Randomized Clinical Trial of Fixation vs Nonfixation of Mesh in Total Extraperitoneal Inguinal Hernioplasty

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Hypothesis: Mesh fixation in the extraperitoneal space during endoscopic total extraperitoneal inguinal hernioplasty might be related to an increase in postoperative pain, morbidity rate, and hospital costs.

Design: Randomized clinical trial.

Setting: University teaching hospital.

Patients: From January 1999 to December 2001, 170 patients with inguinal hernia were invited to participate; 85 patients were randomized to each group.

Intervention: Total extraperitoneal inguinal hernioplasty with or without mesh fixation using staples.

Main Outcome Measures: Operating time, morbidity rate, chronic pain, recurrences, and hospital cost were analyzed. Follow-up was considered complete when it included a physical examination at 24 months (mean, 36±12 months).

Results: The statistical study showed no significant differences with regard to epidemiological factors, hernia type, operating time, morbidity, or recurrences when the mesh was stapled, although the total cost of the process was higher (P<.001).

Conclusions: Stapling the mesh in total extraperitoneal inguinal hernioplasty offers no advantages and increases the cost of the process. Our results suggest the possibility of limiting the use of mesh fixation in total extraperitoneal inguinal hernioplasty to cases of direct bilateral hernias.

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THE NEED OR CONVENIENCE of mesh fixation in total extraperitoneal laparoscopic inguinal hernioplasty (TEP) is still a controversial issue. Some authors recommend systematic fixation of the mesh as a measure to prevent early recurrences, but others have not shown any advantage of fixing the mesh with the endoscopic approach.1-6 This technical detail is therefore of great interest as it may have repercussions on postoperative pain, morbidity and recurrence rates, and hospital costs. The aim of this study is to analyze whether mesh fixation in TEP affects the outcome of patients undergoing surgery for inguinal hernia.

METHODS

PATIENTS

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A randomized, longitudinal, analytical, prospective study was conducted between January 1999 and December 2001 and included 170 patients who underwent TEP. Exclusion criteria were femoral hernia, emergency operation, strangulated hernia, scrotal hernia, patients with a high anesthetic risk (American Society of Anesthesiologists classification IV), neoplasia, acute infection, or mental incompetence. All the perioperative and follow-up data were prospectively collected (Excel, Microsoft Corp, Redmond, Wash). Patients were informed about the trial both verbally and in writing of the possible treatment options and gave their consent. Randomization was achieved preoperatively by computer into 2 groups: TEP with or without mesh fixation by staples (85 patients in each group).

SURGICAL TECHNIQUE

All operations were performed by 2 surgeons with previous experience (more than 3 years and 60 cases). The patients underwent surgery with general or spinal anesthesia using the technique of 3 trocars on the midline. The extraperitoneal space was created by a distension balloon trocar (Spacemaker II Surgical Balloon Dissector; GSI Inc, Cupertino, Calif). The hernial sac was reduced, and the spermatic cord was parietalized for a distance of 4 cm. A self-
expandable, 3-dimensional, anatomical mesh (Parietex; Sofradim, Villefranche sur Saone, France) was used to amply cover the defect. In the fixation group, the mesh was fixed by stapling to the Cooper ligament, rectus muscle, and transversus abdominis muscle. The position of the mesh was ensured during desufflation to prevent folding or buckling.

FOLLOW-UP

Patients were included in a follow-up protocol and reviewed in the Abdominal Wall Unit consulting room at 1 week and at 1, 6, 12, and 24 months. The parameters evaluated were clinical factors (age, sex, previous surgery, and hernia type), morbidity, operating time, ambulatory or admission surgery, and postoperative pain quantified with the visual analog scale ranging from 0 (no pain) to 10 (unbearable pain). Chronic pain was defined as the presence of inguinal or scrotal pain or pain in the mid thigh area, with or without an alteration in sensitivity, as mentioned by the patient and located on physical exploration. Recurrence was defined as a palpable hernia or a clear defect of the abdominal wall, which in the event of doubt was confirmed by ultrasound. Follow-up was considered complete when it included a physical examination at 24 months (mean, 36 ± 12 months).

COST ANALYSIS

A basic study was done of the hospital cost of the process, according to treatment, using the computer data provided by the hospital. All expenses generated by each patient were reviewed and grouped into 3 major categories: (1) hospitalization (staff, operating costs, materials and medicines, radiological costs, intermediate services, structure, stay, and others); (2) prosthesis; and (3) surgery (anesthesia and reanimation, minutes of surgery per number of surgeons, minutes of surgery per rest of the staff, and laparoscopic material).

STATISTICAL ANALYSIS

Patients were analyzed according to surgical treatment. Statistical analysis was done with Statistical Product and Service Solutions software (SPSS Inc., Chicago, Ill.). Means and standard deviations were used to describe quantitative variables, and ratios and confidence intervals were used for qualitative variables. The Kolmogorof-Smirnov test was used to study the normality of the quantitative variables. The Mann-Whitney U test was used for means comparison when a quantitative variable did not follow a normal distribution, and the t test was used for quantitative variables with normal distribution data and equal variance between the 2 groups. The χ² test with Fisher exact correction was used for analysis of qualitative data. P < .05 was considered the limit of significance.

RESULTS

Comparisons of the demographic features and hernia types between the 2 groups are shown in Table 1. Both groups were comparable from an epidemiological point of view. All the patients were operated on using the laparoscopic approach. The total series of patients was characterized by the high percentage of bilateral hernias (34%), recurrences (22%), and history of abdominal surgery (36%), which might reflect the high degree of overspecialization in our Abdominal Wall Unit. It is also worth noting the high frequency of umbilical hernia associated with inguinal hernia (16%). The frequent use of spinal anesthesia (24%), the short mean operating time (42 minutes in unilateral hernias and 47 minutes in bilateral hernias), and the high degree of completion of patients undergoing surgery without hospital admission (98%) demonstrate the experience accumulated across years of using this standardized technique. In the nonfixation group, 2 cases (2.3%) required hospital admission for subcutaneous emphysema and bladder lesion, with stays of 2 and 4 days, respectively. In the fixation group, 4 patients required hospital admission: 2 cases by decision of the surgeon owing to a difficult repair and another 2 cases owing to pain. The intraoperative complications of the technique were 1 punctiform perforation of the bladder, which was sutured by laparoscopy with the patient admitted to the hospital for 4 days with a bladder probe; 3 cases of minor bleeding, which were treated by clamping (2 owing to a lesion of the epigastric vessels and 1 owing to the staples; all were in the mesh fixation group); and 4 cases of thoracocervical subcutaneous emphysema, which resolved in 24 hours (Table 2). During follow-up, we detected 3 cases of recurrence in 2 patients receiving surgery for large-sized direct bilateral inguinal hernias in the nonfixation group. Both of them underwent reoperation at 12 and 24 months by anterior approach (Lichtenstein hernioplasty). In all 3 cases, the mesh had slipped and curled up at the Hesselbach triangle, leaving a new defect directly over the pubis. A second mesh extended over the pubis was used to complete the repair.

The statistical study showed no significant differences between the 2 groups (with and without mesh fixation) with regard to complications, morbidity, postoperative pain (either at 24 hours or 1 month or chronic at 2 years), and recurrences (Table 2). The total cost of the

Table 1. Demographic Characteristics of the Patients Undergoing Surgery for Inguinal Hernia, According to Mesh Fixation

<table>
<thead>
<tr>
<th>Type of Hernia</th>
<th>No Fixation (n = 85)</th>
<th>Fixation (n = 85)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Direct</td>
<td>12 (46.1)</td>
<td>11 (33.3)</td>
<td>.16</td>
</tr>
<tr>
<td>Indirect</td>
<td>39 (66.1)</td>
<td>40 (76.9)</td>
<td></td>
</tr>
<tr>
<td>Other Associated Hernia</td>
<td>16 (18.8)</td>
<td>11 (13.7)</td>
<td>.15</td>
</tr>
<tr>
<td>Right Location</td>
<td>70 (82.4)</td>
<td>70 (82.4)</td>
<td></td>
</tr>
<tr>
<td>Left Location</td>
<td>15 (17.6)</td>
<td>15 (17.6)</td>
<td></td>
</tr>
<tr>
<td>Sex, M/F</td>
<td>69/16</td>
<td>70/15</td>
<td>.39</td>
</tr>
<tr>
<td>Age, years</td>
<td>65 ± 13.1</td>
<td>65 ± 13.1</td>
<td></td>
</tr>
<tr>
<td>Recurrence</td>
<td>21 (18.9)</td>
<td>16 (13.5)</td>
<td>.18</td>
</tr>
<tr>
<td>Hernia Type</td>
<td>12 (33.9)</td>
<td>12 (33.3)</td>
<td>.99</td>
</tr>
</tbody>
</table>
Laparoscopic hernioplasty has been described according to the principles of the Stoppa technique in an attempt to prevent any kind of tension in the hernia repair and amply cover the myopectineal space with minimal surgical aggression. However, it is necessary to fix the mesh in the extraperitoneal space to prevent it from slipping? The question is important because mesh fixation has been related to early recurrence, postoperative pain, and hospital costs. Some authors have tried to tackle the problem with retrospective analyses and prospective series without or with control groups. We present a randomized study.

Analysis of recurrences is one of the most interesting points for assessing the outcome of hernia surgery, but this outcome may be influenced by multiple factors (definition, method and duration of follow-up, percentage of patients lost, indications for surgery, and assessment of the learning curve). The present study has, where possible, taken these variables into account to avoid a final distortion in the results. The use of meshes may have modified the type of manifestation of recurrences in surgery for inguinal hernia. With the classic techniques, only 25% of recurrences were expected at 2 years of follow-up and around 60% with a follow-up of 5 years. With hernioplasties, it is currently thought that all recurrences appear within the first 2 years of follow-up. For this reason, we designed this study with a minimum follow-up of 2 years. The possible causes of recurrences following TEP include inadequate dissection, small size and/or inadequate overlapping of the prosthesis, use of nonelastic prostheses with a high tensile resistance, and inadequate fixation.

We currently use a 3-dimensional (3-layer) mesh with an axis that adapts to the iliopubic tract and Cooper ligament, amply covering the whole of the myopectineal ring. It has a fenestration that is overlapped by the upper layer and gives it a fixation point at the deep inguinal ring to prevent it slipping once the 3 layers are extended. This fenestration and axis allow simple adaptation to the extraperitoneal space thus avoiding the need for major dissections. In our study, only direct hernias appear to have a possibility of recurrence, and this may be explained by some early minor displacement of the medial edge of the mesh over the Cooper ligament and medial edge of the defect. The recurrences detected (direct and bilateral) suggest the presence of a weak zone close to the midline, which despite both meshes overlapping on the midline is not avoided. This seems to be a recommendation for fixing the meshes on their internal side to ensure an adequate fibrosis in this area of conjunction. In the Stoppa operation, the occurrence could be compared with an unsutured medial fenestration on the midline, which we avoid by using a single giant mesh. These results recommend fixing the mesh medially in direct and bilateral defects and increasing the medial overlap by some 4 cm in giant direct unilateral hernias.

At the beginning, the laparoscopic approach was associated with problems of postoperative pain related to nerve lesions due to trapping with sutures. After a decade of anatomical studies of the extraperoperative space, the TEP technique has been standardized and become a safe and efficient approach, offering clear advantages for the patient—regard to pain and time to return to normal activities—over anterior hernioplasties. Fixing the mesh with 3 to 4 staples to the rectus and transversus abdominis muscle cannot be regarded nowadays as a maneuver that risks postoperative pain. Our study confirms that intraoperative complications and morbidity do not differ when a few staples are applied to the posterior abdominal wall.
The main disadvantage of the TEP technique over open tension-free hernioplasties is the higher hospital cost. As a way of economizing, some authors have suggested using nondisposable material, standardizing the technique for ambulatory surgery, selecting only bilateral and recurrent cases, and having it performed always by an experienced team.10,18 With these measures, the laparoscopic approach could become more competitive and cost efficient, as with anterior hernioplasties. Along this line, our study shows that hospital cost can be reduced by eliminating the routine use of mesh fixation. A suture gun in our study shows that hospital cost can be reduced by eliminating the routine use of mesh fixation. A suture gun in our study shows that hospital cost can be reduced by eliminating the routine use of mesh fixation.

In conclusion, mesh fixation in the TEP technique offers no clinical advantages and increases the cost of the process. Our results recommend limiting the use of mesh fixation in the laparoscopic approach to cases of direct bilateral hernias.

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REFERENCES