Stents for Palliation of Obstructive Metastatic Colon Cancer

Impact on Management and Chemotherapy Administration

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Hypothesis: The more rapid and less complicated recovery after palliative stent insertion compared with surgery may theoretically facilitate the early administration of chemotherapy.

Design: A retrospective study.

Setting: University tertiary care referral center.

 Patients: From January 1, 1996, to September 15, 2005, 58 patients with obstructing colon cancer and nonresectable synchronous metastases were treated with self-expanding colonic metallic stent (SEMS) (n = 31) or surgery (n = 27).

Main Outcome Measures: Comparison of the use of SEMS and emergency surgery as palliative measures to treat obstructing colon cancer with special reference to time to chemotherapy administration and survival.

Results: Mortality and morbidity were comparable between the 2 groups. Median hospital stay was shorter after SEMS insertion than after surgery (median, 8.0 vs 13.5 days, respectively; P < .01). Incidence of stoma creation was lower in patients treated with SEMS than in patients treated with surgery (6% vs 37%, respectively; P = .02). The median time to chemotherapy administration was shorter after SEMS insertion than after surgery (14.0 vs 28.5 days, respectively; P = .002). Three patients with SEMS and 0 patients in the surgical group underwent a curative colonic and hepatic resection after downstaging by chemotherapy (P = .27). Two patients (6%) with SEMS and undergoing chemotherapy had a tumor perforation requiring emergency surgery. There was no difference in survival between the 2 groups (median survival, 13.7 months for SEMS vs 11.4 months for surgery; P = .19).

Conclusions: Insertion of SEMS should be the first step to treat obstructing colon cancer with nonresectable synchronous metastases because it allows chemotherapy to be administered earlier, may increase the resectability rate of metastases, and favorably impacts survival. The risk of tumor perforation while receiving chemotherapy requires attention.

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METHODS

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Departments of Surgery (Drs Karoui, Loriau, Laurent, Fagniez, and Cherqui), Gastroenterology (Drs Charachon, Sobhani, and Delchier), Medical Oncology (Drs Delbaldo and Piedbois), and Pathology (Dr Tran Van Nhieu), Hôpital Henri Mondor, Créteil, France.

Previous articles1-5 have indicated an advantage to using self-expanding colonic metallic stent (SEMS) over surgery for palliation of obstructive metastatic colon cancer by reducing hospital stay and avoiding the need for stoma formation with no detrimental effect on morbidity and survival. In addition, SEMS has been reported to provide a better quality of life and to be more cost-effective than palliative chemotherapy.6-7 The more rapid and less complicated recovery after SEMS insertion would also benefit patients with advanced disease because it may allow chemotherapy to be administered earlier.1-5 However, the influence of SEMS in the management of chemotherapy has been less studied in series that have evaluated palliative SEMS for obstructing colon cancer and focused mainly on morbidity.

The aim of our study was to compare the use of SEMS in the palliation of patients with obstructing colon cancer and nonresectable metastatic disease with emergency surgery, with particular reference to time to chemotherapy administration as well as survival, morbidity, hospital stay, and stoma formation rate.

See Invited Critique at end of article

Between January 1, 1996, and September 15, 2005, 58 consecutive patients with obstructing colon cancer and nonresectable synchronous metastases were admitted in the Department of Surgery, Henri Mondor University Hospital, Créteil, France. Thirty-one patients underwent insertion of an SEMS and 27 underwent emergency surgery.
surgery in the study period formed the control group for the patients with nonresectable metastatic disease undergoing open surgery. All of the stents were uncovered Wallstent (Boston Scientific Corp), or Hanarostent (Life Partners Europe, Paris, France) type. The stent was inserted under general anesthesia. Implementation of SEMS in patients with obstructive colon cancer was approved by our institutional review board. Informed consent with full explanation of the procedure and discussion of possible complications was obtained from each patient. The procedure was performed under endoscopy and fluoroscopy by 1 of us (A.C.). A contrast study was obtained from each patient. The procedure was performed under fluoroscopic guidance. In difficult situations, a soft-tipped guidewire was previously passed through the lumen. Balloon dilation was not used. Staging investigations included helical computed tomography of the abdomen, pelvis, and chest. Criteria of unresectability of synchronous metastases were based on imaging studies showing that it was not possible to achieve a curative resection of the metastatic disease in relation to the features of the liver metastases (bilobar multiple lesions, involvement of the hilum or the 3 major hepatic veins, remnant liver volume < 30% after heptectomy) or to the presence of extrahepatic disease. After stenting, data regarding patient demographics, details of procedures, complications, time to chemotherapy, and survival of patients were collected prospectively.

**STENT GROUP**

Insertion of the SEMS was implemented in January 2000 and has since been used as the first treatment option in patients with this condition. Patients with middle- or low-rectal tumors and patients with suspicion of diastatic ischemia of the cecum or associated small-bowel obstruction were not considered candidates for the placement of a stent. All of the stents were uncovered Wallstent (Boston Scientific Corp, Natick, Massachusetts), Wallflex (Boston Scientific Corp., or Hanarostent (Life Partners Europe, Bagnolet, France) type (60-140 mm × 22 mm) and were inserted under general anesthesia. Implementation of SEMS in patients with obstructive colon cancer was approved by our institutional review board. Informed consent with full explanation of the procedure and discussion of possible complications was obtained from each patient. The procedure was performed under endoscopy and fluoroscopy by 1 of us (A.C.). A contrast study was obtained from each patient. The procedure was performed under fluoroscopic guidance. In difficult situations, a soft-tipped guidewire was previously passed through the lumen. Balloon dilation was not used. Staging investigations included helical computed tomography of the abdomen, pelvis, and chest. Criteria of unresectability of synchronous metastases were based on imaging studies showing that it was not possible to achieve a curative resection of the metastatic disease in relation to the features of the liver metastases (bilobar multiple lesions, involvement of the hilum or the 3 major hepatic veins, remnant liver volume < 30% after heptectomy) or to the presence of extrahepatic disease. After stenting, data regarding patient demographics, details of procedures, complications, time to chemotherapy, and survival of patients were collected prospectively.

**SURGERY GROUP**

Patients with nonresectable metastatic disease undergoing open surgery in the study period formed the control group for the study. The types of operation were decided by the surgeon depending on the stage of the disease and the general condition of the patient. Primary resection with primary anastomosis was attempted if possible. Data concerning these control patients were collected retrospectively.

**STATISTICAL AND DATA ANALYSIS**

The outcomes in terms of postprocedure mortality and morbidity, hospital stay, time to chemotherapy administration, late complications, and survival rates for the 2 groups were compared. Categorical variables were compared with the chi² test or Fisher exact test when appropriate. Continuous variables were expressed as medians and ranges and were compared with the Mann-Whitney U test. All of the statistical evaluations were based on the date of the patient’s death or the date of last follow-up. Actuarial survival was calculated using the Kaplan-Meier method with the log-rank test. P < .05 was considered statistically significant. Statistical analysis was performed using StatView statistical software (SAS Institute, Inc, Cary, North Carolina).

**RESULTS**

The 2 groups were comparable in age, sex, American Society of Anesthesiologists score, tumor location, and site of metastases (Table 1).

All but one patient (97%) had a successful SEMS insertion leading to intestinal obstruction relief. One patient required emergency laparotomy and colostomy because of the inability to pass the guidewire through the tumor. There was no procedure-related mortality. Twenty-five patients (81%) had no postprocedure complications. Early complications (within 30 days) occurred in 6 patients (19%). Five patients (16%) with rectosigmoid primary tumor had their SEMS removed after migration in the anal canal. Two of these patients were restented. The other 3 patients remained asymptomatic and required no further procedure. One patient (3%) had minor colonic bleeding that spontaneously cleared in 24 hours without transfusion. No perforation during the procedure was observed.

Five patients (16%) were readmitted for a late complication after a median time of 4 months (range, 3-15 months). Among them, 3 patients (10%) developed a late obstruction of the stent due to stool impaction and tumor ingrowth (n = 1) and tumor ingrowth (n=2). The first patient was successfully managed by enema. The other 2 patients required a colectomy with primary anastomosis 3 or 12 months after SEMS insertion. One of these patients had a suspected additional colonic stricture proximal to the stent at abdominal computed tomographic scan. The other patient had been downstaged to resectable metastatic disease by chemotherapy 12 months after SEMS insertion and underwent curative colectomy and staged hepatectomy. Two other patients underwent an emergency colectomy 3 or 14 months after SEMS insertion because of a tumor perforation by the stent, with the need for a diverting loop ileostomy in 1 case. The perforation was associated in both cases with peritonitis and local peritoneal deposits and adversely affected the postoperative course. These 2 patients were undergoing systemic chemotherapy at the time of perforation.

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**Table 1. Clinical Characteristics of 58 Patients With Obstructing Colorectal Cancer and Nonresectable Synchronous Metastases Treated by Self-expanding Colonic Metallic Stent or Surgery**

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>SEMS (n = 31)</th>
<th>Surgery (n = 27)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Demographic</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age, median (range), y</td>
<td>72 (35-94)</td>
<td>66 (45-88)</td>
<td>.80</td>
</tr>
<tr>
<td>Sex, male/female, No.</td>
<td>15/16</td>
<td>15/12</td>
<td>.68</td>
</tr>
<tr>
<td>ASA score, I/II/III, No.</td>
<td>11/15/5</td>
<td>10/11/6</td>
<td>.92</td>
</tr>
<tr>
<td>Location of primary tumor, No.</td>
<td></td>
<td></td>
<td>.32</td>
</tr>
<tr>
<td>Right colon</td>
<td>3</td>
<td>5</td>
<td></td>
</tr>
<tr>
<td>Transverse colon</td>
<td>3</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Left colon</td>
<td>2</td>
<td>5</td>
<td></td>
</tr>
<tr>
<td>Sigmoid colon or rectosigmoid</td>
<td>23</td>
<td>17</td>
<td></td>
</tr>
<tr>
<td>junction</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Site of metastases, No.</td>
<td></td>
<td></td>
<td>.43</td>
</tr>
<tr>
<td>Liver</td>
<td>17</td>
<td>11</td>
<td></td>
</tr>
<tr>
<td>Liver and lung</td>
<td>3</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Liver and peritoneum</td>
<td>4</td>
<td>6</td>
<td></td>
</tr>
<tr>
<td>Peritoneum</td>
<td>2</td>
<td>8</td>
<td></td>
</tr>
<tr>
<td>Lung</td>
<td>1</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Others, bones, brain</td>
<td>4</td>
<td>0</td>
<td></td>
</tr>
</tbody>
</table>

Abbreviations: ASA, American Society of Anesthesiologists; SEMS, self-expanding colonic metallic stent.
metastases became resectable after downstaging by systemic chemotherapy and underwent a curative colectomy and hepatic resection, with a 2-stage hepatectomy for 2 patients. No patient in the surgery group became resectable while undergoing chemotherapy. Thirteen patients treated by SEMS and 4 patients in the control group were alive at the time of last follow-up. The median survival times after the intervention were 13.7 and 11.4 months in the SEMS and surgery groups, respectively (Figure). Although there was a trend toward higher survival in patients who had SEMS insertion, the difference was not statistically significant (log-rank, 1.064; \( P = .19 \)).

The management of patients with obstructing colon cancer and nonresectable synchronous metastases is challenging. Until recently, the main concerns in this palliative setting have been symptom relief and quality of life. However, the occurrence of new chemotherapy agents that may improve survival should be taken into account. Our study confirms that SEMS shortens the hospital stay and avoids the need for colostomy in most patients, and it shows that SEMS allows chemotherapy to be administered earlier with a potential benefit on survival. To our knowledge, our study is the first account of specific outcomes of SEMS while receiving chemotherapy and the risk of late tumor perforation.

Two recent retrospective studies\(^4,5\) have compared palliative placement of metallic stents with emergency surgery for patients with obstructing colon cancer and nonresectable synchronous metastases but have excluded right-sided and transverse lesions from stenting because of the difficulty of the procedure. These 2 studies showed lower morbidity, significantly lower stoma creation, fewer patients with intensive care requirement, and shorter median hospital stay in the stent group compared with the surgery group. In our study, which included right-sided and transverse obstructing cancers (\( n = 11 \)), there were no differences in the SEMS group vs the surgery group in rates of mortality (0% vs 4%).

### Table 2. Comparison of Outcomes in 58 Patients With Obstructing Colon Cancer and Nonresectable Synchronous Metastases Treated by Self-expanding Colonic Metallic Stent or Surgery

<table>
<thead>
<tr>
<th>Outcome</th>
<th>SEMS (( n = 31 ))</th>
<th>Surgery (( n = 27 ))</th>
<th>( P ) Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mortality, No. (%)</td>
<td>0 (1) (4)</td>
<td>1 (1) (4)</td>
<td>.46</td>
</tr>
<tr>
<td>Overall morbidity, No. (%)</td>
<td>11 (35)</td>
<td>13 (48)</td>
<td>.92</td>
</tr>
<tr>
<td>Overall reoperation, No. (%)</td>
<td>5 (16)(^a)</td>
<td>3 (11)</td>
<td>.78</td>
</tr>
<tr>
<td>Hospital stay, median (range), d</td>
<td>8.0 (1-39)</td>
<td>13.5 (8-53)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Early complication within 30 d, No.</td>
<td>6</td>
<td>11</td>
<td>.09</td>
</tr>
<tr>
<td>Reoperation for early complication, No.</td>
<td>0</td>
<td>2</td>
<td>.22</td>
</tr>
<tr>
<td>Late complication, No.</td>
<td>5</td>
<td>2</td>
<td>.12</td>
</tr>
<tr>
<td>Reoperation for late complication, No.</td>
<td>4</td>
<td>1</td>
<td>.90</td>
</tr>
<tr>
<td>Stoma formation, No. (%)</td>
<td>2 (6)(^b)</td>
<td>10 (37)</td>
<td>.02</td>
</tr>
<tr>
<td>Chemotherapy administered after procedure, No. (%)</td>
<td>22 (71)</td>
<td>16 (59)</td>
<td>.56</td>
</tr>
<tr>
<td>Time to chemotherapy administration, median (range), d</td>
<td>14.0 (3-60)</td>
<td>28.5 (10-112)</td>
<td>.002</td>
</tr>
</tbody>
</table>

Abbreviation: SEMS, self-expanding colonic metallic stent.

\(^{a}\) Includes a patient who needed a colostomy because of initial failure of the procedure.

\(^{b}\) A temporary loop ileostomy was performed for 1 patient.

In the surgery group (\( n = 27 \)), resection of the tumor was performed in 18 patients (66%) and primary anastomosis was carried out in 16 patients (60%). The types of operation were segmental colectomy and anastomosis (\( n = 14 \)), subtotal colectomy with ileorectal anastomosis (\( n = 2 \)), Hartmann procedure (\( n = 2 \)), defunctioning colostomy (\( n = 8 \)), and bypass (\( n = 1 \)). There was 1 hospital death from myocardial infarction 3 days after colostomy by laparotomy. Sixteen patients (59%) had no postoperative complications. Eleven patients (41%) experienced 1 or more early complications, including anastomotic leak (\( n = 1 \)), abdominal wound abscess (\( n = 1 \)), peristomal abscess (\( n = 1 \)), intra-abdominal collection (\( n = 2 \)), small-bowel obstruction (\( n = 4 \)), urinary tract infection (\( n = 2 \)), chest infection (\( n = 2 \)), and phlebothrombosis (\( n = 1 \)). Two patients (7%) required further surgery, including division of adhesion (\( n = 1 \)) and drainage of an intra-abdominal collection (\( n = 1 \)). Two patients (7%) developed the late complications of colostomy prolapse (\( n = 1 \)) and incisional hernia that required reoperation (\( n = 1 \)).

Mortality, overall morbidity (including early and late complications), and reoperation rates were similar in the 2 groups (Table 2). The median overall hospital stay for all admissions was 8.0 days (range, 1-39 days) in the SEMS group and 13.5 days (range, 8-53 days) in the surgery group \(( P < .001 \)). Incidence of stoma creation was significantly lower in patients treated with SEMS than patients treated with surgery (6% vs 37%, respectively; \( P = .002 \)).

Twenty-two patients (71%) treated with SEMS and 16 patients (59%) who underwent emergency surgery had systemic chemotherapy administration after the intervention (\( P = .56 \) (Table 2). The median time to chemotherapy administration was significantly shorter in patients who had SEMS insertion (median, 14.0 days; range, 3-60 days) compared with patients who underwent emergency surgery (median, 28.5 days; range, 10-112 days) \(( P = .002 \)). Three patients in the SEMS group with previously nonresectable liver
respectively; \( P = .46 \) and morbidity (35% vs 48%, respectively; \( P = .82 \)). Insertion of an SEMS was associated with a more rapid recovery than seen with surgery as demonstrated by the shorter median length of hospital stay (median, 8.0 vs 13.5 days, respectively; \( P < .001 \)) and the avoidance of a colostomy in most patients (3% vs 37%, respectively; \( P = .002 \)).

One-stage operation, either subtotal colectomy with ileocolonic anastomosis or segmental resection with primary anastomosis after on-table anterograde irrigation or after intraoperative colonic decompression, has been reported with good results.\(^8\)\(^\text{-}^1^\text{1}\) In our study, adopting such an aggressive approach even in the context of palliation, primary resection could be achieved in only 66% of the patients and primary anastomosis was carried out in 60% of the patients.

The observed 40% colostomy rate in our surgery group reflects the limits of these methods and is consistent with previously published series of emergency palliative surgery for large-bowel obstruction.\(^5\)\(^\text{-}^\text{7}\) This relatively low colostomy rate was further decreased by the use of stents. A recent prospective randomized trial comparing stenting and stoma creation for patients with inoperable malignant colonic obstructions reported that metallic stent provided a better quality of life without the psychological repercussions of a colostomy and appeared to be cost-effective.\(^7\) The impact of SEMS on quality of life, an important issue in palliative treatment, could not be evaluated in this retrospective study.

An additional major advantage of stent insertion is the possibility of earlier administration of chemotherapy, which has been shown to be superior to delayed treatment in terms of quality of life and overall survival.\(^1^\text{2}\)\(^\text{-}^\text{1}^\text{3}\) Indeed in our study, patients in the SEMS group had a shorter delay before starting systemic chemotherapy than patients who underwent emergency surgery (median, 14.0 vs 28.5 days; \( P = .002 \)). Recent chemotherapy drugs such as oxaliplatin or irinotecan hydrochloride in combination with fluorouracil and leucovorin calcium have been shown to be superior to fluorouracil-leucovorin chemotherapy alone in terms of response rate and overall survival.\(^1^\text{4}\)\(^\text{-}^\text{1}^\text{5}\) In our series, 17 patients (77%) in the SEMS group and 6 (38%) in the surgical group received fluorouracil-leucovorin-oxaliplatin and/or irinotecan-leucovorin-fluorouracil chemotherapy postoperatively. The remaining 10 patients who underwent emergency surgery had fluorouracil-leucovorin chemotherapy alone after the intervention, which was the standard treatment for patients with metastatic colorectal cancer before 2000. Consequently, for the SEMS group as compared with the surgery group, the higher median survival (median, 13.7 vs 11.4 months, respectively; \( P = .19 \)) and the higher resectability rate of metastases following downstaging by chemotherapy (10% vs 0%, respectively) we reported may be explained not only by the shorter delay to chemotherapy administration but also by the difference in terms of chemotherapy regimens. Our 13.7-month survival rate is in the higher range of median survival, ranging from 2.7 to 14 months as reported in the published series of more than 20 patients having a palliative stent inserted.\(^\text{4.5.7}\)\(^\text{-}^\text{1}^\text{6}\) It should be emphasized that 3 patients in the stent group but none in the surgery group were downstaged to the point that they could undergo colonic and hepatic resection. We attribute this difference to the efficacy of new chemotherapeutic agents, but it is clear that stent management of the obstructed tumor (avoidance of initial surgery and earlier chemotherapy) had a significant impact on management.

It is important to determine whether systemic chemotherapy may increase the risk of long-term complications of SEMS and particularly the risk of primary tumor perforation. It could be helpful to decide whether palliative SEMS should be used for temporary decompression before resection of the primary tumor.\(^1^\text{7}\) Two patients (6%) in our series underwent an emergency colectomy because of a late tumor perforation by the stent. In both cases, associated peritonitis adversely affected the postoperative course. This late complication has never been described in series that have studied palliative SEMS for obstructing metastatic colon cancer.\(^1^\text{8}\)\(^\text{-}^\text{1}^\text{9}\) From our point of view, patients who are considered for palliative stenting should be given information on the risk of late colonic perforation as a necessary part of the initial counseling. For those having more effective chemotherapy regimens or new biotherapies,\(^2^\)\(^\text{0}\) this is essential. Moreover, this tumor perforation risk while undergoing chemotherapy could lead one to consider palliative SEMS as a bridge to elective surgery for patients with stabilized metastatic disease.

**CONCLUSIONS**

This study suggests that SEMS is the option of choice in the initial management of patients with obstructing colon cancer and nonresectable metastases because it shortens the hospital stay, avoids a stoma in two-thirds of the patients, allows chemotherapy to be administered earlier, and has no detrimental effect on morbidity and survival. The risk of tumor perforation while receiving more effective chemotherapy requires attention and could lead to the consideration of palliative SEMS as a bridge to elective surgery for patients with stabilized or downstaged metastatic disease.

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**Invited Critique**

Dr Karoui and colleagues present a timely, thought-provoking study comparing SEMS with operative management in the setting of obstructing colon cancer with unresectable distant disease. Their experience with this technique further underscores the potential efficacy, safety, and equivalency compared with palliative surgery. However, their enthusiasm stems mostly from demonstrating a significant benefit with decreased hospital stay, stoma formation, and time to chemotherapy—hence, less morbidity. Their proposed paradigm shift from palliative surgery to a less-is-more or bridging-treatment approach appears more relevant when considering that (1) palliative surgery delays administering systemic chemotherapy; (2) recent advances with systemic therapies have improved median survivals approaching 2 years; and (3) operative salvage can be offered in select patients with demonstrable tumor regression (downstaging) or without tumor progression—a distinct survival advantage. Less relevant is the actual impact of stent therapy on salvage resection and ultimate survival. Neither was found to be statistically significant in this study. Although it is encouraging to see salvage therapy (n=3) used in the group treated with SEMS plus chemotherapy, this observation likely rests on surreptiously favorable tumor biology in this highly selected, small group of nonrandomized patients within the SEMS cohort. Indeed, inherent in the design of all retrospective studies is the inability to draw any conclusions about the cause and presence or absence of an observed effect.

The principal message of this article is that SEMS represents a less invasive treatment approach that offers our patients the possibility to initiate state-of-the-art chemotherapy earlier. Whether SEMS offers a more direct benefit in terms of salvageability or improved survival compared with palliative resection remains to be answered in a randomized clinical trial.

At the end of the day, less may be more when comparing the nonsurgical vs surgical palliative approaches. However, an evidence-based dialogue should solely strengthen our understanding of the important relationships between tumor biology, patient selection, and appropriate therapy.

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