Anterior access to the lumbar spine: laparoscopic versus open

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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 authors considered laparoscopic anterior spinal exposure using two 5-mm operating ports and the patient in a steep Trendelenberg position.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised individuals undergoing anterior spinal fusion at the study setting. The authors did not report any specific inclusion or exclusion criteria.

Setting
The setting was secondary care. The study was conducted at Catholic Health Partners (Columbus-St. Joseph Hospital) in Chicago (IL).

Dates to which data relate
The effectiveness data related to January 1997 to April 2001. The dates when the resource use data were collected were not reported. The price year was also not reported.

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

Link between effectiveness and cost data
The costing appears to have been carried out prospectively using the average hospital costs.

Study sample
Power calculations, to optimise the sample size or to quantify the impact of chance on the results, were not conducted. Instead, the sample was selected by including all patients who underwent spinal fusion at the study setting between the dates of the study. Forty-five patients entered the study. Thirty-one patients in whom laparoscopic L5-S1 fusions were performed comprised the study group of interest. These patients had a mean age of 42 years, a mean weight of 83.6 kg, and 17 were men. The authors also included 14 patients in whom L5-S1 open procedures were performed as the comparator group. These patients had a mean age of 38 years, a mean weight of 80.5 kg, and 6 were men. The indications for an open technique rather than a laparoscopic approach were artificial disc protocol, neurosurgeon's
preference, and multiple previous laparotomies. The samples were appropriate for the study question since they included patients who underwent treatment by the two technologies of interest. No specific exclusion criteria were reported.

**Study design**
The analysis was based on a prospective cohort study with patient groups defined by their exposure to one of the two treatment alternatives. The study was conducted at a single centre, the Columbus-St. Joseph hospital, Chicago (IL). The patients were followed for a mean of 12 months (range: 1 - 50). One patient was reported as lost to follow-up. Blinding was not possible due to the nature of the study.

**Analysis of effectiveness**
The analysis of the clinical study was conducted on the basis of the treatment received. The primary health outcomes were:

- operating room time,
- estimated blood loss,
- transfusion requirements,
- length of hospital stay,
- analgesia requirements,
- oral intake resumption and
- significant morbidities.

Although the authors reported summary statistics for the patients, there was no discussion about the comparability of the groups and potential confounding variables. The statistics presented indicated a greater proportion of open patients had had prior abdominal surgery. This may represent a confounding factor that the authors did not attempt to adjust for in their analysis.

**Effectiveness results**
The median operative time was 196 minutes for open and 160 minutes for laparoscopic treatment, (p=0.008).

The median estimated blood loss was 325 cm³ for open and 200 cm³ for laparoscopic treatment, (p=0.029).

The median intravenous analgesia requirement was 2 days for both treatments.

The median time to oral intake was 1 day for both treatments.

The median hospital stay was 3 days for both treatments.

Laparoscopic morbidities included port site bleeding, retrograde ejaculation (2), ileus (3) and conversion to open procedure (4).

Open morbidities included ileus (5).

**Clinical conclusions**
The authors concluded that laparoscopic and open procedures were "comparable" in terms of the outcomes analysed.
Measure of benefits used in the economic analysis
The authors did not estimate a summary measure of benefit. The study was, in effect, a cost-consequences analysis.

Direct costs
A perspective for the costing was not reported. However, from the costs included in the analysis, the authors appear to have been concerned with the immediate costs to the hospital of providing the two procedures. Discounting was not appropriate due to the short time horizon. The unit costs were obtained from the study setting. The quantities were based on the treatment of a single individual, in order to estimate a cost per procedure. The analysis focused on common supplies, approach-specific supplies, operating room time and hospital costs. The dates when the resource use data were collected were not reported, nor was the price year reported.

Statistical analysis of costs
The costs were treated deterministically.

Indirect Costs
The indirect costs were not estimated despite them being potentially relevant. The age of the participants suggests that they might have been economically productive, and time to recover from the procedures might have influenced their ability to return to productive work. Therefore, the indirect costs to society might have been influenced by the treatment received.

Currency
US dollars ($).

Sensitivity analysis
There was no report of sensitivity analyses being carried out.

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

Cost results
The authors reported conflicting results.

In one table (Table 2), the authors reported that the total cost of a laparoscopic procedure was $19,518 and that of an open procedure was $21,091. However, in another table (Table 3), the total costs were $20,591 for the laparoscopic procedure and $19,217 for the open procedure.

During their discussions, the authors focused on the latter results (Table 3).

Synthesis of costs and benefits
Not relevant.

Authors' conclusions
The laparoscopic and open procedures were "comparable in terms of outcome analyses and overall cost".

CRD COMMENTARY - Selection of comparators
The authors compared laparoscopic and open anterior spinal exposure. They chose open procedures as their comparator, as it appears to have been current practice in their setting and is the natural comparator of choice.

**Validity of estimate of measure of effectiveness**

The analysis was based on a prospective cohort study. This type of study allows the authors to compare the two groups, but it does not minimise systematic differences between the groups and, therefore, control for potential confounding factors. The authors described the indications for open versus laparoscopic interventions and these indications may have caused bias in the results. For instance, patients with prior multiple laparotomies underwent open intervention. This may mean that such individuals were more poorly and were inclined to have less positive outcomes, resulting in the open procedure requiring seemingly more operating time, not because the procedure itself is more time-consuming, but because the patients systematically required more attention. The authors could have tried stratifying the groups to demonstrate any potential impact of such confounders. Further, the authors could have used statistical analyses to compare the groups at analysis and test for differences. The study sample was representative of the study population.

**Validity of estimate of measure of benefit**

The authors did not derive a summary measure of health benefit. The analysis was, in effect, a cost-consequences analysis.

**Validity of estimate of costs**

The authors did not report a perspective for the cost analysis. Nevertheless, they appear to have considered the hospital or health care provider perspective, with resource estimates focusing on supplies, operating room costs and hospital bed costs. The conflicting reporting of the costs, and the relatively small absolute difference between the alternatives, suggest that small omissions in cost estimates may have affected the results and the principal conclusions of the study. Moreover, the age groups used in the study were potentially economically productive and treatment may affect this economic productivity, both in the short- and long-term, if symptoms are alleviated. This societal impact could have been incorporated in the analysis. The unit costs were reported separately, thus allowing the reader to understand the key cost-drivers and the costs that were common to both alternatives.

**Other issues**

The authors compared their findings in an extensive discussion of the findings from other related studies, including reasons for differences between the results. However, the issue of generalisability to other studies was not explicitly addressed. Whilst factors such as there being no very specific inclusion and exclusion criteria help to improve generalisability, the generalisability is also limited by the lack of sensitivity and statistical analyses to test the impact of uncertainty on the results presented. Readers should exercise caution when transferring the results, owing to the setting-specific costs used in the analysis. The results do not appear to have been presented selectively. The conclusions reflected the results presented, with the authors reporting the comparability of the two procedures. No limitations were discussed.

**Implications of the study**

The authors did not make any recommendations for policy or practice following their study. They reported that, in their own setting, the choice between laparoscopic and open procedures is determined more by surgeon preference. However, the authors highlighted that there is a small learning curve for laparoscopic procedures. A statistical analysis would be important in further work to attempt to demonstrate a statistical difference between the alternatives, particularly with the comparable costs and effectiveness outcomes presented.

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Other publications of related interest

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