Randomized clinical trial of mesh versus non-mesh primary inguinal hernia repair: Long-term chronic pain at 10 years

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Background. Open mesh or non-mesh inguinal hernia repair may influence the incidence of chronic postoperative pain differently.

Methods. A total of 300 patients scheduled for repair of a primary unilateral inguinal hernia were randomized to non-mesh or mesh repair. The primary outcome measure was clinical outcome including persistent pain and discomfort interfering with daily activity. Long-term results at 3 years of follow-up have been published. Included here are 10-year follow-up results with respect to pain.

Results. Of the 300 patients, 87 patients (30%) died and 49 patients (17%) were lost to follow-up. A total of 153 were physically examined in the outpatient clinic after a median long-term follow-up of 129 months (range, 109 to 148 months). None of the patients in the non-mesh or mesh group suffered from persistent pain and discomfort interfering with daily activity.

Conclusions. Our 10-year follow-up study provides evidence that mesh repair of inguinal hernia is equal to non-mesh repair with respect to long-term persistent pain and discomfort interfering with daily activity. An important new finding from the patient’s perspective is that chronic postoperative pain seems to dissipate over time. (Surgery 2007;142:695-8.)

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The use of prosthetic mesh allows tension-free inguinal hernia repair and has proven to result in less recurrences. Concomitant with popularization of this repair, it has become clear that morbidity associated with this operation mainly consists of chronic groin pain. Long-term randomized studies with 5-year follow-up to investigate chronic groin pain after open mesh versus non-mesh hernia repair have not been published. To determine the influence of the introduction of mesh material on the incidence of chronic pain, we conducted a randomized double-blind study of open non-mesh versus mesh hernia repair. In 2002, we published the 3-year follow-up results, which indicated that mesh repair was comparable to non-mesh repair with respect to chronic postoperative pain at 1, 6, 12, 18, 24, and 36 months.1,2 The purpose of this paper is report the results at 10 years of follow-up.

PATIENTS AND METHODS

Between September 1993 and January 1996, 300 patients older than 18 years of age scheduled for repair of a primary unilateral inguinal hernia were randomized to open mesh or non-mesh repair. Patients could only be enrolled once and were not included if they suffered from bilateral inguinal hernia. Six hospitals participated in the study. The study was designed to mimic clinical reality in general surgery. The conventional method, therefore, was not standardized, and no specialized hernia centers participated in the study. The protocol was approved by the ethics committees of all the participating hospitals.

Non-mesh repair was performed according to each surgeon’s method of choice, provided that 2-0 polypropylene sutures (Prolene; Ethicon, Johnson & Johnson, Sommerville, NJ, US) were used. Mesh repair was performed according to a strict protocol, as described by Lichtenstein and Shulman using a
Prolene or Marlex (CR Bard Inc, Billerica, Mass, US) polypropylene prosthetic mesh of 7.5 × 15-cm. The primary outcome was clinical outcome including persistent pain and discomfort interfering with daily activity 10 years after the procedure.

Follow-up was done by physical examination at the outpatient clinic after 1 week, 1 month, 6 months, 1 year, 2 years, and 3 years. A more meticulous description of the methods has been published previously by Vrijland et al.\(^1\)

Long-term follow-up occurred from June 2005 until January 2006. All patients were asked to complete a questionnaire. If the patients had not replied after a second mailing, they were contacted by telephone, and visited at home if they agreed. Patients were asked whether they suffered from persistent pain and discomfort interfering with daily activity, paroxysmal pain during intensive activity not interfering with daily activity (such as sports or gardening), chronic obstructive pulmonary disease, obstipation, or prostatism. Physical examination was conducted by R.N.v.V. or A.R.W., who were blinded to the type of repair that had been performed.

The number of patients suffering from chronic pain was compared between the mesh and non-mesh groups by intention to treat with the Fisher exact test. All statistical tests were 2-sided; \( P \leq .05 \) was considered significant. All statistical analyses were performed using the Statistical Package for Social Sciences for Windows (SPSS Inc, Chicago, Ill, US).

**RESULTS**

A total of 300 patients were randomized; 11 patients were excluded. Of these, 4 patients appeared to have another type of hernia at operation; 1 patient needed bilateral repair; the operation was cancelled for 3 patients. In spite of inclusion in the trial, 2 patients underwent laparoscopic inguinal hernia repair, and 1 patient withdrew informed consent before operation.

Of the remaining 289 patients, 143 were randomized to the non-mesh repair group and 146 to mesh repair (Fig 1). The type of hernia repair in the non-mesh repair group was Bassini-McVay in 75 patients (52%), Shouldice in 36 (25%), Bassini in 26 (18%), and McVay in 3 (2%). A total of 3 patients received a mesh because the surgeon decided intraoperatively that a mesh would be preferable. In the mesh repair group, 1 patient received a resorbable polyglactin 910 mesh (Vicryl; Ethicon, Johnson & Johnson), which was used in error. In addition, 7 patients did not receive a mesh repair; these operations were marked as conversions.

A total of 87 patients (30%) died within the long-term follow-up period (Fig 1); the causes of death were unrelated to the performed inguinal hernia repair. A total of 49 patients (17%) were lost to follow-up. In the outpatient clinic, 153 patients were
physically examined—80 in the non-mesh group and 73 in the mesh group. Median long-term follow-up of these patients was 128 months (range, 109 to 148 months) and 129 months (range, 112 to 147 months) for non-mesh repair and mesh repair, respectively (Table I). The type of hernia repair in the non-mesh repair group consisted of Bassini-McVay in 41 patients (51%), Shouldice in 16 (20%), Bassini in 20 (25%), and McVay in 3 (4%). Of the 3 patients in the non-mesh group that were converted at baseline to receive a mesh, 1 patient died and 2 did not report any form of pain. In the mesh group, 7 patients were converted at baseline to receive a non-mesh repair; 3 of these patients died and 4 were lost to follow-up.

After a median follow-up of 129 months, none of the patients in either the non-mesh or the mesh group suffered from persistent pain and discomfort interfering with daily activity (Fig 2). Some patients reported paroxysmal pain during intensive activity not interfering with daily activity (such as sports or gardening), which did not last longer than 1 day. This type of paroxysmal pain occurred in 10% of the patients in the non-mesh group and 14% of patients in the mesh group. The type of hernia repair was not significantly correlated with paroxysmal pain during intensive activity not interfering with daily activity (such as sports or gardening), which did not last longer than 1 day.

This type of paroxysmal pain occurred in 10% of the patients in the non-mesh group and 14% of patients in the mesh group. The type of hernia repair was not significantly correlated with paroxysmal pain during intensive activity not interfering with daily activity ($P = .31$). In the non-mesh repair group, 7 patients (9%) suffered from numbness in the groin region compared with 14 patients (19%) in the mesh repair group ($P = .047$). Chronic groin pain was not correlated with the level of experience of the surgeon ($P = .449$) (Table I). Surgeons with a higher level of expertise in hernia surgery performed more non-mesh operations, including 81% of the Shouldice operations and 81% of the Bassini operations. No significant correlation be-

between age, obesity, history of pulmonary disease, constipation, or prostatic disease with groin pain was found (Table I).

**Table I. Characteristics of patients with inguinal hernia in the 10-year follow-up period**

<table>
<thead>
<tr>
<th></th>
<th>Total (N = 153)</th>
<th>Non-mesh repair (N = 80)</th>
<th>Mesh repair (N = 73)</th>
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<tbody>
<tr>
<td>Men</td>
<td>149 (97%)</td>
<td>78 (97%)</td>
<td>71 (97%)</td>
</tr>
<tr>
<td>Age (y): median (range)</td>
<td>66 (30-96)</td>
<td>62 (30-96)</td>
<td>66 (35-87)</td>
</tr>
<tr>
<td>Follow-up (m): median (range)</td>
<td>129 (109-148)</td>
<td>128 (109-148)</td>
<td>129 (112-147)</td>
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<tr>
<td>Body mass index (range)*</td>
<td>24.6 (18.6-34.5)</td>
<td>24.4 (19.0-33.9)</td>
<td>24.4 (18.6-34.5)</td>
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<tr>
<td>Contralateral hernia (%)</td>
<td>35 (23)</td>
<td>20 (35)</td>
<td>15 (21)</td>
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<tr>
<td>COPD (%)</td>
<td>17 (11)</td>
<td>7 (9)</td>
<td>10 (14)</td>
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<tr>
<td>Constipation (%)</td>
<td>7 (5)</td>
<td>4 (5)</td>
<td>3 (4)</td>
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<tr>
<td>Prostatic disease (%)</td>
<td>32 (21)</td>
<td>13 (16)</td>
<td>19 (26)</td>
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<td>Level of expertise:</td>
<td></td>
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<tr>
<td>Resident, senior resident, surgeon (%)</td>
<td>54 (35%)</td>
<td>11 (7%)</td>
<td>88 (58%)</td>
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<td>COPD, chronic obstructive pulmonary disease.</td>
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*The body mass index was calculated as the weight in kilograms divided by the square of height in meters.

![Fig 2. Proportion of patients reporting pain following non-mesh and mesh inguinal hernia repair. *$P = .307$. †$P = .339$. ‡$P = .571$. †$P = .464$ (chi-square test).](image)

**DISCUSSION**

According to a review study by the EU Hernia Trialist Collaboration reviewing all randomized or quasi-randomized trials comparing open-mesh with non-mesh methods published until 1999, a minority of studies reported a measure of postoperative chronic pain. Of the 15 trials included in the review study, 12 compared a flat mesh to non-mesh repairs. The mean or median duration of follow-up of all 15 of the studies ranged from 6 days to 5 years. There were few reported cases of chronic pain, with reported rates similar for mesh and non-mesh groups.3

Individual patient data were collected and a meta-analysis was conducted and published by the Cochrane Library.4 This review reported 17 studies
in which a flat mesh was compared to non-mesh hernia repair, including three previously unpublished studies identified by the EU Trialist Collaboration. The results suggested that persisting pain was less frequent after mesh repair than after non-mesh repair, but this result was dependent on one trial by Koninger et al, and data were not available for 11 of the total of 20 trials included in the study.4,5

Poobalan et al6 reviewed studies investigating postoperative pain after inguinal hernia repair that were published between 1987 and 2000, almost simultaneously to the review mentioned above. Two studies were reported in which open flat mesh and non-mesh repairs were compared, the same study reported by the EU Trialist Collaboration.7 This included a nonrandomized study by Amid et al8 reporting less chronic pain with mesh repair.

Of the studies published after 1999, Nordin et al9 reported no significant difference in chronic pain after 3 years between the Shouldice and Lichtenstein repair (4.2% and 5.6%, respectively), as our our long-term data at 3 years of follow-up suggest. Miedema et al10 reported a higher incidence of chronic pain after the Lichtenstein repair compared with a Shouldice repair (38% and 7%, respectively; \( P < .05 \)). However follow-up included only 60% of patients.

Long-term follow-up is difficult to obtain because many patients undergoing hernia repair are lost to follow-up, do not show up, or have died. The mean age at long-term follow-up was 66 years. Although time-consuming and incomplete because of patients who had died or lost to follow-up, our data indicate that long-term follow-up is of great importance for research regarding inguinal hernia repair.

In our study, none of patients from either group experienced persistent pain interfering with daily activity, suggesting that neuropathic pain that is caused by neuroplastic changes in the central nervous system following nerve injury in the inguinal region, disappears over time.11 According to some, this type of neuropathic pain is the main cause of postoperative chronic pain. Our data, therefore, provide insight into the course of chronic pain that is supposed to be predominantly caused by neuroplastic changes in the central nervous system.

In conclusion, our 10-year follow-up study provides evidence that mesh repair of inguinal hernia is equal to non-mesh repair with respect to long-term chronic pain. It is also the only study to provide follow-up of more than 5 years. An important new finding is that chronic postoperative pain of neuropathic or somatic origin seems to dissipate over time.6,11,12 Because chronic pain can be debilitating, this knowledge is very interesting from the patient’s perspective and, therefore, from the doctor’s perspective as well.

REFERENCES