Laparoscopic gastrostomy and jejunostomy: safety and cost with local vs general anesthesia

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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 health technology studied was the administration of local anaesthesia to patients undergoing laparoscopic gastrostomies and jejunostomies.

Type of intervention
Anaesthesia.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised patients undergoing laparoscopic enteral access procedures in university clinics, who were not contraindicated for either local or general anaesthesia.

Setting
The setting was secondary care. The study was conducted in six university clinics in the state of California, USA.

Dates to which data relate
The dates during which the cost and effectiveness data were obtained were not stated.

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

Link between effectiveness and cost data
With the exception of patients from one study centre for which unit costs were not available, the costing was carried out prospectively using the same study sample as that used in the effectiveness study.

Study sample
The authors stated that the study had 80% power to detect a 20% difference in the resource use between the treatment arms, at a significance level of 0.05. It was, however, unclear whether the sample size was selected on the basis of this power calculation. Twenty-four patients received a local anaesthetic and 24 patients received a general anaesthetic. From the number of patients for whom there were results, it appears that there were no exclusions. The baseline characteristics were given in terms of the demographics, indication, the presence of neurological dysfunction or cancer, the mean serum albumin levels, and the mean serum prealbumin levels.
Study design
The study was a prospective randomised controlled trial. The patients who agreed to randomisation were allocated to the treatment arms according to a predetermined randomisation schedule contained in sealed envelopes. The follow-up was for 30 days after the procedure was undertaken. From the number of patients for whom there were results, it appears that there was no loss to follow-up.

Analysis of effectiveness
The measures of effectiveness were the conversion from local to general anaesthetic, post-operative complications and mortality, and the length of hospital stay. The authors stated that they used an analysis of variance to compare the patients groups at a significance level of 0.05. The analysis was conducted on an intention to treat basis. For example, the data analysis of all the patients in the local anaesthesia group included the patient converted to general anaesthesia. The patients in the local anaesthesia group underwent 15 gastrostomies and 9 jejunostomies. The patients in the general anaesthesia group underwent 17 gastrostomies and 7 jejunostomies.

It was stated that there were no differences between the groups in terms of age, gender, primary diagnosis, or American Society of Anaesthesiologists (ASA) classification. However, only data on the ASA classification were given for each group. In the local anaesthesia group, there were 17 patients of ASA class 3 and 7 of ASA class 4. In the general anaesthesia group, there were 18 patients of ASA class 3 and 6 of ASA class 4.

Effectiveness results
One patient, who was undergoing jejunostomy and who developed cardiac arrhythmia associated with oxygen desaturation, was converted to general anaesthesia in order to intubate to protect the airway.

There were no intra-operative complications.

The major post-operative complications were aspiration pneumonia and bleeding. There was one incidence of aspiration pneumonia reported in the local anaesthesia group, and three in the general anaesthesia group. It was not stated in which group the incidences of bleeding occurred.

Minor post-operative complications occurred in 6 of the local anaesthesia patients and 4 of the general anaesthesia patients.

It was stated that there were no differences between the groups in the rate of major post-operative complications or 30-day mortality, although the rates themselves were not given.

There were no significant differences in length of hospital stay between the local (6 +/- 1 day) and general (8 +/- 2 days) anaesthesia groups.

Clinical conclusions
There appeared to be no significant difference in the measures of effectiveness for the local and general anaesthesia groups, although not all of the results were presented.

Measure of benefits used in the economic analysis
No summary measure of benefit was used in the study. The study was therefore categorised as a cost-consequence analysis.

Direct costs
The resource use data were obtained using the hospital charges derived from the billing information. The charges were converted to costs using a cost-to-charge ratio specific to the institutions in which the study was undertaken. The costs included the charges for the surgeon, anaesthesiologist and nurse anaesthetist, and the cost of the procedure. The only
resource quantity provided was given in terms of the procedure time and the length of hospitalisation. However, the corresponding unit costs were not given. The cost data were not available for one institution (the Veterans Affairs Medical Centre), and this study centre was consequently excluded from the cost analysis. The price year was not reported.

**Statistical analysis of costs**
The authors did not provide details of the tests they used to analyse the cost data.

**Indirect Costs**
The indirect costs were not recorded in this study.

**Currency**
US dollars ($).

**Sensitivity analysis**
A sensitivity analysis was not conducted.

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

**Cost results**
In total, data from 23 patients in the local anaesthesia group, and 19 in the general anaesthesia group, were analysed. The average total cost was $3,652 (standard deviation, SD=861) for patients in the local anaesthesia group and $3,812 (SD=763) for patients in the general anaesthesia group.

**Synthesis of costs and benefits**
Not applicable.

**Authors' conclusions**
Laparoscopic gastronomy or jejunostomy could be performed under local anaesthesia with intravenous conscious sedation of the patient, with similar success as under general anaesthesia and for similar cost.

**CRD COMMENTARY - Selection of comparators**
A justification was given for the comparator. The authors commented that a third alternative could have been regional anaesthesia. This option was excluded as it is rarely used in laparoscopic procedures in their setting.

**Validity of estimate of measure of effectiveness**
Several clinical consequences of the anaesthesia were recorded in this prospective trial, and these appear to have been appropriate for this technology. However, important data on some baseline characteristics and mortality were missing. Also, it was not stated whether any allowance was made for confounding due to differing surgical techniques. The analysis was based on a randomised study, although the trial did not appear to have sufficient power to detect any differences in clinical effectiveness on any of the outcomes measured. Baseline characteristics were used to assess whether the study sample was representative of the study population.
Validity of estimate of measure of benefit
There was no summary measure of benefit (see the commentary on the measure of effectiveness above).

Validity of estimate of costs
The authors presented little information on the recording and valuation of the costs in the study. It was unclear how the costs were measured, and whether all the relevant costs were included in the analysis. Further, the resource use and unit costs were not presented separately, so it was very difficult to assess the validity of these estimates. In addition, this hampered the generalisability of the results to other settings.

Other issues
The authors compared their results favourably to those of other studies. They also addressed the issue of generalisability of the findings from this study, given that all their patients were high-risk, but few in the local group became unconscious. Several factors may limit the transferability of the results to other settings. These are the limited reporting of the patients' characteristics by group, and the lack of transparency in the costing methodology.

Implications of the study
As the authors stated, the lack of difference between the outcomes means that the anaesthesia should be selected according to the clinical conditions and the surgeon's preference. Unfortunately, although their results suggested equal effectiveness there was no evidence to support the choice of anaesthetic by any criteria. Also, as the authors acknowledged, a lack of statistical difference could have been due to the lack of power. In view of the large contribution of operating room time and anaesthesiologist's fee to the cost, the authors suggested that carrying out the procedures in an endoscopy suite without an anaesthetist could provide further savings. However, this study was not designed to test this hypothesis.

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