Comparison of Clinical Outcomes between Endoscopic and Radiologic Placement of Self-expandable Metal Stent in Patients with Malignant Colorectal Obstruction

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Background/Aims: This study compared the clinical outcomes between endoscopic and radiologic placement of self-expandable metal stent (SEMS) in patients with malignant colorectal obstruction.

Methods: In total, 111 patients were retrospectively enrolled in this study between January 2003 and June 2011 at Seoul National University Boramae Hospital. Technical and clinical success rates, complication rates, and stent patency were compared between using an endoscopic (n=73) or radiologic (n=38) method during the SEMS placement procedure.

Results: The technical success rate was higher in the endoscopic method than in the radiologic method (100% [73/73] vs. 92.1% [35/38], respectively; p=0.038). In addition, in 3 of the remaining 35 patients in the radiologic-method group, adjuvant endoscopic assistance was required. In the six patients (including the three aforementioned patients), the causes of technical failure were the inability to pass the guidewire into an obstructive lesion due to a tortuous, curved angulation of the sigmoid or descending colon (n=4), and a difficult approach to a lesion located at the descending or transverse colon (n=2). The clinical success rate, complication rate, and stent patency did not differ significantly between the two methods (p=0.424, 0.303, and 0.423, respectively).

Conclusions: When the colorectal obstruction had a tortuous, curved angulation of the colon or was located at or proximal to the descending colon, the endoscopic method of SEMS placement appears to be more useful than the radiologic method. However, once SEMS placement was technically successful, the clinical success rate, complication rate, and stent patency did not differ with the method of insertion. (Korean J Gastroenterol 2013;61:22-29)

Key Words: Colorectal neoplasm; Stent; Endoscope; Interventional radiology

INTRODUCTION

It is well known that placement of a self-expandable metal stent (SEMS) is a safe and effective option as a palliative treatment for colorectal cancer in patients with inoperable disease, and as a bridge to surgery in patients with acute colorectal obstruction caused by colonic neoplasm involving the rectum or colon.1-3 According to a meta-analysis, colorectal SEMS placement has technical and clinical success rates of 94% and 91%, respectively.4 However, it has been reported

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recently that the clinical outcome of colorectal SEMS placement is significantly affected by operator experience, \(^4\) type of stent, \(^5\) type of stricture, \(^4-7\) and use of chemoradiation. \(^5\)

Colorectal SEMS placement can be performed using either an endoscopic method with the assistance of fluoroscopy, by endoscopists, or a radiologic method using fluoroscopy alone, by interventional radiologists. Although the clinical outcomes of colorectal SEMS placement are known to be similar for the two methods, \(^8\) few studies have compared the clinical outcomes of these two methods of colorectal SEMS placement. The purpose of this study was therefore to directly compare the technical success rate, clinical success rate, complication rate, and stent patency between the endoscopic and radiologic methods of colorectal SEMS placement.

**SUBJECTS AND METHODS**

1. Patients

A total of 118 consecutive patients underwent SEMS placement for symptomatic colorectal obstruction at Seoul National University Boramae Hospital between January 2003 and June 2011. All SEMS placements were performed using either the endoscopic or radiologic method.

All of the patients underwent CT scan to determine the extent of the tumors and to evaluate the site, degree, and length of the obstructive lesion. The histopathologic diagnosis was confirmed by analyzing the results of an endoscopic biopsy procedure that was performed either before or at the time of stent placement. All of the patients underwent colorectal SEMS placement for preoperative colonic decompression or palliation of a malignant obstruction of unresectable cancer.

The inclusion criteria were colorectal malignant obstruction identified using clinical obstructive symptoms and a radiologic examination. The exclusion criteria included nonsymptomatic patients with colorectal obstruction, perforation or peritonitis with clinical evidence, concomitant small-bowel obstruction, or colorectal obstruction caused by benign stricture.

Of the 118 patients who received colorectal SEMS placement, 7 patients were excluded because of follow-up loss of patients during the study. The remaining 111 patients were retrospectively enrolled in our study. We performed this study in accordance with the guidelines of our institutional review board, which approved the study.

2. Colorectal SEMS placement

The stent type was selected according to the preference and experience of each endoscopist or interventional radiologist. Stent length was selected by allowing for the exposure of at least an additional 2-4 cm distal and proximal to the obstructive lesion. The three types of stent used in our study were (1) uncovered Niti-S colonic D type stent (Taewoong Medical, Seoul, Korea); (2) covered Niti-S colonic stent (Taewoong Medical); and (3) the newly developed, covered Comvi stent (Taewoong Medical). The uncovered Niti-S stent is constructed with a mesh of a single strand of nitinol, and has a cylindrical design without flared ends. The covered Niti-S colonic stent is covered with silicone and has uncovered flared end. The covered Niti-S Comvi stent is covered with polytetrafluoroethylene membrane between layers of metal meshwork with uncovered ends. These stents are available in diameters of 18, 20, 22, and 24 mm and lengths of 60, 80, 100, and 120 mm.

All of the stents were placed using either the endoscopic approach by two expert endoscopists (J.B.J. and J.W.K.) or the radiologic approach by two experienced interventional radiologists (Y.H.C. and Y.H.S.). For the endoscopic stent placement, the endoscope (GIF-2T240 or CF-260; Olympus, Tokyo, Japan) was carefully inserted toward the lesion and then one or two clips were placed at least 2 cm distal to the lesion. A 0.035-inch guidewire (Trace Metro, Cook, Bloomington, IN, USA) was passed across the obstruction, into its proximal part. A 5-F biliary catheter was passed through the guidewire across the obstruction, and the length of the obstructive lesion was measured with the aid of an injection of water-soluble contrast dye (Gastrografin; Schering Espana, Madrid, Spain) through the 5-F biliary catheter. A stent-delivery system was advanced over the guidewire through the working channel of the endoscope and was inserted into the obstruction under fluoroscopic guidance. The stent was deployed at the stricture site while pulling back the outer sheath, under combined fluoroscopic and endoscopic guidance.

For the radiologic stent placement, a 0.035-inch guidewire (Radifocus; Terumo, Tokyo, Japan) was advanced across the obstruction under fluoroscopic guidance alone. A 5-F catheter (Torcon NB; Cook) was advanced above the stricture over
the guidewire. After adequately determining the location and length of the stricture, the stent delivery system was coated with lubricating jelly and advanced over the guidewire under fluoroscopic guidance. The pusher catheter was then held in place while the introducing tube was withdrawn. This maneuver released the stent and allowed it to expand within the stricture. After deployment of the stent, the delivery system and the guidewire were removed. When the guidewire could not pass the obstructed lesion under fluoroscopic guidance alone, adjuvant endoscopic assistance was also employed.

A plain radiograph of the abdomen was obtained at 24, 48, and 72 hours after the stent placement to enable evaluation of the position of the stent and the degree of relief from the colonic obstruction.

3. Outcomes

Technical success was defined as successful stent placement across an obstructive lesion. Clinical success was defined as the relief of obstructive colonic symptoms within 96 hours without immediate stent-related complication. Complications were defined as those leading to new symptoms, reobstruction, or alteration of management. Procedure time was measured from the first fluoroscopic image obtained to the last one (including periods of time with and without radiation). CT scans were used to determine whether carcinomatosis was present, defined as the implantation of tumor nodules along the peritoneal surface and contrast enhancement of the parietal peritoneal lining or loculated and/or septated ascitic fluid.

4. Follow-up and stent patency duration

In the patients with palliative stent placement, clinical follow-up or telephone interviews about the recurrence of obstructive symptoms were followed at an interval of 1-3 months. The duration of stent patency was defined as the time from stent placement to stent-related complications. When no stent-related complication occurred, the duration of stent patency was considered as being equal to the survival duration.

5. Statistics

Patients were divided into two groups according to the type of SEMS insertion (endoscopic vs. radiologic placement) that they underwent. Continuous variables were compared with independent-samples t-test, and categorical variables were compared with a chi-square or Fisher exact test for both groups. The mean cumulative duration of stent patency (in days) was estimated by Kaplan-Meier analysis. Stent patency was compared between the two groups using the log-rank test. All statistical analyses were conducted using SPSS software (version 12.0; SPSS Inc., Chicago, IL, USA). A probability value of \( p < 0.05 \) was considered significant.

RESULTS

1. Patient characteristics

SEMS placement was conducted using the endoscopic and radiologic methods in 73 (65.7%) and 38 (34.2%) of the 111 patients who were included in this study, respectively. There were 61 male patients, and the patients were aged 67.1±12.4 years (mean±SD; range, 33-91 years). Primary colorectal cancer was present in 104 patients (93.7%), and 7 patients (6.3%) had metastatic cancers from the stomach or ovary. The locations of the malignant obstruction (in order of decreasing frequency) were the sigmoid colon (62.1%), rectum (21.6%), descending colon (9.0%), transverse colon (5.4%), and ascending colon (1.8%). SEMS placement was performed for the palliation of obstruction in 52 patients (46.8%) and as a bridge to surgery in the remaining 59 patients (53.2%). The types of stent inserted were uncovered (75.9%) and covered (24.1%); technical failure occurred in 3 of the 38 patients in radiologic-method group. Five patients received two overlapping stents because of a long stricture at presentation.

The baseline variables, such as patient-related factors (including sex, age, location of obstruction, stages, presence of carcinomatosis, etiology of the obstruction, purpose of stenting, and length of obstruction), stent-related factors (including the type, diameter, and length of the stent, and the number of stents inserted at presentation), procedure time and palliative chemotherapy after SEMS insertion in the pal-
The technical success rate was significantly higher when using the endoscopic method than when using the radiologic method (100% [67/67] vs. 92.1% [35/38], respectively; p=0.038; Table 2). Three of the 38 (7.9%) patients in the radiologic-method group experienced technical failure, the causes of which were inability to pass guidewire through the obstruction in the sigmoid colon (n=2), and a difficult approach to the obstruction site of the transverse colon (n=1). All of the patients ultimately underwent successful surgical decompression.

In three of the remaining 35 (8.6%) patients in whom stent placement by the radiologic method was successful, adjuvant endoscopic guidance was required to pass the guidewire into the obstructive lesion because of an inability to pass the guidewire through the obstructive lesion in the sigmoid colon.

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### Table 1. Baseline Characteristics of the Patients with Malignant Colorectal Obstruction according to the Method of Stent Placement

| Characteristic              | Endoscopic method (n=73) | Radiologic method (n=38) | p-value |
|----------------------------|--------------------------|--------------------------|---------|
| Sex (male/female)          | 38/35 (52.1/47.9)        | 23/15 (60.5/39.5)        | 0.395   |
| Age (yr)                   | 67.0±13.0 (33-91)        | 67.2±11.4 (38-85)        | 0.929   |
| Locations of obstruction   |                          |                          | 0.260*  |
| Left colon                 | 66 (90.4)                | 37 (97.4)                |         |
| Rectum                     | 15 (20.5)                | 9 (23.7)                 |         |
| Sigmoid                    | 43 (58.9)                | 26 (68.4)                |         |
| Descending                 | 8 (11.0)                 | 2 (5.3)                  |         |
| Right colon                | 7 (9.6)                  | 1 (2.7)                  |         |
| Transverse                 | 5 (6.8)                  | 1 (2.6)                  |         |
| Ascending                  | 2 (2.7)                  | 0                        |         |
| Stages                     |                          |                          | 0.748   |
| No metastasis              | 38 (52.1)                | 21 (55.3)                |         |
| Metastasis                 | 35 (47.9)                | 17 (44.7)                |         |
| Carcinomatosis             |                          |                          | 0.427   |
| Absent                     | 62 (84.9)                | 30 (78.9)                |         |
| Present                    | 11 (15.1)                | 8 (21.1)                 |         |
| Etiology                   |                          |                          | 1.000*  |
| Intrinsic                  | 68 (93.2)                | 36 (94.7)                |         |
| Extrinsic                  | 5 (6.8)                  | 2 (5.3)                  |         |
| Gastric                    | 3 (60.0)                 | 2 (100.0)                |         |
| Gynecologic                | 2 (40.0)                 | 0 (0.0)                  |         |
| Purposes of stenting       |                          |                          | 0.054   |
| Palliative                 | 39 (53.4)                | 13 (34.2)                |         |
| Preoperative               | 34 (46.6)                | 25 (65.8)                |         |
| Length of obstruction (mm) | 39.4±14.1                | 44.2±17.3                | 0.125   |
| Types of inserted stent    |                          |                          | 0.086   |
| Uncovered                  | 59 (80.8)                | 23 (65.7)                |         |
| Covered                    | 14 (19.2)                | 12 (34.3)                |         |
| Diameter of stent (mm)     | 23.2±1.6                 | 23.3±2.7                 | 0.916   |
| Length of stent (mm)       | 103.0±28.4               | 102.3±21.6               | 0.894   |
| No. of inserted stents at presentation |          |                          | 0.658   |
| One                        | 70 (95.9)                | 33 (94.3)                |         |
| Two                        | 3 (4.1)                  | 2 (5.7)                  |         |
| Total procedure time (min) | 25±15                    | 31±15                    | 0.066   |
| Palliative chemotherapy     | n=39                     | n=13                     | 0.733   |
| Yes                        | 12 (30.8)                | 3 (23.1)                 |         |
| No                         | 27 (69.2)                | 10 (76.9)                |         |

Values are presented as number (%) or mean±SD (range).

*Left vs. right colon.

Intrinsic vs. extrinsic.

Palliative treatment group only.
Table 2. Technical and Clinical Success Rates, and Causes of Technical and Clinical Failures

|                          | Endoscopic method | Radiologic method | p-value |
|--------------------------|-------------------|-------------------|---------|
| Technical success        | 73 (100)          | 35 (92.1)         | 0.038   |
| Causes of technical failure |                |                   |         |
| Inability to pass guidewire | 0 (0.0)          | 2 (5.3)           | 0.115   |
| Approach difficulties    | 0 (0.0)           | 1 (2.6)           | 0.342   |
| Clinical success         | 67 (91.8)         | 34 (97.1)*        | 0.424   |
| Causes of clinical failure |                |                   |         |
| Incomplete expansion     | 2 (2.7)           | 1 (2.9)           | 1.000   |
| Additional obstruction   | 1 (1.4)           | 0 (0.0)           | 1.000   |
| Perforation              | 2 (2.7)           | 0 (0.0)           | 1.000   |
| Migration                | 1 (1.4)           | 0 (0.0)           | 1.000   |

Values are presented as number (%).

*Excluding the three patients with technical failure.

On the other hand, in the radiologic-method group, 34 of the 35 patients (97.1%) received clinically successful stent placement. The remaining patient who experienced clinical failure underwent surgical management with a good outcome. The clinical success rate did not ultimately differ significantly between the endoscopic- and radiologic-method groups (91.8% vs. 97.1%, respectively; p=0.424).

4. Complications

During the follow-up period after stent insertion, 12 of the 37 (32.4%) patients in the endoscopic-method group and 2 of the 13 (15.4%) patients in the radiologic-method group experienced stent malfunction due to various types of complications (Table 3) including tumor ingrowth (n=8) and overgrowth (n=1), stent migration (n=3), colon perforation (n=1), and fecal impaction (n=1). The complication rate did not differ significantly between the endoscopic- and radiologic-treatment groups (32.4% vs. 15.4%, respectively; p=0.303).

Tumor ingrowth occurred in eight patients who received an uncovered stent in the endoscopic-guidance group, of whom seven patients received covered stent and one underwent a surgical operation. Stent migration was found in one and two patients receiving covered stents in the endoscopic and radiologic groups, respectively. The patient in the endoscopic and one from the radiologic-guidance group were treated with restenting; the other patient from the radiologic-guidance group refused any retreatment for the migration. In the endoscopic-guidance group, one patient with tumor overgrowth was treated with restenting, one with colon perforation was treated with surgery, and one with fecal impact was treated with endoscopic removal.
5. Stent patency

The median stent patency data are shown in Fig. 1. The median cumulative duration of stent patency did not differ significantly between the endoscopic-guidance group (70 days; 95% CI, 34.5-105.5 days) and the radiologic-guidance group (93 days; 95% CI, 56.6-129.4 days; p=0.428).

DISCUSSION

A colorectal SEMS may be inserted using either an endoscopic method or a radiologic method. Although these methods are reported to have similar clinical outcomes, they have distinct advantages and disadvantages.11-13 The advantages of the radiologic method are that it is more comfortable for the patient than the endoscopic method, and sedation is usually unnecessary. Moreover, interventional radiologists have more experience in the manipulation of hydrophilic guidewires.14-16

However, when an obstructive lesion is located in the tortuous, curved angulation of the sigmoid or descending colons, it is more difficult for the angiographic catheter to pass the stenotic lesion using the radiologic method alone. In this situation the angiographic catheter may not only be prolapsed into the greater curvature of the tortuous colon, but it may also be technically difficult to control the guidewire due to friction between the inner lumen of the catheter and the outer surface of the guidewire, which may render it impossible to pass the guidewire through the obstruction.17,18 In addition, when the obstructive lesion is located at or proximal to the descending colon, the tortuous, curved anatomy of the left colon and the shortness of the catheter make it difficult to even reach the lesion using the radiologic method alone.19

While various devices, such as the multifunctional gastrointestinal coil catheter,19 Balkin sheath,8 and shuttle sheath20 have been introduced in an attempt to overcome the limitations of placing an angiographic catheter proximal to the descending colon and to prevent the prolapse into the greater curvature of the tortuous, curved sigmoid or descending colon, the limitations of stent insertion using these devices must still be accepted as part of the general procedure because those studies included relatively small numbers of patients and were conducted by interventional radiologists with limited experience. There have even been some reports suggesting that stent placement is more difficult to perform in the descending colon or splenic flexure than in the rectum or sigmoid colon.4,11,21 In our study, similar difficulties were observed in cases of the stent placement using radiologic method alone: inability to pass the guidewire through the obstructive lesion due to tortuous, curved angulation of the sigmoid colon (n=2), and the difficult approach of the angiographic catheter into a lesion located in the transverse colon (n=1).

The advantages of the endoscopic method over the radiologic method are the greater accessibility to the lesion and the ability to pass some stents directly through the working channel of the endoscope. In our study, adjuvant endoscopic assistance was required in three patients from the radiologic-approach group for technically successful placement of the stent. The causes of adjuvant endoscopic assistance were the inability to pass the guidewire through the tortuous anatomy of the sigmoid colon (n=2), and the difficult approach to the obstructive site in the descending colon (n=1).

Few studies have directly compared the technical failure rates between endoscopic and radiologic SEMS placement. In a meta-analysis of colonic SEMS placement, the rate of technical failure tended to be lower in the endoscopic-placement group than in the radiologic-placement group (4.5% vs. 9.6%, respectively; p=0.086).4 Similarly, in the present study, the technical failure rate was significantly lower in the endoscopic-method group than in the radiologic-method group (0% vs. 8%, respectively; p=0.038). Moreover, as mentioned above, in 3 of the remaining 35 patients in the radiologic-placement group who received successful SEMS placement,
adjacent endoscopic assistance was required to achieve successful stent placement. If these three patients were included as cases of technical failure, the technical failure rate was more lower in the endoscopic-method group than in the radiologic-method group (0% vs. 16%, respectively; p=0.001). Therefore, the endoscopic approach for the placement of a colorectal SEMS appeared to be more useful, especially when it was difficult to place the stent because the obstructive lesion was associated with the tortuous, curved anatomy of the colon or was located at or proximal to the descending colon.

Despite technically successful stent placements, clinical failures have been reported in approximately 6% of patients. There are several potential reasons for clinical failures, including the presence of additional lesions of intestinal obstruction, early stent migration, an underlying motility disorder, fecal impaction of an inserted stent, or incomplete expansion of the stent. In the present study, seven patients (6.5%) experienced clinical failure regardless of a technically successful stent placement (stent malfunction in four, perforation in two, and stent migration in one); this rate is similar to that reported previously. However, the rate of clinical failure did not differ significantly between the endoscopic and radiologic approaches (8.2% [6/73] vs. 2.9% [1/35], respectively; p=0.424). Another report also mentioned the possibility of clinical failures that were not associated with any patient or tumor-related factors. These results suggest that technically successful placement of an SEMS through the entire stricture lesion has a far greater effect on SEMS function than do the other clinical risk factors of clinical failure.

One of the main objectives of our study was to compare the complication rate between the endoscopic and radiologic methods of SEMS placement. Among the 69 patients who received a stent for palliative purposes, the complication rate did not differ significantly between the endoscopic- and radiologic-method groups (32.4% [21/37] vs. 15.4% [2/13], respectively; p=0.303). Although tumor ingrowth was more frequent in the endoscopic-method group than in the radiologic-method group in our study (8/37 [21.6%] vs. 0/13 [0%], respectively; p=0.177), there was no significant difference between the groups. It may result from the type of inserted stent (uncovered vs. covered). It has been well known that uncovered stent is more prone to tumor ingrowth than covered stent due to their mesh structure. In our study, uncovered stent was more frequently inserted in the endoscopic-method group than in the radiologic-method group (59/73 [80.8%] vs. 23/38 [65.7%], respectively; p=0.086). As a result of this difference in inserted stent, overall complications, including tumor ingrowth, may be more frequent in the endoscopic-method group than in the radiologic-method group, despite statistical insignificance. According to a meta-analysis results for palliative colonic SEMS insertion, the rates of stent migration, re-obstruction, and perforation were 12%, 7%, and 4%, respectively. The corresponding values for the current study were 4%, 14%, and 1%. The differences in these values between the studies may be due to differences in operator experience, the type of stent, the type of stricture, and the use of chemoradiation.

The median duration of stent patency was 106 days (range, 68-288 days) in previous studies, while it was 70 days (range, 40-100 days) in the present study. The disparity may be related to differences in demographic factors, underlying malignancies, or stent types. Moreover, in the present study, the median duration of stent patency did not differ significantly between the endoscopic- and radiologic-place ment groups (70 days vs. 93 days, respectively; p=0.428), a finding that may be associated with the similarity of the aforementioned factors between the two groups.

Our study was subject to several limitations. First, it was a retrospective, not prospective, single center study. Selection bias of choosing method of stent placement (endoscopic vs. radiologic) and stent type (uncovered vs. covered) might be involved because stents were selected preference and experience of physician. Second, the purposes of stenting (palliative vs. preoperative) tended to differ between the endoscopic- and radiologic-method groups, despite the lack of statistical significance (p=0.054). This difference may be attributed to physician’s preference that radiologic method might be advantageous over endoscopic method as preoperative treatment, especially when bowel preparation is inadequate, or in patients who have low compliance or poor general condition to endoscopic method. Third, statistical comparisons with regard to baseline characteristics, technical success, clinical success, and complications may not be accurate because the present study included relatively fewer patients in the radiologic-method group than in the endoscopic-method group. However, to the best of our knowledge,
there have been no previous studies directly comparing the clinical outcomes of SEMS placement methods. The current study thus provides valuable data. However, further large-scale, randomized, prospective studies are necessary to overcome the aforementioned limitations.

Within the limitations of this study, we can conclude that when the colorectal obstruction has a tortuous, curved angulation of the sigmoid or descending colon, or is located at or proximal to the descending colon, the endoscopic method is more useful than the radiologic method for the placement of a colorectal SEMS, and that once the SEMS placement is technically successful, the clinical success rate, complication rate, and stent patency do not vary with the method of insertion.

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