A Japanese prospective multicenter study of self-expandable metal stent placement for malignant colorectal obstruction: short-term safety and efficacy within 7 days of stent procedure in 513 cases CME

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Background: Endoscopic self-expandable metal stent placement has been used as an alternative to surgery for malignant colorectal obstruction; however, factors affecting its clinical outcome are unclear.

Objective: To clarify the short-term safety and efficacy of endoscopic self-expandable metal stent placement for malignant colorectal obstruction and to identify factors associated with its clinical and technical failure.

Design: Prospective clinical cohort study.

Setting: Fourteen academic centers and 32 community hospitals.

Patients: A total of 513 consecutive patients with malignant colorectal obstruction.

Intervention: Endoscopic self-expandable metal stent placement, sharing of stent placement methods among participating facilities.

Main Outcome Measurements: The primary endpoint was clinical success, defined as symptom and radiological finding resolution within 24 hours. Secondary endpoints were technical success and adverse events. The follow-up period was 7 days.

Results: The clinical and technical success rates were 95.5% and 97.9%, respectively. Major adverse events included perforation (2.1%), stent migration (1.0%), and stent occlusion (0.8%). The main causes of perforation were the procedure itself (0.8%) and comorbidities (obstructive colitis and impending perforation) not apparent before stent placement (0.6%). Extrinsic tumor origin was independently associated with the clinical failure after stent placement (odds ratio 4.23; 95% confidence interval, 1.21-14.79; $P = .02$). Stricture marking trended toward a negative association with technical failure ($P = .09$).

Limitations: Noncomparative study.

Conclusion: Strict inclusion criteria and stricture marking may improve the technical and clinical success of stent placement. (Gastrointest Endosc 2015;82:697-707.)

Abbreviations: BTS, bridge to surgery; CROSS, ColoRectal Obstruction Scoring System; PAL, palliative; PS, performance status; SEMS, self-expandable metal stent.

DISCLOSURE: *Dr Matsu has received personal fees from Boston Scientific Japan. Dr Yoshida has received personal fees from Boston Scientific Japan, Century Medical Inc, and ZEON. Dr Isayama has received donations and fees from Boston Scientific Japan, Century Medical Inc, and Taewong Medical. Dr Kuwai has received personal fees from Boston Scientific Japan, Dr Maetani has received personal frees from Boston Scientific Japan, Century Medical Inc, Piolax Medical Devices, and MC Medica. Dr Shimada has received personal fees from Boston Scientific Japan. Dr Saito has received personal fees from Boston Scientific Japan and Century Medical Inc. Dr Koizuma has received personal fees from Century Medical Inc and Olympus Medical Systems. Dr Sasaki has received personal fees from Boston Scientific Japan and Piolax Medical Devices. Dr Saida has received grants and personal fees from Boston Scientific Japan, Century Medical Inc, and Olympus Medical Systems. All other authors disclosed no financial relationships relevant to this publication.*

See CME section; p. 718.

0016-5107/$36.00
http://dx.doi.org/10.1016/j.gie.2015.03.1978

Received October 13, 2014. Accepted March 25, 2015.

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A 2008 study reported colorectal cancer as the second most common cancer in Japan.[1] At diagnosis, 15% to 20% of colorectal cancer patients present with symptoms of acute obstruction.[2,3] Conventionally, patients with malignant large-bowel obstruction receive emergency surgery. Recently, endoscopic stent procedures with self-expandable metal stents (SEMSs) have been used as an alternative to emergency surgery.[4-7] SEMS placement increases primary anastomosis and decreases stoma creation and/or permanent stoma.[8] SEMS placement is also effective for palliation of obstruction symptoms due to primary and metastatic colon cancer.[9]

SEMSs may result in adverse events, including perforation. Perforation can increase the risk of peritoneal carcinomatosis and septic and life-threatening conditions.[10-13] Thus, stent intervention can result in a noncurable and lethal state in previously curable colorectal cancer patients.

A review of randomized clinical trials of SEMS placement showed remarkably high clinical (6.9%) and silent perforation (14%) rates in patients with large-bowel obstruction.[14] On the other hand, the stent placement success rate and associated decompression rate were 70.7% and 69.0%, respectively, which are relatively low compared with previous studies (92%-96.2% and 88%-92%, respectively).[6,15,16] To accurately evaluate the advantages and risks of SEMSs, proper stent placement is required. Furthermore, in Japan, the safety and efficacy of SEMS placement are unclear because, until December 2011, colonic SEMSs were only used in clinical research.[17,18] In January 2012, this procedure was covered by national health insurance in Japan.

This study is the largest prospective, multicenter feasibility study of colonic SEMS placement in patients with malignant colorectal obstruction. We focused on the short-term (7-day follow-up) safety and efficacy of SEMSs in a per-protocol analysis cohort. In addition, factors associated with the clinical and technical success of SEMSs were evaluated.

PATIENTS AND METHODS

Study design

This prospective, observational, single-arm multicenter clinical trial was conducted from March 2012 to October 2013. This study was registered with the University Hospital Medical Information Network Clinical Trial Registry (UMIN000007953). Before study startup, a Web site (http://colon-stent.com/) was launched, and the standard methods of SEMS placement, based on previously published data, were posted.[15,18,19] Furthermore, we established the Colonic Stent Safe Procedure Research Group of the Japan Gastroenterological Endoscopy Society and held a workshop to discuss tips and tricks of SEMS placement. More than 140 physicians participated in the workshop, and several experienced doctors presented their experience in developing safe SEMS placement procedures. Stent placement methods considered to be adequate and standard were discussed among the physicians at the participating facilities. The summary was subsequently updated on the Web site as a brief guideline. Before SEMS placement was introduced at each institution, we requested each member to promote cooperation among endoscopists and surgeons to prepare for adverse events.

Patients with acute colorectal obstructions or symptomatic strictures secondary to malignant neoplasms were enrolled in the study. Forty-six facilities (14 academic centers and 32 community hospitals) participated in the study. Institutional review board approval was obtained for patient enrollment before the start of the study. Each patient gave consent to undergo the procedure and participate in the study. Registration was done online through the Web site before or immediately after the procedure. Patient registration continued until study completion. At enrollment, treatment intent (bridge to surgery [BTS] or palliative [PAL]) was determined based on malignant disease stage, coexisting illness, age, and, in some cases, patient choice. SEMS placement was performed or supervised by board-certified endoscopists of the Japan Gastroenterological Endoscopy Society. CT was performed before SEMS placement in almost all patients. Malignancy of intrinsic origin was confirmed through endoscopic biopsy or macroscopic tumor findings. In extrinsic tumor origin, malignancy was confirmed through CT or other imaging modalities. All clinical data were prospectively collected.

Inclusion and exclusion criteria

Patients with colorectal obstructions secondary to malignant neoplasms were included in the registry. Exclusion criteria at the time of stent placement were previous colonic stent placement, enteral ischemia, suspected or impending perforation, intra-abdominal abscess/perforation, contraindication to endoscopic treatment, and any use of the stent other than those specifically outlined under the indications for use. Patients with comorbidities identified after SEMS placement were included to clarify the adverse effects of the procedure. Such patients were included because comorbidities may initially go undetected in an emergency care situation.

Definitions of colonic obstruction and evaluation of obstruction symptoms

Occlusive state was divided into 2 groups, complete and incomplete obstructions. Complete colonic obstruction was confirmed by any of the following events: inability to pass flatus, inability of water-soluble contrast to pass proximal to the lesion, and inability to endoscopically visualize the proximal lumen.[20] The remaining cases were defined as incomplete obstruction.

To assess oral intake level and abdominal symptoms before and after the procedure, we constructed a scoring system similar to that used for eating state assessment in patients with malignant gastric outlet obstruction.[21] The