Diagn Interv Radiol 2015; 21:167–172


INTERVENTIONAL RADIOLOGY
ORIGINAL ARTICLE

# Clinical effect of double coaxial self-expandable metallic stent in management of malignant colon obstruction

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PURPOSE
We aimed to evaluate the clinical effectiveness and safety of double coaxial self-expandable metallic stent (DCSEMS) in management of malignant colonic obstruction as a bridge to surgery or palliation for inoperable patients.

METHODS
Between April 2006 and December 2012, 49 patients (27 males and 22 females; median age, 68 years; age range, 38–91 years) were selected to receive decompressive therapy for malignant colonic obstruction by implanting a DCSEMS. Application of DCSEMS was attempted in 49 patients under fluoroscopic guidance. The obstruction was located in the transverse colon (n=2), descending colon (n=7), sigmoid colon (n=24), rectosigmoid junction (n=6), and the rectum (n=10). The intended use of DCSEMS was as a bridge to elective surgery in 23 patients and palliation in 26 patients.

RESULTS
Clinical success, defined as >50% dilatation of the stent with subsequent symptomatic improvement, was achieved in 48 of 49 patients (98%). The stent was properly inserted in all patients. No immediate major procedure-related complications occurred. One patient in the bridge-to-surgery group had colon perforation three days after DCSEMS application. Four patients had late migrations of the double stent.

CONCLUSION
Application of DCSEMS is safe and effective in management of malignant colonic obstruction; it prevents stent migration and tumor ingrowth and lowers perforation rate during the stent application.

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Received 4 July 2014, revision requested 21 July 2014, final revision received 16 September 2014, accepted 22 September 2014.

Published online 13 February 2015.
DOI 10.5152/dir.2014.14260

Fluoroscopic or endoscopic placement of either bare or covered expandable metallic stents was shown to be a safe, easy, and effective technique as a bridge to surgery and palliative treatment of colorectal cancer (1, 2). However, tumor ingrowth and stent migration have been reported as weaknesses in conventional single bare and covered stents, respectively (2–4). The use of bare stents has been hindered by progressive tumor ingrowth through the wire filaments of the bare stents and food residue or hard fecal impaction proximal to or at the level of the stent insertion site (5, 6). In contrast, the use of covered expandable metallic stents has been associated with stent migration (5, 7). To overcome the limitations associated with conventional bare and covered stents, a double coaxial self-expandable metallic stent (DCSEMS) has been developed to combine the strengths of bare and covered stents (7, 8).

The purpose of the present study was to report our experiences with fluoroscopic-guided placement of double stents in management of malignant colorectal obstruction as a bridge to surgery or palliative treatment.

## Methods

Informed consent was obtained from each patient and/or the legal guardian after the risks and benefits of the treatment were fully explained. Our Institutional Review Board approved this retrospective study.

### *Patients*

Between April 2006 and December 2012, the images and clinical reports of 49 consecutive patients (27 males and 22 females; median age, 66 years; age range, 38–91 years) with malignant colorectal obstruction, who received decompressed therapy by DCSEMS implantation were reviewed retrospectively. DCSEMS was used for palliation in 26 patients and as a bridge to elective surgery in 23 patients. Patient selection criteria included the site of obstruction from the transverse colon to the distal rectum and absence of bowel perforation. Age, general health status, and tumor stage were not used as exclusion criteria. Computed tomography (CT) confirmed the obstruction sites as transverse colon (n=2), descending colon (n=7), sigmoid colon (n=24), rectosigmoid junction (n=6), and rectum (n=10). The cause of obstruction at the time of stent insertion was colon adenocarcinoma in all 49 patients. The possibility of combined proximal lesions was excluded on the basis of CT findings.

### *Stents and delivery systems*

The partly membrane-covered (interior covered by polyurethane) and bare stents (Hanarostent, MITech) were designed and constructed for

use in the colon (Fig. 1a, 1b). The partly membrane-covered and bare stents are finely meshed, self-expanding, and made of biomedical nickel titanium alloy wires; they are flexible and have radio-opaque markers at each end. The proximal and distal flanged ends are 80–160 mm in length and 24 mm in diameter with mildly flayed ends. The expansion force of the covered stent was 1.95 Newton (N) in the middle and 1.20 N at both ends. The expansion force of the bared stent was 1.87 N in the middle and 1.17 N at both ends. The expansion force of the double stent was 4.04 N in the middle and 2.78 N at both ends. The expansion force was measured by LR5K PLUS testing machine (Ametek Lloyd). The resulting total radial force of combined double stent was twice the radial force of a single stent.

The 4 mm delivery system is made up of an outer sheath and an inner sheath. The outer sheath is locked with a handle and the inner sheath consists of a proximal stainless-steel tube shaft and a distal polymer shaft (Fig. 1c).

*Stent insertion technique*

The patients were placed in the left lateral decubitus or prone position. Under the fluoroscopic guidance, the colorectal cancer related stenosis sites were verified using double contrast study of an iso-osmolar radiocontrast (Optiray, Mallinckrodt Imaging) and room air. A 0.035-inch regular hydrophilic guidewire (Terumo) and a 7 F angiographic catheter (Guider Softip, Boston Scientific) were inserted. The wire and catheter combination was gently inserted until it crossed the lesion, and the catheter was further advanced afterwards. The size of the lesion was measured in order to select the appropriate stent length. The metallic stent measured 24 mm in diameter. The length of the metallic stent was determined so that at least an additional 5 cm (2.5 cm beyond each side of the proximal and distal portions of the actual stricture) would be provided in addition to the actual stricture length to cover the entire lesion. Under fluoroscopic guidance, a stent delivery system (4 mm in diameter) containing an outer stent (sheath, compressed outer bare stent, and pusher catheter) was advanced over the guidewire to cross the lesion. The pusher catheter was held in place with one hand, while the sheath was slowly withdrawn in a continuous motion with the other. This freed the stent, allowing it to lie within the stricture and expand. Another stent delivery system containing the inner covered stent was then inserted over the guidewire, resulting in coaxial placement of the inner stent within the outer bare stent. The outer and the inner stents were loaded separately in their own delivery systems. To confirm the full expansion and accurate placement of the stents, the patients were followed up with plain abdomen radiography 24 and 72 hours after the procedure (Fig. 2).

*Definitions*

Technical success was defined as DCSEMS placement which covered the obstructing lesion, as well as at least 2.5 cm of normal bowel proximal and distal to the lesion. Clinical success was declared when the metallic stent was confirmed to have expanded by at least 50% with radiologic evidence suggesting improvement of the obstruction, gas and stool passage were restored, and symptoms were improved (9).

Minor complications were defined as events that caused no significant clinical sequelae, necessitating no further therapy other than overnight observation. Major complications were defined as events necessitating therapy, unplanned increase in the level of care,

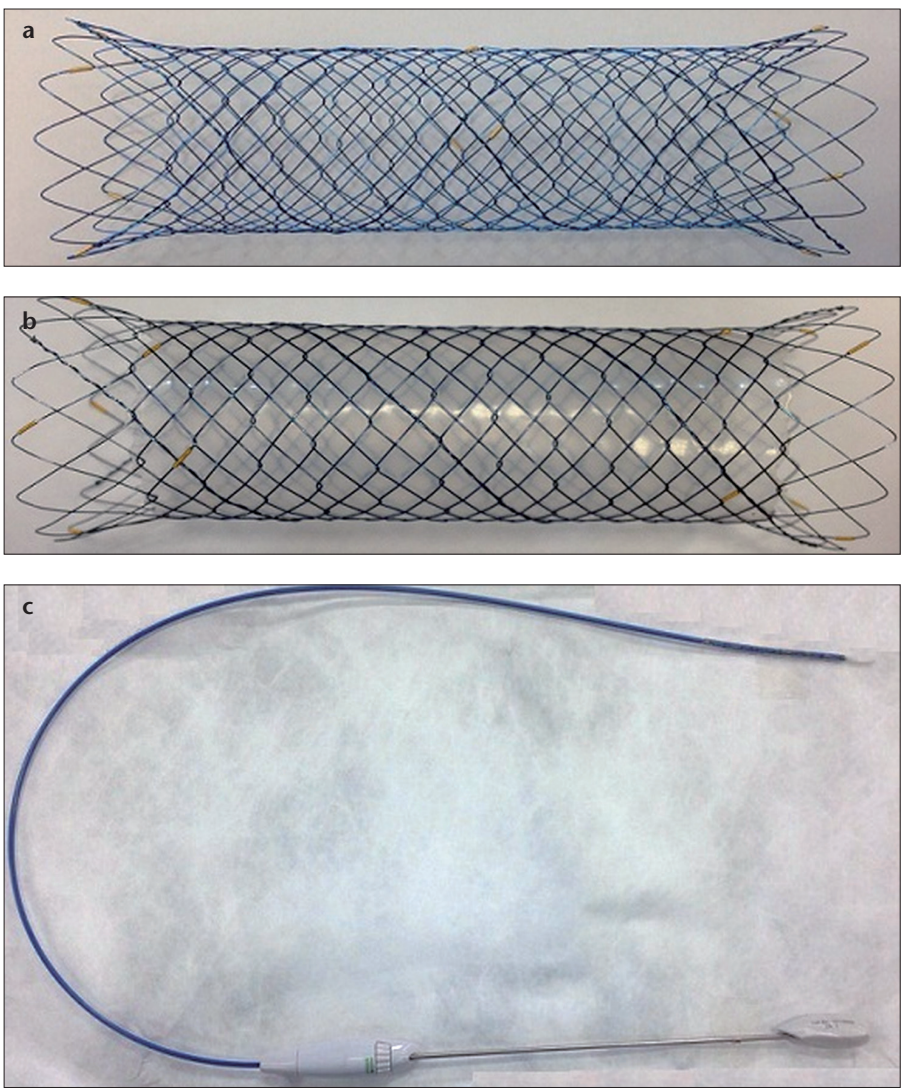


**Figure 1. a–c.** Stents and delivery system. Panel **(a)** shows an outer bare stent, 24 mm in diameter, with flares. Panel **(b)** shows an inner covered stent, 24 mm in diameter, with flares; the covered stent is bare at both ends. Panel **(c)** displays the delivery system with the outer sheath (4 mm in diameter), which is locked with a handle, compressed stent, and inner sheath.

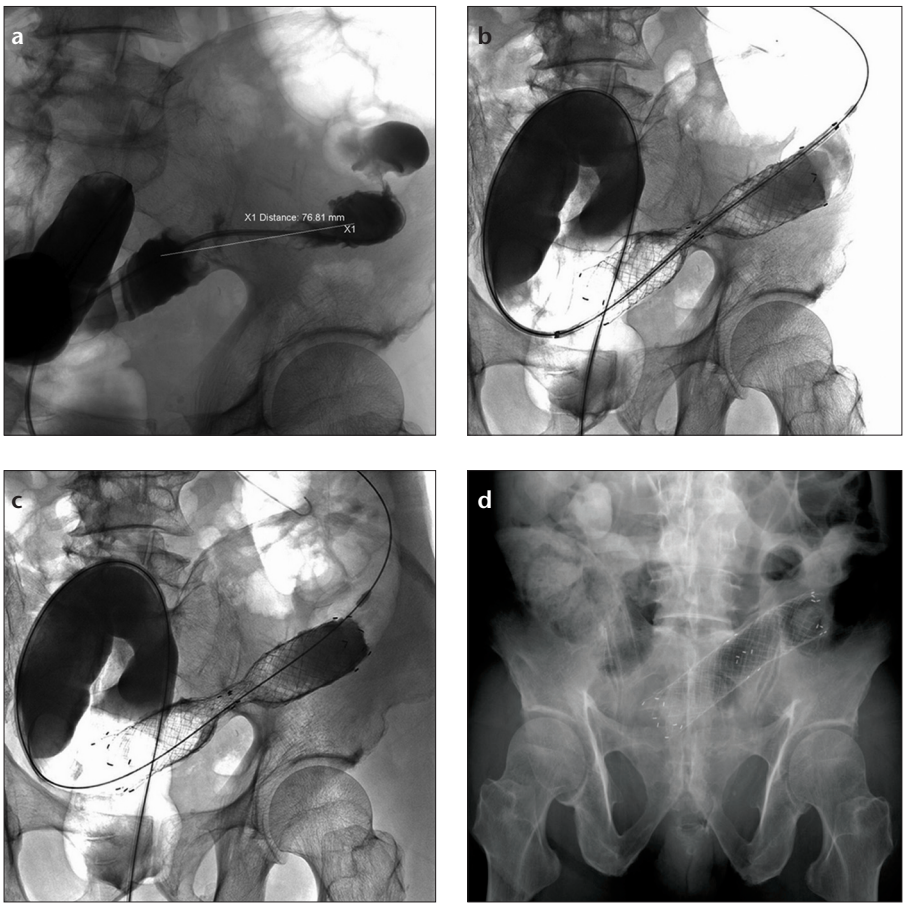


**Figure 2. a–d.** Stent placement within the sigmoid colon. Retrograde contrast-enhanced image **(a)** shows the measurements before stent application. Panel **(b)** displays application of outer stent via the guidewire. Panel **(c)** shows coaxial application of the inner stent via the guidewire. DCSEMS is successfully placed with appropriate distance above the proximal and distal margins of the tumor lesion. Full expansion of the inserted stents is visible on the 24-hour kidney-ureter-bladder radiography **(d)**.

prolonged hospitalization, or events that resulted in permanent adverse sequelae (10). Early complications were defined as complications occurring during the procedure or within a day after stent application. Early migration was defined as migration occurring within one week and late migration as occurring after one week.

## Results

Stents were properly inserted in all 49 patients, which confirmed technical success. Clinical success, defined as >50% dilatation of the stent with subsequent symptomatic improvement, was achieved in 48 of 49 patients (98%). Clinical failure occurred in one case; an emergent Hartman's procedure was performed, which revealed vegetable residues proximal to the lesion. Perforation of the colon occurred in one patient three days after stent insertion (2%). Mild anal pain persisted in one patient because the stent was close to the anus.

Detailed data for the bridge-to-surgery group is presented in Table 1. Among 23 patients who had primary colorectal cancer, 21 underwent subsequent elective surgical resection. Two patients underwent Hartman's procedure due to stent obstruction by hardly fixed vegetable residue and colon perforation, respectively. The median time to operation was 14 days (range, 6–27 days) and there were no migrations prior to surgery.

Detailed data for the palliative group is presented in Table 2. Stent placement was considered as the definitive palliative treatment of colonic obstruction due to inoperable primary colon cancer and pancreatic cancer invasion. Four patients experienced late stent migration at three weeks and at three, 11, and 26 months, respectively. In one patient, tumor ingrowth was detected on follow-up colonoscopy.

## Discussion

This study was designed to evaluate the usefulness and safety of double stenting for the management of acute malignant colon obstruction. In our study, DCSEMS was successfully applied in 48 of 49 patients of colon cancer and their colonic obstruction symptom was resolved.

It has been estimated that 7%–29% of patients with colorectal cancer present with near or complete bowel obstruction (11). Traditional management for patients who have either subtotal or complete malignant colon obstruction is associated with higher morbidity and mortality rates, reduced quality of life, and a need for a second operation (3, 12). Preoperative stent insertion can avoid emergency operation with colostomy and enable elective one-stage surgery at a later point in time (12).

The use of self-expandable metallic stents as a bridge to elective surgery is becoming more widely accepted; the safety and effectiveness of their placement for palliative treatment of malignant colorectal obstruction is also well known. (1, 12–14). However, tumor ingrowth and stent migration have been reported as weaknesses in conventional single bare and covered stents, respectively (2–4). The purpose of double stent is to maximize the benefits of bare and covered stents. In our results, the radial force doubled when calculated with two overlapping stents. The high radial force of the double stent helps with faster expansion of the stenotic loop, resulting in effective decompression of the distended proximal bowel loops in patients with colon obstruction. The sooner stent obtains normal caliber, the better obstructive symptoms are relieved. This system is also expected to reduce migration and tumor ingrowth.

Baron et al. (5) suggested that preoperative stenting decompression allows clinical stabilization of the patients so that preoperative arrangements such as colonic preparation, treatment of coexisting medical illnesses, determination of the exact extent of malignan-

**Table 1.** Details of patients with DCSEMS placement for bridge to surgery

| No. | Sex/ age (yrs) | Diagnosis | Site of obstruction | Stent insertion | Subsequent treatment | Complication | Days to surgery |
|---|---|---|---|---|---|---|---|
| 2 | M/72 | Primary colon CA | Sigmoid | Successful | LHC | No | 28 |
| 3 | M/54 | Primary colon CA | Sigmoid | Successful | AR, CT | No | 14 |
| 4 | M/70 | Primary colon CA | Descending | Successful | LHC | No | 11 |
| 5 | M/77 | Primary colon CA | Descending | Successful | Hartman operation | Hardly fixed vegetable residue | |
| 6 | M/50 | Primary colon CA | Sigmoid | Successful | LAR | No | 6 |
| 7 | M/61 | Primary rectal CA | Rectum | Successful | LAR | No | 11 |
| 8 | M/71 | Primary colon CA | Sigmoid | Successful | Hartman operation | Perforation | 3 |
| 9 | F/52 | Primary colon CA | Descending | Successful | LHC | No | 9 |
| 10 | M/75 | Primary colon CA | Rectosigmoid | Successful | LAR | No | 16 |
| 11 | M/77 | Primary colon CA | Transverse | Successful | LHC | No | 6 |
| 12 | F/78 | Primary colon CA | Descending | Successful | LHC | No | 17 |
| 13 | M/85 | Primary colon CA | Sigmoid | Successful | AR | No | 16 |
| 14 | F/73 | Primary colon CA | Sigmoid | Successful | Sigmoidectomy | No | 10 |
| 15 | M/59 | Primary rectal CA | Proximal rectum | Successful | LAR | No | 25 |
| 16 | F/63 | Primary rectal CA | Proximal rectum | Successful | LAR | No | 13 |
| 17 | M/48 | Primary colon CA | Rectosigmoid | Successful | LAR | No | 31 |
| 18 | F/49 | Primary colon CA | Sigmoid | Successful | LHC | No | 4 |
| 19 | F/66 | Primary colon CA | Sigmoid | Successful | LHC | No | 15 |
| 20 | F/77 | Primary colon CA | Rectosigmoid | Successful | LAR | No | 22 |
| 21 | M/72 | Primary colon CA | Sigmoid | Successful | LHC | No | 13 |
| 22 | M/54 | Primary colon CA | Sigmoid | Successful | LHC | No | 10 |
| 23 | F/77 | Primary colon CA | Sigmoid | Successful | LHC | No | 25 |

M, male; CA, cancer; LHC, left hemicolectomy; AR, anterior resection; CT, chemotherapy; LAR, low anterior resection; F, female.

cy, and administration of preoperative chemoradiation therapy can be made, and successful laparoscopic resection can be performed. Another important issue regarding the preoperative management of colorectal cancer patients is the presence of synchronous cancers and adenomas, the incidence of which varies from 2.7% to 6.5% (15). The problem is further compounded by the increased frequency of synchronous neoplasm in patients with obstructing cancers compared with patients with nonobstructing cancers (16). In cases performed as a bridge to surgery, we placed DCSEMS in order to quickly secure an effective and even lumen diameter. Although there are no reports on the early effective diameter of inserted stents, our experience revealed that single application of a large diameter (22 or 24 mm) bare stent could not always secure a sufficiently large early-stage effective diameter for colonoscopy. Use of DCSEMS allowed us to obtain a more circular, uniform, and effective diameter.

In pooled analysis, migration has been documented to occur in approximately 3% of patients in the bridge-to-surgery group and 14% of patients in the palliation group (2). Migration is usually detected on follow-up radiography within one week of insertion (in 61% of patients with migration) (2). According to Fan et al. (6), early migration prior to surgery occurred in two of 19 patients in the bridge-to-surgery group (10%). In our study, there were no early migrations in either group, although delayed migration occurred in four patients in the palliation group (9.3%). We treated 49 patients with malignant colorectal obstruction with DCSEMS without early migration. The lower early migration rate in our study compared with the rates reported by previous studies (2, 6) can be possibly explained by tissue reactions induced by incorporation of flares in the inner and outer stents, and augmentation of the radial force by the presence of double stents. We lodged the inner partially covered stent 1 cm proximal to the outer stent. Direct colon contact of the proximal uncovered flare leads to its incorporation in the colon wall and induces a tissue reaction. We thought that this reaction and the interaction of the proximal flare meshes with the outer stent could enhance stent anchoring and resistance to shear stress from the colonic peristalsis during passage of the residual stool. All patients with delayed migration showed a better response to chemotherapy

**Table 2.** Details of patients with DCSEMS placement for palliation

| No. | Sex/ age (yrs) | Diagnosis | Site of obstruction | Stent insertion | Subsequent treatment | Minor complication | Late complication |
|---|---|---|---|---|---|---|---|
| 1 | M/64 | Primary colon CA with CP and LM | Sigmoid | Successful | CT | No | |
| 2 | M/75 | Primary colon CA with LM | Sigmoid | Successful | CT | No | Late migration (26 months) |
| 3 | M/41 | Primary colon CA with LM | Rectosigmoid | Successful | RT CT | No | Late migration (3 months) |
| 4 | M/38 | Primary colon CA with CP and LM | Rectosigmoid | Successful | | No | |
| 5 | F/61 | Primary colon CA with LM | Sigmoid | Successful | CT | No | Tumor ingrowth (11 months) |
| 6 | F/63 | Primary colon CA with LM and lung Mt | Sigmoid | Successful | CT | No | Tumor ingrowth (10 months) |
| 7 | M/83 | Primary colon CA with LM | Sigmoid | Successful | | No | |
| 8 | M/80 | Primary rectal CA with lung Mt | Proximal rectum | Successful | CT | No | |
| 9 | M/65 | Primary colon CA with LM | Descending | Successful | CT | No | |
| 10 | M/67 | Primary colon CA with LM | Descending | Successful | CT | No | |
| 11 | M/56 | Primary rectal CA with LM, and lung Mt | Distal rectum | Successful | CT | No | |
| 12 | F/53 | Primary colon CA with brain Mt | Sigmoid | Successful | CT | No | |
| 13 | F/79 | Primary colon CA with lung Mt | Sigmoid | Successful | | No | |
| 14 | F/49 | Primary colon CA with LM | Descending | Successful | CT | No | Late migration (3 weeks) |
| 15 | F/64 | Primary colon CA with LM | Sigmoid | Successful | CT | No | |
| 16 | F/61 | Primary colon CA with LM | Proximal rectum | Successful | CT | No | |
| 17 | F/65 | Primary colon CA with LM | Rectosigmoid | Successful | CT | No | Late migration (3 months) |
| 18 | F/80 | Primary colon CA with neck node Mt | Rectosigmoid | Successful | | No | |
| 19 | M/67 | Primary colon CA with CP | Sigmoid | Successful | CT | No | |
| 20 | F/61 | Primary rectal CA with LM lung Mt | Proximal rectum | Successful | | No | |
| 21 | M/84 | Primary colon CA with LM | Sigmoid | Successful | CT | No | |
| 22 | M/80 | Primary colon CA with CP | Transverse | Successful | CT | No | |
| 23 | F/69 | Primary rectal CA with LM | Proximal rectum | Successful | CT | No | |
| 24 | M/49 | Primary rectal CA with LM lung Mt | Rectum | Successful | CT | No | |
| 25 | F/80 | Primary colon CA with LM | Sigmoid | Successful | CT | No | |
| 26 | F/91 | Primary colon CA with LM | Sigmoid | Successful | CT | No | |

M, male; CA, cancer; CP, carcinomatosis peritonei; LM, liver metastasis; CT, chemotherapy; RT, radiation therapy; F, female; Mt, metastasis.

compared to others, suggesting that primary lesion debulking may have reduced the external radial tensile force surrounding the double stent leading to stent migration.

A systematic review showed that the overall perforation was observed in 3.8% of patients after colorectal self-expandable metallic stent placement (2). Most perforations were apparent within one week after stent deployment and were caused by stent insertion itself, balloon dilatation of strictures to obtain access, excessive manipulation of the guidewire, or device erosion through the colonic wall (17). Other groups (8, 18) postulated that the higher perforation rate of the dual design expandable stent in their study was probably due to the use of larger stents, especially the 38 mm flared ends of the inner bare stents, and a high rate of complete bowel obstruction. According to Song et al. (8), the majority of perforations are related to stent wires, balloon dilatation, tight strictures (especially in the tortuous sigmoid colon), and the use of stents with larger diameters. In our study only one patient developed perforation (1/49, 2%). The lower rate of perforation could be attributed to the use of the 4 mm delivery system, application of more flexible wires, decrease in the diameter of both flare ends of the deployed stents, and a procedure without balloon dilatation. We suggest that the major cause of perforation is the weakness of the colon due to cancer rather than the procedure. When used in regions with severe angulations or in cases with friable tumor tissue, who are planned to receive post-stent chemotherapy with bevaczumab (avastin), the stronger straightening force may increase the risk of perforation (19, 20). Therefore, when there is severe angulation in the stenotic segment due to cancer or when the patient has plans for post-stenting targeted therapy, single stent should be considered instead of the double stent. In our study, clinical failure occurred in one case due to impaction of hard

vegetable residues proximal to the lesion. Fluoroscopy-guided application of stents with larger effective diameters in comparison with stents in the through-the-scope technique and assistance of colonoscopy for irrigation or mechanical grinding may reduce the clinical failure rate.

The limitations of our study include its retrospective design and the small number of involved patients.

In conclusion, the DCSEMS with a 4 mm stent delivery system is safe, easy to use, and effective for malignant colonic obstruction, preventing early stent migration and tumor ingrowth, and lowering the perforation rate during stent application. However, in order to corroborate the superiority of this double stenting procedure over other types of stents, randomized prospective studies will be needed in larger patient groups.

### Conflict of interest disclosure

The authors declared no conflicts of interest.

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