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


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Background: The optimum method for inguinal hernia repair has not yet been determined. The recurrence rate for non-mesh methods varies between 0.2 and 33 per cent. The value of tension-free repair with prosthetic mesh remains to be confirmed. The aim of this study was to compare mesh and non-mesh suture repair of primary inguinal hernias with respect to clinical outcome, quality of life and cost in a multicentre randomized trial in general hospitals.

Methods: Between September 1993 and January 1996, all patients scheduled for repair of a unilateral primary inguinal hernia were randomized to non-mesh or mesh repair. The patients were followed up at 1 week and at 1, 6, 12, 18, 24 and 36 months. Clinical outcome, quality of life and costs were registered.

Results: Three hundred patients were randomized of whom 11 were excluded. Three-year recurrence rates differed significantly: 7 per cent for non-mesh repair (n = 143) and 1 per cent for mesh repair (n = 146) (P = 0.009). There were no differences in clinical variables, quality of life and costs.

Conclusion: Mesh repair of primary inguinal hernia repair is superior to non-mesh repair with regard to hernia recurrence and is cost-effective. Postoperative complications, pain and quality of life did not differ between groups.

Introduction

Inguinal hernia repair is the most frequently performed operation in the Netherlands. Consequently, failure of inguinal hernia repair not only affects individual patients but also has a great impact on society. Failure leads to increased patient discomfort, reoperations and sick-leave, and so may result in a considerable economic burden. No consensus has yet been reached about the best surgical approach to inguinal hernia repair, which should show good cost-effective clinical results.

Recurrence rates after non-mesh suture repair of inguinal hernia vary between 0.2 and 33 per cent, depending on the surgical method, experience, length of follow-up and type of hospital. Tension-free hernia repair, or repair with the use of mesh, was popularized by Lichtenstein and Schulman. This method was associated with a lower recurrence rate than suture repair in a non-randomized study of primary inguinal hernia repair and in two randomized studies.

The aim of this study was to establish the value of open mesh repair for primary inguinal hernia in the general hospital setting, not only with respect to clinical outcome but also quality of life and cost. A multicentre randomized trial with long-term follow-up was conducted.

Patients and methods

Between September 1993 and January 1996, patients older than 18 years scheduled for repair of a primary unilateral inguinal hernia were randomized to non-mesh or mesh repair. Patients could only be enrolled once and were not included if they suffered from bilateral inguinal hernia.
Patients were informed about the trial both verbally and in writing. Six hospitals participated in the study. Randomization was achieved by calling an independent randomization centre, where computer-generated lists were available, stratified by hospital. The protocol was approved by the ethics committees of all participating hospitals.

Age, obesity, intermittent high abdominal pressure (cough, constipation, prostatism) and factors that may interfere with wound healing (diabetes, use of steroid medication, smoking) were noted. Obesity was defined as a body mass index of 30 kg/m² or more. The type of inguinal hernia was also noted.

Evaluation of operation-related factors included surgical technique, type of anaesthesia, clinical setting or day care, and whether the operation was performed by a surgeon or by a surgical resident. Drainage, wound haematoma, seroma, wound dehiscence and wound infection were also recorded. Wound infection was defined as discharge of pus from the wound.

At the induction of anaesthesia, a single dose of intravenous broad-spectrum antibiotics was administered according to hospital protocol. Non-mesh repair was performed according to the surgeons’ method of choice, provided that 2/0 polypropylene sutures (Prolene®; Ethicon, Johnson & Johnson, Somerville, New Jersey, USA) were used. Mesh repair was performed according to a strict protocol as described by Lichtenstein and Shulman15 using a Prolene® or Marlex® (C. R. Bard, Billerica, Massachusetts, USA) polypropylene prosthetic mesh of 7.5 × 15 cm to avoid tension on the suture lines. The duration of surgery (from first incision to last skin suture), hospital stay and time off work were noted. Patients were followed up at 1 week and at 1, 6, 12, 18, 24 and 36 months. Awareness of hernia recurrence and complaints about the groin were noted and the groin was examined physically for recurrence of inguinal hernia. Hernia recurrence was defined as a bulge or weakness in the operative area exacerbated by a Valsalva manoeuvre and palpable outside the external ring. Hernia recurrence and death were the study endpoints. Patients who did not visit the outpatient department for follow-up at 36 months were asked to complete a questionnaire, and were visited at home by a physician who was not aware of the method used for inguinal hernia repair. If recurrences were found after follow-up had terminated, they were not included in the statistical analysis in accordance with the protocol.

To assess quality of life (or current health state) before and after surgery, the Dutch version of the EuroQol EQ-5D and the EuroQol Visual Analogue Scale (VAS)18,19 was administered for self-completion by patients before operation and 1 week, 1 month and 6 months after operation.

To determine the cost-effectiveness of both methods of inguinal hernia repair, a questionnaire about costs was completed 1 and 6 months after surgery. This included questions about the need for help from a general practitioner, nurse or housekeeper, the need for pain medication and the duration of sick-leave. Cost-effectiveness also involved quality of life- and operation-related factors, such as duration of surgery, duration of hospital stay and time off work.

Statistical analysis was done with the Statistical Product and Service Solutions software (SPSS, Chicago, Illinois, USA). Percentages and continuous variables were compared using Fisher’s exact test and Mann–Whitney U test respectively. Cumulative recurrence rates were calculated and compared using Kaplan–Meier curves and the log rank test. P values given are two sided; \( P = 0.05 \) was considered the limit of significance. The primary analysis was by intention to treat. A univariate regression analysis for the non-mesh repair group was performed.

**Results**

Three hundred patients were randomized. Eleven patients were excluded. In four patients another type of hernia was demonstrated at operation. One patient needed bilateral repair. The operation was cancelled for three patients. In spite of inclusion in the trial two patients underwent laparoscopic inguinal hernia repair and one patient withdrew consent before operation. Preoperative characteristics were well matched between the two groups (Table 1). Eight patients (3 per cent) were women.

<table>
<thead>
<tr>
<th></th>
<th>Non-mesh repair group</th>
<th>Mesh repair group</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)*</td>
<td>53 (19–85)</td>
<td>58 (24–83)</td>
</tr>
<tr>
<td>Body mass index (kg/m²)*</td>
<td>25 (19–34)</td>
<td>25 (18–34)</td>
</tr>
<tr>
<td>Prostatism†</td>
<td>14 of 140</td>
<td>12 of 141</td>
</tr>
<tr>
<td>Constipation</td>
<td>11 of 143</td>
<td>10 of 146</td>
</tr>
<tr>
<td>Coughing</td>
<td>22 of 143</td>
<td>25 of 146</td>
</tr>
<tr>
<td>Diabetes</td>
<td>8 of 143</td>
<td>2 of 146</td>
</tr>
<tr>
<td>Use of steroids</td>
<td>2 of 143</td>
<td>4 of 146</td>
</tr>
<tr>
<td>Type of hernia</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Indirect</td>
<td>67</td>
<td>75</td>
</tr>
<tr>
<td>Direct</td>
<td>45</td>
<td>37</td>
</tr>
<tr>
<td>Combined</td>
<td>27</td>
<td>29</td>
</tr>
<tr>
<td>Not described</td>
<td>4</td>
<td>5</td>
</tr>
</tbody>
</table>

*Values are median (range). †Men only
Table 2 Cumulative recurrence rates 1–36 months of follow-up after primary inguinal hernia repair

<table>
<thead>
<tr>
<th>Time after operation (months)</th>
<th>No. at risk for recurrence</th>
<th>Cumulative recurrence rate (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non-mesh repair</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>143</td>
<td>0</td>
</tr>
<tr>
<td>6</td>
<td>137</td>
<td>1(1)</td>
</tr>
<tr>
<td>12</td>
<td>131</td>
<td>1(1)</td>
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<tr>
<td>18</td>
<td>127</td>
<td>1(1)</td>
</tr>
<tr>
<td>24</td>
<td>125</td>
<td>0(2)</td>
</tr>
<tr>
<td>36</td>
<td>119</td>
<td>7(2)</td>
</tr>
<tr>
<td>Mesh repair</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>146</td>
<td>0</td>
</tr>
<tr>
<td>6</td>
<td>138</td>
<td>0</td>
</tr>
<tr>
<td>12</td>
<td>138</td>
<td>0</td>
</tr>
<tr>
<td>18</td>
<td>133</td>
<td>0</td>
</tr>
<tr>
<td>24</td>
<td>131</td>
<td>0</td>
</tr>
<tr>
<td>36</td>
<td>122</td>
<td>1(1)</td>
</tr>
</tbody>
</table>

Values in parentheses are s.e.

Intention-to-treat analysis

Of the remaining 289 patients, 143 had been randomized to non-mesh repair and 146 to mesh repair. The type of inguinal hernia repair in the non-mesh repair group was Bassini–McVay in 75 patients (52 per cent), Shouldice in 36 (25 per cent), Bassini in 26 (18 per cent) and McVay in three (2 per cent). Three patients received a mesh because the surgeon decided at operation that a mesh repair was preferable. These procedures were marked as conversions. In the mesh repair group, 125 patients received a Prolene© mesh, whereas Marlex® was used in 13. On one occasion a resorbable polyglactin 910 mesh (Vicryl®; Ethicon, Johnson & Johnson) was used in error. Seven patients did not receive a mesh repair and these operations were marked as conversions.

Thirteen patients (4 per cent) died within the follow-up period from causes unrelated to inguinal hernia and more than 1 month after hernia repair. Follow-up was complete for 254 patients (88 per cent). Thirty-five patients (12 per cent) were lost to follow-up; 12 patients withdrew from follow-up, 12 patients could not be traced and 11 patients were followed up in writing at 36 months but were not physically examined at this time. All patients were included in the analysis with their follow-up censored at the time of last physical examination.

Recurrences

During the 3-year follow-up, nine recurrences were found in the non-mesh repair group and one in the mesh repair group. The only recurrence in the mesh group occurred in the patient who received a resorbable mesh in error. The 3-year cumulative recurrence rates in the non-mesh and mesh repair groups were 7 and 1 per cent respectively \( (P = 0.009) \) (Table 2).

Exclusion of the patient who received a resorbable mesh from the analysis (major trial violation) decreased the 3-year cumulative recurrence rate from 1 per cent to zero, increasing the difference between groups \( (P = 0.002) \). There were no recurrences after inguinal hernia operations that were converted peroperatively.

Univariate analysis

The non-mesh repair group was associated with a significantly higher recurrence rate. Risk factors were evaluated within this group. The recurrence rate was higher for older patients; 3-year recurrence rates for patients younger than 65 years of age and older patients were 3 and 16 per cent respectively \( (P = 0.01) \). Other patient characteristics and wound complications were not identified as significant risk factors.

Operation-related factors

Median duration of surgery was 45 min for both non-mesh repair (range 19–105 min) and mesh repair (range 20–120 min). Seventy-nine per cent of patients were treated in a clinical setting and 21 per cent in day care; there was no difference between treatment groups. Median hospital stay was 2 days in both groups, with a range of 0–14 and 0–11 days respectively. Median time off work was 17 (range 0–56) days after non-mesh repair and 19 (range 2–113) days after mesh repair.

The type of anaesthesia did not differ between the groups (general 62 per cent, epidural 23 per cent, spinal 15 per cent). The type of hernia encountered at operation was comparable between the two groups (Table 1). In the non-mesh group, there was no recurrence of an indirect hernia, four recurrences of direct hernias and five recurrences of combined hernias. Surgeons and residents assisted by a surgeon operated on comparable numbers of patients (68 versus 78 and 78 versus 66 respectively). Of the ten patients with a recurrence, six were primarily treated by a surgeon and four by a resident \( (P \) not significant).

Complications

There was no significant difference between the non-mesh and mesh repair groups regarding postoperative wound infection (none of 143 versus one of 146; \( P = 0.32 \)), wound dehiscence (none of 143 versus one of 146; \( P = 0.32 \)), haematoma (17 of 143 versus 15 of 146; \( P = 0.66 \)) and
seroma (none of 143 versus four of 146; \(P = 0.62\)). In the non-mesh group one patient suffered from urinary retention and one patient from pneumonia. Apart from recurrences, there were no long-term complications.

Postoperative pain (week 1: 45 of 140 versus 58 of 140 \((P = 0.11)\); 36 months: nine of 125 versus eight of 129 \((P = 0.73)\) and discomfort (week 1: 78 of 140 versus 72 of 140 \((P = 0.42)\); 36 months: 13 of 125 versus 11 of 129 \((P = 0.60)\) were similar at all timepoints.

Quality of life

The response rate for the Euroqol questionnaire and VAS ranged from 49 to 74 per cent for the non-mesh repair group and from 56 to 79 per cent in the mesh group, varying between timepoints. The quality of life did not differ significantly between groups at any timepoint. There were no significant differences between mean(s.d.) values for EuroQol EQ-5D or EuroQol VAS measured in the general population (85(8)19 and 81(14)20 respectively) and either study group (Figs 1 and 2).

Cost

The two groups paid a similar number of visits to the general practitioner (six of 143 and eight of 146 for non-mesh versus mesh repair) and required the assistance of a nurse or a housekeeper in a comparable number of cases (four of 143 versus two of 146). Use of analgesics was comparable (nine versus seven patients).

No difference was noted in operation-related factors and quality of life. Cost-effectiveness was therefore determined by the costs of polypropylene mesh (€53) and by the number of recurrences requiring reoperation. Repair of a recurrent inguinal hernia costs approximately €1600 in a Dutch hospital, including the specialists’ fees, use of the operating room and a hospital stay of 2 days. To prevent the nine recurrences in the non-mesh group from developing, 143 meshes should have been used in hernia repair in this group, resulting in additional operating costs of €7579 for the whole group. At least €6821 would have been saved if mesh had been used for all repairs.

Discussion

Inguinal hernia repair performed by suturing and displacement of anatomic structures may lead to excessive tension on the suture line and surrounding tissue. Subsequently, tissue ischaemia and suture cut-out may occur, resulting in recurrence. The use of prosthetic mesh allows tension-free repair of inguinal hernia and, in theory, better results. The current series proves the superiority of this method over non-mesh repair in the long term with regard to hernia recurrence; in addition, there was no increase in cost, complications or postoperative pain and quality of life was comparable.

The incidence of complications did not differ significantly between groups, similar to the results of other randomized trials comparing mesh and non-mesh repair4,5,17,21. The reluctance of surgeons to use poly-
propylene mesh because of an assumed increase in the incidence of postoperative complications is thus unjustified. Postoperative pain and discomfort, duration of surgery, hospital stay and time off work were comparable in the two groups, as has been shown previously\textsuperscript{3,5,17,21}, although Barth et al.\textsuperscript{4} reported a significantly longer duration of surgery in the non-mesh repair group and Prior et al.\textsuperscript{21} described significantly less postoperative pain in the mesh group.

Quality of life evaluation showed no differences between the two operative groups, and thus was only determined by the number of recurrences after inguinal hernia repair. The additional cost of mesh for mesh repair was less than the cost of operating on recurrences, confirming that mesh inguinal hernia repair is a cost-effective method.

In conclusion, mesh inguinal hernia repair was associated with a lower recurrence rate than non-mesh repair; indeed, a recurrence rate of zero is within reach. No differences were found in complication rate, postoperative pain and quality of life, and mesh repair proved to be cost-effective. Therefore, mesh repair is the method of choice for primary inguinal hernia repair.

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References