Randomized clinical trial

Randomized clinical trial of mesh fixation with glue or sutures for Lichtenstein hernia repair

C. Hoyuela[1], M. Juvany[1], F. Carvajal[1], A. Veres[3], D. Troyano[1], M. Trias[1], A. Martrat[1], J. Ardid[1], J. Obiols[1] and M. López-Cano[2]

[1]Department of General and Digestive Surgery, Hospital Platón, and [2]Department of General Surgery, Hospital Universitari Vall d'Hebron, Universitat Autònoma de Barcelona, Barcelona, and [3]Department of Surgery, Hospital de la Cerdanya, Puigcerdà, Spain

Correspondence to: Dr C. Hoyuela, Department of General and Digestive Surgery, Hospital Platón, Universitat Autònoma de Barcelona, c/ Platón 21, 08006 Barcelona, Spain (e-mail: carloshoyuela@gmail.com)

Background: **Pain is the most likely reason for delay in resuming normal activities after groin hernia repair. The primary aim of this study was to determine whether the use of glue to fix the mesh instead of sutures reduced acute postoperative pain after inguinal hernia repair. Secondary objectives were to compare postoperative complications, chronic pain and early recurrence rates during 1-year follow-up.**

Methods: **Some 370 patients who underwent Lichtenstein hernia repair were randomized to receive either glue (Histoacryl®) or non-absorbable polypropylene sutures for fixation of lightweight polypropylene mesh. Postoperative complications, pain and recurrence were evaluated by an independent blinded observer.**

Results: **Postoperative pain at 8 h, 24 h, 7 days and 30 days was less when glue was used instead of sutures for all measures ($P < 0{\cdot}001$). The operation was significantly quicker using glue (mean(s.d.) 35·3(8·7) min *versus* 39·9(11·1) min for sutures; $P < 0{\cdot}001$). There were no significant differences between the groups in terms of postoperative complications, chronic pain and early recurrence at 1-year follow-up.**

Conclusion: **Atraumatic mesh fixation with glue was quicker and resulted in less acute postoperative pain than sutures for Lichtenstein hernia repair. Registration number: NCT02632097 (http://www.clinicaltrials.gov).**

Presented in part to the World Conference on Abdominal Wall Hernia Surgery, Milan, Italy, April 2015

Paper accepted 9 December 2016

Published online 20 February 2017 in Wiley Online Library (www.bjs.co.uk). **DOI:** 10.1002/bjs.10488

Introduction

Inguinal hernia repair is one of the most common surgical procedures[1–3]. Lichtenstein hernia repair is simple, safe and easy to learn, with very good results in terms of morbidity, and a very low recurrence rate[4–7].

Postoperative pain is the most likely cause of delayed recovery after open hernia repair. A significant number of patients (10–30 per cent) suffer chronic pain after mesh-based hernia repair[7,8]. The development of chronic pain is a concern because its onset is unpredictable[9], but correlates with the severity of acute postoperative pain[10]. Any strategy to reduce postoperative pain would allow patients to resume their normal activities more quickly.

Because hernia repair with, or without mesh implantation results in similar rates of groin discomfort, direct damage or entrapment of local nerves by fixative sutures is considered a major underlying factor[6,8,11,12]. Non-traumatic methods to fix the mesh during hernia repair are an attractive option: absorbable sutures, adhesive or self-gripping meshes, and a variety of tissue adhesives (biological or synthetic) have been tested[6,9,11,13–24].

The hypothesis here was that the use of a sutureless non-traumatic method to fix the mesh during groin hernia repair could reduce postoperative pain compared with the classical suture method of Lichtenstein hernia repair.

Methods

A multicentre double-blind prospective randomized trial was conducted in two different community hospitals (Hospital Platón, Barcelona, and Hospital de la Cerdanya, Puigcerdà). The study was registered as NCT02632097 at ClinicalTrials.gov. This trial was approved by the ethics research committee of the Catalan Union of Hospitals

(CEIC 15/92). All general surgeons of both hospitals participated in the trial, whatever their expertise.

Between November 2013 and November 2015, all patients with primary unilateral groin hernia were evaluated for inclusion in the trial. Inclusion criteria were: patients over 18 years old suffering from uncomplicated primary unilateral hernia, candidates for elective day surgery with no significant cardiopulmonary, hepatic or renal impairment[25]. Exclusion criteria were: bilateral hernia, known femoral hernia, large scrotal hernia, recurrent hernia, infected or contaminated field, emergency operation for complicated hernia, mental illness, or patient refusal and/or absence of informed consent. All included patients signed a standard consent form after being informed about the trial.

The primary endpoint of the study was to determine the amount of postoperative acute pain in the groin, measured using a visual analogue scale (VAS) score ranging from 0 to 10. Secondary endpoints included duration of surgery (from start of incision to skin closure), postoperative complications (30 days), chronic pain (defined as persistent discomfort or inguinal pain VAS score of 3 or more that persisted for more than 3 months after surgery[26]) and early recurrences, defined as clinical recurrence or those confirmed by ultrasound examination after 1-year follow-up.

The following variables were also collected: age, sex, BMI, smoking status and associated co-morbidities (arterial hypertension, diabetes, chronic obstructive pulmonary disease, and use of anticoagulants and/or antiplatelet drugs). Anaesthetic risk was measured according to the ASA classification system[27]. Hernias were classified according to European Hernia Society recommendations[28]. Anaesthetic techniques included intravenous general anaesthesia, epidural or spinal anaesthesia, or direct local anaesthesia. Local anaesthesia was always used in combination with intravenous sedation with midazolam or propofol. Prolonged hospital stay (more than 12 h) and readmission (patients who returned for medical consultation before scheduled follow-up) were also recorded. Surgeons were considered junior when they had less than 5 years' experience. All data were collected prospectively.

Randomization and blinding

Eligible patients were randomized 1 : 1 using a computer-generated protocol that also assigned the patient a tracking number (Excel® for Windows® 2010; Microsoft, Redmond, Washington, USA). Treatment allocations were sealed in numbered envelopes, and staff recruiting patients did not know in advance which treatment the next person would get. During the intervention, operating room nurses opened the envelope at the moment the surgical team positioned the mesh. The fixation method did not appear in the operation records. Staff conducting the follow-up (a third senior surgeon who did not participate in the operation) and patients were blinded to the allocation.

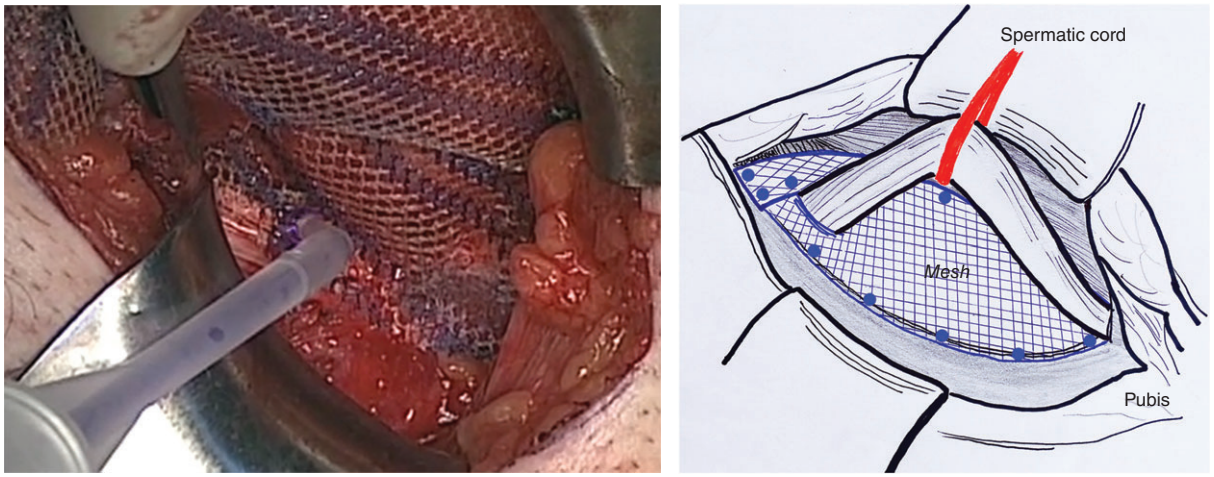
Surgical technique

All patients underwent an open hernia repair according to the Lichtenstein technique with inversion of the hernia sac, without ligation[3,4]. Antibiotic prophylaxis with 1 g cefazolin was administered routinely 30 min before the skin incision. Local anaesthetic blockade with 20 ml of 0·25 per cent bupivacaine of the iliohypogastric and ilioinguinal nerves was performed in all patients (including those who had general or spinal anaesthesia).

A tailored, oval-shaped 7·5 × 15-cm lightweight polypropylene mesh (Optilene® 60 g/m^2; B. Braun, Melsungen, Germany) was placed exceeding the pubic tubercle by 2 cm and fixed to the inguinal ligament. In men, the upper edge of the mesh always surrounded the spermatic cord, as a scarf, before being fixed to the inguinal ligament.

In the suture group, the mesh was fixed with 2/0 non-absorbable polypropylene (Prolene®; Ethicon, Somerville, New Jersey, USA). A running suture started medially to the pubis, running along the inguinal ligament. The superior edge of the mesh was sutured with a few interrupted stitches. In the glue group, sutures were replaced by liquid drops of *n*-butyl-2-cyanoacrylate (Histoacryl®; B. Braun Surgical SA, Rubí, Barcelona, Spain), using 0·5 ml glue for each repair (*Fig. 1*). The regional nerves were identified and carefully preserved whenever possible. The aponeurosis of the external oblique muscle was closed with a running suture of polyglactin 2/0 (Vicryl®; Ethicon) or polyglycolic acid (Novosyn®; B. Braun), and the skin was closed with a running absorbable suture (Monocryl® 3/0; Ethicon) in all patients.

After the procedure, the patient was monitored for 60–180 min in the ambulatory unit and then discharged. Paracetamol 1 g every 8 h plus dexketoprofen 25 mg every 8 h for 7 days was prescribed to all patients for postoperative analgesia. Patients were encouraged to walk at 1–2 h after the procedure. The only recommendation was to avoid lifting weights and doing crunches for 10 days. A specific sheet including the VAS was given to the patients at the time of discharge to record any incidents during the follow-up. All operations were done on a morning operating list.



a Gluing of mesh to inguinal ligament **b** Placement of drops of glue to fix the mesh

Fig. 1 **a** Intraoperative application of glue to fix the mesh to the inguinal ligament. **b** Diagram of hernia repair using drops of glue to fix the mesh

Postoperative follow-up

Patients were interviewed by telephone 8 and 24 h after the procedure. Postoperative complications were evaluated by clinical examination in outpatients after 7 and 30 days, 6 months, 1 year and then annually. In the case of recurrence and/or reoperation, the patient was excluded from further follow-up.

Evaluation of surgical-site infection (SSI) was based on Centers for Disease Control and Prevention definitions[29]. Seroma, skin bruising and wound haematoma were evaluated and recorded[30]. The severity of complications was reported using the Clavien–Dindo classification[31].

Statistical analysis

The sample size was calculated to explore differences in postoperative pain between the groups. Accepting an α risk of 0·05 and a statistical power defined as 90 per cent (β risk = 0·1) in a two-sided test, 165 subjects were necessary in each group to recognize a statistically significant difference in pain score of at least 1 VAS unit. The common standard deviation was assumed to be 2·5, and the maximum dropout rate was 20 per cent.

Categorical variables were measured with frequencies and percentages, using the χ^2 and Fisher's exact tests to compare the groups. All quantitative variables were expressed as mean(s.d.) values, and compared using the non-parametric Mann–Whitney *U* test.

Statistical significance was established when *P* values were less than 0·050. All statistical analyses were performed using SPSS® version 18.0 for Windows® (IBM, Armonk, New York, USA).

Results

A total of 370 patients met the final selection criteria to be included in the trial and were randomized into the two groups. There were 332 men and 38 women, with a mean age of 59·8 (range 19–87) years. After randomization, 188 patients were included in the glue group and 182 in the suture group (*Fig. 2*).

All randomized patients received the intended treatment. The groups did not differ in age, sex, BMI, co-morbidities, anaesthetic risk, type of hernia or size of the defect (*Table 1*). There were no significant differences in the anaesthetic technique employed or in the expertise of the surgeons who performed the hernia repair (*Table 2*).

The mean duration of operation was significantly shorter (by almost 5 min) when mesh was fixed with glue (35·3(8·7) min *versus* 39·9(11·1) min in the suture group).

No intraoperative complications were observed. Only one patient (glue group) had reoperation, for an early postoperative haemorrhage (Clavien–Dindo grade IIIA); they remained in hospital for 48 h.

All patients attended the 7- and 30-day outpatient follow-up. The types and severity of postoperative complications are listed in *Table 3*; there were no significant differences between the groups. All of the complications (except the reoperation) were minor (Clavien–Dindo grade I or II). The most frequently observed problem was

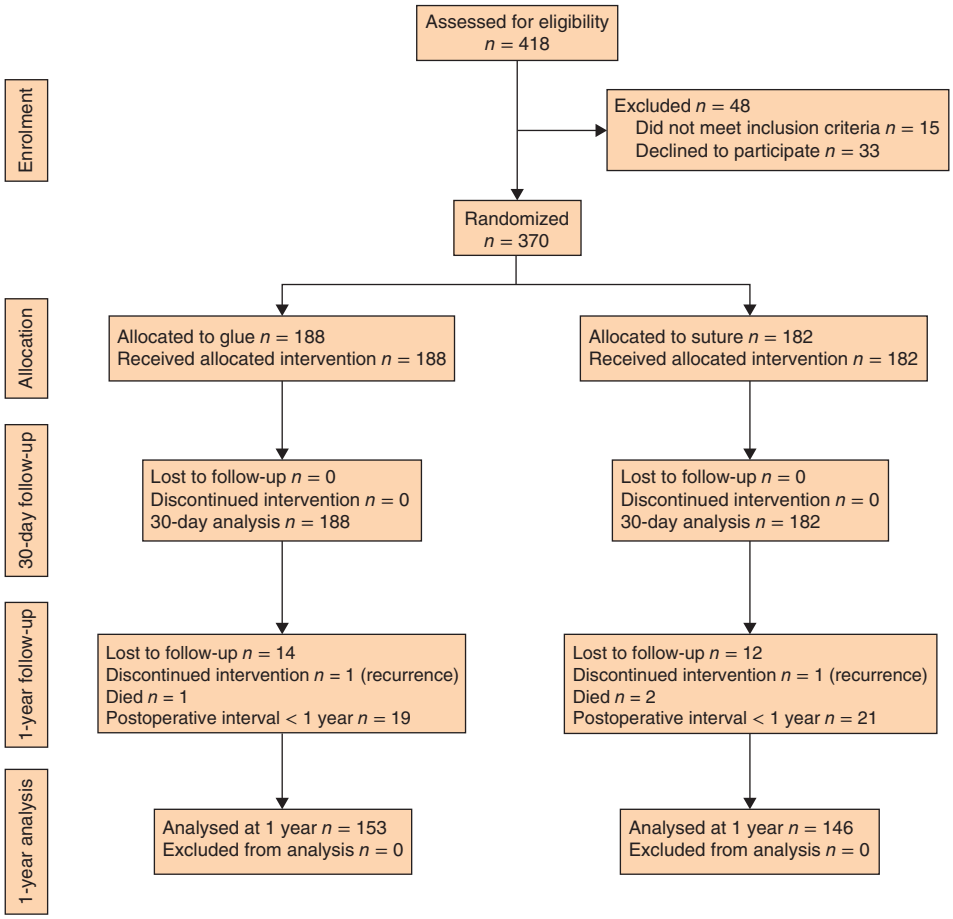


Fig. 2 CONSORT diagram for the trial

Table 1 Demographic data of patients undergoing hernia repair

	Glue ($n = 188$)	Suture ($n = 182$)
Age (years)*	60·6(14·9)	59·0(13·5)
Sex ratio (M : F)	170 : 18	162 : 20
BMI (kg/m^2)*	25·7(3·6)	26·0(3·5)
Co-morbidity		
Arterial hypertension	74 (39·4)	62 (34·1)
Smoking	72 (38·3)	86 (47·3)
Ex-smoker	32 (17·0)	38 (20·9)
Diabetes mellitus	25 (13·3)	18 (9·9)
Chronic obstructive pulmonary disease	16 (8·5)	24 (13·2)
Use of anticoagulants/antiplatelet drugs	25 (13·3)	17 (9·3)
ASA fitness grade[27]		
I	48 (25·5)	63 (34·6)
II	126 (67·0)	105 (57·7)
III–IV	14 (7·4)	14 (7·7)

Values in parentheses are percentages unless indicated otherwise; *values are mean(s.d.).

bruising, which was attributable to infiltration of local anaesthetic in the majority of cases. The overall SSI rate was low (1·4 per cent). Two patients developed wound infection with positive bacterial cultures; both responded to a conservative approach. No mesh needed to be removed or explanted.

Analysis of VAS pain scores demonstrated that the use of glue reduced acute postoperative pain during the first postoperative month ($P < 0·001$). All mean(s.d.) measures of VAS at 8 h (3·7(2·4) *versus* 4·9(2·5)), 24 h (3·4(2·2) *versus* 4·4(2·3)), 7 days (1·6(1·6) *versus* 2·4(1·8)) and 30 days (0·5(1·0) *versus* 1·1(1·4)) were significantly lower in the glue group (*Fig. 3*).

A total of 299 patients (80·8 per cent) achieved 1-year clinical follow-up. No differences were observed in terms of chronic pain at 1-year follow-up ($P = 0·467$) (*Fig. 3*).

Eleven patients in each group reported a 1-year VAS score of 3 or more (7·2 per cent in the glue group *versus* 7·5 per cent in the suture group). One patient in each group developed early hernia recurrence (0·7 per cent in both groups).

Table 2 Intraoperative data and results

	Glue ($n = 188$)	Suture ($n = 182$)	P‡
Type of anaesthesia			0·065
Local + sedation	85 (45·2)	103 (56·6)	
Spinal	101 (53·7)	77 (42·3)	
General	2 (1·1)	2 (1·1)	
Hernia type†			0·834
Medial	63 (33·5)	57 (31·3)	
Lateral	112 (59·6)	110 (60·4)	
Combined	13 (6·9)	15 (8·2)	
Hernia size (cm)†			0·331
< 1·5 (type 1)	6 (3·2)	3 (1·6)	
≥ 1.5 and ≤ 3 (type 2)	64 (34·0)	74 (40·7)	
> 3 (type 3)	118 (62·8)	105 (57·7)	
Status of surgeon			0·309
Junior	81 (43·1)	88 (48·4)	
Senior	107 (56·9)	94 (51·6)	
Duration of operation (min)*	35·3(8·7)	39·9(11·1)	< 0·001§

Values in parentheses are percentages unless indicated otherwise; *values are mean(s.d.). †According to European Hernia Society classification[28]. ‡χ^2 or Fisher's exact test, except §Mann–Whitney U test.

Table 3 Complications and adverse events after hernia repair

	Glue ($n = 188$)	Suture ($n = 182$)	Total	P*
Haemorrhagic events				0·258
Skin bruising	38 (20·2)	41 (22·5)	79 (21·4)	
Wound haematoma	6 (3·2)	7 (3·8)	13 (3·5)	
Haemorrhage (reoperation)	1 (0·5)	0 (0)	1 (0·3)	
Readmission	4 (2·1)	4 (2·2)	10 (2·2)	1·000
Seroma	1 (0·5)	1 (0·5)	2 (0·5)	1·000
Surgical-site infection	3 (1·6)	2 (1·1)	5 (1·4)	1·000
Superficial	2	2		
Deep	1	0		
Reoperation for mesh removal	0	0		
Orchitis	3 (1·6)	1 (0·5)	4 (1·1)	0·623

Values in parentheses are percentages. *χ^2 or Fisher's exact test.

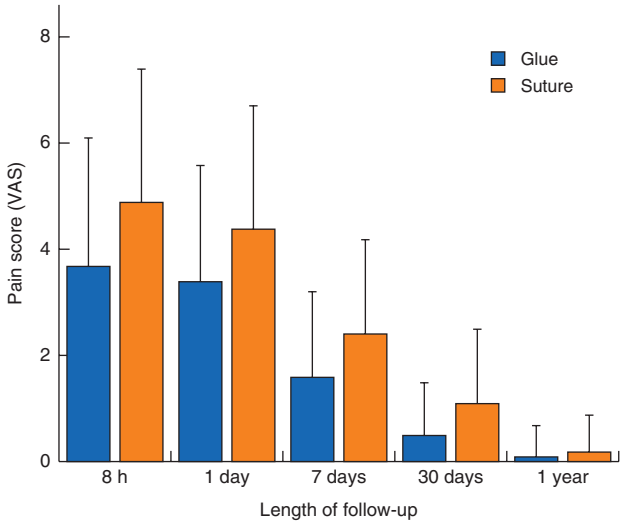


Fig. 3 Mean(s.d.) postoperative pain scores in glue and suture groups, measured by visual analogue scale (VAS)

Discussion

The results of this trial showed that the use of glue to fix the mesh caused less postoperative pain than sutures after open hernia repair, with otherwise comparable results in early recurrence rates. These results are consistent with other reports and meta-analyses published to date[17,18,21,22]. This significant difference in acute pain, although mild in intensity, can be considered clinically relevant[32]. However, caution is needed given the standard deviation observed for all pain measures in both groups.

The use of glue did not increase the rate or severity of postoperative complications, and no adverse events related to its use were observed. The mean duration of surgery was significantly shorter when the mesh was fixed with glue (by 5 min), and therefore the use of glue could make high-volume ambulatory surgery units more efficient. These results suggest that glue is a reasonable option for mesh fixation during open hernia repair, especially in patients prone to pain[6].

The differences in acute pain favouring glue disappeared during the first postoperative year. Although two different meta-analyses[18,22] reported that glue also reduced the incidence of chronic pain, this finding was not replicated here, or in other reports[6,11,19,23]. Chronic pain after groin hernia surgery remains an ongoing concern, regardless of the method used to fix the mesh. Self-gripping meshes appear to be comparable to adhesives in terms of pain reduction[9,18,33–35]. A recent study[23] did not find notable differences in terms of postoperative pain and complications between self-gripping mesh or cyanoacrylate *versus* sutures. In addition, higher recurrence rates of up to 5·5 per cent after 1 year have been reported using these meshes[9]. The main drawback of the self-gripping mesh is the higher cost compared with that of conventional polypropylene mesh; the use of human fibrin glue has the same economic problem[23], bearing in mind that its results are comparable to those of synthetic glue[20].

It is well established that the laparoscopic approach is superior to open hernia repair in terms of chronic pain, with no difference in the hernia recurrence rate[35–37]. However, the spread of laparoscopic surgery among surgeons has been limited by factors such as the greater technical difficulty, the need for general anaesthesia, the economic costs and the risk of severe complications[2,36]. Open Lichtenstein hernia repair remains the most accepted

technique worldwide. This technique is less expensive and simpler to perform than laparoscopic repair; it can be performed under local anaesthesia, and its results are easily reproduced. In some countries, this technique might be the only procedure available because of limited resources.

Limitations of this trial include that 1-year follow-up is short for assessing the long-term recurrence rate of the mesh fixation with glue. This trial remains open for assessment of the long-term results; however, early recurrence by clinical examination was low in both groups, with no differences between glue and sutures. In addition, preoperative pain measurement was not obtained, limiting the baseline pain comparison. Further, this study was designed to measure one pain dimension (intensity), and it is well known that pain is subjective and related to multiple factors. Finally, the number of patients analysed in each group could be insufficient to find differences regarding chronic pain, given the low number of patients suffering from chronic pain in this series (7·2 and 7·5 per cent in the glue and suture groups respectively).

The strengths of this study are the randomized design and the double-blind follow-up of the outcomes in outpatients, providing reliable results regarding the acute postoperative pain.

The results of this trial showed that mesh fixation with glue was associated with less acute postoperative pain than non-absorbable sutures after Lichtenstein hernia repair. However, mesh fixation with this glue appears to have no effect on chronic pain.

Acknowledgements

This work was performed as part of the doctoral programme in surgery and morphological sciences of Universitat Autònoma de Barcelona. The authors thank S. Mojal for statistical analysis and J. María Balibrea del Castillo for support.

Disclosure: The authors declare no conflict of interest.

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