A randomized, controlled, clinical study of laparoscopic vs open tension-free inguinal hernia repair


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
Surgical treatment of inguinal hernia.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
Patients with unilateral (primary or recurrent) or bilateral hernias.

Setting
Hospital. The study was carried out in Italy.

Dates to which data relate
The effectiveness and cost data were collected during the period April 1994 - March 1996. The price year was 1997.

Source of effectiveness data
The evidence for final outcomes was derived from a single study.

Link between effectiveness and cost data
The costing was undertaken on the same patient sample as that used in the effectiveness study. The costing was carried out prospectively alongside the effectiveness study.

Study sample
108 patients were randomised between the experimental group (52 patients, 48 males, 4 females, age 54 +/- 15.3 years; weight 73 +/-9.2 kg; height 169.9cm +/- 7.9cm; ASA I 23 patients; ASA II 29 patients) and the control group (56 patients, 51 males, 5 females, age 55.6 +/-15.2 years; weight 74.4 +/- 10.8 kg; height 171.2cm +/- 6.7 cm; ASA I 26 patients; ASA II 30 patients). No power calculations were used to determine the sample size. Only low-risk patients were included in the study (ASA I or II). Patients were diagnosed with unilateral (primary or recurrent) or bilateral hernia. High-risk patients (ASA III and IV) were not included, nor were pregnant patients or patients younger than 18 years of age. Patients with incarcerated hernias, congenital hernias (Nyhus type I), massive scrotal or sliding hernias (Nyhus type IIIB), or with a history of multiple recurrent hernias were also excluded. Additional exclusion criteria were the presence of previous pelvic surgery, coagulation disorders, and the presence of other abdominal diseases amenable
to surgical treatment that could be performed laparoscopically during the same operation. Patients with a personal preference for one of the two procedures and those who had been referred from their general practitioner to receive a specific type of procedure were not included in the study protocol.

**Study design**

The study was a multi-centre, prospective, randomised, controlled clinical study. Patients were randomised on the basis of a random number generator table. Follow-up visits were scheduled at 7 days, and 1, 3, 6, 12, 24, and 30 months post-operatively. No patients were lost to follow-up. Post-operative pain was assessed by patients and two independent observers.

**Analysis of effectiveness**

The analysis of the clinical study was based on intention to treat. The primary health outcomes studied included operating time, complications, post-operative pain, return to normal activity, and recurrences. The Visual Analogue Scale (VAS) was used by patients to assess post-operative pain levels. At analysis, both groups were comparable in terms of gender, age, weight, height, ASA class, the time that the hernia had been present, the number of patients who had been wearing an inguinal truss, the distribution of hernias according to type (unilateral, bilateral) and Nyhus classification.

**Effectiveness results**

Operating time in patients with unilateral primary hernias was 66.6 minutes (+/- 21.9) in the laparoscopic group and 48.2 minutes (+/-22.9) in the open group, (p=0.002). No statistically significant difference was observed in the operating time in patients with unilateral recurrent hernias: 71.1 minutes (+/- 31.4) after TAPP and 41.2 minutes (+/- 8.5) after open repair, (p=0.094). Likewise no statistically significant difference in operating time was found in patients with bilateral hernias: 85.7 minutes (+/- 32.3) after TAPP and 75.9 minutes (+/- 43.3) after open repair, (p=0.495). No statistically significant difference was observed in the incidence of intra-operative complications. No patient in the laparoscopic group required conversion to open surgery, and all operations were performed under general anaesthesia.

In the open group, general anaesthesia and epidural analgesia were performed in one and two cases, respectively. Local anaesthesia was performed in the remaining 53 cases. Patients in the TAPP group rated pain at rest (VAS: median of 2, 25th-75th percentile: 1-3) at 48 hours after the operation significantly higher than patients in the open group (VAS: median of 1, 25th-75th percentile: 1-2). No p-value was provided. No significant differences in pain at rest were observed at the other time intervals (before the operation, and 6, 9, 24 hours and 7 days after the operation). No difference in post-operative pain was observed between the two groups of patients as rated by two independent observers on a 5-point scale at time intervals of 6, 9, 24 and 48 hours post-operatively, as well as 7 days post-operatively.

Patients from the TAPP group took a significantly longer time (p=0.03) to complete the described exercise within the first 9 hours post-operatively than patients in the open group. This difference disappeared at subsequent observations (24 and 48 hours, 7 days). Patients in the open group consumed significantly more placebo tablets between 24 and 48 hours post-operatively than those who underwent TAPP (p=0.008). No difference between the two groups was observed in terms of intramuscular analgesic consumption. The incidence of post-operative in-hospital complications (haematoma, hydrocele, paresthesia) was not statistically different in the two groups. The occurrence of inguinal seroma was higher in the TAPP group than in the open group.

Mortality was nil in both groups. No significant difference was observed in patient recovery in terms of walking (p=0.494), eating (p=0.242), and passing stool (p=0.077). At 48 hours after the operation, no significant difference was observed in terms of wound edema, wound redness (p=0.199) and post-operative urinary retention (p=0.307). There was no difference in length of hospital stay between the two groups (p=0.880). Mild to discomforting pain in the inguinal region after 7 days (p=0.027), night pain after 3 months (p=0.017), and inguinal hardening after 3 months (21% in the open group versus 4% in the TAPP group, p=0.007) were more frequent in the open group.

No statistically significant difference was observed for the occurrence of mild/discomforting pain in the pubic tubercle.
and the anterior superior iliac spine and for the occurrence of other local complications (wound infection, haematoma, seroma, paresthesia). There was no statistically significant difference between the two groups for time required before the patient resumed unrestricted activity. Median (25th-75th percentile) time to return to work was 15 (range: 10 - 25) days after TAPP and 14 (range: 7 - 30) days after open procedure; time to return to sport was 20 (range: 10 - 30) days after TAPP and 20 (range: 7 - 30) days after the open procedure. There was no significant difference between patients with unilateral and bilateral hernias. Finally, no significant difference was observed in terms of hernia recurrence.

**Clinical conclusions**

TAPP is associated with less post-operative pain, an early return to work, and a low recurrence rate. On the other hand, TAPP may be associated with an increased potential for both major and minor complications.

**Modelling**

No modelling was undertaken.

**Measure of benefits used in the economic analysis**

The main benefit measure was patients’ post-operative quality of life. The Visual Analogue Scale (VAS) was used to assess post-operative pain at rest. Health states were valued by 108 patients and two independent observers at 6, 9, 24, 48 hours, 7 days, and 1, 3, 6, 12, 24 and 30 months after the operation during home visits.

**Direct costs**

Direct costs were confined to operating theatre costs which included the cost of disposable instruments, but not medical fees or anaesthesia costs. Costs were not discounted. Quantities and costs were not reported separately. The quantity/cost boundary adopted was that of the hospital. The estimation of quantities and costs was based on actual data. Data relating to resource use were collected at each centre and then sent on to the co-ordinating centre. The price year was 1997.

**Statistical analysis of costs**

Chi-square and Fisher’s exact test (two-tailed) for categorical variables and Student's t-test and the Wilcoxon rank sum test for quantitative variables were the statistical methods employed. A significance level of 0.05 was assigned.

**Indirect Costs**

No indirect costs were included.

**Currency**

Italian lire (L). A conversion was undertaken at the exchange rate of 1,680 Italian lire to 1 US dollar.

**Sensitivity analysis**

No sensitivity analysis was undertaken.

**Estimated benefits used in the economic analysis**

At rest, the median VAS score was higher for the TAPP group than the open group at 48 hours after the operation. Mild to discomforting pain in the inguinal region after 7 days (p=0.027), night pain after 3 months (p=0.017), and inguinal hardening after 3 months (21% in the open group versus 4% in the TAPP group, p=0.007) were more frequent in the open group. No significant differences were observed in terms of the return to normal activity between the two groups.
Cost results
Operating theatre costs in the TAPP group were $1,249 (+/- 68.53), significantly higher (p<0.001) than the corresponding costs in the open group ($306.4 +/- 172.7).

Synthesis of costs and benefits
The cost and benefit measures were not combined into a cost-effectiveness ratio.

Authors' conclusions
TAPP is associated with less post-operative pain than the open procedure. The increase in operating theatre costs, however, was dramatic and was not compensated by a shorter time away from work. TAPP should not be adopted routinely unless its costs can be drastically reduced.

CRD COMMENTARY - Selection of comparators
The choice of the comparator was justified.

Validity of estimate of measure of benefit
The measure of benefit seems to be valid. The authors are to be congratulated for eliciting health state values from both patients and independent observers. The use of, and the comparison between, other methods to elicit health state values and VAS could have yielded interesting insights. The authors could have justified the use of VAS although the choice between the various elicitation methods is not clear even from a methodological point of view.

Validity of estimate of costs
The cost measure was very restrictive: the costs of anaesthesia, hospitalisation and medical fees were not included. No allowance was made for economic benefits of earlier return to work. It is therefore difficult to assess the applicability of the cost results to other settings.

Other issues
Although the reporting of the effectiveness results was extensive, it sometimes lacked detail. The omission of a sensitivity analysis is justified because of the large cost differential between the two groups. The issue of generalisability to other settings or countries was not addressed. It is not possible to draw firm conclusions about the recurrence rate since this would require a large sample size and a very long follow-up period. The authors acknowledged that the valuation of health states by patients may have been influenced by prior patient expectations. The small sample size may be a cause for concern. The design of the study means that no conclusions about post-operative hospital stay can be reached. The authors did not give an explanation for a possibly contradictory result: at 48 hours post-operatively, VAS pain scores were higher in the TAPP group, although use of pain medication was higher in the open group. Finally, one should bear in mind that learning effects are involved in newer technologies such as TAPP which may affect the results.

Implications of the study
A number of well-designed, prospective, randomised controlled clinical trials should compare a laparoscopic procedure that employs mesh placed posteriorly with an open procedure that uses the same type of mesh placed anteriorly.

Source of funding
None stated.

Bibliographic details
Other publications of related interest


Indexing Status
Subject indexing assigned by NLM

MeSH
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