Thoracic epidural versus patient-controlled analgesia in elective bowel resections

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
The use of thoracic epidural analgesia and systemic analgesia in patients undergoing elective bowel resections.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis

Study population
The study population comprised men or women aged 18 years or older, who were scheduled to undergo an elective small bowel or colon resection with a primary anastomosis. The exclusion criteria included patients aged less than 18 years, steroid use, unprepped bowel for colon surgery, systemic anticoagulation and systemic infection. Other exclusion criteria were the presence of gastrostomy or jejunostomy tube, a platelet count of less than 100,000, inability to communicate, and the presence of spinal stenosis. Those who were unwilling to participate were also excluded.

Setting
The setting was secondary care. The economic analysis was conducted in Wichita (KS), USA.

Dates to which data relate
The effectiveness and resource data were collected from July 1999 to August 2000. The price year was not reported.

Source of effectiveness data
The effectiveness data were derived from a single study.

Link between effectiveness and cost data
The costing was carried out prospectively on the same sample of patients as that used in the effectiveness study.

Study sample
Power calculations were not reported. A single surgeon identified eligible patients at the study institution. Forty-nine patients scheduled to undergo elective bowel resection were enrolled in the study. Five of these patients were removed after enrolment: one patients required mechanical ventilation for more than 24 hours after surgery, three had no pain scores, and one had extensive bowel necrosis associated with no resection. The final study sample comprised 23 patients (14 women) in the epidural (EPI) group and 21 patients (10 women) in the patient-controlled analgesia (PCA) group. The mean age of the patients was 61.3 (+/- 13.4) years in the EPI group and 65.1 (+/- 12.2) years in the PCA group. Patients in both arms of the study were cared for by a standardised protocol.
Study design
The study was a prospective randomised controlled trial that was conducted in a single centre. The trial was not blinded, owing to ethical concerns about placing an epidural catheter as a placebo. The duration of follow-up was until discharge. Those patients unable to actively participate in their pain self-assessment after surgery were dropped from the study.

Analysis of effectiveness
The analysis of the clinical study was conducted on the basis of treatment completers only. The primary health outcomes used were pain scores, postoperative interval to first flatus, first bowel movement and hospital discharge. The pain scores were obtained every 24 hours by a member of the research team using a visual analogue pain scale (0 = no pain, 100 = worst pain imaginable), along with an assessment of the patient’s satisfaction with their pain control. Other outcomes recorded were:

- the occurrence of postoperative fever (>= 100.7 degrees F),
- urinary retention (unable to void within 8 hours after removal of Foley catheter),
- urinary tract infection,
- anastomotic breakdown, and
- epidural failure (requiring removal of the epidural and switching to PCA).

Patient demographics, preoperative morbidities, and American Society of Anaesthesiologists’ (ASA) classification were similar among the EPI and PCA groups. Diabetes was found in six patients in the PCA group, but not in the EPI group, (p=0.006).

Effectiveness results
The pain scores were significantly lower in the EPI group on postoperative days 1, (p=0.042) through 3, (p=0.002).

A total of 9.5% of patients (n=2) in the PCA arm of the study received a change in pain medicine, compared with 26% of patients (n=6) in the EPI arm. The difference was not statistically significant, (p=0.1548).

Time to removal of the epidural or PCA was significantly longer in the EPI group (3.7 +/- 1.3 days) than the PCA group (3.0 +/- 0.6 days), (p=0.0361).

The interval to removal of nasogastric tubes after surgery was similar between the two groups (1.6 +/- 1.7 days versus 1.1 +/- 0.4 days).

Although not significant, patients in the EPI arm of the study tolerated a regular diet a mean of 1 day later than those in the PCA group.

There was no difference in time to first flatus or bowel movement between the two groups.

Although not significant, the EPI group took a mean of 1.5 days longer to satisfy the study discharge criteria (5.4 +/- 2.7 days versus 3.9 +/- 1.7 days).

The mean interval to actual hospital discharge was not significantly different between the groups (6.1 +/- 2.7 days versus 5.9 +/- 3.0 days).

Overall, the EPI group had a significantly higher number of complications (61% versus 29%; p=0.032). The incidence of postoperative fever (>= 100.7 degrees F) was significantly higher in the EPI group than in the PCA group (52% versus 19%; p=0.023). In addition, the mean temperature was significantly higher in the EPI group (101 versus 100
degrees F; p=0.0168).

Clinical conclusions
The authors did not provide a synthetic clinical conclusion.

Measure of benefits used in the economic analysis
No summary benefit measure was used in the economic evaluation. In effect, a cost-consequences analysis was undertaken.

Direct costs
The perspective adopted was not reported. Hospital direct costs were included in the analysis. These covered EPI analgesia and the hospital room. The cost of analgesia was calculated by adding the cost of the medication (EPI or PCA), pump (EPI or PCA), anaesthesiologist insertion fee (EPI) and daily anaesthesiologist fee (EPI). No additional details on the cost analysis were provided. The unit costs and the quantities of resources used were not presented separately. The source of the unit costs and the price year were not reported. The resource use data were based on actual data coming from the sample of patients involved in the effectiveness study. Discounting was not relevant as all the costs were incurred during less than one year.

Statistical analysis of costs
Statistical analyses of the costs were carried out using chi-squared analysis and analysis of variance.

Indirect Costs
The indirect costs were not included.

Currency
US dollars ($).

Sensitivity analysis
Sensitivity analyses were not performed.

Estimated benefits used in the economic analysis
See the 'Effectiveness Results' section.

Cost results
The cost for EPI analgesia ($394 +/- 77) was significantly higher than for PCA analgesia ($154 +/- 62), (p=0.0001).

The cost for the hospital room was not significantly different between the groups.

The total cost was significantly higher for the EPI group ($3,630 +/- 1,214) than for the PCA group ($3,479 +/- 2,420), (p=0.0044).

Synthesis of costs and benefits
A synthesis of costs and benefits was not relevant as a cost-consequences analysis was carried out.
Authors' conclusions
While thoracic epidural (EPI) analgesia provided superior pain control, it did not translate into a quicker return of bowel function or earlier discharge of the patient. In addition, it did not offer a significant advantage over patient-controlled analgesia (PCA) in return of bowel function after bowel resection. Further, the EPI group had a significantly higher complication rate and costs.

CRD COMMENTARY - Selection of comparators
The choice of the comparator (systemic analgesia) was justified as it represented the common practice for pain control after bowel resection. You should decide whether it represents a valid comparator in your own setting.

Validity of estimate of measure of effectiveness
A prospective randomised controlled study was performed, which was appropriate for the study question. Power calculations were not carried out and the sample size was probably too small to detect some significant differences in outcomes between the groups. The study groups were comparable at baseline, thus any confounding factors were probably low. The investigators were not blinded to the allocation of patients to the study groups; therefore, assessment biases might have occurred and this might have had some impact on the results of the analysis. The data came from a single centre and this may hinder the generalisability of the results to other settings.

Validity of estimate of measure of benefit
No summary benefit measure was used in the analysis because a cost-consequences analysis was carried out. Please refer to the comments in the 'Validity of estimate of measure of effectiveness' field (above).

Validity of estimate of costs
The perspective of the study was not stated. However, it seems that the perspective adopted was that of the hospital, in which case all the relevant categories of costs were included in the analysis. The cost of the first visit to the anaesthesiologist was excluded, probably because it was common to both procedures. Details on the unit costs and resource quantities were not reported, which limits the transferability of the economic analysis to other settings. The price year was not reported and this limits reflation exercises. Discounting was not carried out since the costs were incurred during less than one year. Statistical tests of the costs were performed when the cost estimates were compared. It was discussed in the paper that the costs incurred might have been protocol driven, in which case the costs of the PCA group might be been overestimated.

Other issues
The authors compared their results with other published studies, finding both similar and different effectiveness results. They did not address the issue of the generalisability of the study results to other settings. The results were not reported selectively and the conclusions reflected the scope of the study. The authors did not report any limitations of their study. Sensitivity analyses were not performed to take variability in the cost or effectiveness data into consideration. Consequently, caution should be exercised when extrapolating the study results to different contexts.

Implications of the study
The authors did not make any recommendations for policy or practice as a result of their study.

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None stated.

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**Other publications of related interest**


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