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Clinical outcomes after multiple self-expandable metallic stent placement using stent-in-stent technique for malignant gastric outlet obstruction

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Abstract

Self-expandable metallic stent (SEMS) placement is widely used for relieving symptoms in malignant gastric outlet obstruction (MGOO). This study aimed to evaluate the efficacy and safety of multiple gastroduodenal stent placement using the stent-in-stent technique and to identify factors predictive of stent patency.

We retrospectively analyzed data from 170 patients with GOO receiving SEMS using the stent-in-stent technique between July 2006 and July 2018. Of these, 90 had been treated with SEMS placement for MGOO. Technical and clinical success rates were evaluated. Clinical outcomes and predictors of stent patency were also analyzed.

Second SEMS placement was used in 34.4% of cases and 9.7% were treated with third SEMS placement because of prior stent dysfunction. Median stent patency time was 15.7 weeks for the first SEMS, 10.4 weeks for the second, and 11.3 weeks for the third. The technical and clinical success rates were 100% and 97.8% for the first SEMS, 100% and 90.3% for the second, respectively, and both 100% for the third. Multivariable analysis showed that use of covered SEMS and chemotherapy after first and second SEMS placement was significant predictors of stent patency. Serious complications such as bleeding or perforation did not occur in any patient.

Second and third gastroduodenal SEMS placement using the stent-in-stent technique is safe and effective for management of first stent dysfunction in MGOO. Stent patency is significantly associated with the use of covered SEMS and chemotherapy after SEMS placement.

Abbreviations: CT = computed tomography, GOO = gastric outlet obstruction, GOOSS = gastric outlet obstruction scoring system, IQR = interquartile range, MGOO = malignant gastric outlet obstruction, SEMS = self-expandable metallic stent.

Keywords: malignant gastric outlet obstruction, predictive factor, self-expandable metallic stent, stent patency, stent-in-stent technique

1. Introduction

Malignant gastric outlet obstruction (MGOO) is a late complication of advanced gastrointestinal or pancreatobiliary malignancies.[1] Prognoses of these advanced cancers are still poor and the median overall survival is approximately 1 year.[2–4] MGOO dramatically reduces the quality of life in patients with limited life expectancy. Patients have nausea, vomiting, poor appetite, intolerance to oral feeding, and weight loss.[5] It is important to alleviate obstructive symptoms to improve the quality of life in terminal patients.

Self-expandable metallic stent (SEMS) placement has been widely used to relieve obstructive symptoms of MGOO and is considered an alternative to surgical bypass such as gastro-jejunostomy, especially in patients with a limited life span or those in poor general condition.[6–8] The placement of a SEMS has several advantages compared to surgical bypass, including early time to oral intake, faster symptom relief, lower morbidity and mortality, shorter hospital stay, and decreased cost.[7,9–11] As a result of recent advances in cancer treatment, patients treated with SEMS for MGOO can live longer than expected.[5] In these cases, the SEMS is often clogged and requires second SEMS placement.

Multiple SEMS placement is usually performed using a stent-in-stent technique, which involves the insertion of a stent into the stenotic portion of the prior stent.[12] Previous reports on multiple gastroduodenal SEMS placement after first stent dysfunction are limited. Therefore, our aim was to assess the efficacy and safety of multiple gastroduodenal SEMS placement using the stent-in-stent technique and to identify factors predictive of stent patency.

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2. Materials and methods

2.1. Patient population

Between July 2006 and July 2018, 170 patients with gastric outlet obstruction (GOO) underwent gastroduodenal SEMS placement using a stent-in-stent technique. Of these, 90 had been treated with gastroduodenal SEMS placement for MGOO. Gastroduodenal SEMS placement was performed at Gangnam Severance Hospital in Seoul, Korea. Dysfunction of a prior stent was confirmed endoscopically. Contraindications to multiple gastroduodenal SEMS placement were inability to tolerate the endoscopic procedure due to poor general condition. Peritoneal carcinomatosis and massive ascites were not considered contraindications to multiple gastroduodenal SEMS placement. Informed consent was obtained from all patients before the procedure. The study protocol conformed to the ethical guidelines of the World Medical Association Declaration of Helsinki and was approved by the Institutional Review Board of Gangnam Severance Hospital (IRB No: 3-2018-0365).

2.2. Self-expandable metallic stent placement and follow-up

Computed tomography (CT) and upper endoscopy were performed to evaluate the obstruction site and stricture length before SEMS placement. All SEMS placement was performed using upper endoscopy through the working channels under fluoroscopic guidance. The endoscope was carefully inserted near the obstruction site and the causes of prior stent dysfunction were evaluated endoscopically. A guidewire was passed through the obstruction site and water-soluble radiographic contrast was injected to identify the length and location of the obstruction. The length of SEMS was determined by the stricture length, with an additional 2 to 3 cm on each side to ensure adequate margins after placement.

Abdominal X-ray images were routinely taken after SEMS placement to monitor SEMS expansion. Oral liquid intake was allowed after the procedure and soft solids were allowed later. Patients were permitted to eat a full diet as tolerated. Chemotherapy including oral anticancer drug regimens and radiotherapy were allowed after SEMS placement if the patients remained in good general condition. If obstructive symptoms recurred during follow-up, upper endoscopy and CT were performed to evaluate the cause of obstruction. The next SEMS was inserted to relieve obstructive symptoms using the stent-in-stent technique.

2.3. Evaluation of the degree of gastric outlet obstruction

The degree of obstruction was assessed using the gastric outlet obstruction scoring system (GOOSS).[13] Scoring is based on the level of oral intake. For example, 0: no oral intake, 1: liquids only, 3: low-residue or full diet.

2.4. Definitions

Clinical outcomes of multiple gastroduodenal SEMS placement were evaluated according to the following criteria:

(1) technical success,
(2) clinical success,
(3) status of oral intake evaluated with GOOSS,
(4) stent patency time,
(5) stent dysfunction,
(6) reintervention rate, and
(7) complications.

Technical success was defined as precise SEMS placement at the obstruction site and adequate SEMS expansion. Clinical success was defined as improvement in GOOSS score after SEMS placement. Stent patency time was defined as the period between SEMS insertion and SEMS restenosis. Stent dysfunction was defined as recurrence of obstructive symptoms and failure to resume oral intake. Causes of obstruction were classified as ingrowth, overgrowth, fracture, or extrinsic obstruction on upper endoscopic findings or fluoroscopic imaging. Complications were monitored after SEMS placement.

2.5. Data collection

All data, including radiologic reports, procedure reports, and blood biochemistry results, were obtained from medical records. The retrospectively collected data included baseline characteristics, primary cancer site, cancer stage, the presence of peritoneal dissemination and ascites, chemotherapy/radiotherapy treatment, GOOSS score, adverse events, and stent patency time. This study was approved by the Institutional Review Board of the Gangnam Severance Hospital.

2.6. Statistical analysis

Categorical variables were presented as a number (percentage). The stent patency time was expressed as median ± Interquartile Range (IQR) or actual range. Univariate analysis of stent patency was analyzed with simple linear regression. Variables with P values $< .05$ in univariate analysis were evaluated subsequently with multivariate analysis. The multivariate analysis was analyzed using multiple linear regression and the chi-squared test. Statistical significance was defined as a P value $< .05$. An improvement in GOOSS score after SEMS placement was analyzed with the paired t test. SPSS ver. 23.0 for Windows (SPSS, Chicago, IL) was used for all statistical analyses.

3. Results

3.1. Patient characteristics

Baseline characteristics are summarized in Table 1. The mean age in our study group was 72.1 years, and 59 were males (65.6%). Gastric cancer (73.3%) predominated, followed by pancreatic cancer (12.2%) and cholangiocarcinoma (7.8%). These patients were inoperable, with 82 (91.1%) already at stage IV. Peritoneal carcinomatosis was present in 53 patients (58.9%) before the first gastroduodenal SEMS placement and 27 (50.9%) had ascites. Among these patients, 17 (18.9%) failed to resume any oral intake.

3.2. Clinical outcomes

Table 2 shows the details after first SEMS placement. The pylorus (54.4%) was the most common obstruction site in the stomach and an uncovered SEMS (67.8%) was used more often than a covered SEMS for initial placement. An 8 cm long SEMS (33.3%) was most frequently inserted in this population and the median patency time for the first SEMS was 15.7 weeks (IQR 3–21 weeks). Technical success was achieved in all patients and clinical success was attained in 88 (97.8%). After first SEMS placement,

Table 1

Baseline patient characteristics.

Characteristics	n (%)
Sex	
Male	59 (65.7)
Female	31 (34.3)
Age (year, mean) (range)	72.1 (31–96)
Primary cancer site	
Gastric cancer	66 (73.3)
Pancreatic cancer	11 (12.2)
Cholangiocarcinoma	7 (7.8)
Gallbladder cancer	5 (5.6)
Other	1 (1.1)
GOOSS score	
Mean	1.06
0	17 (18.9)
1	51 (56.7)
2	22 (24.4)
Peritoneal carcinomatosis	53 (58.9)
No ascites (n)	26
Ascites (n)	27
Cancer stage	
Non-IV	8 (8.9)
IV	82 (91.1)
Chemotherapy before 1st SEMS placement	
No	53 (58.9)
Yes	37 (41.1)

GOOSS = gastric outlet obstruction scoring system, SEMS = self-expandable metallic stent (SEMS).

Table 2

Clinical outcomes after first self-expandable metallic stent (SEMS) placement.

	n (%)
Obstruction site in stomach	
Body	15 (16.7)
Antrum	25 (27.8)
Pylorus	50 (5.55)
First stent type	
Uncovered	61 (67.8)
Covered	29 (32.2)
Length of stent (cm)	
Mean	8.89
6	21 (23.3)
8	30 (33.4)
10	17 (18.9)
12	22 (24.4)
Median time of 1st stent patency (weeks, IQR)	15.7 (3–21)
GOOSS score (after 1st SEMS placement)	
mean	2.54
1	2 (2.2)
2	40 (44.4)
3	48 (53.4)
Technical success	90 (100)
Clinical success	88 (97.8)
Chemotherapy after 1st SEMS placement	
No	42 (46.7)
Yes	48 (53.3)
Peritoneal carcinomatosis	
No	25 (27.8)
Yes	65 (72.2)
Complication	0 (0)

GOOSS = gastric outlet obstruction scoring system, SEMS = self-expandable metallic stent (SEMS).

Table 3

Clinical outcomes after second self-expandable metallic stent (SEMS) placement.

	n (%)
Reason for 1st SEMS dysfunction	
Ingrowth	24 (77.4)
Overgrowth	4 (12.9)
Fracture	1 (3.2)
Extrinsic obstruction	2 (6.5)
GOOSS score (before 2nd SEMS placement)	
Mean	1.0
0	5 (16.1)
1	21 (67.8)
2	5 (16.1)
Second stent type	
Uncovered	14 (45.2)
Covered	17 (54.8)
Length of stent (cm)	
Mean	9.61
6	4 (12.9)
8	10 (32.3)
10	7 (22.6)
12	9 (29.0)
14	1 (3.2)
Median time of 2nd stent patency (weeks, IQR)	10.4 (1–13)
GOOSS score (after 2nd SEMS placement)	
Mean	2.48
1	3 (9.7)
2	10 (32.3)
3	18 (58.0)
Technical success	31 (100)
Clinical success	28 (90.3)
Chemotherapy after 2nd SEMS placement	
No	21 (67.7)
Yes	10 (32.3)

GOOSS = gastric outlet obstruction scoring system, SEMS = self-expandable metallic stent (SEMS).

48 patients (53.3%) were able to take a low-residue or full diet, and the median GOOSS score was significantly improved from 1.06 to 2.54 ($P < .001$). Systemic chemotherapy was performed in 42 patients (46.7%) and 65 (72.2%) had peritoneal carcinomatosis.

Table 3 shows the details of second SEMS placement. First, stent dysfunction was observed in 31 patients (34.4%). The major indication was stent occlusion caused by tumor ingrowth (77.4%) or overgrowth (12.9%). A covered SEMS (54.8%) was used more often than an uncovered SEMS for second placement, and the median patency time for the second SEMS was 10.4 weeks (IQR 1–13 weeks). Technical success was achieved in all patients, with clinical success in 28 (90.3%). After second SEMS placement, 18 patients (58.1%) were able to take a low-residue or full diet, and the median GOOSS score was significantly improved from 1.0 to 2.48 ($P < .001$). Systemic chemotherapy was performed in 21 patients (67.7%).

3.3. Comparison of clinical outcomes after first, second, and third SEMS placement

Comparison of clinical outcomes after first, second, and third SEMS placement is shown in Table 4. Among 90 patients who received first SEMS placement, 31 (34.4%) underwent second SEMS placement for symptom relief. Among 31 patients who received second SEMS placement, 3 (9.7%) underwent third SEMS placement. Median stent patency time was 15.7 weeks for

Table 4

Comparison of clinical outcomes after first, second, and third self-expandable metallic stent (SEMS) placement.

	1st SEMS	2nd SEMS	3rd SEMS
Number of patients (n, %)	90 (100)	31/90 (34.4)	3/31 (9.7)
Median stent patency time (weeks) (IQR or range)	15.7 (3–21)	10.4 (1–13)	11.3 (1–29)
Mean length of stent (cm)	8.89	9.61	10.66
Technical success (n, %)	90/90 (100)	31/31 (100)	3/3 (100)
Clinical success (n, %)	88/90 (97.8)	28/31 (90.3)	3/3 (100)
Mean GOOSS score			
before stent placement	1.06	1.00	1.33
after stent placement	2.54	2.48	3
Chemotherapy after stent placement (n, %)	48/90 (53.3)	10/31 (32.3)	2/3 (66.6)
Complications	0	0	0

GOOSS = gastric outlet obstruction scoring system, SEMS = self-expandable metallic stent (SEMS).

the first SEMS, 10.4 weeks for the second, and 11.3 weeks for the third. Technical success was achieved in all patients (100%) and the clinical success rate was 97.8% for first SEMS, 90.3% for second SEMS, and 100% for third SEMS. The mean GOOSS scores were improved after first, second, and third SEMS placement. Figure 1 shows endoscopic and fluoroscopic imaging of patient who underwent first (A), second (B), and third (C) SEMS placement. This 52-year-old male patient diagnosed with advanced gastric cancer with partial GOO.

3.4. Factors predictive of stent patency

Univariate analysis showed that tumor origin and type of first SEMS, chemotherapy after first SEMS placement, and complications were factors predictive of patency. However, in multivariate analysis, only the type of SEMS and chemotherapy after first SEMS placement were independent predictors (Table 5). Univariate analysis showed that the type of second SEMS and chemotherapy after second SEMS placement were predictive of patency. Multivariate analysis showed that only chemotherapy after second SEMS placement was significantly associated with stent patency (Table 6).

4. Discussion

Endoscopic SEMS placement has been accepted as a safe and effective palliative measure for MGOO that enables oral intake.[14–16] SEMS placement has gradually replaced surgical gastrojejunostomy for the treatment of MGOO.[17] A meta-analysis of treatment using stents vs surgical gastrojejunostomy reported in 2010 by Ly et al[18] showed that endoscopic stenting was associated with increased tolerance of oral intake, shorter time to initiation of oral intake, and shorter hospital stay after the procedure.

However, obstructive symptoms can be problematic with first stent dysfunction. Re-obstruction occurred in 13% to 26% of

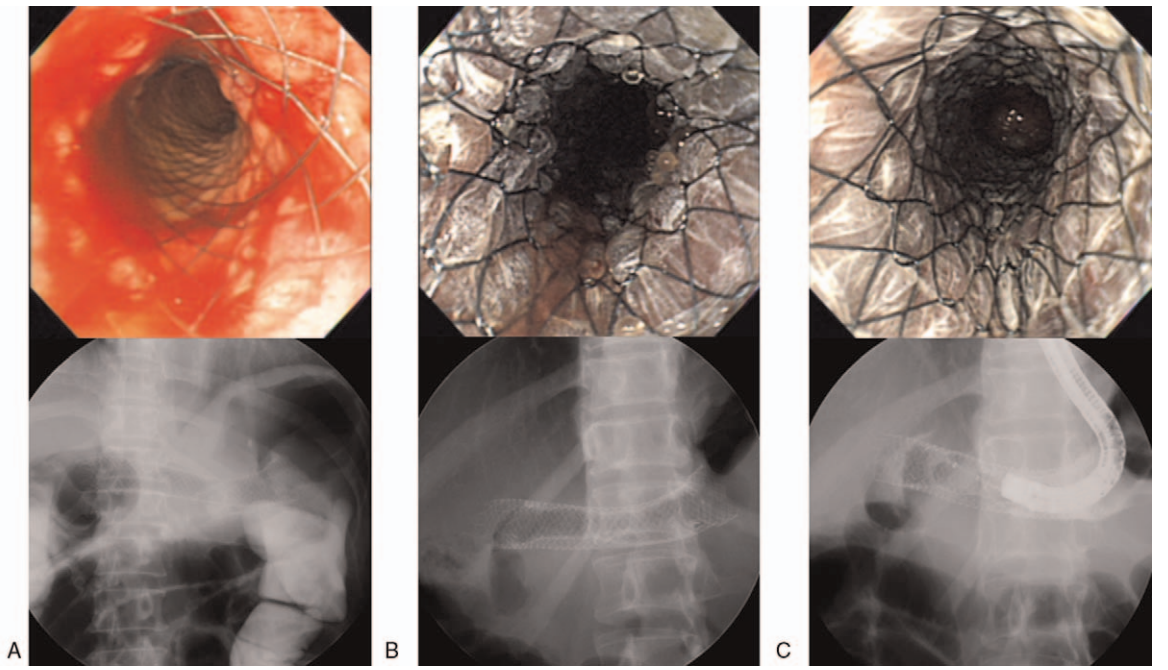

Figure 1. Endoscopic and fluoroscopic imaging of patient who underwent first (A), second (B), and third (C) SEMS placement for MGOO. MGOO = malignant gastric outlet obstruction, SEMS = self-expandable metallic stent.

Table 5

Univariate and multivariate analysis of first self-expandable metallic stent (SEMS) patency.

	Univariate analysis			Multivariate analysis	
Variable	**n**	**%**	***P***	**Odd ratio (95% CI)**	***P***
Tumor origin			.019		.364
Non-gastric	66	73.3		.271 (.096–4.111)	
Gastric cancer	24	26.7		Reference	
Peritoneal carcinomatosis			.134		
No	37	41.1			
Yes	53	58.9			
Ascites			.092		
No	63	70			
Yes	27	30			
Location of obstruction			.919		
Body	15	16.7			
Antrum	25	27.8			
Pylorus	49	55.5			
Length of stenosis			.351		
≤6 cm	48	53.3			
>6 cm	42	46.7			
GOOSS before 1st SEMS placement			.542		
0	17	18.9			
1	51	56.7			
2	22	24.4			
3	0	0			
Chemotherapy before 1st SEMS placement			.719		
No	53	58.9			
Yes	37	41.1			
Type of 1st SEMS			.000		.001
Uncovered	61	67.8		4.549 (5.156−19.065)	
Covered	29	32.2		Reference	
Length of 1st SEMS			.298		
≤8 cm	51	56.7			
>8 cm	39	43.3			
GOOSS after 1st SEMS placement			.071		
0	0	0			
1	2	2.2			
2	40	44.4			
3	48	53.4			
Chemotherapy after 1st SEMS placement			.001		.006
No	42	46.7		8.248 (2.732−15.972)	
Yes	48	53.3		Reference	

GOOSS = gastric outlet obstruction scoring system, SEMS = self-expandable metallic stent (SEMS).

patients who underwent SEMS placement because of stent dysfunction caused by tumor progression.[15,19] For patients who experience stent dysfunction, additional SEMS placement is usually required to correct for the loss of first stent patency.[20] Second and third gastroduodenal SEMS placement is usually performed using a stent-in-stent technique, which involves the insertion of a stent into the stenotic portion of the prior stent. Stent-in-stent technique is an effective treatment for patients with MGOO who have occluded first stents.[12]

We analyzed the clinical outcomes of multiple gastroduodenal SEMS placement. Among the 170 patients, 34.4% underwent second SEMS placement and 9.7% underwent third SEMS placement because of prior stent dysfunction. In this study, multiple SEMS placement was safe and effective for obstructive symptoms caused by dysfunction of first SEMS. The technical and clinical success rates were 100% and 97.8% for the first SEMS, 100% and 90.3% for the second, respectively, and both 100% for the third. These results were similar to those of previous studies that reported technical success rates of 92% to 100% and clinical success rates of 75% to 92% with palliative SEMS placement in MGOO.[21–25] The mean GOOSS scores increased after first SEMS placement as well as additional SEMS placement. The median stent patency time was 15.7 weeks for the first SEMS, 10.4 weeks for the second, and 11.3 weeks for the third. These results showed that the efficacy and safety of second and third gastroduodenal SEMS placement were similar to those of first SEMS placement. Sasaki et al[5] reported that the perforation rate was higher after second stent placement than after first stent placement (13.8% vs 0%; $P = .02$). However, there were no procedure-related adverse events such as bleeding or perforation after first, second, or third SEMS placement in our study.

We also identified factors predictive of stent patency. A few studies of factors affecting stent patency have been published. Telford et al reported that chemotherapy after stent insertion was significantly associated with prolongation of oral intake.[26] Their study was the first to assess the factors predictive of stent patency in the treatment of inoperable MGOO through stent insertion. Since then, other studies have reported similar results following the use of chemotherapy.[23,27,28] Kim et al reported chemotherapy to be a significant protective factor against restenosis.[28] In

Table 6

Univariate and multivariate analysis of second SEMS patency.

	Univariate analysis			Multivariate analysis	
Variable	**n**	**%**	***P***	**Odd ratio (95% CI)**	***P***
GOOSS before 2nd SEMS placement			.917		
0	5	77.4			
1	21	12.9			
2	5	3.2			
3	0	6.5			
Type of 2nd SEMS			.014		.102
Uncovered	14	45.2		4.125 (.839–20.283)	
Covered	17	54.8		Reference	
Length of 2nd SEMS			.157		
≤9 cm	14	45.2			
>9 cm	17	54.8			
GOOSS after 2nd SEMS placement 0			.830		
1	0	0			
2	2	9.7			
3	10	32.3			
	18	58.0			
Chemotherapy after 2nd SEMS placement			.000		.003
No	21	67.7		7.467 (4.889–20.769)	
Yes	10	32.3		Reference	

GOOSS = gastric outlet obstruction scoring system, SEMS = self-expandable metallic stent (SEMS).

addition to chemotherapy, the stent type and type of malignant obstructive lesion have been proposed as predictive of stent patency.[23,29] However, other studies have reported that stent type and the type of malignant obstructive lesion have no significant association with stent patency.[30–32] Consequently, this is an important subject for further investigation.[17]

In our multivariate analysis, covered SEMS and chemotherapy after first and second SEMS placement were significant predictors of stent patency. Performing chemotherapy after SEMS placement may reduce or stabilize the tumor burden, diminish tumor growth through the stent mesh, or overgrowth at the stent edges, and prolong the duration of oral intake.[17,20] The patients who received chemotherapy had better performance status and longer stent patency than those who did not. A covered SEMS may have a more favorable outcome than an uncovered stent in the treatment of GOO caused by primary gastrointestinal cancer.[23] Moreover, a covered SEMS can extend stent patency by reducing the risk of stent obstruction due to tumor ingrowth or mucosal hyperplasia.[33] However, there is no consensus regarding the use of covered SEMS to treat GOO because only a few prospective randomized comparison studies have been reported. Therefore, the choice of covered or uncovered SEMS depends on the operator's preference or lesion characteristics.[25]

The first stent patency was related to both covered SEMS and chemotherapy after placement, but the second stent patency was related only to chemotherapy after SEMS placement. This suggests that it may be important to reduce the tumor burden with chemotherapy rather than changing the stent type as the number of stents increases. This is because stent patency becomes more consistent with survival over time.

Our study had several limitations. First, this was a single-center study with a small sample size. Second, this study was conducted in a retrospective manner, and SEMS patency was assessed with GOOSS instead of second-look endoscopy, which was only performed for selected patients who experienced stent dysfunction. Third, SEMS placements were performed by several different endoscopists. Fourth, various malignancies with different prognoses may influence SEMS patency, particularly with addition of chemotherapy.

In conclusion, second and third gastroduodenal SEMS placement using the stent-in-stent technique is safe and effective for first SEMS dysfunction in MGOO. Patency is significantly associated with the use of covered SEMS and chemotherapy after SEMS placement.

Author contributions

Young Min Kim and Jin Won Mo: Study concept and design, acquisition, analysis, and interpretation of data, statistical analysis, and drafting of manuscript.
Seung Yong Shin, Young Hoon Youn, and Hyojin Park: Important intellectual content and study supervision.
Jie-Hyun Kim: Study concept and design, analysis and interpretation of data, important intellectual content, and study supervision.
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