



Palliative Medicine Original Article

The Role of Self-Expandable Metallic Stents in the Treatment of Malignant Strictures in all Segments of the Gastrointestinal Tract

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ABSTRACT

Objectives: Management of malignant gastrointestinal (GI) obstruction presents a significant challenge. Most patients are in a profoundly decompensated state due to underlying malignancy and are not ideal candidates for invasive surgical procedures. Self-expandable metallic stents (SEMSs) are used to provide permanent or temporary patency in all endoscopically accessible stenosis of the GI tract. In this study, it is aimed to analyse the characteristics and the efficacy of patients with malignant stenosis treated with SEMS, in all segments of the GI tract.

Material and Methods: The sample consisted of 60 patients who underwent SEMS replacement, between 10 March 2014 and 16 December 2020, to treat malignant-related strictures in the GI tract at the Gastroenterology Department of the Health Sciences University Umraniye Training and Research Hospital. The data of the patients, hospital data processing database and electronic endoscopic database records were retrospectively scanned and recorded. The general characteristics of the patients and the treatment-related features were analysed.

Results: The mean age of patients who were placed SEMS was 69.7 ± 13.7 years. Uncovered (15%, $n: 9$), fully covered (13.3%, $n: 8$), or partially covered (71.6%, $n: 43$) SEMS were successfully placed in all patients. Clinical success in patients with SEMS was 85.7% in the esophagus, 100% in the small intestine and 90.9% in the stomach and colon. About 11.4% migration, 14.2% pain, 11.4% overgrowth and 5.7% ingrowth were detected in patients who had SEMS placed in the oesophagus. Pain was detected in 9.1% and ingrowth in 18.2% of patients who had SEMS placed in the stomach. Pain was detected in 18.2% of the patients who had SEMS placed in the colon and migration was found in 9.1%.

Conclusion: SEMS implant is a minimally invasive effective method in the palliative treatment of malignant strictures of the GI tract.

Keywords: Malignant stricture, Self-expandable metallic stents, Palliative treatment

INTRODUCTION

Malignant obstructions of the gastrointestinal (GI) tract cause serious symptoms and signs, regardless of their level. These symptoms and signs can also develop acutely. Providing lumen openings with self-expandable metallic stents (SEMSs) is one of the most important treatment methods.

Dysphagia is the most important symptom of malignant strictures of the oesophagus. In these patients, it is aimed to improve the quality of life and reduce the complications related to the disease and additional treatments by correcting the nutritional deficiency. Palliation of oesophageal malignant strictures with SEMS has been used as an effective treatment for approximately two decades.^[1]

In malignant gastric outlet obstructions, primary malignancy of the antrum, pylorus and duodenum of the stomach or infiltration of adjacent organ malignancies, obstruction caused by compression may lead to a decrease in the quality of life and the nutritional status of the patient. In these patients, palliative gastrojejunostomy surgery and enteral SEMS are the treatment options used for the palliation of the stenosis.^[2] Malignant colonic obstruction has been reported in approximately 8–29% of colon cancers. These patients require immediate decompression therapy. Although the classical treatment of these patients is emergency surgery and stoma opening, the risk of morbidity and mortality is higher than elective surgery. In these patients, palliation of the obstruction with SEMS is used as bridging therapy for elective surgery.^[3]

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Received: 15 October 2021 Accepted: 19 November 2022 Epub Ahead of Print: 11 January 2023 Published: 20 January 2023 DOI: 10.25259/IJPC_106_2021

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In addition, SEMS used to treat malignant/benign strictures and fistulas, perforations of the upper GI tract to maintain lumen patency, facilitate nutritional intake and improve quality of life, sealing of perforation and leaks.^[4,5] Although the technical success of the procedure is generally over 80%, complications such as migration, bleeding, perforation and pain related to SEMS have been reported at varying rates during and after stent placement.^[5] In Turkey, literature data on SEMS application and its complications are sparse. In this retrospective observational study, we aim to analyse the general characteristics, clinical success and complications of SEMS replacement in patients with GI tract malignancy.

MATERIAL AND METHODS

Patients included in the study were 60 patients who underwent SEMS replacement, between 10 March 2014 and 16 December 2020, to treat malignant-related strictures in the GI tract at the Gastroenterology Department of the Health Sciences University Umraniye Training and Research Hospital. Patient files were analysed retrospectively.

Endoscopic reports, pictures and videos and fluoroscopic views of the patients were examined and the stent characteristics used in the treatment were recorded. Demographic characteristics, diagnosis of patients, technical and clinical success of each procedure, also complications during the procedure and follow-up, and survival of patients after the procedure were recorded.

The procedures were performed under sedation administered by an anaesthesiologist. All procedures were performed under fluoroscopy. Before upper GI stent placement, stenosis length and features were determined with endoscopic (slim endoscope Fujinon VP-4450 HD, Fujinon EG 590WR gastroscope), fluoroscopic and/or radiologic (computed tomography) assessment. At the end of the procedure fluoroscopy, the endoscopic assessment was used to determine the SEMS location. In each patient with colorectal malignancy, through-the-scope SEMS (TSSEMS) was used for proximal lesions. TSSEMS or fluoroscopy-assisted colonic SEMS placement was used in a patient with distal (rectosigmoid) obstructions.

Technical success

The procedure was defined as technical success when SEMS covered the stricture fully and opened. The procedure was defined as clinical success when the patient tolerated enteral feeding after SEMS placement in patients with a malignant oesophageal stricture.

In patients with malignant colorectal stricture, the procedure was defined as technical success when SEMS covered the stricture fully and opened. Gas and stool discharge after procedure was defined as clinical success.

Assessment of adverse events: After SEMS placement, patients went through endoscopic inspection in case of suspicion of bleeding, persistent pain and/or obstruction. Direct

radiography was performed to check for migration, and revision was conducted through endoscopic intervention. Patients went through endoscopic inspection to evaluate ingrowth and overgrowth over suspicion of reobstruction in the GIS during prolonged follow-ups. Routine control imaging or endoscopic control was not performed when patients presented no complaints during follow-up. The surveys of the patients were calculated at time the SEMS is active and the time of death.

Informed consent was obtained from all patients for the procedure and anaesthesia. The procedures were performed under sedation administered by an anaesthesiologist.

Patients who underwent only biliary stenting due to malignant biliary obstruction, patients without pathological diagnosis of malignancy or benign aetiology and patients with missing data records were excluded from the study. All consecutive patients except these patients were included in the study.

The study was approved by the Ethics Committee of Health Sciences University Umraniye Training and Research Hospital (Date: 8 April 2021&No: B.10.1.TKH.4.34.H.GP.01/99).

RESULTS

SEMSs were placed in 60 patients due to malignancy-related obstruction in the GI tract. Patients had a mean age of 69.7 ± 13.7 years. Uncovered (15%, *n*: 9), fully covered (13.3%, *n*: 8) or partially covered (71.6%, *n*: 43) SEMSs were successfully placed in all patients. [Table 1] shows the characteristics of patients and treatment. [Table 2] shows the clinical success, complications and survivals of patients.

Post-procedure bleeding occurred in 4 (11.4%) patients with SEMS placed in the oesophagus. Therefore, control endoscopy was performed, and blood stopper was sprayed, after which there was no further bleeding. Four patients (11.4%) presented with migration and underwent a revision procedure with a gastroscope. One of those patients underwent SEMS-in-SEMS placement due to ingrowth 6 months after the first procedure. Four patients (11.4%) developed overgrowth. One of those patients underwent SEMS-in-SEMS placement 3 months after the first procedure. Another one underwent percutaneous endoscopic jejunostomy. The other two patients did not undergo any procedure because they could not tolerate it. Ingrowth was detected in 2 patients (5.7%) who underwent SEMS-in-SEMS placement 4 and 3 months after the first procedure. One patient had his fully covered SEMS removed 28 days after the procedure because he presented with lymphoma external compression. He, then, continued to receive systemic therapy. Two uncovered SEMS patients with malignancy infiltrating the pylorus developed ingrowth 5 and 7 months after surgery. However, no intervention was performed because the lumen was completely closed. Survival was 20.6 days in patients who had SEMS placed in the small intestine, and

Table 1: Descriptive and treatment characteristics of patients.

Parameters	Mean SD (%)	(%)	(%)	(%)
Age	69.7±13.7			
Gender	<i>n</i>	<i>n</i>	<i>n</i>	<i>n</i>
Male	38 (63.3)			
Female	22 (37.7)			
Diagnosis treatment (SEMS)		Uncovered	Partial	Fully covered
Oesophageal adenocarcinoma	22 (36.7)	-	22 (100)	-
Oesophageal squamous cell carcinoma	12 (20)	-	11 (91.7)	1 (8.3)
NHL compression of the oesophagus	1 (1.7)	-	-	1 (100)
Cardia adenocarcinoma	4 (6.7)	-	3 (75)	1 (25)
Distal gastric adenocarcinoma	7 (11.7)	5 (71.4)	2 (28.6)	-
Duodenal (GIST and adenocarcinoma)	2 (3.3)	2 (100)	-	-
Adenocarcinoma of the ileum	1 (1.7)	-	1 (100)	-
Adenocarcinoma of the colon	6 (10)	2 (33.3)	3 (50)	1 (16.7)
Adenocarcinoma of the rectum	5 (8.3)	-	1 (20)	4 (80)

NHL: Non-Hodgkin lymphoma, GIST: Gastrointestinal stromal tumour, SEMS: Self-expandable metallic stent

Table 2: Clinical success, complications of SEMS placement and survivals of patients.

Parameters	Oesophagus (%)	Stomach (%)	Small intestine (%)	Colon (%)
<i>n</i> (%)	35	11	3	11
Technical success	100	100	100	100
Clinical success	85.7	90.9	100	90.9
Survey (Mean)*	114.6 days	117 days	20.6 days	52.6 days
Complication	<i>n</i>	<i>n</i>	<i>n</i>	<i>n</i>
Migration	4 (11.4)	-	-	1 (9.1)
Bleeding	4 (11.4)	-	-	-
Pain	5 (14.2)	1 (9.1)	-	2 (18.2)
Overgrowth	4 (11.4)	-	-	-
Ingrowth	2 (5.7)	2 (18.2)	-	-
Perforation	-	-	-	-
Fistula	-	-	-	-

*All patients died except for one patient with SEMS placed in the oesophagus and six patients with SEMS placed in the colon

the rate of late complications was not evaluated; however, no early complications were detected in these patients. One patient underwent partially covered SEMS placement in the ascending colon and another underwent fully covered SEMS placement in the transverse colon for palliative purposes. Those two patients had no complications, and therefore, they continued to receive systemic treatment. Two patients with rectal cancer underwent fully covered SEMS placement as a bridge to surgery. They were operated on 3 weeks later. One patient with rectal cancer underwent partially covered SEMS placement as a bridge to surgery and developed migration 2 days after the procedure. SEMS was removed and replaced with an uncovered SEMS. The patient was operated on 3 weeks after the procedure. Fully covered SEMSs were placed in two patients for palliative purposes. One patient had pain that regressed with analgesic, while the other patient had no complications.

DISCUSSION

Oesophageal cancer has high mortality and morbidity rates. It is the sixth most common cause of cancer death.^[6] Progressive dysphagia usually develops when the oesophageal lumen diameter is <13 mm. Despite advances in diagnostic and therapeutic methods, the 5-year survival rate of people with oesophageal cancer ranges from 15% to 20%.^[7,8] Oesophageal stent placement is an option to alleviate dysphagia and maintain enteral feeding in patients with advanced malignancies. SEMSs are used for palliative treatment. Although SEMSs are widely used, they can cause complications, such as pain, bleeding, burial, migration, fistula, ingrowth and overgrowth.^[9] SEMS placement for a malignant oesophageal stricture is considered a technical success, while the post-operative regression of dysphagia and the tolerance of enteral feeding are considered a clinical success. Chandan *et al.* (2020) have recently conducted a

meta-analysis and reported the technical and clinical success rates of oesophageal SEMS placement as 94.7% (95% CI 89.9–97.3) and 82.1% (95% CI 67.1–91.2), respectively.^[10] In our sample, the technical success rate was 100%, probably because we used both fluoroscopy and endoscopy for the procedure. In our sample, the clinical success rate was 85.7%, which was similar to what has been reported by earlier studies.^[10,11] Up to six out of 10 patients may experience post-procedural pain,^[12] which may last 10 days and be reduced to a tolerable level by analgesics without having to remove the SEMS.^[13] Five of our patients (14.2%) reported pain. We did not have to remove their SEMS as we prescribed analgesics to relieve their pain. The main complication of SEMS is migration, with an incidence rate of 10–30%.^[14] So *et al.* reported the migration rate as 36% in patients after fully covered SEMS placement.^[11] We found the migration rate to be 11.4%. Those patients underwent revision procedure with a gastroscope and developed no migration afterward. Our migration rate was low probably because we mostly placed partially covered SEMS (97.1%). Tumour ingrowth or overgrowth is a late complication of the procedure. The incidence rate of tumour ingrowth with uncovered SEMS ranges from 17% to 36%.^[15] The incidence rate of tumour outgrowth with oesophageal SEMS ranges from 4% to 18%.^[16] Vakil *et al.* reported that nine out of 30 patients with uncovered SEMS but only one out of 32 patients with fully covered SEMS developed ingrowth.^[17] We detected ingrowth in 2 patients (5.7%). Patients with partially covered SEMS are more likely to develop tumour ingrowth than those with fully covered SEMS but less likely to develop tumour ingrowth than those with uncovered SEMS. Partially covered SEMS can be the oesophageal stents of choice for palliative purposes because they are less likely to cause migration and ingrowth and allow for intervention in case of migration. We observed overgrowth in 4 patients (11.4%), similar to what was reported by earlier studies.^[16,18] Patients with a proximal gastric obstruction present with clinical findings similar to those of patients with oesophageal obstruction. Patients with gastric outlet obstruction present with nausea (90%), vomiting (83%), regurgitation (69%) and abdominal pain (66%). More than 7 out of 10 patients with malignant gastric obstruction cannot tolerate solid foods, while four out of 10 have no oral intake.^[19] Treatment options are endoscopic stent placement, surgical bypass and gastrojejunostomy operations, jejunal feeding tube insertion, percutaneous gastrostomy jejunostomy percutaneous endoscopic gastrostomy and pharmacological treatments that improve gastric emptying and achieve symptomatic relief.^[20–22] Patients undergo SEMS placement to treat strictures transition to oral feeding earlier and stay in the hospital for a shorter period than those who undergo gastrojejunostomy.^[20,23] We had four patients with a malignant stricture in the cardia. We placed partially covered SEMS in three of them and a fully covered SEMS in one. One

patient continued to be fed with liquid food because he could not tolerate solid food. Another patient had pain, which was treated with analgesics. Other patients did not develop any complications. We had seven patients with a malignancy infiltrating the pylorus. We placed uncovered SEMS in five of them and partially covered SEMS in two. Two patients with uncovered SEMS developed ingrowth 5 and 7 months after surgery, which resulted in complete clogging of the stents. As a result, we could not pass the stricture and could not place new SEMS. Technical success was 100%, clinical success was 90.9% and the ingrowth rate was 18.1% in patients with malignant gastric stricture, which was similar to what has been reported by a recent meta-analysis.^[24]

Tejero *et al.* were the first to identify SEMS placement as a bridge to elective surgery in patients with malignant colorectal strictures. That procedure has yielded contradictory health outcomes since then.^[25] In colorectal malignancies, SEMS has been used for the continuity of the enteral passage and to bridge emergency surgery to elective one.^[26] The rationale behind that process is to achieve rapid and efficient decompression of the large bowel, minimise the risk of bacterial translocation and ensure the right oncological staging, physiological optimisation and resuscitation before surgery in an elective setting.^[27] We placed one partially covered SEMS in an ascending colon and one fully covered SEMS in a transverse colon. The procedures were effective and did not cause any complications. We successfully placed two partially covered and two uncovered SEMS in sigmoid colons. The patients developed no complications. Five patients had rectal malignancies. We placed fully covered SEMS in four of them and a partially covered SEMS in one. Two patients with fully covered SEMS had pain, which was treated with analgesics. One patient with a fully covered SEMS had tenesmus, and therefore, we removed the SEMS. One patient with a partially covered SEMS developed migration, and therefore, we performed a revision procedure with colonoscopy. We placed two fully covered and one partially covered SEMS in three rectums. Those patients were operated on. We placed SEMS in 11 patients with colorectal malignancies. The technical and clinical success rates were 100% and 90.9%, respectively. Boland *et al.* conducted a meta-analysis to evaluate the short-term outcomes of SEMS placement and reported the general technical and clinical success rates as 81.1% and 76.1%, respectively.^[28] Our technical success rate was high, probably because we used colonoscopy and fluoroscopy to perform the procedures. Khot *et al.* conducted a systematic review and found that one out of 10 patients who underwent technically successful SEMS placement developed migration, with one out of four taking place in the first 3 days after the procedure.^[29] We observed migration in only one patient (9.09%), which occurred 2 days after SEMS placement. Watt *et al.* performed a systematic review to compare the health outcomes of emergency surgery

and elective surgery after SEMS placement as a bridge. They showed that elective surgery after SEMS placement had a higher rate of primary anastomosis than emergency surgery. Patients in the elective surgery group stayed in the hospital for a shorter time and had a lower colostomy rate than those in the emergency surgery group.^[30] Tilney *et al.* conducted a meta-analysis comparing SEMS bridge therapy and open surgery and found that patients in the SEMS bridge therapy group had a shorter hospital stay, lower stoma formation rates and fewer medical complications.^[31] We implemented SEMS placement as bridging therapy before surgery on three patients with the left colon malignancies. Those patients underwent elective surgery and developed no post-SEMS and post-surgery complications.

As far as we know, this study is the first to demonstrate the effectiveness of SEMS placed in all GI tract segments. This study had two limitations. First, this was a retrospective study. Second, we did not check on patients periodically after SEMS placement procedures.

CONCLUSION

Enteral feeding is critical in patients with malignancies. We think that SEMS placement is an effective palliative treatment option for the entire GI tract. The most important cause of the difference between the technical and clinical success rates of SEMS placement is the performance of the patient. Therefore, SEMS should be placed in eligible patients earlier, and enteral feeding should be sustained.

SEMS placement as a bridge to surgery provides more optimal conditions for surgery and reduces the risk of postoperative complications in patients with colorectal malignancies. In the near future, SEMS will be used more widely and cause fewer complications thanks to advances in stent technology and an increase in the number of studies in this field.

Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

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How to cite this article: Çağatay AK, Sayar S, Kılıç ET, Kahraman S, Öztürk O, Özdi K. The role of self-expandable metallic stents in the treatment of malignant strictures in all segments of the gastrointestinal tract. *Indian J Palliat Care* 2023;29:64-9.