Cost-effectiveness of alternative methods of surgical repair of inguinal hernia
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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
Several approaches for inguinal hernia repair (IHR) were examined. These included open non-mesh repair, open flat mesh repair, and two types of laparoscopic repair, namely transabdominal preperitoneal (TAPP) repair and totally extraperitoneal (TEP) repair.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised a hypothetical cohort of patients undergoing IHR.

Setting
The setting was a hospital. The economic study was carried out in the UK.

Dates to which data relate
The effectiveness data came from studies published in 2001 and 2002. The costs and resource use data were derived from studies published between 1998 and 2001. The costs were expressed in 2000/2001 values.

Source of effectiveness data
The effectiveness evidence was derived from a synthesis of completed studies and authors' opinions.

Modelling
A Markov model was constructed to examine the cumulative costs and benefits associated with each method of IHR. Four possible health states were considered. These were operation, successful operation, re-operation and death. The model followed a hypothetical cohort of patients from initial operation through convalescence (operation state), to their return to usual activities (successful operation state). The patients could remain in this state until they died (death state), or could suffer a recurrence and have a re-operation (re-operation state). The time horizon of the model was 5 years. The cycle length was not reported.

Outcomes assessed in the review
The outcomes assessed were:

the recurrence rates,
the time to return to usual activities,

the proportion of people with long-term pain,

the length of stay, and

the operation time.

The mortality rate was also estimated from the literature.

**Study designs and other criteria for inclusion in the review**
A systematic review of RCTs and quasi-RCTs was carried out to identify relevant studies. Mortality data were derived from Scottish life tables.

**Sources searched to identify primary studies**
MEDLINE and the Cochrane CENTRAL Register were searched. Further studies were identified from the reference lists of known trials, relevant websites and through the EU Hernia Trialists Collaboration.

**Criteria used to ensure the validity of primary studies**
The use of RCTs ensured the validity of the sources used.

**Methods used to judge relevance and validity, and for extracting data**
Not stated.

**Number of primary studies included**
A total of 58 RCTs and 11,174 patients were included in the three reviews considered in the study. A fourth source was used for mortality.

**Methods of combining primary studies**
The primary studies were combined using meta-analyses, where appropriate.

**Investigation of differences between primary studies**
Not stated.

**Results of the review**
The annual probability of death for a 45-year-old male patient was 0.63%.

The annual probability of recurrence was 1.53% with TAPP repair (odd ratio, OR, versus open flat mesh 1.01, 95% confidence interval, CI: 0.56 - 1.85), 1.47% with TEP repair (OR versus open flat mesh 0.97, 95% CI: 0.34 - 2.77), 1.52% with open flat mesh (OR versus open non-mesh 0.27, 95% CI: 0.17 - 0.38), and 5.84% with open non-mesh.

The operation time was 61.10 minutes with TAPP repair, 51.75 minutes with TEP repair, 46.46 minutes with open flat mesh, and 49.53 minutes with open non-mesh.

The length of stay was 1 day for all techniques.

The time to return to usual activities was 8 days (95% CI: 7 - 9) with TAPP repair, 7 days (95% CI: 7 - 7) with TEP repair, 11 days (95% CI: 11 - 11) with open flat mesh, and 18 days (95% CI: 17 - 19) with open non-mesh.
The probability of long-term pain was 0.05 with TAPP repair, 0.01 with TEP repair, 0.08 with open flat mesh, and 0.12 with open non-mesh.

The ORs and CIs for differences in the probability of long-term pain and operation lengths were also reported.

**Methods used to derive estimates of effectiveness**
The authors made some assumptions that were used in the decision model.

**Estimates of effectiveness and key assumptions**
It was assumed that each treatment would have equal mortality. If a recurrence occurred, the inguinal hernia would be repaired using the same technique as the initial operation. All patients required general anaesthesia.

**Measure of benefits used in the economic analysis**
A number of model outputs were considered in the economic evaluation. These included time at usual activities, patients with long-term pain, and incidence of recurrences. The number of recurrences avoided was considered the main benefit measure. A discount rate of 6% was applied to the estimated benefits.

**Direct costs**
An annual discount rate of 6% was applied to the costs incurred over more than 2 years. The unit costs were presented separately from the quantities of resources used for some items. The main health services included in the economic evaluation were those associated with the initial operative period (initial operation and hospitalisation) and any subsequent re-hospitalisation. Staff, equipment, and theatre costs were included. The costs of operative and postoperative complications were not explicitly modelled as their impact was captured through longer operative times and hospitalisations. Similarly, the costs of management in the community were excluded because they were negligible. Under the base-case scenario, disposable rather than usable equipment was considered for laparoscopic surgery.

The cost/resource boundary of the health care system was adopted. The costs and resource use data were derived from the three trials alongside which an economic evaluation had been conducted. Investigators were contacted for the original spreadsheets or detailed information on the resources used and unit costs. Efforts were made to make the primary economic data comparable. All of the costs were expressed in 2000/2001 values.

**Statistical analysis of costs**
The costs were treated deterministically in the base-case.

**Indirect Costs**
The indirect costs were not considered in the economic evaluation.

**Currency**
The costs were estimated in UK pounds sterling () and Dutch guilders (Dfl) and then converted into Euros (Euro). The exchange rates were 1 = Euro1.59 and Dfl 1 = Euro0.45.

**Sensitivity analysis**
Probability distributions (Weinbull and Normal) were constructed using the mean and 95% CIs provided by the meta-analysis. These were then used in a probabilistic analysis using a Monte Carlo simulation (5,000 iterations). The use of reusable rather than disposable laparoscopic equipment was also investigated. Other assumptions made in the decision model were also varied in the sensitivity analysis.
Estimated benefits used in the economic analysis

Incremental results over the 5-year time horizon were reported. In the comparison between open flat mesh and open non-mesh, open flat mesh led to 10.7 (95% CI: 9.3 - 12) days more time at usual activities, 45 (95% CI: 6 - 73) fewer people per 1,000 with long-term pain, and 180 (95% CI: 145 - 293) fewer recurrences per 1,000 patients over open non-mesh.

In the comparison between laparoscopic approaches and open flat mesh, laparoscopic approaches resulted in more time at usual activities (TEP: 4.3 more days, 95% CI: 0.4 - 8.2; TAPP: 3.2 more days, 95% CI: 1.8 - 4.5) and fewer people having long-term pain (TEP: 67 fewer people per 1,000, 95% CI: 41 - 107; TAPP: 32 fewer people per 1,000, 95% CI: 12 - 57). However, there were 3.6 fewer serious complications per 1,000 procedures with open flat mesh. Similar recurrences were observed.

In the comparison between TEP and TAPP repair, there was a trend favouring TEP repair in terms of time to return to usual activities and pain.

Cost results

Incremental results over the 5-year time horizon were reported.

In the comparison between open flat mesh and open non-mesh, the initial operation costs were lower with open non-mesh. However, over the long term, open flat mesh led to mean savings of Euro152 (95% CI: 92 - 218).

In the comparison between laparoscopic approaches and open flat mesh, open flat mesh led to lower long-term costs versus both TEP (mean savings Euro160, 95% CI: 100 - 281) and TAPP (mean savings Euro256, 95% CI: 219 - 323) repair.

In the comparison between TEP and TAPP repair, there was a trend favouring TEP repair in terms of long-term costs.

Synthesis of costs and benefits

Incremental costs and benefits were presented using a balance sheet, with the main cost-effectiveness ratio being the cost per recurrence avoided (which was not actually calculated). Open non-mesh was dominated by open mesh repair (more costly and less effective).

In the comparison between laparoscopic approaches and open flat mesh, the sensitivity analysis showed that, if disposable equipment were used, the cost-advantage of open flat mesh would increase. Further, there was a 34.5% chance that TEP repair (43.9% for TAPP) would prevent more recurrences and be more costly than open flat mesh repair. There was only a 21.6% chance that the incremental cost per recurrence avoided for TEP repair compared with open flat mesh would be less than Euro10,000 when reusable laparoscopic equipment was used (when disposable equipment was used, the probability was less than 1.5%). Likewise, for the comparison of TAPP repair with open flat mesh, there were 10.4% and 0.02% chances that the incremental cost per recurrence avoided would be less than Euro10,000 for reusable and disposable laparoscopic equipment, respectively.

Cost-effective acceptability curves were constructed to compare TEP with open mesh repair using three different sources for the unit costs and resource use. Overall, the results of the cost-effective acceptability curve suggested that there was a very small probability that TEP could be considered cost-effective.

In the comparison between TEP and TAPP repair, the probabilistic sensitivity analysis showed that there was nearly a 40% chance that TEP repair was dominant, or was associated with an incremental cost per recurrence avoided of less than Euro1,000. In contrast, the probability that TAPP repair was dominant, or was associated with an incremental cost per recurrence avoided of less than Euro1,000, was less than 0.1%.

In general, the use of disposable laparoscopic equipment increased the cost of laparoscopic surgery.

Authors' conclusions
In patients requiring inguinal hernia repair (IHR), open flat mesh repair dominated open non-mesh repair, which was both more expensive and less effective. Open flat mesh repair was more cost-effective than laparoscopic approaches, which were associated with less long-term pain and an earlier return to usual activities. The evidence on the comparison between the two laparoscopic approaches was less sound, but the analysis suggested that totally extraperitoneal (TEP) repair was highly unlikely to be dominated by transabdominal preperitoneal (TAPP) repair and could be superior.

**CRD COMMENTARY - Selection of comparators**
The authors stated that the four methods for IHR were the most commonly used approaches. Plug and mesh and preperitoneal mesh repair were also performed, but were not considered as relevant comparators because of the paucity of available data. You should decide whether they are valid comparators in your own setting.

**Validity of estimate of measure of effectiveness**
The effectiveness evidence was derived from three well-conducted systematic reviews of the literature. Meta-analyses were conducted to combine the primary studies. Extensive details of the methods and conduct of the reviews were provided. Most of the data were based on patient-level information. The validity of the analysis was ensured by including only RCTs. Each estimate was assigned a probability distribution, which was used in the probabilistic sensitivity analysis. Some assumptions were also made and were then varied in the sensitivity analysis.

**Validity of estimate of measure of benefit**
The summary benefit measure was specific to the disease considered in the study. It is not comparable with the benefits of other health care interventions. The model outputs were discounted using an annual rate of 6%. The impact of the interventions on quality of life was not assessed.

**Validity of estimate of costs**
The perspective adopted in the study was reported and all the relevant categories of costs were included in the economic evaluation. The authors justified the exclusion of some categories of costs. The indirect costs were not included because of the lack of generalisable data on the opportunity costs of time away from usual activities. Both the unit costs and quantities of resource use data were estimated from three prior economic evaluations of RCTs. Original data were requested to re-run the economic analysis using primary cost data. The price year was reported, which enhances the possibility of performing reflation exercises in other settings. The sources of all the data were provided.

**Other issues**
The authors did not make extensive comparisons of their findings with those from other studies, but it should be noted that their analysis was based on several published studies. The issue of uncertainty was extensively addressed in the probabilistic sensitivity analysis. The authors highlighted that the comparison between the two laparoscopic approaches was not based on direct comparison data. It was noted that open repair could be performed under local or regional anaesthesia, while laparoscopic surgery required general anaesthesia in most cases. This would further reduce the cost-effectiveness of the laparoscopic approaches. The authors justified the choice of the time horizon, which enabled all relevant clinical and economic outcomes to be included in the analysis.

**Implications of the study**
The study results supported the use of open flat mesh repair for the treatment of inguinal hernia. The role of laparoscopic treatments was less clear. The authors noted that clinical guidelines should reflect local circumstances.

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