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Long term results of cyanoacrylate glue versus suture fixation for mesh in Lichtenstein hernia repair: A prospective randomized controlled trial

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Abstract

Background: Controversies exist as to the best method of mesh fixation in Lichtenstein hernioplasty. The aim of this study was to compare cyanoacrylate glue fixation with suture fixation of mesh, with regards to recurrence rate and chronic groin pain.

Methods: This was a prospective randomized controlled study conducted in a peripheral hospital over a period of seven years. One hundred and fifty six patients of Lichtenstein hernia repair were included. Mesh was fixed by sutures and cyanoacrylate glue in 78 patients each. Only those patients were completed the follow up of 4 years were included in the final analysis.

Results: The mean operative time in suture fixation was 62.56 ± 10.31 versus 52.12 ± 8.68 minutes in glue fixation ($p < 0.0001$). The intra-operative complication rates did not differ significantly between the two techniques ($p = 0.7613$). The post-operative pain scores were significantly lesser in the glue group [5.78 ± 0.17 versus 6.71 ± 0.29 , $p = 0.0341$]. Among the suture fixation group four (12.90%) patients had chronic groin pain, at the end of four-year follow up, as compared to three (10.71%) patients in the glue group ($p = 0.7342$). The severity of chronic groin pain was also not found to be statistically different [5.23 ± 0.09 in suture group versus 5.18 ± 0.11 in glue group, $p = 0.7954$]. The recurrence rates were similar between the two groups.

Conclusion: The frequency and severity of chronic groin pain, and recurrence rate do not depend on the method of mesh fixation.

Keywords: Cyanoacrylate glue, groin hernia, lichtenstein repair, inguinal hernia, chronic groin pain, recurrence

Introduction

To the contemporary surgeon, it would be unthinkable to expect a career without being competent enough in the performance of repair for inguinal hernias. The lifetime risk of groin hernia is 27 - 43% in men and 3 - 6% in women. Worldwide, more than 20 million people undergo inguinal hernia repair annually [1]. In majority of cases, surgical intervention is successful, however, recurrences necessitate reoperations in 10 - 15% of cases [2]. Another major long-term disability that occurs in about 10 - 12% of surgical repairs is chronic groin pain, which is defined as inguinal pain lasting for more than three months [3].

The Lichtenstein repair with an onlay placement of mesh is the criterion standard for open inguinal hernia surgery [4]. Some of the complications of mesh fixation include: mesh migration, hernia recurrence, "meshoma" formation, chronic pain, and infection [5-7]. The various mesh fixation methods in open inguinal hernia repair are: staples, self-fixing, fibrin sealants, glues and sutures [5-8]. Controversies exist as to the best method of fixation. It has been suggested that using glue, in preference to suture, to fix the mesh may decrease the incidence of post-operative pain including chronic groin pain [8-10]. Most of the papers published on chronic groin pain include only a follow-up of 1 year [8-11]. With this thing in mind we conducted a study comparing cyanoacrylate glue (CG) fixation with suture fixation of mesh, in Lichtenstein hernioplasty, with a minimum follow-up of four years.

Methods

This study was a prospective randomized controlled trial comprising of a cohort of 156 patients, 78 each for suture fixation and CG fixation of mesh in Lichtenstein repair.

A computer-generated chart did the randomization. All the repairs were done by a single surgeon (the corresponding author) with primary aim being comparison of recurrence and chronic groin pain in suture versus CG fixation of mesh in Lichtenstein repair. This study was conducted between March 2012 and March 2019 at a peripheral hospital of Kashmir. Patients were operated during the first three years till March 2015.

All of the cases were admitted on an elective basis and only the uncomplicated hernias were taken up for the study. Patients with bilateral and recurrent hernias were excluded from the study along with females, children less than 16 years of age and those with contraindications for general anaesthesia. All of the patients were advised to empty their urinary bladder just before surgery. Lichtenstein repair was done in the standard fashion. In one group, interrupted 2-0 polypropylene sutures (Prolene®; Ethicon by Johnson & Johnson India Pvt. Ltd., Mumbai, IN) were used to fix the mesh to the pubic tubercle, inguinal ligament and the conjoint tendon, while as in the other group, CG (Netacryl®; Dr Reddy's Laboratories Ltd., Hyderabad, IN) was used to fix the

mesh at these sites.

Various intraoperative and postoperative parameters like operative time, complications, postoperative pain, postoperative stay, time to return to activities of daily life and recurrence rates were evaluated. The operative time was defined as the time taken from incising the skin to the time of suturing/stapling of skin. Postoperative pain was measured by visual analog scale (VAS). The pain scores were obtained at 1, 2, 4, 6, 8, 12 and 24 hours postoperatively. Analgesics were administered if the VAS score was > 6. Wound was inspected for any soakage or signs of infection. The follow up was initially done every fortnightly for two months and thereafter monthly for the first year and then every three months for the next three years for a total follow up of four years and the time taken for return to routine work and any recurrence was noted. Patients were also interviewed for chronic groin pain on follow up, which was defined as pain in the inguinal region persisting beyond 3 months. If chronic groin was present, VAS score was used to assess its severity.

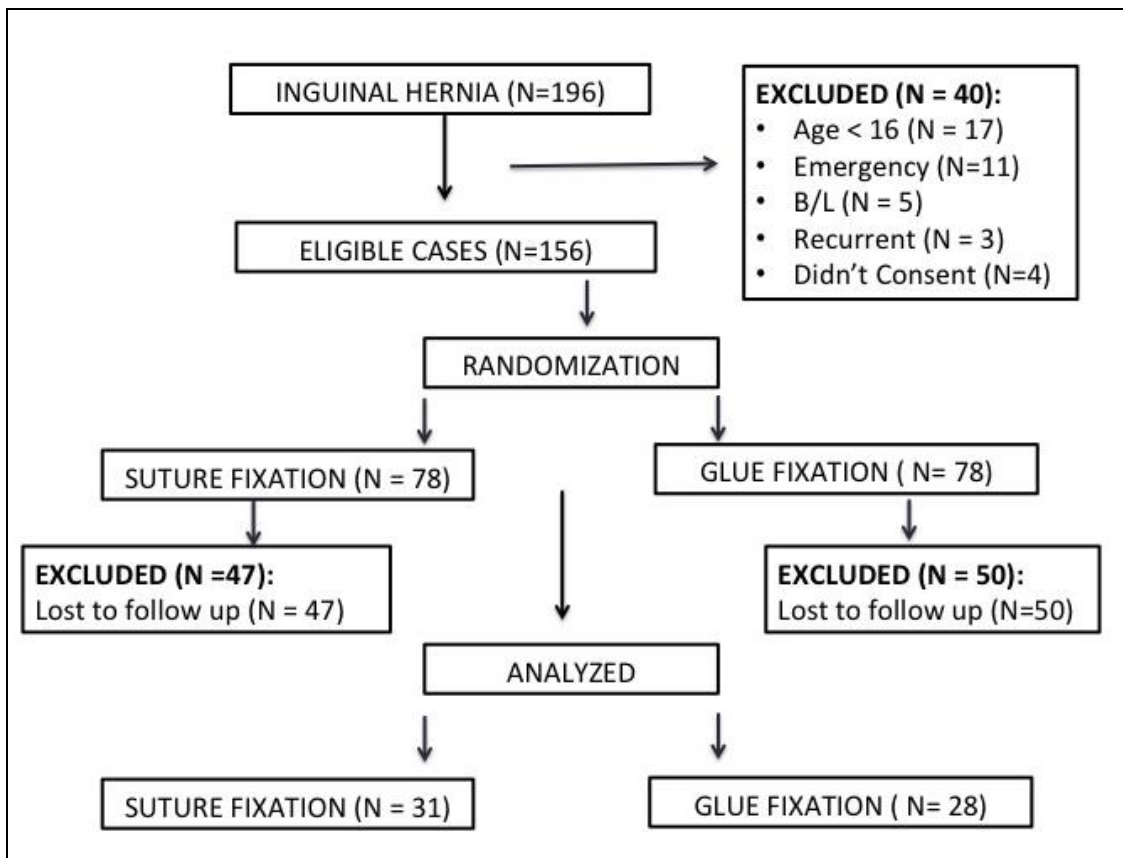


Fig 1: The CONSORT flow diagram of the study.

An approval from the institutional ethical committee was obtained for the purpose of this study. A written and informed consent was taken from the patients for publication and analysis of their data after explaining to them the protocol of the study in their own language. This clinical trial was registered with the local trials registry (CT-11/2012). The data thus collected was compiled and analyzed using SPSS version 22 for Mac (IBM Corporation, New York, 2012). To calculate the P-value, Fisher's exact test and Pearson's chi-square test were applied to compare the frequencies for categorical parameters, and the unpaired t-test was used to compare the means (2-tailed) among continuous variables. The results were calculated on 95% confidence interval. A P-value < 0.05 was considered significant.

Results

During the study period a total of 196 inguinal hernia patients were treated, out of which 40 were excluded as they did not meet the criteria of study protocol. The remaining 156 patients, who underwent Lichtenstein repair, were offered mesh fixation by CG or suture in equal numbers. In the suture fixation group, 47 patients were lost to follow-up and were not included for final analysis. In the CG fixation group, 50 patients were lost to follow up and were not included for final analysis. Thus a total of 31 patients of suture fixation and 28 patients of CG fixation were included in the final analysis [Figure 1].

The baseline parameters were similar in both the groups and all efforts were made to minimize the confounding factors [Table 1]. The mean operative time was significantly increased in the

suture fixation group as compared to the CG fixation group (62.56 ± 10.31 versus 52.12 ± 8.68 minutes, $p < 0.0001$). The total number of intra-operative complications were similar in the two groups [1 (3.22%) versus 1 (3.57%), $p = 0.7648$]. Bleeding was encountered in one patients in each group ($p = 0.7648$), and was easily controlled by local methods and did not need any transfusion. There were no other intra-operative complications

noted in either of the groups.

The mean postoperative pain scores (VAS) were significantly lower in the CG group [5.78 ± 0.17 versus 6.71 ± 0.29 , $p = 0.0341$]. The total number of post-operative complications was similar in both the groups. The various post-operative variables are given in Table 2.

Table 1: Baseline Parameters of the two groups

Parameter	Suture Fixation (N=31)	Glue Fixation (N=28)	P Value	
Mean Age (Years)	52.34 ± 9.42	56.72 ± 8.35	0.7821	
Mean BMI (Kg/m ²)	23.45 ± 0.21	23.12 ± 0.19	0.9665	
EHS Type (N)	Medial	12 (38.70%)	10 (35.72%)	0.3132
	Lateral	19 (61.29%)	18 (64.28%)	0.7954
	Femoral	0	0	-
Defect Size (N)	I (< 1.5 cm)	8 (25.80%)	8 (28.57%)	0.9231
	II (1.5 – 3 cm)	18 (58.06%)	17 (60.71%)	0.8986
	III (> 3 cm)	5 (16.12%)	3 (10.71%)	0.5324

The recurrence rate at four-year follow up was not statistically different in suture group as compared to the CG group [1 (3.22%) versus 1 (3.57%), $p = 0.7648$]. Among the suture fixation group four (12.90%) patients had chronic groin pain, at the end of four-year follow up, as compared to three (10.71%) patients in the CG group ($p = 0.7342$). The severity of chronic groin pain was also not found to be statistically different in the two groups at the end of four years of follow up [5.23 ± 0.09 in suture group versus 5.18 ± 0.11 in CG group, $p = 0.7954$].

Discussion

Inguinal hernia repair is one of the most commonly performed surgeries in the world. Lichtenstein hernioplasty has Grade 'A' recommendation for primary unilateral uncomplicated hernias as per the European Hernia Society guidelines [12]. The mesh fixation in Lichtenstein repair can be accomplished in many ways [5-8]. Synthetic mesh fixation in hernia repair involves a consideration of the strength of fixation versus the risk of trauma to local tissues. The method of fixation of the mesh is one of the factors that have been blamed for postoperative pain. It has been postulated that sutures, mostly non-absorbable, can increase pain by nerve entrapment or foreign body reaction and non-traumatic methods of fixation produce less pain without compromising the outcome [13].

Consensus does not exist about the "best fixation method" and

most of the decisions on fixation depend upon individual preference [3]. Any evidence that reports on a particular fixation method improving various outcome measures may have a significant impact on clinical practice. The current paper reports on the comparison of method of mesh fixation (CG versus suture) in Lichtenstein repair in a homogenous population over a three-year period with an analysis after a follow-up of four years at a district level hospital. To the best of our knowledge, this is the first study in English literature that reports on the severity and incidence of chronic groin pain at four years after Lichtenstein hernioplasty.

The method of mesh fixation was not found to have any significant influence on the intraoperative complication rate or recurrence rate or chronic groin pain rate. In the current study, we found that the operative time was lower with glue as compared to the suture fixing method, as consistent with all the studies. Pain in the immediate post-operative period, is also significantly lower in the glue mesh fixation patients. Although long-term recurrence rates have not been determined and large hernias often have been excluded, none of the randomized controlled studies and meta-analyses conducted till date have reported any significant difference in the recurrence rate in suture versus glue fixation of mesh in Lichtenstein hernioplasty [3, 12-16]. Even with a fairly long follow-up of four-years, the results of our study are consistent with these reports.

Table 2: Post-operative variables of the two groups

Parameter	Suture Fixation (N=31)	Glue Fixation (N=28)	P Value	
Mean Pain Scores (VAS)	6.71 ± 0.29	5.78 ± 0.17	0.0341	
Mean Postop Stay (Days)	1.42 ± 0.37	1.12 ± 0.11	0.0425	
Complications (N)	Seroma	1 (3.22%)	1 (3.57%)	0.7648
	Wound Infection	0	0	-
	Testicular Swelling	1 (3.22%)	1 (3.57%)	0.7648
	Hematoma formation	1 (3.22%)	1 (3.57%)	0.7648
Total Complications (N)	3 (9.67%)	3 (10.71%)	0.7613	
Return to normal Activity (Days)	15.23 ± 1.31	12.24 ± 1.08	0.0312	

Any pain persisting in the groin beyond a period of three months after surgery is known as chronic groin pain [3]. In our study we did not find any difference either in frequency or on the intensity of chronic groin pain at the end of four year follow up in the two groups. Most of the studies published till date have measured chronic pain incidence at 3 months, or at 6 months, and longest only at 1 year [14-22]. The combined chronic pain rates for mesh fixation of various types were: 14.7% for sutures, 7.6% for glue,

3.7% for fibrin sealant, and 18.2% for self-fixing meshes [3]. We believe that with a longer follow-up, the chronic groin pain stabilizes and is independent of the method of fixation, but further studies are warranted to substantiate the facts.

The major causes of postoperative pain are the stretching of the wound during surgery and the length of the fascial incision [23]. As more of stretching occurs during suture fixation of mesh, it is but natural to expect that acute post-operative pain would be

more in the suture fixation group, which was indeed the case. The maximum scores of pain were observed at 4 hours postoperatively in both the groups, presumably due to exhaustion of the effects of analgesia and anesthesia. Less acute postoperative pain translated into early ambulation, acceptance of orals, and discharge of patients in the CG group. This was also reflected in the earlier resumption of routine work by this group of patients. As most of the patients undergoing CG fixation were discharged within the first postoperative day [24 hour period], we believe that this method of fixation might be beneficial in surgeries planned on a day care basis.

The present study has some potential limitations. We acknowledge the fact that more than 50% of the study population was lost to follow-up, but, this reflects the fact that we strongly adhered to our study protocol and only included those participants who completed a follow-up of four years. The sample size was small and the population was homogenous, so extrapolation of results to other parts of the globe may not be valid. Our study was not a double-blinded one. However, the pain assessment was somewhat blinded as all scoring was performed by the attending nurse who was unaware of the ongoing study.

Conclusion

The results of the current study fail to document any definite advantage of glue fixation over suture fixation as regards the incidence and severity of chronic groin pain. Though the glue fixation method scores over suture fixation as regards to the operative time and acute post-operative pain. The recurrence rates are similar in both the methods of fixation.

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