A new approach in laparoscopic repair of inguinal and femoral hernias

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Abstract
The aim of this study to analyze results of a new method which eliminates complications associated with the classic mesh fixation areas and does not increase recurrence rates. This prospective study included a total of 70 patients applied with inguinal or femoral hernia repair with the laparoscopic TEP method. The patients were randomly separated into two groups as Group 1 applied with tack fixation and Group 2 applied with plug mesh and subcutaneous vicryl fixation. The groups were followed up and compared. The group applied with the newly-developed repair technique of plug mesh and vicryl fixation were observed to have a shorter length of stay in hospital, a lower requirement for postoperative analgesia, and reduced urinary retention and seroma rates. No difference was determined between the two groups in respect of operating time and return to normal activities. In the 24-month follow-up period, there was no significant difference in respect of hernia recurrence. The results of the study showed that the use of the newly-developed repair technique of plug mesh and vicryl fixation in laparoscopic TEP inguinal hernia repair increased the life quality after surgery. There are also cost advantages. This is a technique that can be selected for suitable patients.

Keywords: Hernia, plug, fixation, TEP, laparoscopic, pain

Introduction
Inguinal hernia repair is one of the most frequently applied operations in general surgery practice. Due to reduced recurrence rates, tension-free hernia repairs made with mesh are preferred. Since laparoscopic hernia repairs were first introduced by Dulucq in 1992, these have tended to be more popular than open repairs because of various advantages [1].

Currently, approximately 20% of all inguinal hernia repairs are made with a laparoscopic approach. The most preferred method is total extra peritoneal patch plasty (TEP). Although there are some advantages specific to transabdominal pre-peritoneal patch plasty (TAPP) repair, complications such as intra-abdominal organ injury have a more severe course. This study was based on our previous study in which the TAPP approach was evaluated but in this new study, the TEP approach was selected [2]. In classic TEP inguinal hernia repair, the potential hernia development area is covered with mesh and the mesh is generally fixed to the abdominal wall with spiral tacks. Although mesh fixation is controversial, it has reduced recurrence rates [3]. However, fixation with tacks can cause the development of some complications such as nerve damage and chronic pain. The femoral branch of the genitofemoral nerve and the lateral femoral cutaneous nerve have been reported to be damaged at the rate of 2%-4% in laparoscopic hernia repair [4].

In the light of the previous study, the aim of this study was to reduce the complication rates by eliminating mesh fixation with tacks in the pre-peritoneal area with a novel method of subcutaneous fixation of the mesh and to reduce recurrence rates [2].

Materials and Methods
Approval for this prospective, randomized study conducted between 2013 and 2015 was granted by the Local Ethics Committee of S.B. Istanbul Training and Research Hospital.

The study included 35 male patients aged 18-80 years, who were diagnosed with inguinal or femoral hernia and had an American Society of Anesthesiologists (ASA) score of 1-2. Patients were excluded if they had contra-indications to general anesthesia, drug or alcohol dependence, coagulopathy, or a history of hernia surgery. The 70 patients were randomly separated into 2 groups according to preoperative body mass index (BMI) and age as Group 1 who were applied with classic tack mesh fixation and Group 2 who were applied with plug mesh subcutaneous vicryl fixation. The procedure was performed by a single surgeon experienced...
in laparoscopic TEP. The data were collected in a double-blind manner with no knowledge of the groups.

Surgical technique
The TEP laparoscopic inguinal hernia repair was applied under general anesthesia with the patient in a mild Trendelenburg position. A Foley catheter was placed in position before the procedure and prophylactic antibiotics were administered at the incision stage.

A 1-cm infra-umbilical skin incision was made then an incision to the anterior fascia of the rectus sheath. With lateral retraction of the rectus muscle, the area was exposed between the rectus muscle and the posterior fascia of the rectus sheath. A 10-mm trocar was inserted and the pre-peritoneal space was insufflated with CO2 to a pressure of 12 mmHg. Using a 0° video telescope, the pre-peritoneal space was dissected as far as the space of Retzius, then two 5-mm trocars were inserted on the midline, one just above the pubic symphysis and the other midway between the lower port and the camera port. Following the dissection and reduction of the peritoneal sac, a 10 x 15 cm polypropylene mesh (Prolene-polypropylene mesh, Ethicon) was inserted and spread to cover the myopectineal orifice. At this stage, one of two identical sealed envelopes was selected by one of the surgical team. One envelope contained a paper on which “plug fixation” was written and the other had a paper stating “tack fixation”. In the classic tack mesh fixation group (Group 1), the mesh was fixed to the Cooper’s ligament and the anterior abdominal wall using 4-7 metal, spiral tacks (Covidien ProTackTM Tyco Autosuture 5 mm stapler).

In the plug mesh subcutaneous fixation group (Group 2), a polypropylene mesh 15 x 15 cm in size was cut in a T-shape 2.5 cm from the edge and the short sides were rolled round into a cigar shape to form a plug. A third of the plug side of the mesh was folded over itself and fixed to itself with a vicryl suture. Thus, a 10 x 15 cm mesh was obtained which was folded over itself as a plug in the posterior third (Figure 1). The tip of the plug was fixed by gently drawing the vicryl suture together and this suture was left long to be pulled below the skin.

![Image](image_url)

**Figure 1.** The plug mesh subcutaneous fixation (AC 2.5 cm, CB 10cm, AD 15cm)

By adjusting this prepared mesh plug from the camera port according to the medial lateral co-ordination of the placement of the defect, it was placed in the pre-peritoneal area. With the aid of a conventional laparoscopic instrument, the vicryl suture left long at the top of the plug was carefully advanced subcutaneously from the hernia defect in the pre-peritoneal area and taken outside the skin with a 1-2 mm cut applied to the skin. Thus, by sliding the plug within the defect, the mesh was spread to the pre-peritoneal area in such a way as to cover the myopectineal orifice. The vicryl suture taken outside was fixed subcutaneously.

Perioperative evaluation
The preoperative level of pain of the patients was determined using the Numeric Rating Scale (0= no pain, 10= severe pain). During the operation, the degree of difficulty of the procedure was graded (0=not difficult, 1=slightly difficult, 2= very difficult). A record was made for each patient of the pain level, requirement for analgesia, development of complications, time to discharge from hospital, and time to return to work. After discharge from hospital, the patients were called for follow-up examinations at 7 days, then at 1, 6 and 24 months and were evaluated in respect of hematoma, seroma, orchitis, and findings of mesh infection, pain and recurrence.

Statistical analysis
Analysis of the study data was performed using SPSS Statistics software version 22.0. Conformity of the variables to normal distribution was assessed using the Kolmogorov–Smirnov test. The Independent Samples t test was applied for the analysis of quantitative data. Where appropriate, the Chi-square test was used for the analysis of qualitative data, otherwise the Fisher’s Exact test was applied. A value of p<0.05 was considered statistically significant. All p values were two-sided.

In respect of sample size, the number of cases included (70) was determined to have 100% power in respect of postoperative pain score and 80% power in respect of urinary retention and seroma development.

Results
The demographic characteristics of the patients are summarized in Table 1.

<table>
<thead>
<tr>
<th>Table 1. Demographic characteristics of the patients</th>
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<tbody>
<tr>
<td>Group 1</td>
</tr>
<tr>
<td>---------</td>
</tr>
<tr>
<td>Age (years)</td>
</tr>
<tr>
<td>BMI</td>
</tr>
<tr>
<td>Hernia type</td>
</tr>
<tr>
<td>Indirect</td>
</tr>
<tr>
<td>Direct</td>
</tr>
<tr>
<td>Femoral</td>
</tr>
<tr>
<td>ASA</td>
</tr>
<tr>
<td>1</td>
</tr>
<tr>
<td>2</td>
</tr>
</tbody>
</table>

No complications were observed intraoperatively. All the patients were discharged on postoperative Day 1.

Higher pain levels were observed in the first hour postoperatively in the Group 1 patients (Table 2) but the difference between the groups was not statistically significant. Patients in Group 2 had a statistically significantly lower requirement for analgesia in the first postoperative hour compared to patients in Group 1. The
length of stay in hospital was shorter in Group 2 than in Group 1 (p=0.001). Urinary retention was seen in 7 (2.45%) patients in Group 1 and in 1 (0.35%) patient in Group 2 and the difference was statistically significant (p=0.001). There was no statistically significant difference between the groups in respect of the difficulty of the operation or of the time to return to work. In the long-term follow-up, there was no nerve damage or recurrence in any patient. Complaints of a moderate degree of pain were reported by 3 patients in Group 1. In the early postoperative follow-up period, seroma was observed in 7 (2.45%) patients in Group 1 and in 0 patients in Group 2, and the difference was statistically significant.

<table>
<thead>
<tr>
<th>Table 2. Postoperative findings</th>
<th>Group 1 n:35</th>
<th>Group 2 n:35</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Operating time (mins)</td>
<td>60.2±12.4</td>
<td>58.4±16.5</td>
<td>0.65</td>
</tr>
<tr>
<td>Length of stay (days)</td>
<td>16.0±10.5</td>
<td>9.1±5.2</td>
<td>0.001</td>
</tr>
<tr>
<td>Pain (0-10) Preop</td>
<td>0.9±2.3</td>
<td>0.5±1.9</td>
<td>0.45</td>
</tr>
<tr>
<td>Postop analgesia</td>
<td>4.50±1.08</td>
<td>2.37±1.0</td>
<td>0.03</td>
</tr>
<tr>
<td>Urinary retention</td>
<td>7</td>
<td>1</td>
<td>0.001</td>
</tr>
<tr>
<td>Degree of difficulty of operation</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Difficult</td>
<td>4</td>
<td>5</td>
<td></td>
</tr>
<tr>
<td>Moderately difficult</td>
<td>8</td>
<td>7</td>
<td></td>
</tr>
<tr>
<td>Not difficult</td>
<td>23</td>
<td>23</td>
<td></td>
</tr>
<tr>
<td>Postoperative early stage (7th day)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hematoma</td>
<td>0</td>
<td>0</td>
<td>0.001</td>
</tr>
<tr>
<td>Seroma</td>
<td>7</td>
<td>0</td>
<td>0.88</td>
</tr>
<tr>
<td>Orchitis</td>
<td>0</td>
<td>1</td>
<td></td>
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<tr>
<td>Infection</td>
<td>0</td>
<td>0</td>
<td></td>
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</tbody>
</table>

Discussion

In laparoscopic TEP inguinal hernia repair, the necessity for fixation of the mesh to the pre-peritoneal area with tacks to prevent recurrence is controversial. Several experts have concerns that the mesh could migrate if not fixed and could cause recurrence. In several randomized, prospective, controlled studies, mesh fixation has been compared with non-fixed repair and research is ongoing for the best method of mesh fixation. The traditional fixation of mesh with tacks can prevent movement and recurrence [5,6]. However, it can also increase both costs and chronic pain in particular [7-10]. Khajanchee et al reported an increase in neuropathic complications in a series of 172 cases applied with laparoscopic inguinal hernia repair with mesh fixation [11]. Just as there are reports stating that not fixing the mesh does not increase recurrence rates some specific studies have emphasized the need for mesh fixation [12-15]. Lau and Patil reported an increase in recurrence rates in cases applied with repair without mesh fixation, especially in those with large defects. In 16 an extensive series of 686 cases, Dehal et al reported a higher rate of recurrence in the cases not applied with mesh fixation compared with literature [13].

With the newly-developed technique that is presented here, it was aimed to eliminate complications associated with mesh fixation with tacks and to reduce the recurrence rate by making the fixation in a safer location. Moreover, urinary retention, which can develop associated with mesh fixation with tacks, was not observed with this method in this study. The reason for this could be related to the lower level of postoperative pain and the reduced requirement for narcotic agents. In a study by Lau and Patil, the level of postoperative pain was found to be significantly higher in the group applied with mesh fixation compared to those where fixation was not applied (p< 0.05) [16]. Taylor et al found the pain scores to be extremely high in patients applied with mesh fixation. An interesting point of that study was that in cases where the fixation was made with more than 6 tacks, the pain scores were measured at a significantly higher level [17].

In the current study, the postoperative pain levels of the patients in Group 2 who were applied with tacks to the pre-peritoneal area were determined to be statistically significantly lower.

Koch et al reported that the postoperative use of narcotic agents was a risk factor for the development of urinary retention [18].

In a series of 1220 cases, the rate of seroma development was reported as 0.52%-37.8% and urinary retention as 0.38%-8.3% [19]. Mulroy reported that urinary retention was increased associated with the increased sympathetic stimulus of postoperative pain [20]. In the novel method used in the current study, the patients had a reduced need for narcotic agents.

In some studies, the development of seroma has been seen to be a frequently encountered problem related to laparoscopic hernia repair and can be perceived by the patients as a recurrence of the hernia [21]. In the current study, although seroma developed in 7 patients in Group 1, it did not develop in any of the Group 2 patients. In this respect, the recommended new technique was seen to be of benefit.

Conclusion

No cost analysis was made in the current study. However, the elimination of tacks in mesh fixation is seen to be a factor in costs. Previous studies have reported that fixation of the mesh with tacks increased the cost of the operation from 120 USD to 375 USD [22].

In laparoscopic TEP hernia repair, some complications can develop associated with fixation of the mesh to the pre-peritoneal area. In the method of plug mesh subcutaneous vicryl fixation, recommended in this study, there was seen to be a reduction in complication rates with no increase in recurrence rates. In selected patients, this method is safe and advantageous. Nevertheless, there is a need for further studies with analyses of larger series and subgroups.

Competing interests
The authors declare that they have no competing interest

Financial Disclosure
The financial support for this study was provided by the investigators themselves.

Ethical approval
Approval for this prospective, randomized study conducted between 2013 and 2015 was granted by the Local Ethics Committee of S.B. Istanbul Training and Research Hospital.

Reference


