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REVIEW

Success and safety of endoscopic treatments for concomitant biliary and duodenal malignant stenosis: A review of the literature

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Abstract

Synchronous biliary and duodenal malignant obstruction is a challenging endoscopic scenario in patients affected with ampullary, peri-ampullary, and pancreatic head neoplasia. Surgical bypass is no longer the gold-standard therapy for these patients, as simultaneous endoscopic biliary and duodenal stenting is currently a feasible and widely used technique, with a high technical success in expert hands. In recent years, endoscopic ultrasonography (EUS) has evolved

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from a diagnostic to a therapeutic procedure, and is now increasingly used to guide biliary drainage, especially in cases of failed endoscopic retrograde cholangiopancreatography (ERCP). The advent of lumen-apposing metal stents (LAMS) has expanded EUS therapeutic options, and changed the management of synchronous bilioduodenal stenosis. The most recent literature regarding endoscopic treatments for synchronous biliary and duodenal malignant stenosis has been reviewed to determine the best endoscopic approach, also considering the advent of an interventional EUS approach using LAMS.

Key words: Malignant biliary strictures; Malignant duodenal stenosis; Bilio-duodenal stenosis; Biliary self-expandable metal stent; Duodenal self-expandable metal stent; Lumen-apposing metal stents; Gastro-jejunostomy

Core tip: Concomitant biliary and duodenal malignant obstruction is a challenging endoscopic scenario in patients affected by ampullary, peri-ampullary and pancreatic head neoplasia. Surgical by-pass is no longer the gold-standard therapy for these patients, as simultaneous endoscopic biliary and duodenal stenting is a nowadays a feasible and widely used technique, with a high technical success in expert hands. The most recent literature regarding endoscopic treatments for concomitant biliary and duodenal malignant stenosis has been reviewed, to determine the best endoscopic approach considering also the advent of interventional endoscopic ultrasonography approach using lumen apposing metal stents.

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INTRODUCTION

Ampullary and periampullary malignant diseases, such as pancreatic cancer, cholangiocarcinoma, gallbladder cancer, and peripancreatic metastatic lesions are usually diagnosed at an advanced stage in which surgery is no longer indicated or the patients are unfit for surgical resection. Therefore, the treatments these patients can undergo are only palliative and, in some cases, chemotherapy is not indicated due to an end-stage disease. The survival of these patients is often not longer than 6 mo[1,2]. Ampullary and periampullary malignant disease can cause biliary or duodenal obstruction, and in previous case series between 6% and 9% of patients, following the placement of plastic stents for malignant biliary obstruction, developed a duodenal obstruction requiring surgical palliation with a gastrojejunostomy (GJS)[3]. Today, in the presence of a duodenal stenosis, the endoscopic stenting is preferred to the GJS, in the treatment for palliation of the gastric outlet obstruction (GOO), also because of the lower procedural costs and lesser hospital stay[4,5], even if readmission and mortality rates can be similar[6]. The advent of the self-expandable metal stent (SEMS) has widened the therapeutic options, increasing the quality of life for these patients. The same consideration can be made for the malignant biliary obstructions for which the hepaticojejunostomy has been supplanted by biliary SEMS placement. The clinical success rate of duodenal SEMS placement in patients affected by GOO is from 84% to 93%, and a technical success rate ranging between 93% and 97%[7-9].Over and tissue ingrowth, SEMS displacement, impaction of solid food can be possible adverse events after self-expandable stent placement. This eventuality require further endoscopic intervention in the 20%-25% of these patients[10].

The treatment can be even more challenging when biliary and duodenal obstruction arise simultaneously. We aimed to systematically evaluate the published literature on the endoscopic approaches to bilioduodenal stenosis, also taking into account the advent of the EUS approach to the biliary tree using the lumen-apposing metal stents (LAMS).

LITERATURE SEARCH

A search of the literature was done in order to identify studies including patients with synchronous biliary and duodenal stenosis, published from January 1st 2000 until June 2018, using the main electronic databases (PubMed, Scopus, and Google Scholar and the Cochrane Library). The medical literature was searched using the following keywords: Biliary stenosis, duodenal stenosis, stenting, self-expanding metallic stent, SEMS, lumen-apposing metal stent, and LAMS. Only studies in English were evaluated. Studies considering outcomes of non- synchronous biliary and duodenal stenosis were excluded.

ROLE OF ERCP IN THE MANAGEMENT OF SYNCHRONOUS BILIARY AND DUODENAL STENOSIS

Technique

A proposed classification of synchronous malignant bilioduodenal stenosis was proposed by Mutignani *et al*[11] in 2007. Three different types of synchronous bilioduodenal stenosis have been described based on clinical scenarios: type I, in which duodenal strictures are present in the duodenal bulb or in the duodenal genu; type II, in which the duodenal stenosis involves the papilla; and type III, in which duodenal stenosis occurs distally from the papilla, without its involvement. On the basis of this classification, the type of synchronous biliary stenosis determines the endoscopic palliative approach.

The most difficult scenarios for draining the biliary tree usually occur in the presence of the type I or II synchronous duodenal stricture. Nevertheless, if the duodenoscope passes through the duodenal stricture, endoscopic retrograde cholangiopancreatography (ERCP) can be performed, whereas if the duodenoscope does not pass across the stricture a duodenal uncovered metal stent has to be deployed. The common bile duct (CBD) is cannulated through the mesh of the duodenal stent and, after the sphincterotomy, the duodenal mesh can be dilated by pneumatic dilation. If the papilla is "jailed" by the enteral stent, argon plasma coagulation or rat-tooth forceps can be used to trim the enteral mesh to gain access to the ampulla.

Evidence

Currently, there are published studies stating that biliary stenting should not be attempted due to duodenal stenosis. The reported technical success of duodenal and biliary stent insertion in synchronous bilioduodenal stenosis ranges from 82.1% to 94.4%. The literature search found three prospective studies and eight retrospective studies regarding the efficacy of combined biliary and duodenal stenting during the same session (Table 1)[12-20]. The only prospective study is by Mutignani *et al*[11], and was published in 2007. It comprised a consecutive series of 64 patients, of whom 14 had concurrent biliary and duodenal obstruction. Duodenal SEMS occlusion, after concomitant bilioduodenal stenting is not dependently associated with a higher risk of biliary occlusion of the SEMS; however, the majority of patients do not require further re-intervention for stent occlusion.

At present, the largest series of patients with synchronous bilio-duodenal malignant strictures comes from the Japanese group of Hori *et al*[21], published in 2018. They retrospectively evaluated a total of 109 patients. The authors reported a technical success for resolution of synchronous bilioduodenal strictures of 99.1%, with an improvement of symptoms for biliary and duodenal obstruction of 81.7%. The rate of recurring biliary obstruction was 22.9%, and that of recurring duodenal obstruction was 11.9%, with a median time of 87 and 76 d, respectively. In the multivariable analysis, the significant data that emerged from this study was that duodenal uncovered SEMS was significantly associated with recurrent biliary obstruction. On the other hand, no predictive factors for recurrent duodenal obstruction were found, and the type of the duodenal SEMS was not associated with the duodenal obstruction time.

Synchronous bilioduodenal stenting was first reported in 1994[22]. Duodenal FCSEMSs carry a risk of obstructive jaundice, or pancreatitis, because of the possibility of the stent to cover the papilla by the covering of the FCSEMS. Though the effectiveness and safety of placement of a fully-covered SEMS (FCSEMS) across the major papilla has been reported[23], to our knowledge, no published manuscript comparing the clinical outcomes of duodenal uncovered SEMS *vs* FCSEMS in patients affected by synchronous bilioduodenal malignant strictures have been published. Hamada *et al*[24] showed as the placement of a duodenal stent is a risk factor for the

Table 1 Results of the studies in which endoscopic retrograde cholangiopancreatography and upper operative endoscopy for the treatment of bilio-duodenal malignant stenosis were performed

Ref.	Study design	Intervention	Patient (*n*)	Technical success *n* (%)	Clinical success *n* (%)	Adverse events
Kaw *et al*[12], 2003	Retrospective	Combined biliary and duodenal stenting	18 (18 concomitant)	17/18 (94.4)	16/17 (94.1)	None
Profili *et al*[12], 2003	Case series	Combined biliary and duodenal stenting	4 (4 concomitant)	4/4 (100)	4/4 (100)	In one case transient increase of amylase and lipase
Vanbiervliet *et al*[19], 2004	Prospective	Biliary stents were placed in patients previously treated with duodenal stents	18	17/18 (94.4)	17/18 (94.4)	None
Maire *et al*[13], 2006	Retrospective	Combined biliary and duodenal stenting	100 (23 with bilio-duodenal stenosis; 6 concomitant)	21/23 (91) (the study reports the overall technical success)	21/21 (100)	None
Mutignani *et al*[11], 2007	Prospective	Combined biliary and duodenal stenting	64 (14 concomitant)	10/14 (71.4)	Not reported only for the patients undergone concomitant bilio-duodenal stenting	Cholecistitis (1 patient): 10%
Moon *et al*[18], 2009	Prospective	Combined biliary and duodenal stenting	8 (8 concomitant)	8/8 (100) (Duodenal stent); 7/8 (87.5) (Biliary stent)	7/7 (100)	1/8 (12.5%) mild pancreatitis
Katsinelos *et al*[14], 2010	Retrospective	Combined biliary and duodenal stenting	39 (7 concomitant)	32/37 (82) (the study report the overall technical success)	Not reported only for the patients undergone concomitant bilio-duodenal stenting	3/32 (9.3%) post-sphincterotomy bleeding
Hamada *et al*[16], 2011	Retrospective	Combined biliary and duodenal stenting	18 (4 concomitant)	4/4 (100)	Not reported only for the patients undergone concomitant bilio-duodenal stenting	NR
Tonozuka *et al*[17], 2013	Retrospective	Combined biliary and duodenal stenting	11 (11 concomitant: 8 EUS-BD and 3 ERCP-BD)	3/3 (100)	3/3 (100)	No adverse events
Canena *et al*[15], 2014	Retrospective	Combined biliary and duodenal stenting	50 (15 concomitant)	13/15 (86.7)	Not reported only for the patients undergone concomitant bilio-duodenal stenting	Not reported only for the patients undergone concomitant bilio-duodenal stenting

ERCP: Endoscopic retrograde cholangiopancreatography; EUS: Endoscopic ultrasonography; BD: Biliary drainage.

dysfunction of a biliary SEMS, likely caused by increased duodeno-biliary reflux.

ROLE OF EUS IN THE MANAGEMENT OF SYNCHRONOUS BILIARY AND DUODENAL STENOSIS: EUS AS RESCUE THERAPY WHEN ERCP FAILS

In the last years, endoscopic ultrasonography (EUS) has widely changed from a diagnostic to a therapeutic tool, and is now progressively more performed for the endoscopic biliary drainage (BD) in cases of failed attempt of ERCP[25-26].

Technique

In the management of EUS drainage, for the linear-array echoendoscope, with a 3.8 mm diameter channel, must be used because it allows the passage of large accessories. Two possible puncture routes for EUS-BD can be performed: trans-gastric for left intrahepatic bile duct drainage or the trans-duodenal (from the bulb) for the drainage of the extrahepatic bile duct.

Two major EUS-guided approaches have been used: the transgastric intrahepatic approach and the transduodenal extrahepatic approaches, the latters with 3 different techniques: (1) EUS-guided choledochoduonenostomy; (2) EUS-guided transduodenal

extrahepatic or EUS-guided rendez-vous technique (EUS-RV); and (3) EUS-guided biliary antegrograde stenting. EUS-RV is indicated in the patients with a previous failed attempt of ERCP but presents a good endoscopic access to the Vater's papilla or to the anastomosic site. Different to the trans-luminal stenting, EUS-RV conserve the anatomical integrity of the biliary ducts and without creating a fistula between the biliary duct and the duodenal lumen.

Performing EUS drainage, the use of the color Doppler is mandatory to identify the possible interposed vessels between the lumen wall and the selected duct. The selected duct can be punctured, for the drainage, with a 19- or 22-gauge (G) needle. The 19 G needle is preferable because it allows the passage of a 0.035-inch guide-wire, which provides more stiffness. The 22 G needle lodges only a 0.018-inch guide-wire, which presents a major risk of displacement during the accessories exchanges. After accessing the selected duct with the 19 G or the 22 G needle, injection of a contrast medium can be useful to perform a cholangiogram to confirm the correct position of the needle inside the duct, and to clearly identify the stricture. Thereafter, using X-ray guidance, the guide-wire is advanced in the duct through the needle[27-31].

If the chosen drainage is transmurally from the gastric wall, the intrahepatic ducts of the left liver side can be drained [hepaticogastrostomy (HGS)], while if the chosen duct is the CBD, the drainage can be performed from the bulb [choledochoduodenostomy (CDS)]. CDS can be performed using LAMS, which do not necessarily require the placement of a guidewire, obtaining direct access into the CBD when dilated. If the guidewire exits the ampulla, ERCP can be done to complete the drainage, using the rendez-vous technique. When the release of the LAMS is performed through the puncture route or across the stenosis or the papilla in an anterograde way, different accessories could be used to enlarge the punctured site, as the bougies (6 or 7 Fr), the balloons for pneumatic dilation (4 or 6 mm) or a cystotome (8.5 Fr). However, the use of LAMS has currently supplanted this route and has now become the main technique for BD. Both plastic and metal stents are used for HGS or choledoco-duodenostomy, though the partially-covered and fully-covered SEMS (FCSEMS) are most often used to prevent stent migration and bile leakage.

LAMS have recently changed the management of synchronous bilioduodenal stenosis. EUS biliary drainage is a salvage therapy reserved for type I and type II bilioduodenal stenosis when ERCP fails or as primary modality, especially if there is synchronous GOO and in patients with distorted anatomy. In malignant biliary obstruction (MBO) with synchronous GOO, ERCP may not be possible because the papilla cannot be reached[32].

EUS-BD is generally performed using a direct transluminal approach. Less frequently, the antegrade approach is used. If enteral stenting is needed for synchronous GOO to allow the passage of a duodenoscope, ERCP is the preferred way to approach the CBD, despite high failure rates[33]. In these cases, EUS-BD can be considered a primary approach (Figure 1). The two possible EUS approaches are the CDS and HGS. Literature data on EUS-BD report an acceptable technical and clinical success. In a systematic review involving 1192 patients in 42 studies, EUS-BD was shown to have a technical and clinical success rate of 94.7% and 91.7%, respectively[34]. These data were recently confirmed in an international multicenter prospective series, where technical and clinical success rates were 95.8% and 89.5%, respectively, with an adverse event rate of 10.5%[35]. However, in consideration of the significant rates of adverse events with EUS-BD, ERCP remains the standard of care for the management of biliary obstruction, with EUS-BD as a rescue modality when ERCP fails. In the presence of malignant biliary obstruction with synchronous GOO, EUS-BD or percutaneous transhepatic biliary drainage (PTBD) can be considered the first-line treatments. In these cases, the majority of centers prefer PTBD to EUS-BD because of the higher expertise and experience of the radiologist in performing the procedure compared with the endoscopist performing EUS-BD.

Evidence

Literature data comparing EUS-BD with PTBD in patients with MBO have shown comparable technical success rates (94.1% for EUS-BD *vs* 96.9% for PTBD) and clinical success (87.5% for EUS-BD and 87.1% for PTBD), but with fewer adverse events for EUS-BD (8.8% for EUS-BD *vs* 31.2% for PTBD, $P = 0.022$)[36]. Nevertheless, overall comparative studies of the two modalities appear to favor EUS-BD[37,38]. Moreover, the major advantage of EUS-BD compared with PTBD is the possibility of performing the procedure during the same session of the failed ERCP[39]. Overall, EUS-BD appears to be an important therapeutic option in the management of MBO in the presence of synchronous GOO, and the major limitation of the implementation of EUS-BD is a lack of expertise. Recent developments, such as the one-step LAMS for EUS-BD, make the procedure easier and safer. In a systematic review of prospective and retrospective series, including series in which the EUS-BD was performed in two steps, the adverse

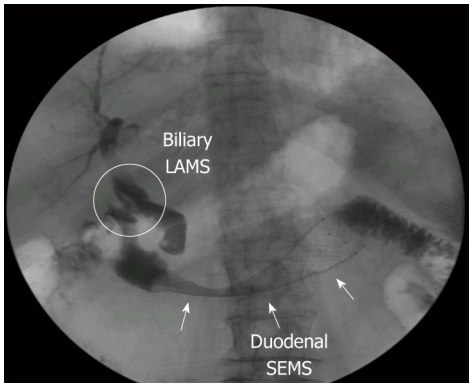

Figure 1 Radiological features of a lumen-apposing metal stent placed with endoscopic ultrasonography choledoco-duodenostomy with a duodenal self-expandable metal stent in a synchronous bilio-duodenal stenosis. LAMS: Lumen-apposing metal stent; SEMS: Self-expandable metal stent.

event rate was 23.3%, including peritonitis 1.3%, bleeding 4%, cholangitis 2.4%, pneumoperitoneum 3%, bile leakage 4%, stent migration 2.7% and abdominal pain 1.5%[31]. The recent advent of LAMS and the one-step EUS-BD stent system has increased the safety of EUS-BD, with an overall rate of adverse events reported as ranging from 7% to 10.5%[40]. Results of the studies in which EUS for the treatment of bilio-duodenal malignant stenosis was performed are summarized in Table 2[41-51].

Stent migration is another potential serious adverse event of EUS-BD, especially in the setting of HGS. This risk can be minimized by ensuring appropriate stent length and avoiding the placement of partially covered metal stents. If stent migration occurs, any collection should be drained *via* an interventional radiology approach. Finally, patients with cholangitis or bleeding following EUS-BD should also be managed by a multidisciplinary team, including a radiologist performing PTBD for cholangitis and for embolization, with surgical backup for refractory bleeding.

CONCLUSION

Synchronous biliary and duodenal malignant obstruction is a challenging endoscopic scenario in patients affected with periampullary neoplasia. Surgical bypass has long been the gold standard therapy for these patients. Synchronous endoscopic biliary and duodenal stenting is a feasible technique, with a high rate of technical success. ERCP plus duodenal stenting is currently the preferred endoscopic therapy for these patients. We suggest performing endoscopic transpapillary biliary drainage before duodenal stent insertion if the duodenoscope can pass through the duodenal stricture, whereas, if the duodenal stricture cannot be passed, deploying an uncovered duodenal metal stent across the stricture before performing ERCP is recommended. EUS-BD should be performed by expert operators in cases of type I and type II bilio-duodenal stenosis according to the Mutignani classification, when the ERCP fails or as primary modality in patients with distorted anatomy. Optimal clinical results and a low number of patients with this condition reported in the published series discussed in this paper should underline a possible bias. The future development of dedicated accessories and instruments, supported by further data, can contribute to the continual evolution of EUS-BD, which could become the first-line treatment option in patients with MBO in the near future.

Table 2 Results of the studies in which endoscopic ultrasonography for the treatment of bilio-duodenal malignant stenosis was performed

Ref.	Study design	Intervention	Patient (*n*)	Technical success *n* (%)	Clinical success *n* (%)	Adverse events
Giovannini *et al*[41], 2001	Case report	EUS-guided biliary drainage (failed) Placement through the duodenum of a 10-F plastic stent	1	1 (100%)	1 (100%)	None
Iwamuro *et al*[42], 2010	Retrospective	EUS-guided combined biliary and duodenal stent placement	7	7 (100%)	7 (100%)	2 bile leakage
Binmoeller *et al*[44], 2012	Case report	EUS-guided choledocoduodenostomy + overlapping self-expanding metal enteral stent	1	1 (100%)	1 (100%)	None
Itoi *et al*[43], 2012	Retrospective	Only stent placement under EUS guidance	15	15 (100%)	15 (100%)	1 stent migration
Khashab *et al*[46], 2015	Retrospective	EUS-guided gastroenterostomy	9	8 (90%)	8 (90%)	None
Glessing *et al*[49], 2015	Case report	EUS guided combined biliary and duodenal stent placement	1	1 (100%)	1 (100%)	None
Anderloni *et al*[47], 2016	Case series	Endoscopic ultrasound-guided biliary drainage (Single-session double-stent placement biliary and duodenal stent)	4	4 (100%)	4 (100%)	None
Belletrutti *et al*[51], 2010	Case report	Transduodenal EUS-guided biliary drainage performed through an existing enteral wall stent	1	1 (100%)	1 (100%)	None
Rai *et al*[50], 2018	Retrospective	Endoscopic ultrasound-guided choledochoduodenostomy	30	28/30 (93.3%)	28/28 (100%)	3: 1 bile leak, 1 hemobilia, 1 stent block

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