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Carcinomatosis matters: clinical outcomes and prognostic factors for clinical success of stent placement in malignant gastric outlet obstruction

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Abstract
Background Although carcinomatosis is not a contraindication to stenting in selected patients with malignant gastric outlet obstruction (GOO), associate factors for clinical success rate of self-expandable metallic stent (SEMS) placement in GOO patients with carcinomatosis have not been fully characterized.
Methods We analyzed a total 228 patients who were scheduled for SEMS placement for malignant GOO in tertiary-care academic medical center. All patients were treated with an uncovered or covered SEMS by using the over-the-wire placement procedure. We retrospectively evaluated clinical outcomes of SEMS placement.
Results Technical success was achieved in all patients. Patients were categorized into two groups according to the presence of carcinomatosis. Clinical success rates of patients without carcinomatosis group and with carcinomatosis group were 93.9 % (92 of 98) and 80.8 % (105 of 130), respectively ($P = 0.004$). In subgroup analysis of patients with carcinomatosis, the clinical success rate was lower in patients with ascites (64.8 %) than in those without ascites (92.1 %, $P < 0.001$). Multivariate logistic regression model revealed that carcinomatosis without ascites did not decrease clinical success rate compared with absence of carcinomatosis; meanwhile, carcinomatosis with ascites showed lower clinical success rates compared with absence of carcinomatosis (adjusted odds ratio 0.163, 95 % confidence interval 0.058–0.461). In addition, poor performance status [Eastern Cooperative Oncology Group (ECOG) status ≥3, adjusted odds ratio 0.178, 95 % confidence interval 0.078–0.409] was also an independent poor predictive factor for clinical success of SEMS placement.
Conclusions In palliation for malignant GOO, the status of carcinomatosis with ascites and poor performance status (ECOG status ≥3) are significant predictive factors for poor clinical success of SEMS placement.

Keywords Ascites · Carcinomatosis · Gastric outlet obstruction · Self-expandable metallic stent · SEMS

Obstruction of the stomach by unresectable gastrointestinal (GI) cancer leads to significant morbidity, including abdominal pain, nausea, vomiting, and cachexia, all of which seriously impair quality of life [1, 2]. Treatments focus on providing relief from obstructive symptoms. In the past, surgical bypass was the treatment of choice for these patients. However, over the last decade, self-expandable metallic stents (SEMSs) have become widely used for the treatment of malignant gastric outlet obstruction (GOO) because SEMS placement has lower morbidity and mortality rates, shorter hospital stay durations, and lower costs than the surgical bypass procedure [3–5].

Generally, peritoneal disease is considered as a relative contraindication to SEMS treatment in GOO [6–9]. Recent study has shown that carcinomatosis is not a contraindication to stenting in selected patients with malignant GOO [10]. However, clinically, we have frequently experienced poor outcomes of SEMS placement in the palliation of malignant GOO in patients with carcinomatosis. At present, there have been few reports of the clinical outcomes

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after SEMS placement in patients with peritoneal carcinomatosis. Therefore, we conducted this study to evaluate whether the presence of carcinomatosis reduces the clinical success rate of SEMS placement in patients with malignant GOO. This study aims to evaluate the clinical outcomes and determine the predictive factors for the clinical success of SEMS placement in GOO patients with and without carcinomatosis.

Patients and methods

Patients

We retrospectively evaluated the clinical records of patients with malignant GOO who were treated with SEMS at Severance Hospital, Yonsei University College of Medicine, Seoul, Korea, between January 1996 and April 2010.

All patients had pathologically proven malignancy. None was a candidate for curative surgical treatment as a result of advanced or metastatic disease or poor functional status. All patients had a symptomatic obstruction. The diagnosis of GOO was based on endoscopic and radiologic tests including upper GI barium study and fluoroscopy.

Patients with evidence of other obstructions in the GI tract, previous gastric, periampullary, or duodenal surgery or gastrojejunostomy for malignant GOO, were excluded. In addition, we excluded all patients who showed evidence of obstruction in other areas of the GI tract, such as the small bowel, in radiologic image studies.

We collected the following data from medical records: demographics, stent type, technical outcome, clinical outcome, previous palliative chemotherapy history, grade of obstruction, evidence of carcinomatosis or ascites, number of metastatic sites, reintervention, and patency of SEMS. Carcinomatosis was confirmed by abnormal findings on computed tomography (CT) scan including soft tissue infiltration of the mesentery or omentum, nodular lesions in the paracolic gutter or rectal shelf, and peritoneal wall thickening. When a CT scan revealed suspicious findings, exploratory laparotomy was performed for pathologic confirmation. Additionally, evidence of ascites was confirmed by CT scan. Metastatic sites included metastasis to distant lymph nodes, distant organs, and peritoneum. This study was approved by the Institutional Review Board of Severance Hospital.

Placement of SEMS

All procedures were carried out under endoscopic and fluoroscopic guidance with the patients under conscious sedation with intravenous midazolam and/or propofol. The endoscope (GIF-2T240; Olympus, Tokyo, Japan) was carefully inserted into the site of the obstruction. When the stenosis was identified, a guidewire (Jagwire, Boston Scientific, Natick, MA, USA) was passed through it via a catheter (ERCP-Catheter, MTW Endoskopie, Wesel, Germany). The length of the obstructing lesion was measured by injecting the water-soluble radiographic contrast material Gastrografin (Scherring, West Sussex, UK) through a 5F biliary catheter. The stent was longer than the stenosis by at least an additional 1–2 cm on each side in order to ensure adequate coverage. After the guidewire was passed through the site of obstruction, the stent delivery system was advanced over the guidewire and through the working channel under fluoroscopic guidance. The stent was released and deployed at the stricture site while the outer sheath was pulled back under both fluoroscopic and endoscopic guidance. After stent deployment, the position of the stent was assessed both radiographically and endoscopically.

All SEMSs used were commercially available and manufactured by various companies: Covered or uncovered Hanaro stents (M.I.Tech, Seoul, Korea), covered or uncovered Niti-S pyloric stents (Taewoong Medical, Seoul, Korea), covered Niti-S Comvi pyloric stents (Taewoong Medical, Seoul, Korea), uncovered Niti-S pyloric D-type stents (Taewoong Medical, Seoul, Korea), and uncovered WallFlex stents (Boston Scientific, Natick, MA, USA). The stents which were used ranged from 18 to 20 mm in diameter and 6–16 cm in length. Stent type, size, and length were chosen on the basis of the characteristics of the obstruction and the operator's experience.

Patients started a diet that was based on their symptoms of obstruction at full SEMS extension. After SEMS placement, adjuvant chemotherapy was administered when the patients showed improvement in their obstruction symptoms and their Eastern Cooperative Oncology Group (ECOG) performance status was below 2.

Definition and assessment of clinical outcomes

The outcomes of SEMS placement were evaluated according to the following components: technical success, clinical success, and stent patency. Technical success was defined as the successful deployment of the stent, its proper positioning, and good passage of contrast media through the stenotic area. Clinical success was defined as the ability to tolerate oral intake without vomiting 5 days after the stents were deployed. The degree of oral intake was assessed by the gastric outlet obstruction scoring system (GOOSS) proposed by Adler and Baron [11]: 0, no oral intake; 1, liquid only; 2, soft solid food; and 3, a low-reside or full diet. Changes in the degree of oral intake were

evaluated at 5 days after stent deployment. Clinical failure was defined as a failure to resume oral intake or no improvement in GOOSS after stenting.

The predictive factors for clinical success were analyzed. The potential predictive factors of clinical success were: patient age at the time of stent placement, sex, length of stent, ECOG status, type of stent, previous chemotherapy history, or the presence of carcinomatosis or ascites. Stent patency was defined as the period between stent deployment and the recurrence of obstructive symptoms due to stent obstruction as confirmed by endoscopy, fluoroscopy, or radiography.

Statistical analysis

Categorical variables were compared by χ^2 or Fisher's exact tests. Continuous variables are presented as mean (±SD) or median (range) and were compared by the independent *t* test or the Mann–Whitney *U* test. Cumulative stent patency and patient survival were estimated using Kaplan–Meier analysis. Logistic regression analysis was performed in order to identify predictive variables of clinical success. *P* values of less than 0.05 were considered statistically significant. All statistical analyses were performed using the statistical software package SPSS 17.0 for Windows (SPSS Inc., Chicago, IL, USA).

Results

Patient characteristics and clinical courses

A total of 228 patients with malignant GOO underwent SEMS placement. Technical success in SEMS placement was achieved in all patients. The median duration of follow-up was 118.5 days (range, 6–1,678 days; interquartile range, 48.5–219 days).

Table 1 shows the baseline patient characteristics, the types of SEMS, and the treatment before stent insertion. The median patient age was 61 years (range, 26–94 years), and the patient population was predominantly male (71.1 %). Sites of obstruction were the peripyloric region in 210 (92.1 %) patients and the duodenal region in 18 (7.9 %) patients. The most common cause of GOO was gastric cancer (92.1 %), followed by pancreatobiliary and duodenal cancer (7.9 %). Radiologic findings including upper GI barium study and fluoroscopy showed complete obstruction in 94 (41.2 %) patients and partial obstruction in 134 (58.8 %) patients. One hundred and thirty patients were identified as having carcinomatosis. Of these, 54 had ascites. Approximately 58 % of patients (132 of 228) received uncovered stents and 42 % (96 of 228) received

Table 1 Baseline characteristics of 228 patients

Characteristic	Value
Age	
Median (range), years	61 (26–94)
<65 years	137 (60.1)
≥65 years	91 (39.9)
Gender	
Male	162 (71.1)
Female	66 (28.9)
ECOG	
0	6 (2.0)
1	62 (27.2)
2	88 (38.6)
3	68 (29.8)
4	4 (1.8)
Etiology	
Gastric cancer	210 (92.1)
Pancreatic cancer	11 (4.8)
Duodenal cancer	2 (0.9)
Ampulla of Vater cancer	2 (0.9)
Gallbladder cancer	3 (1.3)
Obstruction site	
Peripyloric region	210 (92.1)
Duodenal region	18 (7.9)
Grade of obstruction	
Partial	134 (58.8)
Complete	94 (41.2)
Carcinomatosis	130 (57.0)
Ascites	54 (23.7)
No. of metastatic sites[a]	
0	13 (5.7)
1	58 (25.4)
2	87 (38.2)
≥3	70 (30.7)
Stent	
Uncovered	132 (57.9)
Covered	96 (42.1)
Length of stent	
Median (range), cm	9 (6–16)
<9 cm	110 (48.2)
≥9 cm	118 (51.8)
Previous chemotherapy	101 (44.3)
GOOSS status	
Before stent insertion, median (range)	1 (0–2)
After stent insertion, median (range)	2 (0–3)

SEMS self-expandable metallic stent, *ECOG* Eastern Cooperative Oncology Group, *GOOSS* gastric outlet obstruction scoring system

Data are presented as *n* (%) unless otherwise indicated

[a] Metastatic sites included metastasis to distant lymph nodes, distant organs, and peritoneum

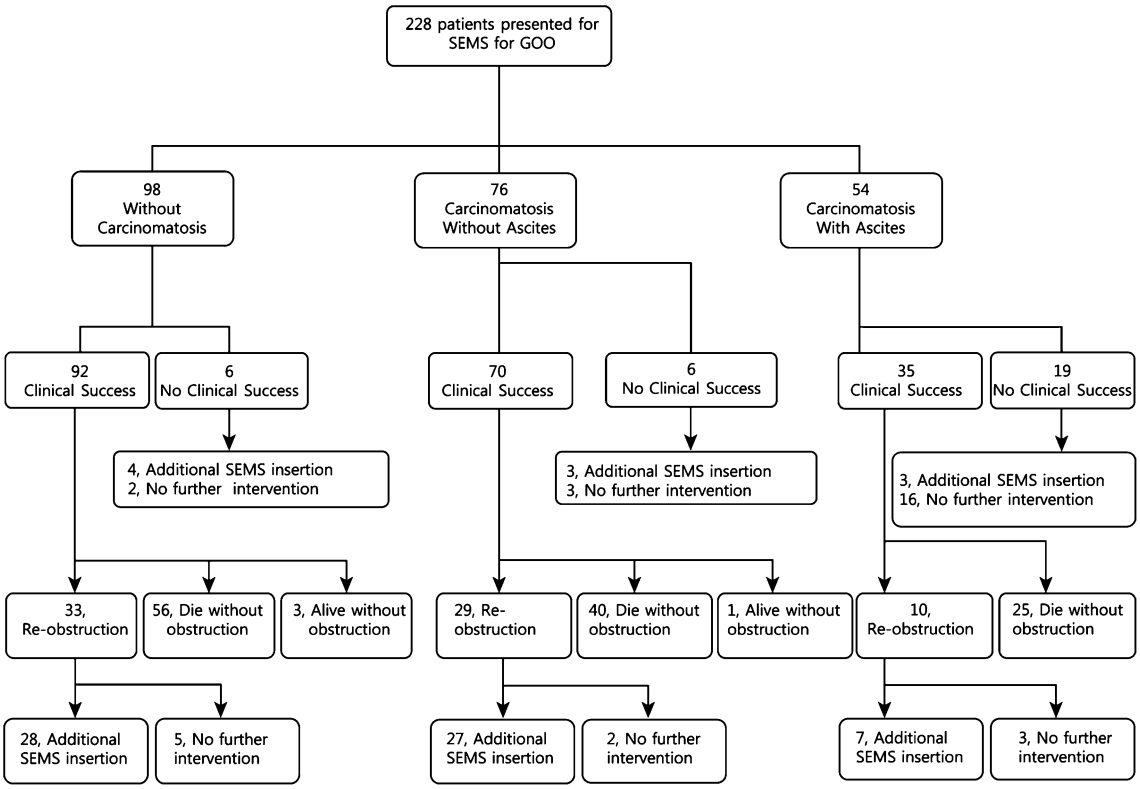

Fig. 1 Flow chart of clinical courses

covered stents. One hundred and one patients (44.3 %) received previous palliative chemotherapy therapy.

Figure 1 shows a flowchart of clinical courses. Clinical success was achieved in 86.4 % of patients (197 of 228). In patients without carcinomatosis, clinical success was achieved in 93.9 % of patients (92 of 98). Of these, 33 patients (35.9 %) required further endoscopic intervention, and 28 of these patients were treated with additional SEMS placement.

In the group of patients with carcinomatosis, clinical success was achieved in 80.8 % of patients (105 of 130). Of these patients, 39 (30 %; 29 patients without ascites and 10 patients with ascites) required further endoscopic intervention. Of these, 27 patients without ascites and 7 patients with ascites were treated with additional SEMS placement.

Outcomes and predictive factors of clinical success after SEMS placement in relation to malignancy status

Ninety-eight patients without carcinomatosis and 130 patients with carcinomatosis were treated with SEMS (Table 2). Patients without carcinomatosis tended to be older (≥65 years) than patients with carcinomatosis ($P = 0.007$). There were significant differences in the mean GOOSS status after SEMS placement between the two groups ($P = 0.010$). Furthermore, clinical success rate was statistically significantly higher in patients without carcinomatosis than in those with carcinomatosis (93.9 vs. 80.8 %; $P = 0.004$). However, sex, ECOG status, grade of obstruction, stent type, and previous chemotherapy history did not differ between the two groups. We further classified patients with carcinomatosis into two groups according to presence of ascites. In subgroup analysis of patients with carcinomatosis, clinical success rate was lower in patients with ascites (64.8 %) than in those without ascites (92.1 %, $P < 0.001$). We performed univariate and multivariate logistic regression analyses in order to detect putative predictors of the clinical success of SEMS placement in GOO patients (Table 3). The univariate analysis showed that ECOG status (≥3), carcinomatosis with ascites, and two or more metastatic diseases other than peritoneum were predictors of poor clinical outcomes. In the multivariate analysis, carcinomatosis without ascites was not shown to be a factor associated with clinical success rate, compared with absence of carcinomatosis. Carcinomatosis with ascites, however, showed a lower clinical success rate than that for absence of carcinomatosis [adjusted odds ratio (OR) 0.163, 95 % confidence interval (CI) 0.058–0.461]. In addition, poor performance status (ECOG status ≥3, adjusted OR 0.178, 95 % CI 0.078–0.409) was an independent predictive factor for poor clinical success of SEMS placement. On the contrary, multiple metastatic diseases (≥2) other than the peritoneum was not an independent

Table 2 Outcomes of SEMS placement in relation to malignancy status in gastric outlet obstruction patients

Characteristic	Without carcinomatosis ($n = 98$)	Carcinomatosis ($n = 130$)	P
Age			0.007
<65 years	49 (50)	88 (67.7)	
≥65 years	49 (50)	42 (32.3)	
Gender			0.284
Male	66 (67.3)	96 (73.8)	
Female	32 (32.7)	34 (26.2)	
ECOG			0.087
<3	73 (74.5)	83 (63.8)	
≥3	25 (25.5)	47 (37.2)	
Previous chemotherapy	41 (43.4)	60 (46.2)	0.516
Grade of obstruction			0.082
Partial	64 (65.3)	70 (53.8)	
Complete	34 (34.7)	60 (46.2)	
Length of stent			0.126
<9 cm	53 (54.1)	57 (43.8)	
≥9 cm	45 (45.9)	73 (56.2)	
Covered stent			0.638
No	55 (56.1)	77 (59.2)	
Yes	43 (43.9)	53 (40.8)	
Clinical success			0.004
No	6 (6.1)	25 (19.2)	
Yes	92 (93.9)	105 (80.8)	
GOOSS status after stent insertion, mean ± SD	2.19 ± 0.67	1.92 ± 0.94	0.010

SEMS self-expandable metallic stent, *ECOG* Eastern Cooperative Oncology Group, *GOOSS* gastric outlet obstruction scoring system

Data are presented as *n* (%) unless otherwise indicated

factor for clinical success, although it tended to lower clinical success (adjusted OR 0.508, 95 % CI 0.210–1.230).

Stent patency

The median stent patency period was 63 days. Stent patency (Fig. 2) did not differ significantly between patients without carcinomatosis and with carcinomatosis (71 days, 95 % CI 51.53–90.47, vs. 52 days, 95 % CI 37.90–66.10; $P = 0.077$). Additionally, stent patency (Fig. 3) did not differ significantly between patients with carcinomatosis without ascites and those with ascites (60 days, 95 % CI 47.91–72.09, vs. 43 days, 95 % CI 23.71–66.29; $P = 0.592$).

Discussion

Malignant GOO is a common late distressing complication of many GI and other metastatic cancers. Currently, SEMS placement is a popular method for the treatment of malignant GOO because it allows for shorter hospitalization periods and rapid restoration of gastric motility with lower costs and fewer complications compared to surgical treatments [3–5].

We analyzed the clinical outcomes of SEMS placement and identified predictive factors for clinical success in treating malignant GOO. In the present study, technical success was achieved in all patients regardless of grade of obstruction. In addition, clinical success rate was not influenced by grade of obstruction before SEMS placement. On the contrary, carcinomatosis was a predictor of poor clinical outcome for determining the clinical success of SEMS placement in malignant GOO. Furthermore, ascites in patients with carcinomatosis was a strong predictive factor of the poor clinical success of SEMS placement in carcinomatosis patients. To date, there are very few studies demonstrating the clinical importance of ascites in carcinomatosis patients who undergo SEMS placement [12]. To our knowledge, this is the largest study focusing on ascites as associated predictive factors of SEMS placement with malignant GOO ever performed at a single institution.

Clinically, peritoneal carcinomatosis has been considered to be a relative contraindication to SEMS placement for GOO [6–9]. Furthermore, previous studies did not actively place SEMS in peritoneal carcinomatosis patients. In addition, the theoretical risk has not often been studied objectively.

However, one recent study reported that carcinomatosis should not be considered a contraindication to SEMS placement in selected patients with malignant GOO [10]. These contradictory results compared with our study could be explained by differences in the characteristics of the enrolled patients. Most importantly, our study had a larger portion of patients with ascites compared with the previous study. Further, most of the patients enrolled in our study were gastric cancer patients, and very few had pancreatobiliary cancer. These differences in clinical factors between the patient populations may be why the clinical importance of ascites has not been as obvious as in previous studies.

In terms of carcinomatosis in patients with GOO, younger patients were more common in the carcinomatosis group in our study. This result can be partly explained by the fact that most enrolled patients had gastric cancer. Previous studies showed that patients with gastric cancer

Table 3 Associate factors for clinical success of SEMS placement in malignant gastric outlet obstruction patients

Characteristic	Crude OR	95 % CI	*P*	Adjusted OR	95 % CI	*P*
Age (≥65 years)	1.243	0.565–2.736	0.589			
Female gender	0.598	0.272–1.314	0.201			
ECOG ≥ 3	0.166	0.073–0.377	<0.001	0.178	0.078–0.409	<0.001
Previous chemotherapy	0.711	0.333–1.519	0.379			
Complete obstruction	0.830	0.387–1.780	0.633			
Stent length (≥9 cm)	0.544	0.248–1.196	0.130			
Covered stent	1.008	0.468–2.172	0.984			
Carcinomatosis	0.274	0.108–0.697	0.007			
No carcinomatosis	1			1		
Carcinomatosis and no ascites	0.761	0.235–2.460	0.648	0.699	0.209–2.330	0.559
Carcinomatosis and ascites	0.120	0.044–0.326	<0.001	0.163	0.058–0.461	0.001
Multiple metastatic diseases other than peritoneum[a]	0.377	0169–0.841	0.017	0.508	0.210–1.230	0.133

SEMS self-expandable metallic stent, *OR* odds ratio, *CI* confidence interval, *ECOG* Eastern Cooperative Oncology Group

[a] This variable included patients who had two or more metastatic sites other than peritoneum

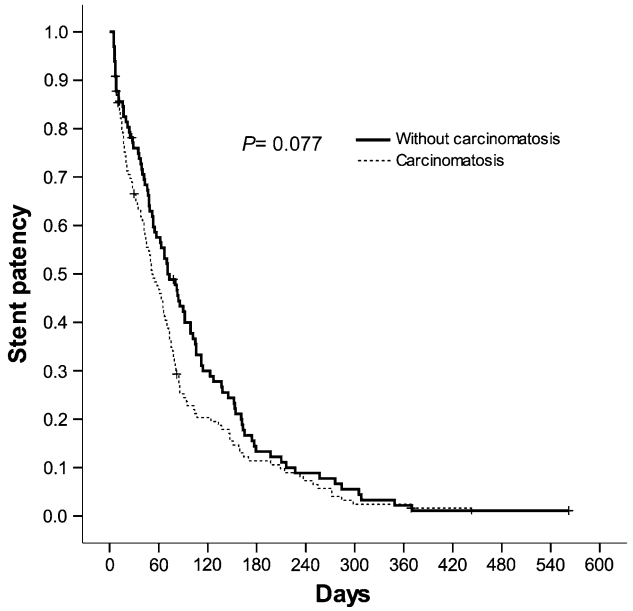

Fig. 2 Kaplan–Meier plots of cumulative stents patency according to malignancy status in gastric outlet obstruction patients. Cumulative stent patency did not differ between the patients without carcinomatosis and those with carcinomatosis (71 days, 95 % CI 51.53–90.47, vs. 52 days, 95 % CI 37.90–66.10; $P = 0.077$)

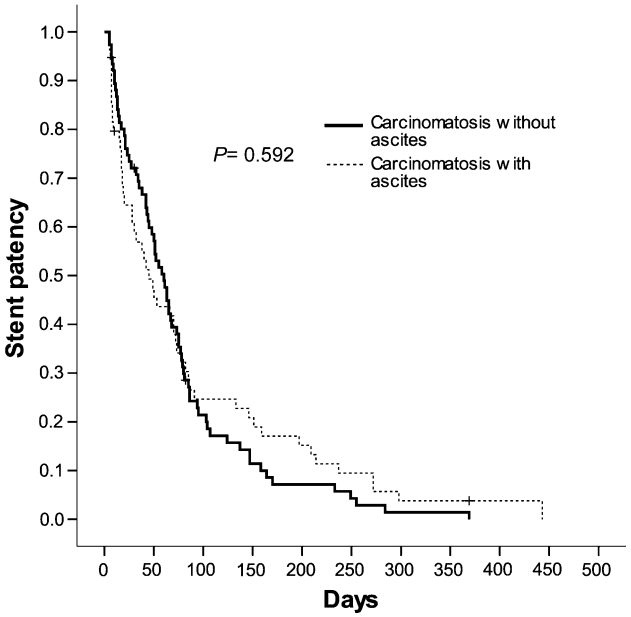

Fig. 3 Kaplan–Meier plots for cumulative stents patency according to the presence of ascites in gastric outlet obstruction patients with carcinomatosis. Cumulative stent patency did not differ between the patients without ascites and those with ascites (60 days, 95 % CI 47.91–72.09, vs. 43 days, 95 % CI 23.71–66.29; $P = 0.592$)

with peritoneal carcinomatosis are typically younger in age (<65 years) in Korea [13]. There was a significant difference in GOOSS status after SEMS placement according to the presence of carcinomatosis or ascites. Generally, the presence of carcinomatosis or ascites can result in diminished bowel movements [14]. Therefore, in these circumstances, the degree of symptom improvement after SEMS placement might be different in the presence of carcinomatosis or ascites.

Though there was no difference in stent patency after SEMS placement between patients without carcinomatosis and those with carcinomatosis, there was a significant difference in clinical success. In addition, multivariate analysis showed that poor performance status (ECOG status ≥3) and carcinomatosis with ascites were independent risk factors for poor clinical success of SEMS placement. These findings suggested that SEMS placement may be an option for palliative treatment in patients with good

performance status who do not have ascites even if carcinomatosis is present. Selection of SEMS placement, however, should be considered carefully in patients with poor performance status or in patients who show carcinomatosis with ascites. These results could be explained by several factors. First, about half of advanced cancer patients report distressing GI symptoms, including anorexia, nausea, vomiting, weight loss, constipation, early satiety, and dysphagia [15, 16]. Gastric emptying of liquids and solid food appears to be slightly accelerated at lower exercise intensity [17], and colonic transit time is accelerated after physical activity [18–20]. However, poor performance status (ECOG status $\geq$3) patients are capable of only limited self-care, and are confined to a bed or a chair for more than 50 % of waking hours in most situations and are hard-pressed to exercise at low intensity. These overall patient conditions might impair the clinical success of SEMS placement, even if SEMS placement is technically successful. Second, previous studies have shown that documented peritoneal carcinomatosis is a relative contraindication to SEMS placement for malignant GOO because of the high risk for multilevel small bowel obstruction [6–8]. In our study, even if no definite small bowel obstruction was detected by radiologic study in the carcinomatosis group, there was still a possibility of cancer infiltration to the small bowel. This spread could affect both colonic transit time and gastric emptying time. Third, nonmalignant ascites without carcinomatosis can also impair gastric motility [14]. Malignant ascites is a pathologic condition due to primary malignancy, and it can cause peritumoral inflammation [21, 22]. This inflammation can alter GI motor function and induce dysmotility [23, 24].

Our study has several limitations. First, this was a single-center and retrospective study. Second, GOO was mostly due to gastric cancer in the enrolled patients, and the portion of pancreatobiliary malignancy was very small. Therefore, our results may not represent all types of malignant GOO. Third, we could not evaluate the clinical success rate of SEMS placement according to the amount of ascites because it is difficult to objectively classify the amount of ascites from radiologic images.

Even though this study had some limitations, we demonstrated the clinical importance of carcinomatosis and ascites in GOO patients who are scheduled for insertion of SEMS. Further larger-scale, prospective, randomized studies are warranted to validate our results.

In conclusion, our study showed that carcinomatosis with ascites and poor performance status (ECOG status $\geq$3) were predictors of poor clinical success of SEMS placement in GOO patients with GI malignancy. Therefore, physicians should consider the effectiveness of SEMS placement for carcinomatosis patients who have ascites or poor performance status.

Disclosures Han Ho Jeon, Chan Hyuk Park, Jun Chul Park, Choong Nam Shim, Sunyong Kim, Hyun Jik Lee, Hyuk Lee, Sung Kwan Shin, Sang Kil Lee, and Yong Chan Lee have no conflicts of interest or financial ties to disclose.

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