REVIEW

International consensus statements for endoscopic management of distal biliary stricture

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Abstract

Distal biliary strictures (DBS) are common and may be caused by both malignant and benign pathologies. While endoscopic procedures play a major role in their management, a comprehensive review of the subject is still lacking. Our consensus statements were formulated by a group of expert Asian pancreatico-biliary interventional endoscopists, following a proposal from the Digestive Endoscopy Society of Taiwan, the Thai Association for Gastrointestinal Endoscopy, and the Tokyo Conference of Asian Pancreato-biliary Interventional Endoscopy. Based on a literature review utilizing Medline, Cochrane library, and Embase databases, a total of 19 consensus statements on DBS were made on diagnosis, endoscopic drainage, benign biliary stricture, malignant biliary stricture, and management of recurrent biliary obstruction and other complications. Our consensus statements provide comprehensive guidance for the endoscopic management of DBS.

Introduction

Distal biliary strictures (DBS) are common and may be caused by both malignant and benign pathologies. While endoscopic procedures play a major role in their management, a comprehensive review of the subject is still lacking, which has impact on diagnosis (imaging and pathological) and treatment (indications, procedure options, and outcomes). The consensus statements presented here were formulated following a literature review and discussion among international experts. The aim is to provide comprehensive guidance for the endoscopic management of DBS.

Methods

The consensus statements were formulated by a group of expert Asian pancreatico-biliary interventional endoscopists, some of whom perform interventional radiology procedures and operative surgical procedures in their routine clinical practice, following a proposal from the Digestive Endoscopy Society of Taiwan (DEST), the Thai Association for Gastrointestinal Endoscopy (TAGE), and the Tokyo Conference of Asian Pancreato-biliary Interventional Endoscopy (T-CAP).

Based on a literature review utilizing Medline, Cochrane library, and Embase databases, first draft clinical questions (CQs) were developed by a planning panel (HI, RR, HPW, IY, YN, and HK). These first draft CQs were discussed via the internet and revised by each author. A face-to-face meeting was conducted in June 2017 in Tokyo, Japan. After further discussion and revision, the statements were voted on by all attendees (YN, HI, HPW, RR, CK, IY, HK, JHM, JL, SL, TR, DWS, DKL, DM, FD, WL, PVD, MA, AI, AK, MK, SR, and TF). The evidence level and recommendation grade were evaluated using the evidence leveling system (Table 1).[1] The discussion continued until an agreement of greater than 80% was achieved for recommendation Level A or B. Finally, after voting, a total of 19 consensus statements were agreed upon. The second draft of consensus statements was presented for open discussion at Asia Pacific Digestive Week (APDW) in September 2017 in Hong Kong. Subsequently, the revised statements were discussed among the faculty members

Table 1 Quality of evidence, classification of recommendations and voting schema of the modified Canadian Task Force on the periodic health examination

Level/grade	Description
Levels of evidence	
A (strong)	Strongly confident in the effect of estimate.
B (moderate)	Moderately confident in the effect of estimate.
C (weak)	Confidence in the effect of estimate is limited.
D (very weak)	Almost no confidence in the effect of estimate.
Classification of the recommendation	
1	Strong recommendation
2	Weak recommendation
Voting on the recommendation	
A	Accept completely
B	Accept with some reservations
C	Accept with major reservations
D	Reject with reservations
E	Reject completely

via the internet. The resultant manuscript was evaluated by three expert endoscopists (MW, TI, and BD) and was finalized by each author.

Definition of distal biliary stricture. Numerous studies have reported on DBS, but anatomical definitions vary. The most commonly used definitions used include stenosis of the distal third of the extrahepatic bile duct,[2] the intrapancreatic portion of the common bile duct, or the distal half of the extrahepatic bile duct.[3] Some papers on the subject do not provide a definition. As the focus of our consensus statements is on endoscopic management and the intra-pancreatic portion[4] of the common bile duct cannot be determined on endoscopic retrograde cholangio-pancreatography (ERCP), we have excluded the use of the intrapancreatic bile duct as a definition. There was a debate during the face-to-face meeting, but there were no clear reasons to select one over the other. Hence, we define DBS as abnormal narrowing of the distal half, which includes the distal third, of the extrahepatic bile duct.

Consensus statements

Diagnosis

CQ1. What strategy is recommended for diagnosis of distal biliary strictures?.

Statement 1-1. The diagnostic strategy for evaluating a DBS is determined by the possible etiology, clinical features, abnormal liver biochemistries, and/or cross-sectional imaging.

> Evidence level: D
> Recommendation: 1
> Agreement: A, 0%; B, 100%; C, 0%; D, 0%

Statement 1-2. In patients with DBS, ERCP and/or endoscopic ultrasound (EUS) are often helpful in establishing the etiology.

> Evidence level: A
> Recommendation: 1
> Agreement: A, 96%; B, 4%; C, 0%; D, 0%

First of all, detailed history taking and physical examination should be performed. Painless jaundice with Courvoisier's sign[5] and a previous history of malignancy raises the possibility of malignant biliary stricture (MBS). Meanwhile, a history of pancreatitis in heavy drinkers suggests the presence of chronic pancreatitis as a cause of biliary stricture. In addition to hepatobiliary enzymes, some serum markers may help in the diagnosis of DBS. Serum carbohydrate antigen (CA) 19–9 is a tumor marker useful for pancreato-biliary cancer with a sensitivity of 70–80% in pancreatic cancer and 50–80% in biliary tract cancer.[6,7] However, CA19–9 increases in the presence of cholestasis and cholangitis, and false positive results are possible in cases with DBS. IgG4 related diseases including autoimmune pancreatitis can be a cause of DBS and serum IgG4 level is high in about 80% of autoimmune pancreatitis.
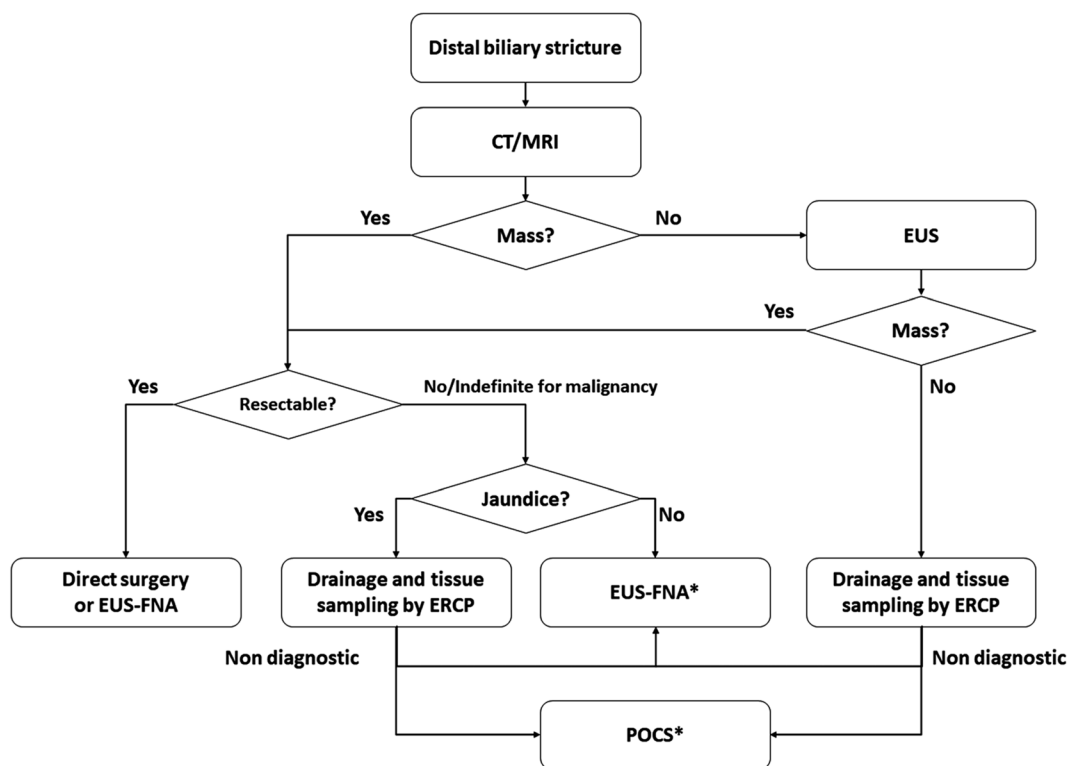
Figure 1 The diagnostic strategy and tissue sampling approach for a distal biliary stricture. *EUS-FNA is recommended for an extrinsic biliary stricture and POCS for an intrinsic biliary stricture. CT, computed tomography; ERCP, endoscopic retrograde cholangio-pancreatography; EUS, endoscopic ultrasound; EUS-FNA, endoscopic ultrasound-guided fine needle aspiration; MRI, magnetic resonance imaging; POCS, peroral cholangioscopy.

The diagnostic strategy for evaluating DBS should take into account the presence of jaundice or abnormal liver biochemistry, findings of cross-sectional imaging, and probability of resectability, if a tumor is detected (Fig. 1). When a pancreatic tumor causing DBS is noted on cross-sectional imaging, EUS-guided fine needle aspiration (EUS-FNA) is helpful in establishing a tissue diagnosis. Notably, EUS may detect occult periampullary tumors in patients who present with DBS but without a mass on cross-sectional imaging.[8,9] In jaundiced patients, ERCP is an appropriate first-line procedure as both diagnostic and therapeutic maneuvers can be performed including transpapillary brush cytology or forceps biopsy and biliary drainage. The diagnostic yield of EUS-guided and transpapillary tissue sampling is discussed later in CQ3. In summary, the diagnostic strategy should be directed by the presence of jaundice and initial cross-sectional imaging.

CQ2. What is the role of cross-sectional imaging?.

Statement 2. Contrast-enhanced computed tomography (CT) or magnetic resonance imaging (MRI) is necessary for the detection and characterization of a mass and to determine resectability of malignant lesions.

Evidence level: A
Recommendation: 1
Agreement: A, 100%; B, 0%; C, 0%; D, 0%

Cross-sectional imaging such as contrast-enhanced CT or MRI is commonly utilized in clinical practice to assess patients with DBS. Both CT and MRI have high diagnostic accuracy for identification and characterization of primary lesions[10,11] and to determine resectability of malignancy.[11,12] Therefore, multiphasic contrast-enhanced CT or MRI should be performed in the initial evaluation of patients with DBS prior to invasive procedures such as EUS or ERCP. CT and MRI confer the additional advantage of potentially detecting distant metastasis.

CQ3. What is the optimal approach for tissue acquisition?.

Statement 3. ERCP-guided tissue acquisition should be attempted when biliary drainage is required. EUS-FNA is preferred when cross-sectional imaging reveals a mass associated with the stricture or when ERCP-guided tissue acquisition is unsuccessful.

Evidence level: A
Recommendation: 1
Agreement: A, 100%; B, 0%; C, 0%; D, 0%

EUS-FNA provides both high sensitivity and specificity in diagnosing a pancreatic mass. In a meta-analysis, the pooled sensitivity and specificity of EUS-FNA in correctly diagnosing pancreatic masses was 86.8% (95% confidence interval, CI, [85.5, 87.9]) and 95.8% (95% CI [94.6, 96.7]).[13] In cases with biliary stricture,

the sensitivity and specificity of EUS-FNA for characterizing the biliary stricture was 80% and 97%, respectively.[14] The diagnostic yield is lower in the absence of a mass,[15] but EUS can detect small (<2 cm) pancreatic lesions. In one retrospective study, the sensitivity of EUS-FNA was 87.3% in pancreatic neoplasm without a definitive mass on CT.[16]

In cases requiring endoscopic biliary drainage, a tissue diagnosis may be made during ERCP. In a meta-analysis,[17] the pooled sensitivity and specificity of brush cytology for the diagnosis of a MBS was 45% (95% CI [40%, 50%]) and 99% (95% CI [98%, 100%]), respectively. Intraductal forceps biopsies had a pooled sensitivity and specificity of 48.1% (95% CI [42.8%, 53.4%]) and 99.2% (95% CI [97.6%, 99.8%]), respectively. In another study, the sensitivity of transpapillary tissue sampling during ERCP was 49% compared with 75% by EUS-FNA.[18] The cause of the biliary stricture also affects diagnostic yield.[19] Diagnostic accuracy of ERCP-guided tissue sampling was 81.8% and 67.8% in intrinsic and extrinsic biliary strictures ($P = 0.023$), respectively. As most DBS are associated with obstructive jaundice or cholangitis, transpapillary biliary drainage is usually necessary to relieve symptoms. Therefore, we recommend that transpapillary tissue sampling should be attempted at the time of biliary drainage during ERCP. If transpapillary tissue sampling is non-diagnostic or if early biliary drainage is unnecessary, we recommend EUS-FNA to secure the pathological diagnosis, especially when the DBS is associated with a mass. Despite concerns that the presence of a biliary stent may compromise the accuracy of EUS imaging, most studies have reported that an indwelling biliary stent does not adversely affect the diagnostic yield of EUS-FNA.[20] Alternatively, EUS and ERCP may be performed in a single session for evaluation of obstructive jaundice as a result of a pancreatic mass.[21,22] While EUS-FNA can provide a histopathological diagnosis with high sensitivity, biliary drainage may be effected via ERCP in the same session. With this single session approach, EUS-FNA may be performed without interference from an indwelling stent, and repeated sedation can be avoided. Our proposal for the pathological diagnostic approach is shown in Figure 1. The diagnostic approach, with either transpapillary tissue sampling during ERCP or EUS-FNA, should also be determined according to local expertise and/or the costs associated with each procedure and the requisite devices.

CQ4. What are the roles of advanced imaging modalities for distal biliary stricture?.

Statement 4. Per-oral cholangioscopy (POCS) and intraductal ultrasonography may improve the characterization of DBS.

> Evidence level: C
> Recommendation: 2
> Agreement: A, 50%; B, 45%; C, 5%; D, 0%

The addition of POCS and intraductal ultrasonography (IDUS) during ERCP may increase diagnostic yield. In a prospective study of 26 cases of indeterminate biliary stricture, cholangioscopy-guided biopsy using biopsy forceps dedicated for POCS provided higher sensitivity and accuracy (76.5% and 84.6%) compared with brush cytology (5.8% and 38.5%) and conventional forceps

biopsies (29.4% and 53.9%).[23] Notably, in another prospective study, the accuracy of POCS-directed biopsies was 82% in 33 patients in whom ERCP-guided brushing or biopsy was inconclusive.[24] Recently, a digital, single operator cholangioscope has been introduced,[25,26] which provides improved intraductal visualization and maneuverability. It has shown promising results, with sensitivity and specificity in excess of 80% in both visual inspection and cholangioscopy-guided biopsy. As we discussed in CQ3, however, the indication of POCS should be considered after EUS because EUS-FNA showed better diagnostic yield in the extrinsic stricture as a result of a pancreatic mass. The EUS first approach would reduce the need, cost, and adverse events (AEs) of POCS.[27] Furthermore, maneuverability and visualization of POCS are often limited in the very DBS because of the unstable scope position. In a retrospective analysis of 397 cases with indeterminate biliary stricture, IDUS was useful in predicting malignancy with a sensitivity, specificity, and accuracy of 93%, 89%, and 91%, respectively.[28] However, most studies on the utility of IDUS and POCS included both hilar and DBS and did not evaluate their specific use in DBS. Probe-based confocal laser endomicroscopy, which can provide in vivo imaging during ERCP, is reportedly useful for diagnosing indeterminate biliary strictures, but its role in clinical practice is yet to be determined because of poor interobserver agreement and cost.[29]

Endoscopic drainage
CQ5. When is endoscopic biliary drainage indicated?.

Statement 5–1. Endoscopic biliary drainage is indicated for the treatment of cholangitis and for relief of cholestasis.

> Evidence level: A
> Recommendation: 1
> Agreement: A, 95%; B, 0%; C, 5%; D, 0%

Statement 5–2. Endoscopic stenting is generally considered to be primary therapy for benign biliary strictures (BBS).

> Evidence level: A
> Recommendation: 1
> Agreement: A, 90%; B, 5%; C, 5%; D, 0%

Statement 5–3. Endoscopic stenting is the preferred therapy for palliation of cholestasis in unresectable MBS.

> Evidence level: A
> Recommendation: 1
> Agreement: A, 68%; B, 32%; C, 0%; D, 0%

Benign and malignant pathologies may cause DBS. Whereas the etiology of DBS should be sought in every patient, not all patients with DBS require biliary drainage. Where there is no evidence of cholestasis or cholangitis, drainage may not be necessary. Biliary drainage should be performed if there is cholangitis and/or cholestasis to relieve the associated clinical symptoms. There are a number of treatment options for biliary drainage: Surgical bypass, percutaneous transhepatic biliary (or gallbladder) drainage, and endoscopic biliary drainage, either by the transpapillary route

during ERCP or EUS guided. In general, endoscopic biliary drainage is considered less invasive and affords a better quality of life. When biliary drainage is indicated, endoscopic stenting is considered the initial technique of choice. The indication for endoscopic biliary drainage differs between benign and malignant etiologies. For BBS, such as post-surgical strictures and strictures secondary to chronic pancreatitis, endoscopic biliary stenting is performed for the relief of cholestasis and to dilate the stricture. For patients with obstructive jaundice due to benign pathologies like autoimmune pancreatitis or lymphoma, in whom the stricture is expected to fully resolve with medical management, biliary drainage may not be required. In patients with unresectable malignant DBS, however, endoscopic biliary stenting is performed primarily for palliation. For resectable malignant DBS, please see CQ10.

CQ6. What type of endoscopic biliary drainage is available for distal biliary stricture?.

Statement 6. ERCP with transpapillary stenting is the mainstay of biliary drainage; EUS-guided biliary drainage (EUS-BD) is an alternative endoscopic treatment when ERCP is not possible.

> Evidence level: A
> Recommendation: 1
> Agreement: A, 68%; B, 32%; C, 0%; D, 0%

In patients with DBS, biliary drainage may be achieved during ERCP or percutaneous transhepatic biliary drainage (PTBD). ERCP is preferred over PTBD as no fluid or electrolyte losses occur and cutaneous puncture-site pain is avoided. ERCP, in expert hands, is also associated with significantly higher clinical success and requires fewer re-interventions.[30,31] However, difficult biliary cannulation at ERCP, which accounts for up to 10% of all ERCPs, is associated with a higher risk of ERCP-related complications.[32] In addition, ERCP may not be technically possible in the presence of duodenal obstruction and surgically altered anatomy. PTBD has long been utilized as an alternative non-endoscopic drainage method in cases with failed ERCP and is still the standard alternative technique in many centers. EUS-guided biliary drainage (EUS-BD) has been reported as an alternative modality after failed ERCP where expertise is available[33,34]; this is further discussed in CQ8.

CQ7. How should we follow patients after biliary stent placement?.

Statement 7–1. In patients with benign DBS, ERCP with planned stent exchange or removal is recommended.

> Evidence level: C
> Recommendation: 2
> Agreement: A, 100%; B, 0%; C, 0%; D, 0%

Statement 7–2. In patients with malignant DBS treated with a metal stent, endoscopic re-intervention is performed on demand.

> Evidence level: C
> Recommendation: 2

> Agreement: A, 100%; B, 0%; C, 0%; D, 0%

Statement 7–3. In patients with MBS treated with plastic stent (PS), planned or on-demand endoscopic re-intervention may be done.

> Evidence level: C
> Recommendation: 2
> Agreement: A, 61%; B, 39%; C, 0%; D, 0%

Stent dysfunction, due to either stent occlusion or migration, is a potentially serious adverse event (AE) that can result in life-threatening cholangitis. The optimal surveillance strategy to prevent or detect early recurrent biliary obstruction (RBO) is yet to be determined due to the limited number of studies directly addressing this question.[35–37] At the minimum, we recommend that all patients receive education so as to recognize the signs and symptoms of RBO and the importance of seeking early medical intervention.

Two main post-stent placement follow-up strategies have been described.

Planned stent exchange. Planned stent exchange is utilized for all patients with BBS and can be considered in patients with MBS treated with PS if close clinical follow up is not available and/or if life expectancy is greater than 3 months.

On-demand endoscopic intervention. In this strategy, ERCP is performed when signs of RBO are present. Monitoring strategies to detect early RBO have not been well studied and are mostly based on empiric evidence and extrapolation from the published literature. Furthermore, the management approach is dependent on local resources (availability and cost of laboratory and imaging evaluations) and patient factors (distance a patient has to travel for follow-up visits).[38] Possible monitoring options include outpatient clinic visits with evaluation of liver chemistry, with or without supplemental periodic remote monitoring of liver chemistry. When physical examination or liver chemistry suggests possible stent dysfunction, transabdominal ultrasound and/or plain abdominal film can be performed to assess stent position and to evaluate for the presence or absence of pneumobilia. The absence of pre-existing pneumobilia may indicate stent occlusion. On-demand endoscopic intervention is the preferred strategy in patients with MBS treated with self-expandable metallic stents (SEMS). On-demand stent exchange can be also considered in patients with MBS treated with PS if close clinical follow up is available and/or if the patient has a life expectancy of less than 3 months. However, this approach is not recommended in those without full knowledge of the signs and symptoms of cholangitis because delayed re-intervention can lead to serious consequences.

CQ8. When should endoscopic ultrasound-guided biliary drainage be considered?.

Statement 8. Where expertise is available, EUS-BD may be an option in these situations: (i) failed ERCP, (ii) Post-surgical
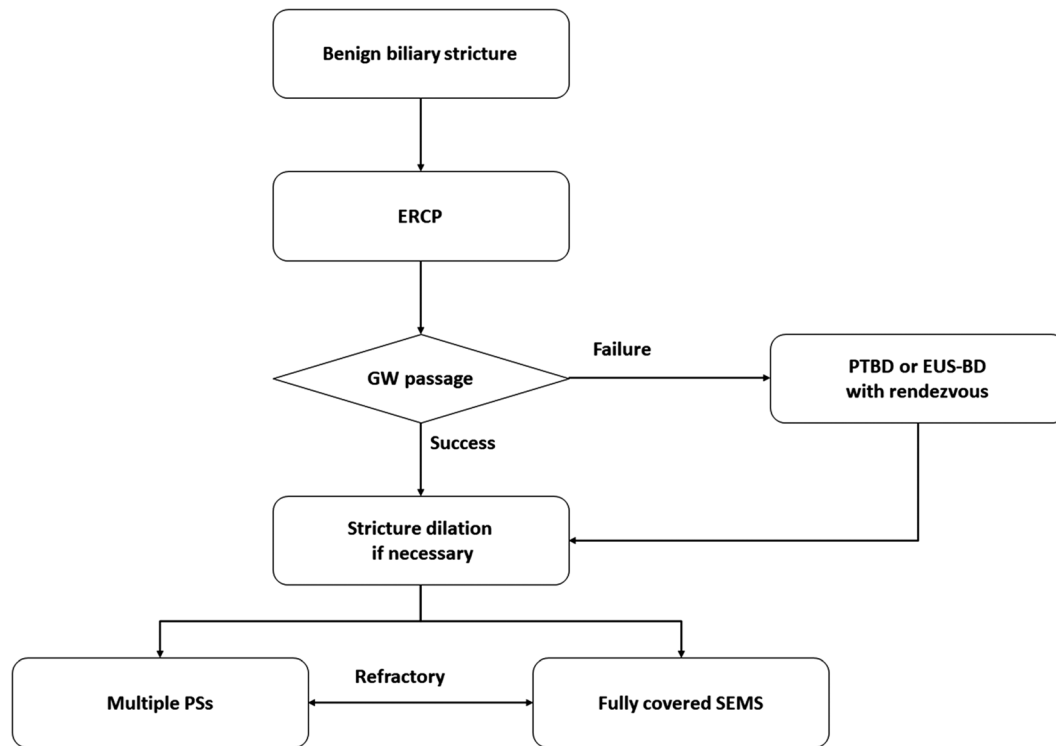
Figure 2 Treatment algorithm for management of benign biliary stricture. ERCP, endoscopic retrograde cholangio-pancreatography; EUS-BD, EUS-guided biliary drainage; GW, guidewire; PS, plastic stent; PTBD, percutaneous transhepatic biliary drainage; SEMS, self-expandable metallic stent.

anatomy, and (iii) difficult biliary cannulation.

Evidence level: B
Recommendation: 1
Agreement: A, 67%; B, 33%; C, 0%; D, 0%

Transpapillary biliary stent placement is the mainstay of endoscopic management of DBS. ERCP can be technically difficult or may fail to achieve biliary drainage due to duodenal obstruction by benign or malignant pathologies, periampullary tumor involvement, the presence of a periampullary diverticulum, or surgically altered anatomy. Although surgical or percutaneous techniques have long been utilized in these situations, the development of EUS-BD has provided a less invasive therapeutic approach. EUS-BD may be categorized according to the route of approach and site of biliary drainage: choledochoduodenostomy, hepaticogastrostomy (HGS), rendezvous technique and antegrade biliary stenting. Initially, PS were the only device used in EUS-BD. Over the last decade, SEMS have become an option for EUS-BD.[33] Recently, the use of lumen apposing metal stents has been reported for choledochoduodenostomy, with the advantage of a lower theoretical risk of bile leakage.[39] In addition, a specially designed SEMS and PS have been proposed for use in HGS.[40,41] The technique of EUS-BD has not been standardized and can be complicated by severe AEs such as bile leak and stent dislocation.[42] EUS-BD should therefore be performed by experienced therapeutic endoscopists. A recent consensus guideline discusses key issues associated with EUS-BD in detail.[43]

Although there are some reports on the utility of EUS-BD for hepaticojejunostomy strictures,[44] the role of EUS-BD in the management of BBS requires further study. Given the lack of standardization of EUS-BD and the potential risk of severe AEs, PTBD should be considered the standard of care where expertise in EUS-BD is not available.

Benign biliary stricture

CQ9. What strategy is recommended for benign biliary stricture?.

Statement 9. Multiple PS or a fully covered SEMS are recommended options for the treatment of benign biliary strictures.

Evidence level: A
Recommendation: 1
Agreement: A, 89%; B, 11%; C, 0%; D, 0%

Endoscopic management is considered as a first-line treatment for BBS because of its safety, effectiveness, and less-invasive nature when compared with surgery or percutaneous techniques. The recently published Asian-Pacific consensus guidelines summarized the endoscopic management of BBS.[45] Our proposal for endoscopic management of BBS is shown in Figure 2. First, a guidewire should be passed across the stricture. If the stricture is tight, pre-stenting dilation may be necessary using a bougie or a balloon dilator. In general, balloon dilation alone or

placement of a single PS is insufficient treatment for BBS,[45–47] and placement of multiple large-bore PS has been established as standard treatment.[48,49] The initial reports of uncovered SEMS for treatment of BBS showed this to be a poor option because of stent occlusion by ingrowth of reactive tissue, rendering the stent unremovable.[46] Several prospective studies have demonstrated the utility of fully covered SEMS for the treatment of BBS.[50,51] The use of a fully covered SEMS resulted in a similar success rate, with fewer procedures needed and shorter procedure duration, when compared with placement of multiple PS.[52–54] Local resources and expertise can guide the decision to use either multiple PS or fully covered SEMS. In cases with BBS, fully covered SEMS should be removed after completion of treatment as per protocol (4–6 months in general or per manufacturer recommendation) to prevent degradation of the covering membrane and ingrowth of hyperplastic tissue.[50] Magnetic compression anastomosis is also reported as a treatment option for BBS.[55]

Malignant biliary stricture

CQ10–1. Which patients require endoscopic biliary drainage before surgery?.

Statement 10–1. Pre-operative drainage should not be routinely performed, but is indicated in patients with cholangitis, in those planned for neo-adjuvant chemotherapy, and when a delay in surgery is anticipated.

> Evidence level: A
> Recommendation: 1
> Agreement: A, 80%; B, 20%; C, 0%; D, 0%

CQ10–2. What type of stents should be used before surgery?.

Statement 10–2. In patients who require endoscopic drainage before surgery, a SEMS may be preferred over a PS.

> Evidence level: A
> Recommendation: 1
> Agreement: A, 90%; B, 10%; C, 0%; D, 0%

Currently, routine preoperative biliary drainage (PBD) is not recommended. A randomized controlled trial (RCT) reported an increase in perioperative complications when PBD was performed for patients with MBS due to pancreatic cancer, in whom early surgery was planned. While a subsequent Dutch study[56] showed that the use of fully covered SEMS reduced perioperative AE compared with PS (24% *vs* 46%), a Korean RCT[57] failed to show superiority of fully covered SEMS over PS in terms of AE (16.3% *vs* 16.3%) and re-interventions (14.0% *vs* 16.3%). This discrepancy probably arises from the different lead times to surgery: 5 weeks in the Dutch study and 2 weeks in the Korean study. In clinical practice, however, surgery is often delayed due to the limited operation room time. Surgery is also increasingly delayed when neoadjuvant chemotherapy is employed. Therefore, PBD is required to treat cholangitis when surgery is delayed due to operation room unavailability or neoadjuvant chemotherapy. PS may prematurely occlude delaying surgery or neoadjuvant chemotherapy. PBD using fully covered SEMS may assure longer stent patency and be more cost effective.[58]

CQ11–1. What type of stent is preferred for unresectable malignant distal biliary stricture?.

Statement 11–1. A SEMS is preferred over a PS in patients with unresectable malignant DBS.

> Evidence level: A
> Recommendation: 1
> Agreement: A, 88%; B, 12%; C, 0%; D, 0%

CQ11–2. What type of metal stent is preferred for unresectable malignant distal biliary stricture?.

Statement 11–2. A covered SEMS may be preferred over an uncovered SEMS, especially in patients with unresectable pancreatic cancer.

> Evidence level: B
> Recommendation: 1
> Agreement: A, 67%; B, 33%; C, 0%; D, 0%

Six RCTs[59–64] and two meta-analyses[65,66] have compared covered and uncovered SEMS's for unresectable malignant DBS resulting from various pathologies including pancreatic cancer. The conclusions of the two meta-analyses differed in terms of stent patency.[65,66] However, two RCTs[63,64] and subgroup analysis in a third RCT[59] focusing on pancreatic cancer reported longer patency of covered SEMS. Regarding AE, covered and uncovered SEMS are comparable. The two meta-analyses reported no difference in rates of cholecystitis and pancreatitis.[65,66] Some endoscopists avoid covering the cystic duct takeoff to prevent cholecystitis after covered SEMS placement. Three RCTs showed that covered SEMS are prone to migration but covered SEMS with anti-migration features may reduce the risk of migration.[64] Finally, there is no cost effectiveness analysis comparing covered and uncovered SEMS for unresectable MBS. As the differential cost of covered SEMS varies by the insurance system and market, the cost–benefit analysis is likely to vary based on the cost of using a covered SEMS in each country.

CQ12. What is the impact of chemotherapy on patients with a biliary stent in situ?.

Statement 12. Chemotherapy does not appear to increase the risk of stent occlusion, but may increase the stent migration risk in patients with a biliary stent in situ.

> Evidence level: C
> Recommendation: No
> Agreement: A, 80%; B, 20%; C, 0%; D, 0%

Table 2 Definition of causes of recurrent biliary obstruction

Cause of recurrent biliary obstruction	Definition
Tissue ingrowth/mucosal hyperplasia	Growth of tumor or hyperplastic mucosa into the lumen of SEMS
Tissue overgrowth	Tumor or tissue growth beyond the ends of SEMS
Sludge, hemobilia, and food impaction	Occlusion of stent lumen by biliary sludge accumulation, clots, and food impaction
Bile duct kinking	Obstruction at a proximal or distal end of SEMS due to an angulated bile duct
Stent kinking	Obstruction of stent lumen due to sharp bending of a SEMS because of an angulated bile duct or tumor growth
Stent collapse	Collapse of stent structure due to tumor growth or other causes (compression by another stent etc.)

SEMS, self-expandable metallic stent.

Data on the effects of chemotherapy on the outcomes of biliary stents are limited. Theoretically, neutropenia induced by chemotherapy can lead to bacterial overgrowth and subsequent cholangitis. It can also result in tumor shrinkage with partial resolution of biliary strictures leading to stent migration. It has been reported that preoperative chemoradiation therapy in locally advanced pancreatic cancer[67] and chemotherapy in unresectable pancreatobiliary cancer[68] were not associated with increased stent-related complications. In patients with unresectable pancreatic cancer, gemcitabine chemotherapy did not increase stent occlusion or stent-related complications of SEMS. However, stent migration tended to be higher in the gemcitabine group (17% *vs* 3%).[69] In a further recent, large-scale study of 291 biliary stents (151 SEMS and 140 PS), stent patency was comparable in cases with and without chemo (radio)therapy.[70] Neoadjuvant treatment is increasingly utilized in patients with pancreatic cancer without distant metastasis. SEMS have demonstrated longer stent patency than PS in this neoadjuvant setting. Overall, regardless of resectability status, a covered SEMS is recommended in terms of stent patency and cost effectiveness.[58]

CQ13. What is the recommended endoscopic treatment for patients with unresectable malignant dual biliary and duodenal strictures?.

Statement 13. Endoscopic biliary and duodenal metallic stenting is an option in patients with unresectable malignant dual biliary and duodenal strictures. EUS-BD is a promising treatment option for patients with an indwelling duodenal stent.

Evidence level: C
Recommendation: 2
Agreement: A, 50%; B, 45%; C, 5%; D, 0%

The reported rate of combined MBS and gastric outlet obstruction (GOO) in advanced pancreatic cancer is approximately 30%.[71–73] Historically, double bypass surgery was performed; however, the development of endoscopic interventions allows less invasive palliation. While endoscopic biliary stent placement is the standard of care for MBS, endoscopic duodenal stent placement is performed for GOO in patients with a poor prognosis and surgical gastrojejunostomy in patients with longer life expectancy. Surgical gastrojejunostomy is more invasive, but it enables a longer duration of oral intake.[74,75] In patients with combined MBS and GOO, retrospective studies report that endoscopic double stenting is associated with a high technical success rate and an acceptable AE rate.[71,76–81] In the presence of a duodenal stent, ERCP is technically challenging,[82] and the long-term outcomes are suboptimal.[83] EUS-BD is increasingly reported as a rescue therapy for failed ERCP. GOO is one of the major causes of ERCP failure. EUS-BD, and especially EUS-HGS, which results in bile drainage away from the duodenal stent, may potentially provide longer biliary stent patency[84,85] and may be an alternative to transpapillary stenting in patients with combined MBS and GOO. Meanwhile, the trans-gastric approach is reportedly associated with a higher risk of AEs.[86] The procedure selected should therefore be determined by local expertise.

CQ14. What are adjunctive endoscopic treatments for malignant distal biliary stricture?.

Statement 14. Endo-biliary photodynamic therapy (PDT), radiofrequency ablation (RFA) and drug-eluting stents (DES) are considered investigational therapies for malignant DBS.

Evidence level: B (PDT), C (RFA), D (DES)
Recommendation: 2
Agreement: A, 85%; B, 15%; C, 0%; D, 0%.

Adjunctive endoscopic therapy for unresectable malignant DBS includes intraductal PDT, RFA, and DES,[87] of which the first two are more promising therapies. PDT, primarily used for cholangiocarcinoma, is a two-step process in which a photosensitizing drug having affinity for neoplastic tissue (photosensitizer) is administered, followed by selective tumor irradiation with light of a defined wavelength (intraductal laser photo-radiation). The interaction between light and photosensitizing agent causes tumor cell death due to the formation of oxygen free radicals. PDT has been reported to increase stent patency, quality of life, and survival.[88–91] The major drawback is systemic photosensitivity, which occurs in 10% of cases. Intraductal RFA is primarily used in MBS (cholangiocarcinoma or pancreatic cancer) prior to stent placement.[92] It has high technical success rates and an acceptable safety profile.[93] As biliary RFA locally ablates the tumor, it is expected to improve stent patency. It reportedly provides similar survival to PDT, with a good cost effectiveness profile and avoidance of photosensitivity.[94] Intraductal RFA has also been reported to be useful in treating tissue ingrowth or overgrowth resulting in occlusion of biliary SEMS.[95–98] RCTs are required to further assess the efficacy of adjunctive endoscopic therapies.

Management of recurrent biliary obstruction and other complications. The current literature assesses numerous variants of biliary stents that have occluded or malfunctioned, making inter-study comparisons difficult. For this consensus guideline, we chose the term RBO, which can result from either stent occlusion or migration, as described in the Tokyo Criteria 2014[99] and defined it as the recurrence of jaundice and/or cholangitis following stent insertion. Causes of stent occlusion may be tumor-related (tissue ingrowth and overgrowth) or non-tumor related (sludge, food impaction, mucosal hyperplasia, hemobilia, and kinking of the bile duct). The definition of each cause of stent occlusion is shown in Table 2.

Complications other than RBO are also clinically important as they may necessitate additional interventions or hospitalization and may significantly impair the patient's quality of life. Stent-related complications include pancreatitis, cholecystitis, non-occlusion cholangitis, bleeding, ulceration, penetration, perforation, and complications associated with the stent placement procedure (perforation, desaturation, aspiration pneumonia, etc.).

CQ15. What is the approach to cholangitis in patients with an indwelling biliary stent?.

Statement 15. Cholangitis in patients with an indwelling biliary stent suggests RBO and may require early endoscopic re-intervention.

Evidence level: C
Recommendation: 1
Agreement: A, 100%; B, 0%; C, 0%; D, 0%

Patients with an indwelling biliary stent may present with symptoms of cholangitis such as fever, pain, and jaundice. RBO is not uncommon in patients with an indwelling biliary stent who present with acute cholangitis. Careful physical examination as well as cross-sectional imaging are recommended prior to endoscopic procedures. Cholangitis may be life threatening if untreated and may require early re-intervention to resolve RBO. The therapeutic approach to cholangitis is determined by an evaluation of the etiology and severity.

CQ16. What management is recommended for abdominal pain in patients with an indwelling biliary stent?.

Statement 16. In a patient with an indwelling biliary stent who presents with unexplained abdominal pain, evaluation with CT should be considered.

Evidence level: C
Recommendation: 2
Agreement: A, 80%; B, 20%; C, 0%; D, 0%

Patients may develop delayed stent-related complications. The complication, as well as the time point at which it occurs, relates to the type of stent used (plastic *vs* SEMS;[100] covered *vs* uncovered SEMS).[66] Some of the complications that can manifest as abdominal pain are proximal or distal migration with or without biliary obstruction, impaction, or perforation.

A plain radiograph of the abdomen only allows assessment of stent position in a 2-D plane. This might be useful if the stent has migrated significantly (e.g. a migrated PS to the colon[101]) or if a perforation has occurred as suggested by extraluminal gas. The sensitivity of plain X-ray is low, however, and the study may not detect retroperitoneal perforation. The optimal imaging modality to investigate abdominal pain in a patient with an indwelling stent is CT. CT accurately defines biliary stent position and the presence of biliary dilatation and also detects, with high sensitivity, the presence of free gas (both intra- and retroperitoneal). Contrast-enhanced CT better defines stent position in relation to the surrounding organs and vasculature and may demonstrate a cause for abdominal pain other than stent dysfunction (e.g. mesenteric ischemia from vascular occlusion).[102,103] While CT is associated with a significant cost, radiation exposure, and the potential for contrast-associated complications, it has distinct advantages over plain radiography and endoscopic assessment (which is relatively invasive) and represents the best modality for initial evaluation.

If no cause for abdominal pain has been determined after appropriate imaging, the possibility of stent-related mucosal ulceration should be considered and endoscopy should be performed.[104] Occluded or migrated plastic biliary stents can be readily removed and can be replaced. The removal of a SEMS may be challenging.[104] If a SEMS is found to have migrated distally and is causing mucosal ulceration, the intra-luminal section may be trimmed.[104–106] Further details on the management of SEMS dysfunction are discussed later.

CQ17. What strategy is recommended for the prevention and management of stent migration?.

Statement 17. To reduce the risk of migration of covered metal stents, partially covered metal stents or fully covered metal stents with special anti-migration design can be used.

Evidence level: C
Recommendation: 2
Agreement: A, 74%; B, 26%; C, 0%; D, 0%

Compared with PS, SEMS have a larger diameter and in general offer a longer duration of stent patency.[100] For benign DBS, a covered SEMS is preferred to uncovered SEMS as the stent needs to be removed after stricture resolution. However, stent migration is a key disadvantage of covered SEMS. To reduce the risk of stent migration, partially or fully covered SEMS with special anti-migration design features may be used, although there is a paucity of supporting data. Partially covered SEMS have bare ends, which embed into the biliary epithelium, thereby preventing migration.

Different designs of fully covered SEMS are currently available. Anti-migration features include anchoring flaps, flared ends, or differential radial expansive forces.[107] There are few well-designed comparative studies, however, to determine which design works best. One randomized study[108] showed that a stent with an anti-migration flap migrated less often than a flared-end stent. A double pigtail PS may be deployed within a fully covered SEMS, overlapping its ends, thereby serving as an anchor.[108]

CQ18. What complications may occur after biliary stenting, other than recurrent biliary obstruction?.

Statement 18. Biliary stent-related AEs other than RBO include pancreatitis, cholecystitis, bleeding, ulceration, non-occlusive cholangitis, penetration, and perforation.

> Evidence level: A
> Recommendation: No
> Agreement: A, 100%; B, 0%; C, 0%; D, 0%

Biliary stent-related AEs other than RBO can diminish the quality of life of patients with either MBS or BBS and may necessitate the interruption of chemotherapy, potentially reducing survival of patients with MBS. Physicians should be aware of the risk factors for and the management of stent related AEs. The rates of postprocedure pancreatitis were 0–5.1% in SEMS and 0–12.5% in PS.[100] The risk factors for pancreatitis were the use of SEMS, non-pancreatic cancer, and SEMS with high axial force.[109,110] The rates of cholecystitis was 0–12.2% in metal stents and 0–8.9% in PS.[100] The risk factors for cholecystitis after MS placement were tumor involvement to the cystic duct, gallstones, and SEMS with high axial force.[111–113]

CQ19. When is removal of a metallic stent indicated?.

Statement 19–1. SEMS removal or replacement should be considered if stent-related complications occur.

> Evidence level: C
> Recommendation: 1
> Agreement: A, 100%; B, 0%; C, 0%; D, 0%

Statement 19–2. Where an uncovered SEMS or partially covered SEMS has been erroneously placed in a patient with BBS, endoscopic removal should be considered as soon as possible.

> Evidence level: C
> Recommendation: 1
> Agreement: A, 90%; B, 10%; C, 0%; D, 0%

In cases of RBO and stent-related complications, stent removal and/or replacement should be considered whenever possible. Removal of SEMS, particularly uncovered SEMS, can be technically difficult.[114–116] The approach to RBO in patients with distal MBS depends on the etiology. Placement of a fully covered SEMS within an uncovered SEMS, obstructed by tumor ingrowth, is recommended (stent in stent technique).[117–119] An obstructed fully covered SEMS is best managed by stent removal and placement of a new fully covered SEMS rather than the stent-in-stent technique or attempts at clearance by balloon sweeping.[120]

A fully covered SEMS is a treatment option for BBS (see Statement 9). Uncovered or partially covered SEMS may occlude due to tissue hyperplasia through the stent mesh. Stent embedment occurs within 1 week making removal difficult or impossible. Therefore, uncovered or partially covered SEMS should not be used for BBS. If one of these SEMS variants has been erroneously placed, endoscopic removal should be considered as soon as possible. The

stent-in-stent technique utilizing a fully covered SEMS may be useful.[121]

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