Technical View

Technical tips and troubleshooting of endoscopic biliary drainage for unresectable malignant hilar biliary obstruction

Running head: Multistenting for hilar biliary obstruction

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Abstract

Unresectable malignant hilar biliary obstruction (MHBO) occurs in various diseases, such as cholangiocarcinoma, gallbladder carcinoma, hepatocellular carcinoma, pancreatic cancer, and lymph node metastasis of the hilum of the liver. The majority of patients with advanced MHBO are not candidates for surgical resection because of the tumor location in the hepatic hilum and adjacent areas, advanced tumor stage, or comorbidities. Therefore, these patients often have a poor prognosis in terms of survival and quality of life. Most of these patients will require non-surgical, palliative biliary drainage. To date, various biliary drainage techniques for unresectable MHBO (UMHBO) have been reported. Of these techniques, endoscopic biliary drainage is currently considered to be the most safe and minimally invasive procedure. However, endoscopic biliary drainage for UMHBO is still not standardized regarding the optimal stent, drainage area, stenting method, and reintervention technique. Recently, towards standardization of this technique for UMHBO, clinical research and trials including randomized controlled trials have been performed. In this article, we reviewed the most important issues regarding endoscopic biliary drainage for UMHBO, focusing on prospective studies. We also described in detail the techniques and future perspectives of endoscopic biliary drainage in patients with UMHBO.

Keywords:

Biliary drainage, Hilar biliary obstruction, Stenting, Stent-in-stent, Side-by-side

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Video clip count: 5

Introduction

The purpose of biliary drainage for unresectable malignant hilar biliary obstruction (UMHBO) is the treatment of cholangitis and jaundice. This technique is very important because it directly improves the quality of life and survival of UMHBO patients. However, the management of biliary drainage for UMHBO is still challenging. Because of the advantages and recent advances in endoscopic biliary drainage compared with percutaneous and surgical approaches, such as minimal invasiveness, shorter length of hospitalization, less mortality, and the availability of various types of drainage devices, endoscopic biliary drainage is the currently preferred approach. However, there is still no consensus in terms of an optimal endoscopic biliary drainage approach. Controversy exists over the optimal type of stent, drainage area, and stenting method. Here, we reviewed the techniques and pitfalls of endoscopic self-expandable metallic stent (SEMS) placement for UMHBO, and the methods of managing SEMS dysfunction.

Plastic stent versus SEMS: which should be selected for UMHBO?

Both the plastic stent (PS) and the SEMS can be used for biliary drainage in UMHBO. Theoretically, the SEMS should generate more favorable results than the PS.

Two types of SEMS are available: uncovered and covered. The uncovered SEMS is generally suitable for UMHBO. The covered SEMS can prevent tumor ingrowth but may cause occlusion of intrahepatic bile ducts. Therefore, the use of covered SEMSs in UMHBO is limited for patients with an unsuitable anatomy.

To date, 2 randomized controlled trials (RCTs) [1,2] and 1 prospective multicenter cohort study [3] have revealed the superiority of the SEMS to the PS owing to its longer patency, fewer reinterventions and lower overall cost (**Table 1**). The Asia-Pacific Working Group [4] reported that the SEMS is superior to the PS in patients with Bismuth classification type II, III, and IV UMHBO whose predicted survival period is longer than 3 months, in terms of outcome and cost-effectiveness.

Unilateral or bilateral biliary drainage: which should be selected for UMHBO drainage?

The selection of unilateral versus bilateral biliary drainage for UMHBO is under debate. Two RCTs [2,5] revealed that there are no significant differences in the rate of successful drainage and complications between unilateral and bilateral biliary drainage both in the PS and SEMS groups (**Table 2**). Bilateral biliary drainage might be physiologically advantageous for prolongation of stent patency. Vienne *et al*. [6]

suggested that drainage of more than 50% of the liver volume is an important predictor of effective biliary drainage in patients with UMHBO. The Asia-Pacific Working Group [4] also recommended that the goal of palliative stenting is the drainage of an adequate liver volume of more than 50%. However, drainage of such a large volume generally requires more than 2 stents, and its feasibility depends on the anatomy of individuals. In Bismuth classification type II, III, and IV UMHBO, bilateral biliary drainage is preferred for the drainage of 50% of the liver volume or to manage cholangitis that cannot be controlled with a single stent. Mukai *et al*. [2] reported that about half of the patients with previous unilateral drainage to reduce cholangitis and jaundice required further bilateral drainage.

Stent-in-stent or side-by-side: which method should be selected?

Endoscopic bilateral SEMS placement for UMHBO has been considered technically difficult and challenging. According to a working party of the American Society for Gastrointestinal Endoscopy (ASGE) [7], this procedure is classified as level 3 (difficult). For UMHBO, endoscopic bilateral SEMSs can be placed using either the stent-in-stent (SIS) or side-by-side (SBS) technique. In the SIS technique, the first SEMS is placed across the bifurcation and the second SEMS is passed within and then through the interstices into the contralateral intrahepatic bile duct. On the other hand, in the SBS technique, 2 SEMSs are inserted parallel to each other into the right and left hepatic ducts. Presently, there is insufficient data to conclude as to which technique is more preferable. The most commonly utilized technique is SBS placement. However, recently developed dedicated SEMS for the SIS technique have enabled a higher success rate for SEMS placement. SIS has the advantage of avoiding excessive expansion of the bile duct where the SEMSs overlap compared with SBS. To date, 2 retrospective studies have examined the differences between SIS and SBS [8,9]. Naitoh *et al*. [8] found that the incidence of complications (cholecystitis, cholangitis, and liver abscess) is higher for SBS placement than for SIS placement in bilateral SEMS stenting for UMHBO. The cause of cholecystitis was considered to be excessive expansion of the biliary duct in the region of the SEMS overlap, leading to occlusion of the cystic duct. With regard to cholangitis, it has been reported that SBS placement causes portal vein occlusion and increases the rate of cholangitis because of excessive expansion of the bile duct by the parallel stents. In terms of cumulative stent patency, SBS placement tends to be more effective than SIS placement. Furthermore, Naitoh *et al*. [8] described that there were significantly more patients with an advanced Bismuth classification in the SIS group than in the SBS group. On the other hand, Kim *et al*. [9]

reported no significant difference regarding stent patency and rate of complications between SIS and SBS. The major problem of these previous retrospective studies [8,9] is the mechanical property of the SEMS, such as SBS placement using an SEMS with high axial and radial force. High axial force is not suitable for placing a stent through an acute bend in the hilar bile duct. On the other hand, an SEMS with low axial force is suitable for biliary drainage of UMHBO patients [10]. The optimal radial force level has not been determined to date, because no comparative studies have been performed. However, SEMSs of high radial force may lead to better clinical outcomes than SEMSs of low radial force.

An ideal SEMS for performing SIS requires a wide mesh (particularly the first SEMS), a small diameter delivery system (particularly the second SEMS), and good pushability. The mesh size of the laser cut type SEMS was larger than that of the braided type. Furthermore, the diameter of the delivery system of the laser cut type SEMS was smaller than that of the braided type SEMS. These factors may have contributed to the difference in technical success rate between them. Recently, we revealed that a laser cut type SEMS with large mesh and thin delivery system might be preferable for SIS technique [11]. On the other hand, SEMSs for performing SBS require a high degree of flexibility, elasticity, minimal shortening, and a small diameter delivery system (**Table 3**). To date, there have been no comparative studies regarding the material of SEMSs such as laser cut type versus bladed type. On the basis of clinical experience, there are no significant differences in stent patency and complications between laser cut and bladed type SEMSs.

Standard endoscopic protocol prior to bilateral stenting

All patients should be examined by multidetector-row computed tomography (MDCT) or magnetic resonance cholangiography (MRCP) for the evaluation of resectability of the liver prior to biliary stenting. Surgical unresectability is determined by the criteria reported in our study [12-15]. Cytopathological diagnosis is confirmed by transpapillary cytology, biopsy, or endoscopic ultrasound-guided fine-needle aspiration biopsy. The target bile duct for biliary drainage is determined by MDCT or MRCP. If bile duct invasion involving 3 or more branches with ipsilateral lobe atrophy is found, unilateral biliary drainage of the other lobe is recommended. Diagnostic endoscopic retrograde cholangiopancreatography (ERCP) is then performed using a therapeutic duodenoscope, which has a 4.2 mm channel, a 15° backward oblique angle, and an elevator function (TJF-240 and TJF-260V, Olympus Medical Systems Corp., Tokyo, Japan). After selective bile duct cannulation, the length and degree of the stricture is evaluated by ERCP. In ERCP, attention should be paid to minimize the amount of contrast medium used, to avoid segmental cholangitis of the undrained area. Although this principle generally applies to stent placement, particular care should be taken not to aggravate possible pre-existing occlusions of the bile duct associated with UMHBO [16]. A standard ERCP catheter is used to successfully perform cholangiography during guidewire manipulation with a 0.025-inch or 0.035-inch guidewire (endoscopy catheter article no. 0120211, 1.6 mm diameter; MTW Endoskopie, Wesel, Germany) (**Fig. 1**). A 0.025-inch hydrophilic hard-type and angle tip guidewire (VisiGlide™ or VisiGlide 2™, Olympus Medical Systems Corp.) (**Fig. 2**), with the same stiffness as a regular 0.035-inch guidewire, was used for ease of manipulation. If a VisiGlide™ or VisiGlide 2™ could not be advanced into the targeted bile duct, a 0.025-inch or 0.035-inch hydrophilic soft-type guidewire (Radifocus®, Terumo, Tokyo, Japan) (**Fig. 3**) combined with various bendable (**Fig. 4**), rotatable sphincterotome catheters (**Fig. 5**) or multi-lumen catheters (**Fig. 6**) recommended for advancing into the targeted bile duct. A guidewire is first passed through the bile duct stricture followed by a standard ERCP catheter. If a standard ERCP catheter cannot be advanced through the stricture, dilation of the stricture is subsequently performed with the following endoscopic devices according to our prospective cohort study [17]: (1) a tapered ERCP catheter; (2) a standard balloon catheter; (3) a biliary dilation catheter (Soehendra□ biliary dilation catheter, SBDC-6, Cook Japan, Tokyo, Japan) (**Fig. 7**); (4) a screw drill (Soehendra□ stent retriever, SSR-7, Cook Japan) (**Fig. 8**); and (5) a 6-Fr wire-guided diathermic dilator (Cysto-Gastro-Set, Endo-Flex GmbH, Voerde, Germany) (**Fig. 9**), coaxial with the guidewire, in blended cut mode. If a SEMS cannot be advanced through the stricture, a standard guidewire should be subsequently exchange to the stiff-type guidewire (**Video S1**).

SIS technique (Fig. 10) (Video S2)

In the SIS technique, the foremost targeted bile duct for the first SEMS placement is the most difficult to advance through, including the first bile duct branching from the common bile duct, as well as bile ducts that are strongly bended or difficult to cannulate. This is because the resistance in advancing the delivery system is very strong. For example, the initially targeted bile duct for bilateral biliary drainage is usually the left or right posterior hepatic duct, and the secondary targeted bile duct is the right anterior hepatic duct.

Endoscopic sphincterotomy is performed on the basis of each endoscopist’s judgement. First, 2 guidewires are placed in each of the targeted intrahepatic bile ducts.

Next, the first SEMS is inserted into the targeted bile duct along a guidewire. The other guidewire should be outside of the first SEMS and be used as a "landmark" guidewire for bile duct bifurcation. Advancement of the first SEMS through the targeted intrahepatic bile duct along the "seeking" guidewire becomes easier by the existence of the "landmark" guidewire [18,19]. After placement of the first SEMS, the guidewire inside the expanded SEMS is gradually withdrawn to the central position of the first SEMS. Then, the contralateral intrahepatic bile duct is sought through the mesh of the first SEMS along the other guidewire. After the "seeking" guidewire is placed into the targeted bile duct, a standard ERCP catheter is advanced along the "seeking" guidewire through the mesh of the first SEMS.

Finally, the second SEMS is placed through the mesh of the first SEMS along the "seeking" guidewire. If seeking through the first SEMS is difficult, Radifocus® (**Fig. 3**) with a bendable catheter (**Fig. 4**), rotatable sphincterotome catheter (**Fig. 5**) or multi-lumen catheter (**Fig. 6**) may be more suitable. If Radifocus® is used, it is necessary to exchange the guidewire to a "leading" guidewire such as VisiGlide™ or VisiGlide 2™ for deployment of the second SEMS. Kawamoto *et al*. reported that it is impossible to satisfy the conflicting guidewire requirements with a single guidewire [17]. The "seeking" guidewire requires pliability, whereas the "leading" guidewire requires stiffness. If the standard ERCP catheter or second SEMS is unlikely to pass through the mesh of the first SEMS, the mesh requires dilation. The same devices and methods to dilate the biliary stricture are used to dilate the mesh (**Fig. 11**) (**Video S3**). Particularly for the above, the first SEMS is inserted into the left hepatic duct. The second SEMS is placed through the mesh of the first SEMS into the right anterior or posterior hepatic ducts. These SEMSs partially overlap with each other in the common hepatic duct (Y-shaped configuration) and branch out in 2 directions (**Fig. 10**). For high-grade UMHBOs (Bismuth type IIIa or IV), which involve the left, right anterior, and right posterior hepatic ducts, 3-branched or 4-branched SIS is sometimes required for the management of jaundice or cholangitis when using the SIS technique for the placement of 2 SEMSs. Balloon dilation before SEMS placement is performed for a high-grade stricture on the basis of the expertise of the endoscopist.

SBS technique (Fig. 12) (Video S4)

After placement of the first SEMS, insertion of the second SEMS may be difficult owing to impaction or resistance of the second SEMS delivery system against the first SEMS. If placement of the 2 SEMSs is not conducted simultaneously, the first SEMS should have a small diameter and be inserted immediately following the first

SEMS. Hookey *et al*. [20] reported the utility of placing a temporary PS for enhanced facilitation of bilateral SEMS placement. Placement of 2 SEMSs using the SBS technique can also result in excessive mechanical expansion of the lumen of the common bile duct and might cause inflammation of the surrounding tissue, such as fat tissue as well as blood vessels (pseudoaneurysm, portal vein thrombus, or bilioportal fistula). Recently, an SEMS with a small diameter (6-Fr) delivery system (Zilver635□, Cook Japan) has been developed. This stent enables the placement of 2 SEMSs simultaneously in a single step by the SBS technique [21-24]. First, 2 guidewires are advanced into the targeted intrahepatic bile ducts. Then, 2 SEMSs are simultaneously advanced and placed into the targeted intrahepatic bile ducts through the endoscopic channel. If the 2 SEMSs are difficult to insert into the channel of the duodenoscope, a small amount of liquid lubricant or hydrochloride jelly should be placed into the channel to facilitate insertion. The position of the distal ends of the SEMSs for UMHBO is under debate. The distal ends of both SEMSs should be placed at the same level in the common bile duct or in the duodenum to facilitate future transpapillary access to both sides of the liver in case of occlusion of the initial SEMS [25,26]. However, to place the distal ends of both SEMSs at the same level in the duodenum is sometimes difficult. Long SEMSs, such as those 10-cm to 12-cm in length, are used for placement in the duodenum. Endoscopic sphincterotomy is also required when the distal end of SEMSs are placed in the duodenum.

Reintervention technique for occluded SEMSs

Additional endoscopic or percutaneous transhepatic biliary drainage (PTBD) is performed when the initial SEMS becomes occluded. Endoscopic biliary drainage is usually preferred for these cases. However, the choices of reintervention are still controversial.

Ridtitid *et al*. reported that there was no significant difference in outcome between patients who received reintervention for UMHBO with either a PS, SEMS, or PTBD (n = 6, 3, and 4, respectively) [27]. The following are some examples of reinterventions.

For clearing debris, a wire-guided retrieval balloon catheter can be used, in which an inflated balloon is pulled through the duct. Alternatively, the debris can be washed out by the injection of saline. In cases of tumor ingrowth, the PS is inserted through the occluded SEMS. The devices and methods to pass through a stricture are the same as those used for SEMS placement. The placement of multiple PSs through previously inserted SEMSs is sometimes difficult. Recently developed dedicated PSs, such as the “Through The Mesh” (TTM) stent (Gadelius Medical, Tokyo, Japan) enable easier insertion (**Fig. 11**). This PS is 7 Fr in diameter with a proximal pigtail-shaped end and a distal end with a tapered hook tip without a flap [28] (**Video S5**).

Future perspectives of biliary drainage for UMHBO

Endoscopic ultrasound (EUS)-guided biliary drainage (EUS-BD) has been developed as an alternative for failed endoscopic biliary drainage, PTBD, or inaccessible papilla of Vater. In particular, EUS-guided transluminal intrahepatic biliary drainage (EUS-guided hepaticogastrostomy or hepaticoesophagostomy) can drain a left intrahepatic bile duct obstruction. However, EUS-BD is technically challenging and the rate of complications is still high [29,30]. A combination of endoscopic transpapillary drainage for the right intrahepatic bile duct with EUS-guided hepaticogastrostomy or esophagostomy for the left intrahepatic bile duct is limited for patients with an inaccessible and occluded SEMS placement in the right intrahepatic bile duct. Recently, Park *et al.* [31] have reported the utility of EUS-guided hepaticoduodenostomy from the duodenal bulb for isolated right intrahepatic duct obstructions. Therefore, theoretically, bilateral biliary drainage for UMHBO is possible by a combination of EUS-guided hepaticogastrostomy or hepaticoesophagostomy with EUS-guided hepaticoduodenostomy. Although EUS-BD appears to be promising, it should only be performed in selected patients. The safety and efficacy of this technique have not yet been adequately validated because of the small sample size in which it was performed, and the very limited population requiring this procedure. A multicenter prospective study to confirm the safety and efficacy of EUS-BD should be performed in the future.

Conclusions

We reviewed the current status of biliary drainage for UMHBO. We also discussed the techniques for endoscopic biliary SEMS placement and endoscopic management of dysfunctions of SEMSs for UMHBO. Endoscopic biliary SEMS placement is currently the most ideal stenting method for UMHBO. However, the material of the SEMS (laser cut or bladed type), method of SEMS placement (necessity of endoscopic sphincterotomy, SIS or SBS, how to locate the distal end of SBS stents), and management of SEMS dysfunction (PS or SEMS) are still matters of debate.

Conflict of interest

None declared.

Author contributions

Drafting of manuscript: H. Kawakami

Revisions of manuscript: T. Itoi, M. Kuwatani, K. Kawakubo, Y. Kubota, and N. Sakamoto

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Figure legends

Fig. 1

Standard ERCP catheter that is used to perform cholangiography during guidewire manipulation with a 0.025-inch or 0.035-inch guidewire (endoscopy catheter no. 0120211, 1.6 mm diameter; MTW Endoskopie).

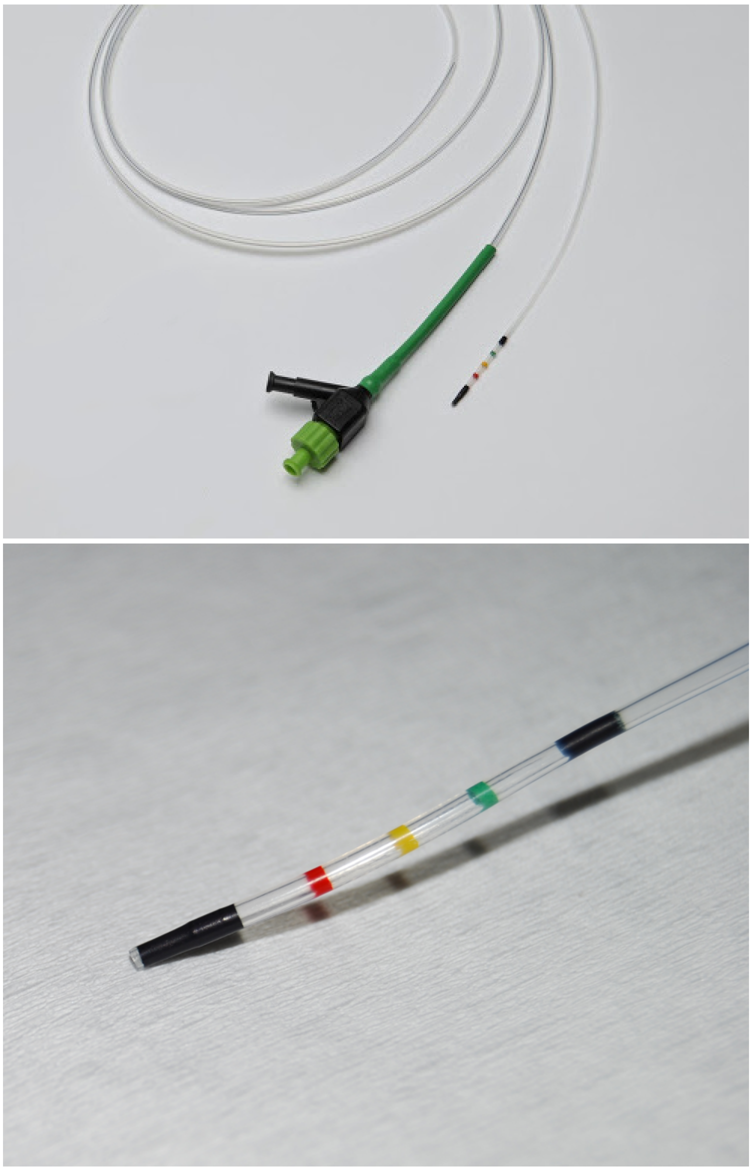
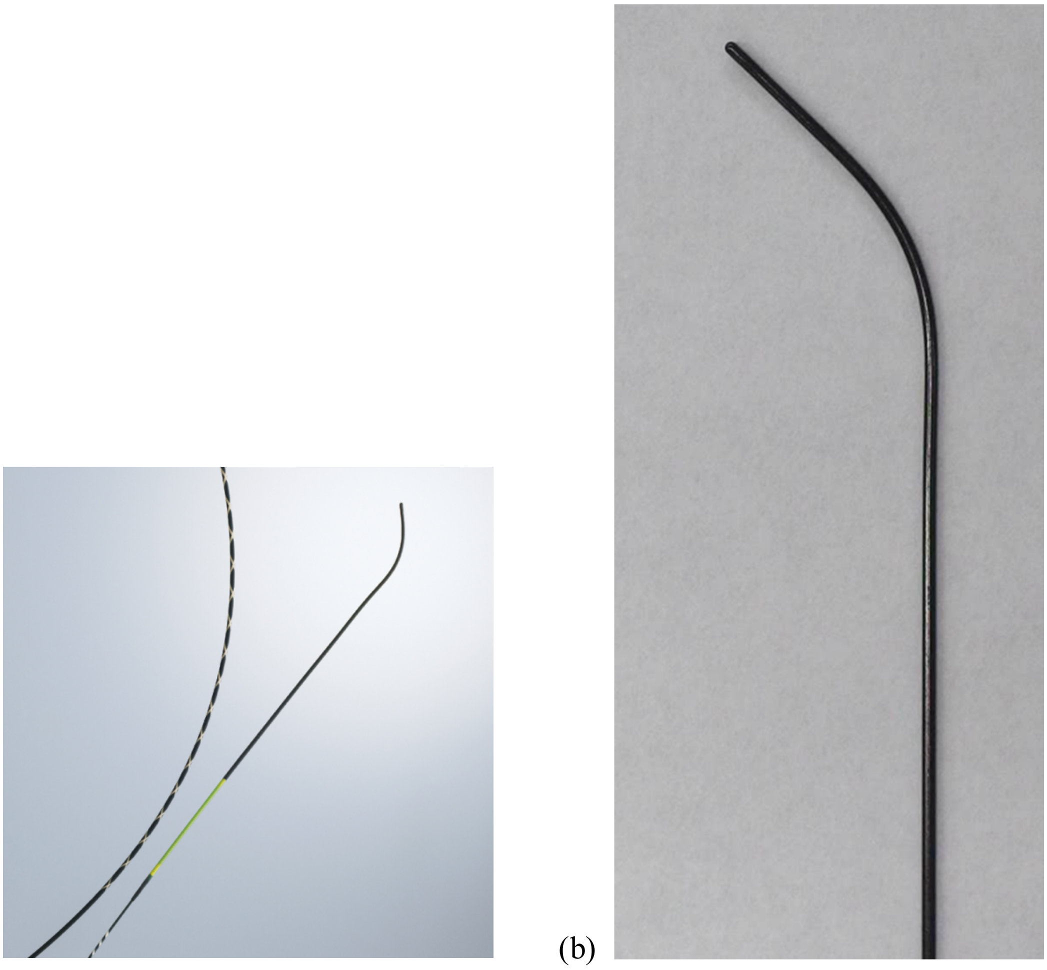


Fig. 2

Hydrophilic hard-type and angle tip guidewire (0.025 inch; VisiGlide™ (Figure 2a,b), VisiGlide 2™ (Figure 2c,d), Olympus Medical Systems Corp., Tokyo, Japan).



(a) (b)

(c) 

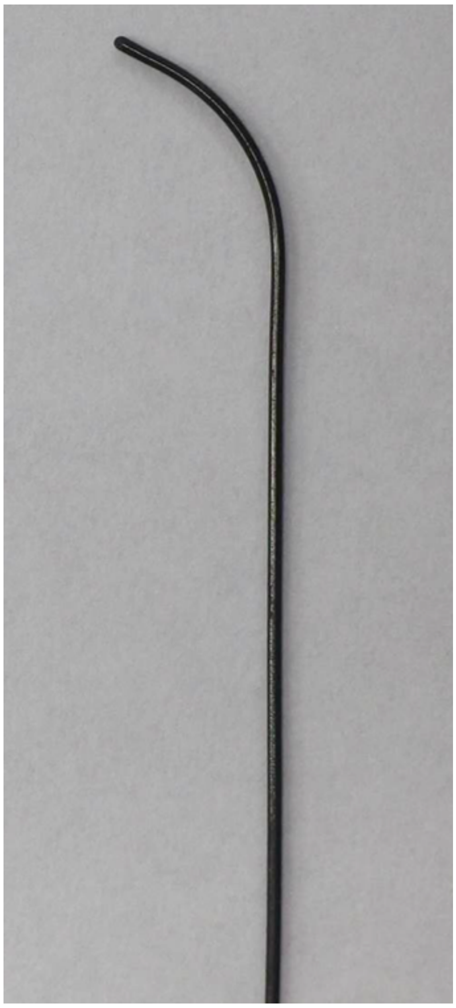
(d) 

Fig. 3

Hydrophilic soft-type guidewire (0.025 inch or 0.035 inch; Radifocus®, Terumo, Tokyo, Japan)

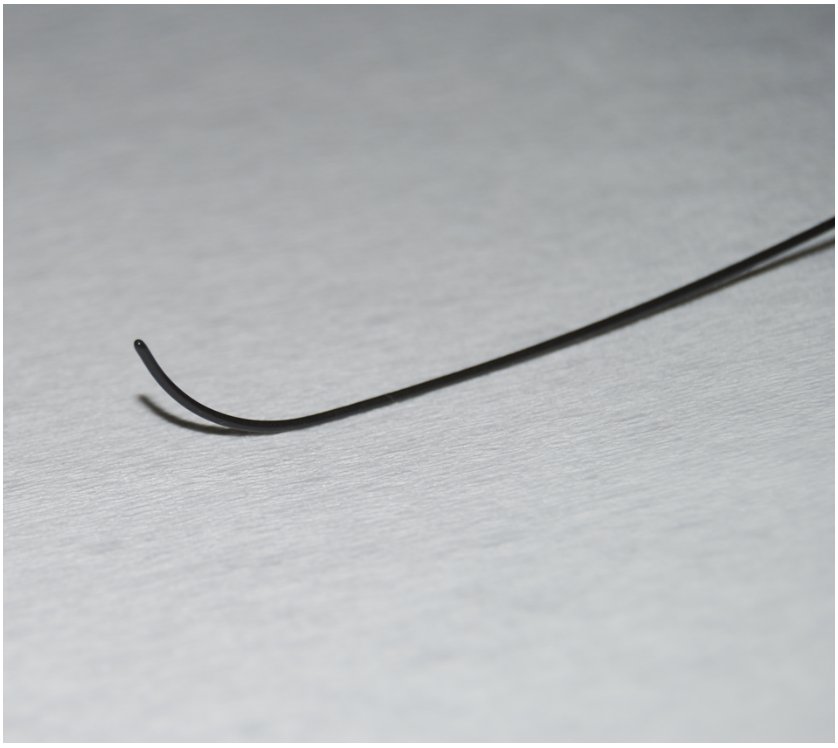


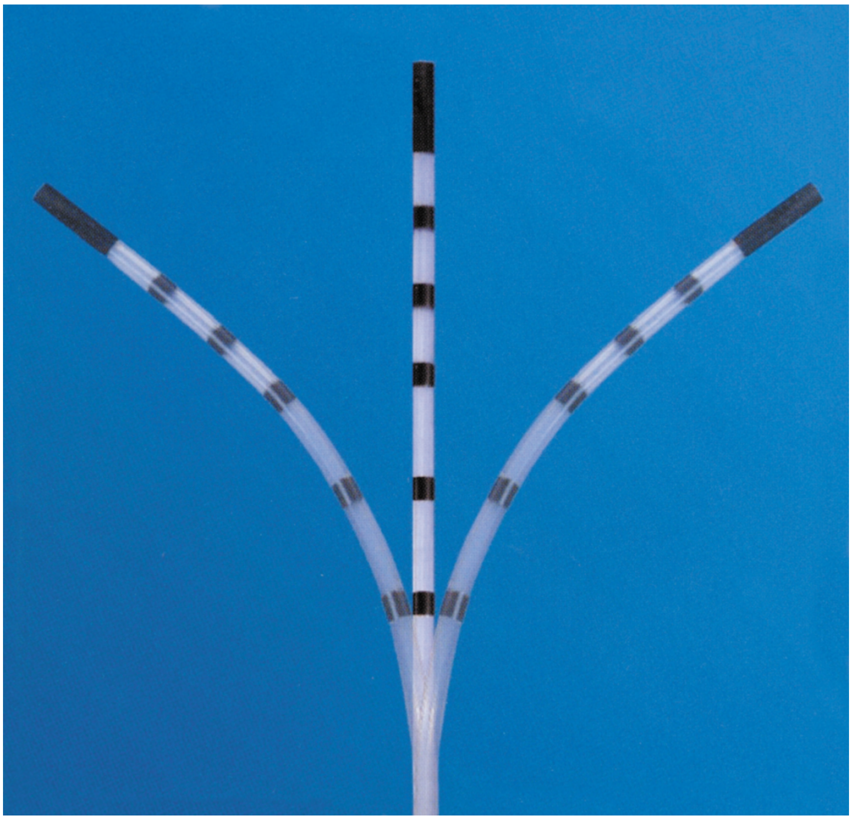
Fig. 4

Bendable catheters

(a,b) Swing-tip catheter (Olympus Medical Systems Corp.)

(c,d) Controllable ERCP catheter (MTW Endoskopie, Wesel, Germany)

(a)  (b) 

(c) 

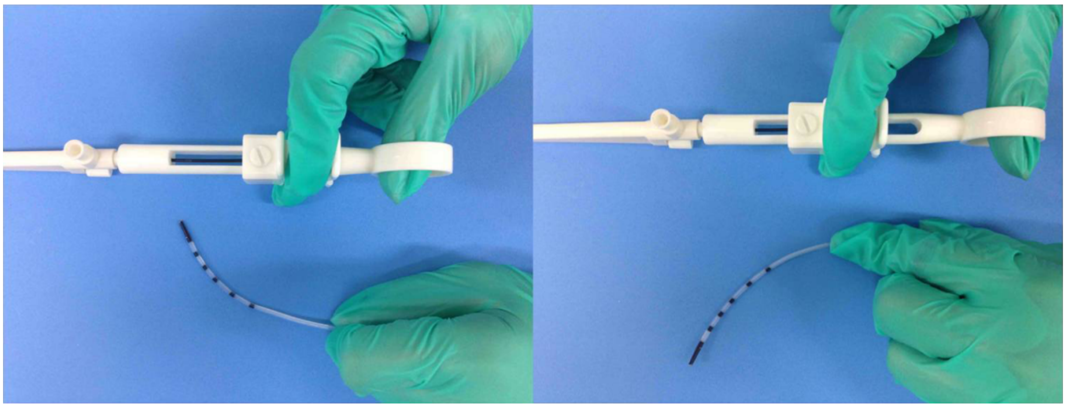
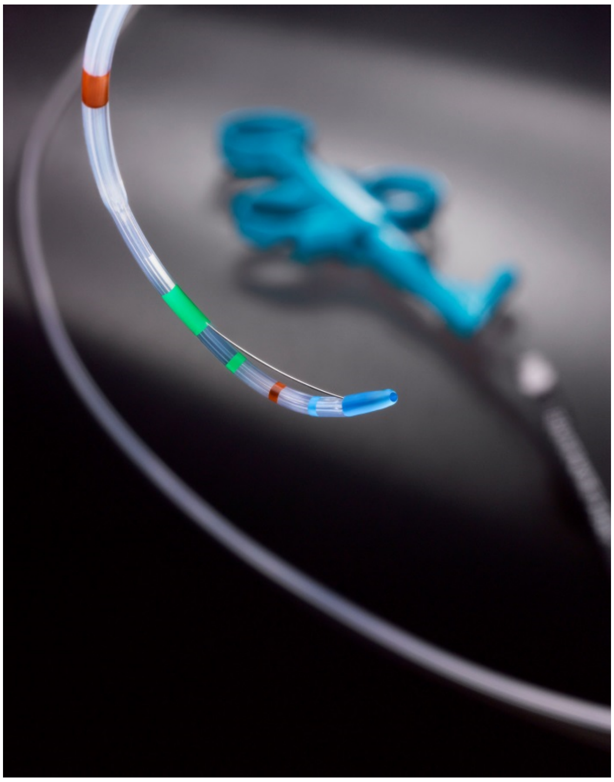
(d) 

Fig. 5

Rotatable sphincterotome catheters

(a) TRUEtome ™ (Boston Scientific Japan, Tokyo, Japan)

(b) Fusion OMNI-TOME(Cook Japan, Tokyo, Japan)



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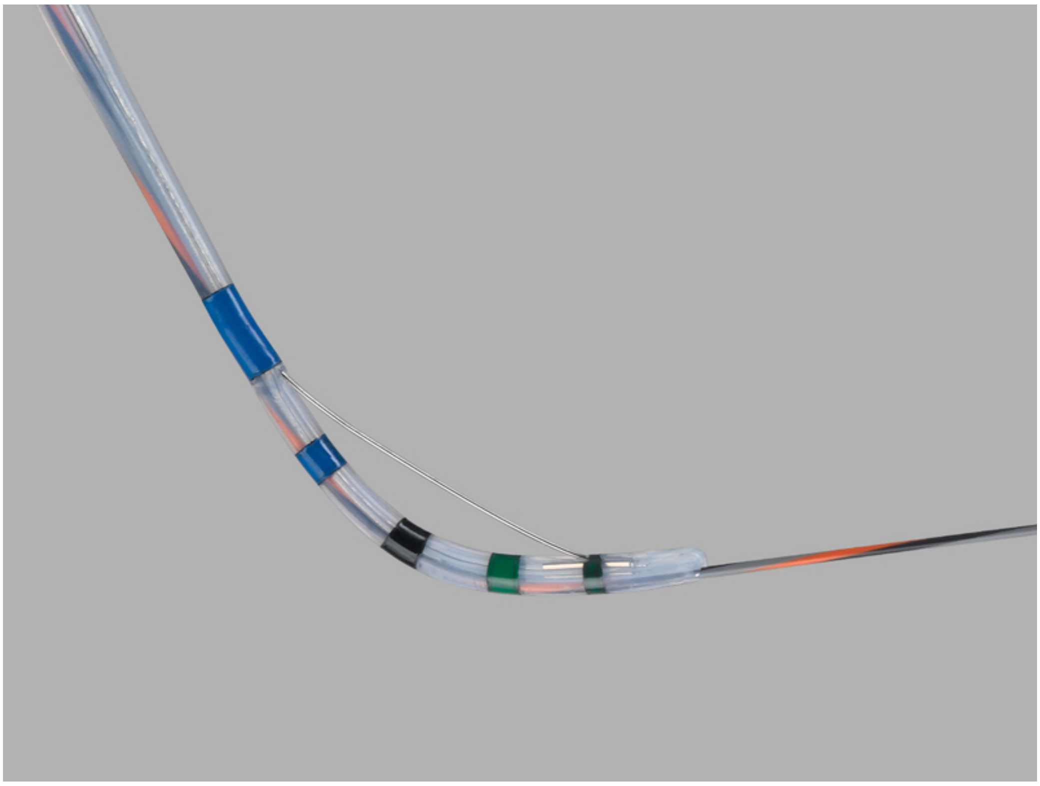


(b)

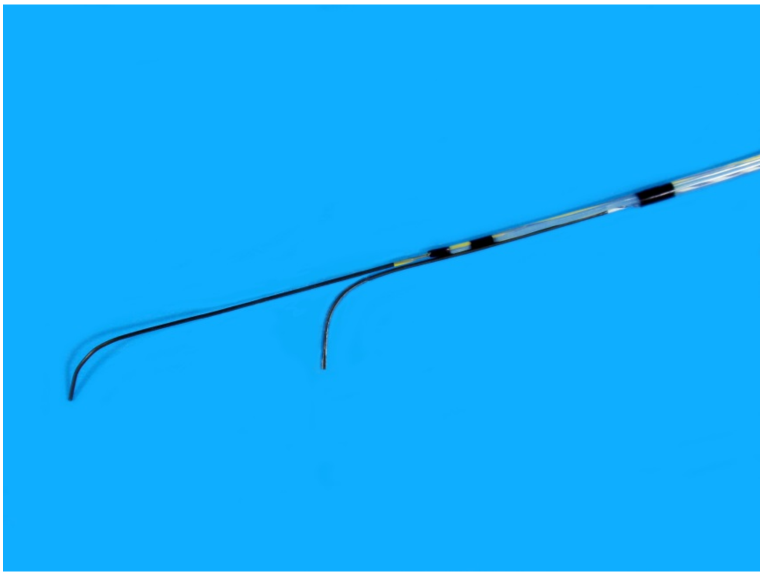
Fig. 6

Multi-lumen catheters

(a) Uneven Double Lumen catheter (Piolax Medical Device Inc., Kanagawa, Japan)

(b) Bouncer Multi-Path Occlusion Balloon (Cook Japan, Tokyo, Japan)

(c) Haber Ramp Catheter (Cook Japan, Tokyo, Japan)



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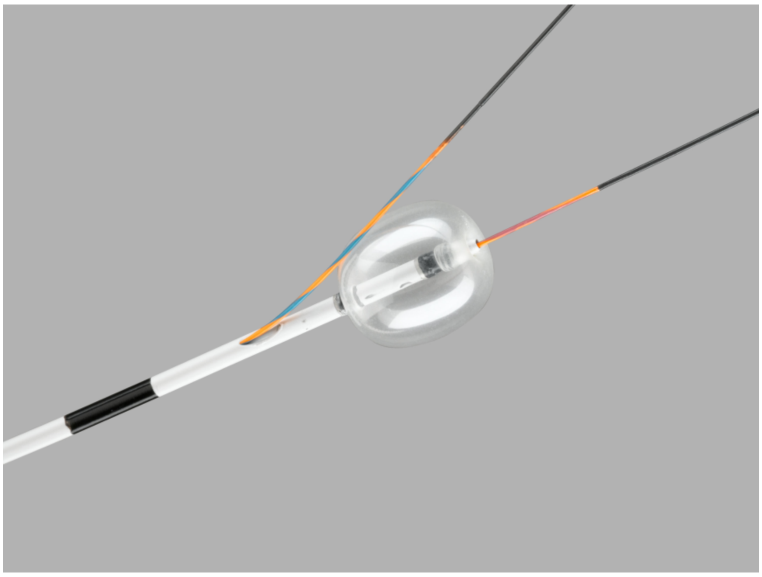

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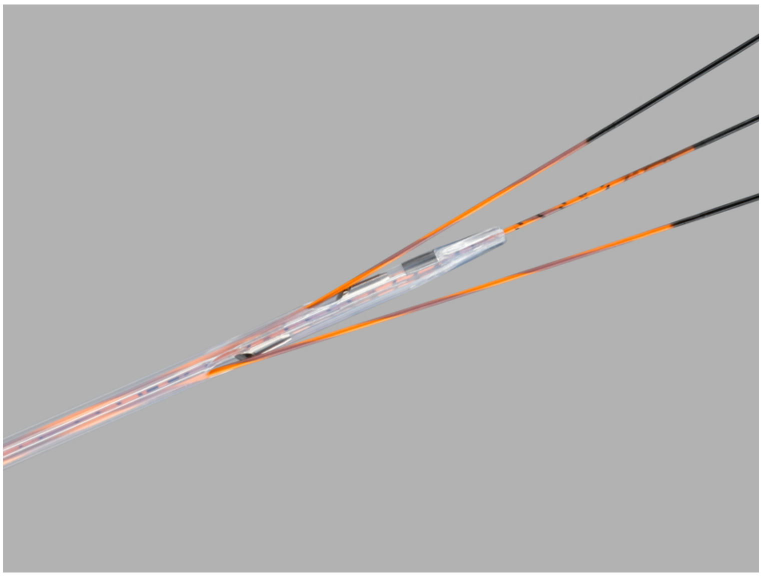
(c) 

Fig. 7

Biliary dilation catheter (Soehendra[®] biliary dilation catheter, SBDC-6, Cook Japan)

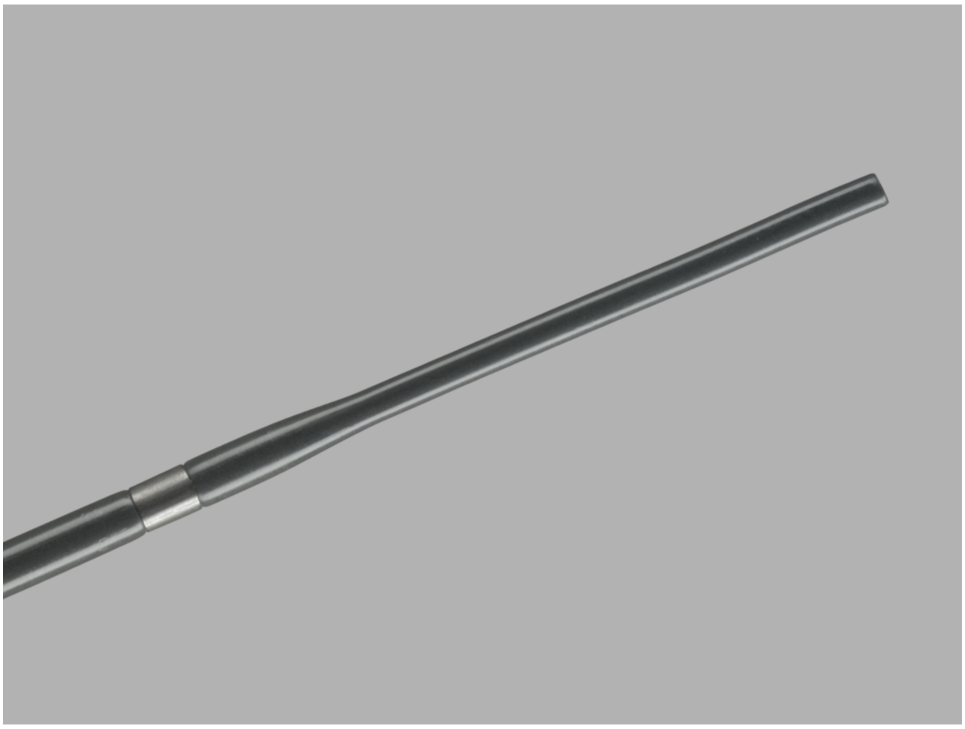


Fig. 8

Screw drill (Soehendra stent retriever, SSR-7, Cook Japan)

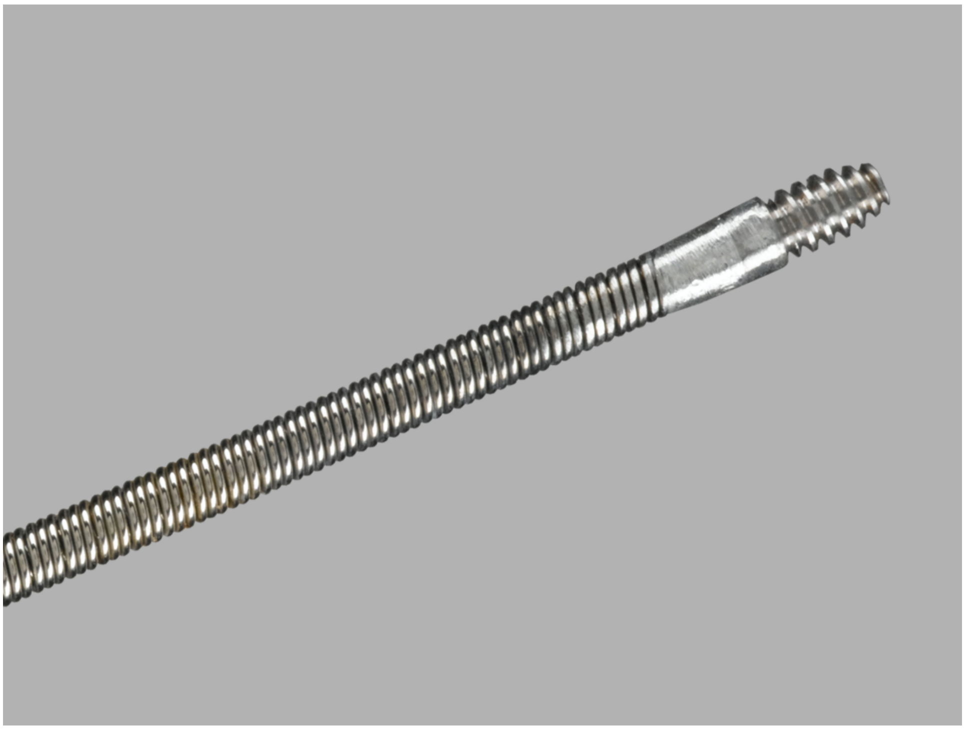


Fig. 9

Wire-guided diathermic dilator (6 Fr; Cysto-Gastro-Set, Endo-Flex GmbH, Germany)

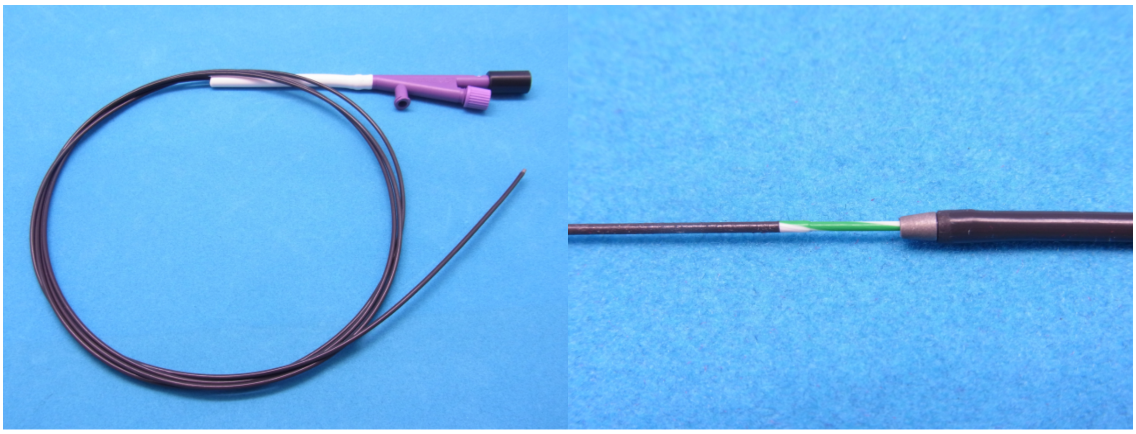


Fig. 10

Stent-in-stent technique

(a) A guidewire is placed at each of the targeted intrahepatic bile ducts.

(b) The first self-expandable metallic stent (SEMS) is inserted into the targeted intrahepatic bile duct along a guidewire.

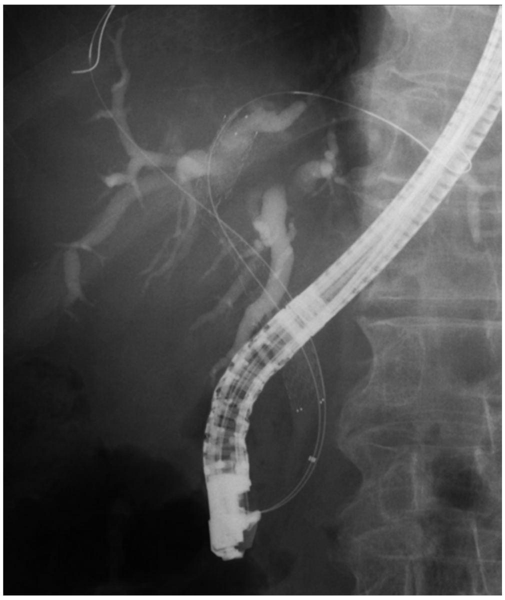
(c) The first SEMS is placed along the guidewire.

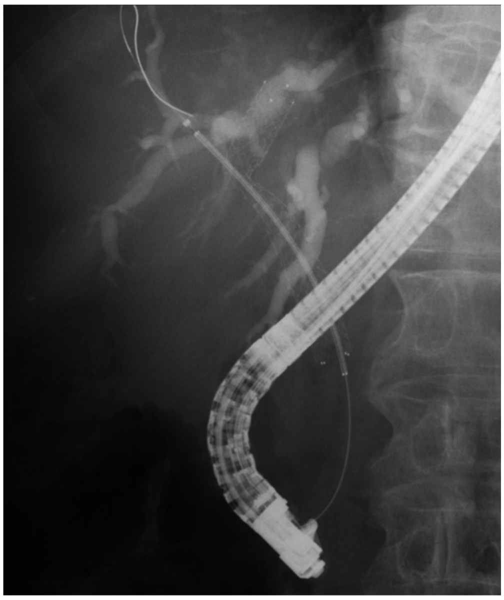
(d) The second SEMS is inserted into the contralateral intrahepatic bile duct along a guidewire that is advanced through the mesh of the first SEMS.

(e) Finally, the second SEMS is placed through the mesh of the first SEMS.

(f) Two SEMSs placed into the targeted intrahepatic bile ducts by the stent-in-stent technique.

(a)  (b) 

(c) 

(d) 

(e) 

(f) 

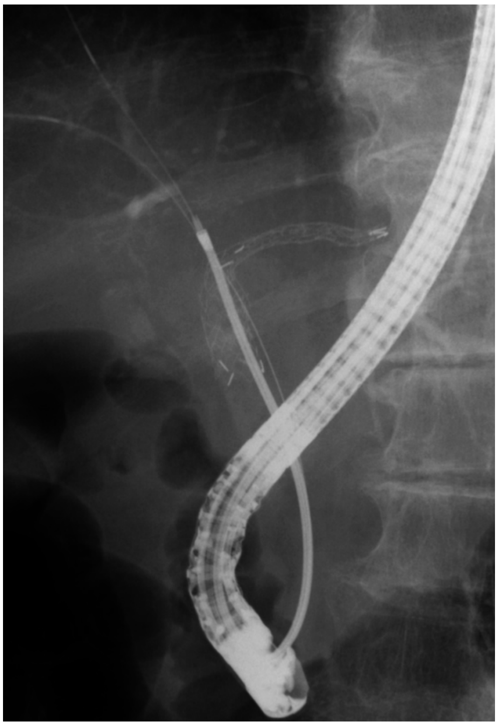
Fig. 11

Dilation technique of the mesh of the SEMS.

(a) Conventional dilation catheter cannot advanced through the mesh of the first SEMS.

(b,c) The Soehendra® stent retriever is used as a screw drill to break through the mesh of the first SEMS.

(a)



(b)

(c)

Fig. 12

Side-by-side placement technique

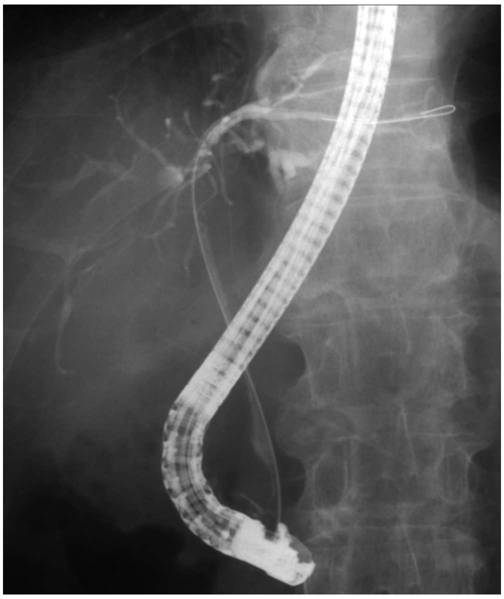
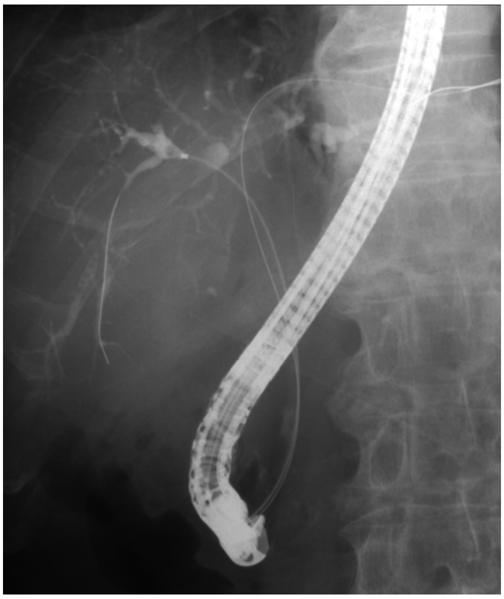
(a) The first guidewire is placed in the targeted intrahepatic bile duct.

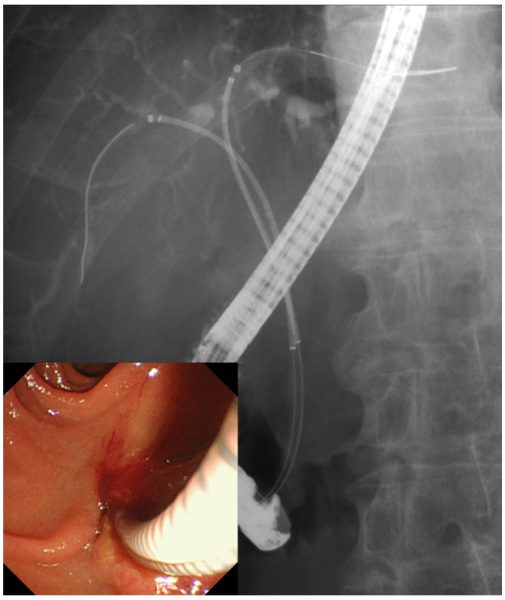
(b) The second guidewire is placed in the contralateral targeted intrahepatic bile duct.

(c) Two SEMSs are simultaneously advanced into the targeted intrahepatic bile ducts through an endoscopic channel (inset: endoscopic view of insertion of the Zilver635□ stent).

(d) Finally, the 2 SEMSs are placed simultaneously.

(e) Two SEMSs placed into the targeted intrahepatic bile ducts by the side-by-side technique.

(a)  (b) 


(c)


(d)


(e)

Fig. 13

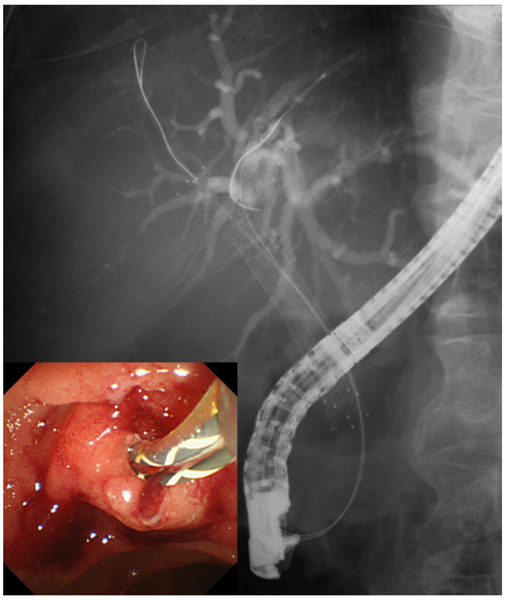
“Through The Mesh” (TTM) stent (Gadelius Medical K.K., Tokyo, Japan)

(a) A guidewire is placed at each of the 2 targeted intrahepatic bile ducts through the occluded SEMSs (inset: endoscopic view of the 2 guidewires).

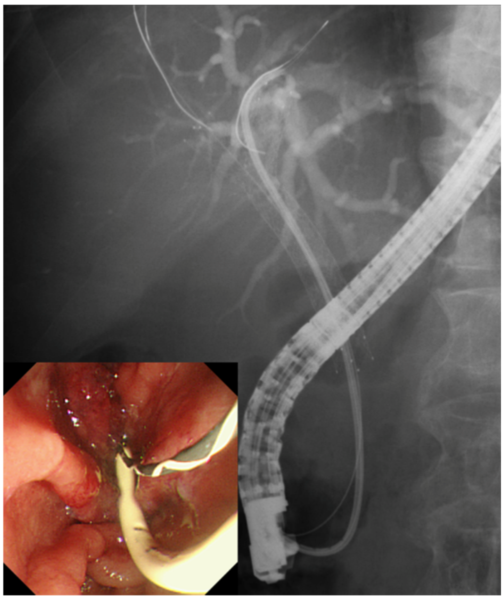
(b) The first TTM stent is advanced and placed along the first guidewire in the targeted intrahepatic bile duct through the first occluded SEMS (inset: endoscopic view of the TTM stent).

(c) The second TTM stent is advanced and placed along the second guidewire in the targeted intrahepatic bile duct through the second occluded SEMS (inset: endoscopic view of the 2 TTM stents).

(d) Two TTM stents placed in the targeted intrahepatic bile ducts.

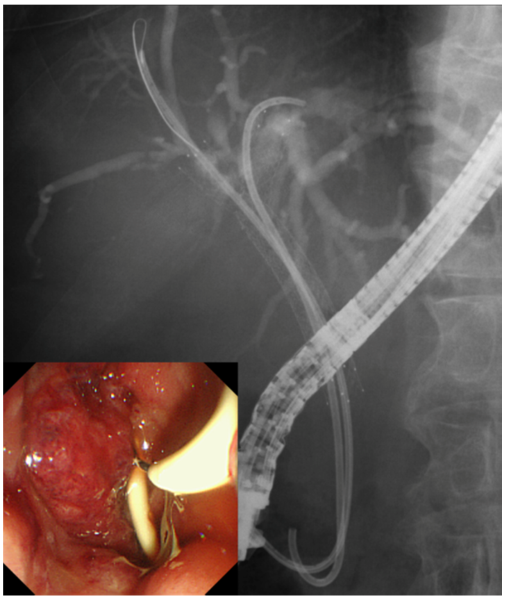


(a)

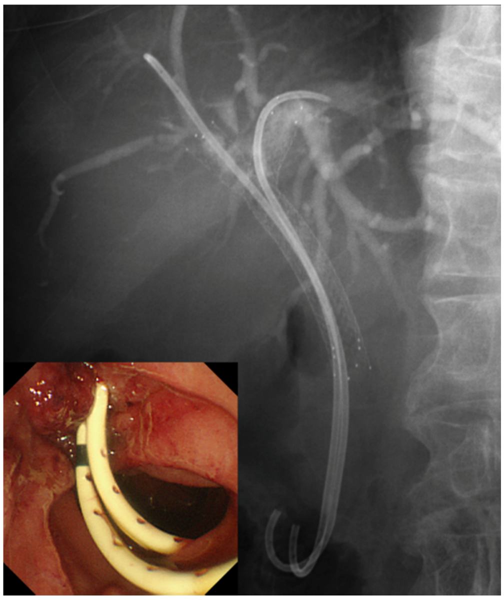


(b)

(c)



(d)



Video S1

The stiff-type guidewire should be used for insertion of the SEMS when a SEMS could be advanced through the stricture.

Video S2 (Stent-in-stent technique)

First, 2 guidewires were advanced through the malignant hilar biliary obstruction into the bilateral intrahepatic bile ducts. Subsequently, the first SEMS was inserted along 1 of the 2 guidewires. Finally, the second SEMS was inserted into the contralateral intrahepatic bile duct through the first SEMS.

Video S3 (Soehendra® stent retriever technique)

A Soehenrda® stent retriever was advanced along the guidewire, and turned clockwise to dilate the mesh of the first SEMS.

Video S4 (Side-by-side technique)

First, 2 guidewires were advanced through the malignant hilar biliary obstruction into the bilateral intrahepatic bile ducts. Subsequently, 2 SEMSs were simultaneously inserted along the 2 guidewires.

Video S5 (TTM stent placement)

Double TTM stents were advanced through the occluded double SEMSs.

Table 1-1 Comparison between plastic stent and self-expandable metallic stent for malignant hilar biliary obstruction

Author	Year	Journal	Reference number	Study design	No. of patients		Technical success	
					PS	SEMS	PS	SEMS
Wagner	1993	Endoscopy	1	RCT	9	11	88.9% (8/9)	100% (11/11)
Perdue	2008	GIE	3	Prospective cohort	28	34	84.8% (28/33)	97.1% (34/35)
Mukai	2013	JHBPSci	2	RCT	30	30	100% (30/30)	100% (30/30)

RCT, randomized controlled trial; ND, not described; PS, plastic stent; SEMS, self-expandable metallic stent

Table 1-2 Comparison between plastic stent and self-expandable metallic stent for malignant hilar biliary obstruction

Stent patency		Early stent dysfunction		Late stent dysfunction	
PS	SEMS	PS	SEMS	PS	SEMS
ND	ND	22.2% (2/9)	0	50% (3/6)	18.2% (2/11)
75% (30-day outcome)	93.9% (30-day outcome)	39.3% (11/28)	11.8% (4/34)	ND	ND
112 days (50% patency)	359 days (50% patency)	ND	ND	81% (6-months patency)	20% (6-months patency)

Table 1-3 Comparison between plastic stent and self-expandable metallic stent for malignant hilar biliary obstruction

No. of reintervention		Cost		
PS	SEMS	PS	SEMS	
2.4	0.4	6,867.52	4,992.40	Deutsch Mark
ND	ND	ND	ND	
1.8	0.63	2,154,190	1,121080	Japanese Yen

Table 2-1 Comparison between unilateral and bilateral biliary drainage for malignant hilar biliary obstruction

Author	Year	Journal	Reference number	Stent	Study design	No. of patients	Technical success
De Palma	2003	GIE	5	SEMS	Unilateral	79	88.6% (70/79)
					Bilateral (SBS)	78	76.9% (60/78)
Mukai	2013	JHBPSci	2	PS	Unilateral	15	100% (15/15)
					Bilateral	15	100% (15/15)
				SEMS	Unilateral	14	100% (14/14)
					Bilateral (SIS)	16	100% (16/16)

SEMS, self-expandable metallic stent; PS, plastic stent; SBS, side-by-side; SIS, stent-in-stent; ND, not described

Table 2-2 Comparison between unilateral and bilateral biliary drainage for malignant hilar biliary obstruction

Early complications	Late complications	Successful reinterventions
18.9% (14/79)	39.7% (27/68)	ND
26.9% (21/78)	39.1% (25/64)	ND
66.7% (10/15)	ND	100% (10/10)
73.3% (11/15)	ND	72.7% (8/11)
28.6% (4/14)	ND	100% (4/4)
50% (8/16)	ND	62.5% (5/8)

Table 3 Characteristics of the stent-in-stent and side-by-side

	Stent-in-stent	Side-by-side
Preferred countries	Japan and Korea	US and Europe
Advantages	Bigger SEMS diameter in the common bile duct	Smaller SEMS lumen in the common bile duct
Disadvantages	Technically challenging to insert the third SEMS	Very technically challenging to insert the third SEMS
	Occlusion in the first SEMS interferes with intervention	Concern of SEMS compressing right hepatic artery and portal vein
	Technically challenging to perform reintervention for occluded SEMSs	Technically challenging to perform reintervention for occluded SEMSs
	First SEMS requires a small diameter delivery system	Both SEMSs require a small diameter delivery system
	Second SEMS requires a small diameter delivery system	Requires a long SEMS to insert the distal end to the duodenum

SEMS, self-expandable metallic stent