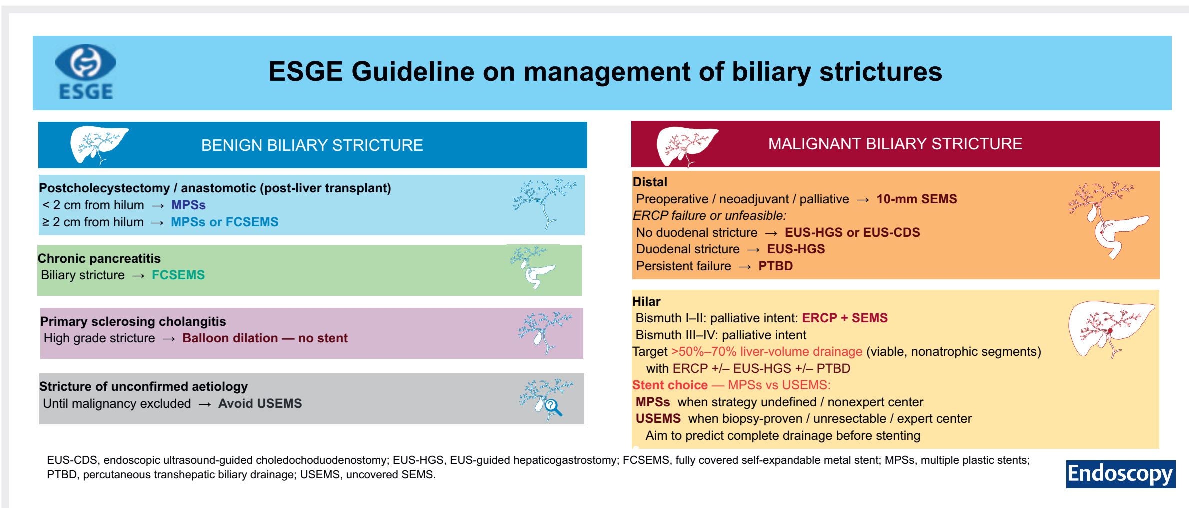
Biliary stricture management: European Society of Gastrointestinal Endoscopy (ESGE) Guideline

GRAPHICAL ABSTRACT



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MAIN RECOMMENDATIONS

Benign biliary strictures

1 ESGE suggests temporary insertion of multiple plastic stents (MPSs) to treat postcholecystectomy benign biliary strictures.
A fully covered self-expandable metal stent (FCSEMS) can be considered in these patients when the stricture is located >2 cm distally from the main hepatic confluence or for patients who are noncompliant with repeated endoscopic retrograde cholangiopancreatographies (ERCPs).

2 ESGE suggests treating anastomotic biliary strictures following liver transplantation with either MPSs or temporary insertion of an FCSEMS when located >2 cm distally from the main hepatic confluence.

3 ESGE suggests treating biliary strictures secondary to chronic pancreatitis with temporary insertion (6–12 months) of an FCSEMS.

4 ESGE suggests using balloon dilation alone for high grade biliary strictures secondary to primary sclerosing cholangitis. There is no added benefit of stenting following balloon dilation, and stenting may increase the risk of adverse events.

5 ESGE suggests avoiding the insertion of uncovered SEMSs (USEMSs) for the drainage of extrahepatic biliary obstruction of unconfirmed etiology.

Distal malignant biliary strictures

6 ESGE recommends the endoscopic placement of a 10-mm diameter SEMS for preoperative biliary drainage (PBD) of extrahepatic malignant biliary obstruction (MBO).

7 ESGE recommends the endoscopic placement of a 10-mm diameter SEMS for neoadjuvant biliary drainage of extrahepatic pathologically confirmed MBO.

8 ESGE recommends endoscopic over surgical or percutaneous biliary drainage for primary decompression of inoperable, extrahepatic MBO.

Hilar malignant biliary strictures

9 ESGE recommends ERCP over percutaneous transhepatic biliary drainage (PTBD) for PBD in hilar malignant obstruction.

10 ESGE suggests palliative drainage of malignant hilar strictures by means of ERCP for Bismuth types I–II. For Bismuth III–IV, ERCP or a combination of ERCP with endoscopic ultrasound-guided biliary drainage (EUS-BD) is preferable over primary PTBD. Complementary drainage using PTBD might be required in some cases.

11 ESGE suggests obtaining drainage of more than 50%, and ideally 70% or more, of the viable nonatrophic liver volume for palliative drainage of proven malignant Bismuth II–IV strictures, using a multimodal approach (EUS-BD/PTBD if needed, as complementary methods to ERCP).

12 ESGE suggests using either plastic stents or USEMSs for palliative drainage of proven malignant hilar obstruction. ESGE suggests a plastic stent when the optimal drainage strategy has not been defined. ESGE suggests using a USEMS in expert centers to reduce the need for revisional procedures based on the patient's expected survival and the likelihood of achieving complete biliary drainage.

Malignant biliary stricture in cases of failed or unfeasible ERCP

13 ESGE recommends EUS-BD over PTBD in cases of malignant biliary stricture following failed or unfeasible ERCP.
In patients with distal stricture, ESGE suggests using EUS-guided hepaticogastrostomy (EUS-HGS) where a duodenal stricture is present, and either EUS-HGS or EUS-guided choledochoduodenostomy where there is no duodenal stricture.
ESGE suggests using PTBD when EUS-BD fails or is not feasible.

ABBREVIATIONS

ABS	anastomotic biliary stricture
AE	adverse event
BBS	benign biliary stricture
CBD	common bile duct
DBE	double-balloon enteroscopy
DPPT	double-pigtail plastic stent
EA-ERCP	enteroscopy-assisted ERCP
EBD	endoscopic balloon dilation
EDGE	endoscopic ultrasound-directed transgastric ERCP
ERCP	endoscopic retrograde cholangiopancreatography
EUS	endoscopic ultrasound
EUS-BD	EUS-guided biliary drainage
EUS-CDS	EUS-guided choledochoduodenostomy
EUS-GBD	EUS-guided gallbladder drainage
EUS-HGS	EUS-guided hepaticogastrostomy
EUS-HJS	EUS-guided hepaticojejunostomy
EUS-RV	EUS-assisted rendezvous biliary drainage technique
FCSEMS	fully covered SEMS
LAMS	lumen-apposing metal stent
LA-ERCP	laparoscopy-assisted ERCP
MBO	malignant biliary obstruction
MPSs	multiple plastic stents
MRCP	magnetic resonance cholangiopancreatography
NBS	nonanastomotic biliary stricture
PBD	preoperative biliary drainage
PCSEMS	partially covered SEMS
PEP	post-ERCP pancreatitis
PSC	primary sclerosing cholangitis
PTBD	percutaneous transhepatic biliary drainage
RCT	randomized controlled trial
RYGB	Roux-en-Y gastric bypass
SBE	single-balloon enteroscopy
SEMS	self-expandable metal stent
USEMS	uncovered SEMS

SOURCE AND SCOPE

This guideline is an official statement of the European Society of Gastrointestinal Endoscopy (ESGE). ESGE guidelines represent a consensus of best practice based on the available evidence at the time of preparation. They are intended to be an educational tool to provide information that may support endoscopists in providing care to patients.

1 Introduction

Biliary strictures, defined as a narrowing of the intrahepatic or extrahepatic biliary system, with concomitant upstream biliary duct dilatation, are associated in most cases with symptoms (e.g. jaundice, pruritus, or sepsis secondary to cholangitis or liver abscesses) or with a risk of long-term complications such as secondary biliary cirrhosis, justifying the need for clinical intervention. Given the differences in their specific management, the required work-up to distinguish benign from malignant origins of a biliary stricture, appropriately adapted for its location and presentation, has been addressed by a previous guideline [1]. Several minimally invasive technical approaches have been developed over time to treat biliary strictures by dilation and/or stenting using endoscopic retrograde cholangiopancreatography (ERCP), percutaneous transhepatic biliary drainage (PTBD), or, more recently, endoscopic ultrasound-guided biliary drainage (EUS-BD). These techniques have been demonstrated to be associated with lower morbidity compared with surgery, and should be tailored to the etiology, clinical situation, and anatomy of each patient.

The European Society of Gastrointestinal Endoscopy (ESGE) commissioned this guideline in 2025 to deal specifically with biliary stricture management, updating the previous 2018 version of the biliary stenting guidelines [2] and harmonizing the clinical perspective with the therapeutic EUS guidelines published in 2022 [3]. The present work is independent of the biliary stricture diagnosis guideline (2025) [1], the chronic pancreatitis management guideline updated in 2018 [4], and the ERCP adverse event (AE) guidelines (2020) [5]. The goal of this guideline is to provide evidence-based recommendations (based on Grading of Recommendations Assessment, Development and Evaluation (GRADE) criteria [6]) focusing on the following sections: benign biliary stricture (BBS), malignant biliary stricture, surgically altered anatomy or inaccessible papilla, and second attempts after failure. Recommendations are issued focusing on the implications for patients.

2 Methods

The ESGE Guidelines Committee Chair (K.T.) appointed a leader (A.L.) who invited a list of authors (the panel) to participate in project development, and four task forces were created to deal with different aspects of the guideline. Task force members were allocated to different task forces (**Table 1s**, see online-only Supplementary material) and were asked to disclose any potential financial or intellectual conflicts of interest. The guideline was developed using the GRADE framework [6] (**Table 2s**). The relevant clinical questions were developed a priori, listed in the PICO (patient, intervention, control, outcome) format, and validated by the panel (**Table 3s**).

Each task force performed a systematic literature search using PubMed/MEDLINE, Embase, Scopus, and the Cochrane library, with the help of a professional librarian, and with added manual searches, to identify publications from 2017 to August 2024 (restricted to papers published in the English language), focusing on meta-analyses and published prospective studies, particularly randomized controlled trials (RCTs), performed in humans. Further manual searches were performed up to 2025 at the time of final manuscript editing to ensure coherent updated discussion. Retrospective analyses and pilot studies were also included if they addressed topics not covered in the prospective studies. After further exploration of their content, all relevant articles were included and summarized in the literature tables for the key topics. Further details on the methodology of ESGE guideline development have been reported elsewhere [7].

In addition, various exchanges and an on-site meeting were held during ESGE Days 2025 with the guideline leader (A.L.) and the task force leaders to discuss and finalize the recommendations. When an adaptation of a recommendation and its quality of evidence was needed, decisions were taken after obtaining a consensus among involved authors, taking into account its implementation, feasibility, cost/resource use, need of specific expertise, and implications, and the justification was added in a specific paragraph at the end of the relevant section of the guideline.

By November 2025, a draft of all the recommendations was prepared. Following approval by the leader (A.L.), the draft was reviewed by two members of the ESGE Governing Board and by external reviewers, and it was then sent for further comments to the ESGE National Societies and individual members. After agreement on a final version, the manuscript was submitted to the journal *Endoscopy* for publication. All authors agreed on the final version of the manuscript. The Guideline was issued in 2026 and will be considered for review if new and relevant evidence becomes available. Any updates to the Guideline in the interim period will be noted on the ESGE website: www.esge.com/esge-guidelines.html.

3 Recommendations

A summary of the main recommendations and comparison with the 2018 (stenting) and 2022 (therapeutic EUS) guidelines is presented in ▶ **Table 1**. An illustration of the new main recommendations is presented in ▶ **Fig. 1**.

▶ **Table 1** ESGE biliary stricture management guideline update 2025: summary of recommendations.

a) Benign biliary strictures	
2017 endoscopic biliary stenting guideline	**2025 update on endoscopic biliary stricture management**
Benign biliary strictures	
ESGE recommends temporary insertion of multiple plastic stents (MPSs) or of a fully covered SEMS for treatment of benign biliary strictures. Strong recommendation, moderate quality evidence. The choice between the two strategies depends on the etiology of the stricture, its location, the CBD diameter, and endoscopist experience.	Updated by pathology type.
ESGE suggests, for multiple plastic stenting, insertion of the maximum number of stents possible every 3–4 months for a total duration of 12 months and, for treatment with FCSEMS, insertion of an 8–10-mm diameter FCSEMS for a dwell stenting period of 6 months. Weak recommendation, low quality evidence.	Updated by pathology type.
Postcholecystectomy biliary stricture	
ESGE suggests temporary insertion of MPSs for the treatment of benign biliary strictures complicating cholecystectomy; an FCSEMS can be an alternative for strictures located >2 cm from the main hepatic confluence. Weak recommendation, moderate quality evidence.	ESGE suggests temporary insertion of MPSs to treat postcholecystectomy benign biliary strictures. An FCSEMS can be considered in these patients when the stricture is located >2 cm distally from the main hepatic confluence or for patients who are noncompliant with repeated ERCPs. Conditional recommendation, very low quality of evidence.
Anastomotic stricture after liver transplantation	
ESGE suggests temporary insertion of MPSs for the treatment of benign anastomotic biliary strictures following orthotopic liver transplantation pending further evidence about FCSEMS. Weak recommendation, moderate quality evidence	ESGE suggests treating anastomotic biliary strictures following liver transplantation with either MPSs or temporary insertion of an FCSEMS when located >2 cm distally from the main hepatic confluence. Conditional recommendation, low quality of evidence.
Nonanastomotic stricture after liver transplantation	
	ESGE suggests managing nonanastomotic biliary strictures amenable to endoscopic treatment following liver transplantation with temporary insertion of MPSs together with balloon dilation if needed. Conditional recommendation, very low quality of evidence.

Chronic pancreatitis-associated biliary stricture	
ESGE suggests the temporary insertion of MPSs or of an FCSEMS for treating benign biliary strictures related to chronic pancreatitis. Weak recommendation, moderate quality evidence.	ESGE suggests treating biliary strictures secondary to chronic pancreatitis with temporary insertion (6–12 months) of an FCSEMS. Conditional recommendation, low quality of evidence.
Primary sclerosing cholangitis-associated biliary stricture	
PSC guidelines 2017 ESGE/EASL suggest that the choice between stenting and balloon dilation should be left to the endoscopist's discretion. Weak recommendation, low quality evidence.	ESGE suggests using balloon dilation alone for high grade biliary strictures secondary to PSC. There is no added benefit of stenting following balloon dilation, and stenting may increase the risk of adverse events. Conditional recommendation, low quality of evidence.
b) Malignant biliary strictures	
2017 endoscopic biliary stenting guideline	**2025 update on endoscopic biliary stricture management**
Suspected malignant biliary obstruction	
ESGE recommends against the insertion of USEMS for the drainage of extrahepatic biliary obstruction of unconfirmed etiology. Strong recommendation, low quality evidence.	ESGE suggests avoiding the insertion of USEMSs for the drainage of extrahepatic biliary obstruction of unconfirmed etiology. Conditional recommendation, low quality of evidence.
Extrahepatic malignant biliary stricture: preoperative	
ESGE recommends against routine preoperative biliary drainage in patients with malignant extrahepatic biliary obstruction; preoperative biliary drainage should be reserved for patients with cholangitis, severe symptomatic jaundice (e.g. intense pruritus), or delayed surgery, or for before neoadjuvant chemotherapy in jaundiced patients. Strong recommendation, moderate quality evidence.	ESGE suggests offering preoperative biliary drainage to patients with extrahepatic malignant biliary obstruction (MBO) with cholangitis, severe symptomatic jaundice (e.g. intense pruritus), or delayed surgery after 2 weeks, or before neoadjuvant chemotherapy in jaundiced patients. Routine preoperative biliary drainage may be avoidable in patients with extrahepatic MBO when upfront surgery is planned within 1–2 weeks. Conditional recommendation, low quality of evidence.
ESGE recommends the endoscopic placement of a 10-mm diameter SEMS for preoperative biliary drainage of extrahepatic MBO. Strong recommendation, moderate quality evidence.	ESGE recommends the endoscopic placement of a 10-mm diameter SEMS for preoperative biliary drainage of extrahepatic MBO. Strong recommendation, moderate quality of evidence.
	Extrahepatic MBO: neoadjuvant
	ESGE recommends the endoscopic placement of a 10-mm diameter SEMS for neoadjuvant biliary drainage of extrahepatic pathologically confirmed MBO. Strong recommendation, moderate quality of evidence.
Extrahepatic MBO: palliative	
ESGE recommends that decompression of extrahepatic MBO be performed via ERCP rather than by surgery or percutaneously. Strong recommendation, moderate quality evidence.	ESGE recommends endoscopic over surgical or percutaneous biliary drainage for primary decompression of inoperable, extrahepatic MBO. Strong recommendation, moderate quality of evidence.
SGE recommends SEMS insertion for palliative drainage of extrahepatic MBO. Strong recommendation, high quality evidence. ESGE recommends restricting the use of EUS-BD to cases where biliary drainage using standard ERCP techniques has failed. Strong recommendation, low quality evidence.	ESGE recommends SEMS insertion for palliative drainage of extrahepatic MBO of confirmed etiology. Strong recommendation, high quality evidence.
2021 therapeutic EUS guideline ESGE recommends ERCP for primary drainage of distal MBO, but EUS-BD could also be used in this setting for inoperable patients at high volume expert centers. Strong recommendation, moderate quality evidence.	ESGE suggests favoring ERCP for primary drainage of distal MBO, but EUS-BD could also be used as an alternative to primary ERCP for palliative biliary drainage in selected patients with distal MBO, in expert centers. Conditional recommendation, low quality of evidence.
Malignant bilioduodenal obstruction	
ESGE suggests endoscopic insertion of a biliary SEMS and an uncovered duodenal SEMS in patients with both biliary and duodenal malignant obstruction. Weak recommendation, low quality evidence.	See final entry in section d of this table.

Stent dysfunction	
ESGE suggests that in a patient with a distal malignant biliary stricture and a nonfunctioning stent, a plastic stent should be replaced by a SEMS and, in the case of a SEMS, a plastic stent or a new SEMS should be inserted within the original SEMS. Weak recommendation, moderate quality evidence.	No recommendation or suggestion.
Malignant hilar strictures	
ESGE recommends performing drainage of malignant hilar strictures in high volume centers with a hepatobiliary MDT. Strong recommendation, moderate quality evidence.	ESGE recommends performing drainage of malignant hilar strictures in high volume centers with a hepatobiliary MDT. Strong recommendation, moderate quality evidence.
Hilar stricture: preoperative	
ESGE suggests against routine preoperative biliary drainage in patients with malignant hilar obstruction. The indication and route for preoperative biliary drainage should be decided by an MDT based on patient characteristics and institutional experience. Weak recommendation, low quality evidence.	ESGE suggests against routine preoperative biliary drainage in patients with malignant hilar obstruction. Indications and routes of drainage must be determined following an MDT discussion based on patient characteristics and institutional experience. Conditional recommendation, low quality of evidence. ESGE recommends ERCP over PTBD for preoperative biliary drainage in hilar malignant obstruction. Strong recommendation, moderate quality of evidence.
Hilar stricture: palliative	
ESGE suggests palliative drainage of malignant hilar strictures by means of ERCP for Bismuth types I and II, and PTBD or a combination of PTBD and ERCP for Bismuth types III and IV, to be modulated according to local expertise. Weak recommendation, low quality evidence.	ESGE suggests palliative drainage of malignant hilar strictures by means of ERCP for Bismuth types I–II. For Bismuth III–IV, ERCP or a combination of ERCP with EUS-BD is preferable over primary PTBD. Complementary drainage using PTBD might be required in some cases. Conditional recommendation, very low quality of evidence.
ESGE suggests, for palliative endoscopic drainage of Bismuth types II–IV strictures, drainage of ≥ 50% of the liver volume and avoidance of the opacification of biliary ducts that will not be drained. Weak recommendation, low quality evidence.	ESGE suggests obtaining drainage of more than 50%, and ideally 70% or more, of the viable nonatrophic liver volume for palliative drainage of proven malignant Bismuth III–V strictures, using a multimodal approach (EUS-BD/PTBD if needed, as complementary methods to ERCP). Conditional recommendation, low quality of evidence.
ESGE recommends USEMSs for palliative drainage of malignant hilar obstruction. Strong recommendation, moderate quality evidence.	ESGE suggests using either plastic stents or USEMSs for palliative drainage of proven malignant hilar obstruction. ESGE suggests a plastic stent when the optimal drainage strategy has not been defined. ESGE suggests using a USEMS in expert centers to reduce the need for revisional procedures based on the patient's expected survival and the likelihood of achieving complete biliary drainage. Conditional recommendation, moderate quality of evidence.
c) Surgically altered anatomy/inaccessible papilla	
2021 therapeutic EUS guideline (nothing in 2017 biliary stenting guideline)	**2025 update on endoscopic biliary stricture management**
All postsurgical conditions	**ERCP in Billroth II anatomy**
ESGE suggests EUS-BD only after failed enteroscopy-assisted ERCP (EA-ERCP) in the management of benign postsurgical biliary obstruction or CBD stones. Weak recommendation, low quality evidence. ESGE suggests EUS-BD in postsurgical MBO and a long biliary limb with dilated intrahepatic bile ducts. Weak recommendation, low quality evidence.	ESGE suggests that in cases of Billroth II postsurgical anatomy, ERCP with front- or side-viewing endoscopes can be considered. Depending on local expertise, EUS-assisted or EUS-guided techniques can be undertaken when ERCP is unsuccessful. Conditional recommendation, moderate quality of evidence.
	Biliary drainage after pancreaticoduodenectomy
	ESGE suggests that, in patients with previous pancreaticoduodenectomy, EA-ERCP, EUS, and PTBD may be considered. ▪ For benign biliary strictures, EA-ERCP should be considered as the first-line option. EUS-BD may be proposed in selected cases, particularly when multiple biliary interventions are expected or if the index EA-ERCP was difficult. PTBD, including percutaneous cholangioscopy, may be considered in specific cases, such as right-sided hepatolithiasis or when other techniques have failed.

	▪ For malignant biliary strictures, EA-ERCP or EUS-BD (either antegrade or EUS-HGS / EUS-HJS) is recommended as first-line therapy, according to anatomical constraints and local expertise. PTBD is recommended as the second-line option. EUS-directed transenteric ERCP requires further evaluation. Conditional recommendation, low quality of evidence.
	Biliary drainage after RYGB
	ESGE suggests that in patients with previous RYGB, EDGE or EA-ERCP may be considered. ▪ For benign biliary strictures, EDGE is suggested as the first-line approach, unless there is specific expertise in EA-ERCP. ▪ For malignant biliary strictures, EUS-BD (either antegrade stenting or EUS-HGS / EUS-HJS) is often the preferred option, although EDGE, EA-ERCP, and PTBD may also be considered based on anatomical constraints and local expertise. Conditional recommendation, low quality of evidence.
	Biliary drainage after partial/total gastrectomy (Roux-en-Y jejunojejunal anastomosis)
	ESGE suggests that in patients with partial or total gastrectomy with a Roux-en-Y jejunojejunal anastomosis, EA-ERCP, EUS-BD, and PTBD can be considered. ▪ For benign biliary strictures, EA-ERCP should be considered as first-line option. EUS-BD may be proposed in selected cases, particularly when multiple biliary interventions are expected. PTBD, including percutaneous cholangioscopy, may be considered in specific indications, such as CBD or intrahepatic stones, or in cases where other techniques have failed. ▪ For malignant biliary strictures, EUS-BD (either antegrade or EUS-HGS / EUS-HJS) or PTBD are suggested as first-line approaches in expert centers. Conditional recommendation, low quality of evidence.
	Biliary drainage after Roux-en-Y hepaticojejunostomy
	ESGE suggests endoscopic over percutaneous biliary drainage in patients with Roux-en-Y hepaticojejunostomy, owing to its safer profile. ▪ For benign biliary stricture, EA-ERCP or EUS-BD techniques, such as antegrade drainage or EUS-HGS, are viable options. Additionally, EUS-directed transenteric ERCP may be considered in selected cases, particularly for postsurgical complications of hepaticojejunostomy. ▪ For malignant biliary strictures, EUS-BD, with antegrade drainage or EUS-HGS, is recommended as a first-line approach. ▪ PTBD can be considered as a second-line approach for benign and malignant indications. Conditional recommendation, low quality of evidence.
	Inaccessible papilla
	ESGE recommends EUS-BD over PTBD in cases of malignant biliary stricture following failed or unfeasible ERCP. In patients with distal stricture, ESGE suggests using EUS-HGS where a duodenal stricture is present, and either EUS-HGS or EUS-CDS where there is no duodenal stricture. ESGE suggests using PTBD when EUS-BD fails or is not feasible. Strong recommendation, moderate quality of evidence.
d) ERCP failure: second attempt	
2017 endoscopic biliary stenting guideline/ 2021 therapeutic EUS guideline	**2025 update on endoscopic biliary stricture management**
	Benign biliary stricture: accessible papilla, ERCP failure (failed cannulation/stricture passage)
ESGE suggests an EUS-RV technique after a second failed ERCP in benign biliary disease and normal gastrointestinal anatomy in high volume expert centers. Weak recommendation, low quality evidence.	ESGE suggests using rendezvous over transmural drainage where ERCP has failed for benign biliary strictures. Conditional recommendation, low quality of evidence.

	Malignant biliary stricture: accessible papilla, ERCP failure, no duodenal stricture
ESGE recommends the use of EUS-BD over PTBD after failed ERCP in distal MBO when local expertise is available. Strong recommendation, moderate quality evidence. ESGE suggests EUS-BD with hepaticogastrostomy only for inoperable hilar MBO with a dilated left hepatic duct when inadequately drained by ERCP and/or PTBD in high volume expert centers. Weak recommendation, moderate quality evidence. ESGE recommends the use of EUS-BD over PTBD after failed ERCP in distal MBO when local expertise is available. Strong recommendation, moderate quality evidence.	ESGE suggests EUS-guided transmural drainage over PTBD for MBO after failed ERCP. Conditional recommendation, low quality of evidence.
	Malignant biliary stricture: accessible papilla, ERCP failure, with duodenal stricture
ESGE suggests endoscopic insertion of a biliary SEMS and an uncovered duodenal SEMS in patients with both biliary and duodenal malignant obstruction. Weak recommendation, low quality evidence.	ESGE suggests EUS-BD over surgical bypass or percutaneous drainage in the setting of double malignant biliary and gastric outlet obstruction, where expertise is available. In this scenario, EUS-HGS is associated with reduced risk of recurrent biliary obstruction compared with EUS-CDS. Conditional recommendation, very low quality of evidence.

CBD, common bile duct; EA-ERCP, enteroscopy-assisted ERCP; EASL, European Association for the Study of the Liver; EDGE, endoscopic ultrasound-directed transgastric ERCP; ERCP, endoscopic retrograde cholangiopancreatography; EUS, endoscopic ultrasound; EUS-BD, EUS-guided biliary drainage; EUS-CDS, EUS-guided choledochoduodenostomy; EUS-HGS, EUS-guided hepaticogastrostomy; EUS-HJS, EUS-guided hepaticojejunostomy; EUS-RV, EUS-assisted rendezvous biliary drainage technique; FCSEMS, fully covered self-expandable metal stent; MBO, malignant biliary obstruction; MDT, multidisciplinary team; MPSs, multiple plastic stents; PSC, primary sclerosing cholangitis; PTBD, percutaneous transhepatic biliary drainage; RYGB, Roux-en-Y gastric bypass; SEMS, self-expandable metal stent; USEMS, uncovered SEMS.

3.1 Benign biliary stricture

The natural evolution of BBSs with a sustained rise in liver function test (LFT) values has been associated with the development of long-term infective complications (e.g. cholangitis, liver abscess) and liver function deterioration (e.g. liver fibrosis, secondary biliary cirrhosis – 7.3% in chronic pancreatitis-related BBS) [4, 8, 9, 10]. Regression of liver fibrosis has been documented in surgical series after drainage of BBS (secondary to chronic pancreatitis and cholecystectomy), but no studies have evaluated the results of endoscopic treatment with multiple plastic stents (MPSs) or fully covered self-expandable metal stents (FCSEMSs) (**Table 4.1s**). It can be assumed that surgical or endoscopic biliary drainage resulting in normalization of LFTs can prevent the liver function deterioration that is observed in the case of untreated BBS. Since 2017, no major novel evidence has suggested changing the practice of starting endotherapy for the treatment of BBS with persistent increase in the LFTs for more than a month and/or the presence of cholangitis. The choice between MPSs and an FCSEMS depends on the etiology of the stricture, its location, common bile duct (CBD) diameter, and the endoscopist's experience. Practically, the following treatments can be suggested: MPSs, insertion of the maximum number of stents, with stent exchange every 3–4 months over a total period of 12 months; FCSEMS, insertion of an 8–10-mm diameter FCSEMS for a stent indwell period of 6–12 months.

3.1.1 Benign biliary stricture after cholecystectomy

RECOMMENDATION

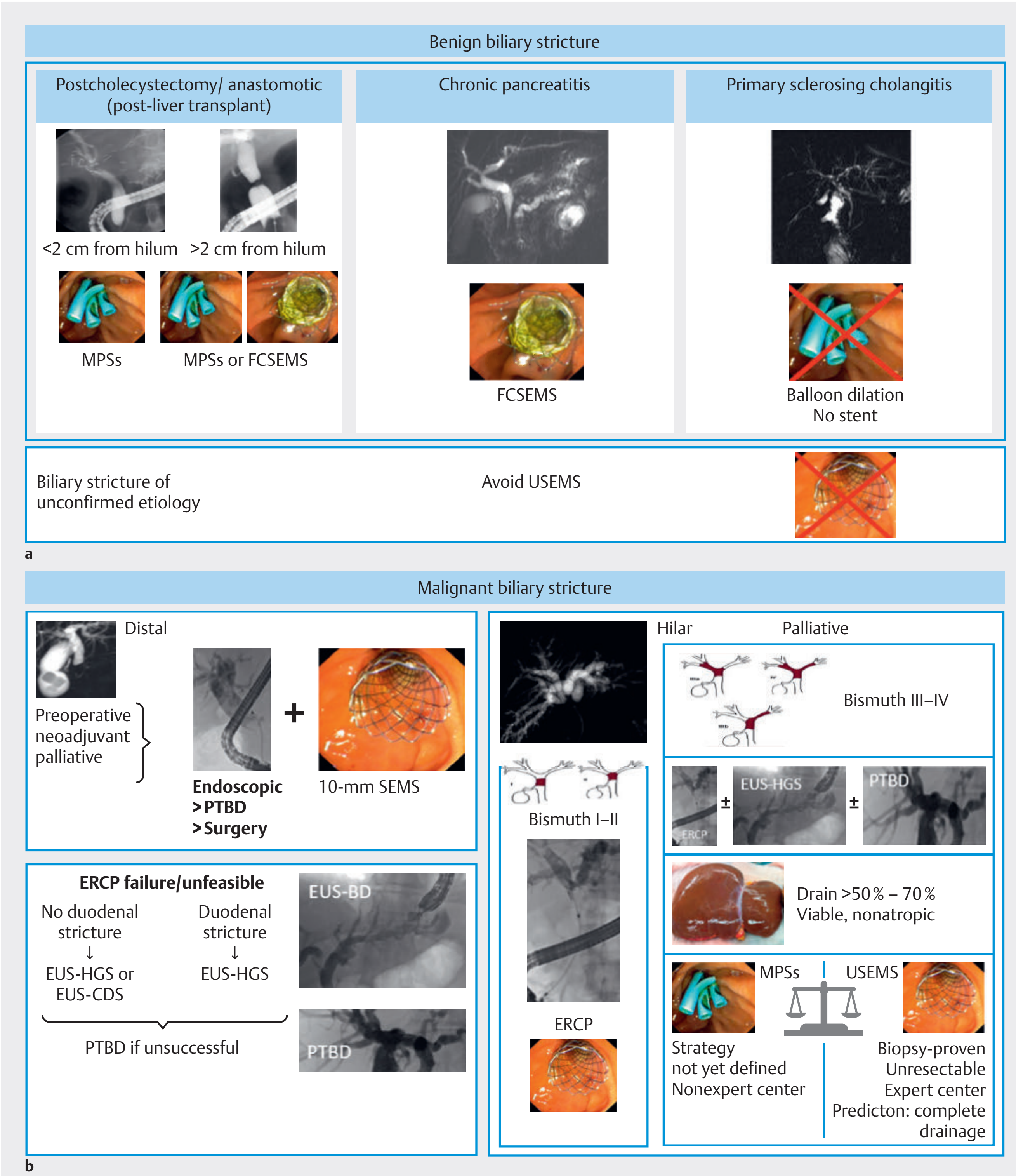
ESGE suggests temporary insertion of multiple plastic stents to treat postcholecystectomy benign biliary strictures.

An FCSEMS can be considered in these patients when the stricture is located >2 cm distally from the main hepatic confluence or for patients who are noncompliant with repeated ERCPs.

Conditional recommendation, very low quality of evidence.

Postcholecystectomy BBSs are rare (<1%) and occur close to the main hepatic confluence in almost half of cases [11], especially in the era of laparoscopic surgery. The choice between MPSs and an FCSEMS depends on the involvement or not of the main hepatic confluence, patient compliance with repeated ERCPs, and evaluation of stricture recurrence rate and AEs during long-term follow-up (**Table 4.2s**).

A recent meta-analysis [12] comparing MPSs and covered SEMSs to manage BBS showed similar results in terms of stricture resolution, AEs, and stricture recurrence. Covered SEMSs had a higher migration rate, but required significantly fewer ERCPs, which can be translated into lower healthcare costs overall. These results do not necessarily apply to postcholecystectomy BBSs owing to the paucity of available data and the particular anatomy of postcholecystectomy BBS, involving the hilum in almost half of the cases [11]. In fact, only one RCT



▶ **Fig. 1** An illustration of the new main recommendations for: **a** benign biliary strictures; **b** malignant biliary strictures.
ERCP, endoscopic retrograde cholangiopancreatography; EUS-CDS, EUS-guided choledochoduodenostomy; EUS-HGS, EUS-guided hepatico-gastrostomy; FCSEMS, fully covered metal stent; MPSs, multiple plastic stents; PTBD, percutaneous transhepatic biliary drainage; SEMS, self-expandable metal stent; USEMS, uncovered SEMS.

[13], which included 31 patients, has compared MPSs and partially covered SEMSs (PCSEMSs) to dilate BBSs, which were mostly secondary to cholecystectomy. Based on magnetic resonance cholangiopancreatography (MRCP) findings, the long-term (5-year) biliary patency rate was higher for PCSEMSs compared with MPSs (81.7% vs. 71.9%; $P = 0.02$), but AEs were numerically more frequent with SEMSs (40% vs. 25%; $P = 0.37$). However, this study raised several concerns owing to the small number of patients enrolled, lack of detail in the study protocol, and the infrequent use of PCSEMSs, raising concerns about stent removability. A large retrospective series [11], which included 154 patients with postcholecystectomy BBS treated with MPSs, described a low stricture recurrence rate (9.4%) after a mean follow-up of 11 years from stent removal. Unscheduled stent exchange due to AEs (e.g. cholangitis, jaundice, pain) was necessary in 7.4% of the MPS patients and one patient had ileal perforation due to stent migration and required urgent surgery.

One small prospective multicenter series [14] enrolled 18 patients with postcholecystectomy BBS located >2 cm from the main hepatic confluence who were treated with an FCSEMS; the stent indwelling period was 10–12 months. After a mean follow-up of 5 years from stent removal, only 61% of the patients had not required further treatments. The FCSEMS migration rate was 16.7%, and the AE rate (e.g. cholangitis, pancreatitis) was 38.9%. Interestingly, endoscopic retreatment was always possible after failure of MPSs or FCSEMSs, not precluding a surgical approach if needed.

MPSs have shown sustained results during long-term follow-up compared with FCSEMSs in the setting of postcholecystectomy BBS. MPSs can be adapted for strictures involving the main hepatic confluence and should be suggested as the first-line treatment for patients with postcholecystectomy BBS.

FCSEMSs can be considered for strictures located >2 cm from the hepatic hilum, especially in patients who are noncompliant with repeated ERCPs (**Fig. 1s**)

Given the lack of comparative studies and systematic reviews and meta-analyses in this field, the task force issued a conditional recommendation with very low quality of evidence in favor of the temporary insertion of MPSs compared with an FCSEMS, which is mainly based on expert consensus extrapolated from indirect evidence.

3.1.2 Benign biliary stricture after liver transplantation: anastomotic stricture

RECOMMENDATION

ESGE suggests treating anastomotic biliary strictures following liver transplantation with either MPSs or temporary insertion of an FCSEMS when located >2 cm distally from the main hepatic confluence.
Conditional recommendation, low quality of evidence.

Biliary strictures after orthotopic liver transplantation are reported with an overall incidence of 4%–20% and are divided into anastomotic biliary strictures (ABSs) and nonanastomotic biliary strictures (NBSs), with ABSs occurring more frequently than NBSs [15, 16].

Two treatment options are available to obtain permanent dilation of ABSs with endoscopic drainage:

a) temporary insertion (usually 6-month indwelling period) of an FCSEMS, via transpapillary or intraductal route, is associated with fewer interventions and lower overall cost
b) insertion, every 3–4 months, of an increasing number of plastic stents, for 1 year (MPSs), is associated with improved long-term results (**Table 4.3s**)

The main advantage of FCSEMSs over MPSs is the need for two ERCPs to obtain ABS resolution with MPSs. Fewer ERCPs is associated with reduced overall cost and improved patient compliance. According to recent meta-analyses [17, 18], FCSEMSs offer similar ABS resolution and AE rates to MPSs. The diameter of an FCSEMS is commonly 10 mm (8 mm can be considered according to the patient's anatomy) and the stent is usually left in place for 6 months. The main issue with FCSEMSs is the risk of migration (proximal or distal partial/complete), resulting in an increased incidence of ABS recurrence compared with MPSs during a follow-up of 1–2 years. Three studies reported a mean 5-year follow-up [19, 20, 21]: one RCT [19] using transpapillary FCSEMSs showed 36% ABS recurrence compared with 7% with MPSs; another single-arm, prospective, multicenter study [20] reported a 51% recurrence rate using transpapillary FCSEMSs; the third study, which was comparative but retrospective, had a similar ABS recurrence rate for FCSEMSs and MPSs (33.3% vs. 28.6%, respectively) after a 5-year mean follow-up – notably, the authors used an intraductal FCSEMS with antimigration properties [21].

FCSEMSs with antimigration flaps were developed to improve ABS dilation. Two retrospective studies [22, 23] have compared transpapillary FCSEMSs and antimigration FCSEMSs: one study [23] had a significantly higher ABS resolution rate and fewer recurrences with antimigration FCSEMSs, while the other [22] reported similar results, but also included patients with refractory ABSs.

Although it is more expensive and associated with a longer treatment period, treatment with MPSs is very effective, considering their low ABS recurrence rate (3%–6%) during a follow-up of longer than 5 years [24, 25].

FCSEMS treatment for ABSs is well standardized: once the stent is correctly deployed, it reaches the maximum diameter in almost all cases, as long as migration does not occur.

MPS placement is technically demanding and ABS dilation depends on operator experience in inserting the maximum number of plastic stents at each ERCP. The complexity of MPSs is also related to the need to remove and replace plastic stents at each treatment. A recent study [25] proposed a simplified MPS protocol: plastic stents were added at each ERCP, without their removal, and this protocol was compared retrospectively with conventional stent exchange. ABS resolution, ABS recurrence, and AEs were similar, without an increase in infective complications (e.g. cholangitis) during treatment. The sequential stent addition MPS protocol significantly reduced procedure time, fluoroscopy time, and costs (fewer devices were needed for each procedure), maintaining excellent long-term results [26].

MPSs with the stent addition protocol represents a valuable alternative stenting technique, especially when intraductal FCSEMSs or antimigration FCSEMSs are not available.

Endoscopic sphincterotomy is needed to apply the MPS protocol, to place and remove an intraductal FCSEMS, and to reduce the risk of pancreatitis related to transpapillary FCSEMS insertion [27, 28]. In the specific setting of living donor transplantation, biliary stricture has been reported in up to 40% of cases, with lower success rates in treating strictures by an endoscopic approach depending on the angulation of the stricture [29].

In summary, a recent meta-analysis demonstrated that FCSEMS placement is associated with similar ABS resolution and AEs to MPSs. Patient and societal advantages of using FCSEMSs include a reduced number of ERCPs and overall costs. Anatomical constraints (>2 cm from the hilum) and the risk of migration of FCSEMSs keep MPSs as a valid option.

The task force downgraded the quality of evidence to low owing to the high risk of inconsistency and imprecision (**Table 5.1s**). Therefore, the task force agreed on a conditional recommendation supporting either the use of MPSs or temporary insertion of an FCSEMS in post-liver transplantation anastomotic strictures.

3.1.3 Benign biliary stricture after liver transplantation: nonanastomotic stricture

RECOMMENDATION
ESGE suggests managing nonanastomotic biliary strictures amenable to endoscopic treatment following liver transplantation with temporary insertion of MPSs together with balloon dilation if needed.
Conditional recommendation, very low quality of evidence.

Seven risk factors for nonanastomotic biliary stricture (NBS) development after liver transplantation were identified in a recent meta-analysis [30], including deceased cardiac death donor; primary sclerosing cholangitis (PSC) as an indication for orthotopic liver transplantation; Roux-en-Y bile duct reconstruction; hepatic artery thrombosis; longer cold and warm ischemia time; and total operative times. NBS develops secondary to ischemic cholangiopathy, involving the bile ducts within the graft, while the biliary anastomosis is not usually stenotic, resulting in a complex and chronic disease with limited possibilities for definitive treatment, leaving redo liver transplantation as the only therapeutic possibility in many cases.

Biliary cast syndrome can be associated with NBS, representing the evolution of the disease, as shown from cholangiographic evaluations [31].

Four types of ischemic cholangiopathy have been described [32]: the "confluence dominant type," involving the hilum, can be successfully managed with MPSs; the "minor form," which rarely needs stent insertion and redo liver transplantation; and the "diffuse necrosis" and "multifocal progressive" patterns, which are largely stent dependent, and in which redo liver transplantation is almost universally required. An NBS amenable to endoscopic treatment commonly extends to the hilum and segmental/subsegmental intrahepatic bile ducts.

ERCP can be used to treat NBS by extraction of biliary casts, balloon dilation, and stenting of hilar/intrahepatic strictures, prolonging graft function and reducing the need for redo liver transplantation in some cases. Drainage in those with NBS is challenging, requiring selective cannulation of the intrahepatic radicles, balloon dilation of the strictures (commonly up to 4–6 mm), and insertion of MPSs to achieve dilation and complete drainage of the intrahepatic ducts to reduce the risk of cholangitis. Stent exchange is planned every 3–4 months over 1 year, but a recent paper [15] proposed continuing the dilation treatment until stricture resolution without an established timeframe. This strategy reflects the nature of NBS, which can evolve and recur over time. Endoscopic management of NBS can be considered a "bridge to redo liver transplantation," especially when the stricture did not respond to dilation with MPSs [33].

No studies have compared the results of using ERCP with dilation and/or stenting to drain and dilate NBSs versus no ERCP (**Table 4.4s**). One prospective [32] and five retrospective studies [15, 31, 33, 34, 35], which included a total of 162 patients, evaluated endoscopic stenting of NBS with MPSs or a single plastic stent; balloon dilation of the strictures was performed before stenting, if needed. The NBS resolution rate was between 41% and 60% in the retrospective studies, whereas the long-term (1–8 years) success rates dropped to 21%. Cholangitis during the stent program was the most common AE, reported in up to 74% of cases [35].

Given the lack of comparative studies and systematic reviews and meta-analyses in this field, the task force issued a conditional recommendation with very low quality of evidence in favor of the temporary insertion of MPSs together with balloon dilation if needed.

3.1.4 Benign biliary stricture secondary to chronic pancreatitis

RECOMMENDATION
ESGE suggests treating biliary strictures secondary to chronic pancreatitis with temporary insertion (6–12 months) of an FCSEMS.
Conditional recommendation, low quality of evidence.

BBSs due to chronic pancreatitis generally arise from chronic inflammation and fibrosis in the pancreas, leading to external compression or fibrotic stricture formation within the bile duct [36]. The biliary stricture involves the distal intrapancreatic bile duct, resulting in a longer stenosis compared with postoperative BBSs. These anatomical considerations explain the 60%–70% stricture resolution rate after endotherapy on long-term follow-up [37].

Key indications for intervention include jaundice, cholangitis (to prevent progression to sepsis), and prolonged cholestasis (elevated alkaline phosphatase for over a month), to prevent the development of secondary biliary cirrhosis [38]. Endoscopic therapy is the preferred initial intervention for most patients, with surgery reserved for those cases where endotherapy fails [39, 40].

The following treatment options have been evaluated in studies.

- **ERCP with MPSs:** Starting with one or two 10-Fr plastic stents, stents are exchanged every 3–4 months, with gradual dilation and placement of MPSs over a 12-month period – the goal being to achieve maximal dilation of the biliary stricture [38] – with reported success rates for stricture resolution ranging from 60% to 92% [38, 41] and a reported up to 17% rate of recurrence, often necessitating further intervention [36]. The main disadvantages of MPSs are the need for multiple ERCP sessions, the risk of stent occlusion, and patient noncompliance with repeated procedures.
- **ERCP with an FCSEMS:** An FCSEMS is placed across the stricture during ERCP and is generally left in place for 6–12 months before its removal [37]. An FCSEMS can achieve similar or superior dilation compared with MPSs owing to its larger caliber, corresponding to the diameter achieved with six or more plastic stents [41]. Studies have shown FCSEMSs to be comparable to MPSs in terms of stricture resolution (90%–92%) [37, 38, 42]. Additionally, the use of an FCSEMS is associated with fewer ERCP sessions, reducing the need for frequent procedures [39, 40].

The major concerns with FCSEMSs include stent migration (reported in 7%–25% of cases), which can be resolved with antimigration mechanisms like anchoring flaps, and rare cases of cholecystitis [40, 42]; however, overall complications such as cholangitis or pancreatitis appear comparable to MPS placement [40]. An important consideration is the careful positioning of the FCSEMS to avoid obstruction of the cystic duct [36, 40].

FCSEMS indwell time is an open issue in chronic pancreatitis-related BBS. Some authors proposed a longer (10–12 months) stenting period to consolidate the dilation [43, 44]. The risk of hyperplastic tissue ingrowth/overgrowth and FCSEMS embedding is rare (near 3%–4%) but, when present, complex procedures like the "SEMS-in-SEMS" technique are needed [45]. A 6-month FCSEMS indwell time seems safer [38, 42, 46]; however, no direct comparisons between 6 months or 10–12 months of FCSEMS indwell have been conducted.

Comparative outcomes (Table 4.5 s) In a recent RCT by Ramchandani et al. [44], involving 164 patients with chronic pancreatitis-related strictures, 84 patients received MPSs while 80 received a single FCSEMS over a 12-month period. After 2 years of follow-up, stricture resolution rates were similar between the two groups: 75.8% in the FCSEMS arm and 77.1% in the MPSs arm. However, the FCSEMS group required significantly fewer ERCP procedures on average to achieve stricture resolution (2.6 vs. 3.9; $P<0.001$), suggesting a potential reduction in procedural burden for patients treated with an FCSEMS.

Another RCT by Haapamäki et al. [38] reported comparable 2-year stricture-free success rates of 90% in the MPSs group and 92% in the FCSEMS group after 6 months of stenting, with no significant difference between the groups ($P=0.41$). This suggests that both approaches offer similar long-term outcomes, with FCSEMSs providing a more streamlined treatment option for some patients.

Additionally, a third RCT by Coté et al. [46] included 112 patients with BBSs, of whom 35 had chronic pancreatitis. Patients were randomized to receive either MPSs (replaced every 3 months) or a single FCSEMS for 6 months. This study also demonstrated noninferior stricture resolution rates for FCSEMSs (92.6%) compared with MPSs (85.4%), with FCSEMSs requiring fewer ERCP procedures ($P<0.001$). A 12-month follow-up confirmed the durability of these outcomes.

No significant differences were observed in these studies in terms of stricture recurrence, migration, or moderate-to-severe AEs between the two groups.

Concerning long-term outcomes, a single-arm prospective study [37] reported a 5-year follow-up after FCSEMS removal in 118 patients with chronic pancreatitis-related biliary strictures: 61.6% of the patients remained stent free, increasing to 77.4% in those patients who had had initial stricture resolution.

A recent meta-analysis based on these three RCTs concluded there were no differences between FCSEMSs and MPSs in rates of stricture resolution (odds ratio [OR] 0.59, 95%CI 0.19 to 1.81; $I^2=50.6\%$), time to stricture resolution (MPSs vs. FCSEMS: median [interquartile range] 199.5 [95] days vs. 184 [38] days; $P=0.15$), procedural time (mean difference 8.26, 95%CI −6.24 to 22.76; $I^2=83\%$), AEs (OR 0.67, 95%CI 0.35 to 1.30; $I^2=0\%$), or mortality. MPS use was associated with more ERCPs (mean difference 1.42, 95%CI 1.50 to 1.70; $P<0.01$), and a higher number of stents were used (7.0 vs. 4.4 vs. 1.3; $P<0.001$) [47].

Summary With similar efficacy and safety, FCSEMSs for treating BBSs related to chronic pancreatitis have the advantage of requiring fewer ERCPs than MPSs.

The task force downgraded the quality of evidence owing to the high risk of inconsistency and imprecision (**Table 5.2s**). Therefore, a conditional recommendation supporting the temporary insertion (6–12 months) of an FCSEMS was issued.

3.1.5 Benign biliary stricture secondary to primary sclerosing cholangitis

RECOMMENDATION

ESGE suggests using balloon dilation alone for high grade biliary strictures secondary to primary sclerosing cholangitis. There is no added benefit of stenting following balloon dilation, and stenting may increase the risk of adverse events (mainly cholangitis).

Conditional recommendation, low quality of evidence.

PSC is a chronic cholestatic liver disease characterized by inflammation and fibrosis with subsequent development of multiple biliary strictures and dilatations. Patients with more advanced disease can benefit from endotherapy for the management of "dominant" or "high grade" strictures [48]. The new definition of a high grade stricture diagnosed during MRCP is a stricture causing 75% reduction in the duct diameter in the CBD or hepatic ducts. High grade biliary strictures in PSC are also associated with an increased risk of cholangiocarcinoma, requiring brush cytology or biopsy during ERCP, with or without cholangioscopy. High grade biliary strictures in the setting of PSC are amenable to endoscopic dilation after evaluation of the biliary anatomy with MRCP. ERCP can obtain relief of jaundice/cholestasis in PSC via stricture dilation with balloons (**Table 4.6s**). When placed in selected rare cases, stents in the setting of PSC should be removed within 1–2 weeks to avoid infectious complications.

IgG4-related cholangitis is a separate rare disorder mimicking PSC and cholangiocarcinoma. The diagnosis relies on the HISORt criteria (histology, imaging [MRCP], serology [serum IgG4 levels], organ involvement [associated autoimmune pancreatitis, sialadenitis], and response to steroid treatment). When there is clinical suspicion, immunosuppressive therapy is the key to management, confirming the diagnosis when a response occurs. Endoscopic biliary drainage is reserved for septic cholangitis or long-lasting fibrotic phenotype strictures, preferably using just balloon dilation, with short-course stenting only in cases that are refractory to endoscopic balloon dilation (EBD) [48].

Therapeutic options evaluated in PSC The following are the possible therapeutic options available.

- **ERCP with balloon dilation** Gotthardt et al. [49] conducted a long-term study evaluating the outcomes of repeated EBD in 96 PSC patients with high grade strictures. Over a 20-year period, patients underwent repeated dilations. There was an 81% transplant-free survival rate at 5 years and transplant-free survival was 52% at 10 years. This study demonstrates that EBD of high grade strictures can effectively preserve liver function in PSC patients over extended periods. According to a meta-analysis of 10 studies, which included 456 patients and assessed outcomes of EBD alone vs. EBD and stenting [50], EBD has a clinical success rate of 86.5% compared with 70.8% with stenting (P<0.001) and a technical success rate of 96.8%. The recurrence-free rate varies, but generally ranges from 9–12 months, which may necessitate repeated dilations in patients with progressive disease. A multicenter RCT found no significant difference in recurrence rates between short-term stenting and EBD for high grade strictures in PSC [51].
- **ERCP with plastic stenting** A study by van Milligen de Witt et al. [52] reviewed the effects of endoscopic stent therapy in 25 PSC patients with high grade strictures. Technical success was achieved in 84% of cases, and 57% of patients maintained stable liver function, without symptoms, at a mean follow-up of 29 months post-stent removal. Additionally, 19% of patients who relapsed responded to further endoscopic therapy, while early complications were reported in 14% of patients. This study concluded that endoscopic stent therapy is safe and effective, particularly for managing acute disease exacerbations due to extrahepatic strictures in PSC.
- **ERCP with FCSEMSs** In terms of refractory, high grade strictures, a retrospective study by Sbeit et al. [53] evaluated the use of FCSEMSs in patients unresponsive to EBD or plastic stents. In this study of 20 PSC patients with resistant strictures, FCSEMSs were placed for 3 months. At 1 month, 80% of patients showed improvement in weakness and 35% in pruritus, with similar improvements noted at 6 months post-stent removal. Cholangiographic resolution of the high grade stricture was achieved in 65% of patients after stent removal, although 30% experienced recurrence within 12 months. The study concluded that temporary placement of an FCSEMS is a feasible, safe, and effective option for managing refractory PSC-related strictures.

Comparative outcomes Ponsioen et al. [51] conducted a multicenter, open-label, randomized trial comparing EBD versus short-term stenting in PSC patients with high grade strictures. Among 65 randomized patients, the cumulative recurrence-free rate of the primary high grade strictures was equal in both groups. The overall median recurrence-free rate and initial failure rate were equal in both groups (EBD 52% vs. stenting 44%; P = 0.89); however, procedure-related severe AEs were significantly higher in the stent group (6.7% vs. 45.4%; P = 0.01).

A retrospective study by Kaya et al. [54] compared the outcomes of EBD alone with EBD followed by stenting in 71 PSC patients with high grade strictures. While cholestasis improvement was similar in the two groups, stenting was linked to a higher complication rate (30% vs. 6%; P = 0.001) and incidence of acute cholangitis (P = 0.004)

In a retrospective study by Han et al. [55], 169 PSC patients with high grade strictures were treated either with EBD and stenting (115 patients) or EBD alone (54 patients). After 1 year of follow-up, transplant-free survival rates were similar between the two groups; however, patients who received both stenting and dilation had more advanced PSC and experienced a significantly higher rate of complications compared with the EBD-alone group (33% vs. 21.8%).

Two meta-analyses [50, 56] compared the results of EBD vs. EBD plus stenting in PSC high grade strictures. In the first one, nine studies were included (one RCT, four prospective, four retrospective studies), with a total of 458 patients. EBD alone was found to be superior to dilation plus stenting in terms of technical (96.8% vs. 91.9%) and clinical (86.5% vs. 70.8%) success, with a lower AE rate (11.2% vs. 26.9%), including cholangitis. In the second meta-analysis, seven studies were included (one RCT and six retrospective studies), totaling 660 patients. The clinical efficacy was similar for EBD and stenting (85% vs. 84.9%), with fewer interventions needed in the EBD group (2.7 vs. 6.5; P < 0.001) and there being fewer AEs (15% vs. 44%), particularly cholangitis (3.2% vs. 16.8%).

In conclusion Recent data from an RCT [51] and two meta-analyses [50, 56] support the role of EBD alone in obtaining better clinical success with a reduction of infectious complications in the management of PSC patients with high grade strictures. When stenting is needed in patients with PSC, plastic stents are preferred, with their early removal within 1–2 weeks, to avoid cholangitis secondary to stent occlusion from debris. The role of FCSEMSs in PSC is still under evaluation, but they might be an option for selected refractory cases [53].

The task force issued a conditional recommendation with a low quality of evidence because of the high risk of indirectness and imprecision (**Table 5.3s**).

3.2 Malignant biliary strictures

RECOMMENDATION

ESGE suggests avoiding the insertion of uncovered SEMSs for the drainage of extrahepatic biliary obstruction of unconfirmed etiology.
Conditional recommendation, low quality of evidence.

In large series, 5%–10% of patients undergoing surgery for pancreatic cancer prove to have benign disease at surgery [57]. Uncovered SEMSs (USEMSs) are difficult or impossible to remove and, if misplaced in indeterminate biliary strictures, may jeopardize the possibility of adequately assessing the etiology of a stricture by magnetic resonance imaging or by EUS owing to artefacts, sampling tissue with an intraductal brush or biopsy forceps, and assessing its cholangioscopic appearance [1]. In patients who subsequently survive long term with a benign condition, the misplacement of a USEMS could be associated with increased numbers of required reinterventions and the associated risks of biliary obstruction.

3.2.1 Distal malignant biliary stricture: preoperative and neoadjuvant biliary drainage

RECOMMENDATION

ESGE suggests offering preoperative biliary drainage (PBD) to patients with extrahepatic malignant biliary obstruction and cholangitis, severe symptomatic jaundice (e.g. intense pruritus), or delayed surgery after 2 weeks, or before neoadjuvant chemotherapy in jaundiced patients.
Routine PBD may be avoidable in patients with extrahepatic malignant biliary obstruction when upfront surgery is planned within 1–2 weeks.
Conditional recommendation, low quality of evidence.

A landmark RCT [58] comparing upfront surgery within 1 week (96 patients) with preoperative biliary drainage (PBD) using plastic stents followed by surgery 4–6 weeks later (106 patients) reported that PBD prior to surgery for pancreatic head carcinoma increased the severe AE rate (74% vs. 39%; relative risk 0.54, 95%CI 0.41 to 0.71; P<0.001), but was not associated with differences in surgical complications between the groups (47% vs. 37%; nonsignificant). Interestingly, in the PBD group, the 46% AE rate included 30% stent dysfunction and 26% cholangitis. This study was limited by the exclusion of patients with bilirubin values exceeding 250 µmol/L (14 mg/dL), the specific design of the surgical timings in the two groups, and the choice of plastic stents, which are now known to be associated with more dysfunction than the recently recommended SEMSs for use in this setting.

Several meta-analyses published before the last ESGE guidelines suggested that PBD did not influence mortality rates, but might worsen morbidity compared with direct surgery. More recent retrospective studies have reported varying postoperative complication rates that either support PBD [59, 60, 61] or favor direct surgery [62, 63]. These differences can be explained by differences in the population characteristics and methods (e.g. percutaneous or endoscopic drainage), and confounding bias (**Table 6.1s**). Taken together, the lower stent dysfunction rates observed in the studies using SEMSs in the preoperative setting and the expanding use of neoadjuvant chemotherapy before surgery argue in favor of more frequently offering patients preoperative biliary drainage using a SEMS.

The evidence supporting this statement was based on a single RCT (**Table 7s**). Therefore, given the impossibility of assessing the risk of inconsistency and indirectness, and the need for further RCTs in this field, the task force issued a conditional recommendation with a low quality of evidence.

RECOMMENDATION

ESGE recommends the endoscopic placement of a 10-mm diameter SEMS for preoperative biliary drainage of extrahepatic malignant biliary obstruction.
Strong recommendation, moderate quality of evidence.

The endoscopic approach to biliary drainage remains preferable over percutaneous management. The preference for an endoscopic approach is based on increased overall survival and a decreased incidence of liver metastasis associated with this approach, as demonstrated recently for distal cholangiocarcinoma [64], and by two meta-analyses for different types of malignancies [65, 66].

Adding the accumulating evidence to the previous ESGE guidelines [2], a recent systematic review and meta-analysis aggregated 12 studies involving 683 patients, comprising two RCTs, one prospective study, and nine retrospective cohorts [67]. Compared with plastic stents, the use of a SEMS was associated with longer stent patency and fewer endoscopic reinterventions, but more post-ERCP AEs (post-ERCP pancreatitis [PEP] 10.7% vs. 4.7%) and a comparable rate of complications after surgery. Of note, mainly PCSEMSs or FCSEMSs were used in this study, involving 8/12 studies offering neoadjuvant therapy to patients, with no data about the use of sphincterotomy before covered SEMS placement, an intervention that is known to increase the risk of PEP. A recent matched prospective trial compared the use of a modified FCSEMS to plastic stents for PBD, demonstrating reduced AE rates (6.9% vs. 27%; P = 0.04) and reduced need for reintervention (0% vs. 20.7%) with the use of the modified FCSEMS [68] (**Table 6.1s**).

The quality of evidence was downgraded to moderate owing to the risk of indirectness (**Table 7s**). Therefore, the task force issued a strong recommendation, with a moderate quality of evidence.

RECOMMENDATION
ESGE recommends the endoscopic placement of a 10-mm diameter SEMS for neoadjuvant biliary drainage of extrahepatic pathologically confirmed malignant biliary obstruction.
Strong recommendation, moderate quality of evidence.

For neoadjuvant biliary drainage, one new RCT reported results that are concordant with the ESGE 2018 statement. The RCT evaluated FCSEMSs against plastic stents in 67 patients and observed less stent dysfunction (18.2% vs. 72.8%; $P=0.02$), fewer reinterventions, and a lower risk of AEs with SEMSs [69] (**Table 6.2s**).

Another RCT in 119 patients, who were randomized to receive an FCSEMS or a USEMS for preoperative biliary drainage in the setting of neoadjuvant therapy, observed similar rates of biliary drainage, reintervention, and AEs [70]. Interestingly, the use of a 4-cm stent was predictive of the need for reintervention, arguing the insertion of a 6-cm SEMS may be preferable.

The quality of evidence was downgraded to moderate owing to the risk of indirectness (**Table 7s**), and a strong recommendation, with moderate quality of evidence, was issued.

3.2.2 Distal malignant biliary stricture: palliative drainage

RECOMMENDATION
ESGE recommends endoscopic over surgical or percutaneous biliary drainage for primary decompression of inoperable, extrahepatic malignant biliary obstruction.
Strong recommendation, moderate quality of evidence.

RECOMMENDATION
ESGE recommends SEMS insertion for palliative drainage of extrahepatic malignant biliary obstruction of confirmed etiology.
Strong recommendation, high quality of evidence.

RECOMMENDATION
ESGE suggests favoring ERCP for primary drainage of distal malignant biliary obstruction, but EUS-guided biliary drainage (EUS-BD) could also be used as an alternative to primary ERCP for palliative biliary drainage in selected patients with distal malignant biliary obstruction, in expert centers.
Conditional recommendation, low quality of evidence.

Type of SEMS for ERCP For palliative drainage, multiple meta-analyses were cited in the ESGE guideline in 2018 that demonstrated the advantages of SEMSs over plastic stents in terms of patient survival, stent dysfunction, and the need for reintervention/cholangitis.

Recently, several prospective and retrospective studies have confirmed these data, with longer stent patency observed with USEMSs compared with plastic stents (**Table 6.3s**).

The theoretical advantage of covered SEMSs is the reduced risk of tumor ingrowth but covered SEMSs also carry higher risks of stent migration, tumor overgrowth, and sludge formation. A recent RCT [71] and previous meta-analyses comparing covered SEMSs (FCSEMS and PCSEMS) and USEMSs in this setting did not report any differences in stent dysfunction, reintervention rates, or survival [2].

Innovative tricks to decrease migration or ingrowth have recently been described.

- A recent RCT showed that, when associated with coaxial double-pigtail stent insertion, FCSEMS migration is reduced from 40% to 15% ($P=0.02$) and stent patency prolonged from 173 days to 237 days ($P=0.048$) [72] (**Table 6.5s**)
- The use of a newly designed multihole SEMS, where multiple small side holes are present in the stent membrane, was associated with less recurrent biliary obstruction (21%), less ingrowth (13%), and less migration (2.6%) compared with USEMSs and FCSEMSs, respectively [73]
- A prospective study on modified FCSEMSs with antimigration features observed a significantly lower risk of stent migration and longer patency compared with conventional FCSEMSs [74].

Interestingly, a recent meta-analysis [75] that specifically compared PCSEMSs to FCSEMSs, including 62 studies (3327 patients treated with FCSEMSs, 2322 with PCSEMSs), reported a significantly longer time to recurrent biliary obstruction with PCSEMSs (369 days, 95%CI 290 to 449 days) than with FCSEMSs (238 days, 95%CI 191 to 268 days) in a subanalysis of a prospective trial of unresectable distal MBO, while the rate of AEs was not different.

The task force decided to keep the first two statements, given the absence of new evidence challenging them in the recent literature. The quality of evidence on type of SEMS was downgraded to low owing to the risk of indirectness and imprecision (**Table 7s**), and the task force issued a conditional recommendation, with low quality of evidence, in favor of using PCSEMSs.

EUS-BD Two meta-analyses of RCTs comparing EUS-BD to ERCP for primary palliative biliary drainage [76, 77] showed that EUS-BD and ERCP had similar rates of technical success, clinical success, safety, and stent patency. The technical success of EUS-BD using lumen-apposing metal stents (LAMSs) was reported to be superior to ERCP in both meta-analyses, mainly due to one of the included RCTs [78], which reported a surprising low (76%) technical success rate in the ERCP group. In one of the meta-analyses, only studies of EUS-BD using SEMSs had lower reintervention rates compared with ERCP, this long-term outcome difference being mainly due to one of the studies where a significant proportion of the included procedures were hepaticogastrostomies [79]. Of note, there was heterogeneity of the type of SEMS (USEMS, PCSEMS, or FCSEMS) used in the ERCP group as comparison. With regard to the similar safety observed with ERCP and EUS-BD, careful examination of the included studies revealed that rectal nonsteroidal anti-inflammatories (NSAIDs) were not delivered in one of the studies [79], which reported a 14.8% rate of PEP, and were delivered to only 57% of the patients treated by ERCP in a second study [80] (**Table 6.4s**).

Potential publication biases have been discussed regarding these data [76], reported mainly by expert centers in therapeutic EUS, with potential under-reporting of bad outcome data using EUS-BD, as revealed by recently published real-life data. Real-world data have reported that 7% of the procedures are associated with technical failures (risk factors being CBD diameter ≤15 mm and low operator experience [≤10 LAMS placements]), with a mortality rate as high as 12% at 30 days [81]. For EUS-BD, LAMS misdeployment was recently studied in a cohort of 152 patients where, on multivariate analysis, CBD diameter ≤15 mm was associated with increased odds of misdeployment and technical failure [82]. Recent evidence is clear about the bad outcomes associated with EUS-BD using choledochoduodenostomy (EUS-CDS) in patients with duodenal stricture [83], due to increased risk of food impaction, and about the high long-term dysfunction rate of EUS-BD using LAMSs if no FCSEMS or coaxial double-pigtail plastic stent (DPPT) is inserted through the LAMS [84, 85, 86, 87, 88], with a reported 10% pooled rate of dysfunction and 12% reintervention rate in a large meta-analysis [89]. Of note, a recent study from a high volume expert center demonstrated that the need for EUS-BD using a LAMS for primary biliary drainage of distal MBO is present in only a minority of cases (6.6%) [90].

Taken together, recent data suggest that, in expert hands, EUS-BD as a primary biliary drainage method might be an alternative to ERCP with SEMS placement for palliative drainage of distal MBO when the CBD diameter is ≥12 mm, but more unbiased quality data are needed to eventually generalize and change a paradigm based on massive worldwide experience with ERCP in this setting.

The task force downgraded the quality of evidence owing to the moderate risk of bias in the literature and the high risk of indirectness (**Table 7s**). Therefore, the task force issued a conditional recommendation, with a low quality of evidence.

3.2.3 Hilar/intrahepatic malignant biliary stricture: preoperative drainage

RECOMMENDATION

ESGE recommends performing drainage of malignant hilar strictures in high volume centers with a hepatobiliary multidisciplinary team.

Strong recommendation, moderate quality evidence.

RECOMMENDATION

ESGE suggests against routine preoperative biliary drainage in patients with malignant hilar obstruction. Indications and routes of drainage must be determined following a multidisciplinary team discussion based on patient characteristics and institutional experience.

Conditional recommendation, low quality evidence.

RECOMMENDATION

ESGE recommends ERCP over percutaneous transhepatic biliary drainage (PTBD) for preoperative biliary drainage in hilar malignant obstruction.

Strong recommendation, moderate quality of evidence.

As stated in the previous ESGE guidelines [2], assessment and drainage of malignant hilar biliary strictures should be performed in high volume centers with a dedicated multidisciplinary team, to ensure better outcomes. The indication for drainage should be discussed, based on resectability and the clinical situation of the patient, and various therapeutic modalities considered (e.g. portal embolization and extension of required surgery) [91, 92].

For patients with resectable disease and an indication for biliary drainage (e.g. severe jaundice, cholangitis, predicted future liver remnant volume of ≤ 30 % following surgery), both ERCP and PTBD are available modalities. A recent RCT including 54 patients with potentially resectable perihilar cholangiocarcinoma and biliary obstruction of the future liver remnant compared endoscopic biliary drainage with ERCP (n = 27) to PTBD (n = 27). The study reported comparable severe preoperative drainage-related AEs (67% vs. 63%), but a higher overall mortality rate in the PTBD group (41% vs. 11%), leading to a premature termination of the study [93]. Seeding, with potential metastasis found at the laparotomy scar can be a concern for both routes, but appears to be higher for PTBD [94]. A recent meta-analysis focused on the rate of implantation metastases, including 10 studies and 1085 patients who had undergone endoscopic or percutaneous drainage for MBO, confirmed that PTBD was related to a higher risk of implantation metastases (OR 0.35, 95%CI 0.23 to 0.53; P<0.001) [65] (**Table 6.6s**).

The task force decided to keep the two first statements in light of the absence of new evidence challenging their validity in the recent literature.

The quality of evidence informing the comparison between ERCP and PTBD was downgraded to moderate because the risk of inconsistency could not be assessed (evidence based on a single RCT) (**Table 8s**).

3.2.4 Hilar/intrahepatic malignant biliary stricture: palliative drainage

RECOMMENDATION

ESGE suggests palliative drainage of malignant hilar strictures by means of ERCP for Bismuth types I–II. For Bismuth III–IV, ERCP or a combination of ERCP with EUS-BD is preferable over primary PTBD. Complementary drainage using PTBD might be required in some cases.

Conditional recommendation, very low quality of evidence.

The goals of obtaining qualitative palliative drainage for hilar MBO are to solve obstructive symptoms and prevent or treat cholangitis, to ensure access to oncological treatment and reduce the need for revision and readmission as much as possible. The difficulty of hilar strictures relates to their anatomical complexity and the need to adequately drain dilated biliary ducts from nonatrophic liver segments [95]. The previous version of the ESGE biliary stenting guidelines published in 2018 proposed ERCP for Bismuth I and II, and PTBD or combining ERCP and PTBD for Bismuth III–IV, following local expertise. Recent data associated with the development of EUS-guided hepaticogastrostomy (EUS-HGS) and procedure-related mortality associated with PTBD challenge the statement from 2018.

ERCP vs. PTBD A recently published meta-analysis comparing ERCP and PTBD for the drainage of hilar malignant stricture, mixing preoperative and palliative settings, showed superior therapeutic success in the PTBD group (OR 3.5, 95%CI 2.1 to 6.0), with higher cholangitis (OR 1.7, 95%CI 0.9 to 3.1) and reintervention rates (OR 11.5, 95%CI 3.5 to 37.7) in the ERCP group [96]. The main limits of this study were that only one of the 11 studies included in the meta-analysis was an RCT, all the other studies were retrospective. A majority of the lesion types included were Bismuth III–IV (74% of the cohort), with only 30% of the cohort having been treated with bilateral drainage (only 23% bilateral drainage in the ERCP group for 68% of Bismuth III–IV in the ERCP group).

Among the studies included in the meta-analysis, the only study published after 2017, the end date of the literature search for the previous ESGE guideline on biliary stenting, is an RCT from Coelen et al. [93]. Although designed in a preoperative setting, this RCT compared PTBD to ERCP for hilar malignant biliary drainage and was closed prematurely owing to higher mortality in the PTBD group (41% vs. 11%; RR 3.7, 95% CI 1.2 to 11.7; $P = 0 \cdot 03$), with a trend toward a higher cholangitis rate in the PTBD group (59% vs. 37%; $P > 0.05$).

More recent data, from a bicenter retrospective study reported by Lubbe et al. [97] on palliative hilar biliary drainage by ERCP (153 patients) and PTBD (140 patients), reported similar rates of technical (98% vs. 99%; $P = 0.8$) and therapeutic success (81.7 vs. 73%; $P = 0.2$). ERCP had more sustained drainage success compared with PTBD, with a 3-month gain in the duration of therapeutic success after ERCP drainage (95%CI 26 to 160 days; $P = 0.006$). AE analysis demonstrated equivalent cholangitis rates (21% vs. 24%), more pancreatitis in the ERCP group (9.4% vs. 0%), and increased procedure-related death in the PTBD group (6.0% vs. 15.8%; $P < 0.001$) (**Table 6.7s**).

EUS-HGS Recent developments in EUS-BD have been applied to palliative treatment of hilar MBO, using mainly EUS-HGS, sometimes using the bridging technique when left-to-right SEMSs are implanted, or with complementary hepaticoduodenostomy to drain the right segments. Hepaticogastrostomy is generally performed using the placement of dedicated partially covered stents to avoid bile leakage and stent migration.

Specific data on the use of these techniques for malignant hilar stricture drainage have been reported in a review by Nakai et al., reporting on 88 cases, with a technical success rate of 98%, high clinical success (75%), and a low rate of AEs (8%) [98].

Further retrospective studies have reported experience with using EUS-HGS for hilar malignant biliary drainage in 20, 34, and 41 cases, with high rates of technical success (91%–100%), clinical success ranging from 65% to 100%, and AE rates of 13%–35%, depending on definitions [99, 100, 101]. In the study by Schoch et al., clinical success and access to chemotherapy after EUS-HGS were both associated with improved survival [100] (**Table 6.7s**).

EUS-HGS vs. PTBD In a propensity score-matched analysis comparing EUS-HGS to PTBD, Koutlas et al. demonstrated a better clinical success rate (100% vs. 75%) and a better safety profile (AEs 13% vs. 58%), with fewer reinterventions, shorter hospital stay, and shorter procedure times with EUS-HGS compared with PTBD [101] (**Table 6.7s**).

Conclusion Limitations of the available evidence in palliative hilar MBO drainage concern PTBD, where the majority of evidence of its increased morbidity compared with endoscopic drainage comes from good quality RCTs dedicated to preoperative drainage (and not palliative drainage).

The task force downgraded the quality of evidence to very low owing to the high risk of bias in the literature, imprecision, and publication bias (**Table 8s**). Therefore, a conditional recommendation with very low quality of evidence was issued.

RECOMMENDATION

ESGE suggests obtaining drainage of more than 50%, and ideally 70% or more, of the viable nonatrophic liver volume for palliative drainage of proven malignant Bismuth II–IV strictures, using a multimodal approach (EUS-BD/PTBD if needed, as complementary methods to ERCP).

Conditional recommendation, low quality of evidence.

One RCT assessed the question of whether to drain palliative hilar malignant stricture using unilateral (n = 66) or bilateral SEMS (n = 67) insertion. Although the technical success rates were similar (95.5% vs. 100%), the rates of clinical success (95.3% vs. 84.9%; $P = 0.047$) and primary reintervention (42.6% vs. 60.3%; $P = 0.049$), and the median cumulative stent patency duration (252 days vs. 139 days) were all in favor of bilateral SEMS insertion [102].

Two systematic reviews, mainly based on retrospective series, were published on this topic, both demonstrating a reduction in the need for reintervention and prolonged stent patency with bilateral drainage [103, 104].

A recent large multicenter retrospective study on 236 patients with hilar MBO compared unilateral to bilateral stenting using SEMSs. Although technical success was higher using unilateral stenting 98.8% vs. 82.5%; $P < 0.001$), clinical success was higher in the bilateral SEMS group (85.7% vs. 70.5%; $P = 0.03$), with reduced postprocedure mortality (hazard ratio [HR] 0.36; $P < 0.01$), and prolonged survival (median 828 vs. 202 days; $P < 0.01$) [105].

Of note, unilateral vs. bilateral liver drainage is not applicable to all cases (i. e. post-hepatectomy, massive neoplastic infiltration of one liver lobe, atrophic segments) and caution must be taken not to attempt to intubate atrophic segments as this is associated with an increased post-ERCP cholangitis rate [106]. In 2010, a study demonstrated that clinical success is better when more than 50% of the liver is drained (OR 4.5; $P = 0.001$), with improved survival (119 days vs. 59 days; $P = 0.005$) [106].

More recent studies are challenging the cutoff of 50% of the liver volume as a target for liver drainage. A single-center, retrospective study systematically collected a cohort of 60 patients and demonstrated that patients with ≥80% of the liver drained for palliation of hilar MBO (Bismuth type II 29%, III 34%, IV 37%) had better survival (8.5 months vs. 3.5 months; $P < 0.001$), whatever the technique (ERCP +/− EUS-BD +/− PTBD) used for biliary drainage [107]. A receiver operating characteristic (ROC) curve was used to predict the possibility of administering chemotherapy to the patient, the threshold being 71% of the liver drained (92% vs. 44%; OR 0.06, 95%CI 0.01 to 0.32; $P = 0.008$).

Similarly, another retrospective single-center study demonstrated, in 90 patients with hilar MBO receiving palliative chemotherapy, that draining more than 80% of the liver, assessed by a 3D image volume analyzer, was associated with improved survival (450 days vs. 224 days; $P = 0.003$), but no difference in time to recurrent biliary obstruction (median 201 days, 95%CI 155 to 317 days) [108]. In multivariate analysis, the presence of cholangiocarcinoma (HR 0.3, 95%CI 0.2 to 0.5; $P < 0.001$) and drainage of more than 80% of the liver (HR 0.35, 95%CI 0.2 to 0.6; $P = 0.003$) were both independent predictive factors of survival.

Lastly, a recent retrospective, single-center study on 82 patients with Bismuth II, III, or IV hilar strictures treated with ERCP for palliative drainage assessed the preoperative liver volumetry and ERCP drained segments, with clinical success defined by a 50% decrease in bilirubinemia or normalization within 2 weeks [109]. The study showed a correlation between clinical success and >50% of the liver drained (OR 4.15, 95%CI 1.4 to 12.5; $P = 0.02$) and >2 liver sectors drained (OR 8.5, 95%CI 2.7 to 26.7%; $P < 0.001$), independently of the presence of unilateral or bilateral drainage (**Tables 6.7s** and **8s**).

Practically, preprocedural drainage imaging is required to assess potential segments to drain, excluding the ones that are atrophic or massively infiltrated by the tumor. Classically, clinicians should recognize the main sectors as right anterior (V–VIII), right posterior (VI–VII), and specify whether they are separated by tumor infiltration; left segments II and III and also specify whether they are separated by tumor infiltration. MRCP will provide the relevant information to define the strategy adequately. The percentage of liver drained is obtained by dividing the segments drained by the nonatrophic/non-resected segments in place. Liver volumetry obtained by 3D computed tomography reconstructions prior to drainage has also been described as a valuable tool for response to drainage prediction [108].

The task force downgraded the quality of evidence to low owing to the indirectness in the unilateral vs. bilateral stenting meta-analysis, and owing to the absence of meta-analyses or comparative trials assessing the percentage of liver drained (**Table 8s**). Therefore, a consensus for conditional recommendation, with a low quality of evidence, was issued.

RECOMMENDATION

ESGE suggests using either plastic stents or uncovered SEMSs for palliative drainage of proven malignant hilar obstruction. ESGE suggests a plastic stent when the optimal drainage strategy has not been defined. ESGE suggests using an uncovered SEMS in expert centers to reduce the need for revisional procedures based on the patient's expected survival and the likelihood of achieving complete biliary drainage.

Conditional recommendation, moderate quality of evidence.

Not much new evidence has been published on the use of USEMSs compared with plastic stents for palliative drainage of hilar MBO since the last ESGE biliary stenting guidelines, with the recommendations made then proposed on the basis of three meta-analyses that demonstrated the advantage of USEMSs in terms of stent dysfunction, need for reintervention, and improved survival, compared with plastic stents [2].

Improvements in oncological therapy, with some patients experiencing prolonged survival and/or remissions, have led to the need to address the question of using FCSEMSs for drainage of hilar MBO, with the aim of providing benefit from the long-term patency of SEMSs, while being able to remove them when needed.

A recent RCT compared the use of a 7-Fr plastic stent versus a 6-mm FCSEMS for drainage of 50 patients with non-resectable hilar MBO. Although the migration rate was higher with FCSEMSs (48% vs. 16%; $P = 0.02$), the mean time to recurrent biliary obstruction was higher in the FCSEMS group (190 days vs. 96 days; $P = 0.02$), with a higher reintervention rate in the plastic stent group (40% vs. 16%; $P = 0.04$) and no difference in AEs [110]. Two recent retrospective studies, which included 54 and 22 patients with non-resectable hilar MBO, reported the experience of using a slim (6-mm) FCSEMS for palliative drainage: the median times to recurrent biliary obstruction were 181 days and 113 days, respectively, with 100% reintervention success (stent removal and replacement of new ones) in both series, but with an interesting safety profile (1.8% cholangitis and no liver abscesses in the first series; 3.1% cholecystitis and 6.3% delayed complications [e.g. liver abscess] in the second series) [111, 112]. Up until now, no RCTs have compared USEMSs with FCSEMSs for non-resectable hilar MBO to determine whether replacement of FCSEMSs in long survivors would be a better option.

In light of the massive amount of evidence in favor of the use of USEMSs for drainage of non-resectable hilar MBO, and the need for more safety and comparative data on the use of FCSEMSs in this context, ESGE recommends the use of USEMSs for this indication (**Table 6.7s**).

Despite this evidence, the task force acknowledged that many of these studies analyzed the time to first stent dysfunction and did not fully capture long-term outcomes. Moreover, systematic plastic stent exchange, as is done as the standard of care for benign strictures, was not proposed. Although mostly associated with the insertion of SEMS in SEMS, a technique that precludes easy revision, emerging evidence suggests that, over time, USEMSs may be associated with an increased and earlier need for percutaneous drainage compared with plastic stents [113]. In addition, a USEMS represents a definitive intervention, and suboptimal initial drainage may limit the possibility of further endoscopic optimization. Therefore, the task force emphasized that the choice of stent should be further individualized based on disease stage, expected survival, the likelihood of achieving complete biliary drainage, and the feasibility of future endoscopic interventions.

The task force consensus was therefore in favor of a conditional recommendation, with a moderate quality of evidence.

3.2.5 How to solve stent dysfunction in malignant stricture

When stent dysfunction occurs in a SEMS in a patient with distal MBO, insertion of either an uncovered or covered SEMS appears to be equally effective with regard to stent patency, according to an RCT by Lee et al. [114] and reconfirmed by a more recent retrospective study [115].

With regard to SEMS dysfunction in patients with proximal MBO, the data are conflicting: one retrospective study showed no difference regarding reobstruction, whether plastic or metal stents were placed into the initial SEMS, while another retrospective study reported a significant difference in favor of SEMS insertion [116, 117] (**Table 6.8s**).

EUS-BD with a LAMS is an emerging technique in distal MBO. Various prospective studies have revealed a dysfunction rate ranging from 16% to 55% within 6 months [84, 86, 87]. A recent meta-analysis including 21 studies and 1435 patients reported a dysfunction rate of 10%, requiring a reintervention in 12% of cases [89]. The dysfunction appears to be mitigated by placing an FCSEMS or a coaxial DPPT through the LAMS [85] (**Table 6.9s**).

3.3 Biliary stricture management in surgically altered anatomy or inaccessible papilla

While ERCP is the standard treatment for biliary disorders in normal anatomic conditions, biliary drainage in patients with surgically altered anatomy (summarized in **Fig. 2s**) presents unique challenges [118, 119], driven by both anatomical and technical factors. First, intubating an anastomosis can be difficult owing to altered pathways and adhesions. Second, the length of the afferent jejunal limb significantly impacts intubation success. Third, cannulating an intact papilla from a distal approach is more challenging than accessing a bilioenteric or pancreatoenteric anastomosis. Finally, the absence of an elevator in certain endoscopes and the use of nonspecialized accessory catheters can further hinder cannulation and therapeutic interventions. These factors may warrant the use of other advanced endoscopic techniques that require specialized training and equipment.

ERCP is a high risk procedure [5], with surgically altered anatomy further elevating the risk of complications, which range from 0% to 19.5% in this patient population [120]. Perforation is the most common and potentially fatal AE, followed by bleeding, cholangitis, mucosal tears, and PEP. Perforations can occur at various levels, often due to difficult intubation across sharp angulations or excessive looping. Barotrauma is a unique risk, especially in closed-loop systems, and can lead to severe complications such as intestinal rupture. Detailed information on these AEs can be found in other ESGE Guidelines [5, 120, 121, 122, 123].

The alternative drainage approaches, including enteroscopy-assisted ERCP, therapeutic EUS, and PTBD, are also not without complications.

Taken together, endoscopists performing biliary drainage in patients with surgically altered anatomy must obtain all available details on the anatomy of the patient, and must be familiar with potential AEs. It is recommended that such procedures are performed in units fully equipped to diagnose and manage any complications that may arise, and in centers where all drainage techniques and complication management expertise is available if required.

3.3.1 ERCP in patients with Billroth II anatomy

RECOMMENDATION

ESGE suggests that in cases of Billroth II postsurgical anatomy, ERCP with front- or side-viewing endoscopes can be considered. Depending on local expertise, EUS-assisted or EUS-guided techniques can be undertaken when ERCP is unsuccessful.

Conditional recommendation, moderate quality of evidence.

ERCP in patients with Billroth II gastrectomy has been considered a challenging procedure, related to afferent limb intubation, identification and biliary cannulation, and performance of the sphincterotomy in the inverted papilla. An ERCP has however been considered an acceptable approach for Billroth II for many years [124]. The efficacy and safety of using a duodenoscope or a front-viewing scope with a cap in Billroth II anatomy appear to be equivalent, based on two recent systematic reviews, plus one prospective and two retrospective series [125, 126, 127, 128, 129] (**Tables 9s** and **10s**).

If an ERCP is unsuccessful in patients with a biliary stricture, EUS-assisted or EUS-guided techniques can be undertaken depending on local expertise (e.g. EUS-assisted rendezvous [EUS-RV], EUS-guided antegrade stenting, EUS-guided transmural drainage) [3].

3.3.2 Biliary drainage in patients with previous pancreaticoduodenectomy

RECOMMENDATION

ESGE suggests that, in patients with previous pancreaticoduodenectomy, enteroscopy-assisted ERCP (EA-ERCP), EUS, and PTBD may be considered.

For benign biliary strictures, EA-ERCP should be considered as the first-line option. EUS-BD may be proposed in selected cases, particularly when multiple biliary interventions are expected or if the index EA-ERCP was difficult. PTBD, including percutaneous cholangioscopy, may be considered in specific cases, such as right-sided hepatolithiasis or when other techniques have failed.

For malignant biliary strictures, EA-ERCP or EUS-BD (either antegrade or EUS-guided hepaticogastrostomy [EUS-HGS]/EUS-guided hepaticojejunostomy [EUS-HJS]) is recommended as first-line therapy, according to anatomical constraints and local expertise. PTBD is recommended as the second-line option. EUS-directed transenteric ERCP requires further evaluation.

Conditional recommendation, low quality of evidence.

EA-ERCP has acceptable rates of success and, although inferior to EUS-BD, it has a more favorable AE rate. The evidence supporting the success of EA-ERCP or EUS-BD in patients with a prior Whipple procedure is primarily derived from systematic reviews and meta-analyses, mixing the types of surgically altered anatomy, with only one cohort study examining both EUS-BD and EA-ERCP [130, 131, 132, 133, 134]. No randomized trials have compared the two techniques.

In a comparative cohort reported by Khashab et al. [134], where 15/98 patients had undergone a Whipple procedure, 49 patients were treated with EUS-BD and 49 with EA-ERCP. The clinical success rate for EUS-BD was 88%, compared with 59.1% for EA-ERCP (mostly via double-balloon enteroscopy [DBE]). The AE rate was 20.4% for EUS-BD and 4% for EA-ERCP.

EA-ERCP is been reported in several meta-analyses to have a procedural success rate of 61.7%–75.8% and an AE rate of 6.6% with single-balloon enteroscopy (SBE)-assisted ERCP in surgically altered anatomy [135, 136], although DBE-assisted ERCP has been reported to have a procedural success rate of 93%, with a 4% rate of AEs, in a cohort of 1323 patient with surgically altered anatomy, which included 312 patients who had undergone a Whipple procedure [137]. Better success was reported with short DBE scopes (<200 cm), which allow for the use of standard ERCP accessories, compared with long DBE scopes (>200 cm).

A meta-analysis reported that EUS-BD has a technical success rate of 97.8%, and a clinical success rate of 94.9%, with a 12.8% AE rate in a large (n = 409) cohort of patients with surgically altered anatomy, including 70 cases with previous Whipple surgery [138].

Finally, EUS-directed transenteric ERCP is a technique in which a gastroenteric or entero-enteric anastomosis is created between the proximal gastrointestinal tract and the small-bowel loop containing the ampulla/bilioenteric anastomosis, using a LAMS. This facilitates standard ERCP via the anastomosis and offers the additional benefit of enabling complex treatments such as cholangioscopy-directed lithotripsy for large stones. This procedure has been described in multiple case reports, with the largest series coming from Mutignani et al. [139] (**Table 9s**).

The task force issued a conditional recommendation, with a low quality of evidence owing to the high risk of indirectness and imprecision (**Table 10s**).

3.3.3 Biliary drainage in patients with previous Roux-en-Y gastric bypass

RECOMMENDATION

ESGE suggests that in patients with previous Roux-en-Y gastric bypass (RYGB), EUS-directed transgastric ERCP (EDGE) or EA-ERCP may be considered.

For benign biliary strictures, EDGE is suggested as the first-line approach, unless there is specific expertise in EA-ERCP.

For malignant biliary strictures, EUS-BD (either antegrade stenting or EUS-HGS/EUS-HJS) is often the preferred option, although EDGE, EA-ERCP, and PTBD may also be considered based on anatomical constraints and local expertise.

Conditional recommendation, low quality of evidence.

EUS-directed transgastric ERCP (EDGE) is an advanced endoscopic procedure involving the creation of a temporary EUS-guided anastomosis between the gastric pouch and the excluded stomach, that is subsequently used to perform a standard ERCP. The procedure should only be performed in centers with expertise in advanced EUS techniques. One of the advantages of EDGE is that it retains access to the bile duct for ERCP after the procedure, which can be crucial in the event of complications, such as sphincterotomy bleeding or when further interventions are required (e.g. large-stone lithotripsy, BBS management). However, it typically involves at least two endoscopic procedures (EDGE as the first step, ERCP as the second step, and final LAMS removal). The routine use of a 20-mm LAMS, along with techniques for anchoring the LAMS, has made single-session EDGE possible (i. e. LAMS placement and ERCP in the same procedure). Further procedures will be needed to remove the LAMS at a later time to avoid weight regain.

For EA-ERCP, Roux-en-Y gastric bypass (RYGB) requires the enteroscope to traverse a significantly longer segment of the small bowel, with potentially sharp angulations and adhesions, especially at the entero-enteral anastomosis. If a long double-balloon enteroscope is used, it limits the range of accessories available for cannulation and the completion of endoscopic therapy. DBE is more effective than SBE, and advanced enteroscopic skills are necessary to achieve the same efficacy as EDGE or laparoscopy-assisted ERCP (LA-ERCP), which may limit the availability of EA-ERCP.

In the context of palliative care for malignancy, the priority is to achieve biliary drainage as efficiently as possible, with a focus on obtaining long-lasting stent patency. While EUS-BD remains an option, the postsurgical anatomy may make it difficult to access the left side of the liver from the gastric pouch, which could hinder either EUS-HGS or antegrade stenting via EUS. In such cases, EDGE and PTBD remain viable options, depending on the patient's functional status and local expertise. PTBD remains a viable option in expert centers to treat malignant stricture in a single session with direct SEMS placement.

EA-ERCP in RYGB Three significant systematic reviews and meta-analyses have been published that examined EA-ERCP in RYGB patients [135, 136, 137]. Unfortunately, as all of them included other types of surgically altered anatomy, only one of them [136] specifically broke down success rates for RYGB. The success rate for EA-ERCP was reported to be 61.7%–76.4% with SBE in RYGB, with an AE rate of 6.5%–6.6% [135, 136], and 90%–94% with DBE-ERCP, with an AE rate of 4% [137].

Although infrequently used for biliary stricture management, LA-ERCP has been extensively studied in RYGB, with four systematic reviews and meta-analyses focusing solely on LA-ERCP, with stone extraction as the main indication: reported cannulation success rates were 95.3%–98.5%, whereas AE rates were reported to be up to 20.6%, with a majority of these related to the laparoscopy [140, 141, 142, 143].

Technical comparison was reported in a meta-analysis including LA-ERCP (403 patients), SBE-ERCP (166 patients), and DBE-ERCP (71 patients). Native papilla cannulation rates were 95.7%, 62.2%, and 82.2%, respectively, with AE rates of 18%, 9.9%, and 2%, respectively [144].

EDGE in RYGB There have been two meta-analyses that focused solely on EDGE: Prakash et al. [145] and Su et al. [146] reported on 169 and 585 procedures, respectively, with 94%–98% ERCP success rates and AE rates of 14%–18%, including stent malposition or dislodgement (4%), pain (2%), bleeding (2%), persistent fistula (1%), and perforation (1%). Of note, LAMS dislodgement was lower for the 20-mm LAMS compared with the 15-mm LAMS. Data from two meta-analyses [97, 98] comparing EDGE with EA-ERCP concluded that EDGE had superior efficacy (94.8%–100%) over EA-ERCP (66%–66.3%), and superior safety (AE rate, 9.6%–14.9% vs. 14.7%–16%, respectively), with a faster procedure rate (61 vs. 169 minutes) and shorter length of stay (1.8 vs. 6.9 days).

EUS-BD in RYGB Tanisaka et al. published a meta-analysis on EUS-BD in 409 patients with surgically altered anatomy, primarily for malignant indications [138]. The clinical success rate was 94%, with an AE rate of 12.8%; however, the study showed significant heterogeneity, making it difficult to derive efficacy analysis for RYGB specifically (**Table 9s**).

The task force issued a conditional recommendation, with a low quality of evidence owing to the high risk of indirectness and imprecision (**Table 10s**).

3.3.4 Biliary drainage in patients with previous gastrectomy with a Roux-en-Y jejunojejunal anastomosis

RECOMMENDATION

ESGE suggests that in patients with a partial or total gastrectomy with a Roux-en-Y jejunojejunal anastomosis, EA-ERCP, EUS-BD, and PTBD can be considered.

For benign biliary strictures, EA-ERCP should be considered as the first-line option. EUS-BD may be proposed in selected cases, particularly when multiple biliary interventions are expected. PTBD, including percutaneous cholangioscopy, may be considered in specific indications, such as CBD or intrahepatic stones, or in cases where other techniques have failed.

For malignant biliary strictures, EUS-BD (either antegrade or EUS-HGS/EUS-HJS) or PTBD are suggested as first-line approaches in expert centers.

Conditional recommendation, low quality of evidence.

Most studies evaluating biliary drainage techniques in cases with benign indications and partial or total gastrectomy with a Roux-en-Y jejunojejunal anastomosis have focused on colonoscopy-assisted ERCP or EA-ERCP. The success rate for accessing the papilla using an adult or pediatric colonoscope has been reported to be 68%, with biliary cannulation rates ranging from 72.7% to 85.4% [147, 148]. The use of a cap-assisted scope progression has also proven beneficial [149]. EA-ERCP using SBE or DBE techniques has demonstrated biliary cannulation rates of 78.8%–90.9% and clinical success rates of 78.1%–100% [150, 151, 152, 153, 154, 155, 156]. A meta-analysis of 403 patients with Roux-en-Y gastrectomy reported a biliary cannulation rate of 88.1% and procedural success rate of 76.4% [136], both lower compared with other anatomical configurations [152].

EUS-BD has been primarily assessed in patients with malignant indications [138]. Regarding benign indications, particularly in stone removal, EUS-guided antegrade drainage and EUS-HGS or EUS-HJS [157, 158, 159, 160, 161, 162] have been described in small series [157], showing comparable outcomes to EA-ERCP [151]. Notably, a multicenter study involving 21 patients who underwent EUS-HJS reported a clinical success rate of 80%, with an AE rate of 33% [163].

EUS-directed transenteric ERCP may be another option in highly selected cases; however, outcomes have been less often reported compared with EDGE, and technical variables make this procedure less standardized [164].

PTBD has also demonstrated acceptable outcomes, better than EA-ERCP in these scenarios [165], and comparative representative studies specific to the Roux-en-Y jejunojejunal anastomosis anatomy are lacking compared with EUS-BD [166]. Recently, percutaneous-assisted cholangioscopy has been shown to be particularly useful in cases of hepatolithiasis and large CBD stones, with an AE rate of 19.6% [167, 168, 169], a scenario that might occur above a biliary stricture (**Tables 9s**).

The task force issued a conditional recommendation with low quality of evidence owing to the high risk of indirectness and imprecision (**Table 10s**).

3.3.5 Biliary drainage in patients with previous Roux-en-Y hepaticojejunostomy

RECOMMENDATION

ESGE suggests endoscopic over percutaneous biliary drainage in patients with Roux-en-Y hepaticojejunostomy, owing to its better safety profile.

For benign biliary strictures, EA-ERCP or EUS-BD techniques, such as antegrade drainage or EUS-HGS, are viable options. Additionally, EUS-directed transenteric ERCP may be considered in selected cases, particularly for postsurgical complications of hepaticojejunostomy.

For malignant biliary strictures, EUS-BD, with antegrade drainage or EUS-HGS, is recommended as a first-line approach.

PTBD can be considered as a second-line approach for benign and malignant indications.

Conditional recommendation, low quality of evidence.

Roux-en-Y hepaticojejunostomy is a surgical technique performed for biliary reconstruction. Endoscopic access has similar success, but lower AE rates than PTBD.

EA-ERCP has reported technical success rates of 86%–93% [152, 156, 170], although total procedural success rates were lower, at 60.6%, in a cohort of 221 patients [152].

EUS-guided hepaticoenterostomy [171], with or without transhepatic cholangioscopy [172] and/or antegrade drainage [173], can be considered in benign conditions. Additionally, EUS-directed transenteric ERCP, through an EUS-guided anastomosis made using a LAMS, may be proposed in selected cases [174, 175, 176, 177], particularly for postsurgical complications of hepaticojejunostomy [177].

For malignant conditions, EUS-BD has demonstrated higher technical and clinical success rates compared with EA-ERCP [178]. Techniques such as EUS-guided transmural stenting alone, antegrade stenting, or a combination of these have been successfully used in cases of distal MBO [160].

PTBD has been evaluated in small series [179, 180, 181, 182]. While PTBD achieves similar complete stone removal rates to EA-ERCP, it is associated with higher AE rates in patients with hepatolithiasis [183, 184], and requires more frequent interventions in post-liver transplantation patients [185]. Specifically, percutaneous cholangioscopy [186] has proven feasible and effective, but might be associated with a significantly higher AE rate (45% vs. 10%) compared with EA-ERCP, as reported in a retrospective study of 40 patients [184] (**Table 9s**).

The task force issued a conditional recommendation with low quality of evidence owing to the high risk of indirectness and imprecision (**Table 10s**).

3.3.6 Biliary drainage in patients with inaccessible papilla

RECOMMENDATION

ESGE recommends EUS-BD over PTBD in cases of malignant biliary stricture following failed or unfeasible ERCP.

In patients with distal stricture, ESGE suggests using EUS-HGS where a duodenal stricture is present, and either EUS-HGS or EUS-guided choledochoduodenostomy (EUS-CDS) where there is no duodenal stricture.

ESGE suggests using PTBD when EUS-BD fails or is not feasible.

Strong recommendation, moderate quality of evidence.

PTBD may achieve comparable technical and clinical success rates to EUS-BD; however, it is associated with a higher incidence of AEs.

In patients where ERCP has failed or is not feasible, EUS-BD, including EUS antegrade drainage, EUS-CDS, EUS-HGS, and EUS-guided gallbladder drainage (EUS-GBD), has been described as an effective alternative.

Several meta-analyses have evaluated EUS-CDS and EUS-HGS, reporting comparable technical and clinical success rates [187, 188, 189]. While some studies have reported higher AE rates with EUS-HGS [190, 191], a recent meta-analysis reported an acceptable AE rate of 12% [192]. For EUS-CDS, using either a LAMS [193, 194, 195, 196] or a SEMS [197], the reported AE rate is 9.3% and the reintervention rate is 8.3% [198]. However, duodenal stenosis has been described as a risk factor for long-term obstruction following EUS-CDS [87, 199]. In this context, EUS-CDS has demonstrated higher rates of postprocedural AEs (42.9% vs. 7.7%) and biliary dysfunction (71.4% vs. 16.7%) compared with EUS-HGS [83].

Although much less established than other EUS-BD techniques, EUS-GBD has also been proposed as a rescue therapy when the cystic duct is patent. A multicenter study reported a clinical success rate of 81.3% [200], with results comparable with EUS-CDS in another observational series [201], but data on follow-up of patients with more than 4 months of survival are missing.

PTBD has demonstrated a trend toward higher AEs in a systematic review, with no significant differences in clinical success when compared with EUS-HGS and EUS-CDS [202]. Retrospective studies comparing PTBD and EUS-CDS also reported similar results, with PTBD associated with higher rates of AEs

[203, 204, 205] and reintervention [204]. An RCT comparing PTBD and EUS-HGS further confirmed higher AE and reintervention rates in the PTBD group [206] (**Tables 9s**).

The task force issued a strong recommendation with moderate quality of evidence owing to the risk of publication bias reported in the meta-analyses supporting this statement [183, 184, 185] (**Table 10s**).

3.4 Biliary stricture management after failure: second attempt

ERCP may fail in up to 10%–20% of patients [207], with a limit not exceeding 5% in expert centers proposed by the ESGE performance measures initiative [208], which recommends referring patients to a more experienced colleague or center in cases of failure. Reasons for failure may involve neoplastic infiltration, unnegotiable biliary stenosis, surgically altered anatomy and/or duodenal stenosis, and also difficult cannulation.

In such instances, a repeat attempt at ERCP has been reported to be successful in up to 82% of cases [2], by waiting at least 2 days and optimizing patient sedation, team preparation, availability of ancillary material, and referral to a more expert endoscopist or institution. A general algorithm is proposed in **Fig. 3s**.

3.4.1 Second attempt for benign biliary stricture (accessible papilla)

RECOMMENDATION
ESGE suggests using rendezvous over transmural drainage where ERCP has failed for benign biliary strictures.
Conditional recommendation, low quality of evidence.

As an alternative to repeat ERCP after 2–4 days, as proposed in the last ESGE therapeutic EUS guidelines, the EUS-RV technique has been suggested in cases of ERCP failure for benign stenosis [3]. Knowing the expected long-term survival in such cases, surgical hepaticojejunostomy might be discussed in some situations, but this is associated with long-term complications (e.g. stricture in 9%–15%, cholangitis), and surgical choledochoduodenostomy has also been reported to be associated with long-term complications [209, 210, 211].

As a consequence, the goal of management of benign stenosis after ERCP failure is to allow ERCP management (ERCP repeated by an expert or rendezvous technique) with the aim of preserving the anatomy.

EUS-RV First described by Mallery et al. [212], EUS-RV is a challenging technique with a relatively high rate of failure. Although technical success has been reported to reach 77%–86.1%, with a 14% AE rate, in a meta-analysis [213], a recent retrospective series [166] from two tertiary centers reported a 25% technical failure rate, attenuating the encouraging data from the meta-analysis. Recent prospective and retrospectives series of EUS-RV for benign stricture have reported better results (92% technical success) and fewer AEs for benign strictures [214, 215].

Percutaneous rendezvous The available data come from retrospective series. A French cohort of 84 patients treated using the percutaneous rendezvous technique reported a success rate of 95.2%, but with important morbidity (19.5% [9.5% related specifically to the rendezvous]) and mortality of 3.5% [216]. A German study on 244 patients, including 28.7% with benign strictures and 50.8% with altered anatomy, comparing PTBD to the percutaneous rendezvous technique, demonstrated decreased morbidity in the rendezvous group (16.6% vs. 26.4%), with a technical success rate of 80.4% [217].

Comparative outcomes (EUS-RV vs. percutaneous rendezvous) A recent meta-analysis [218] compared EUS-RV to percutaneous rendezvous, comparing 524 patients in 19 studies treated with EUS-RV with 591 patients in 13 studies treated with percutaneous rendezvous. Technical success was similar (89.2% vs. 95.8%) in the subgroup with benign stenosis for EUS-RV (7 studies, 84 patients) and percutaneous rendezvous (7 studies, 180 patients), and in the subgroup with normal anatomy (90.7% vs. 95.5%; 16 studies, 413 patients, and 9 studies, 340 patients). Overall AEs were similar for EUS-RV (9.8%) and for percutaneous rendezvous (13.4%). Pancreatitis and bile leakage were higher with EUS-RV (2.5% vs. 0.8% and 3% vs. 0.6%). Both techniques had similar technical success and AE rates in this meta-analysis. Limitations of the study were the considerable heterogeneity in the technical success rate, the absence of studies directly comparing EUS-RV and percutaneous rendezvous, and the retrospective aspect of the series. There is therefore insufficient data to recommend EUS-RV over percutaneous rendezvous (**Table 11s**).

EUS-BD using retrievable stents with EUS-guided antegrade stenting or EUS-HGS have been reported anecdotally for benign strictures. Evidence is lacking regarding their safety and long-term outcomes [159, 219, 220, 221].

The task force issued a conditional recommendation, with a low quality of evidence owing to the risk of indirectness and imprecision (**Table 12s**).

3.4.2 Second attempt for malignant biliary stricture without duodenal stricture (accessible papilla)

RECOMMENDATION
ESGE suggests EUS-guided transmural drainage over PTBD for malignant biliary obstruction after failed ERCP
Conditional recommendation, low quality of evidence.

PTBD has been considered the standard alternative for ERCP failure. It may however be contraindicated in some situations (e.g. ascites) and is burdened by a non-negligible rate of morbidity and an intrinsic discomfort related to the percutaneous drain [222, 223]. EUS-BD offers different routes of drainage by rendezvous, antegrade stenting, or transmural drainage using EUS-CDS and EUS-HGS [3]. There are insufficient data to recommend the extrahepatic versus the intrahepatic approach.

In the setting of MBO and failed ERCP with an accessible papilla:

- there is no direct evidence comparing repeat ERCP with EUS-BD
- based on four meta-analyses [202, 224, 225, 226] and three RCTs [206, 224, 225], there is low quality evidence to support the argument that EUS-BD has similar technical and clinical success compared with PTBD, but with a reduced risk of AEs (OR 0.25, 95%CI 0.10 to 0.61; $I^2 = 0\%$) and recurrent biliary obstruction (OR 0.05, 95%CI 0.01 to 0.25; $I^2 = 0\%$); of note, no RCTs have included EUS-CDS performed with a LAMS
- for EUS-BD, based on two meta-analyses [188, 202] and one RCT [225], there is very low quality of evidence supporting the argument that EUS-HGS and EUS-CDS with a SEMS have similar technical and clinical success; however, no RCTs have included EUS-CDS performed with a LAMS, which would potentially improve the ease and safety of the procedure
- EUS-BD demonstrates reduced total treatment costs when compared with PTBD, especially when also accounting for hospital stay and reinterventions [204, 205]
- EUS-GBD with a LAMS has recently emerged as a back-up strategy for failed ERCP and unfavorable EUS-CDS [201]
- one small RCT has reported comparable efficacy and safety of surgical hepaticojejunostomy and EUS-CDS with a SEMS [226] (**Table 13s**).

An international survey assessed patient perspectives by enrolling 327 patients scheduled to undergo ERCP for MBO. Based on simulated scenarios, more than 80% of patients preferred EUS-BD to PTBD for ERCP failure because of the absence of a percutaneous drain and the possibility of a one-stage procedure to achieve clinical success [227]. This rate increased where EUS-BD expertise was available and decreased in line with an increasing rate of AEs [228], supporting the need to improve proficiency and safety as a driver for EUS-BD adoption.

In distal MBO with adequate biliary dilatation, EUS-CDS with a LAMS can further increase the simplicity of EUS-BD, by allowing single-step, free-hand advancement of an electrocautery-enhanced LAMS without any device exchange. This is strictly dependent on adequate biliary dilatation, usually >15 mm [82].

The most recent meta-analysis [89] reported >90% technical and clinical success, with a roughly 10% rate of early AEs (mostly mild or moderate) and a roughly 10% rate of reintervention. However, EUS-CDS with a LAMS is unfavorable in cases involving pyloroduodenal invasion [87, 229], gastric outlet obstruction [83], and mildly dilated CBD, as well as in proximal/hilar malignant stenosis, where EUS-HGS should be preferred [3]. EUS-GBD can be used as an acceptable rescue drainage modality in distal MBO, provided that the cystic duct is patent [201]. Caution must be taken with EUS-CDS, as demonstrated by recently published real-world data on technical complications, which reported a 12% rate of 30-day mortality [81].

There is insufficient evidence to restrict the use of EUS-CDS in patients with potentially resectable disease, but follow-up data from two cohorts (one prospective and one retrospective) have demonstrated LAMS dysfunction in 32%–55% of cases after EUS-CDS [84, 229]. Case series have demonstrated no increased rate of postsurgical AEs [230], with the presumed advantage of a reduced rate of PEP for early or even upfront adoption for preoperative EBD. Limited evidence is available for EUS-HGS [231]. These data suggest multidisciplinary discussion should be undertaken in patients where EUS-BD is foreseen in the preoperative setting, taking into account also the advantages of EUS-BD in terms of safety, potentially translating into higher and faster access to neoadjuvant treatment and/or surgery.

The task force issued a conditional recommendation with low quality of evidence owing to the risk of indirectness and imprecision (**Table 14s**).

3.4.3 Second attempt for malignant biliary stricture with duodenal stricture (accessible papilla)

RECOMMENDATION

ESGE suggests EUS-BD over surgical bypass or percutaneous drainage in the setting of double malignant biliary and gastric outlet obstruction, where expertise is available.

In this scenario, EUS-HGS is associated with reduced risk of recurrent biliary obstruction compared with EUS-CDS.

Conditional recommendation, very low quality of evidence.

The performance of ERCP is suboptimal in patients with duodenal stricture and/or indwelling duodenal stents, achieving variable technical success in tertiary referral centers [232, 233, 234, 235]. Inconsistent results have been reported, suggesting that EUS-BD might be associated with higher rates of technical success than ERCP in this scenario. Yamao et al. have reported a significantly higher rate of technical success (95% vs. 56%) in this setting [236]; however, in an older study, EUS-BD was associated with increased AEs, but this study involved transmural drainage with plastic stents, a clinical technique that has now been abandoned [237]. More consistently, the rate of recurrent biliary obstruction appears to be lower and time to recurrent biliary obstruction longer in cases of EUS-HGS, as the drainage is far from the tumor site. These results add to the body of literature supporting the advantage of EUS-BD over PTBD [202, 238].

Although more technically challenging, recent data have provided more evidence to support EUS-HGS over EUS-CDS in this specific setting, owing to longer drainage patency with EUS-HGS, being far from the tumor location, and increased risk of ascending cholangitis or stent dysfunction using EUS-CDS, especially with the use of a LAMS, with the risk of stent obstruction due to food impaction above the duodenal stricture [83, 87, 229].

In the setting of MBO and duodenal stenosis, after failed ERCP:

- there is no direct evidence comparing repeat ERCP with EUS-BD
- there is no direct evidence comparing EUS-BD with PTBD in the specific scenario of duodenal stenosis

- based on a pooled analysis of available data from four small observational studies (three retrospective [199, 239, 240] and one prospective [83]) in the setting of combined biliary and gastric outlet obstruction, EUS-CDS is associated with an increased risk of recurrent biliary obstruction (RR 5.04, 95%CI 2.09 to 12.14; I^2 = 0%) compared with EUS-HGS, with similar risk of AEs. Two studies included EUS-CDS performed with a LAMS, and one with a SEMS; two studies included gastric outlet obstruction treated with EUS-guided gastroenterostomy and one with duodenal SEMSs
- EUS-guided double bypass (EUS-guided gastroenterostomy + EUS-BD) compared with surgical double bypass demonstrates similar technical and clinical success, with significantly reduced rates of AEs (especially severe) and shorter hospitalization in one retrospective study [241] (**Table 15s**).

Finally, intubating a previously placed gastroenteric LAMS to retrogradely reach the papilla is one additional reported strategy to achieve biliary drainage in the setting of double obstruction [242]. When these EUS-BD possibilities are paired with the increasingly reported advantages of EUS-guided gastroenterostomy over duodenal stenting or surgical bypass in treating gastric outlet obstruction [243, 244, 245, 246, 247], this may call for centralization of patients with double obstruction in centers where advanced interventional EUS expertise is available.

Management of patients of this complexity should be performed after multidisciplinary discussion, accounting for extensive radiological evaluation of the specific anatomy, resectability status, oncological perspective on presumed life expectancy, and frailty of the patient.

The task force issued a conditional recommendation with very low quality of evidence because of the risk of indirectness, imprecision and the moderate risk of bias in the literature (**Table 16s**).

3.5 Periprocedural and technical aspects of biliary stenting

3.5.1 Antibiotic prophylaxis

For some procedures (e.g. predicted incomplete biliary drainage, hilar stricture management, those in immunocompromised patients or with PSC, cholangioscopy), antibiotics should be administered before ERCP. These recommendations have been described in great detail in the ESGE ERCP-related AEs guidelines and must be followed [5].

3.5.2 Post-ERCP pancreatitis prophylaxis

For ERCPs, rectal administration of 100 mg diclofenac or indomethacin in all patients without contraindication, hyperhydration, and use of a prophylactic pancreatic stent should be properly applied following ESGE guidelines [5].

3.5.3 Stent registry

Maintaining a registry for patients with biliary stents, in particular for patients with BBS, and recalling these patients for stent removal/exchange has been recommended in the ESGE biliary stenting guidelines in 2017 [2], because forgotten stents may be extremely difficult to remove and scheduled stent exchange/removal has been demonstrated to reduce septic complications. No major new data have been published on this topic, which remains a critically important aspect of the management of patients with biliary strictures and must be applied.

3.6 Environmental impact

The environmental impact of endoscopic management of biliary strictures using ERCP and EUS (including stenting and dilation) is driven mainly by single-use devices, energy for intensive imaging, cautery, and long-lasting procedures, extensive sterilization processes, also taking into consideration that sometimes more than one endoscope is used (back-to-back use of the echoendoscope and the duodenoscope) for interventional procedures in the biliary tract, and waste disposal (the waste from therapeutic procedures is more than double that of diagnostic endoscopies) [248], with cumulative effects influenced by disease type (benign vs. malignant) and the need for repeat interventions. While no specific evidence has been derived from disease-specific biliary studies, most evidence comes from life-cycle assessments, waste audits, and sustainability analyses, and scientific society guidance documents [249].

The most relevant evidence to this guideline comes from a prospective study conducted at the Asian Institute of Gastroenterology Hospitals that comprehensively assessed greenhouse gas emissions and waste generation of gastrointestinal procedures, the majority of which were ERCPs [248]. Although the results of this study cannot be directly generalized, one of the key drivers of the environmental impact of endoscopy, detected also in a European study that included non-ERCP procedures only [250], is the greenhouse gas emissions related to patients travelling to and from the hospital, which ranges from 45% of the total procedure-related carbon footprint in France to more than 80% in India. This is of paramount importance as repeated regular plastic stent replacements are recommended for the management of BBSs, and a direct comparison with the SEMS placement strategy's environmental impact is not yet available.

The authors also highlighted the positive impact of recycling hospital waste in India – 25.7% of the total waste in India compared to 9%–20% in US centers [251, 252] – as demonstrated by substantial CO_2 emission reduction. In comparison to evidence from the USA, direct landfill disposal accounted for 9.5% of the generated waste, while the US centers reported 61%–63% [251, 252]. While this comparison should be interpreted cautiously owing to the difference in procedure mix, among other factors, it highlights the beneficial effects of structured waste recycling.

Another barrier to reducing the carbon footprint of interventional biliary endoscopy is the avoidance of reprocessed ERCP and reusable EUS devices [253]. This topic was recently reintroduced by the ESGE Position Statement on reducing the environmental footprint of gastrointestinal endoscopy [249], as so far no infectious outbreaks have been reported with reusable devices and past outbreaks were linked to inadequate reprocessing of duodenoscopes. Currently, European Union legislation states that the reprocessing of devices is allowed only when permitted by national law, primarily for reusable devices. Therefore, this matter should be addressed locally, on a case-by-case basis.

3.7 Unmet needs and evidence gaps

As is evident above, most of the recommendations in this Guideline are based on low quality evidence. Even if it is not feasible for all the questions, there is a clinical need for further high quality prospective studies and RCTs, given the constant technical evolution of therapeutic endoscopy. Various identified unmet needs include: updated trials on preoperative biliary drainage with SEMSs compared with upfront pancreaticoduodenectomy, because the use of plastic stents in this scenario is outdated; high quality comparative trials on the use of newly designed FCSEMSs with antimigration systems for BBS; RCTs comparing the insertion of MPSs with FCSEMSs in benign post-cholecystectomy biliary stricture management; prospective extended experience in maximum biliary drainage and prospective evaluation of liver volumetry for palliative hilar MBO with survival and access to chemotherapy as the main outcomes; RCTs comparing PCSEMSs with USEMSs in palliative drainage of distal MBO; comparative trials on the route of drainage in patients with surgically altered anatomy; reported cohorts on the route of drainage in cases of ERCP failure for BBS. Another major gap in the literature is the required number of EUS or ERCP procedures and their associated cost and environmental impact to achieve clinical success as recognized outcomes when comparing procedures. Further research in this field should align with defined criteria from the ESGE E-SPARE framework [254].

Disclaimer

ESGE Guidelines represent a consensus of best practice based on the available evidence at the time of preparation. They may not apply to all situations and should be interpreted in the setting of specific clinical scenarios and resource availability. They are intended to be an educational tool to provide information that may support endoscopists in providing care to patients. They are not rules and should not be used either to replace clinical judgement or to establish a legal standard of care. Healthcare organizations that are practicing advanced procedures (e.g. complex ERCP, therapeutic EUS, PTBD, EA-ERCP) require dedicated training programs [255], annual case volume exposure, and knowledge of each clinician's own limits, with regional organization of expert center referral systems.

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Conflict of Interest

M. Arvanitakis has received lecture fees from Boston Scientific (2024 to present). G. Johnson is on the advisory board and has provided educational consultancy for Boston Scientific (2022 to present) and is on the advisory board of Olympus (2025 to present). E. Perez-Cuadrado Robles has provided consultancy to Boston Scientific (2024 to present). G. Vanella has provided consultancy to Boston Scientific (2022 to present). J. van Hooft has received consultancy fees from Olympus and lecture fees from Fujifilm and Cook Medical (all 2024 to present). F. Caillol, A. Facciorusso, C. Gerges, L. Kylänpää, A. Lemmers, K.S. Liem, M. Petrone, M. Ramchandani, S. Teles de Campos, T. C. Tham, K. Triantafyllou, and A. Tringali declare that they have no conflict of interest.

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Supplementary material

Biliary stricture management: European Society of Gastrointestinal Endoscopy (ESGE) Guideline
Supplementary material

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Table 1s. **Task forces and working groups**

Benign biliary stricture	Malignant biliary stricture	Surgically altered anatomy/inaccessible papilla	Failed ERCP/ further line of drainage route
Andrea Tringali (TF leader)	**Jeanin van Hooft (TF leader)**	**Sara Teles de Campos (TF leader)**	**Mariachiara Petrone (TF leader)**
Mohan Ramchandani	Sem Lieng,	Gavin Johnson	Giuseppe Vanella
Leena Kylänpäa	Marianna Arvanitakis	Enrique Perez-Cuadrado Robles	Fabrice Caillol
	Christian Gerges		Arnaud Lemmers

Table 2s Interpretation of the certainty in evidence of effects and of strong and conditional recommendations using the Grading of Recommendations Assessment, Development and Evaluation (GRADE) framework.

Certainty	**Description**	
High	*We are very confident that the true effect lies close to that of the estimate of the effect*	
Moderate	*We are moderately confident in the effect estimate. The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different*	
Low	*Our confidence in the effect estimate is limited. The true effect may be substantially different from the estimate of the effect*	
Very Low	*We have very little confidence in the effect estimate. The true effect is likely to be substantially different from the estimate of effect*	
Implications	**Strong recommandation**	**Conditional recommandation**
For patients	*Most individuals in this situation would want the recommended course of action and only a small proportion would not*	*Most individuals in this situation would want the suggested course of action, but many would not*

For clinicians	*Most individuals should receive the intervention. Formal decision aids are not likely to be needed to help individuals make decisions consistent with their values and preferences*	*Different choices will be appropriate for individual patients consistent with their values and preferences. Use shared decision-making. Decision aids may be useful in helping patients make decisions consistent with their individual risks, values, and preferences*
For policy makers	*The recommendation can be adapted as policy or performance measure in most situations*	*Policymaking will require substantial debate and involvement of various stakeholders. Performance measures should assess whether decision-making is appropriate*

Tables 3s: PICO questions

TF1: Benign biliary stricture

Clinical question	Population	Intervention	Comparator	Outcomes
Benign biliary stricture: when to attempt stricture calibration treatment?	Patients with benign biliary stricture (different etiologies: post-surgical, trauma, chronic pancreatitis, PSC,…)	ERCP + dilation+/-stent	vs natural evolution of the stricture	prevention of cholangitis, secondary liver cirrhosis, liver graft, derivative bilio-enteric surgery

Benign biliary stricture after cholecystectomy: How to attempt stricture calibration treatment?	Patients with post-cholecystectomy benign biliary stricture	ERCP + FcSEMS	vs ERCP+ multiple plastic stents	stricture resolution, reduction in recurrence of cholangitis, need for liver transplantation, bilio-enteric surgical anastomosis
Benign biliary stricture after liver transplantation: How to attempt stricture calibration treatment for **anastomotic** stricture?	Patients with post-liver transplantation anastomotic benign biliary stricture	ERCP + FcSEMS	vs ERCP+ multiple plastic stents	stricture resolution, reduction in recurrence of cholangitis, need for redo liver transplantation, bilio-enteric surgical anastomosis
Benign biliary stricture after liver transplantation: How to attempt stricture calibration treatment for **non anastomotic stricture / biliary cast syndrome**?	Patients with post-liver transplantation non anastomotic benign biliary stricture	ERCP + dilation+/- plastic stent	vs no ERCP	stricture resolution, reduction in recurrence of cholangitis, need for redo liver transplantation, bilio-enteric surgical anastomosis

Benign biliary stricture from chronic pancreatitis: How to attempt stricture calibration treatment?	Patients with benign biliary stricture secondary from chronic pancreatitis	ERCP + FcSEMS	vs ERCP+ multiple plastic stents	stricture resolution, reduction in recurrence of cholangitis, need for redo liver transplantation, bilio-enteric surgical anastomosis
Benign biliary stricture from PSC: How to attempt stricture calibration treatment?	Patients with benign biliary stricture secondary from PSC	ERCP + plastic stent	vs ERCP+ dilation (PICO 1) vs ERCP + FC-SEMS (PICO 2).	stricture resolution, reduction in recurrence of cholangitis, need for redo liver transplantation, bilio-enteric surgical anastomosis

TF2: Malignant biliary stricture

Clinical question		Population	Interventi on	Comparator	Outcomes
Distal malignant biliary stricture: preoperative drainage: when and how to stent?		Patients with distal malignant biliary stricture with possible further cephalic Duodenopancreatectomy (CDP)	ERCP + NcSEMS	vs ERCP+ FcSEMS (PICO 1) vs ERCP+PcSEMS (PICO 2) vs ERCP+plastic stent (PICO 3) vs no preop drainage (PICO 4) vs EUS CDS with LAMS (PICO 5)	surgery (CDP) safety (complications), need for reinterventions (ERCP) before surgery (stent migration/tumor ingrowth/overgrowth/sludge obstruction), time to surgery, cholangitis resolution/recurrence, postponed surgery due to ERCP complications (acute pancreatitis,..)
Distal malignant biliary stricture: neoadjuvant drainage: when and how to stent?		Patients with distal malignant biliary stricture with indication for neoadjuvant CT/CT-RXT and possible further cephalic Duodenopancreatectomy (CDP)	ERCP + NcSEMS	vs ERCP+ FcSEMS (PICO 1) vs ERCP+PcSEMS (PICO 2) vs ERCP+plastic stent (PICO 3) vs no preop drainage (PICO 4) vs EUS CDS with LAMS (PICO 5)	cholangitis prevention/resolution, obstructive symptoms resolution (jaundice, pruritus), possibility to deliver proper neoadjuvant oncologic treatment, need for reintervention (ERCP) (stent migration/tumor ingrowth/overgrowth/sludge obstruction)
Distal malignant biliary stricture: palliative drainage: when and how to stent?		Patients with distal malignant biliary stricture in palliation /palliative oncologic treatment	ERCP + NcSEMS	vs ERCP+ FcSEMS (PICO 1) vs ERCP+PcSEMS (PICO 2) vs ERCP+plastic stent	cholangitis prevention/resolution, obstructive symptoms resolution (jaundice, pruritus), possibility to

				(PICO 3) vs no preop drainage (PICO 4) vs EUS CDS with LAMS (PICO 5)	deliver proper oncologic treatment, need for reintervention (ERCP) (stent migration/tumor ingrowth/overgrowth/sludge obstruction)
Hilar / intra-hepatic malignant stricture: preoperative drainage: when and how to stent?		Patients with hilar/intra-hepatic malignant biliary stricture with potential plan for surgery	ERCP + unilateral plastic stent	vs ERCP+ bilateral plastic stent (PICO 1) vs no preop drainage (PICO 2) vs PTC with external drainage (PICO 3)	cholangitis prevention/resolution, obstructive symptoms resolution (jaundice, pruritus), surgery (Hepatectomy) safety (complications), need for reinterventions (ERCP) before surgery (stent migration/ sludge obstruction), time to surgery, cholangitis resolution/recurrence, postponed surgery due to ERCP complications (acute pancreatitis, sepsis, liver abcesses..)
Hilar / intra-hepatic malignant stricture: palliative drainage: when and how to stent?		Patients with hilar/intrahepatic malignant biliary stricture in palliation /palliative oncologic treatment (stratifying following Bismuth classification)	ERCP + NcSEMS	vs PTC+SEMS vs Hepatico-gastrostomy+SEMS	cholangitis prevention/resolution, obstructive symptoms resolution (jaundice, pruritus), possibility to deliver proper oncologic treatment, need for reintervention (ERCP/PTC/EUS-BD) (stent

					migration/tumor ingrowth/overgrowth/sludge obstruction)
		Patients with hilar/intrahepatic malignant biliary stricture in palliation /palliative oncologic treatment	ERCP + NcSEMS	vs ERCP+ plastic stents (PICO 1) vs ERCP+FcSEMS (PICO 2)	cholangitis prevention/resolution, obstructive symptoms resolution (jaundice, pruritus), possibility to deliver proper oncologic treatment, need for reintervention (ERCP) (stent migration/tumor ingrowth/overgrowth/sludge obstruction)
		Patients with hilar/intrahepatic malignant biliary stricture in palliation /palliative oncologic treatment	ERCP + unilateral NcSEMS	vs ERCP+ bilateral NcSEMS (PICO1)	cholangitis prevention/resolution, obstructive symptoms resolution (jaundice, pruritus), possibility to deliver proper oncologic treatment, need for reintervention (ERCP) (stent migration/tumor ingrowth/overgrowth/sludge obstruction)
Stent dysfunction in malignant stricture: how to solve?		Patients with malignant biliary stricture treated with **previous SEMS with signs of dysfunction** (stratify distal / hilar)	ERCP + new NcSEMS in previous SEMS	vs ERCP+ plastic stent (PICO1) vs ERCP+Fc/PcSEMS in previous SEMS (PICO2)	cholangitis prevention/resolution, obstructive symptoms resolution (jaundice, pruritus), possibility to deliver proper oncologic treatment, need for

					reintervention (ERCP) (stent migration/tumor ingrowth/overgrowth/sludge obstruction)
		Patients with malignant biliary stricture treated with **previous LAMS with signs of dysfunction**	EUS-CDS with LAMS	vs ERCP+ plastic stent (straight/double pigtail) (PICO 1) vs ERCP + Pc/FcSEMS (PICO 2)	cholangitis prevention/resolution, obstructive symptoms resolution (jaundice, pruritus), possibility to deliver proper oncologic treatment, need for reintervention (ERCP) (stent migration/tumor ingrowth/overgrowth/sludge obstruction)

TF3: **Surgically altered anatomy / inaccessible papilla**

Clinical question	**Population**	**Intervention**	**Comparator**	**Outcomes**
What is the preferred route to attempt biliary drainage for **benign stricture management in case of RYGBP**	Patients with benign biliary stricture and altered anatomy (RYGBP)	EDGE+ ERCP	vs laparoscopic transgastric assisted ERCP (PICO 1) vs PTC (PICO2) vs enteroscopy assisted ERCP (PICO3)	technical success / number of interventions / clinical success / safety (complication rate)
What is the preferred route to attempt biliary drainage for **benign stricture management in case of total gastrectomy with RY jejuno-jejunal anastomosis**	Patients with benign biliary stricture and altered anatomy (total gastrectomy with RY jejuno-jejunal anastomosis)	Entero- ERCP	vs PTC (PICO1)	technical success / number of interventions / clinical success / safety (complication rate)
What is the preferred route to attempt biliary drainage for **benign stricture management in case of cephalic duodenopancreatectomy**	Patients with benign biliary stricture and altered anatomy (cephalic duodenopancreatectomy)	ERCP (pediatric colonoscope/duodenoscope)	vs entero-ERCP (PICO 1) vs PTC (PICO2) vs hepatico-gastrostomy (PICO3)	technical success / number of interventions / clinical success / safety (complication rate)

What is the preferred route to attempt biliary drainage for **benign stricture management in case of hepatico-jejunostomy**	Patients with benign biliary stricture and altered anatomy (hepatico-jejunostomy)	Entero-ERCP	vs PTC (PICO1) vs hepatico-gastrostomy (PICO2)	technical success / number of interventions / clinical success / safety (complication rate)
What is the preferred route to attempt biliary drainage for **malignant stricture** management in case of (to be stratified in distal / hilar) **RYGBP**	Patients with malignant biliary stricture and altered anatomy (RYGBP)	EDGE+ ERCP	vs laparoscopic transgastric assisted ERCP (PICO 1) vs PTC (PICO2)	technical success / number of interventions / clinical success / safety (complication rate)
What is the preferred route to attempt biliary drainage for **malignant stricture** management in case of (to be stratified in distal / hilar) **total gastrectomy with RY jejuno-jejunal anastomosis**	Patients with malignant biliary stricture and altered anatomy (total gastrectomy with RY jejuno-jejunal anastomosis)	Entero- ERCP	vs PTC (PICO1)	technical success / number of interventions / clinical success / safety (complication rate)
What is the preferred route to attempt biliary drainage for **malignant stricture** management in case of (to be stratified in distal / hilar) **cephalic duodenopancreatectomy**	Patients with malignant biliary stricture and altered anatomy (cephalic duodenopancreatectomy)	ERCP (pediatric colonoscope/duodenoscope)	vs entero-ERCP (PICO 1) vs PTC (PICO2) vs hepatico-gastrostomy (PICO3)	technical success / number of interventions / clinical success / safety (complication rate)

What is the preferred route to attempt biliary drainage for **malignant stricture** management in case of (to be stratified in distal / hilar) **hepatico-jejunostomy**	Patients with malignant biliary stricture and altered anatomy (hepatico-jejunostomy)	Entero-ERCP	vs PTC (PICO1) vs hepatico-gastrostomy (PICO2)	technical success / number of interventions / clinical success / safety (complication rate)
What is the preferred route to attempt biliary drainage for **malignant stricture** management in case of (to be stratified in distal / hilar) **inaccessible papilla and duodenal stricture**	Patients with malignant biliary stricture and inaccessible papilla AND duodenal stricture	Hepatico-gastrostomy	vs PTC (PICO1) vs Choledoco-duodenostomy /gastrostomy (PICO2)	technical success / number of interventions / clinical success / safety (complication rate) / stent dysfunction
What is the preferred route to attempt biliary drainage for **malignant stricture** management in case of (to be stratified in distal / hilar) **inaccessible papilla and no duodenal stricture**	Patients with malignant biliary stricture and inaccessible papilla AND no duodenal stricture	Hepatico-gastrostomy	vs PTC (PICO1) vs Choledoco-duodenostomy /gastrostomy (PICO2)	technical success / number of interventions / clinical success / safety (complication rate) / stent dysfunction

TF 4. ERCP failure: second attempt

Clinical question	Population	Intervention	Comparator	Outcomes
What is the preferred route to attempt biliary drainage for **benign stricture** management in case of **ERCP failure** (accessible papilla; failed cannulation or failed passage of the stricture by guidewire/stent)	Patients with benign biliary stricture and normal anatomy and accessible papilla with previous ERCP failure	repeat ERCP in expert hands	vs PTC rendez-vous (PICO1) vs extra-hepatic EUS guided rendez-vous (PICO2) vs Intrahepatic EUS guided rendez-vous (PICO 3) vs PTC + drain (PICO 4) vs Choledoco-duodenostomy +stent(PICO 5) vs HG +stent(PICO 6)	technical success / procedure time / quality of life / number of interventions / clinical success / safety (complication rate) / stent dysfunction
What is the preferred route to attempt biliary drainage **for malignant stricture** management in case of **ERCP failure** (accessible papilla)	Patients with malignant biliary stricture and normal anatomy and accessible papilla with previous ERCP failure AND **no duodenal stricture**	repeat ERCP in expert hands	vs PTC rendez-vous (PICO1) vs Extra-hepatic EUS guided rendez-vous (PICO2) vs Intrahepatic EUS guided rendez-vous (PICO 3) vs PTC + drain (PICO 4) vs Choledoco-duodenostomy +stent(PICO 5) vs HG +stent(PICO 6) vs gallbladder drainage (PICO 7)	technical success / procedure time / quality of life / number of interventions / clinical success / safety (complication rate) / stent dysfunction

	Patients with malignant biliary stricture and normal anatomy and accessible papilla with previous ERCP failure AND **with duodenal stricture**	repeat ERCP in expert hands	vs PTC rendez-vous (PICO1) vs Extra-hepatic EUS guided rendez-vous (PICO2) vs Intrahepatic EUS guided rendez-vous (PICO 3) vs PTC + drain (PICO 4) vs Choledoco-duodenostomy +duodenal stent(PICO 5) vs HepaticoGastrostomy +EUS guided gastroenterostomy(PICO 6) vs Choledoco-duodenostomy+EUS guided gastroenterostomy (PICO 7) vs HepaticoGastrostomy+duodenal stent (PICO 8)	technical success / procedure time / quality of life / number of interventions / clinical success / safety (complication rate) / stent dysfunction

Table 4s: TF1 studies extraction

4.1s: When to attempt stricture calibration treatment?

Author (year)	Methods		Population			Intervention			Outcomes		Remarks
	Design		N	Age, years	Inclusion criteria	Protocol (details) of Intervention	Protocol (details) of Comparison	Mean or Median Follow-up	Outcome measures (+ definitions)	Principal findings	
ERCP and stenting Vs Natural history of benign biliary strictures: NO COMPARATIVE STUDIES FOUND											
Assessment of liver fibrosis before and after surgical drainage of iatrogenic Benign Biliary Strictures											
Rajendran, J (2024)	Observ ational	P	47	39 (mean)	Iatrogenic benign biliary strictures (BBS)	To evaluate the impact of BBS repair on liver function using FibroScan	LFTs and Liver fibrosis before and after surgical repair of BBS	15 months (range 9-36)	Regression of fibrosis using a noninvasive modality (FibroScan)	-Reason for biliary injury: 44 post cholecystectomy 2 traumatic; 1 stone induced -Mean interval between biliary injury and hepaticojejunostomy: 7 months **Prevention of cholangitis:** no patients had early cholangitis during early f-up **-Prevention of secondary liver cirrhosis:** Fibrosis score (FibroScan): Before. After repair F0: 4 22 F1: 11 19 F2: 13 4 F3: 16 2 F4: 3 0 Duration from injury to repair and duration of jaundice: important predictors of fibrosis (P= 0.03 and P= 0.001) **Liver graft:** NA **Derivative bilio-enteric surgery:** Significant improvement in LFTs and regression of fibrosis after surgical repair of BBS	Small sample size, single center study Elastography values should be interpreted with caution in the presence of raised bilirubin as it carries the risk of overestimation of fibrosis
Abbreviations: BBS: Benign Biliary Strictures; LFTs: Liver Function Tests; NA: Not Applicable / Not Addressed; P: Prospective											

- Rajendran J, Irrinki S, Gupta V, Singh V, Sinha SK, Lal A, Kurdia K, Das A, Yadav TD. Elastography for Evaluation of Regression in Liver Fibrosis After Surgical Biliary Drainage for Benign Biliary Strictures: A Practical Possibility? J Clin Gastroenterol. 2024 May-Jun 01;58(5):502-506. doi: 10.1097/MCG.0000000000001895. Epub 2023 Jul 31. PMID: 37725412.

4.2s: How to attempt stricture calibration treatment?

Author (year)	Methods		Population			Intervention			Outcomes		Remarks
	Design		N	Age, years	Inclusion criteria	Protocol (details) of Intervention	Protocol (details) of Comparison	Mean or Median Follow-up	Outcome measures (+ definitions)	Principal findings	
Covered SEMS Vs Multiple plastic stents to dilate post-Cholecystectomy strictures											
Artifon EL (2012)	RCT SC	P	31	45	Patients with post-surgical BBS	PC-SEMS **4-5 months indwelling stent period**	MPS	5 and 6 years	Bile duct patency evaluated with Magnetic Resonance Cholangiography Treatment success (60-70% reduction of bilirubin value after 6 weeks)	**Stricture resolution:** Long-term patency rate after biliary drainage: statistically higher with PC-SEMS (81% Vs 71% p= 0.02) **Reduction in recurrence of cholangitis:** NA Adverse events higher in PC-SEMS group (40% Vs 25% p=0.37) **Need for liver transplantation:** NA **Need for bilio-digestive anastomosis:** NA	-Protocol and measures of success not detailed -PC- SEMS not common for BBS. Possible difficulty in removal not detailed in the paper
Multiple plastic stents to dilate post-Cholecystectomy strictures											
Costamagna G (2022)	Cohort study SC	R	154	53 (median)	Patients with post-cholecystectomy BBS	MPS (progressive insertion every 3 months for 1 year)	N/A	11.1 ± 4.9 years (mean)	Stricture recurrence rate (cholangitis occurrence and/or LFTs worsening during follow-up)	43% involving the hilum Mean maximum number of stents: 4.3 ±1.6 Mean n° of ERCPs: 4.2 ± 1.5 Mean treatment duration 11.8 ±6.4 months **Stricture resolution:** 9.4% Stricture recurrence rate **Reduction in recurrence of cholangitis:** 7.4% AEs; 16% cholangitis during 11y follow-up **Need for liver transplantation:** NA **Need for bilio-digestive anastomosis:** 2/127 patients (1.6%) Statistical analysis revealed no risk factors for PCBS recurrence after MPS	Absence of a control group 14.8% patients lost to follow-up
Fully Covered SEMS to dilate post-Cholecystectomy strictures											
Tringali A (2019)	Cohort study MC (n=13)	P	18	54 (mean)	Patients with post-cholecystectomy BBS	FC- SEMS (transpapillary)	N/A	5 years (mean)	Fraction of stent-free patients 5 years after FC-SEMS removal	Strictures not involving the hilum **Stricture resolution:**	Absence of a control group Small sample size

Author (year)	Methods		Population			Intervention			Outcomes		Remarks
	Design		N	Age, years	Inclusion criteria	Protocol (details) of Intervention	Protocol (details) of Comparison	Mean or Median Follow-up	Outcome measures (+ definitions)	Principal findings	
						10-12 months indwelling stent period			Stricture resolution rate (absence of a biliary stricture requiring restenting) Stricture recurrence (need for restenting after strict resol)	29% stricture recurrence (restented during study period) 16.7% complete distal migration 39% stent or removal related AEs **Reduction in recurrence of cholangitis:** 1/13 (7.7%) cholangitis during 5 year follow-up **Need for liver transplantation:** NA **Need for bilio-digestive anastomosis:** 1/18 patients (5.6%)	FC-SEMS limited to stricture >2cm from the main hepatic confluence (risk of side-branch occlusion)

Abbreviations.
BBS: Benign Biliary Strictures; FC-SEMS: Fully Covered Self-Expandable Metal Stent; LFTs: Liver Function Tests; MC: Multi-Centre; MPS: Multiple plastic stents; NA: Not Applicable / Not Addressed; P: Prospective; PC-SEMS: Partially Covered Self-Expandable Metal Stent; R: Retrospective; RCT: Randomized Controlled Trial; SC: Single-Centre.

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- Tringali A, Reddy DN, Ponchon T, Neuhaus H, Lladó FG, Navarrete C, Bruno MJ, Kortan PP, Lakhtakia S, Peetermans J, Rousseau M, Carr-Locke D, Devière J, Costamagna G; Benign Biliary Stenoses Working Group. Treatment of post-cholecystectomy biliary strictures with fully-covered self-expanding metal stents - results after 5 years of follow-up. BMC Gastroenterol. 2019 Dec 12;19(1):214. doi: 10.1186/s12876-019-1129-3. PMID: 31830897; PMCID: PMC6909597.

4.3s: Benign biliary stricture after liver transplantation: How to attempt stricture calibration treatment for anastomotic stricture?

Author (year)	Methods		Population			Intervention			Outcomes			Remarks
	Design		N	Age	Inclusion criteria	Protocol (details) of Intervention	Protocol (details) of Comparison	Follow-up	Outcome measures (+definitions)	Outcomes of interest	Principal findings	
Fully covered SEMS Vs Multiple plastic stents to dilate <u>anastomotic biliary strictures (ABS)</u> after liver transplantation												
Papaefthymiou A (2024)	SRMA	NA	9 studies (3 RCTs, 5 Retrospective, 1 Prospective non randomized) (687 patients)	Range 23-69 years	Comparative studies and RCTs evaluationg FC-SEMS vs MPS to dilate ABS complicating liver transplantation	8-10 mm FC-SEMS (1 study 6-8 mm intraductal) Only 82 pts had Intraductal FC-SEMS	MPS protocol (plastic stent exchange and increase every 3-4 months for 1 year)	12-64 months	ABS resolution ABS recurrence Treatment duration Number of ERCPs Adverse events Stent migration Costs	**Stricture resolution:** 89.7% FC-SEMS Vs 88.5% MPS (NS) *ABS recurrence* 24.3% FC-SEMS (all) Vs 14.8% MPS (NS) 22% FC-SEMS (conventional) Vs 10.6% MPS (NS) 25.6% FC-SEMS (intraductal) Vs 29% MPS (NS) *Migration* 14% FC-SEMS Vs 18.5% MPS (NS) 9.4% FC-SEMS (intraductal) Vs 18.5% MPS Adverse events: 29.6% FC-SEMS Vs 27.6% (NS) **Reduction in recurrence of cholangitis:** 14.3% FC-SEMS Vs 11% (NS) **Need for redo liver transplantation:** NA **Bilio-enteric surgical anastomosis:** NA	Intraductal FC-SEMS higher stricture resolution rate 95.6% Vs 80.9% MPS, marginally failed to achieve significancy Overall ABS recurrence rate higher with FC-SEMS Intraductal FC-SEMS most cost-effective strategy	Stricture recurrence not evaluated according to the length of follow-up which is 1-2 years in 4/5 studies Stent migration not analyzed
Baraldo S (2025)	SRMA	NA	5 studies (RCTs) (245 patients)	NA	RCTs comparing FC-SEMS and MPS to dilate ABS	8-10 mm FC-SEMS	MPS protocol	1 to 5 years	ABS resolution ABS recurrence	**Stricture resolution:** 83% FC-SEMS Vs 85% MPS (NS)	FC-SEMS and MPS for ABS after liver transplantation: similar stricture resolution rate and adverse events.	Stricture recurrence was not

Author (year)	Methods		Population			Intervention			Outcomes			Remarks
	Design		N	Age	Inclusion criteria	Protocol (details) of Intervention	Protocol (details) of Comparison	Follow-up	Outcome measures (+definitions)	Outcomes of interest	Principal findings	
					complicating liver transplantation	1/5 papers used 8 mm diameter in 30% of the cases (Cotè 2016) 1/5 papers used Intraductal FC-SEMS (Kaffes 2014) Only 10 pts with intraductal FC-SEMS	(plastic stent exchange and increase every 3-4 months for 1 year)		Treatment duration Number of ERCPs Costs Adverse events	ABS recurrence 24% FC-SEMS Vs 9% MPS (NS) Treatment duration 183 days FC-SEMS Vs 279 days MPS (p=0.03) Number of ERCPs 2.5 FC-SEMS Vs 4.3 MPS (p=0.05) Costs: No statistical difference (consider indirect costs in favor of FC-SEMS: as travel expenses, absence from work) Adverse events 24% FC-SEMS Vs 22% MPS (NS) **Reduction in recurrence of cholangitis:** similar risk of post-procedure cholangitis **Need for redo liver transplantation:** NA **Bilio-enteric surgical anastomosis:** NA	FC-SEMS: reduced costs, quicker treatment and less ERCPs needed to treat the ABS compared to MPS ABS recurrence more than 2 times higher with FC-SEMS but not statistically significant	evaluated according to the length of follow-up which is 1-2 years in 4/5 studies Stent migration not analyzed

Abbreviations: ABS: Anastomotic Biliary Strictures; FC-SEMS: Fully Covered Self-Expandable Metal Stent; MC: Multi-Centre; MPS: Multiple plastic stents; NA: Not Applicable / Not Addressed; NS: Not Significant; SRMA: Systematic Review and Meta-analysis; RCT: Randomized Controlled Trial; SC: Single-Centre.

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The following papers are included in Baraldo S et al (2025) and Papaefthymioua et al (2024) meta-analysis and some are retrospective (Martins 2015, Cantù 2019 , Jang 2020).

Author (year)	Methods		Population			Intervention			Outcomes			Remarks
	Design		N	Age	Inclusion criteria	Protocol (details) of Intervention	Protocol (details) of Comparison	Follow-up	Outcome measures (+definitions)	Outcomes of interest	Principal findings	
Transpapillary Fully covered SEMS Vs Multiple plastic stents to dilate <u>anastomotic biliary strictures (ABS)</u> after liver transplantation												
Martins FP, 2015	Cohort Study SC	R	48 vs 109	Mean 54.5 vs 48.8y	all ERCPs performed between 5/2006-6/2014 in deceased OLT recipients with duct-to-duct anastomosis and suspected biliary complications. ABS definition: a dominant short narrowing at the anastomotic site.	Covered self-expandable metal stents (cSEMS) were deployed with or without sphincterotomy and removed after a **3-mo period if a PCSEMS was used or after 6 mo in case of FCSEMS.**	Plastic stents were initially placed after EST and stricture balloon dilation. ERCP was repeated at 3-mo intervals for stent exchange, following a progressive balloon dilation and increasing number of stents protocol at each session, until 12 mo of therapy	Mean 620.3 vs 690.8 days	**Primary outcome:** ABS resolution rate if was no more than a minimum waist at cholangiography and a 10 mm balloon could easily pass through the anastomosis **Secondary outcomes:** technical success rate, number or ERCPs required per patient, number of stents placed, stent indwelling, stricture recurrence rate and therapy for recurrent ABS Stricture recurrence defined as clinical laboratorial and/or imaging evidence of new obstruction at the anastomosis level	**Stricture resolution:** 86.8% vs 91% **Reduction in recurrence of cholangitis:** Stricture recurrence after a median follow up of 20 mo was observed in 30.3% vs 7.7% **Need for redo liver transplantation:** NA **Bilio-enteric surgical anastomosis:** Referred to surgery: 4 patients vs 2 patients	Mean treatment duration, n:o procedures and stents required were lower in the metal stent group. Acute pancreatitis was the most common complication, 17.1% vs 4.1%.	Biliary SEMS were placed without EST, which we started to perform after recognizing a high rate of pancreatitis in these patients. PCSEMS were also used in our early experience, when fully covered SEMS were not available
Cote GA, 2016	RCT MC (n=8)	P	37/36	55.4 vs 56.4	Benign bile duct stricture located at least 2 cm below the hepatic confluence and coupled with related signs or symptoms (eg, any elevation in liver test results, jaundice, or cholangitis). A stricture was defined as any narrowing of the extrahepatic bile duct that	FcSEMS (WallFlex) of sufficient length to traverse the stricture and the papilla. To minimize migration, an 8-mm diameter FcSEMS was used for bile ducts measuring 6 to 7 mm and a 10-mm diameter for bile ducts	Stricture was dilated to the maximum safest diameter according to endoscopist judgment, and the maximum cumulative diameter of plastic stents was deployed. Repeat ERCP was performed 3 to 4 months later, when all	12mo	To assess whether use of FcSEMS is noninferior to plastic stents with respect to stricture resolution.	**Stricture resolution:** 33/37 vs 31/36 **Reduction in recurrence of cholangitis:** NA **Need for redo liver transplantation:** NA	Among patients with benign biliary strictures and a bile duct diameter 6mmor more in whom the covered metallic stent would not overlap the cystic duct, cSEMS were not inferior to multiple plastic stents after 12 months in achieving	Included all kinds of benign biliary strictest. Total no of patients 112.

Author (year)	Methods		Population			Intervention			Outcomes			Remarks
	Design		N	Age	Inclusion criteria	Protocol (details) of Intervention	Protocol (details) of Comparison	Follow-up	Outcome measures (+definitions)	Outcomes of interest	Principal findings	
					was less than 75% of the diameter of the unaffected duct	8 mm or greater. Follow-up ERCPwas performed 6 months after randomization. For those with a persistent stricture at repeat ERCP, the FcSEMS was replaced for another 6-month interval	plastic stents were removed and the stricture was assessed for resolution. If the stricture persisted, then the cumulative diameter of plastic stents was up-sized to the greatest extent feasible. Until stricture resolution, ERCPs were repeated every 3 to 4 months with plastic stent up-sizing as needed			**Bilio-enteric surgical anastomosis:** NA	stricture resolution. Metallic stents should be considered an appropriate option in patients such as these. Stricture recurrence 5/33 vs 1/31 **Migration: FC SEMS 25%, MPS 16%**	
Tal O, 2017	RCT MC (n=4)	P	58 (48: 24+24 completed follow-up)	median 58, range 32-72	Patients with deceased donor liver transplantation and ABS in ERC	FC-SEMS 10mm, either across the papilla or fully inside	MPS, every 6 to 12 weeks stent exchange	At least 1 year (median follow-up of 500 days (range, 48-1317 days)	Radiomorphologic resolution of the stricture with narrowing of the anastomosis less than 30% of the diameter of CBD. The primary endpoint was the number of endoscopic interventions until ABS resolution. Secondary endpoints were frequency of adverse	**Stricture resolution:** Initial treatment success rates were high with 23 (95.8%) in the MPS group and 24 (100%) for cSEMSs (P=1) MPS (n=24) underwent a median of 4 (range, 3-12) endoscopic retrograde cholangiography examinations, whereas those in the cSEMS group (n=24) underwent a median of 2 (range, 2-12) sessions until ABS resolution (P < .001). Reduction in recurrence of cholangitis : NA	A median of 8 (range, 2-32) stents was used until ABS resolution within the MPS group and 1 (range, 1-24) in the cSEMS group (P < .0001). cSEMS migration occurred in 8 (33.3%) patients. Treatment duration did not differ significantly.. Five (20.8%) patients in both groups showed stricture recurrence after a median follow-up of 500 days (range, 48-1317 days) **Migration: FC SEMS 33%, MPS NA**	

Author (year)	Methods		Population			Intervention			Outcomes			Remarks
	Design		N	Age	Inclusion criteria	Protocol (details) of Intervention	Protocol (details) of Comparison	Follow-up	Outcome measures (+definitions)	Outcomes of interest	Principal findings	
									events, treatment success rates, and time to treatment success and recurrence of ABS	Need for redo liver transplantation: NA Bilio-enteric surgical anastomosis: NA		
Martins FP, 2018	RCT SC (n=4)	P	30 vs 29	Median 54 vs 50y	diagnosis of ABS and indication for endoscopic therapy. The stricture should be located at least 2 cm below hepatic confluence. Randomization occurred after successful passage of a guidewire through the stricture into the proximal biliary tree during index ERC.	FC-SEMS group, the length of the stent was determined according to the distance measured from the biliary anastomosis to the papilla. The stents should be long enough to be 1 cm above the stricture, and exteriorize the papilla for no more than 1 cm. A FcSEMS (Wallflex, Boston Scientific, 10 mm in diameter, 60 or 80 mm in length) was then advanced over the guidewire, with or without	MPS group, biliary sphincterotomy was performed to allow placement of multiple stents. The ABS was dilated with a hydrostatic balloon to the maximum safe diameter at the endoscopist's discretion (6-10 mm), and the maximum number of plastic stents that could be accommodated within the stricture was deployed. ERCP was repeated at 3-month intervals. All plastic stents were then removed, the stricture was progressively dilated, and an increasing number of	Median 1092 vs 989 d	**Primary endpoint:** ABS resolution. Investigators determined successful stricture resolution if, at the final stent removal, there was no or only minimum waist discerned on cholangiography and a 12-mm extraction balloon could easily pass through the anastomosis. Treatment failure was defined as persistence of stricture at the final	**Stricture resolution:** 83.3% in the FcSEMS group and 96.5% in the MPS group (P=0.19) **Reduction in recurrence of cholangitis:** NA **Need for redo liver transplantation:** NA **Bilio-enteric surgical anastomosis:** NA	FcSEMSs were comparable with MPSs regarding post-OLT ABS resolution. FcSEMSs allowed fewer procedures and had a positive effect on cost. Duration of treatment with FcSEMSs should be further investigated. **Sphincterotomy should be considered for all patients.** Stricture recurrence 32% in median 4.9 months in FcSEMS vs none in the MPS group. Adverse events occurred in 23.3% and 6.4% of ERCPs in the FcSEMS and MPS groups, respectively (P < .01). Acute pancreatitis was the most common procedure-related adverse event, occurring in 13.3% in the FcSEMS group and 2.1% in the MPS group (P < .01). **Migration: FC SEMS 10%, MPS 3%**	

Author (year)	Methods		Population			Intervention			Outcomes			Remarks
	Design		N	Age	Inclusion criteria	Protocol (details) of Intervention	Protocol (details) of Comparison	Follow-up	Outcome measures (+definitions)	Outcomes of interest	Principal findings	
						sphincterotomy, until final deployment. Dilation was not performed unless necessary. Removal was scheduled after 6-month indwelling	stents were placed at each session, until 12 months of therapy.		ERCP for stent removal, at 6 or 12 months after the index therapeutic ERCP for the cSEMS and MPS groups, respectively.			
Cantù P, 2019	Cohort Study MC (n=16)	R	181 (101 MPS, 26 with FC-SEMS, 54 with single plastic stent	Median 59	patients were considered for anastomotic stricture treatments in case of any alteration of liver tests persisting within 3 months and magnetic resonance or Kehr cholangiography being consistent with anasto-motic stricture	A 10-mm metal stent was used in 24 patients (92%) and 8-mm metal stent was used in the remaining two (8%) patients. The median duration of metal stenting was 5 (IQR 3-6) months	**Multistenting:** 10-Fr stents was placed as the maximum stenting procedure. The median duration of multistenting therapy was 9 (IQR 6-12) mo. **Single stenting:** a 10 Fr stent was placed in 87% of single stenting LT patients, a 8.5 Fr and 7 Fr was placed in 5.5% both, and a 11.5 Fr was used in 2% of cases	Median 25mo	The aims are to retrospectively analyse the available data on the workload and types of endotherapies dedicated to the ABS Severe stricture was defined in case of a reduction of the diameter of the common bile duct by more than 90% at the level of the anastomosis, while mild stricture in case of a reduction by <90%	**Stricture resolution:** 88% vs 88% vs 61% (single) **Reduction in recurrence of cholangitis:** Stricture recurrence FcSEMS 48%; MPS 11%, single 27%. **Need for redo liver transplantation:** n.a **Bilio-enteric surgical anastomosis:** surgery was performed in 14 patients (two plastic multistenting and 12 single stenting patients		

Author (year)	Methods		Population			Intervention			Outcomes			Remarks
	Design		N	Age	Inclusion criteria	Protocol (details) of Intervention	Protocol (details) of Comparison	Follow-up	Outcome measures (+definitions)	Outcomes of interest	Principal findings	
Jang S, 2020	Cohort Study SC	R	158 (109 pat MPS only)	Mean 57y	(OLT) patients who underwent ERCP with stent placement for the management of ABS were identified. Only those who completed both the insertion and removal of biliary stent from our institution were included. All study subjects received plastic stent at their index ERCP. The subjects in MPS group received treatments with plastic stents only throughout the study period, whereas the subjects in FCSEMS group received metal stent in varying stage of their treatment period.	FCSEMS group received metal stent in varying stage of their treatment period (All study subjects received plastic stent at their index ERCP) Median 102 days stent insertion	MPS only group Median 187 days stent insertion	The stricture free durations (612.5 days for FCSEMS group and 763.5 days for PS group *P* = 0.41)	**primary outcome**: ABS resolution. Definition all 3: 1st, the endoscopy note must contain specific terms “resolved” and/or “no longer present/ visible” when describing ABS upon stent removal. 2nd, endoscopy note or fluoroscopic image(s) must portray adequate drainage of contrast 3rd, no stent was replaced upon the removal of previously placed one(s). **Secondary outcomes:** costs, n° of ERCPs for stricture resolution, rates of stricture recurrence, stricture free intervals, and adverse outcomes (pancreatitis, cholangitis, and unplanned ERCP due	**Stricture resolution:** Of 158 patients enrolled, 125 (79.1%) achieved ABS resolution. Similar resolution rates between MPS group and FCSEMS group were observed: 79.8% among MPS group and 77.6% among FCSEMS transition group (*P* = 0.75). **Reduction in recurrence of cholangitis:** Cholangitis occurred 6.1% vs 3.3% **Need for redo liver transplantation:** NA **Bilio-enteric surgical anastomosis:** NA	Early utilization of FCSEMS can deliver up to 25% savings in the total procedure cost while providing comparable rates of stricture resolution. The rates of technical success 98% vs 99%, stricture recurrence 23.7% vs 25.3%, adverse outcomes, and stricture free durations 612.5 vs 763.5 days were also comparable between the two groups.	Hard to find the total follow-up or definitons

Author (year)	Methods		Population			Intervention			Outcomes			Remarks
	Design		N	Age	Inclusion criteria	Protocol (details) of Intervention	Protocol (details) of Comparison	Follow-up	Outcome measures (+definitions)	Outcomes of interest	Principal findings	
									to suspected bile duct re-occlusion.			
Cantù P 2021	RCT SC	P	15 vs 15	Median 59 vs 53	ABS was confirmed at ERCP when impaction or difficult passage through the anastomosis of a Fogarty catheter inflated to the same diameter as the common bile duct above the anastomosis was seen	FC-SEMS for 6 mo	MPS: a progressive increase in the number of 10 Fr plastic stents at 3-month intervals was planned with an overall duration of treatment of 9 to 12 months according to the rate of improvement of the AS	Median 60 mo	Aim was to compare the costs, long-term effectiveness and adverse events of ABS treatment with traditional MPS versus FCSEMS after liver transplantation	**Stricture resolution:** 73% vs 93% **Reduction in recurrence of cholangitis:** cholangitis occurred 7% vs 2.1% **Need for redo liver transplantation:** n.a **Bilio-enteric surgical anastomosis:** 1 patient vs 0	ABS recurrence occurred in 36% of FCSEMS and 7% of MPS patients (P = NS) **Migration: FC SEMS 29%, MPS 3%**	In the subgroup of LT patients in clini-cal remission after first-line treatment, treatment costs were 41% lower per FCSEMS patient compared with MPS patients. FCSEMS did not perform better than MPS. FCSEMS migration increased the rate of re-treatment and costs

Abbreviations
ABS: Anastomotic Biliary Strictures; EST: Endoscopic Sphincterotomy; FC-SEMS: Fully Covered Self-Expandable Metal Stent; MC: Multi-Centre; MPS: Multiple plastic stents; NA: Not Applicable / Not Addressed; P: Prospective; R: Retrospective; RCT: Randomized Controlled Trial; SC: Single-Centre.

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- *The following papers are included in Baraldo S et al (2025) and Papaefthymioua et al (2024) meta-analysis*

Author (year)	**Methods**		**Population**			**Intervention**			**Outcomes**			**Remarks**
	Design		**N**	**Age**	**Inclusion criteria**	**Protocol (details) of Intervention**	**Protocol (details) of Comparison**	**Follow-up**	**Outcome measures (+ definitions)**	**Outcomes of interest**	**Principal findings**	
Intraductal Fully Covered SEMS Vs Multiple plastic stents to dilate <u>anastomotic biliary strictures (ABS)</u> after liver transplantation												
Kaffes et al 2014	RCT MC (n=2)	P	20 (10 intraductal FC-SEMS vs 10 MPS)	38-69	Patients with liver transplant at ERCP and anastomotic stricture BBS (defined as a narrowing occluding more than 70% of the lumen)	Intraductal Kaffes FC-SEMS 10 mm, 4 cm, **12 weeks**	MPS, every 12 weeks stent exchange until resolution of the stricture or up to 1 year	24.5 mo range 4–38 in the FCSEMS arm	Stricture resolution (no definition) whether FCSEMSs decrease overall numbers of ERCPs needed to achieve	**Stricture resolution:** 10/10 (FC-SEMS) vs 8/10 (MPS)	Median number of ERCPs performed per patient in the FCSEMS was 2 *versus* 4.5 ($p = 0.0001$) in the MPS arm. Stricture resolution was achieved in all 10 patients	Small sample size Possible suboptomal treatment

Author (year)	Methods		Population			Intervention			Outcomes			Remarks
	Design		N	Age	Inclusion criteria	Protocol (details) of Intervention	Protocol (details) of Comparison	Follow-up	Outcome measures (+ definitions)	Outcomes of interest	Principal findings	
								23mo (range 1–42) in the MPS arm	stricture resolution and to establish the safety, efficacy and cost-effectiveness in this setting.	**Reduction in recurrence of cholangitis:** Cholangitis 10% (FC-SMS) vs 40% (MPS) **Need for redo liver transplantation:** NA **Bilio-enteric surgical anastomosis:** NA	with FC-SEMSs compared with 8/10 in the MPS arm [*p* = not significant (NS)]. Complications occurred in 1/10 patients in the FCSEMS arm *versus* 5/10 in the plastic arm (*p* = 0.051). Days in hospital for complications was 6 in the FC-SEMS *versus* 56 in the MPS arm (*p* = 0.11). Cost analysis shows that the FC-SEMS arm was more cost effective. No cases of FC-SEMS migration were seen. **Migration** absent for Intraductal FC-SEMS (Vs 10 % for MPS)	with MPS (overall mean 7.5 stents/patient but mean maximum number of stent not specified) Medium term follow-up available (2 years)
Zeair et al 2017	Cohort study SC	R	39 (23 FC-SEMS vs 16 plastic stent)	Mean 50.7 vs 49.7 (years)	A newly detected biliary ABS after OLT, and FCSEMS insertion or balloon dilatation with subsequent PBS placement in endoscopic management of ABS	Conventional FcSEMS 11 + Kaffes 12 for **6 months**	PBS was inserted, preferably a 10 Fr calibre Advanix™ Biliary Stent or Flexima™ Biliary Stent (Boston Scientific Corporation, Natick, MA, USA). After 3 months, ERCP was repeated, the stent was removed, and the stricture was assessed again. If the stricture persisted, the whole procedure was repeated; otherwise, the patient was placed on clinical follow-up	NA	The aim was to compare the results of the new FCSEMS (Kaffes) with the standard ERCP stricture management protocol and with conventional FCSEMS insertion	**Stricture resolution:** 91% (FC-SEMS) vs 69% (Plastic stent) **Reduction in recurrence of cholangitis:** Cholangitis occurred 2 vs 1 patients **Need for redo liver transplantation:** 2 vs 1 patient **Bilio-enteric surgical anastomosis:** 1 vs 3 hepaticojejunostomy	ABS recurrence after PBS placement was observed in 36.36% of control subjects. In the study group, ABS reoccurred only in 9.52% of subjects; however, the difference did not reach statistical significance (P=0.170). Recurrence rates in patients after conventional FCSEMS and new-type FCSEMS (Kaffes) implantation were similar **Migration** absent for Intraductal FC-SEMS	Treatment with plastic stents was suboprimal (a single plastic stent was placed and exchanged after 3 mo)
Sissingh et al 2023	Cohort study MC (n=2)	R	80 (44 FC-SEMS vs 36	Median 58 vs 52 (years)	ABS confirmed by ERCP, defined as a dominant narrowing at the biliary anastomotic site on cholangiography, and Inraductal FC-SEMS (Kaffes)	The minimal stricture distance to the biliary confluence had to be approximately 2 cm.	In the MPS group, 1 or more 10F Advanix Biliary stents (Boston Scientific, Marlborough, Mass, USA) were placed across the stricture. With each successive ERCP every 6 to 12 weeks,	52 vs 64 months	The aim was to determine the performance of Intraductal FC-SEMS compared with MPS based on the	**Stricture resolution:** 93% vs 97% **Reduction in recurrence of cholangitis:** Cholangitis occurred 13.6%vs 25%	2.0 ERCPs per patient (IQR 2.0-3.0) was required to achieve stricture resolution in the Intraductal FC-SEMS arm versus 4.0 ERCPs (IQR 3.0-5.0) in the MPS arm (P < .05).	Intraductal FC-SEMS had similar ABS resolution and

Author (year)	Methods		Population			Intervention			Outcomes			Remarks
	Design		N	Age	Inclusion criteria	Protocol (details) of Intervention	Protocol (details) of Comparison	Follow-up	Outcome measures (+ definitions)	Outcomes of interest	Principal findings	
			plastic stent)		placement in patients from Leiden or MPS placement in patients from Groningen	Based on the diameter of the bile duct on cholangiography, the diameter of the Intraductal FC-SEMS was determined. Over the guidewire, an 8-mm or 10-mm-wide/40-mm-long Niti-S Kaffes. for **6 months**	stents were removed and, after further balloon dilation (if technically feasible), replaced with an increasing number of plastic stents until the desired diameter had been reached.		number of ERCPs needed to reach efficacy, which is reflected by stricture resolution and stricture recurrence, and safety for the treatment of ABS. **Stricture resolution** defined as free contrast flow across the previous stricture.	**Need for redo liver transplantation:** NA **Bilio-enteric surgical anastomosis:** NA	The median total days of hospitalization was shorter in patients treated with Intraductal - FC-SEMS than in patients treated with MPS (6.0 days [IQR 4.0-8.8] vs 11.0 days [IQR 7.3-19.3]; P < .05). In the Intraductal FC-SEMS group, 14/44 (33.3%) patients experienced stricture recurrence after initial stricture resolution versus 10/36 (28.6%) in the MPS group **Migration**: 16% Intraductal FC-SEMS 39 % MPS	recurrence rate compared to MPS but required less ERCPs. Long-term follow-up (near 5 years)

Abbreviations
ABS: Anastomotic Biliary Stricture; FC-SEMS: Fully Covered Self-Expandable Metal Stent; MC: Multi-Centre; MPS: Multiple plastic stents; NA: Not Applicable / Not Addressed; SC: Single-Centre; P: Prospective; R: Retrospective; RCT: Randomized Controlled Trial;

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Author (year)	Methods		Population			Intervention			Outcomes			Remarks
	Design		N	Age	Inclusion criteria	Protocol (details) of Intervention	Protocol (details) of Comparison	Follow-up	Outcome measures (+ definitions)	Outcomes of interest	Principal findings	
Fully Covered SEMS with antimigration flaps Vs Fully Covered SEMS with flared ends to dilate anastomotic biliary strictures (ABS) after liver transplantation												
Bordaçahar B, (2018)	Cohort Study (2 arms) SC	R	125 57 aFC-SEMS (with flaps) Vs 68 cFC-SEMS (flared)	Mean 55.5 years	Patients with liver transplant and ABS considered significant in the following situations: jaundice associated with or without hyperthermia >38.5 C leading to a suspicion of cholangitis, abnormal liver function tests (increased levels of cholestasis enzymes, including alkaline phosphatase and/or bilirubin), and absence of spontaneous bilio-digestive emptying during ERCP SEMS indwelling time 6 months	aFC-SEMS (with flaps)	cFC-SEMS (flared ends)	Median 28 months (12-66)	The resolution of the ABS was considered satisfactory if an inflated 12-mm diam-eter extraction balloon could be passed through the stricture Primary outcome: migration rate	**Stricture resolution:** 93% aFC-SEMS 66.2% cFC-SEMS (p<0.001) Stricture recurrence 12.3% aFC-SEMS 55.9% cFC-SEMS (p<0.001) Adverse events rate: similar in the 2 groups (aFC-SEMS Vs cFC-SEMS) **Reduction in recurrence of cholangitis:** NA **Need for redo liver transplantation:** NA **Bilio-enteric surgical anastomosis:** NA	Migration rate: 8.7% aFC-SEMS 61.7% cFC-SEMS (p=0.006) aFC-SEMS significantly decreased the risk of stent migration, improved stricture resolution at the time of stent removal, and reduced the rate of stricture recurrence during follow-up	Retrospective study without randomization mixed the primary treatments with those undertaken for relapses after implantation of MPS
Fuentes-Valenzuela E, 2023	Cohort Study (2 arms) SC	R	102 62 aFC-SEMS (with flaps)	Median 58 years	Patients with liver transplant and ABS (an isolated fibrotic stricture localized within one centimeter of the surgical anastomosis)	aFC-SEMS (with flaps)	cFC-SEMS (flared ends)	Median 52 months	Stricture resolution (no definition) whether FCSEMSs decrease overall numbers of ERCPs needed to achieve	**Stricture resolution:** 92,5% aFC-SEMS 93.5% cFC-SEMS (p=ns) Stricture recurrence 21% aFC-SEMS	Migration rate: 37.3% aFC-SEMS 65.8% cFC-SEMS (p=0.006)	Endoscopic follow-up protocol was not entirely uniform

Author (year)	Methods		Population			Intervention			Outcomes			Remarks
	Design		N	Age	Inclusion criteria	Protocol (details) of Intervention	Protocol (details) of Comparison	Follow-up	Outcome measures (+ definitions)	Outcomes of interest	Principal findings	
			Vs 40 cFC-SEMS (flared)		SEMS indwelling time 4-8 months				stricture resolution and to establish the safety, efficacy and cost-effectiveness in this setting.	30% cFC-SEMS (p=ns) Adverse events 11.3% aFC-SEMS 20% cFC-SEMS (p=ns) **Reduction in recurrence of cholangitis:** NA **Need for redo liver transplantation:** 1 re-trasplantation due to autoimmune hepatitis recurrence **Bilio-enteric surgical anastomosis:** NA	Naïve patients had less migration rate and higher stricture resolution rate than patients previously treated with plastic stents	during the study period.

Abbreviations
ABS: Anastomotic Biliary Stricture; aFC-SEMS: Antimigration Fully Covered Self-Expandable Metal Stent; cFC-SEMS: Conventional Fully Covered Self-Expandable Metal Stent; MPS: Multiple Plastic Stents; NA: Not Applicable / Not Addressed; SC: Single-Centre; R: Retrospective;

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Author (year)	Methods		Population			Intervention			Outcomes			Remarks
	Design		N	Age	Inclusion criteria	Protocol (details) of Intervention	Protocol (details) of Comparison	Follow-up	Outcome measures (+ definitions)	Outcomes of interest	Principal findings	
MPS with stents exchange and increment Vs MPS with stent addition to dilate anastomotic biliary strictures (ABS) after liver transplantation												
Barakat M (2018)	Cohort Study (2 arms) SC	R	77 45 MPS with stent exchange and increment Vs 32 MPS with stent addition	Mean age 62 and 56 years	Patients who underwent Orthotopic Liver Transplantation complicated by development of an ABS were included. None of the patients had undergone prior endotherapy for ABS management	MPS with stent exchange and insertion of an increased number of plastic stents	MPS with stent addition (without removal of previous stents)	Minimum 6 months (range 7-88)	Stricture resolution Adverse events Fluoroscopy time Procedure time Costs	**Stricture resolution:** all the cases Stricture recurrence: 2/45 (4.4%) MPS exchange 1/32 (3.1%) MPS addition **Reduction in recurrence of cholangitis:** 1.4% MPS exchange 0% MPS addition Fluoroscopy time 3.4 min MPS exchange 1.2 min MPS addition (p<0.001) (64.5% less) Procedure time 29.3 min MPS exchange 17.1 min MPS addition (p<0.001) (42.8% less) Costs 759 USD, MPS exchange 274 USD, MPS addition (p<0.001) (63.8% less) **Need for redo liver transplantation:** NA **Bilio-enteric surgical anastomosis:** NA	Sequential stent addition in MPS protocol significantly reduced procedure time, fluoroscopy time, costs (less devices per procedure) Stricture resolution was obtained in all the cases with both protocols Stricture recurrence was <5% in both cases The rate of infective complication was absent in the sequential addition strategy	Short follow-up period. Retrospective study
Abbreviations ABS: Anastomotic Biliary Stricture; MPS: Multiple Plastic Stents; NA: Not Applicable / Not Addressed; SC: Single-Centre; R: Retrospective;												

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4.4s: Benign biliary stricture after liver transplantation: How to attempt stricture calibration treatment for NON-anastomotic stricture / biliary cast syndrome?

Author (year)	Methods		Population			Intervention			Outcomes			Remarks
	Design		N	Age	Inclusion criteria	Protocol (details) of Intervention	Protocol (details) of Comparison	Follow-up	Outcome measures (+ definitions)	Outcomes of interest	Principal findings	
Rizk et al 1998 (Old study, not included in the text)	Cohort Study SC	R	12	Median 46.3	Biliary strictures after liver transplantation treated by ERCP were identified: cholestatic liver chemistry pattern in nine patients (75%), bacteremic cholangitis in two (17.0%), and a stricture on T-tube cholangiogram in one (8%)	During ERCP, 4 or 6 mm dilating balloons (Maxforce; Microvasive Inc., Natick, Mass.) were used. After dilation, 10F or 11.5F stents (Wilson-Cook Inc., Winston-Salem, N.C.) were positioned across the stricture. Strictures were stented for at least 8 weeks and then re-evaluated by a scheduled follow-up ERCP	NA	35.7mo	Therapy was defined as successful if a patient did not require stenting or balloon dilation for 360 consecutive days	**Stricture resolution**: 16% Reduction in recurrence of cholangitis: NA **Need for redo liver transplantation**: 0 **Bilio-enteric surgical anastomosis**: 0	Donor hepatic duct strictures required significantly longer therapy than anastomotic strictures (median days 185 versus 67, *p* 5 0.02). Twenty-two months after the first endoscopic treatment, 73% of the donor hepatic duct stricture group were stent free compared with 90% of the anastomotic group (*p* = 0.02)	

Author (year)	Methods		Population			Intervention			Outcomes			Remarks
	Design		N	Age	Inclusion criteria	Protocol (details) of Intervention	Protocol (details) of Comparison	Follow-up	Outcome measures (+ definitions)	Outcomes of interest	Principal findings	
Graziadei et al 2006	Cohort Study SC	P	19	Mean 51y	Biliary strictures were suspected in liver transplant recipients who presented with either elevated cholestatic liver enzymes and/or sonographic evidence of a dilated biliary system. Presence of strictures was confirmed by ERC. A significant biliary stenosis was defined as an abrupt luminal narrowing with proximal ductal dilatation	Biliary strictures were dilated with 4-, 8- or 10-m diameter balloons. In case of persistence or early recurrence of stricture after balloon-dilatation or in the presence of a bile leak, 7-10 Fr plastic stents were placed across the stricture. If feasible, a second stent was placed alongside the first. After approximately 3 months (sooner if the patients developed cholangitis), at a second ERC, stents were extracted, the strictures were dilated, and 1 or 2 stents were inserted. Again, after about 3 months, this sequence was repeated until the strictures were resolved. In cases of choledocholithiasis, biliary stones were removed by using a basket and/or a standard retrieval balloon	NA	Median 40.2mo (also ABS included)	the long-term efficacy and safety of endoscopic treatment of NAS and AS in liver transplant patients, and to evaluate whether LT patients endoscopically treated for biliary strictures have reduced patient or graft survival compared to patients who did not develop biliary strictures. **Definition:** Successful long-term treatment of biliary strictures: complete resolution of clinical symptoms, such as pruritus, normalization of cholestatic liver enzymes (excluding elevated liver enzymes due to other causes), and normal sonographic findings in association with a cholangiogram without significant strictures and bile flow impairment and no subsequent requirement for interventional procedures	**Stricture resolution:** 4/19 (21%) **Reduction in recurrence of cholangitis**: 12/19 (63%) **Need for redo liver transplantation**: 4 patients **Bilio-enteric surgical anastomosis**: 3 patients	Patients with NAS required a longer duration and higher frequency of endoscopic treatment, and significant clinical improvement could be achieved in the majority of patients	

Author (year)	Methods		Population			Intervention			Outcomes			Remarks
	Design		N	Age	Inclusion criteria	Protocol (details) of Intervention	Protocol (details) of Comparison	Follow-up	Outcome measures (+ definitions)	Outcomes of interest	Principal findings	
Tabibian et al 2009	Cohort Study SC	R	15	59 y median	Fifteen patients who were diagnosed with post-OLT NAS between January 2003 and June 2007	During the initial ERCP, usually only 1 stent was placed across an NAS; during subsequent ERCPs, progressive dilation and insertion of maximal or multiple stents was performed as allowed by stricture tightness and rigidity. In cases of hilar and intrahepatic NAS, as were seen in 10 of 15 patients, because multiple stents were deployed in various ducts, not every strictured duct had a maximal number of stents at all times (because of CBD or hepatic- duct caliber restrictions). When only 1 or 2 stents were in place, ERCP was performed at 3-month intervals or as clinically indicated	NA	Median 12 months	This protocol was followed until endoscopic treatment success was achieved, as defined by (1) improvement or normalization of cholangiographic appearance, with good biliary drainage, (2) reduction in alkaline phosphatase and serum total bilirubin levels to normal or near normal, with good graft function, and (3) relief of cholestatic symptoms, such as jaundice and pruritus. When a patient continued to have worsening cholestatic signs or symptoms because of biliary obstruction, despite this treatment protocol, for more than 3 to 4 weeks, the patient was considered an endoscopic treatment failure and was referred for retransplantation.	**Stricture resolution**: 9/15=60% **Reduction in recurrence of cholangitis**: na **Need for redo liver transplantation**: 2 **Bilio-enteric surgical anastomosis**: na	Endoscopic treatment of NAS with multiple stenting appeared to be effective and safe, required relatively few ERCPs, and was seldom associated with cholangiographic, biochemical, or symptomatic recurrence.	
Barbaro et al. 2021	Cohort Study SC	R	24	Median 52y	All patients who underwent ERCP	Extraction of stones/sludge/casts	NA	median 70.3 months	**The primary outcome** was the endoscopic treatment success.	**Stricture resolution**: 12/24 (50%)	1 patient developed stricture recurrence 5 years after completion of treatment. This	

Author (year)	Methods		Population			Intervention			Outcomes			Remarks
	Design		N	Age	Inclusion criteria	Protocol (details) of Intervention	Protocol (details) of Comparison	Follow-up	Outcome measures (+ definitions)	Outcomes of interest	Principal findings	
					between 1/1997 and 12/2015 for biliary complications following deceased donor liver transplantation Non-anastomotic strictures were defined as strictures located at least 5 mm proximal to the anastomosis and were identified by T-tube cholangiography, MRC, or ERCP	above the NAS, was attempted during the index treatment using Dormia baskets or Fogarty balloons; if bile ducts cleaning was not possible it was completed during subsequent ERCPs after dilation of the stricture. Insertion of the maximum number of plastic stents (7, 8.5, 10 Fr), according to stricture tightness and size of the bile ducts above and below the stricture. Planned endoscopic re-evaluation after 3 months (stent removal, cholangiography to assess stricture morphology, extraction of sludge/casts when needed, and reinsertion of an increased number of stents if possible)			**Secondary outcomes** were the technical success, the short and long-term safety, and the analysis of the predictive factors associated with endoscopic treatment failure. Endoscopic treatment success was defined as resolution of the stricture demonstrated by cholangiography at the end of the protocol intended as stent removal, with relief of biliary obstruction symptoms (itching, cholangitis). Long-term endoscopic treatment success was defined as persistence of the resolution of the biliary stricture with sustained improvement of LFTs without episodes of cholangitis for at least 2 years	**Reduction in recurrence of cholangitis**: 50% **Need for redo liver transplantation**: 4 patients **Bilio-enteric surgical anastomosis: NA**	patient underwent successful retreatment with four sessions of ERCP during a 1-year period. Endoscopic treatment of NAS is unsatisfactory. However, patients who respond to endoscopic treatment maintain the response over time. Prompt treatment of acute cholangitis due to stents occlusion is advised in these patients to avoid high mortality rates	
Lemmers A 2021	Cohort Study SC	R	14		Patients with biliary cast syndrome undergoing endoscopic therapy	Biliary cast removal by ERCP.	NA	58 months (median)	Primary outcome: evaluate the accuracy of standard diagnosis criteria of Bile Cast Syndrome based	**Stricture resolution:**	Complete cast extraction in 12/14 patients (85.7%)	

Author (year)	Methods		Population			Intervention			Outcomes			Remarks
	Design		N	Age	Inclusion criteria	Protocol (details) of Intervention	Protocol (details) of Comparison	Follow-up	Outcome measures (+ definitions)	Outcomes of interest	Principal findings	
						In case of concomitant NAS or NAS appeared during follow-uopmultiple plastic stents were inserted and exchanged every 3-4 months for 1 year or until stricture disappearance			on MRCP when compared with the systematic description of their cholangiogram obtained during ERCP Secondary outcomes included the analysis of stricture resolution, clinical and survival outcomes of endoscopic treatment for patients with Bile Cast Syndrome, and their comparison with outcomes of endoscopic treatment of other biliary complications after liver transplantation (anastomotic strictures and NAS without casts).	**Reduction in recurrence of cholangitis:** **Need for redo liver transplantation:** NA **Bilio-enteric surgical anastomosis:** NA	11 (85%) patients developed NAS during follow-up treated with MPS 10/11 had NAS resolution after a median of 5 ERCPs (4-9) and a mean treatment duration of 12 months (5-19) 6/10 (60%) <u>complete</u> NAS resolution 4/10 NAS recurrence after a median of 14 months (1-84)	
Michael et al 2023	Cohort Study SC	R	35	Median 64	Included were all patients who (I) underwent liver transplantation and (II) developed	The biliary stents placed were plastic stents (Biliary endoprosthesis, type double pigtail, size 7Fr to 10Fr, Optimed,	NA	A total of 287 patients underwent liver transplantatio	Non anastomotic stricture NAS was defined: one or multiple strictures in the biliary tract system not related to the anastomotic region.	**Stricture resolution:** 41% **Reduction in recurrence of**	The median duration of the ERCP-based stent program was 34 months, with a median of 14 performed ERCPs. Casts were extracted in 23 (66%) patients, and bile	Hard to understand the follow-up time

Author (year)	Methods		Population			Intervention			Outcomes			Remarks
	Design		N	Age	Inclusion criteria	Protocol (details) of Intervention	Protocol (details) of Comparison	Follow-up	Outcome measures (+ definitions)	Outcomes of interest	Principal findings	
					NAS (either IBL or ITBL) with (III) subsequent ERCP-based stent program at University Hospital in Frankfurt Germany	Ettlingen, Germany) or metal stents (Nitri-STM Stent, TaeWoong Medical, Gimpo-si, Republic of Korea). Insertion of stents increasing in size and/or number was the aim, with the insertion of up to four stents at one time. The severity of strictures was assessed by the endoscopists performing the procedure into either persisting or resolved biliary strictures. If ERCP showed normalized drainage, the endoscopic stent program was terminated. These patients underwent further clinical and sonographic follow-up every 3–6 months.		n between 2008 to 2016. Of these patients, 40 patients (13.9%) were diagnosed with NAS (ITBL: 32, 11.1%; IBL: 8; 2.2%). Follow-up was ended in May 2020	“ERCP-based stent program” is defined as all endoscopic stenting treatments performed in each patient with NAS after liver transplantation until successful resolution of NAS with removal of all stents, switch to a surgical approach, death, or end of follow-up	**cholangitis:** The most common complications during the ERCP-based stent program were cholangitis in 26 (74%) patients **Need for redo liver transplantation:** NA **Bilio-enteric surgical anastomosis:** n=5, 14%	stones were removed in 20 (57%) patients. Casts (p = 0.01) and bile stones (p = 0.04) were significantly more often extracted in those patients who only underwent endoscopy, but no further multidisciplinary treatment.	
Zhang CC 2023	Cohort Study SC	R	55	51	Nonanastomotic strictures defined as strictures with an involvement of the donor hepatic bile duct up to .5 cm proximal to the biliary	Balloon dilatation (4-6-8 mm) of the stricture and plastic or metal stent insertion at operator discretion	NA	8 years (mean)	Primary endpoint: overall survival Secondary outcome parameters were: recurrence of biliary strictures, procedure-related adverse events, treatment failure Sustained clinical success: absence	Overall survival 13,9 years Treatment failure 45.5% Stricture recurrence: 27.3%	Balloon dilatation in all the patients 43.6 % additional stenting (n= 24) 7/24 SEMS Non-anastomotic strictures	

Author (year)	Methods	Population			Intervention			Outcomes			Remarks
	Design	N	Age	Inclusion criteria	Protocol (details) of Intervention	Protocol (details) of Comparison	Follow-up	Outcome measures (+ definitions)	Outcomes of interest	Principal findings	
				anastomosis and/or intrahepatic biliary strictures	Planned repeated dilatation 4 weeks after the first treatment; from the third treatment dilatations were planned every 8 weeks after until stricture resolution ***(protocol until 2006)*** Planned repeated dilatation 4 weeks after the first treatment; from the third treatment dilatations were planned after 3 and 6 months weeks until stricture resolution ***(protocol after 2006)***			of further endoscopic interventions for 3 months after completion of the initial endoscopic therapy (normalized lab, absence of symptoms (cholangitis or jaundice). Initial technical success was the successful passage of the stricture with a guidewire, followed by endoscopic treatment Primary clinical success: improvement and successful therapy of cholangitis and/or normalization or a decrease of 50% compared with Liver function tests within 7 days of the index ERCP. Assisted clinical success: long-term clinical course of patients without persistent abnormal cholestatic laboratory parameters or cholangitis with an indispensable need for endoscopic treatments	Sustained clinical success 54.5% Initial technical success 72.7% Primary clinical success 69.1% Assisted clinical success: 0% **Stricture resolution:** 54,5% **Reduction in recurrence of cholangitis:** 24.2% cholangitis **Need for redo liver transplantation:** n= 8 (32%) **Bilio-enteric surgical anastomosis:** n=9, (36%)	are more difficult to treat and result in lower success rates compered to anastomotic strictures The scheduled endoscopic treatment of anastomotic and nonanastomotic strictures after liver transplantation is effective and safe, with high success and low adverse event rate	

Abbreviations
SC: Single-Centre; R: Retrospective; P: Prospective; NAS: Non-Anastomotic biliary Stricture; MPS: Multiple Plastic Stents; NA: Not Applicable / Not Addressed;

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4.5s: Benign biliary stricture from chronic pancreatitis: How to attempt stricture calibration treatment?

Author (year)	Methods		Population			Intervention			Outcomes			Remarks
	Design		N	Age	Inclusion criteria	Protocol (details) of Intervention	Protocol (details) of Comparison	Follow-up	Outcome measures (+ definitions)	Outcomes of interest	Principal findings	
Fully Covered SEMS Vs Multiple plastic stents to dilate BBS secondary to Chronic Pancreatitis												
Draganov 2002	Retrospective		9	51.4	BBS Post op-66% CP-31% IDIOPATHIC-3%	Sequential placement of multiple plastic stents	Nil	48 months	CP patients stricture resolution was seen in 44% of patients		Overall, sequential insertion of multiple stents achieved stricture resolution in 18 patients (62%). In BBS secondary to CP ,stricture resolution was seen in 44% of patients	
Pozsar J 2004	Retrospective		29	50.8	BBS secondary to CP	MPS elective stent changing/restenting at 3-month intervals or any time when it was urgently indicated.	NIL	12.9 MONTHS			Eighteen patients (60%) had complete radiologic and sero- logic recovery after a mean of 21.1 months overall stenting time and had a stent free follow-up period for a mean of 12.1 months without recurrence of stricture.	

Author (year)	Methods		Population			Intervention			Outcomes			Remarks
	Design		N	Age	Inclusion criteria	Protocol (details) of Intervention	Protocol (details) of Comparison	Follow-up	Outcome measures (+ definitions)	Outcomes of interest	Principal findings	
Catalano (2004)	Prospective		34 Single plastic (retrospective) 12 MPS		BBS secondary to CP	MPS 12 patients in Group II underwent placement of multiple simultaneous stents at 3-month intervals (single 10F stents added sequentially) over a mean of 14 months	Single plastic The 34 patients had single stent (10F, 7-9 cm) placement, with exchange at 3 to 6 month intervals (1-4 exchanges) over a mean of 21 months.	4.2 (PS) 3.9 (MPS)	Clinical success was measured by comparing biochemical tests of liver function, episodes of cholangitis, and the diameter of the CBD stenosis before and after treatment	Clinical success SPS -24% MPS -92%	The overall clinical success rate in patients treated with a single stent was 24% compared with 92% for those treated with multiple simultaneous stents (8/34 vs. 11/12, respectively; p < 0.01)	
Mahajan et al (2009)		44 Cp: 19 (43%)	53.5 y		The inclusion criteria for enrollment were (1) age 18 years or older and (2) clinical symptoms of biliary obstruction. The exclusion criteria were (1) patients for whom endoscopy was contraindicated, (2) patients with peripheral or hilar strictures, and(3) with suspected malignant strictures	CSEMSs placed were 10 mm in diameter and fully covered	Efficacy and complication rates of CSEMSs in the treatment of BBS	3.8 m after removal SEMS	Stricture resolution and morbidity	Resolution of the BBS: CP: 11/17 (65%) Overall: 34 of 41 patients (83%) after a median postremoval follow-up time of 3.8 months Complications: Placement CP: 2/19 (11%) Overall: 6 (14%) Removal: CP: 1/19 (5%) Overall: 4 (9%) Stents complications: CP: 2/19 (11%) Overall: 4 (9%)	Temporary placement of CSEMSs for BBS may offer an alternative to plastic stenting. Further investigation is required to further assess safety and long-term efficacy	

Author (year)	Methods		Population			Intervention			Outcomes			Remarks
	Design		N	Age	Inclusion criteria	Protocol (details) of Intervention	Protocol (details) of Comparison	Follow-up	Outcome measures (+ definitions)	Outcomes of interest	Principal findings	
Perri et al (2012)	prospective, single-center trial		17	52 y	age 18 years of age and older, (2) symptomatic common bile duct strictures secondary to CP (leading to anicteric cholestasis, cholangitis, or jaundice) that persisted 3 months or more after placement of a single 10F plastic stent, and (3) patients who were unfit for surgery or patient refusal of surgery	Nitinol FCSEMSs 10 mm in diameter. The inner part of the stent is covered by silicone at both ends (3 cm) and by polytetrafluoroethylene (PTFE) in the central part. Stent removal was planned after 6 months (T0). Follow-up was done at 6-month intervals (LFT and telephone interview)	cSEMS UE-SEMSs were placed in the first 7 patients and FE-SEMSs in the latter 10 patients.	24 m	Primary endpoint: resolution rate of CP-related BBS after temporary insertion of FCSEMSs. Secondary endpoints: (1) SEMS removability, (2) normalization of LFT results during stenting period and during long-term followup, and (3) SEMS-related complications Clinical success: disappearance of the stricture after stent removal or spontaneous distal migration without the need for any retreatment during the 24- month follow-up period. Stricture recurrence during follow-up: onset of jaundice, cholangitis, and abnormal LFT results together with cholangiographic evidence of BBS.	The migration rate was 100% for UE-SEMSs and 40% for FE-SEMSs SEMS removal successful in all 6 patients with the stent still correctly in place and in all of the patients with intrabiliary migrated UE-SEMSs. Stricture resolution at the 6-month: 12 (70.6%) UE-SEMS: 3 FE-SEMS: 9 At 12 months of follow-up, persistent asymptomatic BBS resolution with normalization of LFT: UE-SEMS: 43% FE-SEMS: 80% After 24 months, 8 of 15 patients (53%) had normal LFT results Stent-related cholangitis: more frequently observed in patients with UE-SEMSs and shorter stents (40 mm and 50 mm in length), and proximal migration was observed only in patients with UE-SEMSs	Eight patients completed the 24 months of follow-up without stricture recurrence. 2 died without recurrence	

Author (year)	Methods		Population			Intervention			Outcomes			Remarks
	Design		N	Age	Inclusion criteria	Protocol (details) of Intervention	Protocol (details) of Comparison	Follow-up	Outcome measures (+ definitions)	Outcomes of interest	Principal findings	
Deviere et al (2014)	Prospective non randomized study		187 CP: 127	52.5 y	benign biliary strictures	received FCSEMS Removal was scheduled at 10-12 months for chronic pancreatitis	FCSEMS	20.4 m	Primary outcome: removal success defined as either (a) scheduled endoscopic stent removal with no removal-related serious adverse events (SAEs) up to 1 mo post removal or (b) spontaneous stent passage without need for immediate restenting. Secondary outcome: stricture resolution, stricture recurrence and stentor removal-related SAEs. Stricture resolution was defined as the absence of stricture requiring restenting at the end of study FCSEMS indwell. Stricture recurrence was the need for restenting of a previously resolved stricture	Removal success CP: 80.5% OLT: 63.4% CCY: 61.1% (p = 0.017) CP migration rates, below 5% through 6 mo. CP Stricture resolution 90.5% Overal stricture resolution: 90.1% Stent- or removal-related serious adverse events: CP: 28 (22%) Overall: 51 (27.3%) The overall rate of recurrence over this period was 14.8% .Low recurrence in CP (18 months): 10,5%	In a large prospective multinational study, removal success of FCSEMS after extended indwell and stricture resolution were achieved for approximately 75% of patients.	
Saxena et al (2015)	Retrospective		123 CP: 30	62 y	Patients with BBS [biliary calculi (BC), CP,	FCSEMSs in BBS	FCSEMSs were placed as first-line treatment in some patients with a new	18.5 m	Stricture resolution and adverse events	stricture resolution: CP: 27 (90%) Overall: 88 (81 %)	Majority of BBS can be successfully managed with 1–2 consecutive FCSEMS with stent dwell time of 6 months.	

Author (year)	Methods		Population			Intervention			Outcomes			Remarks
	Design		N	Age	Inclusion criteria	Protocol (details) of Intervention	Protocol (details) of Comparison	Follow-up	Outcome measures (+ definitions)	Outcomes of interest	Principal findings	
					orthotopic liver transplant (OLT) anastomosis, PSC, ampullary stenosis (AS), post-surgical, and other indications (		diagnosis of BBS or as second-line treatment in patients who had failed therapy with plastic stents and at the discretion of the endoscopist.		related to ERCP and/or stenting Stricture resolution: presence of at least one of the following criteria: absence of waist at cholangiogram, reduction of proximal duct size and improvement of liver function tests, ability to pass a retrieval balloon through the stricture, and drainage of contrast. Timing of stent removal was at the discretion of the endoscopist Stricture recurrence: abnormalities in liver function tests and the need for re-stenting after initial stricture resolution and a period of stent removal.	success after single FCSEMS: 70 (80 %) success after two FCSEMS sessions: 18 (20 %) Stricture resolution was associated with longer SEMS dwell times (24.4 vs. 13 weeks, p = 0.02). Stricture recurrence: 5 patients (2 in CP) 3 patients required surgery for treatment of refractory strictures. Stent migration (9.7 %) stent occlusion (4.9 %), cholangitis (4.1 %), and pancreatitis (3.3 %). one case of stent fracture during removal, and one stent could not be removed. one death due to cholangitis CP:Stricture recurrence occurred in 4.1 % (5/121) of patients in our study; 2 CP.		
Haapamäki et al (2015)	Prospective, multicenter,		60	53 y	CP-associated BBS	First ERCP: 10 fr stent	Assess the safety and feasibility of cSEMS compared with multiple plastic stents	40 m	Long-term stricture resolution defined by normal liver function tests and	2 years Stricture-free success rate cSEMS: 92% PS: 90%	A 6-month treatment with either six 10-Fr plastic stents or with one 10-mm cSEMS produced good long-term relief	

Author (year)	Methods		Population			Intervention			Outcomes			Remarks
	Design		N	Age	Inclusion criteria	Protocol (details) of Intervention	Protocol (details) of Comparison	Follow-up	Outcome measures (+ definitions)	Outcomes of interest	Principal findings	
	randomized study					Second ERCP: Dilation with an 8-mm balloon before stent placement in both groups. Then 3 PS (then until 6) or cSEMS	PS (n 30) vs FCSEMS (n 28) Clinical follow-up were performed at 6 months and 2 years after stent removal.		abdominal ultrasound. Stent removability after 6 months of stenting.	(P= 0.405). Recurrence: success rates cSEMS: 91% (20/22) PS: 88% (22/25) (P= 1.000). Stent migration: cSEMS: 7% PS: 10% (P= 1.000). Adverse events: cSEMS: 8/28 (29%) PS: 7/30 (23%) (P= 0.767).	of biliary stricture caused by chronic pancreatitis.	
Coté, et al (2016)	Randomized Clinical Trial		112	55 y	benign bile duct stricture located at least 2 cm below the hepatic confluence and coupled with related signs or symptoms	plastic stents group: until stricture resolution, ERCPs were repeated every 3 to 4 months with plastic	PS (n 55) vs FCSEMS (n 57) CP PS (n17)- FCSEMS (n 18)	12 m	Stricture resolution Stricture recurrence. Technical success: was defined as successful	Balloon dilatation during their index ERCP: cSEMS: 14% PS: 80% (*P* < .001) Stricture resolution: cSEMS: 50/54 (92.6%) PS: 41/48 (85.4%)	cSEMS were not inferior to multiple plastic stents after 12 months in achieving stricture resolution. The mean number of ERCPs to achieve resolution was lower for cSEMS (2.14) vs plastic (3.24)	

Author (year)	Methods		Population			Intervention			Outcomes			Remarks
	Design		N	Age	Inclusion criteria	Protocol (details) of Intervention	Protocol (details) of Comparison	Follow-up	Outcome measures (+ definitions)	Outcomes of interest	Principal findings	
						stent up-sizing as needed. cSEMS group: ERCP was performed 6 months after randomization. For those with a persistent stricture at repeat ERCP, the cSEMS was replaced for another 6-month interval.			endoscopic placement and removal of stents. Adverse events: A major or severe adverse event was defined by the need for procedural intervention or hospitalization; all other adverse events were classified as minor.	(*P* < .001) Number of days to resolution based on the Kaplan-Meier method cSEMS: 181 days PS: 225 days (*P* = .006) Number of ERCPs cSEMS mean 2.14 PS mean 3.24 (*P* < .001) Recurrent biliary stricture: cSEMS: 7/50 (14%) PS: 2/41 (4.9%) (*P* = .18) Adverse events: cSEMS: 0.36 PS: 0.23 (*P* = .31) Severe adverse events cSEMS: 0.13 PS: 0.06 (*P* = .72)		
Chaput et al 2016	Prospectively		99 CP 42	55 y	Inclusion criteria were a history of chronic pancreatitis, sustained impairment of liver function tests and a biliary stricture associated with	Consecutive patients presenting with a BBS were considered for temporary placement of FCSEMS	evaluate the efficacy of fully covered self-expandable metal stents (FCSEMS) in BBS.	12 months	Early success rate was defined as the absence of biliary stricture or as a minimal residual anomaly on post-stent ERCP. Secondary outcomes were the final success and	Early success: CP: 94.7% Overall early success: 84.9% Final success: 57/73 (78.1%)	FCSEMS placement is efficient for patients with BBS, in particular for chronic pancreatitis patients. Stent extraction after 6 months indwelling, although generally feasible, may fail in a few cases.	

Author (year)	Methods		Population			Intervention			Outcomes			Rem arks
	Design		N	Age	Inclusion criteria	Protocol (details) of Intervention	Protocol (details) of Comparison	Foll ow-up	Outcome measures (+ definitions)	Outcomes of interest	Principal findings	
					ductal dilation detected by ultrasonography (US), computed tomog- raphy (CT), or magnetic resonance imaging (MRI), with a minimum distance of 2cm between the upper stricture's edge and the lower limit of the main biliary confluence or liver hilum.				stricture recurrence rates as well as procedure-related morbidity.	Recurrence of biliary stricture: 16/73 (21.9%) Less in CP Stenting associated complications were minor: 22 (23.9%) Migration: 23 (25%)		
Ohyama 2017	Prospective		10	56.9	BBS secondary to CP	MPS Multiple plastic stents (7F, 8.5F, and 10F) and increased stents at intervals of 2 or 3 mo. Stents were removed approximately 1	nil		Patients were followed for ≥ 6 mo after therapy, interviewed for cholestasis symptoms, and underwent liver function testing every visit.		Complete stricture dilation after therapy was achieved in six (60.0%) patients.	

Author (year)	Methods	Population			Intervention			Outcomes			Remarks
	Design	N	Age	Inclusion criteria	Protocol (details) of Intervention	Protocol (details) of Comparison	Follow-up	Outcome measures (+ definitions)	Outcomes of interest	Principal findings	
					year after initial stenting.						
Schmidt (2017)	Multicenter, prospective, single-arm study	43 CP: 24	58.3 y	BBS and necessity of stent treatment	cSEMS placed either endoscop- ically or percutaneously	self-expanding nitinol stent-graft that is fully covered end to end with a nonporous, nonbiodegradable membrane made of expanded ePTFE and FEP	15 months after stent removal	Evaluate the safety and efficacy of temporary fcSEMS treatment in patients with BBS. Technical success: safe and successful endoscopic or percutaneous deployment of the fcSEMS	Stent delivery successfully: 100.0% endoscopically (76.7%), percutaneously (23.3%) attempted stent removals successful ly: 100% Complications: no	In the subgroup of patients with CP, Stricture reso- lution: 21/24. In this subgroup, stricture resolution without necessity of further treatment: 16/21 (76.2%). Stent migration: two patients (5.2%) Stricture recurrence during a follow-: 25 (8%)	

Author (year)	Methods		Population			Intervention			Outcomes			Remarks
	Design		N	Age	Inclusion criteria	Protocol (details) of Intervention	Protocol (details) of Comparison	Follow-up	Outcome measures (+ definitions)	Outcomes of interest	Principal findings	
									Clinical success: successful treatment of the stricture upon implant; stent patency; viability of treatment (defined as stricture resolution or improvement with no requirement of re-stenting after fcSEMS removal); and stricture patency/recurrence on follow-up visits. Stent-associated complications.	Stricture resolved (stent fully expanded): 42/43 (97.6%) Stricture resolution upon stent retrieval: 38/ 43 CP stricture resolution: 21/24 Viability of treatment: 30/ 38 (78.9%) Stimated primary patency at nine months: 73.0%	two years post-implant: two patients (one CP) Temporary placement of the fcSEMS is a feasible, safe and effective treatment for BBS. The design of the device used in this study accounts for very low migration rates and facilitates easy stent retrieval, even after it has been in place for up to 11 months.	
Lakhtakia (2020)	Prospective		118	52.1	CP-associated BBSs;	The primary efficacy endpoint for this long-term follow-up study was stricture resolution defined as being stent-free from the time of initial removal (or spontaneous migration)	Total 127 118- 5yrs follow up available	5 years	61.6%- stent free at 5 years	Those who had initial stricture resolution ,77.4% continued to be stent free	In patients with symptomatic BBSs secondary to CP, 5 years after placement of a single FCSEMS intended for 10 to 12 months indwell, more than 60% remained asymptomatic and stent-free with an acceptable safety profile.	

Author (year)	Methods		Population			Intervention			Outcomes			Remarks
	Design		N	Age	Inclusion criteria	Protocol (details) of Intervention	Protocol (details) of Comparison	Follow-up	Outcome measures (+ definitions)	Outcomes of interest	Principal findings	
						without clinical or biochemical signs of biliary obstruction.						
Ramchandani et al (2021)	open-label, multicenter, randomized noninferiority clinical trial		164	52 y	Symptomatic CP-associated BBS	MPS arm had 3 or 4 side-by-side PS stenting procedures during the 12-month treatment period. FCSEMS during 12- month	PS (n 84) vs FCSEMS (n 80)	24 m	Stricture resolution status at 24 months. Numbers of ERCPs Number of stents placed Procedure related serious adverse events	Technical success cSEMS: 98.6% PS: 97.6% Stricture resolution cSEMS: 47/62 (75.8%**)** PS: 54/70 (77.1%) (P .008) Number of ERCPs cSEMS: 2.6 PS: 3.9 (P < .001)	Endotherapy of CP-associated BBS has similar efficacy and safety for 12-month treatment using MPS compared with a single FCSEMS, with FCSEMS requiring fewer ERCPs over 2 years	

Author (year)	Methods	Population			Intervention			Outcomes			Remarks
	Design	N	Age	Inclusion criteria	Protocol (details) of Intervention	Protocol (details) of Comparison	Follow-up	Outcome measures (+ definitions)	Outcomes of interest	Principal findings	
									Median total treatment duration during the study cSEMS: 11.8 months PS: 11.8 months Number of stents placed cSEMS: 1.3 ± .6 PS: 7.0 ± 4.4 (P < .001) Serious adverse events cSEMS: 19 (23.8%) PS: 16 (19.0%) (P .568)		

Abbreviations.
BBS: Benign Biliary Strictures; CP: Chronic pancreatitis; MPS: Multiple plastic stents; FC-SEMS: Fully Covered Self-Expandable Metal Stent; NA: Not Applicable / Not Addressed; RCT: Randomized Controlled Trial; SC: Single-Centre;

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4.6s: Benign biliary stricture from PSC: How to attempt stricture calibration treatment?

Author (year)	Design		Number of patients	Age	**Inclusion criteria**	**Protocol (details) of Intervention**	**Protocol (details) of Comparison**	**Follow-up**	**Outcome measures (+ definitions)**	**Outcome of interest**	Principal findings	Remarks
Lee 1995	Retro	53			Dominant stricture with PSC. 22 Patients Balloon and Stent 31 patients balloon alone					41 of 53 patients (77%) had improvements of their clinical symptoms, liver function tests, or cholangiograms.		
De Wit 1996	Retrospective	25		42Y	25 PSC patients evaluated. Endoscopic stent placement was preceded by standard sphincterotomy in 18 of the 25 patients. Stricture dilation prior to stent placement was performed with 8 mm balloons in 3 patients, with 6F and 7F Soehendra catheters in 3 patients, and with short-term placement ofa nasobiliary drain in another 3 patients.			29 m (2 to 120		endoscopic therapy was technically successful in 21 (84%) of the 25 PSC patients evaluated		

Author (year)	Design		Number of patients	Age	**Inclusion criteria**	**Protocol (details) of Intervention**	**Protocol (details) of Comparison**	**Follow-up**	**Outcome measures (+ definitions)**	**Outcome of interest**	Principal findings	Remarks
Kaya et al (2001)	Retrospective	71		49	Endoscopic balloon dilation alone: 34 Balloon dilation plus stent placement: 37	Stents placed: percutaneously: 19 Endoscopically: 14 using both interventions: 4		Median 24 months	Procedural and clinical data were recorded.	number of intervention-related complications Stent group: 30 Balloon dilatation: 6, (*p* 0.001) incidence of acute cholangitis: more common in the stent group compared to the balloon dilation group. (*p* 0.004) Complications: percutaneous stent placement 23 endoscopic placement 7 (*p* 0.001). Endoscopic stenting group: 7/14 balloon-dilation group: 6/34 (*p* 0.02) no significant difference between the two groups with regards to improving cholestasis. Median number of interventions stent group: 5 balloon-dilation group : 2 (*p* 0.001).	There was no additional obvious benefit from stenting after balloon dilation in the treatment of dominant strictures in PSC patients. Stenting was associated with more complications, and its role after dilation should be assessed in a randomized trial rather than being accepted as routinely indicated in this setting	

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Johnson (2006)	Retrospective	10						20 years			Endoscopic balloon dilation of PSC patients presenting with biliary strictures and cholangitis may have long-term benefit in addition to short-term symptomatic relief.	
Gluck et al (2008)	Retrospective	N of procedures: 317 84 DS and/or deteriorating clinical status		48y	PSC and dominant strictures endoscopic therapy for treatment of dominant strictures and/or deteriorating clinical status: 84	balloon dilation of strictures (with 4 to 8 mm dilators) temporary placement of removable plastic endoprostheses (7 F to 10 F),	Balloon dilatation: 59 Temporary stent: 43	76 months	Actual survival for endoscopically treated patients was compared with predicted survival using the Mayo Clinic natural history model for PSC.	Observed patient survival at years 3 and 4 was significantly higher than that predicted by the Mayo Clinic natural history model for PSC (P = 0.021). Complications: 23/317 procedures performed (7.3%),	Patients with PSC who have a deteriorating clinical course benefited from endoscopic therapy to provide drainage of bile ducts, removal of stones, and/or temporary relief from obstructions, with acceptable procedure-related complications and higher than expected 3-year and 4-year survival	
Gotthardt (2010)	Prospective	96			PSC with dominant stenosis A dominant stenosis was defined as a stenosis of the common duct with a diameter of 1.5 mm or less and/or 1.mm or less of a hepatic	Balloon dilation was repeated at 4-week intervals until success, as assessed by opening of the stenosis on repeat cholangiography		20 years		5 years survival free of liver transplantation rate was 81%, and after 10 years, it was 52%.	Repeated endoscopic balloon dilations of dominant stenoses allow the preservation of a functioning common bile duct for many years.	

Author (year)	Design		Number of patients	Age	**Inclusion criteria**	**Protocol (details) of Intervention**	**Protocol (details) of Comparison**	**Follow-up**	**Outcome measures (+ definitions)**	**Outcome of interest**	Principal findings	Remarks
					duct (within 2 cm of the bifurcation).							
Ponsioen et al (2018)	multicenter, open-label, randomized, 1:1 parallel group trial		80 patients were enrolled, and 65 were randomized during ERCP.	40 y	diagnosis of PSC according to the European Association for Study of the Liver 2009 criteria, were between 18 and 75 years of age, and fulfilled at least 1 of the following 5 criteria sets: (1) serum bilirubin level > 3 times the upper limit of normal (ULN); (2) progression of right upper quadrant pain (RUQP), pruritus, fa- tigue, and/or fever attributed to acute bacterial cholangitis by at least 1 grade according to the Amsterdam Cholestatic Complaints Score (ACCS) within the last month, together with a 50% increase of total bilirubin and/or alkaline phosphatase (ALP) within the last 4	patients were randomized during ERCP when a dominant stricture (DS) was identified to: balloon dilatation or short-term stenting for a maximum of 2 weeks. Stenting: A 10F polyethylene stent was inserted and retrieved after 7 days (maximum time, 14 days) Balloon dilatation: DSs were dilated by placing a 4 cm 6 mm–diameter biliary dilation balloon in the stricture(s).	Dominant stricture was defined as any stricture arising in the extrahepatic or left/right main ducts that was deemed functionally relevant by the treating endoscopist/radiologist.	24 months.	Primary endpoint: cumulative recurrence-free rate of the primary DS(s) within 24 months in those patients who did not experience initial failure. Secondary outcomes: occurrence of procedure- related complications, including serious adverse events (SAEs)	The cumulative recurrence-free rate of the primary DS(s) was equal in both groups (P 1.0) Overall median recurrence-free rate Balloon dilatation: 26 weeks Stenting groups: 34 weeks Initial failure Balloon dilatation: 16 of 31 (52%) Stenting group: 15 of 34 (44%) (P .89). Procedure-Related SAEs: Balloon dilatation: 2 (6.7%) Stenting group: 15 (45.4%) (p.001)	In a multicenter random- ized trial of patients with PSC and a dominant stricture, short- term stents were not superior to balloon dilatation and were associated with a significantly higher occurrence of treatment- related SAEs. Balloon dilatation should be the initial treatment of choice for dominant strictures in patients with PSC. This may be particularly relevant to patients with an intact papilla.	

Author (year)	Design		Number of patients	Age	**Inclusion criteria**	**Protocol (details) of Intervention**	**Protocol (details) of Comparison**	**Follow-up**	**Outcome measures (+ definitions)**	**Outcome of interest**	Principal findings	Remarks
					months and absolute value > 1.2 times the ULN; (3) increase of 20% or more of total bili- rubin and/or ALP within the last 4 months and absolute value > 1.2 times the ULN, together with a documented dominant-appearing stricture on MRCP or ERCP < 4 months before screening; (4) progression of RUQP, pruritus, fatigue, and/or fever attributed to bacterial cholangitis by at least 1 grade within the last month, together with total bilirubin and/or ALP > 1.2 times the ULN and a documented dominant stricture on recent MRCP or ERCP < 4 months before screening; (5) summed cholestatic							

Author (year)	Design		Number of patients	Age	**Inclusion criteria**	**Protocol (details) of Intervention**	**Protocol (details) of Comparison**	**Follow-up**	**Outcome measures (+ definitions)**	**Outcome of interest**	Principal findings	Remarks
					complaints score of ! 3, or pruritus ! 2, or RUQP ! 2 at screening, together with total bilirubin and/or ALP > 1.2 times the ULN and a documented dominant stricture on recent MRCP or ERCP < 4 months before screening. Criteria sets 4 and 5 were added to the eligibility criteria							
Shbeit (2021)	Retrospective		20		PSC patients with refractory DS, defined as strictures resistance to conventional therapy (balloon dilatation, plastic biliary stent insertion or both) and who underwent FCMS insertion for 3 months were included.			1 year	1. primary outcome - clinical and laboratory improvement, 2.Secondary outcomes were DS resolution upon stent removal 3- DS recurrence at 12-months after FCMS extraction.	Improvement in weakness and pruritus were seen in 80% and 35%, 75% and 65%, 75% and 35% of patients at 1-3 and 6 months following FCMS removal, respectively. DS resolution was demonstrated in 13 patients (65%) after stent removal at 3-months, and DS recurred in 4 patients (4/13 = 30.7%) at 12-months following stent removal	Temporary 3 months duration FCMS was feasible, safe and effective treatment option among patients with PSC related refractory DS.	

Author (year)	Design		Number of patients	Age	**Inclusion criteria**	**Protocol (details) of Intervention**	**Protocol (details) of Comparison**	**Follow-up**	**Outcome measures (+ definitions)**	**Outcome of interest**	Principal findings	Remarks
Han (2022)	Retrospective	169			PSC with DS With minimum of 1 year follow up	Dilatation was performed as per protocol and stenting, after balloon dilation was performed, a 7, 8.5, or 10Fr plastic stent was placed. Stents were exchanged or removed at 8-week intervals at the discretion of the endoscopist or if ensuing cholangitis symptoms necessitated earlier intervention.	.	1 year	The primary outcome was liver transplantation-free survival, defined as time from ERCP to receipt of transplantation	A total of 169 patients were included in the final analysis, of which 115 received both balloon dilation and stenting and 54 received balloon dilation alone.	There was no difference in transplant rate in both the arms and no difference in risk for transplantation (dilatation cohort adjusted hazard ratio 0.67, 95% CI (0.33-1.32)	
Dhaliwal (2022)	SRMA	1O studies (1 RCT, 3 comparative studies)	Balloon +stent 95 vs balloon 363		PSC with DS	ERCP with Balloon dilation only or followed by stenting			Pooled clinical success was defined in most studies as improvement in liver enzymes or symptoms such as fever, abdominal pain, pruritus, and fatigue. Pooled technical success was defined as the successful completion of the endoscopic procedure. Pooled	The pooled technical success for balloon dilation was 96.8% (95%CI 92.0-98.7%; I2 =75.9%) compared to 91.9% (95%CI 81.3-96.8%; I2 =40.24%) for balloon plus stent, with P<0.001 The pooled clinical success for balloon dilation was 86.5% (95% confidence interval [CI] 66.6-95.4%; I2 =79.7) compared to 70.8% (95%CI 37.7-90.7%; I2	Better outcome with balloon dilation only: better clinical success and safety	

Author (year)	Design		Number of patients	Age	**Inclusion criteria**	**Protocol (details) of Intervention**	**Protocol (details) of Comparison**	**Follow-up**	**Outcome measures (+ definitions)**	**Outcome of interest**	Principal findings	Remarks
									rate of overall AE and significant procedure-related AE subtypes, such as cholangitis, bleeding, perforation, and post-ERCP pancreatitis (PEP), were defined as complications related directly to the procedure	=79.4%) for balloon plus stent, with P<0.001 The pooled rate of overall AE was 11.2% (95% CI 6.6%-18.4%; I2 =91%) for balloon dilation alone and 26.9% (95%CI 9.6-55.9%; I2 =93%) for balloon plus stent, with P<0.001 The pooled rate of cholangitis was 4.8% (95%CI 1.4-14.8%; I2 =49%) for balloon dilation alone and 11.4% (95%CI 3.7-16.2%; I2 =93%) for balloon plus stent, with P<0.001 The pooled rate of post-procedural PEP was 2.2% (95%CI 0.6-7.4%; I2 =81%) for balloon dilation alone and 9.8% (95%CI 3.1-26.8%; I2 =81.7%) for balloon plus stent, with P<0.001		
Garg (2025)	SRMA	7 studies (1 RCT)	660		PSC with DS	ERCP with balloon dilation vs BD+stenting				Clinical efficacy was 85.5% (95% CI, 15.3-99.5; I^2 = 54%) with EBD and 84.9% (95% CI, 56.6-96.1; I^2 = 73%) with stent placement; relative risk (RR), 1.01 (95% CI, 0.89-1.14; I^2 = 72%; P = .02) Number of interventions 2.7 ± 0.39 with EBD and 6.5 ± 0.01 with stent placement (SD 4.55 ± 1.3 [1.48-6.6); P = .00)	Same efficacy of BD and stenting, less number of interventions with EBD, and trend for more safety using EBD	

Author (year)	Design		Number of patients	Age	**Inclusion criteria**	**Protocol (details) of Intervention**	**Protocol (details) of Comparison**	**Follow-up**	**Outcome measures (+ definitions)**	**Outcome of interest**	Principal findings	Remarks
										Adverse events were 44.5% (95% CI, 23.3%-67.9%; I^2 = 63%) with stent placement compared to the EBD, 15.0% (95% CI, 8.5-15.0; I^2 = 51%); RR, 0.29 (95% CI, 0.14-0.61; P = .10)		

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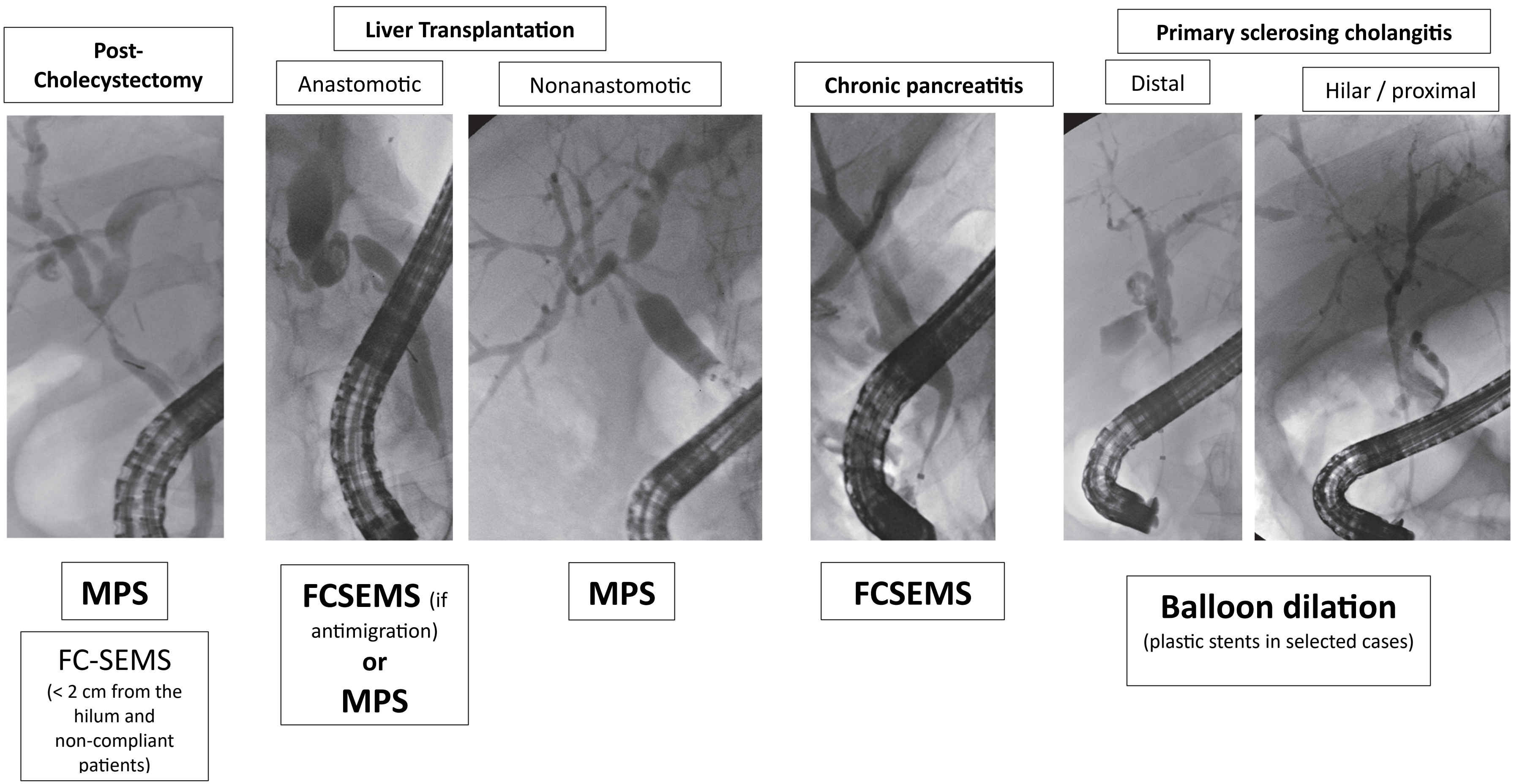
Fig.1s: Stent choice for benign biliary stricture



MPS: Multiple Plastic Stents; FCSEMS Fully Covered-Self Expandable Metal Stents

ndoscopy | DOI 10.1055/a-2921-6492 |

Alternative for ABS

Alternative for NAS

Table 5s: Grade of evidence for TF1: benign biliary stricture

1) **Benign biliary stricture: when to attempt stricture calibration treatment?**
   NO Systematic Review and Meta-analysis

2) **Benign biliary stricture after cholecystectomy: How to attempt stricture calibration treatment?**
   NO Systematic Review and Meta-analysis

3) **Benign biliary stricture after liver transplantation: How to attempt stricture calibration treatment for anastomotic stricture?**
   Grade of Evidence Table 5.1s (see below)

4) **Benign biliary stricture after liver transplantation: How to attempt stricture calibration treatment for NON-anastomotic stricture / biliary cast syndrome?**
   NO Systematic Review and Meta-analysis

5) **Benign biliary stricture from chronic pancreatitis: How to attempt stricture calibration treatment?**
   Grade of Evidence table 5.2s (see below)

6) **Benign biliary stricture from PSC: How to attempt stricture calibration treatment?**
   Grade of Evidence Table 5.3s (see below)

Thieme

Table 5.1s Benign biliary stricture after liver transplantation: How to attempt stricture calibration treatment for anastomotic stricture?

Certainty assessment									Effect estimate	Certainty	Comments
PICO	Ref.	No. of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Publication bias			
FC-SEMS versus MPS	Baraldo S (2025), SRMA	5	RCTs	Low	Yes	No	Yes	No	FC-SEMS were not superior to MPS in terms of ABS resolution and recurrence FC-SEMS are cost effective with a shorter treatment period	⨁◯◯◯ Low	Minority of patients (n=10) with intraductal FC-SEMS

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Table 5.2s Benign biliary stricture after liver transplantation: How to attempt stricture calibration treatment for NON-anastomotic stricture / biliary cast syndrome?

Certainty assessment									Effect estimate	Certainty	Comments
PICO	Ref.	No. of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Publication bias			
Fc-SEMS vs MPS for BS associated to chronic pancreatitis	Sheth (2025), SRMA	3	RCTs	Low	Yes	No	Yes	No	FC-SEMS were not superior to MPS in terms of ABS resolution and recurrence FC-SEMS are cost effective with a shorter treatment period	⨁◯◯◯ Low	Minority of patients (n=10) with intraductal FC-SEMS

Abbreviations.
SEMS: SRMA: Systematic Review and Meta-analysis; RCT: Randomized Clinical Trials; FC-SEMS: Fully Covered Self-Expandable Metal Stents; MPS: Multiple Plastic Stents; BBS: Benign Biliary Strictures;

Sheth SG, Machicado JD, Chhoda A, Chalhoub JM, Forsmark C, Zyromski N, et al. American Society for Gastrointestinal Endoscopy guideline on the role of endoscopy in the management of chronic pancreatitis: methodology and review of evidence. Gastrointest Endosc. 2025;101(1):e1-e53.

Table 5.3s Benign biliary stricture from PSC: How to attempt stricture calibration treatment?

Certainty assessment									Effect estimate	Certainty	Comments
PICO	**Ref.**	**No. of studies**	**Study design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Publication bias**			
Balloon dilatation alone Vs Balloon dilatation + stenting	Dhaliwala AS (2022), MA	10	4 prospective 1 RCT 6retrospective	Moderate	No	Yes	Yes	NA	Better clinical success and safety with EBD	⊕◯◯◯ Low	
	Garg (2025) SRMA	7	1 RCT 6	Moderate	No	Yes	Yes	NA	Same clinical success, less nr procedures with EBD	⊕◯◯◯ Low	

CS: Clinical SuccessMA: Meta-analysis; RCT: Randomized Clinical Trials; SEMS: Self.-Expandable Metal Stents; NA: Nort applicable

Table 6s: TF2: Malignant biliary stricture: literature extraction

Task force 2, Distal malignant biliary stricture, PICOs subdivided (see last column)

2.1 preoperative drainage (n=4)

2.1.1 FCSEMS vs UCSEMS
2.1.2 PCSEMS vs UCSEMS
2.1.3 PS vs UCSEMS
2.1.4 No drainage vs UCSEMS
2.1.5 EUS-BD LAMS vs UCSEMS

2.2 neoadjuvant drainage (n=5)

2.2.1 FCSEMS vs UCSEMS
2.2.2 PCSEMS vs UCSEMS
2.2.3 PS vs UCSEMS
2.2.4 No drainage vs UCSEMS
2.2.5 EUS-BD LAMS vs UCSEMS

2.3 palliative drainage (n=9; 1 meta-analysis)

2.3.1 FCSEMS vs UCSEMS
2.3.2 PCSEMS vs UCSEMS
2.3.3 PS vs UCSEMS
2.3.4 No drainage vs UCSEMS

2.3.5 EUS-BD LAMS vs UCSEMS (5 studies; 2 meta-analyses)

Table 6.1s: Distal malignant biliary stricture: preoperative drainage (PICO 2.1.1/2.1.2/2.1.3)

Author (year)	Methods	Population			Intervention			Outcomes			Remarks
	Design	N	Age, years	Inclusion criteria	Protocol (details) of Intervention	Protocol (details) of Comparison	Mean or Median Follow-up	Outcome measures (+ definitions)	Outcomes of interest	Principal findings	
SEMS vs PS, preoperative drainage: PICO 2.1.1/2.1.2/2.1.3											
Lee (2019)	Prospective	102	NA	MBO, periampullary	ERCP + modified FCSEMS (saddle like shape; M-FCSEMS, 50)	ERCP + C-FCSEMS (52)	NA	TS CS (≥ 50% bili reduction <1 week of stenting) Stent migration Stent occlusion rate Stent patency Reintervention AEs	TS, M-FCSEMS vs C-FCSEMS: 100% vs 100%, P=1.00 CS: 96% vs 94.2%, P=1.00 Stent migration: 8.0% vs 23.1%, P=0.036 Stent occlusion: 23.9% vs 37.5%, P=0.171 Stent patency: 228 vs 157d, P=0.048 Reintervention: 32.0% vs 53.8%, P=0.026 AEs: 10.0% vs 15.4%, P=0.415	Modified FCSEMS with 12-mm diameter and anti-migration feature significantly decreased the risk of stent migration and had longer patency compared with C-FCSEMS in patients with periampullary MBS	PICO 2.1.1 PICO 2.2.1 PICO 2.3.1
Jang (2022)	Retrospective	1,739	NA	MBO	ERCP + SEMS (904)	ERCP + PS (835)	NA	TS CS (33% bili reduction <7d, or symptom resolution) Reintervention Stent occlusion Stent migration AEs	TS, SEMS vs PS: 99.2% vs 99.4%, P=0.659 CS: 94.1% vs 87.4%, P <0.001 Reintervention: 17.1% vs 27.4%, P<0.001 Time to reintervention: 216 vs 25d, P<0.001 Stent occlusion: 14.5% vs 23.1%, P<0.001 Stent migration: 5.1% vs 17.5%, P<0.001 Cholangitis: 2.4% vs 6.9%, P <.001 Pancreatitis: 6.0% vs 3.6%, P=0.021	Given superior efficacy, durability and lower rates of cholangitis, SEMS should be offered as the first line endoscopic treatment option for malignant distal biliary stricture.	PICO 2.1.3 PICO 2.2.3 PICO 2.3.3 FCSEMS/UCSEMS combined
Lee (2019)	Retrospective, matched	85	NA	MBO, preoperative	ERCP + non-flared modified FCSEMS (M-FCSEMS, 29)	ERCP + PS (29)	NA	TS Time to surgery Reintervention before surgery AEs	TS, M-FCSEMS vs PS: 100% vs 100%, P=1.00 Time to surgery: 18.6 ± 10.8d vs 19.3 ± 11.6d; P=0.843 Reintervention: 0.0% vs 20.7%, P=0.023 ERCP-related AEs: 6.9% vs 27.6%, P=0.037	Modified FCSEMS led to lower PBD-related AEs, re-intervention rate, and comparable perioperative AEs compared with PS	PICO 2.1.1
Shamah (2019)	Retrospective	278	67	MBO	ERCP + 8-10mm PCSEMS (213)	ERCP + 8-10mm UCSEMS (65)	Until death or 100d	CS (bilirubin >33% <1wk or >50% <4wk reduction) Stent patency AEs	CS, PCSEMS vs UCSEMS: 98.1% vs 95.5%, P=0.36 Stent patency: 302.5 vs 225.5 d, P=0.72 AEs: 15.5% vs 18.5%, P=0.65 Stent diameter no impact on CS (98.9% vs 95.3%, P = 0.11) or patency duration (239d vs 336d, P = 0.51).	Comparison of PCSEMS vs USEMS and 8 mm versus 10 mm showed no difference in clinical efficacy or AEs between two SEMS coatings and diameter, illustrating that coating and size do not matter in regard to stent choice, despite prior suggestive data	PICO 2.1.2 PICO 2.2.2 PICO 2.3.2

Abbreviations: AEs: Adverse Events; CS: Clinical Success; dMBO: distal Malignant Biliary Obstruction; DO: Duodenal Obstruction; EUS-BD: EUS-guided Biliary Drainage; EUS-CDS: EUS-Choledochoduodenostomy; EUS-HGS: EUS-guided Hepaticogastrostomy; EUS-GBD: EUS-guided Gallbladder Drainage; EUS-RV: EUS-guided Rendez-Vous; HJ: Hepaticojejunostomy; LAMS: Lumen-Apposing Metal Stent; LoHS: Length of Hospital Stay; MC: Multi-Centre; NA: Not Available / Not Applicable; P: Prospective; PTBD: Percutaneous Transhepatic Biliary Drainage; QoL: Quality of Life; R: Retrospective; RBO: Recurrent Biliary Obstruction: TRBO: time to RBO; SAA: Surgically-Altered Anatomy; SEMS: Self-Expandable Metal Stent; SC: Single-Centre; SRMA: Systematic Review and Metanalysis; TS: Technical Success;

Table 6.2s: Distal malignant biliary stricture: neoadjuvant drainage (PICO 2.2.1/2.2.2/2.2.3)

Author (year)	Methods	Population			Intervention			Outcomes			Remarks
	Design	N	Age, years	Inclusion criteria	Protocol (details) of Intervention	Protocol (details) of Comparison	Mean or Median Follow-up	Outcome measures (+ definitions)	Outcomes of interest	Principal findings	
SEMS vs PS, neoadjuvant drainage: PICO 2.2.1/2.2.2/2.2.3											
Tamura (2021)	RCT	22	67	BRPC + MBO, neoadjuvant Rx	ERCP + FCSEMS (11)	ERCP + PS (11)	Until curative intent surgery or BRPC	Stent dysfunction (jaundice/cholangitis) TS Stent patency Stent migration Reinterventions AEs	Stent dysfunction, FC vs PS: 18.2% vs. 72.8%, P=0.015 Stent occlusion: 9.1% vs 72.8%, P=0.015 Stent migration: 9.1% vs 0.0%, P=0.015 N of re-intervention: 0.27 ± 0.65 vs 1.27 ± 1.1, P=0.001 AEs: 18.2% vs 63.6%, P=0.08 Cholangitis: 9.1% vs 63.6%, P=0.024 Medical costs: not different	In patients with BRPC for preoperative biliary drainage, stent dysfunction occurred less frequently with FCSEMSs than with PSs. In addition, FCSEMS and PS provided similar preoperative management of BRPC in terms of the safety of surgery and medical costs	PICO 2.2.1
Seo (2019)	RCT	119	66	MBO, neoadjuvant Rx	ERCP + FCSEMS (59)	ERCP + UCSEMS (60)	Until curative intent surgery or 1 yr	Sustained biliary drainage (no reintervention) Technical success NAtx not completed Stent migration SAEs	Sustained biliary drainage, FC vs UCSEMS: 72.2% vs 72.9%, non-inferiority P=0.01 TS: 98.3% vs 100%, P=0.50 NAtx not completed: 18.2% vs 28.8%, P=0.25 Stent migration: 6.8% vs 0%, P=0.03 SAEs: 23.7% vs 20%, P=0.66	FCSEMSs and UCSEMSs provide similar preoperative management of biliary obstruction in patients with pancreatic cancer receiving NATx, but mechanisms of stent dysfunction depend on stent type, stent length, and presence of the gallbladder	PICO 2.2.1
Lee (2019)	Prospective	102	NA	MBO, periampullary	ERCP + modified FCSEMS (saddle like shape; M-FCSEMS, 50)	ERCP + C-FCSEMS (52)	NA	TS CS (≥ 50% bili reduction <1 week of stenting) Stent migration Stent occlusion rate Stent patency Reintervention AEs	TS, M-FCSEMS vs C-FCSEMS: 100% vs 100%, P=1.00 CS: 96% vs 94.2%, P=1.00 Stent migration: 8.0% vs 23.1%, P=0.036 Stent occlusion: 23.9% vs 37.5%, P=0.171 Stent patency: 228 vs 157d, P=0.048 Reintervention: 32.0% vs 53.8%, P=0.026 AEs: 10.0% vs 15.4%, P=0.415	Modified FCSEMS with 12-mm diameter and anti-migration feature significantly decreased the risk of stent migration and had longer patency compared with C-FCSEMS in patients with periampullary MBS	PICO 2.1.1 PICO 2.2.1 PICO 2.3.1
Jang (2022)	Retrospective	1,739	NA	MBO	ERCP + SEMS (904)	ERCP + PS (835)	NA	TS CS (33% bili reduction <7d, or symptom resolution) Reintervention Stent occlusion Stent migration AEs	TS, SEMS vs PS: 99.2% vs 99.4%, P=0.659 CS: 94.1% vs 87.4%, P <0.001 Reintervention: 17.1% vs 27.4%, P<0.001 Time to reintervention: 216 vs 25d, P<0.001 Stent occlusion: 14.5% vs 23.1%, P<0.001 Stent migration: 5.1% vs 17.5%, P<0.001 Cholangitis: 2.4% vs 6.9%, P <.001 Pancreatitis: 6.0% vs 3.6%, P=0.021	Given superior efficacy, durability and lower rates of cholangitis, SEMS should be offered as the first line endoscopic treatment option for malignant distal biliary stricture.	PICO 2.1.3 PICO 2.2.3 PICO 2.3.3 FCSEMS/UCSEMS combined

Shamah (2019)	Retrospective	278	67	MBO	ERCP + 8-10mm PCSEMS (213)	ERCP + 8-10mm UCSEMS (65)	Until death or 100d	CS (bilirubin >33% <1wk or >50% <4wk reduction) Stent patency AEs	CS, PCSEMS vs UCSEMS: 98.1% vs 95.5%, P=0.36 Stent patency: 302.5 vs 225.5 d, P=0.72 AEs: 15.5% vs 18.5%, P=0.65 Stent diameter no impact on CS (98.9% vs 95.3%, P = 0.11) or patency duration (239d vs 336d, P = 0.51).	Comparison of PCSEMS vs USEMS and 8 mm versus 10 mm showed no difference in clinical efficacy or AEs between two SEMS coatings and diameter, illustrating that coating and size do not matter in regard to stent choice, despite prior suggestive data	PICO 2.1.2 PICO 2.2.2 PICO 2.3.2

Table 6.3s: Distal malignant biliary stricture: palliative drainage (PICO: 2.3.1/2.3.2/2.3.3)

Author (year)	Methods	Population			Intervention			Outcomes			Remarks
	Design	N	Age, years	Inclusion criteria	Protocol (details) of Intervention	Protocol (details) of Comparison	Mean or Median Follow-up	Outcome measures (+ definitions)	Outcomes of interest	Principal findings	
SEMS vs PS, palliative drainage: PICO 2.3.1/2.3.2/2.3.3											
Vanella (2024)	Meta-analysis	62 studies	NA	MBO, palliative	ERCP + FCSEMS (3,327)	ERCP + PCSEMS (2,322)	NA	AEs Recurrent biliary obstruction (RBO) Time to RBO (TRBO)	AEs, FC vs PCSEMS: 12% vs 9.9%; d-value: 0.067 Subanalysis of prospective studies and unresectable diseases: RBO: 27.3% vs. 25.3%; d-value: 0.056 TRBO: 238 vs. 36d; d-value: 0.116 Stent migration: 9.8% vs 4.3%, d-value=0.216	Despite considerable heterogeneity and small standardized differences, PC-SEMSs consistently exhibited longer TRBO than FC-SEMSs across analyses, without any other differences in AE rates, potentially proposing PC-SEMSs as standard comparator and TRBO as primary outcome for future randomized studies on dMBO.	PICO 2.3.1 Preplanned sensitivity analyses
Bernon (2018)	RCT	40	68	MBO, palliative	ERCP + 10Fr UCSEMS (21)	ERCP + 10Fr plastic stent (19)	Until death or 12 mo	Stent failure Survival Re-intervention SAEs	Stent failure, SEMS vs PS: 4.7% vs. 38.8%; P=0.043 Survival: 114 vs 107d, P=0.18 SAE rate: not significantly different	SEMS had longer duration of patency than plastic stents, which recommends their use in the palliative treatment of patients with biliary obstruction due to distal malignant biliary obstruction.	PICO 2.3.3
Conio (2018)	RCT	158	77.5-80	MBO, palliative	ERCP + UCSEMS Niti-S D-type (80)	ERCP + FCSEMS Niti-S biliary ComVi (78)	Until death or 6 mo	Stent patency (from time of stent insertion to time of biliary reintervention due to stent dysfunction or EOF) Survival AEs	TS, FCSEMS vs UCSEMS: 100% vs 100%, P=1.00 Stent patency: 240d vs 541d; P=0.031 Bilirubin improvement: not significantly different Median survival: 134 vs 112d, P=0.23 AEs: 26.4% 13.2%; P=0.061	No significant differences in bilirubin improvement and overall survival between FCSEMSs and USEMSs; higher stent-related AE rate in FCSEMSs. FCSEMSs had a significantly higher migration rate and decreased patency rate compared with USEMSs. USEMSs preferable to FCSEMSs Niti-S stent	PICO 2.3.1
Lee (2017)	Open label RCT	71	66.6	MBO, palliative	ERCP + double bare UCSEMS (DBS, 24)	ERCP + single bare UCSEMS (SBSs; S&G Biotech, 24) ERCP + single bare UCSEMS (SBSt; Taewoong, 23)	Until death or 2015	TS Stent patency duration Stent migration Overall survival Early (<1wk) or late AEs	TS, DBS vs SBSs vs SBSt: 100% vs 100% vs 100%, P=1.00 Stent patency: 212d (±152) DBS vs 124d (±98) SBSs (P=0.02 for noninferior); 116d (±79) SBSt vs DBS (P = 0.010 for noninferior). Stent occlusion: 8.3% vs 45.8% vs 43.5%, P=0.008 Stent migration: 0% vs 4.2% vs 0.0%, P=NS Overall survival: 217 vs 158 vs 180d, P=0.502 Early AEs: 16.7 vs 16.7 vs 8.7%, P=NS	The newly developed DBS is noninferior to the conventional uncovered SEMSs on duration of stent patency and tumor ingrowth occurred less frequently in the DBS group	PICO 2.3.x Large 95%CI

									Late AEs: 4.2 vs 16.7 vs 21.7%, P=0.348		
Lee (2019)	Prospective	102	NA	MBO, periampullary	ERCP + modified FCSEMS (saddle like shape; M-FCSEMS, 50)	ERCP + C-FCSEMS (52)	NA	TS CS (≥ 50% bili reduction <1 week of stenting) Stent migration Stent occlusion rate Stent patency duration Reintervention AEs	TS, M-FCSEMS vs C-FCSEMS: 100% vs 100%, P=1.00 CS: 96% vs 94.2%, P=1.00 Stent migration: 8.0% vs 23.1%, P=0.036 Stent occlusion: 23.9% vs 37.5%, P=0.171 Stent patency duration: 228 vs 157d, P=0.048 Reintervention: 32.0% vs 53.8%, P=0.026 AEs: 10.0% vs 15.4%, P=0.415	Modified FCSEMS with 12-mm diameter and anti-migration feature significantly decreased the risk of stent migration and had longer patency compared with C-FCSEMS in patients with periampullary MBS	PICO 2.1.1 PICO 2.2.1 PICO 2.3.1
Kogure (2018)	Retrospective/ prospective	292	72-74	MBO, palliative	ERCP + FCSEMS Wallflex (151)	ERCP + PCSEMS Wallflex (141)	Until death or March 2013	TS Recurrent biliary obstruction (RBO) Stent occlusion Stent migration Overall survival AEs	TS, FCSEMS vs PCSEMS: 100% vs 100%, P=1.00 RBO: 28% vs. 33%; P=0.378 TRBO: 318 vs. 373d; P=0.382 Stent occlusion: 15% vs 26%, P=0.027 Stent migration: 14 vs. 8%; P=0.113 Overall survival: 229 vs. 196d; P=0.177 Early AEs: 14% vs 17%, P=0.518 Late AEs: 1% vs 4%, P=0.059	FCSEMSs appeared comparable to PCSEMSs in terms of RBO without a significant increase in stent migration rate in patients with unresectable distal MBO	PICO 2.3.1
Kulpatcharapong (2024)	Retrospective (Propensity-Score Matching)	114	65-67	MBO, palliative	ERCP + multi-hole SEMS (MHSEMS, 40)	ERCP + FCSEMS (40) ERCP + UCSEMS (34)	NA	CS (≥ 50% reduction or total bilirubin normalization < 2wks) (Time) to recurrent biliary obstruction (TRBO) Stent migration AEs	CS, MHSEMS vs FCSEMS vs UCSEMS: 95% vs 95% vs 97%, P=0.886 RBO: 21% vs 37% vs 55%, P=0.014 TRBO: 479 vs 353 vs 306d, P=0.005 Stent migration: 2.6% vs 15.8%, P=0.047 AEs: 20% vs 30% vs 14.7%, P=0.266	MHSEMS provided the longest stent patency time with lowest RBO rate compared to conventional SEMS by showing a lower stent migration rate than FCSEMS and a lower tumor ingrowth rate than UCSEMS.	PICO 2.3.1
Jang (2021)	Retrospective	9,728	65	MBO, palliative	ERCP + PS (5,147)	ERCP +SEMS (2,264) Nasobiliary drain followed by PS (1,084) or SEMS (808)	NA	Stent patency N of ERCP or PTBD sessions Post-ERCP pancreatitis (PEP)	Stent patency, PS vs SEMS: 36 vs 37d, P=0.60 N of ERCP or PTBD sessions: 2.2±1.7 vs 1.8±1.4, P<0.0001 PEP: 0.0% vs 0.1%, P=0.10	Initial metal stenting is associated with fewer ERCP or PTBD sessions after initial procedures, which contrasts with the preference for initial plastic stenting in Korea.	PICO 2.3.1 PICO 2.3.2 PICO 2.3.3 Stent type? Health Insurance Review
Shamah (2019)	Retrospective	278	67	MBO	ERCP + 8-10mm PCSEMS (213)	ERCP + 8-10mm UCSEMS (65)	Until death or 100d	CS (bilirubin >33% <1wk or >50% <4wk reduction) Stent patency AEs	CS, PCSEMS vs UCSEMS: 98.1% vs 95.5%, P=0.36 Stent patency: 302.5 vs 225.5 d, P=0.72 AEs: 15.5% vs 18.5%, P=0.65 Stent diameter no impact on CS (98.9% vs 95.3%, P = 0.11) or patency duration (239d vs 336d, P = 0.51).	Comparison of PCSEMS vs USEMS and 8 mm versus 10 mm showed no difference in clinical efficacy or AEs between two SEMS coatings and diameter, illustrating that coating and size do not matter in regard to stent choice, despite prior suggestive data	PICO 2.1.2 PICO 2.2.2 PICO 2.3.2
Budzynska (2018)	Retrospective	114	69.3	MBO, palliative	ERCP + UCSEMS or PCSEMS (20 one-step and 14 two-step SEMS)	ERCP + 10Fr PS (80)	NA	TS Functional success (contrast drainage + decreasing bilirubin) Stent dysfunction	TS, UCSEMS vs PS: 100% vs 100%, P=0.10 Functional success: 99.7% vs 97.6%, P=0.06 Stent dysfunction: 54.9 vs. 38.6%, P=0.008 Stent migration: 9.9 vs 4.8%, P=0.14 TRBO: 120.6d SEMS vs 89.3d, P=0.01	Biliary decompression by SEMS associated with longer patency and reduced number of auxiliary procedures; however, repeated PS insertions still remain the most cost-effective strategy.	PICO 2.3.2 PICO 2.3.3

								Stent migration Time to recurrent biliary occlusion (TRBO) Reintervention Total treatment costs Survival AEs	Reintervention: two-step SEMS (5.7±2.1), PS (3.1±1.7), one-step SEMS (2.0±1.1) (P<0.001). Total costs: two-step SEMS (6511±2196€), PS (2948±1578€), one-step SEMS(2687±1174€) (P<0.001) Survival: two-step SEMS (596±270d), one-step SEMS (276±142 d), PS (207±220d) (P<0.001) AEs: not significantly different		

Thieme

Table 6.4s: Distal malignant biliary stricture: EUS-BD LAMS (PICO 2.1.5/2.2.5/2.3.5)

Author (year)	Methods	Population			Intervention			Outcomes			Remarks
	Design	N	Age	Inclusion criteria	Protocol (details) of Intervention	Protocol (details) of Comparison	FU	Outcome measures (+ definitions)	Outcomes of interest	Principal findings	
Khoury (2024)	SRMA	5 RCTs (519 patients)	NA	MBO, palliative	EUS-BD (5 studies, 263 patients)	ERCP (5 studies, 256 patients)	NA	TS CS Stent patency at 1 yr Reintervention Survival, SDM AEs	TS, EUS-BD vs ERCP: RR 1.06 (0.96-1.17; P=0.27, I^2 64.2%) CS: RR 1.02 (0.97-1.08; P=0.45, I^2 0.0%) Stent patency: RR 1.15 (0.94-1.42; P=0.17 I^2 80.4%,) Reintervention: RR 0.58 (0.37-0.9; P=0.01, I^2 2.15%) Survival: 17.5 (0.37-0.78, P<0.001, I^2 98.4%,) AE: RR 0.85 (0.49-1.46; P=0.55, I^2 32.6%,) SAE: RR 0.97 (0.10-0.17; P=0.98, I^2 0.0%)	EUS-BD showed a statistically significant lower reintervention rate than ERCP, but with similar technical success, stent patency, clinical success, and safety. Technical success of EUS-BD with LAMS was better than ERCP.	PICO 2.3.5
Lauri (2024)	MA	6 RCTs (583 patients)	NA	MBO, primary biliary drainage	EUS-CDS with LAMS, EUS-CDS with SEMS, EUS-HGS, ERCP, and PTBD	Drainage techniques compared to each other	NA	TS CS Reintervention AEs	TS: EUS-CDS LAMS vs EUS-CDS SEMS (RR 1.21, 95 % CI 1.07–1.37) vs ERCP (RR 1.17, 95 % CI 1.07–1.28); SUCRA=0.86. CS, EUS-CDS LAMS vs ERCP: RR 1.12, 1.01–1.25; SUCRA=0.92 Reintervention: ERCP most, SUCRA=0.22 AEs, PTBD worst, SUCRA=0.18	EUS-CDS with LAMS has the highest technical and clinical success rates and is significantly superior to ERCP as upfront technique for dMBO treatment. PTBD should be abandoned as first-line treatment due to the poor safety profile	PICO 2.1.5 Same 5 RCTs as Khoury et al., except for 1 study on ERCP vs PTCD
Chen (2023)	RCT	144	72.0	MBO secondary to borderline resectable, locally advanced, or unresectable peri-ampullary cancers	EUS-BD LAMS 6x8mm or 8x8mm Hot Axios (73)	ERCP + SEMS 10x40/60/80mm UC, PC or FCSEMS (71)	Until death or 1-year follow-up	TS CS (50% decrease in bilirubin <2wks or <25% preprocedure value <4 wks) Stent dysfunction at 1 yr Mortality Early (<≤4d) vs late AEs	TS, EUS-CDS vs ERCP-M: 90.4% vs 83.1%; risk difference 7.3% (95% CI,–4.0-18.8%) indicating noninferiority CS: 84.9% vs 85.9%, P=0.87 Stent dysfunction: 9.6% vs 9.9%, P=0.96 Mortality: 69.9% vs 62.0%, P=0.32 Early AEs: 12.3% vs 12.7%, P=0.95 Late AEs: 15.1% vs 16.9%, P=0.76 Late SAEs: 9.1% vs 41.7%, P=0.16	Although not superior in stent function, EUS-CDS is an efficient and safe alternative to ERCP-M in patients with MDBO	PICO 2.1.5 PICO 2.2.5 PICO 2.3.5
Teoh (2023)	RCT	155	72-75	MBO, palliative	EUS-CDS 8x6mm or 6x6mm LAMS +- in-stent pigtail (79)	ERCP + 10mm PCSEMS (76)	Until 1 year or clinical symptoms	TS CS (>30% bili drop <5d) Stent patency at 1yr Reinterventions Survival, median AEs	TS, EUS-CDS vs PCSEMS: 96% vs 76%, P<0.001 CS: 94% vs 91%, P=0.56 Stent patency: 91.1% vs 88.1%, P=0.52 Reinterventions: 11% vs 13%, P=0.48 Survival: 232.2d vs 202.6d, P=0.28 30-d AEs: 16.5% vs 17.1%, P=1.00	Both procedures could be options for primary biliary drainage in unresectable MDBO. ECDS was associated with higher technical success and shorter procedural time then ERCP. Primary ECDS may be preferred when difficult ERCPs are anticipated.	PICO 2.3.5

Bang (2018)	RCT	67	69	MBO	EUS-BD + 8x60mm FCSEMS (33)	ERCP + 8x60mm FCSEMS (34)	Until death or minimum of 6 months.	TS CS (bilirubin <50% at 2wks) Reinterventions Surgical resection AEs	TS, EUS-BD vs ERCP FCSEMS: 90.9% vs 94.1%, P=0.67 CS: 97% vs 91.2%, P=0.61 Reinterventions 3.0% vs 2.9%, P=0.99 Surgical resection: 15.2% vs 14.7%, P=0.99 AEs: 21.2% vs 14.7% (RR 0.69; 95%CI, 0.24-1.97; P=0.49).	Similar rate of AEs comparing EUS-BD to ERCP for biliary decompression in pancreatic cancer	PICO 2.1.5 PICO 2.2.5 PICO 2.3.5
Paik (2018)	RCT	125	65-68	MBO, palliative	EUS-CDS/HGS PC-SEMS (64)	ERCP + UC/PC/FCSEMS (61)	2 yrs	TS CS (bilirubin <50% of pre-Rx value <1wk and/or <25% <4wks) Stent patency at 6mo Reintervention QOL Overall survival AEs	TS, EUS-BD vs ERCP: 93.8% vs 90.2% (diff. 3.6%, non-inferiority P=0.003 CS: 90.0% vs 94.5%, P=0.49 Stent patency: 85.1% vs 48.9%, P=0.001 Reintervention: 15.6% vs 42.6%, P=0.001 QOL: more preserved in EUS-BD Overall survival: 178d vs. 144d, P=0.92 Late AEs: 4.7% vs 19.4%, P=0.001 PEP: 0.0% vs 14.8%, P=0.001	This study demonstrated comparable technical and clinical success rates between EUS-BD and ERCP in relief of malignant distal biliary obstruction. Substantially longer duration of patency coupled with lower rates of adverse events and reintervention, and more preserved QOL were observed with EUS-BD	PICO 2.3.5 No rectal indomethacin
Park (2018)	RCT	28	66	MBO, palliative	EUS-BD + 10mm PCSEMS (14)	ERCP + 10mm PCSEMS (14)	At least 90d	TS CS (bilirubin <50% <1mo) Stent patency Stent dysfunction Overall survival AEs	TS, EUS-BD vs ERCP: 93% vs 100%, P=1.00 CS: 100% vs 93%, P=1.00 Stent patency: 379 vs 403d, P=0.72 Stent dysfunction: 15.4% vs 30.8%, P=0.65 Overall survival: 197 vs 188d, P=0.58 AEs: 0.0% vs 0.0%, P=1.00	This RCT suggests that EUS-BD has similar safety to ERCP-BD. EUS-BD was not superior to ERCP-BD in terms of relief of malignant biliary obstruction. EUS-BD fewer cases of tumor ingrowth but more food impaction or stent migration.	PICO 2.3.5
Ghoneem (2024)	Prospective, non-randomized	73	64	MBO	EUS-CDS 6 or 8 cm pcSEMS or half-to-half stent (37)	ERCP + 6 or 8 cm pcSEMS or half-to-half stent (36)	3 mo	TS CS (≥50% decreased bilirubin <2wk or <3 mg/dL <1mo) Reintervention AEs	TS, EUS-CDS vs ERCP: 97.3% vs 94.4%, P=0.539 CS: 97.2% vs 100%, P=0.328 Reintervention: 8.3% vs 0.0%, P=0.228 AEs: 0.0% vs 2.9%, P=0.095	Even in developing countries, EUS-CDS is feasible and demonstrates comparable safety and non-inferior efficacy to ERCP when used as primary palliative tool in MDBO	PICO 2.1.5 PICO 2.2.5 PICO 2.3.5 Stent cover differs
Fritzsche (2025)	Retrospective (Propensity-Score Matching)	168		Pancreatoduodenectomy after EUS-CDS vs ERCP for MBO	EUS-CDS (42)	ERCP + FCSEMS (126)	NA	Major postoperative complications Overall postoperative complications Endoscopic reintervention In-hospital mortality	Major postoperative complications, EUS-CDS vs ERCP: 19% vs 33%, RR 0.50; 95%CI, 0.23-1.07 Overall complications: RR 0.95; 95%CI, 0.51-1.76 Endoscopic reintervention: 14.3% vs 31.0%, RR 0.46 (0.21-1.08) In-hospital mortality: 2.4% vs 3.2%, RR 0.80 (0.14-4.68) Results similar after matching. Surgery was not (45%), 'slightly' (28%), 'clearly' (17%) or 'severely' (7%) more complex because of EUS-CDS.	This early experience suggests that preoperative biliary drainage with EUS-CDS does not increase the rate of complications after pancreatoduodenectomy and only infrequently hampers surgical exploration	PICO 2.3.5

Table 6.5s: Distal malignant biliary stricture : Palliation drainage: trick to prevent migration

Author (year)	Methods	Population			Intervention			Outcomes			Remarks
	Design	N	Age	Inclusion criteria	Protocol (details) of Intervention	Protocol (details) of Comparison	FU	Outcome measures (+ definitions)	Outcomes of interest	Principal findings	
Paik (2021)	RCT	68	64	MBO, palliative	ERCP + 10mm diameter FCSEMS/anchor stent 7Fr double pigtail (33)	ERCP + 10mm diameter FCSEMS (35)	6 mo	TS CS (bilirubin <50% of pretreatment value <4 wks) Stent migration at 6 mo Stent patency Survival Stent-related AEs	TS, anchor ERCP vs ERCP: 100% vs 100%, P=1.00 CS: 93.9% vs 82.9%, P=0.26 Stent migration: 15% vs 40%; P=0.02 Stent patency: 237d vs 173d; P=0.048 Overall survival: 75.8% vs. 82.9%; P=0.47 Stent-related AEs: 6.1% vs 11.4%, P=0.67	The additional double pigtail plastic stent anchored the FCSEMS to prevent migration and prolonged patency without any serious adverse events	PICO 2.3.1 Suggest to include Anchor stent

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Table 6.6s: Hilar/intrahepatic malignant biliary stricture: preoperative biliary drainage

Author (year)	Methods		Population			Intervention			Outcomes			Remarks
	Design		N	Age	Inclusion criteria	Protocol (details) of Intervention	Protocol (details) of Comparison	Follow-up	Outcome measures (+ definitions)	Outcomes of interest	Principal findings	
Coelen (2018)	RCT		54		Potentially resectable perihilar CCK and biliary obstruction of the future liver remnant (defined as a bilirubin concentration of >50 μmol/L [2·9 mg/dL]),	Endoscopic biliary drainage (27)	PTC (27)		Severe complications		Higher mortality in the PTC group (11 [41%] of 27 patients) than in the endoscopic biliary drainage group (three [11%] of 27 patients; relative risk 3·67, 95% CI 1·15-11·69; p=0·03). (Coelen, Roos et al. 2018)was similar between the groups (17 [63%] patients in the PTC group vs 18 [67%] in the endoscopic biliary drainage group; relative risk 0·94, 95% CI 0·64-1·40). PTC worse	
Jo (2017)	Retrospective		98		Potentially resectable perihilar CCK with preop drainage	Endoscopic biliary drainage : ENBD (13) EBS (42)	PTC (43)		Technical success rate, complications of PBD, and surgical outcomes		Similar success rates (97.3 %, PTBD; 90.2 %, endoscopic methods) and mead duration to biliary decompression Similar rate of complications (EBS group (42.9 %) and the PTBD (27.9 %, p = 0.149) and ENBD (15.4 %, p = 0.072)). No difference	
Hirano (2014)	Retrospective		141		Potentially resectable perihilar CCK with preop drainage	Endoscopic biliary drainage (74)	PTC (67)	82 mo	postoperative survival and mode of recurrence	Higher risk of seeding	Survival rate for patients who underwent EBD was significantly higher than those who had PTBD (P = 0.004). Multivariate analysis revealed that PTBD was one of the independent factors predictive of poor survival (hazard ratio: 2.075, P = 0.003). Patients with PTBD more frequently developed peritoneal seeding in comparison to those who underwent EBD (P = 0.0003). PTC worse	
Kim (2015)	Retrospective		106		Potentially resectable perihilar CCK with preop drainage	Endoscopic biliary drainage (44)	PTC (62)		Technical success, clinical outcomes, complications	Two cases of seeding with PTC	Procedure-related complications, especially cholangitis and pancreatitis, were significantly more frequent in the EBD group than the PTBD group (PTBD vs EBD 22.6% vs 54.5%, p<0.001). EBD worse	
Kloek (2010)	Retrospective		101		Potentially resectable perihilar CCK with preop drainage	Endoscopic biliary drainage (90)	PTC(11)			Clinical outcomes	Infectious complications were significantly more common in the endoscopic group (48% vs. 9%, P < 0.05). Patients in the EBD group underwent more drainage procedures (2.8 vs. 1.4, P < 0.01) and had a significantly longer drainage period until laparotomy (mean 15 weeks vs. 11 weeks in the	

											PTBD group; P < 0.05). In 30 patients, EBD was converted to PTBD due to failure of the endoscopic approach. EBD worse	
Kawakami (2011)	Retrospective		128		Potentially resectable perihilar CCK with preop drainage	Endoscopic biliary drainage (?(: ENBD and EBS	PTC (?)			Clinical outcomes	Complications were significantly more frequent in the EBS group compared with either the ENBD or PTBD group. Severe complications higher in PTC. PTC worse, ENBD better than EBS	
Wiggers (2015)	Retrospective		245		Potentially resectable perihilar CCK with preop drainage	Endoscopic biliary drainage (157)	PTC (with ot without EBD) (88)	41/35 mo		Survival and seeding	Survival between the PTBD group and EBD-only group was similar (hazard ratio, 1.05; 95 % confidence interval, 0.74-1.49; P = 0.80). Seeding metastases in the laparotomy scar occurred as initial recurrence in 7 patients, including 3 patients (3.4 %) in the PTBD group and 4 patients (2.7 %) in the EBD-only group (P = 0.71). No difference for seeding	
Komaya (2017)	Retrospective		320		Potentially resectable perihilar CCK with preop drainage	Endoscopic biliary drainage (152)	PTC(168)			Survival and seeding	The survival for PTC was significantly lower than that of the endoscopic biliary drainage patients (37.0% vs 44.3% at 5 years, P = .019). Recurrence rate of seeding metastasis was significantly higher in the percutaneous transhepatic biliary drainage patients than in the endoscopic biliary drainage patients (P = .005), PTC worse	
Zhang (2018)	Retrospective		240		Potentially resectable perihilar CCK with preop drainage	Endoscopic biliary drainage (92)	PTC(104)			Survival	Patients who underwent PTBD versus EBD had a comparable long-term DSS (median, 43.7 vs 36.9 months, P = 0.802) and RFS (median, 26.7 vs 24.0 months, P = 0.571). The overall pattern of recurrence relative to regional or distant disease was also the same among patients undergoing PTBD and EBD. No difference	
Yang (2020)	SRMA		10 studies (6 on hilar MBO)		Preop biliary drainage fro resectable MBO Seeding metastasis : primary endpoint of study	Endoscopic biliary drainage (1379)	PTC (1085)		Rate of seeding metastasis: Peritoneal metastasis Catheter-related metastasis		EBD compared to PTBD, is associated to lower rate of seeding metastasis (OR 0.35 (95%CI 0.23-0.53, p<0.00001) EBD compared to PTBD is associated to lower catheter related seeding (OR 0.23 (95%CI 0.12-0.44, p=0.0001) and lower rate of peritoneal metastasis (OR 0.47 (95%CI 0.31-0.74, p=0.008))	

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Table 6.7s: Hilar/intrahepatic malignant biliary stricture: palliative biliary drainage

Author (year)	Methods	Population			Intervention			Outcomes			Remarks
	Design	N	Age	Inclusion criteria	Protocol (details) of Intervention	Protocol (details) of Comparison	Follow-up	Outcome measures (+ definitions)	Outcomes of interest	Principal findings	
ERCP vs PTC for palliative drainage of hilar MBO											
Van Eecke (2022)	SRMA	11 studies (1 RCT, 10 Retrosp)		Preop or Palliative hilar MBO drainage	ERCP (n=784)	PTC (n=635)			Clinical Success AE Mortality	CS OR 3.5 (95%CI 2.05-5.97) Cholangitis OR 1.7 (95%CI 0.92-3.08) Reinterv OR11 (95%CI 3.51-37.7) AE (bleeding, PEP, tube dislodgment) = Mortality: trend higher for PTC	CS, Reinterv,choilangitis favor PTC but comparison bias to poor quality ERCP **Limits: mainly retrospectives cohorts; 74% Bismuth III-IV** **Only 30% bilateral drainage** **Only 23% bilateral drainage in ERCP group for 68% Bismuth III-IV**
Lubbe (2022)	Retrospective, bicentric	293		Palliative hilar MBO	ERCP (153)	PTC (140)		ERCP vs PTC	Access rate Bridging rate TS CS Duration CS Cholangitis PEP Procedure related death	83.5% vs 97.2%, p<0.001 90% vs 84.5%, p=0.11 98.3% vs 99.3%, p=0.8 81.7% vs 73.3%, p=0.2 Higher for ERCP, p=0.009 21.4% vs 24.7%, NS 9.4% vs 0%, p<0.001 6% vs 15.8%, p<0.001	ERCP had similar clinical success but longer duration of clinical success than PTC; higher procedure related mortality in PTC
EUS-Hepaticogastrostomy for palliative drainage of hilar MBO											
Nakai (2019)	Review	11 Retrospective studies		Palliative hilar MBO	EUS-HG (88)	none			TS CS AE	98% 77% 8%	
Winkler (2021)	Retrospective, MC	20	68y	Palliative hilar MBO Bismuth II (4), III (9, IV (7)	EUS-HG (primary drainage 16, as reintervention 4)	None Combined to ERCP (11), PTC (2), ERCP+PTC (1)			TS CS AE Mortality	100% 95% 3.5% 5%	
Schoch (2022)	Retrospective, MC	34	76y	Palliative perihilar cholangiocarcinoma	EUS-HG	none			TS CS AE Survival	97.1% 64.7% 26.5% (2 fatal) 91d (31-263)	Multivariate analysis: predictors of survival: -EUS-HG clinical success (OR 0.23 (95%CI 0.09-0.6, p=0.003))

												- chemotherapy (OR 0.06 (95%CI 0.02-0.23, p<0.001))
Koutlas (2024)	Propensity matched retrospective, MC		96		58/96 malignant biliary obstruction, EUS-HG vs PTC after failed ERCP	EUS-HG (32)	PTC (64)		CS : drop >50% bili at 2 weeks	TS (EUS-HG vs PTC) CS AE Procedure duration Post procedure LOS Reintervention rate	91% vs 98% (p=0.11) 100% vs 75% (p=0.002) 13% vs 58% (p<0.0001) 60 vs 115min (p<0.0001) 2 vs 4d (p<0.0001) 1 vs 3 (p<0.0001)	EUS-HG outperforms PTBD in clinical success, safety and, need for reintervention, and time/LOS
“old studies” ERCP with plastic stent vs SEMS for non resectable hilar MBO; new studies												
Sangchan, A (2012)	RCT		N=108	SEMS 62.7/ PS 57.3	Unresectable complex, Bismuth type II-IV HCA	Prophylactic AB, EST, SEMS or PS insertion in one main duct	Successful stent insertion, successful drainage, stent occlusion, AE	2007-2010	Successful stent insertion was defined as passage of the stent across the stricture into the previously planned he-patic duct. Successful drainage was defined as a decrease in total bilirubin level to less than 30% and 50% of the pretreatment level within 2 and 4 weeks, respectively. Stent occlusion was defined as an increase in bilirubin from the plateau level after stent insertion.	Successful stent insertion rates were not statistically different between the SEMS and PS groups (83.3% vs 85.2%, P .792). SEMS group had higher successful drainage rates (70.4%) than PS group (46.3%,P .011) Median patency time in the SEMS group was longer than that in the PS group (103 days vs 35 days, P .000), PP median survival SEMS vs. PS 154d vs 43d; No difference in complications rate in both arms	Endoscopic biliary drainage with the SEMS provides better adequacy of drainage and longer survival compared with the PS in patients with unresectable complex HCA.	Nine patients in the PS group (19.6%) and 5 patients in the SEMS group (11.1%) required stent ex-change (P .264), and the mean of endoscopic interven-tions in the SEMS and PS groups were 1.16 and 1.23 procedures, respectively (P .528).
Zorron, PU 2015	SR		N=1133/ 13 RCT	69,5	RCT SEMS vs. Plasticstents	Endoscopic palliative biliary drainage with plastic stent vs. SEMS	Subgroup analysis of distal and proximal biliary obstructions	Max. 385.3d	Stent Dysfunction rate, Survival days, costs and time to dysfunction	Stent dysfunction, RD−0.26 (95%CI−0.32 to−0.20), favoring SEMS Survival longer in the SEMS group (187 vs. 162 days, P < 0.0001) Tendency of lower cost (4193.98EUR SEMS vs. 4728.65EUR Plastic P=0.0985) and longer time until stent disfunction (SEMS 250 vs. Plastic 124 days), but no isolated statistical analysis of proximal stenting	SEMS group have a lower dysfunction rate, longer survival, lower cost and longer time to stentsdysfunction	
Xia (2021)	Propensity matched retrospective, multicentric		96 vs 96		Bilateral SEMS vs bilateral PS	Bilateral SEMS (96)	Bilateral plastic (96)		Survival CS Cholangitis Symptom free stent patency	7.2 (6.0-8.5) vs 4.1 months (2.9-5.3), p=0.015 99% vs 71.9%, p<0.001 7.3% vs 26%, p<0.001	Multivariate analysis: SEMS, hilar cholangiocarcinoma and adjuvant oncological treatment wer predictors of survival	

									Nbr interv	9.2 vs 4.8 months, p<0.001 1.3+/-0.6 vs 2.0+/-1.4, p>0.001		
Covered SEMS for non resectable hilar MBO												
Takahashi (2023)	retrospective		N=54		Unresectable malignant hilar biliary obstruction with 6-- mm-- diameter HANARO SFCSEMS (MI Tech, Seoul, Korea)	ERCP, If cholangitis was present, endoscopic nasobiliary drainage (ENBD) was initially performed. 6-mm diameter slim fully covered self-expandable metallic stent (SFCSEMS) was used in a side-by-side (SBS) placement fashion.	SFCSEMS in a Side-by-Side (SBS) fashion. No comparison-discriptive study.	120 days (interquartile range: 67–230 days).	1.Technical Success:Successful placement of the stent in the intended location with sufficient coverage of the stricture. 2.Clinical Success Improvement in jaundice or cholangitis, defined as a 50% reduction in bilirubin levels or normalization within 14 days post-stenting. 3.Recurrent Biliary Obstruction (RBO): Composite endpoint of stent occlusion (sludge/tumor ingrowth) or migration, leading to obstruction of bile flow. 4.Time to Recurrent Biliary Obstruction (TRBO): Time from stent placement to the onset of RBO. 5.Adverse Events (AEs): Complications arising from the procedure, categorized as early (<30 days) or late (≥30 days), such as pancreatitis, cholangitis, or cholecystitis. 6.Procedure Time: The duration from endoscope insertion to removal post-procedure. 7.Re-Intervention Success: Successful removal and replacement of stents after RBO without complications.	1.Efficacy: Technical success: 100% Clinical Success: Achieved in 92.5% of cases with SFCSEMS. TRBO: Median of 181 days for SFCSEMS; longer compared to plastic stents after re-intervention. 2.Safety: Adverse Events: Low overall rate (11.1%), including mild pancreatitis (7.4%) and cholangitis (1.8%). No liver abscesses were observed. 3.Recurrent Biliary Obstruction (RBO): Initial RBO Rate: 35.2% for SFCSEMS. Lower RBO Rate after re-intervention with SFCSEMS (16.7%) compared to plastic stents (81.8%). 4.Re-Intervention Success: 100% technical success in stent removal and replacement for RBO cases. 5.Procedure Time: Mean time of 76.3 minutes for initial SFCSEMS placement. 6.Overall Survival (OS): Median of 117 days, with longer survival observed in patients with effective drainage.	Endoscopic placement of SFCSEMS for unresectable MHBO was effective and feasible with low incidence of segmental cholangitis, and exchange strategy of SFCSEMS was promising.	Efficacy: SFCSEMS provides reliable drainage with high technical (100%) and clinical success (92.5%). • Re-Intervention Advantage: Easy removability and lower recurrent biliary obstruction (16.7%) enhance long-term outcomes. • Safety: Low adverse event rates (11.1%) and no severe complications like liver abscesses highlight its safety profile.

Thieme

									8.Overall Survival (OS): Time from stent placement to the patient's death from any cause.			
Yoshida (2016)	retrospective		N=22		Hilar malignant biliary obstruction (HMBO) classified as Bismuth types II–IV with side-bye-side placement of 6mm Niti-S Biliary S-type Stents (Taewong Medical, Seoul, Korea) (fcSEMS and pcSEMS)	ERCP, EST, bilateral stenting side-bye-side	Comparison Parameters: Primary Outcomes: Technical and clinical success rates. Stent patency (median time before dysfunction or intervention). Secondary Outcomes: Complications (early: <1 month; late: >1 month). Re-intervention success rates.	126 days, with a range from 14 to 985 days	1. Technical Success: Successful Stent deployment in target bile duct. 2. Clinical success: Reduction of total bilirubin to less than half of baseline levels or below the upper normal limit within 14 days. Resolution of cholangitis symptoms within 14 days. 3. Stent patency: time from stent placement to dysfunction, 4. AE, 5. Re-intervention success- Successful removal of malfunctioning stents and placement of new stents during follow-up.	Technical Success: Achieved in 96.9% of procedures. Clinical Success: Observed in 93.5% of cases, with FCSEMS outperforming PCSEMS (100% vs. 87.5%). Durability: Median Stent Patency: Overall: 95 days. FCSEMS: 113 days. PCSEMS: 68 days. Safety: Complications: Early (≤1 month): 3.1% overall (e.g., cholecystitis). Late (>1 month): 6.3% overall (e.g., hepatic abscess). Re-Intervention: Success Rate: 83.3% overall, higher with FCSEMS (100%) compared to PCSEMS (66.6%).	High technical and clinical success rates, with low overall complications, Cholangitis occurred in 3 cases. fcSEMS offers better outcomes for stent patency, safety, and re-intervention effectiveness compared to pcSEMS	Fully covered stents (FCSEMS) demonstrated superior outcomes in terms of patency and re-intervention success, making them preferable in cases where repeat interventions might be required. The low complication rates, including cholangitis, highlight the safety of the side-by-side stenting approach.
Paik (2024)	prospective		N=50		Unresectable malignant hilar biliary obstruction (MHBO). (Bismuth type II, III, or IV.)	Randomization, prophylactic antibiotics, ERCP, wire guided side-by-side Plasticstents or fcSEMS	Outcomes Compared: Primary: Time to recurrent biliary obstruction (TRBO). Secondary: Technical and clinical success rates, stent patency, adverse events, and reintervention rates.	Until death or end of study Median 202 days	**Primary Outcome**: **Time to Recurrent Biliary Obstruction (TRBO)**:Defined as the duration from successful stent placement to the recurrence of symptoms or imaging findings of biliary obstruction requiring reintervention. **Secondary Outcomes**: **Technical Success**: Successful deployment of both stents into the targeted bile ducts with confirmed drainage on fluoroscopy. **Clinical Success**: Resolution of jaundice or cholangitis with a significant reduction in bilirubin levels (<50% of	**Time to Recurrent Biliary Obstruction (TRBO)**: **Metal Stents (MS)**: Median TRBO was significantly longer at **252 days**. **Plastic Stents (PS)**: Median TRBO was **96 days** (*p* < *0.001*). **Technical Success**: Achieved in **100%** of patients in both MS and PS groups. **Clinical Success**: **MS Group**: **96%**. **PS Group**: **88%** (*p* = *0.61*). **Stent Patency**: Median stent patency mirrored TRBO: MS: **252 days**. PS: **96 days**. **Adverse Events**: **Cholangitis**: MS: **16%**. PS: **28%** (*p* = *0.24*). **Pancreatitis**: MS: **4%**. PS: **8%** (*p* = *0.56*). **Reintervention Rate**: **MS Group**: **16%**. **PS Group**: **40%** (*p* = *0.04*).	Fully covered metal stents provided significantly longer stent patency, fewer reinterventions, and comparable safety compared to plastic stents, making them a more effective option for managing malignant hilar biliary obstruction.	The study highlights fully covered metal stents as a preferred option for managing malignant hilar biliary obstruction, particularly in patients requiring durable palliation.

									baseline) within 2 weeks post-procedure. **Stent Patency**: Duration of stent functionality without occlusion or migration. **Adverse Events**: Incidence of procedure-related complications such as cholangitis, pancreatitis, or perforation. **Reintervention Rate**: Frequency of additional procedures needed to manage stent dysfunction or occlusion. **Survival**: Overall survival from the date of stent placement to death or last follow-up.			
Unilateral vs bilateral stenting for palliative hilar MBO drainage												
Lee (2017)	RCT		133		Pathology proven inoperable hilar MBO	Randomisation to bilateral SEMS	Vs unilateral SEMS			TS CS Reintervention rate Cumulative Stent patency Risk of stent patency failure	95.5% sv 100%, p=0.24 **95.3% vs 84.9%, p=0.047** **42.6% vs 60.3%, p=0.049** 252d vs 139d Hiher in unilateral	Multivariate Cox: bilateral SEMS is favorable (HR 0.3 (95% CI 0.172-0.521, p<0.001) Same survival, late AE
Ashat (2019)	SRMA		9 studies (2 RCT, 5R, 2 abstracts)		Inoperable hilar MBO	Bilateral SEMS	Vs unilateral SEMS			TS Reintervention rate Early AE Late AE Stent malfunction	OR 0.17 (95%CI 0.42-1.17, p=0.17) **OR 0.59 (95%CI 0.4-0.87, p=0.009)** OR 1.56 (95%CI 0.31-7.75, p=0.51) OR 0.91 (95%CI 0.58-1.41, p=0.56) OR 0.69 (95%CI 0.42-1.12, p=0.14)	Bilateral SEMS is associated to same technical success, with lower rate of reintervention
Natoh (2023)	SR		2 RCT, 4 R, 1 R+propensity matched		Inoperable MHBO	Bilateral SEMS	Vs unilateral SEMS				Bilateral SEMS: -higher functional success (2/5 studies) -longer TRBO (4/7 studies) -longer survival (2/5 studies)	

Xia (2020)	Retrospective (4 centers) Propensity score matched		1239 advanced MHBO		Advanced MHBO, matched	Bilateral SEMS (87) Unilateral SEMS (97) Bilateral PS (91) Unilateral PS (81)				CS Post ERCP cholangitis Symptom free stent patency Nb reintervention Median Overal survival	98.9 / 83.5 / 71.4 / 65.4%, p<0.01 8 / 17.5 / 26.4 / 29.6%, p=0.002 9.6 / 6.8 / 4.6 / 4.2 months, p<0.01 1.2 / 1.7 / 2.0 / 1.9, p<0.01 7.1 / 4.4 / 4.1 / 2.7 months	Bilateral stenting is superior to unilateral Stenting in **Clinical Success (p=0.024), stent patency (p=0.028), Overall Survival (p=0.04)**
Jo (2021)	Retrospective multicentric		236		Inoperable MHBO	Y type bilateral SEMS	Unilateral SEMS			TS CS Survival	82.5% vs 98.8%, p<0.01 **85.7% vs 70.5%, p=0.028** **Higher for bilateral, p<0.01**	Cox : lymph node compression: higher risk of death (HR 9.8, p=0.003); **Bilateral SEMS reduces post-procedure mortality (HR 0.31, p=0.001)**
Nakshaban di (2024)	Retrospective		N=333	63 (IR 56-72)	Patients with unresectable Bismuth class **II, IIIa, IIIb, and IV** cholangiocarcinoma who require palliation.	ERCP or PTBD with a) Plastic stents (doublepigtail or straight or b) unilateral or bilateral SEMS	Stenttype and unilateral vs. Bilateral stenting regarding: -Technical success -Clinical success. - Adverse event rates. - Time to reintervention. - Mortality rates, especially cholangitis-related.	1997-2023	**Clinical Success**: **Definition**: A reduction in bilirubin levels within two weeks post-procedure, enabling either patient discharge or resumption of cancer/palliative care without requiring another ERCP within the same period. **Technical Success**: **Definition**: Successful deployment of endobiliary stents during the procedure. **Stent-Specific Adverse Events (AEs)**: **Definition**: Composite measure of stent migration, occlusion, tumor ingrowth, or overgrowth. **Time to Reintervention**: **Definition**: Interval from initial ERCP to the need for a repeat procedure. **Overall Survival (OS)**: **Definition**: Time from diagnosis or first procedure to death or last follow-up.	**Clinical Success**: **SEMSs**: Higher in unilateral (91%) vs. bilateral (85%) (**p = 0.054**). **PSs**: Unilateral (85%) vs. bilateral (83%) (**p > 0.05**). Bilateral SEMSs had a higher clinical failure rate than unilateral SEMSs (**p < 0.05**). **Technical Success**: High across all stenting strategies (98%-100%), **no significant difference (p > 0.05)**. **Stent-Specific Adverse Events (AEs)**: **Unilateral**: PSs: 22%, SEMSs: 57%, PS-SEMS: 74% (**p < 0.001**). **Bilateral**: PSs: 15%, SEMSs: 43%, PS-SEMS: 60% (**p < 0.001**). Bilateral SEMSs had significantly higher AE rates than unilateral SEMSs (**p = 0.005**). **Time to Reintervention**: **Unilateral**: SEMSs: Mean 251 days, PSs: Mean 73 days, PS-SEMS: Mean 57 days (**p < 0.001**).	**Self-Expandable Metal Stents (SEMSs)**: Offer higher clinical success and longer patency but have significantly higher rates of adverse events and mortality from cholangitis, especially in bilateral stenting. Challenging to remove, complicating subsequent PTBD. **Plastic Stents (PSs)**: Safer with fewer adverse events and easier compatibility with PTBD. Require more frequent reinterventions due to shorter patency. **Unilateral Stenting**: Generally associated with fewer adverse events and better outcomes compared to bilateral stenting, especially with SEMSs. **Bilateral Stenting**: Higher complication rates without a significant	Tailored stenting strategies are critical based on patient characteristics, disease severity, and expected interventions like PTBD. Evidence does not strongly favor SEMSs over PSs for palliation in malignant hilar biliary obstruction *Limits: mixed procedures types and multiple comparisons, long period (25years) of study, with evolution in practice*

									Percutaneous Transhepatic Biliary Drainage (PTBD) Rates: **Definition**: Proportion of patients requiring PTBD after stenting and the time to PTBD. **Pus Presence on ERCP**: **Definition**: Endoscopic observation of pus during the procedure, indicating potential subclinical cholangitis. **Mortality from Cholangitis**: **Definition**: Deaths directly attributed to cholangitis-related complications	**Bilateral**: SEMSs: Mean 134 days, PSs: Mean 75 days, PS-SEMS: Mean 48 days (**p < 0.005**). **Mortality from Cholangitis**: Higher in **bilateral SEMSs** (52%) vs. unilateral SEMSs (20%) (**p = 0.005**). No significant difference between bilateral and unilateral PSs (**p > 0.05**). **PTBD Rates**: **Unilateral PSs**: 23% vs. **unilateral SEMSs**: 8% (**p = 0.01**). Similar PTBD rates between bilateral PSs and SEMSs (**p > 0.05**). **Overall Survival (OS)**: No significant difference between unilateral and bilateral stenting (**p > 0.05**).	improvement in clinical success or overall survival. Advanced disease (e.g., Bismuth IV) still benefited from bilateral stenting attempts. .	
Extension of biliary drainage and outcome												
Caillol (2019)	Retrospective, monocentric		60	69.8y	Bismuth II (29%), III (34%), IV (37%)	Percentage of liver drained whatever the technique (ERCP+/-PTC+/-EUS-HG)	NA	2015-2016 Median survival 5 (2.3-12.3) months	Defining a threshold of 80% of the liver drained; study of associated prognosis	<80% drained >= 80% drained ROC 0.77 (0.65-0.88) predicted the chance to receive chemotherapy	Worse prognosis (HR 3.25 (1.66-6.36, p<0.001) if less than 80% drained (survival 3.5 months vs 8.5months, p<0.001) Higher percentage of liver drainage was strongly associated with chemotherapy feasibility (92% vs. 44%, p = 0.0008). A ROC curve model was used to predict the possibility to administer chemotherapy to the patient, the threshold being 71% of the liver	

											drained ((92% vs 44%, OR = 0.06 (0.01, 0.32), p = 0.0008	
Morimoto (2023)	Retrospective, monocentric		90		Inoperable MHBO receiving chemotherapy	Percentage of liver drained evaluated using 3D image volume analyser	Associated prognosis	2003-2020	Survival related to volume drained TRBO Multivariate analysis	<80% volume drained >=80% volume drained	Survival is higher in >80% drained group (450d vs 224d, p=0.0033) TRBO similar: 201d >80% liver drained is an independent factor of survival (HR 0.35 (0.2-0.62; p=0.0003), and cholangiocarcinoma (HR 0.3; 0.17-0.5, p<0.0001)	
Nakamura (2025)	Retrospective, monocentric		82	60+/-13y/o	Inoperable Bismuth II, III, IV treated with ERCP (cholangiocarcinoma 32.9%; LNM 23.2%)	Percentage or liver drained (assessment of segments drained and pre-ERCP liver volumetry on CT)		2014-2018	CS: decrease of 50% of bilirubin or normalisation within 2 weeks	CS 60% Correlation of CS with >50% viable liver parenchyma drained (p=0.015; OR 4.15 95%IC 1.4-12.5) Higher CS if more than 2 sectors drained (p<0.001 OR 8.5; 95%IC 2.7-26.7)	No correlation of unilateral/bilateral drainage and CS CCl: Drainage of >50% or >2 sectors is associated to better clinical success regardless of unilateral or bilateral	
Non comparative bilateral stenting cohorts												
Sundaram, S (2023)	Retrospective		43	54.9 (mean)	Hilar cholangiocarcinoma with bilateral SEMS	Bilateral side-by-side or stent-through stent ucSEMS placement,	Bilateral wire placement and SEMS deployment into left intrahepatic duct followed by right intrahepatic duct. No comparison- descriptive study	Death or end of study 2017-2021	- Technical success was defined as passage of the stent across the stricture, along with the flow of contrast medium and/ or bile through the stent. - Functional success was defined as a decrease by more than 50% at two weeks in bilirubin or to less than 3 mg/dL at four weeks. - Immediate complications with 30-day mortality, -Requirement of re-intervention and stent patency	- Technical success 41/43 (95.3%) - Functional success was achieved in 39 patients (95.1%). - AE 10/43 (23.26%) - Median stent patency 137 days (interquartile range [IQR] 80–214 days). Re-intervention 4/43 (9.3%) after mean 295.7 days.	Endoscopic bilateral SEMS in complex malignant hilar obstruction has good outcomes in the form of technical success, functional success and stent patency.	Median overall survival was 153 days (IQR 108–234 days).

Takahashi, K (2023)	Retrospective		N=89	71 (median)	Patients with unresectable hilar malignant biliary stricture and bilateral stenting with ucSEMS	Bilateral side-by-side or stent-through stent ucSEMS placement,	Bilateral wire placement and SEMS deployment into left intrahepatic duct followed by right intrahepatic duct.	Death or 2006-2022	Technical Success Rate Definition: Successful deployment of the stent into the target bile duct without procedural complications. Clinical Success; Definition: A decrease in serum total bilirubin levels to less than 50% of the pre-treatment value or below 2.0 mg/dL within 14 days of stent placement without requiring additional drainage. Recurrent Biliary Obstruction (RBO) and time to RBO; Definition: stent occlusion (blockage) or stent migration (displacement) resulting in bile flow obstruction. Adverse Event Rate; Procedure Time; Overall Survival	Clinical Success: Achieved in 79.7% (SBS) and 80.0% (PSIS) of cases — no significant difference. 2.RBO Rate: 32.8% (SBS) vs. 28.0% (PSIS) — no significant difference. 3. Cumulative TRBO: Median 224 days (SBS) vs. 178 days (PSIS) — no significant difference. 4. Adverse Events: Occurred in 20.3% (SBS) and 12.0% (PSIS) — no significant difference. 5. Procedure Time: Median 43 minutes (SBS) vs. 62 minutes (PSIS) — significantly longer for PSIS. 6.Technical Success: High in both groups — 90% (SBS) and 100% (PSIS) for first re-intervention. 7.Re-intervention Rate: 31.2% (SBS) vs. 28.0% (PSIS) — no significant difference. 8.Overall Survival: Median 212 days (SBS) vs. 160 days (PSIS) — no significant difference	No significant differences were noted in the clinical success rate, adverse event rate, time to RBO, or overall survival between the SBS and PSIS groups, other than the significantly longer procedure time in the partial stent in stent group.	1. Efficacy: • Both Side-by-Side (SBS) and Partial Stent-in-Stent (PSIS) techniques showed similar clinical success, adverse event rates, and survival outcomes. This indicates that either method can be effective for managing malignant hilar biliary strictures. 2. Procedure Complexity: • PSIS had a significantly longer procedure time despite being performed more often by expert endoscopists. This reflects its complexity, which may impact its feasibility in less experienced hands or in settings with limited time or resources. SBS might be more practical for routine use due to its shorter procedure time and lower dependency on advanced expertise. PSIS could be reserved for specific cases where its unique advantages (e.g., reduced bile duct dilation) are desired.

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Table 6.8s: Malignant biliary stricture treated with SEMS: signs of dysfunction

Author (year)	Methods		Population			Intervention			Outcomes			Remarks
	Design		N	Age	Inclusion criteria	Protocol (details) of Intervention	Protocol (details) of Comparison	Follow-up	Outcome measures (+ definitions)	Outcomes of interest	Principal findings	
Yoon (2010)	Retrospective		56	66	Re-intervention after first Endoscopic (46) or percuteanous (10) insertion of SEMS for MBO distal (33) and prox (23)	Insertion of a second SEMS (29/USEMS:19/ cSEMS 10)	Insertion of a plastic stent (10 Fr) (27)	200 SEMS/ 133 PS d	Stent occlusion (cholangitis or increase of bili>2xfrom baseline)		SEMS: Stent occlusion after a median of 186 d (range, 11-285 d) in 16 patients (55.2%) PS: stent occlusion after a median of 101 d (range, 2-194 d) in 18 patients (66.7%) in the PS group (P = 0.118 for time to stent occlusion, P = 0.379 for stent occlusion rate). No difference	Dist and prox
Rogart (2008)	Retrospective		27	66	Reintervention after first endoscopic insertion of SEMS for MBO distal	Insertion of a second SEMS (14)	Insertion of a plastic stent (10 Fr)(11) Or ballon sweeping (2)	285d(sems) /188d(PS)/ 194d(balloon)	Stent occlusion and need for reintervention	Incremental cost analysis showed both uncovered SEMSs and plastic stents to be cost effective strategies.	Second SEMS (provided the lowest reocclusion rate (43% vs 55% for plastic stent and 100% for mechanical) and longest time to reintervention (median 172 days vs 66 days for plastic stent and 43 days for mechanical, P:.05). SEMS, better	dist
Tejedor-Tejada (2024)	Retrospective		41	NR	Reintervention with SEMS after first endoscopic insertion of SEMS for MBO distal	Insertion of a second fcSEMS (20)	Insertion of a second uSEMS (21)	510 days	Primary outcomes : technical and clinical success of SEMS placement. Secondary outcomes: adverse events	Multivariate analysis indicated that sex (HR=0.909, 0.852-0.970), antitumor treatment (HR=0.248, 0.032-0.441), stent patency (HR=0.992, 0.986-0.998) and clinical success (HR=0.133, 0.026-	Technical (100% vs 85.5%) and clinical (100% vs 95.2%) success rates were similar in FCSEMS and UCSEMS groups. Median duration of stent patency of FCSEMS (220 days, IQR 137.5-442.5) was longer than UCSEMS (150 days, IQR 110-362.5) (P=0.395), although	dist

									(AEs), patency and survival	0.690) were significant factors for overall survival.	stent dysfunction within 6 months was not different between groups FCSEMS better	
Nennstiel (2018)	Retrospective		79	67/65	Reintervention after first endoscopic insertion of SEMS for MBO distal and prox	Insertion of a second SEMS (10)	Insertion of a plastic stent (10 Fr)(58) Or ballon sweeping (4) or PTC (7)	95d (PS)/102d (SEMS)	Stent occlusion (debris or ingrowth and bili elevation) and need for reintervention Costs Survival	In patients with survival time of more than three months, significantly more patients treated with plastic stents needed re-interventions than patients treated with second SEMS (93.3% vs. 57.1%, P = 0.037).	Median overall secondary stent patency (88 vs. 143 days, P = 0.069), median survival time (95 vs. 192 days, P = 0.116), median subsequent intervention rate (53.4% vs. 40.0%, P = 0.501) and median case charge (€5145 vs. €3473, P = 0.803) similar between .SEMS and PS similar. SEMS better if longer survival rates	Dist (80%) and prox (20%)
Lee (2016)	RCT		43	NR	Reintervention with SEMS after first endoscopic insertion of SEMS for MBO distal	Insertion of a second fcSEMS (22)	Insertion of a second uSEMS (21)	308 d(CSEMS)/ 300d (uSEMS)	Primary outcome :overall stent patency. Secondary outcome: time-to-stent occlusion, patient survival, cause of stent occlusion, and adverse events.		Median stent patency of cSEMS and uSEMS was 112.0 and 181.0 days, respectively, (P = 0.373). Causes of occlusion were stent clogging (36.4%) and tumor ingrowth (33.3%) in cSEMS and uSEMS groups, respectively. No significant difference in median survival between the groups (median: 308 vs 300 days; P = 0.325). No differences between cSEMS and uSEMS.	distal

Table 6.9s: Malignant biliary stricture treated with previous LAMS: signs of dysfunction

Author (year)	Methods		Population			Intervention			Outcomes			Remarks
	Design		N	Age	Inclusion criteria	Protocol (details) of Intervention	Protocol (details) of Comparison	Follow-up	Outcome measures (+ definitions)	Outcomes of interest	Principal findings	
Vanella (2023)	Prospective		93	70	All consecutive patients undergoing EUS-CDS for distal MBO.	Placement of a coaxial DPPS (12)	Balloon swipe (3) or other (through the LAMS SEMS (2) transpapillary SEMS (3) , treatment of GOO (3)..)	184d (survival)	Primary: LAMS dysfunction during follow-up both as rate (proportion) and time-to-event (dysfunction-free survival [DFS]). Secondary outcomes(i) technical success, clinical success (CS), and AEs of (ii)management of dysfunction, and (iii) predictors of dysfunction.		EUS-CDS technical success 91% EUS-CDS clinical success 93% 27/85 patients (31.8%) experienced dysfunction after a mean of 166 (95% CI 91–241) days, Duodenal invasion (hazard ratio 2.7 [95% CI 1.1–6.8]) was the only independent predictor of dysfunction. Dysfunctions managed endoscopically mostly by co axial DPT within LAMS	
Fritzche (2024)	Prospective		22	69	All consecutive patients undergoing EUS-CDS for distal MBO.	Index EUS-CDS with LAMS without co-axial stenting	No comparison	6 mo	Primary outcome: technical success. Secondary outcomes: clinical success, adverse events (AEs), and reinterventions.		Technical success 91% AE 5% Stent dysfunction 55% within 6 mo (180 d) Reinterventions 55% (endoscopic reinterventions 8/9)	
Fritzche (2025)	Prospective		27		All consecutive patients undergoing EUS-CDS for distal MBO, without GOO	Index EUS-CDS with LAMS followed by coaxial FCSEMS through LAMS	No comparison	152 d	Primary outcome: stent dysfunction, defined as recurrent jaundice after initial clinical success, ongoing jaundice in combination with persistent bile duct dilatation, or cholangitis.		Technical success EUS-CDS with LAMS 24/27 (89%) Technical success of FCSEMS within LAMS 20/24 (83%)+co axial DPT in 4 patients Clinical success 90% No stent dysfunction	
Geyls (2023)	Prospective		123	73	All consecutive patients undergoing EUS-CDS	Index free hand EUS-CDS with LAMS without coaxial FCSEMS through LAMS	No comparison	242 d	Primary ouctome: stent obstruction during follow-up and identified preoperative risk factors for obstruction. Obstruction defined as: occurrence of cholangitis, cholestasis,		Technical success EUS-BDS with LAMS: 97.5% Clinical success: 91% Biliary obstruction during follow-up: 16%	

									or jaundice, even when it did not require hospitalization and/or reintervention.			
Li (2024)	MA	21 studies	1438		EUS-CDS by using lumen-apposing metal stents (LAMS) in malignant biliary obstruction				Technical and clinical success AE (early,late, overall)		Technical success EUS-BDS with LAMS: 93% Clinical success: 88% Overall AEs: 20,1% Early AE: 10,6%Late AE: 11, 2% Stent dysfunction 10,1%, reintervention: 12,1%	

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Table 7s: Distal malignant biliary stricture: Grade of evidence Table

Certainty assessment								Effect estimate	Certainty	Comments
PICO	No. of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Publication bias			
Preop biliary drainage: ERCP vs direct surgery	1 RCT	Upfront surgery 1wk vs ERCP+PS+surgery after 4-6w	No	Not applicable	Not applicable	No	No	**Same surgical complication (47 vs 37%, NS)** **More ERCP-related complication in preop biliary drainage group** (46%: comprise 30% stent dysfunction, 26% cholangitis)	⨁◯◯◯ Low	Comparative group is outdated; new evidence clearly favor SEMS for preop biliary drainage using ERCP. New quality RCT using comparative timeline and SEMS is required

Preop biliary drainage (neoadjuvant): ERCP +SEMS vs ERCP+PS	2 RCT	FcSEMS vs PS FcSEMS vs uSEMS	no	No	Yes	No	No	**Stent dysfunction: 72.8% (PS) vs 12.8% (FcSEMS), p=0.015** **FcSEMS and uSEMS: similar sustained biliary drainage**	⊕⊕○○ Moderate	Adding evidence to previous RCT (see ESGE guidelines 2018) in favor of SEMS compared to PS
Palliative biliary drainage ERCP +PcSEMS vs ERCP+FcSEMS Vs ERCP+uSEMS	1 MA	62 studies FcSEMS vs PcSEMS	Moderate	No	Yes	Yes	No	RBO: 27.3% vs. 25.3%; d-value: 0.056 TRBO: 238 vs. 369d; d-value: 0.116 Stent migration: 9.8% vs 4.3%, d-value=0.216	⊕○○○ Low	Subanalysis of prospective studies and unresectable diseases:
Palliative biliary drainage ERCP +SEMS vs EUS-BD*	2 MA and SRMA	5 and 6 RCT included ERCP+SEMS vs EUS-BD (EUS-CDS SEMS, EUS-CDS LAMS, EUS-HGs)	Moderate	Not serious	Serious	Not serious	Not serious	**Similar TS, CS, AE, Stent patency**	⊕○○○ Low	*TS with EUS-LAMS higher technical success (bias in reported low rate of success with ERCP) *PEP prevention in ERCP group not optimal in 2 RCT

										*expert EUS-BD centers: data not generalized

*As reported in **Table 7s**, the TF downgraded the quality of evidence due to the moderate risk of bias in the literature and the high risk of indirectness. Therefore, the TF issued a conditional recommendation with low quality of evidence.

NOS scale for assessing the risk of bias

Study	Selection (max 4 stars)	Comparability (max 2 stars)	Outcomes (max 3 stars)	Quality
Van der Gaag (2010)	****	**	***	High
Tamura (2021)	****	**	***	High
Seo (2019)	****	**	***	High

Table 8s: Hilar/intra-hepatic malignant biliary stricture: grade of evidence table

Certainty assessment								Effect estimate	Certainty	Comments
PICO	No. of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Publication bias			
ERCP vs PTBD: safety										
ERCP vs PTBD for preop biliary drainage of hilar MBO	**1**	**RCT**	**No**	**Not applicable**	**No**	**No**	**No**	Mortality relative risk=3.67, 95%CI (1.15-11.69; p=0.03)with PTBD compared to ERCP	⊕⊕○○ Moderate	
ERCP vs PTBD: seeding										
EBD vs PTBD for preop biliary drainage of hilar MBO	**1**	**SRMA** (of retrospective studies)	**No**	**No**	**Yes**	**No**	**No**	Less seeding with EBD compared to PTBD (OR 0.35 (95% CI 0.23-0.53, p<0.00001)	⊕⊕○○ Moderate	6/10 included studies on hilar MBO (others being distal MBO);
ERCP vs PTBD vs EUS-HG: efficacy, safety										
ERCP vs PTBD for palliative drainage of hilar MBO	**6**	**3 R 1 review (R) 1 MA (bad quality data)**	**Serious**	**Not Serious**	**Not Serious**	**Serious**	**Serious**	ERCP outperforms PTBD (longer CS duration, lower procedure	○○○○ Very Low	PTBD related to higher mortality than ERCP in **preop**

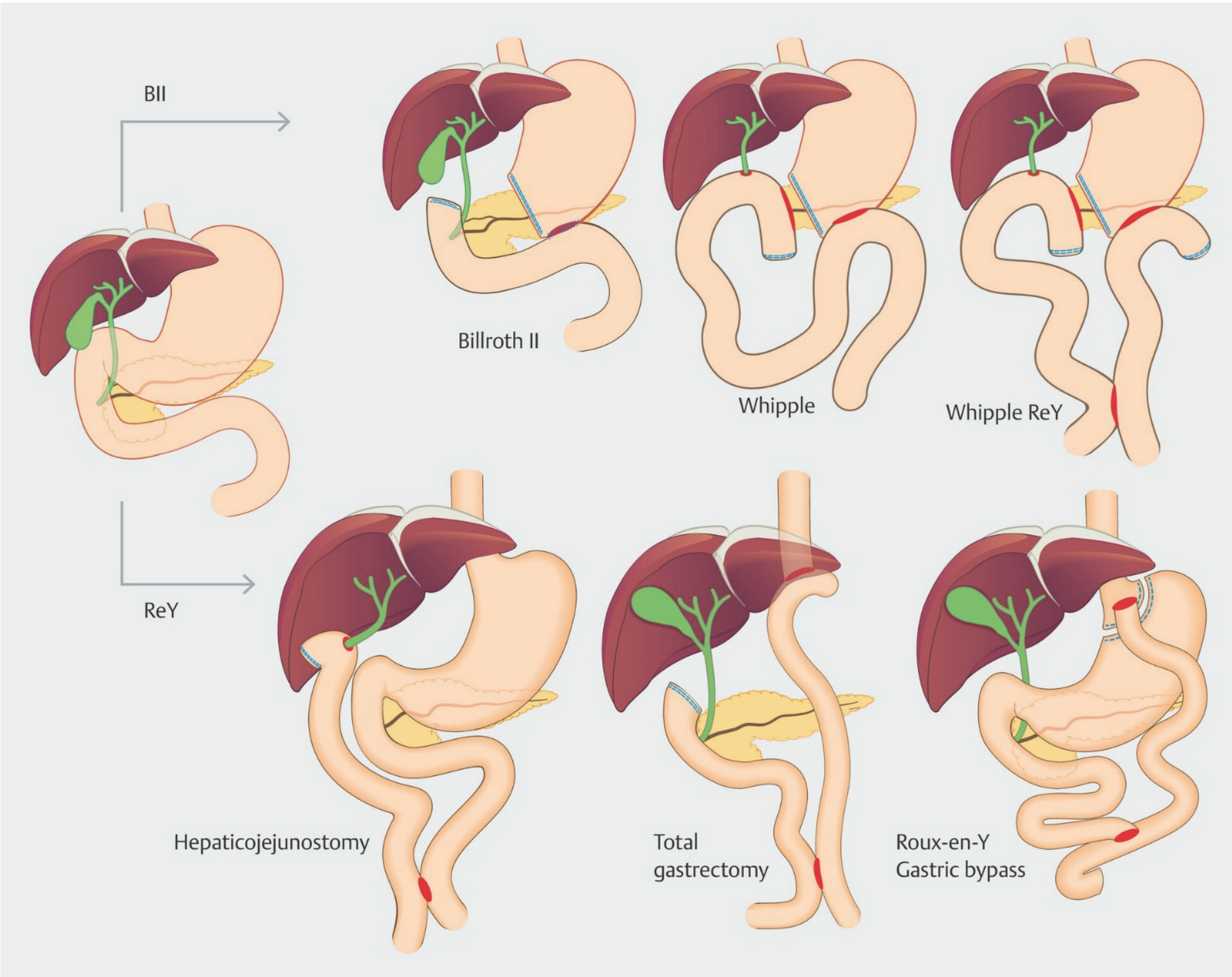
		1 propensity matched						related mortality) EUS-HG outperforms PTBD (CS, safety, need for reinterv...)		biliary drainage of HMBO
Unilateral vs Bilateral SEMS for palliation in MHBO										
Unilateral SEMS vs Bilateral SEMS	**1**	**SRMA** (of 2 RCT, 7 R studies)	**Not serious**	**Not serious**	**Serious**	**Not serious**	**Not serious**	Less reintervention rate with bilateral SEMS compared to unilateral SEMS	⨁⨁○○ Moderate	1 RCT shows improved clinical success with bilateral SEMS 4 studies show reduced mortality (or post-procedure death) if bilateral or more than 80% of liver drained

Abbreviations: PTC: percutaneous Transhepatic cholangiography; MBO: malignant biliary obstruction; SRMA: Systematic Review and Meta-analysis; EBD: Endoscopic Biliary Drainage; EUS-HG: EUS assisted hepatico-gastrostomy; HMBO: Hilar Malignant Biliary Obstruction; CS: Clinical Success; MHBO: Malignant Hilar Biliary Obstruction

NOS scale for assessing the risk of bias

Study	Selection (max 4 stars)	Comparability (max 2 stars)	Outcomes (max 3 stars)	Quality
Coelen 2018	****	**	***	High

Fig. 2s: Common types of surgically altered anatomy (BII – Billroth II type; ReY – Roux-en-Y type).



Source: Moreels TG, Aabakken L, Arvanitakis M et al. Enteroscopy-assisted ERCP in patients with surgically altered anatomy: Multicenter prospective registry (SAMISEN-B) using motorized spiral enteroscopy. Endosc Int Open 2024; 12: 1392–1400. doi:10.1055/a-2443-1514

Table 9s: TF3 (surgically altered anatomy / inaccessible papilla) literature extraction

Author (year)	Methods		Population			Intervention			Outcomes		Remarks
	Design		N	Age, years	Inclusion criteria	Protocol (details) of Intervention	Protocol (details) of Comparison	Mean or Median Follow-up	Outcome measures (+ definitions)	Principal findings	
Billroth II anatomy											
Park 2018(1)	SRMA		2446 in 25 studies (499 vs 1947)			ERCP with front viewing scope	vs side viewing duodenoscope		Success and AE rates	Loop intubation 90.3% vs 86.8% Cannulation 91.1% vs 92.3% Perforation 3.0% vs 3.6% PEP 5.4% vs 2.5%	Forward and side viewing equally effective and safe
Park 2019(2)	SRMA		2669 in 43 studies (664 vs 1432 vs 171 vs 64)			ERCP with front viewing scope	vs side viewing duodenoscope vs balloon assisted vs dual-lumen		Success and AE rates	Cannulation 95.2% vs 95.3% vs 97.5% vs 100% Perforation 1.7% vs 3.6% vs 4.1% vs 0%	
Coskun 2021(3)	P		75 patients with Billroth II anatomy (34 vs 41)			ERCP with front viewing scope	vs side viewing duodenoscope		Success and AE (adverse event) rates	Papilla reached 70.7% (side viewing) vs 91.1% (forward view) Cannulation when papilla reached 100% vs 90.3% Technical success 70.7% vs 82.3% Clinical success 68.3% vs 79.4% (NS) 1 jejunal perforation (side viewing) 1 pancreatitis (front viewing)	Forward and side viewing equally effective and safe
Kim 2023(4)	R		55 matched pairs			ERCP with cap-fitted front viewing scope	vs side viewing duodenoscope		Success and AE rates	Cannulation rates 94.5% vs 98.2% Overall AE 10.9% vs 7.3% (NS) PEP 10.9% vs 5.5% (NS)	Cap-fitted forward and side viewing equally effective and safe
Marquis de Sa 2023(5)	R		83 (31 vs 52)			ERCP with front viewing scope	vs side viewing duodenoscope		Success and AE rates	Papilla reached 71% vs 64% Cannulation 68% vs 52% AE 0% vs 8%	Forward viewing at least as effective and

Author (year)	Methods		Population			Intervention			Outcomes		Remarks
	Design		N	Age, years	Inclusion criteria	Protocol (details) of Intervention	Protocol (details) of Comparison	Mean or Median Follow-up	Outcome measures (+ definitions)	Principal findings	
											safe as side viewing
Whipple surgery											
Chahal 2006	R		88		Whipple patients requiring ERCP	Standard ERCP	Retrospective series		ERCP success	ERCP success	ERCP success biliary 84% ERCP pancreatic 8%
Wang 2010	Case series		13 (3 Whipple)		SAA requiring biliary ERCP	SBE	Prospective series		success	81% success diagnostic Of those 90% successful therapeutically	
Lenze 2014	Cohort study		30 (2 Whipple)		SAA requiring biliary ERCP	SBE	Prospective series		Success	58% overall (unclear rate of Whipple success)	
Inamdar 2015	MA		461 (2 Whipple)		SAA requiring biliary ERCP	SBE	Systematic review and meta-analysis		Success	Overall procedural success 61.7% (100% Whipple)	AE 6.5%
Wang 2020	R		15 (4 Whipple)		SAA requiring biliary ERCP	Balloon assisted enteroscopy (DBE, SBE)	Retrospective		Success	Overall procedural success 86.7% (100% Whipple)	
Anvari 2021	SRMA		1523 (312 Whipple)	2-89	DBE-ERCP in SAA	DBE-ERCP – both < and >200cm DBE scopes	Meta-analysis		(1) reaching the papilla; (2) performing the enteroscopy; (3) diagnostic success; (4) procedural success; (5) AE	90-94% success, AE 4% DBE-ERCP is feasible, safe and effective for the diagnosis and treatment of a wide range of problems in patients with surgically altered anatomy	Not unique to Whipple
Tanisaka 2021	SRMA		1227 (only 3 Whipple)		SBE in surgically altered – HJRoux, RYGB, whipple	SBE for biliary indication	Series and meta-analysis		ERC success	86% enteroscopy 90% cannulation 75% procedure success	Unclear what success rates with Whipple was
Tanisaka 2023	SRMA		409 (70 Whipple)		EUS BD in surgically altered anatomy	EUS BD	Series and meta-analysis			97.8% technical success 94.9% technical success	

Author (year)	Methods		Population			Intervention			Outcomes		Remarks
	Design		N	Age, years	Inclusion criteria	Protocol (details) of Intervention	Protocol (details) of Comparison	Mean or Median Follow-up	Outcome measures (+ definitions)	Principal findings	
										12.8% AE	
Khashab 2016	R Multicentric comparative		49 entero-ERCP 49 EUS BD (11 Whipple)		SAA requiring biliary ERCP	EUS BD or entero-ERCP (pediatric colonoscope 2, SBE in 5 or DBE in 42)			Success	Success: technical 98%, clinical 88% in EUS BD Vs technical 65.3%, clinical 59.1% in entero-ERCP group (11 failed to reach ampulla, 6 failed to cannulate) Procedure duration: 55 vs 95 minutes AE 20% (90% minor) vs 4%	
Mutignani 2023	R		EDEE in 32 patients		RHJ and Whipple (3)	EDEE for biliary adverse events after surgery	Case series		ERCP success	Clinical success 98.7% AE 43% but much lower since use of hot-LAMS	
Roux – en – Y Gastric Bypass (RYGBP)											
Inamdar 2015	MA		461 (rate of RYGB as opposed to RY gastrectomy unclear)		SAA requiring ERCP	SBE	Systematic review and meta-analysis No comparison		Success	Procedural success 61.7 AE 6.5%	
Anvari 2021	SRMA		1523 (157 RYGB)	2-89	DBE-ERCP in SAA	DBE-ERCP – both < and >200cm DBE scopes	Meta-analysis No comparison		(1) reaching the papilla; (2) performing the enteroscopy; (3) diagnostic success; (4) procedural success; (5) adverse events	90-94% success, AE 4% DBE-ERCP is feasible, safe and effective for the diagnosis and treatment of a wide range of	Not unique to RYGB

Author (year)	Methods		Population			Intervention			Outcomes		Remarks
	Design		N	Age, years	Inclusion criteria	Protocol (details) of Intervention	Protocol (details) of Comparison	Mean or Median Follow-up	Outcome measures (+ definitions)	Principal findings	
										problems in patients with surgically altered anatomy.	
Tanisaka 2021	SRMA		1227 (172 RYGB)		SBE in SAA (HJRoux, RYGB, Whipple)	SBE for biliary indication	Series and meta-analysis No comparison		Succes	86% enteroscopy 90% cannulation 75% procedures success	
Banerjee 2017	SR		509		RYGB needing ERCP	LAP-ERCP	Systematic review No comparison	Gastric access and ERCP cannulation	Cannulation	100% gastric access 98.5% cannulation AE 14% (80% from lap)	
Aiolfi 2018	SRMA		850		RYGB needing ERCP	LAP-ERCP	Systematic review and meta-analysis No comparison		ERCP success	99% ERCP success Overall morbidity 14%	
Da Ponte-Neto	SRMA		703: 466 LAP-ERCP; 166 SBE; 71 DBE		RYGB needing ERCP	LAP-ERCP, SBE and DBE	Systematic review and meta-analysis No comparison		ERCP cannulation and success	Successful native papilla cannulation: LAP-ERCP 95.7%, SBE 62.2%, DBE 82.2% AE: 18%, 9.9%, 2%	
Hajibandeh 2021	SRMA		256 patients		RYGB needing ERCP	LAP-ERCP	Systematic review and meta-analysis No comparison			Cannulation 95.3% AE 4.7% PEP, cholangitis 1.7%, perforation 3.7% Procedural time 137 minutes Conversion to open surgery 4.7% LOS 3 days	
Saad 2023	SRMA		1283 (33.7% concomitant		RYGB needing ERCP	LAP-ERCP	Systematic review and meta-analysis			Clinical success 93.8% Overall AE 20.6%, PEP 6.8%, infection 6.1%, bleeding 3.4%, perf 2.5%	

Author (year)	Methods		Population			Intervention			Outcomes		Remarks
	Design		N	Age, years	Inclusion criteria	Protocol (details) of Intervention	Protocol (details) of Comparison	Mean or Median Follow-up	Outcome measures (+ definitions)	Principal findings	
			laparoscopic cholecystectomy)				No comparison			Procedural time 130 minutes LOS 2.7d Conversion to open surgery 7%	
Kedia 2019	R		29 EDGE 43 LAP-ERCP		RYGB needing ERCP	LAP-ERCP and EDGE	Case series in prospective registry		ERCP success	Success: EDGE 96.5% vs. LAP ERCP 97.7% AE: EDGE 24%, LAP-ERCP 19% Procedural Time: 73 minutes vs 184 minutes LOS: 0.8 vs 2.65 days	
Prakash 2022	SR		169 EDGE		RYGB needing ERCP	EDGE	Systematic review No comparison		ERCP success	98% ERCP Minor AE specifically related to EDGE: 18%, including intraprocedural stent migration/malposition (n=27), abdominal pain (n=4). Moderate AE specific to EDGE: 5%, including bleeding (2%), persistent fistula (1%), perforation (1%). Major AE: perforation (n=1)	
Deliwala 2023	SRMA		470 EDGE		RYGB needing ERCP	LAP-ERCP EDGE Entero-ERCP	Systematic review and meta-analysis Primary outcome of EDGE, then EDGE vs LAP-ERCP and EDGE vs entero-ERCP		ERCP success Primary outcome of EDGE, then EDGE vs LAP-ERCP and EDGE vs entero-ERCP	TS 96%, CS 91% AE 17% (failure of fistula closure 17%, stent migration 7%, bleeding 5%, post-EDGE weight gain 4%m, perforation 4%, and PEP 2%) - EDGE vs LAP-ERCP: TS 97% vs 98%	

Author (year)	Methods		Population			Intervention			Outcomes		Remarks
	Design		N	Age, years	Inclusion criteria	Protocol (details) of Intervention	Protocol (details) of Comparison	Mean or Median Follow-up	Outcome measures (+ definitions)	Principal findings	
										AE 13% vs 17.6% Procedural time 75 minutes vs 187 minutes LOS 2.2 days vs 5.4 days - EDGE vs entero-ERCP: Success 100% vs 66% AE 9.6% v 16% Procedural time 61 minutes vs 169 minutes LOS 1.8 days vs 6.9 days	
Su 2023	SRMA		585 EDGE			RYGB needing ERCP	EDGE	Systematic review and meta-analysis No comparison	ERCP success	TS 98%, CS 94% AE 14% (LAMS dislodgement 4% - lower in 20mm than 15mm)	
Gangwani 2024a	SRMA		75 EDGE and 117 LAP-ERCP			RYGB needing ERCP	EDGE vs LAP ERCP	Systematic review and meta-analysis	ERCP success	Same efficacy (RR .994) AE: no significant difference Procedural time: EDGE 91 minutes quicker than LAP-ERCP	
Gangwani 2024b	Network MA		198 EDGE			RYGB needing ERCP for stones	EDGE vs LAP-ERCP EDGE vs entero-ERCP	Network meta-analysis	ERCP success	TS: 94.8% EDGE, 95.0% LAP-ERCP, 66.3% entero-ERCP AE: 14.9%, 20.3%, 14.7%	

Author (year)	Methods		Population			Intervention			Outcomes		Remarks
	Design		N	Age, years	Inclusion criteria	Protocol (details) of Intervention	Protocol (details) of Comparison	Mean or Median Follow-up	Outcome measures (+ definitions)	Principal findings	
			344 LAP-ERCP 480 entero-ERCP							Procedural time: EDGE quicker than entero-ERCP (31 minutes) and quicker than LAP-ERCP(78 minutes)	
Gastrectomy+RY jejuno-jejunal anastomosis											
EUS-BD											
Tanisaka et al, 2023	SRMA		409 patients with SAA		in 18 studies	EUS-guided BD			Technical Success Clinical success Adverse events	EUS-BD is effective for patients with SAA. AEs are not negligible	
Balducci D et al, 2024	R		21 RYG			EUS-guided hepaticojejunostomy using metal stents			Clinical success AEs	80%. 33%	EUS-HJS is an effective and feasible procedure
Park et al 2013	P		2 RYG			EUS-BD			Technical success	57% anterograde drainage in SAA	Anterograde drainage over HGS
Kanno et al 2019	R		10 RYG			EUS-BD			Technical success Clinical success AE	98% in RYG 93% 10%	
Iwashita et al 2020	R		28 RYG			EUS-antegrade biliary stenting	compared to PTBD in distal malignant biliary obstruction		Technical success Clinical success Internalisation success AE rate	97.1% vs 96.6% 97.1% vs 93.1% 97.1% vs 75.9% 11.4% vs 27.9%	EUS-BD may have lower AE rates
Minaga et al 2020	R		19 RYG			EUS-BD			Technical success Clinical success Early AE Late AE	100% 95% 15% 15%	
Matsunami et al 2021	R		RYG 12		(8 EUS-hepaticojejunostomy)	EUS-hepaticoenterost			Technical success Adverse events	92.9% 15.7%	

Author (year)	Methods		Population			Intervention			Outcomes		Remarks
	Design		N	Age, years	Inclusion criteria	Protocol (details) of Intervention	Protocol (details) of Comparison	Mean or Median Follow-up	Outcome measures (+ definitions)	Principal findings	
						omy in benign conditions					
Khashab MA et al 2016	R		RYG 2			EUS-BD					
Iwashita et al	R		14 RYG			EUS-guided antegrade stenting					
Tyberg A et al 2016	R		5 RYG			EUS-guided antegrade stenting or HGS if failure					
Entero-ERCP											
Farina E et al, 2023	R		17 RYG			DBE-ERCP			Technical success. Procedure success Adverse events	76% 85% 0	
Tanisaka Y et al 2022	R		85 RYG			SBE-ERCP			Cannulation success Complete stone extraction success AE	90.6% 68.2% 8.2%	
Yokoyama 2021	R		92 RYG			BE-assisted ERCP			Clinical success	Success of reaching the papilla 90.1%Clinical success: 79%	Effective procedure
Itoi et al 2021	R		15 RYG			SBE-ERCP			Complete stone removal	100%	
Kato S et al 2024	R		19 RYG		12 Entero-ERCP, 7 colonoscopy assisted ERCP	Passive bending colonoscope					
Cho E et al 2022	R		33 RYG			SBE-ERCP			Cannulation success Therapeutic success	78.8% 78.8%	
Tanisaka Y et al, 2022	R		527 RYG			SBE-ERCP			Cannulation success	83.3% 71.7%	

Author (year)	Methods		Population			Intervention			Outcomes		Remarks
	Design		N	Age, years	Inclusion criteria	Protocol (details) of Intervention	Protocol (details) of Comparison	Mean or Median Follow-up	Outcome measures (+ definitions)	Principal findings	
									Total procedural success		
PTBD											
Perez-Cuadrado-Robles E et al 2024	R		40 SAA			Percutaneous assisted cholangioscopy			Clinical success	96.6%	
Rivera et al. 2023	R		40 (13 SAA)			Percutaneous assisted cholangioscopy			Technical sucess	100% Complications 17%	
Boskoski et al. 2024	P multicentric study		50 (30 SAA)			Percutaneous assisted cholangioscopy			Clinical Success Technical Sucess AE	88% 96% 4%	
RY Hepatico-jejunostomy											
EUS-BD											
Tanisaka et al, 2023	SRMA		409 patients with SAA		in 18 studies	EUS-BD			Technical Success Clinical success AE	97.8% 94.9% 12.8%	EUS-BD is effective for patients with SAA. AEs are not negligible
James et al 2018	R		6 RYHJ			EUS-guided hepaticoenterostomy in benign conditions			Deaths during follow-up period	0	
Minaga et al 2020	R		4			EUS-BD			Technical success	100%	
Matsunami et al 2021	R		7			EUS-hepaticoenterostomy in benign conditions			Technical success Median procedure time	6/7 22 minutes	
Yu T et al, 2024	R		4			EUS-antegrade drainage			Technical success	100%	
Ichkhanian Y et al 2020	R		6			EUS-assisted Transjejunal ERCP			Technical success	100%	
PTBD and comparative studies											

Author (year)	Methods		Population			Intervention			Outcomes		Remarks
	Design		N	Age, years	Inclusion criteria	Protocol (details) of Intervention	Protocol (details) of Comparison	Mean or Median Follow-up	Outcome measures (+ definitions)	Principal findings	
Imamine et al, 2015	R		52		Anastomotic biliary stricture	PTBD			Clinical success	83%	
Lee SH et al 2008	R		86		Post LT biliary stricture	PTBD	vs ERCP		Successful intervention rate Number of interventions	60% vs 59.3% 7.2 (PTBD) vs 2.9 (ERCP); p<0.01	Not in RYHJ specifically
Nakamura et al 2024	R		83		(41 PTBD and 42 DBE) Hepato-lithiasis	PTBD	vs Entero-ERCP		Complete stone removal Adverse events	90% vs 86% 29% vs 14%	
Ko GY, 2008	R		83		Post LT anastomotic stricture	PTBD and balloon dilation			Clinical success Recurrence rate	97.6% 15.8%	
Tsutsumi K et al, 2017	R		40		8 PTBD, 32 DBE with HJ for biliary stones	PTBD	and short double-balloon enteroscopy		Biliary access Adverse events	PTBD (100%) DBE (91%) 45% (PTBD) vs 10% DBE	DBE is safer than PTBD
Chon HK et al 2022	R		7		Benign condition	Percutaneous cholangioscopy			Procedure success	100%	
Tsutsumi K, 2017	R		40		(8 PTBD and 32 DBE)	Percutaneous cholangioscopy	vs Entero-ERCP		Biliary access AE	100 vs 91% 45% vs 10%	DBE was useful, with few adverse events
Entero-ERCP											
Yokoyama et al, 2024	R		38 RYHJ			DBE-ERCP for biliary stones					
Tanisaka Y et al 2022	R		221 RYHJ			Short type SBE-ERCP			Enteroscopy access Cannulation access Total procedural success	153/221 (69.2) 138/153 (90.2) 134/221 (60.6)	
Farina E et al, 2023	R		24 RYHJ			DBE-ERCP			Procedure success Adverse events	86% 0%	
Parlak E 2010	R		14			DBE-ERCP			Technical success Number of sessions	13/14 20 sessions in 13 patients	

Author (year)	Methods		Population			Intervention			Outcomes		Remarks
	Design		N	Age, years	Inclusion criteria	Protocol (details) of Intervention	Protocol (details) of Comparison	Mean or Median Follow-up	Outcome measures (+ definitions)	Principal findings	
Inaccessible papilla											
EUS-BD vs PTBD											
Facciorusso et al, 2022	SRMA		5 RCTs			EUS-BD	and PTBD		Clinical success and AE rates	PTBD was found to be inferior to other interventions (PTBD: RR 1.01, 0.88–1.17 with EUS-CDS); RR 1.03, 0.86–1.22 with EUS-HGS	All interventions were comparable in CS PTBD showed a trend towards higher rates of AE
Marx M, 2022	RCT		56 patients		(31 PTBD, 35 EUS-HGS)	PTBD	vs EUS-HGS		Technical success Clinical success	PTBD 100% vs EUS-HGS 94.3% PTBD 66.7% vs EUS-HGS 80%	EUS-HGS has a safest profile with lower risk of reinterventions
Ginestet C, 2022	R		95		50 in EUS-BD group and 45 in PTBD group).	PTBD	vs. EUS CDS in ERCP failure		Clinical success AE	89.3% vs. 45.5%; p<0.0001 2.1% vs. 22.7%; p=0.003	results are in favor of EUS-BD LAMS
Khashab MA,2015	R		73 patients		(51 PTBD 22 EUS-BD)	PTBD	vs EUS-BD		Technical success Clinical success Adverse events	100 vs. 86.4 %, p = 0.007 92.2 vs. 86.4 %, p = 0.40 39.2 vs. 18.2 %	EUS-BD is associated with decreased AE rate and fewer reinterventions
EUS HGS vs EUS-CDS											
Rizqiansyah CY, 2024	SRMA		537 patients		malignant biliary obstruction: 9 nonrandomized studies and 2 RCTs	EUS-HGS	vs EUS-CDS		Technical success Clinical success Adverse events	OR, 0.83; 95% CI, 0.41-1.68 OR, 0.96; 95% CI, 0.51-1.81 OR, 2.01, 95% CI, 1.14-3.59	EUS-CDS has a faster procedure time, lower risk of AE
Uemura RS,2018	SRMA		434 patients		10 studies with	EUS-CDS	vs. EUS-HGS		Technical success Clinical success Adverse events	CDS 94.1% vs. HGS 93.7% 88.5% in CDS and 84.5% in HGS OR=0.97 (95% CI=0.60-1.56)	TS and CS between EUS-CDS and EUS-HGS are comparable
Mao K, 2021	SRMA		13 studies			EUS-CDS	vs. EUS-HGS		Technical success Clinical success	OR: 0.95; 95% CI: 0.51-1.74 OR: 1.13; 95%CI: 0.66-1.94	TS and CS between EUS-CDS and EUS-HGS are comparable

Author (year)	Methods		Population			Intervention			Outcomes		Remarks
	Design		N	Age, years	Inclusion criteria	Protocol (details) of Intervention	Protocol (details) of Comparison	Mean or Median Follow-up	Outcome measures (+ definitions)	Principal findings	
Hedjoudje A, 2018	SRMA		686 patients		17 studies	EUS-CDS	vs EUS-HGS		Technical success Clinical success	96% (HGS) vs 95% (CDS) 84% (HGS) vs 87% (CDS)	EUS-CDS may be a safer approach
Artifon EL,2015	RCT		49 patients (25 HG versus 24 CDS)		failed ERCP	EUS-HGS	vs EUS-CDS		Technical success Clinical success AE	96% (HGS) vs 91% (CDS) 91% (HGS) vs. 77% (CDS). 20% (HGS) vs 12.5% (CDS)	EUS-HGS and EUS-CDS techniques are similar in efficacy and safety
Vanella et al, 2025	P		20 patients		patients with gastric outlet obstruction treated with EUS-gastroentero anastomosis	EUS-CDS	vs EUS-HGS		Technical success Clinical success Adverse events Biliary stent dysfunction	100% vs 100% 100% vs. 92.3%, $p = 0.5$ 42.9% (CDS) vs. 7.7%,(HGs) $p = 0.067$ 71.4% (CDS) vs. 16.7% (HGS), $p = 0.002$	EUS-CDS versus EUS-HGS resulted in a reduced probability of survival without biliary events and an increased risk of biliary dysfunctions
EUS-CDS (no comparison)											
Mohan BP, 2019	SRMA		572 patients		13 studies including	EUS-CDS			AE in EUS-CDs using LAMS	9.3%	Reported AE appeared to be lower with the use of LAMS
Tarrio I, 2023	R		20 patients,		ERCP failure (55.0% of duodenal obstruction)	EUS-CDS			Technical success Clinical success	100% 89.5%	EUS-CDS was effective in biliary decompression of malignant obstructions
Di Mitri et al 2022	R		36		EUS-BD	EUS-guided biliary drainage with LAMS			Technical success Adverse events	80.6% (29/36 patients). 19.4% (7/36)	EUS-BD with LAMS is effective for jaundice palliation after ERCP failure but with considerable AE
Rai P et al, 2018	R		30			EUS-CDS using partially covered stents			Clinical success	93.3%	EUS-CDS with a PC-SEMS has a high TS and CS.

Author (year)	Methods		Population			Intervention			Outcomes		Remarks
	Design		N	Age, years	Inclusion criteria	Protocol (details) of Intervention	Protocol (details) of Comparison	Mean or Median Follow-up	Outcome measures (+ definitions)	Principal findings	
Kunda R , 2016	R		57 patients.		Duodenal obstruction in 41 (71.9 %)	EUS-CDS			Technical success Clinical success Reintervention rate	98.2 % 96.4 % 9.3 %	Safe procedure, with high TS and CS rates.
On W, 2022	R		120 patients			EUS-CDS			Technical success Clinical success Adverse events Reintervention rate	90.8% 94.8% 17.5% 8.3%	
Geyl S,2023	P		123			EUS-CDS			Technical success Clinical success factors for biliary obstruction	97.5% 91% Duodenal stent and CBD<15mm.	Obstruction of LAMS occurred in 16.3% of cases. The presence of duodenal stent and a bile duct thinner than 15 mm are the risk factors of obstruction.
Jacques J, 2019	R		52 patients			EUS-CDS			Technical success Clinical success	88.5 % 100%	EUS-CDS using LAMS is efficacious and safe
EUS-GBD											
Imai H, 2016	R		12			EUS-GBD			Technical success Clinical success Adverse events	100% 91.7% 16.7%	EUS-GBD is a possible alternative
Binda C et al, 2023	R		48 patients		as a rescue therapy	EUS-GBD			Technical success Clinical success Adverse events	100% 81.3% 10.4%	EUs-GBD is a valuable option in terms of technical and clinical success rates
Debourdeau A et al, 2024	R		78 patients		(41 EUS-GBD, 37 EUS-CDS) after failed ERCP	EUS-GBD	vs EUS-CDS		Clinical success	87.8% for EUS-GBD vs 89.2% for EUS-CDS	EUS-GBD and EUS-CDS show comparable clinical success rates and technical success

Author (year)	Methods	Population			Intervention			Outcomes		Remarks
	Design	N	Age, years	Inclusion criteria	Protocol (details) of Intervention	Protocol (details) of Comparison	Mean or Median Follow-up	Outcome measures (+ definitions)	Principal findings	
Abbreviations: SR: Systematic Review Meta-analysis, P: prospective; R: retrospective; TS: Technical Success, CS: Clinical Success; RYHJ: Roux-en-Y Hepatico-jejunal anastomosis; RYGBP: Roux-en-Y Gastric bypass, RYG: Gastrectomy (partial or total) with Roux-en-Y jejuno-jejunal anastomosis; PTBD: Percutaneous Biliary Drainage; Entero-ERCP; DBE: Doubkle-Balloon assisted Enteroscopy, SBE: Single Balloon assisted Enteroscopy; AE: Adverse Events										

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Table 10s: TF3 Grade of evidence table

Certainty assessment								Effect estimate	Certainty	Comments
PICO	**No. of studies**	**Study design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Publication bias**			
Billroth II										
	2	**SRMA**	**Low**	**No**	**Yes**	**Low**	**No**	Forward viewing+cap and side viewing scopes are equally effective	⊕⊕◯◯ Moderate	None
Whipple surgery										
SBE / DBE / EUS	**3**	**SRMA**	**Moderate**	**No**	**Yes**	**Yes**	**No**	entero-ERCP results in fewer AE than EUS-BD	⊕◯◯◯ Low	6/10 included studies on hilar MBO (others being distal MBO)
RYGBP										
Entero-ERCP / Lap-ERCP / EDGE	**3**	**SRMA (2 with technique comparisons)**	**Low**	**No**	**Yes**	**Yes**	**Low**	Entero-ERCP : -safer -Less technical success EDGE: -expertise, -usefull if multiple interventions required	⊕◯◯◯ Low	SRMA have been published examining entero-ERCP in RYGB patients. Unfortunately, as all of them included other types of SAA, only one of them specifically breaks down the

								safety, need for reinterv…)		success rates for RYGB.
Gastrectomy+RY jenuo-jejunal anastomosis										
EUS-BD **Entero-ERCP** **PTBD-cholangioscopy**	**1/1/8** **7** **1/2**	**SRMA/P/R** **R** **P/R**	**Moderate**	**No**	**Yes**	**Yes**	**No**	**Entero-ERCP**: -safer -Less effective (papilla access 68%) **EUS-BD**: CS 80% AE 33%	⊕◯◯◯ Low	Entero-ERCP, PTBD+/- cholangioscopy and EUS-BD need expertise
Hepatico-jejunostomy+RY jejuno-jejunal anastomosis (RYHJ)										
EUS-BD **PTBD** **Entero-ERCP**	**1/5** **5** **4**	**SRMA/ R** **R** **R**	**Moderate**	**No**	**Yes**	**Yes**	**No**	**-Entero-ERCP** safer **-PTBD** and **EUS-BD** are effective, with more AE	⊕◯◯◯ Low	Expertise is required for Entero-ERCP, PTBD and EUS-BD
Inaccessible papilla										
EUS-BD vs PTBD **EUS-HG vs EUS-CDS** **EUS-CDS** **EUS-GBD**	**1/1/2** **4/1/1** **1/7** **3**	**SRMA/RCT/R** **SRMA/RCT/R** **SRMA/R** **R**	**Moderate**	**No**	**No**	**No**	**yes**	**EUS-BD vs PTBD:** Same efficacy, les AE with EUS-BD **EUS-HGS vs CDS**:	⊕⊕◯◯ Moderate	EUS-BD (HG and CDS) need expertise and proper training

								Comparable CS and TS CDS unsafe if duodenal stricture: AE:42.9% (CDS) vs. 7.7%,(HGs) *p* = 0.067 Stent dysfunction 71.4% (CDS) vs. 16.7% (HGS), *p* = 0.002 **EUS-CDS** 9-17% AE		

Fig.3s: Algorithm of biliary stricture management in inaccessible papilla/failure

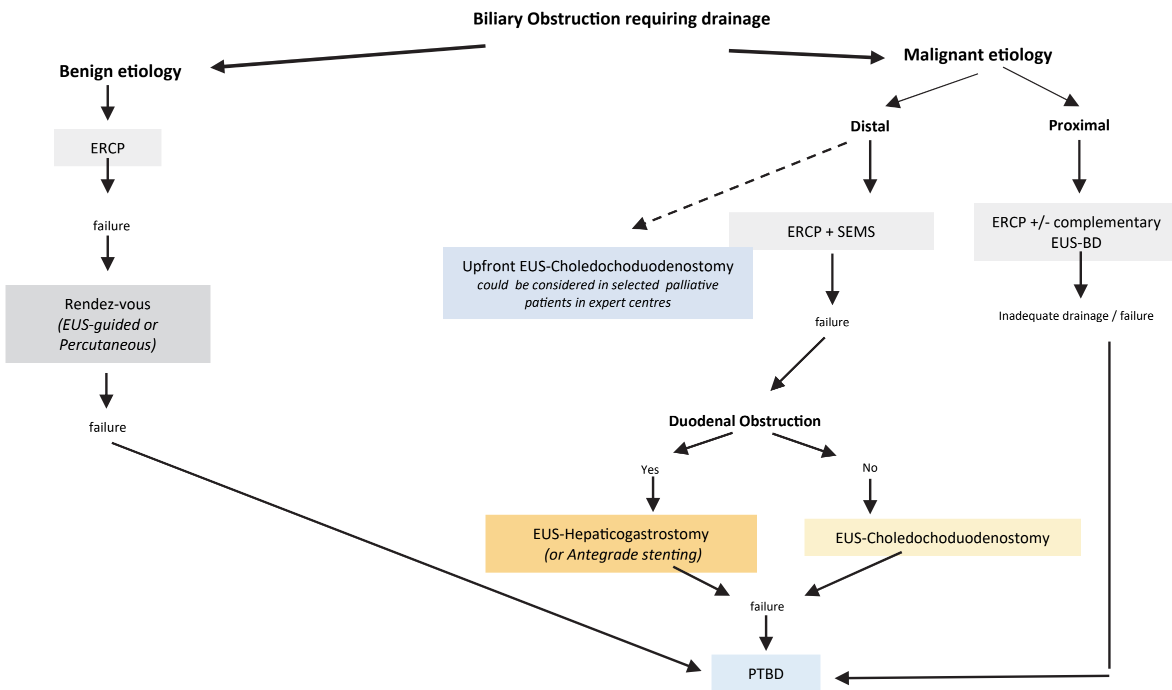

Table 11s: Biliary stricture management in case of failure: second attempt: literature extraction

Author (year)	Methods		Population			Intervention			Outcomes		Remarks
	Design		N	Age, years	Inclusion criteria	Protocol (details) of Intervention	Protocol (details) of Comparison	Follow-up	Outcome measures (+ definitions)	Principal findings	
EUS Rendez-vous											
Klair (2023)	SR MA	NA	342		EUS-RDV for failed ERCP	Benign/malignant	No comparison		TS CS AE	86.1% [95% confidence interval (CI): 78.4-91.3] 80.8% (95% CI: 64.1-90.8) 14% (95% CI: 10.5-18.4)	EUS-RDV feasible ad safe, Need expert center
Vanella (2020)	R	BC	16 RDV		EUS-BD	16% of 104 EUS-BD benign	EUS-RDV 50% of benign indications		TS CS AE	62% (8/10) 100% (8/8) 20%	Benign= subanalysis
Choudhury (2024)	P	RCT MC	100		Difficult ERCP cannulation, benign stricture	RCT EUS-Rv	Precut		TS Time AE (PEP)	92 vs 90% 10 vs 9.8min 12% vs 10% (10 vs 10%)	High incidence in difficult cannulation in 1y
Gornals (2024)	R	MC	69 (40 benign)		EUS-RV	EUS-RV	Benign vs malignant		TS CS AE	78% 74% 24%	Higher failure of EUS RV for malignant stricture
Percutaneous Rendez-vous											
Chivot (2020)	R	MC	84		Second failure of ERCP (21% benign)	PTC-RV Same procedure ERCP 80/84	no		TS AE mortality	95% 19% 9.5%	
Bokemeyer (2019)	R	MC	163 PTC-RV		PTC	PTC-RV among PTC (163 from 553)	no		TS AE	80.4% 23%	Lower AE when PTC-RV compared to PTC (16.6 vs 26.4% p=0.037)
EUS Rendez-Vous vs PTC Rendez-Vous											
Yoon (2024)	SR MA	NA	524 EUS-Rv 591 PTC-RV		EUS-RV vs PTC-RV	19 studies EUS-RV	12 studies PTC-RV		TS TS (benign) TS (SAA) AE	88.7% vs 94.1% (p=0.088) 89.2% vs 95.8% (p=0.068) 58.7% vs 93.1% (p=0.036) 9.8% vs 13.4% (p=0.68)	Less technical succss in EUS-RV in altered anatomy
EUS antegrade stenting (EUS-AG)											
Godat (2007)	R	MC	20 (5% benign)		EUS-BD antegrade stenting	EUS-AG	NA		CS	85%	
Iwashita (2017)	R	MC	20	No benign			NA		TS = CS	95%	

				EUS-AG							
Dhir (2015)	R	MC	208 (36 EUS-AS)		Failure ERCP	EUS-BD (CDS or AG)	Vs ERCP+stent		TS AE	EUS-BD 94% vs ERCP 93% 8.65% (EUS-BD)	Lower AE with EUS-BD than ERCP (PEP 0 vs 4.8%)
Sundaram (2023)	R	MC	54	No benign case	EUS-AG	EUS-AG	no		TS CS	88.7% 95.7%	

Abbreviations: PTC: Percutaneous Transhepatic Cholangiography; EUS-AG: AUS assisted antegrade stenting; EUS-BD: EUS biliary srainage; EUS-RV: EUS-rendez-vous ; PTC-RV : PTC-Rendez-Vous ; TS : technical Success ; CS : Clinical Success ; AE : Adverse Events

Table 12s: Biliary stricture management in case of failure: second attempt: grade of evidence table

Certainty assessment								Effect estimate	Certainty	Comments
PICO	**No. of studies**	**Study design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Publication bias**			
EUS-Rendez-Vous vs PTC-Rendez-Vou	1	SRMA	Moderate	No	Yes	Yes	No	**Same efficacy in normal anatomy EUS-Rendez-Vous Lower efficacy than PTC-Rendez-Vous in SAA**	⨁◯◯◯ Low	Non comparative trials All retrospective series Heterogeneity in technical success rate

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Table 13s: Malignant biliary stricture management in case of failure: second attempt (accessible papilla and no duodenal stricture): literature extraction

Author (year)	Methods		Population			Intervention			Outcomes		Remarks
	Design		N	Age, years	Inclusion criteria	Protocol (details) of Intervention	Protocol (details) of Comparison	Mean or Median Follow-up	Outcome measures (+ definitions)	Principal findings	
Repeated ERCP versus EUS-BD											
No comparatives studies found											
EUS-BD versus PTBD											
Facciorusso, A (2022)	SRMA	NA	5 studies – 217 patients	NA	RCTs including patients with dMBO and failed ERCP	EUS-BD (either EUS-CDS or HGS with SEMS)	PTBD or surgical HJ	Search coverage: up to September 2021	NA	No significant different in CS and AEs among EUS-BD vs. PTBD EUS-CDS vs. EUS-HGS Surgery vs. PTBD EUS-BD vs. Surgery	SUCRA Ranking was higher for Surgery and lower for PTBD for both outcomes.
Wang, Y (2022)	SRMA	NA	9 studies – 535 patients	NA	RCTs or observational studies with MBO	EUS-BD (either EUS-CDS, HGS, RV or AS with plastic stents, SEMS or LAMS)	PTBD	Search coverage: up to January 2021	NA	TS: OR=0.76 (0.17-3.30), p=.71, I^2=69% CS: OR=2.05 (1.19-3.56), p=.01, I^2=28% AEs: OR=0.30 (0.19-0.46), p<.0001, I^2=23%	Sub-analysis restricted to SEMS confirmed the difference on AEs.
Hayat, U (2021)	SRMA	NA	10 studies – 567 + 564 patients	60 (10)	All studies on mBO (4RCT, 6 R (one abstract only)	ES-BD	PTBD	Search coverage: up to July 2019	NA	TS: OR=0.47 (0.20–1.07), I^2=19% (p 0.27) CS: OR=2.24 (1.1–4.5), I^2=0% (p=0.51) AEs: OR=0.09 (0.02–0.38), I^2=88% (p<0.01) Reinterventions: OR=0.27 (0.16–0.45) Lower costs of EUS-BD	Only 3 studies in USA (cost not extrapolable)
Sharaiha, RZ (2017)	SRMA	NA	9 studies – 483 patients		RCTs or Observational comparative studies in patients with BO and failed ERCP	EUS-BD (different techniques)	PTBD	Search coverage: up to September 2016	NA	TS: OR=0.56 (0.22-1.45); I^2=22%; CS: OR=2.22 (1.12-4.35); I^2=0%; AEs: OR=0.23 (0.12-0.47); I^2=57%; Reinterventions: OR=0.13 (0.07-0.24); I^2= 0%; Similar LoHS Costs: EUS-BD more cost-effective.	Outcomes of safety (AEs and reinterventions) confirmed in subanalysis including only RCTs. Several studies included as abstracts only.
Koutlas, NJ 2023	R	SC	32 + 64	66 (53.5, 74.5) - 65.5 (55.5, 73.5)	Benign or Malignant BO and failed ERCP	EUS-HGS	PTBD	138 (49, 248) - 106 (28, 272) 0.11	TS; CS: >50% bilirubin decrease within 15 days or clinical resolution of presenting symptoms AEs;	TS: 91% vs. 98%, p=.11 Procedure duration: 60 vs 115 min, p<.0001 CS: 100% vs. 75%, p=.0021 AEs: 13% vs. 58%, p<.0001 LoHS: 2 vs. 4 days, p=<.0001 Reinterventions: 53%	Benign cases in more than 1/3 of sample.

									RBO: jaundice or cholangitis due to stent obstruction or migration	N of reinterventions: 1 vs 3, p<.0001	
Ginestet, C (2022)	R	SC	50 + 45	76.5 - 74.3	Unresectable dMBO after failed ERCP	EUS-CDS with LAMS	PTBD	NA	TS; CS: fall in bilirubin so as to start chemotherapy within 1 month; AEs; Recurrence: any cholangitis, cholestasis or jaundice	TS: similar when including also PTBD external drain only. CS: 89.3% vs. 45.5%, p<.0001; AEs: 2.12% vs. 22.7%, p=.003; N of procedures: 1 vs. 2, p<.00001 LoHS: 3.5 vs. 8.2 days, p=.001 Recurrences: 6.3% vs. 15.9%, p=0.146 OS: 118.4 vs. 42 days, p=.012 Total cost was significantly lower for EUS-BD	CS, AEs, LoHS, n. of procedures and survival in favor of EUS-CDS with LAMS Surprising low CS in PTC group
Sawas, T (2022)	R	MC	28 + 58	66.4 ± 14.7	Malignant and Benign BO, both as uptfont modality or rescue after failed ERCP (75%)	EUS-CDS with LAMS or SEMS	PTBD	433.9 ± 641	TS; CS: >50% bilirubin decrease within 2 weeks; AEs. Reinterventions	TS: 100% vs 96.6%, p=.03 CS: 84.6% vs. 62.1%, p=.04 AEs. 14.3% vs. 29.3%, p=.14 Reinterventions: 10.7% vs. 77.6%, p<.001 Similar survival	The study includes patients with upfront EUS-BD or PTBD. In subanalysis of MBO, outcomes of reinterventions were confirmed.
Kongkam, P (2021)	R	MC	19 + 17	62 ± 10 - 58.8 ± 12.8	Hilar MBO needing bilateral drainage	ERCP + EUS-BD	PTBD	NA	TS; CS: >50% bilirubin decrease within 15 days AEs; RBO: jaundice or cholangitis due to stent obstruction or migration	TS: 84.2% vs. 100%, p=.23 CS: 78.9% vs. 76.5%, p>0.99 AEs: 26.3% vs. 35.3%, p=.56 RBO: 37.5% vs. 88.2%, p=.002 TRBO: 92 vs. 40 days, p=.06 Similar survival	
Vanella, G (2021)	R	SC	45 + 45	67	Benign or Malignant Hilar BO or SAA	EUS-Intrahepatic Access (HGS or AS)	PTBD	NA	TS; CS: >25% bilirubin decrease or clinical resolution of presenting symptom AEs; RBO: jaundice or cholangitis due to stent obstruction or migration	TS: 93.3% vs. 97.8%, p=.31 CS: 97.4% vs. 79.5%, p=.01 LoHS: 7.5 vs. 11.5 days, p=.01 AEs: 17.8% vs. 24.4%, p=.004 RBO: 15.8% vs. 42.9%, p=.01 TRBO: 118 vs. 81 days, p=.31 Similar survival	33% of SAA; 25% of PTBD could not be internalized
Marx, M (2021)	RCT	MC	35 + 21	64	Benign or Malignant BO and failed ERCP	EUS-HGS	PTBD	EUS-HGS: 89 months; PTBD: 104 months.	TS; CS: >50% bilirubin decrease within 15 days	TS: 94.3% vs. 100%, p=.28 CS: 80% vs. 66.7%, p=.35 AEs: 28.6% vs. 61.9%, p=.0083 Mortality: 11.4% vs. 14.3%, p=1	Trial stopped for excessive complications in the PTBD group:

									AEs; LoHS; Mortality	LoHS: 8 vs. 12 days, p=.11 Reinterventions: 37% vs. 79%, p=.02	PTBD showed
Tellez-Avila, FI (2018)	R	SC	30 + 32	45.5 ± 19.2 - 44 ± 19	Benign or Malignant BO and failed ERCP or inaccessible duodenal portion	EUS-BD (either EUS-RV, EUS-HGS or EUS-CDS with SEMS)	PTBD	NA	TS; CS: symptoms resolution or >50% bilirubin decrease within 30 days; AEs	TS: 90% vs. 78.1%, p=.3 CS: 96% vs. 63%, p=.04 AEs: 6.6% vs. 28.1%, p=.04 Mortality: 0 vs. 9.3%, p=.23 LoHS: 6.5 vs. 12.5 days, p=.009 Lower costs for EUS-BD, p=.03	
Huang, P (2017)	R	SC	36 + 30	68 (48-104)	MBO with failed ERCP	EUS-BD (either EUS-RV, EUS-HGS or EUS-CDS with SEMS)	PTBD	NA	TS; CS: >50% bilirubin decrease within 2 weeks; AEs	TS: 94.4% vs. 86.7%, p>.05 CS: 88.9%, vs. 66.7%, p<.05 AEs: 5.6% vs. 23.3%, p<.05 LoHS: 12 vs. 16 days, p<.05 Higher costs for PTBD	
Sportes, A (2017)	P	MC	31 + 20	69.2 - 67.7	Unresectable MBO not involving the biliary confluence, after Failed ERCP	EUS-HGS with FC-SEMS	PTBD	NA	TS; CS: >50% bilirubin decrease within 1 week; AEs; Reinterventions.	TS: 100% vs. 100%, p=1 CS: 86% vs. 83%, p=.88 AEs: 16% vs. 10%, p=.69 Reinterventions: 2 vs. 21, p=.0001 Unscheduled Reinterventions: 8% vs. 26.7%, p=.19 LoHS: 8 vs. 15 days, p=.002 Survival: 71 vs. 78 days, p=.99	The 2 arms were performed in different hospitals. 37% with SAA, 25% with duodenal obstruction.
Bill JG (2016)	R	SC	25 + 25	66.5 (12.6)	dMBO (failed ERCP not declared)	EUS-RV	PTBD (previous time frame)	37 vs. 11 days	TS; CS: >50% bilirubin decrease; AEs; Reinterventions.	TS: 76% vs. 100%, p=.002 CS: 96% vs. 80% AEs: 16% vs. 12%, p=.68 LoHS: 1 vs. 5 days, p=.022 Reinterventions: 12% vs. 60% p=.001	Conversion of PTBD to metal stent was successful in 40%
Lee, TH (2016)	RCT	MC	34 + 32	66.5 (40-83) – 68.4 (52-82)	Unresectable dMBO after failed ERCP	EUS-BD (either EUS-HGS or EUS-CDS)	PTBD	At least 3 months	TS; CS: >50% bilirubin decrease within 7 days or >95% within 30 days AEs; Stent Patency: until cholangitis, reintervention or death QoL: EORTC QLQ-C30	TS: 94.1% vs 96.9%, p=.008 for non-inferiority CS: 87.5% vs. 87.1%, p=1 AEs: 8.8% vs. 31.2%, p=.022 Reinterventions: 0.34 vs. 0.93, p=.02 Reinterventions: 25% vs. 54.8%, p=.015 QoL: similar LoHS: 6 vs. 12 days, p=.001 Stent patency: 228 vs 220 days, p=.848 OS: p=.828	Inaccessible papilla due to duodenal invasion or SAA; EUS-BD produced fewer AEs and reinterventions. A subsequent cost-effective analysis (Yoon WJ, 2022) demonstrated higher cots of PTBD both for the procedure and the entire treatment

											(including reinterventions)
Sharaia, RZ (2016)	R	SC	47 + 13	67.5	Benign or Malignant BO and failed ERCP	EUS-BD (different interventions, including RV and AS)	PTBD	NA	TS; CS: resoluzion of biliary obstruction without repeated intervention; AEs;	TS: 93.3 vs. 91.6%, p=1 CS: 62.2% vs. 25%, p=.03 AEs: 6.6% vs. 53.8%, p=.001 Reinterventions: 1.3 vs. 4.9; p<.0001	EUS-BD was the only independent predictor of clinical success, and associated to higher AEs, pain scores and number of reinterventions
Khashab, M (2015)	R	SC	22 + 51	66.3 ± 12.4	Unresectable dMBO after failed ERCP	EUS-BD	PTBD	320 days	TS; CS: >50% bilirubin decrease within 7 days and <3 mg/dl within 4 weeks; AEs; Stent patency: up to unscheduled reintervention.	TS: 86.4% vs. 100%, p=.007 CS: 86.4% vs. 92.2%, p=.40 AEs: 18.2% vs. 39.2%, p=.08 Reinterventions: 15.7% vs. 80.4, p<.001 Stent patency and survival were equivalent Costs: 2-times higher in the PTBD group	
Artifon, ELA (2012)	RCT	SC	13 + 12	67 (11.9)	Unresectable dMBO after failed ERCP	EUS-CDS with SEMS	PTBD	79.6 vs. 74.9 days, p=.8	TS; CS; AEs; QoL: SF36	TS: 100% in both groups CS: no difference at 7, 30, 60 and 90 days AEs: no difference, p=.44 QoL: no difference	
EUS-HGS versus EUS-CDS											
Mao, K (2022)	SRMA	NA	13 studies - 759 patients	NA	All studies including EUS-CDS or EUS-HGS, even non-comparative	EUS-HGS with SEMS or plastic stents	EUS-CDS with SEMS or plastic stents	Search coverage: up to November 2020	NA	TS: OR=1.05 (0.57-1.96); I^2=0%; CS: OR=0.88 (0.53-1.52); I^2=19%; AEs: OR=1.00 (0.7-1.43); I^2=36%; Reinterventions: OR=3.03 (1.43-6.67); I^2=0%; Survival: OR=0.93 (0.51-1.72); I^2= 68.1%.	In analyses restricted to FC-SEMS, no difference was found between EUS-CDS and EUS-HGS
Khan, MA (2016)	SRMA	NA	20 studies - 1186 patients (general group)	NA	All studies including EUS-BD in malignant or benign BO	EUS-Intrahepatic Access (for AS or HGS)	EUS-Extrahepatic Access (for AS or CDS)	Search coverage: up to January 2015	NA	TS: OR=0.78 (0.32–1.92), I^2=0%; AEs: OR=2.86 (1.49–5.26), I^2=27%	The MA includes non-comparative studies; In metaregression, dMBDO and transpapillary drainage were associated with higher technical success; intrahepatic access was

											associated with AEs.
Wang, K (2016)	SRMA	NA	42 studies - 1192 patients (general analysis)	NA	All studies including EUS-BD in malignant or benign BO	EUS-Intrahepatic Access (for AS or HGS)	EUS-Extrahepatic Access (for AS or CDS)	NA	NA	TS: 0.74 (0.36-1.52), I^2=25%; CS: 1.19 (0.7-2.0), I^2=3%; AEs: 1.64 (0.97-2.78), I^2=0%.	The MA includes non-comparative studies
Tyberg, A (2022)	R	MC	95 + 87	70	Benign or Malignant BO with failed ERCP	EUS-HGS with plastic stent or SEMS	EUS-CDS with plastic stent, SEMS or LAMS	6 months – 5.6 months	TS; CS: >30% bilirubin decrease within 1 week or normalization within 30 days; Stent patency: up to any dysfunction	TS: 92% vs. 92% CS: 71% vs. 90%, p=.01; AEs: 21% vs. 30%, p=.17 Reintervention: 29% vs. 10% N. of procedures: 1.9 vs. 1.2, p=.0043 Similar survival	Includes cases with SAA. At logistic regression, EUS-CDS was more likely to achieve longer stent patency (OR=4.5 (1.15–17.6, p=.03)
Minaga, K [2019]	RCT	MC	24 + 23	73 (41-88)	dMBO after failed ERCP	EUS-HGS	EUS-CDS with SEMS	NA	TS; CS: >50% bilirubin decrease within 2 weeks AEs; Stent patency: until dysfunction (clinical plus imaging) OS	TS: 87.5% vs. 82.6%, p=.03 for noninferiority CS: 100% vs. 94.7%, p=.475 AEs: 28.6% vs 21.1%, p=.583 Reinterventions: 19% vs. 10.5%, p=.188 Stent patency: 306 vs. not reached: p=.597 OS: 146 vs. 120 days, p=.638	Terminated in advance for slow recruitment; EUS-HGS is non inferior to EUS-CDS
Cho, DH (2017)	P	SC	21 + 33		mBO (proximal or distal) with failed ERCP or uncandidate to ERCP	EUS-HGS with PC-SEMS	EUS-CDS with PC-SEMS	148.5 days	TS: placement of stent and flow of contrast medium CS: >75% bilirubin decrease within 4 weeks	TS: 100% vs. 100% Procedure time: 21 vs. 33 min, p=.943 CS: 85.7% vs. 100%, p=.054 AEs: 19% vs. 15.1%, p=.374 Stent occlusion: 47.6% vs. 15.1%, p=.009 Receiving CHT: 19% vs. 47.4%, p=.029 Stent patency: 166 vs. 329 days, p=.072 Survival: 173 vs. 165 days, p=.130	A fraction of patient was not candidate to ERCP due to duodenal invasion (21 patients)
Khashab, M (2016)	R	MC	61 + 60	65.5 ± 13.5	MBO and failed ERCP	EUS-HGS, mostly SEMS	EUS-CDS, mostly SEMS	151 days	TS: CS: >50% bilirubin decrease within 1 week or <3 mg/dl within 2 weeks.	TS: 91.8% vs. 93.3%, p=.75 CS: 82.1% vs. 85.5%, p=.64 AEs: 19.7% vs. 13.3%, p=.37 LoHS: 12.7 vs. 5.6 days, p<.001 Stent dysfunction: 26.2% vs. 13.3%, with shorter patency, p=.18) Survival: 142 vs. 252 days, p=.36	Duodenal invasion: 37% and Gastric Outlet Obstruction: 27%. On multivariable analysis, plastic stenting and use of noncoaxial electrocautery were

											independently associated with AEs.
Artifon, ELA (2015)	RCT	SC	25 + 24	66.02 (14.83)	Unresectable dMBO after failed ERCP and EUS-RV	EUS-HGS	EUS-CDS with SEMS	90 days	TS; CS: >50% bilirubin decrease QoL: SF-36	TS: 96% vs 91%, p=.609 CS: 91% vs 77%, p=.234 AEs: 20% vs 12.5%, p=.702 QoL: p>0.05 OS: p=.603	Duodenal invasion in 58% and 37% of pts.
Poincloux, L (2014)	R	SC	71 + 30	69.4 ± 13.8 - 72.2 ± 10.3	Malignant (mostly) BO and failed ERCP	EUS-Intrahepatic (mostly HGS with plastic stent or PC-SEMS)	EUS-Extrahepatic (mostly CDS with FC-SEMS)	280 days	TS; CS: >50% bilirubin decrease within 1 month	TS: 98.5% vs. 96.7% CS: 93.8% vs. 93.1%, p=.69 AEs: 22.7% vs. 10% (p=1 for major AEs) Dystunctions: 9.2% vs. 10.3%	Duodenal stenosis: 25%, SAA: 7%
Gupta, K (2014)	R	MC	89 + 145	67.3 ± 14.5	Benign or Malignant BO and failed ERCP	EUS-Intrahepatic (either RV, AS or HGS with plastic or metal stents)	EUS-Extrahepatic (either RV, AS or HGS with plastic or metal stents)	NA	NA	TS: 90.4% vs. 84.3%, p=.15 AEs: 35.6% vs. 32.6%, p=.64 Stent occlusion: 0% vs. 2.3%, p=.07	A trend toward better outcomes was present for metal stents and in malignant diseases.
Kawakubo, K (2013)	R	MC	20 + 44	72 (66.79)	BO with failed or impossible ERCP	EUS-HGS with plastic stents or C-SEMS	EUS-CDS with plastic stents or C-SEMS	94 days	TS: Dysfunction: recurrent jaundice requiring reinterventions	TS: 95% vs. 95% AEs: 30% vs. 14% Stent dysfunction: 32% vs. 21% Time to dysfunction: 62 vs. 103 days	Most included patients with duodenal invasion (84%) rather than failed cannuation. Plastic stenting was more used in the EUS-CDS group
Dhir, V (2013)	R	MC	68	NA	BO (distal 81% and proximal 19%) after failed ERCP	EUS-BD 1) Transhepatic access 2) Transmural route	EUS.BD 1) Transduodenal access 2) Transpapillary route	NA	CS: NA; AEs.	No significant differences in the success rates between the different techniques. Transhepatic versus Transduodenal access was an independent predictor of AEs (p= 0.03)	
Park, DH (2010)	P	SC	31 + 24	61.7 (13)	MBO and failed ERCP	EUS-HGS with plastic stent or SEMS	EUS-CDS with plastic stent or SEMS	NA	NA	TS: 100% vs. 92%, p=.686 CS: 87% vs. 92%, p=.373 AEs: 19% vs. 21%, p=1 Procedure time: 18.5 vs. 16.3 min, p=.381 Stent patency: 132 vs. 153 days, p=.53	Needle-knife fistula creation was an independent predictor of AEs.
EUS-GBD versus EUS-CDS											
Debourdeau A (2024)	R	MC	41 + 37	71 (33–95)	dMBO and failed ERCP	EUS-GBD with LAMS (only transgastric approach)	EUS-CDS with LAMS	4.7 months	TS; CS: >50% bilirubin decrease within 7 days or normalization within 28 days; LAMS dysfunctions.	TS: 100% vs. 94.6%, p=.132 CS: 87.8% vs. 89.2%, p=.8 AEs: 9.8% vs. 13.5%, p=.368 Late AEs: 7.3% vs. 21.6%, p=.042 LAMS dysfunctions: 12.2% vs. 21.62%, p=.364	44.8% of patients with duodenal stenosis. 7-days and 30-days bilirubin

										CHT access: 47.3% vs . 58.3%, p.477 Similar Overall survival and TRBO	reduction was lower in the EUS-GBD group;
Surgery versus EUS-BD											
Artifon, ELA (2015)	RCT	SC	15 + 14	68.1 (SD 19.5) - 65.9 (SD 12.2)	Unresectable dMBO after failed ERCP	Surgical hepaticojejunostomy	EUS-CDS with SEMS	90 days	TS; CS: >50% bilirubin decrease within 7 days QoL: SF-36; AEs; OS.	TS: 94% vs. 88% (p=0.598); CS: 93% vs. 71% (p=0.169); QoL: Statistically significant improvement in functional capacity, physical health, pain, social functioning, and emotional and mental health aspects in both techniques (P<0.05). AEs: 13% vs. 21% (p=0.651) Survival: Median survival time was the same in both groups (82 days).	Surgery and EUS-CDS showed similar outcomes

Abbreviations: AEs: Adverse Events; CS: Clinical Success; dMBO: distal Malignant Biliary Obstruction; DO: Duodenal Obstruction; EUS-BD: EUS-guided Biliary Drainage; EUS-CDS: EUS-Choledochoduodenostomy; EUS-HGS: EUS-guided Hepaticogastrostomy; EUS-GBD: EUS-guided Gallbladder Drainage; EUS-RV: EUS-guided Rendez-Vous; HJ: Hepaticojejunostomy; LAMS: Lumen-Apposing Metal Stent; LoHS: Length of Hospital Stay; MC: Multi-Centre; NA: Not Available / Not Applicable; P: Prospective; PTBD: Percutaneous Transhepatic Biliary Drainage; QoL: Quality of Life; R: Retrospective; RBO: Recurrent Biliary Obstruction: TRBO: time to RBO; SAA: Surgically-Altered Anatomy; SEMS: Self-Expandable Metal Stent; SC: Single-Centre; SRMA: Systematic Review and Metanalysis; TS: Technical Success;

Table 14s: Malignant biliary stricture management in case of failure: second attempt (accessible papilla and no duodenal stricture): GRADE of evidence Table

Certainty assessment									Effect estimate	Certainty	Comments
PICO	**Ref.**	**No. of studies**	**Study design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Publication bias**			
EUS-BD versus PTBD	Facciorusso, A (2022), NMA*	2*	RCTs	Moderate	No	Yes	Yes	No	EUS-CDS and EUS-HGS were not superior to PTBD with SEMS in terms of **CS** and **AEs**.	⊕◯◯◯ Low	Evidence based on network MA of RCTs. Reduced based on

									PTBD showed the lowest performances at SUCRA		**Indirectness** and **Imprecision**. All included RCTs are based on EUS-CDS performed with SEMS rather than on LAMS
	Sharaiha, RZ (2017), SRMA	3	RCTs	Moderate	No	Yes	Yes	No	**TS:** OR=.68 (.14-3.27), I^2=0% **CS:** OR=.96 (.24-3.81), I^2= 0% **AEs:** OR=.25 (.10-.61), I^2=0% **RBO:** OR=.05 (.01-.25), I^2=0%	⨁◯◯◯ Low	Evidence based on RCTs. Reduced based on **Imprecision** (wide confidence intervals) and **Indirectness**: the SRMA was not restricted to malignant BO and all included RCTs are based on EUS-CDS performed with SEMS rather than on LAMS
EUS-CDS versus EUS-HGS	Mao, K (2022), SRMA	13	Observational studies + 1 RCT	Moderate	No	Yes	Yes	No	**TS:** OR=0.8 (0.28-2.32), I^2=0% **CS:** OR=1.48 (0.55-4.01), I^2= 0% **AEs:** OR=1.33 (.48-3.7), I^2=51%	◯◯◯◯ Very Low	Evidence based on observational studies. Reduced by **Imprecision** (and Inconsistency for AEs). EUS-CDS performed

									RBO: OR=.25 (.05-1.34), I^2=0%		with SEMS rather than LAMS

CS: Clinical Success; EUS-CDS: EUS-guided Choledochoduodenostomy; LAMS: Lumen Apposing Metal Stent; mBO: malignant biliary obstruction; NMA: Network Meta-analysis; PTBD: Percutaneous Transhepatic Biliary Drainage; RBO: Recurrent Biliary Obstruction; RCT: Randomized Clinical Trials; SEMS: Self.-Expandable Metal Stents; SUCRA: Surface Under the Cumulative Ranking; TS: Technical Success.
*Network Meta-analysis including 5 RCTs, but only 2 RCTs included direct comparison of EUS-BD with SEMS versus PTBD with SEMS

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A comprehensive diagram can be proposed of approach to failed ERCP, depicting the scenario of malignant versus benign stenosis, accessible versus inaccessible papilla, presence of duodenal stenosis.

Table 15s: Malignant biliary stricture management in case of failure: second attempt (accessible papilla and duodenal stricture): literature extraction

Author (year)	Methods		Population			Intervention			Outcomes		Remarks
	Design		N	Age, years	Inclusion criteria	Protocol (details) of Intervention	Protocol (details) of Comparison	Follow-up	Outcome measures (+ definitions)	Principal findings	
EUS-BD vs. Surgery											
Bronswijk, M (2023)	R	MC	53 + 101	67.4 (12.4) - 64.9 (11.2)	BO and concomitant DO	EUS-BD (either EUS-CDS or HGS or AS with SEMS) + EUS-GE	Surgical Gastroenterostomy and Hepaticojejunostomy	179 – 158 days	TS; CS: >50% bilirubin decrease within 1 month; AEs. RBO: jaundice or cholangitis requiring reintervention	TS: 96.2% vs. 100%, p=.117 CS: 90.6% vs 82.2%, p=.234 AEs: 11.3% vs. 34.7%, p=.002 Severe AEs: 3.8% vs. 19.8%, p=.007 LoHS: 4 vs 13 days, p<.001	
EUS-CDS vs. EUS-HGS											
Vanella, G (2024)	P	SC	7 + 13	63 (61–76) - 67 (60–74)	MBO with DO treated by EUS-GE	EUS-CDS with LAMS + EUS-GE	EUS-HGS with SEMS + EUS-GE	64 – 82 days	TS; CS: >50% bilirubin decrease within 14 days; AEs; RBO: biliary dysfunction requiring hospitalization with escalation of medical care or biliary reintervention; Stent patency	TS: 100% vs. 100%, p=1 Procedure time: 12.5 vs. 50 min, p=.0006 CS: 100% vs. 92.3%, p=.5 AEs: 42.9% vs. 7.7%, p=.07 Biliary dysfunction: 71.4% vs. 16.7%, p=.02 Stent patency: 39 vs. 268 days at Kaplan Meier, log-rank p=.0023 OS: 105 vs. 133 days, p=.9	15% SAA
Vanella, G (2022)	R	MC	18 + 6	67 [60–76]	MBO with DO	EUS-CDS with EUS-GE	EUS-HGS with EUS-GE	74 – 37 days	CS: >50% bilirubin decrease; AEs; RBO: jaundice recurrence after former clinical success. TRBO	CS: 100% vs. 83% AEs: 27.8% vs. 16.7% RBO: 31.3% vs. 0% TRBO: 195 vs. 209 days	Extracted form comparison of 6 drainage combinations. Combinations involving DS were associated with significantly higher RBO (log-rank p=.006)
Ogura, T (2016)	R	SC	13 + 26	71 (10.7) – 70 (8.1)	MBO with DO treated by DS	EUS-CDS with SEMS + DS	EUS-HGS with SEMS + DS	NA	TS; CS: >75% decrease within 30 days; Stent patency: up to stent dysfunction (obstruction or migration + cholangitis)	RBO: 46.2% vs. 7.7%, p=.005 Access to CHT: 23% vs. 35%, p=.42 Survival: HR=0.65 (0.31–1.34), p=.247 Adjusted stent patency: 37 vs. 133 days, HR=0.39 (0.16–0.98), p=.045	6 EUS-CDS underwent conversion to HGS. At logistic regression, EUS-CDS was associated with AEs (OR=10.28 (1.7–62.7), p=.012)
Matsumoto, K (2017)[4]	R	SC	14 + 5	66 (41–91)	MBO with DO treated by DS	EUS-CDS with SEMS or PS + DS	EUS-HGS with SEMS + DS	73 (20–954) days	TS; CS: >75% bilirubin decrease within 30 days;	RBO: 57% vs. 0%	

									RBO: jaundice recurrence Stent patency: TRBO		

Abbreviations: AEs: Adverse Events; DS: Duodenal Stent; CHT: Chemotherapy; CS: Clinical Success; dMBO: distal Malignant Biliary Obstruction; DO: Duodenal Obstruction; EUS-AS: EUS-Antegrade Stenting; EUS-BD: EUS-guided Biliary Drainage; EUS-CDS: EUS-guided Choledochoduodenostomy; EUS-HGS: EUS-guided Hepaticogastrostomy; GOO: Gastric Outlet Obstruction; HR: Hazard Ratio; MC: Multi-Centre; PC: Pancreatic Cancer; R: Retrospective; RBO: Recurrent Biliary Obstruction; SAA: Surgically-Altered Anatomy; SC: Single-Centre; TS: Technical Success; TRBO: Time to RBO.

Table 16s: Malignant biliary stricture management in case of failure: second attempt (accessible papilla and duodenal stricture): GRADE of evidence table (see also Appendix 1s and Figs. 4s–7s for the supporting pooled analysis).

Certainty assessment								Effect estimate	Certainty	Comments
PICO	**No. of studies**	**Study design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Publication bias**			
EUS-CDS versus EUS-HGS in DO	4	Retrospective and Prospective Observational Studies	Moderate	No	Yes	Yes	No	**AEs**: RR=2.93 (0.71-12.05), I^2=0% **RBO**: RR=5.04 (2.09-12.14), I^2=0%	⊕◯◯◯◯ Very Low	Evidence based on observational studies. Reduced based on **Imprecision** (wide confidence intervals, crossing the unity for AEs) and **Indirectness** related to the inclusion criteria: 2 studies included patients in whom GOO was treated by EUS-GE whereas in 2 studies GOO was treated by DS. 2 studies included patients in whom EUS-CDS was performed by LAMS whereas in 2 studies it was performed by tubular SEMS.

DO: Double Obstruction; DS: Duodenal SEMS; EUS-CDS: EUS-guided CholedochoDuodenostomy; EUS-GE: EUS-guided GastroEnterostomy; EUS-HGS: EUS-guided HepaticoGastrostomy; GOO: Gastric Outlet Obstruction; LAMS: Lumen Apposing Metal Stents; RBO: Recurrent Biliary Obstruction; SEMS: Self-Expandable Metal Stents.

Appendix 1s *Pooled analysis supporting ESGE guideline on management of biliary strictures Table 16s.*
TF 4: *What is the preferred route to attempt biliary drainage for malignant stricture management in case of ERCP failure and duodenal stricture?*

Aim

This supplement reports an exploratory pooled analysis derived from the literature search performed for the guideline development process. The analysis was intended to summarize the available comparative evidence retrieved for the relevant clinical question and to provide a transparent account of the quantitative synthesis underpinning the corresponding statement in the guideline.

Methods

A focused pooled analysis was performed using studies identified during the literature review conducted for the ESGE guideline on biliary stricture management.
Comparative studies reporting outcomes for endoscopic ultrasound-guided choledochoduodenostomy (EUS-CDS) and endoscopic ultrasound-guided hepaticogastrostomy (EUS-HGS) in the setting of failed ERCP and duodenal invasion were considered for quantitative synthesis when outcome data were available in a form suitable for extraction.

PICO
P: Patients with malignant biliary stricture and normal anatomy and accessible papilla with previous ERCP failure AND with duodenal stricture
I: EUS-CDS
C: EUS-HGS
O: technical success / clinical success / adverse events / recurrent biliary obstruction

The studies considered for this exploratory pooled analysis correspond to the evidence base identified for the guideline question on malignant biliary stricture management in case of failure: second attempt (accessible papilla and duodenal stricture), as reported in **Table 15** (literature extraction). The overall certainty of evidence for this question is summarized separately in **Table 16** (GRADE of evidence table).
Due to the paucity of data, the outcomes explored in the present supplement were adverse events (AE) and recurrent biliary obstruction (RBO). For each study and outcome, the numbers of events and total patients in each treatment group were extracted from the source

studies. Pooled effect estimates were calculated as risk ratios (RRs) with 95% confidence intervals (CIs), using a Mantel-Haenszel random-effects model.
Statistical heterogeneity was quantified with the I^2 statistic.
Small-study effects/publication bias were explored visually through funnel plots.
Risk of bias of the included observational studies was assessed with the Newcastle-Ottawa Scale (NOS).

Results

Among the four included studies, one was rated as high quality and three as moderate quality. The domain-level NOS assessment is summarized in Table S1.

NOS scale for assessing the risk of bias

Study	Selection (max 4 stars)	Comparability (max 2 stars)	Outcomes (max 3 stars)	Quality
Vanella, G (2024)	****	*	***	High
Vanella, G (2022)	***	*	**	Moderate
Matsumoto, K (2017)	***	*	**	Moderate
Ogura, T (2016)	***	*	**	Moderate

For adverse events, across the contributing studies, the pooled RR was 2.93 (95% CI 0.71-12.05), with no observed statistical heterogeneity (I^2 = 0%). This exploratory analysis did not show a statistically significant difference between EUS-CDS and EUS-HGS for adverse events.
For recurrent biliary obstruction, four studies contributed to the pooled estimate. The pooled RR was 5.04 (95% CI 2.09-12.14), again with no observed statistical heterogeneity (I^2 = 0%). In this exploratory pooled analysis, recurrent biliary obstruction was more frequent in the EUS-CDS group than in the EUS-HGS group.
Because of the limited number of studies, small sample sizes, and the guideline-driven nature of the evidence synthesis, these estimates should be interpreted cautiously.

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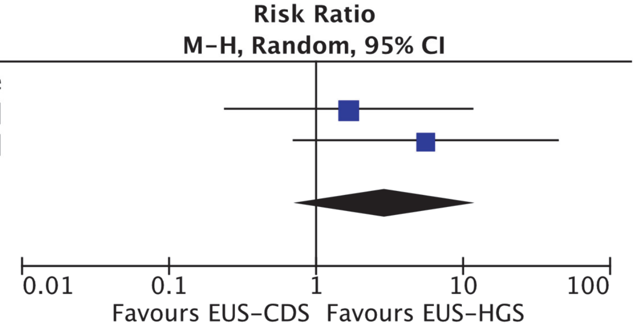
Figure 4s: Forest plot for adverse events (AEs).

Study or Subgroup	EUS-CDS Events	EUS-CDS Total	EUS-HGS Events	EUS-HGS Total	Weight	Risk Ratio M-H, Random, 95% CI
Ogura 2016	0	13	0	26		Not estimable
Vanella 2022	5	18	1	6	53.2%	1.67 [0.24, 11.58]
Vanella 2024	3	7	1	13	46.8%	5.57 [0.70, 44.08]
Total (95% CI)		**38**		**45**	**100.0%**	**2.93 [0.71, 12.05]**
Total events	8		2			

Heterogeneity: $Tau^2 = 0.00$; $Chi^2 = 0.70$, df = 1 (P = 0.40); $I^2 = 0\%$
Test for overall effect: Z = 1.49 (P = 0.14)



Exploratory pooled analysis of adverse events comparing EUS-CDS with EUS-HGS. Effect sizes are reported as risk ratios (Mantel-Haenszel random-effects model) with 95% confidence intervals. One study with zero events in both groups was not estimable for the pooled effect. The overall pooled RR was 2.93 (95% CI 0.71-12.05; $I^2 = 0\%$).

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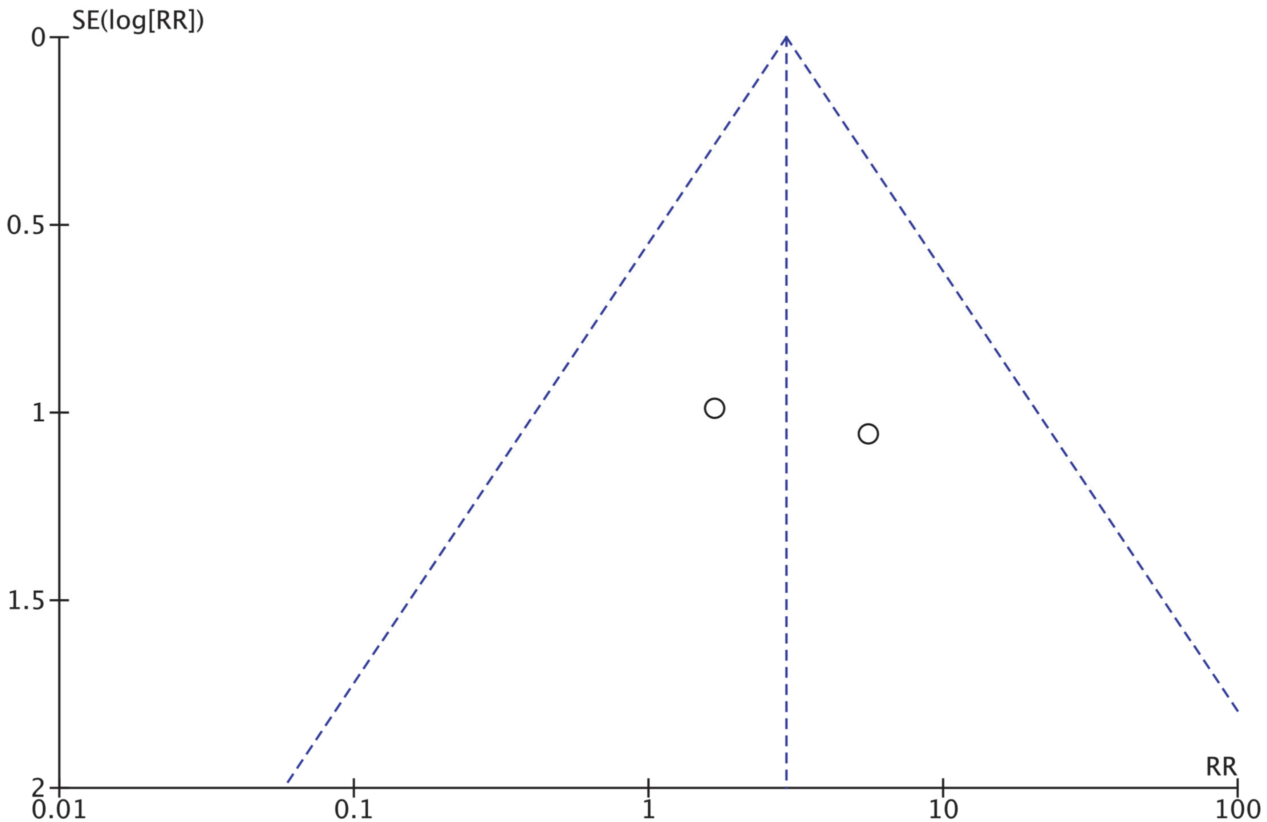
Figure 5s: Funnel plot for adverse events (AEs).



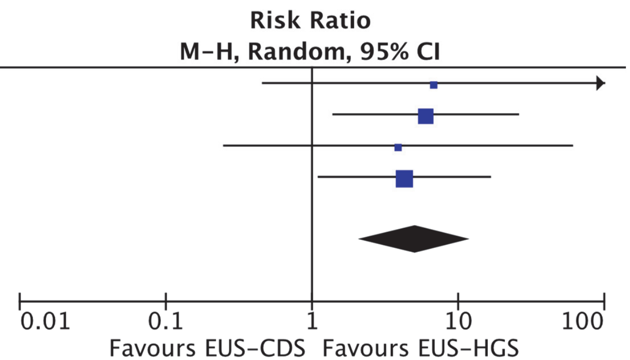
Funnel plot for the adverse events outcome. Because only a very small number of studies were available, the plot is presented for descriptive transparency only; no reliable inference on publication bias or small-study effects can be drawn.

Figure 6s: Forest plot for recurrent biliary obstruction (RBO).

	EUS–CDS		EUS–HGS			Risk Ratio
Study or Subgroup	Events	Total	Events	Total	Weight	M–H, Random, 95% CI
Matsumoto 2017	8	14	0	5	10.7%	6.80 [0.46, 100.22]
Ogura 2016	6	13	2	26	36.5%	6.00 [1.40, 25.71]
Vanella 2022	5	16	0	5	10.3%	3.88 [0.25, 60.21]
Vanella 2024	5	7	2	12	42.5%	4.29 [1.11, 16.52]
Total (95% CI)		**50**		**48**	**100.0%**	**5.04 [2.09, 12.14]**
Total events	24		4			

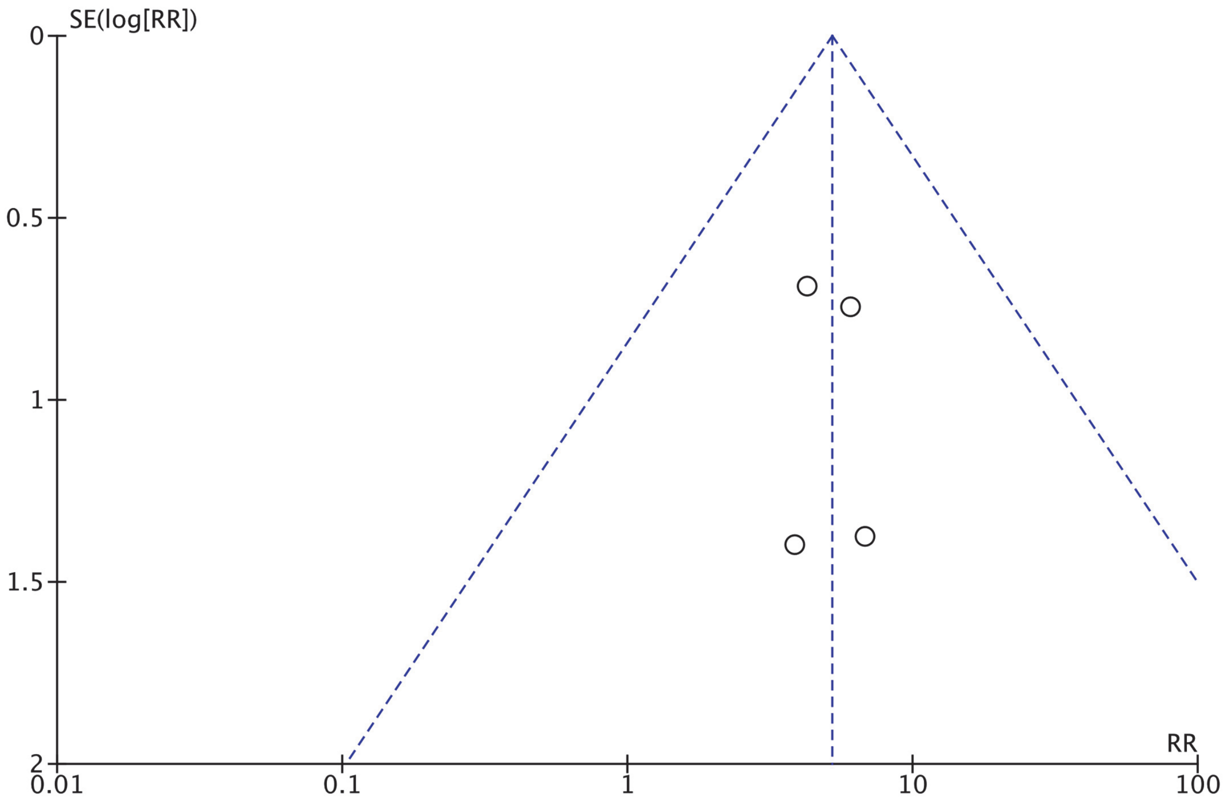
Heterogeneity: $Tau^2 = 0.00$; $Chi^2 = 0.20$, df = 3 (P = 0.98); $I^2 = 0\%$

Test for overall effect: Z = 3.60 (P = 0.0003)



Exploratory pooled analysis of recurrent biliary obstruction comparing EUS-CDS with EUS-HGS. Effect sizes are reported as risk ratios (Mantel-Haenszel random-effects model) with 95% confidence intervals. The overall pooled RR was 5.04 (95% CI 2.09-12.14; $I^2 = 0\%$).

Figure 7s: Funnel plot for recurrent biliary obstruction (RBO).



Funnel plot for the recurrent biliary obstruction outcome. Given the small number of included studies, the figure should be interpreted cautiously and is provided only as a descriptive assessment of possible small-study effects.

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A comprehensive diagram can be proposed of approach to failed ERCP, depicting the scenario of malignant versus benign stenosis, accessible versus inaccessible papilla, presence of duodenal stenosis.