Comparing sutures and human fibrin glue for mesh fixation during open inguinal hernioplasty

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PURPOSE: The aim of this study is to evaluate pain and further disabling complications in patients undergoing Lichtenstein technique for primary inguinal hernia repair by fixing the mesh with fibrin sealant versus sutures.

METHODS: This study was carried out on 116 patients between January 2009 and July 2009. All patients were male, between the ages of 20 and 75 years. Lichtenstein, using a polypropylene mesh as prosthetic material. A total of 116 hernias were operated on. Group I: 54 operations were done using the conventional repair procedure with polypropylene sutures (prolene 2/0) for mesh fixation. Group II: 62 operations were done using fibrin glue for fixation of the mesh. All patients were operated as day cases, with a maximum hospital stay of 12 hours; none required readmission.

RESULTS: No complications were observed in follow-up at 1 week, 1 month, 6 months and 12 months. At 12 months, none of the patients had developed a recurrence. The mean time for complete healing of wound after herniorrhaphy plus fibrin sealant was 8.13±7.88 days (range 6-28 days). This was markedly increased in group 1 patients (mean 12.08±8.59 days, and range 8-32) (p <0.001). 12 months after surgery, The median VAS pain score was significantly lower in group 2 patients (P < 0·001). The mean (SD) duration of incapacity for work was 5 (2-12) days in group 2 (p <0.001).

CONCLUSIONS: This study confirms the effectiveness of fibrin glue in securing prosthetic meshes and reducing chronic inguinal pain.

KEY WORDS: Chronic pain, Fibrin glue, Inguinal hernia repair

Introduction

Inguinal hernia repair is the most frequently performed procedure in general surgery 1. Over the last few years, the placement of a prosthetic mesh in front of the hernia orifice has become an increasingly popular strategy to prevent recurrence. The Lichtenstein technique is widely used because it is easy to learn and it is associated with a low rate of complications and recurrences 2. Several techniques exist that require permanent fixation of the prosthesis to the abdominal wall, usually using tissue-penetrating devices like staples or sutures. However, such techniques can cause post-operative bleeding as well as pain due to nerve compression 3,4. In particular, most reports of chronic pain encountered after tension-free groin hernia repair are related to the use of these tissue-penetrating devices 4-6. Inguinal herniorrhaphy is often performed as a day-case procedure with minimal postoperative morbidity. After inguinal hernia repair, patients can return to work early and enjoy a good quality of life 7. Tisseel® is a biodegradable, biological preparation combining highly concentrated, human plasma-derived fibrinogen (75-115 mg/mL) and thrombin (500 IU/mL). The mixing of these components in
the presence of calcium chloride leads to the development of a three-dimensional matrix of polymerised fibrin fibres in a process mimicking the last step of biological coagulation. Fibrin sealant can, therefore, be used as an adjuvant to haemostasis in a variety of surgical applications. In 1997, Chevrel and Rath first proposed fibrin sealant as an alternate means of mesh fixation in hernia repair, with the aim of reducing the rate of hernia recurrence. Canonico et al. later reported the benefits of fibrin sealant in reducing bleeding complications following hernia repair in patients with impaired coagulation. The results of these studies have encouraged surgeons to use fibrin sealant in daily practice as an atraumatic alternative to mechanical mesh fixation. Increased fibroblast activity even resulted in better and faster incorporation of the mesh material. A lower rate of early postoperative pain with earlier convalescence is reported, but also, and primarily, a reduction in chronic pain in comparison with mesh fixation using staples. A significant decrease in seroma formation is described in most studies.

The aim of this study is to evaluate pain and further disabling complications in patients undergoing Lichtenstein technique for primary inguinal hernia repair by fixing the mesh with fibrin sealant versus sutures (control group).

 Patients and methods

This study was carried out on 116 patients between January 2009 and July 2009. All patients were male, between the ages of 20 and 75 years. All patients were evaluated prospectively. All patients were operated with the same surgical technique in all cases, Lichtenstein, using a polypropylene mesh as prosthetic material. A total of 116 hernias were operated on (Table II) Group I: 54 operations were done using the conventional repair procedure with polypropylene sutures (prolene 2/0) for mesh fixation. Group II: 62 operations were done using fibrin glue for fixation of the mesh. All patients had been followed up for more than 12 months. The inclusion criteria are age > 18 years, elective surgery, primary inguinal hernia and follow-up > 12 months. Exclusion criteria were age > 80 years, emergency (obstruction, strangulation) recurrent hernia, femoral hernia, complicated hernia, obesity. All surgeries were performed by the same most experienced surgeon under local anesthesia. All patients were fully briefed about the surgical procedure and an informed consent was obtained. All patients were operated as day cases, with a maximum hospital stay of 12 hours; none required readmission.

Table I - Operative and postoperative outcomes.

<table>
<thead>
<tr>
<th>Duration of operation (min)</th>
<th>Group 1 (n:54)</th>
<th>Group 2 (n:62)</th>
<th>p value*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pain VAS score</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Short-term follow-up</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(2 days)</td>
<td>4 (2–6)</td>
<td>2 (1–3)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Pain VAS score</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mid-term follow-up</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(30 days)</td>
<td>1.8(0–9)</td>
<td>0.8(0–6)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Pain VAS score</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Long-term follow-up</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(365 days)</td>
<td>0.8(0–6)</td>
<td>0</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Duration of incapacity for work (days)</td>
<td>8 (4–20)</td>
<td>5 (2–12)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Complete healing time(days)</td>
<td>12.08±8.59(8–32)</td>
<td>8.13±7.88(6–28)</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

*Mann–Whitney U test
Group 1 = with suction drains.
Group 2 = without drains. (fibrin sealant)
VAS scale: 0 = no pain, 10 = unbearable pain.
Pain >3 on the VAS is considered to be moderate or severe.

PROCEDURE

Antibiotic prophylaxis was given as a single dose of a third-generation cephalosporin. The inguinal region was prepared and the hernia sac managed according to the Lichtenstein technique. The ilioinguinal nerve, the iliohypogastric nerve and the genital branch of the genitofemoral nerve were identified and preserved. The spermatic cord was then dissected and separated from the posterior wall. The cremaster muscle was incised longi-
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Table II - Per-Operative findings (n=116)

<table>
<thead>
<tr>
<th>Type of hernia</th>
<th>Group 1 (n:54)</th>
<th>Group 2 (n:62)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Side of hernia</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Right</td>
<td>40</td>
<td>48</td>
</tr>
<tr>
<td>Left</td>
<td>12</td>
<td>12</td>
</tr>
<tr>
<td>Bilateral</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Type of hernia</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Direct</td>
<td>22</td>
<td>24</td>
</tr>
<tr>
<td>Indirect</td>
<td>28</td>
<td>36</td>
</tr>
<tr>
<td>Combined</td>
<td>4</td>
<td>2</td>
</tr>
<tr>
<td>(Direct + Indirect)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Discussion

Inguinal hernia repair is the most frequently performed procedure in general surgery. Over the last few years, the placement of a prosthetic mesh in front of the hernia orifice has become an increasingly popular strategy to prevent recurrence. The Lichtenstein technique is widely used because it is easy to learn and it is associated with a low rate of complications and recurrences. Inguinal herniorrhaphy is often performed as a day-case procedure with minimal postoperative morbidity. After inguinal hernia repair, patients can return to work early and enjoy a good quality of life.

The ‘pain complex syndrome’ after hernia repair includes three different aspects: 1) numbness and burning sensation 2) groin discomfort 3) neuralgia, with radiation of pain to the skin of the corresponding hemiscrotum, labium majus and Scarpa’s triangle. Consensus of European Hernia Society, in T.I.M.E.L.I. trial, has defined pain complex syndrome as the presence of one of the three or all of these aspects 1 year after surgery. In terms of percentage, the incidence of pain complex syndrome is assumed to be about 25% of patients undergoing inguinal hernia repair. Moreover, some authors report that a significant proportion of the pain is of neuropathic origin. Because of this, when genitofemoral, ilioinguinal and/or iliohypogastric nerves are damaged by suture entrapment or by contact with mesh, the probability of acute or chronic pain after surgery is very high.

Etiology of postherniorrhaphy pain includes non-neuropathic and neuropathic causes or a combination of both. Non-neuropathic causes include mechanical pressure of folded or wadded mesh, periostial reaction and scar-tissue formation. Neuropathic pain can be caused by com-
pression of one or more nerves by ‘perineural fibrosis’, suture material, staples and tacks or by nerves injuries. So if it is possible to limit the use of suture and fixation devices, chronic groin pain could be reduced. Fibrin sealant (Tissucol; Baxter Healthcare) is a biodegradable adhesive that combines human-derived fibrinogenand thrombin activated by calcium chloride. It has been available commercially for more than 20 years and has been proven to be effective in numerous clinical applications. In addition to its hemostatic action, the fibrinogen component gives the product tensile strength and adhesive properties, and this component promotes fibroblast proliferation.

Tisseel® began to be used in hernia repair from 2002, and quickly became popular as an alternative means of mesh fixation. Regarding the Lichtenstein technique, Canonico et al. assessed the use of fibrin sealant in 80 patients in an Italian study with 12 months follow-up. No complications were observed, and the use of fibrin sealant was considered to be elective for the prevention of local haemorrhagic complications after herniorrhaphy in patients with coagulation disorders. A Spanish study by Hidalgo et al. assessed mesh fixation using fibrin sealant compared with polypropylene sutures in 55 patients treated for bilateral hernia using the Lichtenstein technique. Fibrin sealant and sutures were used for contralateral hernias in each patient. Similar overall outcomes were reported in both inguinal regions, but there was less post-operative pain and less inflammatory reaction associated with fibrin-fixed hernia repairs. Once again, there were no recurrences after 1 year of follow-up. In our series, no recurrences were observed in any group, but Tisseel® group more rapid return to work noted. Mesh repair can be performed under local, general or spinal anaesthesia but many surgeons prefer local anaesthesia especially in the elderly and moribund patients, as it avoids the systemic effects associated with general, spinal and regional anaesthesia. It has a wide safety margin and the cost of mesh repair under local anaesthesia is significantly low. With local anaesthesia, the patient is fully awake and can move about which reduces the hospital stay. Due to early mobility, the postoperative convalescence period is reduced and most of the patients can resume their work within a week. Urinary retention after repair under local anaesthesia is less common as compared to general anaesthesia. The shorter operating, convalescing and ambulating times as well as early discharge means that more elderly and moribund patients can safely undergo repairs.

In adults, undergoing day-case surgery for inguinal hernia, local anesthesia is preferred to general anesthesia to reduce the anaesthetic risk in general and to reduce and incidence of post-operative ileus and urinary retention in particular. Also, local and spinal anesthesia affords the surgeon the opportunity of testing the integrity of the repair on table by asking the patient to cough. No readmission and zero mortality recorded in this study highlights the negligible morbidity and safety associated with day-case surgery for inguinal hernia. This finding is in agreement with other studies that reported less than 0.5% re-admission rates and negligible mortality.

In conclusion, mesh fixation with fibrin sealant in open hernia repair surgery is a simple and suitable. In our study, the use of Tisseel® was associated with a very low rate of post-operative pain. Fibrin sealant appears to be a promising alternative to stapling/suturing for mesh fixation during inguinal hernioplasty.

**References**


