

## A temporary self-expanding metallic stent for malignant colorectal obstruction

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**RESULTS:** Stent placement and removal were technically successful in all patients with no procedure-related complications. Post-procedural complications included stent migration ( $n = 2$ ) and anal pain ( $n = 2$ ). Clinical success was achieved in 31 (93.9%) of 33 patients with resolution of bowel obstruction within 3 d of stent removal. Eleven of the 33 patients died  $73.81 \pm 23.66$  d (range 42-121 d) after removal of the stent without colonic re-obstruction. Clinical success was achieved in another 8 patients without symptoms of obstruction during the follow-up period. Reinsertion of the stent was performed in the remaining 12 patients with re-obstruction after  $84.33 \pm 51.80$  d of follow-up. The mean and median periods of relief of obstructive symptoms were  $97.25 \pm 9.56$  d and  $105 \pm 17.43$  d, respectively, using Kaplan-Meier analysis.

**CONCLUSION:** Temporary SEMS is a safe and effective approach in patients with malignant colorectal obstruction due to low complication rates and good medium-term outcomes.

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### Abstract

**AIM:** To investigate the clinical safety and efficacy of a temporary self-expanding metallic stent (SEMS) for malignant colorectal obstruction.

**METHODS:** From September 2007 to June 2012, 33 patients with malignant colorectal obstruction were treated with a temporary SEMS. The stent had a tubular configuration with a retrieval lasso attached inside the proximal end of the stent to facilitate its removal. The SEMS was removed one week after placement. Clinical examination, abdominal X-ray and a contrast study were prospectively performed and both initial and follow-up data before and at 1 d, 1 wk, and 1 mo, 3 mo, 6 mo and 12 mo after stent placement were obtained. Data collected on the technical and clinical success of the procedures, complications, need for re-insertion and survival were analyzed.

**Key words:** Self-expanding metallic stents; Colorectum; Malignant obstruction; Complications

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### INTRODUCTION

Over the last decade, colorectal stenting has been reported to be an effective method of relieving colonic obstruction in palliative treatment<sup>[1-5]</sup> or as a pre-operative bridge to facilitate one-stage surgical resection of primary colonic tumors<sup>[6-10]</sup>. Overall technical and clinical

success has been reported in 80%-100% of treated patients<sup>[11-15]</sup>. However, metallic stent placement has been plagued by tumor ingrowth (3%-46%) following bare stent placement<sup>[16-19]</sup>, perforation (4%)<sup>[12,13,15,20]</sup>, and stent migration (30%-50%)<sup>[10,21-24]</sup> following covered stent placement.

To overcome these problems, a temporary expandable colorectal stent was devised for use in patients with unresectable malignant colorectal obstruction. Our hypothesis was that the duration of placement of the self-expanding colorectal stent could be reduced to prevent perforation and stent migration. The purpose of this study was to evaluate the clinical safety and efficacy of a temporary self-expandable colorectal stent for the treatment of unresectable malignant colorectal obstruction, with a focus on preventing colonic perforation and stent migration.

## MATERIALS AND METHODS

### Study design

This pilot study was approved by the Institutional Review Board, and informed consent was obtained from all the patients. From September 2007 to June 2012, consecutive patients with malignant colorectal obstruction were treated with a temporary self-expanding metallic stent (Micro-Tech, Nanjing, China) in our department.

Diagnoses were established by reviewing patient histories, computed tomography (CT) imaging, colon studies and pathologic results. Patients were eligible for this procedure if the following criteria were met: (1) documented malignancy; (2) colorectal obstruction as defined by symptoms resulting in difficulty in defecation; (3) expandable metallic stent placement; and (4) life expectancy of more than 6 mo. Exclusion criteria were: (1) nonsymptomatic patients with malignant colorectal obstruction; (2) clinical evidence of perforation or peritonitis combined with multiple small-bowel obstructions; (3) extension of rectal cancer to the anal sphincter; and (4) right-sided acute obstruction (due to difficult access).

### Stent

The colon stent (Micro-Tech) is woven from a single thread of highly elastic nitinol wire 0.16 mm in diameter. The stent had a tubular configuration with an elliptic structure at the proximal and distal ends. The body section was 25-30 mm in diameter when fully expanded and 70-100 mm in length. The elliptic structure at the proximal and distal ends was 5 mm wider in diameter than the body section and 10 mm in length. To facilitate removal of the stent, a retrieval lasso was attached inside the proximal end of the stent to allow removal after placement. For implantation under fluoroscopic guidance, the stent was delivered in a compressed form inside an introducer sheath with a diameter of 16 F.

### Stent placement technique

The procedure was performed by one senior interventional radiologist (Yang RM), who had 18 years of ex-

perience in interventional radiology, under fluoroscopic guidance. Neither analgesia nor sedation was administered during the procedure.

Patients were initially placed in the left lateral decubitus position. Rotating the patient into the supine position allowed for a better anatomic view under fluoroscopy. The site of obstruction was established both endoscopically by direct vision and with water soluble contrast (Ultravist 300, Schering, Guangzhou, China) administered *via* a catheter passed through the endoscope and into the stricture. The procedure we used has been described elsewhere<sup>[1,6,7,10,25]</sup>. After the anal sphincter was lubricated, the distal ends of the tumors were identified by endoscopy. Then, a 0.035-inch guide wire (Radiofocus M; Terumo, Tokyo, Japan) with a 5-Fr catheter (Torcon NB; Cook, Bloomington, United States) was advanced and passed through the area of the stricture. The stricture location, length and morphology of the colon were identified by the injection of 30% diluted nonionic contrast medium (Ultravist) *via* the catheter. To avoid perforation, balloon dilation was not generally performed. After exchanging the guide wire for a 0.035-inch super-stiff guide wire (Boston Scientific/Medi-Tech, Watertown, United States), a 16-Fr delivery system (Micro-Tech) was passed over the stiff guide wire until the proximal and distal edges of the prosthesis bridged the stricture under fluoroscopic control, and the stent was then deployed by pulling back the introducer sheath. Finally, contrast medium (Ultravist) was injected through the catheter to assess correct placement and expansion of the stent.

Upon completion of the procedure, patients were transferred to the ward for observation. Once obstructive symptoms had remitted about one week after stent placement, the stent was grasped by the retrieval lasso and gently pulled out. A contrast study was performed to evaluate the patency to rule out possible concomitant lesions in the proximal and distal colon.

### Postoperative outcome evaluation

Before SEMS placement, a routine workup, including CT of the abdomen and chest, as well as calculation of Karnofsky performance status, was conducted. An abdominal radiograph was taken during hospitalization 1-3 d after placement to confirm the correct deployment and expansion. After successful removal of the stent, patients were monitored in the outpatient clinic until either death, surgery was performed, patient was lost to follow-up or a complication developed. Clinical examination, abdominal X-ray and a contrast study were performed by two of our authors, who gathered both initial and follow-up data before and at 1 d, 1 wk, and 1 mo, 3 mo, 6 mo and 12 mo after stent placement. In cases where clinical exams could not be performed, data were obtained by means of telephone calls to the patient or the closest relative and by reviewing medical records. CT examination or an endoscopic procedure was performed if there was persistence or reappearance of symptoms such as abdominal pain, constipation, or rectal bleeding. Technical and clinical success of the procedure, occur-

rence and timing of complications, and the need for surgical intervention were analyzed.

Patients were considered to have incurable cancer when curative resection of metastatic disease was impossible due to extensive liver metastases or extrahepatic disease. Technical success was defined as successful placement of the SEMS, with correct deployment, positioning at the level of the stenosis, and removal of the stent determined with radiologic procedures. Clinical success was defined as complete colonic decompression and relief of obstructive symptoms as judged by clinical symptoms and radiographic observations, without intervention or device-related complications within 72 h after SEMS removal. Death was considered to be related to SEMS complications if the patient died within 7 d of insertion or removal. Major complications were events leading to surgery or reintervention or requiring admission to the intensive care unit. Perforation, stent obstruction, and migration were considered to be major complications. Mild complications were events leading to rehospitalization or prolonged hospital stay without fulfilling the major complications criteria.

### Statistical analysis

Descriptive data are expressed as the mean  $\pm$  SD. Categorical data are reported as numbers and percentages. Time to considered end points (occurrence of complications, surgical intervention, or death) was determined. Kaplan-Meier analysis of relief of obstructive symptoms was performed to calculate the cumulative rate of clinical success, such as sustained relief of obstruction and lack of complications. All statistical analyses were performed using the SPSS package, version 13.0 (SPSS, Chicago, Illinois, United States).

## RESULTS

### Patients

A total of 38 patients were included in this study initially. Five of these were excluded due to patients being lost to follow-up, thus, a total of 33 eligible patients were included (19 men, 14 women; mean age  $61.55 \pm 14.59$  years, range 30-85 years). Stenoses were located in: the transverse colon ( $n = 3$ ); left colon ( $n = 7$ ); sigmoid colon ( $n = 12$ ); rectum ( $n = 11$ ). The mean distance of the lesion from the anus was 19.23 cm (range 5-71 cm), and the mean lesion length was  $5.97 \pm 2.07$  cm (range 4-12 cm). The obstructions were complete (with no passage of contrast medium during contrast studies before or during stent placement) in 8 patients and incomplete in the remaining 25 patients.

### Technical and initial clinical results

Stent placement in the target colon stricture was technically successful in all patients without procedure-related complications. Initially, all patients required the placement of one stent to cover the length of the obstruction. Complete expansion of the placed stent occurred within 2 d of stent placement. No patient underwent balloon

dilation, either before or after stent placement. The mean procedure time was 42 min (range 30-120 min). Removal of the stents was successful in all patients.

In patients with technically successful removal of the stent, clinical success was achieved in 31 of the 33 patients within 72 h of removal, with a success rate of 93.9%. Two patients who did not achieve clinical success after removal of the stents due to paralytic ileus or extension of the tumor were retreated with the stent.

### Complications

No perforations occurred following placement or removal of the stents. Stent migration occurred in 2 patients (distal partial migration in two patients), and none of these patients required a second stent placement due to improvement of the obstruction at the time of stent removal. Two patients who had a stent placed in the rectum complained of moderate rectal pain within 2 d of stent placement without requiring analgesics.

### Follow-up results

Eleven of the 33 patients died  $73.81 \pm 23.66$  d (range 42-121 d) after removal of the stent without colonic re-obstruction due to diffuse metastatic cancer, cachexia, or myocardial infarction. Clinical success was achieved in 8 patients without symptoms of obstruction. Stent reinsertion was performed in the remaining 12 patients with re-obstruction after a mean follow-up period of  $84.33 \pm 51.80$  d (range 27-201 d). The mean and median periods of relief of obstructive symptoms were  $97.25 \pm 9.56$  d (95%CI: 79, 116) and  $105 \pm 17.43$  d (95%CI: 70, 139), respectively, using Kaplan-Meier analysis.

## DISCUSSION

The present study was designed to test the hypothesis that a temporary self-expanding metallic colorectal stent could reduce the risk of colonic perforation and stent migration. In this uncontrolled prospective study of 33 patients with unresectable malignant colorectal obstruction, temporary self-expanding metallic colorectal stent placement was technically successful in all patients with a clinical success rate of 93.9%. There was no procedure-related mortality or perforations in this study, and all complications were managed without surgical intervention. These results suggest that a temporary self-expanding metallic colorectal stent can be considered a viable and effective treatment for patients with unresectable malignant colorectal obstruction. To date, this is the first report to describe the treatment of unresectable malignant colorectal obstruction with a temporary self-expanding metallic colorectal stent.

Colonic or rectal stent placement is associated with some complications, including stent migration, perforations, rectal bleeding, fecal impaction, abdominal pain, and tenesmus, of which stent migration and perforation are the most serious complications. In systematic reviews, migration was reported to occur in approximately 10%-12% of patients<sup>[15,20]</sup>, and is usually detected on

follow-up radiographs within 1 wk of insertion. A comparatively small diameter and limited flexibility may have contributed to the more frequent occurrence of stent migration in earlier studies<sup>[26]</sup>. Although, Repici *et al*<sup>[1]</sup> and Song *et al*<sup>[6]</sup> have reported a lower migration rate (2% and 3%, respectively) with the use of the newly designed colorectal stents - WallFlex stent and dual stent (with a large diameter and flared ends) in the treatment of malignant colorectal obstruction, however, these stents may result in another serious complication - perforation<sup>[6]</sup>. Song *et al*<sup>[6]</sup> reported the lowest migration rate (0%) in the bridge-to-surgery group, but they also yielded the highest complication rate - colon perforation (22%) in 11 of the 50 patients in the same group after successful placement of the dual stent.

Perforation is found in 3.7%-4.0% of patients with a colorectal SEMS<sup>[15,20]</sup>, which is lower than stent migration, but it is the most serious complication which may threaten the life of patients. Balloon dilatation of a stricture to obtain access can result in excessive manipulation of the wire through the colonic wall and anatomical sites with a comparatively high perforation risk. It is probable that stent design and long-term placement may play an important role in colonic perforation. Large diameter stents with flared ends and the stent eroding through the colonic wall during colonic peristalsis may directly result in perforation.

The ideal colorectal stent should have adequate radial expansile force and smooth edges. Enough radial expansile force is spontaneously and evenly generated, and the final diameter is reached over the course of 2-5 d, so that dilation of the stricture is gentle, as well as effective<sup>[27]</sup>. Thus, predilation is not generally necessary, and the potential for migration is reduced. A colorectal stent with smooth edges, obviating sharp hooks in the stent design, can maximally reduce the risk of perforation. The stent made by Micro-Tech has a relatively large profile and an elliptic structure to prevent stent migration, and the elliptic structure has a shrunk edge at both sides to minimize the risk of perforation and satisfies the requirements for prevention of perforation.

The significant improvement in perforation rate and stent migration during the follow-up period in the present study was predominantly attributable to the stent design and its temporary use, and demonstrated that the stent can be safely used in malignant colorectal obstruction. Our 93.9% clinical success rate in the relief of colonic obstruction following stent removal was in line with that of other researchers who reported 80%-100% relief of colonic obstruction in patients with malignant colorectal obstruction treated with SEMS<sup>[5,9,14,15,20]</sup>, and demonstrated the efficacy of the temporary stent for patients with malignant colorectal obstruction.

Our results have important clinical implications. The use of a temporary self-expanding metallic colorectal stent rather than a long-term self-expanding metallic colorectal stent in patients with unresectable malignant colorectal obstruction will substantially decrease the risk of perforation and stent migration. The findings from

this study may encourage more studies on temporary self-expanding metallic colorectal stents in the palliative treatment of patients with unresectable malignant colorectal obstruction.

Our study has some limitations. The number of patients treated was relatively small with a short lifespan, and death due to rapid progression of the disease may have masked both the benefits and risks of the procedure. Secondly, we did not include a control group, therefore, future randomized trials are needed to compare the temporary self-expanding metallic colorectal stent with the long-term self-expanding metallic colorectal stent in terms of efficacy, risk of complications, and recurrent obstruction, with particular attention to stent migration, tumoral and nontumoral tissue overgrowth and perforation.

In conclusion, our preliminary study demonstrated that the temporary SEMS was a safe and effective approach for colon decompression in patients with colorectal malignant obstruction, with a low rate of complications and good medium-term outcomes. Reinsertion of the stent can be performed in patients with re-obstruction. Although the initial results are promising, longer follow-up and expanded clinical trials are needed.

## COMMENTS

### Background

Colorectal stenting has been reported to be an effective method of relieving colonic obstruction, however, metallic stent placement has been plagued by tumor ingrowth, perforation and migration.

### Research frontiers

A temporary self-expanding metallic stent (SEMS) has been widely used for the treatment of patients with malignant esophageal stenosis, however, the use of this type of stent in patients with malignant colorectal obstruction has rarely been reported. Authors investigated the clinical safety and efficacy of a temporary self-expandable colorectal stent for malignant colorectal obstruction.

### Innovations and breakthroughs

A temporary SEMS was specially devised for the management of patients with malignant colorectal obstruction associated with colonic cancer. All procedures were performed under fluoroscopic control. This is the first study to report the use of a temporary SEMS for malignant colorectal obstruction.

### Applications

By determining the efficacy and safety of a temporary SEMS, this may provide a new therapeutic intervention for the treatment of patients with malignant colorectal obstruction.

### Terminology

Malignant colorectal obstruction is a common presentation of colorectal cancer, accounting for about 15%-20% of initial presentations in patients with colorectal malignancy.

### Peer review

The authors present a prospective study of temporary SEMS for malignant colorectal obstruction, with the aim of investigating the clinical safety and efficacy of the approach. The results reveal that the clinical success was achieved in 31 (93.9%) of 33 patients with resolution of bowel obstruction within 3 d after stent removal, as well as lower complication rates. In addition, the mean and median periods of relief of obstructive symptom were  $97.25 \pm 9.56$  d and  $105 \pm 17.43$  d, respectively. The results are interesting. A temporary SEMS may be a good attempt to seek the new clinical therapy for unresectable colorectal cancer patients and has a potential clinical significance.

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