Influence of operative technique on recurrence rate in Lichtenstein hernioplasty using partially absorbable lightweight mesh

Polish Hernia Study Group

Videosurgery and other miniinvasive techniques 2009; 4 (1): 10–15

Abstract

Introduction: *This randomized study evaluates whether modified implantation technique using partially absorbable monofilament mesh increases the recurrence rate in Lichtenstein hernioplasty.*

Material and methods: *Patients were operated on in 15 centres, blindly randomized into two groups – Ultrapro (UP) and heavyweight polypropylene (PP) mesh. A modified suture technique was used in the Ultrapro group. Follow-up was scheduled for 3, 6, and 12 months. The objective was to assess the incidence of early recurrence rate.*

Results: *Six hundred patients were randomized and, after monitoring visits (leading to the exclusion of 7 hospitals), 392 of them were qualified for the assessment. At 12 months, the recurrence rate did not differ. Four recurrences were observed in the UP group and one in the PP group ($p = 0.493$).*

Conclusions: *The use of partially absorbable light mesh in modified Lichtenstein hernioplasty did not increase the recurrence rate in short-term observation (12 months).*

Key words: *Lichtenstein hernioplasty, lightweight mesh, Ultrapro, operative technique, recurrence, pain.*

Introduction

A unified theory of hernia formation based on experimental and clinical studies on aetiology was published by Bendavid in 2005. According to a concept of congenital metabolic anomalies in connective tissue, hernia seems to be a manifestation of systemic collagen disease [1]. Understanding the mechanisms of hernia formation also has clinical implications. Tension methods widely applied in the 20th century seem insufficient, as they employed deficient host tissue to reinforce the posterior wall of the inguinal canal. Amid has stated that, as he understands this theory, not to use the mesh in hernioplasty is against basic rules of surgery [2]. The theoretical superiority of mesh hernioplasty was confirmed in a meta-analysis of the EU Hernia Trialists Collaboration conducted during 1999-2002 [3]. In the last decades of the 20th century many tension-free methods were described and numerous synthetic implants were introduced to the market, yet Lichtenstein hernioplasty is accepted as a "gold standard" and is most frequently employed and assessed in clinical trials. Recently this method has also been recommended in national standards in the UK, the Netherlands, USA and Poland [4-7]. Mechanical characteristics and inflammatory reaction caused by implants applied in hernia repair are extensively discussed in the literature. Targeted to decrease acute and chronic postoperative pain in the groin, minimization of mesh weight has led to the invention of lightweight and composite meshes. In some clinical studies however, increased recurrence rate up to 5% was noted [8, 9]. The authors concluded that this

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group of meshes, due to their mechanical values, may call for a different implantation technique [9]. This paper gives a detailed description of a modified Lichtenstein technique for composite mesh implantation and addresses its influence on recurrence rate.

Material and methods

Between 2002 and 2004, six hundred patients were evaluated and randomized in the trial. Patients 20-75 years old, diagnosed with primary inguinal hernia were eligible to participate in the study. Patients were recruited and operated on in 15 hospitals in Poland (12 regional and 3 university-based). All patients gave their informed consent. The study was approved by the Ethical Committee of the Medical University of Gdansk for all the participating centres, in accordance with Polish legal regulations. Patients were followed for two years on six in- and outpatient visits (hospital stay, 7 days, 3 and 6 months, one and two years). Hernia characteristics and timing of its occurrence were assessed before surgery. All visits were conducted in a hospital-based setting. Post-operative physical examination was done by a blinded surgeon who was not involved in the surgery. Recurrence was a primary endpoint of the study and was diagnosed on physical examination performed by a surgeon blinded to the type of mesh used. Presence of recurrence was assessed on every visit scheduled in the study flow chart. Additionally, during the hospital stay and until 3 months later, data on perioperative complications (haematoma, seroma, nerve damage), urinary retention, need for urinary catheter placement and wound infection rate were collected. Three months after the randomization had ended, audit visits in all centres were conducted by the supervising committee members. Data were double checked: case report files vs. hospital documentation and vs. random patient's personal reports (visits or telephone interview). In cases of a serious violation of study protocol, e.g. uncompleted CRFs (for reasons other than loss from follow-up) or where incompatibility of the data exceeded 1% (identification of patients not possible, patient does not confirm control visits, lost or lacking original hospital documentation, loss of patient's entire documentation or doubts about the blinding and/or randomization process) the centre was excluded from the trial. In those cases, all of the CRFs from a given hospital were not taken into consideration and were excluded from statistical analysis. Disapproval of the whole centre's documentation was chosen to avoid bias in the trial and in statistical analysis. After audit visits, seven hospitals (208 patients) were excluded from the study.

Operative technique

An operative technique based on the description by Amid was applied [2]. Briefly, the hernia sac was explored and invaginated into the abdominal cavity without opening. Only large scrotal hernia or incarceration with suspicion of ischaemic bowel required opening, ligation and dissection of the hernia sac. All three nerves in the inguinal canal were identified and thoroughly preserved, and the cremaster muscle was not resected. In the control group, a heavyweight polypropylene mesh was implanted (PROLENE, Ethicon GMbH, Hamburg, Germany). In the study group, a lightweight partially absorbable mesh of 7.5 × 15 cm composed from poliglecaprone and polypropylene (Ultrapro®, Ethicon GMbH, Hamburg, Germany) was used for the repair. Due to the absorption of poliglecaprone, the mesh weight decreases by about 50% in 3 months. We noticed that after shaping the mesh, the pores on the margins seemed to be closed (Figure 1). Suturing and extension can unravel such pores and rip the suture. These findings, and characteristic mesh elasticity, led us to

Figure 1. Open pores on the margin after shaping of the mesh

implement three suturing modifications to the basic Lichtenstein technique. A larger suture margin (minimum four pores of mesh) and about half the distance between 'steps' (maximum 1 cm) were used for running sutures on the inguinal ligament. An extra suture was placed to fix the mesh bone between the pubic tubercle and the middle line to prevent mesh overlap from protruding above the pubic bone.

Statistical analysis

Statistical calculations were performed using Statistica 7.1 PL (Polish version) software (StatSoft, Inc, Tulsa, USA). Descriptive statistics were used for characterization of patient groups; mean (standard deviation) or median values (range of values) were given, depending on the type of data and their normal distribution on the interval scale. Normal distribution was verified with the Shapiro-Wilk W test. The data were compared using Student's *t*-test or the Mann Whitney U test as appropriate. Repeated measurements were analyzed using a two-way ANOVA test for repeated measurements, with following analysis of significant differences using the *post-hoc* method (Tukey's HSD test) when appropriate. Categorical data are presented as percentage values and 95% confidence intervals and compared using a χ^2 test, with Yates correction when necessary. The significance level of $p < 0.05$ was adopted.

Results

After the internal audit, of all randomized patients 215 in the Ultrapro (UP) group and 177 in the polypropylene (PP) group were included in the trial database. Randomization data for both groups are presented in Table I. No statistical differences between the groups were seen. Of these patients, 3, 6, 12 and 24-month follow-ups were reached by 100%, 98.02% (4 patients lost), 97.8% (12 patients lost) and 97.8% respectively. The incidence of recurrence was slightly higher in the UP group (1.86%) than in the PP group (0.56%), but statistical significance was not achieved ($p = 0.493$). All recurrences occurred solely in male patients. Analysis of recurrence location showed no correlation of hernia type and site of recurrence. In 3 patients recurrence happened after direct hernia repair (Rutkow type 4) and in 2 after indirect one (Rutkow type 2). In all recurrent cases no local complications or other factors which might have promoted recurrence (concomitant diseases) were present. In most patients, recurrence was found between the pubic bone at the mesh margin. Intraoperatively too small margin of the mesh on the pubic bone (2 cases) or mesh lifted from the bone (2 cases) were found. In one case from the UP group, recurrence occurred at the site of the deep inguinal ring through insufficient mesh closure. A detailed description of patients with recurrence is summarized in Table II.

Discussion

The introduction of tension-free methods in recent decades has revolutionized inguinal hernia repair so profoundly that new evaluation methods were needed to properly assess the results of the treatment. Traditionally in tension methods, due to long

Table I. Baseline patient data (% values and CI)

	Ultra pro *n* = 215	PP *n* = 177	*P* value
Age [years]	56 (18-80)	55.5 (23-87)	0.637
Weight [kg]	77.7 ± 9.7	78.4 ± 10.8	0.513
Height [cm]	175 (160-195)	174 (158-190)	0.402
Type of hernia (Rutkow classification): • 1 (indirect – normal deep inguinal ring) • 2 (indirect – dilated ring < 4 cm) • 3 (indirect – ring > 4 cm) • 4 (direct – large defect of the canal floor) • 5 (direct – small medial orifice) • 6 (combined direct and indirect)	 18% 36% 12% 29.5% 7% 7.5%	 8.5% 37% 12.5% 29% 5% 8%	 0.580
Time from hernia occurrence to operation [days]	12 (0.5-300)	12 (0.5-480)	0.850

Table II. Description of recurrence in the follow-up period

Sex	Age [years]	ASA	Height [cm]	Weight [kg]	Perioperative complications	Hernia type (Rutkow)	Time of recurrence [month]	Recurrence site	Mesh
M	28	2	172	74	no	2	6-12	Pubic bone	UP
M	46	2	176	85	no	6 (2 and 4)	6-12	Pubic bone	UP
M	73	2	166	64	no	4	6-12	Pubic bone	UP
M	71	2	160	60	no	2	6-12	Deep inguinal ring	UP
M	43	2	180	94	no	4	6-12	Pubic bone	PP

convalescence and difficult operative technique, recurrence rate was the usual primary endpoint of treatment and was seen in more than 10% of patients [10]. Introduction of the synthetic mesh decreased the recurrence rate to 1-3% [3]. Yet, some observations published in recent years demonstrated that implanted mesh causes a chronic inflammatory reaction [11]. Additionally, dense heavyweight polypropylene mesh creates a firm scar, a non-elastic structure surrounded by connective tissue, shrinking in the late postoperative period [12]. To solve this problem, large-pore lightweight meshes were introduced to clinical practice. Experimental studies confirmed decreased inflammatory reaction and showed the spatial character of the scar. A soft scar should theoretically decrease the foreign body sensation and pain in the groin. Less mesh shrinkage should also prevent recurrence [12]. Lately, clinical trials were conducted to confirm the theoretical advantage of lightweight implants in inguinal hernioplasty. Some investigators in prospective randomized studies comparing lightweight with heavyweight mesh have observed decreased pain. However, another two studies could not confirm this observation [6, 7, 12]. Moreover, potentially increased risk of recurrence (over 5%) was noted for partially absorbable mesh (Vypro II) in one study [6]. These results clearly do not match many other cohort studies of heavyweight mesh in the Lichtenstein technique, which constantly reported recurrence rate of less than 1% even in 5-year follow-up [3, 13-15]. The authors of the study suspected that lightweight mesh elasticity might affect recurrence and recommended a modification of the implantation technique [9]. In our study, we applied additional sutures to avoid recurrence, but still this modification does not affect the classical Lichtenstein repair procedure and does not change its principles. Additional sutures were not applied in the proximity of the nerves; thus they should not influence post-operative pain either. Elasticity of the mesh requires additional fixation

Table III. Principles of lightweight mesh implantation in Lichtenstein method

1) Mesh size min 7 × 14 cm.
2) Mesh margin on the inguinal ligament of about 1 cm (min 3 mesh pores between margin and suture site) – nonabsorbable suture 2-0.
3) Shorter distance between steps (maximum 1 cm) was used for running sutures on the inguinal ligament.
4) Avoidance of mesh overlap upward protrusion from the bone with one additional suture placed to fix the mesh near the pubic bone between the pubic tubercle and the middle line.
5) Crossing the tails of the mesh behind the spermatic cord and suturing them without any spare space left between the tails.
6) Upper tail of the mesh should be fixed to the inguinal ligament close to the end of the running suture of lower mesh margin with non-absorbable suture (2-0).
7) Dome-shape relaxation is not needed in lightweight mesh due to its superior elasticity – mesh should be implanted flat.

on the pubic tubercle and allows flat implantation (without dome-shaped relaxation). Suture margin on the inguinal ligament was a consequence of mesh properties noticed while cutting the mesh edges (unravelled pores). In this modified suturing technique, mesh will be folded on the margin but in our opinion large pores and flexibility of the material should prevent "dead space" formation. During two years' follow-up we did not observe any late infections or purulent fistulas in the UP group, which seems to confirm this hypothesis.

In the presented study the recurrence rate was higher in the Ultrapro group, although a statistical difference was not achieved. This supports our hypothesis that the modification we applied prevents early recurrence biased by the operative technique. The recurrences seen in the study occurred in the area of the pubic tubercle, which corresponds with the results noted by other authors [16]. Whether recurrence is caused by deficiency of surgical technique (too small mesh margin) or by material properties is a question that definitely calls for consideration. Further observation, planed for 5 years, will answer the question of influence of the material on late recurrence rate. So far, introduced modification of the operative technique did not increase the recurrence rate and the results are comparable with other published cohorts. The described modification was also used to create the guidelines (Table III) for centres involved in the trial and is now used routinely, which should enable it to be assessed in large clinical material in the near future.

Acknowledgments

The authors thank Andrzej Floriańczyk for support of the study idea. The study was supported by a minor grant by Ethicon Poland to cover the costs of workshops and trialists' meetings. Neither physicians nor patients were reimbursed. None of the authors has any direct or indirect financial interest in the product.

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