Use of resterilized polypropylene mesh in inguinal hernia repair: a prospective, randomized study

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 resterilised polypropylene mesh in the repair of inguinal hernias. The original mesh (15 x 10 cm Prolene mesh; Ethicon) was divided into 2 x 2 cm pieces, handled manually and resterilised. After resterilisation, the tensile strength and maximum extension of the mesh were measured. The comparator treatment was to use original mesh, which had not been used before, for the repair.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised patients undergoing primary, unilateral inguinal hernia repair at a hospital. Patients with recurrent or bilateral inguinal hernia were excluded from the study, as were patients undergoing operation as an emergency. Also excluded were patients under 18 years old, those with remote infections, and those with American Society of Anesthesiologists scores higher than 11.

Setting
The setting was secondary care. The economic study was carried out in Turkey.

Dates to which data relate
The effectiveness evidence on surgery dated from 2001 to 2004. Dates for the resource evidence were not given. The price year was not given.

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

Link between effectiveness and cost data
The costing was based on an idea of an average cost per patient, but it seems to have been the theoretical cost rather than that derived from cost data for all of the patients.

Study sample
No power calculations were reported. There was no sample selection: all patients who met the eligibility criteria and gave informed consent were included. There were 91 patients in the original (fresh from the packet) mesh group and 93
patients in the resterilised mesh group.

**Study design**
This was a single-centred randomised controlled trial (RCT) in which the operating room nurse randomised the patients into the two groups using a randomisation table. A blinded investigator collected data on the outcomes.

**Analysis of effectiveness**
The analysis was conducted on an intention to treat basis. The primary health outcome used was the complication rate, which included haematoma formation, chronic pain, need for mesh removal and hernia recurrence. The patients were shown to be comparable at baseline.

**Effectiveness results**
The complication rate was similar in the two patient groups, 16.5% in the original group and 15.1% in the resterilised group, (p=0.89).

The individual components of the complications were very similar in the two groups:

- 2 haematomas in the original group and 1 in the resterilised group,
- 6 patients with infection in the original group and 7 in the resterilised group,
- no cases of mesh removal in the original group and 1 in the resterilised group, and
- 1 recurrence in the original group and no cases in the resterilised group.

The incidence of persistent pain was 6.6% in the original group and 5.4% in the resterilised group.

**Clinical conclusions**
The use of resterilised polypropylene mesh for inguinal hernia repair results in similar rates of infection and complication as the use of original polypropylene mesh (i.e. mesh used immediately once the package has been opened).

**Measure of benefits used in the economic analysis**
No summary measure of benefit was produced. In effect, a cost-consequences analysis was conducted.

**Direct costs**
No discounting was carried out. The estimation of costs was based on actual data obtained from the Turkish National Health Security system on the cost of inguinal hernia repair, which excluded the cost of the mesh, and not from the study. The data obtained from the study were the costs of the original and resterilised mesh. The only information on individual cost components was that of the mesh. No price year was given.

**Statistical analysis of costs**
No statistical analysis of the costs was carried out.

**Indirect Costs**
No indirect costs were included.
Currency
US dollars ($).

Sensitivity analysis
No sensitivity analysis was carried out.

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

Cost results
The cost of open inguinal hernia repair was $308.00, excluding the cost of the mesh.

The cost of using original mesh was $58.50, while the cost of using resterilised mesh was $27.90. Therefore, the extra cost of using original mesh was $30.60.

The authors stated that the proportion of the mesh cost to the total operation cost was 15.9% for the original mesh and 8.3% for the resterilised mesh.

The cost of adverse effects was not dealt with since the costs were not the actual costs incurred by the patients.

Synthesis of costs and benefits
The costs and benefits were not combined as the study was a cost-consequences analysis.

Authors' conclusions
The use of resterilised mesh for open inguinal hernia repair reduces costs and does not lead to any reduction in health outcomes for the patients.

CRD COMMENTARY - Selection of comparators
The choice of the comparator, original mesh, was justified by it being common practice in many settings usually considered to be best practice. You should decide if this represents a valid comparison in your own setting.

Validity of estimate of measure of effectiveness
The source of the effectiveness data was a single study. The study design, an RCT, was appropriate for the hypothesis. As the study sample included all patients meeting the inclusion criteria, it can be assumed that they were representative of the study population. The patients groups were shown to be comparable at analysis, and the analysis of effectiveness was handled credibly. There were no other sources of effectiveness data.

Validity of estimate of measure of benefit
The authors did not derive a summary measure of health benefit. The reader is referred to the comments in the 'Validity of estimate of measure of effectiveness' field (above).

Validity of estimate of costs
From the cost perspective adopted (i.e. the hospital) not all costs were included, as the authors did not include the actual costs incurred. They therefore did not take the costs of any complications into account. As the complication rates were similar between the two groups this might not have made a big difference. The costs were generally not reported separately from the quantities, the exception being the cost of the mesh. Apart from mesh usage, the resource use
quantities were obtained from the Turkish National Health Security System. The unit cost for the mesh was taken for the authors' setting, while the price for the rest of the operation was taken from the Turkish National Health Security System. No statistical, sensitivity, or any other kind of analyses of the quantities or prices were carried out. The price date was not reported.

Other issues
The authors made appropriate comparisons of their results with the findings from other studies. The issue of generalisability to other settings was not addressed. The authors did not present their results selectively and their conclusions reflected the scope of the analysis. The authors noted that a longer follow-up period would be necessary to obtain a full evaluation of the two kinds of mesh. The authors were concerned that the power of their study may not have been sufficient because of the "limited" number of patients.

Implications of the study
The authors concluded that the use of resterilised mesh for inguinal hernia repair results in satisfactory outcomes and lower costs. This result should be verified for a longer time period.

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