Management of iatrogenic injuries due to endoscopic sphincterotomy: Surgical or conservative approaches

Özgür Bostancı¹, Muhammet Battal¹, Pınar Yazıcı¹, Uygar Demir¹, Canan Alkım²

ABSTRACT

Objective: The best therapeutic approach for endoscopic retrograde cholangiopancreatography-related perforations remains controversial; while some authors suggest routine conservative management, others advocate mandatory surgical exploration. We aimed to evaluate our clinical experience of perforations during endoscopic sphincterotomy.

Material and Methods: A retrospective chart review from January 2010 to October 2015 identified 20 patients with endoscopic retrograde cholangiopancreatography-related perforations. Data collection included demographics, time to diagnosis, type of perforation, treatment strategy, surgical procedure, complications, hospital stay, and outcome. All patients were classified into two groups on the basis of radiological and operative findings.

Results: Only five patients underwent surgical treatment, whereas 15 patients were managed conservatively. The mean time to diagnosis was 7.8 hrs (range: 1 to 36 hrs). In patients who underwent surgical treatment, the types of perforations included type I and III in one patient each and type II in three patients. Surgical procedures included laparoscopic and open cholecystectomy with t-tube drainage in two patients each and primary repair of duodenal injury with hepaticojejunostomy in one patient. Among conservatively managed patients, eight, four, and three had type II, type III, and type IV injuries, respectively. Of these 15 patients, 60% (n=9) underwent percutaneous procedures. The mean length of hospital stay was similar for conservatively and surgically treated patients (12 vs. 12.4 days, respectively, p=0.790). One patient (5%) with type I injury died of multiorgan deficiency.

Conclusion: With close follow-up, medical treatment can be beneficial for most patients, and surgical procedures should be reserved for patients with type I (definite) and type II/III injuries; in patients with these clinical parameters, conservative management will likely be unsuccessful.

Keywords: Complication, duodenum perforation, endoscopic retrograde cholangiopancreatography, surgical repair

INTRODUCTION

Endoscopic retrograde cholangiopancreatography (ERCP) was first described in 1968 by McCune et al. (1). It is an invasive method used today for the diagnosis and treatment of pancreatic and biliary diseases. Since the emergence of other non-invasive or less invasive methods, such as magnetic resonance cholangiopancreatography (MRCP) and endoscopic ultrasonography (EUS), respectively, ERCP has been used mainly for treatment (2). This highly invasive procedure is associated with a higher frequency of serious complications, ranging between 4% and 16% (3-7). Although the risk of ERCP-related perforation (ERCP-rP) is low (<1% for patients undergoing sphincterotomy), it is associated with high morbidity and mortality, particularly for patients in whom conservative therapy is unsuccessful and who have a delayed diagnosis of perforation (8-11).

There is still no consensus on whether ERCP-rP should be managed by a conservative or surgical approach. Literature related to the management of ERCP-related complications mostly includes limited case series and case reports (12-14). Although in the past, many authors advocated early surgical management for ERCP-rP, most recent studies have reported good outcomes with conservative management for carefully selected patients (5, 15). Early diagnosis and definition of injury type play major roles in the management of ERCP-rP. Increased experience in endoscopic interventions and emerging technology has enabled clinicians to address these injuries with endoscopic interventional methods. Retroperitoneal perforation related to papillotomy is observed in most patients; intraperitoneal perforation is observed less frequently.

Based on a single center experience with the management of ERCP-rP, we aimed to analyze the types of injuries, surgical options, and outcomes of patients with ERCP-rP.

MATERIAL AND METHODS

Over a five-year period between January 2010 and October 2015, all ERCP procedures (n=3432) that were performed at the Gastroenterology and General Surgery Clinic at Şişli Hamidiye Etfal Training and Research
Hospital were retrospectively reviewed. The 17 patients with a diagnosis of ERCP-rP were enrolled in the study. This study was approved by the institutional review board at our institution (Local Ethics Committee of Şişli Hamidiye Etfal Training and Research Hospital), and informed written consent was obtained from all the reviewed subjects to use their clinical records in this study. The ERCP reports and medical records of the patients with perforations were evaluated. While 13 patients (0.3%) were from our hospital, 4 cases were referred from different hospitals. All patients were classified classified into two groups based on treatment approaches: conservative (C) and surgical (S).

All patients underwent chest X-rays, plain abdominal radiography, abdominal ultrasound (US), and computed abdominal tomography (CAT). Complete blood counts and biochemical profiles were assessed. Data collection included demographic features, indication for ERCP, type of injury, time to diagnosis, treatment approach (conservative or surgery), surgical procedure, length of hospital stay, morbidity and mortality.

The classification of ERCP-rP is shown in Table 1. Based on the type of injury, patients with type I injury underwent surgical treatment, while conservative treatment was mostly preferred for patients with type II, III, and IV injuries. Patients treated with a conservative approach underwent closed monitoring for vital signs, intermittent physical examination, and blood tests. In the presence of at least two of systemic inflammatory response syndrome (SIRS) criteria (sepsis) (10) (body temperature >38°C or <36°C, heart rate >90 pulse/min., respiratory rate >20/min. or PaCO2 <32 mmHg, white blood cell count >12000/mm³ or <4000/mm³, >10% immature neutrophil (bands)), repeat CAT was performed to determine possible free fluid collection or abscess formation. Percutaneous abscess drainage was applied for patients with conservative treatment whose CAT scans revealed intraperitoneal or retroperitoneal localized abscesses during the follow-up period.

For statistical analysis, Statistical Package for the Social Sciences version 20.0 for (IBM Corp.; Armonk, NY, USA) was used. Only descriptive measures were used. Continuous variables were represented as mean±standard deviation or median and range. Categorical variables were represented as percentages.

RESULTS
Of the 3492 ERCP cases during the study period, 59 patients with abdominal pain following ERCP procedures were admitted to the General Surgery Clinic with a preliminary diagnosis of ERCP-rP. Free air in the intraperitoneal and/or retroperitoneal areas, contrast leakage, fever and/or elevated leucocytes, and C-reactive protein were found in 16 patients; they were diagnosed with post-ERCP iatrogenic duodenal perforation (0.4%). In addition, four patients with a diagnosis of ERCP-rP were referred from other hospitals. Only 3 out of 20 patients were diagnosed with perforation due to contrast leakage during ERCP, whereas the remaining patients (85%) were diagnosed during post-ERCP follow-up.

There were 12 female (60%) and 8 male (40%) patients with a mean age of 46 years (range: 23 to 76). The mean time to diagnosis was 7.8 hours (range: 1 to 36 hours). In patients with a suspected perforation, oral intake was ceased and initial treatment with fluids, analgesia and appropriate antibiotics was started. Three patients (17%) initially treated with a conservative approach underwent surgical procedures due to peritonitis findings, fever, and elevated WBC and C-reactive protein during follow-up. The mean duration between diagnosis and surgery was 24 hours (range: 18 to 36).

The mean length of hospital stay was 12 days in the conservative group, whereas it was 12.4 days for the surgery group. In nine patients with conservative treatment (Table 2), percutaneous drainage was performed during follow-up due to intraabdominal abscess. One patient in the surgery group died of sepsis on postoperative day 8. She was diagnosed with perforation 12 hours after ERCP and underwent hepaticojejunostomy. Detailed data for the patients treated with surgical approaches are shown in Table 3.

DISCUSSION
Although ERCP is an invasive procedure, it is still one of the most common procedures used for the diagnosis and treatment of biliary and pancreatic diseases. ERCP is indicated in the diagnosis and treatment of biliary and pancreatic diseases such as bile duct stones, pancreatic duct stones, ampullary neoplasms, and pancreatitis. The indications for ERCP include biliary strictures, ampullary lesions, pancreatic masses, and intraductal papillary mucinous neoplasms.

Table 2. Demographics and diagnosis of patients who were not surgically treated

<table>
<thead>
<tr>
<th>Age</th>
<th>Sex</th>
<th>Indication for ERCP</th>
<th>Type of injury</th>
<th>Time to diagnosis (hours)</th>
<th>Length of hospital stay (days)</th>
</tr>
</thead>
<tbody>
<tr>
<td>54</td>
<td>M</td>
<td>CL</td>
<td>II</td>
<td>2</td>
<td>7</td>
</tr>
<tr>
<td>46</td>
<td>M</td>
<td>CL</td>
<td>III</td>
<td>3</td>
<td>9</td>
</tr>
<tr>
<td>66</td>
<td>F</td>
<td>Periampullary tumor</td>
<td>II</td>
<td>1</td>
<td>12</td>
</tr>
<tr>
<td>38</td>
<td>M</td>
<td>CL</td>
<td>III</td>
<td>1</td>
<td>10</td>
</tr>
<tr>
<td>47</td>
<td>F</td>
<td>Cholangitis</td>
<td>II</td>
<td>2</td>
<td>15</td>
</tr>
<tr>
<td>43</td>
<td>F</td>
<td>CL</td>
<td>II</td>
<td>13</td>
<td>35</td>
</tr>
<tr>
<td>52</td>
<td>F</td>
<td>CL</td>
<td>III</td>
<td>12</td>
<td>26</td>
</tr>
<tr>
<td>71</td>
<td>M</td>
<td>Pancreas tumor</td>
<td>II</td>
<td>3</td>
<td>13</td>
</tr>
<tr>
<td>33</td>
<td>M</td>
<td>CL</td>
<td>III</td>
<td>1</td>
<td>7</td>
</tr>
<tr>
<td>58</td>
<td>M</td>
<td>CL</td>
<td>II</td>
<td>3</td>
<td>6</td>
</tr>
<tr>
<td>45</td>
<td>F</td>
<td>CL</td>
<td>III</td>
<td>8</td>
<td>12</td>
</tr>
<tr>
<td>39</td>
<td>F</td>
<td>CL</td>
<td>IV</td>
<td>1</td>
<td>7</td>
</tr>
<tr>
<td>24</td>
<td>F</td>
<td>Cholangitis</td>
<td>II</td>
<td>8</td>
<td>9</td>
</tr>
<tr>
<td>23</td>
<td>F</td>
<td>Cholangitis</td>
<td>II</td>
<td>2</td>
<td>8</td>
</tr>
<tr>
<td>32</td>
<td>F</td>
<td>CL</td>
<td>II</td>
<td>3</td>
<td>9</td>
</tr>
</tbody>
</table>

M: male; F: female; CL: choledocholithiasis; ERCP: endoscopic retrograde cholangiopancreatography
approach to endoscopic injuries

| Table 3. Detailed data of patients who underwent surgical treatment |
|-----------------|-----------------|-----------------|-----------------|-----------------|
| Age | Sex | Type of injury | Surgical procedure | Time of diagnosis (hours) | Length of hospital stay (days) |
| 76 | F | Choledochal cyst (type I) | Primary repair of injury+HJ+gastroenterostomy | 12 | 8 |
| 43 | M | CL | Lap. chol+exploration of CBD+T-tube drainage | 3 | 7 |
| 52 | F | Cholangitis | T-tube drainage | 24 | 13 |
| 45 | F | CL | Lap. chol+drainage | 18 | 12 |
| 38 | M | CL | Choledoectomy+exploration of CBD+T-tube drainage | 36 | 15 |

M: male; F: female; CL: cholangitis; HJ: hepaticojejunostomy; CBD: common bile duct; Lap. chol: laparoscopic cholecystectomy

*This patient died of multiorgan failure

There has been no consensus on the management of ERCP-related gastrointestinal system perforations to date. Although emergency surgical treatment has been advocated in previous studies, conservative treatment was commonly reported with successful outcomes in appropriate cases in recent series. (10,12, 18, 19). Mortality rates between 7% and 25% were reported in several studies, in which the most common types of perforations were type I and II (12, 19, 20). In our study, the most common type was type II injury (60%); only one patient with type I injury (5%) died of sepsis.

Conservative treatments include endoscopic clip application and percutaneous drainage catheter insertion. Patients diagnosed with retroperitoneal abscess can be managed with percutaneous drainage, which may result in fistula formation. In our study, 60% (9 of 15) patients were managed conservatively by insertion of a percutaneous drainage catheter. Five of these patients required catheter adjustments or additional catheter insertion.

CONCLUSION

Accurate diagnosis and timely intervention are very important in patients with ERCP-rP. Clinical symptoms, imaging methods, and the mechanism of injury should be evaluated, and all these parameters should be considered before deciding whether to operate. Conservative treatment with close follow-up can prevent unnecessary surgery, whereas early operation on patients who fail to respond to medical treatment may prevent morbidity and mortality that can be caused by delayed surgery.

Ethics Committee Approval: Ethics committee approval was received for this study from the ethics committee of Şişli Hamidiye Etfal Training and Research Hospital.

Informed Consent: Written informed consent was obtained from patients who participated in this study.

Peer-review: Externally peer-reviewed.


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

Financial Disclosure: The authors declared that this study has received no financial support.

REFERENCES

Various classification methods have been presented for the definition and classification of ERCP-related perforations (10, 11). In this study, we used the classification system that Stapfer et al. (10) previously introduced. They reported that type I injuries generally require extensive emergency surgical procedures, whereas type II and III injuries with minimal contrast leakage and absence of fluid accumulation can be managed conservatively. Type IV injuries are classified as pseudoperforations related to air pressure during ERCP.

While almost all authors advocate surgical treatment for type I injuries, a debate remains as to whether conservative or surgical strategy should be performed for other types of injuries. Timely diagnosis of ERCP-related perforations is important in establishing better treatment approaches. In cases of perforations involving peritoneal signs, type IV perforations are more commonly diagnosed. In contrast, it is more difficult to detect retroperitoneal perforations, which only can be identified using radiological imaging methods due to post-ERCP abdominal pain. Clinical studies investigating the diagnostic methods for ERCP-related perforations have revealed that CAT is the most sensitive method in patients with high suspicion of perforation (16). Genzlinger et al. (17) reported the efficacy of CAT after ERCP. About one-third of the patients with perforation are diagnosed at the time of ERCP procedure. In our study, diagnosis of perforation was established for only three patients (15%) due to contrast leakage during ERCP. The remaining 17 patients were diagnosed using imaging methods (CAT, US, MRCP).

For better outcomes, diagnosis of the injury and determination of the injury type should be given priority. Informed Consent: Written informed consent was obtained from patients who participated in this study.

Peer-review: Externally peer-reviewed.


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

Financial Disclosure: The authors declared that this study has received no financial support.

REFERENCES
5. Freeman ML. Adverse outcomes of endoscopic retrograde chol-
angiopancreatography: avoidance and management. Gastroin-
test Endosc Clin N Am 2003; 13: 775-798. [CrossRef]
rardinis F, et al. Major early complications from diagnostic and
therapeutic ERCP: a prospective multicenter study. Gastrointest
Endosc 1998; 48: 1-10. [CrossRef]
7. Cotton PB, Garrow DA, Gallagher J, Romagnuolo J. Risk factors
for complications after ERCP: a multivariate analysis of 11,497
procedures over 12 years. Gastrointest Endosc 2009; 70: 80-88.
[CrossRef]
8. Scarlett PY, Falk GL. The management of perforation of the du-
odenum following endoscopic sphincterotomy: a proposal for se-
lective therapy. ANZ J Surg 1994; 64: 843-846. [CrossRef]
9. Cho KB. The management of endoscopic retrograde cholangio-
pancreatography-related duodenal perforation. Clin Endosc 2014;
47: 341-345. [CrossRef]
10. Stapfer M, Selby RR, Stain SC, Katkhouda N, Parekh D, Jabbour
N, et al. Management of duodenal perforation after endoscopic
retrograde cholangiopancreatography and sphincterotomy. Ann
Surg 2000; 232: 191-198. [CrossRef]
Classification and management of perforations complicating en-
doscopic sphincterotomy. Surgery 1999; 126: 658-663. [CrossRef]
S. Complications following endoscopic retrograde cholangio-
pancreatography: minimal invasive surgical recommendations.
PLoS One 2014; 26: e113073. [CrossRef]
S, et al. ERCP-related perforations in the new millennium: A large
tertiary referral center 10-year experience. United European Gastro-
enterol J 2015; 3: 25-30. [CrossRef]
14. Kirtane T, Singhal S. Endoscopic closure of iatrogenic duodenal
perforation when using dual over-the-scope clips. Gastrointest
Endosc 2015; pii: S0016-5107(15)02748-0.
15. Enns R, Eloubeidi MA, Mergener K, Jowell PS, Branch MS, Pappas
TM, et al. ERCP-related perforations: risk factors and manage-
ment. Endoscopy 2002; 34: 293-298. [CrossRef]
16. de Vries JH, Duijnh LE, Dekker W, Guit GL, Ferwerda J, Scholten ET.
CT before and after ERCP: detection of pancreatic pseudotumor,
asymptomatic retroperitoneal perforation, and duodenal diver-
ticulum. Gastrointest Endosc 1997; 45: 231. [CrossRef]
17. Genzlinger JL, McPhee MS, Fisher JK, Jacob KM, Helzberg JH. Sig-
nificance of retroperitoneal air after endoscopic retrograde cholangio-
pancreatography with sphincterotomy. Am J Gastroenterol
1999; 94: 1267-1270. [CrossRef]
WR, et al. Management of duodenal and pancreatico biliary per-
forations associated with periampullary endoscopic procedures.
Am J Surg 2008; 196: 975-981. [CrossRef]
19. Rabie ME, Mir NH, Al Skaini MS, El Hakeem I, Hadad A, Ageely H,
et al. Operative and non-operative management of endoscopic
retrograde cholangiopancreatography-associated duodenal inj-
Perforations following endoscopic retrograde cholangiopan-
creatography: a single institution experience and surgical recom-