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Endoscopic biliary stenting: indications, choice of stents, and results: European Society of Gastrointestinal Endoscopy (ESGE) Clinical Guideline – Updated October 2017

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Appendix e1, Tables e1 – e5
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MAIN RECOMMENDATIONS

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 recommends the endoscopic placement of a 10-mm diameter self-expandable metal stent (SEMS) for preoperative biliary drainage of malignant extrahepatic biliary obstruction.
Strong recommendation, moderate quality evidence.

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

ESGE recommends against the insertion of uncovered SEMS for the drainage of extrahepatic biliary obstruction of unconfirmed etiology.
Strong recommendation, low quality evidence.

ESGE suggests against routine preoperative biliary drainage in patients with malignant hilar obstruction.
Weak recommendation, low quality evidence.

ESGE recommends uncovered SEMSs for palliative drainage of malignant hilar obstruction.
Strong recommendation, moderate quality evidence.

ESGE recommends temporary insertion of multiple plastic stents or of a fully covered SEMS for treatment of benign biliary strictures.
Strong recommendation, moderate quality evidence.

ESGE recommends endoscopic placement of plastic stent(s) to treat bile duct leaks that are not due to transection of the common bile duct or common hepatic duct.
Strong recommendation, moderate quality evidence.

ABBREVIATIONS

ABS	anastomotic biliary stricture
ASA	American Society of Anesthesiologists
BBS	benign biliary stricture
CBD	common bile duct
CI	confidence interval
CRP	C-reactive protein
DDLT	deceased donor liver transplantation
EBS	endoscopic biliary sphincterotomy
ERCP	endoscopic retrograde cholangiopancreatography
ESGE	European Society of Gastrointestinal Endoscopy
EUS-BD	endoscopic ultrasonography-guided biliary drainage
Fr	French
FCSEMS	fully covered self-expandable metal stent
HR	hazard ratio
LAMS	lumen-apposing metal stent
LDLT	living donor liver transplantation
MRI	magnetic resonance imaging
MPS	multiple plastic stents
MHS	malignant hilar stricture
OR	odds ratio
PET	positron emission tomography
PBD	preoperative biliary drainage
PCSEMS	partially covered self-expandable metal stent
PTBD	percutaneous transhepatic biliary drainage
RCT	randomized controlled trial
SEMS	self-expandable metal stent
WHO	World Health Organization
WMD	weighted mean difference

This Guideline is an official statement of the European Society of Gastrointestinal Endoscopy (ESGE). It addresses the indications for and results of biliary stenting as well as the choice of stent.

1. Introduction

The Clinical Guideline on biliary stenting published in 2012 by the European Society of Gastrointestinal Endoscopy (ESGE) made recommendations on the indications and choice of stents for benign and malignant biliary conditions [1]. New evidence has become available since then and is discussed in the present update, and new recommendations are issued. The associated Technology Review that described the models of biliary stents available and the stenting techniques, including advanced techniques such as insertion of multiple plastic stents (MPS), drainage of hilar strictures, retrieval of migrated stents, and combined stenting in patients with both malignant biliary and duodenal obstruction, is considered up-to-date and will be revised when appropriate [2].

2. Methods

ESGE commissioned this Guideline and appointed a guideline leader (J.M.D.) who invited the listed authors to participate in the project development. The key questions were prepared by the coordinating team (J.M.D., A.T., C.H.) and then approved by the other members. The coordinating team formed task force subgroups, each with its own leader, who was assigned key questions (see **Appendix e1**, available online in Supplementary material).

Each task force performed a systematic literature search to prepare evidence-based and well-balanced statements on their assigned key questions. The literature search was performed using MEDLINE and Embase to identify new publications since January 2011 published in English, focusing on meta-analyses and fully published prospective studies, particularly randomized controlled trials (RCTs), performed in humans. Retrospective analyses and pilot studies were also included if they addressed topics not covered in the prospective studies. The Grading of Recommendations Assessment, Development and Evaluation (GRADE) system was adopted to define the strength of recommendation and the quality of evidence [3, 4]. Each task force proposed statements on their assigned key questions which were discussed during a meeting in Dusseldorf, Germany in February 2016. Literature searches were re-run in July 2017. This time-point should be the starting point in the search for new evidence for future updates to this guideline. In December 2017 a draft prepared by J.M.D., A.T., and J.V.H. was sent to all group members for review. The draft was also reviewed by two

members of the ESGE Governing Board, by external reviewers and 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 revised version.

This Guideline was issued in 2018 and will be considered for review in 2022, or sooner if new and relevant evidence becomes available. Any updates to the Guideline in the interim period will be noted on the ESGE website: http://www.esge.com/esge-guidelines.html.

3. Malignant extrahepatic biliary obstruction

3.1. Indications for biliary stenting

3.1.1. Preoperative biliary drainage

RECOMMENDATION

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.

RECOMMENDATION

ESGE recommends the endoscopic placement of a 10-mm diameter self-expandable metal stent (SEMS) for preoperative biliary drainage of extrahepatic malignant biliary obstruction.

Strong recommendation, moderate quality evidence.

Preoperative biliary drainage (PBD) is common practice: a US administrative database study (2573 patients with pancreaticoduodenectomy) found that the PBD rate increased from 30 % to 59 % of patients between 1995 and 2007, with the majority of PBD occurring prior to surgical consultation [5]. Neoadjuvant therapy is increasingly used before surgery for pancreatic adenocarcinoma and it often requires PBD (58 % of 199 patients in a prospective database) [6].

Among 10 unique meta-analyses that assessed the potential benefit of PBD in patients with a distal biliary obstruction (▶ **Table e1**, available online in Supplementary material), none found differences in terms of mortality and, with respect to morbidity, 9 found it to be similar [7 – 12] or higher [13 – 15] with vs. without PBD; a single study reported a lower morbidity (serious adverse events) with vs. without PBD [16]. Although the meta-analyses were limited by the characteristics of the original studies, including selection bias, the use of the percutaneous or the endoscopic route for PBD, and the inclusion in some studies of patients with proximal biliary obstruction, they represent the best available evidence. Of note, two retrospective studies that compared PBD vs. no PBD in a total of 170 patients reported an independent association between endoscopic PBD and shorter patient survival [17, 18].

Apart from well-accepted indications for PBD such as cholangitis, severe jaundice was suggested to be an adequate indication: a recent, mostly retrospective, study (1200 patients) found that a total serum bilirubin ≥ 300 µmol/L was associated with a high risk of severe postoperative complications [19]. Of note, patients with a total serum bilirubin ≥ 250 µmol/L were excluded from the largest RCT of PBD vs. no PBD [20]. On the other hand, a retrospective matched case – control study (152 patients) suggested that even in patients with relatively severe jaundice (bilirubin ≥ 15 mg/dL [256 µmol/L]) classified as grade 2 on the American Society of Anesthesiologists (ASA) scale, PBD presented no advantage [21]. Thus, the validity of severe jaundice as an indication for PBD remains unclear.

If a decision is made to proceed with PBD in patients with malignant distal biliary obstruction who are undergoing curative resection, the endoscopic route is preferred over the percutaneous route because data from three retrospective series with long-term follow-up that compared the two approaches (total, 1213 patients) showed longer patient survival and less frequent peritoneal/liver recurrence in the endoscopic groups [22 – 24].

With respect to the use of plastic stents vs. self-expandable metal stents (SEMSs) for PBD, a meta-analysis (four retrospective and one prospective cohorts; total, 704 patients) found that SEMSs were associated with a lower rate of endoscopic reintervention (3.4 % vs. 14.8 %) and no difference in overall surgical morbidity or mortality [25]. The interval between biliary drainage and surgery was not reported but we calculated that neoadjuvant therapy, an indicator of long PBD duration, was performed in 337 (48 %) patients. In a more recent multicenter RCT (86 patients) comparing plastic stents and fully covered SEMSs (FCSEMSs) there were similar outcomes including need for reintervention, surgery-related adverse events, and mortality, but the interval between biliary drainage and surgery was only 13 days [26].

In the setting of neoadjuvant therapy, an RCT (54 patients) found that use of FCSEMSs resulted in a longer stent patency duration and fewer days of delay in neoadjuvant therapy compared with plastic stents and uncovered SEMSs; total costs associated with PBD were similar for all stent models [27]. Similarly, two retrospective studies (total, 72 patients) found that, compared with SEMSs, plastic stents were associated with more complications; one of the studies also analyzed the delay in neoadjuvant therapy and costs: with SEMSs, the delay was shorter and the total costs were similar [28, 29]. The type of SEMS was stated in one study only (FCSEMS) [29]. FCSEMSs also present the advantage of being removable if surgical resection is finally not performed.

Finally, SEMSs do not compromise R0 resection or increase the risk of local unresectability according to a retrospective analysis of 593 patients [30], but the presence of a biliary plastic stent or SEMS prolongs operative duration [21, 30].

3.1.2. Palliative biliary drainage

3.1.2.1 Route for primary biliary drainage

RECOMMENDATION

ESGE recommends that decompression of malignant extrahepatic biliary obstruction be performed via endoscopic retrograde cholangiopancreatography (ERCP) rather than by surgery or percutaneously.
Strong recommendation, moderate quality evidence.

ESGE recommends restricting the use of EUS-guided biliary drainage to cases where biliary drainage using standard ERCP techniques has failed.
Strong recommendation, low quality evidence.

Biliary stenting through ERCP or percutaneous transhepatic biliary drainage (PTBD) are established techniques described more than 40 years ago as alternatives to surgical biliodigestive anastomosis [31, 32].

Comparison of primary biliary stenting vs. surgical biliodigestive anastomosis for malignant biliary obstruction has been performed in three meta-analyses [33 – 35]; the two most recent ones included five identical RCTs (379 patients), of which four used ERCP and one the percutaneous approach to insert mostly plastic stents (SEMS were used in 15 patients only); two RCTs were added compared with the older meta-analysis [34, 35]. In the two recent meta-analyses, procedure-related complications were more frequent with surgery vs. biliary stenting as well as 30-day mortality (16.3 % vs. 9.6 % as stated by de Lima et al. [34]; incorrectly calculated by Glazer et al. [35]); short-term success rates were similar with both techniques but recurrent biliary obstruction was less frequent after surgical bypass vs. stenting. Of note, the single RCT (30 patients) that used SEMSs found no difference between endoscopy and surgery in terms of late-onset complications and patient readmission [36]. Quality of life was assessed in two RCTs, one of these reported better results for endoscopic stenting [36] while the other one reported similar results for both drainage approaches [37]. The total duration of hospital stay, including patient readmissions, was shorter for biliary stenting vs. surgery in all of the five RCTs. Costs were analyzed in a single RCT: total costs (including readmissions) with endoscopic SEMS placement were approximately half those of surgery (4271 ± 2411 vs. 8321 ± 1821 USD) [38]. A similar difference has been reported in a large multicenter retrospective study that included 622 patients [39].

The comparison of biliary stenting through ERCP vs. PTBD was reported in the analysis of a national database and in two RCTs; all of these studies included both hilar and extrahepatic malignant biliary obstruction. The analysis of a U.S. database (9135 patients) found a lower adverse event rate (8.6 % vs. 12.3 %), a shorter hospitalization, and lower total costs for ERCP vs. PTBD; mortality was not reported [40]. In that study, the lower rate of adverse events associated with endoscopic procedures was observed regardless of the volume of PTBD procedures performed in a center for pancreatic cancer. As mentioned above, endoscopic biliary stenting has been associated with longer patient survival and less frequent peritoneal/liver recurrence in the three retrospective series with long-term follow-up that compared this outcome for both approaches (total, 1213 patients) [22 – 24]. Finally, the two historical RCTs that compared ERCP vs. PTBD (75 and 54 patients) yielded contradictory results in terms of success rate and mortality [41, 42].

Endoscopic ultrasonography-guided biliary drainage (EUS-BD) has been more recently employed and is rapidly gaining acceptance: four meta-analyses (16 – 42 studies including 5 – 12 prospective ones; total, 528 – 1192 patients) reported that EUS-BD was clinically successful in 87 % – 94 % of cases with adverse events reported in 16 % – 29 % [43 – 46]. EUS-BD has mostly been used in malignant conditions (87 % of biliary obstructions in a meta-analysis that included 1186 patients) [43]. EUS-BD had a higher functional success rate in malignant vs. benign conditions in the single meta-analysis that analyzed that outcome, although technical success rates were similar [45].

This technique has mostly been used following failed ERCP (see section 5.4 for more details regarding its position in the treatment algorithm) although it has been used in pilot trials as a first-line option [47, 48].

3.1.2.2 Type of stent

RECOMMENDATION

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

Five meta-analyses have compared SEMSs with plastic stents for the endoscopic drainage of distal malignant biliary obstruction (▶ **Table e2**, available online) [49 – 53]. Compared with plastic stents, SEMSs are associated with a longer patient survival, a lower risk of stent dysfunction/cholangitis, and fewer re-interventions. Costs associated with palliation of malignant biliary obstruction with SEMSs vs. plastic stents have been compared in a meta-analysis (8 RCTs, 311 patients with hilar or extrahepatic malignant biliary obstruction) and in a more recent RCT (18 centers, 219 patients with extrahepatic malignant biliary obstruction) [50, 54]. No significant differences in costs were reported in these studies and the more recent RCT showed total costs were also similar for plastic stents vs. SEMSs in patients with a short survival duration (≤ 3 months) or those with metastatic disease [54]. A follow-up study (140 patients) of that RCT showed that health-related quality of life, both general and disease-specific, was better over time with SEMSs vs. plastic stents [55].

Seven meta-analyses have compared covered vs. uncovered SEMSs (▶ **Table e3**, available online) [56 – 62]; the covered SEMSs used in the original studies included partially covered SEMSs (PCSEMSs) and FCSEMSs. No differences in the propor-

tions of patients with stent dysfunction, overall complications or patient survival were reported, except for stent dysfunction in two meta-analyses [57, 60]. Covered SEMSs were associated with a lower risk of tumor ingrowth but a higher risk of stent migration, tumor overgrowth, and sludge formation. With respect to concerns about cholecystitis following covered SEMS placement [63], the four meta-analyses that reported this outcome found no increased risk of cholecystitis after insertion of covered vs. uncovered SEMS [58 – 61]. Of note, measures taken in some studies to prevent this complication have included placement of the stent covering below the level of the cystic duct implantation in patients with an intact gallbladder [64] and the use of covered SEMS with transmural drainage holes [65]. Finally, nitinol stents have replaced stainless steel stents as they perform better [66, 67].

Specific SEMS designs have been investigated:

- Antireflux covered SEMSs were compared with SEMSs devoid of an antireflux valve (an uncovered SEMS and a covered SEMS) in two RCTs [68, 69]. Both RCTs reported a similar efficacy in decreasing bilirubin serum levels and a longer patency of antireflux vs. conventional SEMS. This is consistent with the finding that duodenal-biliary reflux is independently associated with biliary stone recurrence [70].
- Antimigration systems, including flared ends and anchoring flaps, have been tested with covered SEMSs [71, 72]. Anchoring flaps have yielded promising results in patients with benign strictures [71] but no study has compared identical stent designs with or without an antimigration system, precluding definitive conclusions. Stent models combining antireflux and antimigration systems have been tested in pilot trials [73].
- A radioactive stent, inserted percutaneously, provided longer patient survival than a similar, nonradioactive, stent in an RCT that included 23 patients with malignant biliary obstruction [74]. Another RCT (55 patients) that used a radioactive strand inserted between the stent and the biliary wall also reported prolonged patient survival [75].
- Paclitaxel-eluting stents provided no advantage compared with standard SEMSs in an RCT (72 patients) [76].

Only a few studies comparing different models of plastic stent have been published since 2011. A meta-analysis (five studies including three RCTs, 460 patients) found that double-layer plastic stents present a longer patency period, lower stent occlusion rates, and slightly more adverse events compared to conventional plastic stents [77]. No other specific designs have shown a clear benefit on clinical outcomes [78 – 81].

3.1.3. Drainage of suspected malignant biliary obstruction

RECOMMENDATION

ESGE recommends against the insertion of uncovered SEMS for the drainage of extrahepatic biliary obstruction of unconfirmed etiology.

Strong recommendation, low quality evidence.

In large series, 5 % – 10 % of patients operated for pancreatic cancer prove to have benign disease at surgery [82]. Uncovered SEMSs are known to have poor long-term patency in benign disease [83]. These stents are difficult or impossible to remove and, although a new “stent-in-stent” technique has been successfully used to remove uncovered SEMSs mistakenly inserted in patients with a benign disease [84, 85], this technique is laborious and adverse events are frequent [86].

3.1.4. Treatment of malignant bilioduodenal obstruction

RECOMMENDATION

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.

No study comparing endoscopic vs. surgical approach for combined biliary and duodenal drainage was found. Systematic reviews or meta-analyses have compared the endoscopic and surgical approaches for each condition separately:

- With respect to the bypass of a malignant obstruction of the duodenum/gastric outlet, seven meta-analyses were found (▶ **Table e4**, available online) [87 – 93]: they reported a high technical success rate for both approaches, with clinical success more frequently observed with SEMS vs. surgery in two meta-analyses. Five meta-analyses also reported a shorter delay before oral intake and a shorter duration of hospital stay with SEMS vs. surgery. Overall morbidity was similar for both approaches except in one meta-analysis that reported a lower morbidity with SEMS vs. surgery [89]. Among adverse events, those considered as major were more frequent with SEMS in two meta-analyses [87, 90]. EUS-guided gastroenterostomy using lumen-apposing SEMS (LAMS) has recently been introduced: in two retrospective studies, it was found to provide results similar to surgery and enteral stenting except for a lower incidence of symptom recurrence and need for reintervention compared with enteral stenting [94, 95];
- With respect to the approach for biliary drainage, the recommendation made above to prefer biliary stenting over surgical bypass is even stronger in the setting of malignant duodenal obstruction, as life expectancy of patients who present both duodenal and biliary stricture is short: in a retrospective study (81 patients with bilioduodenal stenting),

median survival was 73 days [96]; even in patients with a "good" prognosis identified by a higher World Health Organization (WHO) score, another study reported a median survival of 139 days [97]. Although the procedure may be technically difficult, success rates of 86 % – 100 % have been reported by experts in a prospective study, with lower success rates reported in cases where the duodenal stricture involves the papilla [98]. The technique and sequence of biliary and duodenal stenting according to different clinical scenarios is detailed in the ESGE Technical Review [2]. In the case of failed duodenal or biliary stenting, other interventions (e. g., PTBD, EUS-BD restricted to research settings) should be considered [99, 100].

4. Stent dysfunction

The diagnosis of stent dysfunction has not been standardized; it is usually based on the combination of clinical criteria and liver function tests, complemented with transabdominal ultrasound in some cases. Ultrasound is useful to search for biliary ductal dilatation, liver metastases, and liver abscesses. Examples of definitions of stent dysfunction used in RCTs are a decline in bilirubin < 20 % following stent insertion (failed biliary drainage), development of cholangitis, jaundice, or a flu-like syndrome, and cholestasis [101]. More recent RCTs have mostly used paraclinical tests, as in the study by Schmidt et al. who defined stent dysfunction as the presence of two of the three following criteria: (a) ultrasound showing new dilatation of intrahepatic or extrahepatic bile ducts; (b) bilirubin ≥ 2 mg/dL (34.2 µmol/L) with an increase ≥ 1 mg/dL (17.1 µmol/L) compared to the value after initial successful drainage, or elevation of alkaline phosphatases/gamma-glutamyl transferase to more than twice the upper limit of normal values with an increase of at least 30 U/L; (c) signs of cholangitis (fever and leukocyte count > 10 000/µL or C-reactive protein (CRP) > 20 mg/dL) [102].

RECOMMENDATION

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.

A meta-analysis (7 retrospective studies, 314 patients) found no difference in stent reocclusion when plastic stents vs. SEMSs were used to treat occluded SEMSs in patients with a malignant biliary obstruction (relative risk 1.24, 95%CI 0.92 – 1.67) [103]. In a more recent RCT, 48 patients with a malignant biliary obstruction who developed stent dysfunction were randomized to insertion of a plastic stent, uncovered SEMS, or PCSEMS [54]. Of these, 11 patients (23 %) again developed stent dysfunction, 8 in the plastic stent group, 1 in the uncovered SEMS group, and 2 in the PCSEMS group, with mean functional durations of 170 days, 367 days, and 326 days, respectively (plastic stent vs. SEMS; $P = 0.026$). No differences in overall costs were found between secondarily placed SEMSs or plastic stents. Another RCT (43 patients with a nonfunctioning uncovered SEMS in a malignant distal biliary obstruction) found no difference in time to stent occlusion between covered vs. uncovered SEMS (112 vs. 181 days, respectively; $P > 0.05$) [104].

Radiofrequency ablation was compared with the insertion of a plastic stent in a retrospective study of 50 patients with a nonfunctioning SEMS in malignant distal or proximal biliary obstruction: although radiofrequency ablation failed in 44 % of patients (a plastic stent was inserted), stent patency duration was longer in the radiofrequency ablation group vs. the control group [105].

Finally, apart from specific stent designs mentioned above, no significant advances for the prevention of biliary stent dysfunction have been made since 2002, when a Cochrane meta-analysis showed the absence of benefit from any systemic treatment [106].

5. Periprocedural and technical aspects of biliary stenting

5.1. Prophylaxis of post-ERCP pancreatitis

RECOMMENDATION

ESGE recommends, for prophylaxis of post-ERCP pancreatitis, routine administration of 100 mg of diclofenac or indomethacin intrarectally immediately before or immediately after ERCP in every patient with no contraindication.

Strong recommendation, moderate quality evidence.

ESGE recommendations about the prophylaxis of post-ERCP pancreatitis have been updated in a specific Guideline to which the reader is referred [107]. One of its main recommendations is to routinely administer 100 mg of diclofenac or indomethacin intrarectally immediately before or immediately after ERCP. We cannot overemphasize this point: despite the continuing accumulation of high quality evidence supporting the efficacy of this simple measure [108] except in low risk patients [109 – 112], and the safety and the low price of diclofenac and indomethacin, their routine use has not been adopted by the majority of endoscopists [113, 114].

5.2. Antibiotic prophylaxis

RECOMMENDATION

ESGE suggests administration of antibiotic prophylaxis before biliary stenting in selected patients (e. g., immunocompromised patients, expected incomplete biliary drainage).

Weak recommendation, moderate quality evidence.

Post-ERCP biliary infection is a serious complication that is fatal in 8 % – 20 % of cases and it is best prevented by complete biliary drainage [115, 116]. A relatively old meta-analysis (5 RCTs, 1029 patients) found the risk of sepsis/cholangitis following ERCP was not significantly decreased by routine antibiotic prophylaxis (odds ratio [OR] 0.91, 95 % confidence interval [CI] 0.39 – 2.15) [117]. More recently, guidelines have recommended antibiotic prophylaxis in patients with expected incomplete drainage of biliary obstruction, followed by a full antibiotic course if adequate drainage is not achieved during the procedure, as well as in patients with liver transplantation [118]. The authors suggested that prophylactic antibiotics may also be of benefit to patients with severe neutropenia (absolute neutrophil count < 500 cells/μL) and/or advanced hematologic malignancy.

Recent studies are summarized below:

- A nationwide prospective study (31 188 patients) found, after adjustment for confounders, a 26 % risk reduction in postoperative adverse events when prophylactic antibiotics were used (OR 0.74, 95%CI 0.69 – 0.79) [119]; nevertheless, the absolute risk reduction in adverse events (2.6 % in unselected patients and 3.8 % in patients with obstructive jaundice) was estimated to be insufficient by the authors to justify routine antibiotic prophylaxis in unselected patients;
- A prospective study (183 unselected patients) found similar incidences of cholangitis with vs. without antibiotic prophylaxis, and all patients who developed cholangitis had incomplete drainage [120];
- A retrospective series (605 unselected patients) found that the increase in the incidence of post-ERCP cholangitis after routine antibiotic prophylaxis had been abandoned (1.7 % vs. 2.0 %) was not statistically significant [121]. In that study, sclerosing cholangitis and incomplete biliary drainage were significant risk factors for postoperative cholangitis;
- Another retrospective study (84 procedures, mostly in patients with sclerosing cholangitis) suggested that addition of antibiotics and antifungal agents to the contrast medium was associated with a lower risk of post-ERCP infectious complications (OR 0.33, 95%CI 0.11 – 0.98), in particular in patients with incomplete biliary drainage [122].

5.3. Endoscopic biliary sphincterotomy

RECOMMENDATION

ESGE suggests against routine endoscopic biliary sphincterotomy before the insertion of a single plastic or an uncovered/partially covered SEMS.

Weak recommendation, moderate quality evidence.

Two meta-analyses have compared biliary stenting with vs. without endoscopic biliary sphincterotomy (EBS) [123, 124]. The first meta-analysis (3 RCTs, 338 patients) found that EBS was associated with a reduced risk of post-ERCP pancreatitis (OR 0.34, 95%CI 0.12 – 0.93) and an increased risk of bleeding (OR 9.70, 95%CI 1.21 – 77.75); no significant difference was reported in the success of stent insertion and the rate of stent migration (OR 2.31, 95%CI 0.70 – 7.63). The second meta-analysis (5 RCTs, 12 comparative observational studies; 2710 patients) confirmed a higher risk of bleeding with EBS (OR 8.89, 95%CI 2.76 – 28.73) but no difference in terms of post-ERCP pancreatitis, stent migration, or occlusion [124]. Subgroup analysis according to the indication for biliary stenting suggested a protective effect of EBS against post-ERCP pancreatitis in patients who had biliary stenting for bile leak ($P = 0.03$) and no difference if biliary stenting was indicated for biliary obstruction. A subgroup analysis of the 6 studies (607 patients) in which SEMS were used found no difference in the incidence of post-ERCP pancreatitis in patients who had EBS or not. With respect to FCSEMS, a hypothetical concern has been raised that their coverage could obstruct the pancreatic outflow, leading to a high incidence of post-ERCP pancreatitis [125].

5.4. Failed biliary stenting

5.4.1 Repeat attempts at ERCP

ERCP initially fails in 10 % – 20 % of patients because of difficult anatomy/inability to cannulate the papilla and to pass a guidewire across the stricture [126]. In such instances, the indication for repeating biliary intervention should be carefully reconsidered: in 7 studies of failed ERCP, ERCP was not repeated in 152 of 517 patients (29 %) [127 – 133]; reasons stated for this choice mostly included poor patient condition, futility, or replacement by another procedure such as endoscopic ultrasonography-guided sampling. In 9 studies that analyzed the role of repeat attempt at ERCP (▶ **Table e5**, available online), repeat ERCP was successful in 442 of 537 patients (82 %). Of note, the three studies that analyzed the timing of repeat ERCP found that ERCP was more frequently successful if it was repeated at least 2 days [129, 131] or 4 days [127] after the first attempt. A suggested explanation includes better visualization of the opening of the bile duct because of decreased edema or disappearance of submucosal injection. Factors that may favor success at repeat ERCP also include better patient sedation and team preparation, availability of ancillary material (e. g., specialized guidewires), and referral to another endoscopist in the same institution or in a high volume center. The morbidity associated with the first and subsequent ERCPs was similar in the studies that reported this outcome.

The reader is referred to the recent ESGE Guideline about the techniques of papillary cannulation and EBS at ERCP that includes an evidence-based algorithm for difficult biliary cannulation [134]. Of note, in patients with complex post-surgical anatomy including Billroth II gastrectomy, ESGE suggests referral to a specialized center.

5.4.2 Role of EUS-BD

More recently, the role of EUS-BD after failed biliary stenting at ERCP has been assessed in the literature:

- A meta-analysis that compared PTBD vs. EUS-BD (3 RCTs and 3 retrospective studies; total, 312 patients) found that clinical success was similar with both techniques (OR 1.48, 95%CI 0.46 – 4.79) but with fewer adverse events in the EUS-BD

group (OR 0.34, 95%CI 0.20 – 0.59); severe adverse events accounted for this difference [135]. The reintervention rates and costs were also lower with EUS-BD. Broadly similar findings were reported in a more recent retrospective study [136];

- An RCT (32 patients with a malignant distal biliary obstruction) found that, compared with surgical hepaticojejunostomy, EUS-BD presented a lower clinical success rate and a higher complication rate but differences were nonsignificant (71 % vs. 93 % and 21 % vs. 13 %, respectively) [137].

The concern has been expressed that EUS-BD might be used as a substitute for poor ERCP technique as the analysis of > 1600 ERCPs in two tertiary referral centers has shown that EUS-BD was required in only 0.6 % and 3.3 % of ERCPs [138, 139]. This aspect should not be disregarded by endoscopists with more experience in EUS-guided intervention than in ERCP.

With respect to the learning curve, a prospective study of 174 attempts at EUS-BD by a single endoscopist experienced in both EUS and ERCP suggested that 33 cases were required for learning EUS-guided hepaticogastrostomy as procedure duration decreased and adverse events tended to be less frequent (36.4 % and 20.8 %, $P = 0.12$) with practice [140].

Two meta-analyses compared the extrahepatic and intrahepatic routes for EUS-BD in subgroup analyses that included 8 and 10 studies [43, 45]: technical and functional success rates were similar with both routes in both studies and, in a single study, adverse events were less frequent with the extrahepatic vs. intrahepatic route (OR 0.40; 95%CI 0.18 – 0.87; $P = 0.022$) [43]. In the particular situation of patients requiring EUS-BD and duodenal stenting, a retrospective study (39 patients) suggested that EUS-guided hepaticogastrostomy could provide longer biliary stent patency than EUS-guided choledochoduodenostomy [141].

With respect to stent choice, SEMSs are more frequently used than plastic stents (525 patients and 58 patients, respectively, in the meta-analysis by Wang et al. [45]); both types of stents provided similar technical and functional success rates but adverse events were more frequent with plastic stents vs. SEMSs (31 % vs. 18 %) [45]. Similar results were reported in an RCT that included 60 patients with EUS-guided choledochoduodenal stenting: SEMSs and plastic stents provided similar success rates but adverse events were more frequent with plastic stents (23 % vs. 13 %) and costs were lower with SEMSs [142]. Of note, fully or partially covered models of standard biliary SEMSs are usually selected for transmural biliary drainage to prevent bile leakage but dedicated SEMSs with a covering and antimigration flaps on one half of the SEMS have recently been tested [143, 144], with some models providing promising results [145 – 147]. Another promising device is a LAMS: in a multicenter retrospective study (57 patients with failed ERCP), LAMSs provided clinical success in 95 % of patients with adverse events reported in 7 %. After a mean follow-up of 5 months, stent migration occurred in one patient (2 %) [147].

6. Particular cases

6.1. Malignant hilar strictures

6.1.1. Tumor assessment and patient referral

RECOMMENDATION

ESGE suggests assessing the resectability of malignant hilar strictures in the absence of biliary stents.

Weak recommendation, low quality evidence.

A meta-analysis (16 studies, 651 patients) found that CT, magnetic resonance imaging (MRI) and positron emission tomography (PET)/CT present similar accuracies for assessing resectability of hilar cholangiocarcinoma (CT, 71 % – 95 %; MRI, 84 % – 93 %; PET/CT, 75 % – 91 %) [148, 149]. The authors acknowledged that imaging techniques are often combined as each technique may provide higher accuracy for a specific item (e. g., vascular invasion for CT, lymph node metastasis for PET/CT). The two studies (not included in the meta-analysis) that compared MRI and CT in identical patients with hilar cholangiocarcinoma (total, 36 patients) found that both techniques had similar accuracies for the evaluation of bile duct involvement [150, 151]. Patients with biliary stents were excluded from these studies as from others because the staging accuracy of both modalities diminishes after biliary stent placement as a result of ductal decompression and imaging artifacts [152]. Measurement of liver volumes by CT and MRI is similarly effective [153, 154]. Experience with EUS staging of hilar malignancy remains very limited.

RECOMMENDATION

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

Strong recommendation, moderate quality evidence.

A meta-analysis (13 studies, 59 437 ERCPs) showed that ERCP success is more frequent when it is performed by high volume vs. low volume endoscopists (OR 1.6, 95%CI 1.2 – 2.1) and in high volume vs. low volume hospitals (OR 2.0, 95%CI 1.6 – 2.5), while adverse events are less frequent when ERCP is performed by high volume endoscopists [155]. As endoscopic stenting in malignant hilar strictures (MHSs) is an advanced procedure with a relatively high risk of failure, and survival is severely hampered after failed drainage [156, 157], the endoscopist's experience is even more important for MHSs than for distal malignant biliary strictures, as is the prompt availability of PTBD. Nevertheless, many patients with MHS are admitted to referral centers with a biliary stent already in place [158].

6.1.2. Preoperative drainage of malignant hilar strictures

RECOMMENDATION
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 a multidisciplinary team based on patient characteristics and institutional experience.
Weak recommendation, low quality evidence.

Two systematic reviews (11 studies, 711 patients and 9 studies, 892 patients) reported that preoperative biliary drainage of hilar cholangiocarcinoma was associated with a higher postoperative morbidity rate, in particular because of infections, and no significant difference in postoperative mortality [159, 160]. However, many authors have suggested that in specific situations (e. g., cholangitis, predicted future liver remnant volume of ≤ 30 % following surgery), preoperative drainage could be indicated [161]. These situations have been associated with a high risk of postoperative liver failure and may thus benefit from portal vein embolization and drainage limited to the future liver remnant segments [162].

With respect to the choice between the endoscopic and percutaneous approaches for preoperative biliary drainage, two meta-analyses (4 retrospective studies, 433 patients, and 3 retrospective studies, 265 patients) reported a similar [163] or higher [164] procedure-related morbidity for ERCP vs. PTBD. On the other hand, a large, more recent, retrospective study (280 patients) found that major postoperative morbidity was more frequent after PTBD vs. ERCP for drainage of MHS [165]. A single meta-analysis analyzed long-term survival; it was shorter following PTBD vs. ERCP (30 % vs. 46 % at 5 years) [163]. A similarly shorter patient survival following PTBD vs. ERCP was reported in three large retrospective studies (793 patients) not included in the meta-analyses [166 – 168]. Peritoneal metastasis was more frequent following PTBD vs. ERCP; it may be associated with the duration of PTBD (60 days or more) and the presence of multiple PTBD catheters [169]. A similar association between preoperative PTBD and shorter survival has not been found in a Western bicentric study (245 patients) with a different use of PTBD catheters [170].

If endoscopic preoperative drainage of MHS is performed, plastic stents or nasobiliary drains are preferred [171]; although less comfortable for the patient, nasobiliary drains are preferred in particular by Japanese authors because of the lower incidence of cholangitis due to tube occlusion [172]. The use of SEMSs for preoperative drainage of MHS is discouraged because of the paucity of the literature [173] and the risk of precluding curative surgery.

6.1.3. Palliative drainage of malignant hilar strictures

RECOMMENDATION
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.

RECOMMENDATION
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.

RECOMMENDATION
ESGE recommends uncovered SEMSs for palliative drainage of malignant hilar obstruction.
Strong recommendation, moderate quality evidence.

A meta-analysis (7 retrospective studies and 2 RCTs, 546 patients) found that PTBD was more frequently successful than ERCP for palliation of Bismuth types III and IV MHS (OR 2.53, 95%CI 1.57 – 4.08) [174]. Overall adverse events and 30-day mortality were similar for both approaches. Bismuth types I and II MHS were not included in the meta-analysis because ERCP was believed to represent the optimal approach for palliative drainage of such strictures. Of note, drainage of Bismuth type I MHS is technically similar to that of extrahepatic biliary strictures. The value of this meta-analysis is limited by the fact that most data were retrospective, including three noncomparative studies. With respect to quality of life, it improves with both approaches [175, 176] but an RCT (54 patients) suggested that some health parameters improve more with PTBD vs. ERCP [177].

An RCT (54 patients with a potentially resectable hilar cholangiocarcinoma) reported a higher perioperative mortality with PTBD vs. ERCP [178]. In a retrospective study (110 patients with a Bismuth type III and IV MHS), failed endoscopic biliary drainage was associated with an acute angle between the common bile duct (CBD) and the left hepatic duct at pre-drainage imaging; this could help to decide on the best individual approach in centers where ERCP is used for draining Bismuth types III and IV MHS [179].

The minimal proportion of liver volume, excluding tumor volume, that should be drained was analyzed in a retrospective study (78 patients): serum bilirubin dropped by ≥ 50 % if 33 % or 50 % of liver volume was drained in patients with either normal liver function/compensated cirrhosis or decompensated cirrhosis, respectively [180]. These results are in line with prior studies [181, 182]; one of these also showed a lower incidence of

cholangitis and longer patient survival with endoscopic drainage of > 50 % of the liver volume [182].

Unilateral and bilateral drainage of MHS have been compared in three meta-analyses [53, 183, 184]. Two of these (7 studies, 634 patients; 4 studies, 562 patients) found a significant difference only in the success of stent insertion (higher with unilateral stenting) while other outcomes were similar, including therapeutic success, cumulative stent patency, complications, and survival. The third meta-analysis (28 mostly noncomparative studies, 2132 patients) reported the following: (i) for plastic stents, no difference for any outcome, including success of stent insertion, overall complications, and 30-day mortality; (ii) for SEMSs, a higher technical success rate, more overall adverse events, less decrease in serum bilirubin, and similar 30-day mortality with unilateral vs. bilateral stenting [183]. In these meta-analyses, the only study that randomized patients to unilateral vs. bilateral stenting used plastic stents, which are no longer standard of care. More recently, a multicenter RCT (133 patients with MHS of Bismuth type ≥ II treated with SEMSs) addressed most biases of the studies included in the above-mentioned meta-analyses, namely the inclusion of patients with Bismuth type I MHS that can be fully drained with a single stent, the use of both SEMS and plastic stent, and the inclusion of patients undergoing palliative drainage as well as PBD: bilateral drainage resulted in fewer reinterventions and a more durable stent patency (median 252 vs. 139 days) [185].

Contrast-free deep cannulation into the ductal systems to be drained has been proposed to prevent post-ERCP cholangitis, a frequent complication after injection of obstructed ducts that are not subsequently drained [186 – 188]. In this technique, pre-ERCP imaging is used as a road map to insert a guidewire into the desired obstructed duct(s) while avoiding injection of contrast medium upstream from the stricture; once the stricture has been crossed bile is aspirated and contrast medium is injected before stent insertion. Various contrast media have been used: air, carbon dioxide (CO2) (to decrease the risk of gas embolism), or iodine contrast. Some authors have proposed no use of contrast at all, delineating the stricture with the waist of the SEMS [189]. Two RCTs (85 patients) [190, 191] and two retrospective studies (235 patients) [192, 193] found that post-ERCP cholangitis was less frequent if air/CO2 rather than iodine contrast was used for cholangiography in patients with Bismuth type ≥ II hilar stricture. Three uncontrolled studies have reported a low (0 – 6 %) rate of post-ERCP cholangitis using iodine contrast for injection upstream from the MHS [194, 195] or using no contrast medium injection [189].

Plastic stents and SEMSs have been compared in three meta-analyses; one of these included three RCTs (188 patients) [50] and the two others included, in addition to these, one prospective and two retrospective studies (total, 800 patients) [51, 53]. One meta-analysis of RCTs showed better results with SEMSs in terms of stent dysfunction (risk difference −0.17, 95%CI −0.28 to −0.06), reintervention (risk difference −0.30, 95%CI −0.54 to −0.06), and mean survival (159 vs. 99 days) [50], while the other meta-analyses reported that SEMSs were also associated with less therapeutic failure (OR 0.28, 95%CI 0.13 – 0.63) [51, 53]. SEMSs are cost-effective according to one RCT [196] and a decision analytic model [197], but not according to a retrospective study [198]. Uncovered SEMS were used in all studies except a recent retrospective series (30 patients) that reported encouraging results with a 6-mm diameter FCSEMS, although liver abscesses were reported in 7 % of patients because of a stent crossing a duct bifurcation; in this pilot study removable FCSEMS were used to prevent stent ingrowth and to facilitate reintervention [199]. Of note, if a decision for palliation has not been taken, plastic stents are recommended because removal of uncovered SEMSs is usually not possible [200].

The "side-by-side" and "stent-in-stent" positioning of multiple SEMSs have been found equivalent in a meta-analysis (4 studies, 158 patients) with respect to the rates of successful stent placement, successful drainage, early and late complications, and stent occlusions [201]. The choice of the technique thus seems to be at the discretion of the endoscopist, with the "side-by-side" and "stent-in-stent" techniques more frequently used in Western and Asian countries, respectively. The insertion of side-by-side SEMSs has become easier with the availability of small-diameter delivery catheters that can be passed simultaneously in a standard therapeutic channel duodenoscope and permit simultaneous SEMS deployment [202]. Different precautions should be taken with each technique (e. g., with the "side-by-side" technique, the SEMSs should cross the papilla or their lower extremities should be positioned at the same level in the CBD to facilitate further stent access).

Dysfunction of plastic stents is treated by stent removal, cleaning of ductal debris, and SEMS insertion, unless the diagnosis is not yet clear or patient life expectancy is very limited. In the case of SEMS occlusion, cleaning of ductal debris with a balloon is suggested, followed by cholangiographic assessment of the degree of tissue ingrowth/overgrowth and subsequent insertion of an inner plastic stent or SEMS [203]; a retrospective study (52 patients) reported a longer patency (131 days vs. 47 days) with SEMSs vs. plastic stents [204]. Radiofrequency ablation might be an alternative option although data are sparse and comparison with insertion of a plastic stent has been reported in only one retrospective study [205].

6.2. Benign strictures

RECOMMENDATION

ESGE recommends temporary insertion of multiple plastic stents 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.

Endoscopy has become the preferred option for treating benign biliary stricture (BBS) [206 – 209]. Endoscopic treatment is performed mostly for BBSs related to liver transplantation or chronic pancreatitis (one third of cases each) and, less frequently, to other causes (e. g., post-cholecystectomy and

post-sphincterotomy strictures); about 85 % of BBSs are located at the level of the CBD [210].

Treatment of BBSs with a single plastic stent or uncovered SEMS has long been abandoned because of poor long-term results [211, 212]. A meta-analysis (four RCTs, 213 patients) found that temporary insertion of either MPS or of a covered SEMS for the treatment of BBSs of various origins provided similar results (ORs [95%CIs] for stricture resolution, recurrence, and adverse events, respectively: 1.07 [0.97 – 1.18], 0.88 0.48 – 1.63], and 1.16 [0.71 – 1.88]) [213]. Fewer ERCPs were required with covered SEMSs (mean difference −1.71, 95%CI −2.34 to −1.09). The largest RCT included in the meta-analysis (112 patients) did not include patients with a BBS located within 2 cm from the hepatic confluence, a CBD diameter < 6 mm, or an intact gallbladder in whom the cystic duct would have been overlapped by a FCSEMS. The two RCTs (20 patients) that analyzed the costs of each treatment found it was approximately half with the use of covered SEMSs [214, 215].

Stricture recurrence after endoscopic treatment is usually managed with repeat endoscopic stent placement [216, 217].

RECOMMENDATION

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.

With plastic stents, the current strategy consists in inserting an increasing number of plastic stents every 3 – 4 months even though some authors have proposed different intervals for stent exchange [218 – 220]. The criteria used for treatment termination have included complete morphologic disappearance of the stricture, passage of a balloon biliary catheter, or a fixed 12-month stenting duration [218, 221, 222]. In most series the stenting duration has been approximately 12 months; a retrospective study (156 patients) reported that stricture recurrence was independently associated with a stricture diameter of less than 75 % compared to that of the surrounding CBD at the end of treatment while the association with stenting duration was significant in univariate analysis only [223].

With respect to SEMSs, partially covered SEMS have been replaced by FCSEMS in this indication because tissue hyperplasia can develop through the bare ends, complicating SEMS removal or causing biliary stricture [224 – 227]. Stent migration is the most frequent adverse event related to FCSEMS (9 % in a meta-analysis of 37 studies, 1677 patients) [228] and it is associated with a 80 % decrease in the odds of stricture resolution [229, 230]. Stent designs aimed at preventing stent migration include flared ends (Wallflex), anchoring fins (Viabil, Hanaro) and a short stent length allowing complete intrabiliary stent deployment (Taewoong) [231]. Anchoring fins were more effective than flared ends to reduce stent migration in a retrospective study (134 patients) but some models have been associated with traumatic biliary mucosal lesions and possibly the development of de novo biliary strictures, including after stent removal (8.1 % of 37 patients in a retrospective study) [232, 233].

The ideal duration of FCSEMS dwell is unknown; in a meta-analysis (37 studies, 1677 patients), the median stenting duration was 4.4 months [228]; another meta-analysis (22 studies, 1298 patients) found a lower stricture recurrence with 6 vs. 3 months or less of stent therapy [213].

With respect to the need for EBS before FCSEMS insertion for this indication, it has been performed in most series [227]; a retrospective series reported a very high incidence of post-ERCP pancreatitis (50.0 %, including one fatal case) that decreased to 12.5 % once EBS was routinely performed [125].

6.2.1. Benign biliary strictures related to chronic pancreatitis

RECOMMENDATION

ESGE suggests the temporary insertion of multiple plastic stents or of an FCSEMS for treating benign biliary strictures related to chronic pancreatitis.

Weak recommendation, moderate quality evidence.

An RCT (60 patients with chronic pancreatitis) found that MPS and covered SEMSs provided similar success rates 2 years after stent removal (88.0 % vs. 90.9 %, respectively) with similar treatment-related morbidity (23.3 % vs. 28.6 %, respectively) [234]. The stenting duration was 6 months in both groups and the removal of covered SEMS was problematic in 4 of 28 patients (14.3 %) because of stent fracture (n = 3) and embedment (n = 1), mostly at the beginning of the authors' experience when partially covered SEMS were used (FCSEMS were used once they became available).

A systematic review concluded that covered SEMSs provided better results than MPS in chronic pancreatitis-related biliary strictures, but it included noncomparative studies only and single plastic stents were used in a significant proportion of patients in all of the three studies labeled as MPS (e. g., 33 % in the study by Eickhoff et al.) [235, 236].

Patient compliance may be particularly problematic in patients with alcoholic chronic pancreatitis, and biliary bypass surgery (e. g., hepaticojejunostomy) remains a valid option for noncompliant patients or if the stricture does not respond to biliary stenting [237].

6.2.2. Benign anastomotic biliary strictures following liver transplantation

RECOMMENDATION

ESGE suggests temporary insertion of multiple plastic stents for the treatment of benign anastomotic biliary strictures following orthotopic liver transplantation pending further evidence about FCSEMS.

Weak recommendation, moderate quality evidence

Anastomotic biliary strictures (ABSs) are more frequent following living donor liver transplantation (LDLT) vs. deceased donor liver transplantation (DDLT); LDLT-related ABSs are also more difficult to treat, with risks of technical treatment failure and of stricture recurrence being 23 % and 25 % higher, respectively [238]. Predictors of failed endoscopic treatment of LDLT-related ABSs include higher liver transplantation recipient age, longer operation duration, pouched morphology of the ABS, multiple ductal anastomosis, and persistent bile leak [239 – 241]. The treatment of LDLT-related ABSs is performed in highly specialized centers and its modalities are not considered in the current Guideline.

Three RCTs (20, 58, and 64 DDLT recipients) compared covered SEMS vs. MPS for the treatment of ABSs: two RCTs reported no difference between groups except for a lower number of ERCPs with FCSEMSs vs. MPS [214, 242], while the largest RCT reported higher stricture recurrence and adverse event rates with covered SEMSs vs. MPS (32.0 % vs. 0 % and 23.3 % vs. 6.4 %, respectively) (the authors did not mention whether SEMSs were fully or partially covered) [215]. These RCTs were not included in a review of 13 noncomparative studies (601 patients) which reported that, in patients with an ABS following DDLT, the stricture resolution rates were higher with MPS vs. FCSEMSs (87.2 % vs. 61.8 %) while recurrence and adverse event rates were similar [243].

6.2.3. Post-cholecystectomy benign biliary strictures

RECOMMENDATION

ESGE suggests temporary insertion of multiple plastic stents for the treatment of benign biliary strictures complicating cholecystectomy; a FCSEMS can be an alternative for strictures located > 2 cm from the main hepatic confluence.

Weak recommendation, moderate quality evidence.

A single RCT (31 patients) compared MPS (average 4.8 stents) vs. PCSEMSs (8 – 10-mm diameter) in patients with BBSs mostly related to cholecystectomy [244]. Adverse event rates were similar with both types of stent and, based on MRI, long-term success was stated to be better with PCSEMSs (81.7 % vs. 71.9 %). However, the significance is doubtful because of the low number of patients and the uncommon, undetailed, measure of success. In the largest RCT that compared MPS vs. FCSEMSs, only 4 of 112 patients (3.6 %) had postoperative injuries that were not related to liver transplantation as many post-cholecystectomy strictures occur too close to the hepatic confluence to accommodate SEMS [245].

On the other hand, the study with the longest follow-up available (> 13 years) used MPS and reported no stricture recurrence in 88.6 % of 35 patients followed retrospectively [216]. Similar results were reported by the same group of authors in a cohort extended to 164 patients with a follow-up of 7 years; notably half of the patients had a post-cholecystectomy BBS that involved the main hepatic confluence, a feature that has become more frequent with the advent of laparoscopic cholecystectomy [246]. For BBSs located > 2 cm from the main hepatic confluence FCSEMS can present the advantage of fewer ERCPs and shorter treatment.

6.3. Biliary leaks

RECOMMENDATION

ESGE recommends endoscopic placement of plastic stent(s) to treat bile duct leaks that are not due to transection of the common bile duct or common hepatic duct.

Strong recommendation, moderate quality evidence.

SEMS may be valuable in the case of refractory bile leak.

ESGE does not recommend a primary endoscopic approach to drain bilomas.

Strong recommendation, low quality evidence.

Various forms of endoscopic treatment, i. e., biliary stenting, EBS, and nasobiliary drainage, are highly effective to treat biliary leaks except in the case of transection of a large duct; of note the time lapse between biliary injury and endoscopic treatment does not seem to affect important outcomes [247].

Some of the available treatment options were compared in three RCTs. One of these (27 patients) found that fistulas tended to close more rapidly with biliary stenting vs. EBS [248]. Another RCT (52 patients) found no difference in terms of efficacy between the placement of a plastic stent alone or combined with EBS [249]. With respect to the stent diameter, an RCT (63 patients) reported similar proportions of patients with leak closure using 7-Fr vs. 10-Fr plastic stents [250]. The duration of stenting has not been specifically investigated; it is 4 – 8 weeks in many studies.

In patients with a post-cholecystectomy bile leak that persisted following the insertion of a single plastic stent, FCSEMSs were superior to MPS in a comparative nonrandomized study (40 patients) [251].

EBS alone is attractive because it does not imply repeat endoscopy but this advantage should be balanced against potential short-term and long-term complications. The latter consist of cholangitis and pancreatitis (OR 1.7 [95%CI 1.3 – 2.4] and 1.5 [95%CI 1.0 – 2.4], respectively, compared with adequate controls at a median follow-up of 15 years) [252].

Case series suggest that temporary transpapillary biliary drainage may also be effective to treat bile leaks due to liver resections [253, 254].

Bilomas are a frequent complication of biliary leaks that may require drainage; this is traditionally performed percutaneously but several case series have reported its feasibility under EUS guidance [255]. A retrospective series (27 patients with liver abscess) has reported a trend for better results as well as a significantly shorter hospital stay for EUS-guided vs. percutaneous drainage [256]. Nevertheless, more data are needed before this approach may be recommended in specific situations [257, 258].

6.4 Failed extraction of biliary stones

RECOMMENDATION

ESGE suggests endoscopic placement of a temporary biliary plastic stent in patients with irretrievable biliary stones.

Weak recommendation, moderate quality evidence.

If CBD stones cannot be removed during ERCP because of patient condition or technical factors, a biliary stent may be inserted to both drain the bile ducts and facilitate delayed stone extraction, as stone size will decrease by a mean of 50 % in 2 – 6 months [259]. An RCT in 86 frail patients has shown that short-term complications tend to be less frequent with this strategy compared with attempted CBD stone removal [260].

Plastic stents have been used in most studies and no comparison between the different types and diameters is available. A meta-analysis (6 studies, 885 patients) showed that the risk of cholangitis is highly increased with permanent stenting vs. elective stent exchange (OR 5.32, 95%CI 2.23 – 12.68) [259]. Therefore, stenting for biliary stones should be considered a temporary measure until bile duct clearance is achieved. The ideal timeframe for stent exchange has not been defined. An RCT (78 patients) has reported a lower incidence of cholangitis following the insertion of a 10-Fr stent if the stent was exchanged every 3 months vs. on demand [261]. These findings are in line with a retrospective study (64 patients) that reported a higher stent patency rate at 3 months with two plastic stents vs. one [262].

FCSEMSs have been used in six retrospective series (total 160 patients) [263] and stones were successfully removed in 127 of 144 attempted cases (88 %), most often with a simple balloon sweep. Adverse events were noted in 29 cases (18 %) and the cost–effectiveness has not been compared with that of plastic stents.

7. Stent registry

RECOMMENDATION

ESGE recommends maintaining a registry of patients with biliary stents, in particular for patients with a benign biliary disease, and to recall them for stent removal/exchange.

Strong recommendation, low quality evidence.

Measures should be taken to avoid leaving biliary stents in place for too long, as “forgotten” stents may be extremely difficult to remove (requiring surgery in 76 % of 21 patients in a retrospective series) and caused death in 6.7 % of patients in a prospective series [264]. Maintaining a registry of stents inserted with the purpose of recalling patients due for stent exchange or removal allowed a decrease in the incidence of stent-related sepsis in an Australian endoscopy unit [265]. An RCT (48 patients) showed that mobile phone reminder messages may increase patient adherence to stent removal/exchange [266]. Of course, patient compliance with repeat interventions should be ensured prior to treatment.

Disclaimer

The legal disclaimer for ESGE Guidelines [3] applies to the current Guideline.

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