

Original Research Article

Suture mesh fixation versus glue mesh fixation in open Lichtenstein inguinal hernia repair

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ABSTRACT

Background: This randomized controlled trials was conducted for systematic comparison of suture mesh fixation (SMF) versus glue mesh fixation (GMF) in open inguinal hernia repair with regards to chronic groin pain, recurrence, operative time, post operative pain and postoperative complications.

Methods: This study was a single-center, prospective randomized, controlled trial of two groups. It compared post-operative outcomes of mesh fixation with suture (Group A) versus glue (Group B). It was done at Baroda Medical College and S.S.G. Hospital, from May 2018 to January 2019 for case study, intervention and followed up for 9 months till October 2019.

Results: Intra operative time duration for mesh fixation is less in Group B (glue mesh fixation) as compare with Group A (suture mesh fixation) with the statistically significant p value of 0.003. Post-operative pain score (mean VAS score) is significantly less in group B. Mean VAS in group A was 1.27 at 3 month while in group B was 1.06 with the p value of 0.048 on 3 month, which is statistically significant. It suggests that chronic groin pain (pain at or after 3 month) significantly less in group B as compared with group A.

Conclusions: Mesh fixation by glue has advantage of less intra operative time duration and less post-operative pain and chronic groin pain as compare to mesh fixation by suture.

Keywords: Suture mesh fixation, Glue mesh fixation, Chronic groin pain, Intra operative time, VAS score

INTRODUCTION

An inguinal hernia is defined as a protrusion of a viscous or a part of a viscous into the inguinal canal either through deep ring or through Hesselbach's triangle.

Since the time Bassini described his technique an ideal hernia repair should be tension free, tissue based, with no potential damage to vital structures, no long term pain or complications and no recurrence. Chronic inguinal pain occurs in 16% to 60% patients postoperatively irrespective of its mild intensity, it substantially affects quality of life of the patient.¹

Many explanations have been proposed for postoperative groin pain which are: neural injury, nerve entrapment, inflammatory response to mesh, type of repair and suture placement. Not much evidence is found on type of suture affecting chronic pain after inguinal hernia repair. The reported incidence of CGP varies from 0.7% to 62.9% in the medical literature.

Lichtenstein hernioplasty first described in 1989 is widely accepted technique for open repair of inguinal hernia due to its safety, efficacy, and low recurrence rates. Even in the laparoscopic era, due to long and complex learning curve of laparoscopic hernia repair, open Lichtenstein tension

free hernioplasty is accepted as gold standard in inguinal hernia repair in modern era.^{2,3}

In post-operative periods, patient may undergo into complications like early recurrence and groin pain, seroma formation, wound infection, hematoma formation and urinary retention.

Early recurrence is usually due to operation related factors like, tissue tension while suturing, suture material used, way of dealing with the sac (either invagination or ligation and excision), type of hernia repair, post-operative infection and other post-operative complications (hematoma, seroma) and at the last experience of the surgeon.⁴

Post-operative pain may be either acute or chronic. Chronic pain is defined as pain persisting beyond the normal tissue healing time: 3 months at groin region after inguinal hernia repair.^{5,6,7}

Use of atraumatic mesh fixation techniques (fibrin or butyl-2-cyanoacrylate glues) have gained popularity in recent years over suture mesh fixation.

Studies have demonstrated advantage of glue mesh fixation like

Decrease operative time. Decrease postoperative pain. Decrease postoperative complication. Decrease recurrence. Decrease length of hospital stay.

In hernia surgery, suture mesh fixation versus glue mesh fixation in open Lichtenstein Inguinal hernia repair is a topic of debate since many years. Various researchers have done many trials on this topic.

Ladwa et al. Seven randomised controlled trials encompassing 1259 patients were retrieved from the electronic databases.¹ There were 628 patients in the SMF group and 653 patients in the GMF group. In the meta-analysis, postoperative complications (RR, 1.07; 95% CI, 0.72, 1.58; $z=0.34$; $p=0.74$), postoperative pain (SMD, 0.31; 95% CI, -0.03, 0.64; $z=1.81$; $p=0.07$), chronic groin pain (RR, 1.60; 95% CI, 0.78, 3.28; $z=1.28$; $p=0.20$) and length of hospital stay (SMD, 0.06; 95% CI, -0.08, 0.20; $z=0.82$; $p=0.41$) were statistically comparable between two techniques of mesh fixation in OIHR. However, GMF was associated with a reduced operating time (SMD, 0.15; 95% CI, 0.03, 0.26; $z=2.38$; $p=0.02$).

Tebala et al forty-five patients were included in the trial. Nineteen patients were randomly allocated to Group A (suture), 26 to group B (glue). In particular, the "glue" technique was considered easier and quicker, early postoperative pain and pain between 48 hours and 1 month after the operation were significantly lower in Group B.⁸ Long term pain shows a clear difference, but this is not statistically significant maybe due to the low number of cases.

Thus, objective of this study was systematic analysis of the randomized, controlled trials comparing suture mesh fixation (SMF) versus glue mesh fixation (GMF) in open inguinal hernia repair with regards to chronic groin pain, recurrence, operative time, post operative pain and postoperative complications.

Aims of study

This study compared suture mesh fixation with N butyl cyanoacrylate glue mesh fixation in open inguinal hernia repair, with regards to:

Primary aim: to evaluate early (up to 48 hours) and late postoperative pain (48 hours to 1 month) and chronic groin pain (pain persisting after 3 months)

Secondary aim: to find out operative time from keeping the mesh on posterior wall up to the starting of closure of external oblique aponeurosis, use and need of pain killers after 24 hours, length of hospital stay, early recurrence rate (within 9 months), post-operative complication (seroma, wound infection).

METHODS

The present study was a single-center, prospective randomized, controlled two group study. The study was done at Baroda Medical College and S.S.G. Hospital from May 2018 to January 2019 for case study, intervention and followed up for 9 months till October 2019.

Inclusion criteria

Patients above 18 years of age operated by open Lichtenstein method of hernia repair will be included in study.

Exclusion criteria

Age <18 years. All patients operated for hernia other than Lichtenstein repair. Patients operated on emergency basis. Recurrent hernia. Patient not giving consent. Patient not fit for anesthesia.

Sample size

The sample size was calculated to be 40 subjects for each of two groups at alpha error 0.05 and 80% power of study. They were randomized into two groups by blind envelop method into – Group A and Group B.

Group A: Mesh fixation was done by suture material (n=40).

Group B: Mesh fixation was done by N-butyl 2-cyanoacrylate glue (n=40).

All the cases in both the groups were followed for a period of 9 months post operatively. Follow up visits were at

seventh day, fifteenth day, at one month, and at third month, six month, nine month after surgery either on OPD basis or by telephonic conversations.

Operative procedure

All the cases undergoing open Lichtenstein tension free hernioplasty under spinal anesthesia.

Statistical methods

Statistical software: The Statistical software namely, MedCalc Software Version 12.5.0, was used for the analysis of the data and Microsoft word and Excel have been used to generate graphs and tables.

Descriptive and inferential statistical analysis has been carried out in the present study.

Results on continuous measurements are presented on Mean±SD (Min-Max) and results on categorical measurements are presented in number (%). Significance is assessed at 5 % level of significance.

The following assumptions on data is made: dependent variables should be normally distributed, samples drawn from the population should be random, cases of the samples should be independent. Student t test (two tailed,

independent) has been used to find the significance of study parameters on continuous scale between two groups (Inter group analysis) on metric parameters. Chi-square/ Fisher Exact test has been used to find the significance of study parameters on categorical scale between two or more groups.

RESULTS

The objectives of this study was to compare suture mesh fixation with glue mesh fixation in open inguinal hernia repair with regards to chronic groin pain, recurrence, operative time, postoperative complications. The observations made in this study between group A and group B are as follows:

No significant difference (p value=0.610) was seen in the mean age of two groups when compared using independent t test. So age factor is ruled out in this study (Table 1).

No significant difference was seen in gender distribution among two groups when compared using chi square test as p value is 0.338 (Table 2).

There was no significant difference in the distribution of DM, HTN and any other co morbidities among two groups when compared using chi square test as p>0.05 (Table 3).

Table 1: Group wise comparison of mean age.

Age in Years	Group A (n=40)		Group B (n=40)		Total (n=80)	
	N	%	N	%	N	%
21-40	7	17.5	8	20	15	18.75
41-60	20	50	20	50	40	50
61-80	13	32.5	12	30	25	31.25
Mean ± SD	54.23±15.012		52.50±15.081		P=0.610	

Table 2: Gender distribution.

Gender	Group A (n=40)		Group B (n=40)		Total (n=80)	
	N	%	N	%	N	%
Male	36	90	38	95	74	92.5
Female	4	10	2	5	6	7.5
P value	0.338 NS					

Table 3: Distribution according to associated comorbidities.

Associated comorbidities	Group A (n=40)		Group B (n=40)		Total (n=80)	
	N	%	N	%	N	%
DM	1	2.5	1	2.5	2	2.5
HTN	2	5.0	2	5.0	4	5.0
Others	0	0	0	0	0	0
No comorbidities	37	92.5	37	92.5	74	92.5
P value	1.0 NS					

Table 4: Distribution according to time taken for fixation of Mesh.

Time Taken for Mesh fixation	Group A (n=40)		Group B (n=40)		Total (n=80)	
	N	%	N	%	N	%
Less than 5 min.	5	12.5	7	17.5	12	15.0
5-10 min.	18	45.0	25	62.5	43	53.8
10-15 min.	5	12.5	8	20.0	13	16.3
15-20 min.	12	30.0	0	0.0	12	15.0
P value	0.003				S	

Table 5: Distribution according to post-operative complications till 15 days.

Groups	Group A (n=40)		Group B (n=40)		Total (n=80)	
	N	%	N	%	N	%
Post operative complications						
No complication	28	70.0	31	77.5	59	73.8
Scrotal oedema	7	17.5	6	15.0	13	16.3
Seroma	4	10.0	3	7.5	7	8.8
Wound infection	1	2.5	0	0.0	1	1.3
P value	0.712 NS					

Table 6: Comparison of mean VAS at different time interval in two groups.

Group	Group A (n=40)		Group B (n=40)		P value (n=80)	
	N	Mean	N	Mean	N	
24- 48 hours	40	6.09	40	4.91	80	0.000
At 7 day	40	4.76	40	3.15	80	0.000
At 15 day	40	4.24	40	2.47	80	0.000
At 1 month	40	2.24	40	1.53	80	0.000
At 3 month	36	1.27	37	1.06	73	0.048
At 6 month	35	1.00	36	1.00	71	-
At 9 month	31	1.00	32	1.00	63	-

Table 7: Comparison of mean postoperative hospital stay in two groups.

Post-operative hospital stay	Group A (n=40)		Group B (n=40)		Total (n=80)	
	N	%	N	%	N	%
Up to 48 hours	2	5	3	7.5	5	6.25
2-3 days	23	57.5	29	72.5	52	65
4-5 days	1	2.5	0	0	1	1.25
6-7 days	14	35	8	20	22	27.5
Mean	4.225		3.675		P=0.317 NS	

Time taken for mesh fixation was found less at statistically significant level in group B, when compared group-wise as $p < 0.05$ (Table 4).

More frequency for complications were reported in group A but it was not statistically significant difference among two groups when compared using chi square test as $p < 0.712$ (Table 5).

VAS score was found to be significantly more among Group A subjects than Group B subjects at 48 hours, at 7th day, 15th day, at 1 month and at 3 months. But at 6 and 9 months VAS score was found to be similar among two groups. It was observed that in patients where glue mesh

fixation is done, had lesser post operative pain as compare to suture mesh fixation however it was not significantly differs in long term follow up (Table 6).

No significant difference was seen in the distribution of the mean post operative hospital stay among two groups as $p > 0.05$ (Table 7).

DISCUSSION

Total 80 patients were included in the present study, which were distributed by blind envelope method in group A (SMF) and in group B (GMF with N-butyl 2 Cyanoacrylate) with 40 patients in each group. Intra

operative findings, post-operative complications along with local recurrence and chronic groin pain in 9 months of follow up period was evaluated.

Age distribution

In our study mean age was between 54.23 ± 15.012 years in group A and 52.50 ± 15.081 years in group B with $p=0.610$, which is statistically not significant and this age distribution is similar in comparison with other studies like Ladwa et al, Jeroukhimov et al, Kharadi et al, Tebula et al, Jenaw et al, Paajanen, Meena et al, Paajanen et al, Lionetti et al¹³, Kim-Fuchs et al, Pierides et al.^{1-3,8-15}

Operation time and mesh fixation time

Ladwa et al did systematic review and meta-analysis involving five studies of subgroup Kim-fuchs et al, Nowobilski et al, Paajanen et al, Testini et al, Campanelli et al for operation time from skin incision to skin closure.^{1,12,14,16-18} While in this study the time for mesh fixation was counted only from putting the mesh to fix the mesh to compare both groups A and B. There was a significant reduction in the whole operating time with GMF compare to SMF during open inguinal hernia repair in above studies.

In our study also significant reduction in time to fix the mesh with GMF in group B compare to group A SMF with p value 0.003 which was statistically significant.

Post-operative pain (VAS Scores) at 3 month for chronic groin pain

Tebula et al found that the mean post operative pain score in Group SMF was 0.8 ± 1.9 and in group GMF was 0 with p value 0.185, which was statistically not significant.⁸

Ladwa et al¹¹ did systematic review and meta-analysis involving four studies for subgroup example: Nowobilski et al, Paajanen et al, Testini et al, Campanelli et al, Wong et al, for post-operative pain following the use of SMF and GMF in open inguinal hernia repair.^{1,12,16-19} Which was statistically not significant.

In our study, mean post-operative pain score is 1.27 ± 0.57 in group A and 1.06 ± 0.343 in group B with p value 0.048, which is statistically significant. Mesh fixation by N-butyl 2-cyanoacrylate glue causes less irritation of nerves as compared to mesh fixed by suture material.

Early complications

As compare to other studies (Jeroukhimov et al, Kharadi et al, Jenaw et al, Paajanen, Meena et al, Paajanen et al) this study shows no significant difference for seroma, scrotal oedema, wound infection and local swelling.^{2,3,9-12}

Late complication: chronic pain and recurrence

Ladwa et al Jenaw et al, Meena et al Lionetti et al found the incidence of chronic groin pain in Group A and in Group B was statistically significant.^{1,9,11,13}

Kim-Fuchs et al Paajanen et al, Jeroukhimov et al, Kharadi et al Paajanen et al Paajanen et al found the incidence of chronic pain in Group A and in Group B was statistically not significant.^{2,3,8,10,12,20}

In our study incidence of chronic pain in group A (n=40) at 3 month was 1.27 and 1.06 in group B (n=40) with p value 0.048. It is found to be statistically significant as in our study, an internationally accepted standard definition of pain (pain beyond 3 months) was used.

In our study, no patient in group A and in group B had recurrence within 9 months of follow up.

Limitations

Small sample size and limited duration follow up for recurrence. As longer duration follow up and multi-centric studies are required for further evaluation. The patients were operated by different surgical teams. It requires multi-centric large randomized control trial studies for better outcome assessment.

CONCLUSION

Based on the results of this study glue mesh fixation approach may be considered as an alternative for mesh fixation in Lichtenstein inguinal Hernia repair. Mesh fixation by glue has advantage of less intra operative time duration and less post-operative pain and chronic groin pain as compared to Mesh fixation by suture. Short term recurrence and complications like seroma, scrotal swelling and wound infection are comparable in both the techniques; however, to judge long term recurrence and other pros and cons of glue mesh fixation larger sample size with multi-centric trials and longer follow up is required in future.

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