# A SURGICALLY-COMPROMISED SITUATION: ERCP-RELATED COMPLICATIONS TEHLİKELİ BİR CERRAHİ DURUM: ERCP'YE BAĞLI KOMPLİKASYONLAR

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#### ABSTRACT

**INTRODUCTION:** In this retrospective study, an evaluation was made of ERCP-related perforations and necrotizing pancreatitis that required surgical intervention.

**MATERIAL AND METHODS:** A total of 1439 ERCP procedures were performed by gastroenterologists and 12 complications that required surgical intervention were identified (0.8%). All of the cases presented in this study were primarily managed conservatively in the Gastroenterology Department and were evaluated by the surgeons when signs and symptoms deteriorated.

**RESULTS:** Patient age was mean 55.5±17.3 years. The mean time from ERCP to surgery was 3.92 days (0-14 days). Of the 12 patients, 6 (50%) died postoperatively. No statistically significant difference was determined between the surviving and not surviving groups in respect of patient age or the mean time from ERCP to operation. The operational technique was decided during the surgery depending on the extent of the perforation and the condition of the peritoneum. The correlation between diagnosis and type of operative procedure was similar in both groups.

**CONCLUSION:** There is no consensus on the surgical management of ERCP-related complications which might result in high mortality rates despite full-care management. Therefore, the main objective of departments dealing with ERCP procedures should be to reduce the risk of ERCP-related complications to a minimum.

*Keywords:* ERCP; complication; hepatobiliary surgery; perforation; necrotizing pancreatitis; duodenum

## INTRODUCTION

Endoscopic retrograde cholangiopancreatography (ERCP) is an endoscopic procedure which is known to be of significant therapeutic and diagnostic benefit for various disorders. Choledocholithiasis, malign and benign pancreatic diseases, and biliary malignancies are the most common disorders for which ERCP is performed. Nevertheless, some complication may develop during or after this procedure, including hemorrhage,

## ÖZET:

**AMAÇ:** Bu retrospektif çalışmada, ERCP'ye bağlı olarak gelişen ve cerrahi müdahale gerektiren perforasyon ve nekrotizan pankreatit vakalarının değerlendirmesi yapılmıştır.

**GEREÇ VE YÖNTEMLER:** Gastroenterologlar tarafından yapılan 1439 ERCP uygulaması değerlendirilmiş ve cerrahi müdahale gerektiren 12 komplikasyon tespit edilmiştir (% 0.8). Bütün vakalar Gastroenteroloji Kliniğinde konservatif olarak takip edilmiş, bulgu ve semptomların düzelmediği hastalar cerrahlar tarafından değerlendirilmiştir.

**BULGULAR:** Ortalama hasta yaşı 55.5±17.3'dir. ERCP ile cerrahi müdahale arasındaki süre ortalama 3.92 gündür (0-14 gün). Oniki hastanın 6'sı cerrahi sonrası kaybedilmiştir (%50). Cerrahi sonrası yaşayan ve yaşamayan gruplar arasında hasta yaşı veya ERCP-cerrahi arası geçen ortalama süre açısından istatistiksel olarak anlamlı bir farklılık yoktur. Uygulanacak cerrahi tekniğe, perforasyonun çapına ve peritonun durumuna göre operasyon sırasında karar verilmiştir. Tanı ile uygulanan cerrahi prosedür arasındaki korelasyon her iki grup için de benzerdir.

**SONUÇ:** Çok iyi tibbi bakıma rağmen yüksek mortalite oranlarıyla sonuçlanan ERCP'ye bağlı komplikasyonların cerrahi yönetiminde kesin bir konsensusa henüz varılamamıştır. Bu nedenle, ana amaç ERCP prosedürleri uygulayan birimlerin ERCP'ye bağlı komplikasyon risklerini minimuma indirmek olmalıdır.

**Anahtar kelimeler:** ERCP, komplikasyon, hepatobilier cerrahi, perforasyon, nekrotizan pankreatit, duodenum

pancreatitis, perforation, cholecystitis, cholangitis, and cardiopulmonary events such as hypoventilation, cardiac arrhythmia, and aspiration. Ileus, hepatic abscess formation, duodenal hematoma, pneumothorax, air in the portal vein, pneumomediastinum, and complications due to therapeutic devices, such as impaction of stone retrieval baskets are other less frequently seen complications. The reported complication rates vary extensively according to differences in sampling of the patients, definition of the

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Aziz Mutlu BARLAS S.B. Ankara Eğitim ve Araştırma Hastanesi Genel Cerrahi Kliniği, Ulucanlar, Ankara. **Tel:** +90 312 595 34 16 **Gsm:** +90 533 635 56 35 **Faks:** +90 312 363 33 30 **e-posta:** barlasmutlu@yahoo.com complications, and design of the studies (1, 2).

Acute pancreatitis is the most commonly seen ERCPrelated complication with an incidence of 2-10%. In the presence of certain risk factors, the incidence of this complication may reach as high as 30%. Even though post-ERCP pancreatitis is usually mild, or occasionally moderate, it may be severe (approximately 0.4-0.6% of all performed procedures) and potentially fatal with mortality rates between 0.1% and 0.5%. Moreover, patients undergoing ERCP may experience asymptomatic hyperamylasemia at a rate of 35-70 % (3).

Perforation, with reported rates between 0.1% and 0.6%, is one of the most serious complications of ERCP. The ERCP-related perforations can be classified into 3 types: sphincterotomy-related periampullary perforation, perforation distant from the papilla, and guide wireinduced perforation. The determined risk factors for perforation include biliary stricture dilation, previous Billroth II gastrectomy, prolonged time of ERCP, sphincterotomy procedure, dysfunction of sphincter of Oddi, and intramural contrast injection. Numerous factors such as clinical and radiological findings, as well as location and site of the perforation influence the decision taken for the proper management procedure. Lower morbidity and mortality rates can be achieved if the perforation is identified in the early post-procedure period and managed appropriately. No surgical procedure is needed in most patients if a periampullary perforation is diagnosed immediately and managed with biliary and duodenal drainage by nasobiliary or nasogastric tubes as well as broad-spectrum antibiotics. Since the detection and diagnosis of perforations distant from the papilla is difficult and frequently delayed, these perforations generally require surgery. The best approach to ERCP-related perforations is usually related to the experience and preferences of the surgeon (1, 2).

Adequate knowledge of the potential complications of ERCP, the risk factors, and the estimated frequency can minimize the severity and incidence of complications. Careful selection of patients, appropriate intervention, familiarity and expertise with the procedure and adequate technology are other factors that can help to decrease the rates of ERCP-related complications (2).

In this retrospective study, an evaluation was made of ERCP-related perforations that required surgical intervention between 2010 and 2016 at a single tertiary hospital. All of the cases presented in this study were primarily managed conservatively in the Gastroenterology Department of the above-mentioned hospital and were evaluated by surgeons when signs and symptoms deteriorated. Thus, only patients that were managed surgically were presented in this study. The diagnostic process, surgical approach options, and treatment outcomes were discussed in the light of current literature.

# MATERIALS AND METHODS

This retrospective analysis was carried out in the General Surgery Department of Ankara Education and Research Hospital. Between January 2010 and March 2016, patients with ERCP-related perforations that required surgical intervention were obtained from computer records, medical report charts, and operation records. These records were reviewed to determine the demographic features of the patients, indications and findings of ERCP procedure, procedural details including sphincterotomy, bile duct stenting, and biliary stone extraction, the radiological and clinical findings of perforations, procedures for diagnosis, the duration between diagnosis and surgery, comorbid conditions, previous ERCP procedures and/or operations, localization of perforation, the surgical procedures performed, complications after surgery, duration of hospital stay, and outcomes of the patients.

Patients who were accepted as difficult ERCP intervention with a probability of complication were hospitalized in the Gastroenterology Department and conservative management was applied with serial clinical assessment, nasogastric decompression and parenteral antibiotics, and if necessary, frequent laboratory tests, intravenous fluid replacement, and close monitoring. Patients with abdominal pain, diffuse peritoneal signs, leukocytosis, or fever following ERCP were evaluated with preliminary diagnostic tests including whole blood count, biochemical tests, and abdominal radiographs to determine probable pancreatitis or perforation. Computed tomography (CT) of the abdomen was performed if direct abdominal graphs or clinical findings presented suspicious findings of perforation. Severe peritonitis, CT examination showing fluid accumulation in intraperitoneal or extraperitoneal areas and extensive extravasation of contrast on ERCP or CT, unresolved remaining problems such as retained biliary stone or hardware that cannot be removed during the ERCP procedure, and duodenal lateral wall injury were the main criteria for surgical intervention in the general surgery consultation. Immediate surgery was performed if the heart rate >120/min, the systolic blood pressure <90 mmHg, axillary temperature >38°C, or the abdominal symptoms and signs indicated peritonitis.

Data analysis was applied using Statistical Package for Social Sciences (SPSS) version 15.0 for Windows (SPSS Inc, Chicago, IL, USA) software. Distribution of all variables about the mean was seen to be normal. Data were stated as mean± standard deviation (SD). To determine from which group the difference originated, the Tukey honestly significant difference (HSD) or Mann-Whitney U multiple comparison tests were used. Statistical significance was set at a value of p<0.05.

# RESULTS

The analysis included 12 patients who were diagnosed with gastrointestinal perforation or necrotizing pancreatitis as an ERCP complication between the years 2010-2016. The group comprised 9 (75%) females and 3 (25%) males. During the defined study period, 1439 ERCP procedures were performed by gastroenterologists and 12 complications that required surgical intervention were identified (0.8%). The average age of the patients was  $55.5\pm17.3$  years (range, 27–88 years). All the ERCP procedures were carried out in the Gastroenterology Department of our hospital. The surgical procedure was performed on all the consulted patients with acute abdominal symptoms and specific radiological findings by the same surgical team.

ERCP procedures were most commonly performed for stones of the common bile duct (9 patients-75%). Other indications were obstructive jaundice, biliary pancreatitis, and common bile duct dilatation. The ERCP applied was diagnostic in 7 (58.3%) cases and therapeutic in 5 (41.7%). Only 1 patient (8%) had previously undergone ERCP and 2 patients (16%) had a history of previous abdominal surgery. Sphincterotomy was applied to all patients, and cannulation of the common bile duct was notified as difficult in the procedure report.

If a patient had at least one or multiple symptoms or signs including fever, abdominal pain, leukocytosis, elevation of amylase level, and nausea and/or vomiting after the procedure, diagnostic procedures were initiated. During the ERCP procedure, 2 (16.6%) perforations were diagnosed and these patients were operated on immediately. The remaining cases (83.4%) were diagnosed from plain abdominal X-ray and/or CT. The main findings were diffuse intraperitoneal fluid, retroperitoneal air bubbles, free peritoneal air, peripancreatic and/or perisplenic fluid, retroperitoneal fluid collection, and pancreatic edema and heterogeneity. The mean time between ERCP and operation was 3.92 days (range, 0-14 days). All the cases were followed up in the intensive care unit postoperatively.

The mean hospitalization time for patients that survived after the operation (6 patients, 50%) was 33.16±26.40 (17-85) days. Four of the ERCPs were diagnostic and 2 were therapeutic. The most common indication for ERCP was choledocholithiasis in 5 patients, (83.3%) and the indication in the remaining 1 patient was obstructive jaundice. The average time between the ERCP procedure and operation was 3.5±3.0 days (range, 1 -9 days). In respect of the hospitalization period between immediate operation and delayed surgery, no significant difference was determined. The longest length of hospitalization (85 days) was determined in a patient with a duodenal perforation. The patient was 50 years old and the operation was performed 1 day after ERCP. The indication of ERCP was obstructive jaundice and the procedure was not completed because of the suspicion of perforation. CT was applied after ERCP. Pararenal and peripancreatic extensive air densities and retroperitoneal fluid collection were detected. Primary repair of duodenal perforation + cholecystectomy + T tube drainage + pyloric exclusion + tube duodenostomy + tube gastrostomy and gastrojejunostomy were performed in

the operation of this patient. The operative management of the other patients included cholecystectomy + T tube drainage + tube duodenostomy + tube gastrostomy and feeding jejunostomy in 1 patient (operative diagnosis was choledochoduodenal perforation), primary repair of duodenum + drainage of abscess + tube duodenostomy + tube gastrostomy in 1 patient (operative diagnosis was duodenal perforation), subtotal pancreatectomy and drainage in 1 patient (operative diagnosis was necrotizing pancreatitis), debridement of necrosis and drainage of the abscess in 2 patients (operative diagnosis of these patients was necrotizing pancreatitis).

Of the 12 patients, 6 (50%) died after the operation. The average age of these patients was 61.00±20.03 years (range, 27-88 years). The mean time between ERCP and operation was 4.33±5.82 days (range, 0-14 days). The operation indications of these patients were duodenal perforation (n=1), choledochoduodenal perforation (n=1), common bile duct perforation (n=2), and necrotizing pancreatitis (n=2). Of these patients, 3 had comorbid diseases, 1 had hypertension, 1 had hypertension and coronary artery disease, and 1 had hypertension and diabetes mellitus. The mean time between operation and death was 20.83 days (range, 2-71 days). The patient who died 2 days postoperatively had posterior duodenal perforation and was 88 years old. The ERCP indication was common bile duct dilatation and surgery was applied 1 day after the ERCP procedure. T tube drainage + pyloric occlusion + gastroenterostomy + feeding jejunostomy were performed during the operation. The operations performed on the other patients were cholecystectomy + T tube drainage in 1 (operative diagnosis was choledochal perforation), cholecystectomy + T tube drainage+ tube duodenostomy + pyloric occlusion + gastrojejunostomy in 1 (operative diagnosis was choledochal perforation), pyloric occlusion + tube duodenostomy + T tube drainage + gastrojejunostomy + primary repair of duodenal perforation in 1 (operative diagnosis was choledochoduodenal perforation), cholecystectomy + subtotal pancreatectomy + drainage in 1 (operative diagnosis was necrotizing pancreatitis), and cholecystectomy + necrosectomy + drainage in 1 patient (operative diagnosis was necrotizing pancreatitis).

The average age of the patients was  $50\pm13.57$  years for those who survived and  $61\pm20.03$  years for who did not, with no significant difference determined. The mean time between ERCP and operation was  $3.50\pm3.01$  days for patients who survived and  $4.33\pm5.81$  days for patients who did not. Between these groups, there was also determined to be no significant difference. The operational technique was decided during the surgery depending on the extent of the perforation and the condition of the peritoneum. The diagnosis/operative procedure correlations were similar for both groups (Table 1).

## DISCUSSION

ERCP is a therapeutic and diagnostic tool commonly used for various pancreatic and biliary disorders. Although the procedure is known to be safe, potential complications include pancreatitis, bleeding, and perforation. Major complications have been reported at rates between 5.4% and 23.0% and overall rates of mortality at 0.1% - 1%. Perforation is a very serious complication of ERCP procedures with a reported incidence of 0.1-0.6% (4). Howard et al. (5) described three types of perforations related to ERCP: (i) guidewire perforations of the duct; (ii) periampullary perforations, and (iii) duodenal perforations distant from the papilla. Another system classifies these perforations as intraperitoneal or retroperitoneal. Retroperitoneal perforations are typically located in the periampullary area and occur as a result of guidewire usage or sphincterotomy whereas intraperitoneal perforations are endoscopy-related perforations and characteristically localized in the lateral duodenal wall. Delayed diagnosis and management following perforation leads to significantly higher mortality rates ranging between 8% and 23% as a result of multiple organ failure and sepsis (4). In the present case series, sphincterotomy was performed on all patients.

The extent and site of injury, time to diagnosis, and the patient's condition are the main factors to be considered when deciding the proper type of management for ERCP-related duodenal perforations (6). However, there is no consensus on guidelines of management and selection criteria for conservative management or surgery. The existing recommendations have been based on case series with a small number of patients. Non-traumatic and traumatic perforations of the duodenum have been traditionally managed by surgical interventions. However, in recent years conservative and selective managements have become the preferred management strategies (4). The treatment of post-ERCP perforations may vary according to the clinical findings and the severity and type of the leakage. Although the application of specific endoscopic closure devices and endoscopic clipping has been used for the treatment of larger perforations, surgical treatment is usually preferred to repair bowel wall perforations (7). If the perforation is detected during the ERCP procedure or the early post-procedure period, endoscopic therapy may be performed on selected patients (6). While surgical intervention is needed for patients with endoscope-induced perforations, periampullary and guidewire perforations, which are often smaller and well contained, can be recognized early and managed conservatively with intense endoscopic drainage and/ or stenting accompanying medical therapy with widespectrum antibiotics and fluid replacement (4, 5). In the current retrospective analysis, all patients were initially managed conservatively in the Gastroenterology Department. The patients with symptoms or signs including abdominal pain, leukocytosis, fever, elevation of amylase level, and nausea and/or vomiting after the procedure were referred to the General Surgery Department. No data were available regarding the number of patients that were managed conservatively in the Gastroenterology Department. Therefore, in

this current study only the surgical approaches are presented and discussed. There was suspicion of perforation during the procedure in only 3 patients and 2 of those were operated on within the first 24 hours following ERCP. Unfortunately, those two patients did not survive. The first patient, who was 60 years old, had a perforation in the distal part of the common bile duct. In the operation, cholecystectomy + T tube drainage + tube duodenostomy + pyloric exclusion + gastrojejunostomy were performed. This patient had hypertension as a comorbid disease and died on postoperative day 71. The second patient was 63 years old, and had a choledochoduodenal perforation with no comorbidity. Primary repair of duodenal perforation + T tube drainage + pyloric exclusion + tube duodenostomy + gastrojejunostomy were performed during the operation and the patient died on postoperative day 4. The patient in whom perforation was suspected during ERCP and underwent surgery 1 day after the procedure was aged 50 years and had a duodenal perforation. This patient survived after the operation, in which primary repair of duodenal perforation + cholecystectomy + T tube drainage + pyloric exclusion + tube duodenostomy + tube gastrostomy + gastrojejunostomy were performed. Although these 3 patients of similar age were operated on within the early period after the perforation and similar operations were performed, 2 died. This situation is difficult to explain.

When there is suspicion of perforation, an abdominal CT should be taken to evaluate the leakage of contrast and any air in the intraperitoneal or retroperitoneal region (7). In the current case series, if a patient had at least one of the symptoms or signs including fever, abdominal pain, elevation of amylase level, leukocytosis, and nausea and/or vomiting after the procedure, diagnostic procedures were initiated. All patients were diagnosed from CT except for the two in whom perforation was suspected during the procedure. The main findings on CT were diffuse intraperitoneal fluid, retroperitoneal air bubbles, free peritoneal air, perisplenic and/or peripancreatic fluid, retroperitoneal fluid collection, and pancreatic heterogeneity and edema. Assalia et al. (8) prospectively evaluated the validity of previously determined clinical and radiological criteria defined for the management of duodenal perforations related to ERCP. In contrast to previous studies, treatment of patients was conducted according to previously determined guidelines and data were achieved prospectively in that study. It was emphasized that for patients with evident peritoneal findings or other signs indicating sepsis and those with contrast leakage, the guidelines recommended surgical management, regardless of the localization or mechanism of injury. According to the data obtained from that study, it was concluded that the most significant factor determining appropriate treatment option was the clinical condition of the patient, and when this is interpreted together with the type of injury and the radiological findings, the optimal guidance

for selective management will be provided. It was also recommended that radiological findings should not be the single determinant of the treatment mode because patients with mild symptoms and signs and small amounts of fluid or air in the peritoneum might be treated conservatively with success.

The surgical management principles for ERCP perforations state two prerequisites: (i) sepsis control through the removal of the source, predominantly biliary stone disorders, and drainage of intraperitoneal and extraperitoneal fluid collections, and (ii) repair of the leakage with or without a diversion procedure. Since surgical outcome of blunt duodenal trauma is known to be worse and duodenal fistula has been seen to develop when only primary repair was applied at more than 24 hrs after the injury, in addition to primary repair of the perforation, a duodenal diversion procedure should be performed in these patients together with the drainage of the retroperitoneal area, especially for cases of type I perforation which present with a high-output duodenal fistula (9).

ERCP-related perforations are usually treated with surgical procedures, including repair of the perforation using omental patch, proper drainage, T-tube drainage with or without cholecystectomy, and pyloric exclusion with gastrojejunostomy (10-12). Sarli et al. (13) reported that a wide series of surgical interventions could be applied for treating ERCP-related perforations, including common bile duct exploration + T-tube drainage, simple retroperitoneal drainage, antrectomy + gastrojejunostomy, insertion of a T-tube into the perforation and repair of the duodenum around this tube, gastrojejunostomy with pyloric exclusion and pancreatico-duodenectomy. In the current study, generally definitive operations were performed.

Various mortality rates have been reported in different published series. A review by Scarlett and Falk (14) examined studies published up to 1994. The mortality rates of surgical interventions performed for ERCPinduced perforations were found to be up to 50 %. In more recent case series, this rate has improved. Avgerinos et al. (15) declared a total mortality rate of 20% and Preetha et al. (16) 16.7 %. In a case series of Alfieri et al. (9) of 30 ERCP-related perforations, duodenal diversion (in 2 cases of type I perforation) was performed on the patients with duodenal perforations who were operated on late. The outcomes were found to be similar to those of patients who were operated on early and treated by simple repair of the perforation. The total mortality rate was 13.3 % and the operative mortality was 26.6 %. Koc et al. (17) applied laparoscopic cholecystectomy (LC)+ laparoscopic common bile duct exploration (LCBDE)+ T-tube drainage+ intraperitoneal and/or retroperitoneal drainage to 6 patients following the failure of conservative management and LCBDE + T-tube drainage with or without LC + retroperitoneal and/or intraperitoneal drainage to 8 patients as primary management. Failure was reported in 2 (14%) patients and the rate of surgical mortality was reported to be 7.1%. In the present retrospective analysis, the mortality rate of the operative group was 50%. This rate was worse than the mortality rates of recent studies, but as previously mentioned, all the patients in this case series were initially managed conservatively in the Gastroenterology Department and no data were available in respect of conservatively managed patients. As stated above, no statistically significant difference was determined between the non-surviving and surviving patient groups in terms of the ages of patients and the mean time between the ERCP procedure and operation in the current retrospective case series. The operational technique was decided during the surgery depending on the extent of the perforation and the condition of the peritoneum. The correlation between diagnosis and operative procedure was similar in both groups. However, the mortality rate was quite high (50%). This confusing situation is difficult to explain with current information about ERCP-related perforations emphasizing that salvage surgery after failed conservative management, delay in diagnosis and intervention, the older age, and multiple operations evidently contribute to poor outcomes. Since there is no consensus of opinion on the surgical management of ERCP-related complications which might result in high mortality rates despite full-care management, minimizing the risk of ERCP-related complications should be the main objective of the departments dealing with ERCP procedures.

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