



REPORT NUMBER 6

*MUHC -Technology Assessment Unit*

# **Should the MUHC approve the use of colorectal stents?**

**A Technology Assessment**

**By**

**The Technology Assessment Unit (TAU) of the  
McGill University Health Centre (MUHC)**

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**Invitation.** This document was designed to assist decision-making in the McGill University Health Center. Others are welcome to make use of it, preferably with acknowledgment. More important, to assist us in making our own evaluation, it would be *deeply appreciated* if potential users could inform us whether it has influenced policy decisions in any way, and even if it has not, whether it has been helpful in informing decision makers.

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## Executive Summary

Colorectal stents are used to relieve acute lower bowel obstruction. They cost approximately \$2200 each. The Technology Assessment Unit (TAU) has been requested to give an opinion on the use of this technology at the MUHC.

- There are two situations in which colorectal stents are used: For the relief of obstruction caused by cancer before proceeding to diagnostic and therapeutic interventions (as a "bridge to surgery"), and for the relief of obstruction when the cancer is inoperable (as palliation). In both situations the only alternative form of management is the operation of colostomy.
- Based on a systematic review of 29 case series reporting 598 attempted stent insertions, it can be concluded that **stents offer a relatively safe and effective alternative to colostomy** in both the above situations, and when used for palliation offer a significantly **superior quality of life**.
- Because of avoidance of the surgical costs and the shorter hospital stay, stent use can be considered **cost equivalent to colostomy** from the point of view of the MUHC.
- However, stent use is **not budget neutral**. The purchase of stents will increase the hospital budget, while the corresponding reduction in load on the operating room and on hospital beds will probably not be realized as a budget saving, but will be taken up by other demands. However, the hospital will thereby become more efficient (more "productive"), in its use of its limited resources.
- No major increase in stent use is anticipated in the short term, but some slow increase seems likely with the passage of time.

### Recommendation

**The TAU committee recommends that the MUHC approve the use of colorectal stents for the relief of large bowel obstruction, both for palliation and whenever clinically indicated as a bridge to ultimate surgical resection.**

# Should be MUHC approve the use of colorectal stents?

## Foreword

On Nov. 14 the Technology Assessment Unit (TAU) of the McGill University Health Centre (MUHC) received a request from Dr. Ewa Sidorowicz, Assistant Director, Professional Services, requesting the TAU to "give its opinion" concerning the use of stents to relieve malignant obstruction of the GI tract, especially colorectal stents in the context of palliation. The present report is prepared in response to her request.

## Method

This report is based on literature search with guidance on contemporary clinical details from surgical and medical specialists.

Keywords: Stent, stent *and* colonic, colorectal, cancer, palliative.

Databanks: PUBMED. NHSCRD (University of York, Centre for Reviews and Dissemination). CCOHTA (Canadian Coordinating Office for Health Technology Assessment). INAHTA (International Association for Health Technology Assessment). BCOHTA (British Columbia Office of Health Technology Assessment). AÉTMIS (Agence d'Évaluation des Technologies et des Modes d'Intervention en Santé). AHFMR (Alberta Heritage Foundation for Medical Research). MCHP (Manitoba Centre for Health Policy). The reference lists of publications. Two stent manufacturers, Boston Scientific and BARD Angiomed.

Time and Language Restrictions: None

Fifty-nine relevant reports were identified consisting of case reports and case series. The present report is largely based on one recent systematic review.

## Introduction

Colorectal cancer is the third most common cancer to be diagnosed and the third leading cause of cancer mortality. In 2002 there were 17,600 new cases diagnosed in Canada, distributed equally among men and women. [CCS, WWW.cancer.ca]. Approximately 85% of colonic surgical emergencies are due to obstruction caused by cancer. Those cancers causing obstruction tend to be at a more advanced stage than non-obstructed cases. Roughly 75% of obstructing colorectal cancers occur in the descending colon or rectosigmoid, sites that are easily accessed by endoscopy.[8].

There are two situations in which colorectal stents are used in the treatment of acute large bowel obstruction caused by cancer. They can be used to relieve obstruction before proceeding to diagnostic studies and ultimate therapeutic surgical intervention as a

”bridge to surgery”, or for the relief of obstruction caused by inoperable cancer, as palliative care. We consider below these applications of stents in the Montreal General and Royal Victoria divisions of the MUHC.

### **Efficacy / Safety**

Colorectal stents have been used to relieve acute obstruction of the lower bowel for the last ten years [4,6,10]. Evidence on which to base estimates of their efficacy and safety remains sparse. They have not been the object of any randomized controlled trials, though numerous case reports and small case series have established that by their use obstruction can be successfully relieved.

In a literature search covering the period January 1990 to December 2000 Khot and colleagues [7] were able to identify 58 reports. In a systematic review of 29 of these, reporting 598 attempted stent insertions, 336(56%) for palliation and 262(44%) as a bridge to elective surgery, there was *technical success*, defined as successful stent placement, in 551 (92 %). *Clinical success*, defined as colonic decompression within 96 hours without other intervention, was achieved in 525 of the 598 attempts (88%). Technical failure in 47 cases (8%) was due to inability to place a guide wire across the lesion (36 cases), malposition of the stent (4 cases) and perforation (2 cases). Overall, perforation occurred in 22 of 598 patients (4%), and caused three deaths (1%). Stent migration was reported in 54 of the 551 technically successful cases (10%). This was managed by simple stent removal in 10 of 54 patients (19%), stent reinsertion in 11 (20%), and surgical intervention in six (11%). In the remaining 26 (48%) no further intervention was deemed necessary. Stent obstruction, occurred in 52 of the 525 clinically successful insertions (10%). It was due to progressive tumor growth in 32(62%), stent migration in 7(13%), and fecal impaction in 13(25%). Bleeding occurred in 27 patients (5%) but required blood transfusion in only three (0.5%).

The above systematic review [7] provides satisfactory evidence that stent placement is a relatively safe and effective alternative to colostomy, either as a "bridge to surgery" or for the palliative treatment of inoperable malignant disease. In the latter role, although no formal studies have been reported, it is clearly preferable to colostomy and it is improbable that any patient would choose colostomy in preference to the relatively simple procedure of stent insertion, or choose to live with a colostomy if this could be avoided. Thus it clearly provides a better quality of life, though the length of life during which this can be enjoyed will vary, depending on the stage of disease in which stenting is used.

Although in the Khot study 333 of 598 patients received the stent intervention as palliation, the length of follow-up was not reported. Another reviewer, who included many of the same reports [5], noted that in 12 reported series there have been follow-ups of from three to nineteen months. Some small series include further details. Tack et al [11] reported on 10 palliative procedures with a mean survival of 204 days after stent insertion, five patients dying with the stent still in position at 180 +/- 38 days. All patients

died because of progression of the initial disease. Five patients with stents in position at death had no clinical or radiological signs of stent obstruction.

Diaz et al [3] followed up 16 consecutive patients after palliative stent placement until death, or termination of the study at 44 months. The stents successfully resolved the clinical obstruction in all patients except one who required colostomy. During follow-up of the remaining 15 patients there was severe bleeding in one, and stent migration requiring reintervention in three. The mean lifespan following the procedure was 130 days. No patients showed clinical symptoms of obstruction at the time of death or termination of the study.

Camúñez et al [2] used stent placement as palliative treatment in 35 patients with a mean follow-up of 93 days. Six patients (17%) died of their underlying disease in the first 30 days. The remaining 29 patients were followed up for a mean of 138 days. No stent migration was revealed by routine barium enema at one month. In 28 patients the stents remained patent. In one patient the stent became occluded due to tumor in-growth 9 months after insertion, and patency was restored with a second insertion. In two patients the stents were expelled spontaneously at 30 and 45 days after insertion due to shrinkage of the malignancy following chemotherapy. Two patients had severe tenesmus related to insertion of stents in the lower portion of the rectum. The estimated primary stent patency rate was 91% at 3, 6, and 9 months. The mean survival time was 147 days.

We may conclude from the above, that for present purposes palliative stent use may offer improved quality of life for three to six months after placement, depending on the stage of disease, and is a satisfactory alternative to colostomy as a bridge for surgery. However, stents are expensive and the issue to be addressed is whether the institution can afford to supply them.

### **Economic Factors**

Since both stenting and colostomy are capable of relieving acute obstruction, and stenting clearly offers a preferable quality of life, the principal issue to consider is their cost. Binkert and colleagues [1] studied both the clinical outcomes and costs of preoperative and palliative treatment with stents in Switzerland. Compared to colostomy, stent placement, when used as a "bridge to surgery" cost 29% less than colostomy. When used for palliation the cost was 20% lower. However, in addition to the inclusion of Physicians fees which are not a charge to the MUHC, the conditions, such as the length of stay in hospital and in ICU in these studies varied significantly from those pertaining at the MUHC today.

A British study (9) compared the cost of management by stent of 16 patients with acute large bowel obstruction with 10 unselected patients previously managed by surgical decompression. They considered total hospital stay, the cost of the radiology suit/operating theatre utility, and running costs, including equipment. They found that the

use of stents caused a significant reduction in total hospital stay when compared to colostomy (2.5 days compared with 13.5 days, respectively) with an average saving of £1760, or Ca\$4,330 (at £1=Ca\$ 2.46). Sufficient details to allow comparison with current MUHC experience were not reported.

For present purposes it is necessary to consider the direct costs at this time of these two procedures, from the point of view of the MUHC. Colorectal stents cost approximately \$2,200 each. Present practice at the MUHC is that before each procedure the patient undergoes evaluative endoscopy in order to determine the site of obstruction and to estimate the length of the stent required. The stent is then inserted endoscopically at a second procedure under fluoroscopic control. The costs of the use of stents and colostomy are compared separately for palliative treatment (Appendix 1) and for use as a bridge to surgery (Appendix 2).

### **Palliation**

When large bowel obstruction due to cancer has progressed beyond the stage of any curable intervention, there are only two options, to relieve the obstruction by colostomy or by use of a stent. **The estimated costs of these two options are virtually identical (Appendix 1). The cost of the use of stents for palliation was estimated to be, on average \$3,064 compared to the cost of colostomy of \$2,922.**

### **Bridge to surgery**

When curative surgery is a possibility, there are three options for the management of acute obstruction. When clinical conditions permit, the surgeon can proceed directly to laparotomy. However, it is deemed preferable to first relieve obstruction, allowing for decompression of the bowel, rehydration, and recovery, before undertaking definitive surgical resection. This can be done by colostomy or by use of a stent. When this is done by stent, discharge from hospital is possible as soon as it is clear that the obstruction has been relieved, normally within two days. When this is done by colostomy, in-hospital convalescence is necessary while the colostomy wound edges heal, normally a period of seven days. **The costs of these two options are also virtually identical (Appendix 2). For the relief of obstruction preceding elective surgery ("bridge to surgery"), the estimated cost of stent use was \$2,872, and the cost of colostomy \$2,922.**

### **Comment.**

From Appendix 1 it is clear that the principal cost determinants are the cost of the stent itself, and the duration of in-hospital treatment following stent use and colostomy. Consultants agree that the estimates of hospital stay used here are accurate within a day or two and are stable at the MUHC at this time.

It must be stressed that these estimates are the direct costs, made from the point of view of the MUHC. Physician charges, the cost of blood, which is supplied by Hema Quebec, at the moment without charge, and costs incurred outside the hospital, such as the cost of colostomy bags, are excluded

## **Budget Impact**

Although the choice between stenting and colostomy can be considered more or less cost neutral to the MUHC, any increase in the use of stents as a replacement for colostomy will have effects on the hospital budget and on different cost centers.

From the point of view of the hospital budget, there will be an increased cost due to purchase of the stents. Although theoretically balanced by a reduced load in the operating room and reduced bed stay as a result of diminished colostomy rates, these "savings" will probably not be realized as cost savings, since any reduction in operating room hours or in bed use will be immediately taken up by other demands. Thus, the hospital's *productivity* will improve but the *charge on the budget will increase*.

In the year 2002 there were 15 stent insertions (all for palliative purposes) at the Montreal General and Royal Victoria divisions of the MUHC, (costing \$33,000 for stent acquisition). While the clinical specialists consulted anticipate no immediate increase in demand they believe stent use may slowly increase over time. Thus, no immediate or substantial impact on the budget of the MUHC is anticipated.

From the point of view of individual cost centers within the MUHC, it should be noted that any further increase in stent use will negatively affect the budget of the cost center that purchases the stents, and as observed above, will not influence the budgets of the operating rooms or hospital wards.

## **Cost-Effectiveness**

Since the choice between the relief of obstruction by stents or by colostomy is cost neutral, their cost-effectiveness is not a pertinent consideration. When used for palliation, stents will permit most patients to avoid the operation of colostomy and the considerable inconvenience of subsequent colostomy management until their demise, a period of perhaps on average six months.

## **Recommendation**

**The TAU Committee recommends that the hospital approve the use of colorectal stents, both for palliation and as a bridge to surgery when clinically indicated.**

## Appendix 1

### **Comparison of stenting and colostomy as *palliative* treatment.**

For the purposes of economic evaluation it is necessary to estimate the frequency of cost generating events associated with each therapeutic option. The following table shows the estimated frequency of such events associated with stent placement, slightly adapted from the data in the systematic review of Khot [7] and colleagues reported above. It also shows the estimated direct cost to the MUHC of each event.

**Table 1**

#### **Estimated direct costs (to MUHC) related to the use of stents for the relief of obstruction in 100 patients with unresectable colorectal cancer**

<b><u>Cost-related Event</u></b>	<b><u>Unit Cost</u></b> \$	<b><u>N</u></b>	<b><u>Total Cost</u></b>
1). Stent acquisition.....	2,200.....	100.....	220,000
2). Evaluative sigmoidoscopy.....	15.....	100.....	1,500
3). Stent insertion.....	71.....	100.....	7,100
4). Failure of insertion (8 and failure to relieve obstruction(4), requiring colostomy .....	2,922.....	12.....	35,064
5). Hemorrhage requiring transfusion.....	43.....	5.....	215
6). Stent displacement (9), requiring: re-insertion (2)( Item 1+3).....	2,271.....	2.....	4,542
or colostomy (1) (Item 4).....	2,922.....	1.....	2,922
7). Late re-occlusion. Re-insertion (Item 1+3).....	2,271.....	9.....	20,439
8). Perforation bowel, requiring laparotomy.....	3,661.....	4.....	14,644
 Total cost per 100 attempted stent insertions, .....			306,426
 <b>Average cost per stent insertion, attempted.....</b>			<b>3,064</b>
 <b>Average cost per colostomy (Item 4).....</b>			<b>2,922</b>

Notes

- 1) Acquisition. Wallstent. Boston Scientific.....\$2,200
- 2) Evaluative sigmoidoscopy. Carried out in the Endoscopy suite. No medication. One nurse, \$30/hr. Procedure duration 15 min +15 min preparation. No post-procedure care. Estimated cost =.....\$15
- 3) Stent insertion. Carried out in the Radiology suite. 15 minutes preparation, one Radiology technician,\$26.60/hr,(\$6.60). Medication: Demerol 50 mg + Valium 5 mg,iv (\$0.71). Procedure duration, 60 minutes. One nurse(\$30), one x-ray technician (\$26.60), Recovery time , 30 minutes x 50% one nurse (\$7.50). Estimated cost =.....\$71.41
- 4) Colostomy.Surgical suite, one hour at \$694/hour. Recovery Room, 4 hours at \$29.38/hour, (\$117.52).Convalescence in surgical ward 7 days at \$293.45/day (\$2,054.15). Follow up, two outpatient visits at \$28.38/ visit,(\$56.76) Estimated cost=..... \$2,922.43
- 5) Hemorrhage, requiring transfusion of two units blood. (Cross matching, \$12.25. Transfusion technician, 30 minutes at \$32/hr (\$16). Nursing time,30 minutes at \$30/hour (\$15). Estimated cost = .....\$43.25
- 8) Laparotomy. Surgical suite, one hour at \$694.35/hour (\$694). Recovery room, 12 hours at \$29.38/hour (\$325.56). Convalescence, surgical ward, 9 days at \$293.45/day(\$2,641.05). Estimated cost =.....\$3,660.96

Cost sources

Blood transfusion (Item 5):Ms Carole Garcia, Ms Tere Quiraga, Ms Bonnie Lyness. Blood Transfusion Service. MUHC.

All other cost data, except stent acquisition and medication costs:  
Mr. Michael Calandriello, Financial Analyst, Department of Finance, MUHC.

## Appendix 2

### **Comparison of colostomy and stenting as *bridge to surgery*.**

When it is elected to relieve acute obstruction by colostomy before proceeding to a laparotomy it is necessary to undergo on average seven days in-hospital convalescence before proceeding home to await elective surgery. Relief of obstruction by stent insertion, would, on average be followed by two day's hospitalization before returning home to await elective surgery. Thus the costs of these two choices can be compared as follows:

**Table 2**

#### **Comparison of the costs of management of obstruction by colostomy and by stent**

	<b><u>Colostomy</u></b>	<b><u>Stent</u></b>
Total costs (see Table 1)=\$2,922		Acquisition, sigmoidoscopy, insertion ( See Table 1, items 1,2,3.)= \$2,286. In-hospital convalescence , 2 days x \$293/day (see Table 1, Item 4)= \$586
<b>Total</b>	<b>\$2,922</b>	<b>\$ 2,872</b>

\*Colostomy maintenance supplies, costing approximately \$85 per month, are not charged to the hospital following discharge. (Personal communication, Nevart Hotakorzian, Enterostomal Therapist)

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