


# Structural or functional abnormality of sphincter of Oddi: an important factor for the recurrence of choledocholithiasis after endoscopic treatment

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## ABSTRACT

A high recurrence rate is undesirable after treatment of common bile duct (CBD) stones. A major risk factor identified for recurrence is that invasive techniques, including surgical or endoscopic treatments, will impair the biliary tract system either by direct incision of the CBD or by cutting or dilating the ampulla of Vater. During endoscopic treatment, two main assisted methods for lithotomy, sphincterotomy and papillary balloon dilation, can result in different degrees of damage to the structure and function of the sphincter of Oddi (SO), contributing to slowing of biliary excretion, cholestasis, biliary bacterial infection, and promotion of bile duct stone recurrence. In this review, the relationship between endoscopic lithotomy and structural impairment or functional abnormality of the SO will be summarized, and their relationship with the recurrence of CBD stones will also be analyzed. Further improvement of these endoscopic methods or exploration of some novel methods, such as endoscopic endoclip papilloplasty, temporary insertion of a self-expandable metal stent, and combined application of peroral cholangioscopy, may aid in providing more appropriate treatment for patients with choledocholithiasis, repair or protect the function and structure of SO, reduce or prevent the recurrence of bile duct stones, and improve patient outcomes.

**Abbreviations:** CBD: Common bile duct; EEP: Endoscopic endoclip papilloplasty; EPBD: Endoscopic papillary balloon dilation; EPLBD: Endoscopic papillary large balloon dilation; EST: Endoscopic sphincterotomy; POCs: Peroral cholangioscopy; QC: Quantitative cholecystography; SO: Sphincter of Oddi

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## Introduction

CBD stones, a digestive disease with a high recurrence rate, account for 10–20% of patients with symptomatic gallstones [1,2]. The methods for the treatment of CBD stones, including endoscopic and surgical techniques, can help to remove all stones but cannot effectively prevent their re-formation. A major risk factor identified for CBD stone recurrence is invasive treatment technology. Either surgical or endoscopic treatments impair the biliary tract system, either by direct incision of the CBD (for example, laparoscopic transductal bile duct exploration) or by cutting or dilating the ampulla of Vater (such as sphincterotomy and papillary balloon dilation) [3,4]. Analyzing the effect of these methods on the post-treatment recurrence of CBD stones and

the underlying mechanisms will be helpful for gastroenterologists to select suitable treatment strategies for patients in the future.

The introduction of endoscopic treatment started a new era in the treatment of choledocholithiasis, and current statistical data suggest that the application of endoscopic lithotomy for the treatment of CBD stones is gradually increasing [5], replacing surgery as the preferred method. Compared with surgical treatment, endoscopic treatment has the advantages of less trauma and shorter recovery period. However, during follow-up, it has been suggested that the recurrence rate of CBD stones after endoscopic treatment is higher than that after surgical treatment [6–10]. A possible reason may be that during the treatment of CBD

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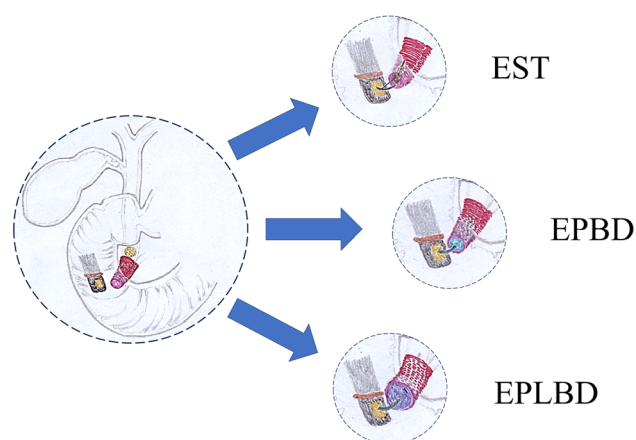
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stones, endoscopic-assisted methods, such as sphincterotomy and papillary balloon dilation, resulted in different degrees of damage to the structure or function of sphincter of Oddi (SO) (Figure 1) [11]. Damaged valve-like function of SO can lead to increased risks of cholestasis, biliary bacterial infection, and inflammation, promoting the formation of recurrent stones. In this review, we will summarize the underlying mechanisms that contribute to the structural impairment or functional abnormality of the SO resulting from endoscopic treatment and their relationship to the recurrence of bile duct stones will also be analyzed.

### **Effect of endoscopic sphincterotomy on the structure and function of SO and contributions to the recurrence of CBD stones**

Endoscopic sphincterotomy (EST), which was first proposed in 1974 [12], has gradually replaced common bile duct exploration and lithotomy as the first-choice treatment for CBD stones, especially for that without gallbladder stones. However, the recurrence of CBD stones after EST has garnered considerable attention. In a study including 365 patients who underwent successful surgical procedures without bilio-enteric diversion, after a median follow-up of 43.2 months (interquartile range, 84 months), 31 patients (8.4%) were diagnosed with recurrent CBD stones, and preoperative EST was the only variable statistically associated with stone recurrence [13], suggesting the contribution of EST to the formation of recurrent CBD stones.



**Figure 1.** Endoscopic-assisted lithotomy resulted in different degrees of damage to the structure or function of sphincter of Oddi.

Endoscopic sphincterotomy (EST) destroys the anatomical structure and function of the sphincter of Oddi (SO) by directly cutting the ampulla of Vater. Endoscopic papillary balloon dilation (EPBD) and endoscopic papillary large balloon dilation (EPLBD) tear the SO by expanding the duodenal papilla to different extents, resulting in different degrees of damage to the structure or function of the SO.

Proper functioning of the SO can result in a suitable pressure difference between the common bile duct and the duodenum to prevent enterobiliary reflux. EST may disrupt the anatomical structure and function of the SO, contributing to the reformation of CBD stones [13]. Using the perfusion catheter technique, Minami et al. measured the pressure difference between the common bile duct and duodenum before and after endoscopic treatment and assessed papillary motor activity by analyzing the basal pressure, frequency, and amplitude of papillary contraction. It was found that after EST, rhythmic contraction of the SO was lost, and the previous gradient pressure between the common bile duct and duodenum was significantly reduced [14]. Lai et al. utilized quantitative cholescintigraphy (QC) to evaluate biliary emptying function and found that after EST treatment, parameters of the time-activity curve of patients during QC were reduced, suggesting that biliary emptying function was impaired [15]. Moreover, in patients with recurrent stones, the biliary tract was found to be more slowly empty. The slowing of biliary excretion after EST may be an important factor leading to cholestasis and promoting the formation of bile duct stones.

Besides, EST could lead to the structural or functional abnormality of SO, which can further cause duodenal-biliary reflux, especially in the conditions when intestinal pressure increased, such as constipation, resulting in regurgitation of the duodenal contents and gut bacteria into biliary tract [16]. Bacterial infection of the biliary system is another factor that induces the recurrence of bile duct stones, which are mainly brown pigment stones [17,18]. Compared with that of patients without EST or other bile duct operation history, the biliary microbiota of patients with a history of EST were significantly enriched in the cluster mainly consisting of gastrointestinal bacteria, indicating the close relationship of EST and duodenal bacterial infection in biliary tract [19]. In the context of concomitant or subsequent cholangitis, bacteria and their endotoxins can further promote the re-formation of bile duct stones by promoting the release of inflammatory factors and increased expression of  $\beta$ -glucuronidase, Mucin 5AC and so on [20–22]. In addition, analysis of the biliary microbial characteristics through next-generation sequencing revealed that the biliary microbiome in patients with postoperative recurrent CBD stones differed from that in the postoperative stable group [23,24]. It was also found that after EST, patients with recurrent CBD stones exhibited increased levels of *Fusobacterium* and *Neisseria* bacteria in the bile, which were also identified as potential biomarkers for patients with high recurrence rates

after the first treatment [23]. Further exploration and identification of specific bacteria that are related to the recurrence of bile duct stones could potentially aid in identifying patients with a high recurrence risk in advance, strengthening the follow-up, and providing intervention treatment earlier and more efficiently.

According to the extent of incision, EST can be classified as small, moderate and large-incision EST: a small incision refers to the one that does not exceed the hooding fold, a large incision is when the incision extends beyond the entire sphincteric mound, and a moderate incision is between the small and large incision [25]. The size of the EST incision is closely related to the degree of SO injury, which in turn is related to stone recurrence [26]. However, merely reducing EST incision cannot effectively reduce the recurrence rate of stones. Takimoto et al. found that the recurrence rate of CBD stones in the small-incision group (17.0%) was higher than that in the medium-incision group (6.4%) [27], and the increased recurrence rate may be related to stone collapse, residual stones, or secondary damage to the SO during the removal of stones through a small incision. For these cases, saline irrigation of the bile duct, or saline irrigation combined with mechanical lithotripsy, may be helpful for reducing residual CBD stones and secondary damage [28,29]. In addition, the disadvantages of small-incision EST can be overcome by papillary balloon dilation. In the study by Mu et al. 300 patients with CBD stones >10mm in diameter were randomly divided into the EST group and small-incision EST plus endoscopic papillary balloon dilation (EPBD) group, and during the 72-month follow-up period, the recurrence rate of CBD stones in the small-incision EST plus EPBD group was significantly lower than that in the EST alone group (1.36% vs. 6.9%, respectively;  $p < 0.05$ ) [30]. Small-incision EST plus EPBD may be a suitable method to reduce the degree of SO injury resulting from EST, with residual stones or secondary damage to the SO during the removal of stones being also avoided, which requires further investigation.

Besides reducing the incision size of EST, for the patients treated by EST with normal or large incision, post-damage repair of the SO may be another method that can be tentatively explored. In 2019, endoclip papilloplasty was proposed to preserve SO function and prevent the recurrence of bile duct stones [31,32]. Wang et al. assessed the feasibility of endoscopic endoclip papilloplasty (EPP) in restoring SO function after EST in domestic pigs and found that after EST, the pressure in the common bile duct, basal pressure, and contraction amplitude of the SO were reduced, while EPP can help to recover them to pre-EST levels [32]. Similarly, in a

prospective pilot study of 30 patients treated with endoclip papilloplasty, it was found that basal pressure, contraction amplitude, and phasic waves per minute of the SO returned to pre-EST levels at 3 weeks. After a follow-up of 18 months (range: 11–25 months), only one of the 30 patients developed recurrent stones, suggesting that endoclip papilloplasty could aid in preserving SO function and may prevent the formation of recurrent stones [33]. It was revealed that the good healing of SO after endoclip papilloplasty, with the scar extending to the biliary opening, was an independent protective factor for choledocholithiasis recurrence, mainly because endoclip papilloplasty helped to restore the sphincter of Oddi and reduce duodenobiliary reflux, bacterial infection and related cholangitis [34]. Continuously improving the repair methods of SO after endoscopic treatment will further improve the curative effect of bile duct stones and reduce or inhibit the re-formation of bile duct stones.

### ***EPBD and endoscopic papillary large balloon dilation contribute to structural impairment or functional abnormality of the SO***

In 1983, EPBD was proposed as a safe and effective alternative to EST for adjunctive treatment of CBD stones [35]. Possibly because of the more frequent need for mechanical lithotripsy and an relatively increased risk of pancreatitis [36–38], EPBD alone is still not advocated for routine use. In 2019, the European Society for Gastrointestinal Endoscopy introduced that EPBD without EST is mainly considered in patients in the presence of coagulopathy or altered anatomy and with stones smaller than 8mm [39]. However, EPBD still seems to be increasingly applied in young patients [40,41], possibly because EPBD has a theoretical advantage in preserving SO function, without irreversible damage. For the effect of EPBD on the structure or function of SO, Mac Mathuna et al. performed sphincter balloon dilation and sphincterotomy in pigs, and staining of papillary sections showed transmural hemorrhage, smooth muscle rupture, and mucosal necrosis in the sphincterotomy group, but no structural distortion or smooth muscle rupture in the sphincter balloon dilation group, suggesting that EPBD can aid in maintaining the integrity of duodenal papillary smooth muscle [42]. However, in the clinic, endoscopic manometry of the SO before, 1 week after, and 1 year after endoscopic treatment revealed that although the base and peak pressure of the SO can recover gradually after EPBD treatment, these manometric parameters were still significantly lower than those before EPBD treatment [43]. These results

suggest that EPBD cannot perfectly preserve SO function, and methods to reduce the effect of treatment on SO function require further investigation.

Endoscopic papillary large balloon dilation (EPLBD), which expands the duodenal papilla using a balloon with a diameter > 10mm (range: 11–20mm), was proposed in 2003 to facilitate the removal of large or difficult bile duct stones [44]. However, large balloon expansion may damage the SO more severely than EPBD [45]. In pigs, after treatment with small sphincterotomy with balloon dilatation (12–20mm), morphological evaluation of the tissue sections revealed that large balloon dilatation tore the bile duct wall, resulting in impaired sphincter function and expansion of extrahepatic bile ducts [46]. Cheon et al. evaluated SO function after EPLBD and EST plus EPLBD using endoscopic manometry and found that both EPLBD alone and EST+EPLBD resulted in sustained and considerable loss of SO function even one year after treatment [47]. Theoretically, EPLBD can protect the function of SO to some extent by reducing or preventing the cutting damage of SO by EST; however, the effect of EPLBD on the structural impairment or functional abnormality of the SO needs to be further revealed, and its relationship with the recurrence of CBD stones also needs to be determined. For the limited EST plus EPLBD, endoclip papilloplasty can also be applied to restore the function of SO, and in a prospective cohort study, it was found that the well healing of SO could reduce the incidence of recurrent choledocholithiasis [34].

### **Comparison of the effect of endoscopic treatment with EST, EPBD or EPLBD on the recurrence of CBD stones**

As mentioned above, none of the main endoscopic-assisted methods can completely protect the function of the SO, and it is still uncertain which method would be the best for CBD stone types. In the past 20 to 30years, the relationship between EST, EPBD, or EPLBD and CBD stone recurrence was gradually revealed, and comparison of their effect on the post-treatment recurrence of different kinds of CBD stones would be helpful for gastroenterologists to select suitable treatment strategies for the patients in the future to reduce or prevent the recurrence of stones.

Compared with EST, EPBD can help maintain the integrity of duodenal papillary smooth muscle [42], preserve SO function at least partly [43], and further promote the expansion of EPBD application. A meta-analysis of randomized controlled trials comparing the outcomes of EPBD and EST demonstrated that with a follow-up of more than one year, EPBD reduced the recurrence of stones by approximately 50%

compared with EST, and among other compared studies and subsequent reported trials, it was also suggested that EPBD could be helpful in reducing the overall recurrence of CBD stones (Table 1) [30,40,43,48–59], although the difference was reported to be significant only in some related studies with follow-up data [30,54,55,57–59].

Analysis of the factors affecting the recurrence of CBD stones after EPBD or EST treatment showed that cholecystectomy after endoscopic treatment is a major factor. After EPBD or EST treatment, the recurrence rate of CBD stones in patients with gallbladder *in situ*, especially those with gallbladder stones, was similar between the two groups, possibly because some of the cases resulted from the re-formation of secondary CBD stones, reducing the difference in recurrence rate between the EPBD and EST groups [43,58]. For patients who underwent cholecystectomy after endoscopic lithotomy, the recurrence rate of CBD stones in the EPBD group reduced correspondingly [43], and the recurrence of stones was even significantly lower than that in the EST group [58], suggesting that combined with cholecystectomy, EPBD could help to reduce the recurrence of CBD stones in suitable patients [40,60].

In addition, with an increase in the diameter of CBD stones, the recurrence rate after EPBD or EST treatment seemed to increase gradually. Natsui et al. found that the recurrence rate of small stones ( $\leq 8$ mm) after EPBD treatment was significantly lower than that after EST treatment, whereas the recurrence rate of large stones ( $> 8$ mm) after endoscopic treatment with EPBD or EST was similar [58]. It was possibly because a relatively large stone should be usually crushed before stone removal, and the function of SO may also be destroyed by extracting the stone fragments, to increase bacterial contamination of the biliary tract after endoscopic treatment [61].

EPLBD is recommended for large or difficult CBD stones [39]. Studies detecting the recurrence rate of CBD stones after EPLBD or EST indicated that there was almost no significant difference between the EPLBD and EST groups (Table 2) [62–70]. However, EPLBD can increase the one-session ductal clearance rate and reduce the requirement of mechanical lithotripsy [68, 71], which would help expand its utilization for large CBD stones [71–73]. In addition, when CBD stones cannot be extracted after complete EST has been performed, EPLBD can also be proposed as the first-line treatment step or as a rescue option for extracting the stones, providing significantly higher CBD stone clearance for large stones ( $\geq 13$ mm) [74].

**Table 1.** Studies with follow-up data for the comparison of CBD stones recurrence after EST or EPBD treatment.

Ref.	Year	Design of study	Country	Study period	Techniques compared	Number of patients, n	Diameter of stones (mm)	Recurrent rate	p	Follow-up time, months
Bergman et al [49] <sup>#</sup>	1997	Randomized controlled trial	Netherlands	1993.01–1994.12	EPBD	101	10.0 ± 5.5 (3–36)	8/101 (7.9%)	p > 0.05	≥6
					EST	101	9.0 ± 3.5 (4–27)	7/101 (6.9%)		
Ochi et al [50] <sup>#</sup>	1999	Randomized controlled trial	Japan	1994.01–1997.04	EPBD	55	8.1 ± 3.4	2/51 (3.9%)	p > 0.05	4–42
					EST	55	8.8 ± 4.2	3/54 (5.6%)		
Yasuda et al [43]	2001	Retrospective	Japan	1995.06–2000.01*	EPBD	235	12.7 (4–47)	23/235 (9.8%)	p > 0.05	36.3 (12–67)
					EST	126	13.6 (5–42)	18/126 (14.3%)		37.4 (12–67)
Yasuda et al [43] <sup>#</sup>	2001	Randomized controlled trial	Japan	1998.01–1999.01	EPBD	35	12.4 ± 3.3 (4–24)	2/35 (5.7%)	p > 0.05	12
					EST	35	12.3 ± 3.2 (5–24)	3/35 (8.6%)		
Natsui et al [51] <sup>#</sup>	2002	Randomized controlled trial	Japan	1997.01–2000.06	EPBD	70	9.2 ± 3.2 (3–22)	3/68 (4.4%)	p > 0.05	29 (12–54)
					EST	70	9.7 ± 2.3 (3–17)	3/69 (4.3%)		30 (12–54)
Lin et al [52] <sup>#</sup>	2004	Randomized controlled trial	Taiwan	2001.01–2001.11	EPBD	51	8 ± 6	3/51 (5.9%)	p > 0.05	16 (12–22)
					EST	53	8 ± 6	4/53 (7.5%)		
Tanaka et al [53] <sup>#</sup>	2004	Randomized controlled trial	Japan	1996–1998	EPBD	16	10.2 ± 3.5	1/16 (6.3%)	p > 0.05	>12
					EST	16	12.4 ± 6.0	4/15 (26.7%)		
Kojima et al [55]	2010	Retrospective	Japan	1996.04–2007.05	EPBD	453	7.7 ± 3.5	31/453 (6.8%)	p < 0.05	≥12
					EST	233	11.1 ± 5.2	40/233 (17.0%)		
Yasuda et al [54] <sup>#</sup>	2010	Randomized controlled trial	Japan	2000.03–2001.03	EPBD	138	6.5 ± 2.1 (2–15)	11/138 (8.0%)	p < 0.05	80.3 (2.1–91.9)
					EST	144	7.0 ± 2.3 (2–16)	25/144 (17.4%)		81.6 (1.3–92.6)
Yu et al [57]	2011	Randomized controlled trial	China	2005.06–2007.05	EPBD	160	10.24 ± 0.89	2.5% (4/160)	p < 0.05	36
					EST	160	9.96 ± 0.91	7.5% (12/160)		
Natsui et al [58]	2013	Prospectively, alternately assigned	Japan	2000.07–2010.06 (Stone diameter ≤ 8 mm)	EPBD	113	5.9 ± 1.4	5/113 (4.4%)	p < 0.05	56.0 ± 36.5
					EST	111	5.8 ± 1.6	14/110 (12.7%)		54.6 ± 31.3
Natsui et al [58]	2013	Prospectively, alternately assigned	Japan	2000.07–2010.06 (Stone diameter > 8 mm)	EPBD	124	13.2 ± 4.0	13/117 (11.1%)	p > 0.05	59.5 ± 37.4
					EST	126	13.3 ± 4.5	15/123 (12.2%)		57.4 ± 33.4
Doi et al [59]	2013	Retrospective cohort study	Japan	1991.10–2011.12	EPBD	246	8 (6–12)	21/246 (8.5%)	p < 0.05	90 (42–139.3)
					EST	246	9 (6–13)	37/246 (15.0%)		93.5 (46.8–129.2)
Seo et al [40]	2014	Randomized controlled trial	Korea	2006.09–2012.08	EPBD	62	7.2 ± 2.08 (3–12)	1/62 (1.6%)	p > 0.05	35.4
					EST	70	7.6 ± 3.12 (3–12)	4/70 (5.8%)		
Lu et al [56]	2014	Retrospective	China	2008.01–2011.06	EPBD	227	10 (3–45)	12/170 (7.06%)	p > 0.05	54.7 (36.7–75.6)
					EST	636	10 (2–40)	59/493 (11.97%)		54.4 (36.7–77.6)
Mu et al [30]	2015	Randomized controlled trial	China	2007.06–2008.06	sEST plus EPBD	147	13.6 ± 3.8	14/147 (9.5%)	p < 0.05	>36
					EST	144	12.9 ± 3.4	29/144 (20.1%)		

EPBD, endoscopic papillary balloon dilation; EST, endoscopic sphincterotomy; sEST plus EPBD, small-incision EST plus EPBD.

\*Except for the period of the randomized trial (1998.01–1999.01).

<sup>#</sup>Included in the meta-analysis [48].

For the treatment of recurrent CBD stones, the ideal therapy should be to remove stones *via* a minimally invasive method, avoid residual stones, and maintain smooth excretion of bile as much as possible, possibly with secondary protection of the SO, because recurrent CBD stones are mainly pigment stones, and the

function of SO in these patients may already be abnormal. Studies with follow-up data comparing the outcomes of EPLBD and EST for the removal of recurrent CBD stones showed that EPLBD treatment could be helpful in reducing the early and late recurrence of stones and multiple recurrences (Table 3) [75–77].



**Table 2.** Studies with follow-up data for the comparison of CBD stones recurrence after EST or EPLBD treatment.

Ref.	Year	Design of study	Country	Study period	Techniques compared	Number of patients, n	Diameter of stones (mm)	Complete stone removal in one session	Mechanical lithotripsy	Recurrent rate	p	Follow-up time, months
Kim et al [62]	2012	Retrospective	Korea	2006.05–2007.12	mEST + EPLBD	100	16.4 ± 6.7	–	–	11/100 (11.0%)	p > 0.05	32.5 ± 4.5 (22–40)
				2004.01–2005.08	EST	109	14.0 ± 4.6	–	–	15/109 (13.8%)		31.8 ± 6.0 (22–41)
Jun et al [63]	2013	Randomized controlled trial	China	2008.01–2012.01	mEST + EPLBD	63	20.6 ± 5.4	51/63 (81.0%)	5/63 (7.9%)	6/63 (9.5%)	p < 0.05	p ≥ 28
					EST	69	20.3 ± 5.3	42/69 (60.9%)	17/69 (24.6%)	8/69 (11.6%)		
Kim et al [64]	2013	Retrospective	Korea	2004.12–2009.03	mEST + EPLBD	101	12.0 (3–25)	–	25/101 (24.8%)	7/101 (6.9%)	p > 0.05	p 13.0 (6–43)
					EST	121	10.0 (2–20)	–	33/121 (27.3%)	7/121 (5.8%)		25.0 (6–48)
Li et al [65]	2014	Randomized controlled trial	China	2008.05–2011.04	mEST + EPLBD	232	<12 (138.60.5 %)+ ≥12 (90.39.5 %)	200/228 (87.7 %)	28/228 (12.3 %)	1/226 (0.44 %)	p < 0.05	p < 12
					EST	230	<12 (141.62.1%)+ ≥12 (86.37.9%)	162/227 (71.4 %)	80/227 (35.2 %)	2/226 (0.88 %)		
Paik et al [66]	2014	Retrospective	Korea	2001.01–2010.07	mEST + EPLBD	49	16.5 ± 0.9	38/49 (77.6%)	14/49 (28.6%)	15/49 (30.6%)	p = 0.05	p 45.1 (10.2–129.5)
					EST	41	16.8 ± 0.8	24/41 (58.5%)	41/41 (100%)	11/41 (26.8 %)		
Guo et al [67]	2014	Retrospective	China	2009.01–2012.12	mEST + EPLBD	64	12.1 ± 2.0 (10–25)	58/64 (90.6%)	3/64 (4.7%)	1/64 (1.6%)	p > 0.05	p < 12
					EST	89	12.9 ± 2.6 (10–27)	79/89 (88.8%)	7/89 (7.9%)	6/89 (6.7%)	p < 0.05	p < 0.05
Omar et al [68]	2017	Randomized controlled trial	Egypt	2014.08–2016.08	EPLBD	61	13.9 ± 2.4	53/61 (86.9%)	6/61 (9.8%)	2/61 (3.3%)	p = 0.01	p –
					EST	63	13.1 ± 2.6	45/63 (71.4%)	11/63 (17.5%)	2/63 (3.2%)		
Xu et al [69]	2017	Retrospective	China	2012.05–2016.04	mEST + EPLBD	73	16.9 ± 4.1	69/73 (94.5%)	5/73 (6.8%)	4/73 (5.5%)	p < 0.05	p 14.1 ± 5.5
					EST	76	16.5 ± 4.7	64/76 (84.2%)	14/76 (18.4%)	3/76 (3.9%)	p < 0.05	12.9 ± 5.5
Kuo et al [70]	2019	Retrospective	Taiwan	2010.01–2018.02	mEST + EPLBD	58	18 (15–35)	57/58 (98.3%)	2/58 (3.4%)	5/58 (8.6%)	p < 0.05	p –
					EPLBD	96	16.5 (15–26)	83/96 (86.5%)	10/96 (10.4%)	4/96 (4.2%)	p > 0.05	p > 0.05
					EST	31	17 (15–27)	26/31 (83.9%)	4/31 (12.9%)	0/31 (0%)		

EPLBD, endoscopic papillary large balloon dilation; mEST + EPLBD, small EST plus EPLBD; EST, endoscopic sphincterotomy.

**Table 3.** Studies with follow-up data for the comparison of the recurrence of recurrent CBD stones after EST or EPLBD treatment.

Ref.	Year	Design of study	Country	Study period	Techniques compared	Number of patients; n	Diameter of stones (mm)	Complete stone removal in one session	p	Mechanical lithotripsy	p	Recurrent rate	p	Follow-up time, months
Harada et al [75]	2013	Retrospective	Japan	2007.12–2010.08	EPLBD	30	18 (10–39)	30/30 (100%)	p >0.05	3/30 (10%)	p <0.001	6/30 (20%)	p <0.05	17.2 (2.7–33)
Tsai et al [76]	2015	Retrospective	Taiwan	2006.04–2007.11 1991.01–2008.12	EST	32	16 (10–30)	28/32 (87.5)		17/32 (53.1%)		17/32 (53.1%)		34.5 (0.3–53.5)
					EPLBD	24	17 ± 7.9	20/23 (87%)	p >0.05	3/23 (13%)	p >0.05	4/23 (17%)	p <0.01	95 ± 58.1
Wang et al [77]	2022	Randomized controlled trial	China	2014.06–2021.06	EST	109	14 ± 7.0	79/99 (80%)		7/99 (7%)		60/99 (60%)		90 ± 45.3
					EPLBD	90	12 (10–15)	86/90 (95.6%)	p <0.05	3/90 (3.3%)	p >0.05	31/90 (34.4%)	p <0.05	55 (39–70)
					EST	90	10 (8–14)	77/90 (85.6%)		8/90 (8.9%)		46/90 (51.1%)		57 (41–72)

EPLBD, endoscopic papillary large balloon dilation; mEST + EPLBD, small EST plus EPLBD; EST, endoscopic sphincterotomy.

EPLBD should be recommended as first-line treatment for patients with recurrent CBD stones, especially those with large stones.

### *Ideas of future exploration and prospect of endoscopic treatment of CBD stones*

Based on the analysis of endoscopic treatment, structural and functional abnormality of SO, and their relationship with the recurrence of CBD stones, ideas for future improvement are as follows: (1) EPBD cannot perfectly preserve SO function, and methods to further reduce the influence of treatment on the function of SO require further exploration; although maybe more expensive, temporary insertion of a self-expandable metal stent to provide a suitable opening of the papilla for the removal of small CBD stones may be more effective in preserving SO function, with post-treatment manometric parameters within the normal range [78]. More prospective studies with larger populations and longer follow-up periods are warranted to detect the long-term postoperative efficacy of this method. (2) Peroral cholangioscopy (POCS), which transforms an 'indirect' radiological visualization to a 'direct' endoscopic visualization of the biliary tree with the assistance of a digital cholangioscope, is increasingly applied in endoscopic lithotomy of difficult bile duct stones [79,80]; EPBD has a theoretical advantage in preserving SO function, especially when performed with a short dilation time and a small balloon size [45, 81]; Combination of peroral cholangioscopy, appropriate EPBD and proper mechanical or laser lithotripsy may further help to expand the application of endoscopic lithotomy for the treatment of CBD stones, providing a better therapeutic effect by protecting SO with minimal stretch damage and avoiding scratching damage of stone fragments. (3) EPLBD is suitable for large or difficult CBD stones, but the structure and function of SO may be damaged to a greater extent, and post-damage repair can help to restore SO function after EST treatment [33, 82]. This method for post-damage repair after EST plus EPLBD treatment may be helpful for reducing the recurrence of CBD stones [34, 83]. (4) For the treatment of recurrent CBD stones, EPLBD treatment could help to reduce the early and late recurrence of stones; however, the re-recurrence rate of recurrent CBD stones after treatment is still rather high, and pharmacological adjuvants may be helpful for this subgroup of patients; ursodeoxycholic acid has been known to have cholegic effects by increasing the flow volume and rate of bile in patients with cholestasis, which is considered to be a risk factor in the recurrence of CBD stones

[84]; ursodeoxycholic acid intervention after endoscopic treatment was recognized as a preventive factor to reduce stone recurrence [85], and whether this effect of ursodeoxycholic acid can help reduce recurrence needs to be demonstrated by more large-sample randomized controlled trials with long-term follow-up.

## Conclusions

Structural impairment and functional abnormalities of the SO are risk factors for the recurrence of bile duct stones after endoscopic treatment. Investigation of the influence of different endoscopic methods on the function and structure of SO can be helpful in selecting optimal treatments for patients with CBD stones, guiding further improvement of these treatment methods, or exploration of novel methods, which may help to further protect the function and structure of SO, reduce or prevent the recurrence of bile duct stones, and improve patient outcomes.

## Authors' contributions

Yang Y and Yao D designed the review; Yang Y, Zhao Z, Wu S, and Yao D collected and analyzed the data and prepared the tables and figures; Yang Y and Yao D drafted the manuscript; Yang Y, Zhao Z, Wu S, and Yao D approved the final version of the manuscript.

## Disclosure statement

No potential conflict of interest was reported by the author(s).

## Ethical approval

This review did not require ethical approval as it was based on previously published studies.

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## Data availability statement

Data sharing is not applicable to this article as no new data were created or analyzed in this study.

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