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Original Article

Comparison of Mesh Fixation and Non-fixation in Totally Extraperitoneal Hernia Repair: A Randomized Controlled Trial

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Abstract

Objective: Many studies have shown that non-fixation of mesh in laparoscopic totally extraperitoneal (TEP) inguinal hernia repair is safe and has no disadvantage compared to mesh fixation; however, most studies contain limited information on hernia-defect size. The purpose of this study was to compare the clinical outcome of non-fixation and fixation of mesh in consecutive elective laparoscopic TEP inguinal hernia repair in any type and size of hernia defect classified by the European Hernia Society (EHS) groin hernia classification to be a part of the level 1 evidence about technique of fixation in TEP.

Patients and Methods: One hundred and ten hernia repairs in 101 patients were enrolled in the trial between July 2022 and August 2023. The patients were randomized to the mesh fixation group (n = 55) or the non-fixation group (n = 55). The primary outcomes were chronic groin pain and recurrence at 6 months. The secondary outcomes were operative time, conversion rates, pain scores, analgesic requirement, time to regular activity, complications, and length of stay. A person blinded to the method of fixation performed statistical analysis.

Results: There were no significant differences between the two groups in baseline demographic characteristics, including age, BMI, sex, ASA classification, EHS hernia classification, and incidence of recurrent defect. More than 90% of hernia defects were larger than 1.5 cm, and more than 25% of defects were > 3 cm. They were statistically similar in both groups in terms of chronic groin pain, operative time, conversion rates, pain scores, analgesic requirement, time to regular activity, length of stay, and complications. Neither group had a recurrence at a minimum follow-up of 6 months.

Conclusions: There was no statistical significance in chronic groin pain and recurrence between fixation and non-fixation groups. The non-fixation approach should be adopted routinely and safely in laparoscopic TEP hernia repair. Even the tack fixation technique applied in this study was not associated with the risk of significant pain level and chronic groin pain; however, it is associated with high operative cost, so it should be used only in very selected situations in TEP.

Keywords: Laparoscopic inguinal hernia repair, TEP, The EHS groin hernia classification, Mesh fixation, Non-fixation

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INTRODUCTION

Laparoscopic total extraperitoneal (TEP) inguinal hernia repair has become one of the gold standards for inguinal hernia repair.¹⁻³ It is associated with less postoperative pain, faster recovery, and earlier return to work.⁴ In the past, fixation of the mesh was a logical step to prevent mesh migration and folding. While mesh fixation was an important step to reduce hernia recurrence, there are studies indicating that fixation can lead to many complications, especially postoperative chronic pain.⁵ In 1999, Ferzil et al. demonstrated the safety of non-fixation of mesh during laparoscopic surgery in TEP. Since then, numerous studies have shown the reliability of non-fixation of mesh in TEP.⁶ According to systematic review and meta-analysis, 25 trials with 3,668 patients (4,038 hernias) were included; mesh non-fixation improves the return to daily life without increasing the risk of hernia recurrence or chronic pain.⁷ However, most of the studies contain only limited information on hernia-defect size,⁸ and a majority of hernia defects were small in some studies.⁹

This randomized controlled study was conducted to compare the clinical outcome of non-fixation and mesh

fixation in consecutive elective laparoscopic TEP inguinal hernia repair in any type and size of the hernia defect, including large direct and recurrence defects. To study the feasibility of non-fixation in larger defects of inguinal hernias, the primary endpoints were chronic groin pain and recurrence at 6 months.

PATIENTS AND METHODS

A randomized controlled trial was carried out between July 2022 and August 2023 by a single surgeon who had already performed > 150 laparoscopic hernia repairs. Approval from the hospital ethics committee was obtained to carry out the study, and the patients' written consent was obtained. Patients who came to OPD with inguinal hernia were evaluated and excluded if under 18 years, unfit for general anesthesia, irreducible hernia, low midline surgical scar, cognitive impairment, and contraindication for NSAIDs used. The flow of patients is shown in Figure 1. The primary endpoints were chronic groin pain and recurrence at 6 months. The secondary endpoints were operative time, conversion rates, pain scores, analgesic requirement, time to regular activity, complications, and length of stay.

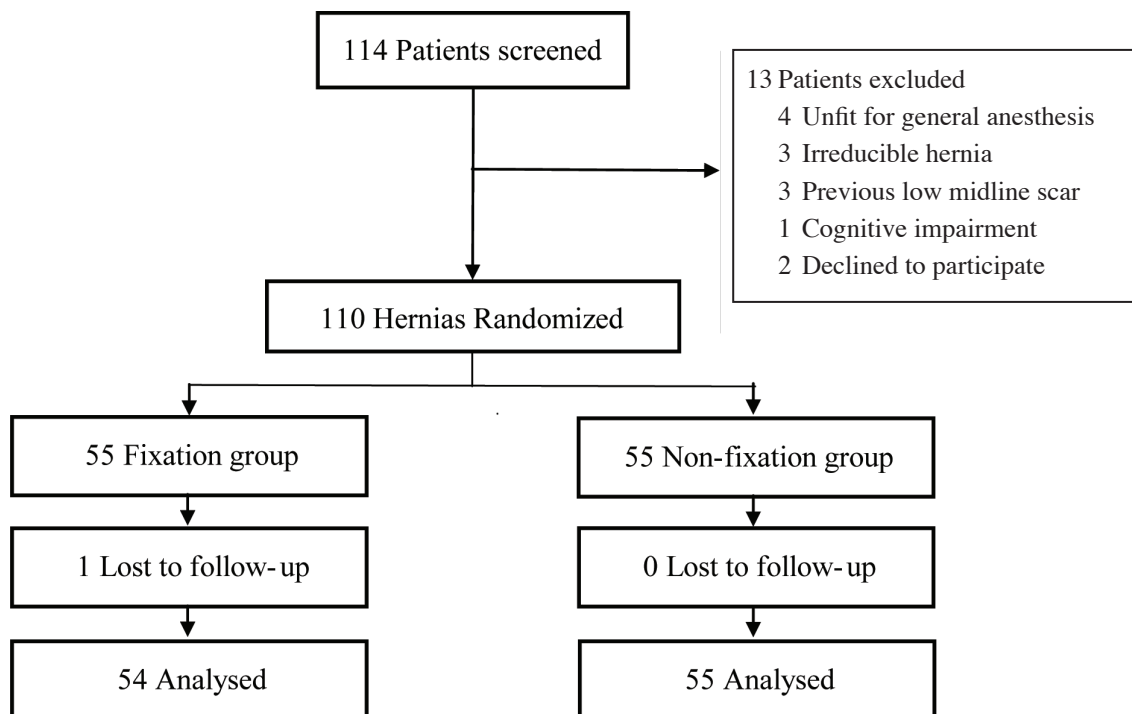


Figure 1 Flow diagram of patients

In the present study, groin hernias were classified by the EHS groin hernia classification and summarized by making a distinction between the anatomic location and the size of the hernia orifice defect in cm; in the case of combined hernia, we categorized the size of hernia according to the largest defect to not oversized the defect. Thus, a direct hernia of 2.5 cm combined with an indirect hernia of 2 cm is depicted as a mixed hernia with a size of 1.5-3 cm. We categorized recurrent hernia as a specific separated group to be easy to interpret and compare between both groups.

All patients were asked to void urine before the procedure in case of inguinoscrotal hernia and recurrence hernia foley catheter was inserted. An infra-umbilical incision was made, and ipsilateral retrorectus space was entered and created inferiorly to the preperitoneal space with round-shaped balloon expansion. The optical port was placed ipsilateral to the larger hernia size for bilateral hernia. Two 5-mm ports were inserted in the midline: the first was placed 4 cm above the pubic symphysis, and another one in between the two ports. Reduction of the hernial sac and development of a preperitoneal pocket following the critical view of the MPO concept.¹⁰ The type of hernia was recorded according to the EHS groin hernia classification.¹¹ The orifice size of the hernia defect was estimated using the 5 mm closed diameter and 20 mm open diameter of the laparoscopic graspers as a guide. All of the M2 or M3 direct defects were closed by using absorbable 3-0 barbed suture (V-Loc 180 3-0 15 cm, Covidien), and pseudosac was pulled and incorporated into the closure (TEP plus technique) before the introduction of the mesh to reduce recurrence and seroma formation.^{12,13} In case of a large indirect hernia that is difficult to complete sac reduction, we transected the sac and closed the proximal end with an end loop to reduce surgical trauma and operation time.¹⁴ After adequate dissection of space then, mesh (uncut 15 × 10 cm Monofilament Macroporous Polyester mesh, Versatex) was introduced to cover the MPO with an overlap of at least 3-4 cm. The mesh fixation technique was randomized into either fixation or non-fixation groups as determined by the intraoperative opening of the envelope in order. In the fixation group, the mesh was fixed by 3 permanent tacks (Autosuture Protack, Covidien), one at Cooper's ligament, and another two tacks at area medial and lateral to epigastric vessel 2 cm above the iliopubic tract.¹⁵ In the non-fixation group, no fixation of the mesh was done. In bilateral hernia,

each side was considered separately in bilateral repairs, giving rise to three possibilities: fixation on both sides, non-fixation on both sides and fixation on one side only. In the last possibility, after the completed dissection of all zones of the inguinal area on both sides, mesh insertion and fixation were performed first on the side randomized to be the fixation group so that any mesh overlap in the midline would not create inadvertent fixation of the other side. No drain was used in all of the patients in this study. The mesh fixation technique was recorded only in the operative note.

Postoperatively, the patient was allowed to take a soft diet after the recovery from general anesthesia. Ibuprofen 400 mg q 8 hr and Acetaminophen 500 mg q 6 hr were used as analgesics for all patients, in case of moderate to severe pain morphine 3 mg was provided on demand in every 6 hr. The amount of morphine consumed and pain score based on the numeric rating scale (NRS) were recorded by nurses on the 12 hrs, 24hrs post-operative. Home medication for all patients was Ibuprofen 400 mg q 8 hr 10 tabs and Acetaminophen 500 mg prn for pain q 6 hr 10 tabs. Patients were called for follow-up at 2 days and 1 week. All patients were seen as part of routine postoperative care two weeks, 3 months, and 6 months after surgery to evaluate any complications, pain score, and recurrence. Chronic groin pain was defined as a pain score > 3 in the groin region on the operative side, persisting beyond 3 months.

Statistical analysis was performed using SPSS software version 25 by a person blinded to the method of mesh fixation. Repeated measure ANOVA models were used to assess change in NRS over time and differences within each group. Comparisons of quantitative data between groups were analyzed using an independent *t*-test, and the Chi-square or Fisher exact probability test was used for qualitative data. *P* < 0.05 was considered statistically significant.

RESULTS

One hundred and ten hernia repairs in 101 patients were enrolled in the trial between July 2022 and August 2023. There were 9 patients who presented with a bilateral hernia, and 92 patients had a unilateral hernia. The mean operative time in unilateral hernia was 59 minutes, and 81 minutes in bilateral hernia. There were no significant differences between the two groups in baseline demographic characteristics, including age, BMI, sex, ASA

classification, EHS hernia classification, and incidence of recurrent defect (Table 1). The mean follow-up period of the present study was 12.4 ± 2.74 months. Ninety-nine

percent of patients returned for clinical follow-up at a minimum of six months.

Table 1 Patient characteristics

Patient characteristics	Fixation group (n = 55)	Non-fixation group (n = 55)	p-value
Age (mean $\pm$ SD)	64.1 (11.9)	63.6 (13.8)	0.859
BMI (mean $\pm$ SD)	22.7 (3.0)	22.9 (3.3)	0.739
Sex (male %)	94.5%	100%	0.079
ASA classification n (%)			
ASA 1	3 (5.5)	4 (7.3)	0.646
ASA 2	37 (67.3)	40 (72.7)	
ASA 3	15 (27.2)	11 (20.0)	
EHS hernia classification n (%); Defect size			
< 1.5 cm	5 (9.1)	5 (9.1)	0.976
1.5-3 cm	35 (63.6)	36 (65.5)	
> 3 cm	15 (27.3)	14 (25.4)	
Hernia type			
Indirect (L)	42 (76.4)	41 (74.5)	0.455
Direct (M)	5 (9.1)	5 (9.1)	
Femoral (F)	2 (3.6)	0	
Mixed	6 (10.9)	9 (16.4)	
Recurrent hernia	5 (9.1)	3 (5.5)	0.463
Side of hernia; Right : Left (%)	49.1 : 50.9	60 : 40	0.251
Follow-up attendance	54 (98.2)	55 (100)	0.315

SD: standard deviation

Direct defect closure was performed in 10 (9.1%) direct hernia sizes M2 and M3 (including 7 cases of M2 hernia, 1 case of M2L1 hernia, 1 case of M3 hernia, and one case of M3L1 hernia). There were 23.6% indirect sac transactions in both groups, and almost all were performed in large indirect hernia sacs. The mean operative time was 57.6 min in the fixation group and 54.7 min in the non-fixation group. There were 2 conversions to the TAPP technique in the fixation group due to the difficulty of completing the operation by extraperitoneal approach in sliding hernia and large scrotal hernia. Peritoneal tears requiring operative closure were 7.3% in the fixation group and 21.8% in the non-fixation group; the *p*-value was 0.031, and techniques used for the closure included

clipping, extracorporeal knot, and endoscopic suturing. They were similar in both groups in postoperative length of stay (*p* = 0.175), postoperative opioid use (*p* = 0.791), or time to regular activity (*p* = 0.299). There was no statistical significance in time taken to regular activity between both groups; more than 95% of cases can do light daily activity by themselves within 2-3 days postoperative.

The most common complication after TEP is seroma, which occurred in 20% of the fixation group and 14.5% of the non-fixation groups. Only 3.6% of seromas needed aspiration in the fixation group and 1.8% in the non-fixation group. Other complications were minor and resolved uneventfully (Table 2).

Table 2 Variables used to compare between groups

	Fixation group (n = 55)	Non-fixation group (n = 55)	p-value
Op time (mean ± SD) (min)	57.6 (19.4)	54.7 (19.5)	0.431
Conversion to TAPP, n (%)	2 (3.6)	0	0.154
Peritoneal condition, n (%)			
No tear	29 (52.7)	19 (34.6)	0.035
Tear (no need to repair)	9 (16.4)	11 (20)	0.621
Closure of peritoneal tear	4 (7.3)	12 (21.8)	0.031
Transection of the hernia sac	13 (23.6)	13 (23.6)	1.000
Length of stay (mean ± SD) (day)	1.2 (0.4)	1.1 (0.3)	0.175
Post op Morphine use (mean ± SD) (mg)	1.5 (1.9)	1.4 (1.8)	0.791
Time taken to return to normal activities, n (%)			
2-3 days	51 (94.4)	54 (98.2)	0.299
4-5 days	3 (5.6)	1 (1.8)	
Complications, n (%)			
Urinary retention	3 (5.5)	1 (1.8)	0.308
Seroma	11 (20.0)	8 (14.5)	0.449
Seroma required aspiration	2 (3.6)	1 (1.8)	0.558
Testicular tenderness	0	1 (1.8)	0.315
Umbilical wound infection	0	1 (1.8)	0.315
Chronic groin pain	1 (1.9)	0	0.495
Recurrence	0	0	1.000

SD: standard deviation; TAPP: transabdominal preperitoneal approach

The ANOVA demonstrated that in each fixation technique, there was no statistical significance in pain level ($p = 0.480$) (Table 3). There were no statistically

significant differences in mean pain scores between the fixation and non-fixation groups at each follow-up time point (Figure 2).

Table 3 Statistical results of the repeated measure ANOVA for the pain levels of patients subjected to Fixation and Non-fixation techniques

Source	SS	df	MS	F-test	p-value	Effect size	Observe Power
Treatment	1.510	1	1.510	0.502	0.480	0.005	0.108
Error	322.157	107	3.011				

SS: Sum of the square; df: degree of freedom; MS: Mean Square

Chronic groin pain was equal in the fixation and non-fixation groups, 1.9% and 0 %, respectively ($p = 0.495$).

At 6 months, no recurrence of hernia was observed.

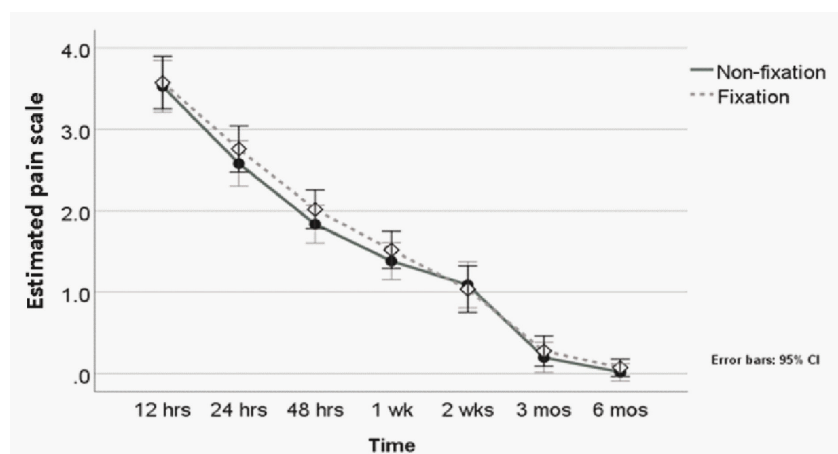


Figure 2 Pain level at each time point for fixation (diamond) and non-fixation (circle) groups

Pain level mean (± SD)	12 hrs	24 hrs	48 hrs	1 wks	2 wks	3 mos	6 mos
Fixation group	3.6 (1.3)	2.8 (1.1)	2.0 (0.9)	1.5 (0.8)	1.0 (1.1)	0.3 (0.7)	0.1 (0.5)
Non-fixation group	3.5 (1.1)	2.6 (0.9)	1.8 (0.9)	1.4 (0.8)	1.1 (1.1)	0.2 (0.6)	0 (0.1)

SD: standard deviation

DISCUSSION

Stabilization of the mesh, even in the absence of any fixation, was explained by two mechanisms. Early stabilization is achieved by the “sandwich effect,” the pressure between the peritoneal layer and the abdominal wall, which is enhanced by adequate dissection for adequate space for placing mesh. In the later period, the mesh is held in place by tissue incorporation into the mesh within 2–3 weeks and collagen deposition by 2 months.^{16,17} Any recurrence because of non-fixation of the mesh would be expected to be an early phenomenon,^{18,19} making the 6-month length of follow-up sufficient to evaluate recurrence for the purposes of the present study.

Even the systematic review and meta-analyses^{20–22} revealed no significant differences in the rates of recurrence or postoperative pain between permanent tack fixation and non-fixation in TEP, but most of the studies contain only limited information on hernia-defect size⁸, and a majority of hernia defects were small in some studies,⁹ given this the EHS classification was used, and the present study had included more than 90% of cases which defect size was larger than 1.5 cm and the size of defect > 3 cm more than 25% of cases and also included recurrent hernia to strengthen the level 1 evidence, especially for the larger size of the hernia.

The results of the present study have shown statistical similarities in both fixation techniques in terms

of chronic groin pain, recurrence rate, operation time, conversion rate, postoperative pain, postoperative opioid requirement, postoperative complications, length of hospital stay, and time to return to regular activity. Even numerous studies have reported a statistically significant increase in pain levels and chronic groin pain related to tack fixation,^{18,19} however, some of them showed significantly higher in the fixation group only for mild pain. The difference between the groups was not statistically significant for moderate and severe pain, which means the clinical significance is doubtful. In addition, the incidence of chronic pain increases proportionately with the number of tacks used, with statistically significant at the cutoff point of six tacks.⁹ The fixation technique in the present study used only 3 tacks in a safe area to avoid nerve injury (at Cooper’s ligament, area medial and lateral to epigastric vessel 2 cm above the iliopubic tract)¹⁵ that is the plausible explanation for why our result in the present study showed no significant difference in pain level and chronic groin pain between the two groups.

The main concerns for non-fixation are mesh migration and hernia recurrence. Mesh stabilization with non-fixation occurred intrinsically due to the mesh’s preperitoneal location in TEP; Choy et al. demonstrated this phenomenon’s effectiveness. They showed that an unfixed mesh could not be induced to move by on-table cycles of hip flexion (confirmed on inspection of the mesh

by re-laparoscopy of the preperitoneal space).²³ More than 5,300 TEP repairs with non-fixation techniques have now been reported. The mean recurrence rate in these series is less than 1% after two years, equal to the recurrence rate of standard repairs with mesh fixation.^{6,8,24-27} However, Many studies have demonstrated a higher recurrence rate associated with the presence of direct and large defects.²⁸ IEHS (International Endohernia Society) guideline 2018 suggested that in almost all cases of inguinal hernia, any type of mesh fixation in TEP repair is unnecessary, except in sizeable direct defect hernias (M3- EHS classification) mesh fixation is recommended. Due to the present study including M3 direct hernia in the study group, our protocol was set to close all direct defects larger than M1 to reduce the recurrence according to the systematic review and meta-analysis,^{12,29-30} which suggested that closure of the medial hernia defect in laparoscopic inguinal hernioplasty minimizes the risk of recurrence without an increase in postoperative pain or complications. The present study showed no statistically significant difference in recurrence rates at six months in both groups and no case of recurrence after TEP repair in this study. There were 10 (9.1%) cases of M2 or M3 direct defect, with 5 cases in each group, which are statistically similar ($p = 1.000$). Even though all 5 cases of direct defect closure in the non-fixation group had no recurrence after 6 months of follow-up, we cannot make any summary due to the study population being too small; further study trials are needed for further evaluation. However, instead of fixation techniques, the critical factors for successful long-term mesh stabilization are adequate preperitoneal dissection, exposing all the peritoneal weak points, and using adequately large pieces of mesh.

Based on this result, a non-fixation approach may be adopted routinely and safely in all elective laparoscopic TEP hernia repair; however, the TEP plus technique has to be performed in all direct defects larger than 1.5 cm.¹² On the contrary, tack Fixation of the mesh (by the techniques described earlier in the part of the surgical technique) even seems no more beneficial in most cases. Still, it can be performed in selected cases where the hernia defect is quite large, and there is a tendency of mesh migration due to there being no increase in pain level, chronic groin pain, and complications.

It was statistically significant in peritoneal tears requiring operative closure, with 7.3% in the fixation group and 21.8% in the non-fixation group, $p = 0.031$. We can't explain this result. However, some studies showed

that peritoneal injury has more frequently occurred in right-sided hernia,³¹ and 60% of cases in the non-fixation group had hernia on the right side compared to the fixation group, 49.1% on the right side. Other independent risk factors for peritoneal tear were indirect hernia type and previous hernia surgery³² which did not support our result due to no difference in these risks in both groups. The present study's overall incidence of peritoneal tear was 32.8% compared to 19.7 - 47% from the previous studies.³¹⁻³⁴ To manage peritoneal defects, we use 5 mm endoclip for minor defects, pre-tied suture loop ligation for medium defects, and intracorporeal suturing for large defects.

Even though there was no cost analysis in the current study, it is obvious that the titanium spiral tack applicator is costly, and RCT studies confirmed that there was a statistically higher total cost in the tack fixation group.^{6,8,35}

CONCLUSION

There was no statistical significance in chronic groin pain and recurrence between fixation and non-fixation groups. The non-fixation approach should be adopted routinely and safely in laparoscopic TEP hernia repair. Even the tack fixation technique applied in this study was not associated with the risk of significant pain level and chronic groin pain; however, it is associated with high operative cost, so it should be used only in very selected situations in TEP.

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