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Comparing chronic pain between fibrin sealant and suture fixation for bilayer polypropylene mesh inguinal hernioplasty: a randomized clinical trial

Jia-Uei Wong, M.D.[a], Tsz-Ho Leung, M.D., M.Sc.[a], Chi-Cheng Huang, M.D., M.Sc.[a,b], Ching-Shui Huang, M.D.[a,c,*]

[a]Division of General Surgery, Department of Surgery, Cathay General Hospital, 280, Sec. 4, Ren-Ai Rd., Taipei 10630, Taiwan; [b]School of Medicine, Fu-Jen Catholic University, Taipei County, Taiwan; [c]Taipei Medical University, Taipei, Taiwan

KEYWORDS:
Bilayer mesh fixation;
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Abstract

BACKGROUND: The aim of this study was to compare the postoperative pain, complications, and recurrence after bilayer polypropylene mesh inguinal hernioplasty using fibrin sealant versus sutures for fixation.

METHODS: Patients were assigned randomly to either a mesh fixed with suture group (n = 26) or a mesh fixed with fibrin sealant group (n = 30). Postoperative pain was evaluated with a visual analogue scale at days 1 and 7, and the first, third, and sixth month postoperatively. Complications and hernia recurrence were recorded.

RESULTS: At each time point after surgery, visual analogue scale pain scores in the fibrin sealant group were lower but there was no statistically significant difference. There were no differences in complications or hernia recurrence between the 2 groups.

CONCLUSIONS: Fibrin sealant is associated with similar rates of complications and recurrence as mesh fixation with sutures. There was no statistical difference in pain 6 months postoperatively between the 2 groups.

Inguinal hernia repair is one of the most commonly performed procedures in general surgery.[1] Tension-free repair using a variety of techniques and prosthetic mesh has become a preferred method of management, and has been found to reduce the rate of recurrence.[2–4] Before tissue ingrowth and incorporation with abdomen wall, the prosthetic mesh typically is fixed to the abdominal wall tissue using staples or sutures; however, these methods of fixation have been associated with acute and chronic pain.[5]

Postherniorrhaphy pain can be caused by compression of one or more nerves by perineural fibrosis, the suture material, staples and tacks, or intraoperative nerve injury.[5–7] Thus, it may be possible to decrease the incidence of postoperative inguinal pain by limiting the use of sutures and staples as fixation devices. Studies have shown that chronic postherniorrhaphy pain is significantly reduced after laparoscopic hernia repair when fibrin glue (Tissucol/Tisseel; Baxter Healthcare, Deerfield, IL) is used instead of staples or sutures to fix the mesh material.[8,9] In addition, it has been

* Corresponding author. Tel.: +886-2-27082121*3312; fax: +886-2-27097984.

E-mail address: gs3312@cgh.org.tw

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shown that fibrin glue provides strong fixation of mesh material in the open repair of inguinal hernias as well as ventral hernias,[10-13] but data to indicate if the use of fibrin glue reduces chronic pain after open inguinal herniorrhaphy are limited.

The aim of this randomized trial was to evaluate chronic postoperative pain, complications, and recurrence after open inguinal hernia repair with bilayer mesh fixed with fibrin sealant versus sutures.

Materials and Methods

Participants

This study was a single-surgeon and single-center prospective, randomized, controlled trial. A total of 226 patients had hernia surgery at Cathay General Hospital from July 15, 2007, to December 15, 2007. During this period, one experienced surgeon performed 97 primary open inguinal hernia repairs. Among the 97 patients, 41 patients were excluded from the study; 38 failed to meet the inclusion criteria, and 3 patients refused to sign the informed consent. Thus, 56 patients were assigned randomly in a 1:1 ratio to a mesh fixed with suture group or a mesh fixed with fibrin glue group. Treatment allocation was performed before initiation. A list of sequential numbers was generated using a simple randomization procedure, with each number randomly assigned to one group. Each patient was assigned a unique number based on his or her order of enrollment. Patients in both treatment groups were blinded as to which treatment they received until the end of the study. Data collectors also were blinded with respect to which surgical treatment the patients received.

Patients were eligible for participation in the study if they had a primary inguinal hernia and were 20 years of age or older. Patients were excluded if they refused to take part in the trial; had recurrent, total scrotal, incarcerated, bilateral, or femoral hernias; were receiving concomitant abdominal surgery, receiving long-term analgesic or steroid treatment; had a history of alcohol or drug abuse; cirrhosis; previous treatment with or hypersensitivity to bovine aprotinin; known immunodeficiency; or severely compromised physical or psychological health. Patients also were excluded if they were participating in another clinical trial or received another investigational drug or device within the 30 days preceding surgery. Patients receiving clopidogrel or warfarin were switched to low-molecular-weight subcutaneous heparin before surgery. This study was approved by the Institutional Review Board of Cathay General Hospital and all patients provided informed consent for participation in the study and for surgery.

Treatment

Hernias were classified based on the Gilbert classification. In the case of direct hernias, the attenuated transversalis fascia was circumcised and reduced with the hernia content. In the case of indirect hernias, the hernia sac was isolated from the cord elements and reduced through the internal ring. All cordal lipoma were removed if present. The ilio-inguinal nerve and iliohypogastric nerve were identified and preserved in all procedures. Two kinds of bilayer monofilament polypropylene mesh were used at the discretion of the surgeon: Prolene Hernia System (PHS; Ethicon, Somerville, NJ), and Bard Modified Kugel Hernia Patch (Davol, Inc., Cranston, RI). In patients who had a relative localized defect of the posterior wall, the PHS system was used; in patients with severe destruction of the posterior wall, the modified Kugel was used. In the suture group, the mesh was fixed with polyglactin monofilament sutures (coated Vicryl; Ethicon, Inc.). Three sutures, loosely tied, were used to fix the onlay mesh on the upper layer in each case. In patients undergoing fibrin glue fixation, the mesh was fixed with 2 mL of Tissucol/Tisseel.

Measurement

Pain was measured by a visual analogue scale (VAS). A VAS is a measurement instrument that measures a characteristic or attitude that is believed to range across a continuum of values and cannot easily be measured directly. Operationally, a VAS is usually a horizontal line, 100 mm in length, anchored by word descriptors at each end. The patient marks on the line the point that they believe represents their perception of their current state. The VAS score is determined by measuring in millimeters from the left hand end of the line to the point that the patient marks. In this study, the left-most side of the scale indicated no pain, the right-most side of the scale indicated very severe pain.

The primary end point was late postoperative pain (intermittent pain, burning sensation, or foreign body sensation) at day 180 postoperatively. The secondary end point was postoperative pain at the 1st, 7th, 30th, and 90th days postoperatively. Postoperative events such as seroma and hematoma formation, infection, and mortality also were recorded.

Statistical analysis

Comparisons between the 2 treatment groups was performed using an independent 2-sample *t* test for continuous variables, and the chi-square/Fisher exact test was used for categoric variables. Repeated-measurements analysis with a linear mixed model was used to assess the treatment and time effects on the VAS score and an independent 2-sample *t* test was used to address the difference of VAS at each time point. Each individual patient is considered as a random effect in the linear mixed model; that is, we consider the VAS change in each patient between the 2 groups during the whole time course. In addition, we only considered the mean VAS difference between the 2 groups at each time point by an independent 2-sample *t* test. In this manner we