Evaluation Of Endoscopic Retrograde Cholangiopancreatography Procedures: A Retrospective Study

Endoskopik Retrograd Kolanjiyopankreatografi İşlemlerinin Değerlendirilmesi: Retrospektif Bir Çalışma

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ÖZET

GİRİŞ ve AMAÇ: Endoskopik retrograd kolanjiyopankreatografi (ERCP) pankreatikobiliyer hastalıkların tanı ve tedavisinde önemli bir yöntemdir. Bu çalışmada ERCP sonuçlarının, işlem sırasında yapılan müdahalelerin, işlem sonrası gelişen komplikasyonların ve ERCP sırasında yapılan müdahaleler ile komplikasyonlar arasındaki ilişkilerin değerlendirilmesi amaçlanmıştır.
YÖNTEM ve GEREÇLER: Çalışmaya 574 hastaya yapılan 774 ERCP işlemi dahil edilmiş ve vakalar retrospektif olarak incelenmiştir.
BULGULAR: Endoskopik kanülizasyon %88,4 vakada başarılıydı. İşlem sonrası en çok rapor edilen sonuçlar sırasıyla koledokolitiyazis (%39,5), koledokta darlık (%22) ve mikrolitiyazis (%20,9) idi. İşlem sonrası klinik olarak anlamlı komplikasyon görülme oranı toplamda %14,8 idi. Pankreatit %9,8, klinik olarak anlamlı kanama %4, kardiyopulmoner komplikasyonlar ise %1,9 oranında görüldü. Mortalite oranı %0,9 olarak bulundu. Başarısız kanülizasyon sonucuna sahip vakalarda daha sık ön kesi yapıldığı tespit edildi (p=0,000). Ön kesi yapılan vakalarda kanama ve pankreatit komplikasyonları daha sık tespit edildi (p=0,009; p=0,007). Pankreatik stent uygulanan vakalarda pankreatit komplikasyonu daha sık tespit edildi (p=0,001).
TARTIŞMA ve SONUÇ: Post-ERCP pankreatit ve kanama riskini azaltmak adına ön kesi işlemlinden mümkün oldukça kaçınılması; başarısız kanülizasyon halinde papillayı daha fazla travmatize etmek yerine işlemin sonraki bir seansa ertelenmesi; PEP riskini azaltmak amacı ile pankreatik stent takılması işleminin ise sadece bu konuda çok deneyimli merkezlerce gerçekleştirilmesi uygun olacaktır.
Anahtar Kelimeler: endoskopik retrograd kolanjiyopankreatografi, sonuçlar, komplikasyonlar, pankreatit, profilaktik stentleme

ABSTRACT

INTRODUCTION: Endoscopic retrograde cholangiopancreatography (ERCP) is an important procedure in diagnosis and treatment of pancreaticobiliary diseases. In this study we aimed to evaluate outcomes, procedural interventions, complications and relations between procedural interventions and complications of ERCP procedures.
METHODS: A total of 774 ERCP procedures performed on 574 patients were included and investigated retrospectively in this study.
RESULTS: Endoscopic cannulation was successful in 88.4% of the cases. The most reported outcomes were choledocholithiasis (39.5%), stenosis in the common bile duct (22%) and microlithiasis (20.9%). The incidence of clinically significant procedure related complications was 14.8% in total. Pancreatitis was observed in 9.8% of the cases, clinically significant bleeding was observed in 4% of the cases, and cardiopulmonary complications were observed in 1.9% of the cases. The mortality rate was found to be 0.9%. Pre-cut sphincterotomy technique was found to be more frequently applied in failed cannulation cases (p=0.000). Post-ERCP bleeding and pancreatitis were observed more frequently in cases which pre-cut sphincterotomy technique was applied (p=0.009; p=0.007). Post-ERCP pancreatitis was found to be more frequent in cases which pancreatic stent implantation was performed (p=0.001).
DISCUSSION AND CONCLUSION: It would be appropriate to avoid pre-cut sphincterotomy as much as possible in order to reduce the risk of post-ERCP pancreatitis and bleeding; to postpone the procedure to a latter session in case of failed cannulation instead of traumatizing the papilla further; and prophylactic pancreatic stenting should only be performed in highly experienced centers.
Keywords: endoscopic retrograde cholangiopancreatography, outcome, complications, pancreatitis, prophylactic stenting

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INTRODUCTION

Since its first description in 1968 by McCune et al., endoscopic retrograde cholangiopancreatography (ERCP) has become an important and widely used procedure in diagnosis and treatment of pancreaticobiliary diseases (1, 2). With the introduction of endoscopic sphincterotomy in 1974, therapeutic use of ERCP has increased (2, 3). Over the years, ERCP has become more of a treatment method than a diagnostic method (4). Approximately 500,000 ERCP procedures are performed annually in the United States, with complications ranging from 4% to 10% and mortality ranging from 0.05% to 1%. Since ERCP is a complicated endoscopic procedure with possible serious complications, purely diagnostic ERCP procedures are now less preferred and has been replaced by less or non-invasive diagnostic methods such as endoscopic ultrasonography (EUS) and MR cholangiopancreatography (MRCP) (5). Although it has higher morbidity and mortality rates compared to other endoscopic procedures, it is possible to accept ERCP a safer procedure compared to surgery.

ERCP can be used in diagnosis and treatment of diseases of the bile duct, pancreatic diseases and ampullary tumors. One of the most common indication of ERCP is choledocholithiasis, which is the most common cause of biliary obstructions. Even though small stones may occasionally be missed, the sensitivity and the specificity of ERCP for detecting common duct stones is over 95%. Endoscopic sphincterotomy and stone extraction is highly successful in these cases in experienced centers (2).

Post-ERCP complications include post-ERCP pancreatitis (PEP), bleeding, perforation, infectious complications such as cholangitis and cholecystitis, cardiopulmonary complications, death and other rare complications such as pneumothorax, contrast allergy and post-sphincterotomy stenosis. PEP is the most common serious post-ERCP complication and is estimated to result in costs exceeding 150 million dollars in the United States annually. With appropriate patient selection, incidence of PEP may decrease. EUS and MRCP are almost equal in detection of pancreaticobiliary diseases such as choledocholithiasis and do not possess the risk of PEP. Therefore it would be appropriate to perform ERCP only if the possibility of therapeutic intervention is high (6).

MATERIALS AND METHODS

A total of 774 ERCP procedures performed on 574 patients between January 2013 and December 2015 in Endoscopy Unit of Gastroenterology Clinic of [Hidden for Blind Review] University Faculty of Medicine Department of Internal Medicine were included in our study. The demographic characteristics of patients; outcomes, procedural interventions, complications and relations between procedural interventions and complications of ERCP procedures were investigated. This study was approved by the Clinical Research Ethics Committee of [Hidden for Blind Review] University Faculty of Medicine (No: 2016/6-21) and complies with research and publication ethics.

Complications were mostly defined according to consensus criteria (7). Pancreatitis is defined as new or worsened abdominal pain (clinical pancreatitis) with an increase in serum amylase to more than 3 times the upper limit of normal at more than 24 hours after the procedure that required admission or prolonged the planned admission to at least 2 days. The patient was not accepted as PEP in cases where amylase was already elevated at the admission and this elevation continued after the procedure. Pancreatitis is graded mild if it required 2 to 3 days of hospitalization; moderate if it required 4 to 10 days of hospitalization; and severe if it required more than 10 days of hospitalization, or if hemorrhagic pancreatitis, abscess, phlegmon or pseudocyst developed, or necessitated percutaneous or surgical intervention, or contributed to death. Bleeding is defined as a drop in hemoglobin concentration of at least 2 g/dL or the need for a blood transfusion within 14 days after the procedure. Clinical findings of the bleeding (such as hematemesis or melena) were not considered for the definition. Bleeding is graded mild (clinically insignificant) if there was no need for a transfusion, moderate if 4 or less transfusions were given, and severe if 5 or more transfusions were given or necessitated angiographic intervention or surgery, or contributed to death. Solely endoscopically

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observed bleeding is also accepted as mild (clinically insignificant).

Statistical Analysis

Statistical analysis of the data was performed using the IBM SPSS Statistics for Windows, Version 21 (Armonk, NY: IBM Corp). Continuous data were presented as mean (±standard deviation) and the categorical data were presented as frequency and percentage (n, %). Pearson's chi-square test and Fisher's exact test was used to compare groups. Bonferroni correction is applied for more than two group comparisons. P values smaller than 0.05 were considered as statistically significant.

RESULTS

The mean age of the cases was 59.63 ± 18.07. The youngest patient was 15 years old and the oldest patient was 96 years old at the time of the procedure. 56.2% of the cases (435 cases) were female patients.

Cases were divided into three groups according to patient age; ≤40 years old, 41 to 59 years old, and ≥60 years old. There were 145 cases (18.7%) in the age group of 40 years and below, 192 cases (24.8%) in the age group of 41 to 59 years, and 437 cases (56.5%) in the age group of 60 years and above.

ERCP was performed only once in 451 (78.6%) of 574 patients who underwent ERCP, and 123 (21.4%) patients had more than one ERCP.

Papillary biopsy was performed in 34 cases (4.4%). Pre-cut sphincterotomy was performed in 54 cases (7%), biliary sphincterotomy was performed in 365 cases (47.2%), and in 36 cases (4.7%) previously existing biliary sphincterotomy was expanded. Pancreatic sphincterotomy was performed in 5 cases (0.6%). Lithotripsy was performed in 20 cases (2.6%). Biliary stent implantation was performed in 282 cases (36.4%) and pancreatic stent implantation was performed in 10 cases (1.3%).

Only single outcome was reported in 721 cases, and in the remaining 53 cases two or three outcomes were reported (e.g. "papillary tumor + choledocholithiasis"). Endoscopic cannulation was successful in 684 cases (88.4%). Only 24 cases (3.1%) were reported to be normal; the remaining 750 cases were reported to have at least one pathologic outcome. The most reported outcomes were choledocholithiasis, stenosis in the common bile duct, and microlithiasis. Outcomes of ERCP was shown in Table 1.

Table 1. Outcomes of ERCP

	n	%
Choledocholithiasis	306	39,5
Stenosis in the common bile duct	170	22
- Stenosis in the distal part of common bile duct	90	11,6
- Stenosis in the middle part of common bile duct	30	3,9
- Stenosis in the proximal part of common bile duct	17	2,2
- Stenosis in the hilar part of common bile duct	32	4,1
- Multiple stenosis in the common bile duct	1	0,1
Microlithiasis	162	20,9
Failed cannulation	90	11,6
Papillary tumor	30	3,9
Normal	24	3,1
Contrast leakage	10	1,3
Choledochal cyst	6	0,8
Stenosis in intrahepatic bile ducts	5	0,6
Other	27	3,5

No procedure related complication was seen in 571 cases (73.8%), and in the remaining 203 cases (26.2%) at least one procedure related complication (clinically significant and insignificant in total) was seen. Of these 203 cases, only single complication was seen in 171 cases, and in the remaining 32 cases two, three or four complications were seen simultaneously. The most seen procedure related complications was bleeding with 119 cases (15.4%), although 4% were clinically significant and 11.4% were clinically insignificant. The second one was pancreatitis and the third one was cardiopulmonary complications. The mortality rate was found to be 0.9% (7 cases). The cause of death was pancreatitis in two cases, bleeding in two cases, cholangiosepsis in two cases, and cardiopulmonary in one case. Complications of ERCP was shown in Table 2.

When the outcomes of ERCP were evaluated according to gender, stenosis in the distal part of the common bile duct was found to be significantly more frequent in males (p=0.004), and papilla tumor was found to be significantly more frequent in females (p=0.002). Apart from these two outcomes, no significant difference was found between genders.

When the complications of ERCP were evaluated according to gender, no significant difference was found between genders.

When the outcomes of ERCP were evaluated according to age groups, failed cannulation (p=0.004) and stenosis in the distal

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part of the common bile duct (p=0.017) were found to be significantly less frequent in the age group of 40 years and below. Microlithiasis was found to be significantly more frequent in the group of 40 years and below compared to the group of 60 years and above (p=0.004). Normal outcome was found to be significantly more frequent in the group of 41-59 years old compared to the group of 60 years and above (p=0.004). Papillary tumor was found to be significantly more frequent in the group of 60 years and above compared to the group of 40 years and below (p=0.005). Apart from these outcomes, no significant difference was found between age groups.

Table 2. Complications of ERCP

	n	%
Bleeding	119	15,4
- Mild (Clinically insignificant)	88	11,4
- Moderate	28	3,6
- Severe	3	0,4
Pancreatitis	76	9,8
- Mild	42	5,4
- Moderate	30	3,9
- Severe	4	0,5
Cardiopulmonary	15	1,9
Cholangitis	13	1,7
Death	7	0,9
Cholecystitis	3	0,4
Perforation	3	0,4
Stone impaction	3	0,4
Biloma	1	0,1
Pancreatic abscess	1	0,1

When the complications of ERCP were evaluated according to age groups, pancreatitis was found to be significantly more frequent in the group of 41-59 years old compared to the group of 60 years and above (p=0.015). Apart from this, no significant difference was found between age groups.

There were no significant relationship between papillary biopsy and bleeding (p=0.117), pancreatitis (p=0.567), or perforation (p=0.567).

Pre-cut sphincterotomy was found to be more frequently performed in failed cannulation cases (p=0.000).

Bleeding and pancreatitis were observed more frequently in cases which pre-cut sphincterotomy was performed (p=0.009; p=0.007).

There were no significant relationship between biliary sphincterotomy and bleeding or pancreatitis (p=0.289; p=0.223). There were also no significant relationship between pancreatic sphincterotomy and bleeding or pancreatitis (p=1.000; p=0.404).

There was no significant relationship between biliary stent implantation and pancreatitis (p=0.093). Pancreatitis was observed more frequently in cases which pancreatic stent implantation was performed (p=0.001).

DISCUSSION

A deep, successful cannulation of the common bile duct and/or pancreatic duct is necessary to perform diagnostic and therapeutic procedures. The rate of successful cannulation in our study was consistent with the literature, given the fact that failed cannulation during ERCP is known to occur 5%-20% of all cases (8).

Only 3.1% of the cases were reported to be normal in our study due to the fact that not diagnostic, but therapeutic ERCP procedures were more commonly performed.

The most reported outcome was choledocholithiasis, and microlithiasis was in the third line in our study. The most common indication for ERCP is choledocholithiasis in the literature. In a study that investigated 1072 ERCP procedures, 46.6% of the procedures were performed with indication for choledocholithiasis (5). Our results were also consistent with other studies, as well (9, 10).

The second most reported outcome was stenosis in the common bile duct. Given the fact that pancreaticobiliary malignancies are more frequently seen over 60 years of age (11) and that more than half of our cases were over 60 years of age, it is reasonable to have this result.

Rate of overall procedure related complications is generally accepted to be between 5% and 10% (11-14). However the definitions used for post-ERCP pancreatitis and bleeding differ in the literature, which naturally affects the ratios. The incidence of procedure related complications was 26.2% in total in our study. The incidence of bleeding (clinically significant and insignificant in total) was 15.4%. The reason of the higher rate of complications seen in our study compared to the literature was because clinically insignificant bleedings were included. When we exclude this, overall incidence of procedure related complications becomes 14.8%, which can be considered acceptable given the fact

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that this university hospital is the highest level healthcare institution in its region and therefore the patient population has a relatively higher risk.

PEP and its severity were defined using the consensus criteria (7). The incidence of PEP is generally accepted to be between 3% and 10% (6, 11, 14-16). However, it can be as high as 42% in high-risk patients (17). The incidence of PEP was 9.8% in our study which was consistent with the literature. In a meta-analysis performed by Kochar et al. (18), 13,296 ERCP procedures were examined and the incidence of PEP was found to be 9.7%, similar to our study.

For the definition of bleeding we have adopted an inhouse criteria. Even though our criteria was similar to the consensus criteria (7), the clinical findings of the bleeding (such as hematemesis or melena) was considered a must be in the consensus criteria, unlike ours. Again, unlike the consensus criteria, the amount of decrease in hemoglobin concentration was accepted as two units instead of three to call it a bleeding in our study. In this respect, the definition of bleeding we used was wider and similar to what Freeman and his colleagues used in their study (19).

It is generally accepted that it is possible to see bleeding endoscopically in 10% to 30% cases after sphincterotomy and this is not accepted as a procedural complication if there is not any clinical findings of the bleeding or a need for blood transfusion (20). Since our study was a retrospective designed study, we have reached the post-procedural clinical status of in-patients by examining their epicrisis reports, and we were not able to reach the post-procedural clinical status of out-patients. In epicrisis reports we have examined, not all of them specified if there was a clinical finding of the bleeding. Due to these reasons we had to keep our bleeding definition wide as possible and accept endoscopically seen bleedings as a complication. To compensate this, the cases in which there was a two or more levels of drop in hemoglobin concentration yet did not require a blood transfusion or an intervention and the cases in which the bleeding was seen endoscopically yet did not require a blood transfusion or an intervention were accepted as clinically insignificant.

The incidence of bleeding is accepted to be between 0.2% and 5% in the literature (15). The incidence of bleeding was found to be 15.4% in our study, however the rate of clinically significant bleeding was 4%. This value was consistent with the literate.

The incidence of cardiopulmonary complications, infectious complications (i.e. cholangitis and cholecystitis), perforation and mortality in our study were also consistent with the literature.

In our study, stenosis in the distal part of the common bile duct was found to be more frequent in males and papilla tumor was found to be more frequent in females. When the complications of ERCP were evaluated according to gender, no significant difference was found between genders. Considering the fact that cholangiocellular carcinomas and pancreatic carcinomas are largely responsible for choledochal strictures and that these two malignancies are more frequent in males (11, 21), it is reasonable to see stenosis in the distal part of the common bile duct more frequently in males. When the epidemiology of papilla tumors is examined, it has been reported that papilla tumors are seen more frequently in males (22), unlike in our study. Although it has been reported that female gender is a risk factor for the development of PEP (6, 18), there was no significant difference in the incidence of PEP between genders in our study.

Failed cannulation and stenosis in the distal part of the common bile duct were found to be less frequent in the age group of 40 years and below in our study. In a study examining the ERCP in the elderly pointed out that failed cannulation is more common in elder patients (23), which was consistent with our study. Considering the fact that neoplasms that cause stenosis in the common bile duct increases with age, it is reasonable that we found stenosis in the distal part of the common bile duct less frequent in the age group of 40 years and below.

Pre-cut sphincterotomy is a technique that is used for difficult cannulations to increase the success of cannulation. It is accepted that pre-cut sphincterotomy increases the incidence of PEP and bleeding (24, 25). In our study, pre-cut sphincterotomy was more frequently performed in cases with failed cannulation, and the incidence of PEP and

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bleeding was higher in this cases, which is consistent with the literature.

Placing pancreatic stents in high-risk patients to reduce the risk of PEP is an increasing approach in recent years (24). Prophylactic pancreatic stent placement was shown to decrease PEP rates in two meta-analyses (26, 27). However, when the papilla is traumatized in cases such as repeated cannulation trials, placing a pancreatic stent to keep the canal open does not reduce the incidence of pancreatitis (28). When the pancreatic stent placement attempt fails, the incidence of pancreatitis increases significantly (29). In our study, PEP was observed more frequently in cases which pancreatic stent implantation was performed. Of the 774 procedures we investigated, only 10 cases involved pancreatic stent implantation and five of them had developed PEP. Although the rate of PEP in patients treated with pancreatic stents was found to be statistically significant, the number of cases with pancreatic stents was low and this was an obstacle for satisfactory interpretation. Still, this might have resulted from operators not having sufficient experience on this method.

In conclusion, in order to obtain higher successful cannulation rates and to reduce procedure related complications, the procedure should be performed in experienced centers. However, no matter how experienced the endoscopist is, it is inevitable to see complications and mortality in a certain extent. For this reason, it is very important to choose patients carefully, and to choose to perform this procedure particularly if the possibility of therapeutic intervention is high.

In order to reduce the risk of post-ERCP pancreatitis and bleeding, it would be appropriate to avoid pre-cut sphincterotomy as much as possible and to postpone the procedure to a latter session in case of failed cannulation instead of traumatizing the papilla further. Prophylactic pancreatic stenting for the prevention of post-ERCP pancreatitis should only be performed in highly experienced centers.

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