

Original Research Article

Evaluation of mesh fixation versus non-fixation in laparoscopic mesh hernioplasty in inguinal hernias

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ABSTRACT

Background: Laparoscopic inguinal hernia repair (LIHR) is usually done by two methods, which vary in approach to the preperitoneal space; transabdominal preperitoneal (TAPP) and totally extraperitoneal (TEP). This study aimed at comparing the effect of mesh fixation and non-fixation in terms of operative time, hospital stay, analgesic requirement, complications and cost analysis with respect to fixation device in LIHR.

Methods: This prospective randomized comparative study included 60 patients of inguinal hernias admitted to the Department of Surgery at Rajendra Hospital, G.M.C, Patiala from July 2016 to September 2017 (duration of study was 15 months). Cases were divided into two groups by draw of lots with group A as mesh fixation (n=30) and group B as non-fixation (n=30).

Results: The results were calculated with chi square test (p value). Results were found to be not significant in two groups in the terms of postoperative analgesia, complications i.e. (intraoperative, postoperative and long term) postoperative hospital stay and time to return for work. The cost of procedure was found to be very high in Group A and results were highly significant (p<0.001).

Conclusion: LIHR repair without mesh fixation shows advantages over mesh fixation, which includes significant less cost of surgery, with comparable intraoperative, postoperative and long-term complications (with no increase in hernia recurrence), hospital stay and mean operative time. Hence, our study favours LIHR without mesh fixation a valuable alternative option.

Keywords: Hernia, Laparoscopic hernia repair, TEP, TAPP, LIHR

INTRODUCTION

LIHR has many advantages over open repairs such as less post-operative pain, early return to daily activities and to work, lesser incidence of neurogenic pain, bleeding, infection, and seroma. Secondly, the inguinal and femoral areas can be inspected bilaterally, bilateral hernias can be repaired in one sitting, and in patients with unilateral hernias, unexpected contralateral hernias can be repaired concomitantly.¹ Thirdly, laparoscopic hernia repair avoids the previous operative site in patients with

recurrent hernia, decreasing the risk for nerve injuries or ischemic orchitis.² LIHR is similar to the concept of inguinal hernia repair proposed by Stoppa.³ 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 study is to compare the outcomes and complications of fixation vs non-fixation of mesh in LIHR. Despite the long period since TEP approach was first described by McKernan and Laws in 1993, there is still debate about the clinical significance of mesh fixation.

METHODS

Inclusion criteria

Patients who were willing to participate and provided informed consent, were included in the study. Patients diagnosed clinically with direct and indirect inguinal hernia, unilateral, and bi-lateral inguinal hernias were included in the study.

Exclusion criteria

Patients that were unfit for general anaesthesia, who didn't give the consent, who were diagnosed with acute abdomen with strangulated or infarcted bowel, Incarcerated hernias, patient with densely scarred abdomen were excluded from the study. They were randomized by a draw of lots method into two groups, one of which underwent LIHR with a polypropylene mesh fixed with Protack (5mm) and the other groups underwent surgery without the mesh being fixed. A 15×15 cm polypropylene, monofilament, nonabsorbable mesh that weighed 80 g/m² and had a thickness of 0.50 mm and pore size of 0.5×0.7 mm was used for all patients. The study period was 15 months (July 2016 to September 2017). All the surgeries were performed by a single surgeon. The design of the study was prospective randomized comparative study.

Protack autosuture 5 mm (COVIDIEN) tacker with 30 helical fasteners was selected as a fixation device in Group A. Statistical method applied was chi square test; if $p < 0.05$ then the difference is statistically significant otherwise non-significant.

The study was approved by the ethical committee of Government Medical College and Rajendra Hospital, Patiala (as a part of Postgraduate thesis).

Limitation of the study was non availability of Inguinal MRI for direct measurement of mesh migration.

Procedure

Under general anaesthesia, we have done TEP and TAPP (only when peritoneal breach during TEP or sac reduction with TEP is difficult) technique with direct telescopic dissection of the midline preperitoneal tunnel for all patients. Polypropylene mesh that measures 15×15 cm was used in every case to cover all potential inguinal defects. Mesh fixation was done in all cases of Group A at least in mesh was fixed at 2 points; one at pectineal/coopers' ligament, and another one was 1 cm laterally above the anterior superior iliac spine taking care that no fixation was done in both triangles of pain and doom. Fixation device selected was protack autosuture 5mm (COVIDIEN) tacker with 30 helical fasteners in group A, while in group B, the mesh was inserted without any fixation in all cases.

RESULTS

This study included 60 patients (5 bilateral cases giving 65 total number of hernia repairs) randomized into 2 groups. Group A (mesh fixation) included 30 patients with inguinal hernia; 27 unilateral hernias (14 right and 13 left sided) and 3 bilateral hernias giving total of 33 hernias. Group B (mesh non-fixation group) included 30 patients with inguinal hernia; 28 unilateral hernias (18 right and 10 left sided) and 2 bilateral hernias giving total of 32 hernias. Patients' age ranged in group A from 24 - 67 years old and in group B 16 - 70 years (mean age was 47.37 and 48.67 years; (p value > 0.05). Two and Three are female cases respectively in group A and B in this study.

Duration of illness in group A range from 15 days to 2 yrs and in group B from 1 month to 3 yrs with a mean of 5.23 months and 5.73 months respectively (p value > 0.05)

Rescue analgesic doses were administered on demand of the patient after assessing VAS at 6, 24 and 48 hrs of surgery. In group A, the dose of injectable analgesic required ranged from 2-5 doses with mean of 2.67 ± 0.922 and in group B, the dose of injectable analgesic ranged from 2-4 doses with mean of 2.27 ± 0.253 . (p value > 0.05) (Table 1)

Table 1: Comparison for analgesic requirement.

DOAR (no. of ampoules)	Group A		Group B	
	No.	%	No.	%
2-3	18	60.0	24	80.00
3-4	5	16.67	4	13.33
≥4	7	23.33	2	6.67
Total	30	100.0	30	100.0
Range	2-5		2-4	
Mean ±SD	2.67±0.922		2.27±0.253	
Chi Square	3.746			
P value	0.154			
Significance	NS			

Operative time ranged from 35 to 70 minutes in group A and from 25 to 60 minutes in group B (mean operative time 50.06 and 47.26 minutes; (p value > 0.05). In bilateral cases, operative time was measured for each side alone by adding the initial access time to both sides. There was conversion from TEP to TAPP one and three cases respectively in case of group A or B (Table 3).

The important time was calculated from the first stroke of knife to last stitch of closure. In group A operative time ranged from 35 minutes to 70 minutes with mean duration of 50.06 ± 9.88 minutes where as in group B it ranged from 25 to 60 minutes with mean duration of 47.26 ± 9.03 minutes. The difference was found to be non-significant ($p = 0.445$) (Table 3).

Table 2: Comparison of complications in two groups.

S. no.	Complications	Group A (n=30)		Group B (n=30)		P value	
		No	%	No	%		
1	Intra OP	Hemorrhage	1	3.33	1	3.33	1 (>0.05)
		Bladder injury	0	-	0	-	-
		Conversion to TAPP	1	3.33	3	10	0.3 (>0.05)
		Conversion to open	0	-	0	-	-
2	Post OP	Fever	0	-	1	3.33	0.313 (>0.05)
		Urinary Retention	3	10	2	6.67	0.640 (>0.05)
		Wound Seroma	3	10	0	-	0.076 (>0.05)
		Wound infection	0	-	1	3.33	0.313 (>0.05)
		Surgical emphysema	0	-	0	-	-
		Testicular swelling	0	-	0	-	-
		Testicular Tenderness	0	-	0	-	-
3	Late	Chronic groin pain(>6mon)	1	3.33	0	-	0.313 (>0.05)
		Orchitis	0	-	0	-	-
		Testicular atrophy	0	-	0	-	-
		Recurrence	0	-	0	-	-

Table 3: Comparison of operative time.

Operative time	Group A		Group B	
	No.	%	No.	%
<45 min	15	50.0	13	43.33
46-60 min	12	40.0	17	56.67
61-75 min	3	10.0	0	0.0
total	30	100.0	30	100.0
Range	35-70 min		25-60 min	
Mean ±SD	50.06±9.88(min)		47.26±9.03(min)	
P value	0.445			
Significance	NS			

Table 4: Cost of procedure.

Variables	Group A (Rs)	Group B (Rs)
Mesh	700-1000	700-1000
Hospital stay	30rs /day	30rs /day
Operation fees	1000/-	1000/-
Fixation device	2430	No
Mean±SD	7601.30±71.43	5101.20±127.98
P value	<0.001	
Significance	Highly significant	

Mean cost of procedure in group A was 7601.30 ±71.43 Rs and in group B was 5101±127.98 Rs. The results came out to be highly significant (p value <0.001).

The postoperative hospital stays on comparison in both groups showed that the mean postoperative hospital stay in patients in group A was 2.00±0.78 days whereas in patients of group B it was 1.66±0.84 days. This was found to be statistically non-significant (p>0.05).

Table 5: Comparison of postoperative hospital stay.

Admitted for post op days	Group A		Group B	
	No.	%	No.	%
0-2	8	26.67	16	53.33
2-4	21	70.0	13	43.33
4-6	1	3.33	1	3.33
Total	30	100.0	30	100.0
Range	1-4 Days		1-4 Days	
Mean±SD	2.00±0.78		1.66±0.84	
Chi Square	4.549			
P value	0.103			
Significance	NS			

Follow up

All the patients were called for follow up in surgery OPD on the 10th postoperative day when the sutures were removed, 1 month, 3 months and 6 months. However, patients operated early in this study were followed three monthly till the end of the study and the check up for all in the complications was done. The mean follow-up period of the present study was 9.36± 2.46 months. The minimum follow-up period of the study was 6 months. 73% patients were followed for less than 1 year and 27% patients were followed for more than 1 year. This study represents follow up results as shown

At 10th pod follow up, 7 patients in group A and 3 in group B had pain/discomfort in groin area (calculated by VAS) for which patients needed upscaling of already prescribed oral analgesics. None of the patients in group A but 1 patient in group B had superficial wound infection, for which pus c/s sent and antibiotics were prescribed accordingly. None of the patient had swelling/, recurrence/ mesh migration during this period. With VAS any score from 1-10 was considered as “yes” for pain.

Table 6: Comparison at 10th post op day.

S. no.	Complication	Group A (n=30)		Group B (n=30)		P value	Significance
		No	%	No	%		
1	Pain/discomfort	7	23.33	3	10	0.166	NS
2	Wound infection	0	-	1	3.33	0.313	NS
3	Ambulation	Normal	-	Normal	-	>0.05	NS
4	Swelling	-	-	-	-	>0.05	NS
5	Recurrence	-	-	-	-	>0.05	NS
6.	Mesh migration	-	-	-	-	>0.05	NS
7	Total complications	7	23.33	4	13.3	>0.05	NS

Table 7: Comparison of follow up (1 month).

S. no.	Complication	Group A (n=30)		Group B (n=30)		P value	Significance
		No.	%	No.	%		
1	Pain/discomfort	4	13.33%	2	6.67	>0.05	NS
2	Wound infection	0	-	0	-	>0.05	NS
3	Ambulation	Normal	-	Normal	-	>0.05	NS
4	Swelling	-	-	-	-	>0.05	NS
5	Recurrence	-	-	-	-	>0.05	NS
6	Total complications	4	13.33	2	6.67	>0.05	NS

Table 8: Comparison of follow up (3 month).

S. no.	Complication	Group A (n=30)		Group B (n=30)		P value	Significance
		No	%	No	%		
1	Pain/discomfort	2	6.67	1	3.33	>0.05	NS
2	Wound infection	0	-	0	-	>0.05	NS
3	Ambulation	Normal	-	Normal	-	>0.05	NS
4	Swelling	0	-	-	-	>0.05	NS
5	Recurrence	0	-	-	-	>0.05	NS
5	Total complications	2	6.67	1	3.33	>0.05	NS

Table 9: Comparison of follow up (6 month).

S. no.	Complication	Group A (n=30)		Group B (n=30)		P value	Significance
		No.	%	No.	%		
1	Pain/discomfort	1	3.33	0	-	>0.05	NS
2	Wound infection	0	-	0	-	>0.05	NS
3	Ambulation	Normal	-	Normal	-	>0.05	NS
4	Swelling	0	-	-	-	>0.05	NS
5	Recurrence	0	-	-	-	>0.05	NS
6	Mesh migration	0	-	0	-	>0.05	NS
5	Total complications	1	3.33	0	-	>0.05	NS

At 1 month follow up, 4 patients in group A and 2 patients in group B had pain/discomfort in groin area for which they were prescribed oral analgesics. None of the patients in group A/B had wound infection, swelling, recurrence during this period.

At 3 months follow up, 2 patients in group A and one patient in group B had pain/discomfort in groin area for which they were prescribed oral analgesics. None of the

patients in group A/B had wound infection, swelling, recurrence during this period.

At 6 months follow up, one of the patients in group A or none in group B had pain/discomfort in groin area. No patient in either group had wound infection, swelling, recurrence /mesh migration during this period.

DISCUSSION

Laparoscopic groin hernia can be repaired by three different techniques TAPP, Intraabdominal onlay mesh repair (IPOM), TEP. In TEP, complications associated with incision of peritoneum or intraabdominal placement of mesh are avoided because the mesh is placed between the underside of the abdominal wall and the peritoneum, fixing the mesh to Cooper's ligament and the aponeurotic sling.²

Overall, 14 cases and 18 cases out of group A and B were of right-side inguinal hernia and rest were left sided. Out of these cases 5 in group A and 6 in group B were direct. Total patients with left inguinal hernia were 13 in group A and 10 in group B and out of these 6 in group A and 5 in group B were direct in each group. Three patients had recurrent hernia; all the other were primary hernias. In group A, 3 patients and in Group B 2 patients had bilateral hernia, all were repaired at the same time. Present study had 38% direct and 68% had indirect component of hernias with 55% as right sided hernias, 38% as left sided hernias and 7% as both sided; states that right sided indirect components were more common in a multi centre trial conducted by , there were 686 patients with 869 hernias; 366 (42.1%) were direct, 414 (47.6%) were indirect, 22 (2.5%) were femoral, and 67 (7.7%) were combination hernias.⁴

The mean operative time and length of hospital stay were similar in both fixation and non-fixation of mesh groups concluded by states that the mean operative time was significantly higher in the mesh fixation group.^{5,6}

In group A operative time ranged from 35 minutes to 70 minutes with mean duration of 50.06 ± 9.88 min where as in group B it ranged from 25 to 60 minutes with mean duration of 47.26 ± 9.03 min. The results were found to be non-significant in contrast to Ta as the time of application of tacker in group A and no tacker application in group B is somehow comparable as tacker itself is an automatic suture device and it take very less time to fire it plus the fixation was done only at two points which causes hardly a difference. In our study one patient in each group had minor hemorrhage; which was associated during dissection of sac in group A and was controlled by electrocautery, and in group B it was associated during skeletonization of cord structures which was also controlled in same way. Placing all trocars under direct vision, higher magnification in laparoscopy, no dissection in triangle of doom, high end energy sources, experience surgeon probably avoided major hemorrhage in this study.

Spaw et al named the triangle, formed by vas deferens on medial side, testicular vessels on lateral side with apex at internal ring and peritoneal reflection at the base.⁷ The triangle of doom contains the external iliac artery and vein. Direct pressure tamponade or electro diathermy is usually sufficient, though rarely a trans fascial or intracorporeal suture may be necessary. In our study 3

patients (10%) in group A and 2 patients (6.67%) in group B had urinary retention because of which patients were catheterized, the difference was found to be statistically non-significant.

Increase age, male sex, general anesthesia, increased narcotic analgesia and postoperative intravenous fluid administration are the important risk factors associated with increased incidence of urinary retention in LIHR.

The localized accumulation of serum is common with the use of synthetic mesh in hernia repairs, and is probably a physiological reaction to the foreign body. They usually resolve spontaneously and should not be aspirated repeatedly otherwise bacterial contamination can occur.⁴

Garg P et al and Sajid MS et al concluded that there is no significant difference in seroma formation in fixation and non-fixation groups.^{5,9}

Our study showed seroma formation in 3 cases (10% cases) in group A, none in group B. All of them resolved spontaneously with conservative management. Difference was not found to be significant in favour with Garg P et al and Sajid MS et al.^{5,9}

Seroma formation can be avoided by minimizing dissection of the hernial sac from the cord structures, fixing the direct sac to pubic bone and fenestrating the transversalis fascia in a direct hernia.

Superficial wound infection can be resolved by treatment with a combination of antibiotics and wound drainage, whereas deep-seated mesh infection, which can lead to chronic groin sepsis, usually requires removal of the mesh. When infection occurs in a prosthetic repair it is wise to drain the infection, which is usually superficial, it is rarely necessary to remove the mesh.¹⁰

3 male patients were evaluated who developed postoperative mesh infection after LIHR. In all the three cases, infection could not be stopped after diagnosis despite drainage and antibiotic coverage, and then it was decided to remove the mesh.

In our study, there was no case in group A with wound infection, 1 case (3.3%) in group B had wound infection, which was treated by antibiotics according to pus c/s there arose no need for mesh removal. Careful preoperative skin preparation, preoperative surgical area hair removal, atraumatic dissection and gentle tissue handling and aseptic handling of mesh (changing of gloves before mesh insertion) prevented deep seated wound infection in present study.

Recurrences after TEP usually occur within first 6 months after surgery, as the result of a technical error.¹¹

A mesh size of 10×15 cm is recommended in laparoscopic repairs without fixation. In our study, a standard of 15×15 cm polypropylene mesh tailored into

15x13 cm was used which ensured a wide overlap of the myopectineal orifice.

Elimination of tack fixation of mesh in TEP inguinal hernia repair is associated with no difference in the risk of hernia recurrence as stated by Sajid et al. In our study none of the study groups had recurrence in favour of the literature as described above, which showed that non-fixation of mesh in TEP repair was not associated with an increased risk of hernia recurrence. In our study as there was no case of early recurrence which is an indirect evidence that there was no significant mesh migration in either of the group. We couldn't feel any abnormal swelling or any mesh at superficial ring or so when examined on POD 10th and 6 months post op; mesh would only be palpable if there is any significant migration of mesh. (Clinical examination was done by same surgeon)

Non-fixation of mesh is not a risk for mesh migration can be explained by the fact that whenever the extra pneumoperitoneum is deflated, the peritoneum tends to return completely to its original position, fixing the mesh against the pelvic wall as a "sandwich." Our study represents early recurrences only as long term follow up is limited in this series.

In the present study, the mean cost of surgery in rupees in without fixation of mesh (Group B) group is less compared to with fixation of mesh (Group A). Group B (Rs.5101) versus Group A (Rs.7601.30), p value <0.0001. The cost of surgery in Group B was significantly less compared to Group A.

Tam KW et al, Taylor C et al concluded that elimination of tack fixation of mesh in TEP repair is associated with significantly decreased operative cost^{6,12}

CONCLUSION

LIHR repair without mesh fixation shows advantages over mesh fixation, which includes significant less cost of surgery, with comparable post-operative complications, hospital stay and mean operative time with no increase in rate of hernia recurrence.

Hence our study favours the LIHR without mesh fixation a valuable alternative option in inguinal hernia repairs.

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