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
Received: June 3, 2010 Revised: July 14, 2010 Accepted: July 21, 2010 Published online: November 14, 2010

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.

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

Peer reviewers: Dr. John S Leeds, MBChB (Honours), MRCP, Honorary Clinical Lecturer in Gastroenterology, Gastroenterology and Liver Unit, Royal Hallamshire Hospital, Glossop Road, Sheffield, S10 2JF, United Kingdom; Hiroyuki Uehara, MD, PhD, Chief, Division of Pancreatology, Department of Gastroenterology, Osaka Medical Center for Cancer and Cardiovascular Diseases, 1-3-3 Nakamichi, Higashinari, Osaka 537-8511, Japan

Yoon WJ, Ryu JK, Lee JW, Ahn DW, Kim YT, Yoon YB, Woo SM, Lee WJ. Endoscopic management of occluded metal biliary stents: Metal versus 10F plastic stents. World J Gastroenterol 2010; 16(42): 5347-5352 Available from: URL: http://www.wjgnet.com/1007-9327/full/v16/i42/5347.htm DOI: http://dx.doi.org/10.3748/wjg.v16.i42.5347
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 might be more economical if the cost of endoscopic retrograde choledangiopancreatography (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 ≥ two-fold increase in the serum bilirubin level above the baseline after initial SEMS insertion), or when the total serum bilirubin level was increased ≥ 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 (≤ 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 χ² 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
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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 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).

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[13] 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. 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. 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. demonstrated that covered SEMS were superior to uncovered SEMS for the management of occluded SEMSs. However, the study by Rogart et al. 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.

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**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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S- Editor Tian L  L- Editor Logan S  E- Editor Lin YP