

Is human fibrin sealant a possible choice for the fixation of laparoscopic inguinal hernia repair? A single center experience and the analysis of the results after 326 TAPP in two years

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SUMMARY: Is human fibrin sealant a possible choice for the fixation of laparoscopic inguinal hernia repair? A single center experience and the analysis of the results after 326 TAPP in two years.

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Background. Groin hernioplasty is most intervention performed in the worldwide. The present study aimed to evaluate a combination between ultralight mesh and fibrin human sealant in the laparoscopic treatment of inguinal hernia.

Patients and methods. This retrospective study included consecutive patients who underwent laparoscopic transabdominal preperitoneal hernioplasty (TAPP) from 1st of January 2015 to 31st of Decem-

ber 2016. Demographics, surgical data and postoperative outcomes were entered in an anonymized prospective database. Prospective long-term follow-up carried out in all patients.

Results. One hundred eighty-four patients with a median age 57.5 (range 19-84) and median BMI (Body Mass Index) of 28.5 (range 18.5-31.5) were included. A median follow-up of 25 months (median 13-35) was carried out. Five recurrences (1.5%) and two cases of missed lipoma were observed and operated. Chronic pain (CP) was observed in eleven (9%) patients but in 9 patients it decreased spontaneously.

Conclusions. Combination of ultralight mesh and Evicel® in TAPP operation is a safe solution for the treatment of groin hernia. Recurrences and chronic pain are similar to other combination of fibrin sealant and meshes. Moreover action of Evicel® may provide to improve the hemostasis and consequently hematoma of the cord.

KEY WORDS: TAPP - Fibrin human sealant - Groin hernia.

Background

Groin hernia repairs are likely the most common surgical procedures performed worldwide; in fact, in 2003 Rutkow reported approximately 800,000 herniated inguinal operations per year in the United States, and in the world it was estimated that 20 million operations were performed yearly (1, 2). At present, about 5-10% of the male population worldwide is affected by groin hernia and the risk of developing a groin hernia is 25% in a lifetime (3, 4).

The first laparoscopic approach to treat inguinal hernia with minimal invasive technique was reported in 1982, but only in 1990 Ger and colleagues described results in a set of 12 patients treated laparoscopically for groin hernia (5). From the beginning, the laparoscopic approach was controversial; some authors described technical difficulties in treating what was considered rather simple with the open technique. Moreover, the costs of this operation, the long learning curve entailed and the need for skilled surgeons have prevented the laparo-endoscopic approach from becoming widespread (6). However, after initial suspiciousness towards the approach, many authors reported good results in the use of laparoscopic surgery for groin hernia. Furthermore, the reduction of chronic pain, the early postoperative return to daily activities, and the evolution of

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different kinds of meshes and fixation systems have enabled the widespread of the laparo-endoscopic treatment of groin hernia. At present, some hospital centers have reported that the laparoscopic approach is the treatment of choice in treating groin hernia (7). The World Guidelines for Groin Inguinal Hernia of the Hernia Surge Group strongly recommend the laparo-endoscopic treatment for recurrent bilateral groin hernias in general, and also for unilateral hernias upon condition that the surgeon is highly experienced in such operations (8). Also, the EAES Consensus Development Conference on endoscopic repair of groin hernias recommended (2013) the endoscopic treatment for unilateral or bilateral and for primary or recurrent hernias (9). Many kinds of invasive and non-invasive methods of fixation have been described and illustrated in literature to reduce post-operative pain and prevent recurrence. The aim of this paper is to analyze, retrospectively, short and long-term outcomes of fibrin glue (Evicel®) used in laparoscopic transabdominal hernioplasty (TAPP) in a prospective database to prevent hematoma or bleeding and facilitate adhesion of the mesh.

Patients and methods

This is a retrospective study about our prospective database conducted by a division of General and Emergency Surgery of San Valentino Hospital, Montebelluna. Three out of 187 patients were excluded from the study given that the meshes were fixed with tacks: in two cases the hernia was bi-recurrent, and in the other case the glue dispenser in the course of the operation was malfunctioning. Consequently 184 patients, from 1 January 2015 to 31 December 2016, underwent laparoscopic groin hernia repair with the TAPP technique using Evicel® and were thereafter included in a prospective database; a clinical follow up was performed at 1 week, 6 months and 1 year after the operation. Then the patients were reached by phone at 24-36 months and invited to come to the hospital if clinical suspicious. The follow-up was performed by two surgeons involved in the operations. Dynamic ultrasound and CT scan were performed only when there was a doubt about a diagnosis of recurrence or to detect a possible complication. Our exclusion criteria to perform a TAPP were: ASA ≥ 4 , pregnancy, previous prostatectomy, incarcerated hernia, patients younger than 18 years of age, and closed angle glau-

coma. All the procedures using the same standardized technique described by Bittner were performed by the same four surgeons experienced in laparoscopic hernioplasty (7). Antithrombotic prophylaxis was performed using the Caprini score and antibiotic prophylaxis was performed in all patients with a single dose of cephalosporin (10). All operations were carried out under general anesthesia. The standard size of the mesh was 15x12cm. The urinary catheter and nasogastric tube were inserted routinely and were removed before extubation. Post-operative chronic pain was evaluated by the Visual Analogue Score (VAS) and chronic pain was defined VAS >3 lasting longer than 3 months. The following were evaluated: operative time, hospital stay, early complications (bleeding, visceral injuries, infection, seroma or hematoma) and late complications (recurrence rate, chronic pain and trocar site hernia).

Results

After a median follow-up of 18 months (range 3-32) the short- and long-term outcomes of the 184 patients treated with TAPP were evaluated. Between 1 January 2015 and 31 December 2016, 326 TAPPs were performed in a single center. Median age was 57.5 (range 19-84) and median BMI (body mass index) was 28.5 (range 18.5-31.5); 166 patients were male and 18 female. Seventy-seven patients (41%) had undergone previous abdominal surgery, laparotomy in 68 cases and laparoscopy in 9. There were 142 patients (77%) with bilateral groin hernia and 42 (23%) with monolateral. One-hundred-and-sixteen hernias were on the left side and 168 were on the right. The characteristics of the hernias are summarized in Table 1. Two-hundred-and-seventy-six hernias (84.5%) were treated with an ULTRAPRO® partially-absorbable lightweight mesh and 50 (15.5%) with a polypropylene mesh. Three-hundred-and-

TABLE 1 - TYPE OF HERNIA.

Type of hernia	N°	Percentage %
Direct	170	52
Indirect	140	43
Femoral	12	3.5
Inguino-scrotal	4	1
Recurrence	77	23.5

twenty-two meshes were fixed with 5ml of fibrin sealant Evicel®. The mean operative time was 107 min. (range 30-260 min.). In 53 cases (29.5%) two different types of operations were being carried out at the same time; these are summarized in Table 2. Sixty-one (34%) patients reported ASA score 1, 111 patients (61%) reported ASA score 2 and 9 (5%) patients reported ASA score 3. No TAPP technique was converted to traditional open anterior. Three intra-operative complications (1%) were reported. Complications entailed a lesion of epigastric vessels and all cases were treated with intra-operative ligation of the vessels by clips. The mean length of post-operative stay was 1.1 days (1-11). No mortality was reported. Post-operative complications are summarized in Table 3. Follow up rate was 100% at 12 months and 98% at 24 months. During the long follow-up, five recurrences (1.5%) at 18 months (range 12-24 months) after the operation and two missed lipomas were observed and treated with traditional anterior repair. Post-operative pain was reported in 11 patients (6%), however it subsided naturally in 9 cases after one month from the intervention. Two patients reported chronic pain and were treated with medical pain therapy and at present are still in treatment.

TABLE 2 - ASSOCIATED SURGERY.

Type of surgery	N° of cases	Percentage (%)
Adhesiolysis	34	10.5
Cholecystectomy	3	1
Umbilical herniorrhaphy	46	14
Ligation of spermatic vessels	2	0.5

TABLE 3 - COMPLICATIONS.

Type of complication	N°	Percentage (%)
Seroma	7	2
Hematoma of the cord	21	6.5
Infection	-	-
Urinary retention	6	1.8
Pulmonary infection	-	-

Discussion

Recurrence rate is one of most important endpoints in the treatment of groin hernia and one of

the first questions asked by patients. In fact, since the introduction of prosthetic meshes for the treatment of groin hernia, the incidence of recurrence has decreased progressively for open and laparoscopic surgery (11). Many authors and Cochrane Reviews have shown recurrence rates from 0 to 5% without difference between laparoscopic and open hernioplasty (12-14). It is clear that a long follow-up is extremely important to detect recurrence although recently Bouras et al. have shown that recurrence time was shorter for laparoscopic repair compared to open technique (15). We are aware that there are many technical factors that affect the results and durability of laparoscopic inguinal hernia repair. As early as 1997, Stoppa et al. described the mechanisms of recurrence after groin hernioplasty; also many other authors have published articles analyzing recurrence after TAPP (16, 17). Surgeon experience is certainly a major factor in reducing recurrence of laparoscopic hernioplasty as shown by Felix in a multicenter study, however the skills of the surgeon are not the only crucial factor in accomplishing this target (17). We could sort out causes of recurrence into three groups: causes related to the patient (malnutrition, obesity, steroids, type II diabetes, chronic lung disease, collagen status, smoking, family history, etc.); causes related to the experience of the surgeon (possible complications); and causes related to the mesh (type, size, fixation) (18, 19). Hematoma is considered a minor complication after TAPP by the surgeon, but in some cases it could be related to major complications such as infection and, mainly, dislocation of the mesh. Evicel® is a human fibrin sealant and helps coagulation; this feature is important because, in our experience, it reduces bleeding and the formation of hematoma. Indeed, our findings do not show the presence of symptomatic hematoma. Three recurrences occurred in this study because the mesh was not large enough to cover the entire defect of the hernia; other two incidents were improperly labelled as recurrent as triggered by the missed lipoma of the spermatic cord, and in any case the patients were reoperated. The incidence of lipoma is generally 20% and is related to the body mass index. Missed and, as a result, not treated lipoma is a possible complication of TAPP. In this case, if a peritoneal defect is not detected, but upon inspection herniation is present, the presence of a lipoma must be suspected (20). We believe that the surgeon's experience in

the laparoscopic treatment of groin hernia is important to prevent this type of complication that in fact is not so uncommon (20, 21). The exploration of the pre-peritoneal space and cord structure is equally important to reduce the risk of missed lipoma, but in any case this manoeuvre can cause the bleeding of spermatic vessels and the formation of hematoma and subsequently the possible dislocation of the mesh (20-22). It is fundamental to prevent this type of bleeding and there are very good grounds to believe that Evicel® is extremely helpful. The second problem after operations for a groin hernia is post-operative pain. Many authors described different kinds of fixation of the mesh; however, in 2013 international Consensus Conference made it clear that, except for large direct hernia, it is crucial to avoid using tack or suture fixations (9). An interesting meta-analysis and systematic review carried out by Kaul et al. observed that the use of fibrin glue versus tack fixation obtained similar recurrence's rate while, on other hand chronic pain would be inferior in the group with fibrin glue fixation (23). Laparoscopic inguinal hernioplasty chronic pain is an unresolved problem and at present it is one of the main factor in determining quality of life for patients and the early return to their daily activities. Many authors have shown that this complication is a result of two kinds of mistakes: the entrapment of a nerve or a damage with tacks and therefore the inflammation of the pubis with osteitis (24, 25). Poobalan has described three kinds of chronic pain (CP) syndrome: neuropathic, visceral and somatic but there are few data about a natural course of CP (25). The incidence of CP is 1-2% in patients treated laparoscopically and is less compared to open repair; studies by De Jonge et al. concluded that quality of life is better in groups of patients treated with the laparoscopic approach (26, 27). At present, many studies have focused their attention on quality of life and male fertility after inguinal hernia repair. Young age, pre-operative pain and pain one week after the operation were considered independent factors of CP in the case of inguinal hernia repair (26). Several studies reported that mesh non-fixation is a safe solution for Total Extra Peritoneal (TEP) laparoscopic procedure, but, at the same time, general medical literature does not yet agree in which case fixation and non-fixation is the safer solution for patient treated with TAPP (27, 28). The combination of the mesh and kind of fixation

is not the only factor for success, however it is crucial to obtain a low rate of chronic pain; at present, for non-invasive fixation of the inguinal hernia repair we can use synthetic, semi-synthetic and fibrin glue. Moreover, in the fibrin glue the strength of the fixation is related to the concentration of thrombin (29). Kockerling et al. shown significant differences in the combination of different kinds of meshes and fibrin glue and they achieved good results in the combination to ULTRAPRO® with Evicel® (30). Our results show that incidence of CP is similar to data found in literature and we believe that this result depends on the experience of the surgeons and the use of the fibrin sealant. Quality of life with low rate of chronic pain resulted being two very important features in order to consider this operation successful. However, another item to consider is related to intra- and post-operative complications. It must be pointed out that groin hernia operations can be performed via anterior approach with a very low rate of intraoperative and post-operative major complications, according to the Clavien-Dindo score (31). Our series recorded three intra-operative bleeding of epigastric vessels treated with intra-operative ligation by clip, but no conversion to the anterior approach; procedure time and hospitalization stay were consistent with normal standards. Our series recorded that the association with other kinds of simultaneous surgical procedures did not increase the incidence of complications, in fact affecting only the length of the operation. In this study, the recurrence and chronic pain rates are than in literature, and this is particularly important considering that a new combination of meshes and fibrin glue was used. We believe that the combination of the features of the lightweight mesh ULTRAPRO® and the fibrin sealant Evicel® in the treatment of laparoscopic groin hernia is a good solution, but it is also clear that future randomized trials are necessary.

Conflict of interest statement

Sartori Alberto, De Luca Maurizio, Clemente Nicola, De Luca Alberto, Scaffidi Guido, Elena Vendramin, Claudio Campagnaro have no conflict of interest to disclose.

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Availability of data and materials

The data supporting the conclusions of this article are included within the article. Data are available from the corresponding author upon reasonable request.

Authors' contributions

Sartori was the lead Author and conceived this study. De Luca M. contributed to data analysis and the writing of the article. All authors reviewed the

paper. All authors approved the final version of the manuscript.

Competing interests

The authors declare that they have no competing interests.

Consent for publication

This retrospective study was approved by the Ethical Board of Treviso and was conducted in accordance with the Declaration of Helsinki. Informed consent was obtained from all individuals included in the study.

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