

Experience of the National Institute of Cancer Research in managing obstructions of the gastric tract outlet and colon with self expanding metal stents (SEMS)

Ricardo Oliveros Wilches, MD,¹ Ricardo Sánchez, MD,¹ René Marcelo Escobar Pérez, MD.¹

¹ Gastroenterology Group, National Cancer Institute in Bogotá, Colombia

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Abstract

Objective: The objectives of this study were to study, learn from, and understand the experience in the use of self-expanding metal stents to manage malignant obstructions of the colon and to describe the demographic, clinical and pathological characteristics of patients at the National Cancer Institute (NCI) during the period from January 1, 2010 to September 30, 2012. **Methods:** This was an observational, descriptive, retrospective study of a series of cases that included patients with gastric tract or colon obstructions. Clinical characteristics, factors involved in the technical and clinical success of SEMS insertion, and the influence of these devices in morbidity and mortality are analyzed. **Results:** Ninety-six patients were included: seventy-three had duodenal SEMS and 23 had colorectal SEMS. The mean age of these patients was 63.7 years. Technical success for duodenal SEMS insertion was 97.2 % and clinical success was 93.1 %. Technical success and clinical success for colorectal SEMS were both 91.3%. Complications occurred in eight patients, three of whom required surgery. The average life expectancy after the procedure was 102 days for duodenal SEMS and 159 days for colorectal SEMS. No mortality secondary to procedures occurred. **Conclusions:** The insertion of a SEMS is a minimally invasive procedure that has proven to be an effective palliative treatment and an alternative for reducing ostomy complications and for reducing costs.

Keywords

Colon obstruction, self-expanding metallic stent, malignant tumor.

INTRODUCTION

Since the introduction of self-expanding metal stents (SEMS) in the 1990s (1-4), they have become a safe option for treatment of various obstructive processes in the gastrointestinal tract. Many patients in every part of the world who have had esophageal, duodenal, biliary or colon obstructions have been treated with SEMS to restore intestinal permeability (4-7).

Traditionally, palliation has been surgical, but due to its invasiveness and the generally poor condition of these patients, surgery has had a morbidity rate of 20% to 30 % (1, 2). Palliation of obstructions with metal stents has been reported to have promising results (3-12). In particular, the

use of duodenal stents has proven itself to be an effective non-surgical alternative that has lower rates of morbidity, shorter hospital stays and lower treatment costs.

SEMS may be used in two contexts: as a temporary preliminary measure in cancer treatment or as definitive palliative treatment. They also allow accurate staging of tumors in either case, and unlike emergency can be an elective treatment with presumably lower morbidity and mortality rates. In addition, the condition of patients with volume depletion and metabolic disorders secondary to obstruction of the gastrointestinal tract can be optimized faster and better with SEMS (9, 10). Placement of colonic SEMS has the particular and important advantage of avoiding creation of either temporary or permanent colostomies (11-13).

MATERIALS AND METHODS

The study included all patients at the gastrointestinal surgery service of the National Cancer Institute from January 1, 2010 to September 30, 2012 who fulfilled the following criteria. Patients were over 18 years of age, had had gastrointestinal or extra-gastrointestinal neoplasms which were histologically confirmed, and who had had an SEM inserted endoscopically in the duodenum or colon. A form was designed to record all epidemiological and clinical data including age; gender; place of origin; histological diagnosis; clinical stage; metastatic sites; location of stenosis; Karnofsky score; ECOG score; comorbidities; symptoms; prior chemotherapy and radiotherapy; need for endoscopic dilatation; SEMS insertion date; objective; number, size and type of stent; number of insertion attempts; complications; need for laparotomy; laparotomies performed; time between the procedure and return to oral feeding; time between the procedure and first stool; hospital stay; mortality and date of death or last check-up. All data was subsequently extracted from the SAP electronic medical record system.

The Ethics Committee at the National Cancer Institute where research was conducted approved the study protocol. Since the study included only reviews of medical records without risk from the ethical point of view, there was no need for informed consent. Privacy of patients' statistical data results were guaranteed.

Percentages were used to describe the categorical variables while numerical variables were analyzed with means, medians, and measures of dispersion such as standard deviation and interquartile range depending on the variable. Kaplan Meier survival functions were calculated to analyze mortality. Reference dates used were the date of stent insertion and the date of death. Cases without an indication of date of death were excluded from analysis. Data was analyzed using STATA software version 11.

At the National Cancer Institute, STEMS are inserted into the duodenum and colon endoscopically. Unlike other institutions, it is not routine to perform a GI series or barium enema to assess the length of the stenosis prior to the procedure. Also, no prophylactic antibiotics are used, and local anesthesia and conscious sedation are used instead of other anesthetic procedures. A 470cm super-stiff guide (Boston Scientific/Medi-tech) and dual channel therapeutic endoscopy equipment (Olympus, Tokyo) are used. Occasionally a pediatric diagnostic endoscope is used to bridge the obstructive lesion. A stent that is 4cm longer than the stenosis is always used to prevent tumor growth in the ends.

The use of endoscopic dilatation is up to the gastrointestinal surgeon that is performing the procedure and dilations are never performed after placement of the stent. Patients

are allowed only a clear liquid diet until four hours after the procedure is performed. After that patients are slowly allowed to eat and drink food and beverages that they can tolerate. Following placement of duodenal SEMS, patients are only allowed liquid diets to avoid obstruction by food debris whereas following placement of colonic SEMS patients are allowed to advance to soft foods. No radiological follow-ups are performed. Once the patient has oral tolerance and has produced stool, she or he is discharged and is followed up as an outpatient.

Technical success was defined as the proper placement of the stent at the planned site without complications within the first 72 hours after the procedure. Clinical success was defined as improvement in symptoms of obstruction, return to normal diet, ability to control stools, and maintenance of proper electrolyte status without the need for a surgical procedure after stent placement.

RESULTS

Ninety-six cases of SEMS insertion were collected between January 2010 and September 2012. Of these 73 were duodenal and 23 were colorectal. The average age of the patients was 63.7 (± 13.7) years, and ages ranged from 28 years to 95 years old. Fifty-seven were men (59.4%) and 39 were women (40.6%). Other epidemiological data are shown in Table 1.

In 93 cases, the stent was properly inserted in a single try. Ninety-four patients received uncoated nitinol Wallflex stents (Boston Scientific; Boston, MA USA) and 2 patients received uncoated nitinol Song stents (Tecnostent; Medellin, Colombia).

Duodenal stents were properly inserted in 97.2 % of the cases, and colorectal stents were properly inserted in 91.3%. Eight complications developed: four stents migrated, one rectal perforation occurred, one duodenal perforation occurred, one new obstruction was caused by food debris, and one stent fragmented. This case was treated by removal of the fragments. Sixteen months later a new stent was inserted.

Three patients required surgery. The patient who suffered the rectal perforation (which was proximal to the tumor) required a laparotomy, drainage of peritonitis, suturing of the rectum and a colostomy. Following surgery the patient was treated for cancer and underwent anterior resection of the rectum. The patient was still alive at the end of this study. Another case was a duodenal perforation distal to the tumor in a patient with lymphoma. This required a laparotomy, suturing of the duodenum and repositioning of the stent. The patient received chemotherapy for lymphoma and is still alive. The third case was a duodenal SEMS that migrated in a patient with lymphoma. This required a gastrojejunostomy. It was performed five days after the inser-

tion of the stent. Following surgery the patient was treated for cancer t and is still alive.

Table 1. Demographic, clinical and procedural information about SEMS insertion.

Variables		Value	Percentage
Age		63.7	
Gender	Male	57	59.4
	Female	39	40.6
Etiology	Gastric carcinoma	60	62.5
	Sigmoid carcinoma	4	4.2
	Rectal carcinoma	18	18.7
	Cholangiocarcinoma	3	3.1
	Others	11	11.5
Clinical Stage	II	4	4.2
	III	23	24
	IV	60	62.5
	No information	9	9.3
Metastasis location	Liver	30	50
	Lungs	7	11.6
	Others	11	18.3
Stenosis location	Gastric Body	2	2.1
	Antrum	18	18.8
	Pylorus	39	40.6
	Duodenum	12	12.5
	Sigmoid	4	4.1
	Rectum	19	19.8
	Others	2	2.1
Karnofsky Index		72	
ECOG		1.9	
Comorbidity	Heart failure	5	5.2
	High blood pressure	9	9.8
	Diabetes	3	3.1
	Heart disease	9	9.8
	Chronic renal failure	5	5.2
	EPOC	10	10.4
	Others	21	21.9
Symptoms	Dysphagia	11	11.4
	Nausea	71	74
	Vomiting	63	65.6
	Abdominal distention	19	19.8
	Absence of flatus	6	6.2
	Absence of stool	23	24
Prior chemotherapy		12	12.5
Prior radiation therapy		4	4.1
Objective of Stent	Palliative	81	84.4
	Prior to treatment	15	15.6
Dilation	Plugs	16	16.7
	Balloon	7	7.3
	Both	3	3.1
Number of Prosthetics	One	90	93.7
	Two	6	6.3

On average, patients began to ingest food orally at 0.77 (± 1.1) days and produced their first stools at 1.07 (± 0.9) days. Consequently, the overall clinical success of this procedure was of 91.7 %.

Of the patients who did not tolerate oral ingestion after the procedure, six died within a few days. One of had a duodenal stent that migrated. A gastrojejunostomy was then performed on this patient. Another patient had a malignant bowel obstruction that had not been diagnosed prior to the procedure. Only improved support care could be given. The average hospital stay was 3.16 (± 5.35) days with a range from zero to thirty days range. It is important to mention that 19 patients (19.7%) were discharged from the institution on the same day that their stents were placed, and 29 patients were discharged the next day (30.2%) (Figure 1).

The technical and clinical results mentioned above are shown in Table 2.

Table 2. Complications, clinical success and average survival rates.

	Duodenal n=73	%	Colonic n=23	%
Successful insertion of stent	71	97.2	21	91.3
Complications	4	5.4	4	17.4
	Perforation: 1		Perforation: 1	
	Migration: 2		Migration: 2	
	Obstruction: 1		Fragmentation: 1	
Need for surgery	2	2.7	1	4.3
Oral feeding after procedure	67	91.8	21	91.3
Production of stool	69	94.5	21	91.3
Clinical success	--	93.1	--	91.3
Hospital stay	3.1 days		3.1 days	
Average length of survival	102 days		159 days	

The analysis of survival or mortality of patients who underwent these procedures showed no information about mortality in 18 cases while 18 patients had survived until the time of completion of the study (9 duodenal SEMS and 9 colonic SEMS). There were no deaths related to this procedure. Deaths during the first 30 days were due to underlying diseases and comorbidities.

Of the eight cases in which complications were present 6 still survived at the time of completion of the study and in 2 cases (migration and obstruction by food debris) mortality information is unknown.

Deaths were reported in 58 cases with a tracking range between zero and 34.2 months. The average survival time was 102 days for patients with duodenal SEMS (range

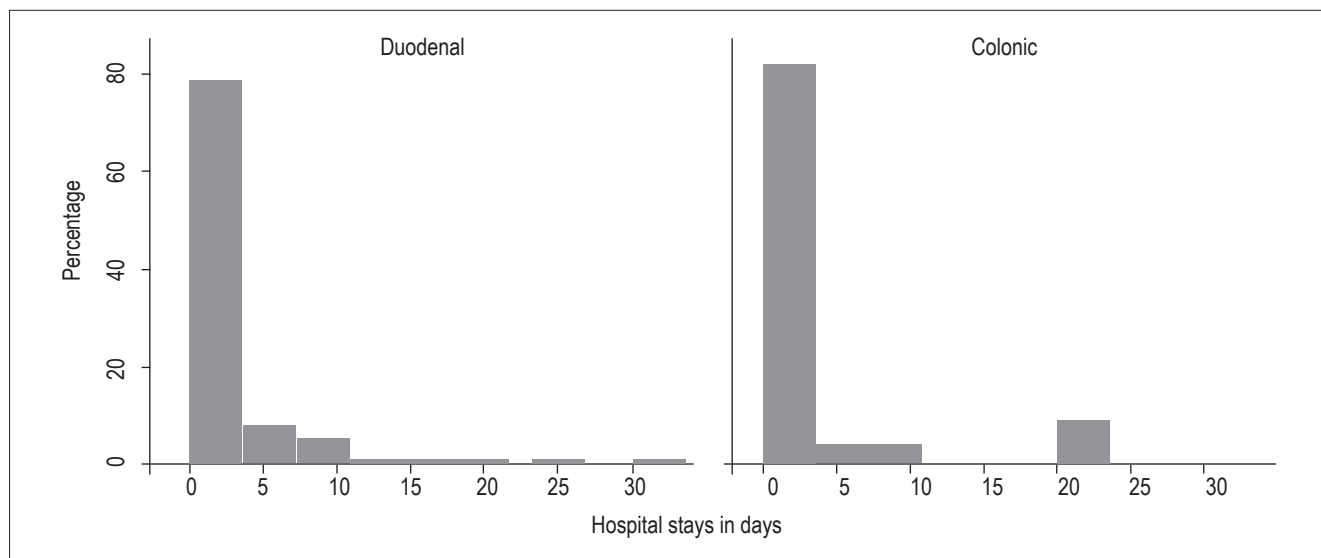


Figure 1. Hospital stay after SEMS insertion procedure.

1-743) and 159 days (range 17-577) for colorectal SEMS. This shows a rate of 12.9 deaths per 100 patients/month (95% CI: 9.9 to 16.7 months), which is illustrated as a Kaplan-Meier overall survival curve in Figure 2.

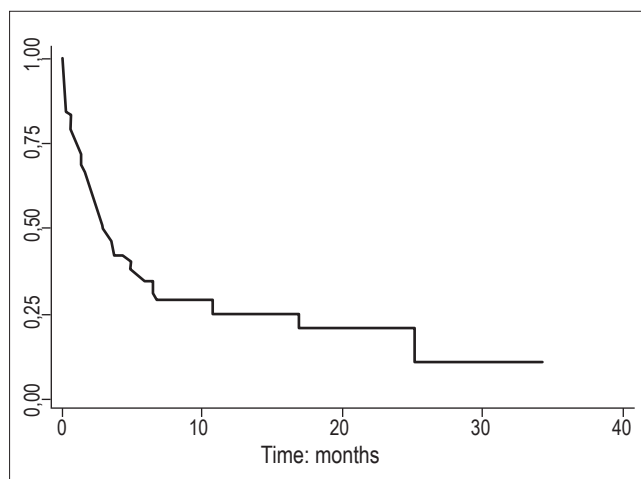


Figure 2. Kaplan-Meier overall survival curve.

Details of mortality rates according to stent location are shown in Table 3 while survival curves are shown in Figure 3 where we can observe an improved survival rate in patients with colonic SEMS (logarithmic range test, $\chi^2=6.83$; $p=0.0089$).

Table 3. Mortality rate depending on SEMS type.

Stent	Person-time	Deaths	Rate	LI – 95% CI	LS – 95% CI
Duodenal	288.9	49	16.96	12.81	22.44
Colonic	160.7	9	56.0	2.91	10.76
Total	449.6	58	12.9	9.97	16.68

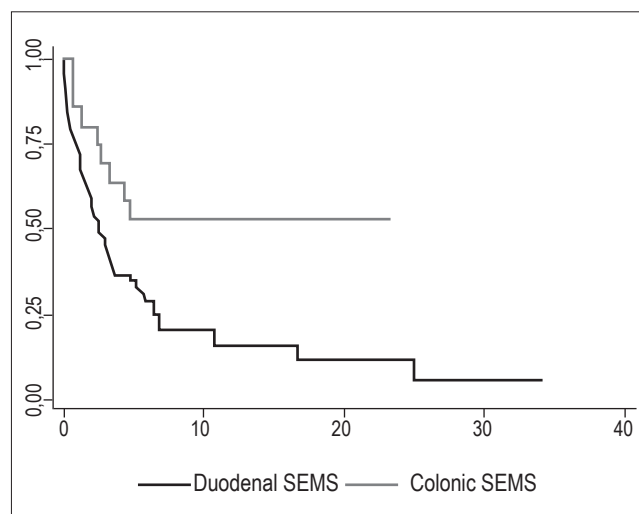


Figure 3. Kaplan-Meier survival curves.

DISCUSSION

Duodenal SEMS

Placement of a SEMS has had good results in palliation of malignant gastroduodenal obstructions because it avoids the use of surgical shunts, allows a quicker return to oral feeding, has lower costs and shorter hospital stays, and has low morbidity and mortality rates. Malignant obstructions develop in 15% of patients with unresectable tumors in the antropyloric region. The morbidity rate for surgical bypasses in these cases is 20% to 25% with a 2% perioperative mortality rate (14).

Gastroenteroanastomosis is a gastric bypass method that can be done either through laparotomy or laparoscopy. It has been traditionally regarded as the preferred method of palliation because it achieves technical success in 90 % of cases and clinical improvement in 78%. However, 59 % of patients are left with delayed gastric emptying while patients who receive a stent can eat the next day in over 60 % of cases (14).

In our study, patients were able to resume oral feeding sooner than had previously been reported: 91.8 % of the patients returned to oral feeding while 94.5 % produced stool. Therefore, the clinical success of the insertion of duodenal SEMS in our study is 93.1 % which far exceeds the reported clinical success rates for surgical bypasses and duodenal stent insertion (14, 15).

The technical success rate for inserting duodenal SEMS reported in the literature is about 95 % (15). In our study, the technical success rate was inserted 97.2 %. In contrast to some groups in other institutions that compulsorily required fluoroscopy to achieve high success rates, it should be noted that we do not use fluoroscopy at the Instituto Nacional de Cancerología (16).

It is worth mentioning that because of administrative constraints in the institution where this study was conducted, fluoroscopy was not always available. One result is that the gastrointestinal surgeons have accumulated extensive experience in stent insertion relying on careful attention to anatomical landmarks and use of pediatric equipment when needed.

Complications related to stent insertion include bleeding, food occlusion, perforations, necrosis of tumors, fistula formation and the growth of tumors within the stent causing obstructions (17).

Failure of an expandable stent after placement is due to progression of the disease in 61 % of cases, stent migration in 20 %, and complications related to the procedure other than to the stent itself or its expansion in 15 % of the cases. It is known that in up to 17 % of patients the tumor grows into the stent or its ends. Bile duct blockage is much rarer, occurring in less than 1% of cases (18). In this study, the overall complication rate for cases of duodenal SEMS was

showed 5.4% which is much lower than those reported in the literature.

The literature suggests that hospital stays may extend to two weeks when bypass surgery is performed, while the average hospital stay for patients who undergo stenting is 3.1 days (19, 20). Our study's average hospital stay of 3.1 days is exactly the same as that reported in the literature.

Median survival time after placement of gastroduodenal stents is 90 days and up to 80 % of patients live at least 1 month. It has been reported that the Karnofsky index improves by 40% to 60% one month after insertion of an expandable stent (21). In our study, patients who received a SEMS with a palliative aim had average survival times of 102 days. From this information, it can be deduced that patients should be carefully selected, as has been recommended in other articles, since the use of SEMS is not recommended for patients whose life expectancies are less than a month.

Colonic SEMS

It is known that 80 % of obstructions are due to colonic neoplasms and that between 8 and 30 % of colon cancer cases begin as acute obstructions. Over 80% of the neoplasms are located in the left colon and the rectum. The area which is most frequently obstructed is the splenic flexure, but tumors in other segments of the left colon form obstructions 25% of the time (22). Since obstructions occur in advanced stages of the disease, patients with malignant colonic obstructions have higher risks of treatment failing and lower survival rates than do patients who do not present obstructions.

Urgent colorectal surgery has morbidity rates between 10 and 36 % and mortality rates between 6 and 30%. Colostomies have large high impacts on quality of life, even more so when 60% of colostomies become permanent. In addition, curative resection of colorectal cancer is not possible in up to 25 % of cases due to the extent of tumor invasion, distal metastasis or severe comorbidities (25).

Placement of metallic colorectal stents has a high success rate, and improvement of obstructions has been reported in 70% to 95 % of cases. Repici et al. reported that the placement of stents was possible and successful in 93% of cases and concluded that their use is safe and effective. Technical success rates vary between 90 and 100 %. The average procedure time is 75 minutes with a range from 28 to 180 minutes. Intestinal decompression is observed within 24 hours in approximately 85 % of cases and within 96 hours in 92% of cases (26).

A systematic review of 29 clinical trials with 598 stent inserts between 1990 and 2000 reported 336 stents inserted for palliation and 262 as bridges to elective surgery.

Technical success, defined as successful stent placement, we reported in 551 patients (92 %) and clinical success, defined as colonic decompression within 96 hours without further intervention, was achieved in 525 of 598 attempts (88%). Intestinal perforations occurred in 4% of cases, SEMS migration in 10%, obstruction due to tumor growth in 10% and bleeding in 5% (27).

A study by Castaño et al. found a 6% mortality rate when obstructions were resolved which is much lower than the 22% mortality rate which is accepted for surgical procedures. In addition, the study reported a 12% complication rate which is well below the 20% to 25 % rate recognized for emergency surgery for obstructions in the left colon (28).

A recent meta-analysis that compared the results of stenting against those of surgery for colonic obstructions showed numerous advantages for SEMS. These include the 93% technical success rate, shorter hospital stays (7.7 days $p < 0.001$), lower rates mortality ($p = 0.03$), fewer complications ($p < 0.001$) and fewer ostomies at any time during follow-up (OR 0.02, $p < 0.001$). Survival rates are not affected when stents are used as a bridge to later surgery (29).

Our study's technical and clinical success rate for insertion of colonic SEMS was 91.3 % figure which is within the range reported in clinical studies.

Four out of 23 cases (17.4%) in our study overall complications, but it should be mentioned that two cases of migration of colonic SEMS occurred long after procedures had been done. This complication rate is significantly lower than the overall rate of complications of 29 % reported in the systematic review and meta-analysis mentioned above (7, 29). In our study there were no procedure-related deaths. Also, the average hospital stay was 3.1 days which is significantly less than those reported in other studies (30, 31).

In our study, the median survival time of patients who died after insertion of a colorectal stent was 159 days. This far exceeds that reported in literature because in cases in which colorectal obstructions are not resolved mortality is certain, and, if a colostomy is performed, perioperative mortality can be as high as 22 % (28).

CONCLUSIONS

The insertion of a self-expanding metal stent is a strategy that provides satisfactory results for palliation of malignant gastroduodenal and colorectal obstructions. It has very low mortality rates and a continuously declining complication rate. Over the years, stenting has surpassed the surgical procedures used to be commonly considered for these patients. This study clearly demonstrates these great benefits can even include success rates higher than those presented in the national and international literature.

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