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Usefulness of a Guiding Sheath for Fluoroscopic Colorectal Stent Placement

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Objective: To investigate the technical feasibility, clinical usefulness, and safety of a guiding sheath in fluoroscopic stent placement for patients with malignant colorectal obstructions.

Materials and Methods: Between June 2007 and January 2011, fluoroscopic placement of a dual colorectal stent was attempted in a total of 97 patients with malignant colorectal obstructions. A polytetrafluoroethylene guiding sheath was used in patients in whom a stent delivery system failed to reach the obstruction. Usefulness of the sheath was evaluated depending on whether the sheath could successfully assist the stent delivery system reach its area of interest.

Results: The guiding sheath was needed in 22 patients (15 men, 7 women; age range, 33-77 years; mean age, 59 years). The overall success rate for passing the sheath to the area of interest was 100%. There were no procedure-related deaths or major complications. The majority of the patients reported mild discomfort. In 2 of 22 patients with successful passing of the sheath to the area of interest, stent placement failed because of failure in the negotiation of a guide wire through the obstruction.

Conclusion: Using a guiding sheath seems to be easy, safe and useful in fluoroscopic stent placement for patients with malignant colorectal obstructions.

Index terms: *Colon; Interventional procedure; Stenosis or obstructions; Stents and prostheses*

INTRODUCTION

Recently, fluoroscopic or endoscopic placement of expandable metallic stents has been increasingly used as a safe preoperative or palliative treatment of malignant colorectal obstructions (1-5). In colorectal stent placement, however, passage of a guide wire and stent delivery system through an area of obstruction poses a major challenge. The presence of a tortuous or redundant sigmoid colon or a splenic or hepatic flexure of the transverse colon poses difficulties in passage of the stent delivery system to the obstruction site as a result of multiple loop formations in the tortuous or redundant portion, which leads to loss

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of forward movement secondary to buckling of the stent delivery system on its way to the area of obstruction (6, 7).

To overcome the problem, we developed a guiding sheath that we used in selected patients in whom passage of a stent delivery system to the obstruction failed during fluoroscopic stent placement in patients with malignant colorectal obstructions. The aim of this study was to prospectively investigate the technical feasibility, clinical usefulness, and safety of a guiding sheath in fluoroscopic stent placement for patients with malignant colorectal obstructions.

MATERIALS AND METHODS

Patients

Informed consent for placement of an expandable metallic stent with use of a guiding sheath was obtained for each patient, and our institutional review board approved this prospective study. Between June 2007 and January 2011, fluoroscopic placement of a dual colorectal stent (S&G Biotech, Seongnam, Korea) was performed in a total of 97 consecutive patients with malignant colorectal obstructions (Table 1). The sites of obstruction were at the ascending colon in 3 patients, at the transverse colon in 21 patients, at the descending colon in 9 patients, and at the sigmoid colon or rectum in 64 patients. Inclusion criteria for dual stent placement were as follows: 1) documented malignancy; 2) colorectal obstruction as defined by symptoms that resulted in defecation difficulty. 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.

Table 1. Characteristics of 97 Patients in Study Population

	No.	%
Patients	97	100
Mean age (year, range)	59 (22-88)	
Sex (male, female ratio)	59 : 38	61 : 39
Stricture length (cm, range)	5.8 (2-15)	
< 5 cm	33	34
5 cm to < 10 cm	52	54
10 cm to < 15 cm	12	12
Location of obstruction		
Ascending colon	3	3
Transverse colon	21	22
Descending colon	9	9
Sigmoid colon or rectum	64	66
Source of malignancy		
Colon cancer	70	72
Stomach cancer	17	18
Pancreatic cancer	6	6
Ovarian cancer	2	2
Cholangiocarcinoma	2	2
Indication		
Palliation	64	66
Pre operation	33	34

The guiding sheath was used in patients in whom passing a stent delivery system to the area of interest failed under fluoroscopic guidance because of buckling of the stent delivery system in a tortuous or redundant portion of the colon.

Guiding Sheath Construction

The guiding sheath was made of a straight polytetrafluoroethylene tube (Sang-A Flontec Co. LTD., Incheon, Korea). The tube was 5.5 and 6.8 mm in its inner and outer diameters, respectively. The distal part of the sheath was bent using a heat-gun, thus creating J-shaped curved tips. A tungsten wire was attached to the distal tip of the sheaths for radio-opacity with 12% polyurethane covering for surface smoothness. The distal 3 cm section of the sheath was positioned at an angle approximately 80 degrees to the axis (Fig. 1). The sheaths for obstructions from the rectum to the descending colon, from the splenic

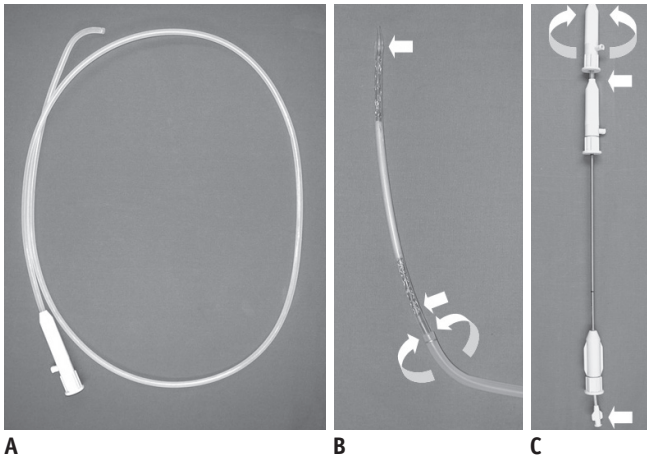

Fig. 1. Photographs of guiding sheath and stent delivery system.
Photograph shows guiding sheath **(A)**, distal end **(B)** of stent delivery system (arrows) loaded in sheath (curved arrows), and proximal end **(C)** of stent delivery system (arrows) loaded in sheath (curved arrows).

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flexure to the middle portion of the transverse colon, and from the middle portion of the transverse colon to the cecum were 90 cm, 120 cm, and 150 cm long, respectively.

Techniques for Stent Placement and Usage of the Guiding Sheath

The dual stent with its placement technique has previously been described in detail (5, 8, 9). Briefly, the dual stent (S&G Biotech, Seongnam, Korea) consisted of an outer stent and an inner bare nitinol stent. The stent introducer system (S&G Biotech) consisted of a Teflon sheath 4.5 mm in outer diameter, a pusher coil catheter, and a guiding olive tip. The outer and inner stents were loaded in their own Teflon sheaths.

Drugs for anesthesia or sedation were not used. With the patient in the left lateral decubitus position, a stiff-angled, 260-cm-long, 0.035-inch exchange guide wire (Radifocus M; Terumo, Tokyo, Japan) was inserted under fluoroscopic guidance through the anus across the obstruction with the help of a sizing coil catheter (S&G Biotech). The exchange guide wire was replaced with a super-stiff 260-cm-long guide wire (Medi-tech/Boston Scientific, Watertown, MA, USA), and the sizing coil catheter was removed with the super-stiff guide wire left in place. Under fluoroscopic guidance, a stent delivery system loading the outer stent was passed over the super-stiff guide wire through the

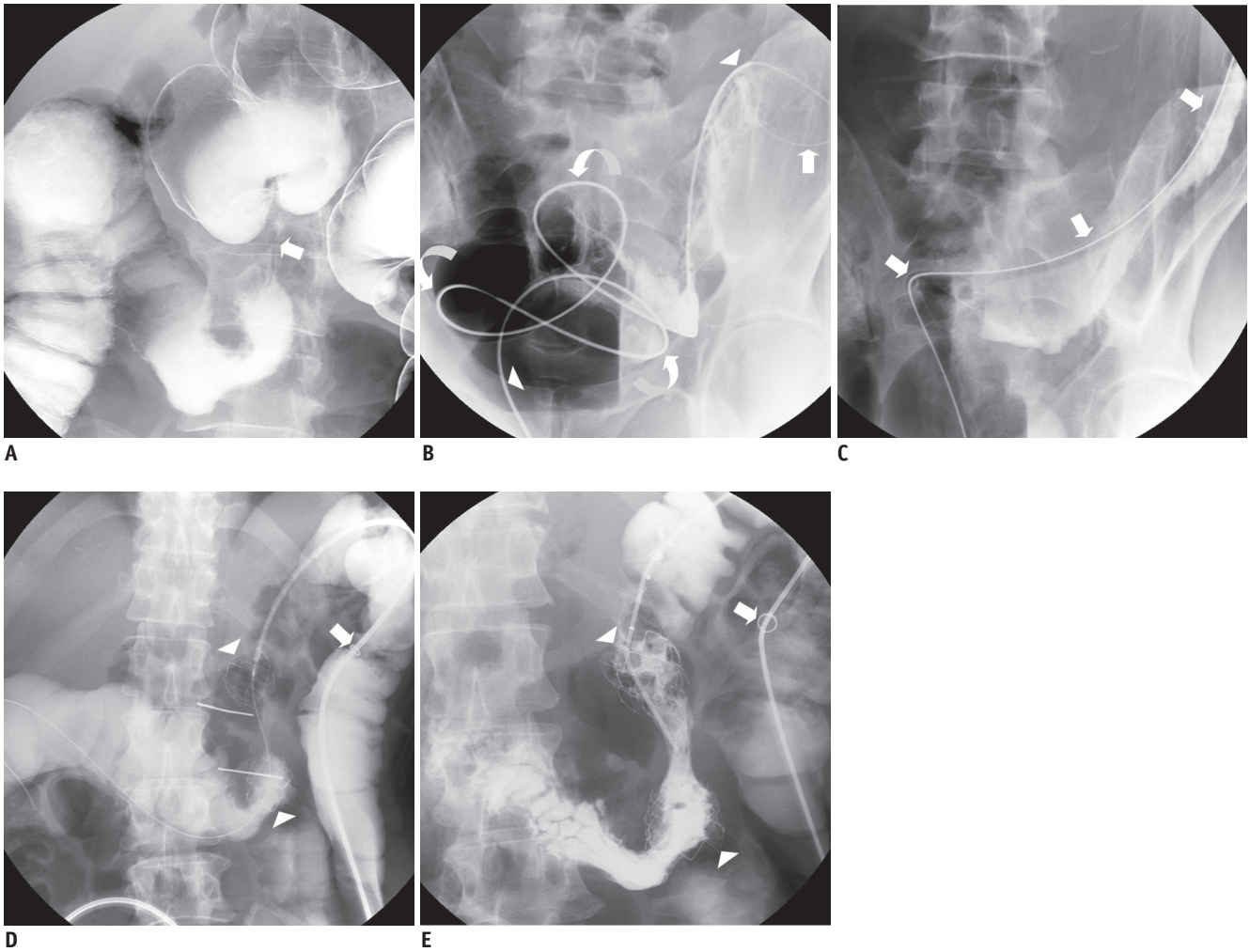

Fig. 2. Radiographs obtained before and during stent placement in patient with recurrent gastric cancer involving middle portion of transverse colon.

A. Barium study before stent placement shows near complete obstruction (arrow). **B.** Radiograph obtained during negotiation of coil catheter (arrowheads) with guide wire (arrow) shows tortuous sigmoid colon (curved arrows). **C.** Straightening of sigmoid colon using guiding sheath with stiff guide wire (arrows). **D.** Radiograph obtained just prior to passage of stent delivery system for coaxial placement of inner bare stent into outer stent (arrowheads). Note radiopaque tip (arrow) of sheath located in descending colon. **E.** Water soluble contrast media study immediately after placement of stent shows good flow of contrast medium through stent (arrowheads). Note radiopaque tip (arrow) of sheath located in descending colon.

obstruction. After placement of the outer stent, the stent delivery system was removed with the super-stiff J-tip guide wire left in place. A stent delivery system loading the inner bare stent was then advanced over the guide wire to place the inner bare stent coaxially into the outer stent.

The guiding sheath was used for cases where a stent delivery system failed to reach the site of obstruction due to a tortuous or redundant sigmoid colon or a hepatic or splenic flexure of the transverse colon. The stent delivery system was introduced into the sheath until its tip passed through the sheath. The sheath loading the stent delivery system was then passed over the guide wire until the tip of the sheath passed through the redundant colonic portion (Fig. 2).

Analysis of Results

We determined the success rate of passing the sheath to the area of interest, assessed the patient's tolerance of the procedure, and recorded complications associated with the procedure. The success of sheath passing was defined as successful passage of the sheath through the redundant sigmoid colon or hepatic or splenic flexure of the transverse colon to the area of interest under fluoroscopic guidance. We used Fisher's exact test to determine the number of patients who needed a guiding sheath varied according to the site of the lesion.

RESULTS

The guiding sheath was needed in 22 of 97 patients (15 men, 7 women; age range, 33-77 years; mean age, 59 years). The obstruction was complete in 5 patients and incomplete in the remaining 17 patients. As for the site of colonic obstruction, all three patients (100%) with obstruction at the ascending colon, 12 of 21 patients (57%) with obstruction at the transverse colon, 4 of 9 patients (44%) with obstruction at the descending colon, and 3 of 64 patients (3%) with obstruction at the sigmoid colon or rectum required use of the sheath (Table 2). The number of patients who needed the sheath was significantly different between the sites of obstructions ($p < 0.001$). Underlying causes of etiology include cholangiocarcinoma (n = 1) and colon (n = 9), gastric (n = 8), and pancreatic (n = 4) cancers. The average length of the stricture was 64 mm (range, 42 mm to 140 mm).

Table 2. Usage of Sheath with regard to Location of Obstruction

Location of Obstruction	No. of Patients	*No. of Sheaths (%)	*P*-value
Ascending colon	3	3 (100%)	< 0.001
Transverse colon	21	12 (57%)	
Descending colon	9	4 (44%)	
Sigmoid colon or rectum	64	3 (5%)	
Total number	97	22	

Note.— *No. of patients who needed sheath.

The overall success rate for passing the sheath to the area of interest was 100%. There were no procedure-related deaths or major complications. The majority of the patients reported mild discomfort during insertion of the sheath to the area of interest. In 2 of 22 patients with successful passing of the sheath to the area of interest, stent placement failed because of failure in the negotiation of a guide wire through the obstruction.

DISCUSSION

Technical difficulties in colorectal stent placement are generally more frequent with proximal obstructions than with distal ones, which accounts for the fact that there are fewer reports of right-sided colonic stent placement (10-12). In cases with a redundant sigmoid colon or a splenic or hepatic flexure of the transverse colon, advancement of a stent delivery system to the obstruction is difficult due to the colonic redundancy and tortuosity (6, 7). In these situations, stabilization of the stent delivery system can be achieved using an endoscope (13). Stent delivery systems for covered stents, however, are too large to be placed through the working channel of the therapeutic endoscope (5, 9, 14). In our study, the sheath proved instrumental in providing the necessary support for successful passage of the stent delivery systems through the tortuous or redundant portion of the colon to the obstruction under fluoroscopic guidance. The sheath as a stiffening device was needed in 22 of 97 patients (22.7%), and the overall success rate for passing the sheath through the tortuous or redundant sigmoid colon or the hepatic or splenic flexures of the transverse colon to the area of interest was 100%.

With regard to dual stent placement, a stent delivery system loading the outer stent should be first passed over the guide wire through the obstruction. After placement of the outer stent, its stent delivery system should be removed with the guide wire left in place. A stent delivery system loading the inner bare stent is then advanced over

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the guide wire to place the inner bare stent coaxially into the outer stent. The sizing coil catheter is also used twice for measurement of the obstruction length prior to stent placement and during the water soluble contrast media study immediately after stent placement. Multiple passages of the stent delivery system and the sizing coil catheter over the guide wire through the obstruction can be difficult and time-consuming, particularly in patients with redundant sigmoid colon or flexures of the transverse colon. We found that the sheath in such cases was useful in replacing the stent delivery system and the coil catheter due to the simplicity and ease of use of the replacement technique.

Sebastian et al. (15) carried out a systematic review of 54 publications on colorectal stent placement published between January 1990 and May 2003. The 54 publications included a total of 1198 patients with malignant obstructions. The stent was placed under endoscopic guidance in 1%, combined endoscopic and fluoroscopic guidance in 69%, and under fluoroscopic guidance in 30%. The overall technical success rates in individual series varied from 64% to 100% (median 94%). The technical failure rates were 5.8% at the rectosigmoid area, 14.5% at the descending colon, and 15.4% at the transverse and ascending colon. Baron et al. (13, 16) concluded that stents may be safely placed into the right colon using endoscopic techniques and that stent placement under fluoroscopic guidance should be limited to the left colon; whereas, Mainar et al. (1) argued that the endoscopic approach is associated with greater patient discomfort and risks for complications. In our experience, straightening of the redundant colon and stabilization of the stent delivery system were achieved using the guiding sheath. We believe that fluoroscopic stent placement can be applied to the left colon obstruction given the superior patient tolerability of the fluoroscopic technique with its use of a delivery system with a small bore.

With regard to the site of colonic obstruction, we found that more proximal lesions were associated with a greater need for the sheath (Table 1). For example, all three patients (100%) with obstruction at the ascending colon, 57% of the patients (n = 21) with obstruction at the transverse colon, 44% of the patients (n = 9) with obstruction at the descending colon, and 3% of the patients (n = 64) with obstruction at the sigmoid colon or rectum required use of the sheath. The sheath appears to substantially facilitate fluoroscopic placement in the right colon, and its use warrants further investigation. In conclusion, using the guiding sheath seems to be easy, safe and useful in fluoroscopic stent placement for patients with malignant colorectal obstructions.

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