



A PROSPECTIVE STUDY OF N-BUTYL CYANO ACRYLATE GLUE FIXATION VERSUS SUTURE FIXATION OF MESH IN OPEN REPAIR OF INGUINAL HERNIA

General Surgery

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ABSTRACT

BACKGROUND: The face of inguinal hernia surgery has been under constant evolution with improvements in surgical technique; together with the development of new prosthetic materials and a better understanding of how to use them. Till date, prevention of recurrence was the primary goal of any hernia surgery. With the advent of newer techniques the current focus has shifted to minimizing post-operative pain while continuing to ensure that the primary goal is met. The objective of our study was to compare suture fixation of the mesh with non-mechanical fixation using n-butyl cyanoacrylate (NBCA) glue for open inguinal hernia repair. **METHODS:** A prospective randomized controlled study was carried out at the General surgery department of J.L.N. Hospital, Ajmer between January 2019 and January 2020 consisting of 120 patients with uncomplicated inguinal hernia undergoing standard Lichtenstein's mesh hernioplasty. Endpoints studied were postoperative acute and chronic pain, analgesic requirement in the post-operative period, duration of surgery and complications in the post operative period. **RESULTS:** Operative time was significantly lesser in glue group as compare to suture group. There was no significant difference in the post-operative pain during the entire timeline except at 24 hrs post procedure. However, 2 patients in suture group had chronic pain and complained of mild pain at 6 months follow up and even beyond. Post-operative complications were comparable in both groups. **CONCLUSION:** Our study help us to conclude that mesh fixation with N butyl 2 cyanoacrylate glue is superior to sutures in several aspects.

KEYWORDS

Mesh fixation, N – butyl 2 – cyano acrylate glue, Sutures, Post operative pain

INTRODUCTION

Hernia is a very common occurrence in the surgical OPD and one of the initial procedures that a general surgery resident learns to master. The face of inguinal hernia surgery has been under constant evolution with improvements in surgical technique; together with the development of new prosthetic materials and a better understanding of how to use them. Repair of hernia, minimizing the intraoperative and postoperative complications, early return to normal routine and minimizing the chance of recurrence are main goals of inguinal hernia surgery.

Till date, prevention of recurrence was the primary goal of any hernia surgery. With the advent of newer techniques the current focus has shifted to minimizing post-operative pain while continuing to ensure that the primary goal is met.

A mesh-based repair with Lichtenstein's technique or a laparoscopic repair is recommended for inguinal hernia. One of the main problems associated with mesh repair is chronic groin pain,¹ which occurs as a result of nerve entrapment during mesh fixation.

The current surgical options for mesh fixation include, but are not limited to, sutures, tacks or staples, self-fixing meshes and fibrin or other glues.² Both mechanical and non-mechanical mesh fixation have their own benefits and drawbacks. However, there is no consensus among doctors on the best method for mesh fixation. The choice of options often depends on surgeons' personal preference².

The objective of our study was to compare suture fixation of mesh with non-mechanical fixation using n-butyl cyanoacrylate (NBCA) glue for open inguinal hernia repair. During the comparative study following aspects were compared –

- The operative time, measured from skin incision to closure.
- Pain in post operative period and requirement of analgesia.
- Complications.

MATERIALS AND METHODS

A prospective randomized controlled study was carried out at the General surgery department of J.L.N. Hospital, Ajmer between January 2019 and January 2020 consisting of 120 patients with uncomplicated inguinal hernia undergoing standard Lichtenstein's mesh hernioplasty. These patients were followed up over a period of

six months. Approval from hospital ethical committee was obtained beforehand.

Patients were randomized into 60 patients in the suture mesh fixation group (group A) and 60 patients in n-butyl 2-cyanoacrylate glue mesh fixation group (group B). Randomization was done using sealed envelopes with random numbers in the operating theatre. Patients were blinded about group allocation. In order to maintain uniformity in the surgery performed; patients operated by the same surgical team were included in the study. Operating surgeon was told about method of mesh fixation at time of mesh fixation.

Patients were explained about the study in detail before procuring their consent. Patients with irreducible, obstructed, strangulated, incarcerated or recurrent hernia were excluded from the study. After admission patients were evaluated according to protocol. Completer history, clinical examination and relevant investigations were done, after which fitness for anaesthesia was obtained.

All the patients included in the study were informed about the randomization of the procedure whereby either suture or NBCA glue could be used for mesh fixation during his/her surgery. Details of the procedure and the type of anaesthesia including their advantages, disadvantages and possible complications were explained to the patient.

Routine preoperative preparations included part preparation, keeping the patient fasting overnight, injection of tetanus toxoid, sedation at night and preoperative does of Inj. Cefotaxime 1 gm I/V just before the operation (after AST).

Surgical procedure was as follows. After appropriate anaesthesia (regional or general) patient was made to lie supine on the operating table and painting and drapping was done. An inguinal skin crease incision was made on the operating side. Subcutaneous tissue separated and reached upto external oblique aponeurosis. Superficial inguinal ring was identified and external oblique aponeurosis was cut along the superficial inguinal ring. Inguinal canal was opened. Cord structures were identified and lifted at the level of pubic tubercle. There may be a direct or indirect sac present. Direct sac was buried by taking continuous sutures on the posterior wall. If indirect sac was present; sac was separated from the cord structures upto the deep inguinal ring,

sac opened, contents reduced and the proximal end of the sac was transfixed at the level of deep inguinal ring, distal end of the sac, if present was left open. Space was created for placement of mesh. Mesh was placed over the posterior wall and was fixed with polypropylene suture or NBGA glue; any one depending on which group the patient belongs to. After mesh fixation haemostasis was ensured and wound closure was done in layers and sterile dressing applied. Duration of surgery from skin incision to skin closure was recorded.

For post-operative pain, One dose of non-steroidal analgesic (injection diclofenac 50 mg) was given per-operative and this was repeated after 12 hrs. Thereafter, analgesics (diclofenac 50 mg + paracetamol 500 mg tablets) were provided on demand only. Patients were discharged on 4th post operative day. The patients were asked to rate their pain on a visual analogue scale (VAS) on the 1st to 4th post-operative days. Patients were called for follow-up at 7 days, 1-month, 3months and 6 months. At each follow-up, clinical history was elicited for pain, groin discomfort or swelling and recurrence.

Endpoints studied were postoperative acute and chronic pain, analgesic requirement in the post-operative period, duration of surgery and complications in the post operative period.

STATISTICS

The data analysis was done using SPSS-22 software. For categorical variables chi-square test was used. For continuous variables independent samples's *t*-test was used. *p*-value <0.05 was considered as significant.

RESULTS

A total of 120 patients were included in the study, where 60 patients underwent mesh fixation by NBGA glue (Group A) and the other 60 underwent mesh fixation by prolene 3-0 suture (Group B).

Among these 117 were male and 3 were female patients. All patients were in the age group 30 – 80 years. Most of the patients were discharged on the fourth post-operative day and most could resume routine activity at the end of one week.

In the study, mean duration of surgery in the two groups was 45.10 minutes (SD = 29.32). The mean duration of surgery in glue group was 37.45 minutes and in suture group it was 52.75 minutes.

Operative time was significantly lesser in glue group as compare to suture group (Table 1). However, this is not solely because of the method of mesh fixation. The type of sac encountered and the time consumed in dealing with the sac also plays a significant role.

Subjective pain was analysed using the Visual Analogue Pain Score System (1-10), on post-operative day 1, day 2, day 3, day 4, 1 week, 2 weeks, 1 month, 3 months and 6 months post operatively.

The pain at 12 hours was taken as the baseline score with which a comparison was made of the subsequent pain scores at 24, 48, 72 hours, 1 week, 2 weeks, 1 month, and 6 months. The mean VAS pain score at 24 hours was found to be 2.77 ± 0.93 and 3.20 ± 1.27 in the glue and suture groups respectively, thus showing a significant difference ($p < 0.05$).

The mean VAS score was 1.77 ± 0.59 and 1.97 ± 1.22 in the glue and suture groups, respectively at 48 hours.

The mean pain score at 1 week is found to be 0.06 ± 0.25 in the glue group and 0.30 ± 0.92 in the suture group. There is a Insignificant difference in the pain perceived in both the groups as the *p* value is more than 0.05. At 1 month, no pain in the glue group and is 0.35 ± 0.89 in the suture group.

Hence in the immediate post-operative period mean pain score in the suture group was higher at 24 hrs post operatively; although this could be attributed to several factors and is not specific to the use of glue versus suture for mesh fixation. However there was no significant difference in pain scores further on in the time line assessed (Graph 1).

However, 2 patients in suture group had chronic pain and complained of mild pain at 6 months follow up and even beyond.

Analgesic requirement over and above the routine doses, given on SOS

basis was assessed. No need of analgesia in glue group was found after 48 hours and in suture group 52 patients needed analgesia at 48 hours and 9 patients needed analgesia at the end of one week. However, 2 patients, both males, in the suture group continued to require oral analgesics even at 6 months post operatively. The results however were not statistically significant (Table 2)

In terms of post-operative complications both groups had cases of seroma formation - 3 in glue group (Group A) and 2 in suture group (Group B); probably because NBGA glue is more biologically reactive leading to increased inflammatory reaction. But this was not statistically significant ($p > 0.05$). To reach a statistical significance however a larger study pool is required. Also, three patients in Group A and two in group B developed hematoma in the post operative period which was evacuated and resolved without any complications. Three of these patient were on anticoagulants pre operatively (in view of history of cardiac illness), and anticoagulants were restarted after resolution of hematoma in the postoperative period (as per consultation with cardiologist). Two patients in group A and 3 in group B developed urinary retention in immediate post-operative period, however these patients were already on treatment for BPH pre-operatively. One patient in each group developed wound infection and were managed with regular dressing and antibiotics support. (Table 4)

DISCUSSION :

At the turn of the last century several major developments have occurred in the face of hernia repair surgery. As a result the focus of successful hernia repair has changed. Surgeons were previously concerned with ensuring that there was no post operative recurrence. With this problem having been dealt with; most surgeons now pay regards to avoiding postoperative and chronic pain and hematoma/seroma formation. These have now replaced recurrence as the standard of successful hernia repair.

The introduction of surgical mesh to create a tension-free repair in inguinal hernia surgery in the 1990s was quickly used worldwide as a better surgical technique due to decreased rates of recurrence. Debate is still ongoing on the best surgical approach for this tension-free mesh repair. Chronic groin pain is the most common complication after inguinal hernioplasty.

With the advent of different types of mesh fixation this concern is being dealt with. In 2001, the authors of a large scale study proposed to use fibrin sealants to fix the mesh^[5]. Several experienced surgeons at specialized centres went even further, when they used bigger meshes and did not fix them at all. Some investigators observed a marked increase in recurrence, but others noted only a slight increase, especially since the introduction of light weight meshes. After a decade attempting to cope with recurrence, the present decade must address chronic pain.

Tissue adhesives were introduced in medical practice during the 1960s. Since then, they have been used in numerous procedures like skin closure, suture reinforcement, arteriovenous embolization, endoscopic treatment of ulcers and varices, and fixation of meshes in abdominal wall defect repair. Two types of tissue adhesive for mesh fixation are available in surgical practice: fibrin glue and cyanoacrylate tissue glue.

The use of cyanoacrylate glue in open Lichtenstein repair was reported in 1993^[4] and in laparoscopic hernia repair was first described in 1998^[5]. N-butyl cyanoacrylate is a butyl polymer of cyanoacrylate, an acrylic resin, which undergoes an exothermic reaction in presence of water to form a bond in about 5 seconds that finalises in about a minute. hence the mesh has to be held in place against the underlying tissue after applying NBGA for this period. Among the different polymers of cyanoacrylate, butyl polymer forms the stronger bond.

After the initial reports, this method did not gain much acceptance possibly due to the tendency of NBGA glue to solidify immediately on contact with organic matter and fears about its cytotoxicity. The latter concern was ill-founded owing to the long documented use of over 30 years of this chemical in the treatment of gastric fundic varices, where it is injected intravariceally or peri-variceally.^[6] Its biocompatibility, toxicological safety, and tolerance was demonstrated in both in vitro studies and in vivo implantation studies on animals.^[7] This fact led to several authors using NBGA glue for mesh fixation in open Lichtenstein hernia instead of suture fixation.^[8]

An experimental study on 30 white male mice, found that cyanoacrylate glue can be used effectively as a method for closure of the abdominal wounds and can be used for mesh fixation without complications. The usage of glue in mesh fixation has significantly proved its efficacy with regard to decreasing the time needed for mesh fixation in open inguinal hernia repair, as overall operative time was shorter using glue mesh fixation (<40 min after herniorrhaphy in 88.9% of our cases).

Most of the pilot studies used for comparison included middle aged patients. In one study, majority of the patients (17 in the glue group and 19 in the suture group) were from the age group between 31-60 years indicating that the patients in the study were predominantly middle aged. Another study included 156 patients (12 women and 144 men; mean age 58, range 17-85 yr) and operated on 167 hernias; 11 of which were bilateral.

One author found that he took 41.8 minutes to complete a hernia surgery on an average with the use of glue and 52.6 minutes with the use of suture^[9]. An average difference of 10.8 minutes was seen between the 2 methods with the procedure taking a comparatively longer time to complete when suture was used. This difference was found to be statistically significant. This was in accordance with our study where the operative time was significantly lesser in glue group as compared to suture group. Other meta-analysis and systemic reviews have also shown that the surgical procedure with the use of glue is significantly faster as compared to suture^[16,17,24]. In contrast, an author demonstrated no significant difference in the duration of surgery when fibrin glue, N-butyl cyano acrylate glue or suture was used for mesh fixation^[10].

Chronic groin pain, also called as inguinodynia 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^[11]. The incidence of chronic pain post inguinal hernia repair is estimated to be 0.5-6%.^[12,13] Chronic groin pain has been defined as the pain in the groin region post hernioplasty lasting beyond a period of 3 months^[14]. It is important to address this issue because a long lasting pain can significantly alter the quality of life of the individuals. Pain experienced post-surgery has been classified into two categories, namely- neuropathic and non-neuropathic. Neuropathic pain is due to the involvement of ilioinguinal, iliohypogastric or genitofemoral nerves during surgery. This type of pain is usually of shooting type, superficial and experienced around the scar and radiating to the scrotum in males or labia in females or to the inner aspect of the thigh. Activities like superficial touch over the scar site, stretching of the hip or walking might trigger this kind of pain. This can be very well prevented by careful identification and preservation of the nerves during surgery and lateralization of the nerve to prevent injury. Use of atraumatic fixing methods like tissue glues prevent the incorporation of the nerves within sutures and finally, use of lightweight meshes induce a thinner fibrotic reaction thus preventing entrapment of the nerves^[15].

Non-neurogenic pain is a constant dull aching pain in the inguinal region which could be due to excessive posterior wall scarring due to heavy weight mesh usage. First bite for mesh fixation is taken at the pubic tubercle. This may induce osteitis of the tubercle and could be a source for pain. The presence of mesh and fibrosis could be perceived as a foreign body sensation and stiffness in the inguinal region. Traumatic mesh fixation using sutures or staplers, or tackers causes tissue damage and thus pain. Creation of a too tight neo deep ring with the mesh causes constriction of the cord structures causes congestion and produces pain. In this era of day care surgery, faster, scarless surgeries, surgeries associated with less pain and earlier discharge from the hospitals are in demand.

In our study, there was no significant difference in the post-operative pain during the entire timeline except at 24 hrs post procedure. Other authors in their study have found that the pain from 48 hours to 1 month (immediate post-operative pain) post-surgery is lower in the glue group as compared to suture^[19,20,21]. However, no significant difference could be appreciated between the 2 methods in terms of chronic pain.

However, in our study, 2 patients in suture group had chronic pain and complained of mild pain at 6 months follow up and even beyond. For this to reach a statistical significance, a larger pool of data is required.

Various surgeons have demonstrated that fibrin glue and N-butyl-2-

cyanoacrylate are better tolerated than sutures by patients, and that the glues lead to better results during initial follow up and a better trend in long-term data^[10,16]. Single surgeon studies, systemic review and meta-analysis have also shown a significantly lower immediate and chronic pain following surgery for inguinal hernia using glue^[22,23,24]. Trauma to the tissues with suture incites inflammatory reaction at the suture points. Use of glue has shown a reduced inflammatory response at the site according to one author^[8]. However, some authors have not found any significant difference in chronic post-operative pain in both the groups^[17,25,26].

In our study Hematoma and seroma was found more in glue group (5.00%) as compare to suture group (3.33%). Urinary retention was more in suture group (5.00%) as compare to glue group (3.33%). However this was not statistically significant and was not related to the method of mesh fixation. One author found no complications in the form of seroma, wound infection, hematoma, ecchymoses had occurred in his study in either of the groups^[9].

The study has several limitations as it is a single blinded study with limited sample size and limited duration. In spite of these limitations, the strength of this study is its homogeneity as it is a single center, single surgeon study.

CONCLUSION

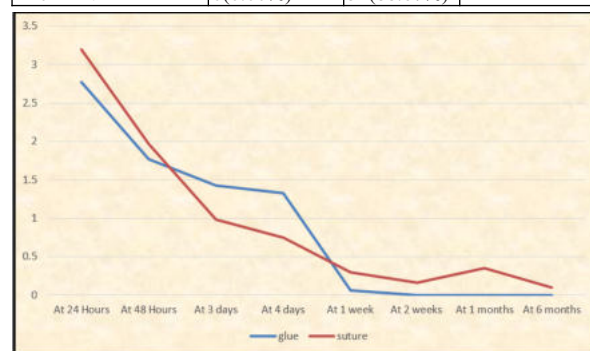
Our study help us to conclude that mesh fixation with N butyl 2 cyanoacrylate glue is superior to sutures in several aspects. Glue reduces the operative time which can be useful in high volume centres. The immediate postoperative and chronic postoperative pain are also considerably lower with glue with no added intraoperative or postoperative complications.

In the terms of cost effectiveness; 0.5 ml of NBCA glue costs about Rs. 600 and a prolene suture costs approximately Rs. 300. Hence, sutures are found to be more cost-effective. However, patients who develop chronic groin pain as a result of nerve entrapment require long term analgesics which would add to the disease cost. This along with the reduced quality of life definitely outweighs the cost of using NBCA glue.

Lichtenstein's tension-free mesh hernioplasty continues to be the gold standard method of hernia repair. Hence glue can be considered as a good replacement for suture in inguinal hernia repair expecting lesser postoperative morbidities and a better quality of life.

Table 1. Comparison of duration of surgery in both the groups

Duration of surgery	Glue	Suture	p-value
<40 mint	60(100.00%)	8(11.33%)	0.001
>40 Mint	0(0.00%)	52(88.67%)	



Graph 1. Line diagram showing comparison of VAS Score at different time period in both group

Table 2. Comparison of Duration of analgesia in both group

Duration of analgesia required	Glue		Suture		p-value
	No	Percentage	No	Percentage	
24 Hours	60	100.00	60	100.00	0.99
48 Hours	50	83.33	52	86.67	0.798
1 weeks	3	5.00	9	15.00	
1 month	1	1.67	4	6.68	
3 month	0	0.00	2	3.33	
6 month	0	0.00	2	3.33	

Table 3. Comparison of post-operative complication rates between both groups

Complication	Glue		Suture		p-value
	No.	Percentage	No.	Percentage	
Hematoma	3	5.00	2	3.33	0.99
Seroma	3	5.00	2	3.33	0.99
Wound infection	1	1.67	1	1.67	0.99
Urinary retention	2	3.33	3	5.00	0.99

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