

Colonic stent vs. emergency surgery for management of acute left-sided malignant colonic obstruction: a decision analysis

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Background: Acute colonic obstruction because of malignancy is often a surgical emergency. Surgical decompression with colostomy with or without resection and eventual re-anastomosis is the traditional treatment of choice. Endoscopic colonic stent insertion effectively decompresses the obstructed colon, allowing for surgery to be performed electively. This study sought to determine the cost-effectiveness of colonic stent vs. surgery for emergent management of acute malignant colonic obstruction.

Methods: Decision analysis was used to calculate the cost-effectiveness of two competing strategies in a hypothetical patient presenting with acute, complete, malignant colonic obstruction: (1) emergent colonic stent followed by elective surgical resection and re-anastomosis; (2) emergent surgical resection followed by diversion (Hartmann's procedure) or primary anastomosis. Cost estimates were obtained from a third-party payer perspective. Primary outcome measures were mortality, stoma requirement, and total number of operative procedures.

Results: Colonic stent resulted in 23% fewer operative procedures per patient (1.01 vs. 1.32 operations per patient), an 83% reduction in stoma requirement (7% vs. 43%), and lower procedure-related mortality (5% vs. 11%). Colonic stent was associated with a lower mean cost per patient (\$45,709 vs. \$49,941).

Conclusions: Colonic stent insertion followed by elective surgery appears more effective and less costly than emergency surgery under base-case conditions. This finding remains robust over a wide range of assumptions for clinical inputs in sensitivity analysis. Our findings suggest that colonic stent insertion should be offered, whenever feasible, as a bridge to elective surgery in patients presenting with malignant colonic obstruction. (*Gastrointest Endosc* 2004;60:865-74.)

Acute malignant colonic obstruction is a common surgical emergency, one that is associated with significant morbidity and mortality.^{1,2} Despite wide-

spread colorectal cancer screening, approximately a fourth of patients with colorectal malignancy present with acute colonic obstruction.²⁻⁴ The current standard of care for patients with acute malignant distal colonic obstruction is Hartmann's procedure,^{5,6} which involves surgical decompression via formation of a colostomy and resection of the primary tumor. After the initial surgery, patients must wait at least 8 weeks before the colostomy can be safely reversed, and they often are required to wait much longer for adequate bowel continuity to be restored.^{6,7} Furthermore, many patients cannot undergo reversal of the colostomy because of advanced age and comorbid conditions, and thus must be content with a permanent stoma.^{3,8} In addition to the increased costs associated with stoma care, these patients report a significantly lower mean health-related quality of life than similar patients without a colostomy.⁹⁻¹²

Some surgeons advocate a one-stage resection and primary anastomosis, thereby avoiding the need for a stoma.^{13,14} However, this approach is not feasible in every patient with colonic obstruction and is still associated with a significant risk of complications

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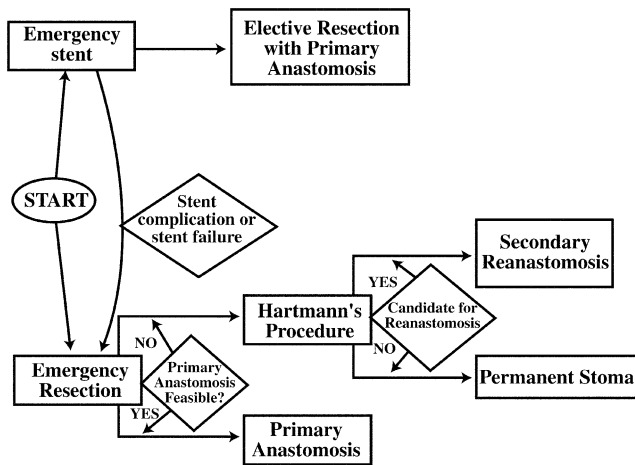


Figure 1. Schematic of competing strategies.

and death.^{15,16} Regardless of the approach, emergency surgery for colonic obstruction is associated with a mortality rate that exceeds 10% in most series and may be as high as 30%.⁴ It is recognized that emergency abdominal surgery is associated with higher risks of death and complications than the same operation performed on an urgent or elective basis.⁴ In this setting, therefore, a technique that alleviates obstruction, while allowing for surgery to be delayed, may be useful.

Endoscopic colonic stent insertion is advocated as a “bridge to surgery” in patients with potentially resectable malignant disease.¹⁷⁻¹⁹ An endoscopically placed stent relieves symptoms of colonic obstruction and allows for medical resuscitation, optimization of comorbid disorders, bowel preparation, and staging.^{20,21} The colonic tumor can then be resected electively, thereby, in theory, decreasing surgical risk of complications and death.²² Furthermore, bowel decompression and preparation increases the likelihood of successful primary anastomosis and minimizes the need for colostomy. A colonic stent, as a bridge to elective surgery, may also lead to shorter hospitalization, fewer surgical procedures, and less time in intensive care compared with emergency surgery.²³ However, colonic stent placement may not be technically possible or clinically successful, and the procedure is associated with risks of bleeding, stent migration, and bowel perforation. In addition, self-expanding metallic stents are expensive (\$1500-\$1800 each) and can be placed only by physicians with specialized training.

Although colonic stent insertion in the setting of acute, malignant colonic obstruction may be a potential alternative to surgery, there is no randomized controlled trial that compares clinical or economic outcomes between patients managed with emer-

gency surgery vs. emergency colonic stent followed by elective surgery. Therefore, it was our decision to seek to determine the cost-effectiveness of colonic stent placement for management of patients with acute malignant colonic obstruction.

PATIENTS AND METHODS

Decision analysis is a quantitative method for estimating the cost-effectiveness of alternative management strategies under conditions of uncertainty.²⁴ By using decision analysis software (DATA version 4.0; TreeAge Software, Boston, Mass.), two competing strategies for the management of acute colonic obstruction were evaluated: (1) emergency surgery with either Hartmann’s procedure or primary resection and re-anastomosis and (2) emergency placement of a colonic stent, followed by later elective surgery.

Base-case patient

The base-case patient was a 70-year old person who presented with symptoms suggestive of complete acute distal colonic obstruction.²⁵ There was no personal history of colorectal malignancy or benign colonic disease, nor any symptom or clinical finding to suggest acute diverticulitis. It was assumed that emergency CT immediately after presentation demonstrated a tumor in the left colon (excluding the rectum), dilatation of the proximal colon, and no evidence of metastatic disease. This patient was considered to be a candidate for curative surgery.

Competing strategies (Fig. 1)

Emergency surgery. Patients managed with this strategy, which served as the referent strategy for the analysis, were promptly taken to the operating room emergently for resection of the obstructing tumor. It was assumed that the surgeon first attempted a one-stage resection with colonic washout and primary anastomosis, and then performed a Hartmann’s procedure if primary anastomosis was not feasible. If metastatic disease was found or if gross carcinomatosis was discovered at laparotomy, a palliative diverting colostomy was performed, and the tumor was left in situ. If a primary anastomosis was performed, then there was a 4% chance of developing a significant anastomotic leak that would require re-operation and creation of a temporary colostomy.^{15,16} While in the hospital, patients were evaluated on a daily basis by the attending surgeon. All patients who had emergency surgery remained in the intensive care unit for 2 days, followed by a 12-day stay on the surgical ward. Patients who developed an anastomotic leak stayed an additional 3 days in the intensive care unit.

Patients who underwent a Hartmann’s procedure had a temporary colostomy for an average of 8 weeks. Between 50% and 75% of all patients with a colostomy established at surgery for colorectal malignancy became candidates for a surgical re-anastomosis.³ It was assumed that 75% of patients with a colostomy created at the time of the Hartmann’s procedure had an attempt at restoration of bowel continuity.

Table 1. Probability estimates for key variables

	Base-case value, %	References
Surgical mortality		
Elective surgery (resection and primary anastomosis)	4	25
Emergency surgery, any	10	4,5,16,25,26,29,47,48
Secondary re-anastomosis	1	3
Colonic stent		
Clinical success	88	18,20,21,23,54-103
Clinical failure	12	18,20,21,23,54-103
Uncomplicated clinical failure	8	18,20,21,23,54-103
Perforation	3.5	18,20,21,23,54-103
Procedure-related death	0.5	18,20,21,23,54-103
Probability of obtaining Hartmann's procedure on emergent basis	59	25,53
Secondary re-anastomosis rates	75	3
Gross carcinomatosis or unresectable disease on laparotomy after negative abdominal CT	5	
Stent obstruction or migration at 6 mo	24	103

A value at the high end of the range was chosen to account for the assumption that the base-case patient had no evidence of disseminated malignancy, which would normally be a contraindication for reversal of colostomy. If performed, secondary re-anastomosis surgery was associated with a mortality rate of 1%. It was assumed that no anastomotic leaks occurred after elective secondary re-anastomosis. This assumption biases the model in favor of the emergency surgery. Patients undergoing surgery for secondary re-anastomosis of a previously performed Hartmann's procedure were hospitalized for 8 days. While in the hospital, patients were seen and examined on a daily basis by the attending surgeon. After discharge, all patients were evaluated by their surgeon every 2 months.

Emergency colonic stent, followed by emergency surgery. In this strategy, patients had up-front endoscopic placement, under fluoroscopic guidance, of a colonic stent across the obstruction. If stent placement was successful, the patient was admitted to a general surgical ward, received a colonic purge, and subsequently underwent elective tumor resection and primary anastomosis. Patients found to have metastatic disease or carcinomatosis at surgery did not undergo resection, and the stent was left in situ. If stent placement was technically unsuccessful, or if a complication occurred during placement, the patient then underwent an emergent Hartmann's procedure and thereafter was managed as described for the emergency surgery strategy.

Elective colonic stent placement was assumed to increase the hospital stay by 5 days, including the time required to place the stent and to prepare the colon for elective surgery. While in the hospital, patients were seen and were examined on a daily basis by the attending surgeon. After discharge, all patients were seen by their surgeon every 2 months.

It was assumed that some patients with a stent left in situ sustained a complication of chronic stent placement, including migration and re-obstruction. If either complica-

tion occurred, the patient was hospitalized and a new stent was placed. These patients had a hospital stay of 5 days.

Time horizon

The analysis was extended to 6 months' duration to account for both in-patient and subsequent out-patient events after initial presentation. A relatively short time horizon was chosen, because it is unlikely that the choice of initial management strategy for acute colonic obstruction would affect conditions that determine long-term morbidity and mortality, specifically, the course of the underlying malignancy or any comorbid conditions.

Data sources

A structured search of published reports from the MEDLINE bibliographic database was performed to identify relevant English-language publications from January 1990 to June 2003.^{3-7,12-16,26-53} The probability of successful stent placement and stent-related complications was obtained from a systematic review of 52 studies of radiographic and endoscopic colonic stent insertion.^{18,20,21,23,54-103} Where there was significant variation in the probabilities of input variables, estimates were chosen that would tend to favor emergency surgery and, therefore, biased the model against the competing medical strategy. A summary of all probability estimates is shown in Table 1.

Costs and outcomes

Costs were estimated from the perspective of a third party payer; only direct health care costs were considered. Aggregate costs for each type of patient encounter and subsequent management strategy are displayed in Table 2; the individual component costs are shown in Table 3. Procedure and physician service cost estimates were obtained from the 2003 American Medical Association Current Procedural Terminology code book and the 2003

Table 2. Aggregate costs of alternate care pathways for malignant colonic obstruction

	Cost (\$)
Hartmann's procedure	
With survival	42,377
In-hospital death	41,858
Emergency resection and primary anastomosis	
With survival	42,530
In-hospital death	41,612
Anastomotic leak with survival	44,329
Mortality after anastomotic leak	44,037
Emergency colonic stent, followed by elective resection and primary anastomosis	
With survival	42,295
In-hospital death	42,088
Elective secondary re-anastomosis	
With survival	23,439
In-hospital death	23,702
Stent re-obstruction or migration	11,928

Table 3. Aggregate costs of alternate care pathways for malignant colonic obstruction

	Cost (\$)
Surgeon's fee for:	
Hartmann's procedure	1,420
Primary resection and re-anastomosis	1,173
Secondary re-anastomosis	902
Stent placement	177.36
Physician's fee for:	
Initial surgical consult	204
Surgical in-patient follow-up visit	47
Surgical out-patient follow-up visit	56
Initial ICU consult	226
ICU follow-up care	136
Emergency room visit	476
Hospital fee for:	
Initial presentation for colonic obstruction (DRG 148: major large-bowel procedure with concurrent comorbidities)	39,048
Secondary re-anastomosis (DRG 152: minor large-bowel procedure with concurrent comorbidities)	22,003
Re-obstruction of long-term stent (DRG 180: GI obstruction with concurrent comorbidities)	10,658
Endolumenal colonic stent	1,750
Stoma supplies and care (per wk)	200

ICU, Intensive care unit; DRG, diagnosis related group.

Medicare Fee Schedule. Costs of in-patient hospital services and supplies, excluding physician fees, were obtained by using the 2003 Medicare Prospective Payment System DRG (diagnosis related group). The cost of the stent

Table 4. Results of decision analysis

	Cost \$	Average No. surgeries per patient	Proportion with stoma (temporary/permanent) % (%)	Mortality %
Elective surgery after colonic stent	45,709	1.03	7/2	5
Emergency surgery	49,941	1.32	43/14	11

apparatus was obtained from the 2003 Medicare fee schedule for durable goods and equipment. Costs of ongoing stoma care were obtained via the 2003 Medicare fee schedule for supplies and durable medical goods. Cost discounting was not performed because of the short time horizon of the analysis.

The main outcomes evaluated were the following: mortality rate, operations required, proportion of patients requiring a stoma, cost per surgical death prevented, cost per stoma avoided, and cost per additional operation avoided.

Cost-effectiveness and sensitivity analyses

The incremental cost-effectiveness ratios (ICER) were calculated between strategies. The ICER represents the additional cost that must be incurred to prevent one additional adverse outcome (stoma requirement, additional operation, surgical death) when adopting the more expensive yet more effective of two competing strategies. Conversely, if one of the management strategies is less costly, yet more effective than its comparator, that strategy is said to be dominant.

Both one-way and two-way sensitivity analyses were performed to evaluate the effects on the results of varying individual cost and probability estimates over ranges exceeding the degree of uncertainty expected, based on medical publications. Threshold values were calculated for variables that would lead to a change in the preferred strategy when traversed.

RESULTS

Outcomes

The colonic stent strategy was preferred over emergency surgical management across all primary outcomes (Table 4). Temporary stomas were required in 7% of patients in the colonic stent arm vs. 43% in the initial surgical arm. Furthermore, 2% of patients in the stent arm required a permanent stoma vs. 14% in the emergency surgery arm. In sensitivity analysis, the proportion of patients requiring stoma became equivalent between arms when 100% of patients in the emergency surgery arm underwent a one-stage operation without requiring re-operation. Moreover, almost three quarters of attempted

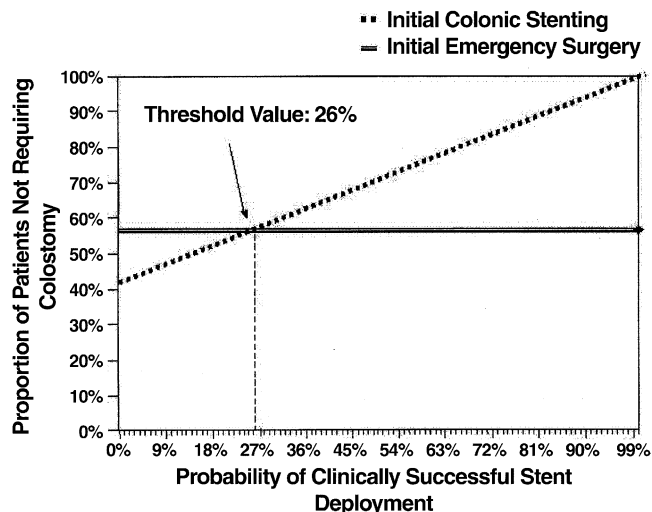


Figure 2. Sensitivity analysis and threshold value on probability of successful stent placement.

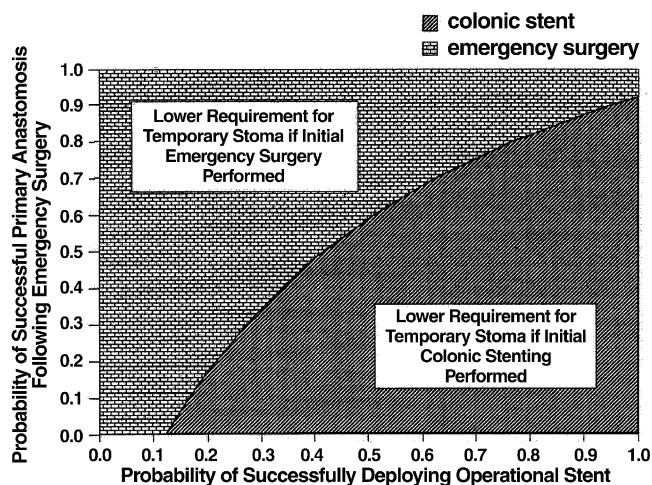


Figure 3. Two-way sensitivity analysis on probability of successful primary anastomosis after emergency surgery vs. probability of successful deployment of colonic stent placement.

stent placements would have to be unsuccessful before emergency surgery became associated with a decreased frequency of temporary stoma requirement (Fig. 2). Two-way sensitivity analysis varying both the rate of successful stent placement and the probability of being able to perform an initial primary anastomosis after emergency colonic resection further reinstates the point that the initial colonic stent is the preferred option to decrease the likelihood of requiring a temporary stoma (Fig. 3).

Patients in the stent arm required a mean of 1.03 operations vs. 1.32 operations in the emergency surgery arm. This finding remained robust

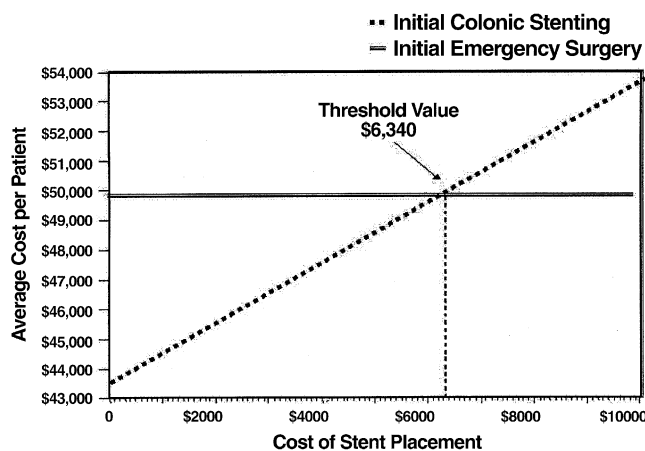


Figure 4. Sensitivity analysis and threshold value of cost of stent placement.

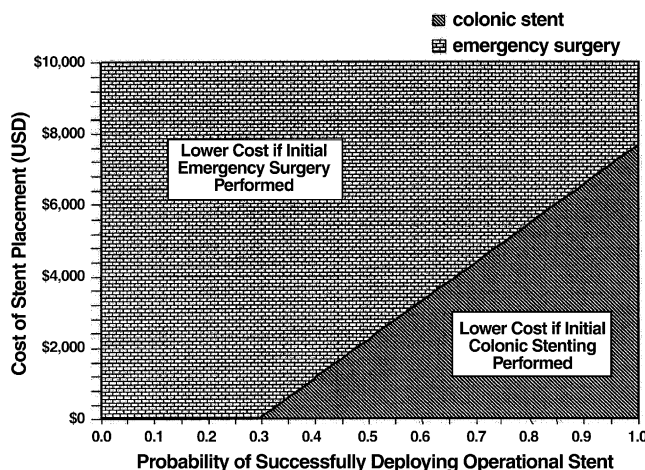


Figure 5. Two-way sensitivity analysis on probability of successful placement of colonic stent and cost of stent placement.

over a wide range of probabilities in the rate of Hartmann’s procedure performed and Hartmann’s procedure secondary re-anastomosis rates. Furthermore, the stent failure rate would have to rise from 12% to 86% before the initial colonic stent resulted in an increased frequency of surgical procedures.

The mortality rate in the emergency surgery arm was 11% vs. 5% in the stent arm. The overall mortality rate became equivalent between the two groups only when emergency colonic surgery was associated with a mortality rate that was nearly identical to that of elective colonic surgery. This is because the mortality rate of the secondary re-anastomosis surgery after a Hartmann’s procedure is roughly equal to the risk of death after stent placement.

Costs

Under base-case conditions, the cost was less per average patient treated in the initial colonic stent arm vs. the emergency surgery arm (\$45,709 vs. \$49,941). The increased cost of emergency surgery was primarily because of the cost of the second hospitalization for re-establishment of bowel continuity for patients who had a Hartmann's procedure. Emergency surgery only became less costly if 98% of patients who had emergency surgery underwent a primary anastomosis as opposed to a Hartmann's procedure. Moreover, the cost of colonic stent placement had to increase from its base-case value of \$2225.00 to over \$6300 before the colonic stent strategy became more expensive (Fig. 4). Last, nearly 100% of all attempts at stent placement would have to be unsuccessful for the costs of the competing strategies to become equivalent. Two-way sensitivity analysis varying both the cost of stent placement and the probability of successful stent placement simultaneously demonstrates that initial emergency surgery is unlikely to be less expensive than initial colonic stent at values for these variables expected to be encountered in clinical practice (Fig. 5).

DISCUSSION

The present analysis suggests that early placement of a colonic stent may be more effective and less expensive than the traditional approach of emergency surgery for management of patients with acute malignant colonic obstruction. Specifically, use of a colonic stent may minimize expensive sequential operations, reduce stoma requirements, and lower overall mortality vs. initial emergency surgery. Moreover, the sensitivity analysis reveals that these findings remain robust over a wide range of clinical scenarios and cost estimates. For example, elective surgery after colonic stent insertion becomes more expensive only when the cost of stent placement exceeds \$6300—a cost that far exceeds the outlays in a typical health care setting.

Accumulating data indicate that emergency surgery for acute malignant obstruction is associated with significant morbidity and mortality.^{4,104} In contrast, our model suggests that colonic stent insertion leads to excessive surgeries only if the clinical success rate of stent placement is less than 14%. No published case series analysis of the rate of technical success of stent placement has demonstrated a success rate below 75%. Therefore, it is unlikely that colonic stent insertion will lead to excessive surgeries in a real-world setting.

The results of the present analysis also demonstrate an 80% reduction in the likelihood of a patient

requiring either a permanent or a temporary stoma. This reduction in stoma requirement occurred despite biasing of the model against a colonic stent by using a relatively high likelihood of primary anastomosis in the emergency setting and a high rate of re-anastomosis after Hartmann's procedure. In reality, a patient undergoing emergency surgery for acute malignant colonic obstruction has more than 6 times the chance of requiring a temporary stoma and is 7 times more likely to require a permanent colostomy than a similar patient who has a colonic stent placed as a bridge to surgery. Furthermore, an initial colonic stent leads to a higher likelihood of stoma requirement only when the rate of technical failure of stent placement exceeds 26%. Moreover, colonic stent insertion leads to excessive stoma requirement only if a Hartmann's procedure can be avoided in nearly 100% of patients presenting with colonic obstruction. Studies performed to quantify the health-related quality of life associated with various colorectal cancer health states demonstrate that patients have a clear preference for maintenance of bowel continuity after colorectal surgery.^{9,10,12} A fear that a stoma will be required has consistently been found among patients awaiting bowel surgery.^{9,10} Therefore, colonic stent placement has great potential for avoiding a long-term decrement in the health-related quality of life for patients who require an emergent intervention for malignant large-bowel obstruction.

The cost findings of the present decision analysis are supported by data from two clinical series: one demonstrated a 12% reduction in the cost of the "bridge-to-surgery" colonic stent compared with a two-stage operative procedure,¹⁰⁵ and the other found savings of up to 20% for pre-operative stent placement compared with surgical management.²³ These cost savings were mainly because of the reduction in length of hospital stay, the number of surgical procedures, and the requirement for intensive care. In addition, the cost of stoma care in the community cannot be overlooked. This includes both the direct costs of enterostomal supplies and also the indirect costs associated with loss of work and lower health-related quality of life.

Although the results of the present analysis may seem intuitive, emergency colonic stent placement followed by elective surgery is not commonplace. There are a number of reasons for this. The colonic stent is a relatively new technology; its use was first reported in 1991.¹⁷ It is only in the last 5 years that the clinical efficacy of stent insertion for malignant colonic obstruction has been demonstrated. Conceivably, many health care providers remain largely unaware of the potential benefits of the colonic stent in this situation. Moreover, whereas most hospitals

in developed nations have surgeons who can perform emergency surgery, many do not have personnel with the training needed for colonic stent insertion (either endoscopically or fluoroscopically) or such capability may not always be available outside of regular working hours. Yet, because colonic stent placement is associated with an average cost savings of almost \$4000 per patient, it would likely remain the less expensive strategy even if the cost of transferring a patient to a facility where a stent can be placed is included.

The present analysis has some limitations. Although issues related to health-related quality of life were explored, the potential quality adjusted life-years saved through colonic stent insertion was not quantified. This is because there are no health utility scores available for disease states in the setting of acute colonic stent insertion. Although studies have derived utility scores associated with having a colostomy, these scores were obtained from patients with conditions distinct from the base-case patient in the current analysis.^{9,106,107} These scores, therefore, are unlikely to accurately represent the true utility of a stoma in the short term. Interestingly, some studies suggest that patients with a colectomy do not report a lower quality of life than similar patients without colectomy.¹⁰ However, this may represent the patient's ability to accommodate to an adverse situation over time. Also, the health-related quality of life increase associated with a colostomy after colectomy for ulcerative colitis likely represents the benefits of curing the underlying disease as opposed to the inherent benefit of the colostomy.

In conclusion, the use of emergent colonic stent placement followed by elective surgery results in lower costs and improved outcomes when compared with current standard management with emergency surgery. The findings of the present analysis remain robust over a range of model probabilities and only fail in the setting of situations unlikely to be encountered in actual clinical practice. Based upon the best available data, it is our recommendation that there be the adoption of stent placement as the first-line therapy for appropriate patients who present with evidence of acute, complete, left-sided, malignant colonic obstruction.

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