Evaluation medico-economique de la cure de hernie inguinale: Shouldice vs laparoscopie

[Medicoeconomic evaluation of inguinal hernia repair: Shouldice repair vs laparoscopy]


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 comparison of conventional Shouldice repair and transperitoneal laparoscopic repair with polypropylene mesh for inguinal hernia.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised men aged over 35 years, with non-complicated and non-recurring unilateral or bilateral inguinal hernia. Female patients or those aged younger than 35 years were excluded from the study. Patients were also excluded if they had a crural, recurring or complicated hernia, had undergone some specified surgical interventions, or had contraindications for celioscopy. The mean age of the patients was 57 years (range: 36 - 76).

Setting
The setting was secondary care. The economic study was carried out in Caen, France.

Dates to which data relate
The effectiveness and resource use analysis took place between May 1994 and September 1995. The price year was not specified.

Source of effectiveness data
The evidence or estimate for the final outcomes was 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 analysis.

Study sample
Power calculations to determine the sample size were not reported. The method used to select the sample was not specified. The initial study sample seems to have been appropriate for the clinical study question. Sixty-four patients were initially included in the trial. Of these, 32 patients were operated on using the Shouldice method, while the remaining 32 were operated on by laparoscopy. The percentage of patients who refused to participate was not specified. Two patients (6%) in the Shouldice group and 7 patients (21%) in the laparoscopy group were excluded from the initial
Sample because their data were not exploitable for the study.

**Study design**
The study was a randomised controlled trial that took place in a single centre. Randomisation was stratified and achieved by drawing envelopes prior to the patient entering the operating theatre. The duration of follow-up was 1 year. The loss to follow-up was nil at 15 days. However, at one year, 6 patients were lost to follow-up (10.9%) and one patient had died. The breakdown by intervention group was not reported. The interventions could not be blinded due to the nature of the surgery. It was not reported whether the assessment of the patients' outcomes was blinded.

**Analysis of effectiveness**
The basis of the analysis of effectiveness was treatment completers only. The primary health outcome used in the analysis was post-operative pain. This was measured by the consumption of analgesics, and by a simple verbal scale (EVS) and verbal analogue scale (EVA). The EVS had five items, i.e. no pain, slight pain, moderate pain, severe pain, extreme pain. The EVA reported the intensity of pain on a scale from 0 to 10. The groups were shown to be comparable at analysis in terms of their age, unilateral and bilateral hernia, and by professional activity or inactivity.

**Effectiveness results**
For post-operative pain measured by the consumption of analgesics, there was no significant difference between the two groups after the operation or at one year. The Shouldice group consumed significantly more analgesics at 15 days, (p<0.01).

For pain measured by the EVS and EVA scales, there was no significant difference between the two groups after the operation, at 15 days or at one year.

**Clinical conclusions**
There was no difference in the post-operative pain between the two groups.

**Measure of benefits used in the economic analysis**
A cost-consequences analysis was performed as no summary health benefit was used.

**Direct costs**
Discounting was not performed as the costs were incurred over less than 2 years. The direct costs included the costs of the drugs, the materials used during the operation, personnel, hospital board and other costs, the exact nature of which was unclear. Some of the quantities, such as the length of operation, were reported separately from the costs. The quantity/cost boundary adopted was that of the hospital. The quantities were estimated from the patients' actual resource consumption. The costs of drugs, materials used during the operation, hospital board and personnel were obtained from the hospital. The other costs were obtained from the French social security. The quantity of resources used was measured between May 1994 and September 1995. The price year was not reported.

**Statistical analysis of costs**
No statistical analysis of the costs was carried out.

**Indirect Costs**
The number of days of work lost due to the intervention were reported, but no costing was performed on these data. The data were obtained from the French insurance system and were derived from actual data.
Currency
French francs (Ffr).

Sensitivity analysis
Sensitivity analyses were not carried out.

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

Cost results
The average total cost for the Shouldice intervention was Ffr 3,922 for a unilateral hernia and Ffr 4,808 for a bilateral hernia.

The average total cost for the laparoscopy intervention was Ffr 8,949 (single-use trocar) and Ffr 7,136 (reusable trocar) for a unilateral hernia, and Ffr 9,570 (single-use trocar) and Ffr 7,763 (reusable trocar) for a bilateral hernia.

Synthesis of costs and benefits
Not relevant.

Authors’ conclusions
Laparoscopic hernia repair does not decrease post-operative pain, hospital stay and return to work, but it is twice as expensive.

CRD COMMENTARY - Selection of comparators
The comparator used, the Shouldice technique, was justified on the grounds that it was the standard intervention for hernia repair. You should decide if this is a widely used health technology in your own setting.

Validity of estimate of measure of effectiveness
The analysis used a randomised controlled trial, which was appropriate for the study question. In addition, the patients groups were shown to be comparable at analysis. However, there were some weaknesses in the analysis of effectiveness. It was not possible to assess whether the study sample was representative of the study population, as the number of patients who refused to participate was not reported or accounted for in the analysis. Moreover, a number of patients were excluded from the sample because of a lack of data, and the potential bias does not appear to have been handled in the analysis. Power calculations were not reported. More information on the instruments used to value the level of pain would have strengthened the measure of effectiveness. In particular, the authors did not report whether these instruments had been externally validated.

Validity of estimate of measure of benefit
The authors did not derive a summary measure of health benefit. Therefore, the analysis was categorised as a cost-consequences study.

Validity of estimate of costs
In general, the costing was weakened by a lack of detailed reporting. While a number of relevant categories of cost were included in the analysis, it was difficult to assess the nature of one of the categories (medico-technical acts). A more detailed description of this category would have been useful. The length of time for which the costs were relevant was not explicitly stated in the study. No statistical analysis of the costs or sensitivity analyses were conducted. Charges may
have been used to proxy prices. The price year was not reported. One strength of the costing was that a number of the quantities were reported separately from the costs.

Other issues
The authors discussed other economic studies but did not report whether their findings were comparable. The issue of generalisability to other settings was not discussed. The authors did not present their results selectively. They reported two possible limitations to their study. First, the sample size may have been too small to show any differences. Second, the minimum age for inclusion in the study (35 years) may have caused the sample to be less professionally active due to the higher age of the patients.

Implications of the study
The results of this study suggest that the laparoscopy procedure for inguinal hernia repair is associated with similar health outcomes but at a greater cost. Future studies should attempt to eliminate the limitations highlighted.

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