Outcomes on mesh fixation vs non-fixation in laparoscopic totally extra peritoneal inguinal hernia repair: a comparative study

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ABSTRACT

Objective: Inguinal hernia repair is one of the most common general surgical procedure, and laparoscopic approach gained popularity over the open approach. This study aimed to compare the clinical effects of TEP inguinal hernioplasty with or without mesh fixation. The primary outcome was acute post-operative pain.

Material and Methods: A retrospective comparative study on a prospectively collected data was conducted in a large DGH in England between January 2017 and December 2019 on 47 patients. The patients were divided into two groups. In group A, mesh fixation was performed with absorbable tackers and in group B no fixation was performed. Patients were followed up to 18 months postoperatively. Data was collected on post-operative pain, cost, recurrences and time taken to return to normal activities. Patients with lower midline scar and complicated inguinal hernias were excluded.

Results: Out of the 47 patients 53% (n= 25) were in group A and 47% (n= 22) in group B. All the patients in both groups were male. The mean postoperative pain score at 72h in group A was 7.12 (SD 1.13) and 4.91 (SD 1.23) in group B (p< 0.001). Group B patients have taken shorter time to return to normal activities in comparison to group A (p< 0.001), while recurrence (2%) rate is higher in group B (p> 0.05).

Conclusion: Pain and time taken to return to normal work postoperatively were significantly less in the non-fixation group. The study recommends non-fixation over fixation as it is feasible, cost-effective, causes less post-operative pain and no differences in terms of recurrences.

Keywords: Inguinal hernia, laparoscopic, mesh, fixation, non-fixation, chronic pain

INTRODUCTION

Inguinal hernias are a significant cause of patient morbidity. It is the most common type of hernia, accounting for 75% of all the abdominal wall hernias. The prevalence of repair ranges from 10 per 100 000 of the population in the United Kingdom to 28 per 100 000 in the United States (1). It has been estimated that over 20 million inguinal hernia operations are carried out each year throughout the world. The lifetime risk is approximately 27% in males and 3% in females (1). Several methods of inguinal hernia repair have been described and have been evolved over time (2,3).

Historically, the first operations for inguinal hernias were performed by the end of the 16th century. In the early 1980s, minimally invasive techniques for inguinal hernia repair were first reported, adding another modality to the management of these hernias (4). Laparoscopic approach of inguinal hernia repair has gained popularity over open approach due to reducing postoperative pain, shorter hospital stay, decreased incidence of urinary retention and earlier return to normal activities (5). National Institute for Health and Care Excellence (NICE) guidelines also advocates the superiority of the laparoscopic approach over open inguinal hernia repair (6). Two laparoscopic techniques have become the mainstay for the repair of these hernias: Trans Abdominal Pre-Peritoneal repair (TAPP) and Totally Extraperitoneal (TEP) repair. Both approaches have been proven to be effective, however, several fundamental differences exist when comparing the two approaches (7-9).

Mesh placement is the most frequently debated issue of TEP or TAPP operation. Mesh can be placed without fixation or can be fixed into place with tackers. However, these metal tackers increase the cost, operative times and there is an increased incidence of
chronic groin pain (2-16%) (5,10-14). One of the main concerns for non-fixation is mesh displacement or migration and subsequently increasing the chances of recurrence. However, several recent studies have shown that non-fixation of the mesh does not lead to an increase in recurrences. Moreover, it has the advantages of shorter operative time and less chronic groin pain when compared to tacker fixation (5,10-14).

The aim of this study was to compare the clinical effects of laparoscopic TEP inguinal hernioplasty with or without mesh fixation. Primary outcome was acute post-operative pain. Secondary outcome measures included time taken to return to normal activities, cost, complications and recurrence rates.

**MATERIAL and METHODS**

A retrospective study on a prospectively collected data was conducted in a large District General Hospital in South-East England between January 2017 and December 2019 on 47 patients with inguinal hernias presenting electively for TEP inguinal hernia repair with accepted written consents. Group A (25 patients) underwent TEP with mesh fixation by absorbable tackers versus Group B (22 patients) who received TEP with mesh non-fixation. Data was collected on post-operative acute and chronic groin pain, recurrences, time taken to return to normal daily activities, cost and any other complications. Timely post-discharge follow-ups were conducted up to 18 months through telephone on the third post-operative day and regular outpatient clinics appointment in 6 months and 12 months interval.

All adult patients with uncomplicated inguinal hernias were included. Exclusion criteria included lower midline scars and complicated (obstructed or strangulated) inguinal hernias. All patients received a single intravenous dose of 1.2 gm. Co-amoxiclav before induction as prophylaxis. The procedure was done under general anesthesia. We did employ urinary bladder catheterization pre-operatively. All procedures performed in this study were in accordance with the ethical standards of trust, and the study was discussed by the local research committee. However, ethical approval was not required as there is no deviation from the current practice and both techniques are widely practiced in the UK. Informed consent was obtained from all individual participants. The study complies with the current laws of the UK.

**Surgical Technique**

Access to the preperitoneal space was obtained by a 10-mm infra-umbilical port placement anterior to the posterior rectus sheath. Once the access was confirmed, dissection of the preperitoneal space was initiated with a balloon dissector to place a 10-mm 30° telescope. The pneumo pressure was 12 mmHg. Two 5-mm ports were placed in the midline, one three finger breadths above the symphysis pubis and the other in between the 10-mm port and 5-mm supra-pubic port, and the entire posterior floor was dissected. Once enough space was created to visualize the pubic symphysis medially, the cord structures entering the deep ring laterally, and adequate lateralization till Anterior Superior Iliac Spine, the hernia was addressed. For indirect hernias, cord dissection was done to isolate the sac completely. Direct hernia defects were identified and contents in the hernia defect were reduced. Once hernia was completely reduced, rolled 12 × 15 cm polypropylene mesh was introduced via the 10-mm port. The mesh was spread to cover the entire myopectineal area to cover the defect. The lower edge must extend well below the level of the inguinal ligament. The lateral part of the patch folded over and extended beyond the iliac vessels. In bilateral hernias, a similar mesh was placed bilaterally. The mesh was fixed with absorbable tackers, medially on Cooper’s ligament and laterally near anterior superior iliac spine. This step was not performed during the mesh non-fixation period. The procedure was completed after complete desufflation under vision until creeping of the peritoneum and its filling over the mesh, ensuring that the inferior border of the mesh will not roll up and closing the port sites with appropriate sutures. Early ambulation was encouraged. The patients were advised to undergo regular daily activities except for lifting heavy weights or involving in strenuous activity/exercise for at least 6-8 weeks.

**Statistical Analysis**

Statistical analysis was performed using SPSS software version 25. Data was expressed as mean ± standard deviation (SD). Comparisons of quantitative data in both groups were analyzed using t-test. Values of p< 0.05 were considered statistically significant.

**RESULTS**

Total eligible patients for the study was 54, however, later 7 patients were excluded. Of the 47 patients, 53% (n= 25) were in Group A and 47% (n= 22) in Group B. All the patients in both groups were male with an overall mean age of 56 years (range: 22-83 years). In group A (fixation group), unilateral hernias were 28% (n= 7) and bilateral hernias were 72% (n= 18), whereas in Group B (non-fixation group), unilateral hernias were 18% (n= 4) and bilateral hernias were 82% (n= 18), (p> 0.05) (Table 1).

Visual analogue pain scale (VAPS) given to patients were used post-operatively at 72 hours for pain assessment via telephone. Mean postoperative pain score in Group A was 7.12 ± 1.13 and 4.91 ± 1.23 in Group B, (p< 0.001) (Figure 1).

Mean time taken to return to normal activities for group B was 4.68 ± 1.62 in comparison to Group A 6.24 ± 1.33, (p< 0.001) (Table 2). The extra cost of the operation for each patient in Group A was approximately GBP 300 for NHS England, which is the added cost for absorbable tackers.

There was one recurrence (2%) encountered in the 18th month follow-up in Group B (p> 0.05), which was statistically insignificant. No cases needed conversion to open hernia repair, and there were no bowel and visceral injuries in our study. No patients developed seroma, hematoma, urinary retention or infection. No cases with
chronic groin pain in this study were encountered in both groups with 15-18-month follow-up.

DISCUSSION
Laparoscopic hernia repair is now recommended for primary inguinal hernia, recurrent inguinal hernia repair and bilateral inguinal hernia (2,3,6). Laparoscopic Totally Extraperitoneal (TEP) repair has gained popularity over Trans Abdominal Pre-Peritoneal repair (TAPP) repair as it does not involve breach into the peritoneal cavity and subsequent risks of visceral injuries (7-9). Inguinal hernias are being considered effectively treated by the TEP laparoscopic approach allowing bilateral repairs in the same sitting by minimally invasive technique. Understanding the posterior inguinal canal anatomy is essential to perform a laparoscopic TEP (17).

In this study, our aim was to ascertain patients’ functional outcomes after a laparoscopic TEP between mesh fixation and non-fixation. Many studies advocate the superiority of the mesh non-fixation over the fixation (15-17,19-21). However, it has remained debatable and controversial. The main concerns for non-fixation are mesh migration and the recurrence rate. In TEP, stabilization of the nonfixed mesh placed between anterior wall

| Variables | Fixations (n= 25) | Non-fixation (n= 22) |
|-----------|------------------|---------------------|
| Age (years) |                      |                      |
| Mean      | 58                | 55                  |
| Sex       |                   |                     |
| Male      | 25                | 22                  |
| Female    | 0                 | 0                   |
| Unilateral Hernias (%) | 7 (28%) | 4 (18%) |
| Bilateral Hernias (%)   | 18 (72%) | 18 (82%) |

Table 1. Patient demographics and characteristics of hernia

| Return to normal activities | Group A (n= 25) [n (%)] | Group B (n= 22) [n (%)] | p     |
|-----------------------------|------------------------|------------------------|-------|
| 2-3 days                    | 1 (4%)                 | 6 (27%)                | <0.001|
| 4-5 days                    | 4 (16%)                | 10 (46%)               | <0.001|
| 6-7 days+                   | 20 (80%)               | 6 (27%)                | <0.001|
| Mean ± SD                   | 6.24 ± 1.33            | 4.68 ± 1.62            |       |
| Median                      | 7                      | 5                      |       |

Table 2. Comparison between the two groups according to time taken to return to normal activities

Figure 1. Comparison of post-operative pain in two groups at 72 hours.
of the abdomen and peritoneum is based on sandwich effect created between tissues. Mesh stabilization without fixation has been well described in the literature (19-21). Meta-analyses have also comprehensively concluded that the recurrence rates are not increased by non-fixation of the mesh (15-18,20). Moreover, the non-fixation procedure can avoid the risk of vessel and nerve injury associated with tacker fixation. Postoperatively within two weeks, the proliferation of mesenchymal cells occurs in the mesh, and in the next two months, the tissue starts to incorporate into the mesh and adequate amount of collagen develops. This eventually strengthens permanent stabilization of mesh in the preperitoneal area.

Several methods of mesh fixation have been described and practiced such as surgical adhesives (Fibrin glue), self-fixating mesh and mechanical fixation (Tackers or sutures). The main reason for fixation is to avoid migration and theoretical recurrences. However, the use of fibrin sealant may lead to fibrin glue reactions, but many studies have proven its efficacy as safe (15,22,23). Suture fixation is barely practised as it is time-consuming and has not shown any benefits over non-fixation or tacker fixation. Tackers are the most common method of mesh fixation. They can be both absorbable and non-absorbable. The main concerns are post-operative acute and chronic pain due to greater risks of nerve injury (5,10,14,19,22). The use of fixation devices in the conjoint tendon or the pubic tubercle can be a causative factor for postoperative pain and discourage early ambulation. Approximately 2-16% of patients may experience persistent pain after laparoscopic inguinal hernia repairs. This may again promote seroma formation and increase hospital stay. Our study also found increased pain scores in the fixation group when we assessed pain at 72h post-surgery and this was statistically significant (Figure 1).

In our study, we also looked at the time taken by the patients to return to their normal activities postoperatively. Non-fixation group took a statistically significant shorter time in comparison to the fixation group in return to their daily activities. Cost is the other issue that needs to be considered while using tackers, and our study indeed showed tackers cost additional money compared to non-fixation. Several meta-analyses and RCTs have shown that non-fixation of mesh leads to decreased cost (16,17,20).

A very important finding in this study was that the non-fixation of mesh did not lead to increased recurrence. This is in agreement to the results of randomized trials and meta-analysis looking at non-fixation of mesh (7,15-17,19-21). Moreover, the superiority of nonfixation method in terms of avoiding potential nerve damage as well as limiting surgical expenses has been acknowledged.

CONCLUSION

Laparoscopic TEP repair for inguinal hernia is recommended for both direct and indirect inguinal hernias as providing a safe operative technique with early recovery and return to normal activities. Our results support the findings of researchers and demonstrate that laparoscopic TEP inguinal hernia repair performed without mesh fixation is a reliable technique. We recommend non-fixation over fixation as it is feasible, cost-effective, causes less post-operative pain and no differences in terms of recurrences. Our study is limited by its limited number of patients and relatively short follow up period. Also, patients were not randomized using RCT, which introduced potential selection bias. However, selection bias is a confounding factor.
Laparoskopik total ekstra-peritoneal inguinal herni tedavisinde sabitlemeli ve sabitlemesiz meş uygulamalarının sonuçları

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ÖZET

Giriş ve Amaç: İnguinal herni onarımı en yaygın cerrahi işlemlerden biri olmakla birlikte laparoskopik yaklaşım açık yaklaşım göre daha büyük popülariteye sahiptir. Bu çalışma, sabitlemeli ve sabitlemesiz meş yerleştirme işlemini önermektedir.

Gereç ve Yöntem: Prospektif olarak toplanan verilerden retrospektif karlaştırılmış bir çalışma Ocak 2017 ve Aralık 2019 tarihleri arasında Inglilterede 47 hastada uygulandı. Hasta grupu gruba ayrıldı. Grup A’da sabitlemeli ve Grup B’de sabitlemesiz meş yerleştirildi.

Bulgular: Grup A ve Grup B’de hem postoperatif ağrı, hem de normal faaliyetlere dönüş süresi anlamlı derecede farklılaşmıştır. Grup A’da sabitlemeli ve Grup B’de sabitlemesiz uygulanmıştır. Grup A’da 72. saatte postoperatif ağrı skoru 7.12 (SD: 1.13), Grup B’de 4.91 (SD: 1.23) idi (p<0,001). Grup A hastalarına nazaran, Grup B hastaları daha erken sürede normal faaliyetlere dönüştü (p<0.001) ancak Grup B’de nüks oranı (%2) daha yüksek (p>0.05).

Sonuç: Postoperatif ağrı ve normal faaliyetlere dönüş sabitlemeli uygulananın daha az postoperatif ağrıya sebep olmasından ve daha az nüks açısından daha düşük olduğu görüldü. Bu nedenle, sabitlemeli uygulananın daha avantajlı olduğu öne sürüldü.

Anahtar Kelimeler: İnguinal herni, laparoskopik, meş, sabitleme, kronik ağrı

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