Randomized clinical trial of non-mesh versus mesh repair of primary inguinal hernia

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 use of mesh, either Prolene or Marlex polypropylene prosthetic mesh (7.5 times 15 cm), for inguinal hernia repair was studied. The comparator was non-mesh repair treatment using 2/0 polypropylene sutures (Prolene).

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis and cost-utility analysis.

Study population
The study population included all patients older than 18 years who were scheduled to undergo repair of a primary unilateral inguinal hernia. Patients were not included if they suffered from bilateral inguinal hernia.

Setting
The setting was a hospital. The economic study was carried out in six hospitals in the Netherlands.

Dates to which data relate
The resource, price and effectiveness data were all obtained during the study period of November 1993 to January 1999.

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

Link between effectiveness and cost data
The cost information was obtained prospectively from the same patients who completed questionnaires at one and 6 months after surgery.

Study sample
Selection took place at six hospitals from November 1993 to January 1996. This selection period produced an initial study sample of 300 patients. After randomisation, 11 patients were excluded. At operation, 4 patients were found to be suffering from a different type of hernia and one patient required bilateral repair. The operation was cancelled for 3 patients. Two patients underwent the wrong operation and one patient withdrew consent before the operation. The study group was left with 143 patients and the control group with 146.

There was no discussion of the sample size, the power of the study, or the method of sample selection. Insufficient
information was provided to assess the appropriateness of the size of the study sample.

**Study design**
The study was a randomised controlled trial. All patients were randomised to either the study (mesh repair) or the control group (non-mesh repair). Stratified hospital randomisation was achieved by calling an independent randomisation centre. The study was a multi-centre trial conducted at 6 hospitals. Follow-up was continued for 36 months. The stages of follow-up were 1 week, and 1, 6, 12, 18, 24 and 36 months. Patients who did not visit the outpatient department after 36 months were asked to fill out a questionnaire and were visited at home. The physician was blinded to the method used for inguinal repair.

Thirteen patients (4%) died within the follow-up period and more than 1 month after hernia repair. The causes of death were unrelated to inguinal hernia. A total of 35 patients (12%) were lost to follow-up. Of these, 12 withdrew from follow-up, 12 could not be traced, and 11 patients were followed up in writing at 36 months but were not physically examined at this time. The distribution of those lost to follow-up across the groups was not reported.

**Analysis of effectiveness**
The basis of the study was intention to treat. The primary health outcome was the number of hernia recurrences. The assessment was carried out through check-ups at the clinic. Other health outcomes analysed included complications such as postoperative wound infection, wound dehiscence, haematoma, seroma, postoperative pain and discomfort.

Quality of life before and after surgery was assessed using the Dutch version of the EuroQol EQ-5D and the EuroQol Visual Analogue Scale. This was administered for self-completion by the patients before the operation and 1 week, 1 month and 6 months after operation. Values for both measures were also obtained from the general population. The valuation tools were not specified.

Operation factors were also reported. These included the median duration of surgery, treatment location, median hospital stay, median time off work, the type of anaesthesia, the type of hernia encountered at operation, and the operator (surgeons or residents assisted by a surgeon). There was no significant difference between the groups for any operation factor.

A univariate statistical analysis was also conducted to identify risk factors associated with recurrence rates.

**Effectiveness results**
The 3-year cumulative recurrence rates were 7% in the non-mesh repair group and 1% in the mesh repair group. The groups were significantly different, (p=0.009). The one patient who experienced a recurrence from the intervention group had received a resorbable mesh, which was a trial violation. The short-term complications that were considered were postoperative wound infection, wound dehiscence, haematoma and seroma. There was no significant difference between the groups in these respects.

The response rate for quality of life ranged from 49 to 74% in the non-mesh repair group and from 56 to 79% in the mesh repair group, varying at different time periods. The quality of life scores did not differ significantly between the groups at any time. The mean results for either methodology were 85 (standard deviation, SD=8) for the general population and 81 (SD=14) for either study group.

**Clinical conclusions**
Compared with non-mesh repair, the use of prosthetic mesh repair for primary inguinal hernias results in significantly fewer recurrences in the long term.

**Measure of benefits used in the economic analysis**
The authors set out with the intention to conduct a cost-effectiveness analysis and cost-utility analysis. However, no
difference was found in the quality of life scores between the study groups. Therefore, the authors decided not to use quality of life scores to derive a quality-adjusted life-year measure of benefit. Since adverse effects were considered as well as the number of hernia recurrences, the analysis was considered a cost-consequences analysis and no summary effectiveness measure was used.

**Direct costs**
Both the hospital and patient costs were included. There was very little breakdown of the unit costs and quantities. The quantities of resources were estimated alongside the clinical trial from September 1993 to January 1999. No price year was reported.

The hospital costs included those for the initial operation, but only the costs of the polypropylene mesh were incorporated. No cost was indicated for the suture (or other) alternative. Other initial operation costs, such as specialists fees, use of operating room (operation duration) and hospital stay were not significantly different between the two strategies. Hence, they were excluded from the analysis. A lump figure was provided for operations for recurrent inguinal hernias. The year(s) of the price and resource data were not stated. The patient costs included visits to the general practitioner, the need for nurse assistance or a housekeeper, and the need for pain medication. A questionnaire about costs was completed at one and 6 months after surgery.

There was no mention of the valuation method, the origin of the prices used, or any adjustment for inflation. It was not stated whether the costs were discounted. Since the follow-up period of the study was 36 months and the costs and benefits could have accrued at any time during this period, both adjustment for inflation and discounting was relevant.

**Statistical analysis of costs**
The costs were given as point estimates and no statistical analysis was conducted.

**Indirect Costs**
The duration of sick-leave was considered as an indirect cost, but no other information was given.

**Currency**
Euros.

**Sensitivity analysis**
No sensitivity analysis was performed.

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

**Cost results**
The total intervention and comparator costs were not stated. The incremental cost of using non-mesh repair compared to mesh repair was Euro 6,821. The knock-on costs of operations were dealt with in the costing. Operation-related cost factors and patient costs were not significantly different.

The paper stated two major costs. The cost of polypropylene mesh was Euro 53 and the cost of a repair of a recurrent inguinal hernia was approximately Euro 1,600.

**Synthesis of costs and benefits**
The costs and benefits were not combined. Although not explicitly reported by the authors, the cost-effectiveness
results indicated that the use of non-mesh was strictly dominated by the use of mesh since it was less efficient (more recurrences) and more expensive (when including the costs of repair of a recurrent inguinal hernia).

Authors' conclusions
The use of mesh for inguinal hernia repair was associated with a lower recurrence rate than non-mesh repair and was also cheaper in the long run. Postoperative complications, pain and quality of life did not differ between the groups.

CRD COMMENTARY - Selection of comparators
The two interventions compared in the analysis represented two commonly used approaches for inguinal hernia repair. You should decide whether they represent currently performed health interventions in your own setting.

Validity of estimate of measure of effectiveness
The analysis of the effectiveness used a multi-centred trial, which was appropriate for the study question. The study design was a randomised controlled trial. The study groups were shown to be comparable at baseline. The outcome evaluation was partially blinded. The study sample appears to have been representative of the study population. All of these are positive indicators of high internal validity. However, power calculations to determine the sample size were not performed. Also, the distribution of the patients lost to follow-up across the study groups was not reported.

The quality of life utility result (i.e. no difference between the study methods) seems to be contrary to the clinical effectiveness results. This raises questions about the sensitivity of the two EuroQol methodologies, given the sample size in this case.

Validity of estimate of measure of benefit
No summary benefit measure was used in the economic analysis.

Validity of estimate of costs
The analysis of costs was performed from a societal perspective and it appears that all the relevant costs were included in the study. For example, hospital, patient and societal costs (sick-leave duration). A survey of patient costs was completed and resources were measured alongside the clinical trial. No power calculations to suggest an appropriate sample size in the cost survey were reported. No discounting of the costs or adjustment for inflation were reported either. No cost was indicated for the suture material. These points limit the internal validity of the cost data.

No statistical analysis of the costs was carried out, the cost being reported only as point estimates, although a study had been done to ascertain cost data. There was very little breakdown of the unit costs and quantities. No price year was reported, making it difficult to inflate the prices for use in future studies. These points limit the generalisability of the results.

Other issues
It would have been useful to have had an explanation for the difference in findings between the number of recurrences (significantly different between groups) and the quality of life scores (not significantly different between groups). The authors stated that the result that there was no difference between the incidence of complications between the groups was consistent with other studies and contrary to surgeons' belief. Postoperative pain and discomfort, duration of surgery, hospital stay and time off work were comparable between the groups. This was consistent with other studies, with the exception of one study that reported a significantly longer duration of surgery in the non-mesh group.

The authors did not comment on the generalisability of the findings to other populations or settings (see 'Validity of Estimate of Costs' section). The study population was only restricted by adulthood and this was a multi-centre trial, which gives the effectiveness results a high level of generalisability.
Implications of the study
Mesh repair is the preferred method for primary inguinal hernia repair. In addition, a common argument against the use of polypropylene mesh - that it increases the incidence of postoperative complications - is unjustified.

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None stated.

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