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ORIGINAL ARTICLE

Open tension-free Lichtenstein repair of inguinal hernia: use of fibrin glue versus sutures for mesh fixation

P. Negro · F. Basile · A. Brescia · G. M. Buonanno · G. Campanelli · S. Canonico · M. Cavalli · G. Corrado · G. Coscarella · N. Di Lorenzo · E. Falletto · L. Fei · M. Francucci · C. Fronticelli Baldelli · A. L. Gaspari · E. Gianetta · A. Marvaso · P. Palumbo · N. Pellegrino · R. Piazzai · P. F. Salvi · C. Stabilini · G. Zanghì

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Abstract
Purpose To investigate pain and other complications following inguinal hernioplasty performed by the Lichtenstein technique with mesh fixation by fibrin glue or sutures.
Methods Five hundred and twenty patients were enrolled in this 12-month observational multicenter study and received either sutures or fibrin glue (Tissucol®/Tisseel®) based on the preference of the surgeon. Pain, numbness, discomfort, recurrence, and other complications were assessed postoperatively and at 1, 3, 6, and 12 months. Pain intensity was assessed by a visual analog scale (VAS; 0 [no pain] to 10 [worst pain]).
Results One hundred and seventy-one patients received sutures and 349 received fibrin glue. During the early postoperative phase, 87.4% of patients in the fibrin glue group and 76.6% of patients in the sutures group were complication-free ($P = 0.001$). Patients who received fibrin glue were also less likely to experience hematoma/ecchymosis than those in the suture group (both $P = 0.001$). The mean pain score was significantly lower in the fibrin group than the sutures group (2.5 vs. 3.2,

P. Negro · P. Palumbo
Azienda Ospedaliera Università degli Studi di Roma "La Sapienza", Rome, Italy

F. Basile · G. Zanghì
Azienda Ospedaliera Vittorio Emanuele, Catania, Italy

A. Brescia · P. F. Salvi
Azienda Ospedaliera San Andrea, Rome, Italy

G. M. Buonanno
Azienda Ospedaliera San Giuseppe Moscati, Avellino, Italy

G. Campanelli · M. Cavalli
Università dell'Insubria di Varese, I.R.C.C.S. Multimedica, Castellanza, Italy

S. Canonico · L. Fei
Seconda Università degli Studi di Napoli, Naples, Italy

G. Corrado
P.O. Unico Villa Malta, A.S.L. Salerno, Sarno, Italy

G. Coscarella · N. Di Lorenzo · A. L. Gaspari
Dipartimento di Scienze Chirurgiche, Università di Roma Tor Vergata, Rome, Italy

E. Falletto · C. Fronticelli Baldelli
Azienda Ospedaliera, Universitaria San Giovanni Battista, Molinette, Turin, Italy

M. Francucci
Azienda Ospedaliera Santa Maria, Terni, Italy

E. Gianetta · C. Stabilini
Azienda Ospedaliera Università San Martino di Genova, Genoa, Italy

A. Marvaso
P.O.S. Anna Rizzoli, A.S.L. Napoli 2, Lacco Ameno, Italy

N. Pellegrino
Ospedale Generale di Zona San Giuseppe Sambiasi, Nardo, Italy

R. Piazzai
Ospedale Santi Carlo e Donnino, Pergola, Italy

P. Negro (✉)
A.O. Policlinico Umberto, Viale del Policlinico, 190, 00133 Rome, Italy
e-mail: pal.negro@libero.it

$P < 0.001$). At 1 month, significantly fewer patients in the fibrin glue group reported pain, numbness, and discomfort compared with patients in the sutures group (all $P < 0.05$). Fibrin glue patients also experienced less intense pain (0.6 vs. 1.2; $P = 0.001$). By 3 months, the between-group differences had disappeared, except for numbness, which was more prevalent in the sutures group. By 12 months, very few patients reported complications.

Conclusions Tissucol fibrin glue for mesh fixation in the Lichtenstein repair of inguinal hernia shows advantages over sutures, including lower incidence of complications such as pain, numbness, and discomfort, and should be considered as a first-line option for mesh fixation in hernioplasty.

Keywords Inguinal hernia · Tension-free hernia repair · Human fibrin glue · Tissucol/Tisseel · Mesh fixation · Postoperative pain

Introduction

The increasing use of mesh procedures in inguinal hernia surgery has led to a substantial decrease in the incidence of hernia recurrence. As a result, surgeons (and, increasingly, their patients) are now focused on other measures reflecting the success of hernia repair. The prevalence of postoperative pain syndromes after open and laparoscopic procedures has been reported to be as high as 30% [1], and some analyses [2] estimate that 12% of patients feel themselves to be restricted in their daily activities because of pain.

Clinical studies have shown that both recurrence and chronic pain after endoscopic hernia repair are influenced by the type of mesh implanted and its method of fixation [3–9]. The ideal mesh fixation should produce no structural damage and be biocompatible in order to reduce the risk of hematoma and seroma [5]. Conventionally, the mesh prosthesis is secured by either sutures or staples. Despite the "tension-free" nature of these hernioplasties, sutures and staples may strangulate muscle fibers, compress regional nerves, or give rise to a lesion, leading to incapacitating pain or dysesthesia [10].

Complications associated with sutured mesh fixation following open groin hernia repair have prompted surgeons to evaluate methods of atraumatic fixation, such as the use of human fibrin glue. Fibrin glue is a biodegradable adhesive combining human-derived fibrinogen and thrombin that replicates the last step of the coagulation cascade. It has been used in a variety of surgical fields for its effectiveness, excellent local tolerability, and relative lack of adverse effects and contraindications. Its adhesive and hemostatic properties have been demonstrated in a number of experimental studies and clinical trials [11–13]. Studies with Tissucol®/Tisseel® fibrin glue (Baxter Healthcare, Deerfield, IL, USA) as a means of mesh fixation in hernia repair have shown promising results [3, 7–9, 14, 15].

The Lichtenstein technique is a standard procedure for open tension-free inguinal hernia repair performed using prosthetic meshes to strengthen the inguinal canal posterior wall [16]. Postoperative quality of life and the rate of postoperative complications are dependent on the type of mesh and method of fixation [3–9, 14], as well as meticulous surgical technique. Importantly, hernia can recur with the Lichtenstein technique if mesh overlap around the hernia orifice is inadequate [17]. Therefore, high-quality fixation methods should be used to properly secure the mesh until it is incorporated into the patient's own tissue. The purpose of our study was to investigate the frequency and severity of postoperative pain and other complications when prosthetic mesh is fixed by using fibrin glue compared with conventional sutures in inguinal hernioplasty performed by the Lichtenstein technique.

Patients and methods

Study design and patients

This was a prospective observational study carried out in 16 centers across Italy with extensive experience in hernia surgery. Male or female patients aged over 18 years of age with a primary unilateral uncomplicated inguinal hernia suitable for Lichtenstein repair were eligible for enrolment. Exclusion criteria included femoral or incarcerated hernia, the need for other abdominal procedure, body mass index (BMI) ≥ 35 kg/m^2, diabetes, immunological or coagulation disorders, warfarin or clopidogrel therapy, steroid therapy for long-term pain control, hypersensitivity to aprotinin, history of drug/alcohol abuse, and psychiatric disorders. Patients received either sutures or fibrin glue for mesh fixation based on the preference of the operating surgeon, as per routine practice.

Ethics committee approvals were obtained from the participating institutions and informed consent was sought from all patients.

Surgical techniques

Suture group

A polypropylene mesh was trimmed to fit the floor of the inguinal canal, and its apex was sutured to the pubic tubercle using a No. 3–0 Prolene suture. The same continuous suture was used to join the lower border of the mesh to the free edge of the inguinal ligament, after an opening was made into its lower edge to accommodate the

spermatic cord. The continuous suture was extended up just medial to the anterior superior iliac spine. Interrupted Prolene sutures were used to suture the two cut edges of the mesh together around the spermatic cord. The inferomedial corner of the mesh was attached, overlapping the pubic tubercle. The mesh was anchored to the conjoined tendon by interrupted sutures (Prolene 3–0). The external oblique aponeurosis was closed using absorbable sutures (Vicryl No. 2).

Fibrin glue group

Fibrin glue alone was sufficient for polypropylene mesh fixation, without the need for additional sutures. Fibrin glue was applied using either a needle or a spray applicator. Surgeons were permitted to use either application method, based on their personal preference.

Outcome measures

The prevalence of inguinal pain, numbness, and discomfort were assessed at hospital discharge until 1 month post-surgery (to determine early postoperative outcomes) and at 1-, 3-, 6-, and 12-month follow-up visits (to determine the medium- to long-term outcomes) via structured interviews with clinical report forms. A visual analog scale (VAS) was used to gauge patient pain intensity, ranging from 0 = no pain to 10 = worst pain. Recurrence due to technical errors, hematoma, ecchymosis, other complications (e.g., seroma, infection), use of analgesia and antibiotics, and time to return to normal activity were assessed. The evaluators were not blinded to treatment. At the time of operation, surgeons assessed the ease of use of fibrin glue application through a score ranging from 1 = very easy to 10 = very difficult.

Statistical analysis

Descriptive statistics were calculated. Differences between the study groups in terms of the proportions experiencing postoperative pain, numbness, discomfort, and recurrence due to technical errors were analyzed by the Chi-squared test. Continuous variables such as pain intensity and time to return to normal activity were analyzed by the Mann–Whitney *U*-test.

Results

Patients

Operations took place from January 2007 to January 2008. Tension-free repair of inguinal hernia was performed in 520 patients, with the fixation of mesh achieved with either fibrin glue (349 patients) or sutures (171 patients). Baseline demographic and clinical characteristics were similar between the treatment groups (Table 1). Our study included 484 (93%) male and 36 (7%) female patients with a mean age of 55 years (range 18–90); 70% of patients were workers or active pensioners. The mean (±SD) VAS pain intensity score in the preoperative phase was 2.9 (±2.0), with no significant difference between the study groups.

In 288 (55%) of patients, inguinal hernias were right-sided, 223 (43%) had left-sided hernias, and 9 (2%) had bilateral hernias, giving a total of 529 hernias. At surgery, hernias were classified according to the European Hernia Society (EHS) criteria [18]: 164 (32%) were L1, 191 (37%) L2, 5 (1%) L3, 65 (13%) M1, 100 (19%) M2, and 3 (1%) M3 (missing data on one hernia).

Of the 520 patients, 470 (90%) completed follow-up visits at 1, 3, 6, and 12 months. Fifty patients discontinued the study, 33/349 (9%) from the fibrin glue group and 17/171 (10%) from the sutures group. Of these 50 patients, 24 did not attend follow-up visits, one withdrew due to adverse events, one died (cardiac arrest), and 24 discontinued for other reasons.

Intra-operative outcomes

Surgery parameters were similar between the treatment groups, with the exception of the mean operating time, which was significantly shorter in patients receiving fibrin glue compared with those receiving sutures (55.6 vs. 61.2 min, $P < 0.001$) (Table 2). Fibrin glue was applied using a needle in 52% of patients and a spray device in 46% of patients (data missing for 2% of patients). In the fibrin glue group, 67% of patients received 1 mL glue, 23% received 2 mL, and 6% received 5 mL (data missing for 4% of patients). The mean VAS score for the ease of fibrin glue application was 1.8 ± 0.8, indicating a high level of ease among surgeons when using Tissucol.

Early postoperative outcomes

During the early postoperative phase (at hospital discharge until 1 month postsurgery), 305/349 (87.4%) of patients in the fibrin glue group and 131/171 (76.6%) of patients in the sutures group were free of complications ($P = 0.001$; Table 3). Patients in the fibrin glue group were also less likely to experience hematoma (1.7 vs. 8.2%) and ecchymosis (8.6 vs. 15.2%) than patients in the sutures group (both $P = 0.001$).

The mean VAS score for the intensity of pain reported by patients was significantly lower in the fibrin group compared with the sutures group (2.5 vs. 3.2, $P < 0.001$). The use of analgesics in the postoperative period was

Table 1 Preoperative patient characteristics

	Fibrin glue ($n = 349$)	Sutures ($n = 171$)	Total ($N = 520$)
Age, mean ± SD (years)	55 ± 15	55 ± 14	55 ± 15
Men, number (%)	325 (93.1)	159 (93.0)	484 (93.1)
BMI, mean ± SD	26 ± 3	26 ± 3	26 ± 3
Hernia location, no. of patients (%)			
Right	188 (53.9)	100 (58.5)	288 (55.4)
Left	152 (43.6)	71 (41.5)	223 (42.9)
Bilateral	9 (2.6)	0 (0.0)	9 (1.7)
Pain intensity on VAS, mean ± SD	3.0 ± 2.0	2.7 ± 1.7	2.9 ± 2.0
Risk factors, no. of patients (%)			
Smoking	162 (46.4)	92 (53.8)	254 (48.8)
COPD	21 (6.0)	18 (10.5)	39 (7.5)
Chronic constipation	28 (8.0)	16 (9.4)	44 (8.5)
Prostatism	41 (11.7)	16 (9.4)	57 (11.0)
EHS classification, no. of hernias (%)[a]			
L1	120 (34.4)	44 (25.7)	164 (31.5)
L2	124 (35.5)	67 (39.2)	191 (36.7)
L3	5 (1.4)	0	5 (1.0)
M1	38 (10.9)	27 (15.8)	65 (12.5)
M2	66 (18.9)	34 (19.9)	100 (19.2)
M3	3 (0.9)	0	3 (0.6)

SD standard deviation; *BMI* body mass index (kg/m^2); *COPD* chronic obstructive pulmonary disease; *VAS* visual analog scale, ranging from 0 (no pain) to 10 (worst pain); *EHS* European Hernia Society

[a] Data missing for one hernia

Table 2 Surgery-related variables

	Fibrin glue ($n = 349$)	Sutures ($n = 171$)	Total ($N = 520$)
Operating time, mean ± SD (min)	55.6 ± 14.6[a]	61.2 ± 14.5	57.5 ± 14.8
Anesthesia, no. of patients (%)			
General	33 (9.5)	28 (16.4)	61 (11.7)
Local	195 (55.9)	80 (46.8)	275 (52.9)
Spinal	117 (33.5)	63 (36.8)	179 (34.4)
NA	4 (1.1)	–	4 (0.8)

SD standard deviation; *NA* not available

[a] $P < 0.001$ versus sutures group, derived from Mann–Whitney *U* testing

similar between groups, with around 64% requiring pain relief.

Fewer patients in the fibrin glue group reported numbness than in the sutures group (12.3 vs. 23.4%, $P = 0.003$). Discomfort was reported in 46.5% of patients, with no differences evident between groups. Six complications occurred: two fever cases (one in each study group), two scrotal hematoma cases (one in each study group), one seroma (sutures group), and one case of abdominal pain (fibrin glue group). More patients in the sutures group received antibiotics than in the fibrin glue group (85.4 vs. 65.6%, $P < 0.001$). No significant difference between groups was noted with regard to the length of hospital stay.

Medium- to long-term outcomes

As shown in Table 4, there were no recurrences due to technical complications throughout the study, except for two cases of direct hernias in the fibrin group at the 3-month assessment. In both cases, the fibrin glue had been sprayed and recurrence was attributed to procedural errors, i.e., inadequate size of the polypropylene mesh.

Figure 1 summarizes the percentage of patients who were suffering from numbness before and after surgery. At 1 month, significantly fewer patients in the fibrin glue group reported pain, numbness, and discomfort compared with patients in the sutures group (all $P < 0.05$; Table 4; Fig. 1). The fibrin glue group patients also experienced less intense pain (mean VAS score 0.6 vs. 1.2; $P = 0.001$; Fig. 2). Fewer than 1% of patients required analgesia. By 3 months, these between-group differences had disappeared, with the exception of numbness, which continued to be more prevalent in the sutures group than in the fibrin glue group (13.7 vs. 4.1%, $P < 0.001$; Fig. 1).

The prevalence of complications continued to decrease throughout the follow-up period, as expected, with no

Table 3 Postoperative complications at hospital discharge and other variables

	Fibrin glue ($n = 349$)	Sutures ($n = 171$)	Total ($N = 520$)
Objective examination, no. of patients (%)[a]			
No complication	305 (87.4)*	131 (76.6)	436 (83.8)
Hematoma	6 (1.7)*	14 (8.2)	20 (3.8)
Ecchymosis	30 (8.6)*	26 (15.2)	56 (10.8)
Other complications (seroma, infection)	3 (0.9)	3 (1.8)	6 (1.2)
Pain intensity on VAS, mean ± SD	2.5 ± 1.7**	3.2 ± 1.8	2.7 ± 1.8
Pain, no. of patients (%)	13 (3.7)***	0 (0.0)	13 (2.5)
Numbness, no. of patients (%)	43 (12.3)****	40 (23.4)	83 (16.0)
Discomfort, no. of patients (%)	156 (44.7)	86 (50.3)	242 (46.5)
Postoperative hospital stay, mean ± SD (days)	1.5 ± 3.5	1.1 ± 1.0	1.4 ± 2.9
Drainage, no. of patients (%)	22 (6.3)	5 (2.9)	27 (5.2)
Drainage time, mean ± SD (days)	1.1 ± 0.4	1.0 ± 0.0	1.1 ± 0.4
Total volume drained, mean ± SD (mL)	40 ± 17	59 ± 10	44 ± 18
Analgesics, no. of patients (%)	220 (63.0)	110 (64.6)	330 (63.5)
Aspirin, paracetamol, NSAIDs	190 (86.4)	102 (92.7)	292 (88.5)
Codeine/dextropropoxyphene	5 (2.3)	0	5 (1.5)
Strong opiates	0	1 (0.9)	1 (0.3)

All *P*-values were derived from Chi-squared testing, except pain intensity, which were derived from Mann–Whitney *U* testing

SD standard deviation, *VAS* visual analog scale ranging from 0 (no pain) to 10 (worst pain), *NSAIDs* non-steroidal anti-inflammatory drugs

[a] Some patients had more than one complication; data were missing for 13 patients

* $P = 0.001$ versus sutures group

** $P < 0.001$ versus sutures group

*** $P = 0.012$ versus sutures group

**** $P = 0.003$ versus sutures group

between-group differences evident at 6 and 12 months follow-up. By 12 months, very few patients in either study group reported pain, numbness, or discomfort (Table 4).

Discussion

This prospective, observational, multicenter study compared fibrin glue versus conventional sutures for mesh fixation in the Lichtenstein repair of inguinal hernia.

The mean operating time was reduced by around 9% in the fibrin glue study group relative to the sutures group ($P < 0.001$) and the mean VAS score for the ease of fibrin glue application was 1.8 (possible score 1–10, with 10 = most difficult), indicating a high level of ease among surgeons when using Tissucol. Patients in the fibrin glue group were also less likely to experience early local hemorrhagic complications (e.g., hematoma, ecchymosis) than patients in the suture group.

At 1 month assessment, patients in the fibrin glue study group reported significantly less pain, numbness, and discomfort compared with patients in the sutures group. There were no differences in the days of sickness absence between the two study groups. At 3 months, numbness continued to be significantly more prevalent in the sutures group, but the between-group differences in all of the other outcome measures had disappeared. Complications continued to decrease in both study groups throughout the 12-month follow-up period, such that only a handful of patients reported complications at 1 year following surgery.

Our findings are largely consistent with the published studies of Tissucol versus sutures for mesh fixation in Lichtenstein hernia repair [7, 15, 19]. A controlled study by Hidalgo et al. [19] assessed mesh fixation using fibrin sealant compared with sutures in 55 patients with bilateral inguinal hernias, in whom mesh fixation was undertaken with sutures on the right hernia and with glue on the left hernia. 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. Two patients reported pubic pain at 6 months, but were free of pain by 12 months; no other early or late complications were observed. In an uncontrolled study, Canonico et al. [7] assessed the use of fibrin sealant in 80 patients who had undergone sutureless Lichtenstein repair of primary unilateral hernia, with Tissucol as a means of mesh fixation. No complications were observed

Table 4 Complications experienced during the 12-month follow-up period

	1 month		3 months		6 months		12 months	
	Fibrin glue ($n = 345$)	Sutures ($n = 171$)	Fibrin glue ($n = 342$)	Sutures ($n = 168$)	Fibrin glue ($n = 334$)	Sutures ($n = 167$)	Fibrin glue ($n = 318$)	Sutures ($n = 150$)
Recurrence due to technical error, no. of patients (%)	0	0	2 (0.6%)	0	0	0	0	0
Pain, no. of patients (%)	47 (13.6%)*	43 (25.1%)	17 (5.0%)	11 (0.7%)	8 (2.4%)	4 (2.4%)	9 (2.8%)	1 (0.7%)
Pain intensity, VAS, mean ± SD	0.6 ± 1.1**	1.2 ± 1.3	0.3 ± 1.0	0.3 ± 0.6	0.2 ± 0.8	0.2 ± 0.9	0.2 ± 0.7	0.1 ± 0.5
Numbness, no. of patients (%)	22 (6.4%)***	34 (19.9%)	14 (4.1%)***	23 (13.7%)	10 (3.0%)	10 (6.0%)	3 (0.9%)	4 (2.7%)
Discomfort, no. of patients (%)	61 (17.7%)****	42 (24.6%)	14 (4.1%)	10 (6.0%)	6 (1.8%)	2 (1.2%)	6 (1.9%)	2 (1.3%)
Other complications, no. of patients (%)								
Infections	1 (0.3%)	1 (0.6%)	1 (0.3%)	0	2 (0.6%)	0	–	–
Other (seroma, hematoma, and scrotal hematoma)	2 (0.6%)†	5 (2.9%)‡	–	–	1 (0.3%)	0	–	–
Analgesics, no. of patients (%)	1 (0.3%)	4 (2.3%)	–	–	–	–	–	–
Sickness absence, mean ± SD (days)	11.6 ± 7.1	12.5 ± 6.3	–	–	–	–	–	–

All *P*-values were derived from Chi-squared testing, except pain intensity and days of sickness absence, which were derived from Mann–Whitney *U* testing

VAS visual analog scale ranging from 0 (no pain) to 10 (worst pain); *SD* standard deviation

* $P < 0.01$ versus sutures group

** $P = 0.001$ versus sutures group

*** $P < 0.001$ versus sutures group

**** $P = 0.028$ versus sutures group

† One seroma, one unspecified

‡ Two scrotal hematomas, one seroma, one fever, one sporadic dysejaculation

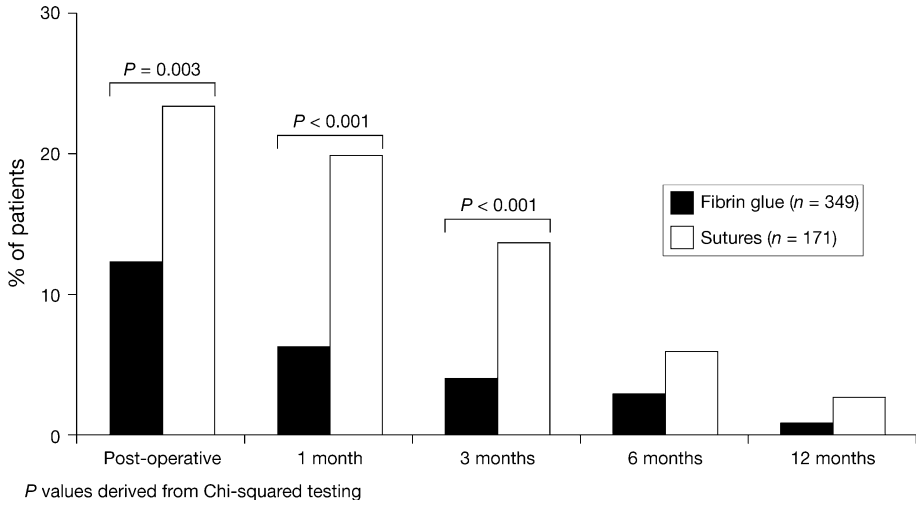

Fig. 1 Percentage of patients suffering from numbness before and after surgery

over 12 months. More definitive conclusions about the effectiveness of fibrin glue in reducing the rate of postoperative complications following Lichtenstein repair comes from the TIMELI (TIssucol/TIsseel for MEsh fixation in LIchtenstein hernia repair) study. This international, controlled, randomized, patient- and evaluator-blinded study compared the 12-month rate of disabling complications (chronic pain/numbness/groin discomfort) following mesh fixation with Tissucol or sutures in patients with inguinal hernia undergoing Lichtenstein repair [6]. At 12 months, the prevalence of ≥1 disabling complication was significantly lower in the Tissucol group than in the sutures group

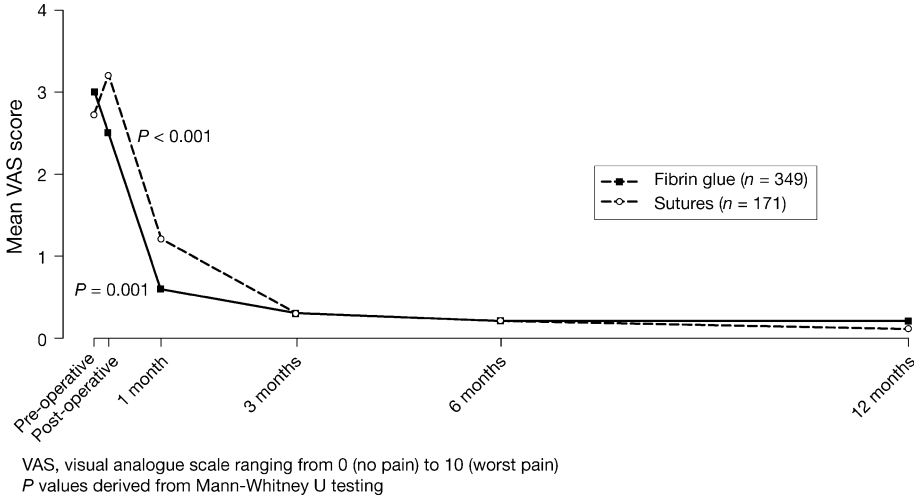

Fig. 2 Pain intensity as assessed by the visual analog scale (VAS) score before and after surgery

(8.1 vs. 14.8%; $P = 0.034$) [15]. Less numbness and groin discomfort were also noted in the Tissucol versus sutures group ($P = 0.019$; $P = 0.049$); only 3/316 patients (0.94%) experienced recurrence (one Tissucol, two sutures).

The notion that fibrin glue fixation is associated with less postoperative pain versus suturing is quite conceivable considering the procedural differences between the two approaches. Suturing the upper edge of the prosthetic mesh to the internal oblique aponeurosis results in marked retraction of the external oblique aponeurosis, subcutaneous fat, and skin as the needle passes. In contrast, minimal tissue retraction is necessary with fibrin glue fixation. More soft tissue retraction naturally leads to greater contusion and short-term pain. Therefore, consistent with our results, less soft tissue contusion and associated postoperative pain seems probable with fibrin glue fixation compared with sutures.

In terms of study weaknesses, our study was not randomized or blinded and no formal power calculations were undertaken. Patients were allocated to sutures or fibrin glue by the operating surgeon as per routine practice; however, both study groups were similar in terms of clinical and demographic characteristics at baseline. The relatively small study population limits the generalization of the findings, and the 12-month follow-up period is too short to provide meaningful information on chronic pain or hernia recurrence with mesh fixation by fibrin glue versus sutures.

Nonetheless, in summary, our study suggests that using fibrin glue to fix mesh in inguinal hernia repair results in significantly less pain, numbness, and discomfort than fixation with sutures during the early postoperative period (at hospital discharge until 1 month postsurgery). This is a period that many would regard as the most critical period in which patients experience the most negative impact on the overall quality of life.

Mesh fixation with fibrin glue in open tension-free Lichtenstein hernia repair is a simple technique that is accompanied by reduction in postoperative inguinal pain. Consequently, fibrin glue should be considered as a first-line option over sutures for mesh fixation in inguinal hernia surgery.

Conflicts of interest The authors declare that they have no conflicts of interest.

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