A new, radially expanding access system for laparoscopic procedures versus conventional cannulas

Turner D J

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
Using radially expanded access (REA) system or conventional cannulas for laparoscopic procedures.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
Patients undergoing outpatient laparoscopic surgical procedures.

Setting
Hospital. The economic study was carried out in California, USA.

Dates to which data relate
The data for the resource use and effectiveness analysis corresponded to patients operated on during the period November 1994 - February 1995. The price year was not clearly reported.

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

Link between effectiveness and cost data
The reported costing, which was undertaken prospectively, was relevant only for the acquisition cost of the devices used on the patients included in the effectiveness analysis.

Study sample
Power calculations were not used to determine the sample size. A total of nineteen women (ranging in aged between 22 and 77 years), who were operated on by the same surgeon, was included in the analysis.

Study design
This was a prospective non-randomised study with concurrent self-controls. Each patient served as her own control and was blinded to which site was treated with which strategy. The study was carried out in a single centre. The duration of follow-up was one month after laparoscopic surgery. The authors reported no loss to follow-up.
Analysis of effectiveness
The intention to treat principal was used in the analysis, with the primary outcome being safety (operative complications and device-related side effect rates) and postoperative patient comfort (higher, lower, or equal pain between sites treated with each strategy). The outcomes were assessed at 1-day, 1-week, and 1-month. The postoperative pain was measured by means of a telephone or office interview.

Effectiveness results
The intervention resulted in no complications or device related-adverse events. There were 2 complications (10.5%), and 3 adverse events (15.8%) with the conventional procedure. The pain rating differed between strategies, the pain associated with REA system sites being lower than that associated with the conventional cannula sites. All the p values of differences in the pain at 1-day, 1-week, and 1 month, were, less than 0.001. The comparison of apportionment of ratings between groups with 5-mm and 12-mm devices showed differences with associated p values above 0.05.

Clinical conclusions
The findings of this study "provide suggestive preliminary evidence in favour of the REA system".

Measure of benefits used in the economic analysis
No summary benefit measure was identified in the economic analysis, and only separate clinical outcomes were reported.

Direct costs
The only costs measured were acquisition costs of the devices. The authors calculated the final cost of the procedure of performing LAVH, with the corresponding quantities reported (number and type of devices employed in the procedure). The price year was not clearly reported, since the authors stated only that the costs corresponded to the period November 1994 - February 1995. Costs associated with the length of operation, which was considered to be a potential source of difference in costs between the strategies, were omitted from the analysis.

Indirect Costs
Not considered.

Currency
US dollars ($).

Sensitivity analysis
No sensitivity analysis was performed.

Estimated benefits used in the economic analysis
Not applicable.

Cost results
The total cost of the REA system for performing a typical LAVH was $225, whereas that of the conventional cannula (without grips) was $324 and the conventional cannula with grips was $344.

Synthesis of costs and benefits
The results were not combined since the intervention was shown to be the dominant strategy.

**Authors’ conclusions**
The present findings support the conclusion that the REA system is an attractive and cost-effective method alternative to conventional cannulas for a range of laparoscopic surgical procedures.

**CRD COMMENTARY - Selection of comparators**
The comparator was the standard tool used in laparoscopic surgeries.

**Validity of estimate of measure of benefit**
The low numbers in the study sample may have adversely affected the validity of the study results.

**Validity of estimate of costs**
The internal validity of the cost analysis was weakened by the fact that not all the costs, apart from those associated with the needle and cannulas used in the procedure, were included in the analysis.

**Other issues**
The conclusions reached by the authors may not be justified given the uncertainties in the data. No adequate comparisons with previously completed studies were reported, nor was the issue of the generalisability of the study findings addressed. The data were not presented selectively.

**Implications of the study**
Further studies are needed before any firm statements about cost-effectiveness of REA system in laparoscopic surgical procedures can be made.

**Source of funding**
None stated.

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