

Original Research Article

Comparing the Clinical Outcome of Non Fixation of Mesh with Mesh Fixation in Laparoscopic Inguinal Hernioplasty (TEP): A Study and Review of Literature

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Abstract: Inguinal hernia is the oldest disease ever since known to mankind. Laparoscopic hernia repair is now a well-established way of treating inguinal hernias. Laparoscopically hernia can be repaired either by TAPP or TEP but later is preferred as it has advantages. But the role of fixation is still controversial. The proposed study was conducted in the Department of Surgery VMMC & Safdarjung hospital, New Delhi. Number of patients included were total of 60 with minimum 30 in each group. Duration of study was 18 months. We gained 14.11 minutes on an average by non-fixation of the mesh. Non fixation technique laparoscopic totally extra peritoneal inguinal hernioplasty is equivalent in terms of complications and early recurrence when compared with results with the fixation technique. There was significant reduction in operative time and post-operative pain and no difference found in hospital stay, recurrence and mesh migration.

Keywords: TEP, Non Fixation, Low Recurrence.

INTRODUCTION

Inguinal hernia is the oldest disease ever since known to mankind [1] and its repair techniques has progressed throughout the ages but the reason for the intervention remains the same, that is continues increase in the size of the inguino-scrotal swelling with increases risk of getting obstruction, strangulated and with failure of conservative methods. Eduardo Bassini was first to proposed successful reconstruction of inguinal floor since then it has evolved rapidly [2]. Hernia repair is the commonest surgery performed over the world and same is true for India [42]. Laparoscopic hernia repair is now a well-established way of treating inguinal hernias after success of laparoscopic cholecystectomy. Better understanding of anatomy of inguinal region with refinement of technique [3-6] has played a very important role in improved outcome of laparoscopic technique. Advantages like reduced post-operative pain,

short hospital stay [7-9], and approachable entire myopectineal orifice with good cosmetic especially in recurrent surgeries [10-15] make it far better than open surgical procedures. Laparoscopically hernia can be repaired either by TAPP or TEP but later is preferred as it has advantages like avoidance of peritoneal breach and its related complications and less operative time especially in bilateral hernia [3]. Approximately 15% of hernias are repaired by TEP in which hernia defect is covered by a mesh placed in preperitoneal space and fixed with spiral tacks, clips or sutures [16]. But the role of fixation is still controversial. Some authors believes mesh to be fixed in every cases to prevent recurrences [17] as it prevents its migration which causes recurrence [19, 20] but it may result in increased post-operative pain and may damage the genito femoral or lateral cutaneous nerves which occurs in 2% to 4% of cases [18]. However it was soon realized that other

factors like adequate parietalisation, the technique, use of proper size of mesh etc. are also involved in recurrence of hernia. Thereby, many surgeons have stopped using tackers for fixation of mesh with equally good and comparable results [21-25] and also post-operative pain is reduced, cost of tackers eliminated and other complications related to tackers is also avoided. This study is comparing the clinical outcome of non-fixation of mesh during laparoscopic inguinal hernia repair with fixation of mesh in TEP. The end points measured would be the total duration of operating time, any intraoperative complications, post-operative pain, duration of hospital stay, time taken to return to routine activities and migration of mesh.

AIMS AND OBJECTIVES

To compare the total duration of operating time and any other intra operative complications, to evaluate post-operative pain, Time taken to return to normal activities and migration of mesh in both the group's fixation and non-fixation in laparoscopic TEP hernioplasty.

MATERIAL AND METHODS

The proposed study was conducted in the Department of Surgery VMMC & Safdarjung hospital, New Delhi. Number of patients included were total of 60 with minimum 30 in each group. Duration of study was 18 months. All adults (>18yrs) irrespective of gender with inguinal hernia were eligible for study. All reducible inguinal hernias was included in the study. Irreducible hernia, Obstructed and strangulated hernias, Inguino-scrotal hernia, and Patient unfit for general Anaesthesia were excluded.

PRE OPERATIVE MANAGEMENT

All patients who came to OPD with hernia were evaluated; and who fulfill the inclusion criteria and willing for laparoscopic TEP hernioplasty was randomized into two groups (group 1 fixation and group 2 non fixation) by sealed envelope method. Diagnosis of hernia was made clinically. All the routine investigations, complete haemogram with Platelet count, Blood sugar, Liver function tests, Kidney function tests and Serum electrolytes along with chest X-ray were done. Patients were admitted in the hospital an evening prior to surgery. Informed verbal and written consent for laparoscopic hernioplasty was taken. All fit patients who underwent laparoscopic hernioplasty received the three doses of cephalosporin antibiotic, first dose at the time of induction of anaesthesia and two doses 12 hourly post operatively.

OPERATIVE PROCEDURE

All Patients were asked to void urine before coming to OT and procedure was done under general anaesthesia by the same surgical team. Monitors, patients, surgeons' alignment were maintained. Monitor

was at the foot end of the patient on the side of hernia and surgeon was at head end on opposite side of hernia. The foot end of the OT table was raised with an upward tilt on the side of the hernia. A short subumbilical incision (2cm) was made and deepened to expose the anterior rectus sheath. A short longitudinal incision was made in the anterior rectus sheath to expose the underlying rectus muscle which was retracted laterally to expose the posterior rectus sheath. The plane between the rectus muscle and the posterior rectus sheath led inferiorly to the extra-peritoneal space with a blunt tipped trocar or a dissecting balloon. A gloved balloon dissector was inserted through the opening in the midline up to pubic symphysis superior to posterior rectus sheath and extra peritoneal space was created with 150 ml of saline infusion and kept for 5 minutes for hemostasis. Hassan port 10mm then inserted and secured with thread and further used as a camera port. Another 5mm port was made 1 finger above the pubic symphysis in the midline. Third 5mm port was inserted in middle of two above mentioned ports in midline. Dissection of retro pubic space of retzius in medial inguinal fossa and lateral inguinal fossa were done using blunt and sharp dissection. All potential sites of hernias were inspected i.e., direct, indirect, obturator & femoral. Hernia sac was reduced. Adequate parietalisation was done. 15 × 15 cm polypropylene mesh tailored to 15x13 cm was inserted, unrolled over myopectineal orifices as per standard guidelines. Mesh was rolled outside and delivered inside via camera port. After right alignment of mesh inside, it was unrolled on the floor. In fixation group mesh was fixed at 3 points at pectineal ligament, about 1 cm above pubic symphysis in anterior abdominal wall and Laterally 1 cm above the anterior superior iliac spine. Tackers (5 mm) made of titanium were used as fixing device. In non-fixation group no fixation of mesh was done. Intra operatively Inj. Marcaine was used at port site and Inj. Morphine (opioids) 0.1mg/kg/wt. was used as an analgesic by anesthetists. Post operatively patient was allowed to take liquids 6 hrs after the recovery from general anaesthesia. On the evening of operation Diclofenac transdermal patches of 100 mg pasted on patient's upper arm. Subsequent analgesia was given as per patient's requirement. Number of days in hospital was considered as the number of night's patient spent in the hospital. Patient was allowed to take normal diet on the post op day 1 and advised to carry on their normal routine work as per their level of comfort. Regular follow up of the patient was done at the time period of 1 week, 1 month, and 3 months and 6 months. Total duration of operative time was calculated from the moment of incision to closure of skin was calculated. Post op morbidity was defined in the form of post-operative pain and severity of pain was assessed using a visual analog pain scale with a scale of 0 to 10. Post-operative pain was assessed after 24 hrs and subsequent follow ups. Displacement of mesh was assessed by

ultrasound (high resolution) at the time of discharge and 6 months. If patient presented with any swelling over operated site, it was differentiated from recurrence with the help of ultrasound for possibility of seroma formation. Seroma was followed up every two weeks up to 3 months and managed conservatively.

OBSERVATION AND RESULT

The present study was conducted in the Department of Surgery, Vardhaman Mahavir Medical College and Safdarjung Hospital, New Delhi over a period of 18 months in which 66 patients who underwent laparoscopic inguinal hernia repair (TEP) were evaluated and randomized into two groups, fixation (group 1) and non-fixation (group 2) by sealed envelope method. Among these groups four patients were converted to TAPP because of loss of space due to pneumoperitoneum; two patients were converted to open mesh hernioplasty, one due to sliding hernia and one due to excessive bleeding, so excluded from study.

Finally 60 patients who fulfilled the inclusion and exclusion criteria were enrolled in the study. Each group successfully underwent laparoscopic inguinal hernia repair (TEP) according to study protocol & follow up was completed in all patients. There was no significant difference found in the age distribution between the two groups. The age of study population range from 20 to 69 years with mean 42.9 ± 5.65 years. Mean age in the group 1 was 42.3 ± 11.35 years and 43.5 ± 11.3 years in group 2. All patients were male in the study population. In study population 33 patients (55%) had direct hernia, 22 patients (45%) had indirect hernia, and 5 patients (8%) had recurrent hernia. In group 1, direct hernia was in 16 patients (53%), indirect in 11 patients (36%) and recurrent in 3 patients (10%) and in group 2 direct hernia was seen in 17 patients (56%), indirect in 11 patients (36%) and recurrent in 2 patients (7%). Both the groups were evenly matched with respect to direct, indirect and recurrent hernia. ($p=0.06$). (Table 1).

Table-1: Various types of hernia seen in study group

Types of hernia	Group 1 N=30	Group 2 N=30	Total N=60	p-value
Direct	16(53%)	17(56%)	33(55%)	0.06*
Indirect	11(47%)	11(44%)	22(45%)	
Recurrent	3(10%)	2(7%)	5(8%)	

*Insignificant p value

Similarly, incidence of unilateral and bilateral hernia in both groups was comparable; ($p=0.07$). In group 1, 21 patients (70%) had unilateral hernia, and 9 patients (30%) had bilateral hernia. In group 2, 22 patients (73%) had unilateral hernia & 8 patients (27%) had bilateral hernia. Overall in total study population 43 patients (72%) had unilateral hernia and 17 patients (28%) had bilateral hernia. The mean operative time in group 1 was 89.66 ± 8.6 minutes. In group 2, mean operative time was 75.55 ± 8.02 minutes. The

difference was statistically significant (p value < 0.001). Post-operative pain and severity of pain was assessed using a visual analogue pain scale with a scale of 0 to 10. A statistically significant reduction of pain scores post operatively at 24 hours (p -value = 0.003), 1 week (p -value = 0.007), 1 month (p -value = 0.001), 3 months (p -value = 0.001) and 6 months (p -value = 0.007) were noted in group 2 as comparable to group 1. (Table 2)

Table-2: Change in the pain score at follow up

Pain score at follow ups	Group 1 (mean \pm SD)	Group 2 (mean \pm SD)	p-value
At 24 hrs	3.63 \pm 1.29	2.33 \pm 0.99	0.003*
1 week	2.33 \pm 1.84	1.2 \pm 0.76	0.007*
1 month	1.66 \pm 0.88	0.56 \pm 0.56	<.001*
3 month	1.16 \pm 0.69	0.26 \pm 0.44	<.001*
6 month	0.9 \pm 0.66	0.26 \pm 0.44	0.007*

*Significant p-value

Most common complication encountered was peritoneal breach occurred in 24 patients (40%) in study population, 11 patients (36%) and 13 patients (43%) in group 1 and group 2 respectively. In 12 patients (20%) bleeding during dissection of space occurred, 5 patients (16%) and 7 patients (23%) in respective groups. All intra operative complications were comparable in both groups. The mean duration of stay in the group 1 was

1.73 ± 0.72 days as compared to 1.4 ± 0.60 days for group 2. The difference was statistically insignificant (p value = 0.56). There were two post-operative complications noted besides pain and those were seroma formation and port site infection. In study population seroma formation occurred in 8 patients (12%) and port site SSI in 3 patients (2%). Both the complications were comparable in both groups with p

value 0.70 for seroma and p value 0.56 for port site SSI. Seroma formation occurred in 5 patients (16%) in group 1 and 3 patients (10%) in group 2. Port site SSI occurred in 2 patients (7%) in group 1 and 1 patient (3%) in group 2. Recurrence was noted in 2 patients (3%) of total study population, with 1 patient (3%) in group 1 and 1 patient (3%) in group 2 which was

statistically insignificant p value 1. Mesh migration was assessed upto 6 months follow up by ultrasound. Mesh migration was present in patients with recurrence only. Migration of mesh was noted in 2 patients (3%) of total study population, with 1 patient (3%) in group 1 and 1 patient (3%) in group 2 which was statistically insignificant p value 1. (Table 3)

Table-3: Comparing the outcome between two groups.

Outcome	Group 1 N=30	Group 2 N=30	Total N=60	p-value
Breach in peritoneum	11 pts (36%)	13 pts (43%)	24 pts (40%)	0.79**
Bleeding during space dissection	5 pts (16%)	7 pts (23%)	12 pts (20%)	0.74**
Mean hospital stay (days)	1.73 ± 0.72	1.40 ± 0.60	NA	0.56**
Seroma	5 pts (16%)	3pts (10%)	8pts (12%)	0.70**
Port site SSI	2pts (7%)	1pts (3%)	3pts (2%)	0.56**
Recurrence	1(3%)	1(3%)	2(3%)	1**
Early(within 1 month)				
Late (after 1 month)	0	0	0	NA
Mesh migration	1(3%)	1(3%)	2(3%)	1**

**Insignificant

DISCUSSION

Inguinal hernia is the oldest disease ever since known to mankind [1] and its repair techniques has progressed throughout the ages but the reason for the intervention remains the same, that is continues increase in the size of the inguino-scrotal swelling with increases risk of getting obstruction, strangulated and with failure of conservative methods. Laparoscopic hernia repair is now a well-established way of treating inguinal hernias after success of laparoscopic cholecystectomy. Laparoscopically hernia can be repaired either by TAPP or TEP but later is preferred as it has advantages like avoidance of peritoneal breach and its related complications and less operative time especially in bilateral hernia [3]. Approximately 15% of hernias are repaired by TEP in which hernia defect is covered by a mesh placed in preperitoneal space and fixed with spiral tacks, clips or sutures [16]. But the role of fixation is still controversial. The mean operative time was 75.55 ± 8.02 minutes in group 2, as compared to 89.66 ± 8.6 minutes in group 1. We gained 14.11 minutes on an average by non-fixation of the mesh. This difference clearly reflected that non-fixation of mesh saved the precious operative time. In this study, the non-fixation of mesh was associated with a statistically significant shorter mean operative time. (P= 0.001). A statistically significant shorter operative time in non-fixation technique as compared to fixation of mesh technique has been attributed to several factors. Fixation of mesh can be done by several ways, either by use of sutures or by using a fixation device which can be titanium tackers or bioabsorbable tackers, fibrosing agent or glue. However fixation of mesh on anterior wall of abdomen

is a very technical challenge. Fixing a mesh by sutural method required a very good skill and very good control on laparoscopic instruments otherwise it may cause a lethal injury to surrounding vessels and other structures. Fixation by tackers/staplers is also a challenging job, initially many surgeons encountered difficulty in fixing tackers especially on cooper's ligament, as it slips. Also, counter pressure has to be applied against the tacker instrument where it has to be fixed. On other hand, we have to keep mesh in place while fixing it with tackers. All these factors increased the length of total operative time and one doesn't have to face all these challenges by not fixing a mesh thereby saving precious operative time as well as eliminating the cost of the tacker device. Previous studies by Tam [26] *et al.* shows just by eliminating fixation of mesh in TEP inguinal hernia repair result in decreased operative cost and reduce total operative time and hospital stay, without making any difference in the risk of hernia recurrence, complications, and postoperative pain. Similar results were shown by Teng. Y.J [24] *et al.* in 772 patients. We observed a statistically significant reduction of pain scores post operatively at 24 hours (p-value=0.003), 1 week (p-value=0.007), 1 month (p-value=0.001), 3 months (p-value=0.001) and 6 months (p-value=0.007) in study population. Previous studies by Lau and Patil [27] *et al.* found that postoperative pain levels were less on coughing in patients in whom the mesh was not fixed (P<0.05). In our study breach of peritoneum was the common factor for pain in both the groups in initial period, however with time patients with tacker fixation were found to have more inguinal and scrotal pain. Similar result was shown by Abdul

Kareem [28] *et al.* with patients complains of pain (neuralgia). Burning sensation (parenthesis), hypoesthesia and hyperesthesia (pain complex syndrome). There was no significant difference in intra operative complication in both groups. We encountered mainly two intra operative complication. In spite of these intra operative complications TEP is considered to be a very safe procedure of hernioplasty. Previous studies by Zamora-Amorós [29] *et al.* concluded that TEP laparoscopic hernioplasty is a very effective and safe procedure in the hands of experienced surgeons with specific training. It is an interesting option in bilateral and recurrent hernia as it obtains satisfactory results in terms of postoperative pain and morbidity. Ashwin [30] *et al.* also considered TEP to be safe procedure. In this study, hospital stay was statistically similar in both groups, 1.73 ± 0.72 days in fixation group vs. 1.40 ± 0.60 days in non-fixation group (P value = 0.56). Recovery time was comparable in both groups in our study. Previous studies held at Lanzhou University, China showed that without increasing the risk of early hernia recurrence, the non-fixation of mesh in TEP appears to be a safe alternative that is associated with less costs, shorter operative time, and hospital stay [24]. Similar by Lau.H [31] *et al.* in 102 consecutive cases of TEP were found to be safe and effective with a success rate of 97%. Postoperative pain was mild and more than 90% of the patients resumed normal outdoor activities within a week. There were two post-operative complications noted besides pain and those were seroma formation and port site infection. Previous studies by Ramshaw [32] *et al.* on Laparoscopic inguinal hernia repair in 1224 consecutive cases conclude that the total extra peritoneal approach for laparoscopic hernioplasty allows for a safe and effective repair with low rates of complication and recurrence. Taylor CJ [33] *et al.* also shows TEP to be an effective and safe procedure with a low recurrence and low prevalence of any complication. However rare case of psoas abscess due to infected mesh was also reported [34]. Also there have been reported cases of migration of mesh into urinary bladder following laparoscopic mesh hernioplasty [35]. The success of any hernia repair is determined by the recurrence rate and the incidence of chronic pain. Previous studies show most recurrences after laparoscopic repair occur within the first year and are attributable to technical error. Previous reports have suggested that recurrences have occurred after repair of direct hernias because of mesh migration [36] or using an inadequately sized mesh to allow for shrinkage [37]. Only 2 recurrences within a period of 6 months were noted in our study. Both patients were having direct hernia. Both the patients had recurrence in early post-operative period that is within 1 month. Mesh migration was assessed upto the 6 months follow up by ultrasound, and found to be in patients with recurrence only. It has emerged from the available literature that recurrence after laparoscopic totally extra

peritoneal hernia repair was most likely because of a failure in surgical technique, and causes other than fixation, such as an incomplete dissection of the myopectineal orifice or improper mesh size, may be important determinants [38]. Whereas a small mesh can contribute to recurrence due to incomplete coverage of the myopectineal orifice, a large mesh in an inadequately dissected space can get furled or wrinkled and result in similar consequences. It merits consideration that inadequate mesh size might have been the prime contributor to recurrences in studies where lack of mesh fixation has been thought to be the cause of recurrence [39]. Experimental studies have suggested that an overlap of 3 or more centimeters is essential in preventing recurrences. A mesh size of 10×15 cm is recommended in laparoscopic repairs without fixation. In our series, a standard of 15×15 -cm polypropylene mesh tailored into 15×13 cm was used which ensured a wide overlap of the myopectineal orifice. All the recurred patients were operated by open hernia methods and we found that in 1 patient mesh was rolled up and in other patient mesh migrated into large direct hernia pseudo sac where mesh was not fixed. Both the patients were diagnosed within the first week of operation. Up rolling of the mesh could be the possibility of technical error in which mesh has not been fully unrolled or migrated while deflating the abdomen. Migration of mesh in direct sac was contributed to firstly large hernia sac and secondly turbulent post-operative period by chronic cough. It is perhaps underappreciated that mesh stabilization may occur intrinsically due to the preperitoneal location of the mesh in TEP. Evidence for this exists. Choy [38] *et al.* found that unfixed mesh could not be induced to move (confirmed on inspection of the mesh by re-laparoscopy of the preperitoneal space) by on-table cycles of hip flexion. This inherent stability was further confirmed by Irving [39] *et al.* through postoperative X-ray studies. Mesh stabilization may occur through a sandwich effect between the intact peritoneal layer and the body wall, maintaining mesh position by even application of abdominal pressure. Limiting the extent of the preperitoneal dissection may act to further discourage any lateral mesh migration. Previous study also supports the fact that eliminating tacks does not lead to an increased rate of recurrence. DE Messenger [40] *et al.* showed TEP hernia repair was associated with a recurrence rate of 1% at 5 years in this series. This recurrence rate following TEP repair compares extremely favorably with open mesh repair. Another study by Choi YY [41] *et al.* in 2012 did TEP repairs in 219 patients. It was found that there was no statistically significant difference in the recurrence rate, seroma formation, and hospital stay. Non fixation technique laparoscopic totally extra peritoneal inguinal hernioplasty is equivalent in terms of complications and early recurrence when compared with results with the fixation technique. There was significant reduction in

operative time and post-operative pain and no difference found in hospital stay, recurrence and mesh migration.

CONCLUSION

Non-fixation technique of laparoscopic totally extra peritoneal inguinal hernioplasty is as effective as fixation in view of complications and recurrence. Our study has shown that a tackless laparoscopic TEP inguinal hernia repair in selected patients can be an alternative to laparoscopic TEP with fixation of mesh as it is associated with higher operative costs and an increased likelihood of developing chronic groin pain. Elimination of mesh fixation did not increase the risk of hernia recurrence. Reduction of cost of tacker is the major deterrent in extending the benefits of laparoscopic hernia repair to the general population. The results of our study are fruitful and can be the factor for use of laparoscopic procedures for hernia repair in low economic country where patients unable to bear the cost of a tacker.

Conflicts of Interest

There is no conflict of interest

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