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RETROSPECTIVE STUDY

Safety and efficacy of a partially covered self-expandable metal stent in benign pyloric obstruction

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Abstract

AIM: To evaluate the safety and efficacy of partially covered self-expandable metallic stents (SEMSs) in benign pyloric obstruction.

METHODS: We retrospectively analyzed data from 10 consecutive patients with peptic ulcer-related pyloric obstructive symptoms (gastric outlet obstruction scoring system (GOOSS) score of 1) between March 2012 and September 2013. The patients were referred to and managed by partially covered SEMS insertion in our tertiary academic center. We assessed the technical success, symptom improvement, and adverse events after stenting.

RESULTS: Early symptoms were improved just 3 d after SEMS placement in all 10 patients. The GOOSS score of all patients improved from 1 to 3. There were no serious immediate adverse events. The overall rate of being symptom free was 90% at a median of 11 mo of follow-up (range: 4-43 mo). Five patients were managed by a rescue SEMS because of failure of previous endoscopic balloon dilatation. Among them, four patients had sustained symptom improvement after the SEMS procedure. During the follow-up period, migration of the SEMS was observed in two patients (20.0%), both of whom had previous endoscopic balloon dilatation before SEMS insertion.

CONCLUSION: Despite the small number in this study, partially covered SEMSs showed a favorable and safe outcome in the treatment of naïve benign pyloric obstruction and in salvage treatment after balloon dilatation failure.

Key words: Benign pyloric obstruction; Balloon dilatation; Self-expandable metallic stent; Gastric outlet obstruction scoring system

Core tip: Partially covered self-expandable metallic stents had a safe and favorable outcome in the treatment of naïve benign pyloric obstruction and in salvage treatment after balloon dilatation failure.

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INTRODUCTION

The causes of benign pyloric obstruction are peptic ulcer, anastomotic structures after gastric surgery, corrosive injury, and stricture secondary to intervention. Among these, peptic ulcer disease is the most common etiology of benign pyloric obstruction[1]. Patients with pyloric obstruction have discomfort with dyspepsia, abdominal bloating, nausea, and vomiting, which results in weight loss and a poor quality of life.

Surgery has been the conventional treatment for the

benign pyloric obstruction[2]. However, it carries a significant risk of postoperative comorbidity and is not always suitable for patients in a poor condition, or for elderly people. Endoscopic balloon dilatation was first conducted by Benjamin *et al*[3]. This procedure has the advantage of being relatively simple for both patients and endoscopists in the treatment of pyloric obstruction. However, the efficacy of balloon dilatation is controversial[4-7]. The self-expandable metal stent (SEMS) was originally developed for treatment of malignant obstruction of the esophagus, colon, and gastric outlet. This treatment showed favorable results comparable to those of surgery for palliation and as a bridge to surgery[8,9]. However, there are few reports on SEMS in benign pyloric obstruction[10,11]. In addition, the partially covered SEMS, which was developed for overcoming the disadvantage of covered or uncovered SEMS, has not been validated for the treatment of benign pyloric obstruction. The aim of this study was to evaluate the safety and efficacy of partially covered SEMSs in benign pyloric obstruction.

MATERIALS AND METHODS

Patients

We retrospectively analyzed data from 10 consecutive patients with peptic ulcer and outlet obstruction referred to and managed by SEMS insertion in our tertiary academic center between March 2012 and September 2013. These patients had a common obstructive symptom of frequent vomiting even with a liquid diet. The benign pyloric obstruction was shown by endoscopic biopsy and imaging study. In all patients, the endoscope could not be passed through the obstructed lumen. All the patients were recommended to undergo surgical treatment initially. However, these patients wanted to undergo endoscopic treatment rather than surgical treatment. Some patients had undergone prior endoscopic balloon dilatation with poor results. This study was approved by the ethics committee of Kyungpook National University Hospital.

SEMS procedure

After the patient was sedated, an endoscope (CF- Q160J; Olympus Optical Co.) was inserted through the stomach with fluoroscopic guidance. After identifying the obstructive pyloric lesion, a biliary guidewire (Jagwire, Boston Scientific Co.) was passed through the working channel of the endoscope. A water-soluble contrast medium (Gastrografin, Bracco Co.) was then injected through the obstructed lumen and the length of the obstruction was measured directly using the guidewire by fluoroscopy. The heavy wire was placed and the delivery system advanced into position under fluoroscopy and endoscopy. A partially covered SEMS was used for all cases. After ascertaining that the position of the delivery system under fluoroscopy and endoscopy was correct, the stent was released from the distal end toward the stricture. After placing the stent, a water-soluble contrast was injected through the stent to check its passage through the stent under fluoroscopy. Good expansion and position of the stent were confirmed by serial abdominal plain radiography.

Evaluation of subjective symptoms after SEMS

The subjective obstructive symptoms of the patient were evaluated with the gastric outlet obstruction scoring system (GOOSS)[12]. The GOOSS value was assigned on a 4-point scale: 0, no oral intake; 1, liquids only; 2, soft solids only; 3, low residue or full diet. The GOOSS score was assessed before and 3 d after the procedure. After discharge, subjective symptoms including GOOSS score and position of the stent by abdominal plain radiography were evaluated at the outpatient department at 1, 2, and 3 mo after the SEMS procedure. If the patients had good subjective symptoms with a GOOSS score of 3, the SEMS was planned to be removed under endoscopy and fluoroscopic guidance at 3-6 mo after insertion.

RESULTS

Baseline characteristics of the patients

Nine of the 10 patients who underwent SEMS insertion were men. The median age at index endoscopy was 56 years (range: 40-71 years). The causes of benign pyloric obstruction were duodenal ulcer in four patients (40.0%) and both gastric and duodenal ulcers in six patients. Five patients underwent endoscopic balloon dilation prior to SEMS insertion (Table 1).

Clinical outcomes and complications

Technical success was achieved in all the 10 patients. The total procedure time was 20.5 ± 11.7 (mean ± SD) minutes. Early symptom improvement at 3 d after SEMS was excellent with a GOOSS score of 3 in all 10 patients. There were no immediate complications such as serious bleeding, bowel perforation, or procedure-related mortality during the SEMS insertion. During follow-up, migrations of the SEMS were observed in two patients (20.0%) (Table 1). In one patient (case number 10), the SEMS migrated 1 day after the procedure. An additional secondary SEMS was inserted at 5 d after the migration of initial SEMS. However, the secondary SEMS also migrated 10 d later. In another patient (case number 8), the SEMS migrated 1 mo after the procedure. However, the symptoms in these two patients were not aggravated after migration of the stent after 4 and 10 mo of follow-up. The overall rate of being symptom free was 90% at a median of 11 mo of follow-up (range: 4-43 mo).

Removal of the SEMS

The removal of the SEMS was performed 3-6 mo after insertion. However, in one patient (case number 2), removal of the SEMS was impossible because the SEMS adhered to adjacent duodenal mucosa. This patient was carefully observed without complications or symptom aggravation during 17 mo of follow-up. The symptoms in another patient (case number 6) decreased to a GOOSS score of 2 after removal of the stent. One patient

Table 1 Patient characteristics and results of partially covered self-expandable metal stent

Case No.	Sex/age (yr)	Etiology	Number of prior endoscopic balloon dilatation	Stent name, company	Stent diameter (mm)	Stent length (mm)	Symptom change[1]	Adverse event	Duration of stenting (mo)	Removal of stent	Follow up duration (mo)
1	M/64	DU	No	Niti-S	20	120	1 - > 3	No	6	Yes	22
2	M/49	DU + GU	No	Hanaro	20	70	1 - > 3	No	17	No[2]	17
3	M/68	DU + GU	No	Hanaro	20	130	1 - > 3	No	6	Yes	12
4	M/51	DU	No	Hanaro	20	90	1 - > 3	No	6	Yes	8
5	M/52	DU + GU	No	Hanaro	20	110	1 - > 3	No	6	No	5
6	M/40	DU + GU	2	Niti-S	20	120	1 - > 3 - > 2[3]	No	4	Yes	43
7	F/71	DU	1	Bona	22	120	1 - > 3	No	19	No	19
8	M/44	DU + GU	1	Niti-S	20	120	1 - > 3	Migration	1	NA	10
9	M/71	DU + GU	1	Hanaro	20	130	1 - > 3 - > 1 - > 3[4]	No	4	No[4]	4
10	M/59	DU	1	Hanaro	20	90	1- > 3	Migration	10 d	NA	4

[1]Evaluated by gastric outlet obstruction scoring system (GOOSS) score; [2]Failure of removal of stent; [3]Aggravated symptoms by GOOSS score 3 to 2 after removal of stent; [4]Symptoms were aggravated by GOOSS score 3 to 1 after removal of stent. After stent was reinserted 2 mo later, the symptoms were improved by GOOSS score 1 to 3. DU: Duodenal ulcer; GU: Gastric ulcer; NA: Not available.

(case number 9) had a GOOSS score of 1 after removal of the stent. This patient underwent SEMS reinsertion and had improved symptoms with a GOOSS score of 3. The other seven patients were maintained without recurrence of obstructive symptoms regardless of removal of stent during the follow-up.

DISCUSSION

Following the advance of through-the-scope techniques, endoscopic therapies were developed for the treatment of benign pyloric obstruction. Among them, endoscopic balloon dilatation is regarded as the first-line option with favorable relief of obstructive symptoms[13]. In a recent study, 21 patients with benign pyloric obstruction were managed by endoscopic balloon dilatation with medication. All patients remained in symptomatic remission during a median follow-up period of 43 mo (range: 5-90 mo)[5]. However, in another study, 84% of patients (16/19) had recurrence of symptoms during a follow-up period of 45 mo (range: 25-96 mo)[14]. In addition, in another study that reported the prospective results of 42 patients with balloon dilatation for benign pyloric obstruction, 14 patients (33%) had surgical intervention for perforation (n = 4) and the overall symptom-free rates declined with the duration of follow-up (85.3% at 12 mo and 68.8% at 48 mo)[15]. In addition, more than two courses of balloon dilatation for symptom relief was the only significant prognostic factor. Recurrent obstruction after balloon dilatation is thought to be related to relatively short dilatation time. When we apply the balloon dilation into the narrow lumen through the endoscope, the real dilatation time against the radical vector force of obstructed lumen is estimated about a few minutes. The dilated lumen tends to return to the original status of the stricture over the course of time after balloon dilation. Therefore, another treatment option with long term effect, such as stenting, is needed for the treatment of benign pyloric obstruction.

In a recent meta-analysis, SEMSs for malignant pyloric obstruction have been shown to have significant clinical success, with a short time from the procedure to the start of oral intake, and lower incidence of morbidity compared with surgery[8]. Although the numbers of patients have been small, previous studies have validated SEMSs in benign pyloric obstruction and found them to be effective[10,16]. In this study of 10 patients with benign pyloric obstruction, SEMSs had excellent results with 100% technical success and immediate symptom improvement. In addition, the overall symptom free rate was 90% after a median of 11 mo of follow-up (range: 4-43 mo). Partially covered SEMSs improved obstructive symptoms for 1 year after 5 times-failed balloon dilatation procedures for benign pyloric obstruction in a recent case study[17]. In our study, five patients had experienced failed balloon dilatation. Among them, four patients had sustained symptom improvement after the SEMS procedure. The other patient (case number 6) also showed moderate symptom improvement of the GOOSS score from 1 to 2. Therefore, SEMSs also could be an alternative treatment for patients who are poor candidates for surgery after failed endoscopic balloon dilatation.

In another recent study, the authors reported on 22 patients who were treated with covered SEMSs for benign pyloric obstruction. During the mean follow-up period of 10.2 mo, 15 patients (62.5%) had stent migration with seven (46.6%) patients showing continued symptom improvement[16]. In malignant pyloric obstruction, migration of the SEMS is one of the major complications. It is more likely to occur with the covered type of SEMS than the uncovered. To reduce the migration rate, an anchoring technique or a long-length SEMS might be considered[18]. In this study, we used a partially covered SEMS and observed migration of the SEMS in two patients (20%). After successful placement of SEMS, retrieval of the SEMS was possible in all but one case. In addition,

the two patients with stent migration had previous balloon dilatation before SEMS insertion. Previous balloon dilation can stretch the stricture tissue in the pylorus and thereby enhance the rate of SEMS migration. In summary, partial SEMSs showed a lower migration rate than covered SEMSs and may be more effective in naïve benign pyloric obstruction.

There is a major concern regarding tissue ingrowth into the stent wall. This makes removal of the stent difficult for not only the uncovered stent but also the covered stent. Removal of the stent is required after improvement of obstructive symptoms. However, there is no guideline about the timing of stent removal. In our study, two patients had an aggravated GOOSS score after stent removal. These patients had a stent duration of 4 mo. Excepting for these two patients and two patients with migrated stents, the other six patients had stent durations over 6 mo and showed no aggravation of symptoms regardless of removal of the stent. Therefore, for SEMSs in benign pyloric obstruction, stent duration over 6 mo may be needed for prolonged symptom improvement.

This study has several limitations. First, the retrospective design with a small number of cases limits our ability to assess the effectiveness of the SEMS in benign pyloric obstruction. Another limitation is that the long-term effectiveness of the SEMS in benign pyloric obstruction has not been evaluated. Third, although the partially covered SEMS showed good results in this study, we did not confirm that the SEMS is better than endoscopic balloon dilatation. Further large, prospective studies comparing the SEMS with endoscopic balloon dilatation or with specific treatment methods according to the site of the benign pyloric obstruction are warranted. We expect our study results could provide the basis for further studies.

In conclusion, partially covered SEMSs had a safe and favorable outcome in the treatment of naïve benign pyloric obstruction and in salvage treatment after balloon dilatation failure. Further prospective, large-scale studies with a longer follow-up period are needed to confirm these results.

COMMENTS

Background

Endoscopic balloon dilatation has the advantage of being relatively simple for both patients and endoscopists in the treatment of benign pyloric obstruction. However, the efficacy of balloon dilatation is controversial, especially long term effectiveness.

Research frontiers

The self-expandable metal stent (SEMS) was originally developed for treatment of malignant obstruction of the esophagus, colon, and gastric outlet. However, there are few reports on SEMS in benign pyloric obstruction.

Innovations and breakthroughs

In addition, the partially covered SEMS, which was developed for overcoming the disadvantage of covered or uncovered SEMS, has not been validated for the treatment of benign pyloric obstruction. The aim of this study was to evaluate the safety and efficacy of partially covered SEMS in benign pyloric obstruction.

Applications

Partially covered SEMSs had a safe and favorable outcome in the treatment of naïve benign pyloric obstruction and in salvage treatment after balloon dilatation failure.

Peer review

The authors present their experience of using partially covered SEMS in the treatment of benign pyloric obstruction. Since there are already similar reports in the literature, a comparative trial would have been more interesting.

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