

## Current status of endoscopic biliary drainage for unresectable malignant hilar biliary strictures

Hironari Kato, Koichiro Tsutsumi, Hirofumi Kawamoto, Hiroyuki Okada

Hironari Kato, Koichiro Tsutsumi, Hiroyuki Okada, Department of Gastroenterology and Hepatology, Okayama University Graduate School of Medicine, Dentistry, and Pharmaceutical Sciences, Kitaku, Okayama 700-8558, Japan

Hirofumi Kawamoto, Department of General Internal Medicine 2, Kawasaki Medical School, Kitaku, Okayama 701-0114, Japan

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**Correspondence to:** Hironari Kato, MD, Department of Gastroenterology and Hepatology, Okayama University Graduate School of Medicine, Dentistry, and Pharmaceutical Sciences, 2-5-1 Shikata-cho, Okayama 700-8558, Japan. [katou-h@cc.okayama-u.ac.jp](mailto:katou-h@cc.okayama-u.ac.jp)  
Telephone: +81-86-2357219  
Fax: +81-86-2255991

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### Abstract

The management of jaundice and cholangitis is

important for improving the prognosis and quality of life of patients with unresectable malignant hilar biliary strictures (UMHBS). In addition, effective chemotherapy, such as a combination of gemcitabine and cisplatin, requires the successful control of jaundice and cholangitis. However, endoscopic drainage for UMHBS is technical demanding, and continuing controversies exist in the selection of the most appropriate devices and techniques for stent deployment. Although metallic stents (MS) are superior to the usual plastic stents in terms of patency, an extensive comparison between MS and "inside stents", which are deployed above the sphincter of Oddi, is necessary. Which techniques are preferred remains as yet unresolved: for instance, whether to use a unilateral or bilateral drainage, or a stent-in-stent or side-by-side method for the deployment of bilateral MS, although a new cell design and thin delivery system for MS allowed us to accomplish successful deployments of bilateral MS. The development of techniques and devices for re-intervention after stent occlusion is also imperative. Further critical investigations of more effective devices and techniques, and increased randomized controlled trials are warranted to resolve these important issues.

**Key words:** Malignant hilar biliary obstruction; Biliary drainage; Metallic stents; Stent-in-stent; Side-by-side

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**Core tip:** The development of useful surgical devices, such as plastic or metallic stents, catheters and guidewires, has allowed us to achieve successful endoscopic drainage for unresectable malignant hilar biliary strictures (UMHBS), a technically demanding procedure. However, the most appropriate method of endoscopic drainage for UMHBS remains a contentious issue: for instance, whether to use a unilateral or bilateral drainage, or a stent-in-stent or side-by-side method for the deployment of bilateral metallic stents (MS) to accomplish successful deployments of bilateral MS.

Further critical investigations of more effective devices and techniques, and increased randomized controlled trials are warranted to resolve these important issues.

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## INTRODUCTION

The management of jaundice and cholangitis is important for improving the prognoses of patients with unresectable malignant hilar biliary strictures (UMHBS). In addition, effective chemotherapy, such as combination therapy with gemcitabine and cisplatin, for the treatment of cholangiocarcinoma requires the coincident effective management of both jaundice and cholangitis. Several methods exist for biliary drainage including: surgical drainage, percutaneous transhepatic drainage using ultrasound, and endoscopic transpapillary drainage. Of these, endoscopic transpapillary drainage has become the favoured method because of its minimal invasiveness while preserving the patient's quality of life. The development of useful surgical devices, such as plastic or metallic stents, catheters and guidewires, has allowed us to achieve successful endoscopic drainage for UMHBS, a technically demanding procedure. However, the most appropriate method of endoscopic drainage for UMHBS remains a contentious issue. In the present study, we review the current literature concerning endoscopic biliary drainage for patients with UMHBS.

## PLASTIC VS METALLIC STENTS, AND NEWLY DESIGNED PLASTIC STENTS

Several studies have highlighted the advantages of metallic stents (MS) compared with plastic stents (PS) (Table 1)<sup>[1-4]</sup>. According to these studies, the median patencies of MS for UMHBS were of longer duration than those of PS (3.4-12.0 mo vs 1.2-6.7 mo); in spite of this, the technical success rate for the deployment of MS was similar to that of PS (83.3%-100% vs 85.2%-100%). In a randomized controlled trial comparing PS and MS as reported by Mukai *et al*<sup>[4]</sup>, the 6-mo patency was significantly higher for the MS patient group than the PS group (81% vs 20%); the 50% patency period was 359 d for the MS group and 112 d for the PS group. In addition, the MS group had the advantage in terms of the number of re-interventions and the total cost of treatment compared with the PS group.

Reports concerning newly designed plastic stents



Figure 1 Multiple "inside stents" deployed above the sphincter of Oddi.

are also increasing. PS occlusion occurs as a result of biofilm formation and bacterial adherence to the wall of the stent following the reflux of duodenal juice into the PS and bile duct. To avoid this phenomenon, Pedersen *et al*<sup>[5]</sup> reported a method of deploying PS above the sphincter of Oddi; such stents were named "inside stents". Recently, several reports have emerged on the deployment of "inside stents" with attached nylon thread that is easily removed from the distal end of the stent for UMHBS (Figure 1). Ishiwatari *et al*<sup>[6]</sup> reported on 26 patients with UMHBS and successfully deployed "inside stents" showing a median patency period of 136 d. Kaneko *et al*<sup>[7]</sup> reported that the patency of "inside stents" was 190 d. Inatomi *et al*<sup>[8]</sup> compared the patency period of conventional PS, MS and "inside stents" and found the patency period of "inside stents" to be significantly longer than that of conventional PS (142 d vs 32 d,  $P = 0.04$ ), but was not significantly different to that of MS (142 d vs 150 d,  $P = 0.83$ ). Further investigation is necessary to determine whether the patency period of "inside stents" is comparable to that of MS. However, the absolute advantage of PS, including "inside stents", are enable to be removed easily compared to MS. We intend to deploy PS more frequently as a temporal drainage procedure if UMHBS are completely cured *via* chemotherapy or other effective treatments.

## UNILATERAL VS BILATERAL DRAINAGE

One of controversies regarding unilateral and bilateral drainage is the perceived technical difficulty of these procedures, with bilateral stent deployment generally thought to be more difficult than unilateral stent deployment. There have only been two randomized controlled trials (RCTs) on this issue to date. In one undertaken by De Palma *et al*<sup>[9]</sup> comparing the unilateral and bilateral deployment of PS, the technical and clinical successes of the bilateral deployment group were significantly lower than those of the unilateral deployment group (Table 2). On the other hand, in a

**Table 1 The results of comparison between metallic and plastic stents**

Ref.	No. of patients		Successful deployment % (n)		P value	Patency (mo)		P value
	MS	PS	MS	PS		MS	PS	
Sangchan <i>et al</i> <sup>[1]</sup>	54	54	83 (45/54)	85 (46/54)	0.792	3.4	1.2	> 0.001
Perdue <i>et al</i> <sup>[2]</sup>	35	33	97 (34/35)	85 (28/33)		NA	NA	
Liberato <i>et al</i> <sup>[3]</sup>	249	231	99 (246/249)	88 (204/231)	> 0.001	6.3	4.7	> 0.0001
Mukai <i>et al</i> <sup>[4]</sup>	30	30	100 (30/30)	100 (30/30)		12	3.7	0.0002

PS: Plastic stents; MS: Metallic stents; NA: Not available.

**Table 2 The results of comparison between unilateral and bilateral stent deployment**

Ref.	No. of patients		Successful deployment [% (n)]		P value	Successful drainage [% (n)]		P value	Stent patency (mo)		P value	Survival period (mo)		P value
	Unilateral	Bilateral	Unilateral	Bilateral		Unilateral	Bilateral		Unilateral	Bilateral		Unilateral	Bilateral	
	De Palma <i>et al</i> <sup>[9]</sup>	PS 79	PS 78	89 (70/79)	77 (60/78)	0.041	81 (64/79)	73 (57/78)	0.0482	NA	NA		4.7	4.7
Mukai <i>et al</i> <sup>[4]</sup>	PS 15	PS 15	100 (15/15)	100 (15/15)		100 (15/15)	100 (15/15)		3.4	3.7	0.746	NA	NA	
	MS 14	MS 16	100 (14/14)	100 (16/16)		100 (14/14)	100 (16/16)		12.1	9.8	0.3467	NA	NA	
Liberato <i>et al</i> <sup>[3]</sup>	PS 27	PS 40	NA	95 (38/40)		NA	95 (38/40)		4.0	4.2	0.0004	NA	NA	
	MS 33	MS 45	NA	93 (42/45)		NA	93 (42/45)		5.6	6.8	> 0.0001	NA	NA	
Chang <i>et al</i> <sup>[10]</sup>	PS or MS 69	PS or MS 29	NA	NA		NA	NA		NA	NA		2.7	7.5	> 0.01
Naitoh <i>et al</i> <sup>[11]</sup>	MS 17	MS 29	100 (17/17)	90 (26/29)		94 (16/17)	90 (25/26)		7.0	16.3	0.009	5.5	6.8	0.559
Iwano <i>et al</i> <sup>[12]</sup>	MS 63	MS 19	95 (60/63)	90 (17/19)		NA	NA		4.4	4.2	0.3220	5.7	6.1	0.4908

PS: Plastic stents; MS: Metallic stents; NA: Not available.

RCT by Mukai *et al*<sup>[4]</sup> comparing PS and MS, successful deployment was achieved in all patients undergoing the deployment of PS or MS, regardless of what type of deployment was employed. In other retrospective studies comparing the unilateral and bilateral deployment of MS, the technical success rate was similar for these two groups<sup>[3,10-12]</sup>. However, evidences of no obvious differences on the difficulty between unilateral and bilateral deployment are not still enough. Further RCTs at high-volume centers are warranted.

Another matter in question is whether bilateral drainage is superior to unilateral drainage in the management of jaundice and cholangitis, which relates to stent patency and survival periods. There are several studies showing no difference between unilateral and bilateral drainage on stent patency and survival periods, but several studies highlight an opposite stance<sup>[3,4,9-12]</sup>. Bilateral drainage, as the initial drainage, may not always be necessary for patients with UMHS for the management of jaundice cholangitis. However, the function of the drained segment of the liver will diminish as the tumor gradually occupies the drain segment, which impacts on patient mortality. Vienne *et al*<sup>[13]</sup> analyzed the outcomes of drainage effectiveness during endoscopic stenting for malignant hilar biliary strictures. The main significant factor associated with drainage effectiveness was a liver volume drainage

of > 50% (odds ratio 4.5,  $P = 0.001$ ), which was associated with longer survival (119 d vs 59 d,  $P = 0.005$ ). In addition, Mukai *et al*<sup>[4]</sup> reported that around 50% of patients required bilateral drainage to reduce jaundice and cholangitis, but instead recommended unilateral drainage. Miura *et al*<sup>[14]</sup> reported the results of preoperative biliary drainage for malignant hilar biliary stricture. Thirty-one of 122 patients (25.4%) initially underwent multiple biliary drainage; however 69 of 122 (56.6%) required multiple biliary drainage by the time of the operation. They concluded that patients with Bismuth-II, Bismuth-IIIa, and Bismuth-IV were at high risk for multiple biliary drainage. These results suggest that effective drainage of a malignant hilar biliary stricture frequently requires bilateral or multiple drainage.

Uchida *et al*<sup>[15]</sup> reported on the relationship between the number of deployed MS, the effectiveness of chemotherapy, the patency period of MS, and the survival period. Patients were divided into two groups, one in which four or three MS were deployed (4- or 3-branched group), or a group in which two or one MS was deployed (2- or 1-branched group). Although neither patency period nor survival time exhibited significant differences between the two groups, among the patients achieving complete response, partial response, or stable disease defined by World Health

**Table 3** The results of comparison between stent-in stent and side-by-side method for deployment of bilateral metallic stents

Ref.	Method for deployment	No. of patients	Successful deployment % (n)	Successful drainage % (n)	Occlusion % (n)	Stent patency (mo)
Kawamoto <i>et al</i> <sup>[16]</sup>	SIS	9	100 (9/9)	100 (9/9)	33 (3/9)	NA
Lee <i>et al</i> <sup>[17]</sup>	SIS	10	80 (8/10)	100 (8/8)	25 (2/8)	7.2
Park <i>et al</i> <sup>[18]</sup>	SIS	35	94 (33/35)	100 (33/33)	6 (2/33)	5
Kim <i>et al</i> <sup>[19]</sup>	SIS	34	85 (29/34)	100 (29/29)	31 (9/29)	6.2
Chahal <i>et al</i> <sup>[20]</sup>	SIS	21	100 (21/21)	NA	38 (8/21)	6.3
Kogure <i>et al</i> <sup>[21]</sup>	SIS	12	100 (12/12)	92 (11/12)	50 (6/12)	6.7
Hwang <i>et al</i> <sup>[22]</sup>	SIS	30	87 (26/30)	100 (26/26)	39 (10/26)	4.7
Lee <i>et al</i> <sup>[23]</sup>	SIS	84	95 (80/84)	93 (78/84)	31 (24/78)	7.9
Dumas <i>et al</i> <sup>[24]</sup>	SBS	45	73 (33/45)	100 (33/33)	3 (1/33)	NA
Cheng <i>et al</i> <sup>[25]</sup>	SBS	36	97 (35/36)	NA	31 (11/35)	5.6
Chennat <i>et al</i> <sup>[26]</sup>	SBS	16	100 (16/16)	75 (11/16)	25 (4/16)	4.3
Lee <i>et al</i> <sup>[27]</sup>	SBS	44	91 (40/44)	98 (39/40)	45 (18/40)	5.2

SIS: Stent-in-stent; SBS: Side-by-side; NA: Not available.



Figure 2 Multiple metallic stents deployed by the stent-in-stent method.



Figure 3 Multiple metallic stents deployed by the side-by-side method.

Organization during chemotherapy, the patency period and survival time of the 4- or 3-branched group were significantly longer than those of the 2- or 1-branched group. They concluded that the deployment of multiple MS prevented biliary infection and deterioration of liver function, which resulted in a long duration of stent patency and the continuation of stable chemotherapy in the disease control group. Consecutive and effective chemotherapy requires the preservation of the functional volume of the liver, and unilateral drainage is less effective than bilateral drainage for this perspective.

## STENT-IN-STENT VS SIDE-BY-SIDE METHODS

Two methods exist for the endoscopic deployment of bilateral MS for UMHS: stent-in-stent (SIS; Figure 2) and side-by-side (SBS; Figure 3) methods. Although several reports have been published on each method, no obvious difference was noted (Table 3). The technical success rate is 80%-100% for SIS<sup>[16-23]</sup> and 73.3%-100% for SBS<sup>[24-27]</sup>, with the patency periods being 140-238 d and 130-169 d, respectively. There are only two retrospective reports on a comparison between

SIS and SBS. The rate of successful deployment did not differ between SIS and SBS in both reports but several uncertainties existed surrounding complications and the patency period of these techniques. Naitoh *et al*<sup>[28]</sup> noted the incidence of complications was significantly higher (44% vs 13%,  $P = 0.016$ ), and the cumulative stent patency was significantly longer, ( $P = 0.047$ ) in the SBS, compared to the SIS, group. The median patency period was 469 in the SBS group and 181 d in the SIS group. On the other hand, no differences in complications rates and the patency period between SIS and SBS were reported by Kim *et al*<sup>[29]</sup>. A prospective randomized control trial, using the same type and diameter of MS, is needed for the evaluation of differences between SIS and SBS methods for the deployment of bilateral MS.

## PROGRESS IN METALLIC STENTS FOR BILATERAL DEPLOYMENT

For the reliable and successful deployment of bilateral MS, several new MS designs have been described. The most difficult part for the successful deployment of a bilateral MS by SIS is the deployment of the second MS.

**Table 4** The results of re-intervention after stent occlusion in the patients undergoing deployment of bilateral metallic stents

Ref.	Method for deployment	No. of patients	Occlusion % ( <i>n</i> )	Endoscopic re-intervention % ( <i>n</i> )	Bilateral or multiple drainage at endoscopic re-intervention % ( <i>n</i> )
Naitoh <i>et al</i> <sup>[28]</sup>	SIS	24	42 (10/24)	90 (9/10)	NA
	SBS	25	20 (5/25)	100 (5/5)	NA
Lee <i>et al</i> <sup>[27]</sup>	SBS	40	45 (18/40)	92 (12/13) <sup>1</sup>	50 (6/12)
Fujii <i>et al</i> <sup>[33]</sup>	SIS	55	55 (30/55)	100 (30/30)	67 (20/30)
Lee <i>et al</i> <sup>[23]</sup>	SIS	78	31 (24/78)	96 (23/24)	83 (20/24)
Law <i>et al</i> <sup>[31]</sup>	SBS	17	53 (9/17)	75 (6/8)	75 (6/8)
	SIS	7	43 (3/7)	100 (3/3)	100 (3/3)

<sup>1</sup>Five patients with comorbidity underwent initial percutaneous intervention. SIS: Stent-in-stent; SBS: Side-by-side; NA: Not available.

This is because, in addition to the stricture, we have to negotiate the mesh of the first metallic stent when placing the second stent. Therefore, the clever cell design of a MS is crucial for the successful deployment of a bilateral MS by SIS. A newly designed MS with a large, open-celled wire mesh for the deployment of a bilateral MS has been reported in several studies<sup>[17,19,21]</sup>, making the deployment of a bilateral MS for UMHS a more feasible procedure. Lee *et al*<sup>[23]</sup> reported on the feasibility and efficacy of a newly designed, closed-cell and cross-wired MS: the technical success rate of endoscopic bilateral SIS deployment was 95.2%, and the median patency period was 238 d.

The difficulty of deployment of a bilateral MS by SBS is also related to the insertion of the second MS along the first MS. This is because we have to advance the second MS against the resistance of the first, already expanded MS. Therefore, although a delivery stuck in the mesh of the initially deployed MS sometimes results in an unsuccessful deployment, a thin delivery overcomes this issue. Kawakubo *et al*<sup>[30]</sup> reported that 6-Fr delivery systems could facilitate a single-step, simultaneous, SBS placement through the accessory channel of the duodenoscope. The rate of successful deployment was 84.6%, and the median procedure time was 25 min. Law *et al*<sup>[31]</sup> reported that a 6-Fr delivery MS were used for the deployment of a bilateral MS in 17 patients by SBS and seven patients by SIS. The rate of successful deployment was 100% for both groups, although SBS was attempted prior to SIS in four of seven patients in the SIS group. The 6-Fr delivery can pass through the mesh of the MS more easily, which may facilitate the deployment of a bilateral MS by not only the SBS, but also the SIS method.

## RE-INTERVENTION AFTER STENT OCCLUSION IN PATIENTS UNDERGOING BILATERAL DEPLOYMENT OF METALLIC STENTS

Biliary tract cancer is the cause of most UMHS, and effective chemotherapeutic agents, such as a gemcitabine plus cisplatin combination, have been described in several reports on the treatment of

unresectable biliary tract cancer. Valle *et al*<sup>[32]</sup> reported that the median overall survival was 11.7 mo among 204 patients receiving a gemcitabine plus cisplatin combination, which is longer than the stent patency period already reported. Therefore, stent occlusion that causes jaundice and cholangitis will often happen in the course of chemotherapy, and re-intervention after stent occlusion plays an important role in continuing effective chemotherapy, especially in patients with the deployment of a bilateral MS whose re-intervention is thought to be difficult.

The results of re-intervention after stent occlusion in patients with a bilateral MS deployment are shown in Table 4. Few reports have analyzed the results of re-intervention in any great detail. Fujii *et al*<sup>[33]</sup> deployed multiple MS using a SIS method in 55 patients with UMHS. Of these patients, 30 developed a MS occlusion. In twenty of the 30 patients, multiple PS deployments were attempted, with successful PS deployment and clinical success achieved in all 20 patients. Lee *et al*<sup>[23]</sup> reported on the success rate of bilateral stent deployment as a re-intervention procedure for patients undergoing the deployment of bilateral MS using a SIS method. Of 24 patients with a MS occlusion in which bilateral stent deployment was attempted, twenty patients achieved a successful deployment of bilateral stents. The clinical success of the deployment of bilateral MS was 79.2% (19/24). Law *et al*<sup>[31]</sup> reported on re-intervention after stent occlusion for 11 patients undergoing the deployment of bilateral MS using an SIS or SBS method. Successful re-intervention was defined as the ability to access and perform interventions in both the right and left hepatic ducts, and this was accomplished in 9 out of 11 patients (3/3 SIS, 6/8 SBS). Re-intervention after stent occlusion will be an important issue to resolve in coming years, with continued improvements seen in the prognosis of patients with UMHS due to effective chemotherapy.

## CONCLUSION

In the present review, we have described the current status of endoscopic biliary drainage in patients with UMHS. Endoscopic biliary drainage for UMHS is still technically demanding, with many unresolved issues,

including the choice of PS or MS, the choice of unilateral or bilateral drainage, and the use of either SIS or SBS deployment of bilateral MS. The development of new devices and techniques for stent deployment, and further randomized controlled trials are warranted to resolve these matters in question. The development of new methods of re-intervention after stent occlusion is also important to manage patient jaundice and cholangitis over a longer time period as continued advances in chemotherapy prolong the survival of patients with UMHBS.

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