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ORIGINAL ARTICLE

S. Canonico · A. Santoriello · F. Campitiello
A. Fattopace · A. Della Corte · I. Sordelli
R. Benevento

Mesh fixation with human fibrin glue (Tissucol) in open tension-free inguinal hernia repair: a preliminary report

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Abstract *Background*: The Lichtenstein technique for inguinal hernia repair is easy to learn and associated with few complications. However, recent studies have suggested that this technique is inferior to some 'sutureless' repair systems in terms of perceived difficulty, operating time, surgeon satisfaction, etc. *Methods*: We employed a sutureless Lichtenstein technique in 80 consecutive patients with primary unilateral inguinal hernia, to assess patient and trainee surgeon outcomes. Human fibrin glue was used in place of conventional sutures. *Results*: The mean operating time was 36 min and all patients were discharged 5–6 h after the operation. On a 100-point visual analogue scale, the surgeons rated the difficulty of the operation as low (mean score, 31), and perceived satisfaction as high (mean score, 84). No complications were observed at 12-month follow-up. *Conclusion*: This study confirms the efficacy of mesh fixation with human fibrin glue, and supports the viability of a sutureless Lichtenstein procedure.

Keywords Unilateral inguinal hernia · Tension-free hernia repair · Human fibrin glue · Mesh fixation

Introduction

In recent years, the trauma experienced by patients undergoing inguinal hernia repair has been reduced due to advances in surgical techniques. Of the current surgical approaches, the Lichtenstein technique is widely used because it is easy to learn and is associated with a low rate of complications and recurrences [1, 2]. To further progress this field, recent studies have focused on two issues (1) the incidence of groin pain at long-term follow-up [3, 4]; and (2) the teaching issues that determine the progress of surgeons training in this technique [5]. For example, Nienhuijs et al. reported that the Lichtenstein technique is inferior to the Prolene Hernia System (Ethicon Inc., Somerville, NJ, USA) and to the mesh plug repair system in terms of operating time, incision length, perceived difficulty and surgeon satisfaction [5]. It has been hypothesised that these results are linked to the use of sutures for mesh fixation [6].

To address the concerns associated with the Lichtenstein technique, we employed a 'sutureless' procedure, using human fibrin glue (HFG) (Tissucol/Tisseel, Baxter Healthcare, Deezfield, IL, USA) as an alternative to sutures for mesh fixation. In this article we report our preliminary experience with this modified technique of open tension-free inguinal hernia repair.

Materials and methods

This prospective observational study took place throughout January 2003 to October 2004. Eighty consecutive patients with primary unilateral inguinal hernia underwent sutureless Lichtenstein hernia repair, under local anaesthesia. Exclusion criteria included recurrent hernia, femoral hernia, urgent cases, insulin-dependent diabetes, obesity (body weight >100 kg for men and >80 kg for women) and psychiatric pathology. Surgery was performed by five experienced trainees (i.e., trainee surgeons who had performed more than ten Lichtenstein procedures), under the supervision of one staff member with extensive experience in hernia repair. All patients were fully briefed about the procedure and informed consent was obtained.

S. Canonico (✉) · A. Santoriello · F. Campitiello
A. Fattopace · A. Della Corte · I. Sordelli · R. Benevento
Department of General Surgery, School of Medicine,
Second University of Naples, Piazza Miraglia 5,
80138 Naples, Italy
E-mail: silvestro.canonico@unina2.it
Tel.: +39-081-5665278
Fax: +39-081-5665278

Surgical technique

The inguinal canal was prepared and the hernial sac managed according to the Lichtenstein technique [7]. The ilioinguinal nerve, the iliohypogastric nerve and the genital branch of the genitofemoral nerve were prepared and preserved in all patients. A 6×11 cm polypropylene mesh (Prolene, Ethicon Inc., Somerville, NJ, USA) was placed on the inguinal floor, overlying the pubic tubercle for a minimum of 1.5 cm, and fixed to the aponeurotic tissue above the pubic tubercle with one nonabsorbable stitch (polypropylene 2/0) taking care to prevent injury to the periosteum of mons pubis. Then the mesh was glued to the inguinal ligament and the internal oblique muscle with HFG (Tissucol/Tisseel, Baxter Healthcare). The glue was prepared from four components: human pooled fibrinogen (75–115 mg/ml), aprotinin (3,000 kallidinogenase inactivator units/ml), human thrombin powder (500 units/ml) and calcium chloride (40 μmol/ml). The components were mixed during the operation to form fibrin, and applied under the mesh by a spraying device, ensuring an even and complete covering of the inguinal floor. Less than 0.5 ml of adhesive was required to complete the entire procedure. The prosthesis was compressed over the glue against the inguinal floor for 2 min. Laterally to the spermatic cord, the upper part of the mesh was flipped over the lower one and they were joined with one polypropylene stitch. After repositioning of the external oblique muscle and Scarpa's fascia, the skin was closed with a subcuticular absorbable suture (3/0 Monocryl; Ethicon Inc., Somerville, NJ, USA).

Operation details, including duration of the operation, were noted immediately after the surgery was completed. At this point, the surgeon also completed visual analogue scale (VAS) scorings of his/her perceived difficulty of, and personal satisfaction with the technique. The VAS was a 100-mm line with limits marking each end, ranging from 'easy' (0) to 'difficult' (100) for the scale of perceived difficulty, and from 'little' (0) to 'high' (100) for perceived satisfaction.

To evaluate complications resulting from the operation, follow-up clinical assessments took place at 7 days, 6 months and 12 months. This included questioning about postoperative pain. When present, pain was ranked as slight, moderate or severe. As part of the 12-month assessment, patients underwent an inguinal ultrasound to exclude hernia recurrence.

Results

The mean age of the 80 patients was 51 years (range 38–86) and 78 (98%) were male. The hernias were indirect in 55 patients (69%), direct in 21 (26%) and combined (indirect and direct) in four patients (5%) (Table 1). The size of the defect, ranked according to the Aachen classification [8], was < 1.5 cm in 13 patients (16%), 1.5–3.0 cm in 48 patients (60%) and > 3.0 cm in 19 patients (24%) (Table 1).

Table 1 Classification of 80 primary unilateral inguinal hernias (78 males, 2 females; mean age 51 years, range 38–86) treated with open tension-free inguinal hernia repair and mesh fixation by means of human fibrin glue

Hernia presentation and size (Aachen classification)	Number (%)
Indirect	55 (69%)
Direct	21 (26%)
Combined	4 (5%)
Total	80 hernias
Aachen class I (< 1.5 cm)	13 (16%)
Aachen class II (1.5–3 cm)	48 (60%)
Aachen class III (> 3 cm)	19 (24%)
Total	80 hernias

The mean skin-to-skin operating time was 36 min (range 25–43) (Table 2). The mean VAS scores for the surgeon's perceived difficulty and satisfaction with the technique were 31 (range 22–38) and 84 (range 78–95), respectively (Fig. 1).

Table 2 Outcomes following open tension-free inguinal hernia repair of 80 hernias during 12 months' follow-up

Measure	Mean
Operating time (min)	36 (range, 25–43)
Hospital stay (days)	< 1
Mortality (cases)	0
Recurences (cases)	0
Neuralgia (cases)	0
Haematoma (cases)	0
Seroma (cases)	0
Scrotal hyperesthesia	0
Persistent pain (cases)	2[a] (2.5%)

[a] At 6 months' follow-up, two patients reported moderate pain at the pubic tubercle. This had disappeared at 12-month follow-up.

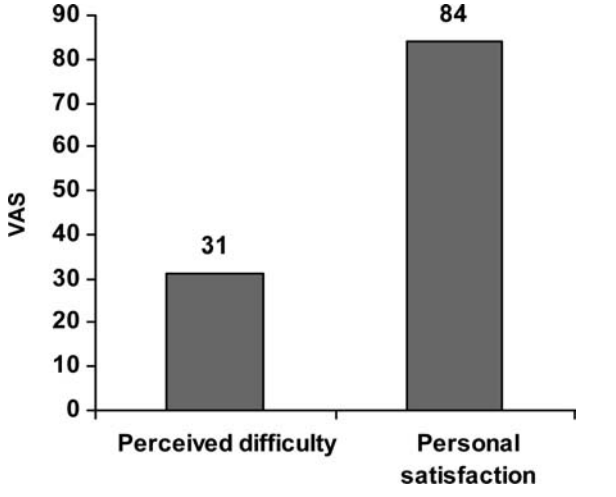

Fig. 1 Mean visual analog scale (VAS) scores (100-point scale) for surgeons following completion of open tension-free inguinal hernia repair and mesh fixation by means of human fibrin glue. 0—'easy' and 100—'difficult' for perceived difficulty; 0—'little' and 100—'high' for personal satisfaction

There were no intra-operative complications. All patients went home 5–6 h after the operation and none required readmission to hospital. No sepsis, mesh rejection or other complications such as haematoma or seroma were recorded at 7-day follow-up. At 6 months, the only complications seen were reports of moderate pain at the pubic tubercle in two patients (2.5%). At 12-month follow-up, no recurrences or late complications, such as scar immobility/fibrosis, neuralgia or scrotal hyperesthesia, were seen (Table 2). The two patients who reported tubercle pain at 6 months were free of tubercle pain at 12 months.

Discussion

The important role of HFG in surgery is supported by extensive experience acquired at an international level. A considerable body of literature has confirmed the effectiveness of this product and has also demonstrated its excellent local tolerability and lack of adverse effects and contraindications [9–12]. Antifibrinolytic agents such as aprotinin are included in the preparation to enhance the life-span of the sealant and prolong its effectiveness. In addition to its haemostatic action, the fibrinogen component gives the product its tensile strength and adhesive properties, and the thrombin component promotes fibroblast proliferation [13]. As a consequence of these properties, HFG has contributed to the improvement of surgical procedures and in some cases, the development of new techniques, such as the treatment of fistulous complications following bowel anastomosis [9].

In a previous study we found that HFG was effective in preventing local haemorrhagic complications after hernioplasty in patients with concurrent coagulation disorders [14]. Studies by other investigators have firmly established the adhesive properties of this biological sealant [15, 16], and excellent results with the use of HFG for prosthetic mesh fixation in laparoscopic extraperitoneal inguinal hernia repair have been reported [17].

A preliminary study on the use of *N*-butyl-2-cyanoacrylate as an alternative adhesive for tension-free inguinal hernia repair has shown that this sealant can clog mesh pores, promoting septic complications [18]. More recently, a clinical trial examining the use of *N*-butyl-cyanoacrylate for fixing the mesh prosthesis in inguinal hernia repair has shown promising early results [19]. However, the cyanoacrylates are chemical sealants and dry too quickly (within 5–7 s), forming a rigid binding. This means that the mesh can be fixed only at a few points at the edges, so that haematomas or seromas can occur under the prosthesis (Helbling and Schlumpf reported a 13.5% incidence of early haematomas [19]. Furthermore, these sealants dry with an exothermic reaction and show a degree of histotoxicity. In contrast, HFG is a biological glue that naturally coagulates and is reabsorbed without changing tissue or mesh characteristics.

Our study shows that mesh fixation with HFG is suitable for use in open tension-free inguinal repair. There were no complications related to the technique. In particular, no haematomas, seromas or neuralgias were observed over 12 months of follow-up. Moreover, the mean operating time was shorter when compared with the mean operating time of the classic Lichtenstein technique at our hospital (36 vs 46 min, respectively), and at other hospitals (e.g., 52 min) [5]. In addition, surgeons reported a low level of perceived difficulty and a high level of satisfaction. This is especially reassuring given that the surgeons were trainees.

In conclusion, our results confirm the efficacy of mesh fixation with HFG and support the viability of a sutureless Lichtenstein procedure. Whether this approach becomes widespread will depend on further evaluation in multicentre controlled trials.

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