ORIGINAL ARTICLE

Efficacy and safety of endoscopic retrograde cholangiopancreatography with endoscopic sphincterotomy and biliary stenting in post-operative bile leaks

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ABSTRACT

BACKGROUND: We evaluated the efficacy and safety of endoscopic retrograde cholangiopancreatography (ERCP), sphincterotomy, balloon biliary tract scanning, and plastic stenting in diagnosing and treating bile duct leakage after laparoscopic cholecystectomy and hydatid cyst surgery in this study.

METHODS: The study evaluated patients who underwent ERCP, sphincterotomy, and stenting for post-operative bile leakage. The patients were grouped under 4 groups (cystic duct stump, sac bed, hydatid cyst, and choledochal) according to the bile leakage detected in the ERCP procedure. The success of the procedure after the ERCP was evaluated by drain extraction time, whether early complications such as bleeding, pancreatitis, and perforation developed due to the ERCP procedure and the presence of obstructive pathology in ERCP.

RESULTS: Clinical improvement was observed in 65/73 (89%) patients who underwent successful ERCP procedures, and their drains could be removed. The mean drain removal time was 32.69±23.32 days. After laparoscopic cholecystectomy, bile leakage was most frequently from the cystic duct stump. There was no difference between the groups in procedural success rates. Drain removal time was shorter in the patient group with leakage from the cystic duct compared to the other three groups ($P<0.05$). After the ERCP procedure, 5/73 (6.9%) patients had minor ERCP complications, which improved with medical treatment. No major ERCP complication was observed. In addition, 25/73 patients (34.2%) had obstructive pathology such as biliary stone and hydatid membrane.

CONCLUSION: In patients with biliary leak due to laparoscopic cholecystectomy and hydatid cyst surgery, ERCP, sphincterotomy, balloon scanning, and plastic stenting are both highly effective and reliable options. They should be considered as the first-choice treatment approach in this patient group.

Keywords: Biliary stenting; endoscopic sphincterotomy; post-operative bile leaks.

INTRODUCTION

Over 200,000 cases of acute cholecystitis are diagnosed annually in the United States, and acute cholecystitis is one of the most common diseases in general surgery clinics.[1] For this reason, laparoscopic cholecystectomy is one of the most performed surgical procedures all over the world. It is less invasive than open cholecystectomy and is considered the gold standard method in the treatment of cholelithiasis.[2,3] Bile leaks are one of the major complications of hepatobi-

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liary surgical operations such as cholecystectomy. The incidence of post-operative bile leaks after cholecystectomy has been reported as 0.1–2%.[4,5] It has been reported that the incidence of bile duct injury in laparoscopic cholecystectomy is 10 times higher than in open cholecystectomy.[6] Biliary tract leakage is the second most common complication of laparoscopic cholecystectomy[7] but intrabiliary rupture is the most serious and common complication of hydatid cyst.[8,9] Furthermore, the formation of biliary fistulae is the most common post-operative complication of hydatid cysts with a post-operative incidence as high as 50–63%.[10,11]

In cases of bile leak, the diagnosis, location, and treatment of the leak are the biggest challenges for the clinician. Diagnosis of bile leak can often be made through imaging studies; however, imaging cannot rule out the diagnosis when the clinical suspicion is high. Endoscopic retrograde cholangiopancreatography (ERCP) has diagnostic and therapeutic roles in such cases.[12-13] The choice of treatment method may vary according to the type of surgical operation performed on the patient, the clinician's experience, and the clinic's facilities. The various interventions available to manage bile leaks include surgical repair, percutaneous drainage, endoscopic drainage, or a combination of these. ERCP comes to mind as the first choice in the treatment of bile leakage after cholecystectomy.[14,15]

The method to be applied in the ERCP procedure may vary according to the clinician's approach and available facilities. Options include sphincterotomy only, sphincterotomy, and stenting, and plastic or metal stenting can be used. Although there are studies on this subject, there have been different reports about the application of a standard method. In this study, we used a single standard method in all cases to diagnose and treat bile duct leakage after laparoscopic cholecystectomy and hydatid cyst surgery. We applied ERCP, sphincterotomy, and biliary tract scanning with balloon and plastic stent to all patients. We evaluated the data of our patients, to whom we applied a single standard approach, by a single experienced endoscopist.

MATERIALS AND METHODS

We evaluated patients who applied to Pamukkale University University Gastroenterology Clinic in this study. Patients who were sent to our clinic, which is considered a reference center for ERCP, after laparoscopic cholecystectomy and hydatid cyst surgery, with the diagnosis of post-operative bile leakage were evaluated. The data were collected from the hospital registry system.

A total of 76 patients who were scheduled for ERCP due to post-operative bile leakage between 2014 and 2022 were evaluated. The age and gender of the patients were recorded. In the ERCP procedure, patients were imaged, and the leak location was determined. The patients then underwent endoscopic sphincterotomy, the biliary tract was scanned with a balloon, and stones and membranes were removed, if any. Afterward, a 10 Fr Amsterdam-type plastic stent was placed in all patients and they were followed up. All procedures were performed by a single experienced endoscopist.

The patients were grouped under 4 groups (cystic duct stump, sac bed, hydatid cyst, and choledochal) according to the bile leakage detected in the ERCP procedure. In the follow-up of the patients after the ERCP procedure, it was recorded whether the discharge from the drains stopped, and if it did, how many days after the ERCP procedure, the drains were removed were recorded. In the follow-up of the patients after ERCP, whether early complications such as bleeding, pancreatitis, and perforation developed due to the ERCP procedure were recorded. This was also recorded if an obstructive pathology such as stone or membrane was detected in ERCP.

After the data were collected, it was evaluated how much of the whole patient group achieved success (clinical recovery and cessation of bile flow from the drain) after the ERCP procedure. The mean drain removal time was also evaluated. The patients were then evaluated in 4 groups according to the location of bile leakage: cystic duct stump, sac bed, hydatid cyst, and common bile duct. The groups were compared for procedure success rate and drain removal time.

The study protocol was approved by the Pamukkale University Faculty of Medicine Invasive Clinical Research Ethics Committee.

Statistical Analysis

Data were analyzed with SPSS 25.0 (IBM SPSS Statistics 25 software (Armonk, NY: IBM Corp.)) software package. Continuous variables were expressed as mean ± standard deviation and categorical variables as numbers and percentages. The one-way ANOVA test was used to compare independent group differences when parametric test assumptions were met. A $P<0.05$ was accepted as statistically significant.

RESULTS

In our study, 76 patients who underwent ERCP due to post-operative bile leakage in our clinic were evaluated. In only 1 patient, the common bile duct could not be cannulated and the ERCP procedure could not be performed on the patient. In 1 of the remaining 75 patients, the common bile duct was ligated in the midsection during the ERCP procedure. In 1 patient, there was a circumferential injury of the common bile duct proximal to the common bile duct and the stent procedure could not be performed. Successful ERCP and stenting were performed in the remaining 73 patients.

The mean age of 73 patients who underwent successful ERCP procedures was 57.46±16.67 years and 47 (64.4%) were male. Clinical improvement was detected in 65 (89%) of 73 patients

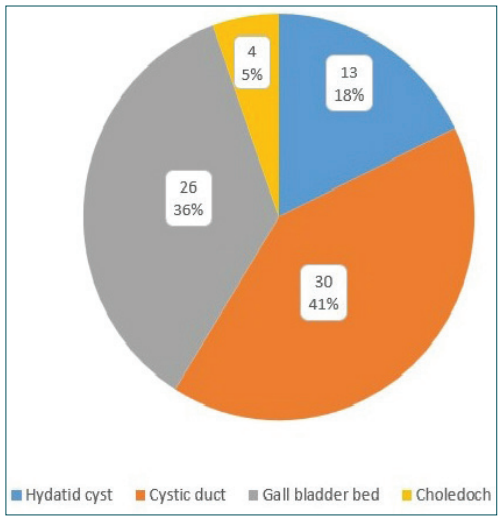

Figure 1. Etiology of bile leakage.

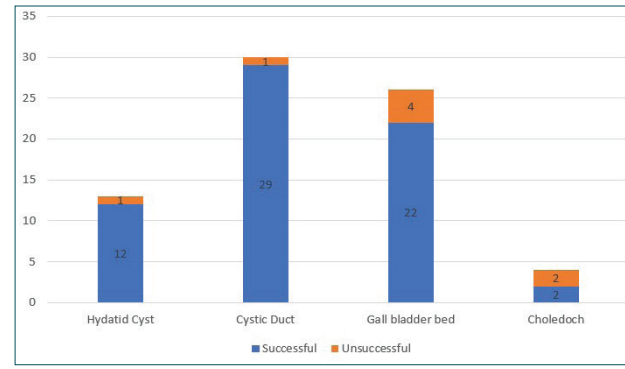

Figure 2. Clinical improvement and drain removal status according to the type of leak.

who underwent ERCP and their drains could be removed. The mean drain removal time of 65 patients with clinical success and drain removal was found to be 32.69±23.32 days.

Patients who underwent successful ERCP were divided into 4 groups according to the etiology of bile leakage detected in the ERCP procedure and their numbers were compared. After laparoscopic cholecystectomy, the site of bile leakage was divided into three groups (cystic duct, sac bed, and common bile duct). It was observed that bile leakage was most frequently from the cystic duct stump after laparoscopic cholecystectomy, but the difference was not statistically significant (Fig. 1).

Among the patients who underwent ERCP for bile leakage after laparoscopic cholecystectomy, clinical improvement was observed in 29/30 patients with cystic duct leakage and 22/26 patients with bladder bed leakage, and the drain could be removed in these patients. However, there was no statistically significant difference between the two groups' procedural success (P=0.115). Clinical improvement after ERCP in 4 groups was compared in terms of drain removal rate (Fig. 2).

The 4 groups were compared for mean drain removal time. Drain removal time was found to be shorter in the patient group with leakage from the cystic duct compared to the other 3 groups (P<0.05) (Table 1).

In the post-procedure follow-up, minor ERCP complications were observed in 5 (6.9%) patients, including 4 patients with mild pancreatitis that improved with medical treatment and 1 patient with bleeding resolved with endoscopic intervention. No major ERCP complication was observed. In addition, in 25 of 73 patients (34.2%), an obstructive pathology such as a biliary stone and hydatid cyst was detected.

DISCUSSION

Common after cholecystectomy and hydatid cyst surgery, bile leak is a difficult-to-manage complication that challenges the surgeon. Although its treatment requires a multidisciplinary approach, endoscopic methods have started to come to the fore. Although the approach varies according to the clinics, ERCP with endoscopic sphincterotomy,[16] biliary stents[17] or its combination is the current standard treatment for postoperative bile leaks. Furthermore, the effectiveness of fully covered self-expandable metallic stents was reported.[18-20]

The basic principle of the ERCP procedure is to eliminate the sphincter pressure with sphincterotomy and to facilitate bile flow into the duodenum with a balloon and stent. Thus, the healing of biliary tract damage will be facilitated.[21,22] Our study showed that endoscopic sphincterotomy and plastic stenting have a high success rate of 89% in patients with bile duct leakage. We determined that this method had a high success rate of 29/30 (96.7%) in leaks from the cystic duct stump. On the other hand, a clinical success rate as high as 22/26 (84.6%) was achieved in leaks from the sac bed and 12/13 (92.3%) in cases of biliary fistulae of hydatid cyst.

In cases of bile leak, the cystic duct remnant is the most common site for bile leak followed by injuries to the ducts within the gallbladder bed, common bile duct, common hepatic duct, and T-tube tracts.[12] In our study, the place of bile

Table 1. Comparison of drain removal time according to bile leakage etiology

Variables	Hydatid cyst	Cystic Channel	Sac bed	Common bile duct	P-value
Drain removal time (days)	55.33±33.54	20.55±10.84	33.60±20.27	46±19.79	0.000

*One-way ANOVA test; P<0.05

leakage after laparoscopic cholecystectomy was cystic duct remnant, gallbladder bed, and common bile duct, in order of frequency. In addition to all these data, clinical improvement and removal of drains in patients with cystic duct stump leakage achieved in a shorter time compared to other groups were considered useful data. In light of these data, it is clear that ERCP, sphincterotomy, and plastic stenting are very effective methods for bile leaks after laparoscopic cholecystectomy and hydatid cyst surgery.

Cannulation and stenting can be performed in almost all of our patients, and only 5 of them had minor complications that can be resolved with medical treatment, proving that ERCP is an effective and safe method in patients with biliary leak due to laparoscopic cholecystectomy and hydatid cyst surgery.

The fact that an obstructive pathology such as stones or membranes was detected in approximately one-third of the patients in the ERCP procedure showed us the importance of pre-operative evaluation of the biliary tract. Thus, it is clear that in this patient group, it is necessary to be more conscious about taking USG and, if necessary, MRCP to evaluate the biliary tract before surgery.

CONCLUSION

ERCP, sphincterotomy, balloon scanning, and plastic stenting method are both highly effective and reliable options in patients with biliary leaks due to laparoscopic cholecystectomy and hydatid cyst surgery. It should be considered the first-choice treatment approach in this patient group.

Ethics Committee Approval: This study was approved by the Pamukkale University Faculty of Medicine Invasive Clinical Research Ethics Committee (Date: 15.11.2022, Decision No: E-60116787-020287521).

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ORİJİNAL ÇALIŞMA - *ÖZ*

Postoperatif safra kaçağı olan olgularda endoskopik retrograd kolanjiyopankreatografi ile endoskopik sfinkterotomi ve biliyer stentlemenin etkinliği ve güvenliği

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AMAÇ: Biz bu çalışmada, laparoskopik kolesistektomi ve kist hidatik cerrahisi sonrası görülen safra yolu kaçağının tanı ve tedavisinde, endoskopik retrograd kolanjiopankreatografi (ERCP), sfinkterotomi, balon ile safra yolu taraması ve plastik stent uygulamasının etkinliğini ve güvenliliğini değerlendirmeyi amaçladık.

GEREÇ VE YÖNTEM: Çalışmada ameliyat sonrası safra kaçağı sebebi ile ERCP, sfinkterotomi, stent işlemi yapılan hastalar değerlendirildi. Hastalar ERCP işleminde saptanan safra kaçağı yerine göre 4 grup altında (sistik kanal güdüğü, kese yatağı, kist hidatik içi, koledok) toplandı. ERCP işlemi sonrası işlem başarısı, dren çekim süresi, ERCP işlemine bağlı, kanama, pankreatit ve perforasyon gibi erken komplikasyon gelişip, gelişmediği, ERCP de obstrüktif patoloji varlığı açısından değerlendirildi.

BULGULAR: Başarılı ERCP işlemi yapılan 65/73 hastada (%89) klinik iyileşme saptandı ve drenleri çekilebildi. Ortalama dren çekme süresi 32.69±23.32 gün saptandı. Laparoskopik kolesistektomi sonrası safra kaçağının en sık sistik kanal güdüğünden olduğu görüldü. Gruplar arasında işlem başarı oranları açısından fark saptanmadı. Sistik kanaldan kaçak olan hasta grubunda dren çekim süresinin diğer 3 gruba göre daha kısa olduğu görüldü ($p<0.05$). ERCP işlemi sonrası 5/73 (%6.9) hastada medikal tedavi ile düzelen, minör ERCP komplikasyonu izlendi. Major ERCP komplikasyonu görülmedi. Ayrıca, 25/73 hastada (%34.2) safra yolunda taş ve kist hidatik membranı gibi obstrüktif bir patoloji saptandı.

TARTIŞMA: Laparoskopik kolesitektomi ve kist hidatik cerrahisine bağlı biliyer kaçak hastalarında, ERCP, sfinkterotomi, balon ile tarama ve plastik stent uygulaması yöntemi hem oldukça etkin, hem de güvenilir bir seçenektir. Bu hasta grubunda ilk tercih edilecek tedavi yaklaşımı olarak değerlendirilmelidir.

Anahtar sözcükler: Endoskopik sfinkterotomi; biliyer stent; postoperatif safra kaçağı.

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