

Comparing laparoscopic totally extraperitoneal inguinal hernia repair with and without mesh fixation



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Remzi Akturk*, Serdar Serinsöz**

*Department of Surgery, Istanbul Gelisim University, Istanbul, Turkey

**Department of Medical Imaging, Beykent University, Istanbul, Turkey

Comparing laparoscopic totally extraperitoneal inguinal hernia repair with and without mesh fixation

AIM: To compare totally extraperitoneal (TEP) repair in uncomplicated primary inguinal hernia patients with and without mesh fixation using tack in terms of peri- and post-operative complications, recurrence, return to work, and hospital stay.

MATERIAL AND METHODS: We retrospectively analyzed the medical records of patients who underwent TEP repair of uncomplicated primary inguinal hernia (American Society of Anesthesiologists score I/III) at our institute from January 2008 to December 2017.

RESULTS: In total, 354 patients were included in this study. There was no statistical difference in the body mass index (BMI) and duration of operation between patients with and without fixation. The mean number of days to return to work was significantly ($p=0.000$) higher in patients with use mesh fixation ($9.06+1.749$) compared to patients without mesh fixation ($7.31+2.097$). There was no difference between the two groups in terms of post-operative complications, except for seroma of the inguinal region, subcutaneous emphysema, and post-operative pain ($p<0.05$). The mean number of days of hospital stay was significantly ($p=0.002$) higher in patients with mesh fixation ($1.11+0.329$) compared to patients without mesh fixation ($1.02+0.149$). Evaluation of peri- and post-operative complications in BMI groups showed that obese patients and other groups had no significant difference ($p>0.05$).

CONCLUSIONS: Non-mesh fixation laparoscopic TEP repair is safe and feasible for primary and relapsed inguinal hernias. Patients experienced less chronic pain, shorter hospital stay, and shorter time to return to work. Furthermore, it might be safe in obese patients but requires additional study to confirm.

KEY WORDS: Hernia, Inguinal hernia, Laparoscopy, Mesh, Surgery

Introduction

Standard guidelines provide guidance on operative methods to reduce peri- and post-operative complications and recurrence rates in groin hernia repair and to increase patient satisfaction¹. Laparoscopic repairs such as totally extraperitoneal (TEP) repair, intraperitoneal Onlay mesh (IPOM) repair, and transabdominal preperitoneal (TAPP) repair are minimally invasive and effective².

In 1990, Ger et al were the first to report laparoscopic inguinal hernia repair. Recently, it has emerged as an alternate method to open hernia repair³. The Advantages of TEP include less post-operative pain, low recurrence rate, and early return to work, whereas disadvantages include a long learning curve, narrow operation area, and unfamiliar anatomical structure. The European Hernia Society (EHS) guidelines recommend TEP as the preferred laparoscopic approach for inguinal hernia repair⁶. Although laparoscopic inguinal hernia repair is a well-known and widely-used method, mesh fixation with staples can cause chronic inguinal pain⁷⁻⁹. The staples or tacks are commonly applied to fix the mesh to the groin. Several surgeons believe that mesh fixation is essential for repair to reduce the risk of mesh folding or migration leading to hernia recurrence¹⁰. Although there is evidence showing that recurrence occurs due to the use of smaller mesh that provides insufficient coverage of potential hernia defect or offhernia dissection area^{11,12}.

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Correspondence to: Remzi Akturk, Department of Surgery, Istanbul Gelisim University, Istanbul, Turkey, (e-mail: dremzi@gmail.com)

Moreover, some studies have also demonstrated that limiting the number of tacks or no tacks at all does not lead to recurrence^{11,12}.

Attempts have been made to avoid the use of tacks during laparoscopic surgeries using either no fixation^{10,13,14}, self-fixating mesh^{7,8,15-18}, or fibrin glue^{8,19-23}. Although peritoneal closure by stapling improves the operating time, it may result in accidental damage to the arteries and nerves of the abdominal wall. The stapler use for peritoneal closure is not essential. Few studies advocate using fibrin glue to fix the mesh which reduces chronic pain and bleeding²⁴.

The current study compared TEP repair in uncomplicated primary inguinal hernia patients with and without fixation in terms of peri- and post-operative complications, recurrence, return to work, and hospital stay. The primary objective of this retrospective analysis was to evaluate the clinical outcomes of TEP inguinal hernia repair with mesh fixation using tacks and without mesh fixation. The secondary objective was to evaluate the recurrence rate and safety of the TEP repair in obese patients.

Material and Methods

This retrospective study analyzed the medical records of 354 adult patients who underwent laparoscopic TEP repair at our institution for uncomplicated inguinal hernia (American Society of Anesthesiologists, ASA score I/II) from January 2008 to December 2017. Patients with significant comorbidities, previous surgery to the inguinoscrotal region, obstructed/strangulated inguinal hernia, ASA score III/IV, severe benign prostatic hyperplasia, acute incarcerated or strangulated hernia, cirrhotic ascites, skin infection on the lower abdomen, or below 18 years of age were excluded. The study was approved by S.B.Ü. İstanbul Education and Research Hospital Clinical Research Ethics Committee (Approval no: 2162). In bilateral inguinal hernias, the more symptomatic side was first repaired. A 30-degree angle laparoscope from the 10 mm port was used. One 5-mm port was placed in between the umbilicus and the pubic bone, and another 5-mm port was placed at the mid-clavicular line lateral of the umbilical port. A light-weight [50 g/m²], non-absorbable [1 mm pore size], stable [16 N/cm], and elastic polypropylene mesh of size 12 cm × 15 cm was used. Intraoperative details, operation time, and complications were recorded.

The operation time was time from making the skin incision to closing it. The conversion was defined as switching to open or other laparoscopic approaches. Following data were collected from the electronic medical records of the patients

- Preoperative characteristics: age, body mass index (BMI), gender, side of hernia, hernia type, ASA score.
- Perioperative variables: operation time, number of tacks.

- Perioperative complications: conversion, bleeding, bowel or bladder damage, other (anesthesia) complications.
- Post-operative outcomes: hospital stay, return to work.
- Post-operative complications: edema of the testis, reoperation, orchitis, chronic pain (continuous pain for 3 months), seroma, ischemia of the testis, recurrence, port side hernia. Post-operative complications were detected and recorded with the help of the radiology unit of our hospital (Fig. 1).

Follow-up

The patients were followed up at 7, 42, 90, 180, and 365 days. Any seroma formation with no improvement for 4 weeks was aspirated with ultrasound guidance. All patients were instructed to walk, drive, continue their work, and avoid heavy activities postoperatively.

The recurrence rate was assessed at 12 months.

This study was a retrospective hence formal consent was not required.

Surgical Technique

Extraperitoneal access was made through a 1-cm incision in the infraumbilical area under general anesthesia. The three standard ports (one 10 mm and two 5 mm ports) were set up. Initially, with 30-degree optics, the work area and a hernia sac dissection were completed by blunt and sharp dissection without using balloons or any other dissection tool. After hemostasis was controlled, the prolene mesh⁶ was spread on the inguinal area and fixed to the pubis with tacks with Covidien protack auto suture fixation (Figs. 2, 3). The prolene mesh was conventionally cut to properly fit the inguinal region. And finally, skin closure was made with a 3/0 vicryl suture.

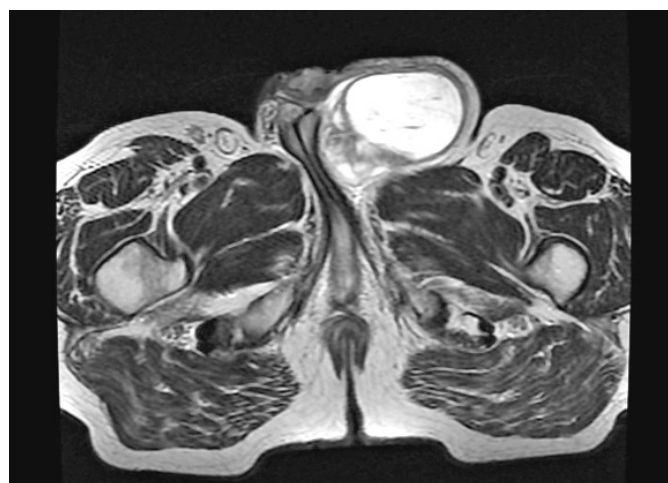


Fig. 1: MRI imaging of seroma of the inguinal area. MRI, magnetic resonance imaging.

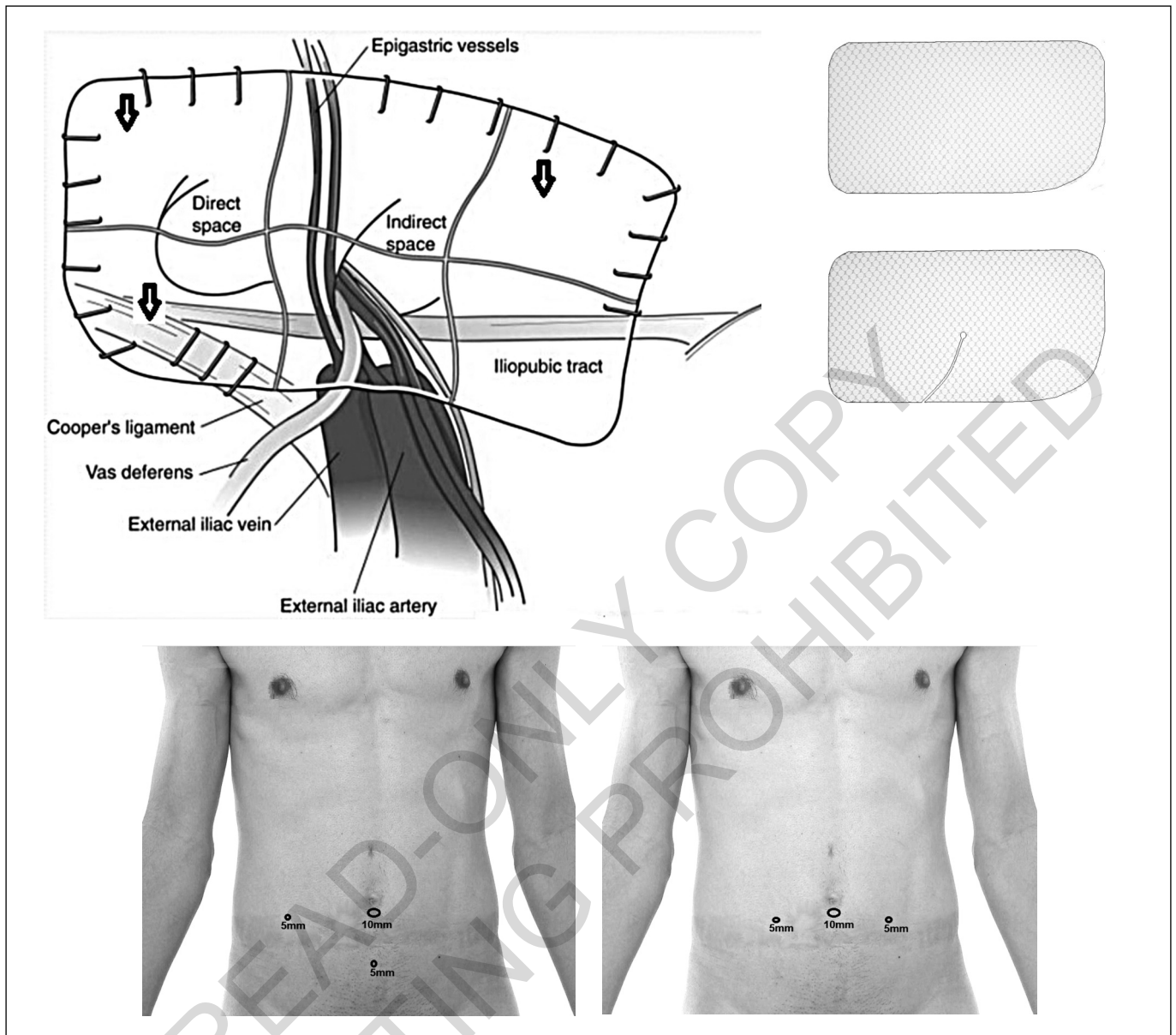


Fig. 2: Laparoscopic total extra-peritoneal repair using mesh fixation with tack. The vertical arrows showing the site of tacks insertion.

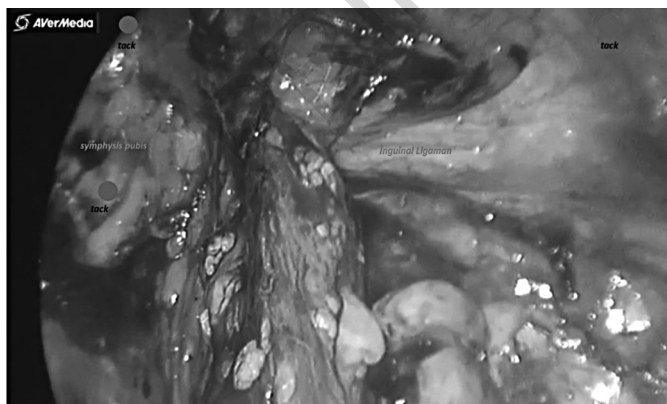


Fig. 3: Laparoscopic total extra-peritoneal repair inguinal region operation view. Purple spots indicating the tacks replacement.

Statistical Analysis

All data analyses were performed via the SPSS software (version 17). Non-parametric tests were used to analyze the data that were not normally distributed. Descriptive statistics such as mean, median, standard deviation, and range were used for analyzing continuous variables. The chi-square test was utilized for comparing the differences in medians between the groups. A frequency table was designed to determine the number of patients in the respective categories. Chi-square/Fisher's exact test was used, as applicable. Post-operative pain trends, within-subject variation were compared using repeated measures test. A p-value of <0.05 was considered to be statistically significant.

Results

We examined records of 360 patients for physical fitness before inclusion in the study. Six patients did not meet the inclusion criteria, hence excluded from the study. The study included a total of 354 patients with an uncomplicated primary inguinal hernia who underwent TEP repair. The included patients were divided into two groups: patients with TEP repair using mesh without fixation (Group I; n=178) and patients with TEP repair with mesh fixation with tacker (Group II; n=176).

Mean age, the number of days to return to work, hospital stay, operation time, and BMI was compared between the patients with and without mesh fixation (Table I). Mean age was significantly ($p=0.000$) higher among patients with mesh fixation (53.61 ± 13.802) as compared to those without mesh fixation (46.70 ± 13.782).

Also, the mean number of days to return to work was significantly ($p=0.000$) higher among patients with mesh fixation (9.06 ± 1.749) as compared to patients without mesh fixation (7.31 ± 2.097). The mean number of days of hospital stay was significantly ($p=0.002$) greater among

patients with mesh fixation (1.11 ± 0.329) than among patients without mesh fixation (1.02 ± 0.149).

There was no significant difference observed in BMI and duration of operation between the two groups. The mean number of days to return to work was significantly ($p=0.000$) higher among patients with mesh fixation (9.06 ± 1.749) as compared to patients without mesh fixation (7.31 ± 2.097).

Distribution of tack use across gender, side of operation (left and bilateral), hernia type (direct and indirect), and ASA score (I and II) was compared between the two groups (Table II). There was no significant difference observed in gender and side of hernia distribution ($p>0.05$). However, hernia type and ASA scores were significantly associated with the tack use ($p<0.05$).

Peri-operative complications (bleeding time, bladder damage, and bowel damage) distribution was compared between the groups (Table III). There was no significant difference observed between the two groups ($p>0.05$). Similarly, there was no significant difference in the distribution of post-operative complications that included edema of testis, reoperation, orchitis, chronic pain, osteitis pubic, testis ischemia, and recurrence rate

TABLE I - Age, BMI, operation time, return to work, and hospital stay distribution according to the use of tack

Use of tacks	Age (Mean \pm SD)	BMI (Mean \pm SD)	Operation time (DK) (Mean \pm SD)	Return to work (day) (Mean \pm SD)	Hospital stay (day) (Mean \pm SD)
Absent (N = 178)	46.70 \pm 13.782	27.54 \pm 2.813	61.94 \pm 13.962	7.31 \pm 2.097	1.02 \pm 0.149
Present (N = 176)	53.61 \pm 13.802	27.87 \pm 2.906	64.4 \pm 15.156	9.06 \pm 1.749	1.11 \pm 0.329
p-value	0.000*	0.338	0.055	0.000*	0.002*
Total (N = 354)	50.14 \pm 14.2	27.71 \pm 2.86	63.16 \pm 14.6	8.18 \pm 2.118	1.06 \pm 0.258

Test applied: Mann Whitney test, *indicates statistically significant difference, SD= Standard deviation

TABLE II - Gender, side of operation, hernia type, and ASA score distribution according to the use of tack

Use of tack	Gender		Side of hernia			Hernia type		ASA score	
	Male N (%)	Female N (%)	Right N (%)	Left N (%)	Bilateral N (%)	Indirect N (%)	Direct N (%)	IN (%)	IIN (%)
Absent	167 (93.8%)	11 (6.2%)	84 (47.2%)	65 (36.5%)	29 (16.3%)	129 (72.5%)	49 (27.5%)	106 (59.6%)	72 (40.4%)
Present	164 (93.2%)	12 (6.8%)	69 (39.2%)	72 (40.9%)	35 (19.9%)	70 (39.8%)	106 (60.2%)	61 (34.7%)	115 (65.3%)
Total	331 (93.5%)	23 (6.5%)	153 (43.2%)	137 (38.7%)	64 (18.1%)	199 (56.2%)	155 (43.8%)	167 (47.2%)	187 (52.8%)
p-Value	0.833	0.304	0.000*	0.000*					

Test applied: Chi square test, *indicates statistically significant difference

TABLE III - Perioperative complication distribution according to the use of tack

Use of tack	BleedingN (%)	Bowel damageN (%)	Bladder damageN (%)	Other (anesthesia)N (%)
Absent	2 (1.1%)	0 (0.0%)	0 (0.0%)	1 (0.6%)
Present	2 (1.1%)	1 (0.6%)	1 (0.6%)	2 (1.1%)
Total	4 (1.1%)	1 (0.3%)	1 (0.3%)	3 (0.8%)
p-Value	1.000	0.497	0.497	0.622

Test applied: Chi square test

TABLE IV - Postoperative complication distribution according to the use of tack

Use of tack	Edema of testis N(%)	Reoperation N(%)	Orchitis N(%)	Chronic pain, Osteitis pubic N(%)	Seroma of inguinal area N(%)	Subcutaneous emphysema N(%)	Post-operative pain N(%)	Testis ischemia N(%)	Recurrence N(%)
Absent	13 (7.3%)	2 (1.1%)	5 (2.8%)	1 (0.6%)	7 (3.9%)	14 (7.9%)	0 (0.0%)	0 (0.0%)	2 (1.1%)
Present	17 (9.7%)	7 (4.0%)	1 (0.6%)	6 (3.4%)	0 (0.0%)	2 (1.1%)	8 (4.5%)	2 (1.1%)	5 (2.8%)
Total	30 (8.5%)	9 (2.5%)	6 (1.7%)	7 (2.0%)	7 (2.0%)	16 (4.5%)	8 (2.3%)	2 (0.6%)	7 (2.0%)
p-value	0.426	0.088	0.102	0.054	0.008*	0.002*	0.004*	0.154	0.246

Test applied: Chi square test, *indicates statistically significant difference

TABLE V - Perioperative complication distribution according to the BMI group

BMI Group	Bleeding N(%)	Bowel Damage N(%)	Bladder Damage N(%)	Conversion N(%)	Tack use N(%)	Other (Anesthesia) N(%)
BMI<30	3 (1.1%)	1 (0.4%)	0 (0.0%)	5 (1.9%)	133 (49.3%)	2 (0.7%)
BMI=>30	1 (1.2%)	0 (0.0%)	1 (1.2%)	1 (1.2%)	43 (51.2%)	1 (1.2%)
Total	4 (1.1%)	1 (0.3%)	1 (0.3%)	6 (1.7%)	176 (49.7%)	3 (0.8%)
p-value	0.952	0.576	0.073	0.682	0.757	0.695

Test applied: Chi square test

between the two groups. However, other post-operative complications, including seroma of inguinal area (p=0.008) and subcutaneous emphysema (p=0.002) were significantly higher in patients without mesh fixation compared to with mesh fixation. In contrast, post-operative pain (p=0.004) was significantly higher in the patients with mesh fixation compared to the patients without mesh fixation (Table IV).

The peri-operative and post-operative complications were also compared between patients with BMI ≥30 and patients with BMI <30 to analyze if obesity has any role in the complications. It was observed that peri- and post operative complications did not vary significantly according to BMI (p>0.05; Tables V, VI).

Discussion

This retrospective study comparing laparoscopic TEP repair with mesh fixation using tack and without mesh fixation in 354 patients showed that laparoscopic TEP repair without mesh fixation is safe and feasible for primary and relapsed inguinal hernias.

In laparoscopic surgery for inguinal hernia repair, the mesh is fixed in the place using sutures, metal tacks or staples, and various forms of glue to prevent its migration or folding. Alternative methods to fix the mesh are fibrin adhesives, acrylate adhesives, and absorbable adhesives, or absorbable tacks for mesh fixation^{13,24,25}. Over time mesh fixation has been associated with post operative chronic pain leading to discussion whether mesh fixation is necessary^{13,25,26}.

A few studies suggest limiting the use of tack fixation in laparoscopic inguinal hernia repair to specific cases

such as large or direct bilateral hernias^{13,25} whereas other studies completely disprove the need for mesh fixation²⁶⁻²⁸.

Khajanchee et al and Taylor et al, in their study observations, reported a high recurrence in the mesh fixation group (5.9% and 0.2%, respectively) than in the non-fixation group (1.9% and 0%). Conversely, Garg et al and Moreno-Egea et al observed recurrence in non-fixation (0.2% and 2.7%, respectively). In this study, the recurrence rate was higher in the fixation group compare to the non-fixation group, but the difference was not statistically significant^{25, 28}.

Guidelines of the International Endohernia Society (IEHS) update in 2015 strongly recommended consideration of non-fixation in all types of inguinal hernias TEP repair except large direct defects (MIII, EHS classification)²⁹. The European Hernia Society's guidelines, 2014 stated that non-absorbable fixation devices are mostly unnecessary in TEP repairs using heavyweight mesh and should be avoided, except in specific cases such as large direct hernias³⁰. A meta-analysis reported no difference in chronic pain between non-fixations versus mechanical fixation TEP repair²⁴. Based on the newer evidence, the guidelines have excluded the former recommendation to consider fibrin glue to minimize chronic pain risk²⁹. Randomized controlled trials to compare self-fixating meshes to fibrin glue have not observed any significant difference in post operative pain at 3 months³¹. The guidelines also recommend the use of a mesh of at least 10x15 cm and size 12x17 cm in larger hernias²⁹. In this study, we used a prolene mesh.

We observed a recurrence rate of 1.1% in patients without mesh fixation compared to 2.8% in patients with mesh fixation. The difference is not statistically significant.

cant. The overall recurrence rate in patients without mesh fixation is 0.5% compared to 0.7% in a patient with mesh fixation²⁹.

The recurrence rate observed in our study is slightly higher than the reported overall rate.

Studies have reported intraoperative bowel damage in 0 to 0.3% of patients in TEP repair^{10,32,33}. Our observations are consistent with these observations as bowel injury was not observed in the non-fixation group compared to 1 patient (0.6%) in the fixation group.

In the Mesh fixation group, the observed rate of seroma/hematoma formation has been significantly higher compared to the non-fixation group. This may be due to irritation caused by the metallic stabilizers leading to increased seroma formation and segmentation of the surgical cavity, which delays absorption of physiological accumulation⁷. In contrast to these observations, we found a significantly higher prevalence of seroma in patients without mesh fixation.

In patients with inguinal hernia undergoing laparoscopic TEP repair, chronic pain incidence of 7.8% -22% has been reported in many studies^{7,16,34}. Taylor et al, in their randomized clinical trial, reported that chronic pain was associated with the number of fixation tacks used for mesh fixation¹³. Whereas Koch et al. observed that though post-operative use of narcotic analgesics is significantly lower in patients with mesh fixation, it did not reduce post operative pain³⁵. When the post-operative complications were examined in our study, inguinal region seroma, subcutaneous emphysema, and post-operative pain were found to be significantly different between the two groups. Chronic pain was comparatively higher in the mesh fixation group than in the group without mesh fixation. Several studies report less post-operative pain in patients who do not have fixation compared to those with fixation^{7,27,29}.

Time taken to return to work or normal activities is a measure of the success of the surgery. Garg et al reported a mean time to return to work of 9.9 ± 3.3 days in the mesh fixation group and 7.6 ± 1.3 days for the non-fixation group²⁸. Whereas a meta-analysis reported the mean time to return to work to be 3.2 days in mesh fixation groups compared to 2.9 days in non-fixation groups¹⁵. Consistent with these results, our study also demonstrated that the time taken to return to work was higher (9.06 ± 1.749) in the mesh fixation group compared to the non-fixation group (7.31 ± 2.097).

Tam et al and Sajid et al in their meta-analyses demonstrated no need for mesh fixation in TEP repair and emphasized the requirement for a large, randomized study to confirm these results^{13,24}. Various factors such as mesh fixation, nature of the hernia, hernia area the complexity of the hernia affect operation time. Some researchers have also demonstrated that operation time is also affected by the BMI as it adversely affects the quality of dissection and visualization of defects, resulting in longer operating hours^{7,34}. We have not made

any such comparison, and it can be an important consideration for future study. Another limitation of our study is being a retrospective study due to which factor like patient satisfaction assessment was not performed.

Conclusions

This retrospective analysis compared the peri -and post-operative characteristics of 354 patients with inguinal hernia undergoing TEP repair with or without mesh fixation using tack. We report less chronic pain, short operative time, and short hospital stay in patients without mesh fixation. Mesh fixation had no effect on the recurrence rate but resulted in osteitis pubis that led to severe chronic pain in five patients who did not respond to any medical treatment. Reoperations were required to remove the tacks in these patients. In conclusion, non-mesh fixation laparoscopic TEP repair is safe and feasible for primary and recurrent inguinal hernias. As the IEHS guideline recommends, mesh fixation in TEP repair of ASA scores I/II inguinal hernias can be avoided. A large prospective clinical trial is recommended to include assessment of patient satisfaction, factors affecting operation time, and safety in obese patients, along with recurrence rate and clinical outcomes of TEP of inguinal hernia with and without mesh fixation.

Riassunto

Lo scopo è quello di confrontare la riparazione totalmente extraperitoneale (TEP) in pazienti con ernia inguinale primaria non complicata con e senza fissazione della rete mediante tack in termini di complicanze peri- e post-operatorie, recidiva, ritorno al lavoro e degenza ospedaliera.

MATERIALI E METODI: Abbiamo analizzato retrospettivamente le cartelle cliniche di 354 pazienti sottoposti a riparazione TEP di ernia inguinale primaria non complicata (punteggio I/II dell'American Society of Anesthesiologists) presso il nostro istituto da gennaio 2008 a dicembre 2017.

RISULTATI: Non c'era alcuna differenza statistica nell'indice di massa corporea (BMI) e nella durata dell'operazione tra i pazienti con e senza fissazione. Il numero medio di giorni per tornare al lavoro era significativamente ($p=0.000$) più alto nei pazienti con fissazione con rete ($9,06 \pm 1,749$) rispetto ai pazienti senza fissazione con rete ($7,31 \pm 2,097$). Non c'era differenza tra i due gruppi in termini di complicanze post-operatorie, ad eccezione del sieroma della regione inguinale, dell'emfisema sottocutaneo e del dolore post-operatorio ($p < 0,05$) in caso di fissazione. Il numero medio di giorni di degenza ospedaliera era significativamente ($p=0,002$) più alto nei pazienti con fissazione della rete ($1,11 + 0,329$) rispetto ai pazienti senza fissazione della rete ($1,02 + 0,149$).

La valutazione delle complicanze peri e postoperatorie nei gruppi BMI ha mostrato che i pazienti obesi e altri gruppi non avevano differenze significative ($p > 0,05$).

CONCLUSIONI: La riparazione laparoscopica TEP senza fissazione della rete è sicura e fattibile sia per le ernie inguinali primitive che recidive. I pazienti hanno sperimentato meno dolore cronico, degenza ospedaliera più breve e tempi più brevi per tornare al lavoro. Inoltre, potrebbe essere sicuro nei pazienti obesi, ma richiede ulteriori studi per confermare.

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