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Original research article

Comparison of n-butyl-2 cyanoacrylate glue with polypropylene sutures for mesh fixation in inguinal hernia repair: A randomised control study

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Abstract

Introduction: Over the course of the past several years, several improvements have been made to the traditional Lichtenstein's hernioplasty approach to reduce the likelihood of post-operative complications and eliminate the possibility of chronic pain. Earlier, mesh fixation was used to be done by suture application. However recently, different non-traumatic alternative methods of mesh fixation like tissue compatible glues are being considered.

Methods: The present randomized control study included a total of 60 patients, randomized equally (n=30 each) into two groups. Patients in group A were operated on for hernia repair using polypropylene 2-0 sutures for mesh fixation while in group B N-Butyl-2 cyanoacrylate glue was used for mesh fixation.

Results: Mesh fixation time was significantly more in patients with propylene sutures than in glue (p=0.001). Total surgery time was also more for patients of propylene suture group with unilateral (73.38±10.75vs 65.42±21.31, p=<0.001) or bilateral (149±51.19vs 136±30.93, p=0.606) hernia, however in patients with bilateral hernia the difference was not statistically significant. Post-operative pain, analgesia requirement, time taken to return to normal activity, and postoperative complications like seroma, hematoma, and local numbness were not statistically significant.

Conclusions: the use of a synthetic tissue adhesive N-butyl-2-cyanoacrylate glue is a feasible option for mesh fixation in patients with simple inguinal hernias undergoing Lichtenstein's hernioplasty, without adversely affecting the clinical outcomes.

Keywords: Inguinal hernia, inguinal canal, hernia, direct hernia, indirect hernia

Introduction

Over the course of the past several years, several improvements have been made to the traditional Lichtenstein's hernioplasty approach to reduce the likelihood of post-operative complications and eliminate the possibility of chronic pain.[3] The incidence of CGP have been found to decreases by careful dissection and preserving the regional nerves intra-operatively. Earlier, mesh fixation was used to be done by suture application. However recently, different non-traumatic alternative methods of mesh fixation like tissue compatible glues are being considered [1]. Since past 20 years tissue glues are being used in various surgical indications like gastroesophageal variceal bleeding, wound closure and to maintain hemostasis during hepatic surgery [2].

The present study compared the short-term outcomes (pain, seroma, hematoma), long-term outcomes (recurrence, chronic pain), time to return to normal activity and mesh fixation time for patients who underwent a Lichtenstein inguinal hernia repair using N-butyl-2-cyanoacrylate glue and polypropylene sutures for fixation of mesh.

Materials and Methods

The present randomized control study was conducted in the Department of General Surgery at Sri Guru Ram Das Institute of Medical Sciences and Research from April 2021 to July 2022. Patients were assessed for inclusion into the study according to inclusion and exclusion criteria. A written informed

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consent was obtained from all patients. A total of 60 patients were selected, and patients were randomized equally (n=30 each) into two groups. Patients in group A were operated on for hernia repair using polypropylene 2-0 sutures for mesh fixation while in group B N-Butyl-2 cyanoacrylate glue was used for mesh fixation.

Inclusion criteria

1. All patients of primary uncomplicated inguinal hernia.
2. Patients above 18 years of age.

Exclusion criteria

1. Recurrent hernia.
2. Femoral hernia.
3. Patients with emergency presentation.
4. Patients with coagulation disorders.
5. Patients with ongoing chemotherapy.
6. Patients with connective tissue disorders.
7. Patients with psychological or physical disorders that could affect the ability to feel and elaborate pain.

Patients were randomized to one of the study groups by using sealed number envelops opened in sequence. Due to apparent technical reasons, it was impossible to blind the surgeon, but the investigators observing the patient in the postoperative period, those analyzing the data, and the participants were all blinded to the group allocation. Both the groups were evaluated for fixation time of the mesh, post-operative pain: 24hr, 7^{th} day, 30^{th} day, seroma and hematoma formation, time to return to normal activity and recurrence. SPSS was used for all analyses. The Chi square test was used to assess categorical data and Student's t test for continuous variables was performed as appropriate. P-value < 0.05 was considered significant.

Results

Both the groups were comparable with respect to age. The mean of age groups was 53.55±17.60 years. The mean age group of patients in group A was 56.50±15.09 while in group B the mean age was 48.60±19.25. No significant difference was observed between the two groups (p>0.05). Majority of patients i.e., 17(28.3%) had age between 51-60 years followed by 11(18.30%) patients between 61-70 years, 8(13.3%) patients between 71-80 years, 7(11.70%) patients between 31-40, another 7(11.70%) patients between 41-50 years. 6(10%) patients between 21-30, 3(5%) patients between 18-20 and only 1(1.7%) patient had age of >80 years. Fourteen patients had comorbidities like diabetes, hypertension, thyroid disorder etc. Patients were equally distributed with respect to comorbidities in both the groups and no significant difference was seen (p>0.05). Forty-seven patients had unilateral hernia while 13 patients had bilateral hernia. Patients were almost equally distributed among both the groups. On comparing grouped data, we observed that for both the groups of unilateral (p = <0.001) and bilateral (p = 0.001) hernia, the mesh fixation time was significantly more in patients in whom mesh fixation was done using propylene suture comparative to patients in which glue was used. Total surgery time was also more for patients of propylene suture group with unilateral (73.38 ± 10.75 vs 65.42 ± 21.31, p = <0.001) or bilateral (149 ± 51.19 vs 136 ± 30.93, p = 0.606) hernia, however in patients with bilateral hernia the difference was statistically not significant.

At 24 hours all the patients in both groups had pain score of 2. At 7^{th} day, we observed that pain in patients with propylene sutures was comparatively more than in patients in whom mesh fixation was done using glue, but no statistically significant difference was seen in pain score (p=0.573). After 30 days postoperatively, 27 patients in both suture and glue group experienced no pain. In glue group, 3 patients had pain, 1 patient with score of 1 and 2 patients with score of 2. In suture group also 3 patients had pain, 2 patients with score of 2 and 1 patient with score of 4. The difference between two groups was statistically non-significant.

Analgesics like paracetamol or non-steroidal-anti-inflammatory drugs or cox-2-selective inhibitors were administered to every patient for 3 to 4 days. However, 1 patient in propylene suture group required additional fentanyl patch as rescue dosage of analgesia and none of the patients in whom mesh fixation was done using N-Butyl-2 Cyanoacrylate Glue required rescue analgesia.

In the current study total 2 patients had seroma formation, 1 in each group and no significant difference was observed regarding the same. Both the patients were managed conservatively. One patient of suture group presented with hematoma postoperatively and was managed conservatively. This association was statistically non-significant (p=0.313).

During first month 27 patients in each group had no pain. In glue group, 3 patients had mild pain with pain scores of 2, while in the suture group, 2(6.7%) patients had pain score of 2 and 1(3.3%) patient had pain score of 4. The difference was statistically non-significant (p=0.54). During second and third month

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27 patients in suture group and 28 in glue group had no pain. Patients in glue group had a pain score 2 in 2 (6.7%) patients while in suture group 2 (6.7%) patients had a pain score of 2 and 1 (3.3%) patient had pain score of 4. No significant difference was seen among both the groups (p=0.601).

One (3.330%) patient in the glue group experienced local numbness at one month while 2 patients (6.70%) in suture group experienced numbness at one month (p=0.554). At 2nd and 3rd month none of the patients in glue group experienced local numbness while 3(10%) patients in suture group experienced local numbness (p=.076). However, the difference was statistically non-significant.

Time to return to normal activity was comparatively more in patients in suture group than the patients of glue group (3.27±.98 days vs 2.37±.76 days). However, the difference was statistically non-significant (p=0.07).

Recurrence was observed only in one patient of glue group at first month. This patient was advised repeat surgery, however the patient was on follow up till the compilation of data.

The cost for 0.25ml of glue used was 377 INR and about 0.5ml of glue was used for mesh fixation per hernia repair amounting to a total of 754 INR. The cost of 1 polypropylene suture used per hernia repair was 513 INR and only one suture was used per hernia repair. Overall total cost for mesh fixation was found to be 241 INR higher in case of cyanoacrylate glue than in case of propylene suture.

Discussion

An inguinal hernia is a common surgical condition and numerous procedures are presently employed to treat it. Due to its multiple advantages over other open techniques, Lichtenstein's tension-free hernia repair is the most performed hernia surgery. By strengthening the inguinal floor defect with a prosthetic mesh, the Lichtenstein technique enables a tension-free repair of the hernia. This technique marked the beginning of an era of inguinal hernia repair. Due to the tension-free method, postoperative discomfort is at a minimum. The surgery is simple, effective, and associated with very low recurrence rates. Like with other open procedures, the most common consequences of open inguinal hernia repair are infection, seroma, chronic pain, and injury to adjacent nerves. As pain, neural, and vascular injuries are more closely associated with suturing, the use of sutures in Lichtenstein procedure for mesh-fixation may lead to the above outcomes [3].

N-butyl 2- Cyanoacrylate can be used as an alternative to sutures for mesh fixation to reduce these complications. Cyanoacrylate (CA) glue is a synthetic acrylic resin that attaches and binds to surfaces within 5 to 6 seconds in the presence of water and hydroxide ions and undergoes exothermic polymerization within 60 seconds. N-butyl-2-Cyanoacrylate is a hybrid tissue sealant that exhibits strong, fast-acting adhesive qualities and is frequently employed in medical applications. In comparison to suturing, its superior protective profiles and wound closing functions have been confirmed via research. According to numerous studies, the closure of wounds using the glue has resulted in favourable long-term outcomes, such as a reduction in infection, a reduction in operative length, and the attainment of cosmetic healing. Comparatively to other adhesives, cyanoacrylate glues maintain a strong connection with biological tissues [4, 5].

Inguinal hernia is usually associated with middle and older age group due to multiple aetiologies associated with increased intra-abdominal pressure and age-related weakness of abdominal wall muscles. In present study the mean age of the patients was 53.55±17.60 years. The mean age group of patients in suture group was 56.50±15.09 while in glue group the mean age was 48.60±19.25. No significant difference was observed between the two groups.

An indirect hernia occurs more often on the right. This is believed to be attributed to the slower closure of patent processes vaginalis on the right side compared to the left. In the current study it was observed that right sided inguinal hernia was seen in 28 (46.70 %) patients while in 19 (31.70 %) left sided hernia was seen. In 13 patients (21.7 %) inguinal hernia was seen bilaterally. No significant difference was seen among both the groups with respect to laterality in present study (p>0.05). Patients were equally distributed among both the groups (glue vs sutures) with respect to laterality. In our study 14 patients had comorbidities and were equally distributed with respect to comorbidities between both groups. No significant difference was seen (p>0.05).

In current study it was observed that total 47 patients had unilateral hernia while 13 patients had bilateral hernia. Patients were almost equally distributed among both the groups. On comparing grouped data, we observed that for both the groups of unilateral and bilateral hernia the mesh fixation time was significantly more of patients in which mesh fixation was done using sutures (p=0.001). Total surgery time was also more for patients of propylene suture group with unilateral (73.38±10.75vs 65.42±21.31, p<0.001) or bilateral (149±51.19vs 136±30.93, p=0.606) hernia, however in patients with bilateral hernia the difference was not statistically significant. The results of the present study were in accordance with the study conducted by shah et al in which also the time for mesh fixation was counted from placing the mesh to completion of fixation of mesh using cyanoacrylate glue and sutures [6]. There was a significant reduction in the whole operating time with glue mesh fixation compared to suture mesh fixation during open inguinal hernia repair in their study. In another study, Jani et al. compared NBCA (n-butyl cyanoacrylate) mesh fixation and suture fixation in patients with inguinal hernia and found that operative

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times for unilateral as well as bilateral hernias were less in NBCA fixation than suture fixation, however the difference did not reach statistical significance [7].

In a study by Houyela et al., the mean duration of operation was significantly shorter (by almost 5 min) when mesh was fixed with glue 35.3 (8.7) min versus 39.9 (11.1) min in the suture group [8]. In a study by Mohammadi Tofigh et al., the length of operation was 64.5±11.2 min in the glue group versus 73.3±10.6 min in the suture group which was significantly shorter in the glue group with p = 0.014 (1). All the above-mentioned studies were in accordance with the present study.

At 24 hours all the patients in both groups had pain score of 2. Following routine basic analgesic regime, analgesics like paracetamol or non-steroidal-anti-inflammatory drugs or cox-2-selective inhibitors were administered to every patient for 3 to 4 days however 1 patient in suture group required additional fentanyl patch as rescue dosage of analgesia and none of the patients in whom mesh fixation was done using N-Butyl-2 Cyanoacrylate Glue required rescue analgesia. This association was however non-significant (p=0.313). At 7 days in both groups, it was observed that pain in patients with propylene sutures was comparatively more than the patients in which mesh fixation was done using glue. This association was however non-significant (p>0.05). After 30 days postoperatively, 27 patients in both suture and glue groups experienced no pain. In glue group, 3 patients had pain, 1 patient with score of 1 and 2 patients with score of 2. In suture group also 3 patients had pain, 2 patients with score of 2 and 1 patient with score of 4. This association was however non-significant (p>0.05). During second and third month, 27 patients in suture group and 28 in glue group had no pain. Patients in group B experienced a pain score of 2 in 2(6.7%%) patients while in group A 2(6.7%) patients experiences pain score of 2 and 1(3.3%) patient experienced pain score of 4. No significant difference was seen among both groups (p=0.601).

Fouda et al. reported that patients who had their meshes fixed with cyanoacrylate glue experienced significantly less pain one week, six months, and one year after surgery than patients who had suture mesh fixation. This was consistent with the current study [9]. Also, the present findings were consistent with a meta-analysis of nine trials by Liu et al. that compared glue as a tissue adhesive to sutures for mesh fixation and found a lower incidence of CGP in the glue group (relative risk=0.42) [10]. In contrast, Matikainen et al.concluded from a long-term randomised trial that cyanoacrylate glue and suture mesh fixation were equivalent in terms of CGP up to seven years after surgery [11]. The comparable pain scores in the latter study might be attributed to the use of absorbable sutures, unlike our study that used non-absorbable polypropylene sutures for mesh fixation.

Early pain which occurs within the 1st week after surgery is mostly attributed to surgical trauma and incision-related pain. Chronic pain which persists more than 3 months after surgery is mostly related to excess fibrosis causing nerve entrapment. The cyanoacrylate glue group was associated with less surgical trauma and thus with less pain at 1 week than the suture fixation group. At 1 month, both the groups had similar pain scores since by 1 month the impact of surgical trauma gets resolved, and at the same time fibrosis is not fully established to induce the pain.

The rate of seroma and hematoma formation was comparable between both groups. One patients of suture group presented with hematoma post operatively while total two patients had seroma formation (1 in each group). This association was non-significant. All the patients with seroma and hematoma were managed conservatively.

The results of the present study were in accordance to study by Fouda et al, [9]. Both the groups were comparable regarding postoperative complications of seroma and hematoma however the results were in discordance with another study by Salah-Eldin Shehata et al. that found the rate of postoperative seroma and hematoma after cyanoacrylate mesh fixation significantly lower than after suture mesh fixation [12]. In our study the rates of seroma and hematoma formation in the two groups were quite similar. Conversely, Liu et al. found the pooled rate of hematoma/seroma formation after mesh fixation with fibrin glue significantly lower than that after suture mesh fixation [10]. The small numbers of patients included to the present study, may explain the comparable rates of complications in the two groups.

A study by Narayanakar et al. showed that 12/50 patients among suture group and 2/50 patients in glue group had developed seroma in post-operative period and this finding was statistically significant with a p < 0.05 [13]. Similar finding was reported by Odobasic et al. with seroma formation in 30% patients of suture group and 3.3% patients of glue group which was statistically significant [14]. Similar study was of Girish and Yetigadda [15]. All the above studies are in discordance with our study as they suggested that seroma type of complication is significantly less present in glue fixation methods compared to conventional suture fixation method.

Study conducted by Odobasic et al. observed 2 hematoma formation in both glue and suture groups [14]. Similarly, another study conducted by Girish and Yetigadda observed that 7% patients in suture group and 4% patients in glue group developed haematoma, which was statistically not significant [15]. Narayanakar et al. in their study observed that 7/50 patients among suture group and 3/50 patients in fibrin glue group had developed haematoma in early post-operative period and this finding was statistically in-significant with a p > 0.05, suggesting that haematoma formation is seen in both types of mesh fixation [13].

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In our study, one (3.33 %) patient in glue group experienced local numbness at one month while 2 patients (6.70 %) in suture group experienced numbness at one month. At 2nd and 3rd month none of the patients in glue group experienced local numbness while 3(10 %) patients in suture group experienced local numbness. However, the difference was statistically non-significant ($p > 0.05$).

Narayanakar et al. observed that among 100 patients (50 each group), 5 patients among control group (propylene sutures) and 1 patient in study group (glue) had developed local numbness in post-operative period. This finding was statistically insignificant with a $p > 0.05$ (13). This suggests that there might be local numbness in both methods with a little high incidence in suture mesh fixation group, but not statistically significant. This was similar to the present study.

In a study by Yassin et al. in a 6-month follow up, glue group had one case (out of 12) with local numbness, while sutures group had three cases (out of 12) having local numbness with no significant difference between the two group with a $p>0.005$ [16].

In present study, recurrence was observed only in one patient of glue group at first month. This patient was advised repeat surgery; however, the patient was on follow up till the compilation of data. In a study by Bharath et al. there was one recurrence in glue group which was in accordance with the present study [17]. Studies by Mohammadi Tofigh et al. [1] and Fouda et al. [9] reported no recurrence.

In present study it was observed that time to return to normal activity was more in patients in suture group than glue group (3.27±.98 days vs 2.37±0.76 days). However, the difference was statistically non-significant ($p=0.07$). The results of the present study was similar to the study conducted by Testini et al [18]. In the suture group, the mean time to return to work was 20.4± 3.38 days, in the fibrin glue group it was 20.3 ±3.94, and in the N-butyl-2-cyanoacrylate group it was 19.8 ± 3.62 days ($p = 0.60$).

The meta-analysis by Colvin et al. showed that the mean time it took for the participants in the studies to return to normal activity varied from 3 to 20 days [19]. Based on the random effects model, there was a reduction in the duration of time to return to normal activities with glue fixation. Nowobilsky et al. in their study showed that in the study group with tissue adhesive, the patients tended to return earlier to their daily activity [20].

During cost analysis the cost for mesh fixation using glue was found to be 241INR more than the cost of mesh fixation using polypropylene 2-0 suture.

Conclusions

To conclude N-butyl-2-cyanoacrylate glue, besides being an alternative to conventional suture for mesh fixation, has some advantages like technical easiness and significant reduction in mesh fixation time. Though use of cyanoacrylate glue was also found to be comparatively better than suture in terms of post-operative pain, local numbness, and patient's recovery time, however the difference was not statistically significant compared to suture group.

Hence, the use of a synthetic tissue adhesive N-butyl-2-cyanoacrylate glue is a feasible option for mesh fixation in patients with simple inguinal hernias undergoing Lichtenstein's hernioplasty, without adversely affecting the clinical outcomes.

Declarations Competing Interests: The authors declare no competing interests.

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