Randomized Controlled Trial of Preservation or Elective Division of Ilioinguinal Nerve on Open Inguinal Hernia Repair With Polypropylene Mesh

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Hypothesis: Our study aimed to evaluate the effect of preservation or elective division of the ilioinguinal nerve on pain and postoperative symptoms after open inguinal hernia repair with mesh.

Design: Double-blind, randomized trial.

Setting: Four public, government-financed hospitals in Italy.

Patients: From January 1, 1997, to June 30, 2002, 813 patients with primary inguinal hernia were randomly allocated to undergo inguinal hernia repair either with ilioinguinal nerve preservation (408 patients, group A) or elective transection (405 patients, group B).

Intervention: Hernia repair with sutureless apposition of a polypropylene mesh.

Main Outcome Measures: The primary outcome was the evaluation of chronic pain 1 year after operation. Secondary outcomes were postoperative symptoms assessment at 1 week and 1, 6, and 12 months after operation. Telephone interview was performed 35.5 months (range, 12-59 months) after operation to assess the presence of chronic pain.

Results: Of the 302 group A and 291 group B patients who made an office visit 1 year postoperatively, pain was absent in 231 (76.5%) and 213 (73%) (difference, 3.30%; 95% confidence interval, –3.68% to 10.28%), mild in 55 (18%) and 60 (21%), moderate in 11 (4%) and 9 (3%), and severe in 5 (2%) and 9 (3%), respectively ($P = .55; \chi^2$ test). At 1-month and 6-month follow-up visits, no difference was found between the 2 groups with respect to pain, but loss of pain or touch sensation were significantly greater when the ilioinguinal nerve was divided. One year after operation, the 2 groups were also comparable with respect to loss of pain sensation, but touch sensation remained decreased in group B. At telephone interview, the presence of chronic pain was similar in both groups.

Conclusions: Pain after open hernia repair with polypropylene mesh is not affected by elective division of the ilioinguinal nerve; sensory disturbances in the area of distribution of the transected nerve are significantly increased.

Arch Surg. 2004;139:755-758

PAIN AFTER INGUINAL HERNIA repair may be an incapacitating complication that represents an important diagnostic and therapeutic challenge. Normal postoperative pain affects patients immediately after surgery and gradually subsides within a few days. Some patients experience chronic debilitating pain that is often unresponsive to medical treatment, including nonsteroidal anti-inflammatory drugs and opiates. Neuropathy is a widely recognized cause of chronic postherniorrhaphy pain. One of the mechanisms responsible for this chronic pain may be the damage to the sensory nerves (ilioinguinal, iliohypogastric, and genitofemoral) passing through the inguinal region. However, elective division of all these sensory nerves may reasonably lead to considerable sensory loss in the inguinal region. Ilioinguinal nerve is normally encountered during open inguinal hernia repair. It may be traumatized during dissection and interfere with placement of the mesh. Our study aimed to assess the influence of preservation vs division of the ilioinguinal nerve on pain and postoperative symptoms after open inguinal hernia repair with polypropylene mesh.

See Invited Critique at end of article
Randomized control trial flowchart.

their general surgeon at the 4 participating public, government-financed hospitals in Italy were considered eligible for the study. Patients with bilateral hernia or a subsequent hernia repair in the observation period were excluded, so the study group was reduced to 813 patients. After approval by local bioethics committees, informed consent was obtained preoperatively on hospital admission. Before operation patients were randomly allocated to undergo hernia mesh repair either with ilioinguinal nerve preservation (group A) or transection (group B). Randomization was computer generated, using numbered and sealed envelopes that were opened in the operating theater before operation.

Operations were performed with the patients under local or spinal anesthesia. A polypropylene mesh was positioned without sutures in the floor of the inguinal canal and in the lateral space under the aponeurosis of the external oblique muscle, according to the technique described by Trabucco. Division of the ilioinguinal nerve was performed lateral to the deep ring to avoid any contact with the mesh. Histologic analysis of a section of the removed nerve was performed to confirm the division of the ilioinguinal nerve.

Postoperative pain was assessed using a 4-point verbal scale (none, mild, moderate, or severe), assigning numerical values of 0 to 3 one week after operation. Mild pain was defined as an occasional disturbance that did not limit normal activities, and severe pain as pain that interfered with normal-day life activities. At 1-month, 6-month, and 1-year follow-up visits, pain experienced during the last week before the visit was assessed using the same scale. Follow-up telephone calls were performed at the end of the study with the aim of assessing the presence and intensity of pain related to the operation, using the same 4-point verbal scale. In addition, during follow-up visits, patients were also tested for the presence of numbness and sensory loss to light touch and pain sensation in the area of distribution of the ilioinguinal nerve.

Follow-up was performed by assessors unaware of the procedure and patients, so the study was conducted in a double-blind fashion. Results were analyzed on an intention-to-treat basis. In particular, patients were analyzed on the basis of randomization, regardless of whether the ilioinguinal nerve was identified. The primary outcome was the evaluation of chronic pain 1 year after operation. Secondary outcomes were symptoms assessment at 1 week and 1, 6, and 12 months after operation and at telephone interview.

Sample size calculation was based on the aim of detecting a difference of 10% in the proportion of patients with absence of chronic pain 1 year after operation, assuming from previous studies that 70% of patients were pain free. With a type I error of 0.05 and a type II error of 0.20 for a 2-tailed test, 291 patients per group were required.

Pearson $\chi^2$ and Yates corrected $\chi^2$ were used for categorical data. Spearman rank correlation coefficient was used as appropriate. All tests were 2-tailed, and the level of significance was .05. The collection and analysis of data were performed using SPSS statistical software version 10.0 (SPSS Inc, Chicago, Ill).

**RESULTS**

The profile of the trial is shown in the Figure. Both groups were comparable with respect to age, sex, type of hernia, and presence of preoperative pain (Table 1). The ilioinguinal nerve was not identified in 55 (13%) of the 408 patients in group A and in 41 (10%) of the 405 patients in group B ($P = .16$, $\chi^2$ with Yates correction for continuity). Postoperative complications were similar in both groups and included wound and/or scrotal hematoma in 31 (8%) of the group A patients and 40 (10%) of the group B patients ($P = .26$, $\chi^2$ with Yates correction for continuity), requiring surgical drainage in 4 and 3 cases, respectively.

One week after operation, in groups A and B, respectively, pain assessed with the use of the 4-point verbal scale was absent in 150 patients (37%) and 141 patients (35%) (difference, 2.00%; 95% confidence interval [CI], −4.59% to 8.59%), mild in 180 (44%) and 183 (45%), moderate in 65 (16%) and 73 (18%), and severe in 13 (3%) and 8 (2%) ($P = .58$, Pearson $\chi^2$ test). Postoperative pain was not correlated with the presence of preoperative pain ($p = 0.064$, $P = .07$, Spearman rank correlation), and no correlation was evidenced in the 2 subgroups (group A: $p = 0.031$, $P = .53$; group B: $p = 0.040$, $P = .43$, Spearman rank correlation).

One month after operation, follow-up visits were performed in 391 group A patients (96%) and 380 group B

![Table 1. Characteristics of Patients](https://example.com/Table1.png)

*Data are given as number (percentage) of patients unless otherwise indicated.
patients (94%). The numbers of patients with pain and loss of sensation in the area of distribution of the ilioinguinal nerve are given in Table 2. In particular, pain was absent in 195 (50%) of 391 patients in group A and 184 (48%) of 380 patients in group B (difference, 2.50%; 95% CI, −4.56% to 9.56%). For the entire cohort, when pain experienced after 1 week was compared with that referred after 1 month, a statistically significant positive relation was evidenced (\( p=0.120, P=.001 \), Spearman rank correlation); similar results were obtained when the 2 subgroups were analyzed (group A: \( p=0.125, P=.02 \); group B: \( p=0.113, P=.03 \), Spearman rank correlation). No difference was found between the 2 groups with respect to the presence of numbness, but loss of pain and touch sensation were significantly greater when the ilioinguinal nerve was divided.

Results of the follow-up visit after 6 months are given in Table 2. The 6-month follow-up was performed in 354 patients (87%) in group A and in 358 patients (88%) in group B. The pain scores are similar in both groups. In particular, pain was absent in 222 group A patients (63%) and 238 group B patients (66%) (difference, 3.80%; 95% CI, −3.22% to 10.82%). For the entire study group and each subgroup, when pain experienced after 6 months was compared with that referred after 1 month, a statistically significant positive relation was found (\( p=0.113, P=.02 \); group A: \( p=0.134, P=.01 \); group B: \( p=0.108, P=.04 \), Spearman rank correlation). The data showed a persisting decrease in touch and pain sensation in group B.

A total of 302 patients (74%) in group A and in 291 patients (72%) in group B attended an office visit 1 year postoperatively. Of the group A and group B patients, pain was absent in 231 (76%) and 213 (73%) (difference, 3.30%; 95% CI, −3.68% to 10.28%), mild in 55 (18%) and 60 (21%), moderate in 11 (4%) and 9 (3%), and severe in 5 (2%) and 9 (3%), respectively (\( P=.55 \); Pearson \( \chi^2 \) test). For the entire cohort, when pain experienced after 1 year was compared with that referred after 6 months, a statistically significant positive relation was found (\( p=0.140, P=.001 \), Spearman rank correlation); similar results were obtained in group A and group B (group A: \( p=0.123, P=.04 \); group B: \( p=0.136, P=.02 \), Spearman rank correlation). Touch sensation remained significantly decreased when the ilioinguinal nerve was removed (Table 2).

### Table 2. Pain Scores and Loss of Sensation at the Follow-up Visits

<table>
<thead>
<tr>
<th>Variable</th>
<th>Group A (n = 391)</th>
<th>Group B (n = 380)</th>
<th>( P ) Value</th>
<th>Group A (n = 354)</th>
<th>Group B (n = 358)</th>
<th>( P ) Value</th>
<th>Group A (n = 380)</th>
<th>Group B (n = 291)</th>
<th>( P ) Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pain score</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Absent</td>
<td>195 (50)</td>
<td>184 (48)</td>
<td>.20†</td>
<td>222 (63)</td>
<td>238 (66)</td>
<td>.22†</td>
<td>231 (76)</td>
<td>213 (73)</td>
<td>.56†</td>
</tr>
<tr>
<td>Mild</td>
<td>108 (28)</td>
<td>128 (34)</td>
<td>.20†</td>
<td>89 (25)</td>
<td>93 (26)</td>
<td>.22†</td>
<td>55 (18)</td>
<td>60 (21)</td>
<td>.39†</td>
</tr>
<tr>
<td>Moderate</td>
<td>66 (17)</td>
<td>49 (13)</td>
<td>.20†</td>
<td>32 (9)</td>
<td>21 (6)</td>
<td>.04†</td>
<td>11 (4)</td>
<td>9 (3)</td>
<td>.06†</td>
</tr>
<tr>
<td>Severe</td>
<td>22 (6)</td>
<td>19 (5)</td>
<td>.01†</td>
<td>11 (3)</td>
<td>6 (2)</td>
<td>.01†</td>
<td>5 (2)</td>
<td>9 (3)</td>
<td>.01†</td>
</tr>
<tr>
<td>Numbness</td>
<td>46 (12)</td>
<td>54 (14)</td>
<td>.19†</td>
<td>12 (3)</td>
<td>18 (5)</td>
<td>.37†</td>
<td>17 (6)</td>
<td>11 (4)</td>
<td>.39†</td>
</tr>
<tr>
<td>Loss of touch sensation</td>
<td>84 (21)</td>
<td>185 (49)</td>
<td>.001‡</td>
<td>21 (6)</td>
<td>104 (29)</td>
<td>.001‡</td>
<td>13 (4)</td>
<td>33 (11)</td>
<td>.002‡</td>
</tr>
<tr>
<td>Loss of pain sensation</td>
<td>176 (45)</td>
<td>211 (56)</td>
<td>.004‡</td>
<td>90 (25)</td>
<td>117 (33)</td>
<td>.004‡</td>
<td>25 (8)</td>
<td>26 (9)</td>
<td>.09‡</td>
</tr>
</tbody>
</table>

*Data are given as (percentage) of patients.
†Pearson \( \chi^2 \) with Yates correction for continuity.

### Table 3. Pain Score at Telephone Follow-up

<table>
<thead>
<tr>
<th>Pain Score</th>
<th>Group A (n = 344)</th>
<th>Group B (n = 334)</th>
<th>( P ) Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Absent</td>
<td>262 (76)</td>
<td>249 (75)</td>
<td>.22†</td>
</tr>
<tr>
<td>Mild</td>
<td>53 (15)</td>
<td>67 (20)</td>
<td>.35†</td>
</tr>
<tr>
<td>Moderate</td>
<td>20 (6)</td>
<td>12 (4)</td>
<td>.04†</td>
</tr>
<tr>
<td>Severe</td>
<td>9 (3)</td>
<td>6 (2)</td>
<td>.14†</td>
</tr>
</tbody>
</table>

*Data are given as number (percentage) of patients.
†Pearson \( \chi^2 \).

A median telephone follow-up of 33.5 months (range, 12-62 months) was performed in 344 patients (84%) in group A and 334 patients (82%) in group B. Pain score was similar in both groups (Table 3). In particular, pain was absent in 262 patients (76%) in group A and 249 patients (75%) in group B (difference, 1.70%; 95% CI, −4.79% to 8.19%).

### COMMENT

Postoperative pain is a significant problem after open inguinal hernia repair. Moderate or severe pain was still present in 11% of patients during mobilization and in 5% at rest 4 weeks after operation in the study by Callesen et al. In the same group of patients, 19% reported some degree of pain at 1-year follow-up; the pain was moderate or severe in 6% of cases. In a large-scale study, chronic pain was present in 28.7% of patients 1 year after hernioplasty, leading to some degree of functional impairment in 11% of patients. In another large-scale study, chronic pain was present in 43% of patients, and it was reported as severe or very severe in 3% of cases. Chronic pain occurred in 30% of patients in the study by Poobalan et al. Tension-free repair of inguinal hernia with mesh prosthesis should lead to less postoperative pain. However, acute postoperative pain was similar in patients who underwent conventional or mesh hernia repair. In a recent meta-analysis of randomized controlled trials, comparing hernia repair with or without mesh, the results showed a significant reduction in chronic pain when mesh was applied; however, there is still a relevant proportion of patients (10.7%) who complained of persisting...
pain after hernia repair with mesh. In our group of study, globally considered, chronic pain 1 year after operation was present in 149 (25%) of 593 patients, and it was described as moderate or severe in 34 (6%) of these patients. The telephone interview showed that the proportion of patients who still experienced chronic pain was considerable at long-term follow-up. No correlation was found between the presence of preoperative pain and the occurrence of postoperative pain. According to other studies, chronic pain was significantly related to the presence and intensity of postoperative pain.

Damage to 1 or more of the 3 nerves passing through the surgical field is suspected to be one of the main causes of chronic postherniorrhaphy pain. This theory is supported by the association between chronic pain and sensory disturbances. A nerve may be damaged during operation as a result of perineural fibrosis, entrapment by staples, sutures, or prosthetic materials, and direct lesions due to stretching, contusion, electrical injury, and partial or complete division of the nerve. Elective division of the ilioinguinal nerve was proposed by hernia surgeons to reduce the risk of its inadvertent damage and consequent chronic pain. Wantz showed that chronic pain was not present in 546 patients who underwent hernia repair with elective division of the ilioinguinal nerve, whereas it was seen in patients with the nerve preserved. No relation between ilioinguinal nerve preservation or elective division and chronic pain was reported in a large study by Cunningham et al. The study by Ravichandran et al was the first to assess the effect of division of the ilioinguinal nerve in a randomized setting. The authors found no evidence to support the benefit of ilioinguinal nerve division with respect to postoperative pain within the limitation of a small sample size. Our data confirm that ilioinguinal nerve division does not affect postoperative pain after mesh repair of the inguinal hernia with the support of a large number of patients and an appropriate long-term follow-up. In particular, considering the primary end point of our trial, after 1 year there was no difference in the rates of patients free from pain in both groups, and the 95% CI for the difference was so low that is was without clinical importance.

After inguinal hernia repair, sensory changes are common. In the study by Ravichandran et al, loss of sensation in the territory supplied by the ilioinguinal nerve occurred in 40% to 45% of patients when the nerve was divided and in 5% to 25% of cases when it was preserved after 6 months. Our data confirm that elective transection of the ilioinguinal nerve leads to a significant increase in the proportion of patients who complain of a decrease in pain and touch sensation in the postoperative period with respect to those with preserved nerve. In particular, touch sensation was still impaired at the 1-year follow-up visit.

In conclusion, our study showed that pain after open hernia repair with polypropylene mesh is a relevant problem and is unaffected by elective division of the ilioinguinal nerve. Moreover, the transection of the ilioinguinal nerve was significantly related to sensory disturbances in the area of distribution of the nerve.

Accepted for publication February 18, 2004.

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REFERENCES