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Review Article

Proper management of inoperable malignant hilar biliary obstruction: Endoscopic retrograde cholangiopancreatography, endoscopic ultrasound, or percutaneous approach?

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A B S T R A C T

Advanced malignant hilar biliary obstrucion (HBO) is commonly caused by hilar cholangiocarcinoma, gallbladder cancer, hepatocelluar carcinoma, or metastatic tumors. Although surgical resection is the only curative treatment, the majority of patients can not undergo surgery due to an advanced inoperable state upon presentation. Therefore, effective biliary drainage is currently the mainstay palliative treatment for symptomatic improvement of HBO. Percutaneous access has been preferred traditionally, especially for advanced HBO because of technical difficulty involved. Recently, primary endoscopic palliation using plastic or metal stents has shown higher technical feasibility and clinical success without increasing the risk of adverse events compared to percutaneous access, even for high-degree HBO. Endoscopic ultrasound (EUS)-guided intervention has also been introduced for primary cases having a failed endoscopy or surgically altered anatomy and for reintervention. However, primary approach methods such as percutaneous, endoscopic retrograde cholangiopancreatography, and EUS have numerous issues involving the use of stents, including the type of stents, the number of stents, the deployment method, and additional efficacy of local therapies. This review describes current effective biliary drainage methods for advanced inoperable HBO based on reported studies.

Keywords: Drainage; Endoscopy; Hilar; Obstruction; Percutaneous

Introduction

Most patients are diagnosed with advanced malignant hilar biliary obstruction (HBO) at an unresectable stage. The presence of severe underlying medical comorbidities, distant metastasis, the involvement of major vascular structures not amenable to reconstruction, bilateral segmental ductal involvement, unilateral segmental ductal extension with contralateral vascular inflow involvement, and inadequate calculated future remnant liver volume are generally considered contraindications for surgical resection.[1] Therefore, they usually receive palliative biliary drainage by endoscopic or percutaneous intervention until the end of life. Effective palliation of jaundice in patients with HBO may improve their quality of life by ameliorating pruritus, general weakness, and poor appetite.

Among various type of HBO, high-grade perihilar stricture usually refers to Bismuth type III and IV in which the stricture site invades the secondary branch of the intrahepatic biliary tract. In general, a high-grade perihilar stricture is often difficult for surgery and multiple drainage to achieve adequate drainage.[2] Asian-Pacific consensus and European Society of Gastrointestinal Endoscopy (ESGE) guideline recommend percutaneous transhepatic biliary drainage (PTBD) or a combination of PTBD and endoscopic retrograde cholangiopancreatography (ERCP) rather than endoscopic drainage primarily, considering the risk of complications and technical difficulties for high-level stenosis of Bismuth type III or higher.[3,4] The primary palliative role of endoscopic ultrasound (EUS) is still challening in advanced HBO.

In this review, we described appropriate drainage methods such as PTBD, ERCP, and recent EUS-guided biliary drainage (EUS-BD) for high-grade inoperable HBO.

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Palliative Drainage for Hilar Biliary Obstruction

The clinical goal of biliary drainage is to ameliorate clinical symptoms and improve the quality of life and survival of patients by prolonging stent patency without increasing adverse events. Therefore, drainage of at least 25% to 50% of the total liver volume is recommended for adequate biliary drainage.[3,5] Specifically, for high-grade strictures such as Bismuth type III or IV, a major factor related to drainage efficiency is drainage of more than 50% of the liver volume.[6] Therefore, if a single stent cannot drain more than 50% of the estimated liver volume, multiple drainage should be performed. Among drainage mehods, PTBD, ERCP, or EUS-guided drainage can be chosen according to the situation (Table 1). The Asian-Pacific consensus prefers percutaneous intervention because outcomes of percutaneous stenting are superior to endoscopic stenting for Bismuth type III or IV.[3] ESGE guideline also recommends PTBD or a combination of PTBD and ERCP for Bismuth type III or IV.[4] The role of EUS-BD has not been demonstrated in consensus or guideline. ESGE recommends restricting the use of EUS-BD to cases where biliary drainage using standard ERCP techniques has failed.[4] However, in specific cases, the use of EUS-BD can be attempted.

Percutaneous Biliary Drainage

Reported studies and meta-analysis have shown that PTBD is still superior to endoscopic drainage for advanced HBO. PTBD has demonstrated higher technical feasibility. It enables a selective lobar approach to perform drainage for a selected bile duct rather than using an endoscopic approach. Retrospective studies have reported that PTBD has higher technical success and durability with comparable complication rates.[7–9] A meta-analysis and systematic review has revealed that PTBD is superior to endoscopic drainage in patients with advanced unresectable hilar malignancies.[10] PTBD has higher technical success rate without showing differences in adverse event rates or 30-day mortality. Asian-Pacific consensus and ESGE update also prefer PTBD over ERCP for bilateral or multi-segmental drainage in high-grade hilar strictures, such as bismuth type III or IV for drainage of liver volume of more than 50%.[3,4] Importantly, PTBD is an useful primary or alternative when conventional ERCP has failed or inaccessible because of surgically altered anatomy or when patients have a poor performance status.

However, PTBD also has some disadvantages such as inconvenience to patients, pain at the puncture site, deterioration of the quality of life, and loss of bile from the body since it requires a drain tube to remain in place. Technically, it is difficult when the intrahepatic bile duct (IHD) is not fully expanded or when multiple liver metastases, ascites, or blood clotting disorders are associated with the disease. Second, for multiple stenting, multiple percutaneous punctures are needed. Two interval steps are usually needed for internal placement of stents. Therefore, the risk of relatively serious complications is worrisome in multiple interventions.

Endoscopic Drainage, Endoscopic Retrograde Cholangiopancreatography

Endoscopic drainage by ERCP is more comfortable for patients and may improve their quality of life. Recent studies have shown that primary ERCP has higher technical and clinical feasibility with promising stent patency for bilateral drainage without increasing the risk of adverse events.[11–23] With the development of various stents and accessories as well as technical advances, an endoscopic approach is now the preferred method. Of course, there are differences depending on the circumstance. If experienced endoscopists are available in high volume centers, primary endoscopic palliation using ERCP might be the first choice, even for advanced inoperable high-degree HBO.

Plastic and metal stents

Plastic stents are the most commonly used for biliary drainage regardless of the level of the stricture because of their easy handling and lower cost. However, the relatively higher rate of stent malfunction due to smaller diameter requires frequent stent exchange for longer surviving patients, which may decrease the cost-effectiveness of such stents and quality of life of patients. Since the development of metal stents, stent patency has been prolonged. Because metal stents have lower reintervention and adverse event rates, the use of metal stents has been increased for cases with advanced HBO.[24–28]

Compared to a plastic stent, a self-expandable metal stent (SEMS) has a relatively larger diameter that can provide more prolonged stent patency. In addition, the open wire mesh of a metal stent does not occlude side branches of IHDs or cystic ducts. Technically, in severe or tight strictures, longer plastic stent insertion by pushing the catheter might be hindered by less pushability. However, SEMS is preloaded in a delivery catheter via a thin delivery system (5.4 to 8.5 Fr according to the manufactures), which facilitates passage across tight biliary strictures due to its good pushability.[29–32] Clinical studies comparing SEMS and plastic stents in HBO have shown a higher success rate of SEMS technically and clinically with prolongation of stent patency by reducing the number of reinterventions, resulting in good cost-effectiveness.[33–36]

Despite these benefits of SEMS, stent occlusion by tumor ingrowth and/or overgrowth can occur in 20% to 50% of cases. In addition, it is very hard to remove embedded stents after malfunctioning of these stents.[11,29,30,37] To overcome this problem, covered SEMS can be used because they do not become embedded, making it easy to remove or exchange them. However, multiple

Table 1 Comparision of PTBD, ERCP, and EUS for Advanced Hilar Biliary Obstrucion

	PTBD	ERCP	EUS
Pros	Well-tailored method Higher technical and clinical success as a primary or rescue technique Possible selective lobar selecion	Well-estabilised method Primary clinical and long term data available	Accessible in altered anatomy or failed ERCP Single step in ERCP room
Cons	Impaired quality of life Relatively high adverse events	Complexity in high-grade strictures Difficult revision in multiple metal stents	Limited data No definite tailored methods and accessories Performed in special centers

PTBD, percutaneous transhepatic biliary drainage; ERCP, endoscopic retrograde cholangiopancreatography; EUS, endoscopic ultrasound.

deployment to perihilar strictures is difficult due to limited narrow space. In addition, it may occlude side branches of IHDs, resulting in complications such as cholangitis and liver abscess. For more than two drainages, the outer sheath will be decreased. Thus, the original benefit of covered SEMS to prolong the patency of stents might be decreased. Moreover, covered SEMS cannot prevent biofilm formation, resulting in sludge or stone formation. Therefore, inserting a covered SEMS is not generally recommended for an advanced HBO. Literature reports on this are currently limited. However, a few recent studies have reported favorable results for fully covered SEMS. Inoue et al[38] have reported technical and clinical success rates of over 90% and liver abscesses occurring in 7% of patients. The median stent patency period in initial bilateral drainages was 210 days. Yoshida et al[39] and Kitamura et al[40] have shown similar technical feasibility. However, median patency durations were only 95 days and 79 days, respectively, in their studies. Although these fully or partially coved SEMS showed higher technical feasibility, they had relatively short stent periods. In addition, they could not exclude peripheral bile duct obstruction. The relatively easy exchange and technical feasibility are useful advantages of covered SEMS. However, patency and adverse event rates of covered SEMS are similar to those of traditional plastic stents. Improvements in stent patency by structural advances in diameter and anti-biofilm properties are warranted in the future. More large-sized prospective comparative studies should also be performed to confirm the efficacy of covered SEMS.

Unilateral versus bilateral drainage

Unilateral (single) drainage

It was well-known that only 25% of the liver volume requires drainage for achieving adequate palliation of obstructive cholestasis and improvement of biochemical parameters.[5] Some studies have shown that bilateral drainage can result in a relatively higher rate of adverse events without prolonging stent patency, which is the main reason why bilateral drainage has not been routinely recommended.[41–44] There is no significant difference in success of drainage, complications, number of endoprosthesis changes, or survival between right bile duct drainage and left bile duct drainage.[45] Therefore, the rationale of a unilateral drain has been established. Some reports also support this rationale. Unilateral stenting with either a metal or plastic stent is usually associated with a higher technical success rate, a lower incidence of complications, and a higher successful drainage rate than bilateral stenting.[41–45] Recent studies using the percutaneous approach have also shown no difference between unilateral drainage and bilateral drainage (Table 2).[46,47] Therefore, it has been suggested that inserting more than one stent should not be justified as a routine procedure in patients with HBO.

Bilateral (multiple) drainage

The factor predicting drainage effectiveness during endoscopic stenting for HBO is drainage > 50%, which is associated with prolonged survival compared to patients with drainage < 50% (119 days vs 59 days; $P = 0.005$).[6] Therefore, bilateral or multiple stenting for drainage > 50% may be warranted to achieve clinical efficacy in patients with a high-degree HBO. The Asian-Pacific consensus recommendation and ESGE guideline also suggest that the goal of palliative stenting is to achieve drainage of an adequate liver volume of more than 50% for Bismuth type II to IV.[3,4]

Chang et al[48] first showed that bilateral metal stents might improve stent patency and survival duration by ensuring adequate drainage in HBO. Inadvertent contrast injection into the IHD

Table 2 Unilateral vs Bilateral Drainage Using SEMS for Advanced HBO

Method	Design	SEMS (*n*)	Technical success	Clinical success	Adverse events	Re-intervention	Stent patency (day)	Survival (day)
Endoscopic method								
Naitoh et al[49]	Retrospective	Uni. (17)	100 (17)	94.1 (16)	64.7 (11)	58.8 (10)	210	166
		Bi. (29)	89.7 (26)	86.2 (25)	65.4 (17)	23.1 (6)	488	205
		P-value	N/A	N/A	N/A	0.02	0.009	0.559
Iwano et al[44]	Retrospective	Uni. (65)	95.2 (60/63)	N/A	36.9 (24)	26.2 (17)	133	170
		Bi. (17)	89.5 (17/19)		41.2 (7)	29.4 (5)	125	184
		P-value	-		-	-	0.322	0.490
Liberato and Canena[33]	Retrospective (plastic+metal)	Uni. (35)	98.8 (total)	97.9 (total)	Early: 2; Late: 24.4 (total)	24.4 (total)	Longer patency in bilateral	-
		Bi. (42)						
		P-value	N/A	N/A	N/A	N/A	N/A	N/A
Mukai et al[34]	RCT (plastic+metal)	Uni. (14)	100 (total)			28.6 (4)	363	219.5
		Bi. (16)				50.0 (8)	295	(total)
		P-value	N/A			N/A	N/A	N/A
Lee et al[50]	RCT	Uni. (66)	100 (66)	84.8 (56)	27.3 (18)	57.6 (38)	139	178
		Bi. (67)	95.5 (64)	95.3 (61)	6.3 (4)	42.2 (27)	252	270
		P-value	N/A	0.047	0.001 (early)	0.079	< 0.01	0.053
Percutaneous method								
Teng et al[46]	Retrospective	Uni. (58)	93.1 (54)	96.4 (53)	9/55	9/55	185	189
		Bi. (52)	90.4 (47)	97.9 (46)	7/47	4/47	198	199
		P-value	0.864	1.00	0.839	0.236	0.999	0.867
Chang et al[47]	Retrospective	Uni. (33)	93.9 (31)	93.5 (29)	4	16.1 (5)	368	200
		Bi. SBS (30)	90.0 (27)	96.3 (26)	7	11.1 (3)	387	198
		P-value	0.912	0.637	0.207	0.58	0.685	0.751

Values are presented as percentage (number), number only, or median.
SEMS, self-expandable metal stent; Uni., unilateral; Bi., bilateral; N/A, not available; RCT, randomized controlled trial; SBS, stent-by-stent.

without adequate drainage is associated with worsened outcomes. Similarly, Naitoh et al[49] have reported a prolonged stent patency in the bilateral group than in the unilateral group (median, 488 days vs 210 days; $P = 0.009$) without showing any significant difference in technical success rate, clinical success rate, early adverse event rate, or late adverse event rate. Liberato and Canena[33] have shown that the reintervention rate for stent occlusion is higher in the unilateral SEMS group than in the bilateral SEMS group (31.4% vs 11.9%, $P = 0.036$). The median stent patency duration was also prolonged in the bilateral SEMS group (29 vs 24 weeks). Multivariate analysis revealed that SEMS placement and bilateral drainage were independent prognostic factors associated with prolonged stent patency.[33] However, these reported results were based on retrospective analysis on SEMS mixed with plastic stents. One randomized study comparing unilateral and bilateral drainage using SEMS in advanced HBO has shown the superiority of bilateral drainage over unilateral drainage in terms of stent patency and reintervention rates.[50] However, there were no significant differences in adverse events between the two groups (Table 2).

Nonetheless, multiple metal stenting is still considered a technically difficult procedure. When bilateral drainage fails after contrast injection past the hilar stricture and into atrophied and/or unintended multiple hepatic segments, post-ERCP cholangitis and abscesses are problematic as they are associated with lower survival rates.[48] The incidence of cholangitis in patients with hilar obstruction is significantly higher than that in those with distal obstructions.[51] However, unintended contrast injection can be avoided or reduced by using magnetic resonance cholangiopancreatography or three-dimensional computed tomography imaging. Based on advanced imaging analysis, targeted and planned endoscopic drainage can reduce unintentional contrast injection associated with post-procedure adverse events such as cholangitis and abscesses.[51–54] Therefore, proper procedures based on prior imaging analysis and performance by experienced endoscopists are highly recommended to reduce adverse events and prolong stent patency and complication-free survival.

Recent reported meta-analysis studies have shown that unilateral metal stent has higher technical success rate than bilateral metal stent, although technical success rates are not sigificant different between metal stents and plastic stents. In addition, there are no significant differences in adverse events between unilateral and bilateral stents.[55–57] One study has shown a lower reintervention rate in bilateral metal stent than in unilateral stent.[56] However, these meta-analysis studies mostly included observational retrospective studies except two randomized controlled trials.

In summary, to effectively drain ≥ 50% of the liver volume for high-degree HBO, multiple drains using SEMS or plastic stents are recommended as primary palliation for patients with advanced or inoperable HBO. Advances in endoscopic techniques and devices may help overcome technical difficulties and achieve more promising results.

Endoscopic bilateral stent–in–stent vs stent–by–stent deployment

Recent reports have shown higher technical and clinical success rates ranging from 73.3% to 100% for experts using bilateral stent-in-stent (SIS) and stent-by-stent (SBS) techniques.[8,11,12,14–16,18–20,22,29,30,58] However, there are still debates over which method provides more effective drainage (Table 3).[20,35,59–61] Naitoh et al[20] have performed a retrospective comparison of these two techniques and found that rates of early and late adverse events, including cholangitis, cholecystitis, and liver abscesses, are higher in the SBS group (11% vs 4% for early adverse events and 32% vs 8% for late adverse events). Despite more frequent adverse events in the SBS group, the cumulative stent patency tended

Table 3 Comparative Studies for Endoscopic SIS vs SBS Deployment for Hilar Biliary Obstrucion

Author	Design	Stent	Sex (male)	Mean age (SD)	Technical success	Clinical success	Early adverse events	Late adverse events	Total adverse events	Occlusion rate	Stent patency (day)	Survival (day)
Naitoh et al[20]	Retrospective	SIS, 24	14	74.6 (8.3)	100 (24)	100 (24/24)	4.2 (1/24)	8.3 (2/24)	12.5 (3/24)	41.7 (10/24)	104	159
		SBS, 28	11	69.5 (11)	89.3 (25)	96.0 (24/25)	10.7 (3/28)	32.0 (8/25)	44.0 (11/25)	20.0 (5/25)	155	198
		P-value	0.137	0.105	0.148	0.51	0.366	0.074	0.016	0.091	0.388	0.952
Kim et al[59]	Retrospective	SIS, 22	17	65.0 (3.1)	100 (22)	81.8 (18)	22.7 (5/22)	50.0 (11/22)	72.7 (16/22)	59.1 (13/22)	134	225
		SBS, 19	11	64.2 (2.8)	100 (19)	78.9 (15)	31.6 (6/19)	36.8 (7/19)	68.4 (13/19)	47.4 (9/19)	118	146
		P-value	0.313	0.637	NS	1	0.725	0.531	N/A	0.538	0.074	0.266
Law and Baron[61]	Retrospective	SIS, 7	Total	68	100 (7)		Total		Total	42.9 (3/7)	Total	
		SBS, 17	19	68	100 (17)	N/A	4/0		4/0	52.9 (9/17)	86	N/A
		P-value		0.99	NS	N/A	N/A	N/A	N/A	0.31	N/A	N/A
Lee et al[60]	RCT	SIS, 34	15	74.5 (10.04)	100 (34)	94.1 (32/34)	11.8 (4/34)	17.6 (6/34)	23.5 (8/34)	44.1 (15/34)	253	209
		SBS, 35	21	72.5 (11.05)	91.4 (32)	90.6 (29/32)	11.4 (4/35)	22.9 (8/35)	28.6 (10/35)	34.3 (12/35)	262	221
		P-value	0.187	0.438	0.081	0.668	0.965	0.591	0.633	0.403	0.865	0.197

Values are presented as number only, percentage (number), or median.
SIS, stent-in-stent; SBS, stent-by-stent; SD, standard deviation; NS, not significant; N/A, not available; RCT, randomized controlled trial.

to be prolonged in the SBS group compared to the SIS group. In contrast, another small-sized study has revealed no difference in terms of adverse events, stent patency, or survival.[59] A randomized comparative study of SIS and SBS deployment has revealed no significant difference in technical feasibility, adverse events, or stent patency duration. Technical feasibility of SIS procedures performed by experts is not different from that of the SBS method. Stent patency rates at three and six months after successful deployment of bilateral SEMS tend to be higher in the SIS group although differences between the two groups are not statistically signfiicant.[60]

A recent meta-analysis has shown that bilateral SIS deployment has a higher technical feasibility than the SBS method in patients with advanced HBO, without showing significant differences in rates of clinical success, adverse events, or occlusion. However, it is difficult to generalize this result because of the lack of quality data and heterogeneity.[62]

SIS and SBS deployment methods might be complementary techniques rather than competitive techniques. Depending on technical difficulty, bile duct dilatation, and the level of experience, an intended method can be switched to another method. Also, in consideration of additional chemoradiotherapy or local therapies, endoscopic palliation strategies such as primary metal stenting and sequential stent exchange with plastic stents should be accommodated considering expected survival or physical status of the patient.

Stent-by-stent deployment

SBS deployment inovolves sequential or simultaneous parallel placement of two SEMS into both IHD or multi-sectoral branches (Fig. 1).[23,63] If possible, distal ends of both stents should be placed at the same level within the common bile duct (CBD) or across the ampulla of Vater. Simultaneous SBS placement is possible using a 6-Fr stent delivery system (Zilver 635; Cook Medical, Winston-Salem, NC, USA).

The advantage of the SBS technique is its technical feasibility. Bilateral SBS deployment is relatively easy after inserting two guidewires. Stent revision is also technically easy when stents cross the major papilla. However, this stent position might be vulnerable to duodenal reflux. Few studies have examined the effect of stent position on patient outcomes in HBO. In malignant bile duct obstruction, the placement of 10-Fr Teflon stents above or across the sphincter of Oddi has shown no difference in stent function.[64] Second, there is a concern about the deployment of two large-diameter parallel SEMS in normal CBD as it might compress the adjacent portal vein and cause thrombosis at the CBD level. On the contrary, the relatively smaller stent diameter compared to the diameter of CBD might decrease stent patency and preclude full expansion of both stents in non-dilated CBD.

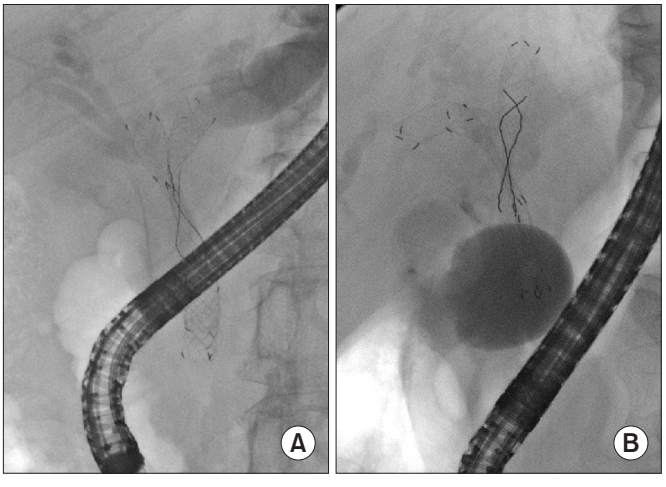

Fig. 1. Endoscopic stent-in-stent (SIS) showing a Y-shaped configuration after the deployment of two stents into both intrahepatic bile ducts (IHDs) due to the second stent passing through the first deployed metal stent. Distal margins of each stent are positioned within the common bile duct (CBD) (A). Stent-by-stent (SBS) deployment shows parallel configuration of two metal stents into both IHDs. Each stent is positioned within the CBD above the level of the major papilla (B).

Stent-in-stent deployment

Alternatively, in SIS deployment, the second stent can cross the central portion of the wire mesh of the previously inserted first SEMS (Fig. 1).[29,30] Therefore, after successful placement, its final Y-shape configuration according to the normal bile duct might be physiological. SIS with less axial force can fit the bile duct configuration well with less pressure to proximal and distal sides of the bile duct wall or surrounding vascular structures.[65] Second, SIS might minimize duodenal reflux, which facilitates cholangitis or biofilm formation because the distal end of the stent in the SIS method is placed above the level of the papilla. Placement of the stent above the intact sphincter of Oddi might prevent duodenal reflux and deposition of organic material or bacteria causing sludges or stone formation in the stent. Third, multi-sectoral drainage through the SIS method is possible as a primary insertion or revision method.[15,66,67]

Despite these benefits, the main issue of the SIS method is its technical difficulty for second stenting or reintervention after stent malfunction. Specifically, when stent malfunctions due to tumor ingrowth, bilaterally crossed wire mesh might prohibit the reinsertion of guidewires or stents regardless of whether the stent is plastic or metal.

SEMS for bilateral drainage

SEMS for bilateral drainage can be divided into small closed-cell or large open-cell types. The large open-cell type (Zilver stent [Wilson-Cook Medical Inc., Winston Salem, NC, USA]; JOSTENT SelfX stent [Abbott Vascular Devices, Redwood City, CA, USA]; Niti-S Y-type or Niti-S large cell D-type [Taewoong Medical, Inc., Seoul, Korea]) is easily dilated by ballooning or a second stent. Therefore, this structure may facilitate primary insertion or reintervention. However, this type of SEMS may be too weak for stent patency due to the vulnerability to tumor ingrowth and relatively decreased radial force on the central portion. Small closed-cell design stents (Bonastent [Standard SciTech Inc., Seoul, Korea]; Wallstent [Boston Scientific Co., Natick, MA, USA]; Hanarostent [M.I. Tech Co., Seoul, Korea]) have a relatively smaller-sized cell which may overcome the weakness of the central portion of the stent by the extent of the stricture or the tumor burden. In contrast, the benefit of the closed or small-cell design makes primary second stent deployment or stent revision in SIS deployment configurations technically difficult. As a mixed form of small closed-cell type, the M-Hilar stent (Bonastent; Standard SciTech, Inc.) has a conventional hook and cross-wired structure on the proximal and distal portions, but on the 25-mm-long central portion, it has only a cross-wired structure to facilitate placement of the contralateral stent across it. These structures may facilitate second stent insertion and decrease stent reintervention limitations. However, there were no proven comparative results regarding the technical feasibility or functionality according to the types of stents. Usually, stents are selected according to the preference of the endoscopist

and availability. An open-cell or cross-wired type is adequate for SIS deployment, as is the closed-cell type for SBS deployment.

Endoscopic Drainage, Endoscopic Ultrasound-Guided Biliary Drainage

EUS-BD is now being increasingly utilized in the rescue or alternative management of malignant biliary obstruction in cases with failed or difficult ERCP.[68,69] Still, primary EUS-BD for unresectable HBO is limited due to restricted data from some specialized centers or experts. However, when conventional ERCP is impossible or when it fails due to gastric outlet obstruction or surgically altered anatomy, EUS-BD can be used as a rescue method at the same unit or as an alternative to PTBD. Intrahepatic approach by hepaticogastrostomy (EUS-HGS) and extrahepatic approach by choledochoduodenostomy (EUS-CDS) can be used. However, EUS-HGS may be mandatory for HBO (Fig. 2).

Definite indications have not been generalized yet. However, EUS-BD can be indicated when primary ERCP fails or when it is inaccessible. Therefore, failed ERCP, surgically altered anatomy, and failed reinterventions by the transpapillary approach can be indicated for EUS-BD in HBO. Contraindications of EUS-BD are similar to those of PTBD, including uncontrolled or severe coagulopathy, massive ascites, intervening vessels, and unstable patient status for an endoscopy. EUS-HGS, hepaticoduodenostomy (HDS), and bridging methods are available (Fig. 2).[70,71]

A EUS-HGS or HDS can be placed in the left or right IHD in the first session after failed ERCP or inaccesible coventional ERCP. While many studies have recently reported results of HGS, studies reporting results of HDS are very limited. EUS-HDS[72,73] employs a right IHD access from the duodenum, which is a complement of EUS-HGS to the left IHD. However, EUS-HDS procedures are performed only in a few expert centers. Therefore, the standard or tailored method of EUS-HDS has not been established thus far. The bridging method is advanced through the hilar stricture into the right IHD as a EUS-HGS method. The deployed metal stent is then advanced accross the hilar stricture followed by a covered SEMS placement from the left IHD to the stomach. During this bridging method, guidewire passage or stent deployment to the right biliary system through the hilar stricture can be technically challenging depending on the angle of left and right IHD confluences.[74] A combined EUS and ERCP approach can be an alternative modified treatment option.[75] This method involves endoscopic transpapillary drainage to the right IHD and EUS-HGS to the left IHD.

Besides EUS-HGS, bridging method, and combined method, multiple stenting using EUS-BD might be theoretically possible. It provides another therapeutic option in sepcific situations. However, dedicated devices and tailored methods are still limited. Higher technical or clinical success with relatively lower complication rates might be attributed to more highly experienced experts in advanced therapeutic centers. Generalization of this technique to every center and endoscopists is currently limited. In the near future, as devices and techniques are developed, EUS-BD might play an important role even in advanced HBO as a primary technique or an alternative to ERCP. Further large-scaled studies with long-term follow-up are needed.

Reintervention

Recurrent biliary obstruction (RBO) rate after placement of bilateral SEMS in HBO has been reported to range from 3% to 45%.[30] Plastic stents or covered SEMS can be exchanged easily. However, bilateral revision using metal stents is more difficult than previous SIS deployment because of crossed wire mesh of stents and tumor ingrowth. Bilateral revision using plastic stents is technically feasible regardless of the bilateral deployment type. Although endoscopic reintervention is usually effective and less invasive, percutaneous or EUS-guided intervention is an alternative when primary endoscopic intervention fails. Specifically, technical success rate of PTBD is higher than its endoscopic success rate. Recently, EUS-BD has also been used as a reintervention in failed ERCP as well as a primary intervention for failed ERCP, although it has many limitations for primary use.[70]

When performing deployment of multiple uncovered SEMS, reinserting metal or plastic stents through the previously deployed stent should be considered. Bilateral SBS deployment across the papilla is relatively easy for revisions. However, SIS or SBS deployment within the CBD level is relatively difficult. A recent systematic review of 10 retrospective studies has revealed that placing a plastic stent as a reintervention might be as effective as a second SEMS in malignant biliary obstruction. Risks of reocclusion and patency duration after the second stent are similar between plastic and SEMS. However, this systematic review included mostly distal biliary obstructions.[76] More large-scaled prospective studies for hilar lesions are needed to validate this finding. The relatively small number of patients with advanced HBO, the relatively short survival time, and patients lost to follow-

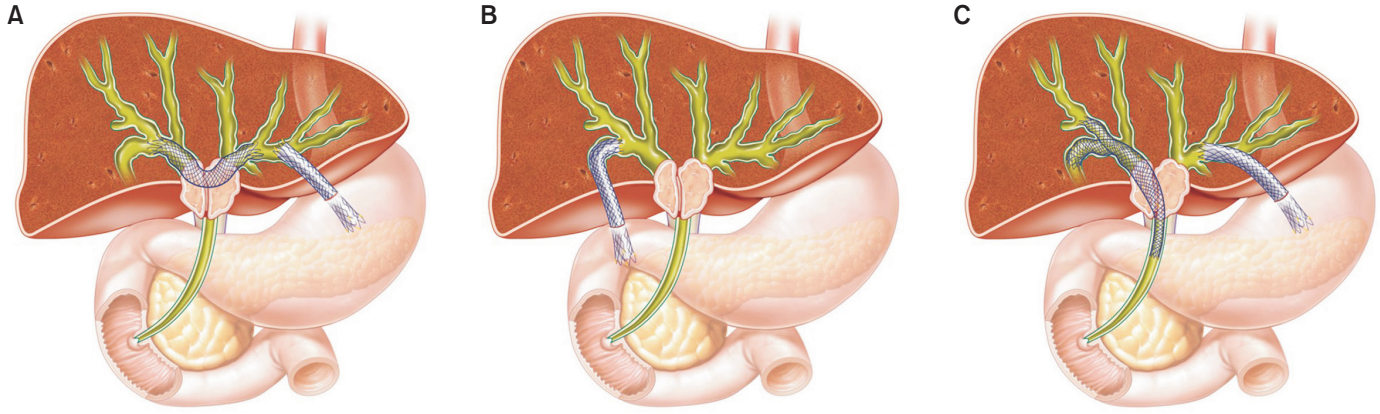

Fig. 2. Endoscopic ultrasound (EUS)-guided biliary drainage methods for advanced hilar biliary obstrucion. (A) Bridging method. (B) EUS-hepaticoduodenostomy. (C) Combined EUS-hepaticogastrostomy and transpapillary bilateral stenting (modified from Nakai et al[70]).

up after stent placement might preclude effective evaluations of those studies.

Still, no definite evidence supports an effective reintervention for occluded SEMS in patients with unresectable HBO. The number of stents, stent types, stent configurations, level of the stent position, and selection of the drainage area are controversial. Choices might be influenced by the experience or preference of the endoscopist. A suitable reintervention method following the RBO of hilar stents is warranted.

Conclusions

The final goal of endoscopic palliation of inoperable or advanced HBO is to improve the quality of life by prolonging stent patency and survival. Therefore, according to the status of the patient, adequate endoscopic palliation with or without local therapies and chemoradiation therapies should be provided. Conventional ERCP drainage strategy including number of stents, materials, and deployment methods should be considerd accoring to the level of obstruction, anatomical change, and future therapeutic plan of the patient. In surgically inoperable or unsuitable patients, an endoscopic intervention can be chosen as the primary palliative approach, even in advanced HBO. PTBD is currently a traditional alternative primary or resucue method in high-degree HBO. EUS intervention is emerging as an effective alternative in recent years desppite the lack of data. Each intervention method has its advantages and disadvantages. Therefore, endoscopists should consider each method as a complementary method instead of a competitive method.

Conflicts of Interest

No potential conflict of interest relevant to this article was reported.

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