



# ERCP licence in the context of medical practices, legal regulations, medical ethics and patient's rights in our country

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## ABSTRACT

Endoscopic Retrograde Cholangiopancreatography (ERCP) is an invasive endoscopic procedure mainly used for hepatobiliary and pancreatic disorders. Although it was first developed by a surgeon, McCune, there is still debate on who can perform this procedure. This problem, which actually needs to be solved within medical ethics, has been brought to the courts, and lawsuits have been filed against general surgeons to prevent them from performing ERCP. The current situation in our country demonstrates that 50-70% of ERCP procedures are performed by general surgeons. In regions where there are not enough gastroenterology specialists, only general surgeons perform this procedure. Today, general surgeons have hundreds of articles on ERCP procedures and studies accepted as international guideline. ERCP procedure -which is in fact a surgical procedure- is included in hepatobiliary surgical procedures in the general surgery core training schedule. General surgeons receive ERCP education in a 6-month challenging program at centers accredited by the Turkish Surgical Society. The problem of ERCP license cannot be solved by legal authorities but by medical, ethical and deontological discussions. Our recommendation here is that the Ministry of Health should associate this procedure with a specific legislation, just like in endoscopy, and establish a specific ERCP training program accepted for license. In this article, the problem of who should perform ERCP was discussed within the framework of legal legislation, medical doctrine and realities of our country.

**Keywords:** ERCP, licence, law, patient's rights

## INTRODUCTION

There is a significant increase in demand for healthcare services provided to patients due to the gradually rising health problems in the world. On the other hand, the healthcare services provided have become different with technological advances, and these innovative ventures are adapted to healthcare services. Endoscopic retrograde cholangiopancreatography (ERCP), one of the most important examples of technology being adapted to healthcare services, is an endoscopic invasive procedure performed for diagnostic and treatment purposes in the bile ducts. ERCP procedure, which was first developed by a surgeon from Ohio named McCune in 1968, is performed by general surgery, gastroenterology and invasive radiology specialists in developed countries such as the United States of America, the United Kingdom and Germany. Surgical history of ERCP procedure introduced to the field of medicine by McCune et al. can be accessed from "Güncel Gastroenteroloji Dergisi" (Journal of Current Gastroenterology) published by the Turkish Gastroenterology Foundation (1).

### The Current Status in Our Country

ERCP procedure, which was first performed in our country in 1977, has also been performed by general surgeons as of 1993 and today, nearly two hundred general surgeons can carry out the ERCP procedure. The number of ERCP procedures performed annually by general surgeons varies between 9.500 and 10.000, and the total number of cases performed until today is assumed to be around 110.000. When it is considered that 15.000-20.000 patients require ERCP procedure annually in our country, it is seen that 50-60% of ERCP procedure is fulfilled by general surgeons. In our country today, general surgeons, along with gastroenterologists, meet a significant part of ERCP load in major cities like Ankara, Istanbul and İzmir.

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On the other hand, this procedure is performed by only general surgeons in many Anatolian cities such as Bandırma, Urfa, Antalya, Uşak, Trabzon, Balıkesir, Afyon, Isparta, Nevşehir, Tekirdağ, Edirne, Konya, Balıkesir, and Rize where a gastroenterology specialist is not present or ERCP procedure cannot be performed even if there is a gastroenterologist. These data can be confirmed by codes 701360, 701370 and 701440 on the database of Ministry of Health with ERCP procedure entries.

ERCP training of general surgeons is executed with a 6-month actual curriculum that has been introduced as a result of consultations held between the Ministry of Health and Turkish Surgical Society (TSS) and has been going on for over ten years (2). The scope of the training program determined by TSS has been prepared by grounding on precedent curriculum programs abroad but also by making many of their parameters more difficult. Compliance to the training program is strictly followed by the documents the trainee submits. Residents also receive ERCP training in centers offering ERCP training programs and include in their professional practice this procedure along with gastroscopy and colonoscopy. This program has both theoretical and practical parts and requires six months of continuous study.

When ERCP training is assessed in terms of academic material, there are three local textbooks on comprehensive technical information of ERCP procedure. Two of these books have been written by general surgeons (3,4). Courses and panels related to ERCP have been implemented in all national congresses such as the 20<sup>th</sup>, 21<sup>st</sup>, and 22<sup>nd</sup> Turkish National Surgical Congresses or the 14<sup>th</sup> and 5<sup>th</sup> Turkish Endoscopic Laparoscopic Surgery Congresses. Hundreds of articles on ERCP written by the general surgeons performing the procedure have been published in national and international journals, and some articles have been included in European Guidelines (5).

### Legal Conditions of ERCP License

ERCP procedure, due to its context, is clearly a surgical procedure. For instance, sphincterotomy is an incision procedure performed with the help of a cautery and sphincterotome, and Dictionary of the Turkish Language Association defines surgery as a medical activity including procedures of incision, suturing, and excision. Law no 1219 (Law on the Mode of Execution of Medicine and Medical Sciences) clearly states that surgical license is required for surgical intervention. Therefore, as is thoroughly pointed out below, general surgeons are capable of and responsible for performing ERCP procedures, and prohibiting them to perform ERCP surgery is against the clear provision of the law. It must be underlined that ERCP procedure is not found under endoscopic procedures but under Hepatobiliary Surgical Procedures in the General Surgery Core Training Program (CTP). After all, the procedure itself is indeed a hepatobiliary surgical procedure, and prohibiting surgeons from this procedure is not only pseudo-scientific but also non-conscientious.

### Who Should Perform ERCP Procedures?

The right and license of a medical practice is regulated as per legal legislation not by the request and opinion of real person and corporate entity. In short, the persons who have the right and license to perform ERCP procedure are determined as per the legislation within the current positive legal framework and by the relevant regulations of the Ministry of Health (6). However, it is not expected nor possible for law to establish legislation for each and every medical intervention. Likewise, it is not the duty of law to make regulations individually for hundreds of practices carried out by surgeons, and it is against the natural flow of life. Fundamentally, lawmakers have meticulously avoided such an elaborative approach. Being that, lawmakers have left other subjects to the ethical values of the members of medicine and sources of medical doctrine as long as they do not constitute contradiction to general legislation. Searching for a solution only on a legal basis draws us away from a permanent solution. There are many court verdicts that contradict one another on who can perform ERCP procedures. For instance, while the decision of the Ministry of Health denying general surgeons' demand for ERCP training has been revoked due to direct opposition to the Constitution in a lawsuit taking place in the Administrative Court of Bursa, a general surgeon has been prohibited from performing ERCP justifying on only the Endoscopy Regulation of the Ministry of Health by the Administrative Court of Ankara (7,8). Therefore, general provisions of the legislation should be considered with regard to who can perform ERCP procedures, and the ethical and deontological norms of medicine should be consulted in fields with legal loophole.

### Legislative Provisions on ERCP Procedures

There is no regulation in our legislation that directly refers to ERCP procedure. The most important legislation that guides us in the right and license of such an invasive procedure is the Law on the Mode of Execution of Medicine and Medical Sciences (9). Article 3 of this Law no. 1219 clearly states that "No one without proper surgical license can perform any surgical intervention". Therefore, according to that law, the right and license of ERCP procedure, which is a surgical procedure as mentioned above, belongs to surgeons. It should be noted that no regulation, by-laws or commune can be against the law, which is the mandatory provision. Again, as per the additional Article 14 of this law, it is stated that "Training curricula of the specialties and the fundamental execution area of the specialties and the framework of the duties and authorities shall be determined by the Board of Specialty in Medicine." A Regulation on Specialty in Medicine has been made by this Board pursuant to the provision of this article, and CTP determining the minimum level of residency training in all specialties have been established immediately afterwards. However, there is no other legislation determining the duties and authorities of relevant specialists of the field other than the programs

specifying the minimum qualities of residency training. Therefore, the debate is rooted in this legislative loophole, and right and license in activities following specialty are considered as per CTP, which is a residency training program. However, CTP, which determines the curriculum of the residency training program, is an advisory document specifying the minimum standards of this training. This document cannot be used as a criterion in determining the right and license of a general surgery specialist. Moreover, within their specialty framework, general surgeons perform many surgical procedures that are not included in Level 1 category of CTP. All kinds of transplants and bariatric surgery, in particular, can be given as examples to these procedures.

The same situation is valid for gastroenterology. Procedures like endoscopic ultrasound (EUS), endoscopic mucosal resection (EMR), endoscopic submucosal dissection, which are included in Level 1 category of gastroenterology CTP, and procedures like submucosal tunneling endoscopic resection and peroral endoscopic myotomy which are not found in the relevant CTP, are also performed by gastroenterologists.

On the other hand, if a resident does not receive any training on ERCP in the clinic where the training is given, he/she does not have direct license to perform this operation solely since this procedure is a Level 2 procedure in CTP. When there is a legal conflict, the individual has to prove with evidence that he/she has received training for this surgical procedure following specialty since he/she did not receive this training during residency. Therefore, CTP is not a document that determines the license of a specialty affirmatively or negatively but is an advisory document specifying the minimum standards of the residency training field. Training in medicine is a dynamic process that continues even after specialty.

On this matter, in the Annex 1/b article of (10), it is stated that "a specialist physician executes his/her profession with the knowledge and skills gained during medical school and specialty training and additionally within the framework of the knowledge and skills gained through vocational training and scientific activities after specification". It is understood by this statement that specialist physicians can include the skills they have gained following their residency training into their professional activities.

It is observed that the problem with ERCP license is frequently debated by justifying endoscopy certification regulation no. 457 and TUK; 2014/405 of the Ministry of Health. Yet, this endoscopy certification program established by the Ministry of Health, Board of Specialty in Medicine has been regulated for only endoscopic procedures, and along with ERCP, procedures like EUS and EMR have been left out of this regulation. However, even though procedures like EUS and EMR that are excluded from this certification regulation are found in Level 1 category of gastroenterology CTP, they are performed by gastroenterologists without being subject to any restrictions. On the other hand, in the

case of general surgery as the specialty field, it is ruled that ERCP procedure is not within the scope of the certification and cannot be performed since it is found in Level 1 category. To the best of our knowledge, since there are no training programs oriented at EUS and EMR in gastroenterology societies as there are in TSS, what should be debated is that with what authority gastroenterologists perform procedures like EUS and EMR.

ERCP training is totally different from endoscopy training. It is not possible for a specialist with only endoscopy certificate to perform ERCP. Thus, general surgeons perform ERCP procedure after having received the basic ERCP training conducted by TSS and with a totally different certificate from that of the above-mentioned one. What should be done by the Ministry of Health, which is already commissioned on this matter by law no 1219, is to standardize the training of ERCP, EUS, EMR and similar procedures that do not currently have a certification regulation at the moment.

Turkish Gastroenterology Association states that general surgeons can perform ERCP but must hold a subspecialty in gastro surgery. Although TGA does not have such authority, the matter should be clarified in a few points:

1. All of a couple of gastro surgeons performing ERCP in our country have received their ERCP training from the program regulated by TSS.
2. ERCP training is not given in any of the 11 centers offering gastro surgery training and, in these centers, ERCP is performed by general surgeons or gastroenterologists.
3. There is no rotation in gastro surgery including gastroenterology. Therefore, it is impossible for a resident to receive ERCP training while doing subspecialty in gastro surgery.
4. When we look at the practices abroad, we see that general surgeons, radiologists and gastroenterologists perform this procedure (11-13).

It is also vital to evaluate the matter on grounds of patient rights. It is necessary to emphasize that the prevention of a patient's right to undergo ERCP procedure due to cholangitis with a general surgeon in whose knowledge, experience and academic qualities are trusted is contradictory to Articles 17 and 54 of the Constitution that regulates patient rights and to the Patient Right Regulation adaptationally made from International Agreements to which Turkey is a party.

## CONCLUSION

Another field of specialization cannot decide on which activities a field of specialization can be engaged in. Therefore, as it is not scientific for gastroenterologists to think that surgeons cannot perform ERCP, it is also unethical and immoral. The decision-making body on this matter is the commissions and regulations to be determined by the Ministry of Health pursuant to law no 1219. What should be done is that a standardized training

program and a legislation should be formed for procedures like ERCP and EUS just as in endoscopy, and certifications should be made accordingly. Until these regulations are made, surgeons naturally receive ERCP training through their professional organization, TSS, with a 6-month training program which is more difficult and scientific than its counterparts in many countries.

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## DERLEME-ÖZET

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## Ülkemizdeki sağlık hizmetleri, mevzuat, tıp etiği ve hasta hakları bağlamında ERCP işlemlerinde ehliyet sorunu

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## ÖZET

Endoskopik retrograd kolanjiopankreatografi (ERCP), esas olarak hepatobiliyer ve pankreas hastalıklarında kullanılan invaziv bir endoskopik işlemdir. Her ne kadar ilk defa bir cerrah olan McCune tarafından tanımlanmışsa da halen bu işlemin kimin yapacağı ile ilgili tartışmalar yaşanmaktadır. Aslında tıbbi etik çerçevesinde çözülmesi gereken bu problem mahkemelere taşınmakta ve genel cerrahların bu işlemi yapmaması için davalar açılmaktadır. Ülkemizdeki gerçek durum değerlendirildiğinde de ERCP işlemlerinin %50-70’inin genel cerrahlar tarafından yapıldığı görülmektedir. Sınırlı sayıda gastroenteroloji uzmanının olduğu bölgelerde de bu işlemi sadece genel cerrahlar gerçekleştirmektedir. Günümüzde genel cerrahların ERCP işlemleriyle ilgili yüzlerce makaleleri, uluslararası kılavuzlara girmiş çalışmaları mevcuttur. Gerçekte bir cerrahi işlem olan ve genel cerrahi çekirdek eğitim programında hepatobiliyer cerrahi işlemler sınıfında yer alan ERCP işlemi Türk Cerrahi Derneği’nin akredite ettiği merkezlerde altı aylık zorlu bir programla öğretilmektedir. ERCP işlemlerinde ehliyet sorunu hukuki mercilerce değil tıbbi, etik ve deontolojik tartışmalarla belirlenir. Burada önerimiz Sağlık Bakanlığı’nın bu işlemi de aynı endoskopide olduğu gibi özel bir mevzuata bağlaması ve ERCP ile ilişkili bir sertifikasyon eğitim programı oluşturmasıdır. Bu çalışmada ERCP işlemini kimin yapması gerektiği sorunsalı hukuki mevzuat, tıbbi doktrin ve ülkemizin reel koşulları çerçevesinde ele tartışılmıştır.

**Anahtar Kelimeler:** ERCP, ehliyet, hukuk, hasta hakları

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