Lichtenstein patch or Perfix plug-and-patch in inguinal hernia: a prospective double-blind randomised controlled trial of short-term outcome

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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
Performing Perfix plug-and-patch repair (a cone-shaped preformed plug and supplementary patch - Perfix Plug; Davol Inc, Cranston, RI, USA) for primary, uncomplicated inguinal hernia.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
Patients over the age of 18 years with an uncomplicated unilateral inguinal hernia. Exclusion criteria were morbid obesity (body mass index greater than 40), irreducible inguinoscrotal hernia, failure to give consent for randomisation, or recurrent hernia.

Setting
Hospital. The economic study was carried out in Plymouth, England.

Dates to which data relate
The dates of the data were not given.

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

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

Study sample
Power calculations were used to determine the sample size: a sample of 70 patients in each group was required to detect a difference in visual analogue scores (VASs) of 10 (with an assumed SD of 20) with a power of 0.84 (2-tailed t test). A total of 141 patients were randomly allocated to receive either a Lichtenstein patch or a Perfix plug-and-patch. The study sample consisted of 68 patients in the Lichtenstein group with a mean age of 50 (range: 21 - 84) years and 73 in the Perfix group with a mean age of 56 (range: 23 - 83) years. There were 3 staff surgeons and 6 residents who operated independently and who participated in the study.
Study design
This was a double-blind (patient and observer), randomised, controlled trial, carried out in a single centre. Patients were contacted by the research nurse assistant by telephone on day 3 and attended the hospital on day 14 for assessment of postoperative complications and the collection of completed VAS proformae, analgesic consumption, and the SF36 questionnaire forms completed on days 3 and 14. Further follow-up was performed at 6 weeks to record the return to normal activity and work. The study appears to have had no loss to follow-up. Patients were allocated by random number in the operating room before application of the mesh to receive either an open Lichtenstein or a Perfix plug-and-patch. The operating surgeon took no part in patient follow-up or the assessment, and both the patient and the research nurse were blinded to the type of mesh hernioplasty performed.

Analysis of effectiveness
The principle used in the analysis of effectiveness appears to have been intention to treat. The primary health outcome was postoperative pain as measured by VAS. Secondary health outcomes were postoperative complications, the duration of the operative procedure, the return to normal activity, time to return to work, the total days of work missed, the number of days during which analgesic medication was taken, and the 8 items on the SF36 questionnaire. The patients recorded VASs for pain assessment during the first 14 days after the operation, and completed SF36 questionnaire to assess quality of life at day 3 and day 14 after the operation. The research nurse assistant recorded any wound or testicular complications at follow-up. Patient groups were shown to be comparable in terms of baseline characteristics.

Effectiveness results
The incision size for the plug-and-patch group was 4.9cm compared with 7.7cm, (p<0.001). Operating time (32 versus 37.6 minutes) was significantly shorter in the plug-and-patch group, (p=0.01). During day 1 through day 8, patients who had undergone the plug-and-patch operation experienced less pain, and their physical functioning on day 3 was significantly better, (p=0.013). Days of analgesic medication (4.0 versus 4.6 days), return to normal activity (2.8 versus 3.6 days), return to work (17.0 versus 20.8), and total days of work missed (14.3 versus 16.1 days) were similar in both groups, (NS for all comparisons). The frequency of postoperative complications in the 2 study groups was not significantly different: there were 6 cases of significant postoperative complications in the Liechtenstein group versus 0 in the Prefix group.

Clinical conclusions
The results of this study indicate that for primary, uncomplicated inguinal hernia the Perfix plug-and-patch repair can be performed through a smaller incision in a shorter operating time compared with a Lichtenstein patch repair. Less pain, as measured by VAS in the first 8 days after operation, was experienced by patients who received the Perfix plug-and-patch, which did not lead to a reduction in analgesic consumption but did marginally improve physical functioning on day 3 compared with the Lichtenstein patch hernioplasty.

Measure of benefits used in the economic analysis
No summary benefit measure was identified in the economic analysis, and only separate effectiveness outcomes were reported.

Direct costs
Costs were not discounted due to the short time frame of the study. Some quantities were reported separately from the costs. Cost analysis covered the overall charges to the hospital associated with the devices used in each operations; while the operating room time was not valued in terms of monetary units (significantly different between the groups) and postoperative analgesic medication (NS). The perspective adopted in the cost analysis appears to have been that of the hospital. Charge data for the devices were used instead of true costs. The price year was not given.

Indirect Costs
Costs were not discounted due to the short time frame of the study. Quantities (the return to normal activity, the return to work, the total days of work missed) were reported separately from the costs. Since the groups were not significantly different in terms of the rate of return to normal activity and work, the monetary values were not calculated.

**Currency**  
US dollars ($). The conversion rate from UK pounds to US dollars was not reported.

**Sensitivity analysis**  
A sensitivity analysis was not conducted.

**Estimated benefits used in the economic analysis**  
Not applicable. The reader is referred to the effectiveness results reported above.

**Cost results**  
Overall hospital costs were greater for the plug-and-patch operation ($120) compared to the Lichtenstein patch ($20) with a negligible saving of operating room time for the plug-and-patch operation (5.6 minutes).

**Synthesis of costs and benefits**  
A synthesis of costs and benefits was not performed.

**Authors' conclusions**  
The extra cost for the preformed Perfix plug-and-patch cannot be justified in terms of speed of postoperative rehabilitation, analgesic consumption, return to normal quality of life, and return to work.

**CRD COMMENTARY - Selection of comparators**  
A justification was given for the choice of the comparator (Lichtenstein patch repair). It was the gold standard in the context in question. You, as a database user, should consider whether this is a widely used health technology in your own setting.

**Validity of estimate of measure of effectiveness**  
The effectiveness results are likely to have high internal validity due to the randomised nature of the study design and the power calculations performed. The groups were comparable with respect to baseline characteristics. The authors acknowledged that the numbers of patients in this study were too small to address the question of postoperative recurrence. The patient sample appears to have been representative of the study population.

**Validity of estimate of measure of benefit**  
The authors did not derive an explicit summary measure of health benefit. The study may therefore be regarded as a cost-consequences analysis.

**Validity of estimate of costs**  
Some quantities were reported separately from the costs. Insufficient details of the methods of cost estimation were given (no information on the price year, the source of charge/cost data, or the conversion rate). The inclusion of charge data instead of true costs may have adversely affected the internal and external validity of the cost results. The effects of alternative procedures on indirect costs were addressed but not quantified. Statistical analysis was performed on resource use data, but not on cost data. Cost results may not be generalisable to other settings due to lack of detailed...
Other issues
The authors’ conclusions appear to be justified. The issue of generalisability to other settings was not addressed. However, appropriate comparisons were made with other studies. The degree to which the study sample was representative of the study population was not addressed.

Implications of the study
The authors recommend that the Lichtenstein patch remain the gold standard for open prosthetic hernioplasty until long-term clinical studies with alternative prostheses such as the Perfix plug-and-patch have demonstrated long-term effectiveness against recurrence. A definitive answer to the question of recurrence rate will require a large multisurgeon, multicentre trial.

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