World Journal of Gastroenterology

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DOI: 10.3748/wjg.v22.i14.3837

World J Gastroenterol 2016 April 14; 22(14): 3837-3844
ISSN 1007-9327 (print) ISSN 2219-2840 (online)

ORIGINAL ARTICLE

Clinical Trials Study

Endoscopic management of unresectable malignant gastroduodenal obstruction with a nitinol uncovered metal stent: A prospective Japanese multicenter study

Reina Sasaki, Yuji Sakai, Toshio Tsuyuguchi, Takao Nishikawa, Tatsuya Fujimoto, Shigeru Mikami, Harutoshi Sugiyama, Osamu Yokosuka

Reina Sasaki, Yuji Sakai, Toshio Tsuyuguchi, Takao Nishikawa, Harutoshi Sugiyama, Osamu Yokosuka, Department of Gastroenterology and Nephrology, Graduate School of Medicine, Chiba University, Chiba 260-8670, Japan

Tatsuya Fujimoto, Department of Gastroenterology, Kimitsu Chuo Hospital, Chiba 260-8670, Japan

Shigeru Mikami, Department of Gastroenterology, Kikkoman General Hospital, Chiba 260-8670, Japan

Author contributions: Sasaki R contributed to collection, organization, analysis, and interpretation of data, and drafting of the manuscript; Sakai Y contributed to conception and design of the study; Tsuyuguchi T final approvaled the manuscript; Nishikawa T critical revision of technical content; Fujimoto T, Mikami S, Sugiyama H and Yokosuka O contributed to collection and organization of data.

Institutional review board statement: This study was conducted under approval our ethical committee.

Clinical trial registration statement: Medical Information Network Clinical Trial Registry (ID: UMIN000005112).

Informed consent statement: All the treatment procedures were performed after obtaining the informed consent in writing from the patients.

Conflict-of-interest statement: The authors have no other disclosures.

Data sharing statement: I share data in the group of us.

Correspondence to: Yuji Sakai, MD, Department of Gastroenterology and Nephrology, Graduate School of Medicine, Chiba University, 1-8-1 Inohana, Chuo-ku, Chiba 260-8670, Japan. sakai4754@yahoo.co.jp
Telephone: +81-43-2262083
Fax: +81-43-2262088

Received: January 23, 2016
Peer-review started: January 23, 2016
First decision: February 18, 2016
Revised: February 25, 2016
Accepted: March 14, 2016
Article in press: March 14, 2016
Published online: April 14, 2016

Abstract

AIM: To determine the safety and efficacy of endoscopic duodenal stent placement in patients with malignant gastric outlet obstruction.

METHODS: This prospective, observational, multicenter study included 39 consecutive patients with malignant gastric outlet obstruction. All patients underwent endoscopic placement of a nitinol, uncovered, self-expandable metal stent. The primary outcome was clinical success at 2 wk after stent placement that was defined as improvement in the Gastric Outlet Obstruction Scoring System score relative to the baseline.

RESULTS: Technical success was achieved in all duodenal stent procedures. Procedure-related complications occurred in 4 patients (10.3%) in the form of mild pneumonitis. No other morbidities or mortalities

were observed. The clinical success rate was 92.3%. The mean survival period after stent placement was 103 d. The mean period of stent patency was 149 d and the patency remained acceptable for the survival period. Stent dysfunction occurred in 3 patients (7.7%) on account of tumor growth.

CONCLUSION: Endoscopic management using duodenal stents for patients with incurable malignant gastric outlet obstruction is safe and improved patients' quality of life.

Key words: Duodenal stenosis; Gastrointestinal stent; Gastric stenosis; Malignant tumors; Metallic stent

Core tip: Endoscopic management using duodenal stents for patients with incurable malignant gastric outlet obstruction is safe and improved patients' quality of life.

Sasaki R, Sakai Y, Tsuyuguchi T, Nishikawa T, Fujimoto T, Mikami S, Sugiyama H, Yokosuka O. Endoscopic management of unresectable malignant gastroduodenal obstruction with a nitinol uncovered metal stent: A prospective Japanese multicenter study. *World J Gastroenterol* 2016; 22(14): 3837-3844 Available from: URL: http://www.wjgnet.com/1007-9327/full/v22/i14/3837.htm DOI: http://dx.doi.org/10.3748/wjg.v22.i14.3837

INTRODUCTION

Approximately 15%-20% of patients with various types of gastrointestinal malignancies, such as gastric cancer or pancreatic cancer, develop gastric outlet obstruction (GOO) during the end stage of their disease[1]. GOO causes nausea, vomiting, and abdominal discomfort, which diminish quality of life[2]. The primary aim of palliation for these patients is relief of obstruction-related symptoms. Traditionally, GOO was treated using open surgical bypass; however this procedure has been reported to be associated with considerable morbidity and mortality[3].

Recently, endoscopic placement of self-expandable metal stents has emerged as an alternative, minimally invasive treatment in cases of malignant GOO. The reported technical success rates have ranged from 94% to 100%, and the clinical success rates have ranged from 84% to 97%[4-10]. Furthermore, stent placement allows faster resumption of food intake, usually tolerated the day after stent placement, and involves a shorter hospital stay than surgical gastrojejunostomy (GJ)[4,11,12]. Previously stent placement involved use of an over-the-wire technique under fluoroscopy. However, recent advances in devices technology have led to stent placement using a through-the-scope technique. The former technique takes much longer to perform, and the placement procedure is complicated and difficult[13].

The objective of this prospective single-arm observation study was to determine the safety and efficacy of endoscopic duodenal stent placement in patients with malignant GOO, including postoperative recurrence.

MATERIALS AND METHODS

Patients

This was a prospective, observational, multicenter study of consecutive patients with malignant GOO, including postoperative recurrence, who were referred to 3 hospitals in Japan (1 university hospital and 2 referral hospitals) for palliative treatment from April 2011 to June 2013. Surgery was contraindicated in these patients, either because the lesion was not resectable or because the patients had advanced metastatic disease. Patients who had symptoms of GOO and a Gastric Outlet Obstruction Scoring System (GOOSS)[14] score (0 = no oral intake, 1 = liquid diet, 2 = soft solid diet, 3 = low residue or normal diet) of $\leqslant$ 2 were considered for inclusion in this study. Exclusion criteria included age < 20 years; obstruction in the proximal stomach, distal small intestine, or colon; previous treatment with metal stent for the same site; and contraindications for endoscopic therapy. The study protocol was approved by the Institutional Review Boards of the Ethics Committees at each hospital and registered with the University Hospital Medical Information Network Clinical Trials Registry (ID: UMIN000005112). Written informed consent was obtained from all patients.

Procedures

The WallFlex duodenal stent (Boston Scientific Japan, Tokyo, Japan) was used to treat all patients in this study. A nitinol, uncovered, self-expandable metal stent, available in lengths of 6, 9, and 12 cm, with a body diameter of 22 mm and a flare diameter of 27 mm at the proximal and distal ends, was used. The stent delivery system had a diameter of 10 Fr and allowed stent placement through the scope.

If patients were suspected of having biliary obstruction, biliary drainage by insertion of a self-expandable metal stent was endoscopically performed in advance or concurrent with duodenal stent placement. Duodenal stent placement was performed with the patient under conscious sedation. A forward-viewing gastrointestinal endoscope (Olympus CF-H260AI; Olympus Medical Systems, Tokyo, Japan) or a lateral-viewing duodenoscope (Olympus TJF-260V; Olympus Medical Systems) with a working channel diameter of $\geqslant$ 3.7 mm was used depending on the site of the stricture. The oral side of the stricture was confirmed by direct endoscopic observation, and the length and shape of

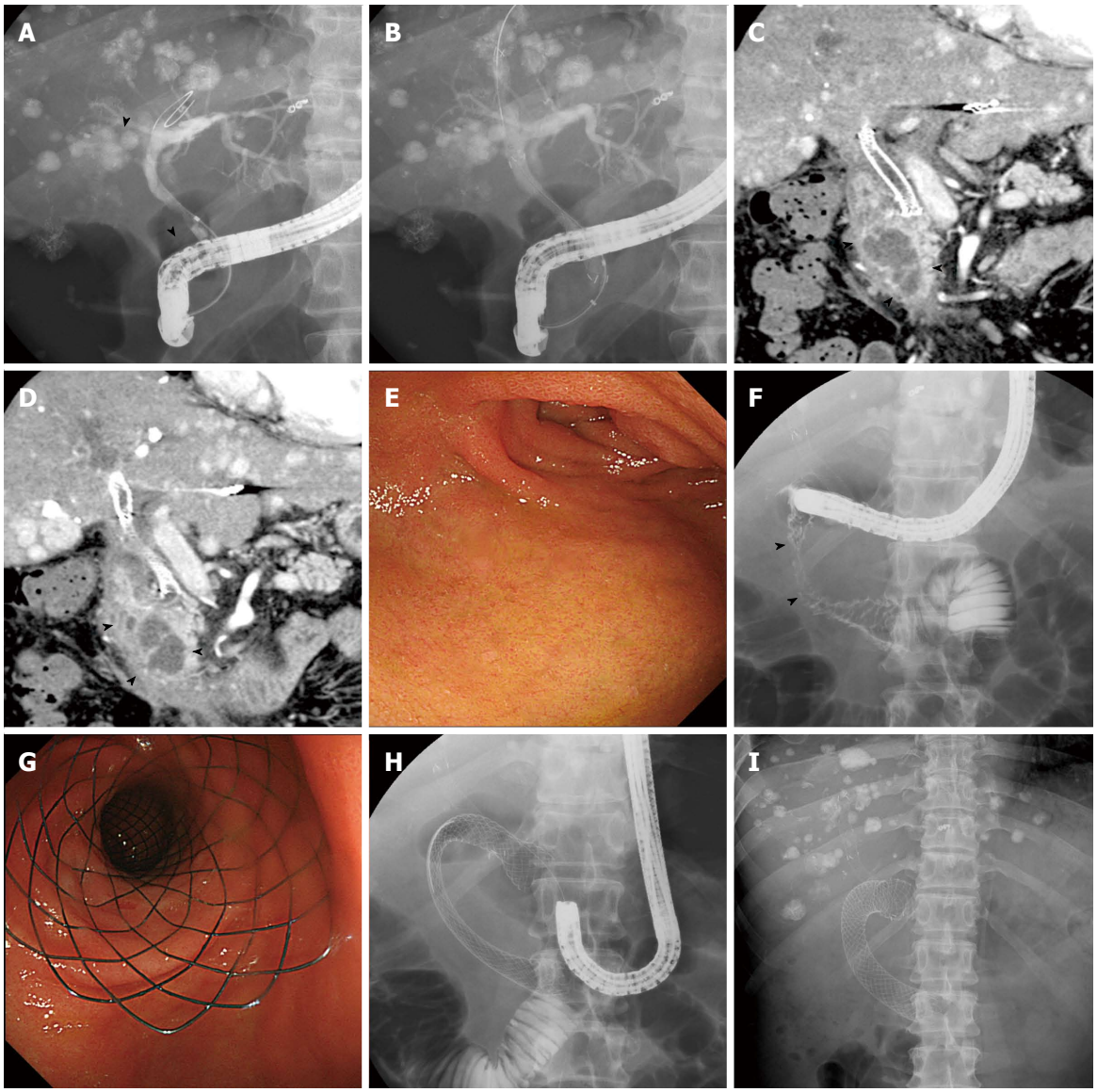

Figure 1 Case of hepatocellular carcinoma. A: Cholangiogram showing a biliary stricture caused by primary tumor and lymph node metastasis in the right hepatic duct and middle bile duct (arrow heads); B: A self-expandable metal stent was inserted endoscopically; C, D: Coronal sections of contrast-enhanced computed tomography images show duodenal invasion of lymph node metastasis (arrow heads); E: Endoscopic view showing the oral side of the stricture at the superior duodenal angle; F: Injection of contrast material demonstrates a stricture in the second duodenal segment (arrow heads); G, H: A nitinol metal stent was placed in the shape of the character "C" from the stomach pylorus to the third duodenal segment (G: Endoscopic view; H: X-ray); I: X-ray image taken 1 wk later shows sufficient expansion and stability of the duodenal stent.

the stricture was assessed fluoroscopically (Figure 1). A catheter and a guidewire were passed through the stricture and the guidewire was used to position the stent delivery system into the stricture. A stent length of $\geqslant$ 2 cm longer than the stricture was selected. The stent was deployed under continuous endoscopic and fluoroscopic control. All procedures were performed by therapeutic endoscopists who performed more than 100 endoscopic procedures per year.

Outcome and definitions

The primary outcome measure of this study was clinical success at 2 wk after stent placement. Clinical success was defined as improvement in the GOOSS score relative to the baseline score. Secondary outcomes included technical success, improvement in the World Health Organization (WHO) performance score, procedure-related complications, overall survival, and stent patency, which was defined as the time period between stent placement and stent dysfunction. Technical success was defined as successful stent placement and deployment at the site of stricture. The 2010 American Society for Gastrointestinal Endoscopy consensus criteria were used to define and grade complications[15].

Data collection

The following data were collected before stent placement: age, sex, medical history, malignant GOO type, clinical stage of cancer according to the TNM

Table 1 Baseline patients and stricture characteristics *n* (%)

Age, yr, mean ± SD (range)	69.2 ± 13.3 (35-90)
Sex (M/F)	25/14
Primary malignancy,	
Gastric cancer	1 (43.6)
Pancreatic cancer	1 (41.0)
Duodenal carcinoma	2 (5.1)
Extrahepatic cholangiocarcinoma	1 (2.6)
Intrahepatic cholangiocarcinoma	1 (2.6)
Ampullary carcinoma	1 (2.6)
Hepatocellular carcinoma (lymph node metastasis)	1 (2.6)
Clinical stage of cancer[1]	
Stage Ⅲ[2]	16 (41.0)
Stage Ⅳ[3]	23 (59.0)
Altered gastrointestinal anatomy	
Gastroduodenostomy after Billroth Ⅰ gastrectomy	3 (7.7)
Gastrojejunostomy after Billroth Ⅱ gastrectomy	1 (2.6)
Gastrojejunostomy after pancreatoduodenectomy	1 (2.6)
Gastrojejunostomy for surgical bypass	1 (2.6)
Location of stricture	
Distal stomach	16 (41.0)
Duodenal bulb	4 (10.3)
Second duodenal segment	4 (10.3)
Second/third duodenal segment	4 (10.3)
Third duodenal segment	5 (12.8)
Anastmosis site (gastrostomy)	6 (15.4)
Stricture length, mm, mean ± SD (range)	42.6 ± 19.8 (15-93)
GOOSS score before stent placement	
0-no oral intake	16 (41.0)
1-liquid diet	18 (46.2)
2-soft solid diet	5 (12.8)
3-low residue or normal diet	0
WHO perfomance score	
0-fully active	7 (17.9)
1-cannot carry out heavy physical work	8 (20.5)
2-up and about > 50% of the day	13 (33.3)
3-up and about < 50% of the day	9 (23.1)
4-bed or chair bound all day	2 (5.1)

[1]TNM classification system (ref.); [2]Including stage ⅢB and ⅢC of gastric cancer; [3]Including stage ⅣA of intrahepatic cholangiocarcinoma and hepatocellular carcinoma. GOOSS: Gastric outlet obstruction scoring system; WHO: World Health Organization.

classification system[16], obstruction site, GOOSS score, and WHO performance score. After stent placement, follow-up data were obtained during inpatient clinic visits when the patient was still hospitalized or during outpatient clinic visits. GOOSS scores and WHO performance scores were collected at 2 wk. The following data were collected until patient death or 18 mo postprocedure: procedure-related complications, additional therapy (chemotherapy, radiotherapy), and stent dysfunction. We confirmed stent dysfunction in a gastrointestinal contrast study and by endoscopy when GOO symptoms recurred.

Statistical analysis

The sample size was calculated on the basis of clinical success after stent placement. Previous reported data indicated that the clinical success rate was approximately 90%[4-10]. Consequently, we estimated that 35 patients would be required to assess the duodenal stent clinical success rate with a confidence interval of 95%, a power of 80%, and a margin of error of 10%. Furthermore, we estimated that as many as 40 patients would be required to account for possible loss of patients during follow-up.

Continuous variables were expressed as the mean, median, standard deviation, standard error, and interquartile range, whereas categorical variables were expressed as counts and percentages. The Wilcoxon signed-rank test was used to assess improvements in the GOOSS score and WHO performance score relative to the baseline scores. Kaplan-Meier analysis was used to calculate overall survival and stent patency. SAS version 9.3 (SAS Institute, Cary, NC, United States) was used to perform all statistical analyses. The significance level was set to $P < 0.05$.

RESULTS

Baseline characteristics

A total of 39 patients [25 men, 14 women; age (mean ± SD): 69.2 ± 13.3 years] underwent duodenal stent placement between April 2011 and June 2013. The patient characteristics are summarized in Table 1. Of the included patients, 17 (43.6%) were diagnosed as having gastric cancer. The remaining patients had pancreatic cancer (16 patients, 41.0%), duodenal cancer (2 patients, 5.1%), extrahepatic cholangiocarcinoma (1 patient, 2.6%), intrahepatic cholangiocarcinoma (1 patient, 2.6%), ampullary carcinoma (1 patient, 2.6%), and hepatocellular carcinoma (1 patient, 2.6%). A pathological diagnosis of malignancy was made for 31 patients (79.5%). Six patients (15.4%) with altered gastrointestinal anatomy had strictures in the surgical anastomosis. Sixteen patients (41.0%) had stricture in the distal stomach, whereas 17 patients (43.6%) had strictures in the duodenum. Before stent placement, 16 (41.0%), 18 (46.2%), 5 (12.8%), and 0 (0%) patients had GOOSS scores of 0, 1, 2, and 3, respectively.

Procedural details

Technical success was achieved in 39 patients (100%). The duodenal stent was placed at the oral side of the papilla in 23 patients (59.0%), on the papilla in 6 patients (15.4%), and at the anal side of the papilla in 10 patients (25.6%). Procedure-related complications occurred in 4 patients (10.3%) in the form of mild pneumonitis. No other morbidities or mortalities were observed.

Clinical success

Clinical success was achieved in 36 of the 39 patients (92.3%). There was no increase/decrease in the GOOSS score for 3 patients (Figure 2A). The GOOSS scores for these patients were 0, 1, and 2, respectively. Oral intake inability in a patient whose GOOSS score remained 0 was caused by progression of a peritoneal carcinomatosis. At inclusion, the mean GOOSS score

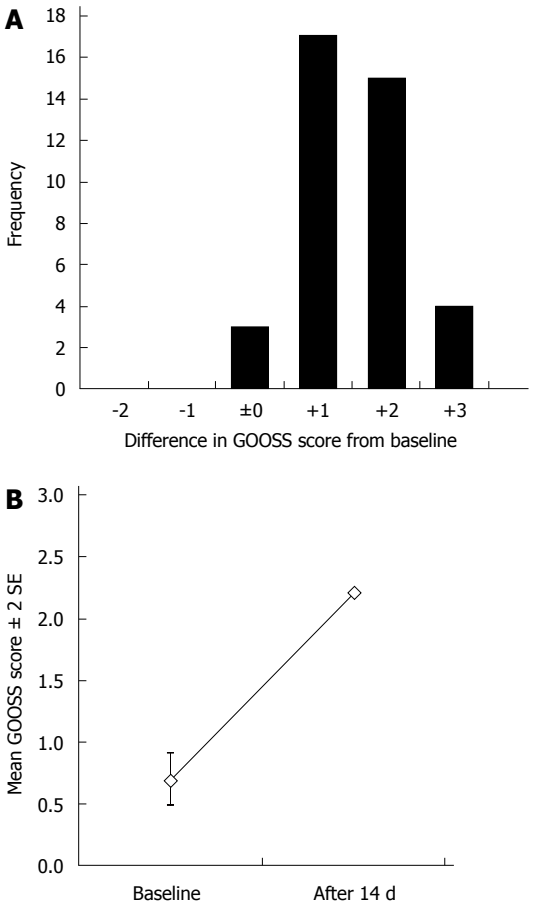

Figure 2 Differences between the Gastric Outlet Obstruction Scoring System score at baseline and at 14 d after stent placement are shown (A) and the mean Gastric Outlet Obstruction Scoring System scores at baseline and after 14 d are shown (B). *P*-value of the Wilcoxon signed-rank test comparison was < 0.0001. GOOSS: Gastric Outlet Obstruction Scoring System.

was 0.69 (Figure 2B). After 14 d of duodenal stent placement, the mean GOOSS score significantly improved to 2.21 ($P < 0.0001$). On the other hand, there was no significant difference in the WHO performance score before and after duodenal stenting (mean, 1.77 *vs* 1.95, $P = 0.57$).

Survival

After duodenal stenting, 15 patients (38.5%) received chemotherapy as an additional treatment of malignancy, and 1 patient (2.6%) received chemoradiation. Thirty-eight patients died during and 1 was alive at the end of the follow-up period. The median survival period of the 39 patients was 50 d, and the mean period was 103 d (Table 2). Four patients survived > 200 d, 2 survived > 300 d, 1 survived > 400 d, and 1 survived > 500 d.

Stent patency

During the follow-up period, 3 patients (7.7%) experienced stent dysfunction, which was caused by tumor growth in all 3 patients. No patient had stent migration (Table 2). The mean period of stent patency

Table 2 Procedure details and study outcomes *n* (%)

Technical success	39 (100)
Relationship of the papilla and stent placement site	
Oral side of the papilla	23 (59.0)
On the papilla	6 (15.4)
Anal side of the papilla	10 (25.6)
Procedure related complication	
Aspiration pneumonitis	4 (10.3)
Bleeding 0	0
Perforation 0	0
Cholangitis 0	0
Motality disorder 0	0
Clinical success	36 (92.3)
Additional treatment of malignancy after stent placement	
Chemotherapy	15 (38.5)
Chemoradiation	1 (2.6)
Survival after stent placement, d	
Median (IQR)	50.0 (25.0-152.0)
mean ± SE	102.9 ± 18.2
Stent patency, d	
Median	Not available
mean ± SE	149.6 (7.2)
Stent dysfunction	
Stent ingrowth	2 (5.1)
Stent overgrowth	1 (2.6)
Stent compression	0
Stent migration	0
Food impaction	0

IQR: Interquartile range.

was 149 d (Figure 3). Stent patency was > 200 d in 2 patients, > 300 d in 2 patients, > 400 d in 1 patient, and > 500 d in 1 patient. All 6 patients with altered gastrointestinal anatomy died without recurrence of GOO symptoms, and the maximum period of stent patency was 77 d. All 3 patients with stent dysfunction underwent reintervention involving stent-in-stent placement of the duodenal stent, and all of them died without experiencing recurrent stent dysfunction. The stent patency periods after reintervention were 41, 73, and 88 d, respectively.

DISCUSSION

We prospectively evaluated outcomes of endoscopic management using a nitinol metal stent in patients with malignant GOO. In this study, the clinical success rate was 92.3%. Recent prospective multicenter studies have reported similar clinical success rates ranging from 85% to 91%[17-21]. Our study showed that the stent patency period was acceptable for the patient survival period.

Endoscopic stent placement or surgical GJ are commonly used palliative treatments for malignant GOO. It has been reported that patients who have undergone stent placement require a shorter time to achieve oral intake and a shorter hospital stay than those who have undergone surgical GJ[4,11,12]. In a previous study, better physical health scores were obtained 1 mo after stent placement than

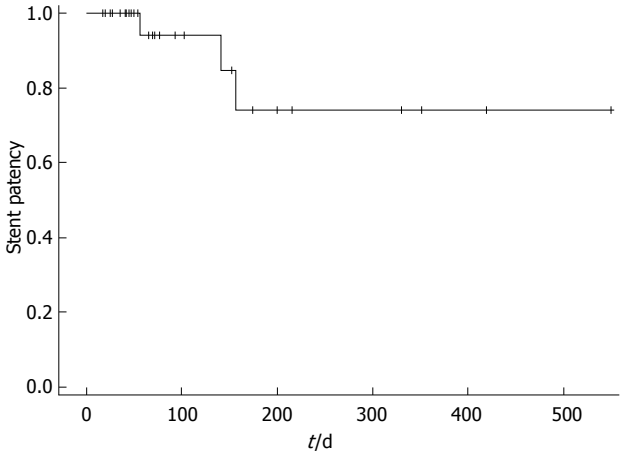

Figure 3 Kaplan-Meier curve showing stent patency.

after laparoscopic GJ[22], whereas fewer recurrent obstructive symptoms were associated with surgical GJ than with stent placement. The SUSTENT study results suggest that GJ should be primarily considered for patients with an expected survival of ⩾ 2 mo and that stent placement should be primarily considered for patients with a shorter anticipated survival[23]. However, in this study, some patients, even those with unresectable malignancies, survived longer after chemotherapy. Moreover, long-term stent patencies were also observed. Further investigation to determine if duodenal stenting should be performed in patients with prognoses expected to be ⩾ 2 mo is necessary. The major late complication associated with duodenal stents was obstruction, which was caused by tumor ingrowth or overgrowth. However, reintervention for obstructed duodenal stents is noninvasive and effective[24]. In addition, in this study, reintervention to correct an obstructed duodenal stent was technically and clinically successful. Patients at the end stage of cancer do not tolerate invasive procedures, and their life expectancy is relatively short; thus, stent placement is preferred for such patients.

In a previous report of uncovered stents for malignant GOO, approximately 19% of patients had tumor ingrowths[25]. If the origin of obstructive malignancies was intraluminal, such as gastric cancer and duodenal cancer, then tumor ingrowth was often induced by uncovered stents. Extraluminal malignancies have a low risk of causing tumor ingrowth[26,27]. In a prospective cohort study[9] and a randomized controlled trial[10] of covered *vs* uncovered metal stents for malignant GOO, there were no differences in the clinical success rate and stent patency but there was a difference in the pattern of late stent failure. In addition, stent migration occurred more frequently for covered stents than for uncovered stents, and restenosis caused by tumor ingrowth occurred more frequently for uncovered stents[9,10]. Similarly, in the present study using uncovered metal stents, there was no stent migration, and only stent dysfunction due to tumor growth was observed.

The currently available duodenal stents are the braided nitinol metal type[8,17,18,20]. Some studies have examined radial force as an expanding force and axial force as a force for recovery to a straight position for various structures and materials in biliary[28] and esophageal[29] metal stents but not in duodenal stents. In esophageal stents, braided nitinol metal stents were reported to have a lower radial force and a higher axial force than non-braided stents[29]. Because the axial force decreases with an increase in stent length[28], kinking and intestinal damage may be prevented by selecting a long stent in the duodenum (Figure 1). Duodenal stents of various structures and materials should be examined to reduce stent dysfunction.

There were some limitations in the present study because we did not conduct a comparative investigation. First, we did not compare metal stent types, such as covered *vs* uncovered metal stents, the structure and material used, or the stent length. Second, stent placement techniques, such as the over-the-wire technique under fluoroscopy and the through-the-scope technique, were not compared. Third, we did not compare endoscopic stenting for malignant GOO with other endoscopic management approaches, such as endoscopic GJ. Van Hooft *et al*[30] reported a prospective multicenter study of endoscopic GJ that used a magnetic anastomotic device and transanastomotic deployment of stents. In an animal study, Itoi *et al*[31] reported an endoscopic ultrasonography-guided GJ technique using a double-balloon enteric tube and a bilateral reflected metal stent. Stent dysfunction may be less likely to occur in routes that avoid the malignant obstruction section than in routes that include the malignant obstruction section. A randomized controlled trial of endoscopic duodenal stenting *vs* endoscopic GJ for malignant GOO is required.

In conclusion, this prospective multicenter study showed that placement of a nitinol, uncovered, self-expandable metal stent in patients with incurable malignant GOO was safe and improved their quality of life.

ACKNOWLEDGMENTS

The authors thank Rintaro Mikata, Shin Yasui, Kiyofumi Ishii, Sadahiro Itoh, Hiroshi Ohyama, Dai Sakamoto, Yuto Watanabe, Masato Nakamura, Ryousaku Azemoto, Yu Yoshida, and Toru Wakamatsu for their contributions in the collection of data.

COMMENTS

Background

Gastric outlet obstruction (GOO) was treated using open surgical bypass; however this procedure has been reported to be associated with considerable morbidity and mortality. Recently, endoscopic placement of self-expandable metal stents has emerged as an alternative, minimally invasive treatment in

cases of malignant GOO.

Research frontiers

Patients of GOO underwent endoscopic placement of a nitinol, uncovered, self-expandable metal stent. The primary outcome was clinical success at 2 wk after stent placement that was defined as improvement in the Gastric Outlet Obstruction Scoring System (GOOSS) score relative to the baseline.

Innovations and breakthroughs

Endoscopic stent placement or surgical gastrojejunostomy (GJ) are commonly used palliative treatments for malignant GOO. This study showed that the stent patency period was acceptable for the patient survival period. At inclusion, the mean GOOSS score was 0.69. After 14 d of duodenal stent placement, the mean GOOSS score significantly improved to 2.21 ($P < 0.0001$). Endoscopic management using duodenal stents for patients with incurable malignant gastric outlet obstruction is safe and improved patients' quality of life.

Applications

Surgery was contraindicated in these patients, either because the lesion was not resectable or because the patients had advanced metastatic disease.

Terminology

Endoscopic management using duodenal stents for patients with incurable malignant gastric outlet obstruction is safe and improved patients' quality of life.

Peer-review

The reviewed paper is very well organized, performed, and written research on actual topic. This article is very interesting and innovating and deserves publication.

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P- Reviewer: Shiryajev YN **S- Editor**: Ma YJ **L- Editor**: A
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ISSN 1007-9327