Palliative Management of Malignant Rectosigmoidal Obstruction. Colostomy vs. Endoscopic Stenting. A Randomized Prospective Trial

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Abstract. Background: Colostomy was the palliative treatment of choice in patients with malignant unresectable rectosigmoid obstruction. Palliative endoscopic treatment of malignant rectosigmoidal obstruction by endoluminal self-expanding metallic stents is nowadays a well-established procedure. Patients and Methods: Twenty-two patients, referred for treatment with diagnosis of malignant obstruction of the rectosigmoid region presenting an advanced unresectable stage, were enrolled. Patients were randomly assigned into two treatment groups (endoscopic stenting vs colostomy) according to random-number tables. The length of procedure, morbidity and mortality rate, canalization of the gastrointestinal tract, restoration of oral intake and hospital stay were assessed. Results: Endoscopic group: The median length of procedure was 36 minutes. No death was observed. None of the patients reported complications. All patients resumed bowel function within 24 hours. The restoration of oral intake was achieved one day after stent placement. The median hospital stay was 2.6 days. Colostomy group: The median length of the operation was 75.4 minutes. No mortality was reported. In 1 patient (9.1%) stoma prolapse was observed 3 days after the operation. Canalization of the gastrointestinal tract was restored when colostomy was opened (on postoperative day 3). All patients were able to resume oral feedings on postoperative day 3. The median hospital stay was 8.1 days. Conclusion: There were no statistically significant differences between the 2 groups concerning morbidity and mortality. Endoscopic stenting was significantly more effective concerning operative time, restoration of bowel function and oral intake and median hospitalization. Our results would suggest that endoscopically placed metal stents offer an effective alternative to surgical palliation in patients suffering from unresectable malignant rectosigmoidal obstruction.

In most patients with advanced colorectal cancer (peritoneal carcinomatosis, multiple metastases, local unresectability) the only treatment option is often permanent colostomy. Rectosigmoidal obstruction due to a malignant tumor usually requires emergency surgical treatment and colostomy is often unavoidable.

The placement of a metallic stent in the colon was first published as a palliative measure in 1991 by Dohmoto (1). Tejero and colleagues (2) introduced the technique of placing the stent under fluoroscopic control before surgery. Since then, a number of reports have appeared suggesting a role of self-expanding metallic stents (SEMS) in the management of acute malignant left-sided colonic strictures (3-6). This procedure is relatively simple and safe and allows prompt relief of obstructive symptoms both for palliative purposes in unresectable tumors and for elective single-stage surgery, avoiding the need for emergency surgery or colostomy (7). Another application is placement of stents in patients with anastomotic colorectal strictures (8-11).

This report describes the authors' experience in the use of SEMS for the management of malignant obstruction of the rectosigmoidal region. To our knowledge, there is no published report of a randomized trial comparing SEMS with surgical palliation. The aim of this study was to compare the results of endoscopic stenting vs. palliative colostomy in a prospective, randomized, unicenter trial.

Patients and Methods

In the period between January 2001 and May 2003, a total of 22 patients with malignant rectosigmoidal obstruction were referred to the Department of Surgery "Pietro Valdoni" of the University of Rome "La Sapienza", Italy. There were 13 men and 9 women, the mean age was 77.2±3.3 years in the stenting group and 76±4.6 years in the colostomy group.

All 22 patients were examined by means of colonoscopy and biopsy. The site of obstruction was located in the sigmoid colon (8 patients) and in the rectum (14 patients). In all cases the tumor was considered nonresectable. CT-scan evaluation was performed.
patients had multiple liver metastases and 4 patients had lung metastases; furthermore, 9 patients had advanced local disease. None of the patients needed urgent surgery. The patients were randomly assigned into two treatment groups according to random-number tables. Group I comprised 11 patients who underwent placement of SEMS and group II the remaining 11 patients in whom colostomy was performed. The selection criteria for SEMS placement included patients with advanced unresectable disease, peritoneal carcinomatosis and/or multiple parenchymatous metastatic disease.

Informed consent had been obtained from each patient.

Endoscopic stenting. According to ASA classification, 4 patients were ASA 1 (healthy patients), 6 patients were ASA 2 (patients suffering from moderate systemic disease) and 1 patient was ASA 3 (patients suffering from severe systemic disease).

In the 11 patients included into the endoscopic group a self-expanding metallic stent (Precision Stent System. Microvasive, Boston Scientific Corporation), measuring 9-12 cm in length, was passed through the stricture, with distal inner above the proximal tumor margin. The length of the stent was 9 cm in 8 patients and 12 cm in 3 patients. The site of obstruction was located in the rectum (7 patients) and in the sigmoid colon (4 patients). The guidewire was inserted through the channel of the endoscope and its position was confirmed by fluoroscopy. The insertion and deployment of the stent were checked by both endoscopic and fluoroscopic guidance. Abdominal plain radiographs were obtained in the day after stent placement.

Colostomy. According to ASA classification, 5 patients were ASA 1, 5 patients were ASA 2 and 1 patient was ASA 3. The obstructing lesions were located in the rectum (7 patients) and in the sigmoid colon (4 patients).

In the 11 patients treated by elective surgery, preoperative mechanical bowel preparation could be achieved without complications. A right transverse colostomy was made under general anaesthesia. All patients were not given oral feedings before stoma opening.

### Table I. Endoscopic stenting vs. colostomy. Results.

<table>
<thead>
<tr>
<th></th>
<th>Endoscopy</th>
<th>Surgery</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. of pts</td>
<td>11</td>
<td>11</td>
</tr>
<tr>
<td>Sex</td>
<td>6 males, 5 females</td>
<td>7 males, 4 females</td>
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<tr>
<td>Mean age</td>
<td>77.2</td>
<td>76</td>
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<tr>
<td>ASA</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>4</td>
<td>6</td>
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<tr>
<td>2</td>
<td>6</td>
<td>5</td>
</tr>
<tr>
<td>3</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Mean operative time</td>
<td>36.8</td>
<td>75.4</td>
</tr>
<tr>
<td>Mortality</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Complication</td>
<td>0</td>
<td>9.1%*</td>
</tr>
<tr>
<td>Mean time for canalization of the gastrointestinal tract and for oral intake (days)</td>
<td>1</td>
<td>3.1</td>
</tr>
<tr>
<td>Median hospital stay (days)</td>
<td>2.6</td>
<td>8.1</td>
</tr>
</tbody>
</table>

* Colostomy prolapse

The results are summarized in Table I.

### Endoscopic group. The procedure succeeded in relieving the obstruction in all patients, without mortality or complications. All patients resumed bowel function within 24 hours. The restoration of oral intake was achieved one day after stent placement without any discomfort or need for infusional support.

The median time required for stent placement was 36±15.0 minutes (range 15-55). The median hospital stay was 2.6±0.8 days (range 2-4).

### Colostomy group. No mortality was observed. One patient (9.1%) had colostomy prolapse 3 days after the operation. Canalization of the gastrointestinal tract was restored when colostomy was opened (on postoperative day 3), except for one patient (on postoperative day 4) (mean 3.1±0.3). Therefore, all patients (except for one individual in whom canalization of the gastrointestinal tract and oral intake were restored on postoperative day 4) were able to resume oral feedings on postoperative day 3 (mean 3.1±0.3).

The mean operative time was 75.4±26.1 minutes (range 35-110). The median hospital stay was 8.1±0.9 days (range 7-10).

### Statistical analysis. There were no statistically significant differences between endoscopic and surgery groups concerning ASA criteria, sex or age. There were no statistically significant differences between the 2 groups even concerning morbidity and mortality.

Endoscopic stenting was significantly more effective concerning operative time (p<0.003), canalization of the gastrointestinal tract and oral intake (p<0.0001) and median hospitalisation (p<0.0001).

### Discussion

Colorectal cancer is the most common cause of large bowel obstruction and between 7% and 29% of patients present with acute clinical picture. Almost 90% of these strictures are located at or distal to the splenic flexure (12-15). It represents a surgical emergency associated with a high degree of morbidity and mortality due to the commonly poor condition of patients (underlying disease, dehydration and electrolyte...
imbalance(16,17). Mortality and morbidity rates for emergency surgical decompression are 15-20% and 50%, respectively, as opposed to a mortality rate of 0.9-6% when patients undergo elective surgery (18,19). Furthermore, colostomy may be permanent in many cases, causing considerable psychological distress and significant impact on the patient's daily life.

To avoid surgery and the creation of a stoma in these patients, non-operative alternatives have been attempted to obtain a patent lumen for the passage of stool. Following the success of biliary and oesophageal stenting, in recent years the procedure has been applied in the gastrointestinal tract, including the treatment of malignant and postoperative strictures. The distal location of the majority of lesions allows for relatively easy insertion and deployment of the stent. Transanal SEMS placement is a promising treatment option in the management of acute malignant colorectal obstruction (20-25).

In patients with limited life expectancy due to unresectable tumor or progressive metastatic disease, stent placement has been shown to be effective for the relief of obstructive symptoms, circumventing the need for palliative colostomy (26-29). As a bridge to elective surgery in patients with resectable disease, SEMS allows a complete preoperative evaluation and a mechanical bowel preparation (25, 29, 30). After the first publication by Dohmoto (1), several authors have reported the cost-effectiveness and safety of SEMS in the management of rectosigmoidal strictures due to non-resectable tumors (10, 23).

Stenting by metallic endoprostheses has the advantage that reocclusion times are increased over laser and that obstruction by tumor ingrowth can often be easily treated by additional laser ablation or by further stenting either in addition to or within the original device (31). SEMS placement can be performed fluoroscopically or under colonoscopic and fluoroscopic assistance.

Complications related to stent placement are reported in the literature (7,22,25,26,30). These include stent dislocation or migration, stent obstruction by tumor ingrowth, colonic perforation, minor rectal bleeding, transient anorectal or abdominal pain, temporary incontinence and fecal impaction.

In our experience with 22 patients who developed a rectosigmoid stricture as a consequence of unresectable tumor, placement of SEMS proved to be both safe and effective in relieving obstructive symptoms. If compared to colostomy outcomes (20, 32), endoscopic stenting is now a well-tolerated procedure, since conscious sedation (Midazolam) is used without any need for general anaesthesia or postoperative support measures. Furthermore, this technique implies an immediate canalization of the gastrointestinal tract and resumption of oral feedings. Finally, SEMS placement permits the shortening of both mean operative time and mean hospital stay.

In conclusion, our results show that SEMS placement is the treatment of choice in the management of unresectable strictures of the left colon and rectum for cancer.

However, further prospective studies assessing long-term outcomes are needed to confirm definitively the efficacy of this therapeutic approach.

References


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