

A Review of the Endoscopic Treatment for Bile Leak Following Cholecystectomy and Hepatic Surgery

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Bile leak occurs in 2-25% of liver transplant, 3-27% of hepatic resection, and 0.1-4% of cholecystectomy cases. The clinical course of bile leak varies depending on the type of surgery that caused the fistula, as well as the type, severity, and timing of bile duct injury. Although infections resulting from bile leak can be life-threatening, the introduction of endoscopic treatment has enabled some patients to avoid reoperation and has reduced the negative impact on quality of life associated with external fistulas for percutaneous drainage. Endoscopic interventions, such as sphincterotomy and stent placement, reduce the pressure gradient between the bile duct and duodenum, facilitating bile drainage through the papilla and promoting the closure of the leak. We reviewed the literature from 2004 to 2024 regarding bile leak following cholecystectomy and liver surgery, examining recommended techniques, timing, and treatment outcomes. In cases of bile leak following cholecystectomy, clinical success was achieved in 72-96% of cases, while success rates for bile leak following liver surgery ranged from 50% to 100%. Although endoscopic treatment is effective, it is not universally applicable, and its limitations must be carefully considered.

Key words: bile leak, cholecystectomy, hepatic surgery, endoscopic retrograde cholangiography, bridging stent placement

The number of patients with biliary tract cancer is increasing [1-3], and despite advances in the management of viral hepatitis, the number of deaths from hepatocellular carcinoma remains high [4,5]. Hepatic and biliary surgeries, including liver resection, liver transplantation, and cholecystectomy, are performed to treat both malignant diseases and benign conditions such as cholelithiasis and cholecystitis.

Bile leak is a major complication of hepatobiliary surgery, with a reported incidence of 2-25% following liver transplantation [6-12] and 3-27% following liver resection [13,14]. Although the introduction of laparoscopic techniques in the late 1980s reduced the inva-

siveness of cholecystectomy, the incidence of bile leak has been reported to be high with laparoscopic procedures [15], ranging from 0.1-4% [16-18].

Infections caused by bile leak are well-known contributors to sepsis and abscess formation, which can be life-threatening [19-21], necessitating prompt treatment. Currently, endoscopy is the standard method for diagnosing and treating bile leak [15,22,23]. However, the management approach varies depending on the specifics of the leak, and the diversity of available endoscopic treatment options has prevented the establishment of a definitive treatment strategy.

This article reviews the management of postoperative bile leak, focusing on endoscopic treatment strategies, to better understand and refine the treatment approach.

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Reviewing Strategy

In this study, hepatobiliary surgeries were categorized into cholecystectomy and hepatic resection/liver transplantation, and findings related to endoscopic treatment for postoperative bile leak were summarized. A literature search was conducted using the PubMed, MEDLINE, and Google Scholar databases from January 2004 to December 2024 using the terms “bile leak,” “ERCP,” “endoscopic treatment,” “cholecystectomy,” “liver transplantation,” “hepatic surgery,” “hepatic resection,” “lobectomy,” “segmentectomy,” “sphincterotomy,” and “stent.” Articles were screened by two independent reviewers (TO and KM) based on their titles and abstracts, and duplicates were excluded. Case reports, studies with a small number of cases (less than 10 cases), studies using metal stents for bile leak following hepatic surgery, articles lacking essential information, and non-English manuscripts were excluded.

We defined two types of success for endoscopic treatment: technical success and clinical success. Technical success was defined as a successful stent placement following successful biliary cannulation. In cases where stent placement was deemed unnecessary, it was defined as the successful completion of necessary procedures, such as sphincterotomy. Clinical success was defined as the resolution of symptoms caused by bile leak with endoscopic treatment. The closure of the leak site and improvement in coexisting strictures were not included in this definition.

Regarding complications, for reports published after 2010, we referred to the ASGE guidelines [24], whereas for earlier studies, we followed the criteria presented in the individual papers, such as those reported by Cotton *et al.* [25].

Endoscopic Management of Bile Leak

The management of bile leak requires a multidisciplinary collaboration involving the hepatobiliary surgeon who performed the procedure as well as interventional radiologists and endoscopists [26]. Early reports described surgical repair as the primary treatment for biliary complications following liver transplantation [27-30]. However, since Binmoeller *et al.* first reported endoscopic treatment of postoperative bile leak in 1991 [31], numerous reports on endoscopic treatments have

been published, and endoscopic retrograde cholangiopancreatography (ERCP) is now considered the first-line approach [32,33]. The goal of ERCP is to reduce the transpapillary pressure gradient, allowing bile to preferentially flow into the duodenum rather than leak at the injury site [34]. This can be achieved using various endoscopic techniques, with the most commonly employed methods being biliary sphincterotomy, biliary stent placement, or a combination of both.

Several options exist for biliary stent placement, with the choice being based primarily on the location and type of stent used. The approach may vary depending on whether bile leak occurs following cholecystectomy or hepatectomy and the specific location of leak within the bile duct. Initially, a stent is placed to bridge the leak site (Fig. 1A-C). However, depending on the location of the leak, diameter and shape of the bile duct, stability of the stent, and guidewire accessibility, the stent may instead be placed in a nearby branch (Fig. 1D, E) or distal to the leak site (Fig. 1F, G). As for the type of stent, the options include plastic or metal stents [35-42], with variations in stent diameter. Metal stents are generally not used for bile leak in the hilar part of the bile duct because they may occlude the side branches. Instead, plastic stents are the primary choice in this region. By contrast, fully covered metal stents are used to treat bile leak in the extrahepatic bile duct because they can completely seal the fistula.

Timing of Intervention

The timing of endoscopic intervention for bile leak is a critical issue, and several studies have been conducted on this topic. The first was a multicenter retrospective study conducted by Adler *et al.* in 2017 and involving 518 patients, most of whom had bile leak following cholecystectomy [43]. In this study, patients were categorized into three groups according to the timing of ERCP—within the first 24 h, on the second or third day, and after the third day. The analysis showed no statistically significant differences in post-ERCP mortality or adverse events based on treatment timing. In 2019, Abbas *et al.* [44] published a retrospective analysis involving 1,028 patients who underwent ERCP for bile leak. Based on the timing of ERCP, the procedures were classified as emergent (within 1 day of bile leak occurrence), urgent (on the second or third day), or expectant (after the third day). The rate of adverse

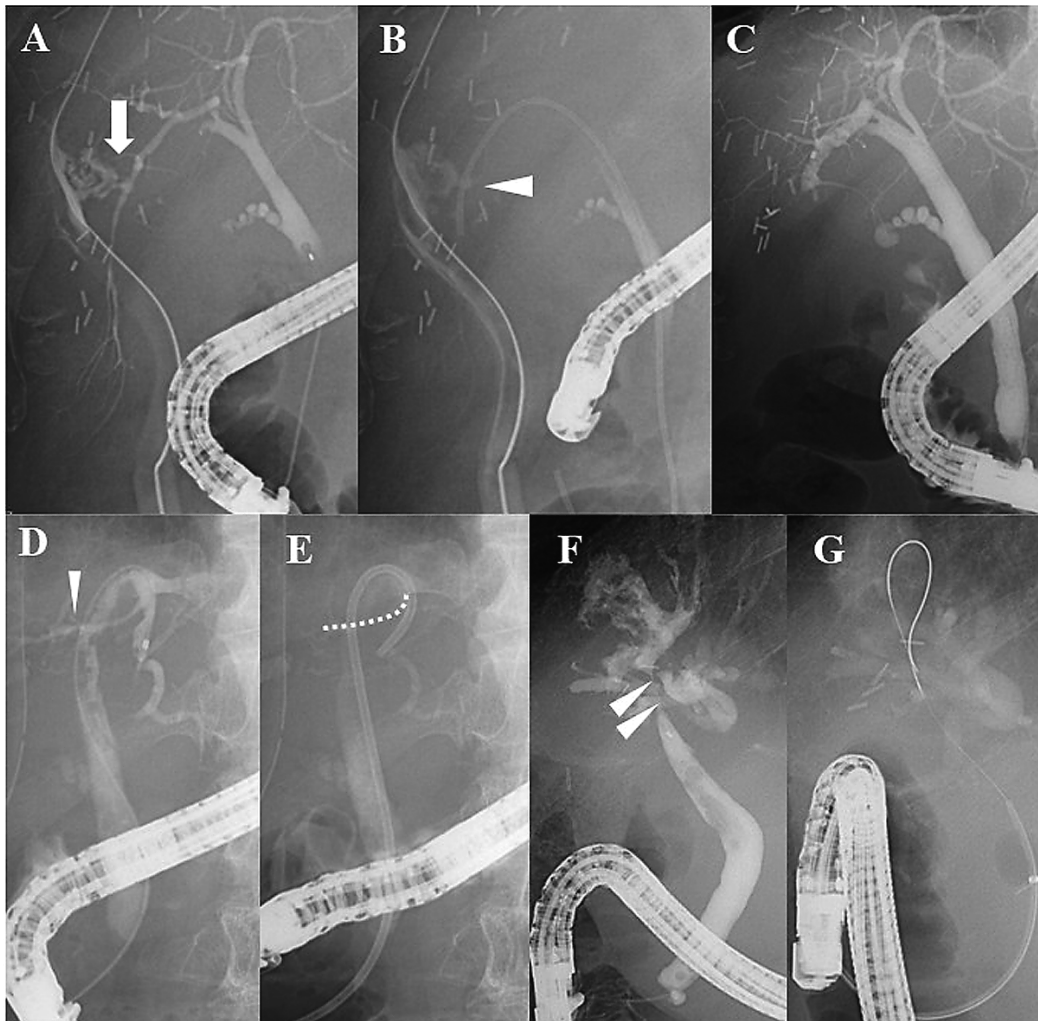


Fig. 1 Case presentations by the location of stent placement. **A-C**, A case with leak-bridging stenting. (A) A bile leak was identified (arrow). (B) A plastic stent was placed to bridge the leak site (arrowhead). (C) After 3 months, the leak was resolved. **D, E**, A case of stent placement in a different branch. (D) Stricture and leak were observed at the site indicated by the arrowhead. (E) Since a stent could not be placed in this branch, it was instead placed in a nearby branch. **F, G**, A case of left lobe graft transplantation. Because an appropriate branch beyond the stricture and leak (arrowhead) could not be accessed (F), an ENBD tube was placed distally for decompression (G).

events did not differ significantly among emergent, urgent, and elective ERCPs. However, in-hospital mortality followed a U-shaped increase, with rates of 5%, 0%, and 2% for emergent, urgent, and elective ERCPs, respectively ($p < 0.001$). The authors suggested that this result may reflect a bias related to the severity of the patients' conditions. Subsequently, in 2021, Desai *et al.* [45] conducted a database-based retrospective observational study involving 1,260 patients. Based on the timing of ERCP following bile leak, the procedures were categorized as emergent (within 1 day),

urgent (1-3 days), or expectant (after 3 days). The authors found that expectant ERCP was associated with a lower risk of adverse events compared to emergent or urgent ERCP ($p = 0.004$). Additionally, readmission rates were lower for expectant ERCP than for the other two timing groups ($p < 0.001$). The authors suggested that emergent ERCP may not be necessary for managing bile leak.

Summarizing the findings from these studies, emergent ERCP did not demonstrate a clear benefit for bile leak, whereas elective ERCP (performed after 3 days)

may be associated with a lower incidence of adverse events. However, as all these studies were retrospective in nature, future prospective studies are required to validate these findings.

Details and Endoscopic Treatment of Bile Leak Following Cholecystectomy

Reports on endoscopic treatment for bile leak following cholecystectomy are summarized in Table 1 [18,32,35,43,46-54]. Among 1,298 cholecystectomies, 13% (n=163) were open surgeries, 80% (n=1,032) were laparoscopic procedures, and 8% (n=102) were converted from laparoscopic to open surgeries.

Among the 1,298 cases in which the site of the leak was specified, the most common location was the cystic duct remnant, reported in 67% of the cases (n=864), followed by the common bile duct/common hepatic duct in 20% (n=263) and Luschka ducts in 13% (n=172). The technical and clinical success rates were achieved in 88-100% and 72-96% of cases, respectively. Adverse events related to ERCP were noted in 2-14% of cases, and post-ERCP pancreatitis was the most common event, being recorded in 4% (n=52) of cases, followed by post-sphincterotomy bleeding in 1% (n=17) of cases. Only a few cases of perforation (n=3) and cholangitis (n=4) (both <0.5%) were noted.

These reports consistently indicate that endoscopic treatment via ERCP is effective for managing bile leak following cholecystectomy; however, specific conclusions vary. Some studies have suggested that low-grade leaks can be managed with sphincterotomy alone, whereas high-grade leaks require stent placement [32,47,53,54]. A combination of these techniques has also been supported [48,49], and bridging the leak site using multiple stents has been proposed as an effective treatment strategy [46]. Additionally, no significant difference in outcomes has been reported based on stent diameter [35], though some studies suggested that metal stents are more effective than plastic [43,51]. A systematic review and meta-analysis concluded that sphincterotomy combined with leak-bridging stenting is the most effective approach [55-57]. Overall, the relevant literature indicates that endoscopic treatment for post-cholecystectomy bile leak is highly effective and has a low complication rate, making it the first-line treatment of choice.

Details and Endoscopic Treatment of Bile Leak Following Hepatic Surgeries

Reports on endoscopic treatment for bile leak following liver surgery, including liver transplantation and hepatic resection, are summarized in Table 2 [7,27,38,58-66]. Among 3,260 liver transplantations and 239 hepatic surgeries, ERCP was performed for bile leak in 278 liver transplantation and 144 hepatic surgery cases.

The locations of bile leak varied by procedure. In liver transplantations, the most common sites were the anastomotic sites (53%, n=148), followed by T-tube-related sites (25%, n=69). For hepatic surgeries, the reported leak sites varied across studies: the intrahepatic bile ducts were implicated in 52% of cases (n=75), the common hepatic/common bile ducts in 31% (n=44), and the hepatic cut surfaces in 15% (n=22). Unlike bile leak following cholecystectomy, leak from the cystic duct remnants was not noted.

The technical and clinical success rates were 76-100% and 50-100%, respectively. Adverse events related to ERCP were reported in 0-10% of cases. Post-ERCP pancreatitis occurred in 3% of the cases (n=15, including one severe case), followed by cholangitis in 2.5% (n=11) and bleeding in 1% (n=5). The incidences of pancreatitis and bleeding were comparable to that of ERCP for post-cholecystectomy bile leak; however, the incidence of cholangitis was slightly higher.

All 13 reviewed studies recommended ERCP and endoscopic treatment. Some studies advocated for stent placement [7,66], with one specifically emphasizing the effectiveness of early stent placement [59]. Other studies highlighted the benefits of bridging leak sites [61,65], an approach that is increasingly gaining consensus in the field. Notably, no study concluded that sphincterotomy alone is sufficient to treat bile leak following hepatic surgery, which presents an interesting contrast to the management of postcholecystectomy bile leak.

Two studies reported that the success rate of endoscopic treatment for bile leak was lower in living donor liver transplantation (LDLT) cases compared with deceased donor liver transplantation (DDLT) cases [38,60]. One study suggested that a combination of percutaneous drainage and endoscopic treatment may be more effective for LDLT cases than for DDLT cases [60]. This finding suggests that endoscopic treatment alone may be insufficient for bile leak in LDLT cases,

Table 1 Endoscopic treatment of bile leak after cholecystectomy

[Ref]	Author	Year	No. of patient	Major surgical procedure	Cystic duct remnant	Leak site, n (%)				Technical success rate, %	Clinical success rate, % (used stents)	Adverse events, % (major events)
						Luschka duct	CBD/CHD	IHD	unknown/other			
18	Tzovaras	2001	20	laparoscopic	16 (80)	0 (0)	3 (15)	1 (5)	0 (0)	100	95 (PS)	5.0 (PEP)
47	Sandha	2004	207	laparoscopic	159 (77)	26 (13)	0 (0)	0 (0)	19 (9)	100	96 (PS)	1.5 (PEP)
32	Kafkes	2005	100	laparoscopic	48 (48)	15 (15)	5 (5)	4 (4)	8 (8)	96	95 (PS)	5.0 (PEP)
46	de Reuver	2007	93	laparoscopic	67 (72)	0 (0)	26 (28)	0 (0)	0 (0)	100	95 (PS)	14.0 (migration)
35	Katsinelos	2008	63	laparoscopic	37 (59)	9 (14)	13 (21)	0 (0)	4 (6)	89	84 (PS)	11.1 (PEP)
48	Sachdev	2012	90	open	45 (50)	0 (0)	34 (38)	0 (0)	11 (12)	88	72 (PS)	11.1 (bleeding)
49	Chinnery	2013	84	laparoscopic	70 (83)	0 (0)	14 (17)	0 (0)	0 (0)	100	83 (PS)	7.1 (PEP)
50	Yun	2015	20	laparoscopic	10 (53)	3 (16)	2 (11)	5 (26)	0 (0)	100	95 (PS)	5.0 (perforation)
51	Canena	2015	40	laparoscopic	28 (70)	0 (0)	12 (30)	0 (0)	0 (0)	100	83 (MS/PS)	5.0 (PEP)
43	Adler	2017	366	laparoscopic	233 (45)	89 (17)	122 (24)	63 (12)	11 (2)	100	89 (PS/MS)	7.1 (PEP)
52	Rainio	2018	99	laparoscopic	60 (58)	21 (20)	13 (13)	0 (0)	0 (0)	90	90 (PS)	6.1 (PEP)
53	Haider	2020	100	laparoscopic	79 (79)	7 (7)	2 (2)	9 (9)	4 (4)	97	90 (PS)	7.0 (PEP)
54	Flumignan	2021	31	laparoscopic	12 (52)	2 (9)	17 (74)	0 (0)	0 (0)	100	94 (MS/PS)	3.2 (PEP)

CBD, common bile duct; CHD, common hepatic duct; IHD, intrahepatic bile duct; PS, plastic stent; MS, metallic stent; PEP, post-ERCP pancreatitis; NA, not available.

Table 2 Endoscopic treatment of bile leak after hepatic surgery

[Ref]	Author	Year	No. of patient	Major type of LT/HR	Leak site, n (%)						Technical success rate, %	Adverse events, % (major events)
					Cut surface	T-tube related	Anasto-mosis	Cystic duct, CBD/CHD	IHD	unknown/other		
27	Pfau	2000	31	DDLT	0 (0)	20 (74)	7 (26)	0 (0)	0 (0)	0 (0)	97	3.2 (PEP/bleeding)
58	Thuluvath	2003	19	DDLT	0 (0)	10 (53)	5 (26)	1 (5)	0 (0)	3 (16)	89	5.2 (PEP)
59	Battachariya	2003	20	lobectomy	0 (0)	0 (0)	0 (0)	2 (10)	15 (75)	3 (15)	100	0
7	Yazumi	2006	16	LDLT	0 (0)	0 (0)	16 (100)	0 (0)	0 (0)	0 (0)	81	NA
38	Tarantino	2008	27	DDLT	0 (0)	0 (0)	27 (100)	0 (0)	0 (0)	0 (0)	100	NA
60	Gomez	2009	10	LDLT	3 (30)	0 (0)	5 (50)	0 (0)	0 (0)	2 (20)	100	10.0 (cholangitis)
61	Dechene	2014	60	lobectomy	0 (0)	0 (0)	0 (0)	22 (37)	17 (28)	0 (0)	100	NA
62	Oh	2015	42	LDLT	0 (0)	12 (29)	27 (64)	3 (7)	0 (0)	0 (0)	76	9.5 (bleeding)
63	Yabe	2017	29	LDLT	0 (0)	0 (0)	25 (43)	22 (38)	11 (19)	0 (0)	90	10.3 (PEP)
64	Elwir	2017	24	LDLT				NA			97	5.0 (cholangitis)
65	Shaible	2017	35	lobectomy	22 (63)	0 (0)	0 (0)	2 (6)	11 (31)	0 (0)	91	NA
66	Sendino	2018	80	DDLT	2 (3)	27 (34)	36 (45)	7 (9)	8 (10)	0 (0)	100	10.0 (PEP)

LT, liver transplantation; HR, hepatic resection; DDLT, deceased donor liver transplantation; LD, living donor liver transplantation; CBD, common bile duct; CHD, common hepatic duct; IHD, intrahepatic bile duct; PEP, post-ERCP pancreatitis; NA, not available.

and early consideration of combined percutaneous drainage is necessary. One important point to note is that Phillips *et al.* [67] cautioned against the use of fully covered self-expandable metal stents (FC-SEMS) in post-transplantation cases due to a high incidence (59%) of long-term complications, such as strictures. They suggested that while SEMS are a less invasive option for controlling leak in liver transplant recipients, the relatively high stricture rate due to the obstruction of side branches or overexpansion of the bile duct following FC-SEMS placement are a potential limitation to their use. Overall, the reported findings suggest that while endoscopic treatment is effective for post-hepatectomy bile leak, some cases do not achieve clinical success with endoscopic treatment alone and require additional interventions, such as percutaneous drainage.

Complications and Limitations of Endoscopic Treatment

Among the complications associated with ERCP, acute pancreatitis warrants the most attention. In some cases, pancreatitis can become severe, potentially leading to life-threatening conditions, such as walled-off necrosis or pseudoaneurysm formation. Other important complications include post-sphincterotomy bleeding, exacerbation of cholangitis due to contrast injection, and gastrointestinal perforation caused by endoscope manipulation [7,18,27,32,35,38,46-54,58-64]. The frequency of complications associated with endoscopic therapy for treating bile leak after cholecystectomy and hepatic surgery was described in the previous section.

The endoscopic treatment for bile leaks becomes challenging in several conditions. First, in a small number of cases, it proves impossible to cannulate the bile duct even though the endoscope reaches the papilla. Second, even after successful biliary cannulation, bile leaks complicated by strictures may present further difficulties. For instance, the guidewire may fail to traverse the stricture, making stent placement impossible. In such cases, percutaneous drainage has traditionally been the salvage approach [68], while interventions under endoscopic ultrasound guidance may offer a promising alternative in the future [69-72]. Third, in cases with extensive bile duct disruption and severe leakage, endoscopic or percutaneous drainage alone may be insufficient, necessitating surgical inter-

ventions. And finally, in patients with a poor general condition who cannot tolerate sedation, endoscopic insertion itself may not be feasible.

Conclusion

Endoscopic treatment is well established as the first-line option for managing bile leak following hepatobiliary surgery. Regarding the timing of intervention, retrospective evidence suggests that an emergency intervention is not always necessary, as it does not significantly reduce the risk of adverse events. In cases of refractory bile leak, early consideration of a combination of percutaneous drainage with endoscopic treatment is essential for effective management.

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