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EDITORIAL

Management of an occluded biliary metallic stent

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Abstract

In patients with a malignant biliary obstruction who require biliary drainage, a self-expandable metallic stent (SEMS) provides longer patency duration than a plastic stent (PS). Nevertheless, a stent occlusion by tumor ingrowth, tumor overgrowth and biliary sludge may develop. There are several methods to manage occluded SEMS. Endoscopic management is the preferred treatment, whereas percutaneous intervention is an alternative approach. Endoscopic treatment involves mechanical cleaning with a balloon and a second stent insertion as stent-in-stent with either PS or SEMS. Technical feasibility, patient survival and cost-effectiveness are important factors that determine the method of re-drainage and stent selection.

Key words: Occluded biliary metallic stent; Re-drainage; Cost effectiveness

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INTRODUCTION

Many studies have shown that the outcomes of palliative endoscopic biliary drainage in patients with malignant biliary obstruction were similar to those with surgical bypass with regards to technical success and functional biliary decompression[1-5]. However, an endoscopic approach provided lower rates of procedure-related mortality and complications, and shorter hospital stay[4,5]. Currently, there are two types of stent that can be selected for endoscopic palliation; plastic stent (PS) and self expandable metallic stent (SEMS). Although a plastic stent is less expensive than SEMS, it provides shorter patency duration due to its smaller diameter[6-12]. For the cost effectiveness purpose, many studies demonstrated that endoscopic placement of SEMS is more appropriate in a patient who may survive longer than 3 mo[7,8,10,11]. In contrast, PS insertion is recommended in a patient with shorter survival[7,8,10,11]. Although SEMS can provide longer patency duration, there are certain factors that may cause recurrent biliary obstruction after the insertion of SEMS[13]. Tumor ingrowth, tumor overgrowth, stent migration and stent occlusion by sludge or debris can occur. The appropriate management of occluded SEMS is still unclear and controversial. We herein present a review on the management of SEMS occlusion based on our own experience and previous reports of this context.

CAUSES OF BILIARY METALLIC STENT OCCLUSION

The occlusion of SEMS is a major late adverse event of SEMS insertion. Many retrospective series have demonstrated that it developed in 5%-40% of patients who underwent an endoscopic palliative treatment with SEMS[14-19]. The causes of occluded SEMS include tumor ingrowth, overgrowth, sludge/debris formation and stent migration (Table 1). The most common cause of SEMS occlusion is tumor ingrowth, which accounted for 60%-90% of all SEMS occlusion[14-19]. This complication is more common in uncovered SEMS, which has an open-mesh, resulting in tissue growing into the stent easily[20,21]. To overcome the problem of tumor ingrowth, a covered stent has been introduced, a membrane made of polyurethane and polyethylene designed to cover the mesh, and therefore tissue and tumor cannot grow into the SEMS lumen. As a trade off, a covered SEMS contains a higher risk for migration because of a smaller degree of biliary tissue embedment.

Many studies have shown that one fourth of all SEMS occlusions resulted from tumor overgrowth[14-19]. Because tumor can grow and invade over both ends of the stent, covered and uncovered SEMSs have an equal chance to develop tumor overgrowth. Hypothetically, a longer SEMS may possibly decrease the risk for tumor overgrowth. However, no studies have been done to confirm this hypothesis.

Colonization or infection by bacteria can create materials that occlude a stent, such as bacterial clump, bile glycoprotein mucin and sludge[22]. Thus, recurrent cholangitis is an important risk developing biliary sludge. This process usually develops after PS insertion; unfortunately, SEMS placement is not exempt. In addition, duodenobiliary reflux was reported as another factor for PS occlusion[23]. Perhaps the larger diameter of SEMS may increase the risk for stent blocking from more duodenobiliary reflux.

To date, the standard approaches for SEMS occlusion are percutaneous biliary drainage, endoscopic cleaning with balloon, and endoscopic re-stenting (PS, uncovered SEMS and covered SEMS). The techniques, results and complications are different among those approaches.

Table 1 The causes of occluded self-expandable metallic stent

	Tham *et al* 1998	Bueno *et al* 2003	Togawa *et al* 2008	Rogart *et al* 2008	Ridtitid *et al* 2010	Cho *et al* 2011
No. of patients	152	592	95	90	154	583
No. of patients with SEMS occlu-sion (uncovered/covered)	44 (44/0)	34 (34/0)	40 (40/0)	27 (23/4)	32 (22/10)	77 (30/47)
Tumor ingrowth (%)	28 (63.6)	20 (58.8)	36 (90)	19 (70.4)	25 (78.1)	53 (68.8)
Tumor overgrowth (%)	3 (6.8)	9 (26.5)	3 (7.5)	3 (11.1)	3 (9.4)	9 (11.7)
Sludge/debris (%)	8 (18.2)	5 (14.7)	1 (2.5)	5 (18.5)	5[1] (15.6)	8 (10.4)
Others	Hyper-plasia 3 Unde-fined 2	-	-	-	Migration 4	Compres-sion/blood clot/mi-gration 7

[1]With tumor overgrowth.

ENDOSCOPIC MANAGEMENT

Endoscopic treatment is widely accepted as the primary mode of managing occluded SEMS. Currently, there are three endoscopic techniques that provide re-drainage for SEMS occlusion: (1) mechanical cleaning with a balloon; (2) PS insertion; and (3) SEMS insertion[14-19].

Placing covered SEMS, uncovered SEMS or PS?

Both SEMS and PS can provide immediate biliary relief in a patient with SEMS occlusion. Stent selection is usually determined by the performing endoscopist. Level of biliary obstruction and patient's survival are important factors for stent selection. Our previous study demonstrated a much shorter stent patency time (50%) in patients with hilar block when compared to non-hilar block[24]. In addition, a patient with advanced liver metastasis carries a significant shorter survival than a patient with early stage of disease[9]. Thus, before restenting of the SEMS occlusion, liver metastasis status needs to be evaluated. For instance, placing only a PS is justified in a patient with pancreatic head cancer with advanced liver metastasis, whereas a patient with low grade hilar cholangiocarcinoma (Bismuth Ⅱ) without liver spread deserves SEMS as a second stent.

Moreover, for a country with financial constraints, cost-effectiveness should be the main concern since there is a significant difference in the cost between PS and SEMS. Therefore, the balance between cost and clinical concern, including stent patency and patient survival, has to be judged individually in every patient according to local expertise and the economic level of each country.

Stent patency: There are several studies that used additional stent placement as stent-in-stent for a re-drainage of SEMS occlusion[14-19]. The patency times of a second stent are shown in Table 2. A study by Tham *et al*[14] demonstrated that there was no significant difference in the duration of second stent patency after placement of either SEMS or PS (75 d; 95% CI 43-107 *vs* 90 d; 95% CI 71-109). Some studies demonstrated that mechanical cleaning with a balloon was less effective than placing the second stent[15,17,18]. In addition, our recent study reported that all patients with stent occlusion by debris were also found to have a concomitant tumor ingrowth. At first, mechanical cleaning was performed but it was insufficient to maintain stent patency and eventually all of our patients required a placement of second stent to maintain patency[18].

A covered SEMS provides a more durable patency

Table 2 The patency time of second drainage and patient survival

	Tham *et al* 1998	Bueno *et al* 2003	Togawa *et al* 2008	Rogart *et al* 2008	Ridtitid *et al* 2010	Cho *et al* 2011
No. of SEMS occlusion	44	34	40	27	32	77
Type of initial SEMS (patients)						
Covered SEMS	0	0	0	4	10	47
Uncovered SEMS	44	34	40	23	22	30
Initial stent patency (d): total				118[a]	60-150[a]	
Covered SEMS	NA	NA	NA	NA	NA	189
Uncovered SEMS	102	125	153	NA	NA	132
Type of second drainage (patients)						
Covered SEMS	0	0	26	9	4	40
Uncovered SEMS	19	4	7	5	10	26
Plastic stent	20	24	7	11	11	11
Mechanical cleaning	5	6	0	2	0	0
PTBD	0	0	0	0	7	0
Second drainage patency (median, d)						
Covered SEMS	NA	NA	220[e]	214[b]	NA	138[c]
Uncovered SEMS	75	192	141[e]	54	100	109
Plastic stent	90	90	58[e]	66	60	88
Mechanical cleaning	34	21	NA	43	NA	NA
PTBD	NA	NA	NA	NA	75	NA
Survival (d)						
Covered SEMS	NA	NA	NA	227	NA	440[d]
Uncovered SEMS	70	NA	NA	389	230[f]	243
Plastic stent	98	NA	NA	188	130	296
Mechanical cleaning	34	NA	NA	194	NA	NA
PTBD	NA	NA	NA	NA	150	NA

NA: Not available; [a]Overall initial stent patency (d); [b]$P < 0.05$ for SEMS *vs* PS and mechanical cleaning; [c]$P < 0.05$ for covered SEMS *vs* PS; [d]$P < 0.001$ for covered SEMS *vs* uncovered SEMS; [e]Mean patency time (d); [f]$P < 0.05$ for SEMS *vs* PS and PTBD. SEMS: Self-expandable metallic stent; PTBD: Percutaneous transhepatic biliary drainage; PS: Plastic stent.

than an uncovered SEMS as the first stent[25]. A recent meta-analysis reported that a covered SEMS provided a longer patency than an uncovered SEMS when inserted as the first stent in patients with unresectable distal malignant biliary obstruction (weight mean difference 60.56 d; 95% CI 25.96-95.17)[25]. In addition, tumor ingrowth was likely to occur more in patients with uncovered SEMS [relative risk (RR) 2.03; 95% CI: 0.08-0.67; P = 0.01], whereas stent migration, tumor overgrowth and sludge formation were more likely to develop in patients with covered SEMS (RR 8.11; 95% CI: 1.47-44.76; P = 0.02; RR: 2.02; 95% CI: 1.08-3.78; P = 0.03; RR: 2.89; 95% CI: 1.27-6.55; P = 0.01, respectively)[25]. Hypothetically, covered SEMS should also provide a longer patency duration when inserted as a second stent after the first SEMS becomes occluded[16,19]. This hypothesis has been supported by two reports[16,19]. Togawa *et al*[16] placed a covered stent in patients with occluded uncovered SEMS and showed that the cumulative duration of the covered SEMS patency was significantly longer than the uncovered one (mean second stent patency = 219.6 d; range 19-1972 d *vs* 141.3 d; range 6-1949 d; P = 0.04). Likewise, Cho *et al*[19] reported a similar outcome (median second stent patency of covered SEMS *vs* uncovered SEMS = 360 d *vs* 221 d; P = 0.002).

The level of biliary obstruction can influence the patency duration of the second stent. Two studies supported that the level of biliary obstruction near the hepatic hilum influenced the shorter duration of a second stent patency[15,18]. Bueno *et al*[15] demonstrated that the patency time was longer for a stent inserted as stent-in-stent for distal biliary stricture as opposed to a second stent inserted for proximal biliary strictures. They reported that the median second stent patency in distal biliary stricture was longer than hilar stricture (128 d; range 11-393 d *vs* 61 d; range 15-263 d). Needless to say, the advantage of the second SEMS for occluded stent at the hepatic hilum is still suboptimal and a better SEMS designed for this purpose is required.

Patient survival: The median survival times of patients with a second intervention are shown in Table 2. The majority of studies demonstrated that that the survival of patients who had SEMS as a second stent was longer than others. There were some limitations from retrospective study designs and this finding may resulted in selection bias. A study by Tham *et al*[14] reported that patients' survival has no influence on stent selection since both SEMS and PS provided similar duration of stent patency. It speculated that patients' survival used for calculation of stent patency in that study was relatively short since it has been shown that the median survival times of the SEMS group and the PS group were only 70 d and 98 d, respectively[14]. In contrast, Rogart *et al*[17] who had patients with longer survival (285 d for SEMS group and 188 d for PS group, respectively) demonstrated the longer patency duration of SEMS than PS (172 d *vs* 66 d, respectively). Similar results have been confirmed by other studies[16,18].

Cost-effectiveness: The best parameter to determine the cost effectiveness of different approaches is the incremental cost effectiveness ratio (ICER) that requires the calculation of stent costs, number of endoscopic retrograde cholangiopancreatography (ERCP) sessions and the cost for one ERCP. The selected intervention can be determined as cost effective if its ICER is less expensive than having an additional procedure. The results of the three studies on ICER of SEMS *vs* ICER of PS are shown in Table 3[14,17,18,26]. We assumed that the SEMS costs in different countries are comparable. The ICERs from those three studies ranged from US $ 1518 to US $ 7015 as a result from the differences in ERCP-procedure cost and number of ERCP sessions. The ERCP-procedure cost is dependent on the cost of living and healthcare reimbursement in different countries. Thus, we can state that SEMS placement for a patient who will survive long enough to require the second stent is cost-effective when the cost of ERCP is at least higher than US $ 1518; otherwise PS placement is more cost-effective.

Table 3 Incremental cost-effectiveness ratio analysis of a second self-expandable metallic stent *vs* plastic stent

Studies	*n*	Approximate cost of each procedure (US $)		Mean number of ERCPs		ICER (US $)
		PS	SEMS	PS	SEMS	
Tham *et al*[14] 1998	38	1044	1956	1.44	1.31	7015
Rogart *et al*[17] 2008	27	2289	3807	1.27	0.89	1518
Ridtitid *et al*[18] 2010	32	460	1500	2	2.45	2311

ICER: Incremental cost-effectiveness ratio; ERCP: Endoscopic retrograde cholangiopancreatography; SEMS: Self-expandable metallic stent; PS: Plastic stent.

Mechanical cleaning with balloon

Generally, mechanical cleaning is performed by flushing with water or saline solution and sludge/debris extraction can succeed with an inflated balloon sweeping through the stent. Hypothetically, this method is definitely correct for an occlusion by only sludge or debris. Three studies compared this procedure to a second stent insertion as stent-in-stent after SEMS occlusion[14,15,17] (shown in Table 2). Bueno *et al*[15] suggested that mechanical cleaning was less effective than SEMS and PS stent insertions (median duration of stent patency after re-intervention 21 d; range 3-263 d, 192 d; range 81-257 d, and 90 d; range 11-393 d, respectively). A similar outcome has also been shown by Rogart *et al*[17] (median days to re-intervention 43 d, 172 d and 66 d; $P < 0.05$ respectively). Although, Tham *et al*[14] demonstrated no significant differences in the durations of the biliary patency among the three methods, there was a trend toward lower patency duration in a group who underwent mechanical cleaning when compared with groups who underwent SEMS and PS insertions (median duration of second patency 34 d; 95% CI: 30-38 d, 75 d; 95% CI: 43-107 d, 90 d; 95% CI: 71-109 d, respectively).

PERCUTANEOUS MANAGEMENT

Percutaneous transhepatic biliary drainage (PTBD) is effective and appropriate for both tumor ingrowth and overgrowth. It is an alternative intervention after failed endoscopic management, particularly in a patient with post bilateral SEMS insertion for hilar block who has an inaccessible desired intrahepatic duct *via* endoscopy. However, the main disadvantages of PTBD are pain, inconvenience and volume/electrolyte loss[18,27]. Our previous study reported that PTBD for re-drainage after SEMS occlusion provided no difference in patency time when compared with PS insertion (75 d; 95% CI: 36-113 d *vs* 60 d; 95% CI: 51-68 d; $P > 0.05$)[18]. However, its patency duration was significantly shorter than the second SEMS (75 d; 95% CI: 36-113 d *vs* 100 d; 95% CI: 72-127 d; $P < 0.05$)[18]. In addition, we found that the main cause of PTBD occlusion was tube re-clogging by debris. Alternatively, a percutaneous approach can provide internal drainage by placing SEMS either directly or under a rendezvous technique[28].

CONCLUSION

In summary, the current management of occluded SEMS includes a second stent insertion (covered SEMS, uncovered SEMS or PS), mechanical cleaning and percutaneous drainage. Mechanical cleaning with a balloon is less effective in a patient with concomitant tumor ingrowth. Endoscopic insertion of SEMS or PS is equally effective for SEMS occlusion in a patient with short survival. In a patient with longer survival and where the cost of ERCP in that institution is higher than US $ 1518, another SEMS insertion is preferred. PTBD is an alternative method when an endoscopic approach is impossible.

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