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BRIEF ARTICLE

Endoscopic management of occluded metal biliary stents: Metal *versus* 10F plastic stents

Won Jae Yoon, Ji Kon Ryu, Jung Won Lee, Dong-Won Ahn, Yong-Tae Kim, Yong Bum Yoon, Sang Myung Woo, Woo Jin Lee

Won Jae Yoon, Ji Kon Ryu, Jung Won Lee, Dong-Won Ahn, Yong-Tae Kim, Yong Bum Yoon, Division of Gastroenterology, Department of Internal Medicine, Seoul National University College of Medicine, 101 Daehang-ro, Jongno-gu, Seoul, 110-744, South Korea
Sang Myung Woo, Woo Jin Lee, Center for Liver Cancer, National Cancer Center, 323 Ilsan-ro, Ilsandong-gu, Goyang-si, Gyeonggi-do, 410-769, South Korea
Author contributions: Yoon WJ and Ryu JK designed the research; Yoon WJ, Lee JW and Ahn DW performed research; Yoon WJ and Ryu JK analyzed the data; Yoon WJ, Yoon YB, Ryu JK, Kim YT, Woo SM and Lee WJ contributed to preparing the manuscript, editing and final approval.
Correspondence to: Ji Kon Ryu, MD, Associate Professor, Division of Gastroenterology, Department of Internal Medicine, Seoul National University College of Medicine, 101 Daehang-ro, Jongno-gu, Seoul, 110-744, South Korea. jkryu@snu.ac.kr
Telephone: +82-2-20721962 Fax: +82-2-7436701
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Abstract

AIM: To compare the efficacy of self-expandable metal stents (SEMSs) with 10F plastic stents (PSs) in the endoscopic management of occluded SEMSs.

METHODS: We retrospectively reviewed the medical records of 56 patients who underwent SEMS insertion for palliation of unresectable malignant biliary obstruction between 2000 and 2007 and subsequent endoscopic retrograde biliary drainage (ERBD) with SEMS or PS for initial SEMS occlusion between 2000 and 2008.

RESULTS: Subsequent ERBD with SEMS was performed in 29 patients and with PS in 27. The median time to stent occlusion after subsequent ERBD was 186 d in the SEMS group and 101 d in the PS group (P = 0.118). Overall median stent patency was 79 d for the SEMS group and 66 d for the PS group (P = 0.379). The mean number of additional biliary drainage procedures after subsequent ERBD in patients that died (n = 50) during the study period was 2.54 ± 4.12 for the SEMS group and 1.85 ± 1.95 for the PS group (P = 0.457). The mean total cost of additional biliary drainage procedures after the occlusion of subsequent SEMS or PS was $410.04 ± 692.60 for the SEMS group and $630.16 ± 671.63 for the PS group (P = 0.260). Tumor ingrowth as the cause of initial SEMS occlusion was the only factor associated with a shorter time to subsequent stent occlusion (101 d for patients with tumor ingrowth *vs* 268 d for patients without tumor ingrowth, P = 0.008).

CONCLUSION: Subsequent ERBD with PSs offered similar patency and number of additional biliary drainage procedures compared to SEMSs in the management of occluded SEMS.

Key words: Stents; Biliary tract neoplasms; Obstructive jaundice; Endoscopy; Endoscopic retrograde cholangiopancreatography

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INTRODUCTION

Endoscopic retrograde biliary drainage (ERBD) is now widely accepted as the standard intervention for the relief of obstructive jaundice in patients with unresectable malignant biliary obstruction[1-3]. Although plastic stents (PSs) were developed earlier, self-expandable metal stents (SEMSs) are now used widely as the initial choice for ERBD in this setting, as SEMSs offer longer patency[4-8]. Although it was suggested that a PS-based biliary drainage strategy may be more economical if the cost of endoscopic retrograde cholangiopancreatography (ERCP) is low relative to that of a SEMS[9,10], our recent retrospective study concluded that a SEMS-based biliary drainage strategy might offer better palliation without a significant increase in drainage-related medical cost, even where the cost of ERCP is low[11].

However, SEMSs do become occluded in some patients. Even covered SEMSs, which were developed to overcome stent occlusion caused by tumor ingrowth, become occluded due to tumor overgrowth, sludge, or migration[12,13]. There are a limited number of reports regarding the management of occluded SEMS, with various results[14-17]. The aim of this study was to compare the efficacy of SEMSs with 10F PSs in subsequent ERBD after the occlusion of initial SEMSs.

MATERIALS AND METHODS

Patients

Patients who underwent SEMS insertion (either endoscopically or percutaneously) for the palliation of unresectable malignant biliary obstruction at Seoul National University Hospital and the National Cancer Center between January 2000 and December 2007, and subsequent ERBD with SEMS or 10F PS for initial SEMS occlusion between January 2000 and December 2008, were evaluated. Patients were excluded when the initial SEMS was occluded within seven days of placement, when the follow-up period after subsequent ERBD was less than eight weeks without documented stent occlusion or patient death, or when endoscopic nasobiliary drainage or a percutaneous transhepatic biliary drainage (PTBD) was performed before the subsequent ERBD. The medical records were reviewed; endoscopic and radiological findings were studied to compare the stent patency and survival of the patients. Additional information on patient survival was obtained by contacting the Resident Service Division of the Ministry of Public Administration and Security, Seoul, Korea.

For patients who died during the study period, the total number and cost of additional biliary drainage procedures after the occlusion of subsequent SEMS or PS (the sum of the costs of ERCP, ERBD, PTBD, PTBD catheter exchange, and stents) were compared between the two groups. The costs were converted from Korean won to U.S. dollars according to annual medical fee schedules and the annual average exchange rate (Table 1)[18-27]. Data were collected until the death of the patient or June 30, 2009. This study was approved by the institutional review boards of the institutions.

Subsequent stent insertion

A diagnosis of SEMS occlusion was made when a patient who had undergone ERBD with a SEMS presented with cholangitis (fever, tenderness in the right upper quadrant or epigastrium, and/or a $\geqslant$ two-fold increase in the serum bilirubin level above the baseline after initial SEMS insertion), or when the total serum bilirubin level was increased $\geqslant$ twofold above the baseline after initial SEMS insertion, even without symptoms or signs of cholangitis. After the diagnosis of SEMS occlusion was made, all patients fit for ERBD underwent the procedure.

ERCP was performed to characterize the cause of the SEMS occlusion using standard- or large-channel duodenoscopes (TJF-240, JF-240, TJF-200, JF-200; Olympus Optical Co., Ltd., Tokyo, Japan). Once stent occlusion was diagnosed, mechanical cleaning with a balloon catheter or a stone extraction basket was usually performed to examine the causes of stent malfunction if the cause was not clear. A guidewire was passed through the stricture, and the stricture length was measured with Tandem RX cannulas (Boston Scientific, Natick, Mass) or Tracer Metro guidewires (Cook Medical, Winston-Salem, NC). After the guidewire had passed through the occluded SEMS, another SEMS or PS was placed through the initial SEMS. Proper placement of the stent was confirmed by fluoroscopy.

In the SEMS group, covered or uncovered Wallstents (Boston Scientific) or uncovered Niti-S stents (Taewoong Medical Inc., Gimpo-si, Korea) were used. In the PS group, 10F Percuflex Amsterdam biliary stents (Boston Scientific), or Cotton-Leung stents (Cook Medical) were used.

Definition of events

Successful subsequent ERBD was defined as placement of the stent across the occluded initial SEMS confirmed by the appropriate radiographic positioning, immediate biliary decompression, and at least a 30% reduction in, or normalization of, the serum bilirubin level ($\leqslant$ 1.2 mg/dL).

Occlusion of subsequent ERBD was diagnosed when the patient developed symptoms or signs of stent occlusion, as described above. Time to stent occlusion was defined as the time between stent insertion and stent occlusion; the overall stent patency was defined as the time between stent insertion and stent occlusion or death of the patient.

Statistical analysis

Qualitative variables were compared using the χ^2 test or Fisher's exact test, where appropriate. The *t* test was used for comparison of quantitative variables. Time to stent occlusion, overall stent patency, and patient survival after the subsequent ERBD were estimated using the Kaplan-Meier method and compared with the log rank test. Factors influencing the time to subsequent stent occlusion were determined using the log-rank test. Two-sided *P*

Table 1 Costs of procedures and stents in US dollars[1]

	Year									
	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009
ERCP	56.45	53.69	53.62	58.14	62.18	71.57	79.48	83.61	76.89	71.45
ERBD	175.48	153.70	153.50	166.46	178.02	204.88	227.50	239.33	204.24	178.73
PTBD	91.66	81.60	81.48	88.37	94.51	108.77	120.77	127.06	150.52	168.09
PTBD tube change	26.65	34.61	34.57	37.49	40.09	46.14	51.23	53.90	67.71	77.82
SEMS	697.80	611.19	628.53	661.92	689.23	770.21	825.67	810.86	688.32	641.93
PS	60.47	52.96	54.46	57.36	59.72	66.74	71.55	74.02	59.55	55.54

[1]Costs converted from Korean won to US dollars according to annual medical fee schedules and the annual average exchange rate. ERCP: Endoscopic retrograde cholangiopancreatography; ERBD: Endoscopic retrograde biliary drainage; PTBD: Percutaneous transhepatic biliary drainage; SEMS: Self-expandable metal stent; PS: Plastic stent.

Table 2 Patient characteristics

	SEMS group	PS group	*P* value
No. of patients	29	27	
Gender (M:F)	18:11	19:8	0.512
Age at initial SEMS insertion, median (yr)	66	66	0.352
Diagnoses			0.277
Pancreatic cancer	15	6	
Common bile duct cancer	3	5	
Hilar cholangiocarcinoma	4	4	
Gallbladder cancer	3	6	
Metastatic lymph nodes	3	2	
Ampulla of Vater cancer	1	3	
Hepatocellular carcinoma	0	1	
Anti-cancer therapy	21	15	0.188

SEMS: Self-expandable metal stent; PS: Plastic stent.

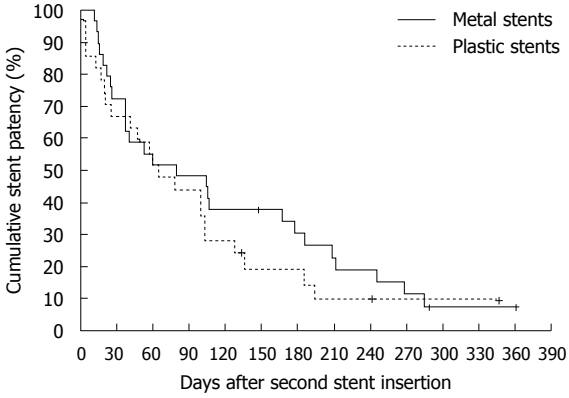

Figure 1 Kaplan-Meier estimation of patency rates of subsequent endoscopic retrograde biliary drainage. There was no significant difference in the patency between self-expandable metal stent and plastic stent ($P = 0.379$).

values of < 0.05 were considered significant. All analyses were performed using SPSS for Windows Ver. 11.0 (SPSS Inc., Chicago, IL).

RESULTS

Patient characteristics

A total of 56 (37 male) patients were evaluated. The median age at initial SEMS insertion was 66 years (range, 38-87 years). The diagnoses were: pancreatic cancer ($n = 21$), gallbladder cancer ($n = 9$), common bile duct cancer ($n = 8$), hilar cholangiocarcinoma ($n = 8$), metastatic lymph nodes ($n = 5$), ampulla of Vater cancer ($n = 4$), and hepatocellular carcinoma ($n = 1$). Thirty-two patients had no biliary drainage procedures prior to the initial SEMS insertion. Initial SEMSs were inserted endoscopically in 46 patients and percutaneously in 10. The median time to occlusion of the first SEMS was 124 d (range, 22-755 d). The causes of the first SEMS occlusion were: tumor ingrowth ($n = 37$), sludge and clogging ($n = 9$), combined ingrowth and sludge ($n = 7$), migration ($n = 2$), and tumor overgrowth ($n = 1$). After occlusion of the initial SEMS, subsequent ERBD with SEMS was performed in 29 patients (uncovered SEMS in 19 and covered SEMS in 10) and PS in 27. Changes in stent selection trends were evident over time. Between 2001 and 2006, 10 SEMSs and 21 PSs were inserted during the subsequent ERBD, whereas between 2007 and 2008, 19 SEMSs and 6 PSs were inserted ($P = 0.001$). No significant difference in the diagnoses of the two stent groups was noted ($P = 0.277$). Twenty-one patients (72.4%) in the SEMS group and 15 (55.6%) in the PS group underwent anti-cancer therapy ($P = 0.188$) (Table 2).

Subsequent ERBD

Stent occlusion after subsequent ERBD occurred after a median of 186 d (range, 11-285 d) in 16 patients (55.2%) in the SEMS group and after a median of 101 d (range, 2-194 d) in 18 patients (66.7%) in the PS group ($P = 0.118$ for time to stent occlusion, $P = 0.379$ for stent occlusion rate). The causes of stent occlusion were tumor ingrowth ($n = 17$), sludge and clogging ($n = 10$), migration ($n = 2$), tumor overgrowth ($n = 2$), duodenal obstruction ($n = 2$), and combined ingrowth and overgrowth ($n = 1$). Overall stent patency was 79 d for the SEMS group and 66 d for the PS group ($P = 0.379$). The cumulative stent patency estimated by the Kaplan-Meier method was 72.4%, 55.2%, 48.3%, and 37.9% for the SEMS group and 66.7%, 55.6%, 40.7%, and 25.9% for the PS group at 30, 60, 90, and 120 d, respectively (Figure 1). There was no correlation between the patency of the first SEMS and subsequent stent that had occluded (correlation coefficient, 0.251, $P = 0.152$).

When adjusted for anti-cancer treatment, the median

Table 3 Comparison of self-expandable metal stent and plastic stent in subsequent endoscopic retrograde biliary drainage (mean ± SD) *n* (%)

	SEMS group (*n* = 29)	PS group (*n* = 27)	*P* value
Follow-up period, median (d)	200	133	0.993
Stent occlusion	16 (55.2)	18 (66.7)	0.379
Time to stent occlusion, median (d)[1]	186	101	0.118
Overall stent patency, median (d)[1,2]	79	66	0.379
No. of additional biliary drainage procedures	2.54 ± 4.12	1.85 ± 1.95	0.457
Total cost of subsequent biliary drainage procedures ($)	410.04 ± 692.60	630.16 ± 671.63	0.260
Survival after subsequent ERBD, median (d)[1]	200	133	0.225

[1]Results of log-rank test; [2]Period between stent insertion and stent occlusion or death of the patient. SEMS: Self-expandable metal stent; PS: Plastic stent; ERBD: Endoscopic retrograde biliary drainage.

time to stent occlusion was not significantly different between the SEMS and PS groups. For the patients who underwent anti-cancer therapy, the median time to stent occlusion was 177 d for the SEMS group and 104 d for the PS group; in patients who did not undergo anti-cancer treatment, the median time to stent occlusion was 186 d for the SEMS group and 79 d for the PS group ($P = 0.120$).

When covered SEMS group ($n = 10$) and uncovered SEMS group ($n = 19$) were compared, the median time to stent occlusion was 208 d (range, 22-268 d) for covered SEMS and 106 d (range, 37-285 d) for uncovered SEMS ($P = 0.659$). The median overall stent patency was 186 d (range, 19-268 d) for the covered SEMS and 60 d (range, 11-285 d) for uncovered SEMS ($P = 0.599$).

Fifty patients died during the study period. The mean number of additional biliary drainage procedures after subsequent ERBD in patients who died during the study period was 2.54 ± 4.12 for the SEMS group and 1.85 ± 1.95 for the PS group ($P = 0.457$). The mean total cost of additional biliary drainage procedures after the occlusion of subsequent SEMS or PS was $410.04 ± 692.60 for the SEMS group and $630.16 ± 671.63 for the PS group ($P = 0.260$). There was no difference in the median follow-up period (200 d for SEMS group *vs* 133 d for PS group, $P = 0.993$). The median survival was not significantly different between the two groups (200 d for SEMS group *vs* 133 d for PS group, $P = 0.225$) (Table 3).

Factors influencing the patency of the subsequent stent, for both SEMSs and PSs, were analyzed. Tumor ingrowth as the cause of the initial SEMS occlusion was the only factor associated with a shorter median time to subsequent stent occlusion (101 d for patients with tumor ingrowth *vs* 268 d for patients without tumor ingrowth, $P = 0.008$). Gender, age at initial SEMS insertion, diagnosis (pancreatic cancer *vs* non-pancreatic cancer), biliary drainage prior to initial SEMS insertion, anti-cancer therapy, and presentation at initial SEMS occlusion with cholangitis had no impact on the subsequent stent patency (Table 4).

Table 4 Univariate analysis of factors associated with time to second stent occlusion

Factor	Time to second stent occlusion, median (d)	*P* value
Sex		0.273
Male (*n* = 37)	103	
Female (*n* = 19)	137	
Age at initial SEMS insertion (yr)		0.697
⩾ 65 (*n* = 31)	137	
< 65 (*n* = 25)	104	
Diagnosis		0.363
Pancreatic cancer (*n* = 21)	137	
Others (*n* = 35)	103	
Biliary drainage prior to initial SEMS insertion		0.924
Yes (*n* = 24)	137	
No (*n* = 32)	104	
Cause of initial SEMS occlusion		0.008
Ingrowth (*n* = 44)	101	
Not ingrowth (*n* = 12)	268	
Anti-cancer therapy		0.444
Yes (*n* = 36)	137	
No (*n* = 20)	103	
Cholangitis on initial SEMS occlusion		0.244
Yes (*n* = 33)	103	
No (*n* = 23)	186	
Covered initial SEMS		0.918
Yes (*n* = 4)	186	
No (*n* = 52)	104	

Results of log-rank test. SEMS: Self-expandable metal stent.

Cox regression analysis demonstrated that tumor ingrowth was associated with shorter time to subsequent stent occlusion (hazard ratio, 8.45; 95% confidence interval, 2.44-29.29; $P = 0.001$).

DISCUSSION

In this retrospective study of the endoscopic management of occluded SEMS for unresectable malignant biliary obstruction, no significant difference was observed for the patency or time to stent occlusion between the PS and the SEMS. In addition, no differences were observed with regard to the number or cost of additional biliary drainage procedures and patient survival. Tumor ingrowth as the cause of the initial SEMS occlusion was the only factor associated with a shorter time to subsequent stent occlusion.

There have been a few retrospective studies regarding the management of occluded SEMSs, with variable results. The study reported by Tham *et al*[15] analyzed 38 patients with 44 Wallstent occlusions. Wallstent occlusion was managed by insertion of another Wallstent in 19, insertion of a PS in 20, and mechanical cleaning in 5 cases. No significant difference in the duration of overall stent patency among the three groups was observed. Another report by Bueno *et al*[14] analyzed 34 patients with Wallstent occlusions. Six patients underwent mechanical cleaning, 4 had placement of a second Wallstent, and 24 had a PS insertion. The median duration of stent patency was 192 d for the second Wallstent, 90 d for the PS, and 21 d for the mechanical cleaning. Although the second Wall-

stent showed a significantly longer duration of patency, this study was limited by the relatively small number of patients who underwent second Wallstent insertion.

Two studies regarding this subject were published in 2008. Togawa *et al*[16] evaluated 40 patients with occluded uncovered SEMSs. Covered SEMSs were inserted in 26 patients, uncovered SEMSs in 7, and PSs in 7. The mean overall patency of the subsequent ERBD was 141.3, 219.6, and 57.9 d for uncovered SEMS, covered SEMS, and PS, respectively. It should be noted that the majority of second SEMSs used in this study were Diamond stents. Rogart *et al*[17] reported that in their experience, placing a second SEMS provided the lowest reocclusion rate and the longest time to reintervention. However, the total number of patients in their study was 27, with a second SEMS insertion in 14, PS insertion in 11, and mechanical cleaning in 2.

Since SEMS and PS did not show significant differences in the time to stent occlusion in our study, the factors influencing the time to subsequent stent occlusion in both groups were assessed. Tumor ingrowth as the cause of initial SEMS occlusion was the only factor associated with shorter time to second stent occlusion, regardless of the material used for the second stent. Tumor ingrowth was the most common cause of the initial SEMS occlusion in this study. Unlike other causes of SEMS occlusion such as tumor overgrowth, sludge or migration, ingrowth may be difficult to overcome by subsequent stent insertion because a long segment of the bile duct might be involved with more compressive force on the stent, thus interfering with the expansion of the SEMS. Moreover, the initial SEMS embedded in the tumor tissue may serve as a rigid framework, adding more resistance to the axial force of the subsequent SEMS. If this was the case, a PS with its fixed diameter may not be inferior to SEMS in subsequent ERBD. A covered SEMS or SEMS with a high radial force may be useful in this setting. Previous reports have shown variable results on this issue. Togawa *et al*[16] demonstrated that covered SEMS were superior to uncovered SEMS for the management of occluded SEMSs. However, the study by Rogart *et al*[17] failed to show that the covered SEMS was superior. A prospective study comparing the efficacy of such SEMSs in the management of initial SEMS occlusion is needed.

The limitations of this study include the following. This was a non-randomized, retrospective study which may result in selection bias. No predefined follow-up protocol was available. Patients with less than 8 wk of follow-up without stent occlusion or death were excluded, since most, if not all, of these patients were lost to follow-up right after the subsequent ERBD. However, this study includes the largest number of patients with SEMS occlusion to date.

In conclusion, subsequent ERBD with PS had similar patency, and number and cost of additional biliary drainage procedures, compared to the SEMS in the endoscopic management of occluded SEMS. Tumor ingrowth as the cause of initial SEMS was the only factor associated with shorter time to second stent occlusion. Therefore, strategies to overcome tumor ingrowth during subsequent ERBD might be beneficial to this subset of patients.

COMMENTS

Background

There are limited data regarding the management of occluded self-expanding metal stents (SEMSs) in palliation of unresectable malignant biliary obstruction.

Innovations and breakthroughs

This study identified tumor ingrowth as the factor associated with shorter time to second stent occlusion.

Applications

In the endoscopic management of occluded SEMS, subsequent endoscopic retrograde biliary drainage with a plastic stent had similar patency and number of additional biliary drainage procedures compared to the SEMS.

Peer review

This is an interesting study in an area without high grade evidence. The authors acknowledge the limitations of their methodology (non-randomized, retrospective).

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