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Randomized clinical trial of fibrin glue versus tacked fixation in laparoscopic groin hernia repair

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Abstract
Background Preliminary studies have indicated clinical advantages of mesh fixation using fibrin glue in transabdominal preperitoneal groin hernia repair (TAPP) compared with tack fixation. The aim of this randomized double-blinded, controlled, clinical trial is to compare fibrin glue with tacks fixation of mesh during TAPP.
Methods One hundred and twelve men with unilateral inguinal hernia were enrolled. Primary outcome was pain during coughing on postoperative day 1. Secondary outcomes were postoperative scores of pain at rest, discomfort, and fatigue (day 1 and cumulated day 0–3), incidence of moderate/severe nausea and/or vomiting, foreign-body sensation, and recurrence after 6 months. Outcome measures were assessed by visual analogue scale (VAS, 0–100 mm), verbal rating scale (no, light, moderate or severe) and numerical rating scales (NRS, 1–10).
Results One hundred patients were available for analysis. The fibrin group ($n = 50$) had significantly less pain during coughing on day 1 compared with the tacks group ($n = 50$) [median 23 (range 0–80) vs 35 (2–100) mm] ($p = 0.020$). Moreover, day 1 scores and all cumulated scores of pain during rest, discomfort, and fatigue were significantly lower in the fibrin group compared with the tacks group (all p-values ≤ 0.02). There was no significant difference in the incidence of nausea and/or vomiting ($p > 0.05$) or recurrence (fibrin glue $n = 2$, tacks $n = 0$, $p = 0.241$). Incidence of foreign-body sensation was significantly lower in the fibrin group at 1 month ($p = 0.006$).
Conclusions Fibrin glue compared with tacks fixation improved the early postoperative outcome after TAPP. The trial was registered at clinicaltrials.gov NCT01000116.

Keywords Fibrin glue · Tacks · TAPP · Pain · Fatigue · Discomfort

Use of a traumatic fixation devices, such as fibrin glue, may reduce early postoperative pain after laparoscopic groin hernia repair compared with tacks and clips fixation [1–4], but findings are not uniform [5, 6]. Reduction of pain during the first days after laparoscopic groin hernia repair may shorten the duration of the convalescence period since pain is an important determinant of duration of convalescence [7–9]. Duration of convalescence and sick leave is of major socioeconomic interest because inguinal hernia repair is the most often conducted gastrointestinal surgical procedure [7, 9–11].

The primary aim of this randomized clinical trial is to evaluate early postoperative pain in patients undergoing laparoscopic groin hernia repair when comparing fibrin glue with tacks fixation. Primary outcome was pain during coughing on postoperative day 1. Secondary outcomes were pain during rest, discomfort, fatigue, and incidence of postoperative nausea and/or vomiting. We also recorded need for analgesics at the postanaesthesia care unit (PACU). In addition, seroma formation, haematoma, foreign-body sensation in the groin and risk of recurrence were registered as tertiary outcomes.

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Materials and methods

The study was approved by The Committee on Biomedical Research Ethics for Region Zealand, Denmark (SJ-138), The Danish Data Protection Agency, and registered at www.clinicaltrials.gov (NCT01000116) before study start. Oral and written information was given to all eligible patients, and informed consent for participation in the trial was obtained before inclusion.

Patients

The trial was conducted at a single-centre surgical department in a private hospital setting. Patients were either self-payer, had private health insurance, or were referred from public hospitals due to waiting list. Men aged 18–80 years, able to understand and speak Danish, and classified with American Society of Anesthesiologists (ASA) class I–III were consecutively included. Furthermore, inclusion criteria were unilateral inguinal or femoral hernia (primary and recurrent hernia). The exclusion criteria were women, inguinoscrotal hernia, bilateral hernia, presumed poor compliance (language disability, dementia, psychiatric disorders etc.) and daily intake of opioids within the last week before operation. Patients with systemic use of steroids or other immunosuppressant medicine, weekly alcohol consumption of more than 21 drinks (one drink equals 12 g pure alcohol) or in case of alternative hernia repair with mesh during the same procedure were also excluded.

At enrolment, a structured interview included information on age, body mass index (BMI), ASA score, status of hernia (primary/recurrence), smoking status and medication. Patients were asked about daily pain during the last 3 months not related to hernia disease (i.e. chronic pain syndrome, chronic headache, low back pain or other musculoskeletal pain) [10].

Outcomes

Main study time points were preoperatively, on day 0 (3 h postoperatively), daily on day 1–3 (at 8.00 pm) and on day 10. In addition, another questionnaire was used for registrations at 1 month and 6 months postoperatively. Patients were reminded [by text message (SMS)] on postoperative day 1 and day 10 to complete registrations. Patients had a structured logbook for self-registration of outcome measures and were instructed to return these by regular mail. The following outcomes were recorded on different scales: A 100-mm visual analogue scale (VAS) was used to measure pain during coughing and rest [endpoints labelled "no pain" (0 mm) and "worst possible pain" (100 mm)] as well as on a verbal rating scale (VRS) (pain during rest: no = 0, light = 1, moderate = 2, severe = 3). Discomfort was evaluated with VAS [endpoints labelled "very comfortable" (0 mm) and "very uncomfortable" (100 mm)]. A numerical rating scale (NRS) (1–10) was used for evaluating fatigue, where 1 = no fatigue and 10 = severe fatigue [12]. Also, nausea (no = 0, light = 1, moderate = 2, severe = 3) and vomiting (defined as number of vomiting episodes) was registered by patients themselves covering the preceding 3 h after operation on day 0. In addition, seroma and haematoma formation were registered on day 10 using VRS (no = 0, light = 1, moderate = 2, severe = 3), and foreign-body sensation in the groin was assessed using 0 = no and 1 = yes by the patients themselves at 1 and 6 months. Patients were also asked about hernia recurrence, and if the answer was "yes" or "suspicion of clinical recurrence" 6 months postoperatively (including reoperation for recurrence), a clinical examination by a blinded investigator was performed for confirmation.

Randomization and blinding

This randomized trial is reported according to the principles of the CONSORT statement 2010 checklist [13]. We used block randomization based on computer-generated sequences with block size of 4 (112 consecutive sealed non-transparent envelopes numbered 1–112). The allocation ratio was 1:1, with 56 envelopes for fibrin glue and 56 envelopes for tacks (for statistical power see below). On the day of operation, the surgeon opened an envelope just before the operation. The surgeon, the anaesthetist and the nurses at the operating theatre were for obvious reasons not blinded, while the patient, the investigator and nurses attending to the patient postoperatively were all blinded to the intervention. The undisclosed code A or B was used in the patient records. The randomization code was concealed until the study was finished and data analyses completed.

Surgery, anaesthesia and analgesia

All patients underwent elective transabdominal preperitoneal groin hernia repair (TAPP) as described in detail elsewhere [14, 15]. The surgical procedures were performed by two experienced laparoscopic surgeons (>1,000 laparoscopic groin hernia repairs each). Tisseel® fibrin glue (BioSurgery; Baxter, Deerfield, IL, USA) or ProTacks™ fixation devices (Auto Suture; Tyco Healthcare, Norwalk, CT, USA) were used for fixation of the mesh as determined by the randomization. Bladeless disposable trocars (3 × 5 mm; Ethicon Endo-Surgery Inc., Johnson & Johnson, Cincinnati, OH, USA) and Ultrapro™ 10 × 15 cm mesh (Ethicon Inc., Johnson & Johnson, USA) were used. At skin opening, the three trocar sites were injected with local anaesthetic

bupivacaine 0.5 %, 20 ml (in total 100 mg). In the fibrin glue group, 2 × 1 ml fibrin glue was used as standard. The tacks group used four to six tacks in the mesh, and the peritoneum was adapted using another four to six tacks.

Patients received similar general anaesthetic and analgesic regimens. Paracetamol (1 g orally) and dexamethasone (8 mg orally) were given 1 h before operation. A single-dose antibiotic prophylaxis of IV cefuroxim 1,500 mg was injected perioperatively. Ten minutes before end of procedure, ketorolac (30 mg) was given intravenously. Analgesic treatment was started at PACU immediately after operation and consisted of paracetamol 1 g orally × 4 daily (starting 4 h after analgesic premedication) and diclofenac 50 mg orally × 3 daily (patients were recommended 4 days of analgesic treatment with paracetamol and diclofenac regardless of pain). IV or capsule oxycodone 5–10 mg was given on request (maximum 30 mg) and tramadol 100 mg on request (maximum 400 mg). Nausea and/or vomiting indicated IV dexamethasone 4 mg (maximum × 2), IV ondansetron 2 mg (maximum × 4) and/or IV droperidol 0.625 mg

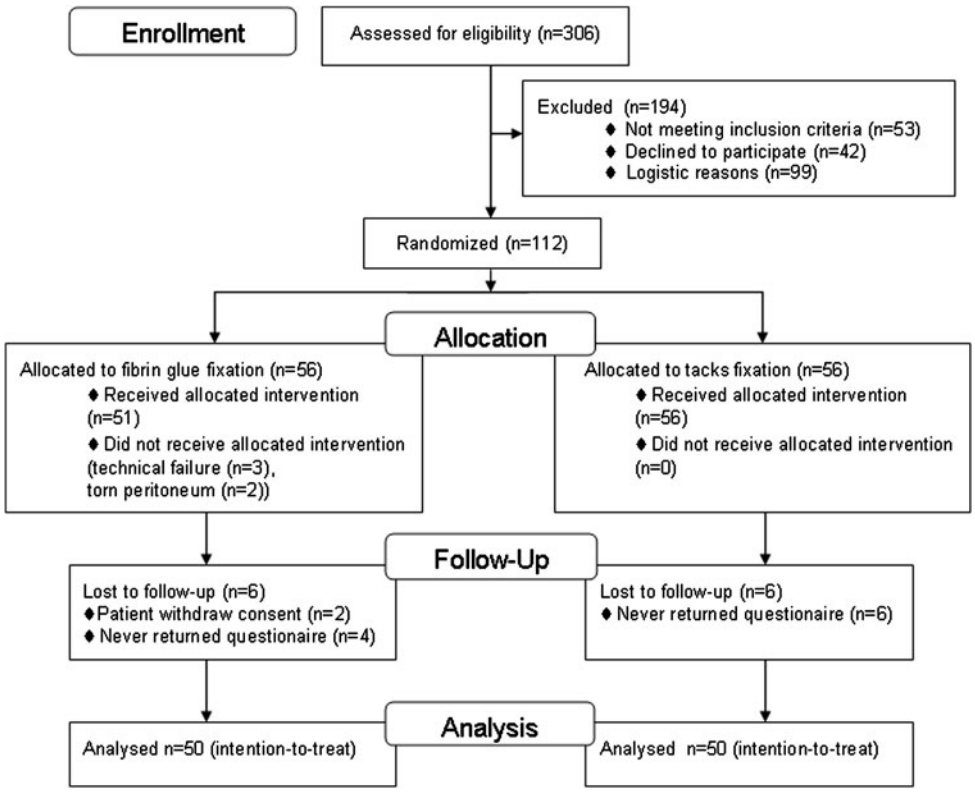

Fig. 1 CONSORT diagram [13] for participants

Table 1 Baseline demographics and surgical details for included participants

	Fibrin glue ($n = 56$)	Tacks ($n = 56$)	p-Value
Age (years)	50 (29–77)	49 (21–73)	0.805
BMI (kg/m^2)	25 (21–33)	25 (20–31)	0.265
ASA I:II:III	46:10:0	42:14:0	0.490
Smokers (no.)	13	11	0.650
Preoperative pain syndrome [10] (no.)	5	5	1
Previous motion sickness (no.)	24	24	1
Previous PONV (no.)	4 out of 41	8 out of 41	0.226
Primary/recurrent hernia	50/6	46/10	0.419
Hernia type (lateral/medial)	36/20	37/19	1
Operation time (min)	30 (19–69)	27 (12–115)	0.123
Fixation (glue or tacks)	2 ml (2–4)	11 tacks (8–17)	–
Use of IV oxycodone at PACU	7	13	0.217
Use of oral oxycodone at PACU	29	34	0.446

Demographics in 112 men undergoing laparoscopic groin hernia repair. Data are median (range) and frequencies

BMI, body mass index (kg/m^2); ASA, American Society of Anesthesiologists class; PONV, postoperative nausea and vomiting; PACU, postanaesthesia care unit

"–" indicates p-value not calculated

(maximum × 4) based on the preference of the attending nurse in the PACU.

Statistical analysis

Sample size calculation was based on an earlier study in patients undergoing TAPP where VAS pain was mean 36.2 mm with SD 20.2 mm at 24 h postoperatively [16]. We designed this study to detect a minimal relevant difference (MIREDIF) of 13 mm in VAS pain on day 1 due to a clinically relevant difference [17, 18]. Statistical type I error was set to 5 % and type II to 20 %, resulting in a sample size of $n = 46$ patients in each arm. We included 50 patients in each arm (100 patients in total). In case of dropouts, additional patients were included by new randomization blocks of four to obtain primary endpoints from a minimum of 100 patients.

Postoperative pain scores during coughing and rest, and discomfort as estimated by VAS (day 0–3) were cumulated for each patient (total scores ranging between 0 and 400)

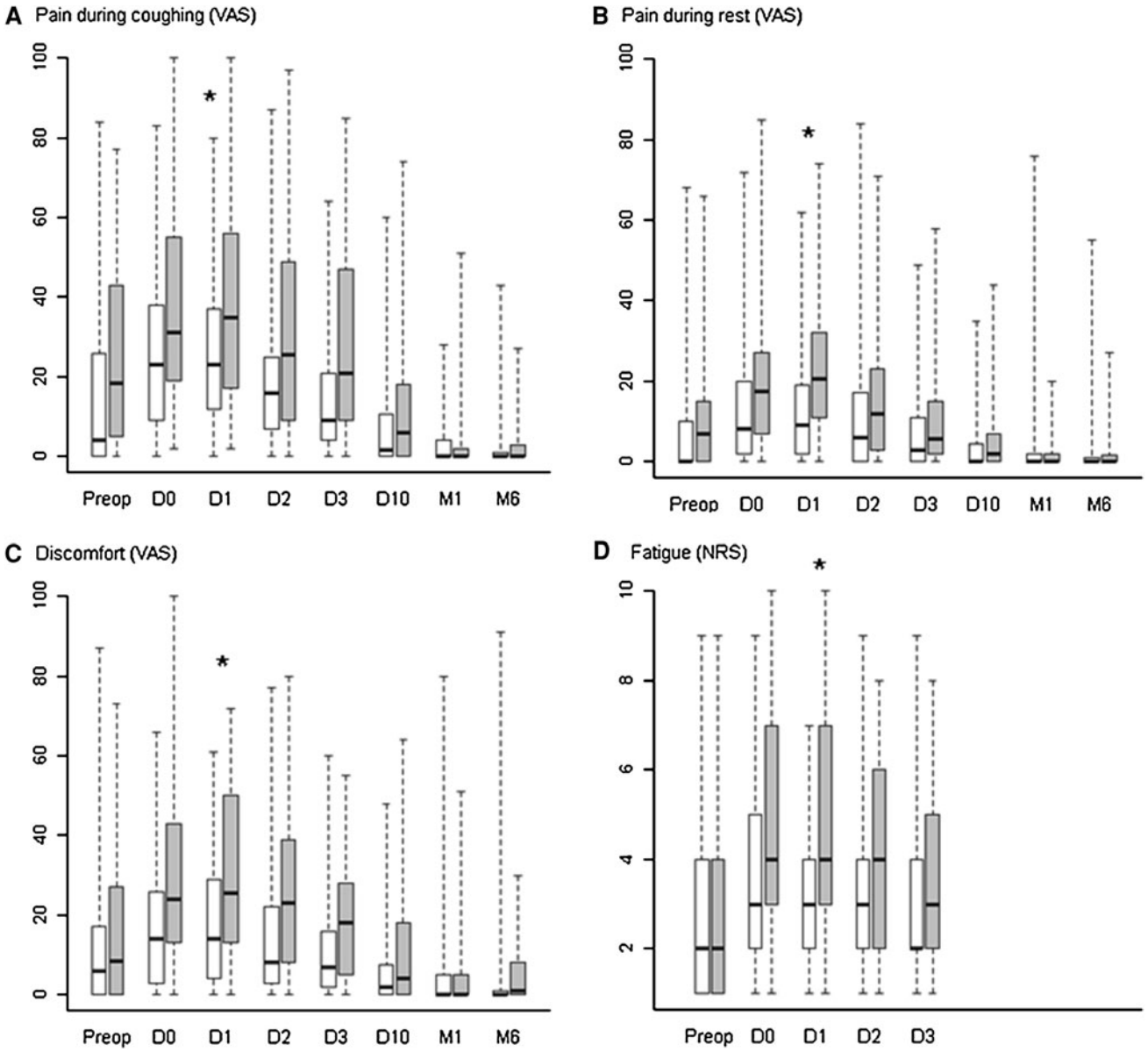

Fig. 2 Primary endpoint was pain during coughing on postoperative day 1. Pain scores as estimated by VAS preoperatively (preop.), day (D) 0–3, day 10, and at 1 and 6 month (M) during **A** coughing and **B** rest. **C** Discomfort as estimated by VAS preoperatively, day 0–3, 10 and at 1 and 6 month. **D** Fatigue as estimated by NRS preoperatively and on day 0–3. *White box* = fibrin group ($n = 50$), *grey box* = tacks group ($n = 50$). Values are presented as median (*horizontal line within box*), 25 and 75 per cent interquartile range (*box*) and range. *$p < 0.05$. For exact *p*-values see Table 2

and used for comparison between groups. Postoperative fatigue as estimated by NRS was cumulated for each patient (total score range 0–40) and used for comparison between groups. Severity of nausea (VRS score) was dichotomized: 0 = no or light nausea, 1 = moderate or severe nausea on day 0. Vomiting was dichotomized: 0 = 0 number of vomiting episodes, 1 ≥ 1 number of vomiting episodes on day 0. Pain as estimated by VRS on day 1 was dichotomized: 0 = no or light pain, 1 = moderate or severe pain. Seroma and haematoma were dichotomized: 0 = no or light, 1 = moderate or severe. Use of analgesics (IV oxycodone and capsule oxycodone) was dichotomized: 0 = 0 mg used on day 0, 1 ≥ 0 mg used on day 0. Non-parametric Mann–Whitney *U*-tests were used to compare the two arms (day 1 and cumulated pain score day 0–3). Fisher's exact test was used when appropriate, and Friedman test was used to evaluate the effect of time on intra- and intergroup variation of VAS and NRS scores. Analysis of co-variance with adjustment for preoperative value was used to correct the difference between groups on day 1 for potential bias in case of baseline imbalance [19]. *p*-Value < 0.05 was considered to be statistically significant. Data are given as median (range), unless otherwise stated. Statistical analysis was performed on an intention-to-treat principle.

Results

Between Sept 2009 and Aug 2011, 112 men were enrolled out of 306 eligible patients (Fig. 1) and randomized into two groups: fibrin glue ($n = 56$) and tacks ($n = 56$). Twelve patients were lost to follow-up (did not return their questionnaires or withdraw consent). Thus, 100 patients completed the study. Patients and surgical characteristics are presented in Table 1. One patient (tacks group) had a small bowel serosa lesion and needed a 10-mm trocar to suture the lesion (patient not excluded from analysis).

The fibrin group had significantly lower pain scores during coughing (VAS) on day 1 compared with the tacks group [median 23 (range 0–80) vs 35 (2–100) mm] ($p = 0.020$) (Fig. 2A) and during rest [9 (0–62) vs 20.5 (0–74) mm] ($p = 0.001$) (Fig. 2B; Table 2). When adjusting for potential bias due to baseline imbalance (Fig. 2A), significance was maintained on day 1 between groups (pain during coughing showed estimated difference of VAS = 10.2 mm; $p = 0.026$). There was significantly lower incidence of moderate/severe pain as estimated by VRS on day 1 in the fibrin group compared with the tacks group (4 vs 20 patients, respectively, $p < 0.001$). Cumulated pain scores (day 0–3) were significantly lower in the fibrin group compared with the tacks group during coughing ($p = 0.007$) and during rest ($p = 0.004$) (Table 2). Discomfort and fatigue scores were significantly lower in the fibrin group compared with the tacks group on day 1 and cumulated day 0–3 (Fig. 2C, D; Table 2). There were overall intragroup changes from preoperative to day 3 in both groups for all endpoints (pain, discomfort and fatigue). Significant intergroup differences with time were observed for pain during rest ($p = 0.007$) and fatigue ($p = 0.009$) (Table 3).

There were no significant differences in incidence of moderate/severe nausea 3 h postoperatively ($n = 1$ vs $n = 2$, fibrin vs tacks, $p = 1.00$) or vomiting ($n = 0$ vs $n = 1$, fibrin vs tacks, $p = 1.00$) between groups. Seroma was reported by three versus five patients ($p = 0.715$) and haematoma by zero versus five patients ($p = 0.056$) on day 10 (fibrin vs tacks). Incidence of foreign-body sensation was significantly lower in the fibrin group at 1 month (7 vs 20 patients, $p = 0.006$) compared with the tacks group but

Table 2 Pain during coughing and rest, discomfort and fatigue on day 1 and cumulated day 0–3

	Fibrin glue ($n = 50$)	Tacks ($n = 50$)	*p*-Value
Pain during coughing			
Day 1	23 (0–80)	35 (2–100)	0.020
Cumulated day 0–3	76 (0–302)	114 (15–380)	0.007
Pain during rest			
Day 1	9 (0–62)	21 (0–74)	0.001
Cumulated day 0–3	27 (0–262)	56 (0–281)	0.004
Discomfort			
Day 1	14 (0–61)	26 (0–72)	0.007
Cumulated day 0–3	54 (0–261)	105 (0–218)	0.002
Fatigue			
Day 1	3 (1–7)	4 (1–10)	0.005
Cumulated day 0–3	12 (4–28)	17 (4–36)	0.020

Numeric and *p*-values for pain during coughing and rest, discomfort and fatigue on day 1 and cumulated day 0–3 are presented (visual analogue scale and numerical rating scale scores). Medians (ranges) are shown. Only data from 2 × 50 patients were analysed because 12 patients were lost to follow-up

Table 3 Intragroup and intergroup comparison

	p-Value		
	Fibrin glue ($n = 50$)	Tacks ($n = 50$)	Intergroup comparison
Pain during coughing	<0.001	<0.001	0.191
Pain during rest	<0.001	<0.001	0.007
Discomfort	<0.001	<0.001	0.198
Fatigue	0.002	<0.001	0.009

Intragroup and intergroup comparison after Friedman's test for pain during coughing, rest, discomfort and fatigue. Only data from 2 × 50 patients were analysed because 12 patients were lost to follow-up

not after 6 months (1 vs 9 patients, fibrin vs tacks, $p = 0.616$). Two patients in the fibrin group underwent reoperation for recurrence within the first 6 months compared with zero patients in the tacks group ($p = 0.241$). Furthermore, five patients suspected clinical recurrence at 6 months (two patients in the fibrin group, three in the tacks group), but no recurrences were found at the clinical examination, which in one patient was supplemented with ultrasonography.

Discussion

In this double-blinded, randomized, controlled trial, fibrin glue compared with tacks fixation significantly reduced postoperative pain, discomfort, fatigue and foreign-body sensation without higher risk of recurrence.

Several studies have compared glue with tack fixation in patients undergoing laparoscopic groin hernia repair [1–6, 20–24]. However, only a small number of these were randomized, controlled trials evaluating postoperative pain during the first week [1–3, 6], and the results are not consistent. Two studies found no significant difference in early postoperative pain between groups after total extraperitoneal (TEP) repair (day 0–6, $n = 93$) [6] and TAPP (day 0–2 and day 10, $n = 89$) [3]. Two other studies demonstrated significantly lower pain scores in the fibrin sealant group after TAPP on day 1–3 ($n = 300$) [2] and on day 7 ($n = 22$) [1]. However, limitations of these studies were insufficient sample size [1], missing details on sample size calculation [1, 2, 25] or lack of blinding [3, 6]. A recent randomized trial in patients undergoing laparoscopic umbilical hernia repair comparing fibrin glue with tacks found, in accordance with the present study, less early postoperative pain and discomfort in the fibrin group [26].

Though the randomization was properly conducted, slight imbalances could be suspected between the treatment groups in pain during coughing at baseline. Thus, an adjustment for potential bias due to baseline imbalance was made to ensure that postoperative differences were not just caused by differences at baseline. Our results of 12 mm (10.2 mm when adjusting for potential bias due to baseline imbalance) lower pain score as estimated by VAS in the fibrin group on postoperative day 1 confirmed our initial hypothesis. Furthermore, findings were uniform for all endpoints in favour of fibrin glue, and therefore glue fixation is likely to enhance recovery in the early postoperative days. In combination with best possible perioperative care with multimodal analgesic treatment [27] etc., the sum of all these interventions improves the early postoperative course. The present study was not powered to investigate the effect of fibrin glue on chronic pain, but fibrin glue has in other studies shown promising results regarding chronic pain without a higher risk of recurrence [25, 28]. Similarly, the size of the patient population was too small and the follow-up period too short to draw final conclusions regarding the recurrence rate after fibrin glue fixation versus tack fixation.

All patients received dexamethasone (8 mg orally) 1 h before operation and perioperative single-dose antibiotic prophylaxis of IV cefuroxim 1,500 mg because this was standard routine at the hospital at the time. The effect of oral dexamethasone is controversial, since a previous study, albeit in cholecystectomy, found no effect of preoperative orally administered steroid on postoperative outcome [29, 30]. Furthermore, routine preoperative antibiotic prophylaxis is not recommended by the International Endohernia Society (IEHS) [31].

Fibrin glue for mesh fixation significantly reduced early postoperative pain, discomfort, fatigue and incidence of foreign-body sensation after laparoscopic groin hernia repair compared with tacks fixation. Use of fibrin glue as fixation method may help in enhancing recovery and thereby shorten convalescence.

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References

1. Boldo E, Armelles A, de Perez LG, Martin F, Aracil JP, Miralles JM, Martinez D, Escrig J (2008) Pain after laparascopic bilateral hernioplasty : Early results of a prospective randomized double-blind study comparing fibrin versus staples. Surg Endosc 22: 1206–1209
2. Olmi S, Scaini A, Erba L, Guaglio M, Croce E (2007) Quantification of pain in laparoscopic transabdominal preperitoneal (TAPP) inguinal hernioplasty identifies marked differences between prosthesis fixation systems. Surgery 142:40–46
3. Fortelny RH, Petter-Puchner AH, May C, Jaksch W, Benesch T, Khakpour Z, Redl H, Glaser KS (2012) The impact of atraumatic fibrin sealant vs. staple mesh fixation in TAPP hernia repair on chronic pain and quality of life: results of a randomized controlled study. Surg Endosc 26:249–254
4. Bittner R, Gmahle E, Gmahle B, Schwarz J, Aasvang E, Kehlet H (2010) Lightweight mesh and noninvasive fixation: an effective concept for prevention of chronic pain with laparoscopic hernia repair (TAPP). Surg Endosc 24:2958–2964

5. Ceccarelli G, Casciola L, Pisanelli MC, Bartoli A, Di ZL, Spaziani A, Biancafarina A, Stefanoni M, Patriti A (2008) Comparing fibrin sealant with staples for mesh fixation in laparoscopic transabdominal hernia repair: a case control-study. Surg Endosc 22:668–673
6. Lau H (2005) Fibrin sealant versus mechanical stapling for mesh fixation during endoscopic extraperitoneal inguinal hernioplasty: a randomized prospective trial. Ann Surg 242:670–675
7. Bay-Nielsen M, Thomsen H, Andersen FH, Bendix JH, Sorensen OK, Skovgaard N, Kehlet H (2004) Convalescence after inguinal herniorrhaphy. Br J Surg 91:362–367
8. Pavlin DJ, Chen C, Penaloza DA, Polissar NL, Buckley FP (2002) Pain as a factor complicating recovery and discharge after ambulatory surgery. Anesth Analg 95:627–634
9. Callesen T, Klarskov B, Bech K, Kehlet H (1999) Short convalescence after inguinal herniorrhaphy with standardised recommendations: duration and reasons for delayed return to work. Eur J Surg 165:236–241
10. Kehlet H, Jensen TS, Woolf CJ (2006) Persistent postsurgical pain: risk factors and prevention. Lancet 367:1618–1625
11. McCormack K, Wake B, Perez J, Fraser C, Cook J, McIntosh E, Vale L, Grant A (2005) Laparoscopic surgery for inguinal hernia repair: systematic review of effectiveness and economic evaluation. Health Technol Assess 9:1–203, iii–iv
12. Christensen T, Bendix T, Kehlet H (1982) Fatigue and cardiorespiratory function following abdominal surgery. Br J Surg 69: 417–419
13. Schulz KF, Altman DG, Moher D (2010) CONSORT 2010 statement: Updated guidelines for reporting parallel group randomised trials. J Pharmacol Pharmacother 1:100–107
14. Bittner R, Schmedt CG, Schwarz J, Kraft K, Leibl BJ (2002) Laparoscopic transperitoneal procedure for routine repair of groin hernia. Br J Surg 89:1062–1066
15. Tolver MA, Strandfelt P, Rosenberg J, Bisgaard T (2011) Pain characteristics after laparoscopic inguinal hernia repair. Surg Endosc 25:3859–3864
16. Tanphiphat C, Tanprayoon T, Sangsubhan C, Chatamra K (1998) Laparoscopic vs open inguinal hernia repair. A randomized, controlled trial. Surg Endosc 12:846–851
17. Gallagher EJ, Liebman M, Bijur PE (2001) Prospective validation of clinically important changes in pain severity measured on a visual analog scale. Ann Emerg Med 38:633–638
18. Todd KH, Funk KG, Funk JP, Bonacci R (1996) Clinical significance of reported changes in pain severity. Ann Emerg Med 27:485–489
19. Wei L, Zhang J (2001) Analysis of data with imbalance in the baseline outcome variable for randomized clinical trials. Drug information journal 35:1201–1214
20. Lovisetto F, Zonta S, Rota E, Mazzilli M, Bardone M, Bottero L, Faillace G, Longoni M (2007) Use of human fibrin glue (Tissucol) versus staples for mesh fixation in laparoscopic transabdominal preperitoneal hernioplasty: a prospective, randomized study. Ann Surg 245:222–231
21. Topart P, Vandenbroucke F, Lozac'h P (2005) Tisseel versus tack staples as mesh fixation in totally extraperitoneal laparoscopic repair of groin hernias: a retrospective analysis. Surg Endosc 19:724–727
22. Schwab R, Willms A, Kroger A, Becker HP (2006) Less chronic pain following mesh fixation using a fibrin sealant in TEP inguinal hernia repair. Hernia 10:272–277
23. Novik B, Hagedorn S, Mork UB, Dahlin K, Skullman S, Dalenback J (2006) Fibrin glue for securing the mesh in laparoscopic totally extraperitoneal inguinal hernia repair: a study with a 40-month prospective follow-up period. Surg Endosc 20:462–467
24. Santoro E, Agresta F, Buscaglia F, Mulieri G, Mazzarolo G, Bedin N, Mulieri M (2007) Preliminary experience using fibrin glue for mesh fixation in 250 patients undergoing minilaparoscopic transabdominal preperitoneal hernia repair. J Laparoendosc Adv Surg Tech A 17:12–15
25. Fortelny RH, Petter-Puchner AH, Glaser KS, Redl H (2012) Use of fibrin sealant (Tisseel/Tissucol) in hernia repair: a systematic review. Surg Endosc 26:1803–1812
26. Eriksen JR, Poornoroozy P, Jorgensen LN, Jacobsen B, Friis-Andersen HU, Rosenberg J (2009) Pain, quality of life and recovery after laparoscopic ventral hernia repair. Hernia 13:13–21
27. Kehlet H, Dahl JB (2003) Anaesthesia, surgery, and challenges in postoperative recovery. Lancet 362:1921–1928
28. Kaul A, Hutfless S, Le H, Hamed SA, Tymitz K, Nguyen H, Marohn MR (2012) Staple versus fibrin glue fixation in laparoscopic total extraperitoneal repair of inguinal hernia: a systematic review and meta-analysis. Surg Endosc 26:1269–1278
29. Bisgaard T, Schulze S, Christian HN, Rosenberg J, Bjerregaard KV (2008) Randomized clinical trial comparing oral prednisone (50 mg) with placebo before laparoscopic cholecystectomy. Surg Endosc 22:566–572
30. Karanicolas PJ, Smith SE, Kanbur B, Davies E, Guyatt GH (2008) The impact of prophylactic dexamethasone on nausea and vomiting after laparoscopic cholecystectomy: a systematic review and meta-analysis. Ann Surg 248:751–762
31. Bittner R, Arregui ME, Bisgaard T, Dudai M, Ferzli GS, Fitzgibbons RJ, Fortelny RH, Klinge U, Kockerling F, Kuhry E et al (2011) Guidelines for laparoscopic (TAPP) and endoscopic (TEP) treatment of inguinal hernia [International Endohernia Society (IEHS)]. Surg Endosc 25:2773–2843