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Comparative Study of Mesh Fixation using Cyanoacrylate Glue versus Fixation by Proline Sutures in Adult Inguinal Hernioplasty

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ABSTRACT

Background: Groin pain after inguinal hernia repair is still a significant problem, especially with the higher incidence of inguinal hernia. Different methods are tried to reduce postoperative groin pain.

The aim of the work: The study aimed to compare mesh fixation using N-butyl 2-cyanoacrylate adhesive glue to sutured mesh fixation in Lichtenstein hernia repair.

Methods: Fourty patients were randomly allocated to one of two equal groups: Group I [glue group], and Group II [sutures group], where polyprolene sutures were used to attach the mesh. Preoperatively, patients were thoroughly assessed and gave their consent. Patients were seen in the outpatient clinic after one week, as well as at one, six, and twelve months after their surgery. Every visit, groin pain was assessed using a visual analogue scale [VAS]. In addition, a recurrence of the hernia, as well as the presence of any complications, were assessed and documented.

Results: Both groups were comparable regarding patient demographics, chronic diseases, smoking, type of hernia or analgesic requirements**.** However, pain was significantly lower one week, t months and 12 months after surgery in glue than sutures group. The mean operative time was significantly shorter in glue than sutures group [45.7±8.15 vs 58.7±7.6 minutes, respectively]. Also, return to work was earlier in glue than sutures group [16.3±3.9 vs 21.3±5.6 days, respectively]. No recurrence was recorded in each group and other postoperative complications were mild and treated conservatively without significant difference between glue and sutures groups.

Conclusion: Cyanoacrylate glue for mesh fixation in Lichtenstein repair of adult inguinal hernia shows advantages over mesh fixation by sutures in terms of immediate and chronic post-operative pain, operative time, and postoperative complications. with no difference in the recurrence rate.

Keywords: Chronic Pain; Inguinal Hernia; Cyanoacrylate glue; Sutures; Mesh.

INTRODUCTION

Inguinal hernia and its repair are still the commonest surgical intervention, and more than 800 sounds of repair performed annually. In 1989, the Lichtenstein hernia repair was introduced and revolutionized hernia surgery. The main advancement was the introduction of a flat mesh on the top of the defect, to prevent muscle stress. This was associated with a reduced rate of recurrence. However, groin discomfort is reported in up to 50% of patients after hernia repair. This discomfort may be due to inflammatory response to the mesh material, nerve lesions, nerve irritation, and/or fixative suture nerve entrapment [1-4].

Hernia surgery with or without the use of mesh leads to an equal incidence rates of chronic groin comfort. Thus, suture induced nerve irritation may be the significant underlying cause of post-hernia repair groin pain. These results in increased popularity of suture-free mesh fixation systems. However, the studies and results of skin staples, spiral stack and tissue adhesive are still preliminary [5-7].

The use of glue in mesh fixation [tissue adhesive] appears to be a promising option to reduce postoperative groin pain and discomfort due to avoidance of direct nerve stimulation or entrapment. Preliminary results of different glue materials demonstrated promising results in reduction of postoperative discomfort [8-10].

THE AIM OF THE WORK

The aim of the current work was to compare mesh fixation using N-butyl 2-cyanoacrylate adhesive glue to sutured mesh fixation in Lichtenstein hernia repair.

PATIENTS AND METHODS

This is a randomized single-blinded controlled trial that was conducted in the general surgery department of Al-Azhar University Hospital in Damietta in the period of April 2019 - December 2020.

Inclusion and exclusion criteria: The study included male patients with primary unilateral uncomplicated inguinal hernias ranging in age from 18 to 65 years old who had undergone surgery in the previous year. The investigation was closed to those who had a bilateral or sliding inguinal hernia, a strangulated or incarcerated hernia, a recurring inguinal hernia, a femoral hernia, or who were nervous about participating in the trial.

Grouping and randomization: In the current study, patients were randomly allocated to one of two equal groups: Group I [glue group], where N-butyl 2 cyanoacrylate tissue glue [Histoacryl®] was used to secure the mesh, and Group II [sutures group], where polyprolene sutures was used to attach the mesh. Internet software was used to carry out the randomization process [www.randomization.com]. The sealed envelope strategy was used to ensure patient confidentiality. When the mesh was being set in this trial, the computer-generated numbers were placed in opaque closed envelopes that were unsealed by a nurse in the operating room, just before the mesh setting. During the enrollment process, patients were not told of the method of fixation or their group assignment, and instead signed a consent to participate.

Preoperative assessment: Patients were asked about their current complaint, any medical co-morbidities, previous surgeries, previous treatment for the current disease, and any predisposing factors [e.g., chronic cough, chronic constipation, and benign prostatic hyperplasia, among other things]. Patients were also questioned about their general well-being. Clinical examinations were performed on the patients to determine which side and type of inguinal hernia they had, as well as to rule out any complications. The categorization of the American Society of Anesthesiologists [ASA] was used to determine anesthetist suitability for anesthesia.

Surgical techniques: Patients gave informed consent after being informed about the nature of the study as well as the potential benefits and risks involved. The procedure of choice is Lichtenstein tension free repair, which was performed under spinal anesthetic. Just before the procedure, a single dose of intra-venous ampicillin sulbactam 1.5 g was given, and it was administered soon after. Using a skin incision 3 cm above and parallel to the medial two-thirds of the inguinal ligament, the skin was removed after cleaning and draping. It was necessary to excise two-superficial fascia layers [the outer Camper's fascia and the inner Scarpa's fascia]. Catgut was used to ligate the superficial pudendal and superficial epigastric vessels, and cautery was used to close them. To retract the skin margins, a self-retaining mastoid or equivalent retractor was implanted **[Figures 1 and 2]**.

On the outside of the skin, parallel to the incision line, an oblique aponeurosis' long axis was excised and stitched together. A longer

incision was made on both ends of the incision, and it was also lengthened medially to cut the margins of the superficial ring's edges. The wound was then closed. A hemostat is used to hold the top leaf in place while the upper leaf is lifted sufficiently to allow for visualization of the conjoined tendon and lateral rectus sheath utilizing peanut dissection. The inguinal ligament is visualized and exposed when the lower leaf is reflected downward from above. It was necessary to dissect the entire inguinal ligament medially and expose it, as well as its shelving edge and iliopubic tract, to improve visualization of the ligament **[Figure 3-5]**.

The ilioinguinal nerve was discovered above and medially, and it is believed to enter the external oblique after penetrating the internal oblique **[Figure 6]**. After meticulous dissection, the ilioinguinal nerve was preserved. The medial and lateral flaps of the cremasteric muscle and fascia were opened longitudinally as medial and lateral flaps. The cremaster vessel had been ligated, and the cremaster muscle had been removed after being ligated proximally and distally, respectively.

The cord was dissected to see what was going on inside. Dissection frequently began at the fundus and progressed towards the neck, which may be distinguished by the presence of additional peritoneal fat. In addition, the neck was located lateral to the inferior epigastric artery. High dissection was carried out beyond the deep ring. At the fundus, the sac was opened. If there were any adhesions, a finger was slid through them to remove them. If there were none, adhesions were freed, and the contents were reduced totally by finger dissection. Sac was twisted to prevent the content from coming back. It was sutured with absorbable suture material [vicryl 2.0] and removed distally [redundant sac]. If the sac extended completely into the scrotum and dissecting it from the scrotum proved problematic, the distal section of the sac was left open after transecting at the superficial ring level. From the internal ring to the public tubercle, the fascia transversalis was incised throughout the length of the canal. Even though it is not required, plication of this fascia was typical [using continuous non absorbable monofilament polypropylene sutures].

The inguinal canal was effectively exposed with the use of the Langenbeck retractor above and the Czerny retractor below and to the medial side. Cord was kept out of the way below. Polypropylene mesh [11 x 6 cm in size] was utilized for the repair; The mesh size was calculated based on the defect width; a sufficient mesh covering 2.5cm above and medially should be used. In this situation, patients were divided into two groups.

Group I [glue group]: The following were the outcomes of mesh fixation employing dots of N butyl 2 cyanoacrylate tissue glue [1ml] **[Figures 7 and 8]**.

Group II [sutures group]: Sutures were used to secure the mesh below the inguinal ligament, with the medial most suture coming from a location near the pubic tubercle. It's critical that the mesh reaches all the way to the pubic tubercle on the medial side [2 cm beyond]. The mesh was large enough to accommodate the defect well beyond the pubic tubercle. The suturing of the mesh was accomplished with interrupted non-absorbable monofilament poly-propylene sutures placed below the inguinal ligaments. To avoid harm to the femoral nerve, the mesh was sutured below the inguinal ligament up to the level of the deep ring but not beyond it. To encapsulate the cord and ilioinguinal nerve, a part of the mesh had been removed horizontally [3 cm top flap 2 cm lower flap]. The sliced part's lower flap was smaller than the upper flap. For this procedure, it was required to extend the lateral tails past the incision area beneath the external oblique all the way up to the level of the anterior superior iliac spine, which was not possible with the previous technique. In the final step, the loose sutures [air lock sutures] used to attach the upper end of the mesh to the conjoined tendon in front of the mesh are used to keep it in place until the next treatment. After being removed, the cord and ilioinguinal nerve were re-implanted in the inguinal canal. To seal the wound, absorbable vicryl sutures were used to suture the external oblique. Sutures are implanted in the subcutaneous tissue at irregular intervals. Continual subcuticular monofilament polypropylene 3 zero interrupted sutures are used to close the skin after surgery **[Figure 9-14]**. Dressing was placed. Liquid intake began 2 hours post the operation was completed. This treatment included intravenous injection of paracetamol to alleviate discomfort. Unless there were any difficulties, On the second postoperative day, all patients were discharged.

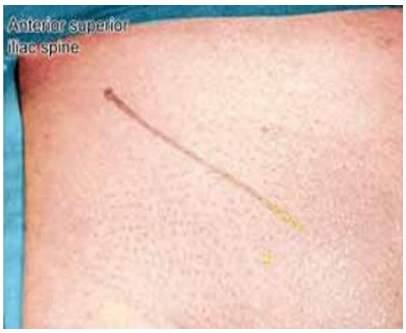


Figure [1]: Incision above and parallel to inguinal ligament

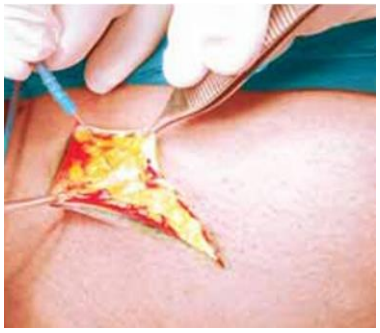


Figure [2]: Subcutaneous tissue and two layers of superficial fascia were incised.

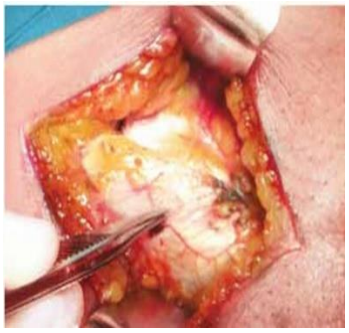


Figure [3]: External oblique aponeurosis was incised

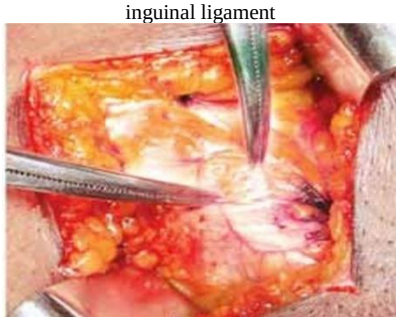
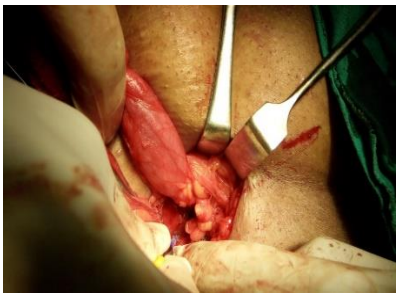


Figure [4]: Edges of the external oblique aponeurosis were held by two hemostats

Figure [5]: Edges of the external oblique aponeurosis was cut up to external ring and laterally beyond deep ring level

Figure [6]: Ilioinguinal nerve enters the external oblique after penetrating the internal oblique



Figures [7]:

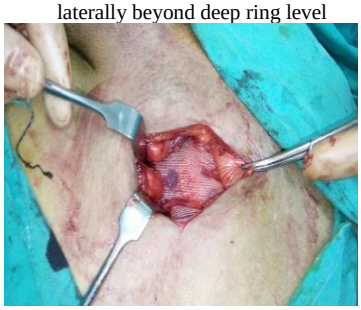


Figure [8]:

The outcomes of mesh fixation employing dots of N butyl 2 cyanoacrylate tissue glue [1ml]

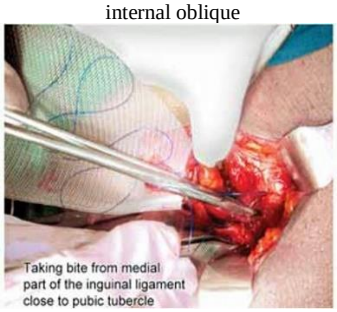


Figure [9]: Taking bite from medial part of the inguinal ligament close to pubic tubercle.

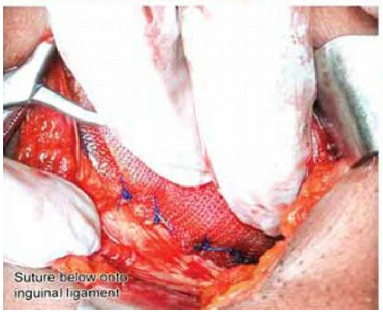


Figure [10]: Suture below inguinal ligament

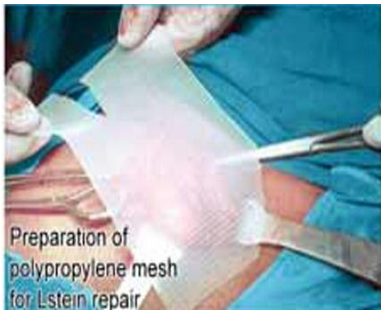


Figure [11]: Preparation of polypropylene mesh for repair

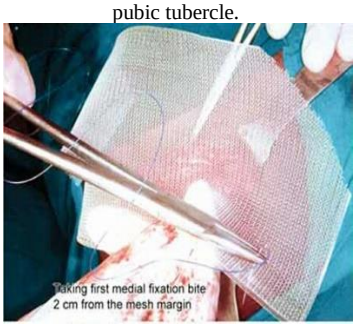


Figure [12]: Taking first medial fixation bite 2cm from the mesh margin.

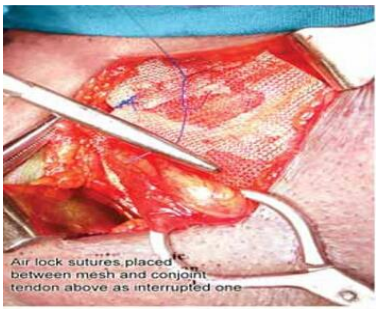


Figure [13]: Air lock sutures placed between mesh and conjoint tendon above as interrupted one.

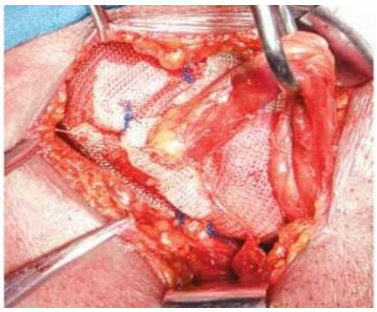


Figure [14]: Mesh in palce

Endpoints and Follow-up

It was decided on the outcome by two people who were not aware of the study's purpose: a general surgery resident and an attendant in general surgery. Patients were seen in the outpatient clinic after one week, as well as at one, six, and twelve months after their surgery.

Every visit, groin pain was assessed using a visual analogue scale [VAS] ranging from 0 to 10, with 0 indicating no pain and 10 indicating the most severe pain possible.

During the follow-up period, the presence of a recurrence of the hernia, as well as the presence of any complications, were assessed and recorded.

There were a few problems, including surgical site infection [SSI], wound hematoma, seroma, dehiscence, testicular edema, and pain.

Consistency or recurrence of groin swelling at the anatomical site of an inguinal hernia is defined as follows, as well as typical hernia symptoms including reducibility and expansible impulse on coughing, was described as recurrence.

Complications were defined as any unintended and unplanned result of the procedure that had an adverse effect on the patient and occurred as a direct result of the procedure. The standard criteria set by the centre for disease and control were used to define Surgical Site Infection [SSI].

Hematoma was defined as a collection of blood or clots in the surgical wound, while seroma was defined as a pocket of sterile clear serous fluid at the site of the incision.

At 12 months postoperatively, the primary outcome of the experiment was Chronic Groin Pain [CGP] in both groups. Hernia recurrence, comorbidities, and surgical time were all secondary outcomes.

Statistical analysis

For the data analysis, we used IBM Corporation's SPSS version 21 [based in Bristol, UK]. The mean and standard deviation, or the median and range, of parametric data were used to express the information. Data that was not parametric was expressed as a proportion of the total. When processing continuous variables, the student's *t*-test was employed, whereas the Fisher exact test or the Chi square test was used when processing categorical variables. To identify the important independent predictors of increased pain VAS following Lichtenstein tension free repair, a multiple linear regression analysis was conducted. P 0.05 was used to assess whether the results of the comparison between the two groups were statistically significant.

RESULTS

In total, 75 patients with inguinal hernia were evaluated over the study period, with 35 patients being excluded because they did not match the study's inclusion and exclusion criteria. A total of 43 patients were included in the trial, with each patient being a member of one of the research groups. Male patients with an average age of 48.2 12.1 years and a BMI of 27.9 2.2 kg/m^2 were included in the study. All the patients in this study had an indirect inguinal hernia, with 36 [90%] having a bubonocele or funicular type and four [ten%] having a scrotal type. The average length of time a complaint lasted was 26.9 17.8 months. Three patients [7.5 percent] were diagnosed with type 2 diabetes, six [15 percent] were diagnosed with hypertension, and 19 [47.5 percent] were smokers. Age, gender distribution, duration of symptoms, hernia type, BMI, medical comorbidities, and smoking history were all similar in both groups, as shown in [Table 1].

The patients in Group I [glue group] reported considerably lower pain scores at 1 week, 6 months, and 12 months following surgery as compared to the patients in Group II [suture group], however the pain score at 1 month was not significantly lower than the pain score in Group II [Table 2].

Table [3] shows that three patients [15 percent] from Group I [glue group] required analgesia, compared to nine patients [45 percent] from Group II [suture group]; however, this difference was not statistically significant [Table 4]. The mean surgical time in Group I [glue fixation] was considerably less than the mean operative time in Group II [suture fixation] [45.7 8.15 minutes vs. 58.7 7.6 minutes, P|<0.001]. The mean time of return to work was significantly earlier in group I [glue group] than group II [sutures group] 16.3±3.9 vs 21.3±5.6]

Table [1]: Baseline characteristics of patients in the two groups

Variable	Group I [n=20], n [%] [glue fixation]	Group II [n=20], n [%] [suture fixation]	P
Mean age in years	47.9±13	49±11.6	0.78
Mean BMI in kg/m^2	27.6±2.3	28.3±2	0.31
The average length of symptom [month]	25.5±18.9	29.2±16.9	0.52
Diabetes mellitus	1 [5%]	2 [10%]	0.42
Hypertension	4 [20%]	2 [10%]	0.18
Smokers [%]	10 [50%]	9 [45%]	0.38
Types of hernia			
Bubonocele or funicular	17 [85%]	19 [95%]	0.16
Scrotal	3 [15%]	1 [5%]	

Table [2]: Pain score of patients in the two groups

Variable	Group I [n=20] Glue group	Group II [n=20] Sutures group	P value
Pain VAS at 1 week	2.8±1.1	3.6±1.2	<0.05*
Pain VAS at 1 month	1.25±0.78	1.2±0.85	0.85
Pain VAS at 6 months	0.4±0.5	1.85±0.76	<0.001*
Pain VAS at 12 months	0.4±0.5	2.85±1.1	<0.001*

VAS: Visual analog scale, * significant

Table [3]: Mean operative time, analgesic requirement, and mean time to return to work in days

Variable	Group I [n=20] Glue group	Group II [n=20] Sutures group	P
Mean operative time in min	45.7±8.15	58.7±7.6	0.007
Analgesic requirement [%]	3 [15]	9 [45]	0.08
Mean time to return to work in days	16.3±3.9	21.3±5.6	0.05

Table [4]: Post-operative complications in the two studied groups

Variable	Group I [n=20] Glue group	Group II [n=20] Sutures group
Seroma [%]	2 [10%]	3[15]
Surgical site infection [%]	0[0%]	1[5%]
Hematoma [%]	0[0%]	1[5%0
Recurrence	0[0%]	0[0%]

DISCUSSION

The purpose of this clinical trial was to see which was better: suture mesh fixation or sutureless fixation using cyanoacrylate tissue adhesive in Lichtenstein tension free repair. All the patients in this study were men, which is consistent with other studies that have found a male predominance in inguinal hernias [11,12]. We picked cyanoacrylate as a tissue glue because it fits all the requirements for a good adhesive: biocompatibility, cheap, and ease of storage and application [13]. Another tissue adhesive that has been linked to excellent results is fibrin glue [14,15]. However, it is more expensive and not commercially available in our area. We chose the butyloctyl cyanoacrylate version because it has excellent tissue compatibility and is widely utilized in medicine and surgery.

The degree of postoperative discomfort after the two ways of fixation was the primary result of this study. When compared to patients who had suture mesh fixation, patients who had mesh fixed with cyanoacrylate had considerably reduced pain levels at 1 week, 6 months, and 12 months after surgery. This conclusion was supported by a meta-analysis of nine trials study compared fibrin glue as a tissue adhesive to sutures for mesh fixation and found that the fibrin glue group had a decreased incidence of chronic groin pain [CGP] [relative risk [RR] = 0.42] [16].

A long-term randomised experiment, on the other hand, concluded that at up to 7 years after surgery, cyanoacrylate glue and suture mesh fixation were equivalent in terms of CGP. The use of absorbable sutures in the earlier study, as opposed to nonabsorbable polypropylene sutures in the current investigation, may account for the similar pain levels [17].

At 1 week, 6 months, and 12 months after surgery, cyanoacrylate mesh fixation was shown to be less painful than suture repair. This conclusion could be explained by the fact that

pain following inguinal hernia repair is divided into two categories: early and late [chronic] pain. Surgical trauma and incision-related pain are the most common causes of early discomfort in the first week after surgery. Excess fibrosis causing nerve entrapment is the most common cause of chronic pain that lasts longer than three months after surgery. At one week, the cyanoacrylate glue group had less surgical stress and hence less discomfort than the suture repair group. Because the influence of surgical trauma has already faded and fibrosis has not fully grown to cause groin discomfort, both groups showed similar pain levels at one month. This is why, at 6 and 12 months after surgery, pain levels in the cyanoacrylate glue group were much lower than those in the suture repair group, because by that time, fibrosis had developed at the suture glue, contributing to the development of CGP [16]. One of the main causes of CGP after inguinal hernia repair is the method of mesh fixation. Different mesh fixation methods have been investigated, including self-gripping meshes, which are more expensive than ordinary meshes [18].

New recurrent hernias and high pain levels at 7 days postoperatively were the sole predictors of CGP after Lichtenstein surgery, according to a regression analysis of 625 patients, while the kind of mesh or the method of mesh fixation were not [19].

In terms of postoperative complications, both groups were comparable, which contradicted the results of another study [12]. After cyanoacrylate fixation, the rate of postoperative morbidity was shown to be much lower following suture fixation. The rates of seroma and hematoma formation were nearly identical in the two groups. Conversely **Liu *et al.*** [16] found that, after-mesh fixation with fibrin glue, the rate of hematoma/seroma formation was much lower than after suture fixation. The modest number of patients in the current study could explain why the two groups had similar rates of problems.

On short-term follow-up, neither group had a recurrence of hernia. The long-term effectiveness of tissue adhesive glue in providing adequate mesh attachment and preventing hernia recurrence has been questioned. Despite the short follow-up in this investigation, previous trials with longer follow-up have already produced similar results, indicating that tissue adhesive glue is successful in preventing hernia recurrence [12, 16, 17].

The results of this study agree with those of **Karigoudar *et al.*** [20], and **de Goede *et al.*** [21], in terms of immediate and long-term pain, which is lower in the glue group, as well as the mean operative time, which was 44.35 minutes in the glue group and 57.33 minutes in the suture group, and this difference was significant.

In the current study, postoperative hematoma, infection, and seroma were less common in the glue group, although the difference was not statistically significant. In both groups, there was no recurrence. Patients in the fibrin glue group were also less likely to experience early local hemorrhagic complications [such as ecchymosis, hematoma] than patients in the suture group, according to **Negro *et al.*** [22], who conducted a multicenter prospective observational study comparing fibrin glue versus sutures for mesh fixation in the Lichtenstein repair of inguinal hernia. In a comprehensive review and meta-analysis published in 2013, **Colvin and his colleagues** [11] found that initial postoperative pain, hematoma, and the time it takes to return to regular activities are all related.

Finally, it could be concluded that cyano-acrylate glue for mesh fixation in Lichtenstein repair of adult inguinal hernia shows advantages over mesh fixation by sutures in terms of immediate and chronic post-operative pain, operative time, and postoperative complications. with no difference in the recurrence rate as no recurrence was documented in both groups. However, the current study has some limitations, including being a single-institution study with a small number of patients and a short follow-up period. To corroborate the outcomes of the current experiment, larger, multicenter trials with longer follow-up are required.

Disclosure: None to be disclosed

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