Comparative Study between Cyanoacrylate Glue versus Sutures for Fixation of Mesh in Inguinal Hernia Open Repair

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Objectives: The Lichtenstein technique is currently the first to repair unilateral primary groin hernias. We aimed to conduct long lateral chain cyanoacrylate as tissue adhesive glue for open inguinal hernias mesh Fixation.

Methodology: 60 patients of inguinal hernia repair were divided randomly into two groups, Group A, sutures did mesh fixation. Group B, mesh fixation was done with cyanoacrylate glue.

Postoperative pain was measured with VAS by direct interview or phone call at 24 hours, 48 hours, seven days, 15 days, one month, three months, and six months after the operation.

Results: There was a statistically significant difference regarding the postoperative pain with a p-value <0.05 between two study groups after 24 hours of operation and after 15 days, 1, 3, and 6 months, with a low mean score among the glue group, which indicated low pain score among glue group.

There was a statistically significant difference with p-value <0.05 between the two study groups regarding operative time with low mean duration among group used glue, which indicated that using glue instead of suture will consume less time in operation.

Conclusion: Mesh fixation with glue causes less postoperative pain, both acute and chronic, than the classical suture fixation, with similar morbidity and recurrence rates.

Key words: Lichtenstein, pain, glue.

Introduction

The Lichtenstein technique is currently the first to repair unilateral primary groin hernias,[1] despite the demonstration of low morbidity and good long-term results,[2] several recent articles demonstrated an unacceptably high rate of chronic inguinal pain with an average incidence of 12%. Still, they sometimes reported high rates as high as 53%.[3-11] Many studies considered chronic postoperative pain as a primary surgical outcome,[9] and few of them evaluated the social impact of post herniorrhaphy chronic pain, which has been reported to affect the social and work life of up to 6% of patients.[3,5,10,12] Considering that some 20 million hernia repairs are performed each year worldwide,[13] it necessarily follows that more than 1 million patients worldwide have their lives negatively modified by chronic pain after an easy hernia repair.

Many factors have been blamed for the development of post herniorrhaphy chronic pain, i.e., the surgeon's experience, presence of pain even before the operation, surgical technique, and mesh fixation. After introducing a tension-free technique, chronic groin pain can be due to nerve entrapment in the suture or the postoperative scar tissue, inflammation of the periosteum of the pubic tubercle traditionally taken into the first stitch, foreign body reaction to the mesh.[14,15] To avoid these problems and reduce the risk of chronic pain, different mesh fixation methods have been considered using tissue compatible glues.

We used long lateral chain cyanoacrylate conducted as tissue adhesive glue for open inguinal hernias mesh fixation.

Patients and methods

This is a prospective randomized study of all patients admitted to Fayoum university hospital for surgical treatment of inguinal hernia disease from May 2016 to March 2017. All patients signed informed consent; the local ethics committee approved the study. This study included 60 patients. They were divided randomly into group A and group B Group A, and mesh fixation was done by sutures. In group B, mesh fixation was done with cyanoacrylate glue.

Male or female patients with inguinal hernia were included.

Recurrent inguinal hernia, complicated inguinal hernia, bilateral cases, patients below 18 years old, patients with preoperative chronic inguinal pain at the site of the hernia, any contraindication for spinal or general anesthesia such as renal, hepatic, or cardiac patients and coagulopathy were excluded

Patient evaluation

The evaluation of the patients included the following:

Operative technique

All patients received spinal anesthesia and 1 gm Ampicillin intravenous at the time of induction of anesthesia. Supine position.

The incision was placed along the lower abdominal crease 2 cm from the midline extending 5_6 cm laterally to the mid inguinal point. The subcutaneous fat was then opened along the incision length, and careful hemostasis was achieved by ligating superficial external pudendal and superficial epigastric vessels.

The Scarpa fascia was similarly opened along the incision length, down to the external oblique aponeurosis. The external inguinal ring and the lower border of the inguinal ligament were visualized.

The external oblique aponeurosis was opened along the incision line, starting from the external ring and extending laterally for up to 5 cm. The ilioinguinal nerve, lying underneath the aponeurosis, was identified and safeguarded during this procedure. The superior and inferior flaps of the external oblique aponeurosis were gently freed from the underlying contents of the inguinal canal and overturned and separated to expose the cremaster with the cord structures, the ilioinguinal and iliohypogastric nerves, the uppermost aponeurotic portion of the internal oblique muscle, and conjoined tendon, and the free lower border of the inguinal ligament.

The spermatic cord and the cremaster were lifted and separated from the pubic bone for about 2 cm beyond the pubic tubercle to extend the Mesh well beyond the pubic tubercle.

When lifting the cord, we include the genitofemoral nerve and the spermatic vessels along with it. All of these structures were encircled in tape for ease of handling. The cord structures encircled in the tape were separated from the inguinal canal floor up to the internal ring.

The cord structures and all of the nerves of the inguinal canal had been visualized; the next step was to identify and isolate the hernia sac. Next, the patient was asked to cough, and the groin region was examined for the presence of an indirect hernia, a direct hernia, a femoral hernia, a combined hernia.

The indirect hernia sac lied anterolateral to the cord structures and was visualized by dividing the cremaster muscle longitudinally. The hernia sac was identified and separated from the spermatic vessels, and the vas deferens up to its neck.

The neck of the hernia sac was transected at the midpoint of the inguinal canal, and the proximal part is suture-ligated. High ligation of the proximal sac was done, and the stump was reduced deep underneath the internal ring. The distal sac was left in place; the anterior wall of the distal sac was incised to prevent postoperative hydrocele formation.

A direct inguinal hernia lay posteromedial to the cord structures. The direct hernia sac was isolated and dissected free. Its contents were reduced, and the peritoneal sac was inverted with placation of the inguinal floor by prolene 2_0.

A 10 × 15 cm piece of polypropylene mesh was used for a Lichtenstein hernioplasty. On the medial side, the sharp corners of the Mesh were trimmed to conform to the patient's anatomy.

To compensate for future shrinkage the Mesh was wide enough to extend 3-4 cm beyond the boundary of the inguinal triangle. To compensate for increased intra-abdominal pressure when the patient stands up, the Mesh was placed lax in the posterior wall of the inguinal canal in such a way that it acquires a domelike wrinkle.

Suture group

The first medial most stitch fixed the mesh 2 cm medial to the pubic tubercle, where the anterior rectus sheath was inserted into the pubic bone. Care was taken not to pass the needle through the periosteum of the bone or the pubic tubercle. The same suture was then used as a continuous suture to fix the lower edge of the Mesh to the free lower border of the inguinal ligament up to a point just lateral to the internal ring.

Next, a slit was made in the lateral end of the Mesh to create a narrower lower tail (The lower one-third) and a wider upper tail (The upper two-thirds). Finally, the slit extended to a medial point to the internal inguinal ring.

The upper tail was then passed underneath the cord in such a way as to position the Mesh posterior to the cord in the inguinal canal, and the spermatic cord was placed between the two tails of the Mesh. The upper tail was then crossed over the lower one, and the two tails were held in artery forceps.

With the Mesh kept lax, its upper edge was then fixed to the rectus sheath, and the internal oblique aponeurosis with two or three interrupted prolene sutures.

The two tails were then tucked together and fixed to the inguinal ligament lateral to the internal ring, thus creating a new internal ring made of Mesh.

Cyanoacrylate glue group

In Group B, the Mesh was fixed with n-butyl-2-cyanoacrylate tissue adhesive glue Attention was paid to avoid dripping The glue on the nerves. Only one vial of glue was used for each patient. One drop was used to fix the Mesh over the pubic tubercle; three drops were used to fix the lower tail of the Mesh over the inguinal ligament. The other three drops were used to fix the upper tail of the Mesh to the rectus sheath and the internal oblique aponeurosis.

The two posterior wings of the Mesh were glued with one drop from the glue vial, paying attention to taking only the Mesh and not any tissue.

All patients had the same polypropylene kind of Mesh (Heavyweight prolene mesh size 10x 15), irrespective of the fixation method.

Hemostasis was ensured in the inguinal canal, which was then closed by suturing the two flaps of the external oblique aponeurosis with vicryl 2_0. Care was taken not to injure the underlying ilioinguinal nerve. Suturing was started laterally and continued medially. Insertion of a suction drain size (16) was done in 13 cases in group A and 10 cases in group B.

Subcutaneous tissue was approximated with interrupted sutures (Vicryl 3_0) to obliterate any dead space, and the skin was approximated with prolene 3_0 sutures.

The operative site was cleaned, and a sterile dressing was applied.

Postoperative analgesic treatment was just a diclofenac sodium intramuscular injection upon the patient's request when the patient was still in the hospital. Oral NSAIDS was prescribed after discharge.

Operative time was measured and recorded per each case from the time of the skin incision till the time of skin closure.

The hospital stay was 48 hours per case, and the drain was removed at the discharge time. After hospital discharge, follow-up visits were done at seven days,15 days, one month, and six months.

Skin Stitches were removed 15 days after the operation. In addition, postoperative inguinal ultrasound was done for the first three cases of glue fixation after one month of the operation to ensure no complication and ensure that the Mesh was in place.

In cases presented with postoperative seroma or scrotal edema, the inguinal ultrasound was done for these cases to ensure the diagnosis, exclude other complications, and know the size of the seroma.

Follow-up visits searched for postoperative pain and postoperative complications such as seroma, wound infection, wound dehiscence, postoperative hydrocele, testicular atrophy, iatrogenic undescended test, or recurrence.

Postoperative pain was measured with VAS by direct interview or phone call at 24 hours, 48 hours, seven days, 15 days, one month, three months, and six months after the operation.

Statistical Analysis

- Data were collected and coded to facilitate data manipulation and double entered into Microsoft Access, and data analysis was performed using SPSS software version 18 in windows 7.
- Simple descriptive analysis in the form of numbers and percentages for qualitative data, and arithmetic means as central tendency measurement, standard deviations as a measure of dispersion for quantitative parametric data, and inferential statistic test:

In-depended student t-Test used to compare measures of two independent groups of quantitative data

Chi-square test to compare two of more than two qualitative groups.

The P-value≤ 0.05 was considered the cut-off value for significance

Results

This study included sixty patients between May 2016 to March 2017. All cases were done at Fayoum University Hospital. Three experienced senior surgeons did all cases. Thirty patients were randomly allocated to group (A) and 30 to group (B).

The age of patients in group (A) ranged between 22 and 55 with mean of the age (36+_ 9.6) years old, age of the patients in group B ranged between (21 and 51) with mean of the age (38+_10.1).

Comparison of means proved no statistical difference between the two groups with a p-value >0.05, indicating proper matching regarding age in **(Table 1)**.

Comparison of operative time means between both groups showed statistical significance. For example, increase in duration in group A (83.7 ±18.6) minutes than in group B (59 ±10.9) minutes with a p-value <0.05. this indicates that using glue instead of suture will consume much less time in operation.

Comparison between the two study groups regarding

postoperative complications shows statistical significance with a p-value <0.05. 86.7% of glue group show free of any complication versus 66.7% among suture group. Also, no patients complained of chronic pain among the glue group versus 23.3% among the suture group **(Table 2)**.

Comparison between both study groups regarding wound infection shows no statistical significance. Three patients show postoperative wound infection, one in group A, two in group B **(Table 2)**.

Comparison between study groups regarding postoperative seroma show no statistical significance four patients developed seroma .two in group A and two in group B **(Table 2)**.

Comparison between different occupations regarding chronic pain proved that there is no statistical significance difference that indicates proper matching between both groups regarding patient occupation **(Table 3)**.

Comparison between the two study groups regarding VAS score after 24 hours of operation and after 15 days, 1, 3, and 6 months show statistical significance difference with p-value <0.05, with low mean score among glue group, which indicated low pain score among glue group.

On the other hand, there is no statistically significant difference with p-value >0.05 regarding VAS score after 48 hours and after seven days. this is illustrated in.

(Table 4) illustrates a statistically significant difference with p-value <0.05 between two study groups regarding VAS score after 1, 3, and 6 months, with low mean score among glue group, which indicated low pain score among glue group

(Table 5) illustrates a statistically significant decrease in VAS score follow-up with a p-value <0.05 among the suture group, decreasing from 6.1 after 24 hours to 0.30 after six months.

Table 1: Comparisons of age in different study groups

Variables	Suture group (n=30)		Glue group (n=30)		p-value	Sig.
	Mean	SD	Mean	SD		
Age (years)	36.4	9.7	38.8	10.1	0.3	NS

Table 2: Comparisons of postoperative complications in different study groups

Postoperative complication	Suture group (n=30)		Glue group (n=30)		p-value	Sig.
	No.	%	No.	%		
Free	20	66.7%	26	86.7%	0.01	**S**
Chronic pain	7	23.3%	0	0%		
Free	20	66.7%	26	86.7%	0.7	NS
Wound infection	1	3.3%	2	6.7%		
Free	20	66.7%	26	86.7%	0.8	NS
Seroma	2	6.7%	2	6.7%		

Table 3: Comparisons of chronic pain in a different occupation

Occupation	Chronic pain				p-value	Sig.
	No (n=53)		Yes (n=7)			
	No.	%	No.	%		
Unemployed	8	15.1%	1	14.3%		
Farmer	10	18.9%	2	28.6%		
Driver	8	15.1%	1	14.3%		
Student	3	5.7%	0	0%		
Carpenter	3	5.7%	0	0%		
Electrician	4	7.5%	0	0%		
Café man	2	3.8%	0	0%	0.8	NS
Lawyer	2	3.8%	0	0%		
Plumber	2	3.8%	0	0%		
Butcher	2	3.8%	0	0%		
Baker	1	1.9%	0	0%		
Painter	3	5.7%	0	0%		
Worker	5	9.4%	3	32.9%		

Table 4: Comparisons of VAS score follow-up after one month in different study groups

VAS score	Suture group (n=30)		Glue group (n=30)		p-value	Sig.
	Mean	SD	Mean	SD		
1 month	1.6	0.9	0.40	0.5	<0.001	HS
3 months	0.9	0.8	0.12	0.3	<0.001	HS
6 months	0.30	0.6	0	0	0.008	HS

Table 5: Comparisons of VAS score follow-up among suture group

VAS score	Suture group (n=30)		p-value	Sig.
	Mean	SD		
24 hrs	6.1	1.4		
48 hrs	3.9	1.2		
7 days	2.8	0.8		
15 days	1.7	0.8	**<0.001**	**HS**
1 month	1.6	0.9		
3 months	0.9	0.8		
6 months	0.30	0.6		

Discussion

This study aimed to analyze one of the commonly blamed factors for postoperative complications, especially postoperative chronic pain. Method of mesh fixation seems to affect the incidence of postoperative complication and post chronic operative pain.

All patients were treated surgically by (Open hernioplasty) in our study. Half of them, group A the Mesh was fixed in the inguinal canal floor by nonabsorbable sutures (Prolene 0-2). The Mesh was fixed to the inguinal canal floor in the second half by cyanoacrylate adhesive glue.

We used the same type of mesh (Heavy weight) prolene mesh and the same size, 10 x 15 cm.

We fixed the meshes in place at the same points in both groups. Only we replaced sutures with glue to study the influence of both fixation techniques in the postoperative complications.

In our study male ratio was 100%. Although inguinal hernia can occur in both sexes, the disorder predominantly affects males with a male to female ratio 9:1.[16]

The primary endpoint of our trial was early and late postoperative pain.

In our study, the two curves of pain had similar trends but different levels of pain score. The peak of pain was in both groups 24 hours after surgery, when the effect of intraoperative anesthesia had wholly vanished, and the patient had restarted, his normal life. There was a statistically significant difference with a p-value <0.05 between the two study groups regarding VAS score after 24 hours of operation and after 15 days, 1,3, and 6 months, with low mean score among the glue group, which indicated low pain score among glue group.

On the other hand, there is no statistically significant difference with p-value >0.05 regarding VAS score after 48 hours and after 7 days.

Patients who had still pain 3 months after surgery most likely will have chronic pain. But there is an exciting trend also in the long run, as the seven patients who still had pain at the 6th-month follow-up visit were in group A.

In our study, The difference in average pain between the two groups is significant at 3 and 6 months after the operation.

However, RCTs by Dabrowiecki et al.[18] & Paajanen et al.[19] failed to find any difference in long-term pain.

Some recent meta-analyses and systematic reviews confirmed a reduction in chronic groin pain and a faster return to normal activities with the use of glue,[17] In contrast, others did not reach the same conclusions.[20,21] With a longer follow up, Kim-Fuchs et al. have been able to demonstrate a trend for less pain in the glue group concerning the suture group up to 5 years after surgery.[22]

From the site of interest, the seven patients who had chronic pain after the surgery in the suture group, six of them their jobs were associated with heavy work(1 driver,2 farmers,3 workers). This may raise the suspicion that the employment status of the patient may be a risk factor for the development of chronic groin pain after the surgery.

The secondary endpoint was the operative time. The duration of the procedure was recorded from the time of skin incision to the time of skin closure. There was a statistically significant difference with p-value <0.05 between the two study groups regarding operative time with low mean duration among group used glue, which indicated that using glue instead of suture will consume much less time in operation.

A study on 1987 patients by Ping Sun, et al. revealed that Fixation with glue was shorter in duration than the suture group (SMD -0.37, 95% CI -0.52 to -0.23; moderate quality of the evidence).[23]

Another study revealed that the glue group's mean length of surgery was 36.7±6.1 minutes, which was slightly more than in the suture group, 36.1±8.9 minutes. However, this difference was not statistically significant.[24]

Two patients from each group were complicated by postoperative seroma. These four patients were closed with suction drains removed 48 hours after the operation. The seroma of each case was treated by conservative follow-up until complete healing reached. No reoperation or re-insertion of the drain was needed. The explanation of the seroma that had happened may be due to the early removal of the drains.

Park et al.[25] suggest that a seroma should be considered a complication only if it persists for more than six weeks, presents continuous growth, or becomes symptomatic. Most seromas resolve spontaneously without any intervention. Seroma is a frequent complication after open repair of inguinal hernia, with a variable incidence that may reach up to 1-10% reported by different groups.[26]

Eight trials involving 1184 participants comparing glue versus sutures reported this outcome (Follow-up 3 to 16.7 months). There was no statistically significant difference between the two groups regarding seroma formation.[23] Superficial Wound infection was recorded in three cases in group A, and two in group B. Culture and sensitivity were done. Pseudomonas was the causative organism in the only one case in group A, and the patient was given carbapenems (Tinam) intravenous injection for one week until complete healing was reached. Klebsiella was the causative organism in the two cases of group B. Third generation cephalosporins (Ceftriaxone) vial injection was given for one week with repeated dressing until the discharge decreased gradually complete healing was reached.

Intravenous 1 gm vial of ampicillin was given to every case with induction of anesthesia. The use of antibiotic prophylaxis for "clean" surgical procedures is controversial. In classic inguinal hernia surgery, rates of wound infections vary from 1% to 14%.[27] Platt et al.[28] and Lazarthes et al.[29] found antibiotic prophylaxis to be of benefit in classic inguinal hernia repairs, but others.[30,31] Failed to document any benefit in terms of prophylaxis.

No recurrence could be detected in both groups during the period of follow-up. However, Kim-Fuchs et al. found a recurrence rate in patients whose Mesh was fixed with glue almost double that in patients whose Mesh was sutured.[22]

In another study made on 1932 patients for comparison between glue and sutures for mesh fixation in open inguinal hernioplasty, with follow up period from 3 up to 60 months with the median length of follow up less than 17 months, no hernia recurrence could be detected in both groups with similar recurrence rate.[23]

In brief, mesh hernioplasty is the essential treatment for inguinal hernia. In our study, all patients underwent surgery using the same technique except mesh fixation.

The follow-up period in our study was six months per case, during which we encountered an increase in the incidence of postoperative chronic pain in group A in which mesh was fixed with sutures.

The study had some limitations as a low number of cases and miscommunication after the period of stitches removal.

Another limitation was the short follow-up period; unfortunately, 6 months could be considered a nonsufficient interval to estimate the recurrence rate, as many can occur long-term.

Conclusion

This trial demonstrated once again that mesh fixation with glue causes less postoperative pain-both acute and chronic than the classical suture fixation, with similar morbidity and recurrence rates.

A large-scale, well-planned double-blinded, randomized controlled trial with a standardized technique and long-term follow-up could give more definitive results.

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