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# Predictors of stent dysfunction after self-expandable metal stent placement for malignant gastric outlet obstruction: tumor ingrowth in uncovered stents and migration of covered stents

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**Abstract**
*Background* Endoscopic metallic stenting is widely accepted as a palliation therapy for malignant gastric outlet obstruction (GOO). However, the predictors of stent dysfunction have not been clarified. We aimed to evaluate the predictors, especially tumor ingrowth in uncovered self-expandable metallic stents (U-SEMS) and migration of covered self-expandable metallic stents (C-SEMS), which are the main causes related to the stent characteristics.
*Methods* In this multicenter retrospective study, we compared patients with U-SEMS and C-SEMS in terms of clinical outcomes, and predictors of stent dysfunction.
*Results* In total, 252 patients (126 with U-SEMS and 126 with C-SEMS) were enrolled. There were no significant differences in technical success, clinical success, GOO score, or time to stent dysfunction. Tumor ingrowth was significantly more frequent in U-SEMS (U-SEMS, 11.90% vs. C-SEMS, 0.79%; $p=0.002$), and stent migration was significantly more frequent for C-SEMS (C-SEMS, 8.73% vs. U-SEMS, 0.79%; $p=0.005$). Karnofsky performance status ($p=0.04$), no presence of ascites ($p=0.02$), and insufficient (<30%) stent expansion ($p=0.003$) were significantly associated with tumor ingrowth in U-SEMS. Meanwhile, a shorter stent length ($p=0.05$) and chemotherapy ($p=0.03$) were predictors of C-SEMS migration.
*Conclusions* Both U-SEMS and C-SEMS are effective with comparable patencies. Tumor ingrowth and stent migration are the main causes of stent dysfunction for U-SEMS and C-SEMS, respectively. With regard to stent dysfunction, U-SEMS might be a good option for patients receiving chemotherapy, while C-SEMS with longer stents for patients in good condition. (Clinical trial registration number: UMIN000024059).

**Keywords** Malignant gastric outlet obstruction · Self-expandable metallic stent · Stent dysfunction · Stent migration · Tumor ingrowth

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Patients with gastric or pancreatobiliary cancer may develop gastric outlet obstruction (GOO) secondary to gastroduodenal stricture or obstruction. Considering the progression of these malignant cancers, treatment with a minimally invasive method is advisable. Gastrojejunostomy (GJ) was historically the standard treatment for malignant GOO. However, placement of a self-expandable metallic stent (SEMS) allows for faster resumption of oral food

intake and shorter hospitalization than does GJ [1, 2]. In recent years, endoscopic SEMS placement has become a feasible alternative to GJ, with more favorable clinical outcomes [3–5]. The efficacy and safety of endoscopic metallic stenting have been reported in patients with various malignant obstructions [6–8] and of various backgrounds [9].

In recent published reports, the technical success rates of endoscopic SEMS placement ranged from approximately 92–100%, whereas the clinical success rates were lower, ranging from approximately 80–91% [10–14]. Although endoscopic SEMS insertion has excellent technical and clinical success rates for relieving GOO symptoms, the clinical efficacy of SEMS is compromised for several reasons [15–17]. The main cause of failure of uncovered SEMS (U-SEMS) is tumor or tissue ingrowth via the stent mesh, which occurs in 4–26% of cases [3, 5, 18–21]. Covered SEMS (C-SEMS) have been designed to prevent this problem. Although C-SEMS prevent tumor ingrowth, stent migration occurs in 16–25% of cases and is a major adverse event requiring re-intervention [22, 23].

Even though many studies have revealed the clinical efficacy of SEMS, the factors that predict stent dysfunction and adverse events have not been fully elucidated [24, 25]. In particular, only a few clinical studies have evaluated the predictive factors of stent dysfunction for U-SEMS and C-SEMS individually. Both tumor ingrowth and migration are closely associated with the specific characteristics of the SEMS structure, and it is therefore advisable to evaluate them separately.

The purpose of the present study was to investigate the predictive factors for stent dysfunction after SEMS placement and to compare the characteristics of U-SEMS and C-SEMS in patients with malignant GOO. Moreover, we evaluated the main causes of stent dysfunction (tumor ingrowth for U-SEMS and stent migration for C-SEMS).

## Patients and methods

### Patients

We retrospectively evaluated 252 consecutive patients with malignant GOO treated by SEMS placement at Nagoya City University Graduate School of Medical Sciences and eight tertiary care referral centers from April 2004 to December 2015. C-SEMS and U-SEMS placements were performed in 126 patients each. Patients were included in this study if they had (1) unresectable malignant pyloroduodenal obstruction or malignant anastomotic obstruction, as shown by endoscopic or radiographic findings, and (2) obstruction of the stomach, duodenum, or jejunum causing nausea, vomiting, reduced oral intake, or weight loss. Patients were excluded if (1) SEMS placement was considered a high-risk endoscopic procedure, or (2) multiple gastrointestinal tract stenoses were present. Written informed consent of the procedure was obtained from all patients in accordance with the Declaration of Helsinki. This study was approved by the Review Board of the Nagoya City University Graduate School of Medical Sciences (approval no. 60160067).

### Technique, equipment, and procedure

For gastroduodenal stenting, a therapeutic endoscope with a working channel diameter of ≥3.7 mm that was either direct-viewing or side-viewing was used to place the SEMS. Patients were sedated with intravenous midazolam (5–10 mg) and pethidine hydrochloride (17.5–35 mg) as needed during SEMS placement. The endoscope was first positioned close to the gastric or duodenal stenosis site, and the GOO was evaluated endoscopically. Contrast medium was injected under fluoroscopic guidance to identify the site and length of the obstruction. An endoscopic retrograde cholangiopancreatography catheter with a biliary guidewire was passed through the stenosis site. After confirming the position and length of the stenosis site by the catheter, we determined the precise length and position of the SEMS. The SEMS was deployed and placed under endoscopic and fluoroscopic guidance.

Four SEMS models ranging from 18 to 22 mm in diameter and 60 to 120 mm in length were used. Two types of C-SEMS, the Ultraflex stent (Boston Scientific Japan, Tokyo, Japan) and Niti-S ComVi stent (Taewoong Medical, Seoul, Korea), were used. Two types of U-SEMS, the WallFlex duodenal stent (Boston Scientific Japan) and Niti-S pyloric stent (Taewoong Medical), were used. SEMS selection was based on the judgment of each endoscopist.

### Data analysis and evaluation

The baseline information collected included sex, age, Karnofsky performance status (KPS) score, GOO scoring system (GOOSS) score, diagnosis, site of obstruction, history of gastrectomy, presence of ascites/liver metastasis/peritoneal dissemination, narcotics for medical use, and chemotherapy after SEMS placement. The GOOSS is a scoring system that depends on the patient's level of oral intake: 0, no oral intake; 1, liquids only; 2, soft solids; and 3, low-residue or full diet [26]. The presence of ascites/liver metastasis/peritoneal dissemination was evaluated by computed tomography (CT) prior to the procedure.

The clinical outcomes were evaluated according to the following criteria: technical success, clinical success, oral intake status evaluated using the GOOSS, duration of stent patency, and adverse events. Technical success was defined

as adequate SEMS placement and precise positioning at the obstruction site, as confirmed by endoscopic combined with fluoroscopic guidance. Clinical success was defined as an improvement in the GOOSS score 3–4 weeks after SEMS placement. Time to stent dysfunction was defined as the period between stent placement and recurrence of obstructive symptoms caused by stent-related adverse events. When no stent-related adverse event occurred, stent patency was considered equal to the survival time from stent placement of the patient. A stent was determined to be dysfunctional if the patient failed to resume oral food intake. The stent expansion rate was defined as the minimum/maximum diameter of the SEMS determined by fluoroscopic imaging on the day of the procedure.

We compared technical success, clinical success, GOOSS score after SEMS placement, adverse event, and time to stent dysfunction between U-SEMS and C-SEMS. The following factors were evaluated as predictive factors for stent dysfunction in univariable and multivariable analyses: age, sex, KPS, primary cancer site, stent type, stent length, site of obstruction, chemotherapy, ascites, liver metastasis, pharmaceutical morphine use, peritoneal dissemination, and stent expansion rate on the day of the procedure. The main causes of adverse events those related to SEMS, namely tumor ingrowth for U-SEMS and migration with/without stent dysfunction for C-SEMS, were evaluated with respect to these same 13 variables.

### Statistical analysis

The Chi-square test and Fisher's exact test were used to compare categorical variables. The Mann–Whitney U-test was used to compare continuous variables. Statistical tests were two-sided, and statistical significance was defined as $p<0.05$. Factors with substantial impacts ($p<0.2$) in the univariable analysis were subsequently evaluated by multivariable analysis. Time to stent dysfunction was estimated by Kaplan–Meier analysis, and curves were compared by the log-rank test. All statistical analyses were performed using IBM SPSS statistical software, version 23 (IBM Corp., Armonk, NY, USA).

## Results

### Patient characteristics

In total, 252 patients with malignant duodenal obstruction were enrolled in this study. The demographic and clinical characteristics of the patients are shown in Table 1. Their median age was 74 years (range 39–101 years). Most common two etiologies of GOO were pancreatic biliary cancer ($n=100$, 39.7%) and gastric cancer ($n=123$, 48.8%). Chemotherapy was performed after SEMS placement in 74 patients (29.4%). The administration of chemotherapy was significantly higher in patients with C-SEMS than U-SEMS [38.1% (48/126) vs. 20.6% (26/126); $p=0.002$].

### Clinical outcomes

The clinical outcomes are summarized in Table 2. Technical success was achieved in 251 of the 252 patients (99.6%). The one case of technical failure occurred because the stent was deployed too distally. Clinical effectiveness was achieved in 215 of the 252 patients (82.1%). The mean GOOSS score improved significantly from 0.27 to 2.30 after SEMS placement ($p<0.001$).

Stent dysfunction occurred in 40 patients (15.9%). Of these, 17 (6.75%) exhibited stent ingrowth, 10 (3.97%) stent overgrowth, 7 (2.78%) stent migration, and 6 (2.38%) insufficient stent expansion. Stent ingrowth was more frequent in the U-SEMS group than in the C-SEMS group (U-SEMS vs. C-SEMS: 11.9% [15/126] vs. 0.79% [2/126], respectively; $p=0.002$). The median time to stent dysfunction

**Table 1** Patient demographics and clinical characteristics ($n=252$)

| | |
|---|---|
| Gender (male/female) | 160/92 |
| Age (median) [range] | 74 [39–101] |
| Karnofsky performance status (100 − 80/70 − 50/40 − 0) | 24/176/52 |
| Gastric outlet obstruction scoring system (0/1/2) | 201/35/16 |
| Diagnosis (pancreatic biliary cancer/gastric cancer/Others) | 100/123/29 |
| Site of obstruction (pylorus/duodenum/anastomosis) | 122/112/18 |
| Prior gastrectomy (yes/no) | 19/233 |
| Ascites (yes/no) | 98/154 |
| Liver metastasis (yes/no) | 94/158 |
| Peritoneal dissemination (yes/no) | 120/132 |
| Narcotics for medical use (yes/no) | 47/205 |
| Chemotherapy after SEMS placement (yes/no) regimen (S-1/S-1+CDDP/gemcitabine/paclitaxel/others) | 74/178 (29/10/10/8/17) |

*CDDP* cis-diamminedichloroplatinum; *SEMS* self-expandable metallic stent

**Table 2** Clinical outcomes and adverse events ($n=252$)

| | Overall | U-SEMS ($n=126$) | C-SEMS ($n=126$) | $p$-value |
|---|---|---|---|---|
| Technical success | 251 (99.6) | 126 (100) | 125 (99.2) | 1 |
| Clinical success | 215 (82.1) | 111 (88.1) | 104 (82.5) | 0.213 |
| GOOSS (0/1/2/3) after SEMS placement | 30/26/34/162 | 9/22/15/80 | 21/4/19/82 | 0.131 |
| Median time to stent dysfunction (days) [95%CI] | 67.5 [52.1–82.9] | 63 [48.6–77.4] | 86 [63.9-108.1] | 0.090 |
| Adverse events | | | | |
| Stent dysfunction | 40 (15.9) | 18 (14.3) | 22 (17.5) | 0.491 |
| Ingrowth | 17 (6.75) | 15 (11.9) | 2 (0.79) | 0.002* |
| Overgrowth | 10 (3.97) | 0 (0) | 10 (7.94) | 0.002* |
| Migration | 7 (2.78) | 1 (0.79) | 6 (4.76) | 0.120 |
| Insufficient stent expansion | 6 (2.38) | 2 (1.59) | 4 (3.17) | 0.684 |
| Perforation | 3 (1.19) | 0 (0) | 3 (2.38) | 0.247 |
| Pancreatitis | 2 (0.79) | 1 (0.79) | 1 (0.79) | 1 |
| Migration with/without stent dysfunction | 12 (4.76) | 1 (0.79) | 11 (8.73) | 0.005* |
| Cholangitis | 2 (0.79) | 1 (0.79) | 1 (0.79) | 1 |
| Pneumonia | 6 (2.38) | 2 (1.59) | 4 (3.17) | 0.684 |
| Bleeding | 1 (0.40) | 0 (0) | 1 (0.79) | 1 |

Values are presented as number (%) or median [range]

*GOOSS* gastric outlet obstruction scoring system; *SEMS* self-expandable metallic stent; *U-SEMS* uncovered self-expandable metallic stent; *C-SEMS* covered self-expandable metallic stent

*$P<0.01$; **$P<0.001$

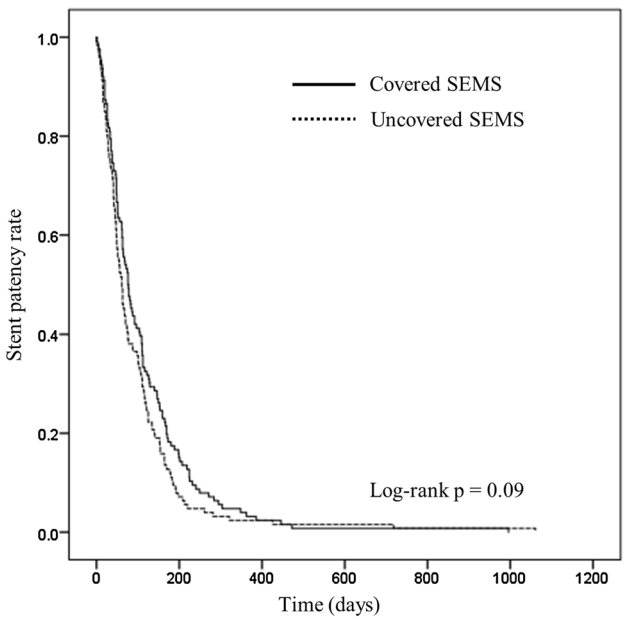


**Fig. 1** Kaplan–Meier plots for cumulative stent patency ($p=0.09$, *log-rank test*). The cumulative stent patency did not differ between the covered SEMS and uncovered SEMS groups. *SEMS* self-expandable metallic stent

was 67.5 days (95% confidence interval [CI], 52.1–82.9 days). Sixty-three days in the U-SEMS group and 86 days in the C-SEMS group, respectively ($p=0.09$) (Fig. 1).

The other adverse events were perforation ($n=3$, 1.19%), mild pancreatitis ($n=2$, 0.79%), stent migration with/without stent dysfunction ($n=12$, 4.76%), cholangitis ($n=2$, 0.79%), pneumonia ($n=6$, 2.38%), and bleeding ($n=1$, 0.40%). Stent migration with/without stent dysfunction was more frequent in the C-SEMS group than in the U-SEMS group (U-SEMS vs. C-SEMS: 0.79% [1/126] vs. 8.73% [11/126], respectively; $p=0.005$). Among the 12 patients with stent migration, 5 (41.7%) did not receive re-intervention because they were asymptomatic.

### Predictive factors for stent dysfunction

Table 3 summarizes the results of the univariable and multivariable analyses of predictive factors for stent dysfunction. Stent dysfunction was observed in 40 (15.9%) of the 252 patients.

In total, age ($p=0.02$), the site of obstruction (pylorus; $p=0.02$), chemotherapy ($p=0.001$), and presence of ascites ($p=0.02$) were significantly associated with stent dysfunction in the univariable analysis. In the multivariable analysis, the site of obstruction ($p=0.03$) was the only significant independent factor for stent dysfunction.

### Predictive factors for stent ingrowth in U-SEMS

The 126 patients who underwent U-SEMS placement were divided into two groups according to whether they

**Table 3** Predictive factors of stent dysfunction

| Variable | Univariable analysis | | Multivariable analysis | |
|---|---|---|---|---|
| | OR | *p*-value | OR | *p*-value |
| Age (<70) | 2.19 (1.11–4.35) | 0.02* | 2.13 (0.99–4.62) | 0.06 |
| Gender (male) | 1.63 (0.77–3.44) | 0.20 | 1.23 (0.55–2.74) | 0.62 |
| KPS (>40) | 2.56 (0.87–7.57) | 0.09 | 1.81 (0.56–5.85) | 0.32 |
| Diagnosis (pancreatobiliary cancer) | 0.81 (0.40–1.63) | 0.55 | | |
| Stent type (covered) | 1.27 (0.64–2.50) | 0.49 | | |
| Stent length (<12 cm) | 1.72 (0.83–3.57) | 0.14 | 1.66 (0.76–3.64) | 0.20 |
| Site of obstruction (pylorus) | 2.24 (1.11–4.54) | 0.02* | 2.38 (1.07–5.28) | 0.03* |
| Chemotherapy (yes) | 3.46 (1.71–6.98) | 0.001** | 1.88 (0.83–4.25) | 0.13 |
| Ascites (yes) | 0.40 (0.18–0.89) | 0.02* | 0.44 (0.19–1.02) | 0.06 |
| Liver metastasis (yes) | 1.01 (0.50–2.03) | 0.98 | | |
| Pharmaceutical morphine use (yes) | 0.74 (0.29–1.87) | 0.52 | | |
| Peritoneal dissemination (yes) | 1.19 (0.60–2.33) | 0.62 | | |
| Stent expansion (<30%) | 1.73 (0.86–3.47) | 0.12 | 1.52 (0.72–3.22) | 0.28 |

Total number of patients $n=252$; stent dysfunction, $n=40$; no stent dysfunction, $n=212$

*KPS* Karnofsky performance status; *OR* odds ratio (95%CI)

*$p<0.05$; **$p<0.01$

developed stent ingrowth ($n=15$) or not ($n=111$). As shown in Table 4, the etiology (pancreatobiliary cancer; $p=0.04$), site of obstruction (pylorus; $p=0.05$), presence of ascites ($p=0.05$), and stent expansion <30% ($p=0.03$) were significantly associated with stent ingrowth in the univariable analysis. In the multivariable analysis, a KPS > 40 ($p=0.04$), no presence of ascites ($p=0.02$), and stent expansion <30% ($p=0.003$) were significantly associated with stent ingrowth.

### Predictive factors for stent migration in C-SEMS

The 126 patients who underwent C-SEMS placement were divided into two groups according to whether they developed stent migration ($n=11$) or not ($n=115$). Table 5 summarizes the predictors of stent migration in patients with a C-SEMS. Stent length < 12 cm (OR 4.94; 95% CI 0.98–25.02; $p=0.05$) and chemotherapy (OR 5.01; 95% CI 1.18–21.34; $p=0.03$) were significantly associated with stent migration in the univariable and multivariable analyses.

**Table 4** Predictive factors of ingrowth in U-SEMS

| Variable | Univariable analysis | | Multivariable analysis | |
|---|---|---|---|---|
| | OR | *p*-value | OR | *p*-value |
| Age (<70) | 1.16 (0.35–3.92) | 0.81 | | |
| Gender (male) | 1.42 (0.45–4.42) | 0.55 | | |
| KPS (>40) | 4.95 (0.62–39.34) | 0.13 | 13.12 (1.16–148.18) | 0.04* |
| Diagnosis (pancreatobiliary cancer) | 0.26 (0.07–0.95) | 0.04* | 0.51 (0.06–4.55) | 0.55 |
| Stent type (niti-S) | 0.61 (0.20–1.90) | 0.39 | | |
| Stent length (<12 cm) | 1.02 (0.30–3.45) | 0.98 | | |
| Site of obstruction (Pylorus) | 3.16 (1.01–9.88) | 0.05* | 5.19 (0.60–44.67) | 0.13 |
| Chemotherapy (yes) | 1.47 (0.43–5.06) | 0.54 | | |
| Ascites (yes) | 0.217 (0.05–1.01) | 0.05* | 0.11 (0.02–0.66) | 0.02* |
| Liver metastasis (yes) | 1.28 (0.42–3.87) | 0.66 | | |
| Pharmaceutical morphine use (yes) | 0.86 (0.23–3.29) | 0.82 | | |
| Peritoneal dissemination (yes) | 0.59 (0.19–1.83) | 0.36 | | |
| Stent expansion (<30%) | 3.44 (1.09–10.88) | 0.03* | 11.76 (2.35–58.89) | 0.003** |

Total number of patients $n=126$; ingrowth, $n=15$; no ingrowth, $n=111$

*KPS* Karnofsky performance status; *OR* odds ratio (95%CI)

*$p<0.05$; **$p<0.01$

**Table 5** Predictive factors of migration in C-SEMS

| Variable | Univariable analysis | | Multivariable analysis | |
|---|---|---|---|---|
| | OR | *P*-value | OR | *p*-value |
| Age (<70) | 2.44 (0.68–8.81) | 0.17 | 1.50 (0.37–6.03) | 0.57 |
| Gender (male) | 0.83 (0.23–3.01) | 0.78 | | |
| KPS (>40) | Inf (0.62–inf) | 0.21 | Inf (0.06–inf) | 1 |
| Diagnosis (pancreatobiliary cancer) | 0.547 (0.16–1.91) | 0.34 | | |
| Stent type (niti-S) | Inf (0.09–inf) | 1 | | |
| Stent length (<12 cm) | 6.06 (1.25–29.31) | 0.03* | 4.94 (0.98–25.02) | 0.05* |
| Site of obstruction (pylorus) | 0.66 (0.19–2.30) | 0.52 | | |
| Chemotherapy (yes) | 7.91 (1.97–31.82) | 0.01* | 5.01 (1.18–21.34) | 0.03* |
| Ascites (yes) | 0.86 (0.24–3.10) | 0.81 | | |
| Liver metastasis (yes) | 1.94 (0.56–6.73) | 0.30 | | |
| Pharmaceutical morphine use (yes) | 0.54 (0.07–4.47) | 0.57 | | |
| Peritoneal dissemination (yes) | 1.31 (0.38–4.53) | 0.67 | | |
| Stent expansion (<30%) | 2.02 (0.49–8.35) | 0.33 | | |

Total number of patients $n = 126$; ingrowth, $n = 11$; no ingrowth, $n = 115$

*KPS* Karnofsky performance status; *OR* odds ratio (95%CI)

*$p < 0.05$

## Discussion

This study demonstrated that endoscopic metallic stenting for malignant GOO has high technical and clinical success with acceptable adverse events. This suggests that endoscopic SEMS placement is a safe and effective palliative therapy for patients with GOO. The improvement in the GOOSS score was good in most patients, which is in agreement with previous studies [19, 27]. In the present multicenter study, we found no significant differences between U-SEMS and C-SEMS in terms of the time to stent dysfunction after endoscopic SEMS placement ($p = 0.09$). However, we revealed predictive factors for stent dysfunction between the U-SEMS and C-SEMS groups. Especially for evaluation of C-SEMS, few studies using multivariate analyses have included a sufficient number of patients to evaluate the predictors of stent migration, which is the main cause of stent dysfunction. Additionally, few studies have evaluated the predictors of the main causes of stent dysfunction individually (tumor ingrowth for U-SEMS and migration for C-SEMS).

Recently, published reports have clarified the efficacy of SEMS placement for the treatment of malignant GOO. The technical success rates of endoscopic stent placement for malignant GOO range from approximately 92–100%, whereas clinical success rates range from approximately 80–91% [10–14]. These results are similar to those of the present study (technical success rate, 99.6%; clinical success rate, 85.3%). Only one technical failure occurred as a result of SEMS deployment being too distal. To deploy a SEMS in the optimal position, the pulling force (i.e., traction force) should be considered to enable appropriate retraction of the delivery catheter [28].

Several retrospective studies have compared the outcomes of C-SEMS and U-SEMS in patients with malignant GOO and have revealed no differences in re-obstruction rates, overall adverse events, or time to stent dysfunction [29, 30]. U-SEMS are often associated with re-stenosis caused by tumor ingrowth through the stent mesh. Covered SEMSs can prevent tumor ingrowth, but their potential for maintaining longer patency in patients with malignant GOO has not yet been proven. The migration rates of C-SEMS reportedly range from 4 to 26% [25, 31–35]. Furthermore, Kim et al. [22] performed a prospective study and found that stent migration was more common in the C-SEMS group [25.8% (8 of 31 patients)] than in the U-SEMS group [2.8% (1 of 36 patients)], whereas re-stenosis due to tumor ingrowth was more common in the U-SEMS than in the C-SEMS group [25.0% (9 of 36 patients) vs. 0.0% (0 of 31 patients), respectively].

Our study demonstrates that insertion of either U-SEMS or C-SEMS is an effective palliative treatment in terms of stent dysfunction. The time to stent dysfunction did not differ between the U-SEMS and C-SEMS groups. Only the site of obstruction (pylorus) was a predictive factor for stent dysfunction among all patients with U-SEMS or C-SEMS placement in the multivariable analysis. The incidence of ingrowth was significantly higher in the U-SEMS than in the C-SEMS group (11.9 vs. 0.79%, $p = 0.002$). On the other hand, stent migration was more frequent in the C-SEMS than in the U-SEMS group (8.73 vs. 0.79%; $p = 0.005$). Therefore, the advantage of C-SEMS in terms

of decreasing the ingrowth rate might be offset by the higher rate of migration and overgrowth in C-SEMS from the viewpoint of total adverse events. In the C-SEMS migration group, six (54.5%) patients underwent re-stenting due to duodenal obstruction symptoms, and five patients developed asymptomatic stent migration. However, in the asymptomatic group ($n=5$), three patients were confirmed to have duodenal obstruction by CT without symptoms of obstruction and were treated with peripheral parental nutrition or total parenteral nutrition. Those patients may have developed obstruction symptoms if they had resumed oral intake.

In terms of tumor ingrowth, which is a main cause of U-SEMS dysfunction, a KPS > 40, no presence of ascites, and stent expansion (<30%) on the day of the procedure were predictive factors in the multivariable analysis. Although most of our patients are in advanced cancer stage, survival after the endoscopic procedure was generally longer in patients of good condition (good performance status/without ascites) than poor condition; therefore, tumor occlusion might be occurred frequently in patients with KPS > 40 and/or in patients who did not have ascites at the time of the procedure. Furthermore, we previously reported that insufficient stent expansion on the procedure day was a stent-related predictive factor for poor oral intake [6]. We hypothesized in that report that slow stent expansion causes tumor progression through the U-SEMS space, which thereby results in ingrowth. Moreover, insufficient stent expansion was observed more frequently in patients with gastrointestinal obstruction due to anastomotic sites or metastatic cancer. These patients might be good candidates for C-SEMS [36].

We also evaluated predictors of stent migration, which is a main cause of C-SEMS dysfunction. The stent length (<12 cm) and chemotherapy were significantly associated with stent migration in the multivariable analysis. Kim et al. [25] reported that stent migration was significantly associated with chemotherapy after stent placement, which supports our data. In that report, predictors were only evaluated with respect to chemotherapy and balloon dilation before or after chemotherapy. We speculate that chemotherapy decreases tumor volume and reduces the alimentary tract compression, which might be the cause of stent migration. We conducted a multivariable analysis of both patient- and stent-related factors. From that standpoint, we recommend the use of a longer C-SEMS to prevent migration. Furthermore, Isayama et al. [37] recommended the use of longer stents to prevent stent occlusion caused by tumor overgrowth or ingrowth at the uncovered portion.

Our study has certain limitations. First, it was retrospective, and selection of the stent type (U-SEMS or C-SEMS) was based on the preference and experience of the physician. Second, in retrospective series, it is common to lose patients if the SEMS is not placed due to the previous failure, therefore, technical success might be low. Third, the rate of chemotherapy after SEMS placement differed between groups; thus, the C-SEMS group showed a trend toward a longer median survival time. Large-scale randomized prospective studies are warranted.

In conclusion, either U-SEMS or C-SEMS placement is an effective treatment for the palliation of unresectable malignant GOO. Although it is required to conduct a comparative study with homogeneous groups, U-SEMS might be a good option for patients planning chemotherapy after SEMS placement, while C-SEMS for patients with good condition (good KPS or no ascites). When a C-SEMS is selected, a longer stent might be preferable in terms of preventing stent migration.

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**Compliance with ethical standards**

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