Comparing sutures and human fibrin glue for mesh fixation during open inguinal hernioplasty

Ann. Ital. Chir., 2016 87: 252-256
pii: S0003469X16019151
www.annitalchir.com

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PURPOSE: *The aim of this study is to evaluate pain and further disabling complications in patients undergoing Lichtenstein technique for primary inguinal hernia repair by fixing the mesh with fibrin sealant versus sutures.*
METHODS: *This study was carried out on 116 patients between January 2009 and July 2009. All patients were male, between the ages of 20 and 75 years. Lichtenstein, using a polypropylene mesh as prosthetic material. A total of 116 hernias were operated on. Group I: 54 operations were done using the conventional repair procedure with polypropylene sutures (prolene 2/0) for mesh fixation. Group II: 62 operations were done using fibrin glue for fixation of the mesh. All patients were operated as day cases, with a maximum hospital stay of 12 hours; none required readmission.*
RESULTS: *No complications were observed in follow-up at 1 week, 1 month, 6 months and 12 months. At 12 months, none of the patients had developed a recurrence. The mean time for complete healing of wound after herniorrhaphy plus fibrin sealant was 8.13±7.88 days (range 6-28 days). This was markedly increased in group 1 patients (mean 12.08±8.59days, and range 8-32) (p <0.001).12 months after surgery, The median VAS pain score was significantly lower in group 2 patients (P < 0·001). The mean (SD) duration of incapacity for work was 5 (2-12) days in group 2(p <0.001).*
CONCLUSIONS: *This study confirms the effectiveness of fibrin glue in securing prosthetic meshes and reducing chronic inguinal pain.*

KEY WORDS: Chronic pain, Fibrin glue, Inguinal hernia repair

Introduction

Inguinal hernia repair is the most frequently performed procedure in general surgery [1]. Over the last few years, the placement of a prosthetic mesh in front of the hernia oriWce has become an increasingly popular strategy to prevent recurrence. The Lichtenstein technique is widely used because it is easy to learn and it is associated with a low rate of complications and recurrences [2]. Several techniques exist that require permanent fixation of the prosthesis to the abdominal wall, usually using tissue-penetrating devices like staples or sutures. However, such techniques can cause post-operative bleeding as well as pain due to nerve compression [3,4]. 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]. Inguinal herniorrhaphy is often performed as a day-case procedure with minimal postoperative morbidity. After inguinal hernia repair, patients can return to work early and enjoy a good quality of life [7]. Tisseel® 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 cal-

Pervenuto in Redazione Marzo 2012. Accettato per la pubblicazione Luglio 2012
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cium chloride leads to the development of a three-dimensional matrix of polymerised fibrin fibres in a process mimickingthe last step of biological coagulation. Fibrin sealant can, therefore, be used as an adjuvant to haemostasis in a variety of surgical applications [8,9]. In 1997, Chevrel and 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 [10]. Canonico et al. [8] later reported the benefits of fibrin sealant in reducing bleeding complications following hernia repair in patients with impaired coagulation. The results of these studies have encouraged surgeons to use fibrin sealant in daily practice as an atraumatic alternative to mechanical mesh fixation. Increased fibroblast activity even resulted in better and faster incorporation of the mesh material [11]. A lower rate of early postoperative pain with earlier reconvalescence is reported, but also, and primarily, a reduction in chronic pain in comparison with mesh fixation using staples[12]. A significant decrease in seroma formation is described in most studies[13].

The aim of this study is to evaluate pain and further disabling complications in patients undergoing Lichtenstein technique for primary inguinal hernia repair by fixing the mesh with fibrin sealant versus sutures (control group).

Patients and methods

This study was carried out on 116 patients between January 2009 and July 2009. All patients were male, between the ages of 20 and 75 years. All patients were evaluated prospectively. All patients were operated with the same surgical technique in all cases, Lichtenstein, using a polypropylene mesh as prosthetic material. A total of 116 hernias were operated on (Table II) Group I: 54 operations were done using the conventional repair procedure with polypropylene sutures (prolene 2/0) for mesh fixation. Group II: 62 operations were done using fibrin glue for fixation of the mesh. All patients had been followed up for more than 12 months. The inclusion criteria are age > 18 years, elective surgery, primary inguinal hernia and follow-up > 12 months. Exclusion criteria wereage > 80 years, emergency (obstruction, strangulation) recurrent hernia, femoral hernia, complicated hernia, obesity. All surgeries were performed by the same most experienced surgeon under local anesthesia. All patients were fully briefed about the surgical procedure and an informed consent was obtained. All patients were operated as day cases, with a maximum hospital stay of 12 hours; none required readmission.

Procedure

Antibiotic prophylaxis was given as a single dose of a third-generation cephalosporin. The inguinal region was prepared and the hernia sac managed according to the Lichtenstein technique. The ilioinguinal nerve, the iliohypogastric nerve and the genital branch of the genitofemoral nerve were identified and preserved. The spermatic cord was then dissected and separated from the posterior wall. The cremaster muscle was incised longitudinally. Two flaps were therefore isolated and resected.

Table I - *Operative and postoperative outcomes.*

Duration of operation (min)	**Group 1(n:54) 30 (20–40)**	**Group 2(n.62) 22(15–40)**	***p* value* 0.001**
Pain VAS score Short-term follow-up (2 days)	4 (2–6)	2 (1–3)	<0.001
Pain VAS score Mid-term follow-up (30 days)	1.8(0-9)	0.8(0-6)	<0.001
Pain VAS score Long-term follow- up (365 days)	0.8(0-6)	0	<0.001
Duration of incapacity for work (days)	8 (4–20)	5 (2–12)	<0.001
Complete healing time(days)	12.08±8.59(8-32)	8.13±7.88(6-28)	<0.001

*Mann–Whitney U test
Group 1 = with suction drains.
Group 2 = without drains. (fibrin selant)
VAS scale: 0 = no pain, 10 = unbearable pain.
Pain >3 on the VAS is considered to be moderate or severe

TABLE II - *Per-Operative findings (n=116)*

		Group 1 (n:54)	Group 2 (n.62)
Side of hernia	Right	40	48
	Left	12	12
	Bilateral	2	2
Type of hernia	Direct	22	24
	Indirect	28	36
	Combined (Direct + Indirect)	4	2

The sac was separated from the cord, resected and then closed with an absorbable suture material. In the suture group (Group I), the prosthesis of 6-11cm was fixed to the pubic tubercle, inguinal ligament and conjoint tendon by interrupted non-absorbable sutures (prolene 2/0) In the fibrin sealant group (Group II). An 6-11cm cm polypropylene mesh was placed on the inguinal canal and glued to the inguinal ligament and to the internal oblique muscle. The glue used was fibrin glue, around 1 ml being required for fixation. After two milliliters of fibrin glue was then sprayed on the anterior side of the mesh, the aponeurosis was closed anterior to the cord structures by an absorbable suture (vicryl 2/0). The operation was terminated by suture of the skin by non-absorbable suture.

The following parameters will be evaluated as secondary endpoints: recurrence; overall wound-healing complication rate (bleeding complications, bruising seroma, wound infection, mesh infection); postoperative pain; use of analgesic drugs; patient's satisfaction; incidence of adverse events; and time to return to normal activities. A close follow-up will be performed (48 hours, 1 month and 12 months) after surgery, with a final evaluation. Visual analog pain scores and quality of life (S.F.12) scores will be used to evaluate the results from the patients.

Statistical Analysis: Length of hospital stay, duration of incapacity to work, follow-up period, duration of operation and VAS pain scores were analysed with the Mann–Whitney *U* test. The probabilities of less than 0.05 were accepted as significant.

Results

We have a good evaluation of our observational study in the patients operated, 12 months after surgery. No complications like hematoma or seroma were observed in follow-up at 1 week, 1 month, 6 months and 12 months. At 12 months, none of the patients had developed a recurrence. There were no recurring hernias in both groups. All patients were questioned specifically on pain and postoperative comfort at 48 h and 30 days after surgery, with clear distinction between the two groups. From these results it was found that comfort was greater in the fibrin glue group and there was less local inflammatory reaction in this area. The operative time was longer in group 1 patients (30 minutes). In this study, postoperative pain was evaluated by a phone call from 48 hours to 12 months after surgery, using a score going from 1 to 10, where 1 corresponded to a pain-free status and 10 to the worst conceivable pain. Assessed 48 h after surgery, patients' mean VAS graded pain score was 4, indicating mild pain in group 1 (Table I). The mean time for complete healing of wound after herniorrhaphy plus fibrin sealant was 8.13±7.88 days (range 6-28 days). This was markedly increased in group 1 patients (mean 12.08±8.59days, and range 8-32) ($p < 0.001$).12 months after surgery. The median VAS pain score was significantly lower in group 2 patients ($P < 0{\cdot}001$) (Table I). The mean (SD) duration of incapacity for work was 5 (2-12) days in group 2($p < 0.001$) (Table I).

Discussion

Inguinal hernia repair is the most frequently performed procedure in general surgery[1]. 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. The Lichtenstein technique is widely used because it is easy to learn and it is associated with a low rate of complications and recurrences [2]. Inguinal herniorrhaphy is often performed as a day-case procedure with minimal postoperative morbidity. After inguinal hernia repair, patients can return to work early and enjoy a good quality of life [7].

The 'pain complex syndrome' after hernia repair includes three different aspects: 1) numbness and burning sensation 2) groin discomfort 3) neuralgia[14,15], with radiation of pain to the skin of the corresponding hemiscrotum, labium majus and Scarpa's triangle. Consensus of European Hernia Society, in TI.ME.LI. trial, has defined pain complex syndrome as the presence of one of the three or all of these aspects 1 year after surgery. In terms of percentage, the incidence of pain complex syndrome is assumed to be about 25% of patients undergoing inguinal hernia repair[16]. Moreover, some authors report that a significant proportion of the pain is of neuropathic origin[1-20]. Because of this, when genitofemoral, ilioinguinal and/or iliohypogastric nerves are damaged by suture entrapment or by contact with mesh, the probability of acute or chronic pain after surgery is very high. Etiology of postherniorrhaphy pain includes non-neuropathic and neuropathic causes or a combination of both. Non-neuropathic causes include mechanical pressure of folded or wadded mesh, periosteal reaction and scar-tissue formation. Neuropathic pain can be caused by compression of one or more nerves by 'perineural fibrosis',

suture material, staples and tacks or by nerves injuries. So if it is possible to limit the use of suture and fixation devices, chronic groin pain could be reduced.

Fibrin sealant (Tissucol; Baxter Healthcare) is a biodegradable adhesive that combines human-derived fibrinogenand thrombin activated by calcium chloride. It has been available commercially for more than 20 years and has been proven to be effective in numerous clinical applications [8,21-23]. In addition to its hemostatic action, the fibrinogen component gives the product tensile strength and adhesive properties [24], and this component promotes fibroblast proliferation [25].

Tisseel® began to be used in hernia repair from 2002, and quickly became popular as an alternative means of mesh fixation. Regarding the Lichtenstein technique, Canonico et al. [8] assessed the use of fibrin sealant in 80 patients in an Italian study with 12 months follow-up. No complications were observed, and the use of fibrin sealant was considered to be elective for the prevention of local haemorrhagic complications after herniorrhaphy in patients with coagulation disorders [8]. A Spanish study by Hidalgo et al. [26] 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 postoperative pain and less inflammatory reaction associated with fibrin-fixed hernia repairs. Once again, there were no recurrences after 1 year of follow-up. In our series, no recurrences were observed in any group, but Tisseel® group more rapid return to work noted.

Mesh repair can be performed under local, general or spinal anaesthesia but many surgeons prefer local anaesthesia especially in the elderly and moribund patients [29], as it avoids the systemic effects associated with general, spinal and regional anaesthesia [27-28]. It has a wide safety margin and the cost of mesh repair under local anaesthesia is significantly low. With local anaesthesia, the patient is fully awake and can move about which reduces the hospital stay. Due to early mobility, the postoperative convalescence period is reduced and most of the patients can resume their work within a week [27]. Urinary retention after repair under local anaesthesia is less common as compared to general anaesthesia [30,31].

The shorter operating, convalescing and ambulating times[12]as well as early discharge means that more elderly and moribund patients can safely undergo repairs [32,33].

In adults, undergoing day-case surgery for inguinal hernia, local anesthesia is preferred to general anaesthesia to reduce the anaesthetic risk in general and to reduce and incidence of post-operative ileus and urinary retention in particular. Also, local and spinal anaesthesia affords the surgeon the opportunity of testing the integrity of the repair on table by asking the patient to cough No re-admission and zero mortality recorded in this study highlights the neglible morbidity and safety associated with day-case surgery for inguinal hernia. This finding is in agreement with other studies that reported less than 0.5% re-admission rates [34,35] and neglible mortality [35-37].

In conclusion, mesh fixation with fibrin sealant in open hernia repair surgery is a simple and suitable. In our study, the use of Tisseel® was associated with a very low rate of post-operative pain. Fibrin sealant appears to be a promising alternative to stapling/suturing for mesh fixation during inguinal hernioplasty.

Riassunto

SCOPO DELLO STUDIO: Valutazione comparativa del dolore e conseguenze disabilitanti nei pazienti sottoposti alla riparazione con la tecnica di Lichtenstein di un'ernia primitiva con la fissazione della rete con collante di fibrina o con suture. Lo studio è stato condotto tra gennaio e luglio 2009 su 116 pazienti, tutti di sesso maschile, e di età compresa tra 20 e 75 anni, operati col la tecnica secondo Lichtenstein, usando come protesi una rete di pilpropilene.

MATERIALE E METODI: Pazienti sono stati suddivisiin due gruppi: nel I Gruppo sono stati inseriti 54 pazienti operati con la tecnica convenzionale usando suture di polipropilene (Prolene 2/0) per la fissazione della rete. Nel II Gruppo sono stati considerati 62 interventi con fissazione della rte con colla di fibrina. Tutti i pazienti sono stati operati in day-surgery, con un massimo di soggiorno in ospedale di 12 ore, e senza nessuna necessità di nuovo ricovero. Non si è registrata nessuna complicazione nel follow-up a 1 settimana, 1 mese, 6 mesi e 12 mesi. Al docicesimo mese nessn paziente ha presentato recidiva. Il tempo medio per la guarigione completa dell'incisione dell'erniectomia eseguita con colla di fibrina è stato di 8.13±7.88 giorni (da 6 a 28 giorni). Questo tempo è stato significativamente maggiore nel I Gruppo (tempo medio 12.08±8.59 giorni (da 8 a 32 giorni) - p <0.001.12 mesi dopo l'intervento il valore medio del punteggio VAS del dolore è stato significativamente inferiore nel II Gruppo di pazienti (p < 0·001). Il tempo medio di incapacità lavorativa (SD) è stato di 5 giorni (tra 5 e 12) nel II Gruppo (p <0.001).

CONCLUSIONI: Lo studio conferma l'efficacia della colla di fibrina nel fissare le meshes e per la riduzione del dolore inguinale cronico.

References

1. Rutkow IM, Robbins AW: *Demographic, classificatory, and socioeconomic aspects of hernia repair in the United States*. Surg Clin North Am, 1993; 73:413-26.

2. Amid PK, Shulman AG, Lichtenstein IL: *A critical evaluation of Lichtenstein tension-free hernioplasty*. Int Surg, 1994; 79:76-79.

3. Lichtenstein IL: *Herniorrhaphy. A personal experience with 6321 cases.* Am J Surg, 1987; 153:553-59.

4. McCormack K, Scott NW, Go PM, Ross S, Grant AM EU: *Hernia Trialists Collaboration. Laparoscopic techniques versus open techniques for inguinal hernia repair*. Cochrane Database Syst Rev 2003; CD001785.

5. Verstraete L, Swannet H: *Long-term follow-up after Lichtenstein hernioplasty in a general surgical unit*. Hernia, 2003; 7:185-90.

6. Kumar S, Wilson RG, Nixon SJ, Macintyre IM: *Chronic pain after laparoscopic and open mesh repair of groin hernia.* Br J Surg, 2002; 89:1476-479.

7. Poobalan AS, Bruce J, Smith WC, King PM, Krukowski ZH, Chambers WA: *A review of chronic pain after inguinal herniorrhaphy.* Clin J Pain, 2003; 19:48-54.

8. Canonico S, Sciaudone G, PaciWco F, Santoriello A: *Inguinal hernia repair in patients with coagulation problems: prevention of postoperative bleeding with human Wbrin glue*. Surgery, 1999; 125:315-17.

9. Mankad PS, Codispoti M: *The role of fibrin sealants in hemostasis*. Am J Surg, 2001; 182(2 Suppl):21-28.

10. Chevrel JP, Rath AM: *The use of fibrin glues in the surgical treatment of incisional hernias*. Hernia, 1997; 1:9-14.

11. Ten Hallers EJ, Jansen JA, Marres HA, Rakhorst G, Verkerke GJ: *Histological assessment of titanium and polypropylene fiber mesh implantation with and without fibrin tissue glue*. J Biomed Mater Res A, 2007; 80:372-80.

12. Lovisetto F, Zonta S, Rota E, Mazzilli M, Bardone M, Bottero L, et al.: *Use of human fibrin glue (Tissucol) versus staples for mesh fixation in laparoscopic trans- abdominal preperitoneal hernioplasty.* Ann Surg, 2007; 245:222-31.

13. Lau H: *Fibrin sealant versus mechanical stapling for mesh fixation during endoscopic extraperitoneal inguinal hernioplasty.* Ann Surg, 2005; 242:670-75.

14. McCormack K: *EU hernia trialist collaboration.* 2003.

15. Verstraete L, Swannet H: *Long term follow-up after Lichtenstein hernioplasty in a general surgical unit*. Hernia, 2003; 7:185-190.

16. Campanelli G, Champault G, Pascual MH, Hoeferlin A, Kingsnorth A, Rosenberg J, Miserez, et al.: *Randomized, controlled, blinded trial of Tissucol/Tisseel for mesh Wxation in patients undergoing Lichtenstein technique for primary inguinal hernia repair: Rationale and study design of the TIMELI trial*. Hernia, 2008;12:159-65.

17. Bay-Nielsen M, Perkins FM, Kehlet H: *Pain and functional impairment 1 year after inguinal herniorrhaphy: A nationwide questionnaire study*. Ann Surg, 2001; 233:1-7.

18. Perkins FM, Kehlet H: *Chronic pain as an outcome of surgery. A review of predictive factors*. Anesthesiology, 2000; 93:1123-133.

19. Amid PK: *A 1-stage surgical treatment for postherniorrhaphy neuropathic pain: triple neurectomy and proximal end implantation without mobilization of the cord.* Arch Surg, 2002; 137:100-04.

20. Condon RE: *Groin pain after hernia repair.* Ann Surg, 2001; 233:8.

21. Canonico S: *The use of human fibrin glue in the surgical operations*. Acta Biomed, 2003; 74:21-25.

22. Toosie K, Gallego K, Stabile BE, Schaber B, French S, de Virgilio C.: *Fibrin glue reduces intraabdominal adhesions to synthetic mesh in a rat ventral hernia model*. Am Surg, 2000; 66:41-45.

23. Fe'rnandez Lobato R, Garcia Septiem J, Ortega Deballon P, Martin Lucas FJ, Ruiz de Adana JC, Limones Esteban M: *Tissucol application in dermolipectomy and incisional hernia repair*. Int Surg, 2001; 86:240-45.

24. Katkhouda N, Mavor E, Friedlander MH, Mason RJ, Kiyabu M, Grant SW, et al.: *Use of fibrin sealant for prosthetic mesh fixation in laparoscopic extraperitoneal inguinal hernia repair*. Ann Surg, 2001; 233:18-25.

25. Zieren J, Castenholz E, Baumgart E, Muller JM: *Effects of fibrin glue factors released from platelets on abdominal hernia repair with a resorbable PGA mesh: Experimental* study. J Surg Res, 1999; 85:267-72.

26. Hidalgo M, Castillo MJ, Eymar JL, Hidalgo A; *Lichtenstein Inguinal hernioplasty: Sutures versus glue*. Hernia, 2005; 9:242-44.

27. Choudry ZA, Khan SA, Islam HRU, Siddique MT, Malik JI: *Lichtenstein repair of inguinal hernia under local anaesthesia. Day case procedure*. Ann King Edwards Med Coll, 2005; 11:367-69.

28. O'Dweyer PJ, Serpell MG, Millar K: *Local or general anaesthesia for open hernia repair: A randomized trial*. Ann Surg, 2003; 237:574-79.

29. Farrakha M, Shyam V, Bebars GA, Yacoub M, Bindu K, Kolli S: *Ambulatory inguinal hernia repair with prolene hernia system*. Hernia, 2006; 10:2-6.

30. Sanjay P, Woodward A: *Inguinal hernia repair; local or general anaesthesia*. Ann R Coll Surg Engl, 2007; 89:497-503.

31. Bay-Nielson M, Kehlet H: *Anaesthesia and post operative morbidity after elective groin hernia repair:a nation wide study*. Acta Anaesthesiol Scand, 2008; 52:169-74.

32. Kehlet H, Aasvang E: *Groin hernia repair: Anaesthesia.* World J Surg, 2006; 30:639-40.

33. Yang B, Liang MJ, Zhang YC: *Use of local or epidural anaesthesia in inguinal hernia repair: A randomized trial*. Zhonghua Wai Ke Za Zhi, 2008; 46:1234-236.

34. Lau H, Lee F: *An audit of the early outcomes of ambulatory inguinal hernia repair at a surgical day-case centre*. Hong Kong Med J, 2000; 6(2):218-20.

35. Adejuyigbe O, Abubakar AM, Sowande OA, Olasinde AA: *Day-case surgery in children in Ile-Ife, Nigeria: An audit*. Nigerian Journal of Surgery, 1998; 5(2):60-63.

36. Ibrahim NA, Ugburo AO, Atoyebi OA: *Early outcome of day surgery for inguinal hernia in sub-urban general hospital in Lagos, Nigeria*. Medical Journal, 2005; 46 (2):33-35.

37. Adeyemi SD, da Rocha-Afodu JT, Olayiwola B: *Outpatient herniotomy with ketamine: A prospective study of 50 herniotomized children and review of 219 herniotomies with ketamine*. West Afr J Med, 1985; 4:151-61.