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REVIEW

# Outcome of stenting in biliary and pancreatic benign and malignant diseases: A comprehensive review

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## Abstract

Endoscopic stenting has become a widely method for the management of various malignant and benign pancreatico-biliary disorders. Biliary and pancreatic stents are devices made of plastic or metal used primarily to establish patency of an obstructed bile or pancreatic duct and may also be used to treat biliary or pancreatic leaks, pancreatic fluid collections and to prevent post-endoscopic retrograde cholangio-pancreatography pancreatitis. In this review, relevant literature search and expert opinions have been used to evaluate the outcome of stenting in biliary and pancreatic benign and malignant diseases.

**Key words:** Endoscopic stenting; Self-expandable metal stent; Plastic stent; Strictures; Leaks; Complications



**Core tip:** Endoscopic stenting plays an indispensable role in the treatment of benign and malignant pancreatico-biliary disorders. This article will cover the indications and outcome of stenting in bilio-pancreatic disease.

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## INTRODUCTION

Endoscopic stenting has become a widely used method for the management of various malignant and benign pancreatico-biliary disorders.

Biliary and pancreatic plastic or metal stents are used primarily to establish patency of an obstructed bile duct or main pancreatic duct (MPD) but may also be used to treat biliary or pancreatic leaks, cholecystitis, large non-removable common bile duct (CBD) stones, pancreatic fluid collections (PFCs) and to prevent post endoscopic retrograde cholangiopancreatography (ERCP) pancreatitis (PEP).

This paper will cover the indications an outcome of the different types of stents currently used, techniques of placement, established and upcoming indications, and complications associated with stent use.

## BENIGN BILIARY DISEASES

### *Benign biliary strictures*

Benign biliary strictures (BBSs) can be caused by post-operative injury (particularly after cholecystectomy), anastomotic injury following orthotopic liver transplantation (OLT), chronic pancreatitis (CP), primary sclerosing cholangitis (PSC), post-endoscopic sphincterotomy (ES) and other less frequent conditions, such as radiation therapy, IgG4 involvement of the bile ducts and portal biliopathy[1].

The choice of the type and the number of stents is dependent mainly on the etiology of BBSs.

In patients with PSC a single plastic stent (PS) for a dominant bile duct stricture can be sufficient, while for most of these diseases the standard endotherapy is dilation with placement of two or more PSs[2,3].

Bergman *et al*[4] treated patients with post-cholecystectomy BBSs with two 10 Fr PSs during one year with exchange every three months and in the cohort patients that completed the 12-mo stenting period, during nine years of follow-up achieved a clinical success rate of 80%.

In similar patients, Costamagna *et al*[5] placed the maximum number of PSs (until four 10 Fr could be placed in the first ERCP) during a year with exchanges every three months and during a 4 years of follow-up achieved a clinical success rate of 97.5%.

These good results were confirmed in the same cohort after a long follow-up (mean 13.7 years, range 11.7 to 19.8) with an 11% stricture recurrence rate, always successfully retreated endoscopically[6].

This approach of progressive dilation with an increasing number of PSs have been undertaken in patients with post-OLT BBSs either anastomotic or non-anastomotic[7-9], in CP strictures[10], or in post-ES strictures[11].

However an important limitation of the multi-stenting strategy is the need of 3 to 4 ERCPs sessions over the one-year period, with implications of patient satisfaction and quality of life, along with important implications for health care costs.

Moreover, while are reported favourable results of endoscopic plastic stenting for post-operative BBSs (post-cholecystectomy and post-OLT) with a recurrence rate of 20% to 30%, approximately 80% of patients with CP treated with plastic stenting may eventually develop relapse of strictures[1].

For these reasons, there continues to be high interest in pursuing alternative endoscopic approaches that may achieve comparable or better results while requiring fewer interventions.

In this setting the use of self-expandable metal stent (SEMS) is an attractive alternative to single or multiple PSs for treatment of BBSs for several technical and economic reasons.

It is technically difficult to place several PSs during the initial endoscopic procedure due to the diameter of the stricture and the size of the bile duct below the stricture. The small diameter delivery system of metal stent allows placement without stricture dilation enabling an easier endoscopic procedure, whilst a single metal stent expands to a large diameter, equivalent to three 10 Fr PSs and can remain in place for a prolonged period of time before removal.

PSs have a limited patency that requires frequent stent exchanges to prevent or manage stent occlusion.

Metal stents may allow dilation of a benign stricture without the need for progressive stent upsizing, thereby reducing the number of requisite ERCPs, so the higher cost of metal stent may be offset by the decrease in ERCPs.

A tapered deployment catheter is likely to obviate the need for pre-treatment with balloon or passage dilation, thereby reducing the number of devices needed at the time of initial ERCP.

The superior patency of metal stent may lower the cumulative number of ERCPs and time required to fully dilate a BBS.

The initial increased cost of a metal stent compared with one or more PSs should be offset by the need to perform fewer procedures.

Uncovered self-expandable metal stents (USEMSs) are not recommended for treatment of BBSs because tissue ingrowth through the mesh of the stent make stent removal impossible, while for this purpose metal stents must be partially-covered (PC), or even better, fully-covered (FC).

The use of PC-SEMSs showed good result, with a technical success of 100% and clinical success rates of 75% to 90% in both post-operative and inflammatory BBSs[12,13].

However, tissue ingrowth through the uncovered areas of stent mesh leads to both premature stent obstruction and embedding of the stent into the biliary wall, making future retrieval of the PC-SEMS difficult and was also noted in some cases that the tissue hyperplasia at the proximal uncovered portion of the stent resulting in a new stricture[14].

Because of limitations related PC-SEMSs, parti-

cularly tissue ingrowth at the uncovered portions, FC-SEMSs were introduced for the treatment of BBSs. The absence of epithelial hyperplasia and embedding of an FCSEMS also allows the possibility of leaving the stent *in situ* for more than 6 mo, if required.

However, in early reports, stent migration was common because of the nature of the FCSEMS used.

Stent migration has been reported to range from 4% to 40%[15-17].

Several designs for anti-migration properties of FC-SEMSs have been developed such as stents with flared ends, anchoring fins and anchoring flaps.

Among studies using stents with anchoring fins to prevent migration, Mahajan *et al*[18] achieved a very high (83%) improvement in biliary stricture with a migration rate of 4.5%, but stent removal was not easy and at cholangioscopic examination, performed in half of the patients after stent removal, found biliary mucosal ulcer formation and haemorrhage induced by the anchoring fins.

The use of FC-SEMSs with flared ends was reported in single and multicenter studies with good resolution rate of BBSs, but with a migration rate ranging between 10% and 31%[19-21].

To overcome the problem of the migration, the use of stent with anchoring flaps design showed excellent results.

Park *et al*[22] compared two types of FC-SEMS in 43 patients with BBSs; one stent had four anchoring flaps at the proximal end and flared distal end, and the other had flared end at both proximal and distal parts without anchoring flaps. After a median of 6 mo, no migration occurred in patients in the anchoring flaps group, while the 33% of patients in the flared end group had migration ($P$ = 0.004). In both groups the FC-SEMSs were removed without difficulty and an immediate improvement of biliary stricture was 91% in the anchoring flaps group and 88% in the flared end group.

These results were also confirmed in a recently prospective multicenter study, in which 24 patients with BBSs were treated with the placement of a FC-SEMS with double lasso and anchoring flaps as first-line therapy. Technical and clinical success were 100% and only one late stent migration occurred (3.3%)[23].

Also with the use of metal stents in most of the published studies stricture resolution rate was noted to be lowest in patients with CP.

However a recent systematic review of the studies published from 2000 to 2012 compared the feasibility, success rate, and complications rate of covered SEMS (376 cases) with multiple PSs (570 cases) in patients with BBSs and showed a significantly higher clinical success rate ($P$ = 0.006) for covered SEMS (77%) compared to PS (33%) in strictures related to CP at 12 mo follow-up and the incidence of late adverse events was lower in patients treated with covered SEMSs compared to PSs ($P$ = 0.02); there were no differences in the success rates of other etiologies, but in all types of BBSs the median number of ERCPs was significantly lower ($P$ = 0.002) with covered SEMSs compared to PSs (1.5 *vs* 3.9)[24].

### Biliary stones

When endoscopic removal of CBD stones fail, insertion of plastic biliary stent to bypass the stone is a useful alternative[25].

Both 7 and 10 Fr straight and double pigtail stents have been used to drain the CBD in patients with irretrievable CBD stones. Placement of a stent is mandatory if biliary clearance cannot be achieved during ERCP, and can be placed temporarily in patients who require more than one session for clearance.

Biliary stenting not only provides a temporary conduit for bile outflow, but stent placement may allow stone extraction to be more successful on the next endoscopic attempt, because the mechanical irritation of the stent due to continuous friction and enhanced by body and intestinal movements, reduce the size of the stone and increase stone fragmentation.

The technical success rate of plastic biliary stenting for CBD stones has been reported to be nearly 100% and the rate of successful stone removal during follow-up has been reported to range from 44% to 92%[26].

Recurrent cholangitis is the most frequent complication of stent occlusion reported between 3.5% and 40%. To prevent this complication a recent RCT compared a group of patients in whom PSs were changed every 3 mo or sooner if symptoms appeared to a group of patients in whom the PSs were changed on demand at the onset of symptoms[27]. The results, suggests stent exchange every 3 mo is the preferred approach[27]. Other complications are stent migration and clogging.

Although metal stents are usually not used in CBD stones, some studies have shown that metal stents have an advantage over PSs in improving subsequent duct clearance and to prevent long-term complications[28,29].

The large diameter of metal stents may facilitate subsequent clearance of bile duct stones, potentially through exerting radial forces to affect stone fragmentation and papillary dilation. Long-term patency may also make metal stent placement an option for patients in whom long-term stenting is desired for any reasons.

### Biliary leaks

Biliary leaks (BLs) are most often a consequence of surgery, such as open or laparoscopic cholecystectomy, OLT and hepatic resection, trauma, or invasive procedures, such as liver biopsy and percutaneous transhepatic cholangiography[30].

A variety of endoscopic techniques have been used to manage BLs. These include ES alone, placement of PS with or without ES, and nasobiliary drainage with

or without ES. The goal of endoscopic treatment is to reduce the pressure gradient between the biliary tree and the duodenum, allowing preferential flow of bile into the duodenum and preventing outflow through the leak[31].

In a study of 207 patients with BL, Sandha *et al*[32] proposed an algorithm, recommending ES alone for minimal leaks (< 200 mL/24 h), insertion of a PS for 4 to 6 wk for more severe leaks, presence of strictures, contraindication to ES or poor post-ES drainage. Using this strategy provides satisfactory results in more than 90% of patients[32]. However in published studies the most frequently used approach is the placement of a 7 Fr or 10 Fr stent with or without ES for 4 to 6 wk, with clinical success ranging between 90% and 100%[33-37].

The placement of PS has some disadvantages. When PSs are used at least one repeated procedure is necessary if occlusion or migration occurs. Furthermore, in patients with major BLs, such as those resulting from damage of the CBD or common hepatic duct (often associated with larger defects) multiple PSs can be inserted into the bile duct in order to fill the bile duct lumen and cross the site of the leak.

When endoscopic treatment fails, surgery remains an option but is not preferable for high-risk patients with severe comorbidities[38].

Recently, PC and FC-SEMS have been used to treat complex BLs, which are not responsive to plastic stenting and also as first-step endoscopic therapy, with a clinical success rate ranging between 70% and 100%[39-42]. The use of metal stents not only reduces the pressure of the sphincter of Oddi but may also close the fistula area.

However metal stents cannot be routinely recommended for management of patients with post-OLT BLs, because a high risk of post removal biliary strictures, especially if FC-SEMSs with fins are used[43].

### *Cholecystitis*

Transpapillary gallbladder stenting can be considered in patients with acute calculous or acalculous cholecystitis when standard treatment options fail or are contraindicated. It is useful for patients who are critically ill and for those with severe comorbidity that precludes a surgical cholecystectomy and/or have contraindications for placement of a percutaneous cholecystostomy tube. Such patients include those with the presence of large amounts of ascites, coagulopathy, or an intervening loop of bowel between the diaphragm and the liver that precludes percutaneous access. Endoscopic stenting is contraindicated in patients with perforated gallbladder, who are too unstable to undergo endoscopy or sedation, or who are pregnant, because of the risks of radiation exposure from a prolonged procedure[44,45].

The technical success rate of transpapillary gallbladder stenting varies from 75% to 100%, with a clinical response rate between 70% and 100% and an adverse event rate ranging between 0% and 20% that include post-ERCP pancreatitis, bleeding, perforation of the cystic duct or gallbladder, stent occlusion, stent migration and sepsis[46-49].

In recent years, endoscopic ultrasonography (EUS) guided drainage has been reported as an alternative to the percutaneous transhepatic gallbladder drainage.

The EUS approach is comparable with radiological approach in terms of the technical feasibility, efficacy and safety, as proved in a recently randomized comparative study[50].

Endoscopic transpapillary gallbladder drainage is subject to low technical success rates due to non visualization of the cystic duct on cholangiography and failure of guidewire passage through the cystic duct into the gallbladder. In these circumstances, EUS-guided drainage is gaining favour as an effective alternative to the transpapillary technique of drainage.

In the first published studies of EUS-guided drainage, PSs were used. However, the placement of these stents often requires large tract dilatation, thus increasing the risk of bile leakage, distal migration and clogging, because their small caliber, which can limit bile flow, especially when the content of the gallbladder is thick.

A good alternative to the use of PSs for EUS-guided drainage is the use of metal stents because of their larger diameters. Occlusion is less likely and can seal the gap between the stent and the fistula tract by its covering and expansion, thereby reducing the risk of bile leakage. However the risk of migration with subsequent leakage remains. Migration may be mitigated by placement of a double pigtail PS through the SEMS.

Recently specific FC-SEMSs have been designed to avoid these drawbacks by either enlarging and bending the flares at the ends of the stent 90°, or by means of a "saddle" shape with distal anchor flanges to ensure both lumen apposition and drainage[51,52].

The preliminary data on the use of lumen apposing metal stent (LAMS) for EUS-guided drainage showed mean technical and clinical success rates of 95% and 95%, respectively and a mean overall adverse event rate of 5%[53,54].

These stents also have been shown to provide an additional advantage of allowing access to the gallbladder lumen using slim (< 10 mm) endoscope to perform biopsy, stone removal or debridement[55,56].

### *Bleeding*

Post-ES and biliary bleeding were historically treated with endoscopic hemostatic techniques such as epinephrine injection, thermal therapy, balloon tamponade, clips, and placement of large bore PSs (10 Fr or larger) to tamponade the bleeding site and to maintain biliary drainage (BD)[57].

Recently the use of covered metal stents have been reported for treatment of bleeding. These stents work

by tamponading the bleeding site while also providing drainage of the bile duct, especially when occluded by blood clots.

Both PC and FC-SEMS were used in a total of 52 cases reported in the literature and based on these series two weeks of FC-SEMS placement is adequate in this setting[58,59].

### *Perforations*

Traditionally, ERCP-related perforations have been managed surgically. However, only duodenal free wall perforations are treated with a prompt surgical intervention, while distal bile duct injuries that result from penetration of the guidewire through the bile duct during cannulation, or perivaterian perforations, occurring after ES, can be treated with a conservative approach with intravenous antibiotics, hydration, pain control and placement of PSs, to prevent bile leakage and formation of collections in the peritoneal or retroperitoneal space[60].

Recently the use of FC-SEMS have been reported to seal perforations (especially if the hole is large) and to prevent bile leakage into the perforation site.

A total of 28 cases are reported in literature and based on these series 4-6 wk of FC-SEMS placement is adequate in this setting[61].

## MALIGNANT BILIARY DISEASES

Endoscopic stenting is the therapeutic modality of choice to decompress the biliary system in pancreaticobiliary malignancies.

Distal malignant biliary obstruction (DMBO) is mainly caused by periampullary tumors, such as carcinoma of the papilla of Vater, pancreatic cancer and distal cholangiocarcinoma, and less commonly by gallbladder carcinoma and metastatic diseases.

Biliary stent placement is a well-established technique for palliation of patients with inoperable DMBO and both PSs and SEMSs are routinely used in current practice.

PSs diameters range from 7 Fr to 12 Fr. Any further increase in PS diameter larger than 10 Fr increases the technical difficulty of placement without improving stent patency. Therefore, a diameter of 10 Fr is thought to be the best combination of patency and technical ease of placement[62].

PSs of 10 Fr have patency rates of approximately 3 mo, are very effective and are inexpensive, however, the short duration of stent patency remains a drawback.

Metal stents, in their fully expanded state, have a lumen diameter three to four times that of PSs. In a recent meta-analyses SEMSs were associated with a significantly longer stent patency ($P < 0.001$), lower reintervention rate ($P = 0.001$) and longer patient survival ($P = 0.014$) in palliation of patients with DMBO when compared to PSs[63].

Therefore, placement of SEMS for palliation of DMBO should be considered especially for patients with a predicted life expectancy of more than 3-4 mo. Uncovered, PC and FC-SEMS are used for palliation of patients with DMBO.

SEMS failure is usually related to tissue ingrowth using the uncovered type, while migration is usually the cause of stent failure using the covered type.

A meta-analysis including only randomized controlled trials that compared stent patency duration and rates of covered *vs* USEMSs demonstrates that there are no differences in the patency rates at 6 or 12 mo between the two types of stents[64]. There were no differences in the rates of pancreatitis, cholecystitis, perforation, bleeding, cholangitis, or recurrent biliary obstruction, as well as no differences in durations of survival or hospital stay, but covered SEMS migrated significantly more frequently than USEMS[64]. There was a decrease in tissue ingrowth but an increased risk of tissue overgrowth in the covered SEMS group when compared with the USEMS group[64].

Two recently randomized trials showed that the stent patency rate was higher in covered SEMSs compared to USEMSs[65,66].

Hu *et al*[65], compared the use of a PC-SEMS with an antireflux valve with an USEMS for the palliation of DMBO and showed that the PC-SEMS has longer patency and reduces the risk of ascending cholangitis.

Kitano *et al*[66], in another randomized trial demonstrated that for palliation of patients with DMBO, PC-SEMSs with an antimigration system had a significantly longer duration of patency ($P = 0.019$) than USEMSs (median: 583 d *vs* 314 d, respectively) with absence of stent migration.

Stent migration mostly affects the patency of covered SEMSs and among the findings reported by Kitano *et al*[66], of particular interest is the absence of migration even with the use of PC-SEMSs.

The risk of migration is related to the conformability of the SEMS in the bile duct, which is influenced by the axial force exerted by the stent.

Stents with high axial force, such as the older stainless steel SEMS, do not conform to the curved bile duct, thus increasing the risk of adverse events especially migration.

Thus, the use of nitinol SEMSs could reduce migration rates, as demonstrated in a recent randomized trial by Soderlund *et al*[67], that compared the patency rate, patients survival, and adverse events in patients with DMBO and palliated with PC-SEMS made from stainless steel or nitinol and showed that stent failure occurred more often in the stainless steel PCSEMS group compared with the nitinol PC-SEMS group ($P = 0.02$); stent migration occurred in 13 patients in the stainless steel group and in 3 patients in the nitinol group ($P = 0.01$).

An increased rate of late adverse events was also demonstrated in a previous retrospective study that compared the use of nitinol and stainless steel USEMS

in malignant biliary obstruction[68].

Biliary stenting is a proven technique for drainage of patients with unresectable DMBO, but its role for preoperative drainage in patients with resectable disease who are favorable surgical candidates remains a matter for debate.

A recent meta-analysis on the effect of preoperative biliary stenting on patients with obstructive jaundice suggest that the drainage should be applied selectively, the drainage time should be > 4 wk and that the SEMSs should be used for drainage[69].

Indeed Sun *et al*[69] compared patients who underwent preoperative drainage to those who did not have preoperative drainage and found overall mortality, overall morbidity, infectious morbidity, incidence of wound infection, intra-abdominal abscess, pancreatic fistulas, bile leak, and delayed gastric emptying were not significantly different. Compared with the non-drainage group, the drainage group had a drainage time of < 4 wk with an increased overall morbidity by 7% to 23%, while the overall morbidity of the drainage group with a drainage time > 4 wk was not significantly different[69]. Compared with the non-drainage group, the overall mortality of the drainage group using SEMSs and PSs as drainage was reduced by 0.5% to 6%, whereas that of the drainage group using PSs was not significantly different[69].

The groups of patients who may benefit from preoperative biliary stenting are those with resectable disease in whom surgery is delayed (*e.g.*, scheduling reasons, further preoperative staging, with underlying comorbidities that require optimization and even improvement in nutritional status) and those with locally advanced or borderline resectable disease requiring neoadjuvant chemotherapy[70].

Metal stents are preferred in these patients because their greater patency rates have shown a cost-benefit advantage in comparison to PSs[71].

Hilar malignant biliary obstruction (HMBO) can be caused by a group of heterogeneous tumors that include cholangiocarcinoma, cancer involving the hepatic confluence by direct extension from gallbladder, liver, and metastatic diseases and is classified according to Bismuth and Corlette into four types[72].

Type Ⅰ lesions is located below the confluence of hepatic ducts, type Ⅱ lesions includes the confluence but do not involve the left or right segmental hepatic ducts, type Ⅲ lesions occlude the common hepatic duct and either the right (Ⅲa) or left (Ⅲb) segmental hepatic ducts and type Ⅳ lesions are multicentric or involve the radicals on both sides.

This classification is helpful in determining and planning endoscopic stent placement.

Both PSs and USEMSs are used for drainage and palliation of HMBO as to not occlude drainage from the contralateral biliary system.

In patients with type Ⅰ lesions jaundice can be easily palliated using a single biliary stent, while palliation of the other types of lesions, especially type Ⅲ and Ⅳ, poses particular difficulties.

In these patients, the risk of incomplete drainage after contrast injection into the biliary system leads to a high incidence of post-procedure cholangitis and for this reason placement of 2 (or sometimes more) stents to drain each occluded segment has been proposed.

Pre-procedure imaging with computed tomography and MRCP is helpful to decide which obstructed segments should be drained and how many stents may be needed. It is important to realize that relief of jaundice generally requires drainage of about 50% of healthy liver or proportionally more in those with underlying dysfunction[73,74].

Therefore, the decision whether to place a single biliary stent or multiple stents depends on the location of strictures, the volume of liver that can be drained to relieve jaundice, and the introduction of contrast into more than 1 segment[75].

The success rate of PS insertion for HMBO is lower than that of DMBO, although relief of symptoms with improvement in quality of life can be achieved in nearly all patients successfully treated[76].

The use of SEMSs for palliation of HMBO is associated with a significantly longer stent patency ($P$ = 0.009) and longer patient survival ($P$ = 0.025) when compared to PSs[63].

In HMBO, SEMSs have been also demonstrated to be more cost-effective and require less subsequent interventions than PSs[77].

In systematic review (10 trials) by Hong *et al*[78], endoscopic placement of SEMSs was associated with a significantly higher successful drainage rate, lower early adverse event rate, longer stent patency and longer patient survival than PS placement. The unilateral biliary stenting group achieved a significantly higher successful stent insertion rate compared with the bilateral stenting group, whereas no difference was observed between groups with respect to successful drainage rate, early and late adverse events, stent patency and patient survival[78].

In another recent meta-analysis (36 studies: 13 for bilateral SEMSs, 8 for unilateral SEMSs, 8 for bilateral PSs and 7 for unilateral PSs) that compared bilateral and unilateral stenting in HMBO, bilateral metal stenting had a lower odds of overall adverse events and an higher odds of lowering bilirubin levels than unilateral metal stenting, but the 30-d mortality was no different[79]. When analyzing the use of PSs separately, unilateral stenting was comparable to bilateral stenting in terms of success, overall adverse events, cholangitis, and 30-d mortality[79].

Various bilateral drainage techniques and newly developed SEMSs are now available.

Bilateral BD with SEMS can be performed by using one of two methods, the side-by-side (SBS) and stent-in-stent (SIS) methods.

The technical success rate of both bilateral drainage techniques range from 73.3% to 100%, with a functional success rate between 75% and 100%[80].

In a recent quantitative review and meta-analysis of the published data regarding the clinical efficacy of the SBS and SIS techniques for achieving bilateral drainage for HMBO, no significant differences with respect to the rates of successful placement, successful drainage, early and late adverse events, stent occlusion, stent patency and patient survival were seen between the two drainage techniques[81].

The need for preoperative BD of resectable HMBO is still controversial.

In a meta-analysis of 11 studies evaluating the benefit of preoperative BD in HMBO, routine performance of preoperative drainage was not shown to be beneficial[82]. In this meta-analysis comparing preoperative BD to no preoperative BD, Liu *et al*[82], not demonstrate a decrease in mortality or postoperative hospital stay in patients undergoing preoperative drainage and in addition there was an increase in postoperative adverse event rates and infectious morbidity in the preoperative drainage group.

However preoperative BD is strongly recommended in selected patients such as those undergoing right lobectomy for lesions type ⅢA or Ⅳ, preoperative portal vein embolization with chemoradiation therapy, biliary infection due to undrained biliary segments and presence of severe pruritus[83].

Controversy remains regarding the use of ES before the placement of biliary stents.

A meta-analysis of randomized controlled trials that compared the clinical outcomes of patients who underwent ES with those that did not undergo ES before stent placement showed the incidence of post-ERCP pancreatitis was significantly lower with ES, the incidence of bleeding was significantly higher in ES group, with no significant difference in stent migration and occlusion[84].

When transpapillary stent placement *via* ERCP fails, owing to anatomical or technical problems such as upper intestinal obstruction, surgically altered anatomy, periampullary diverticulum, or periampullary tumor infiltration, EUS-BD is a good option for biliary decompression in patients with both distal and HMBO[85].

The mean technical and clinical success rates of EUS-guided BD are 91% and 88% respectively, with a mean overall complication rate of 26% and a mortality of 0.4%[86]. Three different EUS-BD approaches have been described: transgastric [hepaticogastrostomy (HPG)], transduodenal (choledochoduodenostomy) stenting, and rendezvous technique[86]. The rendezvous approach is preferred by many endoscopists because it avoids a permanent transluminal fistula which may lead to adverse events[86].

Khashab *et al*[87], in a retrospective series, found no differences between rendezvous and direct transluminal approach in effectiveness and safety.

Artifon *et al*[88], in a recent randomized trial compared the outcomes of HPG and choledoco-duodenostomy (CLD) in patients with unresectable DMBO and suggested that the choice of approach should be left to the endoscopist. They reported a technical success rate of 96% for HPG and 91% for CLD, a clinical success rate of 91% for HPG and 77% for CLD, with a mean procedural time of 47.8 minutes for HPG and 48.8 min for CLD[88]. The adverse event rate was 20% for the HPG group and 12.5% for the CLD group[88].

Various types of stents, including PSs, USEMS, and PC and FC-SEMS were used for the EUS-BD[89-92].

No comparative studies exist, but there appears to be a tendency to use covered SEMSs, instead of PSs.

Partially or FC-SEMSs appears to be a better option for three reasons: firstly, upon full expansion SEMS effectively seal the puncture/dilation tract, which theoretically prevents leakage; secondly, their larger diameter provides better long-term patency, which would decrease the need for SEMS revisions; finally, if dysfunction by tissue growth or clogging occurs, management is somewhat less challenging than with PSs, since a new stent can easily be inserted through the occluded SEMS[93-96].

However, migration can result in serious adverse events that can still occur even with the use of a PC or FCSEMS, especially early after the procedure. Proximal or distal SEMS migration caused by a shortening of the stent after deployment may lead to bile leakage into the peritoneal cavity and lead to fatal adverse events[97-99].

To prevent and reduce this complication two new types of hybrid (distal portion covered and proximal portion uncovered) SEMSs with antimigration systems were developed and preliminary outcomes showed no migration and bile leakage[100-102].

Recently, LAMSs were used for EUS-BD to prevent migration and bile leakage[103-106].

## BENIGN PANCREATIC DISEASES

### *Benign pancreatic duct obstruction*

Benign pancreatic duct obstruction (BPDO) may be the end-result of several different inflammatory processes with stricture formation, from severe acute pancreatitis and ductal disruption, relapsing acute pancreatitis or CP.

Endoscopic placement of PSs and covered SEMs have been used[107].

In the case of CP, BPDO may be caused by strictures, stones, or a combination of both.

Temporary placement of PS has become the standard of care for the endoscopic treatment of MPD strictures in CP. Different protocols have been used at different centers.

PS can remain in place for fixed intervals or exchanged only when symptoms recur[108].

The European Society of Gastrointestinal Endoscopy (ESGE) guidelines recommend treatment of the dominant MPD stricture in patients with CP by inserting a single 10 Fr PS, with stent exchange planned within 1 year even in asymptomatic patients to prevent adverse events related to longstanding PS occlusion[109].

The placement of PSs in the MPD is technically successful in greater than 90% of attempted cases and is followed by immediate and long-term pain relief in approximately 80% and 50% of patients, respectively[110].

When endoscopic treatment with a single PS fails, placement of multiple stents for 6-12 mo is another option.

Costamagna *et al*[111] described placement of multiple 8.5-Fr to 11.5-Fr PSs in 19 patients previously treated with one PS, of whom 84% remained asymptomatic during a follow-up period of 3 years.

This multiple PSs approach is currently used in several centers and might decrease the need for repeated stent exchange. It is thought that pancreatic juice is able to flow between the stents into the duodenum even when occluded. This strategy might be particularly useful not only in patients with MPD strictures persisting after 12 mo of single PS but also in patients with a pancreas divisum because this anatomy is associated with more frequent stricture relapse and pain after PS removal compared with a fused pancreas[112].

When adequate stricture dilation with PSs is not achieved, placement of FC-SEMS into the MPD for 2 to 3 mo is another potential option[113-117].

However, in a recent systematic review no significant difference between the two endoscopic treatment methods was seen[118]. Indeed, the technical success rate was 100% in both groups, the immediate clinical success rate was 100% in FCSEMS and 94.7% in multiple PSs, the migration rate was 8.2% for FCSEMS and 10.5% for multiple PSs, the re-intervention rate was 9.8% for FCSEMS and 15.8% for multiple PSs and pain improvement rate was 85.2% for FCSEMS and 84.2% for multiple PSs[118].

Placement of one or more PS into the MPD is also performed for temporary decompression in patients with BPDO due to stones, before extracorporeal shock wave lithotripsy or at the time of ERCP to allow for passage of additional stone fragments and allow for ductal decompression and prevention of pancreatitis secondary to edema from the performance of pancreatic sphincterotomy[119].

Recently temporary placement of a FCSEMS in the MPD was also used for aiding extraction of large pancreatic duct stones[120].

When transpapillary pancreatic duct stenting fails or is not possible because of postsurgical anatomy, EUS pancreatic duct drainage (PDD) is a good option to treat the BPDO, due to stone or MPD stricture from CP, but also due to post-surgical pancreaticojejunal or pancreaticogastric anastomotic stenosis[121].

However EUS-PDD is a challenging procedure with a technical success rate ranging between 58% and 100%, a clinical success rate ranging between 53% and 100% and a mean adverse event rate of 20%[86].

Technical failures are related to difficulty in orienting the echoendoscope along the axis of the MPD, inability to dilate the transmural tract because of dense fibrosis, and difficulty because of the acute angle at which the MPD is accessed at EUS[122].

Only PSs are used for this purpose, however a high rate of stent dysfunction, migration and duct leaks are reported and numerous endoscopic re-interventions are required[86].

Recently the use of a dedicated pancreatic duct stent designed for EUS-PDD was reported, but the single operator inclusion, small sample size (only 8 patients) and lack of a control group limit generalization of results of this study[123]. However, the technical success of 100%, clinical success of 100%, and only one mild early adverse event (abdominal pain) and no late adverse events during a mean follow-up of 7.4 mo suggest this new stent is effective and safe for EUS-PDD[123].

### *Pancreatic leaks/fistulae*

Pancreatic fistula is defined as leakage of pancreatic fluid as a result of pancreatic duct disruption[124].

Ductal disruptions may be a result from acute and CP, abdominal trauma, following abdominal surgery and after pancreatic surgery[125].

Manifestations of pancreatic duct leakage include PFCs, pancreatic ascites, high amylase pleural effusions, and internal and external pancreatic fistulae.

Endoscopic treatment of pancreatic fistula is most commonly performed using PSs placed through the major or minor papilla. Stent placement promotes duct healing by diverting the flow across the leak site and traversing strictures and the pancreatic sphincter into the duodenum. Endoscopic transpapillary drainage is preferable for treatment of small communicating PFCs (< 6 cm) without solid debris and for treatment of pancreatic ascites, pleural effusion, and external fistula when there is a ductal disruption and no PFC. The success rate of endoscopic transpapillary drainage alone for PFCs ranges from 48% to 100%, 55% to 100% for pancreatic ascites and pleural effusions and 55% to 100% for external fistula[126].

Ductal disruptions refractory to PSs placement can be treated with placement of covered SEMS. Indeed there have been case reports describing successful healing of refractory pancreatic fistulas by placement of both PC and FC-SEMS[127-129].

When transpapillary stenting fails, especially in cases of disconnected duct syndrome (a duct leak with a complete transection of the MPD resulting in an isolated segment of the proximal portion of the pancreas) EUS-PDD is a good alternative endoscopic approach[130].

### *Pancreas divisum*

For patients with symptomatic pancreas divisum (acute recurrent pancreatitis, CP, or chronic abdominal pain) endoscopic therapy is a safe and effective option, with

the best results seen in patients with acute recurrent pancreatitis[131].

Dorsal duct stenting in patients with pancreas divisum and CP decreased overall pain level, pain medication usage, and the number of hospital admissions per year with an improvement in nausea, vomiting and chronic pain[132].

For dorsal duct stenting a 5 Fr, 7 Fr or 10 Fr PSs is placed with or without minor papilla sphincterotomy or with minor papilla balloon dilation, with a clinical success rate of 54% and 90%[133-138].

Although PSs placement may decrease the number of episodes of pancreatitis, particularly for patients with recurrent pancreatitis, it may result in ductal damage that resembles CP and may be persistent in some cases[139].

In patients with pancreas divisum and CP the FCSEMS have been used for relief of abdominal pain that persisted despite pancreatic PSs implantation[140].

### Prevention of post-ERCP pancreatitis

Pancreatic duct stenting has been increasingly used for prevention of PEP. Pancreatic duct stents are thought to reduce the incidence and severity of PEP by facilitating ductal drainage, relieving ductal hypertension from transient procedure-induced stenosis of the pancreatic orifice or over-injection of contrast[141].

There are now several robust studies that confirm the effectiveness of pancreatic duct stenting in preventing PEP, especially in patients at high-risk for PEP[142-144].

The most recent meta-analysis, which included 14 randomized controlled trials involving 1541 patients demonstrated that PS placement prevented post-ERCP pancreatitis compared to no PS placement (7% *vs* 19%; $P < 0.001$)[145]. Moreover this is the first meta-analysis with sufficient power to demonstrate that pancreatic stenting is effective in preventing both mild to moderate and severe PEP[145].

A recent study show that urgent placement or replacement of pancreatic stents shortly after ERCP attenuates the course of evolving PEP with a statistically significant improvement in pain, amylase, lipase, and resolution of systemic inflammatory response syndrome[146].

Small caliber, short and softer 3 Fr or 5 Fr stents are most commonly used due to their ease of placement and higher rate of spontaneous migration compared to longer stents[147].

A systematic review and network meta-analysis suggest that stent diameter is more important for the prevention of PEP than stent design and presence of flanges[148].

In this study the use of 5 Fr stent was superior to the 3 Fr stent for the prevention of PEP in high-risk patients, and the 5 Fr single-pigtail, unflanged stent and 5 Fr straight, flanged stent performed similarly[148]. Both performed better than the 3 Fr stent in preventing post-ERCP pancreatitis[148].

Pancreatic stenting is recommended in patients with difficult cannulation, including double-wire cannulation, precut sphincterotomy, pancreatic (major or minor) sphincterotomy, pancreatic endotherapy, diagnostic or therapeutic ERCP for suspected or confirmed sphincter of Oddi dysfunction, history of PEP, balloon dilation of an intact biliary sphincter, and endoscopic ampullectomy[149].

### PFCs

Indications for PFCs drainage include development of persistent symptoms thought to be related to the presence of the collection or development of a complications related to the collection such as infection, bleeding, biliary, or gastric outlet obstruction.

For drainage of PFCs the decision of which endoscopic approach to use is based on the anatomical relationship of the PFC to the alimentary canal, the presence of ductal system communication, and the size of the collection.

Transpapillary stenting can be considered in case of a PFC communication with the pancreatic ductal system, located in the pancreatic head and is the sole means of drainage if the PFC is smaller (< 6 cm), or if transmural stenting is not feasible owing to distance (*e.g.*, > 1 cm from the enteral lumen) or is contraindicated (*e.g.*, severe coagulopathy)[150,151] with outcomes described above.

In cases of large PFCs with a visible bulge transmural drainage should be the first approach, and both EUS-guided and non-EUS-guided techniques are used.

However EUS-guided drainage of PFCs showed superior technical and treatment success rates and more favorable safety profiles than traditional non-EUS approaches.

Varadarajulu *et al*[152] in 2008 published the first RCT; 30 patients were randomized to undergo PFC drainage by EUS (15) or non-EUS guided drainage (15) over a 6-mo period. Of the 15 patients randomized to EUS, drainage was not undertaken in one because an alternative diagnosis was made. All 14 patients randomized to EUS-guided technique underwent successful drainage (100%), while the procedure was technically successful in only 5 of 15 patients (33%) randomized to non-EUS guided drainage group. All 10 patients who failed drainage by non-EUS guided technique underwent successful PFC drainage on crossover to EUS. Major procedure-related bleeding was encountered in 2 patients in whom non-EUS guided technique was performed.

Mangiavillano *et al*[153], in a series of 21 patients, showed as the technique of single-step EUS-guided drainage was superior to the two-step EUS-guided drainage for PFCs drainage.

Park *et al*[154] enrolled 60 consecutive patients with PFCs, which were randomly divided into two groups to undergo either EUS guided (31) or non-EUS guided

technique (29).

The rate of technically successful drainage was significantly higher for the EUS group (94%) than for the non-EUS guided technique group (72%) ($P$ = 0.039) in intention-to-treat analysis. In cases where non-EUS guided technique failed (8 cases) because the PFCs were non-bulging, a crossover was made to EUS guided technique, which was successfully performed in all these patients. Adverse events occurred in 7% of the EUS group and in 10% of the non-EUS group ($P$ = 0.67). During follow-up, PFC resolution was achieved in 97% in the EUS group and in 91% in the non-EUS group ($P$ = 0.565).

A meta-analysis confirmed the superior technical and treatment success rates and more favorable safety profiles of the EUS guided drainage of PFCs than traditional non-EUS guided technique[155].

The mean technical and clinical success rates reported for EUS guided drainage of PFCs were 97% and 90% respectively, the mean overall adverse event rate was 17% and the mean overall recurrence rate was 8%[86]. The main potential adverse events are bleeding, superinfection, stent migration, perforation and pneumoperitoneum[86].

Many aspects of EUS guided drainage of PFCs have yet to be determined, such as optimal stent size and number, stent type (plastic or metal), as well as stent placement duration.

Evidence supports that keeping PSs in place after PFCs resolution maintains the cystenterostomy tract[156].

For PFCs which contain only fluid (*e.g.*, pseudocysts) the treatment success rates are very high, while for PFCs in which at EUS the contents are not completely anechoic and contain solid material consistent with necrotic tissue, such as pancreatic abscesses or walled-off pancreatic necrosis, clinical resolution is much less than with pseudocysts[157,158].

Traditionally, double pigtail PSs were used for PFC drainage. These stents provide highly secured drainage preventing dislocation and migration.

However, because of their limited size of up to only 10 Fr, these stents are prone to occlusion and endoscopic access to the PFC cavity *via* the fistula is limited.

Siddiqui *et al*[159], in a retrospective study, demonstrated that patients with PFCs containing viscous solid debris-laden fluid, EUS guided drainage *via* a nasocystic irrigation tube alongside transmural stents resulted in a lower stent occlusion rate and better short-term clinical outcomes compared to transmural stents alone.

Therefore is has been suggested that placement of larger or multiple PSs and a nasocystic drainage catheter may facilitate resolution of PFCs, especially those containing significant debris.

Varadarajulu *et al*[160], showed that the necrotic collections drained with two to three transmural tracts, with multiple PSs in each track and a nasocystic irrigation tube, had a better outcomes compared with necrotic collections treated by conventional drainage techniques. Thus it appears that irrigation improves drainage of the necrotic contents.

Unfortunately, during placement of multiple PSs guidewire access may be lost, proximal migration of the first stent into the collection may occur, and additional procedural time is required.

Recently FCSEMSs, traditionally used for the treatment of a biliary diseases, have been used for drainage of PFCs[161-163].

A FCSEMS can be an alternative to conventional drainage with PSs because it offers the option of a larger-diameter access fistula for drainage and may increase the final success rate while it reduces the time to PFC resolution. In addition, only one passage of the guidewire is needed for placement.

In a systematic review of seventeen studies (881 patients) there was no difference in overall treatment success between patients treated with PSs and FCSEMSs (81% *vs* 82%) for both pseudocysts (85% *vs* 83%) and walled-off necrosis (70% *vs* 78%), no difference in adverse event rates (16% *vs* 23%) and recurrence rates (10% *vs* 9%)[164].

Using biliary FCSEMs for PFCs drainage, partial or full migration remains a potentially significant problem. When these stents are used for PFCs, the longer protrusion on both the gastrointestinal tract and the cavity sides entails a risk of contact ulceration, bleeding, and migration.

Lee *et al*[165], in a recent prospective randomized study compared multiple PSs (25 cases) with a new designed FC-SEMSs (25 cases) for the drainage of PFCs, showed that the median procedure time with FC-SEMS was significantly shorter than with PSs (15 min *vs* 29.5 min; $P$ < 0.01), the technical success rate was 100% for both groups, the clinical success rate was 80% for both groups, no adverse events occurred in the FCSEMS group, while adverse events occurred in 2 patients in the PSs group ($P$ = 0.16), one recurrence was observed during follow-up in the FC-SEMS group and none in the PSs group ($P$ = 0.15).

More recently, new dedicated LAMSs for drainage of PFCs, have been developed.

They have a large diameter, a saddle-shape design, with bilateral flanges, and a short length between flanges.

The flanges are designed to provide stent stability with a lumen-to-lumen anchoring effect (to distribute pressure evenly on the luminal wall and securely anchor the stent), thereby reducing the risk of migration and leakage alongside the stent and are fully covered to prevent tissue ingrowth and to enable easy removal[166].

Several studies have evaluated safety and efficacy of LAMSs for EUS-GD drainage of PFCs and reported technical success rates ranging between 89% and 100%, clinical success rates ranging between 77% and 100% and adverse event rates ranging between 9%

and 25%[167-171].

The large diameter of LAMSs enables direct insertion of an endoscope through the lumen of the stent for performing necrosectomy[172,173].

## MALIGNANT PANCREATIC DISEASES

Malignant pancreatic duct obstruction (MPDO) is commonly seen in pancreatic cancer, particularly when the tumor is located in the pancreatic head, and may cause pancreatic duct dilation and "obstructive type" pain[174].

Both PSs (5 Fr to 11.5 Fr in size) and SEMSs have been used for decompression of the pancreatic duct in MPDO, with technical success rates ranging between 81% and 100%, an improvement in pain in between 61% and 100% and an improvement in quality of life in the majority of patients[175-177].

When failure to achieve access to MPD during ERCP occurs because of either failed cannulation or an inaccessible papilla from altered anatomy or proximal duodenal obstruction caused by tumour invasion, MPDO can be treated also with EUS-PDD[178].

## CONCLUSION

Advances in stent design have led to a substantial increase in their use for a variety of benign and malignant pancreticobiliary diseases.

Endoscopic stenting has largely replaced surgery and interventional radiologic management of most pancreaticobiliary diseases both malignant (palliation of biliary strictures) and benign (treatment of strictures, leaks and collections).

The advent of metal stents has revolutionized the approach to these diseases, showing promising results even for the treatment of benign disorders.

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