Original Article

# Comparison of sphincterotomy alone versus sphincterotomy and biliary stent placement for the treatment of postlaparoscopic cholecystectomy biliary leaks

*Hassan A. Abdallah[a], Mansour M. Kabbash[a,b] and Mohie El-Din M. Madany[a]*

*Department of [a]General Surgery, Faculty of Medicine, Aswan University, Aswan, [b]Maxillofacial Surgery, Faculty of Medicine, Sphinx University, Assuit, Egypt.*

## ABSTRACT

**Background:** While a number of endoscopic procedures have demonstrated efficacy in the management of post-cholecystectomy biliary leakage, the optimal treatment is still up for debate. Endoscopic biliary stenting with or without endoscopic sphincterotomy (ES), nasobiliary tube drainage with or without ES, and ES alone are among the endoscopic procedures that have been employed.

**Aim:** Our research aims to assess the safety and effectiveness of biliary stenting in addition to ES versus sphincterotomy alone for the management of biliary leakage following laparoscopic cholecystectomy.

**Patients and Methods:** The study comprised 50 patients in total, divided into two groups of 25 patients each, who had been diagnosed with postlaparoscopic cholecystectomy biliary leakage. Of them, 25 had ES alone, and 25 underwent ES plus the implantation of a biliary stent. The effectiveness of each patient's therapy was then monitored clinically.

**Results:** There were six cases among the group I patients where ES alone was ineffective; four underwent surgical treatment, and two were successfully treated with stent implantation thereafter. Out of the 25 group II patients, only two (8%) cases required surgery to repair the leak following endoscopic retrograde cholangiopancreatography. For groups I and II, the total complication rate was 8 and 16%, respectively.

**Conclusion:** While the ES alone group had a reduced risk of adverse events, biliary stent+ES is more efficacious than ES alone for the treatment of postlaparoscopic cholecystectomy biliary leakage. As a result, the preferred method for endoscopic therapy of post-cholecystectomy biliary leakage should be endoscopic retrograde cholangiopancreatography with stent implantation plus ES, even if it necessitates a further endoscopic procedure to remove the biliary stent.

**Key Words:** Biliary leaks, biliary stenting, cholecystectomy, endoscopic sphincterotomy.

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**Corresponding Author:** Hassan A. Abdallah, MD, Department of General Surgery, Faculty of Medicine, Aswan University, Aswan, Egypt. **Tel.:** +20 106 180 3822, **E-mail:** endoscopyercp@yahoo.com

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## INTRODUCTION

Bile leaks are a possible lethal consequence that can develop during gallbladder removal, hepatic transplantation, liver resection, or liver injury caused by trauma[1]. While most injuries of the bile channel result from gallbladder removal procedures, just 1% of cases do so[2]. Endoscopic treatments have been demonstrated to be quite effective in the treatment of postoperative biliary leakage. The goal of the endoscopic method is to create a low-pressure route to allow the bile to pass out of the leak, enabling it to close. Endoscopic biliary stenting with or without endoscopic sphincterotomy (ES), nasobiliary tube drainage with or without ES, and ES alone are among the endoscopic procedures that have been employed[3]. There is currently no agreement on the best successful endoscopic procedure for post-cholecystectomy biliary leakage – ES alone versus biliary stent plus ES – resulting in practice differences[4–6].

Some workers think that ES alone offers enough drainage[4]. Others feel that stent implantation, in addition to ES, can offer extra drainage and promote healing[5]. In the opinion of some other professionals, leaving a stent in place without ES might increase the risk of post-endoscopic retrograde cholangiopancreatography (ERCP) pancreatitis and raise overall medical expenses without improving the healing of bile leaks[6]. The purpose of our study was to precisely evaluate the rates of safety and efficacy for the two interventional groups (ES+biliary stent vs. ES alone) in the treatment of post-cholecystectomy biliary leakage.

## PATIENTS AND METHODS:

This study assessed two distinct endoscopic treatments for biliary leakage after laparoscopic cholecystectomy in a prospective manner: ES without biliary stenting and ES with biliary stenting. From December 2019 to August 2024, this study was conducted at the Aswan University Hospital's General Surgery Department. The

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study was comprised of 50 patients with symptomatic postlaparoscopic cholecystectomy biliary leakage, split into two groups of 25 patients each.

### *Inclusion criteria*

Patients with post-cholecystectomy biliary leakage were identified clinically or by imaging findings and confirmed endoscopically via ERCP.

### *Exclusion criteria*

Patients with a prior ES, complete bile duct transection, concurrent biliary constrictions under the bile leak level, bile duct ligation, choledocholithiasis, or sphincter of Oddi dysfunction.

A physical examination, laboratory testing (liver function tests, blood picture), and imaging studies (MRCP, CT scan, abdominal ultrasound) were used to evaluate each case. Two therapy groups were randomly assigned to patients.

Every patient underwent ERCP. During the procedure, group I patients received ES alone (Fig. 1), while group II patients had ES+stent implantation (Fig. 2).

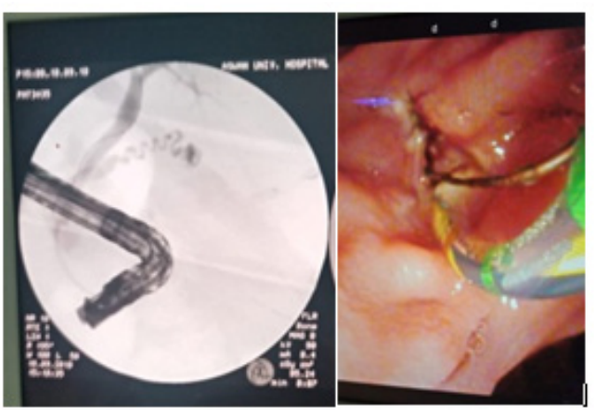

**Fig. 1:** Endoscopic treatment of a bile leak with ES alone.

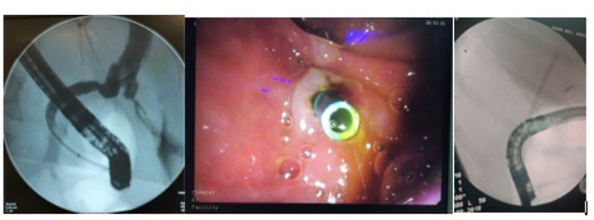

**Fig. 2:** Plastic stent being used during endoscopic therapy of a bile leak.

Extravasation detected before intrahepatic duct filling and without the necessity for an occlusion balloon was termed a high-grade bile leak; low-grade leaks are detected concurrently or just after the intrahepatic ducts have fully opacified.

Following that, each patient was clinically monitored for 8 weeks to ensure effective management. Remission of the clinical manifestations was considered a successful therapy. The clinical result and any concurrent medical issues were taken into consideration while determining the length of hospital stay. The patients were instructed to get in connect with us if any problems developed prior to stent removal after being discharged. Following at least 6 weeks, stent removal was done.

The two groups' ultimate treatment outcomes and post-ERCP problems were compared. The elimination of the clinical manifestations in the absence of recurrence throughout the follow-up was considered the final treatment success. The requirement for salvage surgery or radiology-percutaneous biliary intervention following ERCP was considered endotherapy failure.

The following were the outcome parameters: duration of hospital stay following the index endoscopic intervention; requirement for another procedure (endoscopic or nonendoscopic) in the treatment of bile leak; clinical resolution of bile leak; complications of endoscopic procedure; and interval between the initial endoscopic procedure and the bile leak's clinical elimination.

### *The study includes:*

(1) The locations of the leaks.

(2) The bile duct dilatation.

(3) The need for further surgery to repair the leak following ERCP.

Written informed permission was provided by the patients, and the Aswan University Faculty of Medicine's ethical committee approved the study. Permission to publish all content in this article, including the personal information in the tables, has been granted.

## RESULTS:

Of the 50 biliary leak patients included in this research, 12 were male and 38 were female, between the ages of 23 and 82 (mean, 45 years). Patients were randomly allocated to one of two therapy groups. There were 25 patients in the ES alone group (group I) and 25 patients in the ES plus biliary stent group (group II). Each patient in the stent group received a single 10 Fr stent, which measured 7 cm in 18 patients, 9 cm in four patients, and 12 cm in three patients.

Table 1 summarizes the demographics and clinical features of patients in two groups. Age, the period between the cholecystectomy and index endoscopic treatment, the percentage of abnormal liver function tests, the existence of biliary dilatation, and the grade of the bile leak were all comparable across the two groups. All of the patients had a normal caliber of bile duct.

The following postoperative presentations among the 50 patients suggested a biliary leak: continuous bile flow via or near surgical drains in 42 individuals, biliary flow from two patients' trocar sites, bile flow from the location of an infrahepatic drain removal in two patients and in four patients as abdominal pain and tenderness with a subsequent computed tomography scan of the abdomen showed fluid accumulation (Table 2).

On ERCP, the cystic duct stump was the leak source in 36 individuals (17 in group I and 19 in group II) (Fig. 3), the common bile duct in five individuals (three in group I and two in group II), the common hepatic duct in three individuals (two in group I and one in group II), the right hepatic duct in two patients (one in group I and one in group II) and a liver bed in four patients (two in group I and two in group II) (Table 3).

Table 4 presents a summary of complications. The total complication rate was 8% for group I and 16% for group II. The one instance of bleeding (found in group I) was considered minor, developed 24 h after the procedure, and required neither a transfusion nor any other kind of intervention. In one patient from group I and two from group II, postprocedural pancreatitis was noted. The pancreatitis resolved well and was mild.

For two patients with stent migration (observed in group II), an unscheduled ERCP for insertion of new stents was not attempted, as the migration was asymptomatic and noticed on the scheduled follow-up ERCP procedure. After improving, these patients returned 6 or 7 weeks later to have their stents removed. The repeated ERCP in one case revealed distally migrated stent that passed through the intestine spontaneously with no extravasation of the contrast. The ERCP of the second case revealed proximal migration of the stent with no extravasation of the contrast. Endoscopic retrieval of the migrated biliary stent was successful in the case of proximal migration.

There were no deaths associated with the procedure, nor were there any serious adverse events necessitating an unplanned ERCP. There were no complications during or following the endoscopic stent extraction procedures in group II (stents were removed after 6–8 weeks) (Fig. 4).

There were six cases in the group I patients where ES alone was not therapeutic; two of these cases were effectively treated with stent insertion, and four of the patients had surgical treatment without the need for any further endoscopic therapy. ES alone was therapeutic for the remaining 19 (76%) patients in group I. Following the endoscopic procedure, three of these 19 patients needed further percutaneous intraperitoneal drain implantation to manage the abdominal fluid accumulation (Table 5).

Only two (8%) of the 25 group II patients required surgery after the ERCP to repair the leak, and the ERCP was not classified as therapeutic. They originated from common hepatic leaks. Despite the effective completion of sphincterotomy and stenting in both cases, the leak could not be adequately treated. After the index ERCP, the bile leak stopped for the remaining 23 (92%) patients in group II. Of these 23 patients, one case necessitated the insertion of a supplementary percutaneous intraperitoneal drain in order to manage the collection of abdominal fluid following the endoscopic procedure (Table 5).

When comparing the two methods in terms of the number of days required to extract the surgical drain from the abdomen or stop the drainage following ERCP, there was no statistically significant variation ($P>0.05$). While the sphincterotomy alone group required 6 days to remove the drain, the stent group had an average of 4 days. In the stent group, the average hospital stay was 6 days, ranging from 3 to 13 days in extremes, whereas for individuals with ES alone, the variations ranged from 4 to 18 days, with an average of 8 days (Table 5).

**Table 1:** Patient characteristics based on the procedure

| Characteristics | Group I (ES alone) (*N*=25) [*n* (%)] | Group II (ES and stent) (*N*=25) [*n* (%)] |
|---|---|---|
| Age (mean±SD) (years) | 44.2±11.2 | 46.2±14.1 |
| Sex | | |
| Male | 5 (20) | 7 (28) |
| Female | 20 (80) | 18 (72) |
| Proportion of abnormal LFTs | 15 (60) | 13 (52) |
| High-grade leak | 14 (56) | 17 (68) |
| The time interval between cholecystectomy and endoscopic treatment, days, median | 5 (3–11) | 4 (2–9) |

ES, endoscopic sphincterotomy; LFT, liver function test.

**Table 2:** The clinical manifestations of biliary leakage

| Clinical presentation | Group I (ES alone) (*N*=25) | Group II (ES and stent) (*N*=25) |
|---|---|---|
| Bile flows through the surgical drain | 19 | 23 |
| Bile flow from trocar sites | 1 | 1 |
| Bile flow site of the removed drain | 2 | 0 |
| Abdominal fluid collection | 3 | 1 |

ES, endoscopic sphincterotomy.

**Table 3:** Endoscopic presentation of biliary leaks

| Location of the leak | Group I (ES alone) (*N*=25) | Group II (ES and stent) (*N*=25) |
|---|---|---|
| Cystic duct stump | 17 | 19 |
| Common bile duct | 3 | 2 |
| Common hepatic duct | 2 | 1 |
| Right hepatic duct | 1 | 1 |
| Hepatic bed | 2 | 2 |

ES, endoscopic sphincterotomy.

**Table 4:** Complications following endoscopic sphincterotomy alone (group I) and stenting with sphincterotomy (group II)

| Adverse effect | Group I (ES alone) (*N*=25) | Group II (ES and stent) (*N*=25) |
|---|---|---|
| Pancreatitis | 1 | 2 |
| Bleeding | 1 | 0 |
| Migration of stent | 0 | 2 |
| Total | 2 | 4 |

ES, endoscopic sphincterotomy.

**Table 5:** Outcomes of bile leak – endoscopic sphincterotomy alone versus endoscopic sphincterotomy with biliary stent

| Variables | Group I (ES alone) (*N*=25) [*n* (%)] | Group II (ES and stent) (*N*=25) [*n* (%)] |
|---|---|---|
| Treating of bile leak efficiently with a single endoscopic procedure | 19 (76) | 23 (92) |
| Days required for the leak to stop following the index ERCP, median | 6 (2–14) | 4 (2–11) |
| Duration of hospitalization following the index ERCP, days, median | 8 (4–18) | 6 (3–13) |
| Sum of each patient's endoscopic procedures | | |
| One | 19 | 0 |
| Two | 0 | 25 |
| More than two | 2 | 0 |
| Number of patients who underwent nonendoscopic procedures subsequent to the initial endoscopic procedure | | |
| Percutaneous intraperitoneal drain placement | 3 | 1 |
| Reoperation for suture the leak | 4 | 2 |

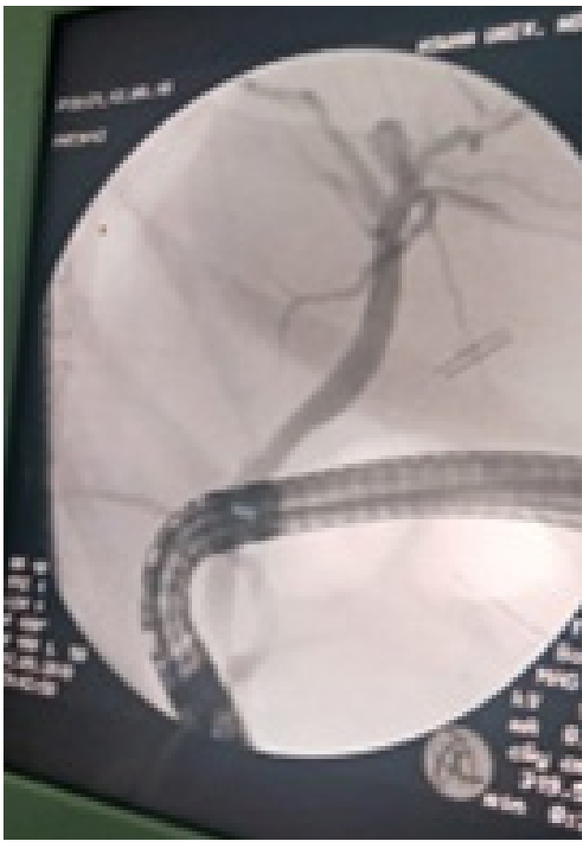

**Fig. 4:** Cholangiogram after stent extraction at week 6. There's no evidence of extravasation.

## DISCUSSION

In this study, ES alone and ES combined with biliary stenting were prospectively evaluated as endoscopic therapy options for biliary leakage after laparoscopic cholecystectomy. Our findings showed that the ES+biliary stent group had a much greater clinical success rate than the ES alone group. Clinical success rates for biliary stent plus ES were 92%, whereas those for ES alone were 76%. This outcome is equivalent to those of previous researches such as Dolay *et al*.[4] and Kaffes *et al*.[7]. According to the findings of the Dolay *et al*.[4] study, biliary stenting appears to be a more successful approach than sphincterotomy in bile leakage after gallbladder removal in the absence of bile duct dilatation. According to Kaffes *et al*.[7] research, stent insertion – regardless of the stent's size – may be preferable to sphincterotomy alone in individuals with post-cholecystectomy bile leak. Forty patients in the Kaffes and colleagues trial had stents alone, 18 had ES alone, and 31 had both stents and ES. Overall, their endoscopic therapeutic success rate was 95%; however, the ES alone group had more patients who required surgery (n=4) and repeat ERCP (n=2) due to absence of healing, while in the stent with ES group, no patients required a repeat ERCP, and just one patient in the stent only group did.

In a study of 1028 cases with bile leak after gallbladder removal, Abbas and colleagues found that stent insertion with or without ES was linked with a reduced likelihood of persistent leak than only ES (3 and 4%, in contrast to 11%). The ES alone group's reduced success rate could be linked to postsphincterotomy edema, which might affect bile's preferred transpapillary flow[2].

These findings go counter to what other investigations, including Chinnery *et al*.[8] have noted. In a retrospective single-center South African cohort, 74% of ES patients with a biliary stent, and 88% of ES patients with no stent experienced clinical success, according to Chinnery *et al*.[8]. Comparably, single-center retrospective research conducted in Germany found that a combination of ES and biliary stent resulted in a 77% success rate in treating 60 patients' bile leakage[9]. In a different trial, ES alone produced a very high success rate for low-grade bile leakage[10]. Unlike our investigation, the Rainio *et al*.[11] research found no distinction in the resolution of leaks between patients managed with sphincterotomy alone and those who also had stent insertion. Overall, these findings show that ES alone is at least as successful as ES with stent placement for bile leakage, if not more. ES alone will reduce the bile duct's flow resistance, enabling leak closure. While the endoscopist's choice determines where to insert the stent, there is disagreement among experts as to whether sealing the leak opening with a stent is necessary or advantageous[12].

Because a second ERCP is not necessary with sphincterotomy alone, costs, times, and complications are reduced[10]. Even while sphincterotomy alone may be useful in dealinging biliary leakage, individuals with normal-caliber bile ducts are more likely to experience complications from a full (long) sphincterotomy that extends to the duodenal wall[13].

The requirement for additional ERCP procedures to remove the biliary stent is the main drawback of stent implantation. This puts the patient at a further expense and exposes them to anesthetic again. Increased risk of pancreatitis, biliary stricture, stent migration, and cholangitis are additional side effects of stent implantation. When it comes to stent removal, there is a higher likelihood of loss to follow-up because, after they are feeling better, patients may not want to have another ERCP, which raises the risk of infections and other problems[14].

The ES alone vs the ES+biliary stent in our trial reduced the requirement for a second endoscopy, which is required for the retrieval of the stent. Additionally, it decreased the risk of adverse events, which was statistically significant (8 vs. 16%) and quantitatively lower in the sphincterotomy alone group than in the

biliary stent+ES group. Reduced healthcare costs would result from these findings, particularly from the requirement for a second endoscopy to remove a stent.

In our trial, the ES+biliary stent minimized the need for nonendoscopic intervention, reduced the length of hospital stay, and decreased the time needed for bile leak repair when compared to ES alone. These findings might have significant clinical consequences for patient care and healthcare use.

As per our findings, individuals treated with ES with biliary stent noticed a speedier healing of the bile leak compared to those treated with ES alone (4 vs. 6 days). Studies with comparable findings have been published. Researchers found that biliary stent implantation led to a quicker time to leak closure (5 vs. 10 days) in individuals with nondilated common biliary channels (≤8 mm in diameter) than sphincterotomy alone in a small study of 27 patients with a bile leak after gallbladder removal[4]. But, in a retrospective single-center cohort of 58 patients with biliary leakage, Chandra *et al*.[15] found that individuals treated with ES alone experienced a faster healing of the bile leak than those managed by ES with the insertion of a stent.

## CONCLUSION

The combination of biliary stent and ES is superior to ES alone in treating biliary leaks following laparoscopic cholecystectomy, even if the rate of side effects was fewer in the ES alone group. So, even if a second endoscopic surgery is required to remove the biliary stent, ERCP with stent implantation plus ES ought to be the favored method for endoscopic therapy of post-cholecystectomy biliary leakage.

## CONFLICT OF INTEREST

There are no conflicts of interest.

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