Objective: The aim was to compare long-term postoperative pain after inguinal hernia surgery using 2 techniques that have shown favorable long-term outcome in previous randomized studies: Lichtenstein using local anesthesia (LLA) and endoscopic total extra-peritoneal repair (TEP) under general anesthesia.

Background: Patients often experience pain after inguinal hernia surgery. These 2 methods in their optimal state have not yet been sufficiently compared.

Methods: A randomized controlled trial was conducted to detect any difference in long-term postoperative inguinal pain. Altogether 384 patients were randomized and operated using either TEP under general anesthesia (n = 193) or LLA (n = 191). One year postoperatively, patients were examined by an independent surgeon and requested to complete the Inguinal Pain Questionnaire (IPQ), a validated questionnaire for the assessment of postoperative inguinal pain.

Results: Three hundred seventy-five (97.7%) patients completed follow-up at 1 year. In the TEP group, 59 (20.7%) patients experienced pain, compared with 62 (33.2%) patients in the LLA group (P = 0.007). Severe pain was reported by 4 patients in the TEP group and 6 patients in the LLA group (2.1% and 3.2%, respectively, P = 0.543). Pain in the operated groin limited the ability to exercise for 5 TEP patients and 14 LLA patients (2.7% and 7.5%, respectively, P = 0.034).

Conclusions: Patients operated with TEP experienced less long-term postoperative pain and less limitation in their ability to exercise than those operated with LLA. The present data justify recommending TEP as the procedure of choice in the surgical treatment of primary inguinal hernia.

Keywords: inguinal hernia, Lichtenstein, local anesthesia, postoperative pain, TEP

Less Pain 1 Year After Total Extra-peritoneal Repair Compared With Lichtenstein Using Local Anesthesia

Data From a Randomized Controlled Clinical Trial

Linn Westin, MD,* Staffan Wollert, MD, PhD† Mikael Ljungdahl, MD, PhD† Gabriel Sandblom, MD, PhD,* Ulf Gunnarsson, MD, PhD,‡ and Ursula Dahlstrand, MD, PhD*

From the CLINTEC, Karolinska Institutet, Stockholm, Sweden; †Department of Surgical Science, Uppsala University, Uppsala, Sweden; and ‡Department of Surgery and Perioperative Science, Umeå University, Umeå, Sweden.

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Reprints: Linn Westin, MD, Center for Digestive Diseases, Karolinska University Hospital, 141 86 Stockholm, Sweden. E-mail: linn.westin@karolinska.se.

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All operations were planned as outpatient procedures, regardless of operation method. The 4 participating surgeons were comfortable with both surgical techniques at the time of the trial and did not have a personal preference for either one of them. In both operating techniques, heavyweight polypropylene mesh was used. Four surgeons, 2 from each hospital, carried out all the procedures in this study. This measure was taken to ensure that the surgeon-related influence on the 2 groups was minimized. Patients allocated to LLA underwent surgery according to the Lichtenstein technique. The mesh was fixated using a nonabsorbable monofilament suture. The local anesthetic, a mixture 1:1 of bupivacaine 5 mg/ml and mepivacaine 10 mg/ml, was administered by the surgeon.

In the TEP procedure, no dissection balloon and only reusable instruments were used. With this approach no fixation of the mesh was recommended. The decision to use staples or glue was made by the surgeon depending on the anatomical circumstances. If so, this was recorded, as was the use of other equipment not usually needed, for example, suction.

The primary outcome was postoperative pain after 1 year. Secondary outcomes were recurrence, difficulties in performing daily activities, postoperative complications, and use of analgesics.

Patients were requested to answer the Inguinal Pain Questionnaire (IPQ) 6 weeks and 1 year after the procedure. The IPQ is a validated questionnaire for studying postoperative pain in the operated groin. Results from the 6-week follow-up have been reported previously. At the 1-year follow-up, patients were given a clinical examination by an independent surgeon with special interest in abdominal wall surgery. A structured questionnaire regarding postoperative complications, reoperations, and recurrence was completed.

Statistical Analyses
Statistical analyses were made using Stata/IC version 12.1 (StataCorp LP, College Station, TX). \( \chi^2 \) test was applied generally, whereas Fisher’s exact test was used when one of the analyzed groups comprised less than 10 patients. Assuming a prevalence of persisting pain of 35% in the Lichtenstein group and 20% in the TEP group, 362 patients would be required to detect a difference at the 95% significance level with a power of 90%. For each patient excluded due to protocol violation 3 extra patients were included to maintain power.

Role of the Funding Source
No sponsor had any role in the design of the study, the collection, analysis or interpretation of data, writing of the report, or making the decision to submit the report for publication.
RESULTS

Randomization was carried out for 389 male patients with primary unilateral inguinal hernia. Of these patients, 384 underwent surgery and 5 patients were excluded before the surgical procedure due to protocol violation. Among the randomized operated patients, 193 were assigned to TEP and 191 to LLA. In Table 1, the baseline characteristics of the 2 patient groups are specified and compared. Follow-up 1 year after surgery was completed by 375 patients (97.7%) (Fig. 1). Eight of these patients refused clinical examination but completed an interview by telephone, including both the IPQ and the other structured questionnaire. Figure 2 shows the distribution of answers regarding most severe pain experienced during the week before completing the IPQ. Persistent pain was reported by 39 (20.7%) patients in the TEP group and 62 (33.2%) patients in the LLA group ($P = 0.007$).

The 2 groups were compared with each other regarding prevalence of persistent severe pain. Pain that impaired concentration on daily activities was defined as severe. Four patients in the TEP group and 6 patients in the LLA group (2.1% and 3.2%, respectively, $P = 0.543$) reported severe pain.

Figure 3 demonstrates answers given to the questions regarding whether pain in the operated groin interfered with specified daily activities. Pain in the operated groin that limited the ability to perform physical exercise was reported by 5 patients in the TEP group and 14 patients in the LLA group (2.7% and 7.5%, respectively; $P = 0.034$). No differences were seen between groups regarding difficulties sitting more than 30 minutes (1 vs. 3, $P = 0.62$), standing longer than 30 minutes (3 vs. 2, $P = 1.00$), rising from a low chair (2 vs. 2, $P = 1.00$), climbing stairs (4 vs. 1, $P = 0.37$), or driving a car (1 vs. 1, $P = 1.00$).

There were 2 recurrences in the TEP group and 4 in the LLA group. There was no significant difference in recurrences between the groups. No significant difference was seen in the use of analgesics. An analgesic (acetaminophen) was used by 1 patient in each group the week before the 1-year follow-up.

DISCUSSION

This randomized controlled trial showed TEP to be superior to LLA with regards to long-term postoperative pain. TEP patients also had less physical activity restrictions after 1 year.

Previous studies have suggested that endoscopic techniques for inguinal hernia repair result in less postoperative pain.13 These studies, however, have not compared TEP with the Lichtenstein technique under optimal circumstances, that is, carried out using local anesthesia.12 According to the European hernia Society guidelines from 2009, TEP is preferred to TAPP for primary unilateral inguinal hernia repair.10,11 Local anesthesia is recommended for open techniques to minimize pain.16 The current study compares persistent postoperative pain after LLA with that after TEP, these being accepted as optimal open and endoscopic techniques.

Our results were well in line with previous studies regarding frequency of long-term postoperative pain.5,6 Persistent mild to moderate pain is a common complication after inguinal hernia surgery. All surgeons should be aware of this and information about this risk should be discussed with the patient as part of the informed consent process.

TEP reduced the risk for mild persistent pain. However, no reduction in severe pain was observed. This may well be explained by insufficient statistical power to detect conditions present in less than 10% of the study group. The study was not designed to detect severe pain and therefore was not primarily powered for this. Nevertheless,

TABLE 1. Baseline Patient Characteristics (n = 375)

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>TEP</th>
<th>LLA</th>
<th>$P$</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years, mean (range))</td>
<td>52.9 (23–79)</td>
<td>53.2 (27–77)</td>
<td>0.98*</td>
</tr>
<tr>
<td>BMI (kg/m$^2$, mean)</td>
<td>26.5</td>
<td>24.9</td>
<td>0.31*</td>
</tr>
<tr>
<td>ASA classification, n (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ASA 1</td>
<td>124 (66.0)</td>
<td>134 (71.7)</td>
<td>0.23†</td>
</tr>
<tr>
<td>ASA 2</td>
<td>62 (33.0)</td>
<td>51 (27.3)</td>
<td>0.23†</td>
</tr>
<tr>
<td>ASA 3</td>
<td>2 (1.1)</td>
<td>2 (1.1)</td>
<td>1.00‡</td>
</tr>
<tr>
<td>Anatomy, n (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Indirect hernia</td>
<td>124 (66.0)</td>
<td>109 (58.3)</td>
<td>0.13‡</td>
</tr>
<tr>
<td>Direct hernia</td>
<td>56 (29.8)</td>
<td>57 (30.5)</td>
<td>0.88‡</td>
</tr>
<tr>
<td>Femoral hernia</td>
<td>1 (0.5)</td>
<td>0</td>
<td>1‡</td>
</tr>
<tr>
<td>Combined</td>
<td>7 (3.8)</td>
<td>20 (10.7)</td>
<td>0.04‡</td>
</tr>
<tr>
<td>Others</td>
<td>0</td>
<td>1 (0.5)</td>
<td>0.50‡</td>
</tr>
</tbody>
</table>

* Mann–Whitney U test.
† Fischer exact test.
‡ Fisher exact test.

FIGURE 2. Distribution of answers to the IPQ question “worst pain experienced during the past week” at follow-up 1 year after surgery. $1 = $no pain$, 2 = $pain that can easily be ignored, $3 = $pain that cannot be ignored but does not affect activities, $4 = $pain affects concentration and activities, $5 = $pain affects most activities. TEP, totally extra-peritoneal endoscopic repair (n = 188); LLA, Lichtenstein repair using local anesthesia (n = 187). Asterisks indicate significant difference (**$P = 0.007$, 0.007, *$P = 0.011$).

FIGURE 3. The percentage of patients who reported pain from the operated groin limiting activities 1 year after surgery. TEP, totally extra-peritoneal endoscopic repair (n = 188); LLA, Lichtenstein repair using local anesthesia (n = 187). The asterisk indicates significant difference ($P = 0.034$).
severe pain limiting daily activities in a minority of the population may be more clinically important than easily ignorable mild pain in a large group.

The influence of the implanted material on the outcome is difficult to evaluate. The same mesh was used in the LLA group as in the TEP group. In LLA, all sutures were nonabsorbable and placed according to the Lichtenstein method.

In the TEP group, glue or staples were used for fixation if this was considered necessary. However, the surgeons participating in the study were recommended not to fixate the mesh if possible. Fixation of the mesh was carried out in one third of cases. Despite the use of fixation materials in some of the TEP procedures, the patients in the TEP group experienced less long-term pain. Heavyweight mesh was used because there was still not enough evidence for lightweight mesh when the trial started. This would also have caused some patients to receive a lightweight and others a heavyweight mesh. To avoid heterogeneity regarding mesh material, heavyweight mesh was used for all patients. Other studies have shown that heavyweight mesh causes more pain and discomfort than lightweight mesh.19,20 This suggests that our results are applicable to procedures with lightweight mesh, and that there may even be less pain.

Handling of the nerves in the inguinal tract in open surgery could be a factor influencing postoperative pain. The protocol did not dictate any particular approach to this. Our general recommendation and practice was to spare the nerves whenever possible, but if a nerve was found to interfere with good mesh placement or be at risk for entrapment, it was excised.

TEP is a proven reliable method for inguinal hernia repair.21 Our results show a clinically significant advantage in favor of TEP regarding long-term postoperative pain, and justifies the use of TEP for routine inguinal hernia surgery. This also raises the question of whether more surgeons should be well acquainted with and skilled in the Lichtenstein technique. Our results suggest that more surgeons should be trained in the execution of TEP. Many surgical residents are well acquainted with a heavily weighted mesh when the trial started. This would have caused some patients to receive a lightweight and others a heavyweight mesh. To avoid heterogeneity regarding mesh material, heavyweight mesh was used for all patients. Other studies have shown that heavyweight mesh causes more pain and discomfort than lightweight mesh.19,20 This suggests that our results are applicable to procedures with lightweight mesh, and that there may even be less pain.

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REFERENCES
