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Comparable Outcomes of Uncovered Metallic Stents and Partially Covered Metallic Stents in Malignant Distal Duodenal Obstruction

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Abbreviations:

MDDO: malignant distal duodenal obstruction; UC-SEMS: uncovered self-expandable metallic stent; PC-SEMS: partially covered self-expandable metallic stent

1. Abstract

1.1. Background/Purpose: Endoscopic management with self-expandable metallic stents (SEMSs) for advanced malignant gastroduodenal obstruction is widely used, however stenting in patients with malignant distal duodenal obstruction (MDDO) is challenging because of the length and flexibility of the endoscope, the curved configuration of the duodenal C-loop, and the angle of the duodenojejunal flexure. Studies focusing on the outcomes of stenting in patients with MDDO are lacking. Therefore, the aim of this study was to investigate the clinical outcomes of uncovered SEMS (UC-SEMS) and partially covered SEMS (PC-SEMS) placement in patients with MDDO.

1.2. Methods: A total of 33 patients with MDDO from February 2012 to June 2018 were enrolled. Twenty-nine patients were in advanced stages. Eighteen patients received UC-SEMSs; 14 patients received PC-SEMSs and one patient failed in stenting. Technical and clinical success rates, improvement of GOOSS score after stenting, complication rate, stent patency, and survival time were compared between the two groups.

1.3. Results: The overall technical success rate was 97%. The clinical success rate was similar in both groups (83.3% for UC-SEMSs vs 78.6% for PC-SEMSs, p = 1). Eleven patients (34.4%) experienced stent failure. There was no difference in stent failure rate between the two groups and stent patency was similar in the two groups (median time to stent failure, PC-SEMS: 91 days vs UC-SEMS: 74 days, p = 0.73).

1.4. Conclusions: The outcomes of endoscopic stenting with UC-SEMSs are comparable to PC-SEMSs in patients with MDDO. However, stent failure is still an issue to be overcome.

2. Introduction

Malignant Gastric Outlet Obstruction (GOO) is often caused by pancreatic cancer, gastric cancer, gallbladder cancer, bile duct cancer,

duodenal cancer, and metastatic tumors [1, 2]. It can cause significant morbidity from malnutrition and dehydration, which impairs the quality of life and may hinder palliative chemotherapy. Since the first publication of using self-expandable metallic stents (SEMSs) in patients with obstructing gastric cancer [3], endoscopic SEMS placement has emerged as an alternative to surgical gastrojejunostomy for palliative treatment, with the advantages of shorter operation time, shorter period to resuming oral intake, and shorter hospital stay [4-7].

Stenting of obstructions in the third and fourth duodenum can be challenging, and the clinical success rate is lower.8 This may be due to the limited length and flexibility of the endoscope, the curved configuration of the duodenal C-loop, and the angle of the duodenojejunal flexure [9, 10]. Furthermore, a retrospective study found that stent patency was shortest in distal malignant gastroduodenal obstructions [11].

Covered SEMSs were introduced to improve the patency of SEMSs by preventing tissue ingrowth, however they have an increased risk of migration [12-14]. Partially covered SEMSs (PC-SEMSs) have uncovered flanges, and they were developed to prevent tissue ingrowth and reduce migration [15]. However, studies regarding SEMS treatment in patients with distal malignant gastroduodenal obstruction are lacking, and most patients in previous studies had malignant pyloric or proximal duodenal obstructions. In addition, most patients with SEMS implantation for malignant obstructions in the third or fourth duodenum received uncovered SEMSs (UC-SEMSs) [16-18]. Therefore, we conducted this retrospective study to investigate the clinical outcomes of SEMS implantation in patients with malignant obstructions involving the third or fourth duodenum, which we referred to as malignant distal duodenal obstruction (MDDO).

3. Materials and Methods

3.1. Study Population

We searched our prospectively maintained endoscopy database for patients who underwent endoscopic placement of SEMSs for MDDO at National Taiwan University Hospital from February 2012 to June 2018. Patients with MDDO, which included the involvement of the horizontal part and ascending part of the duodenum or proximal jejunum, were enrolled. The study was approved by the Institutional Review Board of National Taiwan University Hospital (IRB number: 201902008RINA).

3.2. Data Collection and Definitions

We collected relevant clinical information from electronic medical records, including baseline demographics, primary cancer, cancer stage, stenotic location, stenting type, and outpatient clinic follow-up records. The following data were collected until 16 months after the procedure or the patient died, whichever occurred first: procedure-related complications, additional therapy (chemotherapy or radiotherapy), and stent failure. Malignant tumors in clinical stage 3 or 4 were defined as an advanced stage. The primary outcome of interest was stent failure requiring reintervention. The secondary outcomes were the clinical and technical success of stenting, procedural complications, and survival time.

The severity of obstructive symptoms was evaluated before and at 1 week after stenting according to the standardized gastric outlet obstruction scoring system (GOOSS) score,19 in which grade 0 indicates no oral intake, grade 1 indicates intake of liquids only, grade 2 indicates intake of soft solids, and grade 3 indicates a low-residue or full diet. Technical success of stenting was defined as satisfactory deployment and precise positioning of the stent at the stenosis. Clinical success was defined as at least a 1-point improvement in GOOSS score 1 week after stenting relative to baseline and the absence of total parenteral nutrition. Stent failure was defined as recurrent symptoms of duodenal obstruction, including migration, angulation, food impaction, and tumor ingrowth or overgrowth. The duration of stent patency was defined as the period from stent insertion to stent failure or patient death.

3.3. Stenting Procedure

All metallic stents were implanted using the through-the-scope method by interventional gastroenterologists under combined endoscopic and fluoroscopic guidance. The procedures were performed under general anesthesia. A side-viewing duodenoscope (TJF-200 or TJF-260V with a 4.2-mm working channel, Olympus, Tokyo, Japan), or a forward-viewing colonoscope (CF-HQ290 with a 3.7-mm working channel, Olympus, Tokyo, Japan) was introduced to the stricture site. The stricture was cannulated with a catheter (Tandem XL triple-Lumen ERCP catheter or TRUEtome Cannulating Sphincterotome, Boston Scientific, Natick, MA, USA) and a flexible hydrophilic guidewire (Fixed-Cored Guidewire, COOK, Bloomington, USA; Hydra Jagwire Guidewire ANG, Boston Scientific, Natick, MA, USA; VisiGlide 2, Olympus, Tokyo, Japan). The length of the stricture was assessed and determined fluoroscopically. A stent ≥ 2 cm longer than the stricture20 was chosen and deployed under endoscopic and fluoroscopic control (Figure 1). Balloon dilatation was performed before stenting with a balloon catheter (CRE Balloon Dilatation Catheter, Boston Scientific, Natick, MA, USA) for difficult stenting due to tight stricture. Once the stent had been placed, its position and patency were assessed by flushing contrast medium through it. The UC-SEMSs and PC-SEMSs used in the early phase of this study were the WallFlex duodenal stent (Boston Scientific, Natick, MA, USA) and Comvi Enteral Colonic Stent (Taewoong Medical Co., Gimpo, South Korea), respectively. Uncovered or partially covered BONASTENT duodenum/pylorus stents (Standard Sci Tech Inc., Seoul, South Korea) were used in the late phase of the study. The uncovered parts at both ends of the partially covered metallic stents were 1.5cm in Comvi Enteral Colonic Stent and BONASTENT.

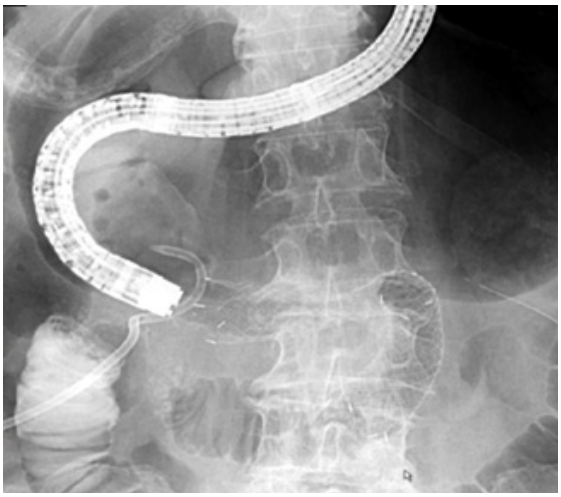

Figure 1: Stenting of malignant distal duodenal obstruction with a metallic stent (arrows), of which the distal end was in the proximal jejunum

3.4. Management of Complications and Stent Failure

We confirmed stent failure in a gastrointestinal contrast study, and by endoscopy when GOO symptoms recurred. In the event of stent failure, insertion of an additional metallic stent using the stent-in-stent method was performed if feasible. Food impaction of the stent was managed endoscopically. Patients with poor clinical outcomes (e.g., progressive malignancy or uncontrolled infection) were prescribed the palliative use of total parenteral nutrition.

3.5. Statistical Analysis

The patients were divided into two groups according to the stent type: the UC-SEMS group, and the PC-SEMS group. All analyses were performed using STATA version 17 and all tests were two-sided. Results were expressed as the mean ± standard deviation (SD) or median with an interquartile range. Differences between the two groups were analyzed using the Mann-Whitney U test for continuous variables, and either the chi-squared or Fisher's exact test for categorical variables. Improvements in GOOSS scores were compared using the Wilcoxon signed-rank test. Cumulative stent patency and survival time after stent placement were analyzed using the Kaplan-Meier method. A P-value < 0.05 was considered to be statistically significant. Potential risk factors related to stent failure were first assessed using univariate analysis, and any factors found to have a substantial impact ($p < 0.2$) were furtherly investigated using multivariate analysis. The following potential risk factors were included in this study: age, sex, patient performance status, underlying malignancy, with biliary stents, stenosis involving the jejunum, post-stenting therapy, stent type, stent length, number of stents, and balloon dilatation before stenting.

4. Results

4.1. Patient Characteristics

A total of 33 patients were included in the study. One patient failed SEMS placement due to an inability to gain access through the obstruction (the technical success rate was 97%). Eighteen patients received UC-SEMSs, which included 7 WallFlex duodenal stents and 11 BONASTENT duodenum/pylorus stents. Fourteen patients received PC-SEMSs, which included 3 Comvi Enteral Colonic Stents and 11 BONASTENT duodenum/pylorus stents (Figure 2). More uncovered metallic stents were placed in the early phase of this study ($p=0.008$). The detailed baseline demographics are listed in Table 1. Of the 32 patients with successful SEMS placement, the average age was 67.41 ± 12.7 years (mean ± SD; range: 46-94 years), and 10 of the patients (31.3%) were male. Causes of malignant obstruction included pancreatic cancer (62.5%), ampullary cancer (9.4%), metastases (15.6%), duodenal cancer (3.1%), bile duct cancer (3.1%), and intraabdominal lymphoma (6.2%). Five patients in the UC-SEMS group and 2 patients in the PC-SEMS group had received surgical treatment for their primary tumors before duodenal stenosis ensues. Twenty-eight patients (87.5%) had an advanced cancer stage, and the distribution was balanced between the two groups. MDDO in 15 patients involved the papilla and in 3 patients involved the duodenal bulb. Two patients (one in each group) had stenosis involving the jejunum. More UC-SEMSs were placed in MDDO involving the papilla while more PC-SEMSs were placed in MDDO without involving the papilla ($p=0.01$). Twenty-four patients (75%) with duodenal stenosis received stenting with a side-viewing duodenoscope and 19 of them were with pancreatic or ampullary cancer.

Eleven patients in the UC-SEMS group and seven patients in the PC-SEMS group had received palliative chemotherapy before stenting, and 11 patients in the UC-SEMS group and five patients in the PC-SEMS group had undergone biliary drainage (endoscopic retrograde biliary drainage, percutaneous transhepatic biliary drainage, or both) before stenting. Two patients in the UC-SEMS group and one patient in the PC-SEMS group received luminal balloon dilatation to introduce the stenting sheath through the tight stricture. One patient in the PC-SEMS group received palliative double stenting for concurrent malignant biliary and duodenal obstructions.

There was no significant difference in GOOSS score before stenting between the two groups. A total of 35 metallic stents were implanted. Two patients in the UC-SEMS group and one patient in the PC-SEMS group required two overlapping stents to cover the whole length of the stenosis. The UC-SEMSs ranged from 20 mm to 22 mm in diameter and 60 mm to 160 mm in length, while the PC-SEMSs ranged from 20 mm to 22 mm in diameter and 120 mm to 160 mm in length.

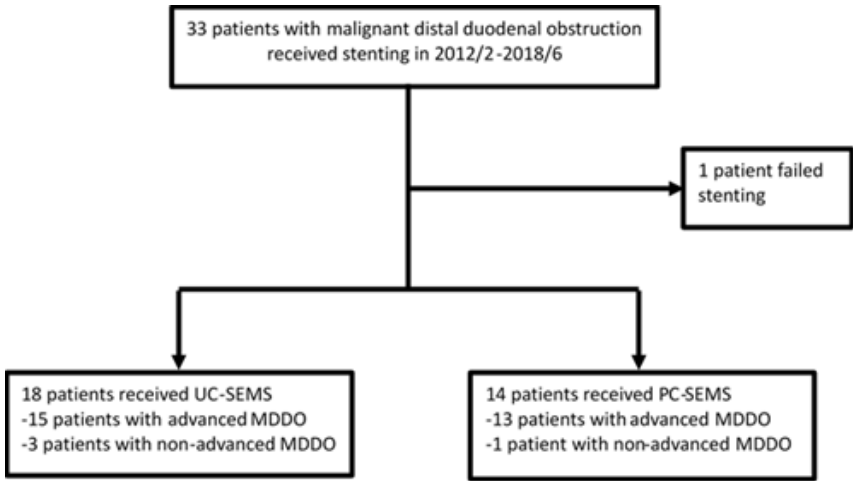

Figure 2: Flow chart of patients included in study

Abbreviation: MDDO: malignant distal duodenal obstruction; UC-SEMS: uncovered self-expandable metallic stent; PC-SEMS: partially covered self-expandable metallic stent

Table 1: Baseline characteristics of the included patients

	Duodenal metallic stent type		*p*-value
	UC-SEMS (n = 18)	PC-SEMS (n = 14)	
Age (years), mean ± SD	67.4 ± 12.3	67.4 ± 13.6	0.79
Male (%)	4 (22.2%)	6 (42.9%)	0.27
Cancer stage			
III	4 (22.2%)	4 (28.6%)	1
IV	11 (61.1%)	9 (64.3%)	
ECOG PS (0/1/2/3/4)	0/2/4/11/1	0/1/3/7/3	0.59
Treatment Before stenting			
Surgery[1]	5 (27.8%)	2 (14.3%)	0.43
Chemotherapy	11 (61.1%)	7 (50%)	0.53
Radiotherapy	0 (0%)	3 (21.4%)	0.07
After stenting			
Chemotherapy	9 (50%)	5 (35.7%)	0.31
Radiotherapy	1	0	
Stenosis involving the papilla	12 (66.7%)	3 (21.4%)	0.01
Stenosis involving the jejunum	1 (5.6%)	1 (7.1%)	1
Previous biliary drainage			
ERBD	8 (44.4%)	2 (14.3%)	0.12
PTBD	1 (5.6%)	2 (14.3%)	0.57
PTBD and ERBD	2 (11.1%)	1 (7.1%)	1
Double stenting[2]	0	1 (7.1%)	0.44
Underlying malignancy			
Pancreatic cancer	12	8	0.43
Ampullary cancer	2	1	
Metastases	2	3	
Duodenal cancer	1	0	
Bile duct cancer	1	0	
Lymphoma	0	2	
Number of stents			
1 stent	16 (88.9%)	13 (92.9%)	1.00
2 stents	2 (11.1%)	1 (7.1%)	
Stent length			
6-12 cm	10 (55.6%)	8 (57.1%)	1.00
14-16 cm	6 (33.3%)	5 (35.7%)	
Two stents	2 (11.1%)	1 (7.1%)	
Stent diameter (mm)	20.7 ± 0.97	20.3 ± 0.73	0.22

[1]Included two patients with distal pancreatectomy and splenectomy, one patient with central pancreatectomy and pancreaticogastrostomy, one patient with atypical hepatectomy, one patient with laparoscopic let nephroureterectomy and bladder cuff resection, one patient with pulmonary lobectomy, one patient with transurethral resection of bladder tumor.

[2]Double stenting indicates performing biliary stenting and duodenal stenting during the same endoscopic examination.

Abbreviations: UC-SEMS, uncovered self-expandable metallic stent; PC-SEMS, partially covered self-expandable metallic stent; SD, standard deviation; ECOG PS, Eastern Cooperative Oncology Group performance status; ERBD, endoscopic retrograde biliary drainage; PTBD, percutaneous transhepatic biliary drainage

4.2. Clinical success rates according to stent type

A significant improvement in GOOSS score was observed in 26 patients (81.3%) 1 week after the procedure (Table 2). The clinical success rates in the UC-SEMS and PC-SEMS groups were 83.3% and 78.6%, respectively (p = 1). Two patients (one in each group) didn't achieve clinical success from tumor compression. Four patients (two in each group) didn't achieve clinical success from sepsis. The improvements in GOOSS scores were similar between the two groups.

4.3. Duration of stent patency, stent failure, and retreatment

There was no significant difference in stent failure rate between the UC-SEMS and PC-SEMS groups (33.3% vs 35.7%, respectively, p = 0.89). Stent patency was not statistically different between the PC-SEMS group and the UC-SEMS group (median duration: 91 days vs 74 days, p = 0.73, Table 2, Figure 3). Eighteen (56.2%) patients without stent failure died from primary malignancy. Stent failure occurred in 11 (34.4%) patients, and the causes of stent failure were tumor ingrowth (n = 6, 54.5%), tumor overgrowth (n = 2, 18.2%), stent angulation (n = 2, 18.2%), and food impaction (n = 1, 9.1%). Tumor ingrowth was more common in the UC-SEMS group (27.8% vs 7.1%, p = 0.19), while tumor overgrowth was more common in the PC-SEMS group (0% vs 14.4%, p = 0.18). Nine patients received reinterventions for the stent failure but 2 patients in the UC-SEMS group received palliative management because of terminal status.

Table 2: Main outcomes and complications

	Duodenal metallic stent type		
	UC-SEMS (n = 18)	PC-SEMS (n = 14)	*p*-value
Clinical success rate	15 (83.3%)	11 (78.6%)	1
GOOSS score			
Pre-stenting (0/1/2/3)	14/4/0/0	13/1/0/0	0.36
Post-stenting (0/1/2/3)	3/1/10/4 [1]	3/1/7/3 [2]	1
Follow-up duration (mean ± SD)	139.7 ± 137.17 days	115.9 ± 123.7 days	0.62
Median duration of stent patency, median (IQR)	74 days (51–147)	91 days (64–122)	0.73
Survival, median (IQR)	81.5 (54–219.5)	93 (32.5–140)	0.98
Complications	2 (11.1%)	1 (7.1%)	1
Aspiration pneumonia	1 (5.6%)	0	1
Obstructive jaundice	1 (5.6%)	1 (7.1%)	0.44
Stent failure	6 (33.3%)	5 (35.7%)	0.89
Tumor ingrowth	5 (27.8%)	1 (7.1%)	0.19
Tumor overgrowth	0	2 (14.4%)	0.18
Stent angulation[3]	1 (5.5%)	1 (7.1%)	1
Food impaction	0	1 (7.1%)	0.44
Interventions for stent failure			
Restenting	4 (22.2%)	3 (21.4%)	1
Balloon dilatation	0	1 (7.1%)	0.44
Removal of food materials	0	1 (7.1%)	0.44

[1]Significant improvement in GOOSS score after stent placement compared with before stent placement (P < 0.001, Wilcoxon signed-rank test).

[2]Significant improvement in GOOSS score after stent placement compared with before stent placement (P < 0.001, Wilcoxon signed-rank test).

[3]Included collapse of the stent lumen from external compression or sharp intestinal angle

Abbreviations: UC-SEMS, uncovered self-expandable metallic stent; PC-SEMS, partially covered self-expandable metallic stent; GOOSS, Gastric Outlet Obstruction Scoring System; SD, standard deviation; IQR, interquartile range

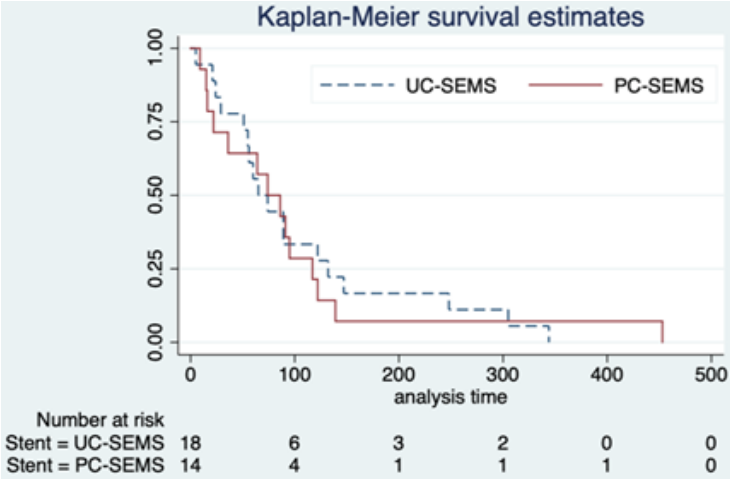

Figure 3: Stent patency of patients with uncovered and partially covered duodenal metallic stents

4.4. Complications and survival time

The complication rates were similar between the UC-SEMS and PC-SEMS groups (11.1% vs 7.1%, respectively, p = 1). One patient developed aspiration pneumonia 2 days after the procedure and subsequently died. Two patients (one in each group) developed obstructive jaundice after the procedure and were managed by the insertion of a metallic stent using a percutaneous approach. No cases of perforation, bleeding or stent migration occurred.

Nine patients in the UC-SEMS group and five patients in the PC-SEMS group received palliative chemotherapy after stenting, and one patient in the UC-SEMS group received palliative radiotherapy after stenting. The median overall survival time was 89 days, and it did not significantly differ between the UC-SEMS and PC-SEMS groups (81.5 days vs 93.0 days, respectively, p = 0.98, Table 2 and Figure 4).

4.5. Risk factors for stent failure

Age, sex, patient performance status, underlying malignancy, with biliary stents, stenosis involving the jejunum, post-stenting therapy, stent type, stent length, number of stents, and balloon dilatation before stenting were evaluated to identify potential factors related to stent failure. The results showed that concurrent biliary stents were associated with duodenal metallic stent failure (OR: 13.03, p=0.046) (Table 3).

Table 3: Univariate analysis and multivariate analysis for risk factors of stent failure

	Univariate analysis		Multivariate analysis	
	OR (95% CI)	*P*-value	HR (95% CI)	*p*-value
Age (>60 years)	2.25 (0.4–13.7)	0.38		
Sex (male)	0.378 (0.03–3.7)	0.41		
ECOG PS (≥3)	2.647 (0.3–26.2)	0.41		
Underlying malignancy	0.2 (0.03–1.5)	0.12	0.2 (0.01–5.4)	0.36
With biliary stents[1]	3.5 (0.76-16.12)	0.1	13.03 (1.05-162.15)	0.046
Stenosis involving the jejunum	1.14 (0.06-20.01)	0.93		
Post-stenting therapy[2]	1.2 (0.2-5.7)	0.83		
Stent factors				
Uncovered	1.4 (0.2–8.1)	0.73		
Length ≥ 14 cm[3]	0.4 (0.03–3.6)	0.38		
Use of two stents	2.4 (0.2–31.8)	0.51		
Balloon dilatation during the procedure	0.1 (0.01–1.1)	0.06	8.6 (0.2–306.6)	0.24

[1]Included biliary plastic stent or biliary metallic stent

[2]Included palliative chemotherapy and radiotherapy

[3]Excluding all patients with two stents

Abbreviations: ECOG PS, Eastern Cooperative Oncology Group performance status; HR, hazard ratio; CI, confidence interval; OR, odds ratio

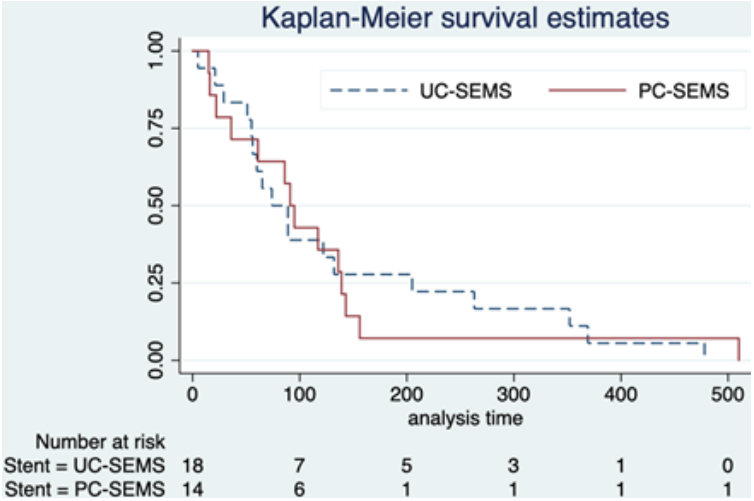

Figure 4: Survival of patients with uncovered and partially covered duodenal metallic stents

5. Discussion

The results of this study demonstrated high technical and clinical success rates (97% and 81.3%, respectively) for SEMS placement in patients with MDDO, which is consistent with previous studies on malignant gastroduodenal obstruction [1, 10, 16, 21]. Stent migration has been reported to cause 25.8%-37.5% of covered SEMS failure [8, 13], while tumor in growth has been reported to cause 20-25% of uncovered SEMS failure in patients with GOO [14, 18, 22, 23]. Partially covered SEMSs with uncovered flanges were designed to prevent tumor ingrowth and reduce migration [15, 24, 25]. In the present study, tumor ingrowth was more common in the patients who received UC-SEMSs, while the patients who received PC-SEMSs had more tumor overgrowth. In contrast to previous reports,12-14 no stent migration was noted in any of our patients. In addition to the design of PC-SEMSs, we speculate that the retroperitoneal location of the distal duodenum and its complex anatomical angles may prevent metallic stents from migration. Our study found that concurrent biliary stents in duodenal metallic stenting were associated with duodenal metallic stent failure. Most of these patients experienced tumor ingrowth. This result may be relative to the underlying malignancy but our patient number is too small to do subgroup analysis.

Two studies comparing different types of stents concluded that PC-SEMSs and UC-SEMSs may have longer stent patency and less migration than fully covered SEMS in patients with GOO [8, 26]. However, around one-third of the patients in the previous studies had an obstruction level distal to the second duodenal portion. Most previous studies including the placement of SEMSs in patients with MDDO used UC-SEMSs, and reported stent patency ranging from 75-175 days.9,10,16,18 The overall median duration of stent patency was 87.5 days in our study and was not statistically different between the two groups. In summary, our results demonstrated similar efficacy between UC-SEMSs and PC-SEMSs in managing MDDO. More UC-SEMSs were chosen in this study when the MDDO involves the papilla to prevent obstructive jaundice [27].

To the best of our knowledge, this is the first study to compare the clinical outcomes of UC-SEMSs and PC-SEMSs in patients with MDDO. The obstruction in all of our patients was at a level distal to the second duodenal portion. Although stent migration did not occur, stent failure still occurred in 34.3% of our patients due to tumor progression. Further palliative methods with longer stent patency, lower complication rate, and high clinical success are needed for patients with MDDO. We recognize that endoscopic ultrasound-guided gastrojejunostomy (EUS-GJ) may have achieved these goals and may have been a better option for these patients. The EUS-GJ procedure is the placement of a lumen-apposing metallic stent between the stomach and jejunum under endoscopic ultrasound to bypass malignant GOO. Two retrospective studies found that EUS-GJ also could achieve a high clinical success rate but with less incidence of stent obstruction, which was around 4% [28, 29].

There are several limitations to this study. First, this is a retrospective study, and selection bias may have existed. Second, only a small number of patients were included, and their cancer status and treatment course were heterogeneous. However, some previous studies have revealed that chemotherapy or certain malignancies may influent stent patency [25, 30]. More studies are needed to determine which population or type of SEMSs are most beneficial or cost-effective for stenting in patients with MDDO.

6. Conclusion

Although there was no stent migration in the PC-SEMS group, endoscopic stenting with UC-SEMSs was comparable to PC-SEMSs in patients with MDDO. However, stent failure is still an issue to be overcome.

7. Acknowledgment

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