Original Research Article

Mesh fixation with fibrin glue in Lichtenstein Hernioplasty

Shabana J Thaha[1], Hemanth S Ghalige[2*], Mahanth H M[3], Satyanarayan V[4], Vinod Ingale[5], Dhananjaya B M[6]

[1]Junior Resident, General Surgery, ESIC MC & PGIMSR, Rajajinagar, Bengaluru,India
[2]Assistant Professor, General Surgery, ESIC MC & PGIMSR,Rajajinagar,Bengaluru,India
[3]Assistant Professor, General Surgery, Raja Rajeswari Medical College, Bengaluru,India
[4]Professor, General Surgery, ESIC MC & PGIMSR,Rajajinagar,Bengaluru,India
[5]Junior Resident, General Surgery, ESIC MC & PGIMSR,Rajajinagar,Bengaluru,India
[6]Senior Resident, General Surgery, BGS GIMS,Bengaluru,India

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Abstract

Introduction: The surgical treatment of inguinal hernias has evolved through several stages to reach a modern and successful era. Inguinal hernia is dealt most commonly by Lichtenstein repair with advance in mesh properties and fixation, new procedures described. Present study undertaken to evaluate Fibrin Glue for fixation of Mesh in Lichtenstein hernia repair.**Aim**: To compare the Lichtenstein hernioplasty with conventional suture mesh fixation and fibrin glue fixation.**Materials and methods**:A prospective study over 2 years involving 72 cases with 2 groups.ie Glue (G group) and Suture (S Group) had 36 patients each were analysed. Operative time, Post-operative pain using Sheffield scale. Time taken to return to their routine activities and total days of hospital stay and other complications of surgery were evaluated. Follow up examination was also planned for 6 months to look for early recurrence and chronic groin pain.**Results**: The operative time was 42.3 minutes in G group and that in S group was 54 minutes. There was no significant difference noted in terms of surgical complications such as hematoma, SSI, ecchymosis, testicular oedema. There was statistical significance in the total number of days stayed in hospital and the numbers of days patients gained to get back to their work and in the development of chronic groin pain.**Conclusion**: Glue fixation of mesh is easily reproducible and less time consuming surgery technique and took lesser time than suture fixation of mesh. The chronic groin pain was absent in glue group and the patients in glue group could gain hospital stay days and easier return to their respective profession as compared to those in suture group. Early return to work and decreased chronic groin pain were advantages for the patient under glue fixation.

Keywords: Fibrin glue, Lichtenstein hernioplasty. chronic groin pain

Introduction

Evolution of inguinal hernia repair over centuries from crude techniques to minimal invasive have occurred. Techniques needed to be refined with each operation, results in modifications of conventional approach to decrease the morbidity of the surgery.The surgical treatment of inguinal hernias has evolved through several stages to reach a modern and successful era. It has been said that the history of groin hernias is the history of surgery itself [1]. An ideal inguinal hernia repair should be tension free, tissue based, with no potential damage to vital structures, no long term pain or complications and no recurrences. Standard of care as of now being Lichtenstein hernioplasty, however when literature search is made regarding the failure, mesh migration is among the more commoner reasons.Fibrin is a biodegradable biological preparation combination of highly concentrated human plasma derived fibrinogen (75-115mg/mL) and thrombin (500IU/mL) [2]. Mixing these components in the presence of calcium chloride leads to the development of a three dimensional matrix of polymerized fibrin fibres in process similar to the biological coagulation.In 1997,Chevrel and Rath first proposed fibrin sealant as an alternate means of mesh fixation in hernia repair, with the aim of reducing the rate of recurrence [3]. Later reported the benefits of fibrin sealant in reducing bleeding complications following hernia repair in patients with impaired coagulation. The purpose of this study is to attempt to establish the influence of this new technique on early clinical outcomes of inguinal hernia repairs and limited study of long term outcomes for mesh used in groin surgeries

**Correspondence*
Dr. Hemanth S Ghalige
Assistant Professor, General Surgery, ESIC MC & PGIMSR, Rajajinagar,Bengaluru,India
E-mail: hemu.gskims@gmail.com

Methods

This study was a single centre, double blind randomized comparative two group surgical study which compares two surgical procedures, as in with conventional Lichtenstein hernioplasty, where mesh fixation by suture material and with fibrin glue. We executed the study on our admitted patients with the diagnosis of primary inguinal hernia in ESIC PGIMSR, Rajajinagar, Bangalore for 24 months .After ethical committee approval with written consent from the patients, they were subjected to either of the surgical method for hernia repair. Individually the procedure and purpose of the study has been conveyed carefully to the patients. The patients were allowed to ask questions freely to make sure that they had understood the entire procedure with the perception of blinding. Patients had also been explained the Sheffield score for pain management in detail

[4,5]. By Sheffield scale for pain.0-no pain,1(mild pain) -no pain at rest but appears during movement,2(moderate) -temporary pain at rest and moderate during movement,3(severe) -constant pain at rest and sever during movement. On the basis of history and clinical examination the diagnosis is made. The detailed history includes age, chief complaints, chronic constipation, urinary complaints etc. history of previous surgeries family history, occupation, marital status etc. same examiner conducted the detailed clinical examination and classification was done based on the European Hernia Society classification [6]. Telephonic contact numbers and detailed address were collected for follow up. The preliminary blood tests were done which was relevant in view of obtain in surgery fitness. A battery of investigations includes, hb % ,random blood sugar, blood urea, serum creatinine, ECG, and routine, urine analysis for sugar, albumin, and microscopy , chest x ray and ultra sound abdomen. If any patient was found to leave any medical contraindication for surgery have been re-evaluated for the surgery after treating the medical condition.

Sample size:Considering mean difference in time taken for surgery to be 12 minutes between G and S group with 95% CI and 80% power, the sample size will be 30 in each group. 10% non-response rate and 10% loss to follow up we will include 36 in each group. We have used Open Epi version 3.03

All the patients with primary uncomplicated inguinal hernia (direct and indirect, unilateral / bilateral) were included in the study. Recurrent hernias and patients who did not consent were excluded from the study.Patients were blinded regarding the type of procedure they were under going and were randomized(computer based randomisation) into either suture fixation group or Fibrin glue group. The procedure was standardised in either group.All surgeries were performed under spinal anaesthesia and polypropylene mesh (heavy weight) 7.5 * 15 cm of same manufacturer. Sheffield score was used for postoperative pain assessment on post op day 1, POD 3,POD 14, POD 14, POD30, POD 90, POD 180. In the suture fixation group an anchor stitch was placed on pubic tubercle and lower border sutured to reflected part of inguinal ligament and conjoint tendon superiorly, using polypropylene 2-0. In the glue group, the same landmarks were utilised then fibrin glue was applied directly from the applicator after preheating and mixing and allowed to set in for 2-3 minutes. External oblique was closed using polypropylene 2-0 in both the groups and patient was followed up at one month,3rd month, 6 months. In the glue fixation group, the mesh is fixed by fibrin glue from the same manufacturer of around 4ml using a duploject system. Operating time was measured as time of entire procedure post anaesthesia. Then the patients have been followed up for postoperative pain using Sheffield score, wound hematoma, wound infection and scrotal swelling. The time for free ambulation, postoperative stay and time to return to routine work was also documented Post op complications, post op pain, hospital stay, return to routine work and return to work analysed.

Statistical Analysis:Descriptive variables expressed in mean, percentage independent 't' test was applied and p value as <0.05 as statistically significant and chi square test for categorised variable. Initial 18 months is utilized for taking patient into study group and last 6 months for follow up and analysis of data

Results

The study population included 72 patients who underwent surgery for inguinal hernia with 36 patients in either group (ie, suture group and glue group). The mean age was 42.6±10.3 years in either group and was not statistically significant as evident in Table 1.

Table 1 :Distribution of patients with age as parameter

			Group		Total	Chi square	P-value
			Glue Closure	Suture Closure			
Age Category	<40 Years	Count	16	16	32	0.014	1.00
		% of Total	22.2%	22.2%	44.4%		
	≥40 Years	Count	20	20	40		
		% of Total	27.8%	27.8%	55.6%		
Total		Count	36	36	72		
		% of Total	50.0%	50.0%	100.0%		
Age (years)		Mean Age	42.4±10.3	42.8±10.0	42.6±10.0	1.58	0.102

Male (96%) were most commonly affected gender in the study group (Table 2). Manual labourors accounted for 79% of the study population who underwent surgery followed by clerks 13% and drivers7%. The association of straining of stools (96%) was noted. However these findings were not statistically significant. Chronic cough was associated in 25% of population but was not statistically significant. Smoking was seen in 38% of the study population. Mean difference in the hospital and work time variables among the study Participants is depicted in Table 3 and shows Operative time, return to work and return to routine activity was statistically significant in glue Group in comparison with Suture group.None of the patients in the study group had ecchymosis, hematoma, SSI. or testicular edema or recurrence.

Table 2 :Gender distribution among study population .

			Group		Total	Chi square	P-value
			Glue Closure	Suture Closure			
Gender	Female	Count	2	1	3	0.346	0.974
		% of Total	2.8%	1.4%	4.2%		
	Male	Count	34	35	69		
		% of Total	47.2%	48.6%	95.8%		
Total		Count	36	36	72		
		% of Total	50.0%	50.0%	100.0%		

Table 3:Mean difference in the hospital and work time variables among the study Participants

	Group	Mean	Std. Deviation	Std. Error Mean	t-value	p-value
Operating time (min)	1.0	42.306	2.5503	.4250	17.899	<0.001
	2.0	54.056	2.9756	.4959		
Hospital stay	1.0	3.444	0.8433	.1405	3.961	0.01
	2.0	4.083	0.7319	.1220		
Routine return	1.0	7.222	0.5268	.1328	0.748	0.091
	2.0	7.083	1.0247	.1708		
Work return	1.0	14.278	0.8489	.1415	5.636	<0.001
	2.0	15.444	0.9085	.1514		

With regards to post operative pain assessment (Tables 4 to 9), the results of pain reduction was similar (not statistically significant) in initial days and only at post operative day 180, Glue group patients were pain free in comparison with Suture group with statistical significance (P=0.0012).

Table 4:Distribution of the study Participants related to the pain status at day 1

		POST OP PAIN -1				Total	Chi square	p-value
		No Pain	Mild	Moderate	Severe			
Glue Closure	Count	0	0	29	07	36	2.320	0.742
	% of Total	0.0	0.0%	40.3%	9.7%	50.0%		
Suture Closure	Count	0	0	26	10	36		
	% of Total	0.0	0.0%	36.2%	13.8%	50.0%		
Total	Count	0	0	55	17	72		
	% of Total	0.0	0.0%	76.4%	24.6%	100.0%		

Table 5:Distribution of the study Participants related to the pain status at day 3

		POST OP PAIN -3				Total	Chi square	p-value
		No Pain	Mild	Moderate	Severe			
Glue Closure	Count	17	15	4	0.0	36	1.345	0.746
	% of Total	23.6%	20.8%	5.6%	0.0	50.0%		
Suture Closure	Count	9	21	6	0.0	36		
	% of Total	12.5%	29.2%	8.3%	0.0	50.0%		
Total	Count	26	36	10	0.0	0		
	% of Total	36.1%	50.0%	13.9%	0.0	0.0		

Table 6: Distribution of the study Participants related to the pain status at day 14

		POST OP PAIN 14				Total	Chi square	p-value
		No Pain	Mild	Moderate	Severe			
Glue Closure	Count	32	4	0	0	36	3.192	0.067
	% of Total	44.4%	5.6%	0.0	0.0	50.0%		
Suture Closure	Count	26	10	0	0	36		
	% of Total	36.1%	13.9%	0.0	0.0	50.0%		
Total	Count	58	14	0	0	0		
	% of Total	80.6%	19.4%	0.0	0.0	0.0		

Table 7: Distribution of the study Participants related to the pain status at day 30

		POST OP PAIN 30				Total	Chi square	p-value
		No Pain	Mild	Moderate	Severe			
Glue Closure	Count	34	2	0	0	36	2.250	0.136
	% of Total	47.2%	2.8%	0.0	0.0	50.0%		

Suture Closure	Count	30	6	0	0	36		
	% of Total	41.7%	8.3%	0.0	0.0	50.0%		
Total	Count	64	8	0	0	0		
	% of Total	88.9%	11.1%	0.0	0.0	0.0		

Table 8: Distribution of the study Participants related to the pain status at 3rd Month

		POST –OP PAIN 3RD MONTH					Chi square	p-value
		No Pain	Mild	Moderate	Severe	Total		
Glue Closure	Count	34	2	0	0	36		
	% of Total	47.2%	2.8%	0.0	0.0	50.0%	2.250	0.136
Suture Closure	Count	30	6	0	0	36		
	% of Total	41.7%	8.3%	0.0	0.0	50.0%		
Total	Count	64	8	0	0	0		
	% of Total	88.9%	11.1%	0.0	0.0	0.0		

Table 9: Distribution of the study Participants related to the pain status at 6th Month

		POST OP PAIN -6 TH MONTH				Total	Chi square	p-value
		No Pain	Mild	Moderate	Severe			
Glue Closure	Count	36	0	0	0	36		
	% of Total	50.0%	0.0%	0.0	0.0	50.0%		
Suture Closure	Count	30	6	0	0	36	7.855	0.0012
	% of Total	41.7%	8.3%	0.0	0.0	50.0%		
Total	Count	66	6	0	0	0		
	% of Total	91.7%	8.3%	0.0	0.0	0.0		

Discussion

The mean age of presentation in our suture mesh fixation was 42.8 years and that of fibrin glue mesh fixation was 42.4 years. On comparison with other studies, an Indian study, reported maximum subjects in the both groups were from age above 60, in our study it was from above 40 in both groups .In the study by Campanelli et al , the average age was 59 years and 58 years in the suture and fibrin group respectively [7].Although our study included both gender participants, the multicentre comparative study group by Campinelli included only male participants. To analyse the mean time difference for operation in this study, it was around 12 minutes and was significant (S>G).When it is compared to the operating time of the other study Girish et al , there showed an inverse relationship where the operating time is more in glue fixation compared to that in suture fixation, though the difference was insignificant there [8].The Campinelli et al showed no significant difference in the operating time among the two groups [7]. Operating time difference in C.Hoyuela et al showed significant values in terms of total operating time (S>G) [9].We could not get any statistically significant difference in pain assessment on Post Operative Day(POD);POD 1, POD 3, POD 14, after one month and after 3 months following surgery. Although the overall pain perception showed an uptrend and a fall. This uptrend and fall fairly well correlated in both studies. The degree of pain though not significant showed a leaning more towards the suture group. The pain assessed on POD at 6 months, which can be considered as the chronic pain showed significant difference in both groups. None of the patients in glue group suffered from any pain by the 6 th month, unlike that in suture group where 6 out of 36 patients perceived pain even after 6 months of surgery. When analysing the post opertive complications, almost all complications had the same trend in both studies. No significant values noted. Similar results were seen in other study, C.Hoyuela et al [**9].**The mean time for return to routine day to day activities is 7.2 days in glue group and that in suture group is 7.08 days which is almost same. Although the glue group patients could get back to their professional work 1 day prior to the number of days taken by the suture group. The p value was less than 0.001 and given a significant value. The total hospital stay analysis was significant in our study with the G group 3.44± 0.84 days and S group with 4.08±0.73 days. When comparing this with Kim-Fusch et al where they had insignificant values [10]. However a common trend of earlier mobilization and discharge was noted in glue group in all studies. The number of patients with recurrence though insignificant with 6 month follow up was similar to other studies as in Campinelli et al [7] and Kim-Fuscher et al [10].

Limitations

Cost of glue versus suture was not considered as all surgeries were conducted under insurance scheme, with no expenditure from the patients.

Conclusion

Operating time for glue mesh fixation took lesser time than that with suture mesh fixation for Lichtenstein hernia. Fixation of mesh with fibrin Glue is quite an easy technique with no potential injury to any underlying vessels or nerve entrapment. The chronic groin pain was absent in fibrin glue mesh fixation and no recurrence with similar complications with glue and suture fixation.

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