ORIGINAL ARTICLE

Palliative treatment of malignant gastroduodenal obstruction with metallic stent: prospective comparison of covered and uncovered stents

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Abstract

Background. The placement of self-expandable metallic stents (SEMS) is known to be effective palliative treatment of malignant gastroduodenal obstruction. There are two types of SEMS – covered and uncovered – each with its own advantages and disadvantages. This study was conducted to compare between the clinical outcomes of covered and uncovered stents in patients with malignant gastroduodenal obstruction.

Patients and methods. The study was conducted prospectively from January 1998 to June 2007 and 154 patients were included. All had symptomatic gastroduodenal obstruction and were not candidates for curative operation. Seventy patients received covered SEMS, while the other 84 received uncovered SEMS. We compared technical and clinical success rates, tumour ingrowth rate, stent migration rate, stent patency time and patient survival in both SEMS groups.

Results. The technical and clinical success rates of the covered and uncovered stent groups did not differ. Stent migration was more frequent in the covered stent group than in the uncovered group (17.1% versus 0%; \( p < 0.0001 \)). Tumour ingrowth was more frequent in the uncovered stent group than in the covered group (16.6% versus 2.9%; \( p = 0.0066 \)). Stent re-intervention rate, stent patency time and patient survival did not differ between groups.

Conclusion. Covered and uncovered stent insertions are technically feasible and effective palliative treatment of malignant gastroduodenal obstruction. Covered stents can reduce the risk of tumour ingrowth, whereas uncovered stents are effective in preventing stent migration. However, covered stents did not differ from uncovered stents in regard to other clinical outcomes.

Key Words: Covered stent, malignant gastroduodenal obstruction, palliative treatment, uncovered stent

Introduction

Malignant gastroduodenal obstruction is a preterminal complication of advanced gastric cancer and periampullary malignancy [1,2]. It causes nausea, vomiting, dysphagia, abdominal discomfort and cachexia, which diminish quality of life [3]. The primary aim of treatment in these patients is palliation of the obstructive symptoms [3,4]. Recently, self-expandable metallic stent (SEMS) insertion has been used as a safe and effective palliative treatment of unresectable malignant gastroduodenal obstruction [5–8]. With uncovered stents there is a risk of tumour ingrowth through the openings between the wire filaments, and tumour ingrowth can cause stent obstruction [7–9]. Covered stents have been used to overcome the increased rate of tumour ingrowth associated with uncovered stents, but there is a risk of stent migration in 21% to 26% of patients [10–13]. Because uncovered and covered stents have their own advantages and disadvantages, it is difficult to determine which type should be used for malignant gastroduodenal obstruction [14–16]. There are no comparative studies available evaluating the clinical effect of covered and uncovered stents in malignant gastroduodenal obstruction. Recently, we reported that there was no advantage of covered stents over uncovered stents in the palliative treatment of malignant colorectal obstruction [17]. The purpose of this present study was therefore to compare the technical feasibility and clinical outcomes in a group with covered or covered stents.
uncovered SEMS insertion for malignant gastroduodenal obstruction.

Methods

Patients

A prospective cohort single-centre study was conducted between January 1998 and June 2007 in 154 patients with malignant gastroduodenal obstruction. Those with malignant obstructions of the site of anastomosis, and with gastric resection after stent insertion, were not included. They were excluded if they showed hemodynamic instability or severe pulmonary insufficiency. We excluded patients with diffuse peritoneal carcinomatosis with bowel encasement and multiple obstructive lesions. The tumour was considered unresectable in patients with advanced and metastatic disease and in old age with medical co-morbidity.

We assigned the patients to two groups: an initial group (treated with uncovered stents) and a late group (treated with covered stents), consecutively and respectively. Seventy patients (50 M, 20 F; mean 67.2 years) were treated with covered stents and 84 (58 M, 26 F; mean 63.3 years) with uncovered stents.

The degree of dysphagia was assessed using the Gastric Outlet Obstruction Scoring System (GOOSS) before and after stent insertion. GOOSS is point-scoring dependent on the patient’s level of oral intake (no/inadequate oral intake = 0; thickened liquids/liquid = 1; semi-solids/low residue diet = 2; unmodified diet = 3) [7]. Patient characteristics are summarized in Table I; there was no difference in demographic features. Informed consent was obtained from all patients and the study was approved by the Institutional Review Board of the Ajou University Hospital.

Equipment

We used both uncovered and covered types of SEMS (Niti-S, pyloric; Taewoong, Gimpo, Korea), which have a diameter of 18 mm and are 60, 80 or 100 mm in length. The stents are made of single-strand mesh of 0.007 inch wire of nitinol, nickel-titanium alloy. The uncovered stent is designed in a fairly cylindrical form with no cover material (Figure 1a). By contrast, the mesh of the covered stent is overlaid with a polyurethane membrane to prevent tumour ingrowth. The covered stent is designed in a dumbbell shape with flange ends; the proximal end has a 1.5 cm bared portion to prevent migration (Figure 1b). The stent was tightly mounted on a delivery system with an outer diameter of 10.5F and overall length 180 cm. These long, thin delivery systems make it possible to insert the stent and deploy it easily through the working channel of the endoscope. We used 2-channel endoscopes with a 3.7 mm

Table I. Patient demographics.

<table>
<thead>
<tr>
<th>Covered stent</th>
<th>Uncovered stent</th>
<th>p-value</th>
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</thead>
<tbody>
<tr>
<td>No. of patients</td>
<td>70</td>
<td>84</td>
</tr>
<tr>
<td>Mean age (yr)</td>
<td>67.2</td>
<td>63.3</td>
</tr>
<tr>
<td>Gender (M:F)</td>
<td>50:20</td>
<td>56:28</td>
</tr>
<tr>
<td>Pre-stent GOOSS</td>
<td>52/28/0/0</td>
<td>61/23/0/0</td>
</tr>
<tr>
<td>Underlying malignancy</td>
<td>ns</td>
<td>ns</td>
</tr>
<tr>
<td>Advanced gastric cancer</td>
<td>57</td>
<td>65</td>
</tr>
<tr>
<td>Pancreatic cancer</td>
<td>7</td>
<td>12</td>
</tr>
<tr>
<td>GB cancer</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Bile duct cancer</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Ampullary cancer</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Duodenal cancer</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Metastasis</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Chemotherapy</td>
<td>8</td>
<td>7</td>
</tr>
</tbody>
</table>

Figure 1. The uncovered and covered type stents used in this study. (a) The uncovered stent type is designed in straight form and not coated with membrane. (b) The covered stent is designed in a dumbbell shape with flange ends and is covered with polyurethane.
working channel (GIF-2T200; Olympus, Tokyo, Japan) and a 300 cm long, 0.035 inch diameter biliary guidewire and standard ERCP catheter.

**Endoscopic technique**

Four senior endoscopists with more than 50 experiences of stent insertion participated in the study. All procedures were carried out under endoscopic and fluoroscopic guidance with the patient under conscious sedation with intravenous propofol and midazolam. The endoscope was carefully inserted in the obstructive site. When the stenosis was identified, a guidewire was passed through it with the use of a biliary catheter. The length of the obstructive lesion was measured by injecting water-soluble contrast dye through a 5F biliary catheter. The stent was at least an additional 1–2 cm longer on each side of the stenosis to allow adequate coverage. After the guidewire was passed through the stricture site, the stent delivery system was advanced over the guidewire through the working channel under fluoroscopic guidance. The stent was released and deployed at the stricture site while the outer sheath was pulled back under fluoroscopic and endoscopic guidance. After stent insertion, plain abdominal films were routinely obtained. Oral intake was allowed after the procedure, beginning with liquid and followed by a semi-solid or soft diet, if possible. If the patient’s general performance was suited for chemotherapy, intravenous or oral chemotherapy was added. Patients were followed up from stent insertion to death, or the end of the study, with clinical check-up and telephone interview at regular intervals (every 1 to 3 months).

**Definition of event**

Technical success was defined as the correct position of a stent across the entire length of the stricture with an established patency with endoscopy or fluoroscopy and radiologic relief of obstruction. Clinical success was defined as relief of vomiting and resumption of diet. Early complications were defined as any adverse effect that occurred during the procedure or within 7 days after stent insertion. Clinical outcome was measured by stent patency time and re-intervention rate to resolve complications such as migration, tumour ingrowth or overgrowth. Follow-up endoscopy was carried out only in patients with recurrent obstruction symptoms.

**Statistics**

Baseline characteristics are expressed as mean ± standard error of the mean (SEM). Comparison of the frequency data was made with the Fisher exact test. Stent patency and duration of patient survival were assessed using the Kaplan-Meier method. A p-value < 0.05 was considered statistically significant. Stent patency was defined as the period between insertion and stent occlusion or patient death. Censored data were defined as patients without stent occlusion and still alive.

**Results**

Demographic features of the groups did not differ (Table I). Most of the underlying malignancy of gastroduodenal obstruction was advanced gastric cancer. Technical and clinical success rates of stent insertion are given in Table II. All covered and uncovered stents were placed successfully and the technical success rate for both groups was 100% (70/70 versus 84/84) (Table II). In 70 patients of the covered stent group, obstructive symptoms were relieved in 69. One patient began to vomit continuously after oral intake and had to depend on total parenteral nutrition (TPN) until death. Three of

Table II. Technical and clinical success rate and early and late complications of stent insertion.

<table>
<thead>
<tr>
<th></th>
<th>Covered stent</th>
<th>Uncovered stent</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Technical success</td>
<td>70/70 (100%)</td>
<td>84/84 (100%)</td>
<td>ns</td>
</tr>
<tr>
<td>Clinical success</td>
<td>69/70 (98.6%)</td>
<td>81/84 (96.4%)</td>
<td>ns</td>
</tr>
<tr>
<td>Post-stent GOOSS</td>
<td>1/0/20/49</td>
<td>2/1/27/54</td>
<td>ns</td>
</tr>
<tr>
<td>Early complication (&lt;1 week)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Migration</td>
<td>5/70 (7.1%)</td>
<td>0/84</td>
<td>0.018</td>
</tr>
<tr>
<td>Tumour incorporation</td>
<td>0/70</td>
<td>1/84 (1.2%)</td>
<td>ns</td>
</tr>
<tr>
<td>Late complication (&gt;1 week)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Migration</td>
<td>7/70 (10.0%)</td>
<td>0/84</td>
<td>0.003</td>
</tr>
<tr>
<td>Tumour incorporation</td>
<td>2/70 (2.9%)</td>
<td>13/84 (15.5%)</td>
<td>0.012</td>
</tr>
<tr>
<td>Overgrowth</td>
<td>3/70 (4.3%)</td>
<td>2/84 (2.4%)</td>
<td>ns</td>
</tr>
<tr>
<td>Re-intervention rate</td>
<td>15/70 (21.4%)</td>
<td>12/84 (14.3%)</td>
<td>ns</td>
</tr>
<tr>
<td>Stent patency time (median) [95% CI]</td>
<td>75 [47, 134]</td>
<td>73 [44, 102]</td>
<td>ns</td>
</tr>
<tr>
<td>Patient survival time (median) [95% CI]</td>
<td>115 [80, 156]</td>
<td>108 [60, 151]</td>
<td>ns</td>
</tr>
</tbody>
</table>
84 patients in the uncovered stent group did not get better after stent insertion (Table II); two had obstructive lesions (in the duodenal third portion and proximal jejunum, respectively), while the other patient had no another obstructive lesion in the GI tract except gastroduodenal obstruction. The obstructive symptoms of patients with duodenal lesion could be relieved with additional insertion of an uncovered stent. The two remaining patients had to depend on conservative management for the remainder of their lives. Clinical success rate was not significantly different between the covered and uncovered stent groups (98.6% versus 96.4%; \( p > 0.05 \)).

Within 7 days after stent insertion, migration occurred in five cases in the covered stent group. Migration was significantly more frequent in the covered stent group than in the uncovered stent group (5/70 versus 0/84; \( p = 0.018 \)) (Table II). Five cases of migration of covered stents were managed with the second stent insertion (uncovered stent for 4, double stent for 1) and obstructive symptoms were released successfully. One case of tumour incorporation occurred in the uncovered stent group. Stent lumen was occluded with invading friable non-cancerous lesion. An endoscope could be passed through the stent with some resistance, but the patient had obstructive symptoms. The covered type stent was placed using the stent-in-stent method to overcome tumour incorporation. There was no procedure-associated significant bleeding, stent malpositioning or perforation.

After 7 days, late stent migration occurred in seven of the covered stent group patients. The risk of late migration was significantly higher in the covered stent group than in the uncovered group (7/70 versus 0/84; \( p = 0.003 \)). An uncovered stent was re-inserted in four cases and two patients refused additional treatment. One case of proximal stent migration induced functional obliteration of the stent by contact of gastric mucosa with the stent orifice. The proximal side of the stent was severed with APC. Tumour ingrowth was significantly more frequent in the uncovered stent group than in the covered group (13/84 versus 2/70; \( p = 0.012 \)). The polyurethane membrane of the covered stent might be eroded and torn by the growing tumour or digestive enzyme. Eleven patients were successfully managed with the insertion of second stents (covered stent for five, double stent for seven). Four patients refused the second stent insertion. Tumour overgrowth occurred in three of the covered stent group and in two of the uncovered group (3/70 versus 2/84; \( p > 0.05 \)). We inserted an overlapping stent at the proximal or distal part of the stent (covered stent for three, uncovered for two) and the symptom was released in all patients. Overall, re-intervention rate did not differ in relation to stent type (15/70 versus 12/84; \( p > 0.05 \)). Median stent patency times of covered and uncovered stents were not significantly different (75 days versus 73 days; \( p > 0.05 \)) (Figure 2). Patient survival times in both groups were not significantly different (115 days versus 109 days; \( p > 0.05 \)) (Table II). Fifteen patients had chemotherapy (8 with oral 5FU, 7 with IV infusion of 5FU and cisplatin or taxotere), but this did not significantly prolong stent patency time (88 days versus 72 days; \( p > 0.05 \)) or patient survival (135 days versus 108 days; \( p > 0.05 \)).

### Discussion

Primary diseases of malignant gastroduodenal obstruction are gastric and duodenal cancers, periampullary malignancy, such as pancreatic cancer, and extrinsic compression by metastatic lymphadenopathy [1–3]. Because of poor results and high morbidity and mortality of palliative bypass surgery, endoscopic insertion of a self-expanding metallic stent (SEMS) has become the palliative treatment of choice for malignant gastroduodenal obstruction [4–6]. However, there is limited recurrence of obstructive symptoms resulting from tumour ingrowth, stent migration and tumour overgrowth. Restenosis by tumour ingrowth is the most common problem of uncovered stents [7,9,18]. Nassif et al. [19] reported a 19.0% tumour ingrowth rate of

![Figure 2. Kaplan-Meier curve of stent patency duration after stent insertion.](image)
uncovered stents for malignant gastric outlet obstruction, which is comparable with the results of our present study. Telford et al. [20] reported no tumour ingrowth of uncovered stents in gastric outlet obstruction, but the majority of patients included had pancreatic cancer, bile duct cancer or other metastatic cancer. Intra-luminal malignancies, such as gastric cancer, can induce tumour ingrowth with uncovered stents, whereas extra-luminal tumours, such as pancreatic cancer, show a different growth pattern and there is a lower risk of tumour ingrowth [20,28]. The covered stent type was developed to reduce the risk of tumour ingrowth [12–15]. A cover membrane has a preventive effect on tumour ingrowth and is assumed to preserve the patency of the stent [13,14]. Jeong [12] and Park et al. [13] reported no case of tumour ingrowth with the covered stent. Despite the merit of preventing tumour ingrowth, the covered stent has the demerit of the risk of stent migration [12,13].

The expanding wire meshes of uncovered stents induce tumour necrosis, embed themselves in the tumour, act as an anchor and prevent stent migration [19]. The expanding force of covered stents is transferred to the tumour through a cover membrane, which causes tumour shrinkage, reduces the friction effect of the tumour and increases the risk of migration [19,21]. To prevent stent migration, some changes have been made in their basic design, including a proximal funnel, a partial covering membrane and a shoulder at the ends [21,22].

In the present study, two cases of tumour ingrowth occurred in the covered stent group. The covering membrane can be damaged by mechanical trauma during the process of stent deployment or chemical degradation with exposure to digestive juice [23]. Chemical degradation of polyurethane after exposure to strongly acidic juice and pancreatic secretion has been reported in several studies [24,25]. Materials such as polyurethane and silicone have been used to cover the surface of stents [10–13]; nevertheless, new chemical-resistant covering materials are necessary to prevent disruption of the covering membrane.

Profili et al. [22] and Kim et al. [26] reported no case of migration of uncovered stents in patients with malignant gastro-duodenal or anastomosis obstruction. Their results are consistent with ours. The risk of tumour ingrowth and the prevention of migration are two sides of the same coin of uncovered stents [27,28]. Because the preventive effect of tumour ingrowth cannot offset the risk of stent migration of covered stents, the re-intervention rates are not significantly different between covered and uncovered stents. To overcome the shortcomings of each type of stent, simultaneous deployment of covered and uncovered stents has been tried with the TTS and non-TTS methods (double stent or coaxial placement method) [29–31]. Song et al. [29] reported that the double stent method can prevent tumour ingrowth and stent migration and significantly prolong stent patency for postoperative anastomosis obstruction. However, the double stent method has the problem of high medical costs because of two stents at once.

The high expanding and restoring force of conventional stents can work as the triggering power of stent migration [32]. The covered conformable stent with an adequate restoring force can be an ideal model resolving the problems of conventional stents. More clinical data are needed to precisely evaluate the new covered conformable stent in patients with malignant gastric outlet obstruction.

We recently reported a late stent migration rate of 40% of the covered type for malignant colorectal obstruction with the same stents as those used in the present study [19]. Late stent migration of the covered stents was significantly more frequent in malignant colorectal obstruction than in gastro-duodenal obstruction (6/15 versus 7/70; p = 0.000). The risk of migration of the uncovered stent was higher in colorectal obstruction than in gastro-duodenal obstruction (5/39 versus 0/84; p = 0.003) [19]. The different migration of stomach and colon may be caused by different clinical situations. The gastric antrum is important for gastric emptying. Advanced gastric cancer causing pyloric obstruction may destroy antral muscle structure and inhibit gastric emptying. The proximal portion of obstructive colon cancer may preserve muscular structure and restore its contraction capacity after stent insertion [33]. While weak gastric emptying cannot induce migration of uncovered stents, strong peristalsis contraction of the colon might lead to migration not only in the covered stent group but also in the uncovered group.

In summary, covered and uncovered SEMS insertions are technically feasible and clinically effective treatments for malignant gastro-duodenal obstruction. The covered stent type can decrease the risk of tumour ingrowth, but there is a significant risk of stent migration. Overall, stent re-intervention rates, stent patency, patient survival time do not differ between the covered and uncovered types. There was therefore no difference between the covered and uncovered stents in the treatment of malignant gastro-duodenal obstructive lesion. A large-scale,
randomized study is needed to find the ideal stent for malignant gastric outlet obstruction.

**Declaration of interest:** The authors report no conflicts of interest. The authors alone are responsible for the content and writing of the paper.

**References**


