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Original article

A comparative clinical trial of totally extraperitoneal groin hernia repair with or without mesh fixation.

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ABSTRACT

The need of mesh fixation in total extra-peritoneal laparoscopic (TEP) inguinal hernioplasty is still controversial issue. The question is important because mesh fixation has been related to post-operative pain, recurrence and increased hospital cost. Whereas various other studies have been done that showed non fixation of mesh is safe, cost effective, associated with less pain, and leads to no increased risk of hernia recurrence .Keeping this in view and resolve the controversial issue, the study was carried out to compare the safety and efficacy of laparoscopic totally extra peritoneal groin hernia repair with and without mesh fixation and in relation to post-operative morbidity in these two group of patients. Methods: Patients were randomized into two groups of 30 each , where a total of 64 repairs were done.In mesh fixation group the mesh was fixed and no fixation was done in other group. Results:The present study showed no statistically significant difference in demographic factors, recurrences, chronic pain seroma in either group. Although the cost was higher in mesh fixation group where tacks had been used as compared to non mesh fixation group.Moreover fixing the mesh in the extra peritoneal space increases the operating time and cost of the repair. Conclusion: In this study we concluded with reasonable confidence that totally extraperitonally groin hernia repair performed without mesh fixation is safe , feasible and cost effective without any increased incidence of early reoccurrence.

Backround

Jean-Louis Dulucq et al. were first to perform laparoscopic Total extra peritoneal repair (TEP) repair, in June 1990[1]. The current concept of laparoscopic repair is based on Stoppa's concept [2] of preperitoneal reinforcement of fascia transversalis over the myopectineal orifice with a large piece of mesh. The mesh is stapled to the abdominal wall and the pubic bone[3].However, is it necessary to fix the mesh in the extra peritoneal space to prevent it from slipping? Some authors have tried to tackle the problem with retrospective analysis and prospective series with or without control groups[4],whereas others recommend systematic fixation of the mesh as a measure to prevent recurrences but others have not shown any advantage of fixing the mesh. The technical detail is therefore of great interest as it may have repercussion in post operative pain, morbidity and recurrence rates including hospital cost[5]. Fixation of mesh is thought to contribute to increased post operative and risk of nerve injury that is estimated to occur in 2-4 percent of laparoscopic inguinal hernia repairs with the most commonly injured nerve being the femoral branch of genitofemoral nerve and the lateral cutaneaous nerve[6] Chronic groin pain represents the most common post operative morbidity after repair of inguinal hernia[7]. The most common type of chronic post operative pain are somatic and neuropathic[7].Fixation of mesh with metal staples, in addition to increasing the cost, may lead to new postoperative groin pain [9] which becomes even chronic for a small percentage of patients[10].There appears to exist an entrenched belief within the wider surgical community that mesh fixation is a vital step in the repair which reduces the risk of mesh folding or migration that could lead to early hernia recurrence.Various studies have shown that non fixation of mesh is safe, cost effective, associated with less pain, and leads to no increased risk of hernia recurrence compared with conventional open hernia repair[11].The prevalence of chronic pain after total extra peritoneal hernia repair varies in literature from 9 to 23% during a mean follow up period ranging from 12 to 65 months[9][11].The total extra peritoneal repair (TEP) without mesh fixation is found to be safe and feasible with no increase in recurrence rates [12].This study was taken up to compare safety and efficacy of laparoscopic totally extra peritoneal groin hernia repair with and without mesh fixation. We specifically focused on the impact of post operative pain, estimated analgesic

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requirement, and incidence of hernia recurrence and post operative morbidity in these two group of patients.

AIMS AND OBJECTIVES

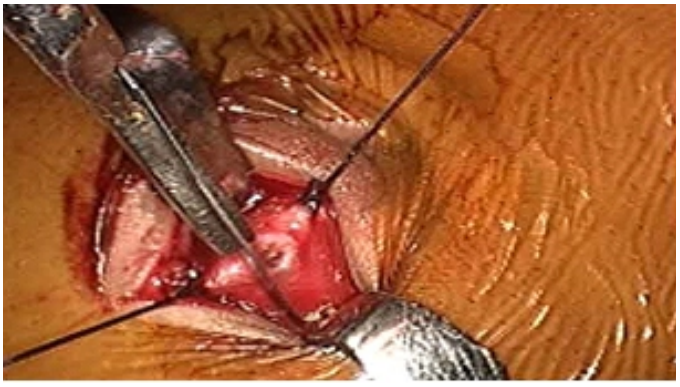
To study the safety and efficacy of laparoscopic totally extra peritoneal groin hernia repair with and without mesh fixation and to compare the post operative morbidity in these two group of patients.

MATERIAL AND METHODS

Standard laparoscopic equipments and instruments were used with no special devices.The study was conducted in 60 patients of groin hernia where 64 laparoscopic repair being carried out as 4 being bilateral.The patients were randomized into two groups 30 patients in each group with two patients of bilateral hernia in each group. All patients of obstructed groin hernia, patients with history of previous pelvic surgery, groin irradiation, active infection, patients below 16 years of age, patient with bleeding diathesis, ascities and patients unsuitable for general anesthesia were excluded from the study.

OPERATIVE TECHNIQUE

After administrating general anesthesia patient was placed in supine position with 15 degree trendelenburg position with arms tucked on the sides. Surgeon stood on the left side of the patient with the monitor at the foot of the table to begin with till the introduction of the first trocar and then surgeon shifted to opposite side of hernia. An incision of 1-1.5 cm was made on the infraumbilical region in the midline.



Incision being placed over anterior rectus shealth between two stay sutures.

After separating the tissues using two curved retractors, the anterior rectus sheath on the same side of hernia would be exposed and a transverse incision of 1-1.5 cm was made over the anterior rectus sheath. The rectus muscle was identified and retracted laterally,using curved artery forceps; a space was made between the muscle and posterior rectus sheath. A blunt cannula was then introduced into the space created and the wound was tightly packed with wet gauze and sutured to prevent gas leak and the silk thread was tied to the trocar to prevent slippage. A 0 degree telescope was then inserted through cannula and the space was created by to and fro movement of telescope under continuous carbon dioxide insufflations at 14mm of mercury. The extraperitoneal space was maintained by an electronic carbon dioxide insufflation with the flow rate of 1-3 liters per minute through the cannula. The working space of extraperitoneal space was maintained at the pre-set level of 14 mm of mercury. After widening the space under direct vision, 0 degree telescope was then replaced by 30 degree telescope.5mm trocar was placed at one third distance from the umbilicus in the midline under vision.Using curved dissector or scissors laterally space was extended deep to the inferior epigastric vessel keeping it attached to the rectus muscle, lateral and cranial dissections was performed till it reaches the line joining the umbilicus and anterior superior iliac spine. Second trocar of 5mm was then introduced at the highest point of dissection between umbilicus and anterior superior iliac spine on the side of hernia. Third trocar of 5mm was introduced midway between the previous trocar and symphysis pubis. The hernia sac was reduced and the peritoneum was retracted cranially.The small indirect sac was dissected out from the cord.A 12 × 15 cm rectangular mesh was introduced into the extra peritoneal space through 10 mm port covering the myopectineal orifice. In one group mesh fixation was carried out using stapler/fibrin sealent/suture at coopers ligament and on the abdomen wall above iliopubic tract.

Mesh fixation with tacks at the Cooper's ligament

In the other group mesh fixation was not done. The carbon dioxide was then exsufflated and the ports closed with 2-0 polyglactin 910 and the skin was closed with staple.

RESULTS

There was no statistically significant difference regarding the preoperative parameters between the two groups as the p value was not significant and both groups were comparable.

Table 1: Comparison of pre-operative parameters

Parameters	Mesh Non Fixation Group [n=30]	Mesh Fixation Group [n=30]	P-value
Mean age	37.1±10.08	39.5±10.31	0.352
Mean BMI	22.73±4.72	21.90±3.65	0.449
Co- morbid condition	7 (23.3%)	10 (33.3%)	0.390
Type of hernia			0.669
A) Direct	10 (33.3%)	7 (23.3%)	
	17 (56.7%)	18 (60%)	
B) Indirect	2 (6.7%)	2 (6.7%)	
C) Mixed	-	-	
D) Femoral	1 (3.3%)	3 (10%)	
E) Recurrent			
Presentation			0.706
A) Unilateral	25 (83.3%)	27 (90%)	
	17 (56.7%)	22 (73.3%)	
i) Right	8 (26.7%)	5 (16.7%)	
ii) Left	5 (16.7%)	3 (10%)	
B) Bilateral			

Duration of surgery in mesh fixation group was 87.75±18.38 minutes while it was 58.15±19.35 minutes in mesh non fixation group. The difference was statistically significant (p=0.0001).

Mesh was fixed in 10 patients with tacks while in 20 patients suture was used to fix the mesh. The site of mesh fixation in mesh fixation group 70% of patients were fixed at cooper's ligament while in 30% were fixed to lateral abdominal wall.

There was no conversion of the procedure either to trans abdominal pre-peritoneal repair or to open repair. Comparision of the intraoperative complication was done, only 3 patients (10%) had bleeding from trocar site in mesh non fixation group, which was statistically non significant with a p value of 0.237 while peritoneal tears were observed in 21 patients (70%) in mesh non fixation group and 23 patients in mesh fixation group which was statistically not significant with a p value of 0.559. The other intraoperative complications observed like bladder injury, bowel injury, injury to vas deferens, injury to iliac vessels, bleeding from inferior epigastric vessels, and anesthesia related complications were not statistically significant difference in either group (p value>0.05), peritoneal tears were never closed in our series. There was no significant adverse effect of intra-peritoneal gas leak on the operative course as the extraperitoneal space could be maintained by intra-peritoneal insertion of Veress needle in the left hypochondrium.

Table2: Distributions of patients according to intra operative complications

Complication	Mesh Non Fixation Group [n=30]	Mesh Fixation Group [n=30]	P-value
Bleeding from Trocar site	3 (10%)	0	0.237
Peritoneal tear	21 (70%)	23 (76.7%)	0.559
Bladder Injury	0	0	-
Bowel Injury	0	0	-
Injury to vas deferens	0	0	-
Injury to iliac vessels	0	0	-
Bleeding from Inferior Epigastric vessel	0	0	-
Anasthesia related complications	0	0	-

The cost effectiveness of TEP repair with mesh fixation increases the cost of the procedure as there is cost of the procedure plus cost of the tacker. Pain on day of surgery at rest was assessed on visual analogue score showed a mean of 2.6±1.16 in mesh fixation group and 2.4±0.86 in mesh non fixation group which was not statistically significant with a p value of 0.530.

Table 3: Distribution of patients according to pain on day of surgery

VAS	Mesh Fixation Group		Mesh Non Fixation Group		P-value
	No.	%age	No.	%age	
Mild (1-3)	23	76.7	28	93.3	0.530
Moderate (4-6)	7	23.3	2	6.7	
Severe (7-10)	0	0	0	0	
Mean±SD	2.6±1.16		2.4±0.86		

Visual analog score of pain assessed on coughing/straining was found to be significantly higher in mesh fixation group(2.8±0.54) from mesh non fixation group(2.3±0.67) p= 0.002.

Table 4: Distribution of patients according to pain on coughing/straining					
VAS	Mesh Fixation Group		Mesh Non Fixation Group		P-value
	No.	%age	No.	%age	
Mild (1-3)	13	43.3	25	83.3	<0.001*
Moderate (4-6)	15	50.0	5	16.7	
Severe (7-10)	2	6.7	0	0	
Mean±SD	3.9±1.53		2.5±0.97		

***Statistically Significant Difference (P-value<0.05)**

The number of parenteral analgesic used on the day of surgery was diclofenac 75mg intramuscular as a single dose.mean number of analgesic required in the mesh fixation group was 2.8±0.54 and 2.3±0.67 in mesh non fixation group statistically significant difference was found as p=0.002.

Table 5: Distribution of patients according to parenteral analgesic used on the day of surgery					
Analgesic Doses	Mesh Fixation Group		Mesh Non Fixation Group		P-value
	No.	%age	No.	%age	
1	0	0.0	5	16.7	0.002*
2	5	16.7	11	36.6	
3	25	83.3	14	46.7	
Mean±SD	2.8±0.54		2.3±0.67		

***Statistically Significant Difference (P-value<0.05)**

The number of oral analgesic tablets consumed in a week following surgery in mesh non fixation group was 14.7±2.34 while it was 15.4±1.94 in mesh fixation group and the difference was not statistically significant.Duration of the hospital stay was 32.9±3.54 hour in mesh fixation group and 34.5±4.64 hour in mesh non fixation group which was statistically not significant (p=0.139) The period of ambulation in mesh fixation group 20% patients were mobile on the day of surgery and rest 80% on first postoperative day while in mesh fixation group 25% patients were mobile on day of surgery and rest 75% on the first post-operative day. This was not statistically significant. Resumption of normal activity in mesh fixation group was 11.1±3.98 days and 9±3.67 days in non mesh fixation group which was not statistically significant (p=0.0911).

Parameters	Mesh Non Fixation Group [n =30]	Mesh Fixation Group [n =30]	P-value
Mean VAS on day of surgery	2.4±0.86	2.6±1.16	0.530
Mean VAS on Coughing	2.5±0.97	3.9±1.53	<0.001*
Mean period of Ambulation (days)	1.4±0.45	1.5±0.68	0.504
Mean number of injectables analgesic used during immediate post operative period	2.3±0.67	2.8±0.54	0.002*
Mean number of oral analgesic tablets used during one week	14.7±2.34	15.4±1.94	0.154
Mean duration of hospital stay (Hours)	32.9±3.54	34.5±4.64	0.139

***Statistically Significant Difference (P-value<0.05)**

On follow up at one week 2 patients had seroma and 3 had port site infection in mesh fixation group and pain in 4 patients in mesh fixation group while two patients had pain in mesh non fixation group. No patient had hematoma , testicular swelling, mesh infection , neuralgia. All the complications were clubbed and statistically fisher test was applied which showed a p value of 0.534 that was not statistically significant.

Table 7: Follow up at 1 week post op:

S.No.	Parameters	Mesh Non Fixation Group n=30	Mesh Fixation Group n=30	Statistical significance (P value)
1	**Pain**			**0.671**
	a) Mild (1-3)	2	4	
	b) Moderate (4-6)			
	c) Severe (7-10)			

2	**Seroma**	0	2	**0.492**
3	**Haematoma**	0	0	**NO**
4	**Testicular Swelling**	0	0	**NO**
5	**Port Site Infection**	0	3	**0.237**
6	**Mesh infection**	0		**NO**
7	**Neuralgia**	0	0(0)	**NO**

The follow up at three weeks only 3 patients has mild pain in mesh non fixation groups while as 4 patients had pain in mesh fixation group, rest no other complication was found at 3 week follow up. Follow up at 6 months there was no complications found in either group. Reoccurrence by means of mesh folding and exposing the hernia defects would be an early phenomenon therefore a follow up of 6 months is justified.The mesh fixation in total extra peritoneal groin hernia repair offered no clinical advantage and increases the cost of the procedure as observed in our study.

DISCUSSION

The issue whether the mesh needs to be fixed in total extra peritoneal repair of groin hernia is far from settled. In our study 90% of patients had unilateral hernia and 10% bilateral hernia in either group. Whereas mesh fixation group had 30% direct, 60% indirect, 5% mixed and 5% recurrent hernia and mesh non fixation group had 25% direct, 60% indirect, 5% mixed and 10% recurrent hernia. There was no patient of femoral hernia in our study. In similar type of study done by Taylor C et al (2008) observed 33% bilateral hernia in either group. While mesh fixation group had 24% direct, 53% indirect, 9% mixed, 4% femoral, 10% recurrent hernia and mesh non fixation group had 25% direct, 52% indirect, 9% mixed and 10% recurrent hernia. The mean duration of surgery in this study in mesh fixation group was 82.75min. and in mesh non fixation group was 58.15min. Similar study conducted by Taylor C et al[11] mean duration of surgery in mesh fixation group was 27min. and in non mesh group was 26.8 min. Study conducted by Egea AM et al[13], mean duration of surgery in mesh fixation group was (45.7±17.9) min and in mesh non fixation group was (39.1 ± 15.3) min. with p value 0.01 statistically not significant. Similarly in our study there was no significant difference in operating time where tacks had been used for fixing the mesh compared to non fixation group. While significant difference in operating time was observed in patients where the suture fixation of mesh had been adopted. This was necessary as the patient could not afford tacker. In the present series visual analog score (VAS) of pain assessed on the day of surgery at rest showed a mean of 2.6±1.16 in fixation group and 2.4±0.86 in non fixation group which is not statistically significant. The similar results were also found by Egea AM et al[13] with a mean of 1.65±1.3 in mesh non fixation group and 1.78±1.4 in mesh fixation group(p=0.26), Taylor C et al[11], Garg P et al[12], Lau H and Patil NG[9]. Whereas visual analog score (VAS) assessed on coughing/straining was found significantly higher mean in mesh fixation group that was 3.9±1.53 from mesh non fixation group where it was 2.5±0.97, which was statistically significant <0.001. In the similar study conducted by Lau H and Patil NG[9] found the prosthetic stapling reported a significantly higher pains score on coughing, but their pain score at rest was equivalent to those of patients without stapling. The mean period of ambulation in the present study showed that in mesh non-fixation group 20% patients were mobile on the day of surgery and rests 80% on the first post operative day, while in fixation group 25% patients were mobile on the day of surgery and rest 75% on the first post operative day. This had shown no statistically significant difference regarding period of ambulation in either group. The similar study done by Garg P et al[12] had also shown no statistically significant difference in two groups regarding the mean period of ambulation.

Chronic pain was defined as the presence of inguinal or scrotal pain or pain in the mid thigh area with or without an alteration in sensitivity, as mentioned by the patient and located on physical examination. In our study we had found no statistically significant difference in incidence of chronic pain in both the groups with a mean follow up of 23.6 weeks in mesh non fixation group and 26.15 in mesh fixation group. Only 2 patients in mesh non fixation group and four in mesh fixation group had pain at three weeks follow up while none at the end of three months and six months follow up. Egea AM et al[13] conducted study with 85 patients in each group and observed no significant difference in post operative pain in either group at 24hr and 1 month. While Topart P et al[16] found that the rate of chronic post operative pain was 14.7% in the tacks/staple group. Similarly statistically significant difference in pain was observed by the study conducted by Taylor C et al[11]. Though the pain was mild in fixation group and did not interfere in daily activities in their study. They advocated selected use of tacks in patients where mesh did not sit well and display the tendency to fold. Garg P et al[12] in a similar study found chronic pain to be present in 24.2% of patients in mesh fixation group and 3.3% in mesh non fixation group, which they found to be statistically significant. In a similar study conducted by Lau H et al[9] observed that selective non stapling of mesh did not confer short term benefits to the patients such as reduced post operative pain and morbidity. Analysis of recurrence is one of the most interesting points for assessing the outcome of hernia surgery. Though our follow up period is less than 1 year, but the intention of our study was not to investigate the long term recurrences rate , reoccurrence by technical error would be expected to a early phenomenon, hence the rationale of follow up of 6 months,. In our study we had not found a single case of recurrence in either group. Egea AM et al[13] conducted a similar study with 85 patient in each group found recurrence in 3 patient in mesh non fixation group (2.7%). In all three cases the mesh had slipped and curled up at the Hasselbach's triangle leaving the new defect directly over the pubis. They were selective in fixing the mesh with the large size direct and bilateral hernias. In our study we had fixed the mesh at cooper's ligament where suture had been used as the material for fixation, while where tacks had been used the mesh was fixed at the cooper's ligament as well as rectus and transverse abdominus muscle. Similar method of mesh fixation with tacks had been adopted by Lau H et al[9], Choy C et al[17] investigated a possible

cause of mesh migration during totally extra peritoneal (TEP) repair. They were of the view that, laparoscopic inguinal hernia repair had a low rate of recurrence in experienced hands, but still could occur as a result of inadequate dissection leading to missed hernias or suboptimal mesh placement. Khajanchee YS et al[4] evaluated 172 laparoscopic herniorrhaphies 105 were accomplished without mesh fixation, and 67 were performed with fixation of mesh to the abdominal wall. There were no significant differences in demographics between the two groups in their study. A non significant increased risk of hernia recurrence with fixation of mesh was observed 4.2 vs. 1.6 per 100 hernia cases. In our series we did not observe post operative complications in either group. The mesh fixation in the total extra peritoneal groin hernia repair offered no clinical advantages and increases the cost of the procedure as observed in our study. Similarly it was observed by Ferzli GS et al[3] that mesh fixation was unnecessary and lead to added cost to the procedure. Egea AM et al[13] conducted a similar study and found that the mean total cost of surgery in the mesh fixation group was significantly higher than the non fixation group (p value= 0.001).

CONCLUSION

We recommend creation of good extra peritoneal space, large size mesh (15 x 12 cm) and optimal placement over the myopectineal orifice, any technical error leading to recurrence would be expected to be an early phenomena and hence the rational for the follow up of mean period of 6 months. Thus we conclude with reasonable confidence that totally extra peritoneal groin hernia repair performed without mesh fixation is safe , feasible and cost effective.

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