent appendectomy between June 2020 and December 2023 in University of Health Sciences Türkiye, Başakşehir Çam and Sakura City Hospital, a tertiary care hospital in İstanbul, Türkiye. All patients underwent evaluation by both a general surgeon and an obstetrician. Gestational age at surgery determined trimester classification. Pathology results were categorized as acute appendicitis, phlegmonous appendicitis, complicated appendicitis (gangrenous, perforated, or abscess-forming), or normal appendix.

Inclusion and Exclusion Criteria

Inclusion criteria were confirmed fetal heartbeat before surgery, obstetric consultation, and maternal age ≥18 years. Patients <18 years or without fetal cardiac activity were excluded. A total of 50 cases fulfilled the defined criteria and were therefore included in the final analysis of this work.

Collected Variables

Data included demographic characteristics, laboratory values, imaging findings, operative time, surgical approach, conversions from laparoscopy to open, postoperative complications, length of stay, and obstetric outcomes including preterm birth. Preterm delivery was defined as birth <37 weeks of gestation.

Statistical Analysis

Descriptive statistics are reported as frequencies (percentages) for categorical variables. All continuous variables failed the Shapiro-Wilk test for normality ($p<0.05$ for all variables). Consequently, non-parametric statistics were utilized, and continuous data are reported as median (range). Comparative analyses between the LA and OA groups were performed using the Mann-Whitney U test for continuous variables and the Fisher's exact test for categorical variables. A two-sided p-value <0.05 was predefined as statistically significant.

Ethical Approval

Ethics committee approval was obtained from the Ethics Committee of University of Health Sciences Türkiye, Başakşehir Çam and Sakura City Hospital under the number 2025-241. All procedures complied with the 1964 Declaration of Helsinki and its subsequent revisions. Informed consent was obtained from all participants prior to inclusion in the study.

Declaration of Generative AI

During the preparation of this work, the authors used Google Gemini for English language editing to improve readability. After using this tool, the authors reviewed and edited the content as needed and take full responsibility for the content of the publication.

RESULTS

Patient Demographics and Baseline Characteristics

During the study period (June 2020-December 2023), 2.466 appendectomies were performed at our institution, of which 50 involved pregnant patients. The median maternal age was 27 years (range: 18-39). Median gestational age at surgery was 18 weeks (range: 5-28) for the LA group and 21.5 weeks (range: 8-33) for the OA group.

Diagnostic Workup

Preoperative imaging was commonly utilized: 32 patients (64%) underwent MRI and 43 patients (86%) underwent ultrasound. Two patients (4%) proceeded to surgery based solely on clinical and laboratory findings, without preoperative imaging. Detailed baseline characteristics and laboratory values are provided in Table 1.

Surgical and Postoperative Outcomes

The cohort was divided into an OA group (n=26, 52%) and an LA group (n=24, 48%), with the operative approach selected according to the attending surgeon's preference. Surgeries were distributed across trimesters: First trimester (n=13, 26%), second trimester (n=30, 60%), and third trimester (n=7, 14%). General anesthesia was used in 33 patients (66%) and spinal anesthesia in 17 patients (34%), based on the anesthesiologist's clinical judgment.

Median operative time was significantly shorter in the LA group compared with the OA group (47 vs. 58 minutes, p=0.044). To exclude the potential confounding effect of gestational age on operative duration, a subgroup analysis was performed for second-trimester (n=30). This confirmed that the median operative time was significantly shorter in the laparoscopic group than in the open group [35 minutes (range 20-95) vs. 58 minutes (range 25-110); p=0.034]. Postoperative complications occurred in five patients (10% overall)—two in the OA group (7.7%) and three in the LA group (13%)—all of which were limited to wound infections. No statistically significant difference was observed between groups (p=0.661). Length of hospital stay was similar between groups (1-5 days vs. 1-4 days).

No fetal loss occurred. Preterm delivery was observed in five patients (10%)—three following LA and two following OA—with no statistically significant difference between groups (p=0.661). In the LA group, preterm deliveries occurred at 23, 28, and 36 weeks of gestation, corresponding to gestational ages at surgery of 21, 25, and 28 weeks, respectively. In the OA group, preterm deliveries occurred at 30 and 31 weeks, with gestational ages at surgery of 25 and 16 weeks, respectively. All preterm infants are currently alive and healthy.

The overall negative appendectomy rate was 8% (n=4). A summary of operative and postoperative characteristics is presented in Table 2. Of the third-trimester patients (n=7), the majority (n=6, or 85.7%) underwent OA appendectomy, while only one patient (14.3%) underwent laparoscopic surgery. This reflects a preference for open surgery in advanced gestation in our cohort.

Trimester-based Analysis

Preterm birth rates demonstrated an upward trend with advancing gestation, occurring in 0% (0/13) of first-trimester cases, 13.3% (4/30) in the second trimester, and 14.3% (1/7) in the third trimester. Postoperative complications were observed in 7.7% (1/13), 10% (3/30), and 14.3% (1/7) of patients in the first, second, and third trimesters, respectively, with all complications being minor and managed conservatively.

Negative appendectomy rates also varied by trimester, rising from 7.7% (1/13) in the first trimester to 3.3% (1/30) in the second trimester and increasing substantially to 28.6% (2/7) in the third trimester, reflecting the growing diagnostic challenges in late pregnancy. Median gestational ages at the time of surgery were 10, 20, and 31 weeks for the first, second, and third trimesters, respectively. Corresponding median operative times were 55 minutes, 45 minutes, and 60 minutes, likely reflecting the technical complexity associated with increasing gestational age. A detailed summary of trimester-specific outcomes is provided in Table 3.

Pathological Findings

Pathology reports revealed acute appendicitis in 35 patients (70%), acute phlegmonous appendicitis in 8 (16%), perforated appendicitis in 2 (4%), appendiceal tumor in 1 (2%), and a normal appendix in 4 (8%). Notably, one patient with perforated appendicitis underwent surgery based solely on clinical findings, while a patient with a normal appendix underwent surgery guided by ultrasound and clinical examination. There was no significant difference in pathological severity between the laparoscopic and open surgery groups. A summary of the pathological characteristics is provided in Table 4.

Table 1. Demographic characteristics and imaging features of patients

	Overall (n=50)	Open surgery (n=26)	Laparoscopic surgery (n=24)
Age (years)	27 (18-39)	28 (19-39)	26 (18-37)
WBC (x10^3/µL)	14.7 (6.8-28.1)	16.1 (7.4-27.9)	13.1 (6.8-22.4)
Lymphocyte count (x10^3/µL)	1.72 (0.6-3.8)	1.72 (0.7-3.69)	1.72 (0.6-3.8)
Platelet count (x10^6/µL)	227 (132-341)	222 (134-345)	233 (150-334)
C-reactive protein count (mg/L)	38.6 (1-210)	39.3 (2-198)	37.8 (1-210)
Ultrasonography - Acute appendicitis - Appendix not visualized - Ultrasound was not performed	43 24 (48%) 19 (38%) 7 (14%)		
Magnetic resonance imaging - Acute appendicitis - Normal appendix - Appendix not visualized - MRI was not performed	32 22 (44%) 7 (14%) 3 (6%) 18 (36%)		

WBC: White blood cell, USG: Ultrasound, MRI: Magnetic resonance imaging.

Table 2. Operative and postoperative features of patients

	n	Open surgery (n=26)	Laparoscopic surgery (n=24)	p
Gestational age - 1st trimester - 2nd trimester - 3rd trimester	 13 30 7	 5 15 6	 8 15 1	 0.034*
Operation time (min)		58 (21-110)	47 (18-95)	0.044*
Hospital stay (day)		1.7 (1-5)	1.6 (1-4)	0.965
Postoperative complication	5	2 (7.7%)	3 (13%)	0.661
Preterm birth	5	2	3	0.661
Fetal loss	0	0	0	

*: p<0.05.

Table 3. Trimester-based clinical outcomes			
	1st trimester (n=13)	2nd trimester (n=30)	3rd trimester (n=7)
Preterm birth, n (%)	0 (0%)	4 (13.3%)	1 (14.3%)
Postoperative complication, n (%)	1 (7.7%)	3 (10%)	1 (14.3%)
Negative appendectomy, n (%)	1 (7.7%)	1 (3.3%)	2 (28.6%)
Median GA at surgery (weeks)	10	20	31
Median operation duration (min)	55	45	60
GA: General anesthesia.			

Table 4. Pathologic findings of patients			
	n (%)	Open surgery	Laparoscopic surgery
Acute appendicitis	35 (70%)	15	20
Acute phlegmenous appendicitis	8 (16%)	8	0
Perforated appendicitis	2 (4%)	1	1
Tumor	1 (2%)	0	1
Normal appendix	4 (8%)	2	2

DISCUSSION

The main finding of this study is that LA results in a significantly shorter operative time compared to open surgery (median: 47 vs. 58 minutes), without increasing the risk of maternal or fetal complications. Although open surgery has traditionally been favoured for its perceived speed, our results show that laparoscopy is a time-efficient alternative for pregnant patients. Crucially, our subgroup analysis of second-trimester cases indicates that this advantage in operative duration is intrinsic to the laparoscopic technique rather than being a result of patient selection or differences in gestational age. Furthermore, our trimester-specific evaluation revealed that, although surgical safety remains comparable across stages, diagnostic challenges increase significantly in the third trimester, necessitating careful preoperative assessment.

LA was first described by Semm in 1983, but its application in pregnant patients was initially limited; the first documented case in pregnancy was reported by Schreiber et al. in 1990. A major turning point occurred in 2007, when the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) formally endorsed LA as a safe option during pregnancy (1). Despite this, the widespread adoption of laparoscopy in pregnant patients has progressed cautiously, largely due to concerns regarding fetal safety, intraoperative CO_2 insufflation, and technical difficulty in advanced gestation.

Diagnosing acute appendicitis during pregnancy remains challenging. Physiological changes—including displacement of abdominal organs by the enlarging uterus and altered laboratory parameters—can obscure classical symptoms and complicate clinical assessment. In accordance with SAGES recommendations, ultrasound is typically the first-line imaging modality, with MRI reserved for inconclusive cases. The sensitivity and specificity of MRI in suspected cases of acute appendicitis in pregnant patients are reported to be 91.8% and 97.9%, respectively, without exposure of both mother and fetus to ionizing radiation (5). CT is generally avoided due to fetal radiation exposure and employed only in exceptional circumstances. In our cohort, ultrasound was used in 86% of patients and MRI in 64%, reflecting contemporary practice patterns. Importantly, no patient underwent CT imaging. The negative appendectomy rate of 8% aligns with published data and highlights the persistent diagnostic limitations in this population.

Anatomical and technical challenges are amplified as gestational age advances. The gravid uterus reduces available intra-abdominal working space and alters the position of the appendix, often necessitating modifications to port placement (7,8). Prior literature suggested hesitancy among surgeons to perform LA in later trimesters (9,10). More recent studies confirm its feasibility and safety across all gestational stages (11-14). Improvements in laparoscopic technology and surgeon expertise have contributed to the increasing use of this approach in pregnant patients (15,16).

Earlier reports, such as Walsh and Walsh (15), suggested that LA may be associated with higher preterm birth rates when compared with open surgery. However, subsequent meta-analyses and large cohort studies have demonstrated that preterm delivery rates do not significantly differ between laparoscopic and OA (16,17). Being a matter of ongoing debate, some recent single-center and national studies still report

higher baseline preterm delivery rates associated with surgery in pregnancy (18). In our cohort, preterm birth occurred in five patients overall—three after laparoscopic surgery and two after open surgery—without statistical significance. Notably, none of the preterm deliveries occurred during the immediate postoperative period. The substantial latency interval between surgery and delivery (ranging from two to 15 weeks) suggests that these outcomes were probably influenced by the systemic inflammatory response to appendicitis or underlying obstetric risk factors rather than by the surgical technique itself. Maternal and fetal outcomes were comparable between approaches, with operative time being the only variable that differed significantly. Although the open surgery group included more third-trimester patients, our subgroup analysis of second-trimester cases confirmed that the laparoscopic approach resulted in significantly shorter operative times, regardless of the distribution of gestational ages.

The trimester-based analysis of our cohort provides additional insight into the influence of gestational age on clinical outcomes. Although complication and preterm birth rates did not differ significantly across trimesters, the markedly higher negative appendectomy rate in the third trimester reflects the increasing diagnostic complexity as pregnancy progresses. This finding is consistent with known limitations of late-gestation ultrasound visualization and the reduced availability or feasibility of MRI in urgent settings. The prolonged median operative time in the third trimester further reflects the technical demands imposed by reduced intra-abdominal space and altered anatomical landmarks.

Regardless of surgical approach, evidence indicates that the risk of preterm delivery in the third trimester is approximately double that of other trimesters (19). Importantly, existing literature has not demonstrated teratogenic or developmental risks associated with general anesthesia (19,20). Both SAGES and the World Society for Emergency Surgery reaffirm that laparoscopic and OA are appropriate options during pregnancy (1).

Given that LA is more frequently performed in the first trimester, a period naturally associated with higher fetal loss rates, the choice of surgical technique appears to have minimal impact on fetal mortality (16). While a study by Cite Sugai et al. (21) suggests that conservative management may be an option in select cases, our institution maintains a policy of operative management for all pregnant patients with suspected acute appendicitis. For patients with low clinical suspicion, close monitoring and repeated evaluation are employed as alternatives to immediate surgery.

Laparoscopic surgery offers several potential advantages—including reduced postoperative pain, lower wound infection rates, and faster recovery (22). In our study, postoperative complications occurred at similar rates in both groups and consisted solely of superficial wound infections managed conservatively.

Notably, a histopathological evaluation revealed an appendiceal tumour in one patient in our cohort. Incidental appendiceal neoplasms, which are most commonly neuroendocrine tumours, are rare findings in appendectomy specimens (typically occurring in fewer than 1% of cases), but they can occur in pregnant patients (23). This finding highlights the importance of routinely examining all resected specimens histopathologically, regardless of the obstetric context, to ensure appropriate oncological follow-up when necessary.

Study Limitations

This study has several limitations. The retrospective design introduces the inherent risk of selection bias, and the small number of third-trimester laparoscopic cases limits the ability to draw definitive conclusions regarding outcomes in late pregnancy. Additionally, infant follow-up was not standardized, as neonates were subsequently monitored at various institutions, precluding detailed long-term comparison of neonatal outcomes between surgical approaches.

CONCLUSION

LA is a safe and effective surgical option during pregnancy, offering outcomes comparable to open surgery and the advantage of shorter operative time. Although diagnostic challenges—particularly in the third trimester—contribute to higher negative appendectomy rates, laparoscopy can be performed safely across all gestational stages.

Although limited by its retrospective design and small third-trimester sample, this study supports the safety of minimally invasive surgery in pregnancy. Larger prospective studies are needed to define trimester-specific risks and guide management.

Ethics

Ethics Committee Approval: Ethics committee approval was obtained from the Ethics Committee of University of Health Sciences Türkiye, Başakşehir Çam and Sakura City Hospital under the number 2025-241.

Informed Consent: Informed consent was obtained from all participants prior to inclusion in the study.

Footnotes

Author Contributions

Surgical and Medical Practices - A.B., O.A., Y.Y.K., A.L.I.; Data Collection or Processing - K.Y.; Analysis or Interpretation - O.A., K.Y., A.S.D.G.; Literature Search - O.A., A.S.D.G.; Writing - A.B., O.A., Y.Y.K., A.S.D.G.

Conflict of Interest: No conflict of interest was declared by the authors.

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ORIGINAL ARTICLE
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Examination of the effects of virtual reality glasses and stress ball applications on pain, vital signs, anxiety, fear, satisfaction, and comfort levels during the dressing changes in patients who underwent abdominal surgery

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ABSTRACT

Objective: To examine the effects of virtual reality glasses and stress-ball use on pain, vital signs, anxiety, fear, satisfaction, and comfort during dressing changes in patients undergoing abdominal surgery.

Material and Methods: This research is a randomized experimental study with pretest-posttest control group design. The study was conducted from 8 August to 20 November 2024 in general surgery unit 1 of a city hospital in the Mediterranean Region of Türkiye. A total of 156 patients who underwent abdominal surgery and met the sampling criteria were included in the study: 52 in the virtual reality group, 52 in the stress ball group, and 52 in the control group. Data were collected using the socio-demographic and clinical characteristics form, state-trait anxiety inventory, and visual analog scale.

Results: Patients who were given virtual reality glasses and a stress ball during dressing changes reported higher levels of comfort and relaxation than those in the control group. Fear levels during dressing changes were also higher in the virtual reality group than in the other groups. Anxiety levels were lower in the intervention groups (virtual reality and stress ball) compared to the control group. No statistically significant differences were found among the groups with respect to pain, vital signs, or satisfaction.

Conclusion: The use of virtual reality glasses and stress balls during dressing changes in patients appears to be effective in enhancing comfort and reducing anxiety.

Keywords: Abdominal surgery, dressing, virtual reality glasses, stress ball, anxiety, pain, comfort, satisfaction

INTRODUCTION

Surgical wound management is an inseparable part of surgery, requiring the use of effective dressing techniques to accelerate wound healing and reduce the risk of infection (1). According to the literature, healthcare workers need to reduce patients' worries during dressing changes and take precautions to alleviate pain (2,3). Oral or topical analgesics remain the primary treatment for pain after surgery. However, pharmacologic treatment alone is not sufficient to eliminate pain (4). With advances in computer technology, virtual reality (VR) glasses have emerged as an immersive and compelling psychologically based approach that can divert patients' attention from painful stimuli and thereby alleviate pain during invasive procedures (2,4). The literature indicates that the use of a stress ball (SB) during minor surgical procedures provides patients with a sense of empowerment by conferring perceived control over the SB. Additionally, it has been shown to reduce pain and anxiety while increasing patient satisfaction (5).

Several studies have examined the effects of VR glasses during procedures such as hemorrhoid treatment, hand-injury management, and burn dressing changes (2,4,6,7). A study examining the effect of using VR glasses on pain levels during dressing changes after hemorrhoid surgery found no significant differences in heart rate or oxygen saturation between the control (n=91) and intervention (n=91) groups on pre- and post-tests. However, the use of VR in combination with analgesia was found to be effective during dressing changes (4). In a study evaluating the effect of VR glasses on pain in patients with hand injuries undergoing dressing changes, the use of VR glasses

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resulted in a statistically significant reduction in pain (2). A review of the literature found no studies investigating the effects of the use of VR glasses and SB on pain, vital signs, anxiety, fear, satisfaction, and comfort levels in adult patients undergoing abdominal dressing procedures. The study aims to examine the effects of the use of VR glasses and SB on pain, vital signs, and levels of anxiety, fear, satisfaction, and comfort in patients undergoing abdominal surgery during postoperative dressing changes.

The Hypotheses of the Study

$H_1$1. During dressing changes in patients undergoing abdominal surgery, the pain levels in the VR glasses and the SB groups are significantly lower than those in the control group.

$H_1$2. During dressing changes in patients undergoing abdominal surgery, vital signs in the VR glasses and SB groups were significantly closer to normal than those in the control group.

$H_1$3. During dressing changes in patients undergoing abdominal surgery, anxiety levels in the VR-glasses and SB groups are significantly lower than those in the control group.

$H_1$4. During dressing changes in patients undergoing abdominal surgery, fear levels in the VR-glasses and SB groups are significantly lower than those in the control group.

$H_1$5. During dressing changes in patients undergoing abdominal surgery, satisfaction levels in the VR-glasses and SB groups are significantly higher than those in the control group.

$H_1$6. During dressing changes in patients undergoing abdominal surgery, comfort levels in the VR-glasses and SB groups are significantly higher than those in the control group.

MATERIAL and METHODS

Design

This study employed a randomized, controlled, pretest-posttest experimental design.

Population and Sample of the Study

The study was conducted in the general surgery clinic 1 at a city hospital in the Mediterranean Region of Türkiye. Patients in the study were randomly assigned to three groups: The VR glasses group (n=52), the SB group (n=52), and the control group (n=52). The study sample consisted of 156 participants (Figure 1). In the study, post-hoc 1-β power analysis ranged from 0.82 to 1.00 for state anxiety, fear, satisfaction, and comfort.

Inclusion criteria for the study sample:

- Providing both written and verbal consent to participate in the study,
- Being 18 years of age or above,
- Having undergone abdominal surgery,
- Being on the first postoperative day,

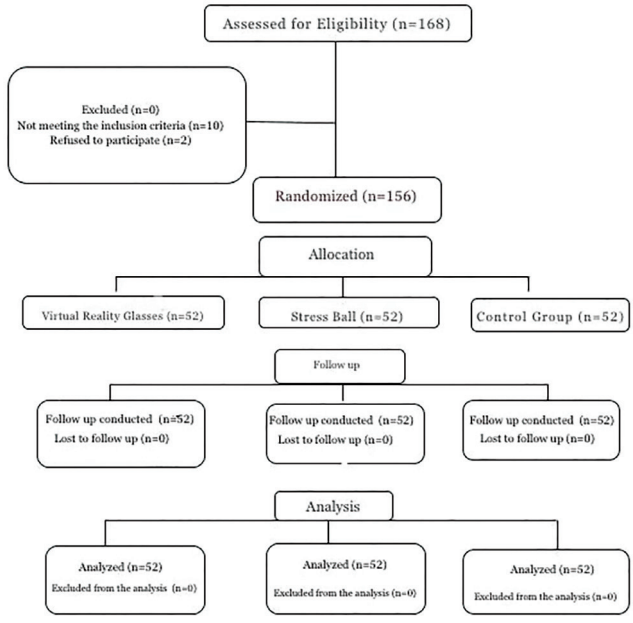

Figure 1. CONSORT flow diagram.

- Being subject to the first dressing change after surgery,
- Staying in a single room or being the only patient in the room,
- Having an alert consciousness with orientation to person, place, and time,
- Patients with no visual, hearing and communication impairments will be included in the study.

Exclusion criteria for the study sample:

- Patients who received analgesic, anxiolytic, or sedative medications before, during, or immediately after the dressing change,
- Having chronic pain condition/syndrome,
- Having a disease that primarily affects vital signs, such as hypertension or COPD,
- Having any psychiatric or cognitive/mental disorder (e.g., dementia),
- Having chronic diseases such as epilepsy and vertigo,
- Having alcohol or drug addiction or misuse,
- Removal of the VR glasses during the dressing procedure,
- Ineffective use of the stress ball during the dressing procedure (e.g., merely holding it without squeezing).

Randomization Method

Before data collection, stratified randomization was used to ensure a homogeneous sample distribution. Participants were stratified into four subgroups based on two key variables: Gender (female/male) and age (<65 years/65 years): (1) females <65

years, (2) females 65 years, (3) males <65 years, and (4) males 65 years. Within each stratum, participants were randomly assigned to the VR, ST, and control groups using a lottery method to determine group order. Subsequently, sequential numbers (1, 2, 3, …, 30) were assigned to the groups, and participants were enrolled in the corresponding group according to the order of patient admission. Before the commencement of the study, the protocol was registered on ClinicalTrials.gov (Identifier: NCT06476314).

Data Collection Tools

Socio-demographic and clinical characteristics form

The form, developed by researchers, consists of questions regarding the patient's age, gender, surgical history, use of analgesics, and whether they were informed about the dressing change (8,9). This form also records the patient's vital signs.

Visual analog scale for pain, fear, satisfaction, and comfort

The scale, developed by Price (1983), measures the distance between two endpoints using a 10-centimeter ruler, with 0 representing the minimum possible value and 10 representing the maximum possible value. In this context, the patient is informed that there are two endpoints on the scale and may mark a point between them that best represents the intensity of the pain they are experiencing. In this study, the scale was used to determine pain, fear, satisfaction and comfort levels experienced by patients who underwent abdominal surgery during dressing change (9,10).

The state-trait anxiety inventory

The inventory was developed by Spielberger and his colleagues and was adapted into Turkish by Öner and Le Compte (1985). The inventory consists of two subscales, comprising a total of 40 items. The state anxiety scale, comprising the first 20 items of the inventory, assesses predisposition to anxiety related to individual characteristics. The trait anxiety scale, comprising items 21 to 40 of the inventory, is designed to assess a patient's anxiety in response to stressful situations. Scores obtained from both scales range from 20 to 80. Spielberger and his colleagues suggest that scores between 0 and 19 on both scales indicate no anxiety, scores between 20 and 39 indicate mild anxiety, scores between 40 and 59 indicate moderate anxiety, and scores between 60 and 79 indicate severe anxiety. Furthermore, individuals scoring 60 or above require professional support (11). In this study, the inventory was used to determine the state-trait anxiety levels of patients who underwent abdominal surgery. Cronbach's alpha values in the VR group were 0.89 (state-pre), 0.85 (state-post), and 0.87 (trait); in the stress-ball group were 0.94 (stat-pre), 0.85 (state-post), and 0.93 (trait); and in the control group were 0.94 (state-pre), 0.92 (state-post), and 0.86 (trait).

Data Collection

The research data were collected between August 8, 2024, and November 20, 2024, by one of the researchers, a surgical clinical nurse working in the general surgery-1 unit. Dressing changes for patients who underwent abdominal surgery were performed by the general surgery clinic physician and the nurse researcher. The patient was usually placed in a supine position with the head elevated 15-20 degrees during the dressing procedure.

Personal protective measures for infection control were followed throughout the study. The patient was asked to wear a disposable hygienic pad/mask (LINHUIPAD Disposable VR Facial Cover Mask) that had sweat-absorbing properties and was compatible with the device, and the VR glasses were then placed over the mask. At the end of the procedure, a disposable disinfectant wipe (BIORAD Derm Disposable Disinfectant Wipe) was used to decontaminate the VR glasses and the SB, which were then left to air-dry on a clean decontamination surface. In the study, the Meta Quest 2 VR glasses were used. Participants were shown a preloaded video featuring natural landscapes. Due to the glasses' display resolution of 1832×1920 pixels, the visual content was perceived as highly clear and detailed. The stereo-speaker feature enabled clear, high-quality sound transmission. The VR glasses, weighing 503 grams, facilitated portability during use and did not cause any discomfort for the participants. The SB used as an exercise tool is egg-shaped, moderately firm, has a diameter of 6 cm, and is made of silicone. Owing to these features, the participants could easily grasp and use it. In the study, all patients' vital signs were measured on the right arm.

In the VR glasses group, patients' demographic characteristics, pain levels, vital signs, state and trait anxiety, fear, satisfaction, and comfort levels were assessed 5-10 minutes before the dressing change. During the dressing change , which lasted approximately 5 minutes, the patient viewed 360-degree nature videos via VR glasses and simultaneously listened to nature sounds. Five to ten minutes after the completion of the dressing procedure, patients' pain levels, vital signs, state anxiety, fear, satisfaction, and comfort levels were re-evaluated, and post-test data were collected. In the SB group, patients' demographic characteristics, pain levels, vital signs, state and trait anxiety, fear, satisfaction, and comfort levels were assessed 5 to 10 minutes before the dressing change. During the dressing procedure, the patient was given a SB and instructed to squeeze the ball once each time they counted to five. Five to ten minutes after the completion of the dressing procedure, patients' pain, vital signs, state anxiety, fear, satisfaction, and comfort were assessed, completing the post-test data collection. Patients in the control group received no intervention other than routine care, and data were collected at the same time as those in the intervention groups.

Statistical Analysis

Data were analyzed using the Statistical Package for Social Sciences (SPSS) version 25.0 (IBM Corp., Armonk, NY, USA). In the study, the chi-square test and One-Way Analysis of Variance (ANOVA) were used to assess the homogeneity of the independent variables across groups. The ANOVA and the Kruskal-Wallis H test were used to compare the intragroup mean scores of the intervention and control groups. The paired-samples t-test and the Wilcoxon signed-rank test were used to assess differences in dependent measurements between two groups (12). For data that meet the assumption of normality and are analyzed using parametric tests, the "dz" effect size should be interpreted as follows: $0.2 \leq dz < 0.5$ indicates a small effect, $0.5 \leq dz < 0.8$ indicates a medium effect, and $dz \geq 0.8$ indicates a large effect. Similarly, the η^2 (eta-squared) effect size is recommended to be interpreted as follows: $0.01 \leq \eta^2 < 0.06$ indicates a small effect; $0.06 \leq \eta^2 < 0.14$ indicates a medium effect; and $\eta^2 \geq 0.14$ indicates a large effect (13). Omega-squared (ω^2) is an effect-size measure used as an alternative to eta-squared in ANOVA and provides more reliable estimates, particularly with small sample sizes. The interpretation of ω^2 is as follows: $0.01 \leq \omega^2 < 0.06$ indicates a small effect, $0.06 \leq \omega^2 < 0.14$ a medium effect, and $\omega^2 \geq 0.14$ a large effect (14).

Ethics Statement

Approval to conduct the study was granted by the Clinical Research Ethics Committee of the Süleyman Demirel University Faculty of Medicine (decision no: 22/326, dated: 18.11.2022). Permission to carry out the study at the city hospital was obtained from the Provincial Directorate of Health (decision no: E-16657963-799-206773439, dated: 11.01.2023). Informed consent was obtained from individuals who met the inclusion criteria and agreed to participate in the study. The consent form included information about the study's purpose, duration, data collection procedures, voluntary participation, the right to withdraw at any time, and the confidentiality of their identities.

RESULTS

Except for economic status (p=0.046), other socio-demographic characteristics of the patients were homogeneously distributed across groups (p>0.05) (Table 1). The distribution of socio-demographic characteristics of patients who underwent abdominal surgery, by group, is presented in Table 1.

Except for time elapsed since previous analgesic use (p=0.011), the other clinical characteristics of the patients were similarly distributed across groups (p>0.05). The distribution of clinical characteristics of patients who underwent abdominal surgery, by group, is given in Table 2 below.

The blood pressure measurements of patients who underwent abdominal surgery did not differ significantly between groups at either pre-test or post-test (p=0.830 and p=0.841, respectively). Within-group analyses showed no significant differences over time in any group (p>0.05). Pulse findings did not show statistically significant differences between the groups for pre- and post-test measurements (p=0.825 and p=0.687, respectively). Within-group comparisons revealed a significant increase in pulse values over time in both the VR glasses group (p<0.001; r=0.51, large effect) and the SB group (p<0.001; r=0.57, large effect). A significant increase was also observed in the control group (p=0.015; r=0.34, a moderate effect). Respiratory rate did not show a statistically significant difference between the groups in terms of pre-test and post-test measurements (p=0.714 and p=0.302, respectively). Within-group comparisons found significant increases over time in the VR glasses group (p<0.001; r=0.58, large effect), the SB group (p=0.001; r=0.45, moderate effect), and the control group (p=0.022; r=0.32, moderate effect). Body temperature differed significantly among groups at pre-test and post-test (p=0.032; η^2=0.04, indicating a small effect). Although an overall significant difference was identified, post-hoc analysis revealed no significant pairwise differences between the groups. Within-group comparisons showed a significant increase over time only in the SB group (p=0.004; dz=0.40; small effect), while no significant changes were detected in the other groups (p>0.05). A statistically significant difference in oxygen saturation (SpO_2) was observed between groups during the pre-test (p=0.004), whereas no significant difference was detected during the post-test (p=0.133). Within-group comparisons revealed a significant increase in SpO_2 values over time in both the VR glasses group (p<0.001; r=0.54, large effect size) and the SB group (p<0.001; r=0.62, large effect size), whereas no significant change was observed in the control group (p=0.935). The Comparison of pre-test and post-test mean values of vital signs within and between groups of patients who underwent abdominal surgery is presented in Table 3 (Supplemental Digital Content 1).

A statistically significant difference in pretest pain levels was found among groups of patients who underwent abdominal surgery (p<0.001; η^2=0.14, large effect). This difference was attributable to higher pain levels in the VR and SB groups than in the control group. No significant difference was found between groups in the post-test measurements (p=0.577, η^2=0.01). Within-group comparisons revealed statistically significant decreases in pain levels in both the VR glasses group (p<0.001, dz=0.83, large effect) and the SB group (p<0.001, dz=0.57, moderate effect). In the control group, a significant increase in pain levels was observed (p<0.001; dz=0.82, large effect). Within- and between-group comparisons of pretest and posttest mean scores for pain, fear, satisfaction, and comfort in patients who underwent abdominal surgery are presented in Table 4 (Supplemental Digital Content 2).

Comparison of fear of dressing changes among the groups revealed a statistically significant difference in pretest measurements (p<0.001). This difference was attributed to the significantly higher levels of fear in the VR glasses and SB groups than in the control group (p<0.001). A significant difference between groups was also observed in post-test measurements (p=0.009), apparently driven by higher fear levels in the VR glasses group than in the other groups. Within-group comparisons revealed statistically significant reductions in fear levels for the VR glasses group (p<0.001, r=0.77; large effect), the SB group (p<0.001, r=0.78; large effect), and the control group (p=0.001, r=0.45; medium effect) (Table 4; Supplemental Digital Content 2).

In terms of satisfaction, no statistically significant differences were found between the groups in either the pre-test (p=0.825) or post-test (p=0.687) measurements. However, within-group comparisons showed significant increases in satisfaction levels in the VR glasses group (p<0.001, r=0.54, large effect) and the SB group (p<0.001, r=0.62, large effect). In contrast, no significant change in satisfaction was observed in the control group (p=0.935; Table 4; Supplemental Digital Content 2).

When the comfort scores were compared between the groups, no statistically significant difference was found in the pre-test measurements (p=0.398). However, a significant difference was found in the post-test measurements (p<0.001). This difference was attributable to significantly higher comfort levels in the VR glasses and SB groups compared with the control group. Within-group comparisons showed a statistically significant increase in comfort levels in the VR glasses group (p<0.001, r=0.81, large effect), in the ST group (p<0.001, r=0.80, large effect), and in the control group (p<0.001, r=0.50, large effect) (Table 4; Supplemental Digital Content 2).

No statistically significant difference in state anxiety was found in the pre-test measurements (p=0.268, ω^2=0.01). Post-test measurements showed a significant difference between

Table 1. Comparison of the distribution of socio-demographic characteristics of patients underwent abdominal surgery by groups (n=156)

Variables	Virtual reality glasses group	Stress ball group	Control group		
	n=52	n=52	n=52	Test significance	
	M ± SD	M ± SD	M ± SD		
Age Min-Max	56.40±16.77 18-88	57.19±16.07 21-83	54.88±17.19 24-81	F=0.257	p=0.774
	n (%)	n (%)	n (%)	χ^2	p
Gender					
Female	29 (55.8)	29 (55.8)	30 (57.7)	0.052	0.974
Male	23 (44.2)	23 (44.2)	22 (42.3)		
Marital status					
Single	8 (15.4)	7 (13.5)	7 (13.5)	0.106	0.948
Married	44 (84.6)	45 (86.5)	45 (86.5)		
Educational status					
Literate	3 (5.8)	1 (1.9)	6 (11.5)	4.665	0.323
Below undergraduate	42 (80.8)	41 (78.8)	39 (75.0)		
Undergraduate level and above	7 (13.5)	10 (19.2)	7 (13.5)		
Employement status					
Homemaker	27 (51.9)	19 (36.5)	26 (50.0)	4.437	0.350
Retired	16 (30.8)	16 (30.8)	15 (28.8)		
Unemployed	9 (17.3)	17 (32.7)	11 (21.2)		
Perceived economic status					
Income less than expense	12 (23.1)	10 (19.2)	18 (34.6)	**9.673**	**0.046**
Income equal to the expense	32 (61.5)	32 (61.5)	33 (63.5)		
Income higher than expense	8 (15.4)	10 (19.2)	1 (1.9)		
Chronic disease status					
Yes	25 (48.1)	27 (51.9)	29 (55.8)	0.616	0.735
No	27 (51.9)	25 (48.1)	23 (44.2)		

SD: Standard deviation, n: number, %: Percentage, Min: Minimum value, Max: Maximum value, χ^2: Pearson chi-square test value, M: Mean.

groups (p<0.001, ω^2 0.15, large effect). It was determined that this difference was caused by higher state anxiety levels in the control group than in the VR and SB groups. Statistically significant decreases in state anxiety levels were observed in within-group comparisons for the VR glasses group (p<0.001, dz=2.37, large effect), the SB group (p<0.001, dz=1.77, large effect), and the control group (p<0.001, dz=0.94, large effect). No significant difference was detected between groups in post-test state anxiety measurements (p=0.336, ω^2=0.01). This finding suggests a similar distribution of trait anxiety levels among the groups. The comparison of pretest and posttest mean scores of state and trait anxiety, within and between groups of patients who underwent abdominal surgery, is presented in Table 5 (Supplemental Digital Contents 3 and 4).

Table 2. Comparison of the distribution of clinical characteristics of patients who underwent abdominal surgery (n=156)

Variables	**Virtual reality glasses group**	**Stress ball group**	**Control group**		
	n=52	**n=52**	**n=52**	**Test significance**	
	M ± SD	**M ± SD**	**M ± SD**		
Pain intensity Min-Max	5.15±1.42 2-8	5.42±1.47 2-9	4.96±1.19 2-8	F=1.498	p=0.227
Duration since the previous analgesic dose/hour Min-Max	8.88±1.08 7-10	8.88±1.06 7-10	8.27±1.39 7-10	**F=4.675**	**p=0.011**
Wound size/cm Min-Max	4.86±2.25 3-10	6.07±3.15 3-15	5.05±2.50 3-15	H=5.485	p=0.064
Qualitative characteristics	**n (%)**	**n (%)**	**n (%)**	**χ^2**	**p**
Medical diagnosis					
Inguinal hernia	19 (36.5)	25 (48.1)	19 (36.5)	-	-
Umbilical hernia	0 (0.0)	2 (3.8)	2 (3.8)		
Sleeve gastrostomy	0 (0.0)	3 (5.8)	1 (1.9)		
Appendicitis	1 (1.9)	2 (3.8)	2 (3.8)		
Cholelithiasis	27 (51.9)	13 (25.0)	24 (46.2)		
Ventral hernia	3 (5.8)	3 (5.8)	1 (1.9)		
Incisional hernia	2 (3.8)	3 (5.8)	2 (3.8)		
Ileus	0 (0.0)	1 (1.9)	0 (0.0)		
Colon CA	0 (0.0)	0 (0.0)	1 (1.9)		
Surgical intervention type					
Urgent surgery	1 (1.9)	4 (7.7)	3 (5.8)	1.845	0.398
Elective surgery	51 (98.1)	48 (92.3)	49 (94.2)		
ASA* level before surgical intervention					
1	4 (7.7)	4 (7.7)	7 (13.5)	5.710	0.222
2	45 (86.5)	38 (73.1)	38 (73.1)		
3	3 (5.8)	10 (19.2)	7 (13.5)		
Anesthesia					
General	34 (65.4)	25 (48.1)	33 (63.5)	3.868	0.145
Spinal	18 (34.6)	27 (51.9)	19 (36.5)		
Surgical history					
Yes	24 (46.2)	28 (53.8)	30 (57.7)	1.440	0.487
No	28 (53.8)	24 (46.2)	22 (42.3)		
General pain intensity of the surgical wound					
Mild	9 (17.3)	7 (13.5)	10 (19.2)	3.450	0.485
Discomforting	43 (82.7)	42 (80.8)	40 (76.9)		
Severe/Intense	0 (0.0)	3 (5.8)	2 (3.8)		

Table 2. Continued					
Variables	**Virtual reality glasses group**	**Stress ball group**	**Control group**		
	n=52	**n=52**	**n=52**	**Test significance**	
	M ± SD	**M ± SD**	**M ± SD**		
Pain frequency at the surgical wound					
Occasionally	8 (15.4)	7 (13.5)	2 (3.8)	8.375	0.212
Sometimes	39 (75.0)	39 (75.0)	45 (86.5)		
Frequently	5 (9.6)	4 (7.7)	5 (9.6)		
Generally	0 (0.0)	2 (3.8)	0 (0.0)		
Duration of postoperative wound pain					
Nightlong	0 (0.0)	0 (0.0)	1 (1.9)	4.947	0.293
During daily activities	38 (73.1)	45 (86.5)	40 (76.9)		
During the rest	14 (26.9)	7 (13.5)	11 (21.2)		
Analgesic use					
Yes	52 (100.0)	52 (100.0)	52 (100.0)	-	-
Dressing change experience					
Yes	25 (48.1)	29 (55.8)	29 (55.8)	0.824	0.662
No	27 (51.9)	23 (44.2)	23 (44.2)		
Dressing care knowledge					
Yes	22 (42.3)	28 (53.8)	29 (55.8)	2.438	0.656
No	28 (53.8)	23 (44.2)	22 (42.3)		
Partially	2 (3.8)	1 (1.9)	1 (1.9)		

M: Mean, SD: Standard deviation, n: Number, %: Percentage, Min: Minimum value, Max: Maximum value, χ2: Pearson chi-square test value, H: Kruskal-Wallis H test value, ASA: American Society of Anesthesiologists classification.

Table 3. Comparison of pre-test and post-test mean values of vital signs within and between groups of patients who underwent abdominal surgery (n=156)

Measurements	**Virtual reality glasses group**		**Stress ball group**		**Control group**		**Comparisons between groups**			
	n=52		**n=52**		**n=52**		**Test**			
Blood pressure	**M ± SD**	**M (IQR)**	**M ± SD**	**M (IQR)**	**M ± SD**	**M (IQR)**	**Significance**		**ES**	**Difference**
Pre-test	121.52±14.89[a]	121 (20)	120.59±17.74[a]	118 (24)	122.50±15.14[a]	121 (20)	F=0.187	p=0.830	η^2=0.00	-
Post-test	122.40±14.82[a]	121 (20)	120.84±17.48[a]	121 (20)	122.47±15.38[a]	121 (20)	F=0.173	p=0.841	η^2=0.00	-
Test	t=-1.944		t=-0.761		t=0.095					
Significance	p=0.057		p=0.450		p=0.925					
ES	dz=0.27		dz=0.11		dz=0.01					
Pulse										
Pre-test	75.02±9.79[a]	72 (13)	74.31±10.46[a]	72 (12)	74.50±11.38[a]	76 (17)	H=0.385	p=0.825	-	-
Post-test	77.25±9.35[a]	76 (12)	76.33±10.63[a]	76 (11)	75.54±10.99[a]	76 (18)	H=0.752	p=0.687	-	-
Test		Z=3.672		Z=4.146		Z=2.441				
Significance		p<0.001		p<0.001		0.015				
ES		r=0.51		r=0.57		r=0.34				
Respiratory rate										
Pre-test	14.46±2.04 [a]	14 (2)	14.33±1.99[a]	14 (2)	14.40±2.75[a]	14 (4)	H=0.674	p=0.714	-	-
Post-test	15.46±2.35[a]	16 (4)	15.12±2.04[a]	16 (2)	14.81±2.69[a]	14 (6)	H=2.393	p=0.302	-	-
Test		Z=4.218		Z=3.247		Z=2.297				
Significance		p<0.001		p=0.001		p=0.022				
ES		r=0.58		r=0.45		r=0.32				

Table 3. Continued

Measurements	Virtual reality glasses group		Stress ball group		Control group		Comparisons between groups			
	n=52		n=52		n=52		Test			
Body temperature	**M ± SD**	**M (IQR)**	**M ± SD**	**M (IQR)**	**M ± SD**	**M (IQR)**	**Significance**		**ES**	**Difference**
Pre-test	36.73±0.26[a]	37 (0)	36.63±0.26[a]	37 (0)	36.63±0.20[a]	37 (0)	F=3.522	p=0.032	η^2=0.04	-
Post- test	36.74±0.25[a]	37 (0)	36.69±0.19[a]	37 (0)	36.66±0.18[a]	37 (0)	F=2.198	p=0.115	η^2=0.03	-
Test	t=-0.393		t=-3.060		t=-1.738					
Significance	p=0.696		p=0.004		p=0.088					
ES	dz=0.07		dz=0.40		dz=0.23					
Oxygen saturation (SpO_2)										
Pre-test	97.31±2.36[ab]	98 (3)	96.88±2.23[b]	97 (2)	98.31±1.70	99 (4)	H=11.158	p=0.004	-	[a]>[b]
Post-test	97.90±1.99[a]	98 (3)	97.63±1.93[a]	98 (2)	98.31±1.81[a]	99 (3)	H=4.037	p=0.133	-	-
Test		Z=3.894		Z=4.435		Z=-0.082				
Significance		p<0.001		p<0.001		p=0.935				
ES		r=0.54		r=0.62		r=0.01				

Mean: M, SD: Standard deviation, n: Number, M (IQR): Median (75th and 25th percentiles), IQR: Interquartile range, t: Paired sample t-test value, F: The One-Way Analysis of variance test value (ANOVA), H: Kruskal-Wallis H test value, Z: Wilcoxon signed-rank test value, ES (r, η^2, dz): Effect size, [a, b]: Different superscript letters indicate significant differences between groups (p<0.05).

Table 4. Within- and between-group comparisons of pretest and posttest mean scores for pain, fear, satisfaction, and comfort in patients who underwent abdominal surgery (n=156)

Measurements	Virtual reality glasses group		Stress ball group		Control group		Comparisons between groups			
	n=52		n=52		n=52		Test			
Pain	**M ± SD**	**M (IQR)**	**M ± SD**	**M (IQR)**	**M ± SD**	**M (IQR)**	**Significance**		**ES**	**Difference**
Pre-test	4.77±1.98[a]	5 (4)	4.79±1.89[a]	5 (3)	3.25±1.62[b]	3 (2)	F=12.022	p<0.001	η^2=0.14	[a]>[b]
Post-test	4.19±1.67[a]	4 (2)	3.87±1.85[a]	4 (2)	3.88±1.82[a]	4 (2)	F=0.552	p=0.577	η^2=0.01	-
Test	t=5.979		t=4.142		t=-5.961					
Significance	p<0.001		p<0.001		p<0.001					
ES	dz=0.83		dz=0.57		dz=0.82					
Fear										
Pre-test	5.87±3.42	7 (6)[a]	5.21±3.44	5 (6)[a]	2.56±2.78	2 (5)[b]	H=26.087	p<0.001	-	[a]>[b]
Post-test	1.94±2.48	1 (4)[a]	0.65±1.28	0 (1)[b]	1.25±2.18	0 (2)[ab]	H=9.501	p=0.009	-	[a]>[b]
Test		Z=-5.570		Z=-5.659		Z=-3.270				
Significance		p<0.001		p<0.001		p=0.001				
ES		r=0.77		r=0.78		r=0.45				
Satisfaction										
Pre-test	8.58±1.13	9 (1)[a]	9.13±0.89	9 (1)[a]	9.08±0.74	9 (1)[a]	H=0.385	p=0.825	-	-
Post- test	10.00±0.00	10 (0)[a]	10.00±0.00	10 (0)[a]	9.25±0.88	9 (1)[a]	H=0.752	p=0.687	-	-
Test		Z=3.894		Z=4.435		Z=-0.082				
Significance		p<0.001		p<0.001		p=0.935				
ES		r=0.54		r=0.62		r=0.01				
Comfort										
Pre-test	6.96±1.68	7 (2)[b]	7.08±1.85	7 (3)[b]	6.37±2.67	6 (5)[b]	H=1.840	p=0.398	-	-
Post-test	9.25±1.87	10 (1)[a]	9.23±1.21	10 (1)[a]	7.40±2.61	8 (5)[b]	H=21.993	p<0.001	-	[a]>[b]
Test		Z=5.850		Z=5.798		Z=3.609				
Significance		p<0.001		p<0.001		p<0.001				
ES		r=0.81		r=0.80		r=0.50				

SD: Standard deviation, n: Number, M (IQR): Median (75th and 25th percentiles), IQR: Interquartile range, t: Paired sample t-test value, F: The One-Way Analysis of variance test value (ANOVA), H: Kruskal-Wallis H test value, Z: Wilcoxon signed rank test value, ES (r, η^2, dz): Effect size, [a, b]: Different superscript letters indicate significant differences between groups (p<0.05), M: Mean.

Table 5. Comparison of pretest and posttest mean scores of state and trait anxiety findings within and between groups in patients who underwent abdominal surgery (n=156)

Measurements	Virtual reality glasses group	Stress ball group	Control group	Comparisons between groups			
	n=52	n=52	n=52	Test			
Stait anxiety	M ± SD	M ± SD	M ± SD	Significance		ES	Difference
Pre-test	43.19±5.39[b]	42.69±8.55[b]	40.98±8.13[b]	W=1.336	p=0.268	ω^2=0.01	-
Post-test	30.02±4.66[b]	30.42±5.35[b]	35.71±7.46[a]	W=11.638	p<0.001	ω^2=0.15	[a]>[b]
Test	t=17.102	t=12.791	t=6.788				
Significance	p<0.001	p<0.001	p<0.001				
ES	dz=2.37	dz=1.77	dz=0.94				
Trait anxiety							
Pre-test	30.73±5.38	32.15±8.27	32.10±4.49	W=1.103	p=0.336	ω^2=0.01	-

SD: Standard deviation, n: Number, t: Paired sample t-test value, W: Welch test value, ES: Effect size, ω^2: Omega-squared effect size value, dz: Effect size value for t-test. [a, b]: Different superscript letters indicate significant differences between groups (p<0.05), M: Mean.

DISCUSSION

The study revealed that the use of VR glasses and SB during dressing changes did not produce statistically significant differences in vital signs between groups of patients who underwent abdominal surgery. However, some remarkable findings were observed when each group was assessed individually. In the intervention groups (VR and SB), significant increases were observed pulse rate and SpO_2 during dressing changes. Both the intervention and control groups showed significant increases in respiratory rate over time. Only within-group comparisons of the SB group showed a significant increase in fever. When blood pressure was examined, no significant differences were found either within or between the groups. Based on these findings, a significant within-group increase indicates that the applications affect physical responses. Pain, anxiety, fear, and similar conditions experienced during invasive procedures such as dressing changes may activate the sympathetic nervous system, leading to increases in pulse rate, respiratory rate, and blood pressure (15). Ding et al. (4) reported an increase in pulse rate during the first postoperative dressing among hemorrhoid patients in both the VR and control groups; however, no significant difference was found between the groups. In a study conducted during another intervention, namely a splinting procedure in children, the VR glasses group showed lower intra-procedural and post-procedural pulse rates. In contrast, oxygen saturation levels during the procedure were higher than pre-procedural values (16). A study conducted in patients undergoing colonoscopy revealed that the use of VR glasses significantly decreased systolic blood pressure and respiratory rate, and increased oxygen saturation (17). In another study conducted during the transrectal prostate biopsy, it was found that VR and SB applications caused significant decreases in diastolic blood pressure, pulse, and respiratory rate, and a significant increase in oxygen saturation (9). The use of an anti-SB during inferior alveolar nerve block injection did not cause significant changes in vital signs, including among individuals under 35 years of age and in both genders (18). Studies have shown that VR and SB during procedural interventions have varied effects on hemodynamic parameters; however, further research is needed to evaluate their impact on vital signs during dressing procedures.

Although no significant differences were found between the groups in post-test pain measurements, pre-test measurements revealed that the intervention groups had statistically significantly higher pain levels. Within-group comparisons revealed a statistically significant decrease in pain levels in the intervention groups. The use of VR glasses and a SB appears to have a positive effect on patients' pain levels. In the present study, patients generally reported moderate pain at their surgical wound sites. Regarding the time elapsed since the previous analgesic use, patients in the intervention groups received pain medication significantly earlier than those in the control group. Among patients with wounds, dressing changes are one of the most common causes of pain (19). A study involving burn patients of various ages showed that use of VR glasses during dressing procedures significantly reduced pain levels (20). Many studies have emphasized that the distracting effect of VR glasses can reduce pain perception in both children and adults during dressing changes (2,4,21-24). In a previous study, pain levels in patients who underwent abscess drainage were assessed before dressing changes, at multiple time points during dressing changes, and after dressing changes. No statistically significant difference was found in post-dressing pain measurements between the group receiving VR combined with analgesics and the control group receiving analgesics alone. In contrast, pain levels measured during the dressing change were reported to be lower in the group receiving VR and analgesics compared with the control group (25). According to a systematic review and meta-analysis, use of VR glasses significantly reduced pain intensity during wound care procedures in adults across all study designs. Also, it enhanced patients' overall wound care experience (26). The pain experienced during clinical procedures

is known as procedural pain (17). Pain is a subjective and multidimensional phenomenon composed of sensory, cognitive, affective, and socio-cultural components (27). The literature indicates that informing patients about the procedure, ensuring their comfort and addressing pain throughout the process, and making them aware of supportive methods, such as distraction or music, to alleviate discomfort or anxiety may reduce pain intensity or prevent pain during dressing changes (28,29). Examination of dressing knowledge in this study showed that 42.3% of the VR group, 53.8% of the SB group, and 55.8% of the control group were familiar with dressing. Psychosocial factors, such as age, gender, culture and traditions, anxiety and depression, and environmental factors, such as resources and the setting and timing of the procedure, may affect patients' unique pain experience (19). Because pain is multidimensional, conducting research with diverse sample groups during dressing procedures will yield more definitive information about the use of VR and SB in wound care.

Among patients who underwent abdominal surgery, pre-test measurements during dressing changes showed that levels of fear in the intervention groups were significantly higher. At post-test, fear levels in the VR group were higher than those in the other groups. In within-group comparisons, significant decreases in fear levels were observed in both the intervention and control groups. This finding suggests that VR and SB may initially increase patient awareness or trigger procedural anxiety because they are unfamiliar to the patient. In this context, VR and SB appear to reduce fear levels throughout the process. Studies have shown that using VR glasses during dressing procedures in pediatric patients reduces fear (30,31). A study of adult diabetic patients reported a decrease in fear of self-injection and self-testing following use of VR and ice (32). On the other hand, in studies involving children or adults, SB application had no positive effect on fear during procedures such as intravenous catheterization (33,34), drawing blood (35,36), and endoscopy (37). Fear is a sudden, undesirable behavioral and emotional response to a real or imagined threat. In healthcare settings, this response becomes particularly pronounced during medical procedures; individuals may develop a fear of such procedures when interacting with healthcare professionals, undergoing medical interventions, or being in the hospital environment. Fear of medical procedures reduces individuals' involvement in the treatment process and negatively affects healthcare delivery (38). In this context, the significant decrease in fear levels observed in both the virtual-reality and stress-ball intervention groups suggests that these distraction techniques may reduce fear of medical procedures. This decrease in fear levels can be explained by a mechanism that diverts the individual's attention from painful stimuli during medical procedures, thereby soothing and regulating emotional responses. However, the high fear levels observed in the intervention groups during the pre-test, the significant decrease during the process, and the elevated fear levels in the VR group at the post-test suggest that further research is needed regarding the use of VR and stress-ball interventions for this variable.

The study found no statistically significant difference in post-test measurements of patient satisfaction between groups of patients who underwent abdominal surgery. However, in within-group comparisons, satisfaction increased in the groups that received VR and SB, while no significant difference in satisfaction was observed in the control group. These results suggest that both distracting interventions have a positive effect on patient satisfaction. A study conducted during dressing changes in burn patients across a wide age range revealed a positive effect on patient satisfaction (20). Hudson et al. (39) reported that the use of distraction techniques—including VR glasses, SBs, nurse interaction, and watching DVDs—during varicose vein treatment did not produce significant differences in patient satisfaction among the groups. Studies have indicated that using smart glasses during procedures such as peripheral intravenous catheter insertion (40,41), blood sampling (42,43), and arteriovenous fistula cannulation (44) increases patient satisfaction. However, to evaluate such interventions effectively, studies are needed that focus on different patient populations, diverse cultural contexts, and long-term effects.

An analysis of the research findings indicates that during dressing changes for patients who underwent abdominal surgery, comfort levels were higher in the intervention groups receiving VR glasses and SB applications than in the control group. According to Kolcaba's Theory of Comfort, when an individual's comfort needs are met, they experience a sense of calmness, peace, relaxation, and the ability to cope with challenges. Kolcaba states that comfort must be addressed in four interrelated contexts: Physical, socio-cultural, psychospiritual, and environmental, all of which influence one another (45). In this context, the interventions applied to patients in the VR and SB groups are thought to have helped them cope better with the dressing procedure, providing a sense of relief. These findings suggest that VR glasses and SB may serve as comfort-enhancing interventions during dressing changes.

Among patients who underwent abdominal surgery, anxiety was lower in the intervention group that received VR and SB than in the control group. A study found that the combined use of VR glasses and analgesics during dressing changes significantly reduced anxiety in pediatric patients (46). Studies have shown that the use of VR during dressing changes not only reduces anxiety levels but may also shorten the duration of the procedure (30,31). In another study of adult diabetic patients, VR and ice application reduced anxiety levels related to self-injection and the testing process (32). VR glasses have a significant effect on anxiety in children and adults during various procedures, including splint applications (16), venous blood collection (47), fluoroscopy-guided interventional

procedures (48), and blood collection procedures (35). Hudson et al. (39) found that distracting techniques (VR glasses, SB, nurse interaction, watching a DVD) during varicose vein treatment reduced intraoperative anxiety. In a study comparing SB and VR during peripheral catheterization, both methods reduced patients' anxiety levels (49). In a study of individuals undergoing endoscopy, use of a SB significantly reduced post-procedure anxiety scores (37). However, unlike other findings, the use of ST during lipoma excision under local anesthesia has been reported to have no significant effect on anxiety (50). Consistent with these results, using VR glasses (providing visual and auditory stimulation) and SB emerge as effective strategies for reducing patient anxiety and distraction during dressing procedures.

Study Limitations

The presence of varied medical diagnoses among patients who underwent abdominal surgery limited the homogeneity of the sample. Since most patients were unfamiliar with VR glasses, introducing the device to them proved challenging. Another limitation of the study was that the video presented through the VR glasses was standardized (the same content was shown to all patients) and did not vary according to individual interests.

CONCLUSION

During dressing changes for patients who underwent abdominal surgery, anxiety was lower in the intervention group using VR and SB than in the control group. The comfort levels were higher in the VR and SB groups than in the control group. Fear levels in the VR glasses group regarding dressing changes were higher than in other groups. No differences between the groups were found in pain, vital signs, or satisfaction. In line with these results, integrating VR glasses and stress-ball use into clinical practice for dressing changes in patients undergoing abdominal surgery is recommended to enhance patient comfort and reduce anxiety. To clarify the effectiveness of VR glasses and SBs in adult patients undergoing dressing procedures with respect to the study variables and to obtain evidence-based information, further research using different samples and methods (such as various educational materials and distraction techniques) is recommended.

Ethics

Ethics Committee Approval: Approval to conduct the study was granted by the Clinical Research Ethics Committee of the Süleyman Demirel University Faculty of Medicine (decision no: 22/326, dated: 18.11.2022). Permission to carry out the study at the city hospital was obtained from the Provincial Directorate of Health (decision no: E-16657963-799-206773439, dated: 11.01.2023).

Informed Consent: Informed consent was obtained from individuals who met the inclusion criteria and agreed to participate in the study.

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Footnotes

Author Contributions

Concept - Z.Y., A.B.; Design - Z.Y., A.B.; Data Collection or Processing - Z.Y., A.B.; Analysis or Interpretation - Z.Y., A.B.; Literature Search - Z.Y., A.B.; Writing - Z.Y., A.B.

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ORIGINAL ARTICLE
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Total mesorectal excision quality as a predictor of overall survival in rectal cancer: A retrospective cohort study

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ABSTRACT

Objective: Achieving complete total mesorectal excision (TME) is considered an important indicator of surgical quality in rectal cancer surgery. However, the impact of TME quality on overall survival (OS) remains controversial. This study aimed to evaluate the association between TME quality and OS in patients undergoing rectal cancer surgery.

Material and Methods: A retrospective analysis was conducted on 171 patients who underwent elective low anterior resection or abdominoperineal resection for rectal cancer between 2021 and 2022. OS was compared between patients with incomplete TME and those with near-complete or complete TME. In addition, clinical and pathological factors associated with TME quality were assessed.

Results: Incomplete TME was independently associated with worse OS [hazard ratio (HR)=2.53, 95% confidence interval (CI) 1.15-5.59, p=0.021], while undergoing a Hartmann procedure showed the strongest negative impact on OS (HR=4.60, 95% CI 2.04-10.38, p<0.001). At 36 months, OS was 86.3% in the near-complete/complete TME group versus 68.3% in the incomplete group (log-rank p=0.008). Factors associated with incomplete TME included lower preoperative albumin levels, larger tumor size, previous abdominal surgery, tumors located closer to the anal verge, lymphovascular invasion, and positive circumferential resection margins.

Conclusion: Incomplete TME was associated with significantly worse OS in patients undergoing rectal cancer surgery. These findings highlight the importance of achieving optimal TME quality. Larger prospective studies are warranted to validate these results.

Keywords: Rectal cancer, total mesorectal excision quality, mesorectal grade, overall survival

INTRODUCTION

Approximately 46,000 new cases of rectal cancer are reported each year in the United States (1). There have been significant developments in the treatment of rectal cancer in recent years. The introduction of neoadjuvant radiotherapy and then total neoadjuvant treatment has contributed greatly to long-term oncologic outcomes (2). Despite these developments, total mesorectal excision (TME), first described by Bill Heald, remains the cornerstone of curative treatment for rectal cancer (3-7).

The completeness of the mesorectal excision specimen is widely regarded as a key indicator of surgical quality. Nagtegaal et al. (8) highlighted that TME quality can be assessed through macroscopic evaluation of the specimen and may influence oncologic outcomes. Consequently, achieving complete TME has become an essential goal for colorectal surgeons. However, existing literature reports conflicting results regarding the prognostic value of TME quality. While several studies have shown that better-quality TME specimens are associated with improved oncologic outcomes (9,10), others have failed to demonstrate a significant relationship between TME quality and prognosis (11,12).

Although TME is considered the standard of care in rectal cancer surgery, the clinical significance of TME quality remains uncertain. The rationale behind our study was to contribute to this ongoing debate by presenting data from our own cohort.

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Specifically, we aimed to evaluate the impact of incomplete TME on survival and to identify factors associated with both prognosis and TME quality.

MATERIAL and METHODS

Study Design and Patient Selection

This study is designed as a retrospective, single-center study. Ethical approval was obtained from the Clinical Research Ethics Committee of the Marmara University Faculty of Medicine (approval number: 09.2025.25-0364, date: 18.04.2025). Patients who underwent rectal surgery at the Department of General Surgery, Marmara University between January 2021 and December 2022 were identified using the hospital information system. In our institution, the standard approach for patients with locally advanced mid-to-low rectal tumors is surgery following neoadjuvant therapy. However, this strategy could not always be applied due to factors such as surgeon preference, patient comorbidities, and individual patient choice. All patients who underwent low anterior resection (LAR) or abdominoperineal resection (APR) were screened. Inclusion criteria consisted of being over 18 years of age and having undergone elective rectal cancer surgery involving TME. Exclusion criteria included the presence of synchronous tumors, distant metastasis at the time of diagnosis, and a history of inflammatory bowel disease.

Patient Demographics and Clinical Data

Demographic and clinical data, including age, sex, body mass index (BMI), American Society of Anesthesiologists (ASA) score, Charlson comorbidity index, albumin level, smoking status, history of previous abdominal surgery, neoadjuvant therapy status, hospital length of stay, and follow-up duration, were collected from patient records. Operative details such as surgical procedure (LAR, APR, or Hartmann) and tumor distance from the anal verge were also recorded. Pathology reports were reviewed to obtain T and N stages, tumor size, number of harvested and positive lymph nodes, TME quality, presence of lymphovascular invasion (LVI) and perineural invasion, circumferential resection margin (CRM) status, and distal resection margin status. Mortality status during follow-up was also documented. TME quality was classified in pathology reports as incomplete, near complete, or complete. In this study, near complete and complete cases were grouped together, while incomplete cases formed a separate group.

Definitions

Tumor staging was determined according to the 8th edition of the American Joint Committee on Cancer TNM classification system. Overall survival (OS) was defined as the time from the date of surgery to the date of death from any cause. CRM positivity was defined as a tumor distance of <1 mm from the mesorectal fascia.

No intraoperative assessment of TME quality by the surgical team was documented in the operative reports or pathology request forms. In addition, no photographic documentation of the surgical specimen or the pelvic operative field after resection was available. Therefore, the classification of TME quality was based exclusively on the macroscopic evaluation of the resected specimen performed by an experienced gastrointestinal pathologist. The quality of TME was assessed according to the macroscopic grading system described by Nagtegaal et al. (8) commonly referred to as the "Quirke classification".

TME quality was categorized into three groups:

-Complete: Well-preserved mesorectum with a smooth surface, only minor superficial irregularities, no surface defects greater than 5 mm in depth; no distal coning observed.

-Near-complete: Moderate mesorectal bulk, irregular mesorectal surface with defects larger than 5 mm but none reaching the muscularis propria, no exposure of the muscularis propria except at the insertion of the levator ani.

-Incomplete: Limited mesorectal tissue with deeper defects exposing the muscularis propria and/or a markedly irregular CRM.

Outcomes of the Study

The primary outcome of this study was to evaluate whether near complete/complete TME is associated with better OS in patients with rectal cancer. Secondary outcomes included identifying other independent predictors of OS, as well as determining clinical and pathological factors associated with TME quality.

Statistical Analysis

Statistical analyses were performed using SPSS software version 21.0 (SPSS Inc., Chicago, IL, USA) and Jamovi version 2.3.28. Continuous variables were summarized as mean ± standard deviation or median with interquartile range (IQR), while categorical variables were expressed as frequencies and percentages. Comparisons between groups were made using the Student's t-test or Mann-Whitney U test for continuous variables, and the chi-square or Fisher's exact test for categorical variables, as appropriate.

OS was estimated using the Kaplan-Meier method and compared between groups using the log-rank test. Cox proportional hazards regression analyses were performed to identify independent predictors of OS. Candidate variables for inclusion in the Cox model were determined based on exploratory univariate and multivariate logistic regression analyses evaluating 36-month mortality, which are presented in Supplementary Tables S1 and S2. Results of the Cox regression analysis are reported as hazard ratios (HR) with 95% confidence intervals (CI) and corresponding p-values. A p-value <0.05 was considered statistically significant.

RESULTS

Between January 2021 and December 2022, the medical records of 246 patients who underwent LAR or APR in our department were reviewed. A total of 171 patients who met the inclusion criteria were included in the analysis (Figure 1). Approximately 60% of the cohort were male, and the mean age was 62.4±11.4 years. The mean BMI was 26.3±4.2 kg/m^2, indicating that the majority of patients were overweight. Most patients had low ASA scores (I-II) (88%, n=149) and did not receive neoadjuvant therapy (56.2%, n=95). The median follow-up duration was 42 months (IQR 13), during which the overall mortality rate was 22% (n=38) (Table 1). The median tumor distance from the anal verge was 8 cm (IQR 9). The most common surgical procedure was LAR in 63.7% of patients, followed by Hartmann's procedure (20.5%) and APR (15.8%).

Regarding pathological staging, 81.2% of patients had early-stage tumors (Tis-T3) and Node-negative disease (N0) was present in 63.5% of patients. Specifically, the distribution of T stages was as follows: T0 in 7.6%, Tis in 1.2%, T1 in 4.1%, T2 in 12.4%, T3 in 55.9%, and T4 in 18.8% of patients (data not shown in table). The median number of harvested lymph nodes was 15 (IQR 9.75). Based on pathological assessment, complete TME was achieved in 51.3% of patients, near-complete TME in 32.5%, and incomplete TME in 16.2%. A positive CRM was observed in 11.8% of cases (Table 2).

In the univariable Cox regression analysis, surgical procedure (Hartmann vs. others), TME quality, Charlson comorbidity index, and serum albumin were significantly associated with OS, while nodal status showed a borderline association (p=0.051). In the multivariable Cox model, only surgical procedure (Hartmann vs. others: HR=4.60, 95% CI 2.04-10.38, p<0.001) and TME quality (incomplete vs. near complete/complete: HR=2.53, 95% CI 1.15-5.59, p=0.021) remained independent predictors of OS, with both Hartmann procedures and incomplete TME being associated with significantly worse survival (Table 3). Kaplan-Meier survival analysis demonstrated significantly worse OS in patients with incomplete TME compared with those with near complete/complete TME. For the entire cohort, the 36-month OS rate was 83.6%. At 36 months, survival was 86.3% in the near complete/complete TME group versus 68.3% in the incomplete group, with 22 observed deaths among 129 patients and 10 deaths among 25 patients, respectively. The log-rank test showed a statistically significant difference between the groups (p=0.008) (Figure 2).

Among the evaluated clinicopathological factors, several variables were significantly associated with TME quality. Patients with incomplete TME had lower preoperative albumin levels

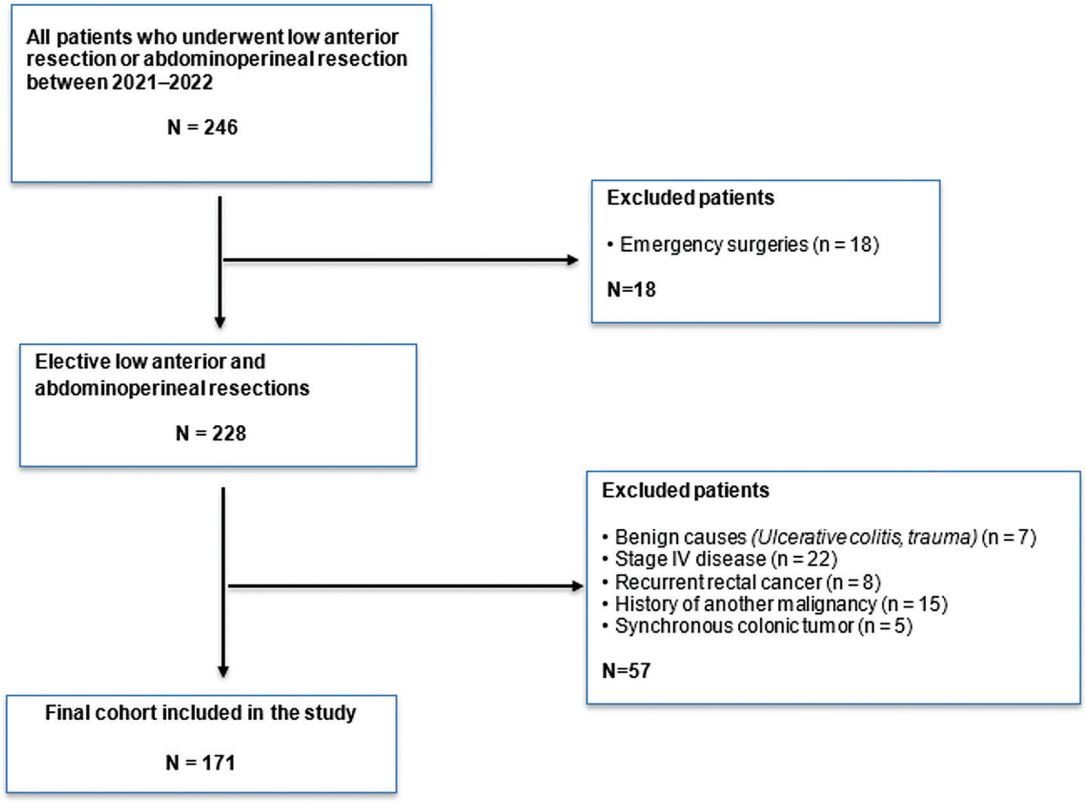

Figure 1. Flow diagram of the study.

[median 41 (IQR 4) vs. 43 (IQR 5.25), p=0.04] and larger tumor size [median 5.0 cm (IQR 3.0) vs. 3.8 cm (IQR 2.5), p=0.05] compared to those with near complete/complete TME. Previous abdominal surgery was more frequent in the incomplete TME group (37.5% vs. 13.9%, p=0.02). Tumors located closer to the anal verge were strongly associated with incomplete TME [median distance 5.0 cm (IQR 6.0) vs. 9.0 cm (IQR 9.0), p<0.001]. Presence of LVI was higher in patients with incomplete TME (22.4% vs. 10.0%, p=0.04). CRM positivity showed the strongest association, being markedly higher in the incomplete group (50.0% vs. 11.8%, p<0.001). Other variables, including age, BMI, ASA score, neoadjuvant therapy, T stage, and surgical procedure, showed no statistically significant differences between groups (Table 4).

DISCUSSION

The quality of TME is widely regarded as a key indicator of the adequacy of rectal cancer surgery. However, whether this attributed importance truly translates into clinically meaningful outcomes has remained a subject of debate. In the present study, we retrospectively analyzed data from 171 patients and found that complete or near-complete TME quality was achieved in approximately 84% of cases, while the rate of positive CRM was 11.8%. In our multivariable Cox regression analysis, incomplete TME was found to be independently associated with worse OS, with a 2.53-fold increased risk of mortality compared to patients with near complete/complete TME. Notably, previous studies investigating the prognostic impact of TME quality have reported inconsistent results, likely due to substantial heterogeneity in study designs, patient populations, and outcome definitions.

In the study by Garoufalia et al. (12), retrospective single-center data were analyzed, and incomplete TME was not found to be associated with any disadvantage in terms of DFS. In this cohort, where complete/near-complete TME was achieved in the majority of patients (87%), the reported rate of pathological CRM positivity was 4.8%. Notably, only 15% of the patients had not received neoadjuvant therapy, and no statistically significant difference in CRM positivity was observed between the complete/near-complete and incomplete TME groups. When comparing these findings with our study, several key distinctions should be highlighted. Our sample size was larger (171 vs. 124),

Table 1. Demographic and baseline characteristics of the study cohort (n=171)

Parameter	Value
Age (years), mean ± SD	62.4±11.4
Sex, n (%) - Female - Male	 69 (40.4%) 102 (59.6%)
BMI (kg/m^2), mean ± SD	26.3±4.2
ASA score, n (%) - Low (I-II) - High (III-IV)	 149 (87.6%) 21 (12.4%)
Charlson comorbidity index, median (IQR)	4 (2)
Albumin (g/L), median (IQR)	41.5 (5)
Smoking status, n (%) - Yes - No	 75 (45.0%) 92 (55.0%)
Previous abdominal surgery, n (%) - Yes - No	 20 (11.8%) 150 (88.2%)
Neoadjuvant therapy, n (%) - Yes - No	 74 (43.8%) 95 (56.2%)
Length of stay (day), median (IQR)	6 (2)
Mortality, n (%) - Yes - No	 38 (22.2%) 133 (77.8%)
Follow-up (months), median (IQR)	42 (13)

SD: Standard deviation, BMI: Body mass index, IQR: Interquartile range, ASA: American Society of Anesthesiologists.

Table 2. Surgical and tumor-related characteristics of the study cohort (n=171)

Parameter	Value
Distance from anal verge (cm), median (IQR)	8 (9)
Type of surgery, n (%) - LAR - Hartmann's procedure - APR	 109 (63.7%) 35 (20.5%) 27 (15.8%)
T stage, n (%) - Early (Tis, T0, T1, T2, T3) - Advanced (T4)	 138 (81.2%) 32 (18.8%)
N stage, n (%) - N0 - N1 - N2	 108 (63.5%) 41 (24.1%) 21 (12.4%)
Number of harvested lymph nodes, median (IQR)	15 (9.75)
Number of positive lymph nodes, median (IQR)	0.0 (1.0)
Lymphovascular invasion, n (%) - Yes - No	 87 (53.4%) 76 (46.6%)
Perineural invasion, n (%) - Yes - No	 54 (33.1%) 109 (66.9%)
TME quality, n (%) - Incomplete - Near complete - Complete	 25 (16.2%) 50 (32.5%) 79 (51.3%)
Distal resection margin, n (%) - Positive - Negative	 8 (4.7%) 163 (95.3%)
Circumferential resection margin, n (%) - Positive - Negative	 20 (11.8%) 150 (88.2%)

IQR: Interquartile range, TME: Total mesorectal excision, LAR: Low anterior resection, APR: Abdominoperineal resection.

Table 3. Cox proportional hazards regression analysis for overall survival		
Variable	**HR (univariable)**	**HR (multivariable)**
Type of surgery (Hartmann's vs. others)	5.64 (2.70-11.76), p<0.001	4.60 (2.04-10.38), p<0.001
TME quality (incomplete vs. others)	2.81 (1.31-6.02), p=0.008	2.53 (1.15-5.59), p=0.021
N stage (positive vs. negative)	2.05 (1.00-4.19), p=0.051	1.97 (0.93-4.20), p=0.078
Charlson comorbidity index (per 1-point increase)	1.23 (1.04-1.45), p=0.016	1.04 (0.87-1.24), p=0.701
Albumin (per 1 g/dL increase)	0.93 (0.88-0.99), p=0.024	0.98 (0.92-1.05), p=0.594
HR: Hazard ratio, TME: Total mesorectal excision.		

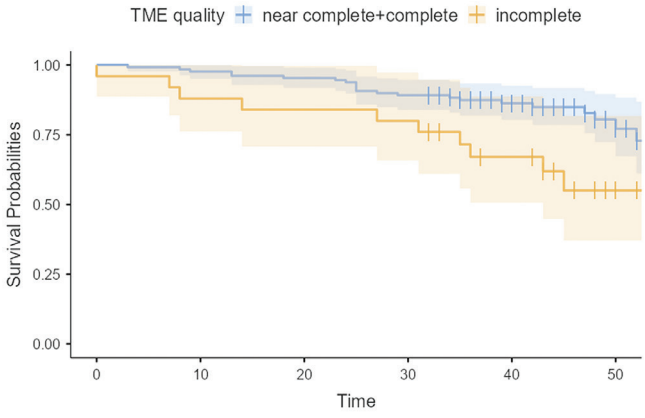

Figure 2. Kaplan-Meier overall survival curves stratified by TME quality (near complete/complete vs. incomplete). Patients with incomplete TME had significantly worse overall survival compared with those with near complete/complete TME (Log-rank χ^2=7.01, p=0.008).

TME: Total mesorectal excision

and the proportion of patients who did not receive neoadjuvant therapy was considerably higher (56.2%). While the rate of achieving complete/near-complete TME was comparable, the CRM positivity rate in our cohort was higher (11.8%). Since neoadjuvant therapy is known to facilitate tumor downstaging and reduce radiologic CRM involvement, the lower rate of neoadjuvant treatment in our population may partly explain the relatively higher incidence of CRM positivity observed. Nevertheless, our reported CRM involvement rate remains consistent with previously published literature (13). Our lower rate of neoadjuvant therapy utilization may partly be explained by the impact of the coronavirus disease-2019 pandemic during the years when our patients underwent surgery, as a surgery-first approach was often preferred to minimize prolonged hospital visits and potential treatment-related risks. Additionally, the proportion of early-stage tumors in our cohort might be higher compared to other studies. However, due to the lack of detailed data on this aspect, we acknowledge this as a limitation of our study.

In our study, the rate of CRM positivity was 50% in the incomplete TME group compared to 11.8% in the complete/near-complete TME group, and this difference was statistically significant. The fact that we identified TME quality as a significant factor influencing OS, while the other study did not find an association with DFS, may be partly explained by this difference in CRM involvement. We believe that the higher rate of CRM positivity in our incomplete TME group is the primary driver of poorer survival outcomes. The recent 2025 study by Alipouriani et al. (14) supports this interpretation. In this study, patients with incomplete TME were stratified based on CRM involvement, and it was demonstrated that the combination of incomplete TME and CRM involvement was associated with increased local recurrence and, similar to our findings, reduced OS. In that study, the 36-month OS rates were approximately 88% for patients without CRM involvement and 48% for those with CRM involvement, whereas in our cohort, the 36-month OS was 86.3% in the near-complete/complete TME group compared to 68.3% in the incomplete TME group. In a study evaluating the prognostic value of assessing TME quality using a two-tier versus three-tier classification system, it was found that patients with complete TME had significantly better DFS and OS compared with those classified as near-complete or incomplete TME (11).

Despite the studies that report findings consistent with ours, a broader review of the literature reveals that most studies have not demonstrated a significant association between TME quality and OS. However, there is comparatively stronger evidence suggesting that incomplete TME is associated with higher rates of local and overall recurrence (9,10,15-17). One of the pioneering studies on this topic, conducted by Nagtegaal et al. (8), presented intriguing findings regarding the impact of TME quality on patient prognosis. They argue that although CRM involvement is significantly higher in the incomplete TME group, the negative impact of incomplete TME on oncologic outcomes cannot be explained solely by its association with CRM. In their analysis excluding CRM-positive cases, overall recurrence remained significantly higher in the incomplete TME group, while no difference in OS was observed. Furthermore, the study emphasizes that the coexistence of incomplete TME and CRM positivity does not always indicate poor surgical quality, as it may also result from advanced tumor size. In our cohort, although there was no significant difference in the distribution of T4 tumors between the incomplete and complete/near-complete TME groups, the median tumor size was notably larger in the incomplete TME group, approaching statistical

Table 4. Factors associated with TME quality			
Variable	**Incomplete TME (n=25)**	**Near complete/complete TME (n=129)**	**p-value (death)**
Age (years), mean ± SD	60.6±14.9	62.2±10.6	p=0.52[3]
Sex (n, %) - Female - Male	 10 (16.4%) 15 (16.1%)	 51 (83.6%) 78 (83.9%)	p=0.96[1]
BMI (kg/m^2), mean ± SD	26.1±4.0	26.5±4.2	p=0.68[3]
ASA score, n (%) - Low (I-II) - High (III-IV)	 23 (17.2%) 2 (10.0%)	 111 (82.8%) 18 (90.0%)	p=0.53[2]
Albumin (g/L), median (IQR)	41 (4)	43 (5.25)	p=0.04[4]
Tumor size (cm), median (IQR)	5 (3)	3.8 (2.5)	p=0.05[4]
Previous abdominal surgery, n (%) - Yes - No	 6 (37.5%) 19 (13.9%)	 10 (62.5%) 118 (86.1%)	p=0.02[2]
Neoadjuvant therapy, n (%) - Yes - No	 10 (14.3%) 15 (18.3%)	 60 (85.7%) 67 (81.7%)	p=0.50[1]
Distance from anal verge (cm), median (IQR)	5 (6)	9 (9)	p<0.001[4]
Type of surgery, n (%) - Hartmann's procedure - LAR/APR	 8 (26.7%) 17 (13.7%)	 22 (73.3%) 107 (86.3%)	p=0.10[2]
T stage, n (%) - Early (Tis, T0, T1, T2, T3) - Advanced (T4)	 19 (15.%) 6 (22.2%)	 108 (85.0%) 21 (77.8%)	p=0.35[1]
Lymphovascular invasion, n (%) - Yes - No	 17 (22.4%) 7 (10.0%)	 59 (77.6%) 63 (90.0%)	p=0.04[1]
Circumferential resection margin, n (%) - Positive - Negative	 9 (50.0%) 16 (11.8%)	 9 (50.0%) 120 (88.2%)	p<0.001[2]

Statistical tests: [1]: Chi-square test; [2]: Fisher's exact test; [3]: Independent samples t-test, [4]: Mann-Whitney U test, SD: Standard deviation, BMI: Body mass index, IQR: Interquartile range, ASA: American Society of Anesthesiologists, TME: Total mesorectal excision, LAR: Low anterior resection, APR: Abdominoperineal resection.

significance (p=0.05). This finding suggests that larger tumors may underlie both the higher rate of incomplete TME and the increased frequency of margin involvement. In recent findings derived from population-based data (17), only 8% of patients were reported to have incomplete TME. Incomplete TME was identified as an independent risk factor for local recurrence (HR=2.73, 95% CI 1.07-7.0). However, no significant association was found between TME quality and distant metastasis or OS. The absence of an OS difference in such a large sample size represents an important finding that warrants consideration.

In our multivariable Cox regression analyses, undergoing a Hartmann procedure had the strongest negative impact on OS, indicating its potential influence on long-term oncological outcomes. In our clinical practice, the Hartmann procedure is typically reserved for older patients with significant comorbidities, impaired physiological status, or unfavorable intraoperative findings, rather than being routinely performed in elective rectal cancer surgery. Similar practice patterns are also reported in the literature, where Hartmann is generally preferred for patients with higher surgical risk or advanced disease (18). Therefore, the higher mortality and poorer OS observed in this subgroup are not unexpected (19,20).

Regarding factors associated with TME quality, we found that lower serum albumin levels, a history of previous abdominal surgery, shorter tumor distance from the anal verge, presence of LVI, and CRM involvement were all significantly correlated with poorer TME quality. Previous abdominal surgery can result in adhesions and distorted anatomical planes, making sharp dissection technically more challenging compared to a virgin abdomen (21,22).

Consequently, the quality of surgical resection may be compromised, which can naturally lead to a higher rate of incomplete TME. In low-lying rectal tumors, the risk of CRM involvement increases (23). As the tumor approaches the anal canal, invasion into adjacent structures such as the prostate or

vaginal wall becomes more likely. Moreover, advancing distally within the narrow pelvic anatomy is technically challenging, which may lead to a higher likelihood of TME plane violations. Lower albumin levels may reflect an increased tumor burden or subclinical obstruction rather than being a direct cause of poorer TME quality, suggesting that albumin may serve as a surrogate marker of more aggressive disease biology (24). Likewise, the presence of LVI is typically associated with more advanced tumor characteristics, which could inherently predispose patients to suboptimal TME planes (25).

Study Limitations

There are several important limitations should be acknowledged. First, the sample size was relatively small and therefore insufficient to reliably evaluate multiple outcomes. Second, this study was based on retrospective data from a single center, which may limit the generalizability of the results. In addition, the retrospective nature of the study precluded the availability of standardized intraoperative documentation, such as surgical assessment of TME quality or photographic recording of the specimen and pelvic operative field, and TME quality assessment relied primarily on pathological evaluation. Moreover, while the relationship between incomplete TME and local recurrence is of particular interest, our analysis was limited by the lack of data on local recurrence, distant metastasis, and DFS. Despite these limitations, our study also has several strengths. Our institution is a high-volume, referral center for colorectal cancer surgery, where resections are performed by experienced colorectal surgeons. Furthermore, all specimens were assessed by gastrointestinal pathologists with substantial expertise. Reporting long-term oncological outcomes in relation to TME quality from such a specialized, high-volume center provides valuable insights and contributes meaningfully to the ongoing discussion in the literature.

CONCLUSION

This study demonstrated that near-complete or complete TME was independently associated with better OS in patients with rectal cancer. However, these findings are based on a single-center retrospective cohort with a relatively small sample size and should be interpreted with caution. Further large-scale, prospective studies focusing on TME quality as a primary outcome are warranted to validate these results and provide more robust evidence.

Ethics

Ethics Committee Approval: Ethical approval was obtained from the Clinical Research Ethics Committee of the Marmara University Faculty of Medicine (approval number: 09.2025.25-0364, date: 18.04.2025).

Informed Consent: As this was a retrospective study using anonymized data, individual informed consent was waived by the Ethics Committee of Marmara University Faculty of Medicine (approval no: 09.2025.25-0364).

Footnotes

Author Contributions

Concept - A.B., M.İ.A., M.F.T., L.S.Ş., W.A.; Design - A.B., M.İ.A., M.F.T., L.S.Ş., W.A.; Data Collection or Processing - A.B., B.D., A.U.C.; Analysis or Interpretation - A.B., B.D., AU.C., M.F.T., L.S.Ş., W.A.; Literature Search - A.B., B.D., M.F.T., L.S.Ş.; Writing - A.B., M.İ.A., A.U.C., M.F.T., W.A.

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ORIGINAL ARTICLE
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Preliminary single-operator experience with ultrasound-guided liver core needle biopsy performed by a supervised general surgery resident

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ABSTRACT

Objective: Ultrasound-guided core needle biopsy (CNB) is essential for diagnosing liver tumors not amenable to resection, but the outcomes of resident-performed CNB are poorly defined. We evaluated the diagnostic performance and safety of liver CNB performed by a single ultrasound-certified general surgery resident under specialist supervision.

Material and Methods: In this retrospective single-center case series, 65 consecutive patients underwent ultrasound-guided liver CNB between July 2022 and January 2025. All procedures constituted the resident's entire initial experience with liver CNB. Diagnostic success was defined as obtaining sufficient tissue for definitive histopathological diagnosis. Predictors of diagnostic success were assessed using univariate analyses and logistic regression. Learning-curve effects were evaluated by comparing early and late tertiles of chronologically ordered cases and by modelling case number as a continuous predictor. The impact of lesion size was examined by subgroup analysis comparing <4 cm and ≥4 cm lesions and by treating the maximal lesion diameter as a continuous variable.

Results: Adequate tissue was obtained in 58/65 biopsies (89.2%), with malignancy confirmed in 49 patients (75.4%) and benign lesions in 9 patients (13.8%). Diagnostic success was 85.7% in the early tertile and 95.5% in the late tertile (p=0.345). Logistic regression showed a non-significant trend toward a higher diagnostic yield over time. Neither lesion size (categorized as <4 cm versus ≥4 cm) nor maximal diameter (analyzed as a continuous variable) was significantly associated with diagnostic success. No immediate or clinically overt delayed complications were observed during 24 hours of in-hospital monitoring.

Conclusion: This preliminary single-operator experience suggests that, under close supervision, an appropriately trained general surgery resident can perform ultrasound-guided liver CNB with a high diagnostic yield and a low observed complication rate. These hypothesis-generating findings support further multi-operator and comparative studies of resident-performed liver CNB.

Keywords: Biopsy, needle, ultrasonography, interventional, liver neoplasms/diagnosis, residents, medical, safety, diagnostic yield

INTRODUCTION

Core needle biopsy (CNB) under ultrasound (US) or computed tomography (CT) guidance is a key diagnostic tool for patients with advanced, multifocal, or suspicious liver tumours that are not suitable for surgical resection. Under these conditions, CNB is the preferred method for obtaining tissue samples from primary or metastatic liver masses that do not meet the criteria for non-invasive diagnosis, allowing further treatment, e.g., the Liver Imaging Reporting and Data System for hepatocellular carcinoma (HCC) diagnosis. Histopathological examination of biopsy specimens is crucial for guiding oncological treatment (1).

The diagnostic accuracy of CNB varies depending on tumour characteristics. While its specificity and positive predictive value for HCC nodules smaller than 2 cm are excellent (100%), sensitivity ranges between 66% and 93%, depending on tumour size, operator experience, pathologist expertise, and needle size (1,2). In cases of advanced pancreatic ductal adenocarcinoma, CNB of liver metastases has been reported to achieve a sensitivity of 97% (3). If a lesion remains suspicious despite a negative initial biopsy, a repeat biopsy may be necessary. However, this carries inherent risks, including bleeding, track seeding, and sampling error, particularly when tumour location complicates access (3).

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US- or CT-guided percutaneous liver biopsy is one of the procedures that should be performed during the general surgery residency training program (4). Developing proficiency in US-guided CNB is particularly important for surgical residents specializing in hepatopancreatobiliary (HPB) surgery. Mastering this minimally invasive technique not only enhances diagnostic accuracy and patient safety but also broadens the surgeon's skill set, preparing trainees to independently manage complex liver pathologies and participate actively in multidisciplinary oncological care.

However, no published studies specifically evaluate the safety and effectiveness of CNB for liver tumours when performed by general surgery residents. Most available literature focuses on the procedure's efficacy and complication rates when conducted by experienced radiologists or hepatologists. While CNB is well-established as a reliable diagnostic tool, its outcomes when performed by surgical trainees remain largely unexamined.

This study aims to analyze the effectiveness and safety of CNB performed by a single general surgery resident for suspicious liver tumors. By addressing this gap, our findings may improve understanding of procedural outcomes when trainees perform CNB under supervision.

MATERIAL and METHODS

We conducted a retrospective analysis of electronic medical records of 65 consecutive patients who underwent US-guided CNB between July 2022 and January 2025. All procedures were performed by a single operator. The operator was a general surgery resident who held a diagnostic ultrasonography certification from the Polish Ultrasound Society. This credential formally attests to competency in diagnostic US examinations but does not, by itself, certify interventional skills. Importantly, this series included all US-guided liver core-needle biopsies performed by the resident during the study period. No prior liver CNB procedures performed by this operator were excluded; therefore, the 65 consecutive cases reported here represent the entire initial learning curve for resident-performed US-guided liver CNB in our unit.

Inclusion criteria:

1. Informed patient consent for the procedure,
2. Age >18 years,
3. Unresectable single or multiple liver mass,
4. High clinical suspicion of malignancy,
5. Prior oncological consultation confirming the patient's eligibility for treatment,
6. Absence of contraindications for CNB.

Exclusion criteria:

1. Prior histopathological confirmation of malignancy,
2. Contraindications for CNB [e.g., severe coagulopathy international normalized ratio (INR) >1.5, platelet count <50,000/mm^3, uncontrolled infections, inability to cooperate during the procedure],
3. Patients disqualified from further oncological treatment due to general condition.

All procedures were performed under hospital conditions and were preceded by a review of the medical history, including imaging diagnostics of underlying disease; assessment of anticoagulant or antiplatelet therapy, which may require temporary discontinuation; blood tests, including a coagulation profile (INR, prothrombin time, activated partial thromboplastin time, platelet count); and liver function tests. US assessment was performed to determine lesion location, size, vascularity, and accessibility.

Patients were placed in the supine or left lateral decubitus position, with the right arm elevated above the head, to optimize access to the liver. All procedures were performed using a sterile technique and real-time US guidance to ensure accuracy and minimize complications.

The procedure began with skin disinfection using an alcohol-based antiseptic, followed by local infiltration with 1% lidocaine. A 3-5-mL dose was injected subcutaneously at the planned needle entry site, and an additional 3-5-mL dose was injected into deeper layers, including the pericapsular region of the liver.

Under real-time US guidance with a convex probe (3.5-7.5 MHz) equipped with an in-line needle guide, a 16G tru-cut biopsy needle was introduced percutaneouslyusing a subcostal or intercostal approach depending on lesion location. A coaxial technique was used when feasible to minimize the risk of bleeding. The needle trajectory was carefully planned to avoid major blood vessels and bile ducts. Once the needle was in position, the automated spring-loaded biopsy device was activated to obtain a core tissue sample measuring approximately 20 mm in length. Depending on the lesion characteristics, one to three passes were performed to optimize the diagnostic yield while minimizing procedural risk (Figure 1).

Following tissue acquisition, US was used to assess for immediate complications, such as hematoma formation or active bleeding. The biopsy needle was then withdrawn, and manual compression was applied to the puncture site for haemostasis. The patient was placed in the supine position for 2 hours and observed in hospital for 24 hours after CNB. Vital signs were monitored at 15-minute intervals for the first hour, followed by 30-minute intervals for the next two hours. The puncture site was periodically examined for signs of bleeding or bile leakage.

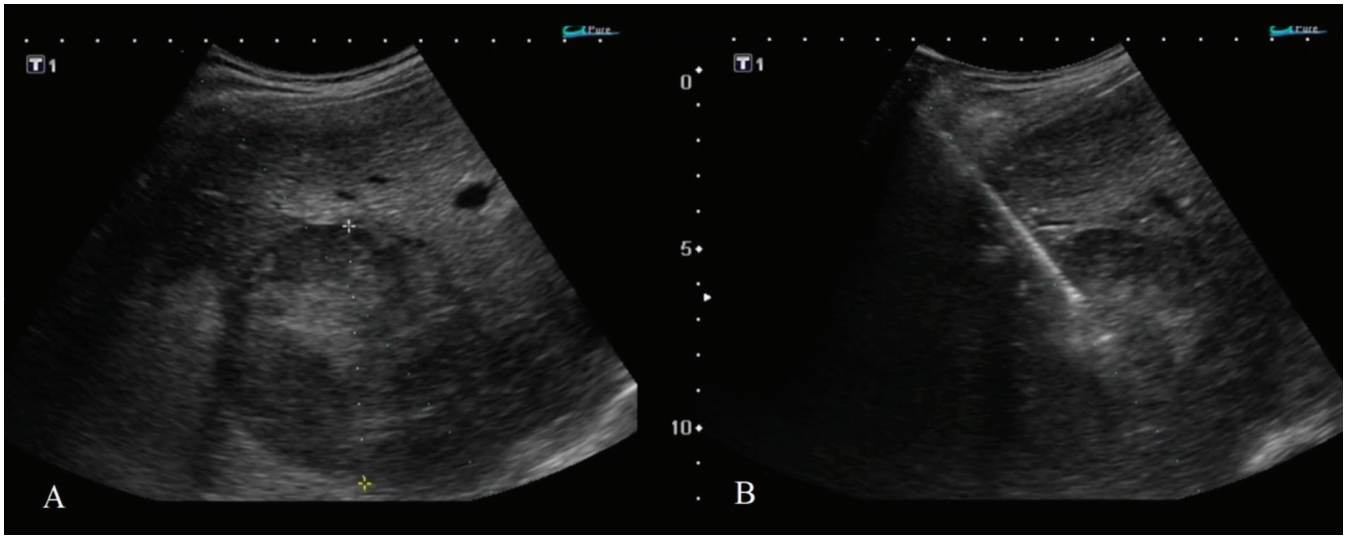

Figure 1. Ultrasound-guided core needle biopsy of the tumour (70 mm in diameter) of the right lobe of the liver. A) The measurement of the tumour. B) Core needle biopsy of the lesion.

Patients were advised to avoid strenuous activity and heavy lifting for the next 48 hours. Pain was managed with metamizolum (1250-2500 mg). Patients were discharged after 24 hours if no complications occurred and were instructed to seek medical attention if they experienced severe pain, hypotension, tachycardia, or symptoms suggesting biliary injury or infection. A follow-up outpatient visit within 7-10 days was scheduled.

This monitoring protocol aimed to detect both early and delayed post-biopsy complications, including events that might occur beyond the usual 4-6-hour observation window recommended for day-case procedures.

Statistical Analysis

Initially, univariate analyses were performed using Spearman's rank correlation for continuous variables and the chi-square test for categorical variables. Subsequently, a simplified logistic regression model was developed based on variables that showed statistical significance ($p<0.05$) in the initial analyses. The primary outcome was successful diagnostic biopsy, defined as obtaining adequate tissue for definitive histopathological diagnosis.

Variables analyzed included patient age, sex, number and location of lesions, lesion size, biopsy access route, number of needle passes, tumor marker concentrations (CA19-9, CA15-3, CA125, CEA, AFP), and procedure-related complications.

Assessment of Learning Curve and Lesion Size

To explore potential learning-curve effects, all 65 procedures were ordered chronologically by biopsy date and assigned case numbers (1-65). The series was then divided into three tertiles of approximately equal size by case number. For descriptive comparison of early and late performance, the first tertile (cases 1-21) and the third tertile (cases 44-65) were used to represent the early and late phases of the operator's experience. Diagnostic success rates between these two phases were compared using Fisher's exact test. In addition, a logistic regression model was fitted with diagnostic success (yes/no) as the dependent variable and case number as a continuous predictor to assess the learning curve across the entire series. Odds ratios (ORs) were reported per 10 additional procedures.

To evaluate the impact of lesion size on diagnostic yield, the maximal lesion diameter was calculated for each patient as the largest value among the three recorded orthogonal dimensions. Summary statistics (mean, median, interquartile range) were obtained for this maximal diameter. For subgroup analysis, lesions were classified by maximum diameter as <4 cm or ≥4 cm, and diagnostic success rates were compared between the two categories using Fisher's exact test. Furthermore, a logistic regression model was constructed with diagnostic success as the outcome and either lesion size category (<4 vs. ≥4 cm) or maximal diameter as a continuous predictor. For the continuous model, ORs were expressed per 10-mm increase in maximal lesion diameter. A two-sided p-value of<0.05 was considered statistically significant.

Ethical approval for this retrospective study was obtained from the Institutional Ethics Committee of Medical University of Lodz (number: RNN/230/25/KE, number: 09.09.2025). Given the retrospective design and analysis of anonymized data, informed consent was not required for participation in the study.

RESULTS

The analysis included 65 patients, comprising 37 men and 28 women. Single focal lesions were identified in 25 patients, while

40 patients had multiple lesions. Biopsies were performed on the left lobe of the liver in 21 cases and on the right lobe in 44 cases. The subcostal approach was used in 63 cases, while the intercostal approach was required in 2 cases. Accurate tissue collection was achieved with 1, 2, and 3 needle passes in 25, 35, and 5 patients, respectively. No patient experienced any early or late complications associated with the procedure (Table 1).

Diagnostic success, defined as obtaining sufficient tissue for definitive histopathological evaluation (including both malignant and benign diagnoses), was achieved in 58 of 65 patients (89.2%). Among these successful biopsies, 49 (75.4%) revealed malignancy, while 9 (13.8%) identified benign conditions, including regenerative nodules, focal steatosis, adenoma, or atypical hemangioma. Primary liver cancer (HCC) was diagnosed in 8 cases (12.3%), and metastatic disease in the remaining cases: Adenocarcinoma of the pancreas and colon [33 pts, 50.8%), neuroendocrine tumours (NET and GNET) in 3 cases (4.6%)], non-small-cell renal cancer in 2 cases [(3.1%), gastrointestinal stromal tumour in 1 case (1.5%)], melanoma in 1 case (1.5%), and small-cell lung cancer in 1 case (1.5%). Seven biopsies (10.8%) were non-diagnostic and required a repeat procedure (Table 2).

Table 1. Patients characteristic

Sex	Male	37	56.92%
	Female	28	43.08%
Age (years)	Mean	68.7	
	Median	73	
	Range	52-84	
Number of lesions	Single	25	38.50%
	Multiple	40	61.50%
Location of CNB	Left lobe	21	32.30%
	Right lobe	44	67.70%
Access	Subcostal	63	96.90%
	Intercostal	2	3.10%
Diameter of CNB lesion (mm)	Mean	53.2	
	Median	43	
	Range	11-150	
Number of needle passes	One	26	40%
	Two	34	52.30%
	Three	5	7.70%
Proper tissue collection	Yes	58	89.2%
	No	7	10.8%
Cancer diagnosis	Positive	49	75.40%
	Negative	16	24.60%
Complications	Yes	0	0%
	No	65	100%

CNB: Core needle biopsy.

Initial statistical analysis identified that performing CNB in patients with multiple liver lesions was a significant factor associated with diagnostic success of US-guided CNB (Spearman's rho =0.34, p=0.006; chi-square test, p=0.021). The regression analysis confirmed that the presence of multiple liver lesions was an independent predictor of diagnostic success [OR =10.36; 95% confidence interval (CI): 1.10-97.62; p=0.041]. This indicates that patients with multiple liver lesions had significantly higher odds of obtaining a definitive histopathological diagnosis than patients with single lesions (Figure 2).

Learning-curve Analysis

When cases were analysed according to chronological tertiles, the first tertile (early phase, cases 1-21) and the third tertile (late phase, cases 44-65) included 21 and 22 procedures, respectively. Diagnostic success rates were 85.7% (18/21) in the early phase and 95.5% (21/22) in the late phase; the difference was not statistically significant (p=0.345). In a logistic regression model including all 65 procedures, case number, treated as a continuous variable, was not significantly associated with diagnostic success. The OR per 10 additional procedures was 1.43 (95% CI 0.90-2.29; p=0.134), indicating a trend toward higher diagnostic yield over time that did not reach statistical significance, rather than reflecting a clear-cut learning-curve effect.

Table 2. Histopathological findings

Histopathological findings	Patients	Percentage
Malignant	49	75.4%
Adencarcioma	33	50.8%
HCC	8	12.3%
NET	2	3.1%
Non-small cell renal cancer	2	3.1%
GIST	1	1.5%
GNET	1	1.5%
Melanoma	1	1.5%
SCLC	1	1.5%
Non-malignant	9	13.8%
Regenerative nodules	3	4.6%
Adenoma	3	4.6%
Focal steatosis	2	3.1%
Atypical haemangioma	1	1.5%
Non-diagnostic	7	10.8%
Necrotic tissue	3	4.6%
Non-diagnostic material	2	3.1%
Proper liver structure	2	3.1%

HCC: Hepatocellular carcinoma, SCLC: Small cell lung cancer, GIST: Gastrointestinal stromal tumor, GNET: Gastrointestinal neuroectodermal tumor.

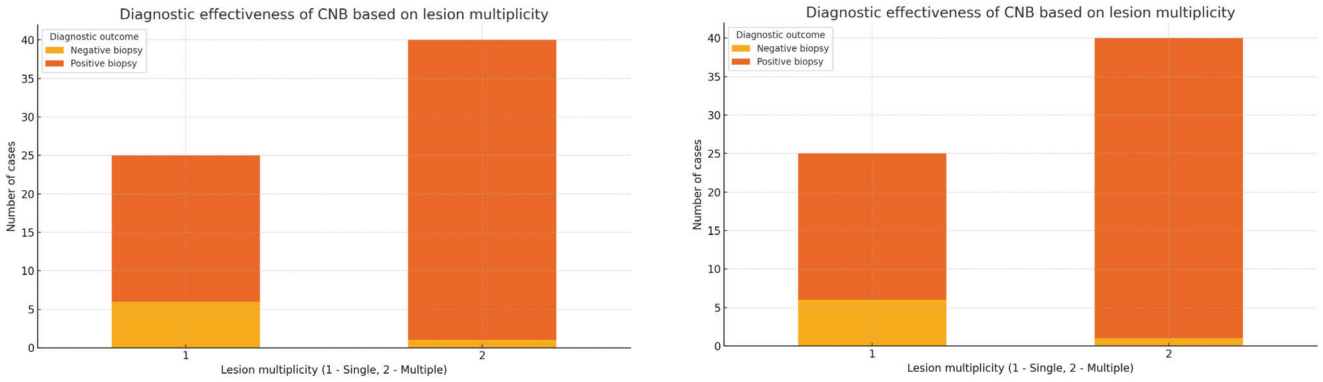

Figure 2. Diagnostic yield of ultrasound-guided core needle biopsy stratified by lesion multiplicity. The bar chart compares positive (diagnostic) and negative (non-diagnostic) biopsy outcomes between patients with single (n=25) and multiple (n=40) liver lesions. Multiplicity significantly predicted diagnostic success (OR=10.36, 95% CI:1.10-97.62, p=0.041).

OR: Odds ratio, CI: Confidence interval

Subgroup Analysis by Lesion Size

The mean maximal diameter of the lesions was 53.5 mm, with a median of 43 mm and an interquartile range of 30-76 mm. Lesions <4 were observed in 28 cases, whereas lesions ≥4 were observed in 37 cases. Diagnostic success was 89.3% (25/28) for lesions <4 cm and 89.2% (33/37) for lesions 64 cm (p=1.000). In a logistic regression model with lesion size category as the predictor, lesions ≥4 cm were not significantly associated with diagnostic success compared with lesions <4 cm (OR 0.65; 95% CI 0.11-3.88; p=0.638).

When maximal lesion diameter was analysed as a continuous variable, no significant association with diagnostic yield was observed. The OR for diagnostic success per 10-mm increase in maximal diameter was 0.97 (95% CI, 0.75-1.24; p=0.779), suggesting that lesion size did not have a measurable effect on biopsy performance in this cohort.

DISCUSSION

The findings of this study provide valuable insights into the safety and effectiveness of US-guided CNB for liver tumors performed by a general surgery resident under supervision. Our results demonstrate that CNB is a highly effective diagnostic tool, achieving a malignancy confirmation rate of 75.4%, with no observed early or late complications. This study contributes to the existing literature by highlighting the feasibility of CNB within surgical training programs, an area that has been largely unexamined.

Notably, the present series documents the resident's initial experience with US-guided liver CNB in its entirety. No earlier liver biopsies performed by the operator were omitted; the 65 consecutive procedures therefore constitute a complete learning curve rather than a selected segment of more advanced practice. Within this context, the absence of a statistically significant improvement in diagnostic yield between the earliest and latest tertiles and the only non-significant trend toward higher success in the logistic regression analysis suggest that acceptable performance can be achieved early when residents trained in diagnostic US are introduced to CNB in a structured, closely supervised training environment.

The 75.4% malignancy-confirmation rate observed in our study aligns with previously reported sensitivities for CNB, which typically range from 66% to 97%, depending on lesion size, operator experience, and histopathological evaluation criteria (4,5). Notably, our study population included a diverse range of malignancies, with metastatic adenocarcinoma being the most common histopathological diagnosis (50.8%), followed by HCC (12.3%). This distribution is consistent with known epidemiological patterns of liver tumors, in which secondary liver malignancies outnumber primary hepatic neoplasms (5).

Previous studies have suggested that factors such as tumor size, number of needle passes, and lesion vascularity influence biopsy yield (6). In our study, the presence of multiple liver lesions likely increased diagnostic yield by increasing overall tumor burden and facilitating the selection and acquisition of representative tissue samples during biopsy.

One of the most striking findings of this study is the complete absence of complications, including bleeding, bile leakage, or tumor seeding. Previous reports have documented CNB-related complication rates between 0.1% and 4% (7,8). The favorable safety profile observed in this study may be attributed to several factors:

- Real-time US guidance, which allows precise needle placement while avoiding major blood vessels.
- Standardized procedural protocol, including the use of a coaxial technique where feasible, minimizing the risk of bleeding.

- Immediate post-procedure monitoring, ensuring early detection of potential adverse events.

The lack of complications also suggests that CNB can be safely performed by surgical residents under appropriate supervision. However, given the small study size, it is essential to interpret this finding cautiously, as rare complications may not have been captured.

Most studies evaluating CNB outcomes have focused on procedures performed by radiologists or hepatologists, with little data on performance by general surgeons or trainees. Our results suggest that, with adequate training, general surgery residents can achieve comparable diagnostic accuracy and safety outcomes. This finding supports the integration of CNB training into general surgery residency programs, particularly for those specializing in HPB surgery.

A systematic review by Rockey et al. (9) reported that CNB performed by radiologists had a sensitivity of 90-95% for HCC, with complication rates below 1%. Similarly, Matsubara et al. (10) found that CNB of pancreatic tumors and metastatic liver tumors demonstrated diagnostic accuracy exceeding 90% when performed by experienced specialists. Our malignancy detection rate is slightly lower than these values, potentially reflecting differences in operator experience and lesion characteristics. Nonetheless, our findings highlight that residents can achieve a high diagnostic yield when working under structured supervision.

These findings reinforce the importance of structured CNB training in surgical residency programs. In many institutions, liver biopsy remains a predominantly radiologist-led procedure, limiting exposure for general surgeons (11). However, as minimally invasive techniques become increasingly relevant in HPB surgery, it is crucial for surgeons to be proficient in interventional techniques such as CNB.

Our institutional policy of 24-hour in-hospital observation after CNB, although more conservative than the 4–6-hour monitoring commonly used for day-case biopsies, may be viewed as both a strength and a limitation. On the one hand, extended observation increased the likelihood of identifying delayed post-biopsy events that might otherwise present after discharge and necessitate readmission. On the other hand, it reduces the direct comparability of our safety outcomes with outpatient protocols and prevents extrapolation of our findings to centres using shorter monitoring periods.

No comparator group of procedures performed by radiologists or hepatologists was included. Our study does not aim to demonstrate equivalence or non-inferiority of resident-performed CNB and should be regarded as hypothesis-generating rather than definitive.

Key training recommendations include:

- Simulation-based learning: Before performing CNB on patients, residents may benefit from practicing with US-guided biopsy simulation models to enhance hand-eye coordination.
- Supervised practice: Residents should initially perform CNB under close supervision, gradually increasing their independence as they gain proficiency.
- Standardized competency assessments should employ objective performance metrics, such as diagnostic accuracy, patient safety, and procedural confidence, to evaluate trainees.
- By implementing these strategies, surgical training programs can ensure that residents acquire the necessary skills to safely and effectively perform CNB.

Future Directions

Further research should focus on:

- Multi-center studies to validate our findings in larger, more diverse patient populations.
- Comparative studies evaluating CNB performance between residents and experienced specialists.
- Long-term outcome analysis to assess rare complications, such as tumor seeding.
- Implementation of standardized training curricula for CNB in surgical education.

Study Limitations

This retrospective single-center study is based on 65 procedures performed by a single diagnostic US–certified general surgery resident under specialist supervision, which limits the generalizability of the findings to other residents, institutions, and training programs. The sample size is too small to reliably detect rare complications or modest predictors of diagnostic success; with zero events, the upper bound of the 95% confidence interval for the true complication rate is still approximately 4.6%. All patients underwent 24-hour in-hospital observation according to local policy; this may have improved detection of delayed events but reduces comparability with outpatient 4-6-hour monitoring protocols and cannot exclude complications arising beyond this period. In addition, no comparator group (e.g. radiologists or hepatologists) was included, and lesion size data were missing for a minority of patients, limiting more detailed subgroup analyses.

CONCLUSION

In this preliminary single-center, single-operator case series, US-guided liver CNB performed by a supervised, diagnostic US-trained general surgery resident was associated with a high diagnostic yield and no clinically overt complications during a 24-hour in-hospital observation period. These results

suggest that within a structured and closely supervised training pathway, selected general surgery residents can safely and effectively perform US-guided liver CNB. However, the findings are hypothesis-generating rather than definitive, and larger multi-operator and multicenter studies, including comparative analyses involving imaging specialists and outpatient monitoring protocols, are needed to confirm and extend these observations.

Ethics

Ethics Committee Approval: Ethical approval for this retrospective study was obtained from the Institutional Ethics Committee of Medical University of Lodz (number: RNN/230/25/KE, number: 09.09.2025).

Informed Consent: Informed consent was not required for participation in the study.

Footnotes

Author Contributions

Surgical and Medical Practices - W.C.; Concept - W.C., J.S., A.K., A.P.; Design - A.D.; Data Collection or Processing - A.S., W.C., A.D., P.H., K.K.; Analysis or Interpretation - W.C., J.S., A.K., A.P.; Literature Search - W.C., T.K., K.S.; Writing - A.S., W.C., A.D., J.S., P.L., K.S.

Conflict of Interest: No conflict of interest was declared by the authors.

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ORIGINAL ARTICLE
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Integration of medical visual documentation into medical education, benefits for medicine, education and treatment

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ABSTRACT

Objective: Medical visual documentation is an important part of medical education. It provides numerous benefits to both. This article argues for the integration of medical photography into medical education.

Material and Methods: A medical visualization and documentation elective course was offered to second-year students at the Kocaeli University Faculty of Medicine. At the end of the 14-week program, a questionnaire was administered to students who participated in the course. The survey results were analyzed using data analysis programs.

Results: According to the survey results, the students stated that the elective course positively impacted their education and experience as future doctors.

Discussion: In many medical schools, both in Turkey and around the world, medical photography training is not integrated into medical education. This presents challenges for medical education and physicians. However, these difficulties can be overcome by providing integrated training and courses for doctors.

Keywords: Cancer, general surgery, laparotomy

INTRODUCTION

The term ""photography"" literally means ""writing with light"". This expression was first used by Sir John Frederick William Herschel. Photography is an art form that captures and preserves moments, reality, and subjects against the passage of time since its emergence. Medical photography, which results from the combination of medicine (a branch of science) and photography, not only ensures permanence but is also utilized in many areas of the health sector. In this utilization process, attention should be given to patient privacy and ethical rules, technical details of photography, and the storage and sharing of photographs in medical visual documentation. The teaching of these terms is one of the issues that should receive greater emphasis in today's medical education (1,2).

Medical photography has developed alongside general photography. The advent of photography, which began approximately two centuries ago with Joseph Nicéphore Niépce, was introduced into medicine through the efforts of individuals such as Simon Peter Hullihen, Hugh Welch Diamond, and Auguste Nelaton, marking the first steps in medical photography (3).

Medical visual documentation has important applications in the healthcare sector. It is used in many areas, such as diagnosis of disease and monitoring of the treatment process; measuring the success of procedures by photographing surgical sites before and after procedures; documenting the stages of surgical procedures and removed body parts (e.g., tissues, organs, limbs); and creating a patient archive (1).

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One area of application that we consider important and will particularly emphasize is its use in education and training for future physicians. Visual materials play a crucial role in medical education. Visual explanations of diseases and surgical techniques contribute substantially to medical students" education. It provides students with an encouraging, creative, memorable, and motivating learning environment. It enables medical students to gain insights into cases or situations they do not encounter in practice through visual elements. It plays an essential role in improving their diagnostic performance and self-confidence in their clinical knowledge (4).

Photographs used in medical research and publications enable information to be presented more clearly and comprehensively. They play an important role in facilitating knowledge transfer between doctors and researchers (1).

In medical visual documentation, images should be obtained in accordance with patient privacy and ethical guidelines. The doctor must obtain informed consent from the patient before taking the photograph (1).

During the consent process, the patient should be informed about the risks to patient privacy and the purposes for which the photograph will be used. Individual permission must be obtained for each specific purpose. While taking the photograph, the doctor should avoid any identifying features that may disclose the patient's identity and should obtain consent by showing the photograph to the patient (5-7).

The storage and sharing of photographs are also included in the ethical discussion. Both the doctor and the institution have a role in storing the photograph. It is necessary to ensure the privacy of photographs shared to exchange treatment-related ideas among doctors (6).

However, this situation should not be forgotten. The patients whose photographs have been taken have the right to withdraw their consent to the photographic session at any time. In this case, issues may arise concerning the use of the photograph (8).

As in general photography, certain elements should be considered in medical photography. It is important in both photography and medicine that photographs are taken properly and accurately convey their content. Photographs should be taken for medical rather than aesthetic reasons (9,10).

Many materials can be photographed in medical visual documentation. To capture these materials with sufficient quality, basic knowledge of photography is required, but need not be extensive. With advances in technology, photographs can be captured using a variety of devices. Specialized programs have been developed to take high-quality medical photos with smartphones. The photograph should be of high quality and convey the information it contains clearly and accurately. To this end, basic photography principles such as lighting, background, appropriate device settings for the material, and use of supporting elements should be applied (9-11).

Although these details regarding medical visual documentation may seem insignificant, they are crucial for performing this task appropriately and to a high standard. Education should be standardized.

In summary, although medical visual documentation is used in many areas of medicine and the health sector, its importance has not been recognized. Universities and organizations in our country and around the world do not pay sufficient attention to this issue. Many doctors do not have sufficient knowledge of this subject, and consequently, problems related to medical visual documentation may arise.

This study argues that these deficiencies in educational systems should be addressed and medical visual documentation should be integrated into curricula.

MATERIAL and METHODS

A medical visual documentation unit and a studio affiliated with this unit were established within the Kocaeli University Faculty of Medicine in 2015. Since its establishment, it has offered the elective course named "Medical Visual and Documentation" annually to a certain number of students. In addition, since 2015, a one-hour compulsory course has been offered to 1st and 2nd-year students. The unit and the course program, which are developed every year, contribute to doctor candidates" knowledge of medical visual documentation.

In 2024, eight students enrolled in this elective course, which is offered annually. The course was held weekly for 14 weeks. The medical section of the courses was taught by Sertaç Ata Güler, a faculty member of the Department of General Surgery, and the photography section was taught by Osman Demir, a faculty member of the Department of Photography, Faculty of Fine Arts, Kocaeli University. In the courses, topics such as the history of photography, notable photographers, the basics of photography, photographic technologies, various cameras, and portraits were discussed. Additionally, topics such as applying these concepts to medical visual documentation, its key aspects, and techniques for medical photography were covered. In addition to the classes, museum visits, photographic analyses, and medical photography practice were conducted. During the museum tour class, the Photography Technologies Museum at the Kocaeli SEKA Paper Museum was visited and examined together with Osman Demir and Sertaç Ata Güler. During medical photography practice, students were divided into groups. Using mobile phones and different type of cameras, students

practiced photographing tissues removed during surgery. As the end-of-course evaluation, a photo exhibition of student photographs taken during practical lessons was organized (Table 1).

At the end of the 14-week schedule, data were to be obtained by conducting a survey of the students regarding the adequacy of the course and the syllabus revised in the 2023-2024 academic year. In the survey, participants were asked about the course, curriculum, photography, and medical visual documentation, and they were requested to indicate how much they agreed with these statements. Finally, students were asked to write their general opinions about the course.

The study protocol was reviewed and approved by the Ethics Committee of Kocaeli University (approval number: 2025/189, date: 14.04.2025).

Statistical Analysis

Statistical evaluation was performed with IBM SPSS 29.0 (IBM Corp., Armonk, NY, USA). Compliance with the normal distribution was examined using Shapiro–Wilk test. Because the assumption of normality was not met, continuous variables were presented as median (25^{th}-75^{th} percentiles). Categorical variables were reported as frequencies and percentages.

RESULTS

According to the survey results, most students had not received any photography training prior to the course. There were no meaningful data to indicate that they had sufficient knowledge of photography or medical visual documentation. All the students used cell phones while taking photos, meantime 2 students had digital cameras (Table 2).

According to the results, students agreed that after the course they had gained more knowledge about Medical Visual Documentation. The students also mostly agreed that the syllabus was sufficient in terms of both theory and practice.

In their general views regarding the course, the students expressed that museum tours, interactive lessons, an exhibition that touched on other aspects of photography, and the presence of a faculty member from the faculty of visual arts had positively affected the course and its program.

Table 1. The 14-week syllabus of the medical visual documentation elective course

Weeks	Faculty member	Course content
Week 1	Faculty Member of Faculty of Medicine	Meeting of faculty members and students, giving information about the content of the course.
Week 2	Faculty Member of Faculty of Fine Arts, Department of Photography	The structurality of photography.
Week 3	Faculty Member of Faculty of Fine Arts, Department of Photography	Introduction of photographic technologies and simple technical details.
Week 4	Faculty Member of faculty of Fine Arts, Department of Photography	Portrait photography.
Week 5	Faculty Member of Faculty of Medicine Faculty Member of Faculty of Fine Arts, Department of Photography	Visiting a museum, studio or institution about photography.
Week 6	Faculty Member of Faculty of Medicine	Introduction to medical visualization and documentation.
Week 7	Faculty Member of Faculty of Medicine	Ethical and legal issues in medical visual documentation.
Week 8	Faculty Member of Faculty of Medicine	Clinical photography.
Week 9	Faculty Member of Faculty of Medicine	Spesmen shooting.
Week 10	Faculty Member of Faculty of Medicine	Intraoperative photography.
Week 11	Faculty Member of Faculty of Medicine	Medical photography practice in the operating room.
Week 12	Faculty Member of Faculty of Medicine	Medical photography practice in the operating room.
Week 13	Faculty Member of Faculty of Medicine	Medical photography practice in the operating room.
Week 14	Faculty Member of Faculty of Medicine Faculty Member of Faculty of Fine Arts, Department of Photography	Completion and evaluation of the photography project.

Table 2. Results of the survey conducted with students	
	Median (IQR)
Age	21 (19.25-21)
My knowledge of photography is sufficient.	3 (3-3)
My knowledge of medical visual documentation prior to taking the course was sufficient.	2 (1.25-2.75)
This course contributed substantially to my professional development in medical visual documentation.	5 (4-5)
If I had the opportunity, I would choose this elective course again.	4.5 (3.25-5)
The theoretical education in the curriculum is sufficient for medical visual documentation.	4.5 (4-5)
Practical training in the curriculum is sufficient for medical visual documentation.	4 (3-4.75)
After the course, I acquired sufficient knowledge of the medical visual documentation process.	4.5 (4-5)
	n
Term 1/term 2	1/7
Cell phone	8
Digital camera	2
Analog camera	0
Tablet	1
Have you received training in photography?	0
Have you received training in medical visual documentation?	1
IQR: Interquartile range.	

DISCUSSION

The Types of Medical Visual Documentation and Its Challenges

Although medical visual documentation is based on photography, it is not merely about taking photographs. Medical photography has its own procedures, concerns, and reservations.

Specimen photographs are usually taken in the operating room. Throughout the surgical procedure, operating-room rules must be observed. Sterilization must not be compromised in any way; the procedure must be strictly observed, and no obstructive actions are permitted. The photography equipment must be cleaned before and after use to maintain the sterility of the operating room.

There is not always sufficient time to photograph the specimen removed from the patient. The specimen may need to be urgently sent for examination. In this case, the specimen should be photographed and delivered to the relevant unit as soon as possible, without interfering with the operation. A dilemma emerges. The dilemma of limited time and quality. It is difficult to take a high-quality photograph within a limited amount of time. In the operating room, sufficient time and an appropriate setting are required to prepare the workspace for photographing the specimen and to provide adequate lighting. However, the specimen removed during the operation should not be removed from the operating room. Otherwise, concerns such as specimen safety, ethical considerations, and the sterilization of locations and equipment used during sampling could arise. Furthermore, the manner in which the specimen is removed prior to photography is crucial for the photographer to obtain a high-quality image. For the specimen photograph to convey information directly, the photographer must first understand both the specimen and the operation. As the medical visualization and documentation team, we create a frosted-glass background for photographing the specimen in the operating room, thereby highlighting the specimen. For lighting, we photograph using room lighting while remaining outside the operating area and observing sterilization. By observing the operation live, we have the opportunity to assess the specimen. In this way, we aim to accurately determine, according to these details, the shape, position, and problematic parts of the specimen and photograph so that the photograph can convey clear information (Figure 1).

Intraoperative photography is similar to specimen photography. It is similar in many ways, such as sterilization rules, attention to and respect for the operation. The shooting technique is distinctive. The structure to be photographed is not removed. The body area where the operation is performed is referred to as the shooting material. Adequate lighting and an appropriate camera position are required to obtain high-quality photographs of this area. Sterilization should not be interrupted while making these adjustments (Figure 2).

Clinical photography differs from specimen and intraoperative photography in several respects. Clinical photography is more flexible regarding location, sterilization, and timing. The patient to be photographed can be brought to a studio or other location that permits higher-quality photography. It has better conditions regarding lighting, background, shooting position, and the preferred shooting device. An important issue in clinical photography is paying the utmost attention to the privacy of the patient being photographed. In addition, factors that could disturb or overwhelm the patient during the photography session should be avoided, and a comfortable process should be ensured for both the photographer and the person being photographed (Figure 3).

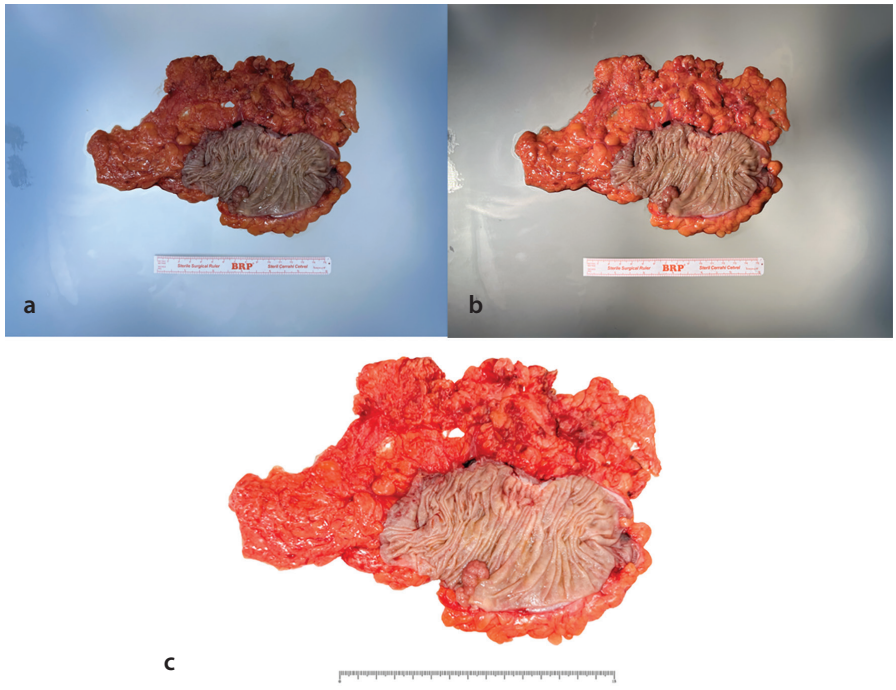

Figure 1. Specimen photographs (a) Shot without proper environmental adjustments. (b) Shot with proper environmental adjustments. (c) Photograph edited with a photo editing program.

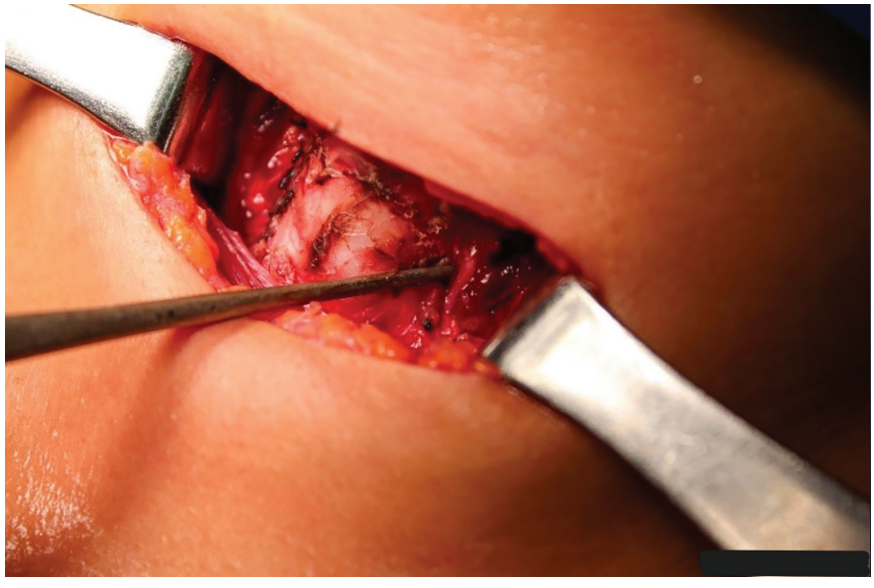

Figure 2. Intraoperative photography.

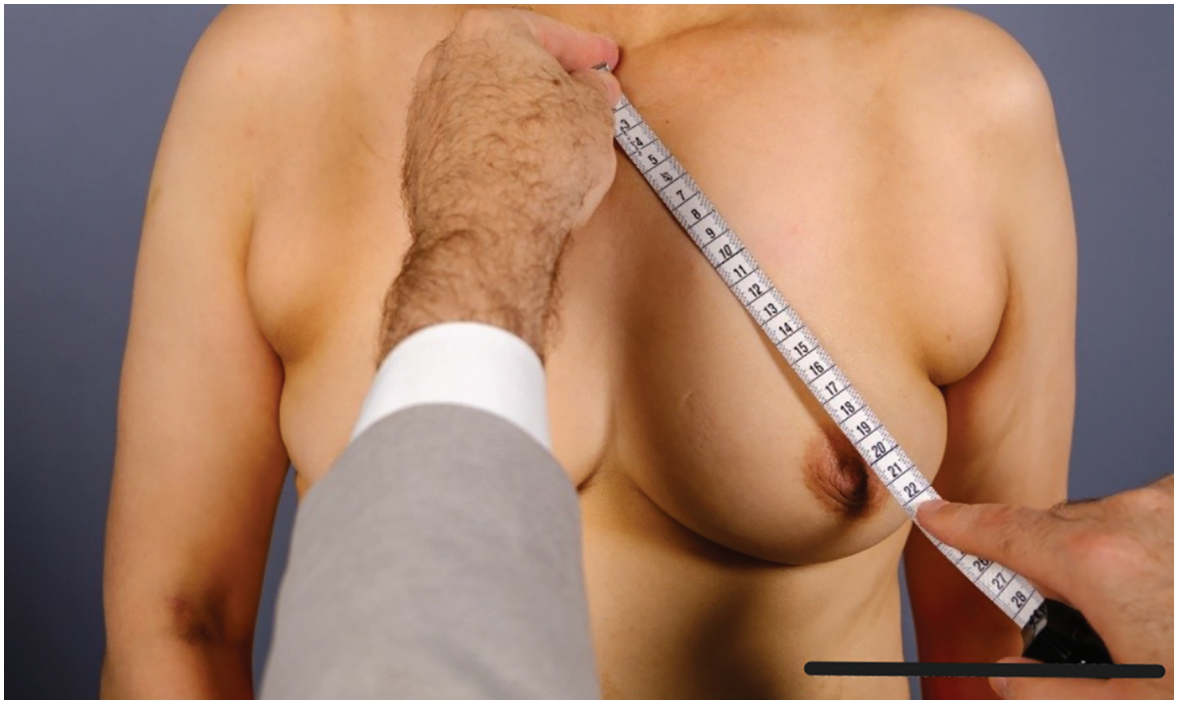

Figure 3. Clinical photography.

Doctor's Insufficent Knowledge About Medical Visual Documentation

Although today's doctors frequently use medical visual documentation in their professional lives as technology develops, they lack sufficient knowledge about it. Many doctors do not have sufficient knowledge of issues such as obtaining consent for medical visual documentation, sharing, storing, and using the photographs taken (12).

Since doctors do not have sufficient knowledge of photography, they have difficulty taking high-quality photographs and cannot ensure that the photographs fully convey the information. This situation negatively affects many aspects of medical visual documentation, including education, research, artificial intelligence-based disease analysis (13), and information exchange among doctors.

Integrating medical visual documentation training into the medical education curriculum is anticipated to enhance the quality and academic utility of visual records, particularly in clinical settings. Visual documentation, now an essential element of modern medicine, serves as a crucial adjunct to clinical practice, leveraging advancements in technology.

The introduction of specialized photography and videography instruction—supported by the faculty of fine arts' photography department and included alongside foundational medical courses such as anatomy and histology—is designed to equip future physicians with the skills necessary to produce high-quality, academically rigorous visual materials. Such comprehensive educational integration remains uncommon within our country's medical faculties.

It will be very useful in clinical practice, particularly for obtaining physicians" own medical visual documents, collecting additional patient data, and facilitating disease follow-up with high-quality, academically effective medical visual documentation taken by themselves.

Inadequacies in Medical Visual Documentation Education

These problems stem from the insufficient integration of medical visual documentation into medical education. In our country and many other countries, medical visual documentation education has not been integrated into medical curricula but has instead been offered as short-term courses, elective courses, or certificate training programs accessible to a limited number of medical students.

Unfortunately, the subject of "medical visual documentation" continues to receive little attention in our country. A few universities in Türkiye offer course programs on this subject across various faculties. The "medicine and photography" elective courses are offered to term 1 students in the Faculty of Medicine at Aydın Adnan Menderes University. İstanbul Medeniyet University Faculty of Medicine, term 4 students are given an elective internship course called "medical photography".

Another university in our country that conducts this work more professionally is Mersin University. The Continuing Education Application and Research Center at Mersin University offers a certificate program in medical photography, led by Tamer Akça. In addition, a 60-hour elective course in medical photography is offered to term 2 students at Mersin Faculty of Medicine. Additionally, students who choose this course are enrolled in the medical photography certificate program at no charge. However, because the relevant departments could not be contacted, insufficient information is available to determine whether this program is still ongoing.

Although medical visual documentation is uncommon in Türkiye, dental photography is more prevalent and is offered as an elective course at many universities. An elective course titled "medical photography" is offered in various departments of the Faculty of Health Sciences at Fenerbahçe University. It is also offered as an elective course titled "medical photography" at the Faculty of Veterinary Medicine at Tekirdağ Namık Kemal University.

The National Health Service has a more standardized approach to medical visual documentation. They provide training in Medical visual documentation at some universities in the country and are also interested in the professional dimension of its.

Training in Medical Visual Documentation is not integrated into medical education, but the responsible units provide guidance to doctors. To practice medical photography professionally, one should first study photography and then obtain a master's degree in medical photography.

In addition, some health institutions in the country have provided short training sessions in medical photography to health workers and general practitioners, tailored to their needs. They achieved positive results within a short time (13).

As the examples we have mentioned and the research we have conducted show, medical visual documentation is a concept that not only consists of taking photographs but also includes other disciplines. As it is frequently used by doctors and healthcare professionals, it requires a standardized training program and integration into medical faculties. At the same time, this program should consist not only of theoretical courses but also of practical, interpretation, and cultural courses. Doctors should be provided with a photographic and artistic perspective and the ability to take photographs as required for medical photography. In this way, the problems can be prevented. A positive contribution can be made to the professional and educational lives of doctors and doctor candidates. Research, development, investigation, and information-sharing activities in the medical and health sectors can be improved with respect to visual quality.

All faculties of medicine in Türkiye were included in the data analysis that we conducted on medical visual documentation education. An attempt was made to identify courses in medical visual documentation by examining the faculties' websites, course schedules, course contents, and academic calendars. Based on the data obtained, lecturers were contacted to obtain information about their courses; however, not all could be reached. The necessary data could not be obtained from the websites of such medical faculties. In some of them, the website provided no information about the aforementioned elements. Some could not be accessed without permission. Some of them offered courses that could be related to medical visual documentation, but course information was unavailable and they could not be included in the study. While editing the article, some websites were revisited and the information was updated.

Due to the large number of medical faculties worldwide, it was not possible to analyze the websites of all of them. In some of the medical faculty websites analyzed, the necessary data could not be obtained for the same reasons.

CONCLUSION

This article advocates for the systematic incorporation of training in medical visual documentation into medical school curricula and presents our proposed program, developed collaboratively by the medical faculty and the Faculty of Fine Arts. Our pilot data and statistical analysis are based on eight participants. Although this sample size is limited, it reflects the current paucity of medical schools offering such training and therefore precludes a multicenter approach at this stage. Our primary objective is to expand access to this educational module, thereby enabling larger-scale studies and generating more robust results as adoption increases at additional institutions. The sample size from which we collect data is small because there are few other medical faculties where these trainings are offered. However, the absence of other medical faculties offering this education prevents this number from increasing. With the integration of these educational programs into medical faculties over time, it will be possible to perform statistical analyses to evaluate educational outcomes for a larger number of medical students.

Ethics

Ethics Committee Approval: The study protocol was reviewed and approved by the Ethics Committee of Kocaeli University (approval number: 2025/189, date: 14.04.2025).

Informed Consent: Informed consent was obtained from patients for medical visual documents and from the medical school students for the research.

Footnotes

Author Contributions

Concept - S.A.G., S.E.G., Z.İ.Y.; Design - S.A.G., S.E.G., Z.İ.Y.; Data Collection or Processing - S.A.G., S.E.G., Z.İ.Y.; Analysis or Interpretation - S.A.G., S.E.G., Z.İ.Y., O.D.;; Literature Search - S.A.G., S.E.G., Z.İ.Y., O.D.; Writing - S.A.G., S.E.G., Z.İ.Y., O.D.

Conflict of Interest: No conflict of interest was declared by the authors.

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ORIGINAL ARTICLE
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Fast, accurate, and cost-effective: E-FAST's breakthrough in optimizing thoracic trauma management

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ABSTRACT

Objective: Evaluating the diagnostic accuracy of extended focused assessment with sonography for trauma (E-FAST) for detecting pneumothorax, hemothorax, and pulmonary contusions using thoracic computed tomography (CT) as the reference standard.

Material and Methods: Retrospective analysis of 202 adult thoracic trauma patients (2016-2021). E-FAST diagnostic accuracy was calculated using CT as reference standard.

Results: E-FAST was performed in 149 patients (74%), who presented with significantly higher injury severity (injury severity score: 25 vs. 17; p=0.018) and hemodynamic instability. E-FAST demonstrated 90% sensitivity for pneumothorax, 86% for hemothorax, and 95% specificity for both conditions. Positive predictive values were 92% for pneumothorax and 89% for hemothorax. E-FAST was superior to chest radiography for detecting pleural complications and facilitated immediate thoracic drainage in 39.1% of cases. Cost analysis revealed four-fold reduction compared to CT.

Conclusion: E-FAST demonstrated high diagnostic accuracy for pneumothorax and hemothorax compared to CT, while also showing superior performance to conventional radiography. E-FAST facilitates rapid bedside assessment and immediate surgical decision-making in critically injured patients. However, the significant selection bias toward critically injured patients limits the conclusions regarding the independent impact on clinical outcomes.

Keywords: Thoracic injuries, ultrasonography, focused assessment with sonography for trauma, emergency medicine, decision making

INTRODUCTION

Thoracic trauma is the second most frequent unintentional injury and the third most common cause of death in polytrauma patients, after abdominal injury and head trauma (1). Among patients with severe trauma, thoracic injuries account for 25% of fatalities (2). Patients with severe injuries and critical thoracic trauma present with the highest rates of prehospital intubation, cardiopulmonary resuscitation, emergency chest tube placement, blood transfusion, and urgent surgical intervention. Prompt recognition, diagnosis, and appropriate management are mandatory to improve outcomes, particularly in tertiary hospitals that manage complex cases. Traditional diagnostic modalities, including chest radiography (CXR) and computed tomography (CT), are clinically effective but constrained by radiation exposure, logistical limitations, and substantial costs, particularly in resource-limited healthcare settings. This highlights the need to explore diagnostic alternatives such as thoracic ultrasonography.

The extended focused assessment with sonography for trauma (E-FAST) has emerged as a rapid, reproducible, noninvasive, and cost-effective bedside tool for thoracic trauma evaluation, demonstrating high sensitivity and specificity for detecting pulmonary contusions, pneumothorax, and hemothorax, and doing so without exposing patients to ionizing radiation (3).

Despite the growing global adoption of E-FAST, data on the diagnostic accuracy, clinical impact, and economic benefits of E-FAST in tertiary hospitals in Brazil remain limited.

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This retrospective study evaluated E-FAST utilization in 202 patients with thoracic trauma at a regional trauma center, with the primary objective of determining the diagnostic accuracy of E-FAST for detecting pneumothorax, hemothorax, and pulmonary contusions, using thoracic CT as the reference standard. The secondary objectives included comparing the diagnostic performance of E-FAST with that of conventional CXR, assessing the impact of E-FAST on surgical decision-making and immediate treatment, evaluating the cost-effectiveness of E-FAST implementation, and determining the influence of E-FAST on clinical outcomes. This study aimed to validate the E-FAST as an effective tool for optimizing thoracic trauma management in high-volume tertiary settings.

MATERIAL and METHODS

This retrospective study reviewed the medical records of 476 patients treated at the Emergency and Trauma Surgery Service at University Hospital of Pontifícia Católica de Campinas, a tertiary referral center with 31 years' experience in complex trauma management, between January 2016 and December 2021. Adults (aged ≥18 years) with confirmed thoracic trauma were included in the study. Patients were excluded if patients aged <18 years, died upon trauma bay admission, or had incomplete medical records, resulting in a final sample size of 202. Incomplete records that were not imputed were excluded to ensure data reliability.

The primary outcome was length of hospital stay (days), with secondary outcomes including the need for mechanical ventilation, the use of vasoactive drugs, and mortality. Data extracted from electronic medical records included demographic variables (age and sex), epidemiological variables (trauma mechanism and time from event to admission), clinical variables [revised trauma score (RTS), thoracic trauma severity score (TTSS), injury severity score (ISS), injury burden, and initial management], and diagnostic and treatment variables. The E-FAST, CXR, and CT findings were systematically compared.

E-FAST examinations were performed at the discretion of attending trauma surgeons, emergency physicians, or general surgery residents (second- and third-year) with variable levels of ultrasound experience, following standardized institutional protocols. The decision to perform E-FAST was not randomized and instead followed institutional protocols that prioritized unstable or high-risk patients, typically those presenting with clinical signs of thoracic injury.

Pneumothorax evaluation involved assessing the anterior chest wall (2^{nd}-6^{th} intercostal spaces, clavicular line) with a linear probe. Normal lung sliding appears as a "marching ants" or "sandy beach" pattern. The absence of pleural sliding combined with a "stratosphere" or "barcode" sign on M-mode served as the diagnostic criterion for pneumothorax. The presence of a lung point is considered pathognomonic of pneumothorax. Hemothorax detection employs two complementary approaches: Curvilinear probe placement in the lower intercostal spaces (6^{th}-8^{th}, posterior axillary line) to detect pleural fluid, which appears as anechoic or hypoechoic areas; and identification of the spinal stripe superior to the diaphragm in bilateral upper-quadrant views. All examinations were performed during the primary survey to guide definitive management.

Statistical Analysis

The diagnostic accuracy of e-FAST was assessed by calculating sensitivity and specificity for detecting pulmonary contusions, pneumothorax, and hemothorax, using thoracic CT as the reference standard.

To address potential selection bias, we performed stratified analyses based on the ISSs and hemodynamic status. Propensity score analysis was conducted to balance the baseline characteristics between patients who underwent E-FAST and those who did not. Chi-square tests were used for categorical variables and Mann-Whitney U tests for continuous variables. Multiple logistic regression was performed to identify independent predictors of E-FAST utilization while controlling for potential confounders, including age, injury mechanism, hemodynamic status, and ISSs. The diagnostic performance was estimated with 95% confidence intervals (CI). A sensitivity analysis was performed to assess the robustness of our findings across different patient subgroups. Statistical significance was set at $p<0.05$, and analyses were performed using SPSS v26, Minitab 21.2, and Excel 2010.

Direct costs were calculated using institutional billing data from the Brazilian Sistema Único de Saúde (SUS). Indirect costs, including personnel time, equipment maintenance, training requirements, and potential costs associated with false-positive results, were not included in this analysis, which represents a limitation of the economic evaluation.

This retrospective, single-center study introduces several potential sources of bias, including selection bias (preferential use of E-FAST in critically ill patients), information bias (variable documentation quality and single-center analysis), and temporal bias (evolving protocols over the 5-year study period). The non-randomized nature of E-FAST utilization and the variable experience of operators represent additional limitations that may affect the generalizability of our findings to other institutions.

The study received approval from the University Hospital of Pontifícia Católica de Campinas-Campinas Research Ethics Committee (CAAE: 58584822.0.0000.5481, number: 466/12, date: April 27, 2022).

RESULTS

Of the 476 medical records reviewed, 202 adults with thoracic trauma were included in the final analysis after excluding 274 cases. The study population demonstrated a significant male predominance (77.9; n=156), with a mean age of 43.6±2.9 years (95% CI).

Emergency medical service transport was used in 69% of cases (n=138), with SAMU 192 representing the most frequent prehospital response system (35.5%). Notably, 79% of patients were admitted within two hours of the traumatic event; prehospital response times were <30 min. The mean hospital length of stay was 8.5±3.6 days, and the mean RTS was 6.29±0.16.

Among the 202 patients, blunt trauma predominated in 172 cases (85.1%), whereas penetrating injuries occurred in 30 patients (14.9%). Road traffic injuries (RTI) were the most common mechanism of injury (41.3%), followed by interpersonal violence (31.8%) and falls (25.4%). Accidental falls occur predominantly from a standing height and are more prevalent among older patients (90%). Within the RTI category, two-wheeled vehicle accidents represented the largest subset (19.2% of the total cases), followed by motor vehicle collisions and rollovers (16.7%). The mechanisms of trauma included penetrating injuries (gunshot wounds in 28 cases, 13.8%; stab wounds, 9.9%) and assaults with blunt objects (11.3%) (Table 1).

Most patients (n=148; 72.9%) were hemodynamically and respiratorily stable on admission to the intensive care unit. Hemodynamic instability (SBP <90 mmHg, base excess >-5, or lactate >3.5 milimol/L) was observed in 30 patients. Regarding injury distribution, 107 patients presented with multisystem trauma involving regions beyond the thorax, whereas only 11.8% of patients sustained isolated thoracic trauma.

Specific thoracic lesions included rib fractures in 141 patients (84 with displacement), simple pneumothorax in 63 patients, simple hemothorax in 38 patients, hemopneumothorax in 17 patients, pulmonary contusion in 15 patients, massive hemothorax in 7 patients, and tension pneumothorax in 4 patients. The TTSS distribution indicated injuries ranging from moderate to severe, with a mean TTSS of 10.2±6.8.

Associated injuries were frequent. Orthopedic fractures occurred in 80 patients, of whom 60% had fractures involving the lower extremities and 27% had pelvic fractures. Traumatic brain injury was present in 70 patients (34.7%), and abdominal and facial trauma affected 46 patients (22.8%). Among the intra-abdominal injuries, splenic trauma was the most common (n=28), followed by hepatic laceration (n=19), diaphragmatic injury (n=10), renal trauma (n=8), and mesenteric injury (n=5). Spinal cord trauma and soft-tissue injuries occurred in 25 and 22 patients, respectively. The mean ISS was 18±4.5; 65% of patients had an ISS >15 (Tables 2 and 3).

Non-operative management with clinical observation was implemented in 66% of cases, whereas 30% required immediate thoracic drainage. Digital thoracostomy followed by tube drainage was necessary in 3% of patients, and an emergency department thoracotomy for resuscitation was performed in 1% of patients. Forty patients required thoracic reintervention, with repeat thoracic drainage the most common procedure, followed

Table 1. Trauma mechanisms in 202 patients

Mechanism	Number	Percentage	Category
Motorcycle	39	19.3	Blunt
Falls	36	17.8	Blunt
Motor	32	15.8	Blunt
Gunshot	28	13.9	Penetrating
Assault	23	11.4	Blunt
Stab	20	9.9	Penetrating
Falls	14	6.9	Blunt
Pedestrian	6	3	Blunt
Bicycle	2	1	Blunt
Horse	2	1	Blunt
Total	202	100	

Blunt trauma: 172 patients (85.1%), Penetrating trauma: 30 patients (14.9%).

Table 2. Thoracic injury patterns

Injury	Number	Percentage	Severity
Rib	141	69.8	84
Simple	63	31.2	-
Simple	38	18.8	-
Hemopneumothorax	17	8.4	-
Pulmonary	15	7.4	-
Massive	7	3.5	-
Tension	4	2	-

Mean thoracic trauma severity score: 10.2±6.8 (moderate to severe injuries).
Patients may have multiple thoracic injuries.

Table 3. Associated extra-thoracic injuries

Injury	Patients	Prevalence	Specific
Orthopedic	80	39.6	Lower Pelvis Upper
Traumatic	70	34.7	All
Abdominal trauma	46	22.8	Splenic Hepatic Diaphragmatic Renal: 8 (17.4%) Mesenteric
Spinal	25	12.4	All
Soft	22	10.9	-

Mean ISS: 18±4.5 (65% of patients with ISS >15)
ISS: Injury severity score, Note: Patients may have multiple associated injuries.

by thoracoscopy; there were also two delayed thoracotomies for empyema or retained hemothorax.

E-FAST was performed in 149 patients (74%) during the admission evaluation. CT was performed in 153 patients (78%), and CXR was performed in 115 (59%).

Significant differences were observed between patients who underwent E-FAST and those who did not. Patients selected for the E-FAST examination presented with a higher mean (ISS: 25 vs. 17; p=0.018), increased hemodynamic instability (50% vs. 32.1%; p=0.014), greater requirement for mechanical ventilation (43.4% vs. 15.5%; p<0.001), and more frequent vasoactive drug support (33.8% vs. 8.8%; p<0.001).

Among the patients who underwent E-FAST, immediate thoracic drainage was performed in 39.1% (n=59) based on the ultrasound findings. In 83% of the cases requiring thoracic decompression, the procedure was performed in the emergency department.

CT imaging identified a mean of 2.54 thoracic lesions per patient, compared with 2.18 per patient among patients without CT evaluation (p=0.025). E-FAST demonstrated superior performance compared with radiography for early assessment of severity (p<0.001 for hemodynamic instability). The diagnostic performance of E-FAST and comparative results are presented in (Tables 4 and 5).

E-FAST utilization was associated with increased morbidity, as 19% of patients were discharged with thoracic sequelae compared with 7.6% of patients without E-FAST (p=0.021). Patients who underwent E-FAST had higher mean values for (RTS: 6.46 vs. 6.00), (ISS: 25 vs. 17), and (TTSS: 17 vs. 7) (p=0.018).

E-FAST guided immediate surgical decision-making and facilitated prompt thoracic drainage in 39.1% of cases (n=59; odds ratio: 0.61, 95%; CI: 0.30-1.25). Diagnostic time was reduced by 20-50 minutes in patients who underwent E-FAST compared with those who underwent conventional imaging workflows.

The overall mortality rate was 9.2% (n=17), with multi-organ failure being the primary cause of death.

Table 4. E-FAST diagnostic performance (using CT as reference standard)

Condition	Sensitivity	Specificity	PPV	NPV	Accuracy	95% CI
Pneumothorax	90%	95%	92%	94%	93%	86-97%
Hemothorax	86%	95%	89%	93%	92%	86-97%
Pulmonary	75%	95%	88%	89%	88%	81-94%

E-FAST vs. chest radiography performance
• Pneumothorax detection : E-FAST 90% vs. CXR 65% sensitivity (p<0.001)
• Hemothorax detection : E-FAST 86% vs. CXR 71% sensitivity (p<0.05)
PPV: Positive predictive value, NPV: Negative predictive value, CI: Confidence interval, CT: Computed tomography, E-FAST: Extended focused assessment with sonography for trauma.

Table 5. CT vs. E-FAST comparative diagnostic performance

Parameter	CT imaging	E-FAST	Statistical
Total	153 (75.7%)	149 (73.8%)	-
Mean	2.54±1.2	2.18±1.0	p=0.025*
Comprehensive	153/153 (100%)	142/149 (95.3%)	p<0.001*
Complex	High	Limited	-
Associated	98/153 (64.1%)	45/149 (30.2%)	p<0.001*

Clinical decision impact:
• CT- guided management changes : 89/153 (58.2%)
• E-FAST- guided immediate interventions: 59/149 (39.6%)
• Diagnostic concordance (when both performed): 127/134 (94.8%)
Diagnostic role definition:
• CT: Gold standard for comprehensive injury assessment and surgical planning
• E-FAST: Rapid screening tool for immediate life-threatening injuries
*: Statistically significant difference (p<0.05), CT: Computed tomography, E-FAST: Extended focused assessment with sonography for trauma.

DISCUSSION

Thoracic trauma represents a significant global health burden, contributing to approximately 25% of all direct trauma-related deaths (4). Our epidemiological findings are consistent with established patterns: Young males (18-40 years) accounted for 77.9% of cases, and RTI were the leading mechanism (41.3%). This disproportionate incidence among young adults emphasizes the critical need for targeted prevention strategies, including enhanced road safety education programs, particularly in middle-income countries (5,6). The high ISS and TTSS scores in our series underscored the complexity of the injuries, with 65% of patients having ISS >15 and frequent multisystem involvement.

The predominance of prehospital transport via SAMU 192 (69% of cases) and the high proportion of patients arriving within two hours (79%) reflect Brazil's improved emergency infrastructure and align with the critical "golden hour" concept (7). This improvement can be attributed to three key factors: Effective triage protocols, consistently trained first responders, and streamlined communication systems

That facilitate rapid transport to definitive trauma care facilities in the United States. However, motorcycle-related trauma (19.2%) and interpersonal violence (31.8%) remained significant concerns in urban settings. Penetrating injuries are often more severe (8). Although blunt trauma is typically associated with higher overall mortality rates, most penetrating thoracic injuries in our series progressed to hemodynamic instability, requiring massive transfusion protocols and immediate surgical interventions.

Multiple studies have validated the diagnostic superiority of E-FAST over conventional imaging. Ding et al.'s (9) meta-analysis reported a pooled sensitivity of 88-99% for ultrasound-based diagnosis of pneumothorax, whereas contemporary literature reports 81-95% sensitivity for hemothorax detection (10-15). Our findings align with this evidence, demonstrating 90% and 86% sensitivity for pneumothorax and hemothorax, respectively, with 95% specificity for both conditions.

Its superior performance compared with supine CXR (sensitivities of 90% vs. 65% for pneumothorax; $p<0.001$) supports current trauma guidelines that recommend ultrasound as the preferred initial imaging modality for unstable patients. This superior performance is particularly relevant because small- and medium-sized pneumothoraces and hemothoraces may be missed on supine CXR; this is especially important in our setting, where 79% of patients arrive within two hours of injury, and underscores the need for rapid diagnostic capabilities during the critical initial assessment period.

CT remains the gold standard for comprehensive thoracic trauma evaluation, providing definitive diagnostic information and injury characterization that E-FAST cannot fully replace. Our finding that CT identified a mean of 2.54 thoracic lesions per patient, compared with 2.18 lesions in patients without CT evaluation ($p=0.025$), reinforces CT's superior comprehensive diagnostic capability. Our institutional protocol appropriately positions E-FAST as a rapid screening tool that complements, rather than replaces, CT imaging. However, the diagnostic limitations of this technique must be considered. Operator variability and patient-related factors, such as subcutaneous emphysema, pleural adhesions, and chronic obstructive pulmonary disease, can compromise diagnostic accuracy and potentially lead to confusion with trauma-related changes.

E-FAST facilitated immediate thoracic drainage decisions in 39.1% of cases, with 83% of decompressions performed in the emergency department, demonstrating its value in rapid therapeutic decision-making. This capability aligns with contemporary management, which favors nonoperative approaches (66% of our cases), while enabling prompt intervention when indicated (16,17). The integration of E-FAST with institutional protocols emphasizing image-based criteria for thoracic drainage (30% of cases) supports evidence-based decision-making. Our implementation of the "35-mm rule" for pneumothorax observation and of the >300 mL threshold for hemothorax drainage aligns with the current literature supporting selective management approaches (18-23).

Another common dilemma faced by trauma surgeons is managing hypotensive patients with penetrating thoracoabdominal injuries, particularly in determining which cavities require surgical exploration. Therefore, bedside ultrasonography is mandatory in such situations. Matsushima et al. (24) demonstrated that pericardial FAST examination was highly sensitive and could reliably determine the need for pericardial exploration, whereas positive abdominal FAST findings warranted exploratory laparotomy.

Study Limitations

The most significant limitation of our study was the substantial selection bias in E-FAST utilization. Patients who underwent E-FAST presented with significantly higher (ISS: 25 vs. 17; $p=0.018$) greater hemodynamic instability (50% vs. 32.1%; $p=0.014$), and increased requirements for intensive interventions, including mechanical ventilation (43.4% vs. 15.5%; $p<0.001$) and vasoactive drug support (33.8% vs. 8.8%; $p<0.001$). This selection pattern, while clinically appropriate for prioritizing critically ill patients, creates a fundamental bias that precludes valid conclusions about the independent impact of E-FAST on clinical outcomes, such as mortality, length of stay, or morbidity. The observed association between E-FAST utilization and increased morbidity (thoracic sequelae: 19% vs. 7.6%; $p=0.021$) likely reflects the

underlying severity of illness rather than the causal effect of the diagnostic modality.

The retrospective, single-center design of our study introduces important limitations that must be considered when interpreting our findings. Data from a single Brazilian tertiary trauma center may not be generalizable to other healthcare systems with different resources, protocols, or patient populations. The retrospective nature of the study introduces potential documentation bias and limits our ability to control for confounding variables that could influence diagnostic accuracy or clinical outcomes. Furthermore, our institutional protocols and operator experience may differ from those of other centers, potentially affecting the reproducibility of our results.

A significant limitation of this study is the lack of a systematic assessment of the operator's experience and training levels. Ultrasound is inherently operator-dependent, and variations in physicians' expertise, training, and experience with E-FAST can significantly affect diagnostic accuracy. This limitation is well-documented in the recent literature and represents a persistent challenge in E-FAST implementation. Tan et al. (25) demonstrated that general surgery residency programs have non-standardized E-FAST training approaches, with some relying solely on Advanced trauma life support protocols, while others employ mixed methods, leading to significantly lower sensitivity rates (35.6%). A positive resident-performed E-FAST was generally accurate (85.6%), but its sensitivity was considerably lower than reported in the literature. Similarly, our institution did not maintain formal records of individual operator competency assessments or standardized training during the study period.

The impact of operator variability is further illustrated by Khosravian et al. (26), who found that 29.8% of E-FAST examinations at a level-1 trauma center were undocumented, technically limited, or incomplete, with the thoracic portion of the E-FAST among the most common sources of diagnostic error. While structured training programs have shown promise, with Cevik et al. (27) reporting an 88% pass rate after standardized 1-hour didactic sessions plus a 4-hour practical training for medical students, the absence of universal competency standards across institutions limits the reproducibility and generalizability of E-FAST diagnostic accuracy studies, including our findings. Furthermore, inadequate documentation practices are highlighted by Shwe et al. (28), who found that 78% of E-FASTs lacked any documentation in the patient's chart, even though an E-FAST was recorded and reviewed during ultrasound quality assurance. These findings underscore the critical need for standardized training protocols and competency-based assessment programs to optimize E-FAST reliability and ensure consistent diagnostic performance across different healthcare settings.

Additional limitations include temporal bias during the five-year study period due to evolving protocols, and a cost analysis limited to direct examination costs that did not capture indirect costs, training requirements, or potential costs associated with false-positive results that may lead to unnecessary interventions.

A fourfold reduction in the cost of E-FAST compared with CT (USD 15 vs. USD 60) represents substantial potential savings for high-volume trauma centers. However, this analysis considered only the direct examination costs and did not account for training requirements, equipment maintenance, or potential costs associated with false-positive results. In addition to economic considerations, E-FAST offers significant radiation safety advantages. Patients in our institution receive 5-10 mSv of radiation exposure per thoracic CT examination, which is approximately ten times that of CXR. E-FAST provides a radiation-free diagnostic alternative, which is particularly important in trauma settings where multiple imaging studies may be required.

Despite limitations due to selection bias, our findings support the integration of E-FAST into trauma protocols for rapid initial assessment, particularly in resource-limited settings where CT availability may be restricted. The Brazilian healthcare system faces substantial challenges in the management of trauma victims, with Campinas facing obstacles such as hospital overcrowding and limited resources. In this context, optimizing CT utilization through selective application is critically important to avoid diagnostic overutilization and reduce healthcare costs.

The utility of E-FAST in mass casualty scenarios was demonstrated during the 2023 earthquakes in Türkiye. Taşkın et al. (29) reported that blunt thoracic trauma was observed in 95.5% of earthquake victims, with 103 patients (57.5%) undergoing E-FAST evaluation in the emergency department. Their study highlighted how E-FAST enabled rapid and accurate clinical decision-making in resource-constrained disaster settings, reinforcing the critical role of point-of-care ultrasound in the assessment of thoracic injuries during mass-casualty events.

When combined with CT for detailed injury characterization, as implemented in our institutional protocol, this approach is consistent with established clinical guidelines. CT should not be replaced when comprehensive diagnosis is required; however, E-FAST serves as a useful adjunct to CT (30). Our institutional protocol demonstrated that the bedside E-FAST application significantly reduced diagnostic time by 20-50 minutes compared with conventional imaging workflows, facilitating rapid surgical decision-making.

Future research should prioritize several key areas to address the limitations of our study. Prospective multicenter randomized controlled trials are needed to eliminate selection bias and determine the true impact of E-FAST on clinical outcomes.

Comprehensive cost-effectiveness analyses should include indirect costs, costs associated with avoided complications, training requirements and associated costs, and costs of false-positive interventions. The development of structured training programs with competency assessments is essential to address operator variability and improve reproducibility across institutions.

CONCLUSION

E-FAST demonstrated high diagnostic accuracy for pneumothorax (90% sensitivity, 95% specificity) and hemothorax (86% sensitivity, 95% specificity) with CT as the reference standard, and it outperformed conventional radiography. E-FAST facilitates rapid bedside assessment and immediate surgical decision-making in critically injured patients. However, the significant selection bias toward critically injured patients limits the conclusions regarding the independent impact on clinical outcomes. These findings support the integration of E-FAST as a complementary diagnostic tool in thoracic trauma protocols.

Ethics

Ethics Committee Approval: The study received approval from the University Hospital of Pontifícia Católica de Campinas-Campinas Research Ethics Committee (CAAE: 58584822.0.0000.5481, number: 466/12, date: April 27, 2022).

Informed Consent: Informed consent was obtained from the parents of all patients or their guardians.

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Footnotes

Author Contributions

Surgical and Medical Practices - G.P.M., J.L.B.A.; Concept - G.P.M., V.F.K., E.S.H., J.L.B.A.; Design - H.H.F.M., V.A.L.M.; Data Collection or Processing - V.F.K., H.H.F.M.; Analysis or Interpretation - G.P.M., V.F.K., V.A.L.M.; Literature Search - G.P.M., E.S.H., V.F.K.; Writing - G.P.M., V.F.K., J.L.B.A.

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ORIGINAL ARTICLE
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Comparison of ultrasound-guided suprainguinal fascia iliaca block and lumbar erector spinae plane block in hip fracture: A single-blind randomized controlled trial

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ABSTRACT

Objective: Hip fractures are common in older adults and are associated with increased morbidity and mortality. Although multimodal anesthesia with peripheral nerve blocks is recommended, the superiority of specific block methods remains unclear. This study compared the postoperative analgesic efficacy of the suprainguinal fascia iliaca block (SFIB) and lumbar erector spinae plane block (LESPB) in patients who underwent hip fracture surgery.

Material and Methods: This single-center, single-blind, randomized controlled trial was conducted at a university hospital (Marmara University Faculty of Medicine, İstanbul, Türkiye) between August 2022 and May 2023. Patients received SFIB, LESPB, or no block before spinal anesthesia. No block-related complications were observed. Postoperative analgesia was provided using patient-controlled intravenous morphine, with tramadol administered as rescue analgesia for NRS pain scores above 4. The primary outcome was 24-hour total opioid consumption. Secondary outcomes included opioid consumption at 6 and 48 hours, pain scores, rescue analgesia requirements, and time to discharge from the intensive care unit and hospital.

Results: A total of 63 patients (mean age 78.5±14.0 years; 46 females and 17 males) with American Society of Anesthesiologists I-III undergoing hip fracture surgery were randomized to SFIB (n=23), LESPB (n=22), or control (n=22). During the first 24 hours, opioid consumption were higher in the control group [18 (9-24.5); p=0.002]. Post-hoc analysis showed a significant difference between the control and SFIB groups [6 (4-9); p<0.001]. The LESPB [13 (5-22)] and control groups were comparable (p>0.016).

Conclusion: SFIB provided the greatest reduction in postoperative opioid use during the first 24 hours after hip fracture surgery. While LESPB appears to be an alternative to SFIB, it produced a reduction in opioid consumption similar to that observed in the control group. Suprainguinal FIB should be prioritized as a component of multimodal analgesia for these surgeries.

Keywords: Erector spinae plane block, hip surgery, opioid consumption, postoperative analgesia, suprainguinal fascia iliaca block

INTRODUCTION

The majority of hip fractures occur in older adults, with over 30% of patients aged ≥85 years (1). A hip fracture is a fracture of the proximal femur extending up to 5 cm below the lesser trochanter (2). These fractures require careful anesthetic management because patients are often of advanced age, frail, and have multiple comorbidities, in addition to experiencing moderate-to-severe postoperative pain.

Several hip fracture guidelines recommend regular use of paracetamol, avoidance of non-steroidal anti-inflammatory drugs (NSAIDs), titration of opioids, including codeine, and application of peripheral nerve blocks (3-7). The susceptibility to the harmful effects of opioids and NSAIDs increases with age (8). Many elderly patients with hip fractures have chronic conditions that these analgesics could worsen, including cardiovascular disease, coagulopathy, decreased renal function, hiatal hernia, a history of gastric or duodenal erosions, vertigo, diverticulitis, or cognitive impairment. Peripheral nerve blocks, as part of regional anesthesia, have been linked to reduced pain, fewer severe opioid-related adverse events, and improved rehabilitation and functional recovery (9-11). Despite these advantages, there is limited high-quality evidence comparing the effectiveness and establishing the superiority of various peripheral nerve blocks in older adults (7,8,12).

The suprainguinal fascia iliaca block (SFIB), as demonstrated by Hebbard et al. (13), spreads more cephalad than the infrainguinal FIB, affecting the terminal branches of the lumbar plexus more proximally. This reliably blocks the femoral, lateral femoral

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cutaneous, and obturator nerves, as well as the articular branches of the hip, providing effective analgesia for hip fractures (14,15).

The erector spinae plane block was first described by Forero et al. (16). Recent studies have suggested that the lumbar ESPB (LESPB) can provide analgesia for the hip by blocking the lumbar plexus (17). A meta-analysis of five randomized controlled trials (RCTs) showed a significant reduction in opioid consumption with LESPB in hip arthroplasty and arthroscopy, although patients with hip fractures were not included (18). At the time of this study, evidence for LESPB in patients with hip fractures was primarily limited to case series, although it showed promise in providing effective analgesia (19-21). Future RCTs are needed to evaluate LESPB to inform guideline recommendations for hip fractures.

We designed a RCT to compare ultrasound-guided suprainguinal FIB and lumbar ESPB for postoperative analgesia in patients with proximal femur fractures. We hypothesized that LESPB would provide analgesia similar to that of SFIB. The primary outcome was the total opioid consumption over 24 h. Secondary outcomes included opioid consumption at 6 and 48 h, pain scores, need for rescue analgesia, and time to discharge from the intensive care unit (ICU) and hospital.

MATERIAL and METHODS

Study Design

Ethics

The randomized trial was conducted after receiving approval from the Institutional Committee (Marmara University Faculty of Medicine Clinical Research Ethics Committee, reference number 09.2022.254, approval date: April 11, 2022) in accordance with the principles outlined in the Declaration of Helsinki. The trial was registered at clinicaltrials.gov (NCT05642975). Written informed consent was obtained from all the patients included in the study. The CONSORT checklist was used for the enrollment and allocation of patients, and the flow chart is shown in Table 1.

Between August 2022 and May 2023, patients aged 18-100 years who underwent unilateral hip fracture surgery under spinal anesthesia and had an American Society of Anesthesiologists (ASA) physical status classification of I-III were included in the study. The exclusion criteria were as follows: Refusal to enroll, request for withdrawal from the study, inability to provide informed consent, contraindications to the local anesthetic agents used, severely impaired renal or hepatic function, bleeding diathesis, chronic corticosteroid use or regular use of strong opioids (e.g., morphine, fentanyl, oxycodone, or methadone), any condition preventing operation of the patient controlled analgesia (PCA) system, and psychiatric disorders.

The study included three groups: the SFIB group, LESPB group, and control group. Patients were randomized using computer-generated block randomization sequences. The allocation was concealed using a password-protected electronic system. Blocks were performed by two authors (EGO, BB) who were not involved in the data collection or analysis. Postoperative assessments were conducted by a blinded member of the pain management team. Outcome assessors and the statistician were blinded to the group allocation.

Anesthesia Management

All patients received a standardized anesthesia protocol (Figure 1). In the operating room, patients underwent standard monitoring using electrocardiography, invasive blood pressure measurement, and pulse oximetry. After confirming hemodynamic stability, intravenous crystalloid infusion was initiated. Supplemental oxygen was administered via a nasal cannula, and intravenous fentanyl (50 µg) was given prior to patient positioning.

Ultrasound Guided Blocks

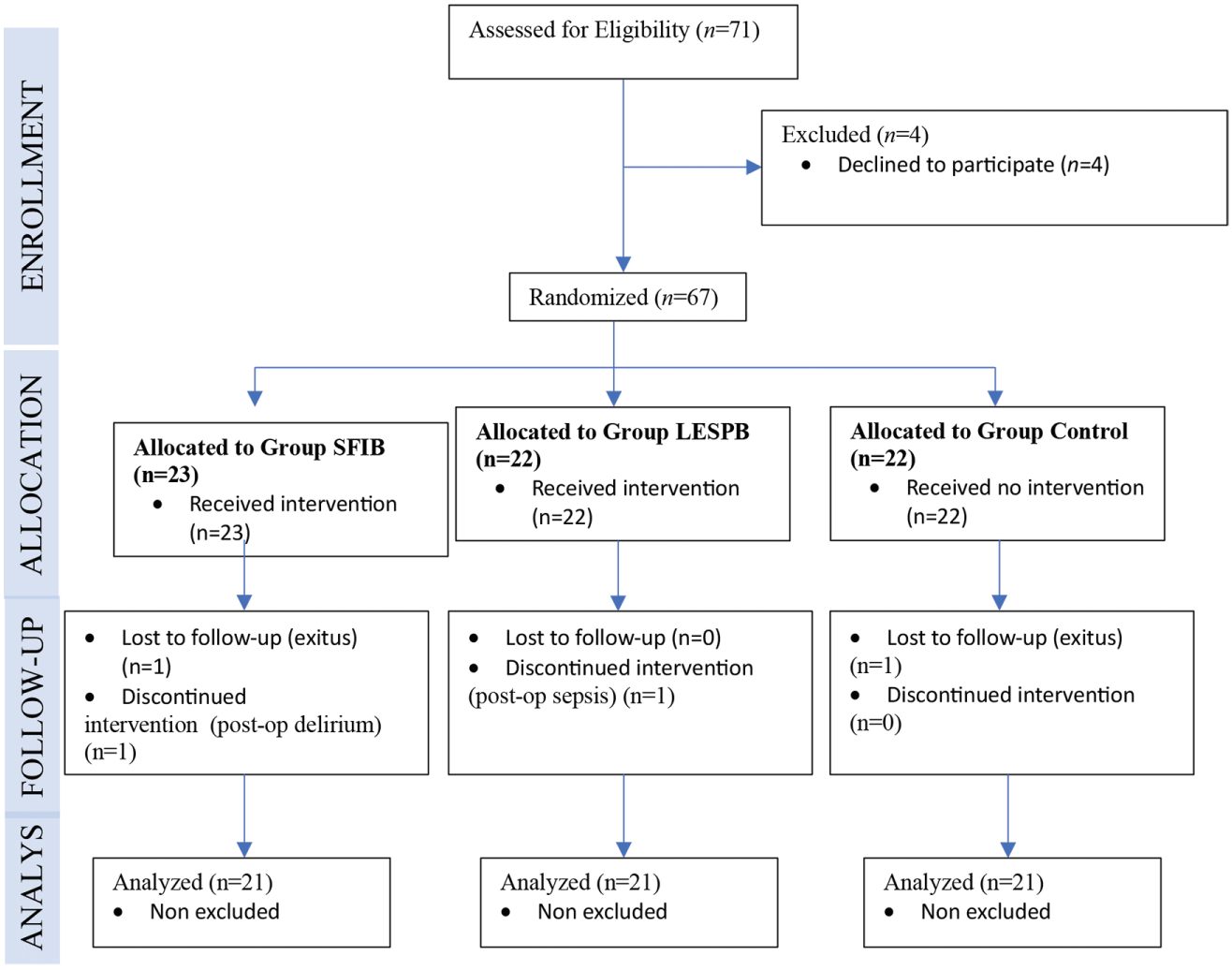
SFIB

In the SFIB group, an ultrasound-guided suprainguinal FIB was performed on the ipsilateral side of the surgical site, using the technique described by Hebbard et al. (13). The patient was positioned supine, and a 12-4 MHz linear ultrasound probe (Sparq Ultrasound, Philips, USA) was used. The probe was placed over the inguinal ligament, near the anterior superior iliac spine, and oriented in the parasagittal plane. It was then moved inferomedially along the inguinal ligament to visualize the bow-tie sign. The iliacus muscle was identified centrally, with the sartorius and internal oblique muscles forming the wings of the bow-tie view, with the fascia iliaca between them. The deep circumflex iliac artery, located just above the fascia iliaca and 1-2 cm above the inguinal ligament, serves as an important anatomical landmark for needle insertion. A 22-G, 80-mm needle (SonoPlex®; Pajunk Medizintechnologie, Geisingen, Germany) was inserted. After confirming the needle position, 30 mL of 0.25% bupivacaine was injected.

LESPB

Patients in the LESPB group were positioned laterally. An ultrasound-guided lumbar ESPB was performed ipsilateral to the surgical site, with needle advancement directed cephalad from the sacrum. The transverse processes of L3-L5 and the erector spinae muscles were identified using ultrasonography.

Table 1. CONSORT flowchart



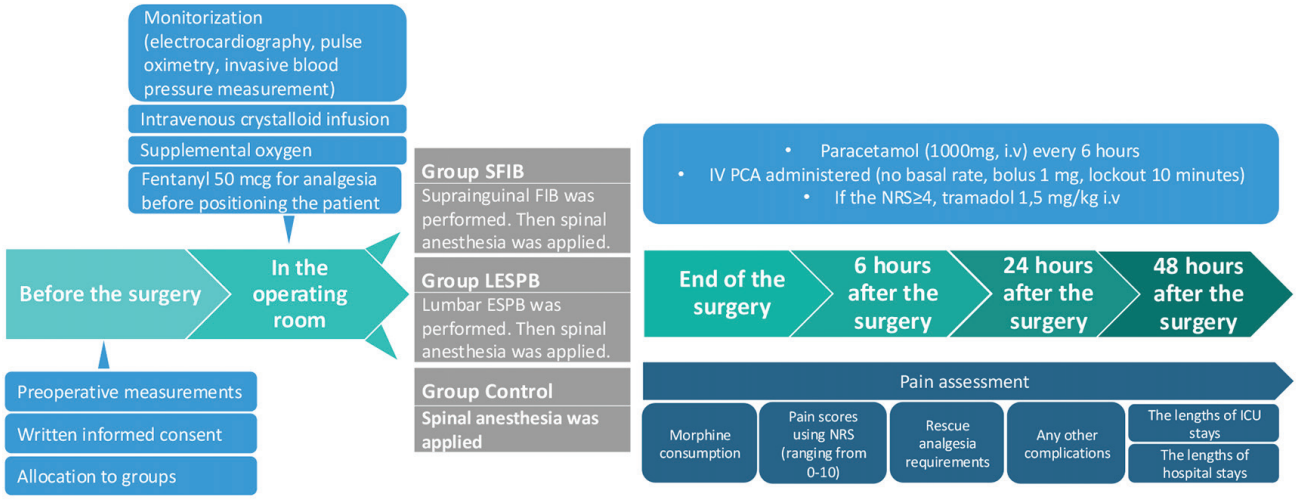


Figure 1. Standardized anesthesia protocol.

IV: Intravenous, PCA: Patient-controlled analgesia, SFIB: Suprainguinal fascia iliaca block, LESPB: Lumbar erector spinae plane block, ICU: Intensive care unit, FIB: Fascia iliaca block, NRS: Numeric rating scale

The curved 6-2 MHz transducer was initially placed on the mid-vertebral line in the sagittal plane and then shifted laterally to visualize the erector spinae muscle and the L3 transverse process. A 100 mm, 21 G needle (Sonoplex® Pajunk Medizintechnologie, Germany) was directed in-plane, with the tip advanced to the fascial plane anterior to the erector spinae muscle at the lateral edge of the transverse process. A total volume of 40 mL of 0.25% bupivacaine was injected. Correct placement was confirmed by the cranial and caudal spread of local anesthetic from the injection site, which dissected the plane between the transverse processes and the erector spinae muscles.

Control Group

In the control group, the same preoperative and postoperative analgesia protocols were applied without blocks. In all groups, spinal anesthesia was administered to patients in the lateral position using 2.5 mL of 0.5% heavy bupivacaine at the L3-L4 level.

After performing both nerve blocks, a pinprick test was used to confirm an adequate sensory blockade in the targeted regions. In the SFIB, the dermatomal areas corresponding to the femoral, obturator, and lateral femoral cutaneous nerves were evaluated. For the lumbar erector spinae plane block, sensory assessment included the dermatomes corresponding to L1-L5 on the anterior, medial, and lateral aspects of the thighs. Block-related and postoperative complications were monitored as safety outcomes. Postoperative analgesia was provided via PCA with intravenous morphine (no basal infusion; 1-mg bolus; 10-minute lockout interval). All patients received scheduled intravenous paracetamol (1000 mg every 6 hours). If the numeric rating scale (NRS) score exceeded 4, tramadol (1.5 mg/kg IV) was administered as rescue analgesia.

Data Collection

Intraoperative demographic data, baseline characteristics, fracture type, and type and duration of surgery were recorded. Postoperatively, at 0, 6, 24, and 48 hours, an independent investigator blinded to group allocation assessed morphine consumption, NRS pain scores (0-10 scale), rescue analgesia requirements, and any complications. ICU and hospital lengths of stay were also documented. Total opioid consumption was calculated by summing the amount of morphine delivered via IV PCA and the dose of rescue tramadol after conversion to intravenous morphine milligram equivalents (MME).

Sample Size

The sample size was calculated based on a pilot study. In our single-center preliminary study (unpublished), with 10 patients in each group, the mean opioid consumption in the first 24 h postoperatively was 9.8±6.1, 10.2±4.9, and 10.87±4.1 in the SFIB, LESPB, and control groups, respectively. We anticipated that perioperative analgesia would result in a 20% reduction in opioid consumption compared with the control group; this reduction was considered significant, with a standard deviation of 5.1. Using G*Power 3.1, a minimum sample size of 19 patients per group was calculated, with a power of 0.80, an alpha level of 0.05, and an effect size of 0.43 for an ANOVA comparing the three groups (22). Considering possible dropouts, the study was designed to include 21 patients in each group.

Statistical Analysis

Statistical analysis of the study data was conducted using the statistical package SPSS version 27 (IBM SPSS Statistics for Windows, Version 27.0. Armonk, NY: IBM Corp.). To compare anesthesia method groups with respect to categorical variables, the chi-square and Fisher's exact tests were employed when necessary. The distribution of continuous variables was assessed using the Shapiro-Wilk test. As the data were not normally distributed, non-parametric tests were applied. Statistical significance was set at $p<0.05$. In cases where a statistically significant difference was detected in the Kruskal-Wallis test, the post-hoc pairwise comparisons between groups were examined using the Mann-Whitney U test. Post-hoc pairwise comparisons were performed using the Bonferroni correction; significance was set at $p<0.016$ (0.05/3 comparisons).

RESULTS

As shown in Table 1, 71 patients with ASA I-III, all presenting with hip fractures, were initially assessed for eligibility. Four patients were subsequently excluded because they declined to participate, and 67 were enrolled. Follow-up for two patients was terminated because of death within the first 24 h postoperatively: One patient in the SFIB group due to pulmonary embolism and one patient in the control group due to myocardial infarction. Additionally, follow-up for another patient from the LESPB group was discontinued due to sepsis within the first 24 h postoperatively; this patient had preexisting immunosuppression. Follow-up for one additional patient in the SFIB group was discontinued because of postoperative delirium, which complicated assessment of consciousness in the ICU. However, all other patients, both in the ICU and the ward, remained conscious, cooperative, and oriented and were actively using the PCA device, which allowed assessment of pain.

The baseline characteristics and demographics are presented in Table 2. These characteristics, including body mass index (body mass index, kg/m^2), ASA status, sex, surgery time, fracture type, and type of surgery, were comparable among the study groups. The patients' ages ranged from 55 to 100 years, with a mean age of 78.5±14.0 years. All procedures were completed uneventfully; no complications related to SFIB, LESPB, or spinal anesthesia were observed.

The average NRS scores remained below 4 at all time intervals and were comparable across study groups (Table 3). This finding indicates that the predefined analgesic target of maintaining NRS scores below 4 throughout the study period was achieved.

Regarding our primary outcome (Figure 2), 24-hour total opioid consumption was significantly higher in the control group [18 (9-24.5)] than in the SFIB group [6 (4-9)] (p<0.001). Opioid consumption were higher in the control group during the first 6 h (p=0.021) and the 6-24 h interval (p=0.01) (Table 4). Post-hoc analysis during these periods showed significant differences between the control and SFIB groups (0-6 h, p=0.008; 6-24 h, p=0.002). The LESPB and control groups were comparable (p>0.016).

The clinical outcomes, including ICU admission, duration of hospital stay, and rescue analgesia details, are presented in Table 3. The duration of ICU stay was 0.18±0.59, 0.65±2.91, and 1.19±5.02 days for the SFIB, LESPB, and control groups, respectively; these differences were not statistically significant. Similarly, the total hospitalization durations were 6.68±4.16, 9.20±9.42, and 6.19±4.45 days for the SFIB, LESPB, and control groups, respectively, with no significant variation among the groups.

Table 2. Demographics and surgical characteristics of the participants

			SFIB	LESPB	Control	p-value
Age (years)		82 (73.5-87)	79 (75-87)	82 (71-87)	82 (79-87)	0.76[a]
BMI (kg/m²)		24.6 (22.9-28.9)	24.1 (23.1-28.3)	24.5 (22.5-28.5)	25.0 (23.0-29.3)	0.83[a]
ASA	**1** **2** **3**	0 24 39	0 (0) 7 (33.3) 14 (66.7)	0 (0) 9 (42.9) 12 (57.1)	0 (0) 8 (38.1) 13 (61.9)	0.54[b]
Sex	**Female** **Male**	46 17	17 (81.0) 4 (19.0)	13 (61.9) 8 (38.1)	16 (76.2) 5 (23.8)	0.26[c]
Type of fracture	**Femoral neck fracture**	22	8 (38.1)	8 (38.1)	6 (28.6)	0.15[b]
	Intertrochanteric fracture	35	9 (42.9)	11 (52.4)	15 (71.4)	
	Subtrochanteric fracture	6	4 (19.0)	2 (9.5)	0 (0.0)	
Type of surgery	**Open reduction**	14	6 (28.6)	4 (19.0)	4 (19.0)	0.33[b]
	Closed reduction	26	5 (23.8)	9 (42.9)	12 (57.2)	
	Arthroplasty	23	10 (47.6)	8 (38.1)	5 (23.8)	
Surgery time (min)		120 (96.5-130)	110 (95-160)	120 (105-130)	120 (90-130)	0.66[a]

[a]: Kruskall-Wallis test, [b]: Fisher's exact test, [c]: Chi-square test, ASA: American Society of Anesthesiologists, BMI: Body mass index, SFIB: Suprainguinal fascia iliaca block, LESPB: Lumbar erector spinae plane block.
Summary statistics are reported as median (interquartile range), mean ± standard deviation, or number (%).

Table 3. Postoperative clinical outcomes

	SFIB	LESPB	Control	p-value
Block failures [n (%)][a]	0 (0)	0 (0)	NA	NA
NRS scores[b]				
0 h	0 (0-1)	0 (0-1)	0 (0-2)	0.50
6th h	1 (0-2)	1 (0-2)	1 (1-3)	0.42
24th h	1 (0-1)	1 (1-2)	2 (2-3)	0.02
48th h	1 (1-2)	1 (1-1)	1 (1-2)	0.07
ICU stay time (day)[b]	0.18±0.59	0.65±2.91	1.19±5.02	0.85
Hospital stay time (day)[b]	6.68±4.16	9.20±9.42	6.19±4.45	0.41
Rescue analgesia requirement **0-6 h** **6-24 h** **24-48 h**	 1 (4.76%) 2 (9.52%) 1 (4.76%)	 4 (19.04%) 5 (23.81%) 1 (4.76%)	 5 (23.81%) 9 (42.86%) 4 (19.04%)	

[a]: Fisher's exact test, [b]: Kruskal-Wallis test [Bonferroni-adjusted significance threshold for NRS scores. p<0.016 (0.05/3 comparisons)], NA: Not applicable, ICU: Intensive care unit, NRS: Numeric rating scale.
Summary statistics are reported as median (interquartile range), mean ± standard deviation, or number (n).

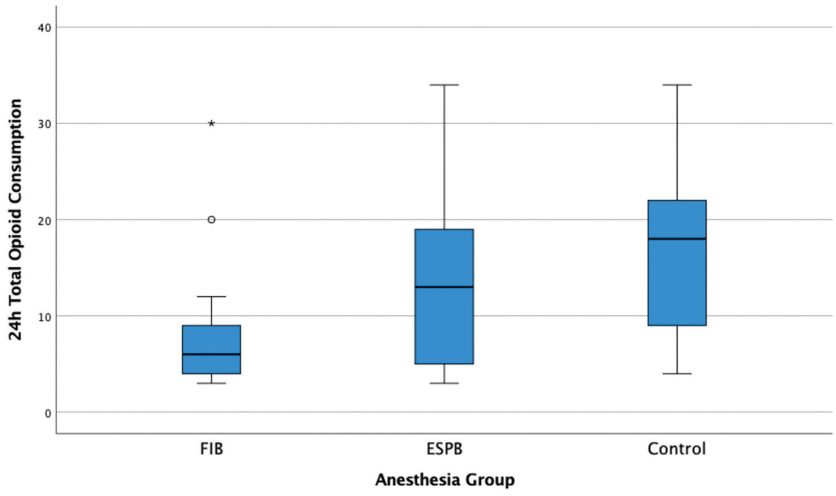


Figure 2. Intravenous opioid consumption during the 24 hours after surgery. Opioid consumption was presented as morphine milligram equivalents. The whiskers are the two lines outside the box that extend to the highest and lowest observations, respectively.

SFIB: Suprainguinal fascia iliaca compartment block, ESPB: Erector spinae plane block, FIB: Fascia iliaca block

Table 4. Postoperative total opioid consumption (MME). Total opioid consumption (milligrams in intravenous morphine equivalents) in the first 48 h after surgery was summarized as the median (interquartile range). Medians from separate time intervals were not additive; therefore, total values were calculated from individual patient-level cumulative opioid consumption

Total opioid consumption (MME)	SFIB	LESPB	Control	Overall p[a]	SFIB vs. LESPB (p, 95% CI)[b]	SFIB vs. control (p, 95% CI)[b]	LESPB vs. control (p, 95% CI)[b]
0-6 h	3 (1.5-4)	5 (2.5-12)	5 (3-13)	0.021	0.041 (-3, 1)	0.008 (-8.5, -0.5)	0.560 (-5, 2)
6-24 h	3 (2-6)	5 (3-12)	7 (4.5-14.5)	0.010	0.156 (-6, 1)	0.002 (-9, -1)	0.158 (-8, 2)
24-48 h	4 (1-5)	4 (1.5-10)	5 (3-11)	0.198	0.156 (-7, 1)	0.03 (-7, 0)	0.56 (-5, 4)
24 h total	6 (4-9)	13 (5-22)	18 (9-24.5)	0.002	0.045 (-12, 2)	<0.001 (-16, -3)	0.222 (-14, 4)

[a]: Kruskal-Wallis test, [b]: Mann-Whitney U test [Bonferroni-adjusted significance threshold, p<0.016 (0.05/3 comparisons)], MME: Morphine milligram equivalents, CI: Confidence interval, SFIB: Suprainguinal fascia iliaca block, LESPB: Lumbar erector spinae plane block. Summary statistics are reported as median (interquartile range), mean ± standard deviation, or number.

DISCUSSION

This RCT demonstrated that SFIB significantly reduced postoperative opioid requirements in the first 24 hours after hip fracture surgery. Post-hoc analyses revealed a significant reduction in postoperative opioid consumption in the SFIB group compared with the control group, whereas opioid consumption between the LESPB and control groups was similar during the first 24 h.

Hip fractures require careful attention because frail elderly patients experience moderate-to-severe pain. Over the years, guidelines, consensus reports, and reviews for hip fracture repair have recommended the implementation of multimodal analgesia during the perioperative period. This approach includes the regular use of paracetamol, avoidance of NSAIDs, and the addition of peripheral nerve blocks to general or spinal anesthesia to minimize opioid requirements for hip fracture repair (2,4,5,7,23). The use of SFIB in hip fracture surgeries has been demonstrated to enhance pain control and reduce opioid requirements (2-4,24). The LESPB, a relatively recent block, was first described by Forero et al. (16). Its analgesic efficacy in the hip region has been demonstrated in recent studies, although it has not yet been included in the guidelines. This study aimed to compare the analgesic efficacy of LESPB and SFIB.

In this three-group RCT, the primary endpoint—total opioid consumption over 24 hours—was lowest in patients receiving SFIB. Notably, SFIB requires a lower local anesthetic volume than LESPB, which may offer an additional clinical advantage. In elective total hip arthroplasty, patients who received LESPB exhibited lower opioid consumption during the first 8 h compared with those who did not receive the block. In contrast, between 8 and 48 hours postoperatively, opioid consumption and pain scores were similar (25). However, another study demonstrated that adding LESPB to the multimodal analgesia protocol for hip arthroplasty did not significantly affect opioid consumption or analgesic efficacy at 12 and 24 hours postoperatively (26).

In a study comparing SFIB with LESPB for hip analgesia in elective total hip arthroplasties, both blocks produced comparable reductions in postoperative pain scores and opioid requirements. Flaviano et al. (27) noted the absence of a control group in their study, which may have resulted in insufficient power to detect a difference in the primary outcome, despite calculating an appropriate sample size. In our three-group study, results in the SFIB and LESPB groups were statistically similar; however, opioid consumption was significantly reduced in the SFIB group compared with the control group, while opioid consumption in the LESPB group was similar to that in the control group. A comparison against a true control group provides a more meaningful assessment of clinical efficacy.

Studies evaluating LESPB in hip operations have primarily been conducted in patients undergoing elective hip arthroplasty. Patients undergoing surgery for hip fractures differ from those undergoing other surgeries because they are typically older, frailer, often require urgent surgery, and frequently have concomitant soft-tissue trauma. Therefore, selecting appropriate perioperative pain-control protocols based on the type of surgery is necessary, given the variability in postoperative pain management across procedures. Most studies demonstrating the effectiveness of LESPB in patients with hip fractures comprise case reports (28).

Our study aimed to achieve effective pain control. In comparing NRS scores, we observed that scores remained below 4 at all time intervals across groups, indicating successful achievement of our initial pain control goal. Comparison of opioid consumption would be unreliable in the presence of inadequate pain control. Thus, we believe that assessing the amount of opioids required for pain control would provide a more accurate representation of the effectiveness of multimodal analgesia.

Although in our study the length of hospital stay among groups was comparable, a REDUCE registry-dependent cohort study involving 178,757 patients aged ≥60 years with hip fractures demonstrated that the use of preoperative FIB or femoral block shortened hospitalization duration (29). The length of hospital stay was evaluated as one of the secondary endpoints in our study, and the sample size for this parameter may have been insufficient.

Our study had several strengths. Including a third control group when comparing SFIB and LESPB in hip fracture surgeries enabled a more reliable assessment of block performance and minimized comparison bias. Having all interventions performed by two experienced clinicians and using a standardized assessment protocol conducted by a blinded evaluator minimized both selection and observer biases.

Study Limitations

One limitation of this study is its single-center design. Additionally, patients were not blinded to the blocks because they were conscious during the perioperative period. In future studies, a double-blind design could be implemented using sham blocks; however, this would require a double-injection protocol because the two blocks require different positions. In this study, we chose a single-blind protocol to avoid the risk of infection associated with double injections. The volumes applied differed between the two block groups. This variation was due to one block being a compartment block and the other being fascial-plane block. These volumes were selected based on recommendations for minimal effective volumes reported in the regional anesthesia literature. Consequently, the LESPB group received a higher total dose of bupivacaine, and we cannot exclude the possibility that the observed analgesic benefit in this group is attributable to the higher dose. Future studies should investigate optimal dosing strategies to more accurately evaluate comparative efficacy.

Across the patient groups, postoperative analgesia was provided via IV-PCA to allow more precise follow-up. Opioid consumption can be reduced through oral multimodal analgesia. Mobilization duration was not included in the data collection because it varied with fracture type and surgical procedure among patients with hip fractures. Longer-term follow-up studies should be planned to assess the effects of reduced opioid consumption on functional status and mortality.

CONCLUSION

In conclusion, this study hypothesized that SFIB and LESPB would exhibit similar postoperative analgesic efficacy in patients undergoing hip fracture surgery. However, SFIB provided superior analgesic efficacy compared with LESPB. While LESPB seems to be an alternative to SFIB, it demonstrated a similar reduction in opioid consumption as that in the control group. As a component of multimodal analgesia for these surgeries, suprainguinal FIB should be prioritized.

Ethics

Ethics Committee Approval: The randomized trial was conducted after receiving approval from the Institutional Committee (Marmara University Faculty of Medicine Clinical Research Ethics Committee, reference number 09.2022.254, approval date: April 11, 2022) in accordance with the principles outlined in the Declaration of Helsinki. The trial was registered at clinicaltrials.gov (NCT05642975).

Informed Consent: Written informed consent was obtained from all the patients included in the study.

Footnotes

Author Contributions

Concept - E.G.Ö., Ö.Ö.; Design - E.G.Ö., Ö.Ö.; Data Collection or Processing - B.B.Ö.; Analysis or Interpretation - B.B.; Literature Search - E.G.Ö., B.B.Ö.; Writing - E.G.Ö., B.B., Ö.Ö.

Conflict of Interest: No conflict of interest was declared by the authors.

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ORIGINAL ARTICLE
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Blood product transfusion in major burned pediatric patients: A case-control study

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ABSTRACT

Objective: To evaluate the impact of blood product transfusions on clinical outcomes, including mortality, dialysis requirement, and infection, in pediatric patients with extensive burns.

Material and Methods: This case-control study included pediatric patients with ≥20% total body surface area burns who were treated at a university hospital burn center between 2012 and 2022. Deceased patients were classified as cases, and discharged patients as controls. The primary outcome was mortality, and the secondary outcomes were dialysis. Multivariable logistic regression was used to assess associations between blood product usage and clinical outcomes, adjusting for burn severity, surgical duration, and infection.

Results: One hundred-thirteen patients were analyzed, with 93 discharged and 20 deceased. Platelet transfusion in the intensive care unit (ICU) was associated with lower mortality (odds ratio: 0.663, 95% confidence interval: 0.484-0.909, p=0.011) but with increased dialysis requirements. Moreover, albumin, red blood cell, and fresh frozen plasma transfusions in the ICU were correlated with an increased risk of infection. Albumin administration in the ICU was associated with decreased mortality (hazard ratio =0.848, 95% confidence interval: 0.735-0.977, p=0.023).

Conclusion: The findings suggest that burn injury severity, the amount of blood products transfused, and the timing of transfusions are critical factors in determining patient outcomes. Future research should focus on establishing evidence-based transfusion thresholds.

Keywords: Pediatric burn, transfusion, mortality, dialysis, infection

INTRODUCTION

Blood transfusion remains a cornerstone in the management of anemia-related perfusion disorders, providing critical support in maintaining adequate oxygen delivery. However, transfusion-related complications continue to pose significant challenges in clinical practice, often leading to hesitation in their use (1,2). A restrictive transfusion strategy with a hemoglobin threshold of ≤7 g/dL has been associated with reduced mortality in critically ill patients compared to a more liberal approach (3). The critical-care study of transfusion requirements also demonstrated a reduction in mortality with a restrictive transfusion strategy (4).

Pediatric patients with major burn injuries often require substantial blood transfusions due to factors such as surgical blood loss, hemodilution from resuscitation fluids, reduced erythropoiesis, increased erythrocyte destruction, and frequent blood sampling (4). Despite advances in surgical techniques, equipment, and supportive care, managing blood loss during and after major burn surgeries remains challenging and often requires substantial transfusion support, particularly in children (5). However, limited data exist on the specific effects of blood and blood-product transfusions on outcomes in pediatric patients with extensive total body surface area (TBSA) burns. The interplay between transfusion practices and the recovery of pediatric burn patients, including mortality, morbidity, and long-term outcomes, has not been thoroughly explored (6). The exact impact of transfusions of blood and blood products on clinical outcomes, the optimal thresholds and strategies for

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their use, and the long-term effects of transfusion practices on recovery and quality of life in pediatric burn survivors remain to be thoroughly investigated. Understanding the effects of transfusion practices in this vulnerable population is critical for optimizing patient care and improving survival outcomes.

This case-control study aimed to assess the impact of blood product transfusions on clinical outcomes in pediatric patients with extensive burn injuries, particularly those with significant TBSA involvement. The primary aim of this study was to assess the association between blood product transfusions (red blood cells, fresh frozen plasma, and platelets) and mortality by comparing transfusion patterns between patients who died (cases) and those who survived (controls). The secondary aim was to evaluate the relationship between blood product transfusions and the requirement for dialysis among pediatric burn patients.

MATERIAL and METHODS

Study Design and Population

This case-control study used data from patients with burns treated at our university hospital's burn and wound care center from 2012 to 2022. This center is a well-equipped burn and wound facility with a total of thirty-six beds, including twenty burn unit beds, ten chronic wound unit beds, and six intensive care unit (ICU) beds. Cases were defined as burn patients who died, and controls as burn patients who survived. Patients were included in the study if they were younger than 18 years, had a TBSA greater than 20%, and presented to the clinic within 48 hours of the injury. Patients were excluded if they refused blood products, received blood at another center before admission, or had incomplete or inaccessible data. Additionally, patients who had hemoglobinopathies, electrical burn injuries, or who died in the first three days were excluded.

Data were collected by clinical staff in the clinic. Institutional Review Board (IRB) of University of Health Sciences Türkiye, Kartal Dr. Lütfi Kırdar City Hospital approval was secured before data collection (protocol no: 2021/514/204/20, date: 22.06.2021), and the study adhered to all relevant IRB guidelines for patient confidentiality and ethical research conduct. Collected data included patient demographics, total blood and blood product transfusion volumes, number of surgical procedures, and laboratory values of hemoglobin, platelet count, INR, and creatinine at admission and discharge. In this context, "discharge" refers to the final recorded laboratory values prior to either hospital discharge or in-hospital mortality. Additional variables recorded included the need for mechanical ventilation in the ICU, duration of hospital and ICU stays, dialysis requirements, frequency of infectious episodes, mortality rates, and complications such as pneumonia and wound infections. Data on transfusions of erythrocytes, fresh frozen plasma, platelet suspensions, albumin, and cryoprecipitate during hospitalization and ICU care were also documented. All patients received transfusions in accordance with the institution's established algorithm for blood product administration.

Covariates

We constructed directed acyclic graphs to identify the minimum set of variables required for adjustment to assess the unconfounded association between blood transfusion and clinical outcomes. For the primary and secondary outcomes (mortality and dialysis requirement, respectively), the necessary adjustment variables were surgery duration and burn severity. These variables were selected based on data availability and their established role in influencing mortality and adverse clinical outcomes. Burn severity was adjusted using TBSA and burn degree, and infection was adjusted using sepsis and pneumonia.

Statistical Analysis

Each patient was assigned a unique protocol number that was used to retrieve the required data from the system. The extracted data were de-identified and recorded in an Excel file for analysis, ensuring patient confidentiality.

The statistical analyses were conducted using STATA version 18. The normality of variable distributions was assessed using visual methods (histograms and Q-Q plots). Data that did not follow a normal distribution were reported as medians [with interquartile ranges (IQR)], while categorical variables were presented as frequencies and percentages. We used Pearson chi-square test to analyze differences between categorical groups, with Fisher's exact test applied when necessary. To compare medians between two independent groups that did not conform to a normal distribution, the Mann-Whitney U test was employed.

To assess the association between blood product transfusion and adverse clinical outcomes, we used multivariable logistic regression adjusted for surgery duration, burn severity, and infection. Results are reported as adjusted odds ratios (aOR), 95% confidence intervals (95% CI) and p-values.

A Cox proportional hazards regression model was used to assess the association between blood product transfusion and patient survival time. The model was adjusted for surgery duration, burn severity (TBSA and degree), and the presence of pneumonia. Results are reported as adjusted hazard ratios (aHRs) with 95% CIs and p-values.

RESULTS

Demographic Data and Clinical Characteristics

During the ten-year study period, data were collected for 209 patients. A CONSORT flow diagram showing the number of patients considered for study inclusion and those excluded, along with the reasons for exclusion, is shown in Figure 1.

Six patients were excluded due to electrical burns. Upon re-evaluation, twenty-six patients were excluded as their burn injuries were deemed ineligible for the study. Fourteen patients were not treated within the first 48 hours, and twenty-one patients had incomplete records. Additionally, twenty-nine patients who died within the first three days were excluded. The study included 113 patients.

Table 1 presents the baseline characteristics of the 113 individuals analyzed. Among them, 93 were discharged (37 females, 56 males) and 20 were deceased (6 females, 14 males). The median age was 2 years in the discharged group and 2.5 years in the deceased group. American Society of Anesthesiologists class I was observed in 80.5% of discharged patients and 16.8% of deceased patients. The median TBSA burned was significantly higher in the deceased group (40%; IQR 30-51) than in the discharged group (30%; IQR 24-37) (p=0.006). First-degree burns were observed in 39.8% of patients in the discharged group and in 25% of patients in the deceased group. Second-degree burns were the most common, affecting 58% of those discharged and 65% of those who died. Third-degree burns were present in 2.2% of the discharged group and 10% of the deceased group.

Furthermore, regarding the occurrence of infection, pneumonia was reported in 4.3% of the discharged group and in 45% of the deceased group. Sepsis occurred in 90.3% of the discharged group, but in 100% of the deceased group. Notably, all patients in both groups developed wound infections.

Comparison of the admission and final laboratory values (Table 2) between the discharged and deceased groups showed that survivors had a median admission creatinine of 0.33 compared with 0.445 in the deceased group (p=0.041). The final creatinine readings for survivors and non-survivors were 0.24 and 0.515,

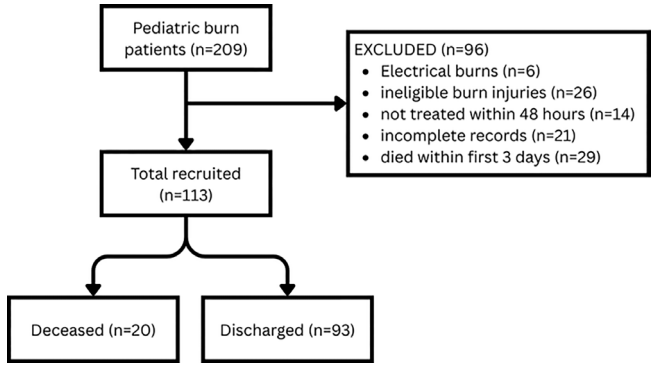

Figure 1. CONSORT flow diagram.

Table 1. Relationship between demographic values and mortality

	n (%)	Discharge (n=93)	Exitus (n=20)	p-value
Male	70 (61.9)	56 (49.6)	14 (12.7)	0.411
Female	43 (38.1)	37 (32.7)	6 (5.3)	
Age [median (IQR)]		2 (1-5)	2.5 (1-10)	0.587
Weight (kg) [median (IQR)]		12 (10-20)	15 (11-25)	0.411
ASA 1	111 (98.2)	91 (80.5)	20 (18.0)	0.414
ASA >2	2 (1.8)	2 (1.8)	0 (0.0)	
TBSA [median (IQR)]		30 (24-37)	40 (30-51)	0.006
1st degree burn	42 (37.2)	37 (32.7)	5 (4.4)	0.138
2nd degree burn	67 (59.3)	54 (47.8)	13 (11.5)	
3rd degree burn	4 (3.5)	2 (1.8)	2 (1.8)	
Hospital stay (day) [median (IQR)]		28 (21-40)	13.5 (8-24)	<0.001
ICU stay (day) [median (IQR)]		8 (4-16)	10.5 (7.5-24)	0.059
Mechanical ventilation duration (day) [median (IQR)]		0 (0-2)	8 (3.5-14)	<0.001
Pneumonia	13 (11.5)	4 (3.5)	9 (7.96)	<0.001
Sepsis	104 (104)	84 (74.3)	20 (17.7)	0.150
Wound infection		93	20	
Dialysis	3 (2.7)	0 (0)	3 (2.7)	<0.001
Number of total procedures [median (IQR)]		3 (2-5)	1 (1-3.75)	0.005
Fasciotomy & escharotomy [median (IQR)]		1 (0-1)	1 (1)	0.100
Debridement & graft [median (IQR)]		2 (1-4)	0 (0-2)	<0.001
Dressing [median (IQR)]		11 (8-15)	5 (2-9.75)	<0.001

ASA: American Society of Anesthesiologists, TBSA: Total body surface area, ICU: Intensive care unit, IQR: Interquartile ranges.

respectively (p-value 0.001). Both groups had similar median hemoglobin levels on admission (13.5 vs. 13.45 g/dL), but had statistically significant differences at discharge (10.5 vs. 8.65 g/dL, p-value <0.001). On admission, both groups had similar median international normalised ratio (INR) values (1.17 vs. 1.15); however, on discharge, survivors had a median INR of 1.0 compared with 1.6 in non-survivors (p<0.001). Survivors had lower platelet counts on admission than non-survivors (377 vs. 437.5), but at discharge survivors had significantly higher platelet counts (503 vs. 62; p<0.001).

Table 3 presents the adjusted odds ratios (ORs) for mortality, infection, and dialysis associated with blood product transfusions and albumin administration. Among the variables analyzed, platelet transfusion in the ICU was significantly associated with decreased odds of mortality (OR: 0.663; 95% CI: 0.484-0.909; p=0.011). This suggests a potential protective effect of platelet transfusion in critically ill pediatric burn patients. Although red blood cell (RBC) transfusion in the ward (OR: 10.662, 95% CI: 0.877-129.597, p=0.063) and in the operating theatre (OT) (OR: 2.175, 95% CI: 0.942-5.021, p=0.069) were associated with trends toward increased mortality, these associations did not reach statistical significance.

Secondly, among variables analyzed for association with infection, RBC transfusion in the ICU (OR: 1.426, 95% CI: 1.044-1.948, p=0.025) and fresh frozen plasma (FFP) transfusion in the ICU (OR: 1.448, 95% CI: 1.052-1.993, p=0.023) were significantly associated with an increased risk of infection. Additionally, albumin transfusion in the ICU was associated with a higher risk of infection (OR: 1.378, 95% CI: 1.034-1.837, p=0.028). These findings indicate that blood product transfusions in the ICU, particularly RBC, FFP, and albumin, may contribute to an increased risk of infection in pediatric burn patients.

Thirdly, platelet transfusion in the ICU was significantly associated with a increased likelihood of requiring dialysis (OR: 1.388, 95% CI: 1.012-1.904, p=0.042). Although RBC transfusion (OR: 1.423, 95% CI: 0.906-2.234, p=0.125) and FFP transfusion (OR: 1.537, 95% CI: 0.878-2.688, p=0.132) in the ICU were associated with increased odds of requiring dialysis, these associations were not statistically significant. These findings highlight a potential association between transfusions of platelets and other blood

Table 2. Impact of laboratory values on mortality/discharge

Lab values	Total number of the patients (n=113) median (IQR)	Discharge (n=93) median (IQR)	Exitus (n=20) median (IQR)	p-value
Admission creatinine [median (IQR)]	0.35 (0.23-0.48)	0.33 (0.23, 0.46)	0.445 (0.335, 0.505)	0.041
Admission INR [median (IQR)]	1.17 (1-1.41)	1.17 (1.05, 1.43)	1.15 (1, 1.355)	0.596
Admission hematocrit [median (IQR)]	40.2 (36.8-44.5)	40.1 (36.9, 44.5)	40.65 (36.2, 45.8)	0.857
Admission hemoglobin [median (IQR)]	13.5 (12-15)	13.5 (12, 14.8)	13.45 (12.3, 15.6)	0.767
Admission platelet (x10^3) [median (IQR)]	385 (304-498)	377 (305, 493)	437.5 (277.5, 522.5)	0.496
Discharge creatinine [median (IQR)]	0.26 (0.17-0.36)	0.24 (0.16, 0.33)	0.515 (0.3, 1.085)	<0.001
Discharge INR [median (IQR)]	1 (0.95-1.11)	1 (0.95, 1.02)	1.6 (1.41, 2.125)	<0.001
Discharge hematocrit [median (IQR)]	30.6 (27.7-33.8)	31.8 (28.7, 34.25)	25.3 (22, 28.1)	<0.001
Discharge hemoglobin [median (IQR)]	10.2 (8.9-11.25)	10.5 (9.6, 11.3)	8.65 (6.95, 9.15)	<0.001
Discharge platelet (x10^3) [median (IQR)]	467 (306-607)	503 (399, 640)	62 (31.5, 132)	<0.001

IQR: Interquartile range, INR: International normalized ratio.

Table 3. Logistic regression-outcome: death, infection, dialysis

	OR (death)	95% CI (death)	p	OR (infection)	95% CI (infection)	p	OR (dialysis)	95% CI (dialysis)	p
RBC tx in ICU	0.949	0.709-1.269	**0.725**	1.426	1.044-1.948	**0.025**	1.423	0.906-2.234	**0.125**
FFP tx in ICU	1.040	0.737-1.467	0.821	1.448	1.052-1.993	0.023	1.537	0.878-2.688	0.132
Plt tx in ICU	0.663	0.484-0.909	0.011	0.916	0.716-1.172	0.489	1.388	1.012-1.904	0.042
RBC tx in OT	2.175	0.942-5.021	**0.069**	0.973	0.656-1.443	**0.893**	0.543	0.077-3.834	**0.541**
FFP tx in OT	1.762	0.831-3.738	0.140	1.038	0.692-1.557	0.855	0.594	0.075-4.711	0.623
RBC tx in the ward	10.662	0.877-129.597	0.063	1.262	0.651-2.446	0.490			
Albumin in ICU	0.818	0.584-1.147	**0.245**	1.378	1.034-1.837	**0.028**	1.284	0.823-2.004	**0.270**

IQR: Interquartile range, RBC tx: Red blood cell transfusion, FFP tx: Fresh frozen plasma transfusion, Plt tx: Platelet transfusion, OT: Operating theatre, ICU: Intensive care unit, OR: Odds ratio, CI: Confidence interval.

products and renal dysfunction among critically ill pediatric burn patients, which warrants further investigation.

Table 4 presents the Cox proportional-hazards model hazard ratios (HRs) for various blood product transfusions and albumin administration in the ICU. RBC transfusion in the ICU was associated with a slight decrease in mortality risk (HR =0.897, 95% CI 0.798-1.007, p=0.068); however, this did not reach statistical significance. FFP transfusion in the ICU (HR =0.907, 95% CI 0.798-1.032, p=0.140) and platelet transfusion in the ICU (HR =0.918, 95% CI 0.724-1.163, p=0.481) also showed no significant association with mortality. Similarly, RBC (HR =0.909, 95% CI 0.767-1.078, p=0.276) and FFP (HR =0.896, 95% CI 0.754-1.066, p=0.217) transfusions in the OT were not significantly associated with mortality. However, albumin administration in the ICU was significantly associated with a reduced mortality risk (HR =0.848, 95% CI 0.735-0.977, p=0.023), suggesting a potential protective effect.

DISCUSSION

In this case-control study, we examined the impact of blood transfusion on critically ill pediatric burn patients. The observed mortality rate was 17.7%. While RBC, FFP, or albumin transfusion in the ICU was not significantly associated with mortality or dialysis requirements, it was linked to an increased risk of infection. Conversely, platelet transfusion in the ICU was significantly associated with lower odds of mortality and an increased likelihood of requiring dialysis. However, it was not linked to the incidence of infection.

Moreover, deceased patients received significantly higher amounts of RBCs, FFP, platelet suspension, and albumin during their stay in the intensive care unit. This suggests that these critically ill patients had more severe clinical presentations, likely requiring greater support, such as transfusion of blood products, to manage ongoing blood loss and complications, including hypovolemia, coagulopathy, and anemia. It is important to note that the higher blood product use in the deceased group does not necessarily indicate a causal relationship with mortality; however, it may be indicative of the severity of their burn injuries and associated complications.

Furthermore, patients receiving RBC and FFP in the ICU had higher odds of requiring dialysis and developing infection. Platelet transfusion in the ICU was associated with higher odds of requiring dialysis. The lower hemoglobin levels in deceased patients compared with discharged patients appear to be multifactorial and primarily associated with the severity of their clinical condition. Deceased patients had a higher mean TBSA burned (40%) than discharged patients (30%). This result indicated that more extensive injuries likely led to greater blood loss and a higher risk of complications during critical illness, such as coagulopathy or destruction of red blood cells.

It should also be noted that the transfusion thresholds for pediatric burn patients vary depending on the clinical context, but general guidelines are often adapted from critical care and burn-specific recommendations (7). These thresholds aim to balance the risks and benefits of transfusion, including ensuring adequate oxygen delivery while minimizing complications such as infections, immune modulation, and volume overload. Each pediatric burn patient is unique, and transfusion decisions should be individualized based on hemodynamic stability, clinical symptoms, laboratory findings, the extent of burn injury, and associated complications (8,9). Close monitoring of the patient's response to transfusions, together with a multidisciplinary team approach, is essential to optimize patient outcomes. Studies focusing on children with burn injuries demonstrated that a restrictive blood transfusion protocol, with a hemoglobin threshold of 7 g/dL, is safe in acute pediatric burn care, potentially reducing medical risks and lowering healthcare costs (10,11). During our study period, The observed mean Hb level was lower in deceased patients (8.6 g/dL) than in discharged patients (10.5 g/dL). This result indicates that a restrictive transfusion strategy may not lead to significantly improved outcomes in critically ill patients with severe burns. While restrictive strategies reduce complications and costs in less critical populations, their impact on survival in high-risk burn patients requires further investigation. We believe that threshold Hb values should be reassessed for transfusion of blood products in this specific patient population.

Additionally, our logistic regression analysis identified that the deceased group had a threefold higher frequency of dialysis requirement and a sevenfold greater number of days of mechanical ventilation. Higher rates of dialysis and mechanical ventilation in the deceased group suggest significant organ dysfunction, including impaired erythropoiesis due to renal insufficiency and systemic inflammation. These factors highlight the complexity of managing anemia and transfusions in pediatric burn patients, particularly in those with severe injuries and multi-organ involvement. Deceased patients had a significantly higher

Table 4. Survival analysis

	Hazard ratio	95% CI	p
RBC tx in ICU	0.897	0.798-1.007	**0.068**
FFP tx in ICU	0.907	0.798-1.032	0.140
Plt tx in ICU	0.918	0.724-1.163	0.481
RBC tx in OR	0.909	0.767-1.078	**0.276**
FFP tx in OR	0.896	0.754-1.066	0.217
Albumin in ICU	0.848	0.735-0.977	**0.023**

IQR: Interquartile range, RBC tx: Red blood cell transfusion, FFP tx: Fresh frozen plasma transfusion, Plt tx: Platelet transfusion, OR: Operating room, CI: Confidence interval, ICU: Intensive care unit.

TBSA burned, which likely led to severe systemic inflammatory responses and multi-organ failure, including acute kidney injury. Other contributing factors could include inflammatory and metabolic complications along with hemodynamic instability. On the other hand, the discharged group had significantly lower creatinine at hospitalization, creatinine at discharge, and INR at discharge than the deceased group. This was consistent with improved renal and coagulation functions. These findings reinforce the importance of early identification and management of organ dysfunction in critically ill pediatric burn patients.

Overall, the study emphasized the critical role of blood transfusions in the management of pediatric burn patients and recognized the need for careful assessment of risks and benefits to optimize outcomes. Further research is required to establish evidence-based transfusion thresholds and strategies specific to this vulnerable population. Our study underscored the challenges in optimizing transfusion strategies for pediatric burn patients. The role of restrictive versus liberal transfusion strategies in this population remains an area of ongoing research. Its applicability in pediatric burn patients requires further investigation.

Study Limitations

This study has several limitations that should be acknowledged. First, as a case-control study, it is inherently subject to biases, such as selection and information biases, which may affect the generalizability of the findings. Additionally, because this study had a retrospective design and data were obtained from medical records that may have contained inconsistencies or missing information, the accuracy and comprehensiveness of the data analysis were inherently limited. Second, the study was conducted at a single-center, which may not reflect practices and outcomes at other institutions that employ different protocols for managing pediatric burn patients. The findings may not be directly applicable to other populations with varying demographic, clinical, or institutional factors. Third, while the study explored the association between blood product transfusions and mortality, causation cannot be established due to the observational design. The higher use of blood products in the deceased group likely reflects the severity of illness rather than a direct causal relationship with mortality. Confounding factors such as the extent of burn injuries, systemic inflammatory responses, and organ dysfunction may have influenced the outcomes, but these variables were not fully accounted for in the analysis. Fourth, the study did not assess long-term outcomes, such as quality of life or functional recovery, which are crucial in understanding the broader implications of transfusion practices in pediatric burn patients. Future studies with larger cohorts and prospective designs are needed to validate the findings and explore the mechanisms underlying the observed associations.

Despite the limitations, the study provides valuable insights into transfusion practices and clinical outcomes among pediatric burn patients and underscores the need for further research to optimize management strategies for this vulnerable population.

CONCLUSION

In conclusion, this case-control study provides valuable insights into the impact of blood product transfusions on clinical outcomes in pediatric patients with extensive TBSA burns. The findings suggest that the severity of burn injury, the amount of blood products transfused, and the timing of transfusions are critical factors in determining patient outcomes. While blood transfusions remain a cornerstone in the management of major burns, further research is needed to define optimal transfusion strategies, identify risk factors for transfusion-related complications, and explore long-term outcomes in pediatric burn survivors. Additionally, the potential for personalized transfusion protocols based on burn severity and individual patient factors warrants further investigation. This study contributes to the growing body of evidence aimed at improving care and survival outcomes for pediatric burn patients.

Ethics

Ethics Committee Approval: Ethical approval was obtained from the University of Health Sciences Türkiye, Kartal Dr. Lütfi Kirdar City Hospital Clinical Research Ethics Committee, İstanbul, Türkiye, under protocol number 2021/514/204/20, dated 22 June 2021.

Informed Consent: Retrospective study.

Footnotes

Author Contributions

Concept - A.S., E.H.Ü., K.T.S.; Design - A.S., E.H.Ü., K.T.S.; Data Collection or Processing - E.H.Ü., S.Y., T.Ş., G.F., M.D., K.T.S.; Analysis or Interpretation - A.S., E.H.Ü., F.R.M., T.Ş., A.Z., K.T.S.; Literature Search - A.S., S.Y., F.R.M., T.Ş., A.Z., K.T.S.; Writing - A.S., F.R.M., K.T.S.

Conflict of Interest: No conflict of interest was declared by the authors.

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ORIGINAL ARTICLE
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Potential use of bioresorbable poly-D-L-lactic acid (PDLLA) plates in rhinoseptoplasty

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ABSTRACT

Objective: Bioresorbable poly-D-L-lactic acid (PDLLA) plates are increasingly used in rhinoseptoplasty due to their biocompatibility, adequate initial mechanical strength, and complete resorption over time. These properties may offer advantages over permanent implants, particularly in complex cases involving post-traumatic nasal deformity. To evaluate the clinical efficacy and safety of PDLLA plates in achieving functional and aesthetic outcomes in primary and reconstructive rhinoseptoplasty.

Material and Methods: A retrospective cohort study was conducted on 37 consecutive patients [23 men, 14 women; median age 37 years, interquartile range (IQR) 30-44] who underwent rhinoseptoplasty between January 2022 and December 2024. The minimum follow-up was 3 months. Primary endpoints included septal stability, complication profile (e.g., infection, extrusion, resorption issues), and patient-reported outcomes. Subjective nasal appearance and symptom burden were assessed using the validated Standardized Cosmesis and Health Nasal Outcomes Survey (SCHNOS). In select cases requiring revision, histopathological evaluation of implantation sites was performed at 12 and 24 months.

Results: He use of pure PDLLA plates provided reliable septal stabilization and facilitated precise dorsal alignment, eliminating the need for autologous graft harvesting in 83.8% of cases. No plate-related infections, extrusions, or delayed resorption events were observed. Patient-reported symptom burden, as measured by the SCHNOS score, improved markedly from a median of 21 (IQR: 15-26) preoperatively to 1 (IQR: 0-1) postoperatively. Histology confirmed complete material resorption by 24 months, with mature collagenous remodeling and an absence of chronic inflammatory infiltrate.

Conclusion: In carefully selected patients, PDLLA plates appear to be a biocompatible and technically feasible adjunct in rhinoseptoplasty, facilitating septal reconstruction, eliminating donor-site morbidity, and yielding improvements in both patient-reported nasal function and aesthetic outcomes. These preliminary findings support further investigation in larger, controlled studies.

Keywords: Rhinoseptoplasty, bioresorbable implant, poly-D-L-lactic acid (PDLLA), septal deviation, Standardized Cosmesis and Health Nasal Outcomes Survey (SCHNOS)

INTRODUCTION

Nasal septal deviation is a highly prevalent condition, affecting up to 86.6% of adults. It is a leading cause of both functional impairments, such as nasal obstruction, and external deformities (1).

Nasal deviation is a common pathology that requires anatomically-based treatment. Septal correction requires a systematic approach to achieve a straight nasal profile. Modern rhinoseptoplasty techniques aim to achieve two objectives simultaneously: Restoring laminar airflow and creating a harmonious nasal contour (2). Moreover, septal deviation and turbinate hypertrophy are associated with impaired olfaction in the obstructed nostril. Surgical correction of these anatomical abnormalities has been shown to improve olfactory function (3). In severe cases, extracorporeal septoplasty may be required. Although this method has demonstrated efficacy in reconstructing severely deviated septa, there is a risk of destabilizing critical anatomical areas, such as the dorsal nasal lines and the keystone area (3). Thus, nasal septal deformity leads to aesthetic and functional consequences, such as impaired breathing and olfaction.

In 2024, plastic surgeons and otolaryngologists preferred rhinoseptoplasty, followed by facelift and blepharoplasty, to correct nasal deviation and restore its normal function. Notably, approximately 80% of surgeons affiliated with the American Academy of Facial Plastic and Reconstructive Surgery report that over 10% of their rhinoplasty patients seek revision procedures (4).

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The correction of nasal deformities requires establishing an anatomically straight septum to provide stable support for the nasal dorsum. While submucous resection is commonly employed, its application is restricted to cases in which the L-strut is not affected by the septal deviation (5). The use of poly-D-L-lactic acid (PDLLA) plates is the most appropriate solution when temporary stabilization is required. The plates maintain structural integrity for 12 weeks, a period that coincides with the critical phase of cartilage remodeling; after this period, the plates undergo complete hydrolytic degradation to CO_2 and H_2O. As a result, there is no need to remove the implant.

Anatomical accuracy is increased by excising the deformed septal cartilage and reconstructing it *ex vivo*. Preliminary studies indicate excellent biocompatibility and minimal chronic inflammatory response (6). This study systematically evaluates clinical, radiologic, functional, and histological outcomes associated with PDLLA-assisted septal reconstruction.

However, this procedure may cause complications, such as instability of the quadrangular cartilage–nasal bone junction, potentially altering the dorsal contour (7).

Technical challenges may arise in cases of a hypoplastic (less than 3 mm in height) or an absent anterior nasal spine (8). Rib cartilage is typically used in primary cases when septal cartilage is insufficient and in revision cases where it has been previously harvested (9). During integration of the cartilage graft, bioresorbable plates provide the necessary structural fixation and stability for 12 weeks due to their perforated design; they also reduce the duration of the surgical intervention and sometimes eliminate the need for additional implant harvesting, which is a major advantage of PDLLA plates (10). The implication is that PDLLA plates are a safe, reliable, and resorbable option for septal reconstruction (10). Macroscopic examination reveals complete resorption of the plates within three months post-insertion, when they cease to provide structural support. Histologically, PDLLA vacuoles become undetectable by 24 months post-implantation, with the areas previously occupied by polymer-containing vacuoles being completely replaced by mature connective tissue without signs of inflammation (11). Due to the ability of the PDLLA plates to be completely resorbed within three months after implantation, possible risks and complications, such as inflammation, allergic reactions, or incomplete resorption of the material, can be minimized.

This study aimed to evaluate the clinical efficacy and safety of bioresorbable PDLLA plates used in primary rhinoseptoplasty to correct deviated nasal septa.

MATERIAL and METHODS

Study Design and Ethics

This single-center retrospective analysis was approved by the Local Ethics Committee at the St. Petersburg State Pediatric Medical University (approval no: 32/06, dated: 08.11.2023) and was conducted in accordance with the Declaration of Helsinki (12).

Patients Selection

Inclusion criteria: Congenital, post-traumatic, or iatrogenic septal deformity amenable to open, combined or closed rhinoseptoplasty. The indications for PDLLA implantation include limited availability of autologous cartilage and bone grafts and post-traumatic, congenital, or iatrogenic deformities requiring additional structural support. In primary cases without cartilage or bone deficiency, only autologous grafts were used. The resorbable plate was primarily employed as a substitute for the perforated cribriform plate, which is commonly used to straighten and reinforce the nasal septum.

Exclusion criteria: Prior structural rhinoseptoplasty, active sinonasal infection, chronic rhinosinusitis.

In all cases, data on sex, age, surgical technique, patient-reported outcomes, and standardized photographs were collected. Patients attended follow-up visits at 14 days and at 1, 3, 6, and 12 months postoperatively.

Histological analyses of tissue samples from the surgical site were performed at 1- and 2-years post-implantation.

Biopsy Procedure

Biopsy specimens were obtained during scheduled minor revision procedures under local anesthesia at 12 and 24 months postoperatively. Biopsies were performed only when contour refinement was clinically indicated; no additional surgical interventions were carried out solely for research purposes. Through a semi-transfixion incision along the left anterior septal margin (≤0.5 cm in length), a small septal fragment (approximately 0.2 cm^2) was dissected supraperichondrially and excised with a scalpel.

Surgical Technique

Following transcolumellar-marginal or hemitransfixion approaches, complete subperichondrial and periosteal elevation was achieved. Deviated cartilaginous and bony elements were excised or reshaped *ex vivo*. A perforated 30×30×0.2-mm pure PDLLA plate (Resorb-X®, KLS Martin, Tuttlingen, Germany) was anchored to the anterior nasal spine or nasal bones via 18-gauge transosseous tunnels. Cartilaginous/bony grafts were sutured to the plate with 5-0 polydioxanone, reconstituting a minimum 25×20-mm neo-L strut. Detailed intraoperative footage is provided in the video (Supplementary content - Video 1) and in Figure 1.

Outcome Measures

Subjective: Pre- and postoperative Standardized Cosmesis and Health Nasal Outcomes Survey (SCHNOS) questionnaires.

Objective: Anterior rhinomanometry (150 Pa reference), computed tomography-based septal deviation angle, and standardized photographs (frontal, lateral, basal, oblique ×2, smiling frontal).

Histology: Haemotoxylin and eosin and Masson's trichrome staining of biopsies at 12 and 24 months.

Statistical Analysis

Data were processed with R 4.3. Potential outliers were identified and handled using interquartile range criteria to minimize measurement error; suspected measurement errors were imputed using variable-specific means. Normality was assessed using the Shapiro-Wilk test. Parametric or non-parametric tests (Student's t-test or Mann-Whitney U test) were applied as appropriate, with α=0.05.

RESULTS

Between January 2022 and December 2024, 37 rhinoseptoplasty procedures were performed using perforated PDLLA plates [23 men and 14 women; mean (standard deviation) age, 37±9 years; range, 19-75 years].

Table 1 presents the distribution of operative times and the difference between SGHNOS scores measured preoperatively and at three months postoperatively, by type of surgical approach. Figure 2 provides a graphical representation of changes in SCHNOS scores.

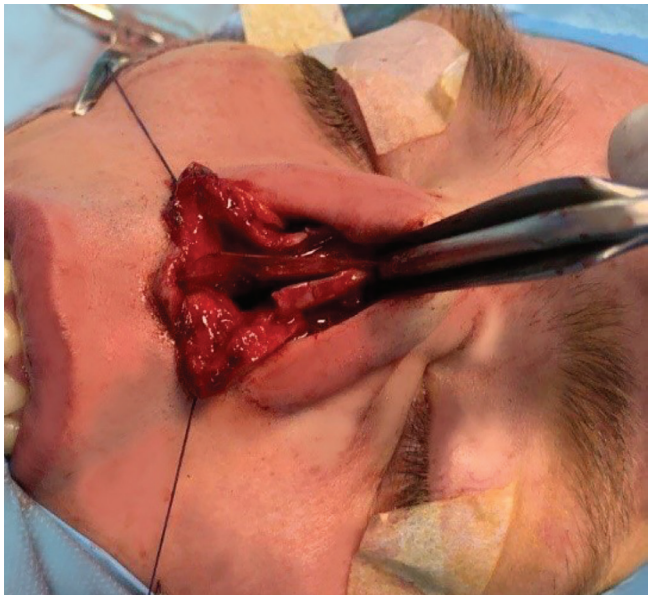


Figure 1. Implantation of a perforated PDLLA plate (30×30×0.2 mm) during rhinoseptoplasty. A perforated plate measuring 30×30×0.2 mm, made of 100% PDLLA, is fixed to the nasal bones and the anterior nasal spine with a monofilament soluble thread, PDS 4-0.

PDLLA: Poly-D-L-lactic acid

The operative time was significantly longer for open approaches, intermediate for combined techniques, and shortest for closed procedures ($p<0.05$). All groups demonstrated statistically significant improvements in SCHNOS scores at 3 months postoperatively, indicating both functional and aesthetic improvements.

No plate-related complications, such as infection, extrusion, or palpable irregularities, were observed during either early postoperative (≤30 days) or late postoperative (≤2 years) intervals.

Table 1. Total operative time and early patient-reported outcome measures ($p<0.05$*)

Surgical approach	Operative time, min [median (IQR***)]	ΔSCHNOS** [0-3 mo, median (IQR)]
Open	215 (182.5-270)	24.5 (18.5-26) → **0.5 (0-1)**
Combined	190 (180-210)	26 (15-27) → **1 (1-2)**
Closed	137.5 (117.5-150)	17 (15-21.5) → **0 (0-1)**

*: $p<0.05$ versus the other approaches (Mann-Whitney U test with Bonferroni correction);
**: ΔSCHNOS: Difference between pre-operative and 3-month Standardized Cosmesis & Health Nasal Outcomes Survey scores
***: IQR stands for interquartile range. IQR: Interquartile range, SCHNOS: Standardized Cosmesis and Health Nasal Outcomes Survey

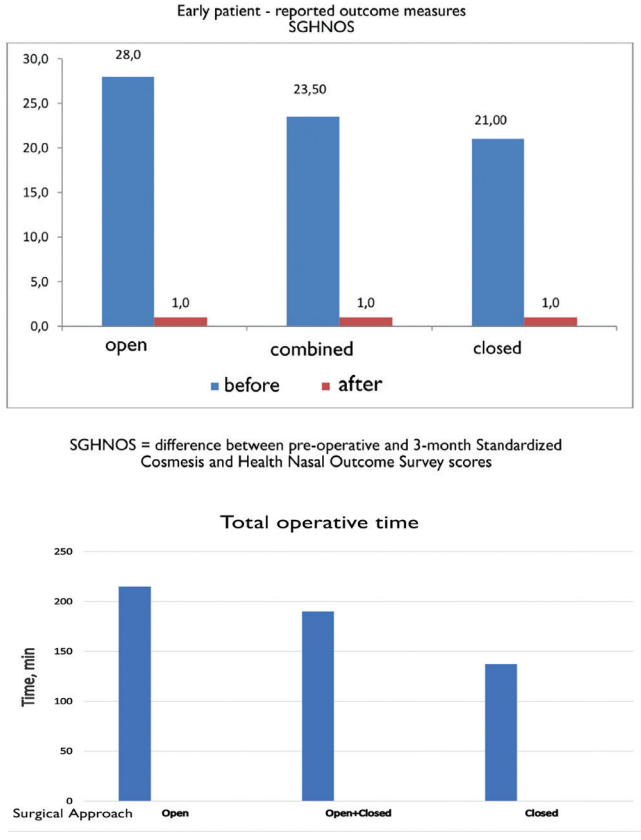


Figure 2. Graphical presentation of SCHNOS score changes.

SCHNOS: Standardized Cosmesis and Health Nasal Outcomes Survey

Comparison with a small subgroup of patients (n=6) who underwent reconstruction of a perforated cribriform plate using only autologous cartilage and bone grafts revealed comparable functional and aesthetic outcomes; however, operative times were longer in this group. The use of PDLLA eliminated donor-site morbidity, minimized the need for autologous graft harvesting, and reduced surgical duration.

Representative Clinical Cases

Case 1: Saddle-nose reconstruction (male, 28 years)

Primary open structural rhinoseptoplasty was performed for a severe post-traumatic L-strut collapse. The PDLLA matrix served as a rigid scaffold for septal reconstruction; no osteotomies were required. Two-year photographic follow-up confirmed restoration of dorsal height and mid-vault symmetry (Figure 3).

Case 2: Cleft-related revision deformity (male, 20 years)

Following two childhood rhinoplasties, the patient presented with caudal septal loss and cicatricial stenosis. A 4×1.5×0.2-cm costal cartilage graft was laminated onto the PDLLA plate to prevent warping. Both aesthetic and airway outcomes remained stable at 24-month follow-up (Figure 4).

Case 3: Post-traumatic septal buckle (female, 22 years)

A primary open procedure achieved septal realignment with PDLLA reinforcement. At 12 months, a minor contour refinement under local anesthesia was performed; excised tissue was submitted for histology (Figure 5).

Histopathology

Biopsies harvested at 12 and 24 months revealed:

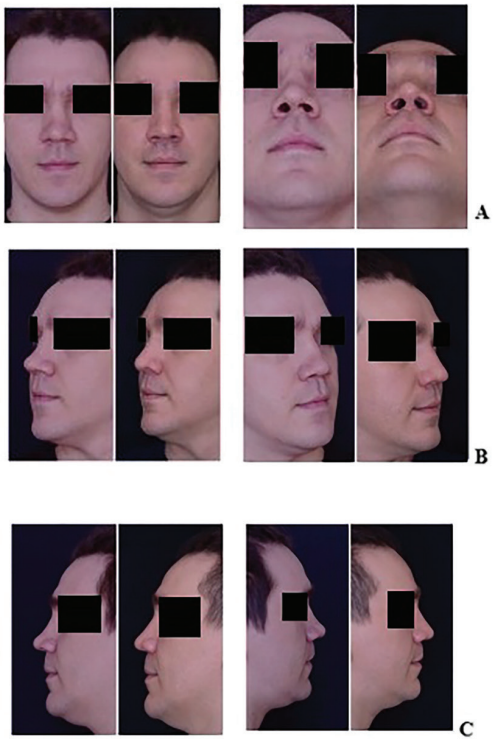
12 months: Intact plate silhouette demarcated by a thin fibrous capsule; sparse macrophages without foreign-body giant cells (Figure 6).

24 months: Complete material resorption; vacuolar footprints replaced by mature, collagenized connective tissue devoid of inflammatory infiltrate (Figure 7).

These findings corroborate the predictable two-phase degradation profile of PDLLA: initial structural retention (approximately 12 weeks), followed by gradual hydrolysis and uneventful incorporation.

DISCUSSION

The open rhinoplasty approach, while requiring extended operative time, demonstrates unparalleled efficacy in addressing complex post-traumatic corrections. In contrast, closed and combined techniques allow shorter operative times for less severe deformities (13-15). The consistent, statistically significant improvement in SCHNOS scores objectively validates the clinical utility of PDLLA reinforcement across different types of nasal surgery.



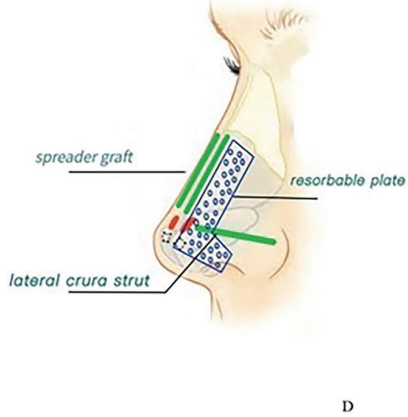


Figure 3. Preoperative and 2-year postoperative photographs of the patient: A – frontal view (at rest) and nasolabial angle view; B – three-quarter view (at rest); C – lateral view (at rest); D – a schematic illustration of the surgical technique.

The use of absorbable PDS foil facilitates this complex and technically demanding procedure. Septal cartilage fragments removed during surgery are sutured to an absorbable PDS foil, creating a stable free graft suitable for precise reimplantation into the nose. The foil stabilizes the cartilage fragments and provides essential structural support to the nasal dorsum during the initial healing phase while maintaining proper cartilaginous positioning. Subsequently, the foil is completely resorbed, thereby avoiding long-term complications associated with other synthetic implants. Numerous studies have confirmed the efficacy of polydioxanone in this application (16-20).

While polydioxanone foils have represented the historical standard for septal graft stabilization, market unavailability in the Russian Federation prompted clinicians to implement PDLLA as a functionally equivalent alternative, given its comparable

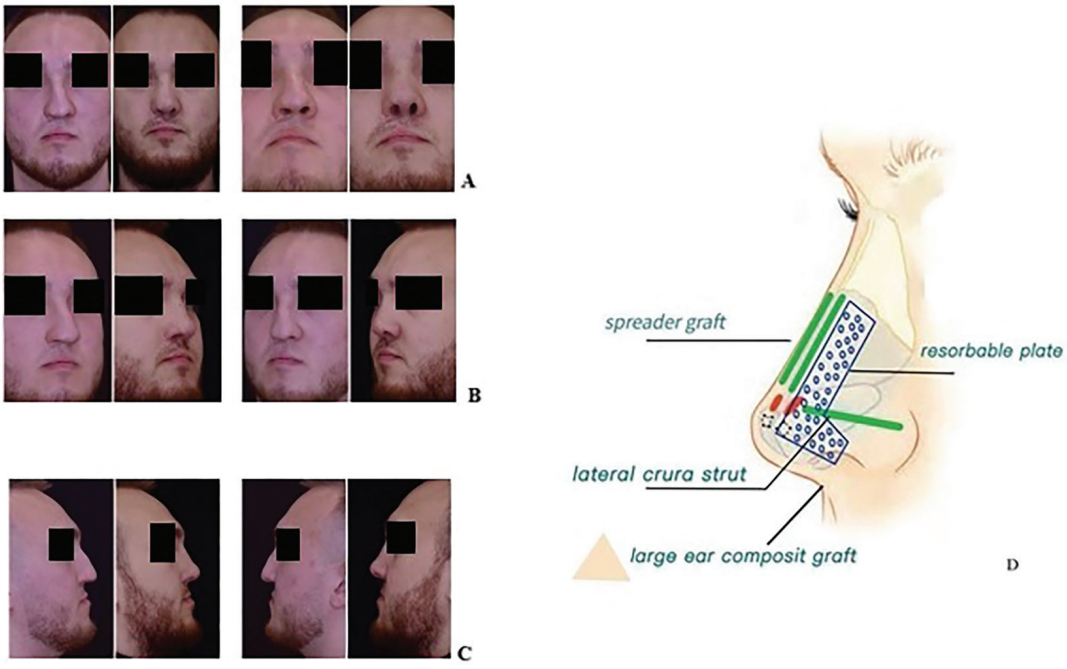


Figure 4. Preoperative and 2-year postoperative photographs of the patient: A – frontal view (at rest) and nasolabial angle view; B – three-quarter view (at rest); C – lateral view (at rest); D – a schematic illustration of the surgical technique.

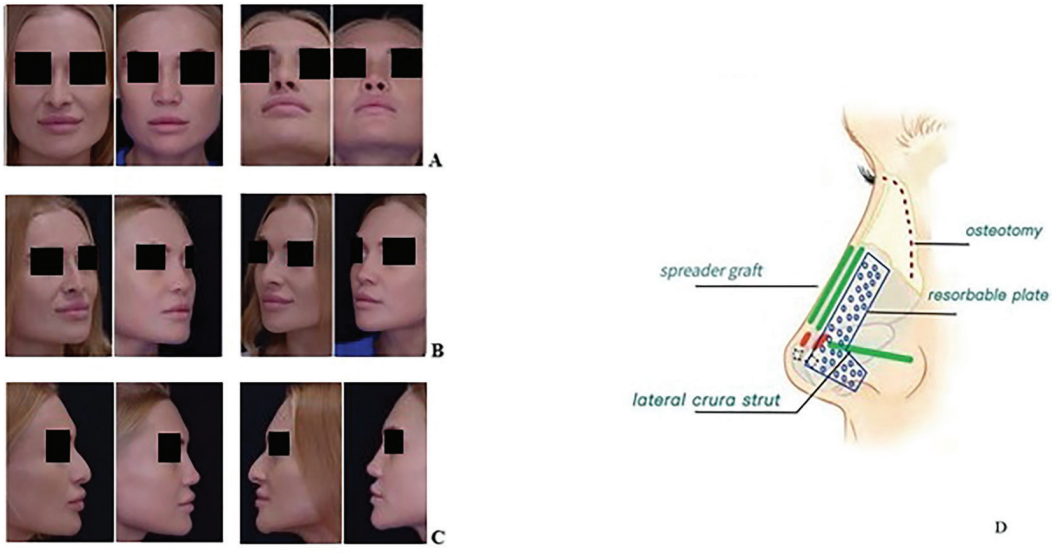


Figure 5. Preoperative and 2-year postoperative photographs of the patient: A – frontal view (at rest) and nasolabial angle view; B – three-quarter view (at rest); C – lateral view (at rest); D – a schematic illustration of the surgical technique.

biomechanical properties and a well-documented safety profile. *In vivo,* macrophage-mediated phagocytosis of degradation particles and subsequent collagen deposition ultimately result in the formation of a structurally competent fibrous neoseptum and the preservation of native cartilage integrity (21). The indications for PDLLA use included the limited availability of autologous cartilage and bone in cases of post-traumatic, congenital, or iatrogenic nasal deformities. In primary cases without cartilage deficiency, reconstruction was performed exclusively with autologous grafts. These selection criteria are described in detail to enhance the reproducibility of the study. Harvesting costal cartilage necessitates a second surgical site, entails donor-site morbidity, and prolongs operative time. The decision to use PDLLA was therefore guided by the aim of minimizing donor-site trauma, avoiding complications associated with rib cartilage harvest, and reducing overall surgical duration. PDLLA provides temporary structural rigidity sufficient to support tissue remodeling during the initial 12–24-week postoperative period and is subsequently fully resorbed.

The use of costal cartilage, while providing abundant graft material, necessitates a second surgical site, carries the risk of donor-site morbidity (e.g., pain, pneumothorax, contour deformities), and significantly prolongs operative time. In contrast, PDLLA offers temporary structural support during the critical early healing phase (approximately 12 weeks), after which it is fully resorbed without leaving a permanent implant. This approach eliminates donor-site complications and streamlines the surgical procedure, making it particularly advantageous for patients with adequate, albeit limited, septal or auricular cartilage.

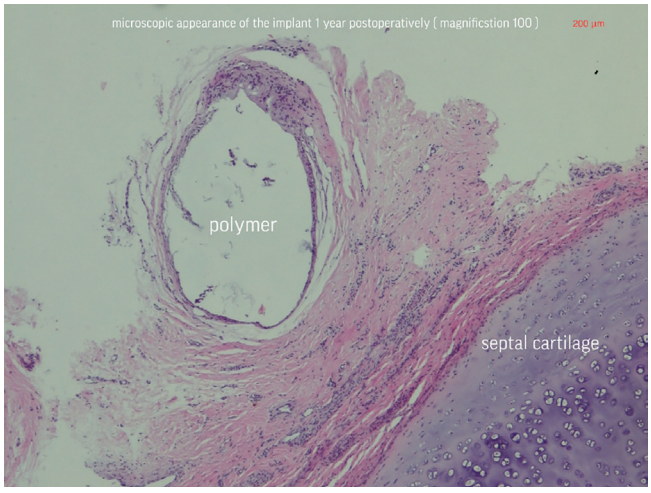


Figure 6. Microscopic appearance of the implant 1 year postoperatively (magnification ×100). Clear, round spaces correspond to the locations of implants. All implant sites are encapsulated. Inset (100x) shows a fibrous connective tissue capsule and mild inflammation (macrophages and a few multinucleated giant cells) within it. Scale bars, 200 µm.

This study introduces two principal innovations: 1) the pioneering use of PDLLA plates for correction of severe septal deviation in primary rhinoseptoplasty; and 2) the assessment of patients' satisfaction using a standardized questionnaire evaluating both functional and aesthetic outcomes, combined with systematic histological analyses performed at 12 and 24 months after polymer-augmented implantation. The study cohort included patients with various types of nasal deformities (congenital, traumatic, iatrogenic, and cleft-related). This heterogeneity in the patient population reflects real-world clinical practice; however, reduces sample homogeneity and may limit the precision of the analysis. Future studies should consider stratification by type of deformity and surgical approach.

Numerous studies have confirmed the biocompatibility of PDLLA-based polymers. Initially, these materials elicit only a minimal tissue response. As degradation progresses into the active phase, a controlled inflammatory response occurs, representing a normal physiological process whereby immune cells clear breakdown product. Macrophages are known to

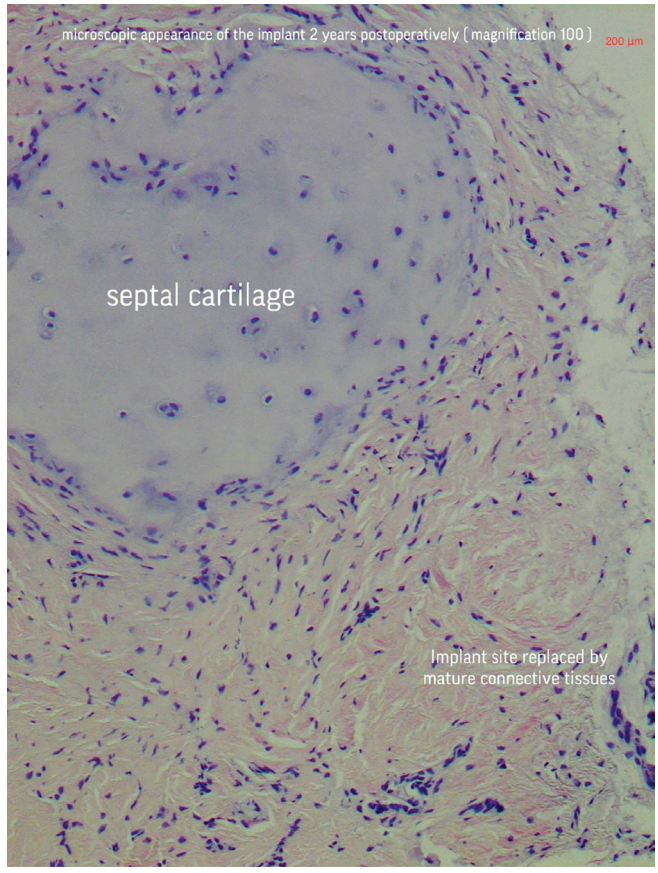


Figure 7. Microscopic appearance of the implant 2 years postoperatively (magnification ×100). A nodular solid site corresponds to the location of the implant. Scale bar: 200 µm. The implant site replaced by mature collagenized connective tissue devoid of inflammation and any evidence of degraded material (complete resolution of implant site).

play a significant role in phagocytosing polymer particles from the biodegradable implant. Concurrently with material resorption, progressive collagen deposition becomes evident at the implantation site. An ovine model study examining PDLLA copolymer implants along the nasal dorsum demonstrated: 1) excellent material tolerance, 2) ongoing volumetric reduction at 18 months, and 3) complete replacement by organized fibrous tissue by 24 months (11). Histopathological analysis revealed preserved cartilage architecture beneath the implant site, with only a defined layer of mature connective tissue forming at the cartilage-implant interface.

The research confirms that degradation byproducts of PDLLA polymers do not adversely affect cartilage or the human body.

Consequently, the integration of septal cartilage with a resorbable PDLLA polymer plate provides both technical advantages during surgery and postoperative benefits inherent to biodegradable materials.

Quantitative assessment of patient satisfaction demonstrates a statistically significant improvement in outcomes across all surgical techniques.

The follow-up period, with a median of twenty-four months, is sufficient to assess early and intermediate outcomes but does not reach the five-year threshold required to rule out late complications such as cartilage warping or contour relapse. Objective assessment was limited to single-pressure rhinomanometry, whereas more advanced techniques–computational fluid dynamics, formal olfactory testing, and blinded photographic analysis–were not carried out. Similarly, the SCHNOS instrument, although validated, is a subjective measure susceptible to respondent bias.

Heterogeneity in etiology and surgical approach was inevitable in routine clinical practice, as patients with congenital, traumatic, cleft-related, and iatrogenic deformities underwent open, closed, or combined approaches; however, such clinical diversity may obscure approach-specific nuances. Finally, the study evaluated only one PDLLA plate geometry from a single manufacturer, leaving open the question of whether alternative dimensions, molecular weights, or copolymer ratios would demonstrate comparable behavior *in vivo*.

Despite certain limitations, this study represents meaningful progress in rhinoseptoplasty. It advances biomaterials research by enabling translation from animal models to clinical application in humans. For the first time, it demonstrates that a PDLLA plate used in rhinoplasty degrades in two stages, is biocompatible, and provides sufficient mechanical strength for septal stabilization. By integrating this technique with the SCHNOS, the study establishes a correlation between material performance and patient satisfaction, thereby bridging materials science with current surgical methods.

The observed maintenance of septal alignment following polymer resorption suggests that stiffening it for twelve weeks is sufficient to support proper bone and cartilage remodeling. Serial biopsies at 12 and 24 months provide rare human evidence of complete polymer resorption and replacement with mature collagen, confirming hypotheses regarding PDLLA resorption in facial tissues.

These findings have direct clinical relevance. In the majority of cases, the PDLLA plate facilitated septal reconstruction; in selected cases, it reduced the need to harvest costal cartilage. This technique reduced donor-site morbidity and shortened the total operative time. The technique provides a valuable alternative in regions where polydioxanone foils remain unavailable, offering surgeons an additional tool for managing complex deformities. Since the fixation method is simple and reliable, use of the PDLLA plate in surgical practice can accelerate the learning process of young specialists and help them maintain consistent dorsal stability.

Preliminary calculations showed that the use of PDLLA plates in surgical practice will, on the one hand, reduce operative time and the need to harvest a transplant, and, on the other hand, decrease the need for revision procedures, making this surgical approach more cost-effective for the healthcare system.

Study Limitations

However, this retrospective study included results from only one hospital, had a limited sample of patients, and lacked a control group for comparison. Extensive studies in numerous health care facilities, with patient monitoring for at least 5 years and measurable airflow analysis, are required to demonstrate the advantages of this method over the conventional one using cartilage from the patient or polydioxanone foil. The sample size (37 patients) limits the ability to detect rare complications and establish statistically significant differences. Further multicenter trials with larger cohorts and long-term follow-up are required to confirm these findings. Additionally, the absence of a control group limits the ability to directly compare outcomes with those obtained using alternative techniques, such as autologous cartilage, PDS foil, or titanium mesh. This gap will be addressed in future randomized controlled trials that include control groups receiving autologous cartilage grafts.

This study employed only standard rhinomanometry at a fixed pressure. In subsequent research, we plan to incorporate additional objective assessment methods, including computational aerodynamics, airflow analysis, and validated olfactory testing.

CONCLUSION

This study provides the first clinical evidence that a perforated, fully bioresorbable PDLLA plate, when sutured to resected

septal cartilage fragments, can serve as a reliable and rigid-yet-temporary scaffold, providing mechanical stability for nasal dorsal aesthetic lines and maintaining physiologic nasal airflow during the critical early remodeling phase. In 37 consecutive patients, this method achieved the following:

- a median surgical duration of 137–215 minutes (depending on the surgical approach),

- a >90% reduction in SCHNOS scores at 3 months (median decrease from 24 (preoperatively) to 1 (postoperatively),

- no implant-related infections or extrusions over a median 24-month follow-up.

Serial histological analysis confirmed a predictable, two-stage hydrolytic degradation of the polymer: encapsulation at 12 months and complete replacement by collagenized connective tissue at 24 months, with no signs of chondrocyte damage or chronic inflammation. The results of the study demonstrated that 12 weeks of temporary support appear sufficient for intermediate-term stabilization; longer follow-up is warranted.

The clinical significance of this study consists of three points:

1. The first-in-human application of PDLLA plates for septal reconstruction,

2. Demonstration of a direct correlation between material performance and patient satisfaction (quantified via SCHNOS),

3. Histopathologic validation of tissue integration, corroborating prior preclinical data.

Future Research

Future research should progress beyond observational studies. A large, randomized, multicenter comparative trial with a 5-year follow-up evaluating PDLLA plates versus autologous cartilage, polydioxanone foils, and titanium meshes would demonstrate their efficacy, safety, and economic benefit. Further studies, such as high-resolution imaging and finite-element modeling, are clearly needed to elucidate the relationship between polymer degradation kinetics, dorsal contour preservation, and plate thickness optimization.

Future studies should focus on: (1) PDLLA materials that can release drugs or substances that promote bone or cartilage growth, (2) patient-specific 3D-printed plates for complicated cases of nasal septal perforation, (3) specialized hybrid copolymers for pediatric applications, and (4) cost-effectiveness analyses that incorporate quality-of-life metrics. These advancements would enhance material performance, expand surgical indications, and improve rhinoseptoplasty outcomes.

Additionally, focused research on revision rhinoplasty, cleft-related deformities, and ethnicity-specific nasal anatomy is needed to validate the efficacy of PDLLA plates across all septal reconstruction indications.

Video 1 Link: https://youtube.com/shorts/dZ4BWmwpU-w

Ethics

Ethics Committee Approval: This single-center retrospective analysis was approved by the Local Ethics Committee at the St. Petersburg State Pediatric Medical University (approval no: 32/06, dated: 08.11.2023).

Informed Consent: Retrospective study.

Footnotes

Author Contributions

Surgical and Medical Practices - A.M., N.K., P.P., M.D.; Concept - A.M., N.K., P.P.; Design - A.M., N.K., P.P.; Data Collection or Processing - A.M., M.D.; Analysis or Interpretation - A.M., N.K., P.P., M.D.; Literature Search - A.M., N.K., P.P., M.D.; Writing - A.M., N.K., P.P., M.D.

Conflict of Interest: No conflict of interest was declared by the authors.

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VIDEO ARTICLE
Turk J Surg 2026;42(1):140-141

Step-by-step single-port retroperitoneal right hemicolectomy with D3-lymph node dissection for right colon cancer

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ABSTRACT

Minimally invasive right hemicolectomy for colon cancer has demonstrated better outcomes than those of open surgery. However, in certain patients, high body mass index, abdominal adhesions, and concomitant cardiopulmonary disease may limit the use of conventional laparoscopy. The use of the retroperitoneal approach preserves the benefits of the minimally invasive approach and expands the range of surgical options. All major steps were performed without access to the abdominal cavity: mobilization, D3 lymph node dissection and vessels ligation. Supplementary video demonstrates a retroperitoneal approach for right hemicolectomy with D3 lymph node dissection that can solve these challenges.

Keywords: Cancer, colon, colorectal cancer, laparoscopic surgery, minimal invasive surgery, retroperitoneal approach

INTRODUCTION

Minimally invasive right hemicolectomy for colon cancer has demonstrated better outcomes than those of open surgery (1). However, in certain patients, high body mass index, abdominal adhesions, and concomitant cardiopulmonary disease may limit the use of conventional laparoscopy (2-4). All main steps were performed without access to the abdominal cavity: mobilization, D3 lymph node dissection and vessels ligation. Video 1 demonstrates a retroperitoneal approach for right hemicolectomy with D3 lymph node dissection that can solve these challenges.

A 65-year-old patient was diagnosed with adenocarcinoma of the ascending colon (cT3N1M0). The retroperitoneal approach was chosen because of a high body mass index of 32.8 kg/m^2. The first trocar was placed paraumbilically for abdominal exploration. After reviewing the abdominal cavity, the pneumoperitoneum was eliminated. An incision for the single-port system was made in the right flank, midway between the right costal arch and iliac spine. A single port was placed in the retroperitoneal space under optical guidance. The retroperitoneal step began with a lateral-to-medial dissection in the interfascial plane between Toldt's and Gerota's fasciae, using the right gonadal vessels and ureter (located posteriorly within this plane) as landmarks. The dissection continued towards the duodenum, and the mesocolic fascia was separated from the anterior pancreatic surface. The trunk of Henle was carefully dissected from the cranial portion of this region. The superior mesenteric vessels were accessed by incising the parietal fascia of the mesocolon.

The next step involved dissecting the intestinal branches of Henle's trunk. The origin of the middle colic vein and right gastroepiploic vein were clipped and cut. After identification, the right gastroepiploic artery was clipped and transected. The final step of the lymph node dissection involved incising the middle colic artery, with fatty tissue containing groups 203 and 223 lymph nodes (per the Japanese Society for Cancer of the Colon and Rectum). Interfascial dissection was performed to completely mobilize the right mesocolon. D3 lymph node dissection was performed.

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The peritoneum was incised in the right lateral canal to connect the retroperitoneal space with the abdominal cavity.

An additional 5 mm trocar was inserted for laparoscopy. Transabdominally, the right lateral canal was dissected cranially and caudally. Subsequently, the mesocolon was transected over the superior mesenteric vessels, starting at a defined location and proceeding towards the distal and proximal resection borders. The hepatocolic ligament was divided to mobilize the hepatic flexure. The bowel was removed from the abdominal cavity through the single-port. The hand-sewn anastomosis was performed extracorporeally. The blood loss was 10 mL, and the operative time was 300 min, with the retroperitoneal dissection lasting 170 min. A total of 34 lymph nodes were harvested, with one tumor deposit identified in the specimen. Histopathological examination confirmed an R0 resection, with all margins free of neoplastic involvement. The patient's recovery was uneventful. Bowel function resumed on day 4, and the length of hospital stay was 9 days. There were no readmissions or reoperations within 30 days.

This technique demonstrates the feasibility of using the retroperitoneal approach for right hemicolectomy. In selected patients, this approach may offer various advantages to the surgeons.

Video Link: https://youtu.be/TBbYY60083E

Ethics

Informed Consent: The authors are accountable for all aspects of the work, ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. The patient provided concent for publication of this report and any accompanying images.

Footnotes

Author Contributions

Concept - S.K.E.; Design - S.K.E.; Data Collection or Processing - P.D.P., Y.C.; Analysis or Interpretation - S.K.E., Y.P.K.; Literature Search - P.D.P, A.Y.K.; Writing - S.K.E., P.D.P., Y.P.K., A.Y.K., Y.C.

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VIDEO ARTICLE
Turk J Surg 2026;42(1):142-143

How I do it: Nerve-sparing laparoscopic low anterior resection: Step by step nerve identification and preservation

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ABSTRACT

Advances in surgical techniques, together with the widespread use of neoadjuvant and adjuvant therapies, have markedly improved disease-free and overall survival in patients with rectal cancer. Nevertheless, urogenital dysfunction remains a significant source of postoperative morbidity, primarily due to the anatomical location of the rectum and its close relationship with the autonomic pelvic nerves. Although the incidence of urological complications has declined to below 10%, sexual dysfunction continues to affect approximately one-quarter of patients. Nerve-sparing total mesorectal excision, performed without compromising oncological principles, has therefore become a critical component of contemporary rectal cancer surgery. Minimally invasive video-assisted techniques, offering magnified visualization and enhanced precision during pelvic dissection, facilitate the accurate identification and preservation of autonomic nerve structures. However, current evidence indicates that awareness and consistent application of nerve-sparing principles remain suboptimal, even among experienced colorectal surgeons. This video systematically demonstrates the key anatomical landmarks and stepwise surgical maneuvers required for effective nerve preservation during total mesorectal excision, aiming to reduce urogenital functional morbidity.

Keywords: Colorectal cancer, laparoscopic surgery, minimal invasive surgery, rectum

INTRODUCTION

Although total mesorectal excision with pelvic autonomic nerve preservation decreased the rates of urinary dysfunction (0-12%) and sexual dysfunction (10-35%) (1), an international survey of high-volume laparoscopic colorectal surgeons demonstrated limited awareness of nerve-sparing anatomy, with reported recognition rates of 81.2% for the hypogastric nerves, 43.5% for the inferior hypogastric plexus, 31.8% for urogenital branches, and only 12.9% for the pelvic splanchnic nerves (2-4). This video aims to systematically demonstrate the key anatomical landmarks and the stepwise surgical maneuvers required for nerve-sparing rectal surgery (Video 1).

CASE REPORT

A 61-year-old female patient was diagnosed with rectal adenocarcinoma. Pelvic magnetic resonance imaging showed minimal rectal wall thickening and no lymphadenopathy. There was no history of neoadjuvant chemotherapy or radiotherapy. The patient underwent a laparoscopic low anterior resection. In the postoperative period, no urogenital dysfunction was observed. The patient maintained normal urinary function and reported no impairment in sexual function during follow-up, indicating successful preservation of autonomic pelvic nerves. Written informed consent was obtained from the patient for publication of the clinical data and accompanying images.

Surgical Technique

Posterior pelvic dissection was initiated by separating the mesorectum from the pelvic autonomic nerves along the proper rectal fascia, with preservation of the hypogastric nerves along the pelvic sidewalls. During the deep posterior pelvic dissection, the lateral ligaments, which are densely adherent to the pelvic plexus, were identified and carefully dissected. In the anterior pelvic dissection, following

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incision of the peritoneum at the level of the peritoneal reflection, Denonvilliers' fascia was identified and the dissection was continued along this plane. The dissection was extended laterally along the seminal vesicles in male patients and along the vaginal wall in female patients. To minimize the risk of nerve and thermal injury during dissection of Denonvilliers' fascia, sharp dissection was preferred, and an energy device was required, low-energy settings were applied. Neurovascular bundles originating from the pelvic plexus course adjacent to the apical region of the seminal vesicles, typically at the 2 o'clock and 10 o'clock positions, before extending toward the urogenital organs. Anterolateral dissection is advanced until it meets the previously established posterolateral plane at the pelvic sidewall, allowing safe separation of the lateral mesorectal fascia from the pelvic plexus.

In conclusion, awareness of pelvic nerve anatomy and identification of anatomically at-risk areas for nerve injury will reduce postoperative urogenital complications and improve patients' quality of life.

Video Link: https://drive.google.com/file/d/18TWwGWQSzVIded3Jc1Dffpvn_02Y02be/view?usp=sharing

Ethics

Informed Consent: Written informed consent was obtained from the patient for publication of the clinical data and accompanying images.

Footnotes

Author Contributions

Concept - K.D.B., A.E.A., A.V., Ş.F.D., A.C., Ş.C.Y.; Design - K.D.B., A.E.A., A.V., Ş.F.D., A.C., Ş.C.Y.; Data Collection or Processing - K.D.B., A.E.A., A.V., Ş.F.D.; Analysis or Interpretation - K.D.B., A.E.A., A.V., Ş.F.D., A.C., Ş.C.Y.; Literature Search - K.D.B., A.E.A., A.V., Ş.F.D., A.C., Ş.C.Y.; Writing - K.D.B., A.E.A., A.V., Ş.F.D.

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CASE REPORT
Turk J Surg 2026;42(1):144-150

A case of early-onset ovarian cancer following bariatric surgery: Highlighting the need for caution in genetically predisposed obese patients

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ABSTRACT

High-grade serous ovarian cancer (HGSOC) is the most lethal gynecologic malignancy, typically affecting postmenopausal women. BRCA1 mutation carriers are at increased risk of developing early-onset disease. While bariatric surgery reduces the incidence of several obesity-related cancers, its potential impact on hormonally driven malignancies in genetically predisposed individuals remains unclear. We report a rare case of early-onset HGSOC in a 21-year-old woman with morbid obesity and type 2 diabetes who underwent Roux-en-Y gastric bypass in 2010. Following significant weight loss, she regained regular menstruation and discontinued insulin therapy. After progressive weight regain, she underwent revisional bariatric surgery in 2020. Three years later, she presented with an ovarian cyst and elevated tumor markers. Imaging suggested malignancy, and biopsy confirmed HGSOC with a BRCA1 mutation. The patient underwent optimal cytoreductive surgery followed by chemotherapy and commenced olaparib maintenance therapy. As of September 2024, she remains disease-free. This case raises the concern that bariatric surgery, by restoring ovulatory function and altering metabolic and hormonal balance, may unmask a latent susceptibility to cancer in genetically predisposed patients. The temporal association between metabolic surgery and early-onset ovarian cancer warrants further investigation into postoperative hormonal shifts and cancer surveillance strategies. Bariatric surgery in women with hereditary cancer syndromes should be approached with caution. Preoperative genetic counseling, multidisciplinary assessment, and long-term oncologic surveillance are essential to ensure patient safety.

Keywords: BRCA1 protein, ovarian neoplasm, bariatric surgery, obesity

INTRODUCTION

Ovarian cancer remains the most lethal gynecologic malignancy despite its relatively low incidence. Although breast cancer is typically diagnosed in postmenopausal women around age 63, carriers of BRCA1 mutations face a markedly increased lifetime risk and an onset approximately a decade earlier (1,2).

The "incessant" ovulation theory, proposed by Fathalla (3), remains central to ovarian carcinogenesis. Cumulative ovulatory exposure causes repeated epithelial microtrauma and DNA damage, which promote malignant transformation, whereas ovulation-suppressing factors such as pregnancy, lactation, or oral contraceptive use reduce ovarian cancer risk. Alongside ovulatory mechanisms, hereditary predisposition, particularly BRCA1/2-associated homologous recombination deficiency, plays a major etiologic role (4).

Although obesity increases the risk of several hormone-related cancers, bariatric surgery typically reduces overall and obesity-associated cancer incidence (5,6). Previous studies have rarely distinguished hormonally-driven tumors by menopausal status, receptor subtype, or hereditary syndromes, leaving uncertainty for genetically predisposed young women.

To our knowledge, no published case has described early-onset high-grade serous ovarian cancer (HGSOC) after bariatric surgery in a BRCA1 mutation carrier, despite literature supporting the key components of this clinical intersection: ovulation-based oncogenesis (5,7), metabolic and hormonal shifts after bariatric surgery,

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and BRCA-driven susceptibility. We report a rare case of early-onset HGSOC in a young BRCA1-mutated woman after bariatric surgery, suggesting an interplay between genetic vulnerability and postoperative metabolic and reproductive recovery. Table 1 summarizes relevant evidence and highlights this gap.

This case report follows the updated SCARE 2023 guidelines (8). Institutional Review Board approval (no. 2501-112-1608) and written informed consent were obtained.

CASE REPORT

In June 2010, a 21-year-old female with severe obesity and uncontrolled diabetes was referred for bariatric surgery. She was 153 cm tall, weighed 103.6 kg [body mass index (BMI) 44.3], and had been on insulin since her diagnosis with Type 2 diabetes mellitus at age 13.

She began menstruating at age 11, but by 17, her cycles became irregular. An evaluation for suspected polycystic ovary syndrome

Table 1. Comparative literature table: Mechanistic and clinical evidence linking metabolic restoration, ovulation, and cancer risk

Mechanistic domain	Study	Key findings	Relevance to current case
Ovulation-based ovarian carcinogenesis	Fathalla MF. 1971, Lancet (3)	The "incessant ovulation" hypothesis proposes that repeated rupture and repair of the ovarian epithelium cause cumulative DNA damage, increasing cancer risk in women with frequent ovulation.	Suggests that postoperative resumption of ovulation after rapid weight loss may re-expose the ovary to repetitive injury and oxidative stress, heightening malignant potential.
	Karst AM and Drapkin R. 2010, J Oncol (4)	A review of evolving models shows that high-grade serous carcinoma often originates from the fallopian tube fimbria. BRCA1 and BRCA2 mutations impair DNA repair, amplifying ovulatory injury.	Links BRCA1-related repair deficiency with ovulatory microtrauma, creating synergistic genomic instability after ovulation resumes.
Ovulatory recovery after bariatric surgery	Samarasinghe SNS et al., 2024, Lancet (5)	The BAMBINI randomized trial showed that bariatric surgery in women with polycystic ovary syndrome increased spontaneous ovulation more than twofold compared with medical therapy and produced concurrent metabolic improvement.	Demonstrates that bariatric surgery restores ovulatory cycles and hormonal activity, potentially reactivating ovulation-related carcinogenic stress in high-risk patients.
	Phan A et al., 2022, Ann Endocrinol (7)	A review showed improved fertility and menstrual regularity after bariatric surgery; however, rapid metabolic changes may transiently reduce ovarian reserve.	This suggests that metabolic recovery reactivates reproductive function, which—while beneficial for fertility—may increase ovulatory exposure in genetically predisposed women.
Bariatric surgery and overall cancer incidence	Wilson RB et al., 2023, Int J Mol Sci (9)	A meta-analysis of >500,000 patients found that bariatric surgery reduces overall and obesity-related cancer incidence but lacked subgroup analyses by sex, menopausal status, or hereditary factors.	This supports a general protective effect but reveals a methodological gap—genetic and hormonal subgroups (e.g., BRCA1 carriers) were not separately analyzed.
	Lim PW et al., 2024, JAMA Surg (6)	Review of longitudinal studies showing reduced risk of breast, endometrial, and ovarian cancer after bariatric surgery, though most studies exclude BRCA carriers and hormone receptor stratification.	Highlights that the protective effect of surgery may not extend to genetically predisposed women; metabolic restoration might unmask latent oncogenic susceptibility.
Paradoxical or heterogeneous effects in hormone-dependent cancers	Frederick A-L et al., 2021, Int J Epigenetics (10)	Obesity increases the risk of postmenopausal breast cancer but decreases the risk of premenopausal breast cancer by epigenetic modulation of estrogen- and progesterone-receptor signaling.	Indicates that obesity's effects on hormone-dependent cancers vary by hormonal status; weight loss may reverse premenopausal protection.
	Atoum MF et al., 2020, Breast Cancer – Basic Clin Res (11)	A review of more than 2.5 million women found that higher body mass index reduces premenopausal breast cancer risk (approximately 8% per 5 kg/m^2 increase) via reduced ovulatory estrogen exposure.	Suggests obesity suppresses ovulatory estrogen activity; recovery of ovulation after surgery may increase susceptibility to hormone-dependent cancers.
	Kim et al., 2018, Int J Epidemiol (12)	Prospective study of BRCA1/2 carriers: higher body mass index at age 18 associated with lower postmenopausal breast cancer risk.	Early-life adiposity may confer transient protection. Metabolic normalization following bariatric surgery could unmask genetic vulnerability.

(PCOS) revealed normal ovarian ultrasound findings but low progesterone levels. She began progesterone therapy in 2007; however, due to poor compliance, she experienced amenorrhea for over six years between ages 17 and 22.

After undergoing laparoscopic Roux-en-Y gastric bypass in 2010, her BMI decreased to 34.9, and insulin therapy was discontinued within one year postoperatively. Along with postoperative weight loss, her regular ovulatory cycles resumed, and she maintained regular menstrual cycles with more than ten cycles per year for several years.

However, her weight gradually increased, and insulin therapy was reinitiated one year postoperatively. Ten years later, in 2020, her weight reached 114 kg (BMI 48.7), and higher insulin doses were required than before surgery.

An upper gastrointestinal series revealed fundal dilatation (Figure 1). Due to concerns about cancer risk in the remnant stomach and the patient's strong request, a revisional resection of the dilated fundus and remnant stomach was performed, reducing BMI to 33.5. Postoperative trends in weight and HbA1c are shown in Figure 2.

In 2019, she was diagnosed with endometrial hyperplasia without atypia, and a levonorgestrel-releasing intrauterine device was inserted. Testing for Prader-Willi syndrome was negative. In 2023, an ultrasound revealed endometrial thickening, a 2-cm left ovarian cyst, and elevated tumor markers, prompting further evaluation. CT scans from 2021 and 2022 showed no significant findings, but computed tomography (CT) and positron emission tomography-CT scans performed in September 2023 revealed peritoneal seeding and nodal metastases (Figure 3).

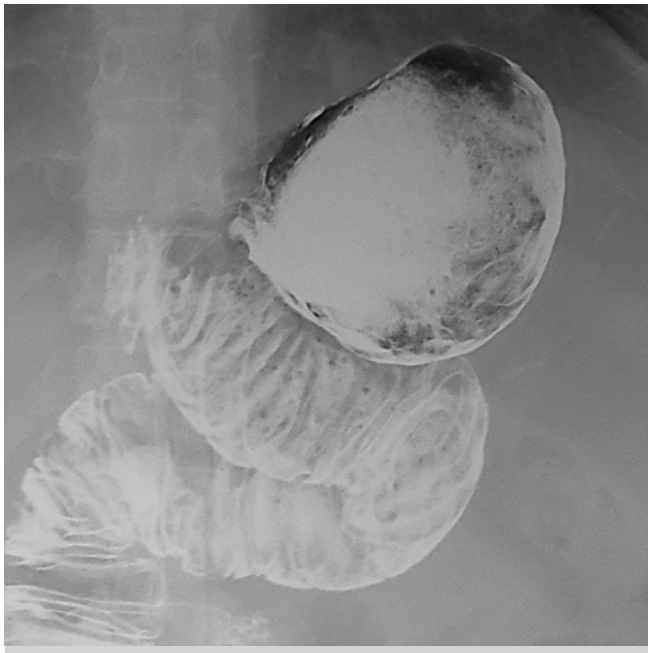

Figure 1. Upper gastrointestinal series after primary bariatric surgery.

A contrast study demonstrated fundal dilatation of the remnant stomach following laparoscopic Roux-en-Y gastric bypass, which prompted revisional resection of the dilated fundus and remnant stomach.

The patient underwent left salpingo-oophorectomy and excision of a pelvic mass; biopsy confirmed HGSOC. In December 2023, she underwent complete cytoreductive surgery followed by six cycles of paclitaxel–carboplatin chemotherapy. Genetic testing confirmed a BRCA1 mutation, and she began olaparib maintenance therapy.

At the time of ovarian cancer diagnosis in September 2023, serum tumor markers were markedly elevated (CA-125: 8,451 U/mL, CA19-9: 35.2 U/mL, CA15-3: 57.6 U/mL, HE4: 365 pmol/L). Pathological examination of the left ovary and fallopian tube revealed HGSOC mainly involving the para-ovarian soft tissue

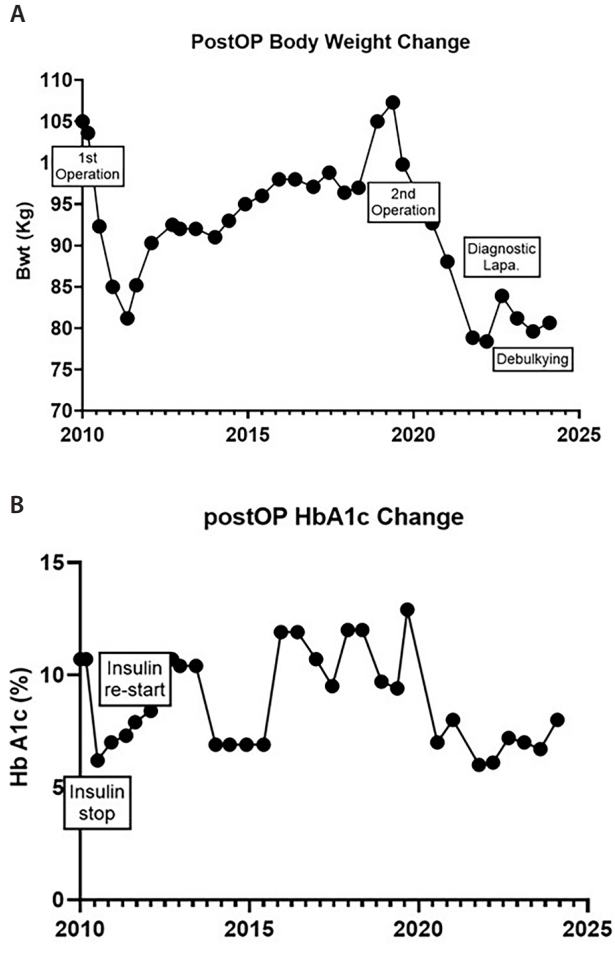

Figure 2. Postoperative metabolic trends. A) Body weight (kg), B) Glycemic control (HbA1c, %)

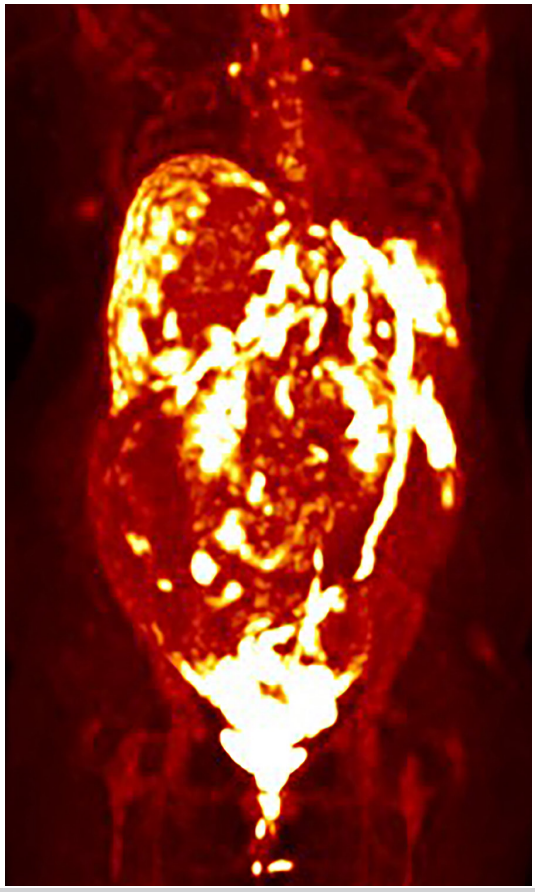

Figure 3. PET-CT at the time of ovarian cancer diagnosis.

Whole-body FDG PET-CT shows hypermetabolic peritoneal implants and multi-station nodal metastases (including cardiophrenic and abdominal chains), findings compatible with metastatic high-grade serous ovarian carcinoma at presentation.

PET-CT: Positron emission tomography-computed tomograhpy, FDG: Fludeoxyglucose

and mesosalpinx, with capsular rupture and surface involvement. The excised bladder mass also showed involvement by carcinoma. Immunohistochemical staining demonstrated p53 overexpression, WT1 positivity, and PAX8 positivity, confirming the diagnosis of HGSOC. The disease was classified as International Federation of Obstetrics and Gynaecology stage IVB, and no macroscopic residual disease was observed after complete cytoreductive surgery.

The patient completed six cycles of paclitaxel-carboplatin chemotherapy followed by maintenance olaparib, achieving normalization of CA-125 and HE4 levels by mid-2024. As of September 2024, she remains disease-free. No known family history of malignancy was identified.

The chronological sequence of metabolic, reproductive, and oncologic events is summarized in Figure 4.

DISCUSSION

Ovarian cancer developing after bariatric surgery is rare, as weight loss typically reduces the risk of malignancy (6,9). This case highlights a possible interaction among metabolic recovery, ovulatory restoration, and genetic susceptibility. While plausible, it remains hypothesis-generating rather than causal, since many BRCA1 carriers develop ovarian cancer independently of metabolic factors. This case serves as an example of mechanistic convergence rather than proof of causality.

Obesity, Weight Loss, and Cancer Risk

Obesity is an established risk factor for several cancers, particularly endometrial and postmenopausal breast cancer, due to hyperestrogenism, low-grade inflammation, and insulin resistance. Bariatric surgery reduces overall and obesity-related malignancy incidence by normalizing metabolic and hormonal

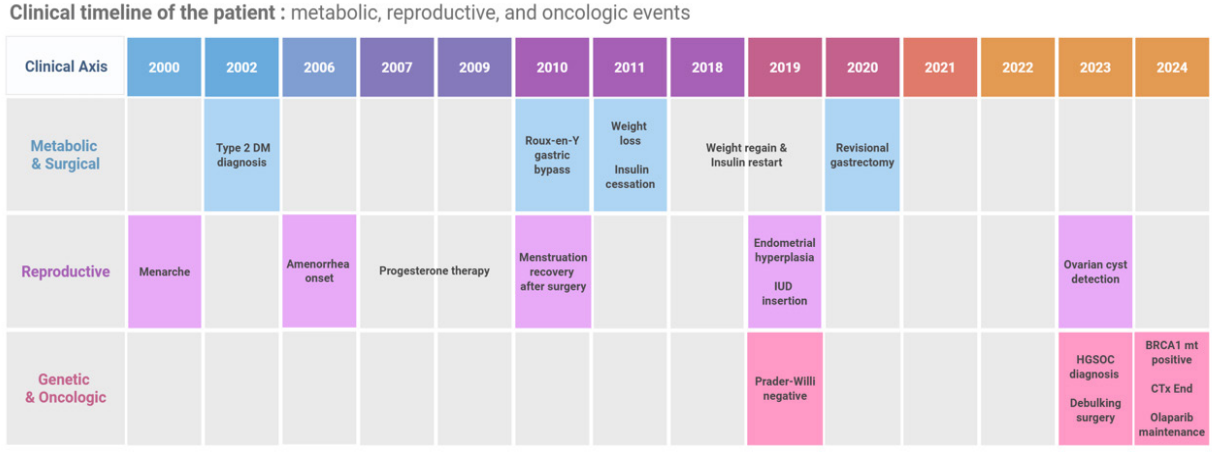

Figure 4. Clinical timeline of metabolic, reproductive, and oncologic events.

The patient's clinical course illustrates the interplay between metabolic recovery, restoration of ovulatory cycles, and subsequent ovarian carcinogenesis in a BRCA1-positive carrier. The timeline highlights key interventions, including two bariatric surgeries (2010 and 2020), hormonal changes, endometrial hyperplasia, and the eventual diagnosis and treatment of high-grade serous ovarian carcinoma in 2023.

parameters. However, most large-scale meta-analyses have not stratified patients by sex, menopausal status, or hereditary cancer risk, limiting their relevance to hormonally driven subgroups (6,9). In contrast, studies on hormone-dependent malignancies, such as breast and endometrial cancers, reveal a paradoxical relationship with obesity (10-12). While obesity increases cancer risk after menopause, it appears to have an inverse association with premenopausal breast cancer, possibly due to hypothalamic-pituitary feedback that suppresses gonadotropin secretion and reduces ovulatory estrogen exposure. Weight loss may thus reverse this protective state and reactivate ovulation, potentially heightening susceptibility in BRCA1 carriers.

Ovulation and Ovarian Carcinogenesis

According to the "incessant ovulation" hypothesis proposed by Fathalla (3), repeated ovulatory rupture and repair of the ovarian epithelium cause microtrauma and reactive oxygen species (ROS)–induced DNA damage, promoting genomic instability (4). BRCA1 mutations exacerbate this by impairing homologous recombination (2). Thus, in genetically predisposed women, continuous ovulation can serve as a facilitating, rather than an initiating, factor in carcinogenesis, synergistically increasing the likelihood of malignant transformation.

Ovulatory Recovery After Bariatric Surgery: Distinct Dynamics

In this case, postoperative weight loss restored regular ovulatory cycles, indicating normalization of endocrine function. However, the mechanism of ovulation recovery after bariatric surgery differs from the mechanism after gradual lifestyle modification in PCOS (5,7). Lifestyle-induced weight reduction restores ovulation slowly by improving insulin sensitivity and androgen balance, whereas bariatric surgery induces abrupt metabolic and hormonal shifts that transiently elevate oxidative metabolism. This may transiently elevate ROS and inflammatory signaling and, in BRCA1-deficient cells, promote carcinogenic changes (2,13).

Oxidative Stress and Long-Term Interval

During the early postoperative period, reduced oral intake and rapid weight loss, accompanied by enhanced fatty acid oxidation, are presumed to cause a transient increase in oxidative stress. Although the initial condition was self-limiting, our patient developed HGSOC over a decade later, suggesting that chronic ovulatory exposure and BRCA1 repair deficiency dominated the late transformation. Early oxidative stress may have served as an initiating promoter of low-grade genomic instability (14). Mechanistically, this process may involve activation of the PI3K/Akt signaling pathway, which has been implicated in ROS-mediated carcinogenesis and BRCA1 dysfunction (15). The Hypothesis regarding the interaction between ROS, BRCA1 mutation, and the PI3K/Akt1 pathway is illustrated in Figure 5.

Genetic Predisposition and Preventive Implications

In this patient, the BRCA1 mutation was identified only after the diagnosis of HGSOC, making preoperative preventive interventions impossible. Nevertheless, this case underscores the importance of identifying hereditary cancer susceptibility before bariatric or other metabolic surgeries. For women with known BRCA mutations, the primary determinant of ovarian cancer risk remains genetic predisposition rather than metabolic factors. Current guidelines recommend risk-reducing bilateral salpingo-oophorectomy after completion of childbearing, typically between the ages of 35 and 40. Until then, suppression of ovulation with oral contraceptives is recommended. However, in women who have undergone bariatric surgery, the absorption and efficacy of oral hormonal agents may be unpredictable due to altered gastrointestinal anatomy. Therefore, alternative preventive approaches, such as non-oral hormonal contraception (e.g., levonorgestrel intrauterine system), should be considered.

The potential risk-benefit balance must be carefully evaluated with individualized counseling. Preoperative genetic testing and multidisciplinary planning can optimize surgical timing, hormonal management, and surveillance strategies, particularly in women at increased hereditary risk for gynecologic malignancy.

This case underscores the need for heightened vigilance when performing bariatric surgery on women with potential hereditary cancer susceptibility, such as BRCA1 mutations. Although bariatric surgery offers metabolic benefits, its interaction with ovulatory recovery and DNA repair defects may modify its protective effects.

Preoperative genetic evaluation should be considered in young women with a family history of metabolic disease or with early-onset metabolic disease. For confirmed BRCA carriers, multidisciplinary counseling should guide surgical timing, fertility, hormonal planning, and surveillance planning. In such patients, ovulation suppression using non-oral hormonal options may serve as a temporary preventive measure until risk-reducing bilateral salpingo-oophorectomy is undertaken.

Ultimately, this case highlights the importance of individualized risk-benefit assessment and long-term follow-up after bariatric surgery, integrating metabolic, reproductive, and genetic perspectives to ensure both oncologic safety and metabolic success.

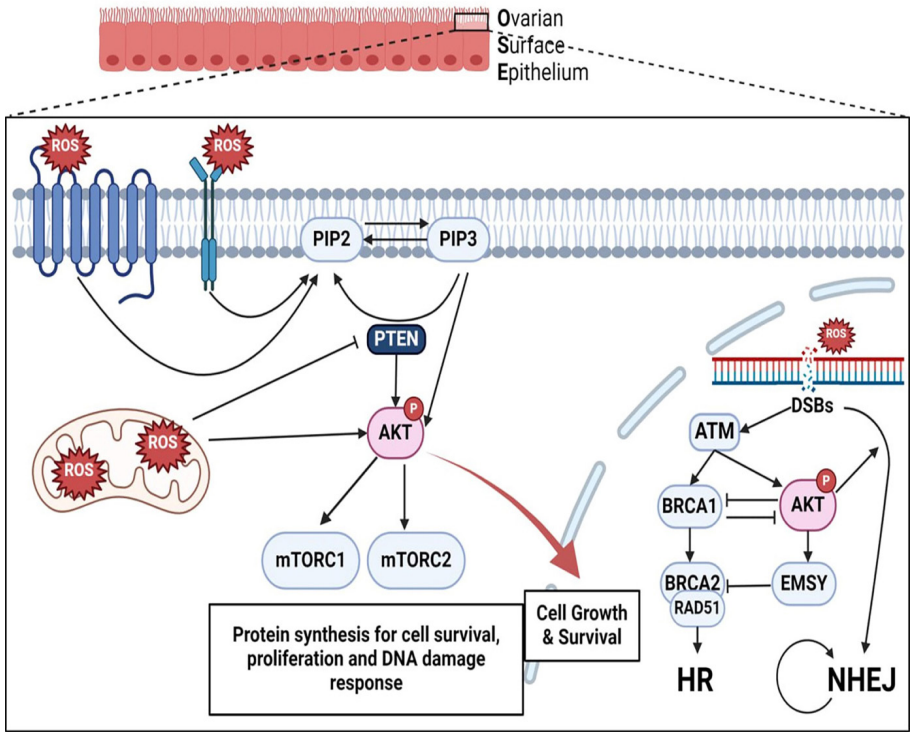

Figure 5. Hypothetical mechanism linking postoperative oxidative stress, BRCA1 deficiency, and PI3K/Akt signaling pathway in ovarian carcinogenesis.

This schematic was created by the authors using BioRender.com and constitutes an original conceptual illustration synthesizing previously published literature.

Hypothesis: ROS, BRCA1 mutation, and PI3K/Akt1 pathway interactions.

ROS directly activates PI3K, which in turn activates AKT. Activated AKT promotes cell survival by inhibiting pro-apoptotic factors and further sustains proliferation through the mTOR pathway. Additionally, ROS can induce double-strand DNA breaks. DNA damage activates ATM, initiating homologous recombination (HR) repair through the BRCA1-BRCA2/RAD51 pathway. HR deficiency caused by BRCA mutations forces tumor cells to rely on alternative error-prone repair mechanisms such as non-homologous end joining (NHEJ), leading to genomic instability and carcinogenesis.

OSE: Ovarian surface epithelium, GPCR: G protein-coupled receptor, RTK: Receptor tyrosine kinase, ROS: Reactive oxygen species, PIP2: Phosphatidylinositol-4,5-bisphosphate, PIP3: Phosphatidylinositol-3,4,5-trisphosphate, PTEN: Phosphatase and tensin homolog, AKT: Protein kinase B, mTORC: Mammalian target of rapamycin complex, DSB: Double-strand break, ATM: Ataxia telangiectasia mutated, BRCA: Breast cancer gene, RAD: Radiation-sensitive protein, EMSY: BRCA2-associated protein, HR: Homologous recombination, NHEJ: Non-homologous end joining

Ethics

Informed Consent: Written consent obtained from the patient.

Footnotes

Author Contributions

Concept - K.P., H.S.K., Y.M.C., C.H.S., H-J.L.; Design - K.P., H.S.K., Y.M.C., C.H.S., H-J.L.; Data Collection or Processing - K.P., J.C.K., S-H.K., J.K.; Analysis or Interpretation - K.P.; Literature Search - K.P., H-J.L.; Writing - K.P., J.C.K., S-H.K., J.K., H.S.K., Y.M.C., C.H.S., H-J.L.

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CASE REPORT
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Delayed diagnosis of isolated common bile duct injury in an infant: Efficacy of transcystic duct catheter in staged surgical management

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ABSTRACT

Isolated common bile duct (CBD) injuries following blunt abdominal trauma are exceptionally rare in infants and often present a diagnostic challenge. Due to the retroperitoneal location of the CBD and the potentially mild peritoneal response to bile leakage, early symptoms may be subtle or absent. As a result, diagnosis is frequently delayed. We present a case of a 2-year-old child who was diagnosed on the 14th day after blunt trauma caused by a falling television unit. Imaging and surgical findings confirmed an isolated CBD injury. The patient was treated with the two-stage surgical approach using transcystic duct catheter drainage followed by delayed reconstruction. The initial procedure involved damage control surgery, including biliary drainage via a transcystic duct catheter and thorough peritoneal irrigation. Four months later, the definitive reconstruction was performed with a Roux-en-Y hepaticojejunostomy. This case emphasizes that isolated CBD injuries, though rare in infants, can follow blunt abdominal trauma and may present with delayed symptoms due to bile's low peritoneal irritancy. This case underscores the rarity and novelty of the transcystic duct catheter approach when managing bile leakage in an infant prior to definitive surgical reconstruction.

Keywords: Excision, gastrointestinal surgery, laparotomy

INTRODUCTION

Isolated injuries of the common bile duct (CBD) following blunt abdominal trauma are exceedingly rare in the pediatric population, especially among infants. The retroperitoneal location and the protective anatomical position of the CBD reduce its susceptibility to direct injury. When such injuries do occur, they are typically associated with concomitant damage to adjacent structures such as the liver, gallbladder, or duodenum. Furthermore, bile leakage into the peritoneal cavity may not provoke a strong inflammatory response in infants, potentially masking clinical signs and delaying diagnosis. This subtle presentation underscores the difficulty in early recognition of extrahepatic biliary tract injuries in young children. Prompt identification of bile duct injuries is essential to prevent serious complications, including biliary peritonitis, sepsis, and long-term stricture formation. However, in the setting of non-specific symptoms or minor liver trauma, isolated CBD injuries may go unrecognized until significant clinical deterioration occurs (1-3).

We report a rare case of an isolated CBD injury in a 2-year-old girl following blunt abdominal trauma from a falling television unit. The delay in diagnosis was attributed to the initially unremarkable imaging findings and the absence of peritoneal signs. The patient was successfully treated using a two-stage surgical approach, in which a transcystic duct catheter provided effective external biliary drainage until definitive reconstruction could be performed under optimal conditions.

CASE REPORT

A 2-year-old girl was admitted to a medical center in her hometown with blunt abdominal trauma sustained after being struck by a falling television unit. The patient was reported to be hemodynamically stable at the initial presentation. The physical examination was within normal limits, and laboratory investigations were

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unremarkable except for moderate elevations in liver enzymes. Abdominal computed tomography (CT) demonstrated preserved solid organ integrity and no evidence of free intra-abdominal fluid. Subsequently, the patient was discharged on the second day based on the decline in liver enzyme levels and the absence of further clinical findings.

The patient was readmitted with complaints of vomiting after three days. A repeat CT scan revealed new free intraperitoneal fluid. Liver function tests worsened, bilirubin levels were elevated, and hemoglobin levels decreased. Progressive deterioration in the patient's clinical condition necessitated transfer to another center. Right upper-quadrant tenderness, acholic stools, and fever were documented in the medical record. Complaints developed after the resumption of oral feeding. Magnetic resonance cholangiopancreatography (MRCP) performed seven days after her transfer demonstrated a 2×1 cm preportal cystic lesion, located near the porta hepatis and ductal cutoff sign (Figure 1A, B). A bile duct injury was diagnosed fourteen days after the trauma.

The patient was subsequently referred to our institution. An exploratory laparotomy was performed, revealing bile staining throughout the peritoneal cavity, including the mesentery, omentum, and porta hepatis. During exploration, a choledochal injury with bilious leakage was identified in the distal portion of the hepatobiliary ligament. An external transcystic biliary drainage catheter was placed via the cystic duct into the CBD. The peritoneal cavity was thoroughly irrigated, and drains were placed to ensure adequate drainage. Postoperative recovery was uneventful. Four months later, definitive biliary reconstruction was performed via a Roux-en-Y portoenterostomy. The transcystic duct catheter, which had been used as a guide, was removed intraoperatively. An anastomosis was constructed between the proximal bile duct near the liver and the dilated common hepatic duct (Figure 1C, D). The patient resumed oral intake on postoperative day 7 and was discharged in good condition. At follow-up, laboratory parameters remained within normal limits. Serial imaging studies, including abdominal ultrasound and MRCP, revealed no abnormalities. The patient has remained asymptomatic and healthy for the past four years.

DISCUSSION

Isolated extrahepatic bile duct injuries are exceedingly rare in infants. These injuries typically result from high-energy blunt trauma and are often accompanied by damage to other intra-abdominal organs. Due to the anatomical protection provided by the liver and gallbladder, the CBD is relatively shielded, making isolated injuries particularly uncommon. In our case, the CBD injury occurred in isolation, without solid-organ damage, and with an initially unremarkable abdominal CT scan. The absence of free intraperitoneal fluid and non-specific early findings contributed to a delay in diagnosis. While most reported pediatric cases of extrahepatic biliary injury involve gallbladder rupture (2), our patient had an intact gallbladder and no obvious intra-abdominal fluid was detected during the initial assessment. Liver enzyme levels normalized rapidly during the early period. However, symptoms such as vomiting and fever developed only after oral feeding was reintroduced. This clinical course, marked by early normalization of transaminases followed by a delayed rise in bilirubin, indicates that bile duct injury in infants may not cause significant hepatocellular damage during the initial post-traumatic phase. MRCP in our patient demonstrated a cystic lesion near the hepatic hilum, despite an intact gallbladder, which likely represented a localized bile collection secondary to transection of the CBD. Similar imaging features—such as the "ductal cutoff sign" or abrupt termination of bile duct continuity—have been reported in the literature as indirect indicators of bile duct injury (4-7). In our case, the cystic configuration likely resulted from bile extravasation tracking either along the hepatoduodenal ligament or into the lesser sac via the foramen of Winslow. Recognizing such subtle imaging clues in the appropriate clinical context is critical for diagnosis.

A distinctive feature of this case was the successful placement of a 4-Fr transcystic duct catheter for external biliary drainage, which significantly contributed to the patient's clinical stabilization. To

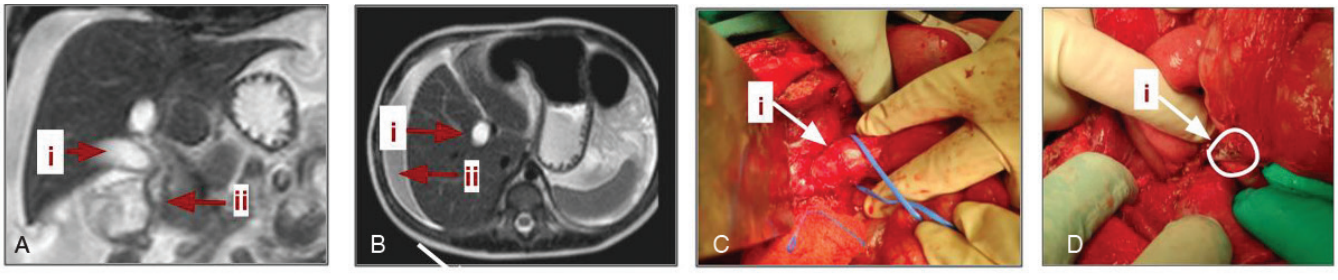

Figure 1A-D. A) Intact gallbladder, ii: ductal cut-off sign on MRI, B) Preportal cystic lesion located near the porta hepatis, ii: bile collection on MRI, C) Dilated extrahepatic biliary ducts, D) Roux-en-Y hepaticojejunostomy and the orifice of the transcystic duct catheter.

MRI: Magnetic resonance imaging

the best of our knowledge, transcystic catheter placement has been described in a limited number of adult cases; this is the first reported instance in the infant population in which such an approach was successfully used for prolonged external drainage following complete transection of the CBD (8-10). In our case, the transcystic catheter provided a minimally invasive and well-tolerated method for temporary biliary drainage. It remained functional for four months, allowing local inflammation to resolve, biliary continuity to be assessed, and definitive reconstruction to be planned under optimal conditions.

CONCLUSION

This case highlights the diagnostic challenges of isolated extrahepatic bile duct injury in infants following blunt abdominal trauma. The absence of free intraperitoneal fluid on initial imaging and the lack of peritoneal signs contributed to a delayed diagnosis. Vomiting was the predominant clinical symptom, which may reflect the lower irritant effect of bile in infants than in older children or adults. A notable radiologic finding was the accumulation of bile within the foramen of Winslow, seen as a localized cystic area near the hepatic hilum on MRCP. This may serve as an indirect indicator of CBD disruption, particularly in the absence of gallbladder injury. Use of a temporary transcystic duct catheter provided safe and effective external biliary drainage. It enabled clinical stabilization, minimized intra-abdominal bile accumulation, and allowed for delayed definitive reconstruction under optimal surgical conditions.

Ethics

Informed Consent: Written informed consent was obtained from the patient's parents. The patient's identity has been protected, and no identifying information is included in this report.

Footnotes

Author Contributions

Concept - M.A., T.K.; Design - M.A., T.K.; Data Collection or Processing - M.A., T.K.; Analysis or Interpretation - M.A.; Literature Search - M.A., D.T.; Writing - M.A., D.T.

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