

Original Research Article

**A COMPARATIVE STUDY OF CYANOACRYLATE
SURGICAL GLUE VS POLYPROPYLENE SUTURE
MATERIAL FOR MESH FIXATION IN OPEN INGUINAL
HERNIA SURGERY**

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Abstract

Inguinal hernia is the most common surgical problem presenting to the surgical OPD. Lichtenstein's tension free hernioplasty is the one of the first surgeries learnt by surgical residents. Pain after inguinal hernia surgery is found to be debilitating and alters the quality of life in several patients. The use of sutures to fix the mesh has been implicated in this. Fixing the mesh using cyanoacrylate glue could avoid this complication by atraumatic fixation of the mesh. This study aimed to compare fixation of mesh with N-butyl 2-cyanoacrylate and with sutures in open inguinal hernia repair in terms of immediate and chronic post-operative pain, operative time, hernia recurrence and any other complications, by the end of 1 year after surgery.

Patients and methods: This comparative study was carried out between May 2018 and December 2020 in the Department of General Surgery, ESIC Medical College & Hospital, Kalaburagi, Karnataka. It is a single-blinded study which included 50 patients of primary inguinal hernia, divided by simple randomization, into two equal groups of 25 each to receive either non-absorbable polypropylene sutures (Group A) or N-butyl 2-cyanoacrylate glue (Group B) for polypropylene mesh fixation. Data was collected according to a carefully planned clinical proforma to note the intra-operative times, immediate post-operative pain in the patients and the rate of chronic pain upto 1 year after surgery, hernia recurrence and other complications, if any.

Conclusion: Fixation of the mesh in Lichtenstein repair with cyanoacrylate tissue adhesive conferred significantly lower pain scores in the early postoperative period and at 6 months and 1 year follow-up than the classical suture fixation, and can be used easily by any surgeon regardless the level of skills with no increase in the early or late recurrence rate.

Keywords: Inguinal hernia, hernia repair, cyanoacrylate glue, mesh fixation

Introduction

Inguinal hernia repair is one of the most common general surgical operations performed worldwide [1]. The Lichtenstein technique is the method of open repair most widely used for treatment of inguinal hernia, with which the incidence of recurrence has been remarkably reduced, and this fact has been the most important quality index in inguinal hernia repair [2]. However, chronic groin pain (CGP), also called as iliodynia is a very commonly encountered postoperative problem which depends on various factors like the method of mesh fixation, type of mesh used and even the subjective threshold of pain [3].

The incidence of chronic pain post inguinal hernia repair is estimated to be 0.5-6% [4, 5]. Chronic groin pain has been defined as the pain in the groin region post hernioplasty lasting beyond a period of 3 months [6].

It has been suggested that nerve irritation inflicted by taking sutures may be the principal mechanism to explain CGP after hernia repair. This has rendered alternative, sutureless techniques for mesh fixation of major interest in inguinal hernia surgery. Nonetheless, only scarce data on the use of staplers, [7] spiral tacks, [8] or tissue adhesives [9-11] have been published. Fixation of the mesh with adhesive glue may be considered a better option to decrease the severity of pain after hernia repairs as it is not associated with nerve irritation or entrapment. Initial reports on different tissue glues reported promising results with a lower degree of postoperative pain [9-12].

Alternative mesh fixation techniques using tissue adhesives have demonstrated promising postoperative outcomes, leading to improved surgeon and patient satisfaction. Mesh fixation with cyanoacrylate tissue adhesive as an alternative to standard suture or tack fixation has been investigated, showing similar or improved postoperative outcomes. These methods of hernia mesh fixation have still not been universally accepted.

The aim of the study was to compare the operative outcomes of mesh fixation with polypropylene suture versus that with N-butyl 2-cyanoacrylate glue. The primary objective was to compare the pain in the immediate postoperative period and chronic postoperative pain. The secondary objectives were to compare- Operative time and the complications such as pain, seroma, ecchymosis and wound infections.

Materials and methods

This simple randomized, prospective, comparative study was carried out between May 2018 and December 2020 in the Department of General Surgery, ESIC Medical College and Hospital, Kalaburagi, Karnataka. The present study includes the first 50 patients of primary inguinal hernia. Simple randomization was done by selecting every alternate patient for polypropylene suture mesh fixation (Group A) and N-butyl 2-cyanoacrylate glue mesh fixation (Group B), with both groups having 25 patients each. The patients to be included in the study were done so after explaining the study to them in detail in their local language and consenting patients meeting the inclusion criteria were included. The study was started after obtaining the approval from the Institutional Ethics Committee.

The subjects were included according to the following inclusion and exclusion criteria. The inclusion criteria were patients of age 25 years and above, with uncomplicated unilateral inguinal hernia, patients undergoing open hernioplasty patients willing for regular follow up.

Whereas patients having recurrent inguinal hernias, complicated inguinal hernias namely obstructed, strangulated, and large hernias with scrotal abdomen, recurrent hernia, bilateral inguinal hernias, patients undergoing other concomitant abdominal surgeries, patients on long term analgesics/steroid treatment, patients having connective tissue disorders were excluded.

All the patients underwent basic pre- operative investigations namely CBC, RBS, RFT, LFT, serum electrolytes, serology, chest X-ray, ECG to rule out comorbidities, and were cleared by physician as fit for surgery. Proper anesthesia fitness was sought and all the cases were performed under spinal anesthesia. Single blinding was done and by the rule of simple randomization, alternate patient was selected for either polypropylene suture mesh fixation (Group A) or N-butyl 2-cyanoacrylate glue mesh fixation (Group B). The total intra-operative time of surgery was noted. Post- operatively the patients were put on basic analgesics and pain was monitored using the visual analogue scoring (VAS) scale which was done by a trained staff that was unaware of the method used. Monitoring of pain was done at 6 hours, 24 hours, 72 hours while at the hospital and the patients were followed up in the OPD at 1 week, 1 month, 3 months, 6 months and 1 year. During the stay, pain, seroma, ecchymosis, wound infections and any other complaints were recorded. Patients were discharged and were asked to follow up on given dates for upto 1 year.

Data analysis and master charting will be done using Microsoft Excel software and the results will be analysed using Statistical Package for Social Science (SPSS).

Results

A total of 50 patients were included in the study out of which 25 patient received non-absorbable polypropylene sutures (Group A) and the other 25 patients received N-butyl 2-cyanoacrylate glue (Group B) for polypropylene mesh fixation, as part of the Lichtenstein’s mesh repair. Both the groups had the majority of the patients in the age group of 25 to 60 (Table No. 1). There was no significant difference in the age of the patients in each group (p= 0.95)

Table No. 1: Age of the patients

Age of the Patients	Group A (Suture)	Group B (Glue)	chi-square	p-value	
25-40 years	10	9	0.092	0.95	Not significant at $p < 0.05$
41- 60 years	12	13			
Above 60 years	3	3			
Total	25	25			

The chi-square statistic is 0.0926. The p-value is 0.95474. The result is not significant at $p < 0.05$.

A comparison of the intra- operative time noted for both the groups showed that the mean time for the surgery with sutures (Group A) was 51.96 minutes, whereas the operative time was considerably less when the mesh fixation was done using N-butyl 2-cyanoacrylate glue, with a mean of 41.56 minutes for the completion of surgery, and this finding was statistically significant ($p < 0.05$) (Table No. 2)

Table No. 2: Results of t test for operative time.

Group	Mean	SD	SEM	t value	DF	P value
Group A (Suture)	51.96	5.92	1.18	6.96	48	<0.05
Group B (Glue)	41.56	4.56	0.91			

A comparison of post-operative pain at 6 hours using VAS scores showed that the average pain score in Group A (Suture) was 6.71 whereas it significantly less (p value < 0.00001) in the Group B (Glue) with the average pain score of 5.02 (Table No. 3). Further the patients were assessed for pain at 24 hours, 72 hours while at the hospital and the patients were followed up in the OPD at 1 week, 1 month, 3 months, 6 months and 1 year, and the percentage reductions in the VAS scorings were noted and tabulated, as given in the Table No. 4. It was found that successive percentage reductions in the Group B was consistently higher than in the Group A, suggesting a higher reduction in post-operative pain in the patients of Group B.

The VAS score at 6 months follow up in the Group A and Group B were 1.12 (SD= 0.268) and 0.04 (SD= 0.08) respectively. This showed that at 6 months follow up, the patients with glue fixation had significantly lower VAS scores (p <0.05). Subsequently, none of the patients with glue fixation complained of pain at the 1 year follow up, whereas the mean VAS score for the patients with suture fixation had also reduced to 0.80, indicating the persistence of a mild pain at the 6 months and 1 year follow-ups.

Table No. 3: Comparison of pain at 6 hours by t test

Group	Mean	SD	SEM	t value	DF	P value
Group A (Suture)	6.71	0.75	0.15	7.1309	48	<0.05
Group B (Glue)	5.02	0.92	0.18			

Table No. 4: Comparison of the VAS scores for pain and the percentage reduction over time

GROUP		6 hrs	24 hrs	72 hrs	1 week	1 month	6 months	1 year
Suture (Group A)	Average Score	6.71	6.01	3.89	2.12	1.23	1.12	0.80
	% reduction in pain		10.43	42.02	68.40	81.67	83.31	88.08
Glue (Group B)	Average Score	5.02	3.78	1.70	0.80	0.20	0.04	0.00
	% reduction in pain		24.70	66.13	84.06	96.00	99.20	0.00

There were no intra-operative complications, no seroma, wound infections or ecchymoses or immediate recurrence at the 6 months and 1 year of follow up.

Discussion

This study was done in the wake of rising questions over the incidence of CGP in the inguinal hernia repairs using sutures for fixation of the mesh. Alternative methods of mesh fixation include staplers, spiral tacks and glue. Atraumatic fixation using surgical glues is an interesting idea that can be introduced as an intermediate option between nonmesh fixation and fixation with tack staples.

On the basis of their composition, surgical glues have been classified into 3 different categories: synthetic glues (cyanoacrylates), biological sealants (fibrin-based), and genetically engineered polymer protein glue. These glues have been tested for years with different surgical purposes. Skin closure, cementation of small bone fragments, [13] or hemostasis in uncontrolled bleeding [14] are only a sample of the initial applications for surgical sealants. Cyanoacrylate tissue adhesive is quite cheap, with respect to fibrin glue; it is easily stored even for long time and can be easily applied. This prospective simple randomized clinical trial was aimed at comparing polypropylene suture mesh fixation with N-butyl 2-cyanoacrylate glue mesh fixation in Lichtenstein open hernia repair.

In our study the operative time for the inguinal hernia surgery with glue fixation was significantly lower than the operative time using sutures, which correlates with a meta-analysis conducted by Goeda et al [15]. Ladwa et al also state from their systemic review that there is a significant difference in the time taken to complete the procedure by the 2 methods with less time taken with glue fixation [16].

The study conducted by Negro P et al shows that there is a significant difference in the pain experienced in the immediate postoperative period between the tissue glue group and the suture group, with the suture group experiencing a higher pain [17]. Our present study also shows that the post operative pain scores using VAS were significantly lower in the patients of glue fixation group when compared to the suture fixation group. Furthermore, Quyn et al have also found a significantly lower acute and chronic pain with glue use in their study [18]. In our study the postoperative pain score at the 6 months and 1 year follow up also showed that the chronic pain was significantly lower with glue as compared to the suture fixing method as consistent with all the studies.

Negro et al also state that the difference in pain between both the groups disappears after 1 month. However, they observed complications like hematoma formation and ecchymoses in the glue group [17]. No complications in the form of seroma, wound infection, hematoma, or ecchymoses have occurred in our study in either of the groups.

A mention has to be made of the limitations of this study. The sample size of this study is small, results with a bigger sample size may vary or show different results. It is also a limited duration study due to which recurrence rates could not be compared and a comment on the long-term efficiency cannot be made. Pain being a subjective symptom and the pain threshold being variable from person to person, a preoperative pain threshold assessment was not done.

Conclusion

N-butyl 2-cyanoacrylate glue is a reliable method for fixation of mesh in the Lichtenstein's mesh repair hernia surgery; it is superior to suture fixation of mesh in several aspects. The glue fixation reduces the operative time significantly with no added untoward complications such as wound infections, seroma or ecchymoses. The immediate postoperative pain and chronic groin pain are also significantly lower in the glue fixation of mesh.

Hence, the N-butyl 2-cyanoacrylate glue can be considered as a good alternative for the suture in fixation of the mesh in Lichtenstein's hernia surgery.

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