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Our Endoscopic Retrograde Cholangiopancreaticography Experiences: Single Center, 688 Patients

Endoskopık Retrograd Kolanjıopankreatıkografı Deneyımlerımız: Tek Merkez, 688 Hasta

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ABSTRACT

Introduction and Aim: Successful ERCP requires deep cannulation of the common bile duct and/or the main pancreatic duct through the major duodenal papilla (papilla of Vater). Complications have been reported in cases of selective biliary cannulation, but this diminishes in experienced hands. The aim of this topic is to evaluate the practices and results in our clinic on how to achieve successful cannulation and sphincterotomy at minimum risk for the patient.

Methods: The results of 688 patients who underwent ERCP in the endoscopy unit of our clinic over a 6-year period (2015-2021) are evaluated. Demographic findings, co-morbidities, duration of the procedure, presence of periampullary diverticulum, difficult cannulation rate, stent use, complication rate and successful cannulation rates of the patients were evaluated.

Results: 58.5% of the patients were female. Heart diseases were found in 44.6% of the patients, kidney diseases in 11.5%, lung diseases in 14.9%, central nervous system diseases in 7.8% and malignancy in 2.1%. The common bile duct diameter is 12.98 ± 3.44 mm, and the mean stone size is 8.70 ± 4.50 mm. Periampullary diverticulum was present in 110 (15.9%) of the patients, and stony gall bladder was present in 48.0% of the patients. Selective cannulation was performed in 77.9% and pre-cut sphincterotomy was performed in 18.2%. Periampullary malignancy was detected in 12.1% of patients, and stent was applied to 22.1% of patients. Failed in 3.1% of patients. Emergency laparotomy was performed in 4 patients (0.6%). Bleeding was found in 58 patients (8.5%), perforation in five patients (0.8%), pancreatitis in 25 patients (4.0%), and mortality in six patients (1.0%).

Conclusions: Although endoscopic retrograde cholangiopancreatography is an effective diagnostic and therapeutic tool, it can lead to serious complications. ERCP indication should be put correctly, procedures should be done by experienced people. In experienced hands, the success rate is high even with anatomical variations and difficult stones.

Key words: Cholangiopancreatography, Endoscopic Retrograde, Sphincterotomy, Endoscopic

ÖZET

Giriş ve Amaç: Başarılı ERCP, majör duodenal papilla (Vater papilla) yoluyla ortak safra kanalı ve/veya ana pankreatik kanalın derin kanülasyonunu gerektirir. Seçici biliyer kanülasyon vakalarında komplikasyonlar bildirilmektedir ancak bu, deneyimli ellerde azalmaktadır. Bu konunun amacı, hasta için minimum risk altında başarılı kanülasyon ve sfinkterotominin nasıl elde edileceğine dair kliniğimizdeki uygulamaları ve sonuçlarını değerlendirmektir.

Yöntemler: 6 yıllık bir süreçte (2015-2021) kliniğimiz endoskopi ünitesinde ERCP uygulanan 688 hastanın sonuçları değerlendirilmektedir. Hastalara ait demografik bulguları, ko-morbiditeleri, işlem süreleri, periampüller divertikül varlığı, zor kanülasyon oranı, stent kullanımı, komplikasyon oranı ve başarılı kanülasyon oranları değerlendirildi.

Bulgular: Hastaların 58.5%'i kadındı. Hastaların 44.6%'sında kalp hastalıkları, 11.5%'inde böbrek hastalıkları, 14.9%'unda akciğer hastalıkları, 7.8%'inde santral sinir sistemi hastalıkları ve 2.1%'inde malignite saptandı. Ortak safra kanal çapı 12.98 ± 3.44 mm olup, ortalama taş büyüklüğü 8.70 ± 4.50 mm dir. Hastaların 110 tanesinde (15.9%) periampüller divertikül mevcut olup, hastaların 48.0%'inde taşlı safra kesesi mevcut idi. 77.9%'unda selektif kanülasyon, 18.2%'sinde pre-cut sfinkterotomi uygulandı. 12.1% hastada periampüller malignite saptanmış olup, 22.1% hastaya stent uygulandı. 3.1% hastada başarısız olundu.

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4 hastada (0.6%) acil laparotomi uygulandı. Toplam 58 hastada (8.5%) kanama, beş hastada (0.8%) perforasyon, 25 hastada (4.0%) pankreatit ve altı hastada (1.0%) mortalite saptandı.

Sonuçlar: Endoskopik retrograd kolanjiopankreatografi, etkin bir tanı ve tedavi aracı olmakla beraber ciddi komplikasyonlara yol açabilir. ERCP endikasyonu doğru konulmalı, işlemler tecrübeli kişilerce yapılmalıdır. Tecrübeli ellerde, anatomik varyasyonlar ve zor taşlar olsa bile başarı oranı yüksektir.

Anahtar kelimeler: Endoskopik retrograd kolanjiyopankreatografi (ERCP), Kanülasyon, Pre-cut, Pankreatit.

INTRODUCTION

Endoscopic retrograde cholangiopancreatography (ERCP) is a widely used technique for the treatment of biliary and pancreatic disorders. McCune applied the technique for the first time in 1968 and Kawai et al. Due to advances in ERCP since the first sphincterotomy was performed (Kılıc, vd. 2019: 290), ERCP has become the gold standard for both diagnosis and treatment of pancreaticobiliary disorders.

The main indications for ERCP are primary or recurrent common bile duct stones (CBDS), malignant or benign strictures of the pancreatobiliary ductal systems, sphincter dysfunction of Oddi, periampullary stenosis, chronic pancreatitis, and post-surgical bile leaks.

Successful ERCP requires deep cannulation of the common bile duct and/or common pancreatic duct through the major duodenal papilla (papilla vateri). Cannulation of the major papilla can be difficult: Cannulation failure is reported in 18% of cases of selective biliary cannulation, but this falls below 5% in experienced hands. Pancreatic duct cannulation can also be difficult in some cases. Difficulty in cannulation leads to prolonged papillary manipulation, and it is known that repeated interventions with or without contrast injection into the pancreatic ductal system increase the risk of post-ERCP pancreatitis (PEP) (Dumonceau, vd. 2020: 127).

Factors associated with difficult biliary cannulation: The probability of successful cannulation is influenced by operator factors (experience) and patient factors (anatomy). Differences in anatomy, such as size, morphology, or orientation of the papilla, as well as the presence of a large periampullary diverticula (PAD) or surgically altered anatomy, can also cause difficult cannulation.

In case of difficult biliary cannulation and involuntary main pancreatic duct access, pre-cut papillotomy is recommended based on papillary morphology. Although pre-cut or selective cannulation attempts offer similar success and overall complication rates, PEP, bleeding and perforation rates are seen more frequently in inexperienced hands in the pre-cut procedure (Jin, vd. 2016: 808).

Biliary duct surgery in the elderly has a serious morbidity and mortality risk. The incidence of acquired duodenal diverticulum is also increasing in these patients (Day, vd. 2014: E28). Therefore, although it is an invasive and difficult application, the endoscopic approach is a better alternative.

Our aim is to evaluate the indications, ERCP cannulation rates and applied methods in patients who underwent ERCP in our clinic over a six-year period, depending on the effects of local anatomical features.

MATERIALS AND METHODS

The medical records of 688 patients who received endoscopic treatment for CBDS at a tertiary referral hospital between January 2015 and April 2021 were retrospectively reviewed. Exclusion criteria were: undergoing surgery that blocked access to the papilla, cases with non-papillary drainage (percutaneous transhepatic biliary drainage) or coagulopathy. All patients included in the study signed a consent form about ERCP and related treatments before any procedure. This study was performed after the Declaration of Helsinki and local ethics committee approval was obtained.

Technical Setup

ERCP was performed under sedation with topical 10% Xylocain® (lidocaine, AstraZeneca, Cambridge, UK) followed by intravenous Aldolan® (pethidine HCl, G.L. Pharma GmbH, Lannach, Austria) and Dormicum® (midazolam, Roche, Basel, Switzerland). Buscopan® (Hyposin-N-butyl bromide, Boehringer Ingelheim, Ingelheim, Germany) was used to reduce intestinal peristalsis.

Procedures were performed using a side view duodenoscopy system (XL; Fujinon system, Tokyo, Japan) and synchronized imaging techniques were obtained to confirm the location of the bile duct (Toshiba E5764SD-P4A, Medison X-ray, Korea). All patients were routinely administered prophylactic antibiotics before ERCP procedures.

In patients with normal-appearing papillae, the procedure was started with the classical approach using a standard sphincterotomy or guide wire. If cannulation could not be achieved despite the above techniques after a reasonable time, the case was defined as "failed" and abandoned. Three days after the first trial, we checked the patient's indications and need for the procedure and repeated the ERCP procedure.

In the second trial, ERCP was started with one of two methods according to the characteristics of the papilla. If the papilla showed failure of ERCP, the procedure was initiated directly with a precut incision. We have proposed a modified technique and specific steps when making the front cut to get the maximum benefit.

The needle-knife precut technique was performed as follows: With a needle-pointed sphincterotomy, an incision is made in the cephalic direction, starting from the entrance of the papilla, and entry into the bile is attempted (classical method). In this method, the mucosa and submucosa are peeled off and slightly pearly swollen sphincters are exposed. Then, the same procedure is applied to the sphincters, and the salmon-colored bile mucosa is opened and cannulation is performed.

Endoscopic sphincterotomy (EST) comes after common bile duct cannulation. After EST, after the guide wire is seen radiographically in the common bile duct, the duct is visualized by giving contrast material and intraluminal stones are cleared with an endoscopic basket or balloon according to the existing pathology. Finally, it is ensured that there are no stones in the lumen with the help of occlusion cholangiography. However, if a large number of square-shaped hard stones are detected during the procedure, larger than the balloon endoscope can capture, a plastic stent is inserted; The patient is treated with ursodeoxycholic acid and called for a repeat appointment.

When patients' initial cannulation fails, nitroglycerin is administered and the procedure is repeated after three days of edema-reducing therapy. The procedure begins by targeting EST with classical cannulation, but needle-blade precut sphincterotomy is performed in cases of unsuccessful EST. Complications such as bleeding, pancreatitis, cholangitis are noted and the patients are followed up in the service.

Bleeding was defined as a decrease in hemoglobin of at least two points without any other source of bleeding on endoscopy. Acute pancreatitis was defined as a three-fold increase in lipase value in the patient's biochemical tests after ERCP. Cholangitis was defined as the appearance of the Charcot triad (pain, fever, jaundice).

In patients who do not develop complications during the procedure, those with normal control blood tests (hemogram, amylase) and abdominal examination findings are discharged.

Follow-Up Assessment

After endoscopic removal of CBDS, patients were called for follow-up 2 weeks later. If there is a stone in the gallbladder, laparoscopic cholecystectomy was planned as soon as the increased gallbladder wall thickness (>3 mm) returned to normal in hepatobiliary ultrasonography. Patients who did not accept surgery or whose gallbladder wall thickness remained high were called for regular control every 2 months and hepatobiliary ultrasonography was performed. When biliary complications were suspected, patients were hospitalized and performed abdominal computed tomography (to exclude the need for acute surgery) and magnetic resonance cholangiopancreatography (MRCP) (to evaluate the biliary tract).

Statistical Analysis

Chi-square and Fisher exact chi-square tests were used for baseline analysis of the results. $P<0.05$ was considered statistically significant. All data analyzes were performed using the SPSS statistical software program, version 18.0 Windows (SPSSInc., Chicago, IL, USA).

RESULTS

A total of 688 patients who received their first endoscopic therapy (ERCP) for CBDS were included in this retrospective analysis. The overall mean age was 61.66 (±15.53) years (range: 18-98 years). Three hundred and sixty-three (52.8%) patients were 65 years or older. The study included 286 male (41.5%) and 402 female (58.5%) patients. Concomitant diseases were observed in the cardiovascular system in 306 patients (44.6%), kidneys in 79 patients (11.5%), respiratory system in 102 patients (14.9%), and central nervous system (CNS) in 67 patients (9.8%). Fourteen patients (2.1%) had non-periampullary malignancies (Table 1).

Table 1. Demographic characteristics and comorbidities of patients who underwent ERCP.

	All (n=688)	%
Sex (Female)	402	58.5
Age (>65)	363	52.8
Komorbidities		
cardiovascular system	306	44.6
kidneys	79	11.5
respiratory system	102	14.9
CNS	67	9.8
malignancies	14	2.1

CNS: Central nervous system.

Among the complaints of the patients who applied to the hospital, the most common reason was jaundice with 78.6%

and high bilirubin values that were noticed when being examined with 9.8%. Other causes include rare causes such as abdominal pain and post-surgical bile leaks.

When the indications for ERCP are examined, choledocholithiasis in 383 patients (55.6%), mechanical icterus in 79 patients (11.4%), wide intrahepatic bile ducts in 63 patients (9.1%), large common bile duct in 43 patients (6.2%), bilirubin and alkaline phosphatase elevation in 29 patients (4.1%). Pancreatic head tumor in 24 patients (3.5%), duodenal tumor in 16 patients (2.3%), distal common bile duct tumor in 15 patients (2.2%), ampulla tumor in 14 patients (2.0%), cholangiocarcinoma in 13 patients (1.8%), six biliary fistula after surgery in 1 patient (1%), Klatskin tumor in 2 patients (0.3%), and other rare causes in one patient (0.1%) (Table).

Table 2. Pre-diagnosis of the patients before ERCP.

	n	%
Choledocholithiasis	383	55.6
Mechanical icterus	79	11.4
Wide intrahepatic bile ducts	63	9.1
Wide choledoch	43	6.2
Bilirubin and alkaline phosphatase elevation	29	4.1
Pancreatic head tumor	24	3.5
Duodenal tumor	16	2.3
Distal common bile duct tumor	15	2.2
Ampulla tumor	14	2.0
Cholangiocarcinoma	13	1.8
Biliary fistula after surgery	6	1.0
Klatskin tumor	2	0.3
Other rare causes	1	0.1

Stones were detected in 388 (56.4%) patients and sludge was detected in 42 (6.1%) patients on MRCP. EST and needle-knife precut were applied to 535 and 125 (18.2%) patients, respectively. First and second cannulations were successful in 526 (76.5%) and 141 (20.4%) patients, respectively. The mean common bile duct diameter of the patients was 12.98 (±3.44) mm. During the procedure, stone/mud was observed in 539 (78.4%) patients, periampullary malignancy in 83 patients (12.1%), and purulent drainage in the common bile duct in 55 patients (8.1%). The mean stone diameter was 8.70 (±4.50) mm, and gallstones were detected in 330 (48.0%) patients. The number of patients who underwent cholecystectomy before the procedure was 186 (27.1%). Nitroglycerin was used in 248 (36.1%) patients. PAD was detected in 110 (15.9%) patients and 12 (1.8%) patients had T-tube in the common bile duct. Stents were placed in the common bile duct of 152 (22.1%) patients (Table 3).

Table 3. Anatomical and clinical features of patients who underwent ERCP

	n	%
Presence of stones in MRCP	388	56.4
EST	535	77.7
Needle-knife sphincterotomy (Pre-cut)	125	18.2
First cannulation	526	76.5
Second cannulation	141	20.4
Average common bile duct diameter	12.98 (±3.44)	
Stone/mud detection	539	78.4
Periampullary malignancy	83	12.1
Purulent discharge from the choledoch	55	8.1
Average stone diameter	8.70 (±4.50)	
GBS in situ	330	48.0
Pre-op CCX	186	27.1
Nitroglycerin use	248	36.1
PAD presence	110	15.9
T-tube in the common bile duct	12	1.8
Stent placement in the common bile duct	152	22.1

MRCP; Magnetic resonance cholangiopancreatography, EST; endoscopic sphincterotomy, GBS; Gall bladder stone, CCX; Cholecystectomy, PAD; Periampular diverticulum.

Perioperative bleeding and perforation occurred in 56 (8.2%) and five (0.8%) patients, respectively. Four (0.6%) patients underwent emergency operation. The mean duration of the procedure was 35.21 (±12.36) minutes and ranged from 21 to 54 minutes. Postoperative bleeding and pancreatitis were observed in two (0.3%) and 25 (4.0%) patients, respectively. Mortality was observed in six (1.0%) patients. The mean hospital stay was 1.54 (±1.23) days (Table 4).

Table 4. ERCP complications, mortality and length of hospital stay.

	n	%
Perioperative Bleeding	56	8.2
Perforation	5	0.8
Emergency Operation	4	0.6
Average processing time (min)	35.21 (±12.36)	
Post-ERCP bleeding	2	0.3
Post-ERCP perforation	25	4.0
Mortality	6	1.0
Average length of hospital stay	1.54 (±1.23)	

DISCUSSION

Common bile duct stones are the most common biliary tract diseases, and endoscopic retrograde cholangiopancreatography (ERCP) is currently accepted as the standard treatment for common bile duct stones (CBDS) with its minimally invasive aspect (Mashiana, vd. 2018: E1296). EST or endoscopic papillary balloon dilatation (EPBD) are treatment modalities for removal of CBDS (Wang, vd. 2021: e24735). EST is very effective for the endoscopic treatment of small CBDS, but large, multiple facet stones require advanced treatment methods (Wu, vd.2021: 1067).

Recently, pre-cut sphincterotomy with a needle-point sphincterotomy, as well as endoscopic papillary large balloon dilatation (EPLBD), have been reported as useful techniques for difficult CBDS (Jin, vd. 2014: 5548).

Choledocholithiasis has been reported with a high rate in elderly patients (> 65 years) (Jayaraj, vd. 2019: 1364). The specific mechanism is not clear, but in the study of Akaydın et al., it is suggested that risk factors secondary to retrograde infection in the papilla, such as common bile duct dilatation and especially PAD, which is associated with the recurrence of stones in elderly patients, increas e the risk of CBDS and this risk is higher in papillae located within the diverticula (Akaydın, vd. 2020: 938). Similarly, in our study, CBDS was found to increase in elderly patients, and it is thought that advanced age (>65 years) is an independent factor for CBDS and difficult cannulation may occur due to papilla sphincter insufficiency and the presence of PAD with increasing age.

In difficult ERCP cases, cannulation is often not possible at the first attempt. In such cases, the second attempt may be precut sphincterotomy. Early use of precut sphincterotomy has been suggested as an approach to prevent excessive and repetitive papillary trauma that may increase the risk of pancreatitis after ERCP (Leghari, vd. 2013: 620). The few randomized controlled trials that have attempted to evaluate differences in complication rates between early precut sphincterotomy and persistent cannulation groups have shown divergent results and are limited by the small sample size and thus insufficient to demonstrate any potential difference between groups (Berry, vd. 2019: 5).

However, some guidelines are needed to reduce the risk of perforation. To achieve maximum effectiveness, the endoscopist should consider the following steps after an unsuccessful cannulation attempt: 1. Define and characterize the anatomy of the papilla (floppy, flat, mobile, indistinct, swollen), 2. Identify the mucosa lining the duct and define the upper border of the bile duct. Make an incision on the mucosa to expose it, 3. Identify the bile duct and perforate until you can observe the bile stained flow, 4. Proceed with the standard sphincterotome and guidewire. In the study of Kırmacı et al., ERCP was applied to 1794 patients and pancreatitis (0.66%) was found in only two of 160 pre-cut patients (Kırmacı, vd. 2021: 55).

One of the reasons for difficult cannulation is ectopic papilla. In our study, ectopic papilla was detected in four patients, one of which was bulbar, and pre-cut sphincterotomy was performed in these patients and it was successful (Hong, vd. 2020: e18536). In the study of Ballı et al., the complication rate of pancreatitis (50%) in patients with ectopic bulbar papilla was found to be higher than the complication rate of pancreatitis (16.7%) in patients without ectopic bulbar papilla (Ballı, vd. 2021: 70). Similarly, in our study, pancreatitis was found in one of the four patients who underwent sphincterotomy to the ectopic bulbar papilla, and bleeding in one.

Randomized trials have been conducted emphasizing the importance of early ERCP in sepsis. In these studies, they applied ERCP to patients with acute biliary pancreatitis and found a decrease in mortality rates caused by biliary sepsis in patients who underwent early ERCP (Novikov, vd. 2021: E927). Similarly, in our study, 99% of the patients were discharged after stone removal and stent placement in patients who presented with cholangitis in sepsis.

Among all procedures in our study, the 30-day mortality score was 1%. In the study performed by Chatterjee et al.,

they reported a general complication rate similar to ours of 5% and a 30-day mortality rate of 2% (10 patients) in all procedures (Chatterjee, vd. 2011: 109). In our study, four patients died from progressive malignancy. The other two deaths were related to underlying medical conditions and there were no deaths directly related to the ERCP procedure itself, such as bleeding, perforation, or pancreatitis.

Our study has several limitations. This was a retrospective analysis conducted at a single tertiary centre, and the results cannot be generalized to all centres. Our study also lacked longitudinal follow-up, so the proportion of patients with subsequent biliary complications is unknown. In addition, techniques such as EPBD were not used. In difficult cannulation, only pre-cut sphincterotomy was applied and exploration was preferred in unsuccessful cases.

The strengths of our study are our success rate in various papilla formations and our low mortality rate.

CONCLUSION

This study demonstrated that the overall rate of adverse events associated with ERCP is low and has a high clinical success rate. ERCP indication should be put correctly, procedures should be performed by experienced people avoiding unnecessary manipulations. In experienced hands, the success rate is high even with anatomical variations and difficult stones.

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