Evaluation of fibrin glue in inguinal hernioplasty

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Abstract: Background: Chronic pain is considered the most serious complication of inguinal hernioplasty after surgical site infection. One of the proposed solutions to this problem is to use tissue adhesive for mesh fixation, which prevents nerve and tissue damage. **Aim:** The aim of this study was to compare the postoperative pain, complications, and hernial recurrence after polypropylene mesh inguinal hernioplasty using fibrin sealant versus sutures for fixation. **Method:** This study was carried out on 60 male patients with primary unilateral inguinal hernia between September 2011 and June 2012. Patients were assigned randomly to either a mesh fixed with suture group A (n = 30) or a mesh fixed with fibrin sealant group B (n = 30). Postoperative pain was evaluated. Complications and hernia recurrence were recorded. **Results**: The two groups were equivalent for inclusion, exclusion criteria and preoperative data. The complication rate was high in suture group. The operative time was shorter in the fibrin sealant group by 8 min. (p = 0.001). There was no hernia recurrence in the fibrin sealant or suture group after follow-up for 12 months. **Conclusions:** This study confirms the effectiveness and advantages of fibrin glue over sutures in reducing post operative and chronic inguinal pain, numbness, discomfort with few complications. It should be considered as a first-line option for mesh fixation in hernioplasty in the future as there are promising and encouraging initial results.

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1. Introduction

One of the most crucial criteria for successful modern inguinal hernia repair is short recovery time combined with postoperative pain as minor as possible. Despite the evident advancement in the domain, these goals are still unachievable. The occurrence of postoperative chronic pain is especially disturbing as it is felt by 0-43% of patients, 11% on average [1]. Inguinal hernia repair is the most frequently performed procedure in general surgery [2]. The standard method for inguinal hernia repair had changed little over a hundred years until the introduction of synthetic mesh. This mesh can be placed by either using an open approach or by using a minimal access laparoscopic technique [3]. Over the last few years, the placement of a prosthetic mesh in front of the hernia orifice has become an increasingly popular strategy to prevent recurrence. Several techniques exist that require permanent fixation of the prosthesis to the abdominal wall, usually using tissue-penetrating devices like staples or sutures [4]. However, such techniques can cause post-operative bleeding as well as pain due to nerve compression [5]. In particular, most reports of chronic pain encountered after tension-free groin hernia repair are related to the use of these tissue-penetrating devices [4-6]. The recognised problem of complications associated with permanent mesh fixation methods in groin hernioplasty prompted the search for other fixation techniques. Fibrin sealant (has been proposed as an alternative, a traumatic method for mesh fixation based on its effective, proven adhesive properties, as well as its potential additional wound-healing properties[7,8,9]. fibrin sealant is a biodegradable, biological preparation combining highly concentrated, human plasma-derived fibrinogen (75–115 mg/mL) and thrombin (500 IU/mL). The mixing of these components in the presence of calcium chloride leads to the development of a three-dimensional matrix of polymerised fibrin fibers in a process mimicking the last step of biological coagulation. Fibrin sealant can, therefore, be used as an adjuvant to haemostasis in a variety of surgical applications [10]. In 1997, **Chevrel & Rath** first proposed fibrin sealant as an alternate means of mesh fixation in hernia repair, with the aim of reducing the rate of hernia recurrence [12]. **Canonico & colleagues**[10]later reported the benefits of fibrin sealant in reducing bleeding complications following hernia repair in patients with impaired coagulation. **Katkhouda & colleagues** [13] employed a pig model using a total extraperitoneal (TEP) technique to evaluate the tensile strength of mesh fixation 12 days after the use of fibrin glue and demonstrated equal strength to staples. The results of these studies have encouraged surgeons to use fibrin sealant in daily practice as a traumatic alternative to mechanical mesh fixation. Promising initial experimental results have shown that the strength of mesh fixation with fibrin glue is at least comparable to those using staples [14].

Increased fibroblast activity even resulted in better and faster incorporation of the mesh material [15]. A lower rate of early postoperative pain with earlier reconvalescence was reported, but also, and primarily, a reduction in chronic pain in comparison with mesh fixation using staples [16]. A significant decrease in seroma formation is described in most studies [17].

The aim of this study was to assess post-operative pain, numbness; discomfort and hernial recurrence after polypropylene mesh (Lichtenstein tension-free technique) inguinal hernioplasty using fibrin glue versus sutures for fixation.

2. Patients And Methods

This study was carried out on 60 male patients with primary unilateral inguinal hernia between September 2011 and June 2012, their ages ranged from 24 to 65 years. All patients were evaluated preoperatively by medical history and clinical examination, and all patients were operated with the same surgical technique (**Lichtenstein)** using a polypropylene mesh as prosthetic material. Patients were assigned randomly into 2 groups; a mesh fixed with suture group A (n = 30) or a mesh fixed with fibrin sealant group B (n = 30). **Group A** (suture group): 30 operations were done using the conventional repair procedure with polypropylene sutures (prolene 2/0) for mesh fixation. **Group B** (sealant group): 30 operations were done using fibrin glue for fixation of the mesh. All patients had been followed up for a minimum of 12 months. *The exclusion criteria*: age more than 65 & less than 18, obesity, emergency (obstruction, strangulation), recurrence or recent infection. All patients were fully informed about the procedure and a written informed consent was obtained. Spinal and epidural anaesthesia were used. Antibiotic prophylaxis with Cephtriaxone was administered on induction and continuing with 1 g every 24 hrs postoperatively for a duration of 3 days. Same surgical procedures were used for the suture group (A) and the fibrin sealant in group (B), apart from the method used to secure the prostheses. An inguinal incision of 5–6 cm was made to expose the external oblique aponeurosis. The ilioinguinal nerve was identified and preserved. The upper and lower portions of the external oblique muscle were separated from the underlying tissues in order to establish a space to allow the subsequent placing of the mesh. The spermatic cord was then dissected and separated from the posterior wall. The cremastric muscle was incised longitudinally. Two flaps were therefore isolated and resected. The sac was separated from the cord, resected and then closed with an absorbable suture material. Then we are reached the stage of mesh fixation. The X-marks are the points of mesh fixation either by suture or dots of fibrin glue **(Fig.1)**. In the suture group (Group A), the mesh of 6-12cm was fixed to the pubic tubercle, inguinal ligament and conjoint tendon by interrupted non-absorbable sutures (prolene 2/0) (Fig. 2). In the fibrin sealant group (Group B), it was secured with fibrin glue at four points, on the deep face of the conjoint tendon. A single point was required to close the slit of the mesh and, thereby, encircle the spermatic cord. This point is only supported by the sides of the mesh and never by the tissues. Two to three milliliters of fibrin glue (prepared from the patient's serum in 10 cases in other 20 patients the glue was bought from an international company) was then sprayed on the anterior side of the mesh (Figs. 3). The aponeurosis was then closed anterior to the cord structures by an absorbable suture (vicryl 2/0). The operation was terminated by suture of the subcutaneous tissue by an absorbable suture (vicryl 2/0) and the skin by non-absorbable suture. Suction drainage was used in group (A). Patients were monitored in a recovery room for a minimum of one hour. Systematic analgesia as non-steroidal anti-inflammatory drugs was used. Intake of liquid diet was resumed in the evening after the operation, and a normal diet was allowed from the next day. Patient was discharged to home from one day after surgery. Post-operative parameters assessment of both groups included local complications, such as infection (wound or mesh), seroma, haematoma, post-operative pain and urinary retention. Also chronic pain and hernial recurrence were assessed during the first year. All patients were closely followed up and evaluated at 72 hours, 1st week, 1st month, 3rd month, 6th month and one year after surgery and had answered a previously established protocol. All patients of each group were contacted to be interviewed and examined at the point of statistical analysis of this study. The objective of the clinical examination was to detect a recurrence. For the postoperative pain sequelae, the criteria defined by **Cunningham & colleagues**, [18] were used to characterize the chronic pain as follows: Mild: occasional pain or discomfort that did not limit activity, with a return to pre-hernia lifestyle. Moderate: pain preventing return to normal preoperative activities (inability to continue any sports or to lift objects without pain). Severe: pain constantly or intermittently present but so severe as to impair normal activities, such as walking. Quality of life was also evaluated.

Statistical analysis

Mean & SD of different variables were estimated. Comparison between the 2 groups was performed using t-test or chi square test. Values of $p<0.05$ were accepted as statistically significant

3. Results

This study included 60 male patients with primary inguinal hernia, on whom fixation of the

mesh was undertaken differently, a mesh fixed with suture group A (n = 30) or a mesh fixed with fibrin sealant group B (n = 30). **Group A** (suture group): 30 operations were done using the conventional repair procedure with polypropylene sutures (prolene 2/0) for mesh fixation. **Group B** (sealant group): 30 operations were done using fibrin glue for fixation of the mesh. The study assessed the results of surgical treatment in both groups. Demographic and surgical variables did not fundamentally differ in both groups **(Table I).** As regards the operative time, a reduction of 8 min (p = 0.001) was observed in fibrin sealant group. As regards the length of hospital stay by days, patients in fibrin sealant group stayed in hospital shorter (median: 2 vs. 3 days; p=0.06).

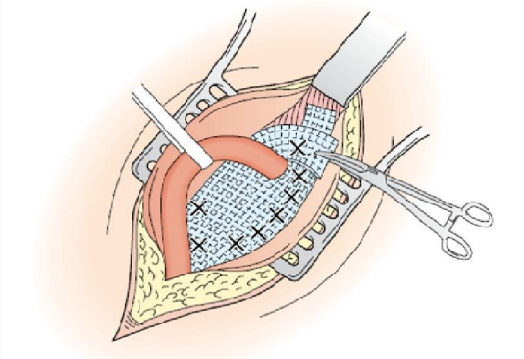

Fig.1: X-marks are the points of mesh fixation either by suture or dots of fibrin glue.

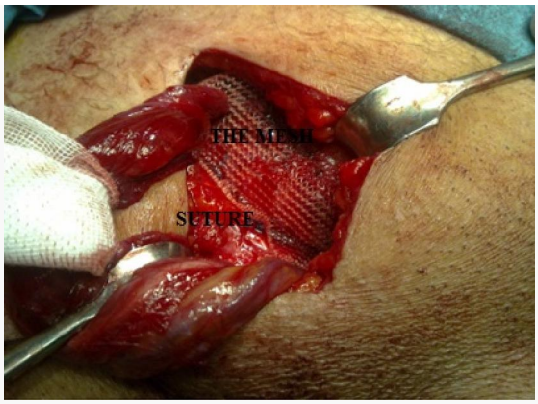

Fig.2: Mesh fixed with suture.

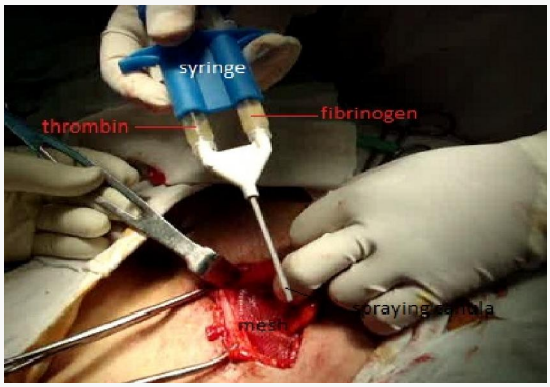

Fig.3: Mesh fixed with fibrin glue.

Table I: Demographic data and details of the surgery in both groups

Variable	Sealant group (n = 30)	Suture group (n = 30)	p- Value
Average age ± standard deviation	45.4 ±13.4	43.4 ±14.8	0.63
Manual work/headwork/no work	20/5/5	22/5/3	0.33
Hernia right side/left	16/14	18/12	0.88
spinal/general anesthesia	18/12	17/13	0.92
Hernia type oblique/direct/both	22/8/0	21/8/1	0.36
Width of hernia ring 1/2/3 fingers	12/12/6	16/12/2	0.28
Dissected hernia sac/reduced	4/26	6/24	0.50
Inguinal nerves dissected/intact	21/9	22/8	0.84
Length of hospital stay (days)	2 [2-4]	3 [2-6]	0.06
Mean operative time (min)	41 ± 6	49 ± 9	0.001

Positioning the mesh was undertaken without any difficulty in both groups. Secondary complications to surgery **(Table II)** which appeared were as follows: Group A: haematoma of the surgical wound in inguinal region occurred in (1/30) patient, and necessitated drainage. Wound seroma occurred in (2/30) patients and was aspirated. Scrotal oedema occurred in (4/30) patients. While in Group B: No haematoma or seroma of the surgical wound in inguinal region was noticed in any patients while scrotal oedema occurred in (1/30) patient and remitted in a short time. The overall complication rate was (7/30) in the suture group vs. (1/30) in the fibrin sealant group. All the complications were treated using conservative methods until hospital discharge. There were no recurring hernias in both groups.

Table II: Postoperative complications:

	Suture group	Fibrin sealant group	*P* value
Hematoma	1/30	0/30	NS
Seroma	2/30	0/30	NS
Scrotal edema	4l30	1/30	0.06
Hernial recurrence	0/30	0/30	NS
Complications	7/30 (23.33%)	1/30 (3.33%)	0.002

NS: non significant

Postoperative pain

All patients were questioned specifically on pain and postoperative comfort and clinical data was verified through physical examination at 48 hrs and 7 days after surgery and there was less local inflammatory reaction at surgical site in sealant group.

As regards pain assessment at 48 hours post operative according to Cunningham's criteria, it was found that, in **suture group**: 2/30 patients presented no pain, 11/30 patients presented mild pain, 16/30 patients had moderate pain and 1/30 patient had severe pain. Pain remitted rapidly in all cases with analgesics (NSAIDs). One patient began with chronic pain of moderate intensity one month after surgery and remained stable, although this was tolerable at 6 months after surgery.

In **sealant group**: 9/30 patients presented no pain, 11/30 patients presented mild pain, 10/30 patients had moderate pain. Pain remitted rapidly in all cases with analgesics. One year following surgery no patients presented chronic pain.

Thirteen patients missed from follow up at 6 months and became 19 patients at 12 month.

So pain was more often present and more frequent in the suture group ($p < 0.05$) **(Table III)**, although tolerable in all cases, few cases requiring higher doses of analgesia. From these results it was found that comfort was greater in the sealant group.

Table III: **Pain severity on individual days of the postoperative period**

Post-operative days	Pain intensity							
	No pain		Mild		Moderate		Severe	
	Group A	Group B	Group A	Group B	Group A	Group B	Group A	Group B
2	2	9	11	11	16	10	1	-
7	5	13	20	15	4	2	1	-
30	8	21	21	8	1	1	-	-
90	12	23	17	7	1	-	-	-
180	13	14	14	5	1	-	-	-
360	15	20	5	1	-	-	-	-

Return to professional activity depended on the kind of job done; the time was significantly longer in the group of manual workers (mean: 45 vs. 30 days; $p<0.05$). Return to daily activities, sport and driving was similar in both groups.

Table IV: Return to normal activity levels in both groups:

Return to activities	Sealant group (n = 30)	Suture group (n = 30)	Value of p
	Mean [range] days		
Daily	3 [2-4]	5 [4-7]	0.23
Manual workers	30 [25-60]	45 [30-90]	0.003
Sport	30 [30-40]	35 [30-45]	0.28
Driving	7 [5-14]	8 [7-14]	0.77

4. Discussion

Inguinal hernia repair is the most frequently performed procedure in general surgery [2]. Over the last few years, the placement of a prosthetic mesh in front of the hernia orifice has become an increasingly popular strategy to prevent recurrence. Several techniques exist that require permanent fixation of the prosthesis to the abdominal wall, usually using tissue-penetrating devices like staples or sutures [4]. However, such techniques can cause post-operative bleeding as well as pain due to nerve entrapment [5]. The presence of postoperative pain in the inguinal

region after surgery for inguinal hernia has been increasingly referred to in the literature of medical journals. Lesions mainly involve the iliohypogastric, ilioinguinal or genito-femoral nerves and may be due to injury of the nerve, trapping in a suture, stretching or even electro-coagulation, which usually occurs during the dissection of the hernia or securing of the mesh. These neurological lesions are frequent as the anatomical variations in the neurological parts of the inguinal region are common [19]. Also, the reaction of the periosteum at pubic tubercle level where the edge of the mesh is attached using a suture, is a source of controversy due to the frequent neuralgias located at this level [20]. Many publications reflect this possibility [21] and for this reason achieving total disappearance of pain after hernia surgery of the abdominal wall has become a key objective. A number of different studies which have appeared tackle the problem of sutures, or the possibility of mesh fixation with no stitches [20]. The use of glues has been advocated for different surgical indications: liver resection, [22] fistulae, [23] intraoperative hemorrhages [24]. These painful sequelae are so frequent that we sought an alternative means of securing the prostheses in order to reduce them. **Katkhouda &colleagues** was the first to demonstrate the probability of a technique of laparoscopic repair using fibrin sealant in animals with promising results [25]. They found best post-surgical tolerance, with less pain and discomfort in the region where glue has been used in keeping the mesh in place with the absence of suture, and therefore with a less inflammatory reaction and less possibility of entrapment of the iliopubic nerve branches. Also, the absence of neuralgia at the pubic tubercle level underlines the importance of sutures in the appearance of this complication. Although the sample size was small, the results in terms of immediate and late post-operative pain were encouraging, with a reduction in both the incidence and severity of the pain. Moreover, this technique is very simple and reproducible, as shown by the significant reduction in mean operative time. These results support other studies evaluating repair by mesh fixation with fibrin sealant for feasibility and technical facility [26].

In the present study, the overall complication rate was 23.33% (7/30) in the suture group vs. 3.33% (1/30) in the fibrin sealant group ($p< 0.002$). Our results coincide with the Italian study results by **Canonico &colleagues** [26] as they do Lichtenstein technique and the mesh was fixed with fibrin sealant in 80 patients with 12 months follow-up. No complications were observed. Also similar results were reported in another study by Ghazy [27]. In a recent study of Sozen & colleagues, [28] No complications were observed in follow-up at 1 week, 1 month, 6 months and 12 months. In our study, haematomas and seromas were less common in the fibrin sealant group. This goes with the fact that fibrin sealant, which is recognized for its haemostatic and healing properties, was also found to be useful for reduction of certain local complications, such as haematomas, seromas or wound sepsis [29]. Also the use of fibrin sealant was considered to be effective for the prevention of local haemorrhagic complications after herniorrhaphy in patients with coagulation disorders [10]. In the present study, postoperative pain was more often present and more frequent in the suture group ($p < 0.05$) than in sealant group. There was less local inflammatory reaction at surgical site in sealant group. This agrees with the results of a Spanish study by **Hidalgo &colleagues**, [30] who assessed mesh fixation using fibrin sealant compared with polypropylene sutures in 55 patients treated for bilateral hernia using the Lichtenstein technique. Fibrin sealant and sutures were used for contralateral hernias in each patient. Similar overall outcomes were reported in both inguinal regions, but there was less post-operative pain and less inflammatory reaction associated with fibrin-fixed hernia repairs. Another studies reported similar results with less postoperative pain [16, 27]. In a recent study, the median VAS (visual analog scale) pain score was significantly lower in patients ($P < 0{\cdot}001$) using fibrin glue for fixation of the mesh [28]. Also In another study, in the early postoperative period, the pain reported by the patients (in adhesive group) was relatively weaker [31]. In our study, there were no recurring hernias in both groups. This agrees with the results of a previous study of Hidalgo & colleagues in which there were no recurrences after 1 year of follow-up [30], also the **Helbling's** study [20] provides similar results, although the follow-up period is even shorter. While one recurrence was seen in the fibrin glue group in a study comparing hernia repair with staples or fibrin glue, and it was attributable to a technical error in fixation of the mesh [16]. In a recent study of Sozen & colleagues [28], none of the patients had developed a recurrence at 12 months. As regards the operative time, a reduction of a mean of 8 min ($p = 0.001$) was observed in fibrin sealant group than suture group. This agrees with a previous study in which reduction of a mean of 9 min observed in fibrin sealant group than suture group [27]. As regards the length of hospital stay by days, patients in fibrin sealant group stayed in hospital shorter (median: 2 vs. 3 days; $p = 0.06$). This agrees with previous studies [16, 31]. Return to work is significantly faster in manual workers in the fibrin glue group than suture group ($p< 0.003$). In a previous study, the mean recovery time for normal physical activity was significantly shorter in the fibrin glue group compared with the staples group (7.9 vs.

9.1 day, respectively; $P < 0.001$) [16]. In another study, patients undergoing adhesive mesh fixation experienced a quicker return to daily household activities [31]. Fibrin sealant is a blood derivative and, therefore, presents a potential risk of infection. Up till now, no case report of hepatitis or HIV seropositivity has been described after the use of this type of product [32]. In our study, fibrin glue was prepared from the patient's serum in 10 cases with no possibility of infection. A previous study [16] assess morbidity following hernia repair with staples (n = 98) or fibrin glue (n = 99). The primary outcomes were early postoperative pain recorded using a visual analog scale (VAS). Secondary outcomes included complications such as nonspecific pain and recurrence. They found that the mean VAS scores were significantly lower in the fibrin glue group versus the staples group ($P < 0.05$). Lastly, the high costs due to spraying the fibrin sealant (2-3 ml) is sufficient for a hernia repair should be weighed with the cost of sutures or staples required for conventional fixation. The cost can be overcome by the reduced operative time, shorter hospital stay, less complication and the early return to work. To conclude, mesh fixation with fibrin sealant in open hernia repair surgery is a simple and reproducible technique. It is accompanied by a reduction in pain intensity (post operative and chronic inguinal pain), complications related to haemostasis (haematoma and seroma) with no increase in the early recurrence rate, less hospital staying and early return to work , an explanatory large-scale randomized prospective study is required to confirm these results.

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