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

Record Status
This is a critical abstract of an economic evaluation that meets the criteria for inclusion on NHS EED. Each abstract contains a brief summary of the methods, the results and conclusions followed by a detailed critical assessment on the reliability of the study and the conclusions drawn.

Health technology
Two strategies for the treatment of patients with acute malignant colonic obstruction were compared. One was the emergency placement of a colonic stent, followed by elective surgical resection and re-anastomosis. The other was emergency surgery with either Hartmann's procedure or primary resection and re-anastomosis.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The base-case patient for the model was a 70-year-old person who presented with symptoms suggestive of complete acute distal colonic obstruction, later confirmed by an emergency computed tomography scan with a diagnosis of left colonic tumour that excludes the rectum and no metastases. There was no personal history of colorectal malignancy or benign colonic disease, nor any symptom or clinical finding to suggest acute diverticulitis. This patient was considered to be a candidate for curative surgery.

Setting
The setting was tertiary care. The economic study was carried out in the USA.

Dates to which data relate
The studies providing the effectiveness evidence dated from 1985 to 2003. Resource use was derived through modelling. Year 2003 prices were used for the cost data.

Source of effectiveness data
The evidence was derived from a review or synthesis of completed studies, and estimates based on authors’ opinions.

Modelling
A decision analysis model was used to calculate the cost-effectiveness of the two competing strategies in a hypothetical patient. The analysis was extended to 6 months' duration to account for both inpatient and subsequent outpatient events after initial presentation. A relatively short time horizon was chosen, because it is unlikely that the choice of the initial treatment strategy for acute colonic obstruction would affect conditions that determine long-term morbidity and mortality.
Outcomes assessed in the review
The clinical model parameters derived from the review were surgical mortality from elective surgery, emergency surgery and secondary re-anastomosis, and colonic stent outcomes.

Study designs and other criteria for inclusion in the review
The authors used randomised clinical trials and primary studies of varying design. The inclusion criteria for the structured search specified articles published in English from January 1990 to June 2003. 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.

Sources searched to identify primary studies
A structured search of MEDLINE was conducted for published reports.

Criteria used to ensure the validity of primary studies
Not reported.

Methods used to judge relevance and validity, and for extracting data
Not reported.

Number of primary studies included
Ninety-four studies were referenced and stated to be incorporated in the review, but only 64 were included in the parameter table.

Methods of combining primary studies
A narrative method was used in general. The authors stated that when significant variations existed in the probability of input variables, estimates were chosen that would tend to favour emergency surgery in order to bias the model against the stent.

Investigation of differences between primary studies
Not reported.

Results of the review
The base-case values for surgical mortality were:

for elective surgery (resection and primary anastomosis), 4%;

for any emergency surgery, 10%; and

for secondary re-anastomosis, 1%.

For colonic stent, the rate of clinical success was 88%;

clinical failure, 12%;

uncomplicated clinical failure, 8%;

perforation, 3.5%; and
procedure-related death, 0.5%.

The probability of obtaining Hartmann's procedure on an emergent basis was 59%;

the secondary re-anastomosis rate was 75%;

gross carcinomatosis or unresectable disease on laparotomy after negative abdominal computed tomography was 5%; and

stent obstruction or migration at 6 months was 24%.

Methods used to derive estimates of effectiveness
The study was based on published data and authors' assumptions.

Estimates of effectiveness and key assumptions
In the emergency surgery strategy, it was assumed that no anastomotic leaks occurred after elective secondary re-anastomosis. This assumption biased the model in favour of emergency surgery. In the strategy of emergency colonic stent, the 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. It was also assumed that some patients with a stent left in situ sustained a complication of chronic stent placement, including migration and re-obstruction.

Measure of benefits used in the economic analysis
The measures of benefits used were the surgical deaths prevented, the stomas avoided and the additional operations avoided.

Direct costs
Only the direct health care costs were considered. The individual component costs included:

the surgeon's fees for each procedure;

the physician's fee for consults, follow-up visits, intensive care unit (ICU) consults, ICU follow-up care and emergency room visits; and

hospital fees for the initial presentation for colonic obstruction, the secondary re-anastomosis, and the re-obstruction of long-term stent.

The costs also included the endolumenal colonic stent, and the stoma supplies and care per week. The quantities were estimated on the basis of actual data and were derived using modelling. Procedural and physician service cost estimates were obtained from published sources from the American Medical Association and the Medicare schedules for each cost category. The price year was 2003. Cost discounting was, appropriately, not performed because of the short time horizon of the analysis (less than two years).

Statistical analysis of costs
No statistical analysis of the costs was reported.

Indirect Costs
The indirect costs were not reported.

Currency
Sensitivity analysis
Both one- 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. The ranges were based on medical publications (although they were not clearly stated). Threshold values were calculated for variables that would lead to a change in the preferred strategy when traversed.

Estimated benefits used in the economic analysis
The colonic stent strategy was preferred over emergency surgical treatment across all primary outcomes. Colonic stent resulted in 23% fewer operative procedures per patient (1.01 versus 1.32 operations per patient), an 83% reduction in stoma requirement (7% versus 43%), and lower procedure-related mortality (5% versus 11%).

The model suggested that colonic stent insertion leads to excessive surgeries only if the clinical success rate of stent placement is less than 14%, whereas the worst published success in the literature is reported to be 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 demonstrated an 80% reduction in the likelihood of a patient requiring either a permanent or a temporary stoma. A patient undergoing emergency surgery was more than 6 times more likely to require a temporary stoma, and was 7 times more likely to require a permanent colostomy than a similar patient who has a colonic stent placed as a bridge to surgery.

Cost results
Under base-case conditions, the cost was less per average patient treated in the initial colonic stent arm versus the emergency surgery arm ($45,709 versus $49,941).

The increased cost of emergency surgery was primarily because of the cost of the second hospitalisation 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 $2,225 to over $6,300 before the colonic stent strategy became more expensive.

Synthesis of costs and benefits
The colonic stent strategy was better than emergency surgical treatment across all primary outcomes, and was also less costly. It dominated emergency surgery in most real-life scenarios.

Authors' conclusions
The use of emergent colonic stent placement followed by elective surgery resulted in lower costs and improved outcomes when compared with current standard treatment with emergency surgery. The finding of the present analysis remained robust over a range of model probabilities and was sensitive only in the setting of situations unlikely to be encountered in actual clinical practice.

CRD COMMENTARY - Selection of comparators
The authors gave adequate justification for the comparators. You should judge whether these strategies are relevant in your setting, or whether other comparators from other emergent surgical procedures could also be relevant.

Validity of estimate of measure of effectiveness
The authors stated that a structured search of published reports and a systematic review of the literature had been undertaken. As there was no randomised controlled trial comparing both strategies, the authors used data from the available studies. One cannot be sure that all relevant literature was identified, although many studies of varying design were retrieved and used to derive the effectiveness measures, and some authors' assumptions were made. The authors justified their assumptions with reference to the medical literature. The estimates were investigated in sensitivity analyses using ranges from the literature, but the authors did not provide a justification for the ranges selected and reported.

**Validity of estimate of measure of benefit**

There was no summary measure of benefit. Please refer to the comments in the 'Validity of estimate of measure of effectiveness' field (above).

**Validity of estimate of costs**

The authors reported that the study had been conducted from a third-party payer perspective. Most of the relevant costs were included, although they were only partially reported because the costs of alternate care pathways were reported in an aggregate manner. The unit costs were taken from published sources. No statistical analysis of the costs was undertaken. To assess the robustness of the estimates used, sensitivity analyses of selected direct costs were conducted and reported. Discounting was not carried out, which was appropriate since the time horizon did not exceed two years. The price year was reported, which will aid any future reflation exercise.

**Other issues**

The issue of generalisability to other settings was not directly addressed. The authors acknowledged a limitation of their study in that the potential quality-adjusted life-years saved through colonic stent insertion was not quantified, mainly because there were no health utility scores available for disease states in the setting of acute colonic stent insertion. The authors' conclusions reflected the scope of the analysis.

**Implications of the study**

Though not based on randomised controlled trials, but on the best available data, the authors' recommendation is that stent placement should be adopted as the first-line and more cost-effective therapy for appropriate patients who present with evidence of acute, complete, left-sided, malignant colonic obstruction. Patients have a clear preference for maintenance of bowel continuity after colorectal surgery, and quality of life could also be improved.

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