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To Evaluate The Outcome in Laparoscopic Total Extra-Peritoneal Repair of Inguinal Hernia With Staple Fixation of Mesh Vs Non-Fixation: A Prospective Observational Study

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Abstract

Introduction: Total Extra-Peritoneal (TEP) approach is a minimally invasive procedure used for Inguinal Hernia repair. In this method mesh is placed in extra-peritoneal space and fixation of mesh done by suture materials or using devices such as tacks staple or tissue glue or no fixation of mesh.

Objective: To evaluate the outcome of the tacks staple fixation of mesh vs non-fixation in laparoscopic TEP repair of inguinal hernia in terms of intra-operative, post-operative and socioeconomic outcomes.

Material and Method: In this prospective study, total 66 patients underwent Laparoscopic Total Extra-Peritoneal repair and were observed into two study groups: Group I (n=33)- with fixation of mesh by absorbable tacks and Group II (n=33)- no fixation of mesh. Post operatively there was a specific follow-up (at 1 week, 1 month, 3 months and 6 months) for surveillance of patients for wound complications, surgical site infections and recurrence.

Results: In this study the mean age was found to be 49.54±10.27 and the majority of patients were in their 4th and 5th decade of life and were male. Hospital stay for the fixation of mesh group was found to be 2.24±0.44 days while that in non-fixation group it was 2.33±0.59 days and the association was found to be statistically insignificant ($p<0.05$). The chronic groin pain was seen in 1 (3.0%) in the fixation group while no chronic groin pain was seen in non-fixation group ($p<0.314$). There was no surgical site infection; seroma formation and recurrence in both the group.

Conclusion: Totally extra peritoneal repair is a safe procedure. Avoidance of fixation of mesh during 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.

Keywords: Laparoscopic TEP repair, Mesh fixation, Staples.

Introduction

In recent years, minimally invasive methods such as trans-abdominal pre-peritoneal (TAPP) and total extra-peritoneal (TEP) approaches have been used for inguinal hernia repair. Although both of these methods are effective, TEP is becoming more popular among surgeons. The technique is simple, rapid, with less postoperative pain, required less analgesic, leads to earlier return to normal activities; fewer long-term complications like groin pain and permanent paraesthesia but an equivalent recurrence rate compared to open mesh repairs. During laparoscopic surgery, the mesh is generally placed and sutured using suture materials or using fixation devices such as staples, tacks, or tissue glue. The purpose of this mesh fixation generally is to avoid early recurrence. Stapling can cause scarring and pain at the staple sites. Placement of the mesh is the most frequently debated issue of laparoscopic TEP repair. Most of the debate concerns to chronic postoperative pain and recurrence, however the use of tacks staple can cause postoperative pain and nerve injury. Nerve injury has been estimated to occur in 2%–4% of laparoscopic inguinal hernioplasties, the most commonly injured nerves being the femoral branch of the genito-femoral nerve and the lateral femoral cutaneous nerve [1]. In addition, the use of staples may increase the cost of the operation. No definitive advantage for fixation of mesh has been proven, other than in instances of large inguinal defects or inadequate size of mesh. It has been suggested that many fixation-related morbidities, including chronic pain, recurrence, prolonged operative time, and increased cost can be avoided using non fixation method [2,3]. Numerous studies have been conducted to assess the reliability of non-fixation of mesh comparing it with the standard procedure. Non-fixation of the mesh has also been tried and proposed as a viable alternative with other inguinal hernia repair methods [4,5].

Aims and Objectives: To evaluate the outcome in laparoscopic total extra-peritoneal repair of inguinal hernia by tacks staple fixation vis a vis non-fixation of mesh in terms of:

(A) Intra operative outcomes - (a) Duration of surgery (b) Peritoneal breach.

(B) Post-operative outcomes- (a) Post op pain (b) Seroma formation(c) Recurrence (d)Chronic groin pain.

(C) Socioeconomic outcomes- Quality of life.

Material and Methods

Place of Study: 7 Air Force Hospital, Kanpur, Uttar Pradesh.

Study Design: Prospective observational study.

Study Duration: The study was spanned over a period of two years early 2017 to Oct 2019.

Study Population: Total 66 patients with inguinal hernia underwent hernia repair using laparoscopic total extra-peritoneal approach.

Inclusion Criteria

- Patients with unilateral reducible inguinal hernia
- Aged 18 - 65 years.
- Either sex

Exclusion Criteria

- Patients with irreducible / obstructed/ strangulated / inguino-scrotal hernia/Past history of lower abdominal surgery
- Associated hernias, *viz.* ventral hernia.
- Patients too frail or unfit for general anesthesia.

Study Interventions: In this study total 66 patients were observed into the two study groups as follows:

Group I (n=33): In these patients underwent inguinal hernia repair using extra-peritoneal laparoscopic procedure and mesh fixation was done with tacks stapler.

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Group II (n=33): In these patients underwent inguinal hernia repair using extra peritoneal laparoscopic procedure and mesh fixation was not done.

Preoperative Workup:

The clinical diagnosis of an inguinal hernia was made by detailed history and clinical examination. All patients being admitted/or managed in outpatients were seen by a surgical consultant to confirm the diagnosis of a hernia. All potential sites of hernias were inspected i.e., direct, indirect, obturator and femoral. Preoperative workup and fitness for general anesthesia was done. Written informed consent was taken from both the studied group patients.

Procedure: As described by Gupta *et al.*[6]. All patients were asked to void urine before coming to Operation Theater and procedure was done under general anesthesia by the same surgical team. Monitors, patients, surgeons' alignment was maintained. Monitor was placed at the foot end of the patient on the side of hernia and surgeon stood 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 sub-umbilical incision (2cm) was made and deepened to expose the anterior rectus sheath. A short transverse 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 air and was kept for 2 minutes for hemostasis. A 10mm port was 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 was 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. Absorbable tacks Staples (5 mm) were used as fixing device. In non-fixation group no fixation of mesh was done. Intra operatively Inj. Bupivacaine 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 anesthesia. On the evening of operation Diclofenac injection 50 mg stat was given. Subsequent analgesia was given as per patient's requirement. Number of days in hospital was considered as the number of nights patient spent in the hospital. Patient was allowed to take normal diet on the post op day 1 and was 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 1week, 1 month, and 3 months and 6 months. Total duration of operative time was calculated from the moment of incision to closure of skin. Post op morbidity was defined in the form of postoperative pain and severity of pain was assessed using a Visual Analog pain Scale (VAS) with a scale of 0 to 10. Postoperative pain was assessed after 24 hrs and subsequent follow ups. All patients were operated

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by 1 of 2 senior surgeons, who also looked into postoperative complications. Various parameters were noted for assessing outcome and complications such as pain scores, duration of surgery, peritoneal breach, chief complaints, hospital stay and surgical site infections in both the groups and also the recurrence of a hernia through follow up and almost same parameters were used for the outcome in the study performed in the past

Method of Measurement of Outcome of Interest:

1. Intraoperative details like Duration of surgery (in min), peritoneal breach (frequency).
2. Postoperative pain (using VAS), seroma formation (frequency), surgical site infection (frequency), recurrence at 6 months (frequency), chronic groin pain at 6 months (frequency).
3. Socioeconomic details like Quality of life (using SF 36 questionnaire).

Follow up: Following discharge from the hospital, all the patients were followed up at following intervals- One month, three months and Six months.

Data Collection Method: The data was collected on a semi-structured questionnaire. Data were filled during hospitalization and after discharge at all the follow up intervals. Records of all the test reports were maintained. All measurements were made under direct observation. The data so collected was fed into computer using MS Excel.

Statistical Methods The data was analyzed using Statistical Package for Social Sciences version 15.0. Chi-square test and independent Samples't'-test were used for analysis. A 'p' value less than 0.05 was considered to indicate statistically significant association.

Ethical Considerations The study was approved by Institutional Ethical Committee. Informed consent was obtained from all the participants. The participation in the study was entirely voluntary.

Results

Table-1 shows demographic profile- The mean age was observed as 49.54±10.27 years with male patients in majority. The various other parameters in both the groups were compared. Chi square test was used to analyze the data and p value < 0.05 was considered significant and > 0.05 insignificant. There was no significant statistical difference between the two groups.

Table 1: Demographic profile

		Fixation group (n=33)	Non Fixation group (n=33)	P value
Gender	Male	32	33	0.314
	Female	01	Nil	
Occupation	Business	15	10	0.072
	Farmer	02	11	
	Housewife	01	Nil	
	Self employed	08	06	
	Others	07	06	
Socio-economic status	Middle	13	16	0.457
	Upper middle	20	17	
Dietary Habit	Non-veg	18	21	0.453
	Veg	15	12	

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Physical activity	Heavy	02	08	0.018
	Moderate	22	23	
	Sedentary	09	02	
Risk Factors	Alcohol	12	16	0.845
	Smoking	15	21	
	Tobacco	07	13	
Co-morbidities	Diabetes	11	11	0.699
	Hypertension	12	15	

Table 2 shows the duration of surgery in mesh fixation group and non-fixation group and the association was found to be statistically significant ($p<0.05$) as in non-fixation group it took significantly less time than fixation group patients

Table 2: Duration of Surgery in Fixation and Non-fixation of Mesh

	Fixation (n=33)	Non-Fixation (n=33)	p-value
Duration of Surgery(in min)	40.96±3.21	38.97±3.51	0.019
Peritoneal Beach	0	0	--

Table 3 shows the mean VAS score distribution in both the groups and the association was found to be statistically significant as mean VAS at 3 hours of fixation group was found to be significantly higher. However, when the mean VAS score at 12 hours and at the time of discharge were compared, there was no statistical difference between the two groups.

Table 3: VAS score distribution

VAS Score	Fixation (n=33)	Non-Fixation (n=33)	p-value
Pain at 3 hour	1.91±0.29	1.27±0.67	<0.001
Pain at 12 hour	0.30±0.46	0.33±0.48	0.796
At discharge	No pain	No pain	--

Table 4 shows the post-operative evaluation of the studied patients and there was no statistical difference in the hospital stays in both the groups ($p>0.05$), chronic groin pain was found in 3.0% patients in mesh fixation group while no patient had experienced pain in non-fixation group ($p>0.05$).

Table 4: Post-operative evaluation

Variables	Fixation (n=33)	Non-Fixation (n=33)	p-value
Seroma Formation	0	0	--
Surgical site Infection	0	0	--
Hospital Stay	2.24±0.44	2.33±0.59	0.485
Chronic Groin Pain	1 (3.0)	0	0.314

Table 5 shows follow up (at 1 week, 1 month, 3 month and 6 month): There was no recurrence of the hernia observed in any of the groups and the association was highly statistically insignificant ($p>0.05$) as shown in.

Table 5: Distribution of patients on the basis of recurrence

Recurrence	Fixation (n=33)	Non-Fixation (n=33)	p-value
Yes	0	0	>0.05
No	33	33	

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Table 6 shows the score of the patients of the questionnaire and the association was found to be statistically significant in the cases of physical functioning, role limitation due to emotional problems and pain (p<0.05), all other parameters showing insignificant association among the groups.

Table 6: Questionnaire (SF-36) Score

SF-36	Fixation (n=33)	Non-Fixation (n=33)	p-value
Physical Functioning	78.03± 10.89	69.1±22.27	0.043
Role limitation due to physical health	83.94 ± 15.19	79.55±18.17	0.291
Role limitation due to emotional problems	100±0	95.96±11.03	0.039
Energy/Fatigue	72.12±2.51	71.51±3.42	0.412
Emotional well-being	88.0±2.83	86.97±4.52	0.271
Social functioning	71.0±10.05	70.95±10.70	0.985
Pain	77.47±7.96	71.44±8.91	0.005
General Health	63.79±7.4	64.1±6.43	0.856
Health Change	58.3±11.96	56.06±10.88	0.429

Discussion

Laparoscopic hernia repair is now recommended as the method of choice for primary inguinal hernia and recurrent inguinal hernia repair as well. Most of the surgeons now recommend doing Total Extra Peritoneal (TEP) repair as it does not involve opening up the peritoneal cavity and moreover lesser chances of visceral injuries. TEP when compared to an open hernia is superior in terms of reduced postoperative pain, shorter hospital stay, decreased incidence of urinary retention and earlier return to normal activities. However, TEP repair requires general anaesthesia. Mesh can be placed without fixation or can be fixed in place with tackers. These tackers increase the cost and there is an increased incidence of chronic groin pain. There are several studies showing non-fixation as a viable option without increased risk of recurrence, but also has the advantages of shorter operative time, less chronic groin pain and overall improved quality of life when compared to mesh fixation by tacks . The current study was planned to compare postoperative pain and recurrence rate in fixation and non-fixation of mesh in TEP inguinal hernia repair. In this prospective observational study of laparoscopic total extra-peritoneal repair, the fixation of mesh by tacks was done in one method and in other mesh placed without fixation. **Ayyaz M et al [8]** have performed a similar type of study comparing fixation versus non-fixation of mesh, **Gupta A et al**[6]**and Abd-Raboh GH et al[7]** have also opted similar methodology to compare the groups.. Present study wasn't done as a case-control study as it was not feasible in two groups involved in a surgical process; as in this studies there were no controls, all patients underwent the operation. Although several studies with large samples assessing the outcomes between fixation and non-fixation techniques in TEP inguinal hernioplasty have been published [9,10] they had a bias because of retrospective analysis and uneven sampling. The present study assessed the operative and postoperative parameters and adverse outcomes in patients undergoing stapled fixation of mesh or without fixation in TEP inguinal hernioplasty.**Tam et al**[11] reported that hernia repair using TEP laparoscopic

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method without mesh fixation could significantly decrease operative time, surgical costs, and length of hospital stay, and they found no difference between mesh fixation and non-fixation methods in terms of hernia recurrence, complications, or postoperative pain. **Sajid et al [12]**, in his study indicated that laparoscopic non-fixation TEP method did not increase recurrence risk, and noted that operative time, postoperative pain, complications, length of hospital stay, and chronic inguinal pain were similar to that detected in cases of mesh fixation method. In a study by **Kumar A et al [13]** who reported the mean age49.4±19.9 which was almost similar to the present study and vast majority of the patients were male and only one out of the total of 66 patients was female. The research performed by Gupta A et al [6] was found 60 male patient and no female while Abd-Raboh OH et al[7] in his study found 57 male patient and 07 female patients which shows a similar pattern.

In current study the majority of patients were businessmen (37.9%) with sedentary (16.6%) or moderate (68.2%) physical activities and most of them were vegetarian (75.8%) and belonging to the upper-middle (56.1%) and middle class (43.9%). The sedentary or moderate physical work patients were mainly affected by these types of problems suggesting prolonged sitting is also one of the factors causing this problem. Majority of patients were smokers (54.5%) followed by an alcoholic (42.2%) and tobacco eaters (30.3%). Smoking increases the risk recurrence. The study by **Modena SF et al [10]** reported that smoking and alcohol consumption causes a lot of damage to humans, which predisposes users to different diseases like hernias. 40.9% patients were found to have hypertension followed by diabetes (33.3%). **Hellspong G et al [14]** reported that diabetes seems to increase the risk of postoperative complications within 30 days of inguinal hernia surgery, especially for complicated diabetes.

In present study patient's right side hernia was dominated (69.7%) followed by left side (30.3%) and the majority of patients having the moderate size of a hernia (59.1%) followed by the smallsize (40.1%). **Meyer Kumar RP et al [15]** reported in their study that Out of 36 patients who had a unilateral hernia, 11 patients had a hernia on the left side and 25 patients on the right side that was similar to the present study. In present study the direct type of a hernia was in the majority of the patients (56.1%) followed by the incomplete nature of a hernia (43.9%) and in all the cases it was incomplete (100.0%). **Gupta A et al** [6] reported the similar kind of result (53.0% direct while 47.0% were an indirect type).

In the present study the duration of surgery in fixation group was found to be 40.96±3.21 minutes while that of the non-fixation group it was 38.97±3.51 minutes and the association was found to be statistically significant ($p<0.05$). **Gupta A et al** [6] reported that the mean operative time was 75.55 ±8.02 minutes in group 2, as compared to 89.66 ± 8.6 minutes in group 1. The non-fixation of mesh was associated with a statistically significant shorter mean operative time. ($P= 0.001$). **Kumar A et al [13]** found the mean operative times for unilateral inguinal hernia for the fixation and non-fixation groups were 41.8 ± 11.4 and 35.9 ± 9.7 min, respectively. This was statistically significant ($p = 0.021$). The same for bilateral hernias, operative times were 66.2 ± 15.6 and 55.3 ± 14.2 min, respectively, for the two groups. This too was statistically significant ($p = 0.018$). Fixation of mesh leads to increased operative time. This has been a repeated outcome of staple fixation versus non-fixation in TEP inguinal repair and has been concluded that elimination of tack fixation of mesh in TEP repair is associated with decreased operative cost

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and significantly reduced operative time. **Alfredo Moreno-Egea et al [16]** also reported the significant association between the two groups operative time (p<0.05). **Buyukasi K et al [17]** reported an insignificant association regarding the operative time of the two groups which was contrasting to the present study. In the present study the mean VAS score of the fixation group was foundto be 1.91±0.29 and that of non-fixation group it was 1.27±0.67 at 3 hours after surgery and the association was found to be statistically significant (p<0.001) while at 12 hours after surgery the association was insignificant (p>0.05) and at the time of discharge no pain was seen in the patients of both the groups. **Gupta A et al** [6] also reported the identical result as in the present study and stated that mean pain score in fixation group was 4.7±0.683 as compared to the non-fixation group which was 4.1±0.860 (p<0.001). A randomized control trial published in 2012 showed that there was no statistically significant difference in pain. **Lau and Patil et al [18]** found that postoperative pain levels were less on coughing in patients in whom the mesh was not fixed (P=0.05). **Kumar A et al [13]** also reported the post-op pain score evaluated using a visual analog scale. The mean pain score was significantly more in the fixation group, 3.44±1.2 versus 3.01±1.0 in the two groups, respectively (p = 0.037). **Reddy RR et al [19]** stated that post-operative pain was significantly less in without fixation of mesh group compared to with mesh fixation group. Pain at duration of 1 week and 1 month is 0 in both groups. This implies that the pain is comparatively more in the fixation group than that in the non-fixation group. In present study no seroma formation or surgical site infection was observed in both the groups, the hospital stay for the fixation group was found to be 2.24±0.44 days while that in non-fixation group it was 2.33±0.59 days and the association was found to be statistically insignificant (p<0.05) also the chronic groin pain was seen in 1 (3.0%) in the fixation group while no chronic groin pain was seen in non-fixation group (p<0.314). **Gupta A et al** [6] also reported the similar findings as in present study as an insignificant association of SSI, Seroma formation, mean hospital stay (p>0.05). It has been shown that mesh fixation with tackers/sutures can lead to increased incidences of both acute and chronic groin pain. **[20].** In present study no recurrence of a hernia was observed in any of the groups and the association was highly statistically insignificant (p>0.05). Identical results were observed by **Buyukasik K et al [17]** stating that no recurrence or nerve injury was determined during follow up examinations. **Kumar A et al [13]** reported 3.4% recurrence in fixation group while 0.0% in non-fixation group (p>0.05). **Koch CA et al [21]** and **Gupta A et al** [6] reported no hernia recurrences were observed in either group (follow-up range, 6 to 30 months) similar to the present study. The SF-36 questionnaire and its association was found to be statistically significant with respect to physical functioning, role limitation due to emotional problems and pain (p<0.05) while other parameters showed insignificant association. (Table-7)

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Table 7: Various studies and Inference

Study	Sample Size	Year	Inference
Gupta A et al[6]	60	2016	Non-fixation technique of laparoscopic totally extra peritoneal inguinal hernioplasty is as effective as fixation in view of complications and recurrence
Abd-Raboh OH et al[7]	58	2017	Totally extra-peritoneal repair for inguinal hernia is a safe procedure that can be a better alternative for open anterior approach repair if the expertise is available, whether with mesh fixation or non-fixation.
Ayyaz M et al[8]	63	2015	Pain was significantly reduced in case of non-fixation of mesh, while urinary retention and recurrence were not significantly different between the two groups.
Kumar A et al[13]	122	2017	Avoidance of fixation of mesh during totallyextra peritoneal repair of inguinal hernias is as safe as mesh fixation with certain advantages
Reddy RR et al[19]	30	2017	TEP inguinal hernia repair without mesh fixation which is better in postoperative pain and cost of surgery, and is not associated with an increased risk of hernia recurrence.

Recommendations

Larger volume studies with longer follow up periods should be done to clarify, more specifically, points like; incidence of chronic groin pain and its relation to mesh fixation, incidence of postoperative seroma, hematoma and surgical emphysema.

Conclusion

Totally extra-peritoneal repair for an inguinal hernia is a safe procedure that can be a better alternative for open anterior approach repair if the expertise is available, whether with mesh fixation or non-fixation.

- Early postoperative pain was slightly higher with mesh fixation
- The duration of surgery was significantly higher in the fixation group than the non-fixation group
- The association of hospital stay was statistically insignificant ($p>0.05$)
- No surgical site infection or seroma formation was observed in any group and chronic pain was observed in one case of fixation group.
- No recurrence of hernia was observed in the follow up of the studied patients

This study reveals that avoidance of fixation of mesh during 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. The collateral advantage would be reduced operative times, lesser post-operative pain, and reduced costs.

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