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Outcome of endoscopic self-expandable metal stents in acute malignant colorectal obstruction at a tertiary center

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ABSTRACT
Background: Malignant colorectal obstruction (MCRO) by advanced colonic cancer occurs in 8-13% of colonic cancer patients. Emergent surgery carries a high mortality and morbidity risk. Endoscopic self-expanding metal stents (SEMS) may be used in acute MCRO.

Aim: Evaluate clinical outcome of SEMS in acute MCRO and efficacy of SEMS placement considering fluoroscopy guidance.

Methods: Retrospective study of patients with acute MCRO that placed SEMS in a 3 years period.

Results: SEMS were placed in 47 patients, followed-up for a median time of 150 days. The intent of stenting was bridge to definitive surgery in 40% of the patients (n = 19) and palliation in the remaining 60% (n = 28). The location of the tumor did not influence the presence of lymph node involvement (p = 0.764) nor metastasis (p = 0.885). Mortality rate at year 1 was 61%. Survival was significantly higher in patients submitted later to combination therapy compared to chemotherapy, surgery or symptomatic treatment (p < 0.001). Fluoroscopy was used in 57% of the procedures.
Clinical success was 79%. A second SEMS was needed during the procedure in 6% of the patients. Rate of early and late complications was 11% and 5%, respectively. Fluoroscopy guidance did not influence the occurrence of immediate ($p = 0.385$), early ($p = 0.950$) or late complications ($p = 0.057$). Thirty-three percent of patients underwent surgery at a later stage, with neo-adjuvant therapy in 18%.

**Conclusions:** SEMS provide a relative safe and successful treatment in a palliative or bridge-to-surgery indication. No significant differences were found in SEMS placement success, early complications or late complications considering fluoroscopy guidance.

**Key words:** Malignant colorectal obstruction. Self-expanding metal stents. Fluoroscopy.

**INTRODUCTION**
Colorectal cancer is among the most common malignant diseases, with a global incidence of 1 million new cases per year, ranking fourth in frequency in men and third in women (1). Malignant colorectal obstruction (MCRO) caused by advanced colonic cancer occurs in 8%-13% of colonic cancer patients (2,3), however, the management of this clinical condition remains controversial (4). Patients with malignant MCRO tend to have advanced disease and be poor surgical candidates. Conventional therapies for relieving malignant colorectal obstruction include surgical resection (potentially curative) or palliative colostomy. Resection is ideally carried out as a single-stage procedure, with anastomosis to restore bowel continuity, but multistage procedures may also be undertaken, first a resection and stoma formation, followed by restoration of continuity. However, a significant proportion of patients (up to 50%) receiving a staged procedure never undergo reversal of the colostomy (5). In the emergency setting, surgery carries a high mortality (15%-20%) and morbidity (45%-50%) risk, with increased prevalence of intensive care stay, infections, and complications related to stomas (1).

Endoscopic self-expanding metal stents (SEMS) may be used in acute MCRO, emerging as an alternative to surgery. In the early 1990s, SEMS were first used for palliation of advanced malignancy (6), being later used to relieve acute obstruction,
as a “bridge” to elective surgery (7). Although effectiveness of the use of colonic SEMS in a palliative or bridge-to-surgery indication is broadly recognized, some have questioned the safety of colonic stenting, particularly as it pertains to colonic perforation (8,9). Recent prospective randomized controlled trials have indicated that SEMS may be less successful at relieving obstruction than indicated from nonrandomized studies (10).

The majority of SEMS are inserted through the endoscope with the use of fluoroscopic guidance, however, the best way for stent placement has not yet been clarified. The aim of this study was to evaluate the clinical outcome of SEMS in patients with acute MCRO and assess efficacy of SEMS placement considering fluoroscopy guidance.

MATERIAL AND METHODS

Retrospective study based on medical records from 47 consecutive patients with acute MCRO that placed SEMS in a tertiary center between January 2011 and December 2013. Acute MCRO diagnosis was defined as the presence of obstructive symptoms and radiological or endoscopic findings of malignant MCRO. SEMS were placed either for palliative or bridge-to-surgery intent. All patients performed a contrast-enhanced CT previous to SEMS placement in order to define the level of the obstruction and provide correct local and distal staging. Perforation was ruled out in all cases. All the neoplasms were located between splenic flexure and 10 cm of the anal verge. Exclusion criteria were previous colonic stent, enteral ischemia, suspected or impending perforation, intra-abdominal abscess or contraindication to endoscopic treatment. All the stents were uncovered (Hanarostent M.I.Tech Co., Inc, Seoul, South Korea).

All the stents were placed under direct visualization, with aid of fluoroscopy in 57%. In the other procedures, ultrathin endoscopes were used. Sedation was used in the majority of the procedures (85%). The length of the stricture was measured fluoroscopically (57%) or endoscopically and the length of stent needed to cross the stricture was determined.

All clinical data was obtained from electronic medical records to assess eligibility for the study. Demographic data was collected including age, location and type of
obstructing lesion, intention of stent (palliation versus bridge to surgery), lymph node invasion and metastasis. Clinical success was defined as the ability to pass stool and tolerate oral diet. Complications of stenting including perforation, migration, re-obstruction and mortality were recorded, as well as patients who were successfully bridged to surgery, or palliated, depending on the specific intent of the stent. Early complications were defined as those occurring in the first 30 days after stent placement and late complications were defined as those occurring after the first 30 days of stent placement. Successful palliation was defined as the patient still being alive, or death without re-obstruction or complication of stenting, at the time of data collection.

Statistics
Categorical variables were described through absolute and relative frequencies and continuous variables were described as mean and standard deviation, median, percentiles, minimum and maximum. Hypotheses were tested about the distribution of continuous variables with non-normal distribution, by using the nonparametric Mann-Whitney and Kruskal-Wallis test, depending on the nature of the hypothesis. Cumulative survival was evaluated using survival analysis. The cumulative probabilities of survival were estimated using the Kaplan-Meier method by using LogRank and Breslow tests. All the reported p values were two-sided, and p values of < 0.05 were considered statistically significant. All data were arranged, processed and analyzed with SPSS® v.20.0 data (Statistical Package for Social Sciences).

RESULTS
Population
Baseline demographic characteristics of all 47 patients are shown in table I. Mean age at diagnosis was 71±13 years old, with patients being followed for a median time of 150 days (P25-75: 23-437). The distal edge of the tumor was located in the descending colon in 13% (n = 6), in the sigmoid colon in 62% (n = 29) and in the rectum (10 cm above the anal verge) in 25% (n = 12). Eighty-one percent of patients (n = 38) had lymph node invasion and 72% (n = 34) had metastatic disease.
Tumor location did not influence the presence of lymph node involvement \((p = 0.764)\) nor metastasis \((p = 0.885)\).

The intent of stenting was bridge to definitive surgery in 40% of the patients \((n = 19)\) and palliation in the remaining 60% \((n = 28)\). Mortality rate at the first year was 61% \((n = 29)\). Survival was significantly higher in patients submitted later to combination therapy compared to chemotherapy, surgery or symptomatic treatment \((p < 0.001)\) (Fig. 1).

**SEMS procedure**

All the SEMS were placed under endoscopic guidance. Fluoroscopy was used in 57% of the procedures \((n = 27)\), with ultrathin endoscopes being used in the remaining procedures, in order to traverse the stenosis. No patient performed dilation previous to SEMS placement. A second stent was needed in 6% of patients \((n = 3)\) due to migration during deployment. The rate of early and late complications was 11% \((n = 5)\) and 5% \((n = 2)\), respectively. Fluoroscopy guidance did not influence the occurrence of immediate \((p = 0.385)\), early \((p = 0.950)\) or late complications \((p = 0.057)\) (Fig. 2).

Thirty-three percent of patients \((n = 8)\) underwent surgery at a later stage, with neo-adjuvant therapy in 18%. The median time interval to surgery when SEMS was used as a bridge to elective surgery was 10 days \((P_{25-75}: 5-20)\). Seventy-eight percent of the patients had conditions to perform the treatment proposed by the oncologic multidisciplinary team.

**Bridging stents \((n = 19)\)**

Of the patients intended to bridge to surgery, 15/19 (79%) were successfully bridged to surgery, with the remaining 4 performing only adjuvant therapy. The distal edge of the tumor was located in the descending colon in 16% \((n = 3)\), in the sigmoid colon in 58% \((n = 11)\) and in the rectum in 26% \((n = 5)\). Fifty-three percent of patients \((n = 10)\) had lymph node invasion and 32% \((n = 6)\) had metastasis. Five patients (26%) were later submitted to a second surgery (metastasectomy). Five patients were death at time of data collection, with mortality rate at year 1 being 16%.
Fifty-three percent of the patients (n = 10) placed SEMS under fluoroscopy guidance. One patient had stent migration during deployment, with need of a second stent. Three patients had early complications, including 1 stent migration (with need of a second stent) and 2 colonic perforations, with need of emergent segmental colectomy and derivative colostomy. There were no late complications. Fluoroscopy did not influence the occurrence of immediate, early or late complications (Table II).

Palliative stents (n = 28)
Of the patients stented for palliation, 22/28 (79%) were successfully palliated at a mean follow-up of 144 (1-1,274) days. The distal edge of the tumor was located in the descending colon in 11% (n = 3), in the sigmoid colon in 64% (n = 18) and in the rectum in 25% (n = 7). All the patients had metastatic disease. All the patients were death at time of data collection, with mortality rate at year 1 being 93%. Sixty-one percent of the patients (n = 17) placed SEMS under fluoroscopy guidance. Two patients (7%) had stent migration during deployment, with need of a second stent, and two patients (7%) had colonic perforation during the first 30 days. One of them was managed non-operatively and died on post-stent day 3, with the other having a segmental colectomy and derivative colostomy. Two patients (7%) had late complications, including one stent migration and 1 tumoral ingrowth, with placement of a second stent in both procedures. Fluoroscopy did not influence the occurrence of immediate, early or late complications (Table II).

DISCUSSION
Patients with acute MCRO tend to have advanced disease and be poor surgical candidates. SEMS have been increasingly used in colonic obstruction, both as a means of palliation, avoiding ostomy creation and as a bridge to safer elective surgery in acute obstruction. The evidence supporting the safety and efficacy of colonic stents comes primarily from retrospective studies. Systematic reviews of this data have reported high rates of clinical success (91-92%) and low rates of severe complication such as perforation (4-4.5%), migration (11%), and re-obstruction (7-12%) (11,12). Recent guidelines from European Society of Gastrointestinal Endoscopy (13) state that SEMS placement, as a bridge to elective surgery, is not
recommended as a standard treatment of symptomatic left-sided acute MCRO unless there is an increased risk of postoperative mortality; SEMS placement is recommended as the preferred treatment for palliation of malignant colonic obstruction.

In our study, SEMS provided a relative safe and successful treatment in bridge-to-surgery indication (79%) with a low complication rate, significantly reducing the mortality and morbidity of emergency surgery, when compared to the literature results. Stent migration during deployment is a well-known immediate complication, which may occur, with or without fluoroscopy guidance, due to the opening of the distal edge of the stent to close to the distal edge of the tumor. To avoid it, there should be at least a margin of 2 cm between the distal edge of the stent and the distal edge of the tumor. In our opinion, when migration occurs, we should not dilate nor replace the first stent due to the risk of perforation. It is relatively easy to resolve this situation, with the placement of a second stent (stent-in-stent). Early complications included 1 stent migration and 4 colonic perforations and late complications included 1 stent migration and 1 tumoral ingrowth. Stent migration is due to the same reason stated above. Colonic perforations are the most worrisome complication from colonic stenting. Perforation rates in the literature (14) for palliation and bridge to surgery are not significantly different and over 80% of them occurs within 30 days of stent placement. They are usually related to concomitant chemotherapy, steroids or radiotherapy, however, none of our patients had those risk factors. Nevertheless, the overall perforation related mortality is far less than that of patients undergoing emergency surgery for bowel obstruction. Tumoral ingrowth is related to the stents being uncovered and may be managed by argon plasma fulguration of placement of a second stent. The efficacy and safety of colonic stenting was very similar to the most recent systematic review and meta-analysis, based only on randomized controlled trials (15), which reported a mean technical success rate of 77%, with a postoperative mortality of 11%. However, this must be balanced with the oncological outcome in patients with a curable colonic cancer, particularly following stent perforation. SEMS’ benefit is more obvious in the palliative setting, allowing 79% of the patients to avoid further need of palliation for bowel obstruction, reducing mortality and morbidity.
As a limitation of the study, we realize that our results report data only from a tertiary and single center, being retrospectively collected. Due to the small number of cases, the lack of association between variables may be due to a type II error. However, there are no previous studies comparing endoscopy and fluoroscopic guidance versus solely endoscopy for stent deployment. No significant differences were noticed regarding success rate of stent placement, early complications and late complications considering fluoroscopy guidance. This may be explained by the use of ultrathin endoscopes, enabling to traverse the stenosis, facilitating placement of the stent, and allowing assessment of the colonic mucosa integrity located upstream the stenosis (16). This way ultrathin endoscopes may be considered as an alternative in centers where fluoroscopy is not available.

REFERENCES


Table I. Baseline demographic characteristics of all 47 patients according to stent intent, fluoroscopy guidance and occurrence of immediate, early and late complications during SEMS placement

<table>
<thead>
<tr>
<th></th>
<th>All stents (n = 47)</th>
<th>Bridging stents (n = 19)</th>
<th>Palliative stents (n = 28)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (median ± standard deviation)</td>
<td>71 ± 13</td>
<td>69 ± 13</td>
<td>73 ± 13</td>
</tr>
<tr>
<td>Tumor location (n; %)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Descending colon</td>
<td>6 (13%)</td>
<td>3 (16%)</td>
<td>3 (11%)</td>
</tr>
<tr>
<td>Sigmoid colon</td>
<td>29 (62%)</td>
<td>11 (58%)</td>
<td>18 (64%)</td>
</tr>
<tr>
<td>Rectum</td>
<td>12 (25%)</td>
<td>5 (26%)</td>
<td>7 (25%)</td>
</tr>
<tr>
<td>Lymph node invasion (n; %)</td>
<td>38 (81%)</td>
<td>10 (53%)</td>
<td>28 (100%)</td>
</tr>
<tr>
<td>Metastasis (n; %)</td>
<td>34 (72%)</td>
<td>6 (32%)</td>
<td>28 (100%)</td>
</tr>
<tr>
<td>Fluoroscopy (n; %)</td>
<td>27 (57%)</td>
<td>10 (53%)</td>
<td>17 (61%)</td>
</tr>
<tr>
<td>Immediate complications (n; %)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stent migration</td>
<td>3 (6%)</td>
<td>1 (5%)</td>
<td>2 (7%)</td>
</tr>
<tr>
<td>Early complications (n; %)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stent migration</td>
<td>1 (2%)</td>
<td>1 (5%)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Colonic perforation</td>
<td>4 (9%)</td>
<td>2 (11%)</td>
<td>2 (7%)</td>
</tr>
<tr>
<td>Late complications (n; %)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stent migration</td>
<td>1 (2%)</td>
<td>0 (0%)</td>
<td>1 (4%)</td>
</tr>
<tr>
<td>Tumoral ingrowth</td>
<td>1 (2%)</td>
<td>0 (0%)</td>
<td>1 (4%)</td>
</tr>
<tr>
<td>Clinical success (n; %)</td>
<td>37 (79%)</td>
<td>15 (79%)</td>
<td>22 (79%)</td>
</tr>
<tr>
<td>Mortality at year 1 (n; %)</td>
<td>29 (61%)</td>
<td>3 (16%)</td>
<td>26 (93%)</td>
</tr>
</tbody>
</table>
Table II. Immediate, early and late complications with ou without fluoroscopy guidance in bridging and palliative stents

<table>
<thead>
<tr>
<th></th>
<th>Bridging stents (n = 19)</th>
<th>Palliative stents (n = 28)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Fluoroscopy guidance</td>
<td>Without fluoroscopy guidance</td>
</tr>
<tr>
<td>Immediate complications</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Early complications</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>Late complications</td>
<td>0</td>
<td>0</td>
</tr>
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</table>

Fig. 1. Cumulative incidence of survival as a function of treatment. Survival was higher in patients submitted later to combination therapy compared to chemotherapy, surgery or symptomatic treatment ($p_{\text{Log Rank}} < 0.001$; $p_{\text{Breslow}} < 0.001$).
Fig. 2. Adverse events regarding stent deployment with or without fluoroscopy guidance. There were no statistical significant differences in the success rate of stent placement (A), early complications (B) and late complications (C).