



# Non-fixation Versus Fixation of Mesh in Totally Extraperitoneal Repair of Inguinal Hernia: a Comparative Study

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## Abstract

Two major issues with laparoscopic inguinal hernia (IH) repair are recurrences and chronic groin pain (CGP). The procedure involves fixing the mesh with the tackers which is believed to increase the rate of CGP due to nerve injuries. Thus, non-fixation of mesh is being proposed but concerns remain regarding increased recurrences. We sought to look at our outcomes after we switched over to non-fixation of mesh in totally extraperitoneal repair (TEP). Retrospective review of prospectively maintained database of 171 repairs was done on 122 patients (fixation 59 and non-fixation 112) during a period of 4 years with an endeavor to complete a minimum of 1 year of clinical follow-up. The primary objective was to assess the recurrence rates and CGP and the secondary objective was to assess operative times, immediate post-op pain, incidence of urinary retention, duration of hospital stay, days taken to return to activity, and cost. The mean operative times for unilateral IH for the fixation and non-fixation groups were  $41.8 \pm 11.4$  and  $35.9 \pm 9.7$  min, respectively ( $p = 0.021$ ), whereas for bilateral were  $66.2 \pm 15.6$  and  $55.3 \pm 14.2$  min, respectively ( $p = 0.018$ ). The mean pain score was  $3.44 \pm 1.2$  versus  $3.01 \pm 1.0$ ; ( $p = 0.037$ ) in the two groups, respectively. At a mean follow-up of  $33.2 \pm 17.0$  and  $18.7 \pm 6.2$  months, the incidence of CGP was 02 (3.4%) and 3 (2.7%) ( $p = 1.000$ ) and recurrences were 02 (3.4%) in the two groups, respectively ( $p = 0.118$ ). Non-fixation of mesh in TEP does not lead to increased recurrence though it does not decrease the incidence of chronic groin pain. Collateral advantage would be decreased operative times, lesser post-operative pain, and decreased costs.

**Keywords** Inguinal hernia · Laparoscopic repair · Totally extraperitoneal repair · Non-fixation of mesh · Recurrence rates · Chronic groin pain

## Introduction

Laparoscopic inguinal hernia surgery (LIHS) is the recommended procedure for bilateral and recurrent inguinal hernias (IH) while it is one of the options dealing with a unilateral IH [1]. Laparoscopic approach to inguinal hernia surgery started in the 1980s. Since then, many techniques of laparoscopic inguinal hernia repair had been developed. Today, only two

techniques are commonly employed—totally extraperitoneal repair (TEP) and the transabdominal preperitoneal repair (TAPP) [2, 3]. Of these two, TEP has emerged as the favored technique [4].

The major issue with hernia surgery has been recurrence. However, now that low recurrence rates are being reported consistently, attention is being drawn to other issues like chronic groin pain (CGP) and quality of life (QOL) [5, 6]. The incidence of CGP groin following IH surgery has been reported between 0.03 and 31% [7, 8].

Improvising and refining surgical techniques is essential for the growth of surgery and to improve outcomes. CGP singularly affects the quality of life in patients undergoing IH surgery and remains a key area for surgeons to improve upon. CGP most often occurs due to nerve damage during LIHS which can be caused during dissection or fixation of mesh. Mesh fixation is usually done by laparoscopic tackers and multiple tacks were being used. Subsequently, in an attempt to reduce CGP, the number of tacks has now been

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reduce to two, one medially over the coopers ligament and another laterally at the level of anterior superior iliac spine [9]. Further, there have been attempts to completely avoid fixation of mesh. The concerns in avoiding mesh fixation are that in an attempt to reduce CGP, we may be increasing the chances of IH recurrence as non-fixation may lead to displacement of mesh. Three meta-analyses have now been published that have shown that non-fixation of mesh does not lead to increased recurrences [10–12].

Going with this body of evidence, we started non-fixation of mesh in TEP. We, in this study, review our experience with non-fixation of mesh and report its results.

## Methods

This is a retrospective review of a prospectively maintained database of all patients undergoing TEP for IH at our center from January 2012 to June 2015. In the initial part of this period, till June 2013, mesh fixation with laparoscopic tackers was routinely done. After this period, in all patients, the mesh was not fixed. All patients completed a minimum of 1-year follow-up. The follow-up data was updated till June 2016.

The aim of this study is to evaluate the outcomes of mesh fixation versus non-fixation in TEP at our center over this period with a primary objective to evaluate the recurrence rates and chronic groin pain and secondary objective to assess the operative times, immediate post-op pain, incidence of urinary retention, duration of hospital stay, days taken to return to activity, and cost.

### Inclusion Criteria

All adult patients with uncomplicated IH were offered TEP.

### Exclusion Criteria

Patients with a large lower midline scars, a complicated hernia or unfit for general anesthesia.

### Operative Procedure

Injection amoxicillin 1000 mg and clavulanic acid 200 mg was given intravenously as prophylaxis at the time of induction along with two additional post-operative doses. The procedure was done under general anesthesia. We did not employ urinary bladder catheterization.

### Technique of TEP Procedure

A 10-mm paraumbilical port was made on the side of the hernia. In bilateral hernias, the port was made on the side of

the larger sac. The rectus muscle was retracted laterally after incising the anterior rectus sheath, and a preperitoneal access was obtained to place a 10-mm trocar for a 10-mm 30° telescope. Pneumo-preperitoneum was created and blunt dissection with the telescope was used to create the preperitoneal space. Two 5-mm ports were placed in the midline, one just 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. Reduction of sac was attempted in all cases but in case of adhesions, sac was divided at the deep ring. Genitofemoral and lateral cutaneous nerves were identified. Fascia over these nerves was kept intact. Peritoneum was teased down, proximal to the point where vas deferens turns medially. The triangle of doom and Hasselbach's triangle were defined. After the dissection, a rolled 12 × 15 cm polypropylene mesh was introduced via the 10-mm port. The mesh was spread to cover the entire myopectineal area on the affected side. In bilateral hernia, both meshes were placed so as to overlap each other in the midline. The mesh was fixed with absorbable tackers, medially on Cooper's ligament and laterally near anterior superior iliac spine above the iliopubic tract. This step was omitted during the mesh non-fixation period. For bilateral IH, the same procedure was repeated on the contralateral side, ensuring a 1–2-cm overlap of the mesh medially. The port sites were closed with skin staplers.

### Post-operative Management

Injection paracetamol 1 g 8 hourly was given to all patients on the day of surgery for analgesia. Oral fluids were allowed 6 h post-operative and progressed to normal diet the next day. Visual analog scale was used to assess pain in the post-op period.

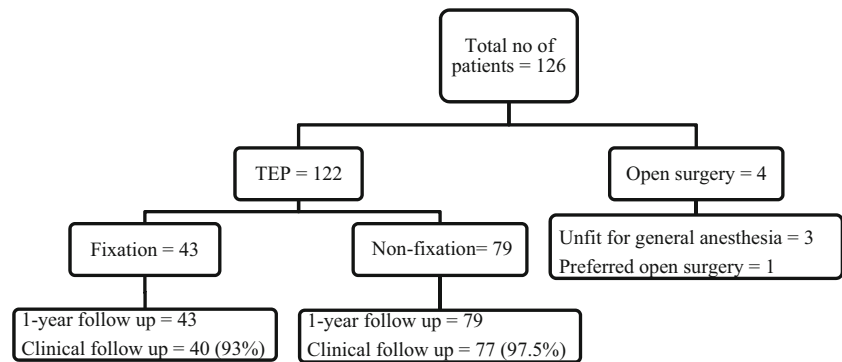
### Follow Up

The patients were regularly followed up. Follow-up was done at 1 week, 3 months, 6 months, and 1 year. All patients completed a minimum of 1 year follow-up and we could achieve nearly 96% clinical follow-up at the end of 1 year of surgery. The follow-up data for those patients who subsequently did not report for further follow-up was obtained by the means of telephonic interview.

### Statistical Analysis

Statistical analysis was done using the statistical software Graphpad available at [www.graphpad.com](http://www.graphpad.com). Continuous data are presented as mean ± standard deviation and categorical data as numbers and percentages. Categorical variables were compared using chi-square test or Fisher's exact test whichever applicable. Continuous variables were compared using

**Fig. 1** Flow chart of patients and the follow-up



Student's *t* test. A *p* value of <0.05 was considered as statistically significant.

## Results

During this period, 175 IH repairs were done in 126 patients at our department. One hundred twenty-two patients underwent laparoscopic and 04 underwent open IH surgery. Till June 2013, 43 patients underwent TEP and all underwent mesh fixation. Thereafter, 79 patients underwent TEP in which the mesh was not fixed (Fig. 1).

## Patient Demographics

Patient characteristics and their clinical profile are given in Table 1. The mean age of the patient was  $49.4 \pm 19.9$  and  $47.1 \pm 13.8$  years in the fixation and non-fixation group, respectively. Expectedly, the vast majority of the patients were males.

**Table 1** Patient demographics and characteristics of hernia

Variables	Fixation ( <i>n</i> = 43)	Non-fixation ( <i>n</i> = 79)
Age (years)		
Mean $\pm$ SD (range)	$49.4 \pm 19.9$ (18–73)	$47.1 \pm 13.8$ (21–79)
Male (%)	42 (97.7)	76 (96.2)
ASA grade (%)		
ASA I	29 (67.4)	49 (62)
ASA II	14 (32.6)	30 (38)
Duration of symptoms (months)		
Mean $\pm$ SD	$22.1 \pm 9.7$	$18.2 \pm 7.2$
Primary hernias (%)	39 (90.7%)	73 (92.4%)
Recurrent hernias (%)	4 (9.3%)	6 (7.6%)
Unilateral (%)	27 (62.8%)	46 (58.2%)
Right	20	33
Left	07	13
Bilateral (%)	16 (37.2%)	33 (41.8%)
Number of repairs	59	112

## Hernia Characteristics

In all, 171 TEP repairs were done in 122 patients. Of the 122 patients, 43 were in the fixation group and 79 in the non-fixation group. In the fixation group, there were 16 bilateral hernias and 33 bilateral hernias in the non-fixation group. Thus, the total number of repairs was 59 and 112 in the two groups, respectively (Table 1).

## Operative Times

The mean operative times for unilateral IH for the fixation and non-fixation groups were  $41.8 \pm 11.4$  and  $35.9 \pm 9.7$  min, respectively. This was statistically significant ( $p = 0.021$ ). The same for bilateral hernias, operative times were  $66.2 \pm 15.6$  and  $55.3 \pm 14.2$  min, respectively, for the two groups. This too was statistically significant ( $p = 0.018$ ). The intra-operative factors and complications are given in Table 2.

## Post-operative Pain

The pain score was evaluated at 24 h post-op using a visual analog scale. The mean pain score was significantly more in the fixation group,  $3.44 \pm 1.2$  versus  $3.01 \pm 1.0$  in the two groups, respectively ( $p = 0.037$ ).

## Hospital Stay and Return to Normal Activity

The hospital stay and days taken to return to normal activity were similar in both groups. The other post-op complications are given in Table 3.

## Chronic Groin Pain and Hernia Recurrence

The overall incidence of CGP was not different in the two groups. The incidence of CGP was 02 (3.4%) and 3 (2.7%) in the fixation and non-fixation groups, respectively, which was not statistically significant ( $p = 1.000$ ). Further, there was no increased incidence of recurrences in the non-fixation group. At a mean follow-up of  $33.2 \pm 17.0$  and  $18.7 \pm 6.2$  months, there were

**Table 2** Intra-operative factors and complications

	Fixation	Non-fixation	<i>p</i> value
Mean operative time (minutes)			
Unilateral	41.8 ± 11.4	35.9 ± 9.7	0.021
Bilateral	66.2 ± 15.6	55.3 ± 14.2	0.018
Conversion	02 (4.6%)	0	0.122
Injury to viscera	Nil	Nil	–
Injury to vas deferens	Nil	Nil	–
Injury to testicular vessels	01 (1.7%)	2 (1.8%)	1.0
Injury to inferior epigastric vessels	01 (1.7%)	4 (3.6%)	0.667
Injury to major vessels	Nil	Nil	–
Extensive surgical emphysema	01 (2.3%)	2 (2.5%)	1.0

02 (3.4%) recurrences in the fixation group while there were none in the non-fixation group, respectively ( $p = 0.118$ ) (Table 4).

## Discussion

Today, the major issue with IH surgery is the incidence of CGP along with recurrence rates. During LIHS, mesh fixation is done routinely in order to prevent mesh migration which may lead to uncovering of the defect and, consequently, increased recurrences. It has been shown that mesh fixation with tackers/sutures can lead to increased incidences of both acute and chronic groin pain [13, 14]. Since CGP majorly affects the QOL of patients undergoing IH surgery, concerns have been drawn towards mesh fixation. However, the opposing view is that if mesh fixation was not done, it would lead to increased recurrences. Three meta-analyses have looked at this issue and have comprehensively concluded that the recurrence rates are not increased by non-fixation of the mesh [10–12].

This retrospective study undertaken at the gastrointestinal and minimally invasive surgery center of a tertiary care

hospital looking into the merits of non-fixation of mesh found that the recurrence rates were not increased but the incidence of CGP was not different from the fixation group. We achieved a minimum of 1-year follow-up for all patients and close to 96% clinical follow-up. A consensus meeting recommended that for recurrence, reporting only a clinical follow-up will be valid [15]. The other significant differences found were shorter operative times and decreased pain scores in the early post-op period in the non-fixation group as compared to the fixation group.

It has been postulated that placement of tacks can damage the nerves directly or indirectly, by fibrosis around the tack which can go on to involve the nerves [16]. The chances of nerve damage go up with the number of tacks being used. Consequently, the practice now is to apply tacks medially in the region of Cooper's ligament and laterally at the level of ASIS [9]. These areas are far away from the nerves. CGP was assessed as defined by International Association of the Study for Pain: Pain persisting beyond the normal tissue healing time assumed to be 3 months [17]. There was no difference in the incidence of CGP in the two groups. This was probably due the surgeons' experience who avoided nerve damage by

**Table 3** Post-operative factors and complications

	Fixation	Non-fixation	<i>p</i> value
Pain score at 24 h	3.44 ± 1.2	3.01 ± 1.0	0.037
Urinary retention	02 (4.6%)	6 (7.5%)	0.713
Seroma at 1 week	04 (6.8%)	5 (4.5%)	0.723
Funiculitis	01 (1.7%)	1 (0.9%)	1.0
Ischemic orchitis	Nil	Nil	–
Ecchymosis	01 (1.7%)	3 (2.7%)	1.0
Wound infections	Nil	Nil	–
Hospital stay (days)	1.42 ± 0.7	1.36 ± 0.8	0.680
Mean ± SD			
Days to return to normal activity	7.91 ± 2.1	7.96 ± 2.0	0.897

**Table 4** Follow-up and short-term outcomes

	Fixation	Non-fixation	<i>p</i> value
Mean follow-up (months)	33.2 ± 17.0	18.7 ± 6.2	
Mesh infection	1 (1.7%)	0	0.357
Chronic groin pain	02 (3.4%)	3 (2.7%)	1.000
Port site hernia	Nil	Nil	–
Recurrence	02 (3.4%)	0	0.118

meticulous dissection and precise placement of tacks. It is recommended that additional tack if used should be placed above the iliopubic tract as the nerves are below this level. However, it has been shown that in up to 15% of cases, the nerves may course above the level of the tract.

A very significant 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 [10–12]. A few studies have used preformed or 3-D meshes to prevent mesh slippage [14, 18]. However, in our study, we did not use any preformed meshes and did not find increased recurrences.

It has been reported by a few studies that use of tacks for fixing mesh leads to increased post-op pain [14, 18]. Our study too found increased scores in the fixation group when we assessed pain at 24 h post-surgery and this was statistically significant. However, the hospital stay as well as the time taken to return to normal activity was similar in the two groups. A consequence of increased pain in the immediate post-op period is the increased incidence of urinary retention which has been reported by a few studies [14, 18, 19]. The overall incidence of urinary retention was similar to reported literature but we did not find an increased incidence in the fixation group.

Fixation of mesh leads to increased operative time. This has been reported by many authors [20] while the most recent meta-analysis did not find a statistically significant difference in operating times in the two groups [12]. Our study revealed that fixation of mesh indeed leads to significantly increased operative times and was found in both unilateral and bilateral IH repairs.

The use of laparoscopic tackers would entail additional costs. Three trials have shown that non-fixation of mesh leads to decreased costs [19–21]. One randomized trial reported that the difference in the two groups was \$120 [19]. Ours is a government-funded hospital and as such estimating costs to the patient is difficult to assess accurately. An endoscopic tackler costs around rupees 20,000. Since the procedure remains the same except for the use of tackler, we can assume that this would be the difference in the cost notwithstanding the cost saved due to lesser operating times. A concern about LIHS has been that it is costlier than open IH surgery. In our

study, in addition to not using tackers, we have avoided using dissecting balloon to create preperitoneal space and a preformed mesh. This would significantly bring down costs of LIHS and could match the cost of open IH repair [19].

Indirect advantages of non-fixation of mesh are that one need not worry about the injuries to the vascular structures and nerves in the preperitoneal space. As Lap TEP has got a steep learning curve, there are less chances of vascular/nerve injuries by the junior surgeons when mesh fixation is not done. Another point to be made is that in the rare event of a mesh infection, the mesh can be extracted easily and comes out in toto.

Our study has some limitations. It is a retrospective study and the fixation group will be akin to a historical control. As is well known, the results of a given surgery tend to improve over time. Thus, we have no conversions and recurrences in the non-fixation group. Also, evident is a longer follow-up in the fixation group. Notwithstanding this, all patients were followed up for a minimum of 1 year and almost all were clinical follow-ups. Since most recurrences occur within the first year post-surgery, we would not consider this as a major issue.

## Conclusion

This study reveals that avoidance of fixation of mesh during totally extra peritoneal repair of inguinal hernias is as safe as mesh fixation with certain advantages. It does not lead to increased recurrence though it does not decrease the incidence of chronic groin pain. Collateral advantage would be decreased operative times, lesser post-operative pain, and decreased costs.

## Compliance with Ethical Standards

**Conflict of Interest** The authors declare that they have no conflict of interest.

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