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# Newly designed flared-end covered versus uncovered self-expandable metallic stents for palliation of malignant colorectal obstruction: a randomized, prospective study

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**Background/Aims:** Self-expandable metallic stents (SEMSs) are widely used as palliative or bridge to surgery treatments in patients with malignant colorectal obstruction (MCO). Stent occlusion is more common with uncovered stents, but stent migration is more common with covered stents. Our purpose was to compare the efficacy and safety of a newly designed covered SEMS with an uncovered proximal flared end (CSEMS-UPF) with that of the conventional uncovered SEMS (UCSEMS) in the treatment of MCO. **Methods:** This prospective randomized trial was conducted at a tertiary-care academic hospital. We enrolled 87 patients with stage 4 cancer and MCO: colorectal cancer in 60 patients and extracolonic cancer in 27 patients. Insertion of UCSEMS was randomly assigned to 43 patients, and 44 patients received the CSEMS-UPF. The primary outcome was the duration of stent patency after successful placement. The secondary outcomes were the number of patients with technical and clinical success and early and late complications from the stent insertion. **Results:** The median patency of the stent did not differ between the UCSEMS and CSEMS-UPF groups (484 [231–737] days vs. 216 [66–366] days, $P=0.242$). The technical and clinical success rates did not differ significantly between the groups, either (100.0% vs. 93.2%, respectively, $P=0.241$; 100.0% vs. 92.7%, respectively, $P=0.112$), nor did the early (n=2 [4.7%] vs. n=4 [9.8%], $P>0.999$) or late (n=12 [27.9%] vs. n=15 [36.6%], $P>0.999$) stent complication rates differ between the groups. **Conclusions:** The UCSEMS and newly developed CSEMS-UPF are similarly effective treatments for MCO, with no differences in the stent migration or occlusion rates (Clinical trial registration number: NCT02640781). **(Intest Res 2025;23:202-212)**

**Key Words:** Self expandable metallic stents; Colorectal neoplasms; Malignant colorectal obstruction

## INTRODUCTION

Cancer is a leading cause of death worldwide, accounting for nearly 10 million deaths in 2020, and the 2nd most common cause of cancer death (916,000 deaths) in 2020 was colorectal cancer (CRC).[1] Acute colorectal obstruction has been reported to occur in 24% of all colorectal malignancies.[2,3] Since the development and introduction of endoscopic colorectal stenting more than 30 years ago, self-expandable metallic stent (SEMS) insertion has been widely used for palliation and as a bridge to surgery in malignant colorectal obstruction (MCO).[4-6] Palliative SEMS placement had several advantages over surgical intervention, including fewer complications, lower stoma rate, shorter hospitalization, and lower mortality rate.[7] A recent meta-analysis showed that palliative SEMS insertion has

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technical and clinical success rates of more than 90%.[8] Although technical success is an important consideration, a durable positive outcome is desirable in patients undergoing stenting as a palliative procedure for unresectable colorectal obstruction. The performance between uncovered and covered stents is similar in the technical and clinical success rates, but uncovered stents are superior because they are associated with fewer complications, lower rates of stent migration, longer duration of patency, and a reduced need for stent reinsertion; covered SEMSs (CSEMSs) have been reported to be vulnerable to migration.[8-11] On the other hand, CSEMSs have the benefit of less tumor ingrowth than uncovered stents. Compared with CSEMSs, the lower migration rate of the uncovered stents seems to be the main factor in their better overall performance, and the difference in the migration rate could be particularly significant in patients with colorectal obstruction caused by extracolonic malignancy. Thus, it is necessary to redesign covered stents to reduce the migration rate. Accordingly, we developed and commercialized a flared-end CSEMS with an uncovered proximal end bent like an umbrella to prevent distal migration of the stent. In this study, we compare the clinical outcomes and safety of the newly designed flared-end covered stents with those of D-Weave uncovered stents in patients with unresectable MCO.

## METHODS

### 1. Patients and Study Design

We enrolled consecutive patients who had symptomatic colorectal obstruction with unresectable malignant tumors that required the 1st placement of a SEMS. The inclusion criteria were as follows: (1) patients aged 20 to 85 years with unresectable MCO caused by either primary CRC or extracolonic malignancy; (2) patients with clinical obstructive symptoms confirmed by abdominal computed tomography or plain abdominal X-ray. Patients were excluded from the study if they had the evidence of (1) bowel perforation or peritonitis; (2) benign colorectal obstruction (e.g., bowel adhesion or benign stricture); (3) multiple strictures; (4) lower rectal obstruction less than 5 cm of the anal verge; (5) inability to receive endoscopy because of poor general condition or contraindication of SEMS insertion; or (6) refusal to participate in this study.

This prospective, randomized, interventional trial was conducted at a tertiary referral hospital (Clinical trial registration number: NCT02640781). All procedures were conducted according to the ethical principles of the Declaration of Helsinki. The Local Ethics Committee of Severance Hospital, Seoul, Korea, approved the study protocol (No. 1-2015-0046). Written informed consent was obtained from all the patients before inclusion.

The patients were randomized 1:1 to receive an uncovered SEMS (UCSEMS) or CSEMS with an uncovered proximal flared end (CSEMS-UPF), with stratification based on primary CRC and extracolonic malignancy. Randomization was performed using a permuted block randomization method with a block size of 4, as generated by an independent statistician.

### 2. Stents and Endoscopic Technique

The covered stents used in this study (CSEMS-UPF) were a biocompatible polytetrafluoroethylene double-layered combination (ComVi enteral colonic stent, flare type; Taewoong Medical, Goyang, Korea) and a conventional D-Weave uncovered stent (Niti-S enteral colonic stent, D type; Taewoong Medical) (Fig. 1). The UPF was expected to reduce stent migration to the distal colon because it could embed itself like an umbrella and prevent stent occlusion, and its interposing polytetrafluoroethylene membrane could prevent tumor ingrowth. Both stents were 24 mm in diameter. The covered stents were

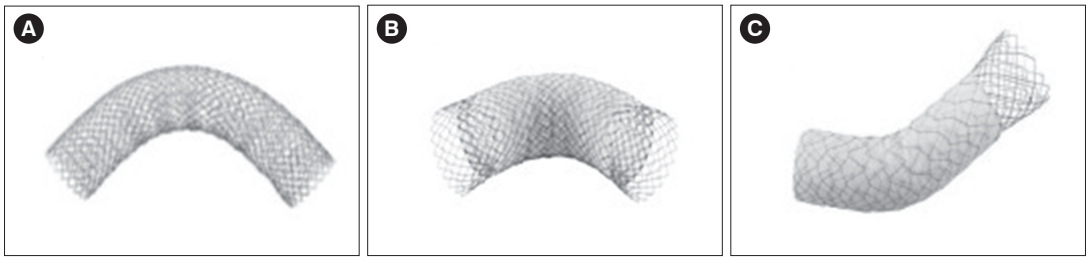


**Fig. 1.** A UCSEMS was compared with a novel CSEMS-UPF in this study. (A) D-Weave UCSEMS (Niti-S enteral colonic stent, D type). The UCSEMS is straight and contains no membrane. (B) Existing CSEMS (Niti-S ComVi enteral colonic stent). (C) Newly developed CSEMS-UPF (ComVi enteral colonic stent, flare type). The novel CSEMS has an antimigration system at the UPF. UCSEMS, uncovered self-expandable metallic stent (SEMS); CSEMS-UPF, covered SEMS with an uncovered proximal flared end.

available in lengths from 60 to 100 mm, and the uncovered stents were available in lengths from 60 to 150 mm.

One of 6 experienced endoscopists (S.J.P., Y.P., H.J.L., J.J.P., J.H.C., or T.I.K.) performed SEMS insertion using fluoroscopy and through-the-scope methods. Simple abdominal radiography was performed during and after the procedures to confirm adequate positioning and the expansion status of the stent.

### 3. Follow-up

An abdominal radiograph was obtained on the first, second, and seventh days after the intervention to check stent expansion and position. Clinical symptoms, including abdominal pain, abdominal distension, vomiting, constipation, hematochezia, and tenesmus, were also assessed on each of those days to evaluate the clinical success rate and check for early complications. Late complications and the duration of stent patency were monitored through physical examinations, clinical symptom checks, and radiologic imaging tests (abdominal radiography or abdomen-pelvis computed tomography) at 1-month follow-up intervals for 24 months after SEMS insertion or until death. Patients who died without stent complications were censored for the time to stent complications. Patients who underwent surgery because chemotherapy and/or radiation improved the primary and metastatic disease were censored for time to stent complications on the operation day. Survival time was measured from the day of SEMS placement to patient death. For patients transferred to another hospital, the date of death was determined by telephone contact.

### 4. Clinical Outcomes and Stent Patency

The primary outcome was the duration of stent patency, measured from stent insertion to the recurrence of obstructive symptoms caused by tumor ingrowth, tumor overgrowth, or stent migration after successful SEMS placement. The secondary outcomes were the number of patients with technical and clinical success and early and late complications from stent insertion in both the UCSEMS and CSEMS-UPF groups throughout the observation period. We also sought to identify factors that might predict stent occlusion or migration. Technical success was defined as adequate deployment across the entire length of the malignant strictures and proper stent expansion. Clinical success was defined as radiologic confirmation of colonic decompression and relief of obstructive symptoms sufficient to improve stool passage within 48 hours of SEMS placement without additional intervention. We classified complications as early (<7 days) and late (≥7 days) according to the duration between SEMS placement and the occurrence of the stent complications. Complications of SEMS placement include bowel perforation, bleeding, stent migration, stent occlusion by stool impaction, tumor ingrowth, and tumor overgrowth. Tumor ingrowth was defined as narrowing of the stent lumen within the bare nitinol wires caused by growing tumor tissue. Tumor overgrowth was defined as narrowing of the stent lumen at the end of the stent body caused by invading tumor tissue.

### 5. Sample Size and Statistical Analysis

The independent statistician calculated the sample size for this study based on the results of previous studies. In published studies, the complication rates of stent occlusion with uncovered and covered stents were 17.2% and 1.9%, respectively, and the stent migration rates were 0.9% and 21.6%, respectively.[11,12] The required number of patients was calculated to be 35 in each group, with a significance level of 0.05 (two-sided) and a power of 0.8. The planned sample size was thus set to 40 patients in each group to accommodate the withdrawal of a few patients.[13]

Continuous variables are expressed as mean ± standard deviation, and were compared using the independent sample *t*-test. Categorical data are expressed as number (%), and were analyzed using the Fisher exact test. The cumulative time of stent patency and cumulative time to stent migration were assessed using Kaplan-Meier analyses. A Cox regression analysis was applied to determine prognostic factors independently associated with stent patency, occlusion, or migration. Odds ratios (ORs) and 95% confidence intervals (CIs) are reported. All statistical analyses were conducted in SPSS version 22 (IBM Corp., Armonk, NY, USA). A *P*-value of <0.05 was considered statistically significant.

## RESULTS

### 1. Recruitment and Participant Flow

Recruitment was performed from December 2015 through December 2019, and the final follow-up was completed in December 2021. One hundred twenty-five patients were initially considered for this study (Fig. 2). In total, 38 patients met the exclusion criteria. Ultimately, 87 patients were randomized, and 43 patients from the UCSEMS group and 44 from the CSEMS-UPF group were included in the intention-to-treat analysis set.

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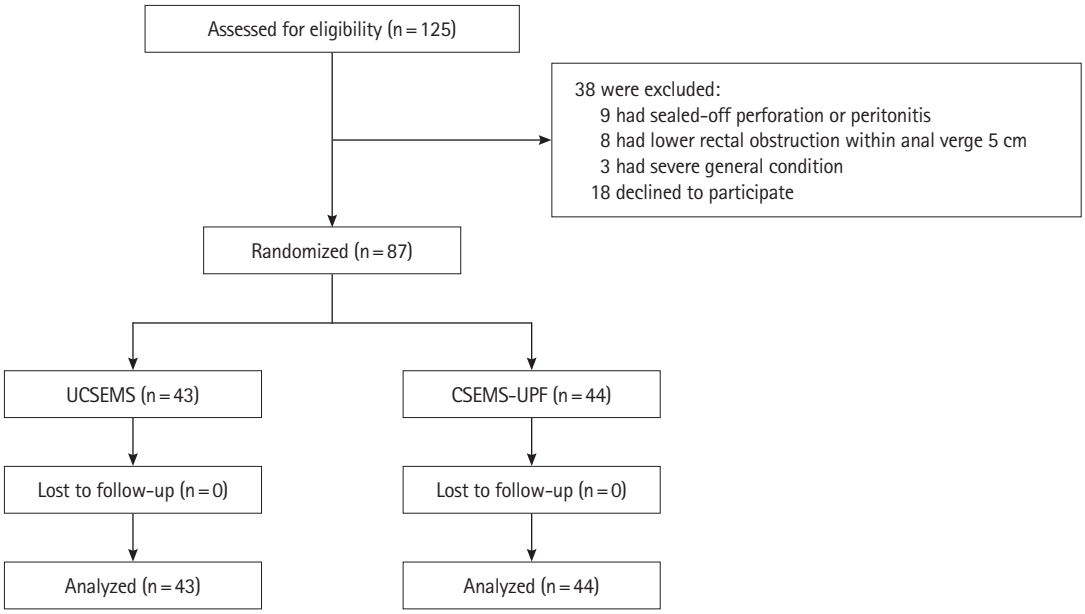


**Fig. 2.** CONSORT (Consolidated Standards of Reporting Trials) flow diagram of patient enrollment. UCSEMS, uncovered self-expandable metallic stent (SEMS); CSEMS-UPF, covered SEMS with uncovered proximal flared end.

**Table 1.** Demographic and Clinical Characteristics of Patients in the UCSEMS and CSEMS-UPF Groups

| Characteristics | UCSEMS | CSEMS-UPF | *P*-value |
|---|---|---|---|
| No. of patients | 43 (49.4) | 44 (50.6) | |
| Sex (male:female) | 28:15 | 25:19 | 0.428 |
| Age (yr) | 59.9 ± 12.7 | 63.5 ± 12.4 | 0.188 |
| Type of primary cancer | | | 0.819 |
| Colorectal cancer | 30 (69.8) | 29 (65.9) | |
| Metastatic cancer | 13 (30.2) | 15 (34.1) | |
| Stomach | 10 | 12 | |
| Pancreas | 1 | 0 | |
| Ovary | 0 | 1 | |
| HCC | 1 | 1 | |
| Others[a] | 1 | 1 | |
| Location of obstruction | | | 0.695 |
| Ascending colon/hepatic flexure | 6 (14.0) | 6 (13.6) | |
| Transverse colon/splenic flexure | 14 (32.6) | 10 (22.7) | |
| Descending colon/sigmoid colon | 12 (27.9) | 18 (40.9) | |
| Rectum | 11 (25.6) | 10 (22.7) | |
| Stent length (cm) | 9.1 ± 3.0 | 7.4 ± 1.6 | 0.002 |

Values are presented as number (%) or mean ± SD.
[a]Others are cholangiocellular carcinoma in UCSEMS and breast cancer in CSEMS-UPF.
UCSEMS, uncovered self-expandable metallic stent (SEMS); CSEMS-UPF, covered SEMS with an uncovered proximal flared end; HCC, hepatocellular carcinoma; SD, standard deviation.

### 2. Patient Characteristics in the UCSEMS and CSEMS-UPF Groups

The male-to-female ratios, mean age, and types of cancer did not differ significantly between the 2 groups. The male-to-female ratio was 28:15 and 25:19 patients ($P = 0.428$) and the mean age was 59.9 ± 12.7 years and 63.5 ± 12.4 years ($P = 0.188$) in the UCSEMS and CSEMS-UPF groups, respectively. The primary disease in the UCSEMS and CSEMS-UPF groups was CRC in 69.8% (n = 30) and 65.9% (n = 29) of patients and metastatic cancer in 30.2% (n = 13) and 34.1% (n = 15), respectively. The metastatic cancer was gastric cancer in 10 and 12 patients and hepatocellular carcinoma in 1 and 1 patient, respectively, with 1 pancreatic cancer patient and 1 cholangiocellular carcinoma patient in the UCSEMS group and 1 ovarian cancer patient and 1 breast cancer patient in the CSEMS-UPF group. The locations of obstruction did not differ between the groups with statistical significance. On the other hand, the mean stent lengths were 9.1 ± 3.0 cm and 7.4 ± 1.6 cm in the UCSEMS and CSEMS-UPF groups, respectively, and that was a significant difference ($P = 0.002$) (Table 1).

In the primary CRC group (n = 59), the male-to-female ratio was 20:10 and 17:12 patients ($P = 0.523$) and the mean age was 59.7 ± 13.5 years and 66.7 ± 11.6 years ($P = 0.037$) in the UCSEMS and CSEMS-UPF groups, respectively. The location of obstruction and stent lengths did not differ significantly between the groups (Table 2). In the extracolonic malignancy

**Table 2.** Demographic and Clinical Characteristics of Patients in the UCSEMS and CSEMS-UPF Groups Stratified by Primary Colorectal Cancer and Extracolonic Malignancy

| Characteristic | Primary colorectal cancer (n=59) | | *P*-value | Extracolonic malignancy (n=28) | | *P*-value |
|---|---|---|---|---|---|---|
| | UCSEMS | CSEMS-UPF | | UCSEMS | CSEMS-UPF | |
| No. of patients | 30 (50.8) | 29 (49.2) | | 13 (46.4) | 15 (53.6) | |
| Sex (male:female) | 20:10 | 17:12 | 0.523 | 8:5 | 8:7 | 0.718 |
| Age (yr) | 59.7±13.5 | 66.7±11.6 | 0.037 | 60.5±11.2 | 57.3±12.0 | 0.485 |
| Type of primary cancer | | | | | | 0.819 |
| Colorectal cancer | 30 (50.8) | 29 (49.2) | | | | |
| Metastatic cancer | | | | 13 (46.4) | 15 (53.6) | |
| Stomach cancer | | | | 10 | 12 | |
| HCC | | | | 1 | 1 | |
| Pancreatic cancer | | | | 1 | 0 | |
| Ovarian cancer | | | | 0 | 1 | |
| Breast cancer | | | | 0 | 1 | |
| CCC | | | | 1 | 0 | |
| Location of obstruction | | | >0.999 | | | 0.101 |
| Ascending colon/hepatic flexure | 6 (20.0) | 5 (17.2) | | 0 | 1 (6.7) | |
| Transverse colon/splenic flexure | 4 (13.3) | 5 (17.2) | | 10 (76.9) | 5 (33.3) | |
| Descending colon/sigmoid colon | 11 (36.6) | 11 (37.9) | | 1 (7.7) | 7 (46.7) | |
| Rectum | 9 (30.0) | 8 (27.6) | | 2 (15.4) | 2 (13.3) | |
| Stent length (cm) | 8.3±2.8 | 7.2±1.6 | 0.079 | 11.0±2.6 | 7.7±1.7 | 0.001 |

Values are presented as number (%) or mean±SD.
UCSEMS, uncovered self-expandable metallic stent (SEMS); CSEMS-UPF, covered SEMS with an uncovered proximal flared end; HCC, hepatocellular carcinoma; CCC, cholangiocellular carcinoma; SD, standard deviation.

group (n=28), the male-to-female ratio was 8:5 and 8:7 patients (*P*=0.718) and the mean age was 60.5±11.2 years and 57.3±12.0 years (*P*=0.485) in the UCSEMS and CSEMS-UPF groups, respectively. The location of obstruction did not differ significantly between the groups, but the mean stent lengths did differ significantly: 11.0±2.6 cm and 7.7±1.7 cm in the UCSEMS and CSEMS-UPF groups, respectively (*P*=0.001) (Table 2).

### 3. Endoscopic Success Rates and Complications between Groups

Technical and clinical success were achieved in high proportions of patients, and no differences were found between the UCSEMS and CSEMS-UPF groups (100.0% vs. 93.2%, respectively, *P*=0.241; 100.0% vs. 92.7%, respectively, *P*=0.112). No differences were found in early complications or late complications (Table 3).

Two patients (4.7%) and 4 patients (9.8%) in the UCSEMS and CSEMS-UPF groups, respectively, had early complications, which was not a significant difference (*P*>0.999). Late complications were reported in 12 out of 43 patients (27.9%) from the UCSEMS group and 15 out of 44 patients (36.6%) from the CSEMS-UPF group. The early complications were stent migration within 1 week, stool impaction, minor bleeding, perforation, and anal discomfort. The late complications were stent migration after 1 week, occlusion due to stool impaction, tumor ingrowth and overgrowth, and minor bleeding. The early and late stent migration rates did not differ between the groups. No procedure-related mortality occurred in either group. When we analyzed the patients based on stratification by primary CRC and extracolonic malignancy, we also found no differences in technical or clinical success or early or late complications between the groups (Table 4).

The median patency of the stents (free of occlusion and migration) also did not differ between the groups (484 [231–737] days vs. 216 [66–366] days, *P*=0.242). The probability of patency at 1, 3, 6, and 12 months was 97.4%, 86.4%, 71.1%, and 53.3% in the UCSEMS group and 87.5%, 78.7%, 65.5%, and 35.7% in the CSEMS-UPF group, respectively (Fig. 3). The UCSEMS

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**Table 3.** Clinical Results among the Overall Patients between the UCSEMS and CSEMS-UPF Groups

| Variable | UCSEMS (n = 43) | CSEMS-UPF (n = 44) | *P*-value |
|---|---|---|---|
| Technical success | 43/43 (100) | 41/44 (93.2) | 0.241 |
| Clinical success | 43/43 (100) | 38/41 (92.7) | 0.112 |
| Cause of technical failure | | | |
| Failure of cannulation | 0 | 2 (4.5) | |
| Failure of SEMS deploy | 0 | 1 (2.3) | |
| Early complications | 2 (4.7) | 4 (9.8) | > 0.999 |
| Stent migration within 1 wk | 0 | 2 (4.9) | |
| Stool impaction | 1 (2.3) | 0 | |
| Minor bleeding | 1 (2.3) | 0 | |
| Perforation | 0 | 1 (2.4) | |
| Anal discomfort | 0 | 1 (2.4) | |
| Procedure-related mortality | 0 | 0 | |
| Late complications | 12 (27.9) | 15 (36.6) | > 0.999 |
| Stent migration after 1 wk | 3 (7.0) | 6 (14.6) | |
| Occlusion | 9 (20.9) | 7 (17.1) | |
| Stool impaction | 3 (7.0) | 0 | |
| Tumor ingrowth or overgrowth | 6 (13.9) | 7 (17.1) | |
| Minor bleeding | 0 | 2 (4.9) | |

Values are presented as number (%).
UCSEMS, uncovered self-expandable metallic stent (SEMS); CSEMS-UPF, covered SEMS with an uncovered proximal flared end.

group had only a tendency toward a lower stent migration rate than the CSEMS-UPF group, but the mean duration to stent migration did not differ significantly between the groups (1,454.4 ± 96.8 days vs. 428.4 ± 72.4 days, $P = 0.080$) (Fig. 4).

### 4. Endoscopic Outcomes between the UCSEMS and CSEMS-UPF Groups Stratified by Primary CRC and Extracolonic Malignancy

Technical and clinical success were achieved in high proportions of patients, and no differences were found between the UCSEMS and CSEMS-UPF groups stratified based on primary CRC and extracolonic malignancy. Additionally, no differences were found in early complications or late complications stratified by primary CRC and extracolonic malignancy (Table 4).

A Kaplan-Meier analysis was performed to compare the median duration of stent patency and migration stratified by primary CRC and extracolonic malignancy. No differences in stent patency ($P = 0.339$) or migration ($P = 0.171$) were found between patients with primary CRC in the UCSEMS and CSEMS-UPF groups (Supplementary Figs. 1 and 2). Furthermore, stent migration ($P = 0.370$) did not differ in patients with extracolonic malignancy in this study (Supplementary Fig. 3).

### 5. Prognostic Factors for Stent Patency and Migration

Cox regression analysis was performed to explore the factors affecting stent patency and migration; no factors predictive of stent patency or migration were found (Table 5). The results reveal that UCSEMS had only a tendency toward lower stent migration than CSEMS-UPF (OR, 0.269; 95% CI, 0.060–1.204; $P = 0.086$) (Table 6). Type of cancer was not a prognostic factor for stent patency (extracolonic malignancy: OR, 1.478; 95% CI, 0.654–3.338; $P = 0.347$) or migration (extracolonic malignancy: OR, 1.208; 95% CI, 0.301–4.849; $P = 0.790$) in this study.

Another Cox regression analysis was conducted to determine the factors predictive of stent patency and migration in the primary CRC group. No factor was predictive of stent patency or migration in the primary CRC group (Supplementary Tables 1 and 2).

## DISCUSSION

This prospective randomized study compared the palliative use of UCSEMS versus CSEMS-UPF for MCO. We hypothesized that the novel CSEMS-UPF would be associated with the prevention of stent migration because of the proximal uncovered flare, and we forecast that it would extend stent patency longer than that reported in published studies. However, we found no differences in the primary (duration of stent patency) or secondary (technical and clinical success rates and early and late complication rates) outcomes between the groups. Also, we found no factors predictive of stent patency or migration. The novel CSEMS-UPF did improve stent patency over a previously used CSEMS without increasing complications.

Several studies have assessed clinical outcomes between patients with a UCSEMS and those with a CSEMS for colorectal obstruction,[6,7,10,14] including 2 randomized controlled trials (RCTs).[11,12] One systematic review and meta-analysis showed that uncovered stents are superior, as indicated by fewer complications, lower stent migration rates, longer patency, and a reduced need for stent reinsertion.[8] Another systematic review and meta-analysis showed that tumor ingrowth occurred more frequently in the UCSEMS group, whereas late migration was more common in the CSEMS group.[15] Our study is the first to evaluate the efficacy of a novel CSEMS-UPF developed to prevent both stent migration and tumor ingrowth in

**Table 4.** Clinical Results among the Overall Patients between the UCSEMS and CSEMS-UPF Groups Stratified by Primary Colorectal Cancer and Extracolonic Malignancy

| Vaiable | Primary colorectal cancer (n=59) | | *P*-value | Extracolonic malignancy (n=28) | | *P*-value |
|---|---|---|---|---|---|---|
| | UCSEMS | CSEMS-UPF | | UCSEMS | CSEMS-UPF | |
| No. of patients | 30 (50.8) | 29 (49.2) | | 13 (46.4) | 15 (53.6) | |
| Technical success | 30/30 (100) | 27/29 (93.1) | 0.237 | 13/13 (100) | 14/15 (93.3) | >0.999 |
| Clinical success | 30/30 (100) | 25/27 (92.6) | 0.220 | 13/13 (100) | 13/14 (92.9) | >0.999 |
| Cause of technical failure | | | | | | |
| Failure of cannulation | 0 | 1 (3.4) | | 0 | 1 (6.7) | |
| Failure of SEMS deploy | 0 | 1 (3.4) | | 0 | 0 | |
| Early complications | 1 (3.3) | 2 (7.4) | >0.999 | 1 (7.7) | 2 (14.3) | >0.999 |
| Stent migration within 1 wk | 0 | 0 | | 0 | 2 (14.3) | |
| Stool impaction | 1 (3.3) | 0 | | 0 | 0 | |
| Minor bleeding | 0 | 0 | | 1 (7.7) | 0 | |
| Perforation | 0 | 1 (3.7) | | 0 | 0 | |
| Anal discomfort | 0 | 1 (3.7) | | 0 | 0 | |
| Procedure-related mortality | 0 | 0 | | 0 | 0 | |
| Late complications | 9 (30.0) | 9 (33.3) | >0.999 | 3 (23.1) | 6 (42.8) | >0.999 |
| Stent migration after 1 wk | 2 (6.7) | 5 (18.5) | | 1 (7.7) | 1 (7.1) | |
| Reocclusion | 7 (23.3) | 2 (7.4) | | 2 (15.4) | 5 (35.7) | |
| Stool impaction | 3 (10.0) | 0 | | 0 | 0 | |
| Tumor ingrowth or overgrowth | 4 (13.3) | 2 (7.4) | | 2 (15.4) | 5 (35.7) | |
| Minor bleeding | 0 | 2 (7.4) | | 0 | 0 | |

Values are presented as number (%).
UCSEMS, uncovered self-expandable metallic stent (SEMS); CSEMS-UPF, covered SEMS with an uncovered proximal flared end.

patients with MCO.

In previous RCTs that compared UCSEMS and CSEMS, the incidence of stent ingrowth was 13.5%–20% in the UCSEMS group and 0%–3.8% in the CSEMS group.[11,12] In most studies, stent occlusion was significantly lower in the CSEMS group than in the UCSEMS group. Surprisingly, however, the incidence of stent occlusion in the CSEMS-UPF group did not differ significantly from that in the UCSEMS group in this study (17.1% vs. 20.9%, respectively, $P>0.999$). In our study, the stent occlusion rate in the CSEMS-UPF group was higher than expected. Stent occlusion might have occurred due to tumor overgrowth at the proximal uncovered flare portion, even in the CSEMS-UPF group, due to the shorter lengths of the novel stents. In fact, in this study, the stent length of the CSEMS-UPF group was significantly shorter than that of the UCSEMS group (7.4±1.6 vs. 9.1±3.0, $P=0.002$). The CSEMS is shorter than the UCSEMS because it is currently commercialized only up to 10 cm. When longer-length CSEMS-UPFs become available, the possibility of stent occlusion by overgrowth is expected to be reduced. Interestingly, stent occlusion by stool impaction was noted in 4 patients (1 as an early complication and 3 as late complications) only in the UCSEMS group. The nitinol mesh without a membrane in the UCSEMS could cause stool impaction because it has enormous surface resistance, making stools more likely to be caught in it.

The migration of the CSEMS is a challenging problem. Many studies have reported that the incidence of stent migration is significantly higher with CSEMSs than UCSEMSs.[14,16-20] Two RCTs revealed that the incidence of stent migration ranges from 16% to 22.2% in patients receiving a CSEMS and from 0.0% to 1.3% in those receiving a UCSEMS.[11,12] A recent meta-analysis compared CSEMS and UCSEMS used as a bridge to surgery or as palliative treatment. UCSEMS was associated with reduced stent migration (risk ratio [RR], 0.29), longer stent patency (mean duration, 18 months), and fewer re-insertions (RR, 0.38) than CSEMS, although the risk of tumor ingrowth was higher (RR, 4.53).[8] In a palliative setting, tumor ingrowth can be treated with stent replacement using stent-in-

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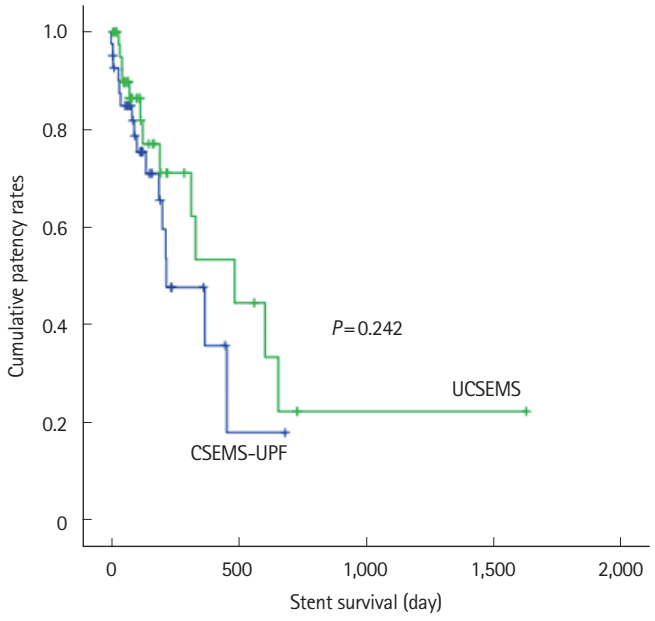


**Fig. 3.** Kaplan-Meier curves for stent patency. The duration of stent patency did not differ significantly between the UCSEMS and CSEMS-UPF groups. Its probability at 1, 3, 6, and 12 months was 97.4%, 86.4%, 71.1%, and 53.3% in the UCSEMS group and 87.5%, 78.7%, 65.5%, and 35.7% in the CSEMS-UPF group, respectively. UCSEMS, uncovered self-expandable metallic stent (SEMS); CSEMS-UPF, covered SEMS with uncovered proximal flared end.

**Table 5.** Multivariate Analysis of the Prognostic Factors Associated with Stent Patency[a]

| Prognostic factor | Odds ratio (95% CI) | *P*-value |
|---|---|---|
| Sex (female) | 1.862 (0.827–4.191) | 0.133 |
| Age | 0.995 (0.967–1.024) | 0.723 |
| Type of primary cancer (metastatic cancer) | 1.478 (0.654–3.338) | 0.347 |
| Type of stent (uncovered stent) | 0.652 (0.287–1.481) | 0.307 |
| Length of stent | 1.080 (0.900–1.295) | 0.408 |

[a]Stent patency: free of occlusion and migration.
CI, confidence interval.

stent techniques.[21,22] Therefore, a recent clinical guideline recommends using UCSEMS in the palliative setting.[23] However, in this RCT, the group that received our newly designed CSEMS-UPF had migration rates, stent patency, and complication rates that did not differ from those of the UCSEMS group, so it is likely to be advantageous in specific cases.

SEMS placement is a reasonable, albeit more technically challenging, alternative for patients with extracolonic malignancy who are not candidates for surgery; however, clinical

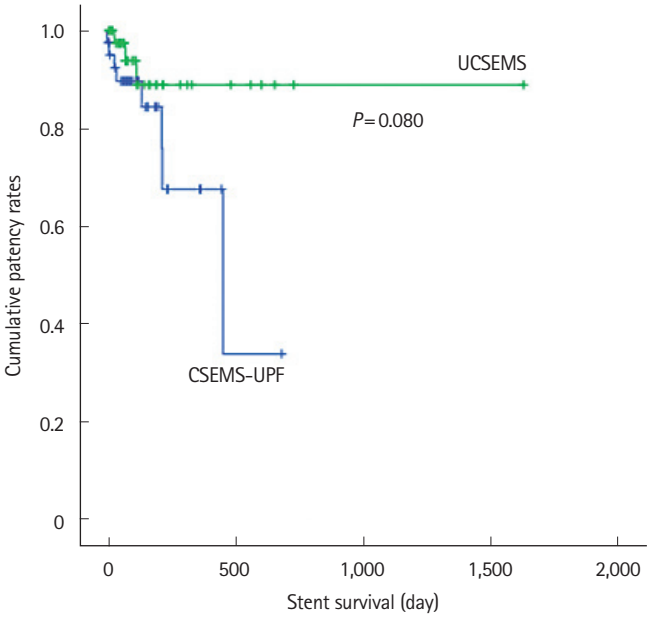


**Fig. 4.** Kaplan-Meier curves for stent migration. Stent migration did not differ significantly between the UCSEMS and CSEMS-UPF groups. UCSEMS, uncovered self-expandable metallic stent (SEMS); CSEMS-UPF, covered SEMS with uncovered proximal flared end.

**Table 6.** Multivariate Analysis of the Prognostic Factors Associated with Stent Migration

| Prognostic factor | Odds ratio (95% CI) | *P*-value |
|---|---|---|
| Sex (female) | 1.373 (0.383–4.921) | 0.627 |
| Age | 1.010 (0.960–1.063) | 0.704 |
| Type of primary cancer (metastatic cancer) | 1.208 (0.301–4.849) | 0.790 |
| Type of stent (uncovered stent) | 0.269 (0.060–1.204) | 0.086 |
| Length of stent | 1.172 (0.865–1.587) | 0.306 |

CI, confidence interval.

success rates are more variable, and complications (including stent migration) are more frequent than with CRC. Furthermore, extracolonic malignancy itself can cause vulnerability to stent migration. Therefore, we stratified and analyzed the CRC and extracolonic malignancy groups separately. Although the patient numbers were small, the duration to stent migration did not differ significantly between the UCSEMS and CSEMS-UPF groups in the patients with extracolonic malignancy (Supplementary Fig. 3). In addition, the median duration to stent migration in the CSEMS-UPF group did not differ ($P=0.825$) between the patients with primary CRC and those with extracolonic malignancy (Supplementary Fig. 4). Thus, the CSEMS-UPF seems to have efficacy in preventing stent

migration compared with the previous CSEMS without a flared end.

Because the risk of tumor perforation in patients who receive chemotherapy is well known, especially the risk of perforation caused by bevacizumab-based chemotherapy, palliative SEMS placement in patients undergoing bevacizumab-based chemotherapy remains debatable. In 1,008 patients who received bevacizumab for metastatic colorectal malignancy, the risk of complications necessitating surgery was 5.9%. In patients already receiving bevacizumab, stent insertion was a significant risk factor for complications requiring surgery (hazard ratio, 5.687).[24] The European Society of Gastrointestinal Endoscopy does not suggest colonic stenting while patients receive antiangiogenic therapy, such as bevacizumab.[23] CSEMS placement can be considered first to reduce the perforation rate in patients receiving bevacizumab chemotherapy at a high risk of surgery and in patients contraindicated for surgery.

Previous studies have investigated factors that predict stent-related events, mainly prognostic factors of technical and clinical failure after SEMS placement.[6,7,16] Kwon et al.[7] reported that peritoneal carcinomatosis was associated with clinical failure and short reintervention-free survival in patients requiring palliative stenting for MCO. Stent expansion >90% on post-procedural day 1 was another predictor of a short reintervention-free survival after clinically successful stenting. Furthermore, Abbas et al.[6] found that carcinomatosis was associated with a lower technical success rate. Clinical success rates were higher in patients with a primary colonic malignancy, while a covered stent, balloon dilation of stricture, lesions in the rectum, and carcinomatosis were associated with a higher risk of complications. In this study, we found no significant predictive factors for stent patency, defined as freedom from stent occlusion and migration. UCSEMS also was not a factor affecting stent patency and migration.

This study has 2 main strengths. First, it was a prospective randomized study conducted in a large-volume hospital. Second, it is the first study to compare the efficacy and safety of UCSEMS and the novel CSEMS-UPF. This study also has 2 main limitations. First, the length of the SEMSs differed: the CSEMSs were available only from 60 to 100 mm in length, including the proximal uncovered flare, whereas the UCSEMSs were available in lengths from 60 to 150 mm. While the CSEMS-UPF stent was limited to a maximum length of 10 cm, inherently introducing potential differences in stent lengths between groups, our primary outcome of technical success was not significantly compromised by this limitation. Although technical failures occurred in 3 cases within the CSEMS-UPF group, these were primarily attributed to cannulation failure in 2 cases and the inability to deploy the stent due to severe angulation of the lesion and adhesions to surrounding organs in one case. None of these failures were directly related to the limited length of the CSEMS-UPF stent. Furthermore, our randomized allocation ensured that the clinical outcome of successful stent placement was comparable between groups, suggesting adequate coverage of the occluded segment. Therefore, despite the inherent length limitations of the CSEMS-UPF stent, we believe that its impact on short-term outcomes, such as technical and clinical success rates, was minimal. In terms of long-term outcome, for the primary outcome of stent patency, the factors associated with stent length, such as overgrowth, might influence long-term results. However, we followed the standard practice of placing stents with approximately 2 cm margins on both sides in all cases to minimize this limitation. Although our study did not demonstrate a statistically significant difference of stent obstruction, the potential impact of stent length on long-term outcomes warrants further investigation. Second, although we calculated a statistically adequate number of enrolled patients and conducted this study accordingly, our sample size is relatively small because the previous RCTs used to estimate the sample size were extremely limited.

In conclusion, the insertion of either the newly developed flared-end covered stent or an uncovered stent is similarly effective for palliative treatment of MCO, without differences in stent patency or migration rate. We failed to demonstrate that the newly designed flared-end covered stents are superior to uncovered stents in preventing stent migration. Therefore, further development of the modified stents is needed to overcome the 2 main complications of SEMS, stent migration and occlusion, in treating obstructing CRCs. Further large-scale, randomized, multicenter studies are required to corroborate the results presented here.

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**Conflict of Interest**

Taewoong Medical (Goyang, Korea) supported the develop-

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**Data Availability Statement**

Data are available upon reasonable request.

**Author Contributions**

Conceptualization: Kim TI. Data curation: all authors. Formal analysis: Park SJ. Investigation: all authors. Methodology; Project administration: Park SJ, Kim TI. Resources: all authors. Software: Park SJ. Supervision: Kim TI. Visualization: Park SJ. Writing - original draft: Park SJ. Writing - review & editing: all authors. Approval of final manuscript: all author.

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**Supplementary Material**

Supplementary materials are available at the Intestinal Research website (https://www.irjournal.org).

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