A prospective randomized outcome and cost comparison of totally extraperitoneal endoscopic hernioplasty versus Lichtenstein hernia operation among employed patients

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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
Two surgical procedures for inguinal hernia repair were compared, totally extraperitoneal endoscopic hernioplasty (TEP) and the open mesh Lichtenstein hernia operation (OPN).

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis, (cost-consequences analysis).

Study population
The study population was people of working age, undergoing inguinal hernia repair in a day case surgery unit. The study sample consisted of 45 employed men with primary unilateral hernias, aged between 21 and 65 years. The inclusion criteria were reported as patients who were suitable for general anaesthesia on an outpatient basis and extraperitoneoscopy. Exclusion criteria were reported as patients with previous major lower abdominal surgery, retirement from work, pregnancy, irreducible hernia and infection.

Setting
The setting was secondary care. The economic study was carried out in Keski-Pohjanmaa Central Hospital, Finland.

Dates to which data relate
The effectiveness and resource data were collected between January and September 1996. All costs were adjusted to 1996 prices.

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

Link between effectiveness and cost data
Costing was undertaken on the same patient sample that was used in the effectiveness study.

Study sample
The authors did not state whether the sample size was determined in the planning phase of the study to assure a certain power, or if power calculations were performed. The study sample was selected from a total of 135 hernia patients who were operated on at Keski-Pohjanmaa Central Hospital. 75 (56%) were considered suitable for surgery in a day-case unit and were of working age. Of these patients, 45 were finally randomised to undergo either a TEP or OPN hernia.
operation. 22 patients with a median age of 44 years (range: 21 - 65) were randomised to the TEP group and 23 patients with a median age of 46 years (range: 22 - 58) to the OPN group.

**Study design**
The study reported a randomised, clinical trial based at a single centre. Randomisation was carried out at the preoperative visit by opening a sealed envelope defining the method of hernia repair. The groups were examined one week after surgery. The median follow-up was reported as 10 months. There were no dropouts after randomisation. No methods to conceal treatment allocation for outcome assessment were reported.

**Analysis of effectiveness**
All the randomised patients were included in the analysis, indicating that an intention to treat analysis was conducted. The following outcomes were assessed in the review: operative time, operation room time, day cases, postoperative stay of all patients, convalescence, physical fitness at one week, patient satisfaction, and postoperative complications and complaints in the recovery room, at one week and at one to two months.

Pain was valued using a visual analogue scale (VAS) rated from 1 to 10, where 1 describes no pain and 10 describes extreme pain. Patient satisfaction was assessed by a questionnaire with a four-dimensional scale, where 4 represents very satisfied and 1 represents very unsatisfied.

The groups were shown to be comparable in terms of age, gender, type of employment and hernia classification. The nature of the procedures, however, dictated that 100% of the TEP group received a general anaesthesia, whereas only 9% of the OPN group opted for this method.

**Effectiveness results**
The following results were reported.

Operative time: TEP = 67.5 minutes (range: 40 - 88), OPN = 53 minutes (range: 42 - 78), (p=0.001);

Operation room time: TEP = 120 minutes (range: 90 - 152), OPN = 95 minutes (range: 75 - 145), (p<0.001);

Day cases TEP = 73%, OPN = 87%;

Postoperative stay of all patients: TEP = 6.25 hours (range: 5.52 - 21), OPN = 4.75 hours (range: 1.75 - 45), (p<0.001);

Convalescence - household chores: TEP = 2.5 days (range: 1 - 4), OPN = 6 days (range: 1 - 31), (p=0.004);

Convalescence - normal life: TEP = 14 days (range: 3 - 35), OPN = 20 days (range: 6 - 46);

Convalescence - return to work: TEP = 12 days (range: 3 - 21), OPN = 17 days (range: 4 - 31), (p=0.01);

Physical fitness at one week - straight leg rise: TEP = 100%, OPN = 91%;

Physical fitness at one week - straight leg rise with both feet: TEP = 95%, OPN = 61%, (p=0.006), physical fitness at one week - squats: TEP = 100%, OPN = 87%;

Physical fitness at one week - sit-ups: TEP = 82%, OPN = 61%;

Patient satisfaction: TEP = 73% very satisfied, 27% satisfied and 0% unsatisfied, OPN = 61% very satisfied, 35% satisfied and 4% unsatisfied;

Postoperative complications and complaints in the recovery room: TEP = 6 (5 of which were due to nausea), OPN = 6;

Postoperative complications and complaints at one week: TEP = 16, OPN = 18;
Postoperative complications and complaints at one-two months, TEP = 1, OPN = 4.

**Clinical conclusions**
The operative time and the time spent in recovery were shorter in the OPN group. However, convalescence was faster and physical performance after one week was better in the TEP group, which felt more pain in recovery but less pain at home. Patient satisfaction did not differ significantly between groups. Overall the authors reported that most of the short-term results favoured the TEP group, due to a 5 day reduction in duration of sick leave.

**Measure of benefits used in the economic analysis**
The outcomes were reported in a disaggregated fashion and as such, a cost-consequences analysis was performed.

**Direct costs**
The cost analysis included the direct costs to the hospital of the operation and anaesthesia, which included wages (doctors', nurses' and other), equipment and supplies (disposables, mesh, other instruments and supplies, extra amortisation for the TEP group, medicines, infusions and other anaesthesia supplies). The unit costs of hospital resources were calculated using the Medicost analysing method, which was reported to be similar to the Activity Based Costing System. Discounting was not carried out due to the short time frame of the study. The authors did not report unit costs and measures of resource use separately. The cost data were adjusted to 1996 prices. The original years for the cost data were not reported.

**Statistical analysis of costs**
The median costs were reported in the study to give a relevant picture of the patient population, which was relatively small. Differences between groups were tested using Mann Whitney U test.

**Indirect Costs**
The indirect costs were reported as the cost of sick leave, which were $2,747 (range: 687 - 4,807) for TEP and $3,892 (range: 916 - 7,069) for OPN. Quantities and costs were not reported separately. The cost per day of sick leave was estimated at three times the average salary cost of the patient, plus the costs of salary to replace the worker, health insurance expenses and other employer costs. The salary cost was estimated from the average salary of the study sample. The adjustment figure of 300% was based on information from the Finnish Confederation of Industry and Employers.

**Currency**
US dollars ($). All costs were adjusted to 1996 prices based on a conversion rate of 1 Finnish Mark = $4.6.

**Sensitivity analysis**
The authors did not perform a sensitivity analysis.

**Estimated benefits used in the economic analysis**
The reader is referred to the effectiveness results reported previously.

**Cost results**
The total costs were reported as follows: TEP = $3,912 (range: 1,816 - 6,126), OPN = $4,661 (range: 1,660 - 8,257), (p=0.2).

The direct costs were TEP = $1,239 (range: 982 - 1,548), OPN = $782 (range: 671 - 1,160). (p<0.001).
The indirect costs of sick leave were TEP = $2,747 (range: 687 - 4,807), OPN = $3,892 (range: 916 - 7,096), (p=0.01).

Discounting was not carried out due to the time frame of the analysis. The costs of adverse effects or recurrence were not accounted for in the analysis.

**Synthesis of costs and benefits**
The costs and benefits were not combined in the study.

**Authors' conclusions**
The authors concluded that TEP hernia repair is more expensive for hospitals but more cost-effective for society, due to the earlier return to work. However, more information is needed about the recurrence rate and long-term morbidity, which also affect the cost-effectiveness of hernia operations.

**CRD COMMENTARY - Selection of comparators**
OPN and TEP would appear to represent relatively new techniques that are both in use in the authors' setting. You as a user of this database should decide if they represent current practice in your own setting.

**Validity of estimate of measure of effectiveness**
The analysis was based on a randomised, clinical trial, which was appropriate for the study question, and the two patient groups were shown to be comparable at analysis. The authors did not report details of the study population characteristics. However, they did report the application of some inclusion and exclusion criteria. A total of 135 hernia patients were operated on during the time of the study, of whom 75 were eligible for day case surgery and 45 entered the trial. The authors did not report whether the sample size was sufficient to detect statistically significant differences in outcomes. There was no indication that patients, or those responsible for outcome assessment, were masked to treatment allocation. One surgeon conducted all the operations. The lack of masked treatment allocation might have resulted in subjective bias in the postoperative care provided, and perceptions of subjective outcome measures.

**Validity of estimate of measure of benefit**
The authors did not derive a measure of health benefit. The analysis was therefore categorised as a cost-consequences analysis.

**Validity of estimate of costs**
Hospital costs and the costs of patient time off work were included. The perspective of the analysis was not explicitly stated. The direct hospital costs included capital and overhead costs where appropriate. The use of hospital resources was estimated from the patient sample and study centre. Quantities and costs were not reported separately. The authors used statistical analysis of differences in total direct and indirect costs to assess uncertainty in the observed data. The authors did not include sensitivity analysis to evaluate uncertainty due to other causes, such as the source of the unit costs data or the method used to derive unit cost information. This may be particularly important for the estimate of cost per day of lost work time which appears to double count the indirect costs of lost production by including both the salary of the employee, and the cost of a replacement. The authors did not report whether the salary costs were adjusted to reflect the baseline level of unemployment. These factors mean that the indirect costs of lost production might be a substantial over estimate. If this were the case, the difference in total costs between the two interventions would be substantially reduced.

The authors performed appropriate currency conversions. Since all costs were incurred over one year, discounting was unnecessary.

**Other issues**
The authors made appropriate comparisons of their findings with those from other studies. The issue of generalisability to other settings was not addressed. The study enrolled working men and this was reflected in the authors’ conclusions. The authors reported a number of further limitations to their study, namely limitations in data concerning recurrence and the issue of inequality associated with calculations of the costs of lost time.

**Implications of the study**
The authors suggested that more information is needed about recurrence rates and long term morbidity rates, which would affect the relative cost-effectiveness of the operations.

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