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【 ORIGINAL ARTICLE 】

The Palliative Effect of Endoscopic Uncovered Self-expandable Metallic Stent Placement Versus Gastrojejunostomy on Malignant Gastric Outlet Obstruction: A Pilot Study with a Retrospective Chart Review in Saga, Japan

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Abstract:

Objective Endoscopic self-expandable metallic stent (SEMS) placement and gastrojejunostomy (GJY) are palliative treatments for malignant gastric outlet obstruction (GOO). The aim of the present study was to compare the palliative effects of these treatments and identify predictors of a poor oral intake after treatment.

Methods and Patients In total, 65 patients with GOO at multiple centers in Saga, Japan, were evaluated. Thirty-eight patients underwent SEMS placement, and 27 underwent GJY from January 2010 to December 2016. The characteristics and outcomes of the two groups were compared to detect predictors of treatment failure.

Results No significant differences in the technical success, clinical success, post-treatment total protein, hospital discharge, duration from eating disability to death, or post-treatment overall survival were present between the SEMS and GJY groups. More patients in the GJY group than in the SEMS group received chemotherapy (51.4% vs. 26.3%, respectively; p=0.042). The period from treatment to the first meal was longer in the GJY group than in the SEMS group (4.5 vs. 3.0 days, respectively; p=0.013). The present study did not identify any risk factors for failure of SEMS placement. Although the stent length tended to be associated with a poor prognosis, the correlation was not statistically significant (odds ratio: 0.60, 95% confidence interval: 0.36-1.01, p=0.053).

Conclusion Patients with GOO started meals more promptly after SEMS than after GJY, but the clinical outcomes were not markedly different between the SEMS and GJY groups. These findings suggest that endoscopic uncovered SEMS placement might be a feasible palliative treatment for GOO.

Key words: gastric cancer, pancreatic cancer, palliative treatment, chemotherapy

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Introduction

Gastric outlet obstruction (GOO) is caused by malignant etiologies, such as gastric cancer, duodenal cancer, pancreatobiliary cancer, hepatocellular cancer, metastatic cancer, and malignant lymphoma (1-4). Patients with malignant GOO develop undesirable clinical symptoms, such as nausea, vomiting, abdominal pain, and difficulty eating, leading to a poor quality of life. Gastrojejunostomy has been performed to resolve these obstruction-induced clinical symptoms (5, 6).

In 1992, Topazian et al. (7) reported that endoscopic self-expandable metallic stent (SEMS) placement was useful for palliation in patients with malignant gastrointestinal obstruction. Many reports have since indicated the efficacy and safety of SEMS placement (8-19). As a result, endoscopic SEMS placement has become an option for treatment of the clinical symptoms of malignant GOO.

Several studies have compared the clinical outcomes of SEMS placement with those of surgical gastrojejunostomy (GJY) for GOO caused by gastric cancer (20-24), pancreaticobiliary cancer (25, 26), and all other etiologies (27-34). One study indicated that SEMS placement for malignant GOO was advantageous for a liquid and/or soft diet with a low rate of procedure-related complications. Another study indicated that the re-intervention rate was higher in association with SEMS placement than GJY (28). Although the greatest advantage of stenting over GJY for malignant GOO might be its low invasiveness, whether or not the clinical outcomes of SEMS placement are comparable with those of GJY remains unclear. No studies have indicated which treatment should be chosen for patients with malignant GOO.

The aim of the present study was to compare the clinical outcomes of SEMS placement with those of GJY for treatment of malignant GOO and identify predictors of a poor oral intake after stenting.

Materials and Methods

Patients

The present retrospective study included patients with clinical GOO caused by stage IV unresectable cancer. The patients underwent endoscopic SEMS placement or GJY at Ureshino Medical Center or Karatsu Red Cross Hospital from January 2010 to December 2016. All patients had a symptomatic obstruction preventing any oral intake except liquids. SEMS placement or GJY was performed for patients with an unresectable malignant pyloroduodenal obstruction or malignant anastomotic obstruction based on the patient's endoscopic and/or radiographic findings, tumor stage, comorbidities, and preferences. Patients with multiple stenoses of the gastrointestinal tract and those who had undergone tentative bypass treatment were excluded from the present study. This study was approved by the ethics committees of Ureshino Medical Center and Karatsu Red Cross Hospital, and the procedures performed were in accordance with the Declaration of Helsinki.

SEMS placement or GJY

One of three types of uncovered SEMS, all with a diameter of 22 mm and length of 60 to 120 mm, was selected by the endoscopist: the Wallflex duodenal stent (Boston Scientific Japan, Tokyo, Japan), the Niti-S pyloric/duodenal stent (Taewoong Medical, Gyeonggi-do, South Korea), or the Evolution duodenal controlled-release stent (Cook Medical Japan, Tokyo, Japan).

The procedure has been explained in detail in previous reports (8-10). In brief, the patients were sedated with diazepam (5-20 mg), pentazocine (7.5-15 mg), and/or midazolam (1-10 mg) during stent placement. SEMS placement was performed through the working channel of a direct-viewing scope with a diameter of ≥3.7 mm. The endoscope was inserted near the obstruction site. Contrast medium was injected under fluoroscopic guidance to identify the site and length of the obstruction. The obstruction was passed with a 7-Fr catheter through a 0.035-inch-diameter, 480-cm-long guide wire (Jagwire; Boston Scientific Japan) for the determination of the most appropriate length and type of stent. The stent delivery system involved insertion over the guide wire through the working channel for the placement of the uncovered SEMS at the obstructive lesion. GJY was performing using conventional side-to-side gastrojejunostomy or modified Divine gastrojejunostomy as previously described (5, 6), with the method selected by the operator.

Data analyses

The GOO score was used to classify each patient's level of oral intake as follows: 0: no oral intake, 1: liquids only, 2: soft solids, and 3: a low-residue diet or full diet (14). Data regarding the sex, age, diagnosis, history of abdominal operations, presence of ascites, serum total protein, and GOO score before treatment were collected as baseline information. The median survival time was defined as the duration of time from the date of SEMS placement or GJY to the date of patient death. The presence of ascites was evaluated by computed tomography and/or ultrasound before the procedure. The clinical outcomes of SEMS placement and GJY were evaluated according to the following parameters: i) technical success; ii) clinical success; iii) period from treatment to first meal; iv) post-treatment total protein; v) the overall survival; vi) post-treatment chemotherapy; and vii) possibility of hospital discharge. Clinical success was defined as improvement of the obstruction, which was indicated by a post-treatment GOO score of 2 or 3.

Statistical analyses

The patients' characteristics are expressed as the median and interquartile range (IQR). Categorical variables were evaluated by the chi-squared test or Fisher's exact test. Continuous variables were examined with Wilcoxon's signed-

Table 1. Characteristics of Patients who Underwent Endoscopic SEMS Placement Versus GJY for Gastric Outlet or/and Duodenal Obstruction.

	SEMS (n=38)	GJY (n=27)	p value
Age (y)	73.0 [65.0-79.0]	75.0 [66.0-81.5]	0.45
Sex			0.80
Male	23 (60.5)	18 (66.7)	
Female	15 (39.5)	9 (33.3)	
Diagnosis			0.038
Gastroduodenal cancer	19 (50.0)	21 (77.8)	
Pancreatobiliary cancer	19 (50.0)	6 (22.2)	
Ascites	11 (28.9)	5 (18.5)	0.39
Surgical history (+)	8 (21.1)	6 (22.2)	1.0
TP before treatment (g/dL)	5.9 [5.5-6.3]	5.6 [5.1-6.2]	0.14
GOO score before treatment			0.45
0	20 (52.6)	17 (63.0)	
1	18 (47.4)	10 (37.0)	

Values are presented as n (%) or median [interquartile range].
SEMS: self-expandable metallic stent, GJY: gastrojejunostomy, TP: total protein, GOO: gastric outlet obstruction

Table 2. Clinical Outcomes of SEMS Placement Versus GJY.

	SEMS (n=38)	GJY (n=27)	p value
Technical success	38 (100.0)	27 (100.0)	1
Clinical success	30 (78.9)	22 (81.5)	0.69
TP after treatment (g/dL)	6.3 [5.9-7.0]	6.2 [5.6-6.8]	0.26
Discharge from the hospital	22 (57.9)	19 (70.4)	0.44
Chemotherapy after treatment	10 (26.3)	14 (51.4)	0.042
Period from treatment to first meal (days)	3.0 [2.0-5.0], n=30	4.5 [4.0-6.0], n=22	0.013
Period from eating disability to death (days)	12.0 [5.0-24.0]	16 [3.2-24.5]	0.95
Overall survival after treatment (days)	79.0 [42.5-196.0]	129.0 [66.8-302.0]	0.15

Values are presented as n (%) or median [interquartile range].
SEMS: self-expandable metallic stent, GJY: gastrojejunostomy, TP: total protein

rank test. Predictors of improvement in the GOO score after stent placement were expressed as the odds ratio (OR) and 95% confidence interval (CI) and evaluated by a logistic regression analysis. Statistical significance was defined as $p<0.05$. A multivariate analysis was performed to determine the optimum model using a stepwise method. The statistical analysis was performed with R version 3.3.3 (R Foundation for Statistical Computing, Vienna, Austria).

Results

The characteristics of the 38 patients who underwent SEMS placement and the 27 who underwent GJY are presented in Table 1. As shown in the table, 23 men (60.5%) underwent SEMS placement at a median age of 73.0 years (IQR, 65.0-79.0 years), and 18 men (66.7%) underwent GJY at a median age of 75.0 years (IQR, 66.0-81.5 years). Obstruction caused by gastroduodenal cancer was significantly more frequent in the GJY group than in the SEMS group (50.0% vs. 77.8%, respectively; p=0.038). Ascites developed in 11 (28.9%) and 5 (18.5%) patients in the SEMS and GJY groups, respectively. A surgical history was present in 8 (21.1%) and 6 (22.2%) patients in the SEMS and GJY groups, respectively. The median total protein level and GOO score before treatment were not markedly different between the two groups.

The clinical outcomes in the SEMS and GJY groups are shown in Table 2. Both treatments for GOO were successfully performed in all patients. As indicated by the clinical success rate, 30 (78.9%) and 22 (81.5%) patients in the SEMS and GJY groups, respectively, achieved a >2-point improvement in the GOO score (p=0.69). The median total protein level after treatment was 6.3 g/dL (IQR, 5.9-7.0 g/dL) in the SEMS group and 6.2 g/dL (IQR, 5.6-6.8 g/dL) in the GJY group (p=0.26). The rate of discharge from the hospital was not markedly different between the two groups [22 (57.9%) patients in the SEMS group and 19 (70.4%) patients in the GJY group]. More patients in the GJY group (n =14, 51.4%) than in the SEMS group (n=10, 26.3%) received chemotherapy for the original cancer (p=0.042). The data was adjusted by the cancer variation, the odd ratio of the SEMS group compared to the GJY group was 0.39,

Table 3. Predictors of Improvement in the GOO Score Determined by a Univariate Logistic Regression Analysis.

	OR [95% CI]	p value
Age	1.00 [0.93-1.09]	0.91
Sex (male vs. female)	0.58 [0.12-2.79]	0.50
Ascites	0.30 [0.06-1.54]	0.15
Serum total protein before treatment	1.36 [0.46-4.02]	0.58
GOO score before treatment (0 vs. 1)	3.43 [0.59-19.80]	0.17
SEMS		
Evolution®	1	
Niti-S®	0.87 [0.07-10.40]	0.91
WallFlex®	2.33 [0.16-34.90]	0.54
Stent length	0.60 [0.36-1.01]	0.053

GOO: gastric outlet obstruction, OR: odds ratio, 95% CI: 95% confidence interval, SEMS: self-expandable metallic stent

Table 4. Predictors of Improvement in the GOO Score with Self-expandable Metallic Stent Determined by a Multivariate Analysis.

	OR [95% CI]	p value
Age	1.00 [0.91-1.10]	0.96
Sex (male vs. female)	0.67 [0.12-3.84]	0.65
Stent length	0.61 [0.36-1.02]	0.06

GOO: gastric outlet obstruction, OR: odds ratio, 95% CI: 95% confidence interval

which was not significant (95% CI: 0.13-1.16, p=0.09). The overall survival after treatment tended to be longer in the GJY group than in the SEMS group (129.0 vs. 79.0 days, respectively), but the difference was not significant (p=0.15). The period of time until the first meal after treatment was significantly shorter in the SEMS group than in the GJY group [3.0 days (IQR, 2.0-5.0) vs. 4.5 days (IQR, 4.0-6.0), respectively; p=0.013].

Table 3 shows the results of the univariate regression analysis for predictors of GOO score improvement in the SEMS group. The following factors were unrelated to GOO score improvement: age (OR: 1.00, 95% CI: 0.93-1.09, p=0.91), sex (OR: 0.58, 95% CI: 0.12-2.79, p=0.50), ascites (OR: 0.30, 95% CI: 0.06-1.54, p=0.15), pretreatment serum total protein level (OR: 1.36, 95% CI: 0.46-4.02, p=0.58), and pretreatment GOO score (OR: 3.43, 95% CI: 0.59-19.8, p=0.17). Stent selection was also unrelated to improvement in the GOO score. Although the stent length was not significantly associated with improvement in the GOO score, a longer stent tended to be associated with poor improvement in ingestion of solids (OR: 0.60, 95% CI: 0.36-1.01, p=0.053).

The results of the multivariate analysis for predictors of GOO score improvement are shown in Table 4. No factors, including the age, sex, and stent length, were predictors of improvement in the GOO score.

Discussion

We demonstrated that most clinical outcomes of SEMS placement for malignant GOO were comparable with those of GJY. Namely, the technical success rate, clinical success rate, post-treatment serum total protein level, hospital discharge rate, period from eating disability to death, and post-treatment overall survival were not markedly different between the two tested groups. These beneficial results of stenting are comparable with the data of previous studies (24-34).

In the present study, the main advantage of stenting over GJY for malignant GOO was the shorter period from treatment to the first meal. This result indicates that stent placement was less invasive than GJY, although we did not evaluate the rate of re-intervention by stenting. In addition, our study showed that the induction rate of chemotherapy after the intervention was higher in the GJY group than in the SEMS group. However, this result might be due to selection bias, as GJY might have been more frequently performed than SEMS placement in patients with a better general condition, and the difference was not significant after adjusting for the type of cancer.

Predictors of unsuccessful improvement in GOO were not clearly indicated by the univariate and multivariate analyses in this study. Several risk factors, including ascites, length of the obstruction, and peritoneal dissemination as indicated in a previous study (19), were not risk factors for unsuccessful stenting, although the length of the stent tended to be a risk factor for unsuccessful stenting without statistical significance. This finding might be a result of incomplete peristalsis due to a long SEMS; further studies on this point are warranted.

The original GOO lesion differed between the two groups. Namely, the rate of GOO caused by pancreatobiliary cancer was higher in the SEMS group, and the rate of GOO caused by gastroduodenal cancer was higher in the GJY group. This difference might have been associated with what type of medical doctor first treated the patient; in Japan, pancreatobiliary cancer is mainly treated by physicians, while advanced gastroduodenal cancer is mainly treated by surgeons.

The present study had several limitations, including the retrospective chart review and several sources of selection bias regarding stenting versus GJY. Our findings support the notion that stenting is equivalent to GJY with respect to relief of obstructive symptoms, suggesting that uncovered SEMS placement might serve as one of the first options for the treatment of malignant GOO.

The authors state that they have no Conflict of Interest (COI).

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