

Endoscopic Retrograde Cholangiopancreatography in Patients with Post-Operative Bile Duct Injuries: Experience of a Tertiary Center in Turkey

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ABSTRACT

Objective: The aim of this study was to determine the effectiveness and safety of endoscopic retrograde cholangiopancreatography (ERCP) in the diagnosis and treatment of post-operative bile duct injuries and to share our experience of a tertiary referral center.

Methods: Patients who underwent ERCP in our hospital due to biliary injuries after biliary surgery between January 2017 and March 2020 were included in this study. Demographic data, etiologies, clinical conditions, endoscopic treatment methods, and results of the patients were analyzed.

Results: A total of 30 patients (16 females and 14 males) were included in this study. Twenty-six patients experienced bile leakage or stenosis after cholecystectomy, and four patients had hepatic hydatid cyst surgery. ERCP was successful in 25 patients (83.3%), but four (13.3%) patients underwent surgery and one patient (3.3%) underwent percutaneous transhepatic cholangiography after failed ERCP. Among the patients who had biliary stenting, biliary leakage was recovered in all of the patients, and repeat ERCP revealed that 18.2% of the patients had stones or mud in the common bile duct. The median time to ERCP was 6.5 days, and there was no difference between early (first 10 days) or late (10-30 days) ERCPs in terms of effectiveness and safety.

Conclusion: ERCP is a safe and effective method that should be considered before percutaneous procedures and surgery, whether surgery to ERCP time is early or late. Biliary stenting effectively recovers biliary leakage, and stent removal by repeat ERCP should be performed to check the common bile duct for stones or mud, instead of solely stent removal.

Keywords: Post-operative bile leakage, ERCP, cholecystectomy, biliary tract injury, biliary fistula

INTRODUCTION

Biliary tract injuries are complications that may develop following surgical procedures involving the biliary tract. The most common causes include laparoscopic cholecystectomies (LC), open cholecystectomies (OC), hepatic hydatid cysts and operations, exploration of the bile duct, biliary malignancy surgeries and several etiologic causes for operations, abdominal trauma, and cholelithiasis.

LC has become widespread after 1990s and has become the first line treatment for symptomatic cholelithiasis today.¹ It has significant advantages over OC, but it is associated with increase in bile duct leakage, and OC is performed in selected cases.² The incidence of biliary tract injuries in LC is between 0.3 and 0.7% and is associated with important mortality and morbidity.^{3,4} Although biliary stenosis is common in cases with OC, the total bile duct injuries are reported as 0.1-0.2%.⁵ The most important factors in the optimal treatment are early detection of injury and the severity of damage, clinical condi-

tion of the patient, and experience and facilities of the physicians.

Endoscopic retrograde cholangiopancreatography (ERCP) is one of the most important methods in the diagnosis and treatment of bile leakage and stenosis. The aim of our study is to determine the effectiveness and safety of ERCP in the diagnosis and treatment of post-operative bile leakage and stenosis and to share our experience.

METHODS

Patients who underwent ERCP due to post-surgical bile injuries at University Hospital between January 2017 and February 2020 were included in the study. This study was approved by the ethics committee of the Hitit University Faculty of Medicine with the number 2020/202. Demographic data, etiologies, clinical conditions, endoscopic treatment methods, and results of the patients were extracted from hospital computer system.

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Routine laboratory tests including complete blood tests, liver tests, and imaging (ultrasonography, computed tomography, and magnetic resonance imaging) findings were examined. The procedures were performed by Fujinon ED-530 XT duodenoscope device under sedo-analgesia performed by an anesthesiologist. After ERCP imaging, sphincterotomy, balloon or basket extraction, catheter or balloon dilatation, and stent replacement were performed if indicated. Data were recorded from patients' ERCP reports.

Injury types were determined by the Amsterdam and Strasberg classification systems.^{6,7} According to Amsterdam classification, Type A is leakage from the cystic duct, Type B is leakage from the major bile ducts, Type C is bile duct strictures without concomitant biliary strictures, and Type D is complete transection of the biliary duct.⁶ The Strasberg classification is as follows: Type A: bile leakage from cystic duct or liver bed without further injury; Type B: partial occlusion of the biliary tree, most frequently of an aberrant right hepatic duct; Type C: bile leak from duct which is not communicating with the common bile duct; Type D: lateral injury of the biliary ducts without loss of continuity; Type E: circumferential injury of biliary tree with a loss of continuity; Type E1: the stricture is located more than 2 cm from bile duct confluence (BDC); Type E2: the stricture is located less than 2 cm from BDC; Type E3: the stricture is located at BDC; Type E4: stricture is involving both right and left bile ducts; and Type E5: all bile ducts are completely occluded.⁷

Endoscopic treatment success criteria were improvement of the symptoms, signs and laboratory values, and decreased biliary drainage. Patients who needed surgery or PTK after the procedure were considered as unsuccessful endoscopic treatment.

Complications of ERCP were identified according to Cotton criteria, which are bleeding, perforation, pancreatitis, cholangitis, cardiopulmonary complications, anesthesia complications, and other complications.⁸ The time period between surgery and ERCP was defined as early (<10 days) and late (≥10 days).

Statistical analyses were performed using the Statistical Package for the Social Sciences version 26.0 (IBM SPSS Corp.; Armonk, NY, USA). Descriptive statistics (frequency, percentage, mean, median, and standard deviation) of the study group

were determined. Nonparametric tests were used for comparing groups, and Chi-square test was used to compare categorical data. $P < .05$ was considered statistically significant.

RESULTS

A total of 30 patients (16 females and 14 males) with a mean age of 56.6 ± 17.4 years (range: 25–86) were included in our study. Common bile duct was selectively cannulated in the first or second procedure in all of the patients (cannulation success rate 100%, $n = 30$). Among the patients, 26 patients had bile leakage or stenosis after cholecystectomy, and four had biliary injury after hepatic hydatid cyst surgery. The most common symptoms and signs in these cases were abdominal pain ($n = 24$, 80%), bile leakage from the percutaneous drainage catheter ($n = 21$, 70%), jaundice, or hyperbilirubinemia ($n = 6$, 20%). ERCP was performed in the early period in 18 patients (60%).

ERCP was successful and sufficient in 25 patients (83.3%), but four (13.3%) patients needed surgery and one patient (3.3%) underwent percutaneous transhepatic cholangiography (PTC) after ERCP. The characteristics of the patients are presented in [Table 1](#).

The 26 patients with post-cholecystectomy complication are summarized in [Table 2](#) and [Figure 1](#) according to Amsterdam and Strasberg classifications. Three patients with Amsterdam Type C/Strasberg Type E3, one patient with Amsterdam Type B/Strasberg Type D, and one patient with Amsterdam Type A/Strasberg Type A could not be treated successfully with ERCP.

Endoscopic sphincterotomy + biliary stent with plastic biliary stents (80%) was used as the main treatment method, and six patients (20%) had received endoscopic sphincterotomy without stenting. In two of these six patients, stenting was not required because leakage was very minimal. In the other four patients, stent could not be inserted because the proximal of stenosis/leakage could not be observed. These four patients had to have additive intervention (one patient had PTC and three patients had surgery).

Among the 24 patients who had biliary stenting, repeated ERCP was performed for the 22 patients whose condition was post-operative biliary leakage (one of the remaining two had repeated surgery despite the stent and the other one had post-operative biliary stricture). While 81.8% ($n = 18/22$) of these 22 patients had normal imaging findings in control ERCP, 18.2% ($n = 4$) patients had stones or mud in the common bile duct. We observed that biliary leakage was recovered in all patients (100%, $n = 22/22$). The remaining patient needed surgery despite ERCP and biliary stenting.

Four patients (13.3%) had cystobiliary fistula after hydatid cyst surgery. These patients were treated with ERCP by sphincterotomy and biliary plastic stent insertion. Treatment success was 100% in patients with cystobiliary fistula.

Laboratory parameters before ERCP are presented in [Table 3](#). Laboratory results were compared according to sex and ERCP time (early or late), and no significant difference was observed between the groups. Our median time to ERCP was 6.5 days,

Main Points

- ERCP is a safe and effective method for post-operative biliary tract injuries that should be considered before percutaneous procedures and reoperation.
- ERCP provides definitive diagnosis in almost all biliary tract injuries and treats successfully in most of them whether surgery to ERCP time is early (first 10 days) or late (10–30 days).
- Biliary stenting effectively recovers biliary leakage, and stent removal should be performed by repeat ERCP to check the common bile duct for stones or mud, instead of solely stent removal.

Table 1. Demographic and Clinical Characteristics of Patients Undergoing ERCP due to Postoperative Bile Duct Injury

	n (total = 30)	%
Age	Between 25 and 86 (median: 58.5)	
Sex		
	Female	16 53.3
	Male	14 46.7
Surgery type		
	Laparoscopic cholecystectomy	19 63.3
	Open cholecystectomy	4 13.3
	Hydatid cyst	4 13.3
	Conversion of laparoscopic to open cholecystectomy	3 10
Bile leakage symptoms		
	Abdominal pain	24 80
	Postoperative biliary drainage	21 70
	Jaundice or hyperbilirubinemia	6 20
Treatment type		
	ERCP	25 83.3
	ERCP+PTC	1 3.3
	ERCP + surgery	4 13.3
ERCP time	Postop 2-30 days (median: 6.5 days)	
	Early (first 10 days)	18 60
	Late (after 10 days)	12 40
Endoscopic treatments		
	Endoscopic sphincterotomy	6 20
	Endoscopic sphincterotomy + biliary stent	24 80
Post ERCP complication		
	No	28 93.3
	Yes (post-ERCP pancreatitis)	2 6.7
Was ERCP sufficient?		
	No	5 16.7
	Yes	25 83.3
The number of ERCP procedure		
	1	8 26.7
	2	18 60
	3	4 13.3

Table 1. (Continued)

		n (total = 30)	%
ERCP diagnosis			
	Post-cholecystectomy stenosis	4	13.3
	Biliary leakage	26	86.7
Prognosis			
	Exitus	1	3.3
	Healed	29	96.7

ERCP, endoscopic retrograde cholangio pancreatography; PTC, percutaneous transhepatic cholangiography.

Table 2. Distribution of Patients with Post-cholecystectomy Cile Duct Injury According to the Amsterdam and Strasberg Classifications

		n = 26	%
Amsterdam type*			
	Type A	17	56.7
	Type B	5	16.7
	Type C	4	13.3
Strasberg type†			
	Type A	17	56.7
	Type C	1	3.3
	Type D	4	13.3
	Type E3	3	10.0
	Type E4	1	3.3

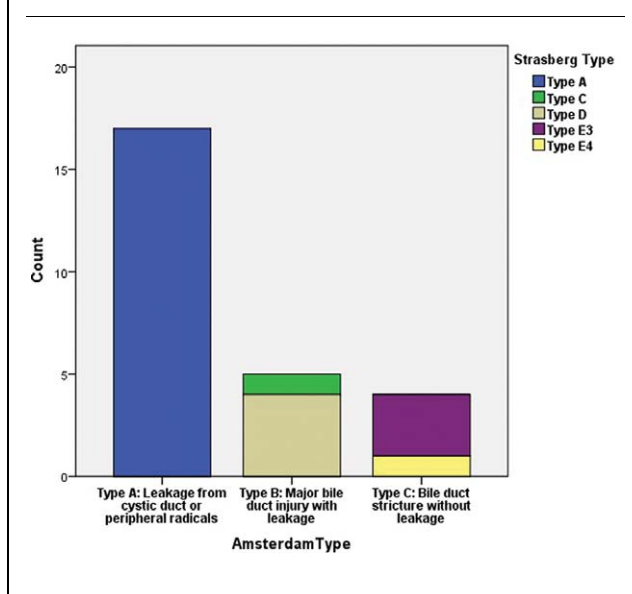
*Amsterdam classification: Type A: leakage from cystic duct or peripheral radicals; Type B: major bile duct injury with leakage; Type C: bile duct stricture without leakage; Type D: complete transection or excision of common bile duct.

†Strasberg classification: Type A: bile leak from cystic duct stump or minor biliary radical in gallbladder fossa; Type B: occluded right posterior sectoral duct; Type C: bile leak from divided right posterior sectoral duct; Type D: bile leak from main bile duct without major tissue loss; Type E1: transected main bile duct with a stricture more than 2 cm from the hilus; Type E2: transected main bile duct with a stricture less than 2 cm from the hilus; Type E3: stricture of the hilus with right and left ducts in communication; Type E4: stricture of the hilus with separation of right and left ducts; Type E5: stricture of the main bile duct and the right posterior sectoral duct.

and there was no difference between early or late ERCPs in terms of effectiveness and safety.

Post-ERCP pancreatitis was observed in two patients (6.7%). One of them had hydatid cyst and the other had LC surgery. Both were female and underwent ERCP in late period (post-operative 30 days). Mild post-ERCP pancreatitis developed in both patients, and improvement was observed with conservative treatment.

Figure 1. Graphic for the patients with post-cholecystectomy bile duct injury according to the Amsterdam and Strasberg classifications.



Mortality occurred in one patient (3.3%). This patient was a 76-year-old male with an LC, who underwent ERCP, sphincterotomy, and biliary stent insertion for Amsterdam Type A and Strasberg Type A bile leakage. Despite the benefits of endoscopic treatment and improvement of clinical/laboratory parameters, he died 11 days after the procedure due to hospital infection and sepsis.

DISCUSSION

Biliary tract injuries that may occur after biliary tract operations are complications that are sometimes difficult to treat, and they require a multidisciplinary approach including surgeons, gastroenterologists, and radiologists.

In addition to the role of endoscopic approach in diagnosis, its efficacy and safety in the treatment of post-operative bile duct

Table 3. Laboratory Assays of Patients Who Underwent ERCP (Before the Procedure)

Pre-ERCP test	Minimum	Maximum	Mean ± std. deviation
WBC ($10^3/\text{mm}^3$)	4.930	19.560	9,379 ± 3,200
Hemoglobin (g/dL)	8.1	14.6	11.27 ± 1.63
PLT ($10^3/\text{mm}^3$)	131	684	281.8 ± 148.7
AST (U/L)	14	212	53.9 ± 49.3
ALT (U/L)	6	214	49.0 ± 54.0
Total bilirubin (mg/dL)	0.2	12.8	1.86 ± 3.2
Direct bilirubin (mg/dL)	0.1	7.7	0.878 ± 1.904
Urea (mg/dL)	12	54	29.07 ± 12.61
Creatinine (mg/dL)	0.3	1.5	0.75 ± 0.30
Sodium (mequiv./L)	131	153	137.5 ± 4.4
Potassium (mmol/L)	3.2	5.1	3.98 ± 0.49

WBC, white blood cell count; PLT, platelet count; AST, aspartate aminotransferase; ALT, alanine aminotransferase.

injuries are now widely accepted.⁹ Even the sphincterotomy alone is useful in some cases via reducing the pressure in the biliary tract and accelerating the closure of the leakage site. But the main suggested and accepted treatment is sphincterotomy with biliary plastic stent insertion if possible.¹⁰⁻¹²

Our study demonstrated that ERCP is associated with high treatment success, minimal invasion, and low complication rates in patients with post-operative bile duct injuries. Our high treatment success rates support the efficacy and safety of endoscopic therapy in accordance with the existing literature.^{10,13-15} The general approach is to insert a biliary stent following ES, which reduces the transpapillary pressure gradient and gives the chance of the recovery of leakage.¹⁰⁻¹² However, the types and properties of stents to be applied are not currently standardized. Katsinelos et al. inserted seven French and 10 French diameter biliary plastic stents in patients with post-operative biliary leakage and showed a similar clinical improvement and treatment success rates in patients. Similarly, Kaffes et al.¹⁰ stated in their study that the stent diameter has no effect on treatment results. In addition, the use of fully covered self-expandable metal stents has increased for post-operative bile injuries in recent years, especially in refractory cases, and successful treatment has been reported with these stents.¹⁶⁻¹⁸

When we examine our patients according to the Amsterdam and Strasberg classifications, we observed that the cystic duct is the most common site for leakage, and the second common site is aberrant branch of the right hepatic duct, which is compatible with the literature.² The literature states that a proportion of patients are injured during surgery and are repaired intraoperatively.¹⁹ However, since our study consisted of

patients who underwent ERCP, we do not have any data of the patients diagnosed intraoperatively.

No significant difference in laboratory data was found between patients who underwent ERCP in the early and late periods, the reason for that might be the low number of patients in this study. In addition to that, it is known that not only laboratory changes but also symptoms and signs play a significant role in the early period of post-operative bile duct injuries.¹⁵

The study performed by Fasoulas et al.¹⁵ reported that "surgery to ERCP" period was long, and the main reason for this might be that the physicians were not aware enough in the post-operative early period. In addition to that, mild symptoms, non-specific clinical presentations, and laboratory assays that do not worsen rapidly may play a role.² Another study showed that referring a patient with bile duct injury after LC after 4 days to a specialist center had experienced more post-treatment complications, more invasive procedures, and longer hospitalization as compared to the patients who referred before 4 days.²⁰ Our median time for ERCP was 6.5 days, which was similar to the literature. On the other hand, the present study showed that ERCP was safe and effective whether "surgery to ERCP" time was early or late.

In our study, four of 26 patients who underwent post-cholecystectomy ERCP had stenosis. Three of them could not be treated with ERCP, and additive intervention was required (surgery or PTC). The last one is still followed up with stent changes with 3-4 months intervals. Parlak et al.²¹ investigated patients with post-cholecystectomy stenosis and reported that increasing the number of stent insertion in recurrent ERCP procedures has favorable effects on long-term stenosis treatment.

Most of the patients in our study needed two procedures of ERCP. The main reason for this is to remove the biliary plastic stents and to check the leakage status of the biliary tract. It is controversial whether the second ERCP is essential in patients with formerly ERCP and biliary plastic stenting for biliary leakage. Studies showed that pathological findings like refractory leakage, stones, and mud can be seen in 22-28% of the patients at the control ERCP in patients with biliary stenting.^{22,23} On the other hand, another study showed that only one of 64 patients in control ERCP had bile duct stones, and that endoscopic stent removal alone without cholangiography could be more optimal for control ERCP.²⁴ Our data showed that 81.8% of our patients who underwent stent insertion on ERCP for biliary leakage had normal imaging on control cholangiography; however, 18.2% had bile duct stones. We observed that biliary leakage was recovered in all of our patients. Because of the high percent of stones or mud in common bile duct, we consider that cholangiography with biliary stent removal at the control ERCP should be routinely performed. However, large-scale prospective randomized studies are needed to support this suggestion. A current approach is to use biodegradable stents for post-operative bile duct leakage, which provides fewer ERCPs. In the study performed by Siiki et al., biliary plastic stents were inserted in 24 patients with post-operative complications, and biodegradable biliary stents were inserted in eight patients; no difference was detected in treatment efficacy between them.²⁵ Because biodegradable biliary stents are expensive and not commonly used, we have used biliary plastic stents in all of our ERCP procedures. However, in the near future, we consider that the use of this kind of stents will increase for post-operative bile duct injury.

The major limitation of our study was its retrospective design and low number of patients. But since our hospital is the reference center of the region, patients generally continued the follow-up at our hospital, which strengthens our data.

CONCLUSION

ERCP is a safe and effective method that might be considered before percutaneous procedures or surgery, providing definitive diagnosis in almost all biliary tract injuries and treating successfully in most of them. Biliary stenting effectively recovers biliary leakage, and stent removal by repeat ERCP should be performed to check the common bile duct for stones or mud, instead of solely stent removal. The management of post-operative biliary injuries must be done by an effective cooperation of the radiologists, surgeons, and gastroenterologists.

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