Polypropylene vs. ePTFE vs. WN mesh for Lichtenstein inguinal hernia repair – a prospective, randomized, double blind pilot study of one-year follow-up

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Abstract

Introduction: *Type of mesh may influence postoperative discomfort after Lichtenstein hernia repair.*
Material and methods: *A total of 75 patients were allocated randomly and blindly into three groups to receive polypropylene (PP), ePTFE or WN mesh. Collected data included: procedure time, pain scores, analgesic medication, time of hospitalization and return to physical activity, complications, quality of life as measured by SF-36 on days 1, 7 and 90.*
Results: *Pain on days 1 and 7 was higher in the PP group ($p < 5 \times 10^{-5}$) and not differ between the ePTFE and WN groups. Incidence of persistent pain was higher in the PP group ($p < 0.002$); there was no chronic pain in the WN group. SF-36 physical scores confirmed those observations. No recurrences were observed in any groups. One late infection of the mesh needing mesh removal was observed in the ePTFE group. No other differences were observed.*
Conclusions: *The study indicates less postoperative pain and lower chronic pain rate with the ePTFE and WN mesh compared with polypropylene.*

Key words: *inguinal hernia, Lichtenstein technique, lightweight mesh, composite mesh, ePTFE, recurrence.*

Introduction

In the last century assessment of post-herniorrhaphy outcome was focused on recurrence. The introduction of synthetic mesh to hernia surgery reduced the recurrence rate to less than 3-5%, and in some centres even less than 1% [1]. Currently attention is focused on chronic postoperative pain, observed in 15 to 30% of patients after hernioplasty, and convalescence time [2-4]. Recent prospective and population-based studies have indicated that up to 6% of patients have moderate to severe pain lasting longer than 3 month [5]. Also, many patients report a feeling of stiffness and foreign body after implantation of the mesh. The studies of EU Hernia Trialists Collaboration and other trials did not find any differences in chronic pain rate between various methods using polypropylene mesh (Lichtenstein, mesh-plug, Trabucco etc.) [6]. The present study examined whether the theoretical advantage of other kinds of implanted synthetic material decreased the rate of pain directly after, 3 months after, and one year after the operation. The study was designed for a small group to document the point of any further

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Table I. Patients' baseline data

	Age	BMI > 35	Sex	Employment status			ASA
				Labour	Sedentary	Retired	
Surgimesh WN	59	4	25 M	9	5	11	16-I 9-II
Micromesh Gore	56.12	6	25 M	11	7	7	14-I 10-II 1-III
Polypropylene	53.88	5	21 M 4 F	12	6	7	17-I 8-II

M – men, F – female

studies looking for new materials to replace polypropylene in hernia surgery.

Material and methods

A total of 75 patients were involved in the study. All of them underwent Lichtenstein primary inguinal hernia repair using Lichtenstein technique, according to a standard described by Amid [7]. Standardized local anaesthesia procedure using 3 nerve block was used in the study [8]. Patients were over 18 years of age and had given informed consent for participation. Exclusion criteria were femoral hernia, emergency operation (strangulation) and skin infection in the groin. Summarized baseline data are presented in Table I.

No differences in demographic characteristics or medical history were present between treated groups. The type and size of hernia were essentially the same for each group (Table II).

Randomization was performed during the operation after the preparation of the hernia sac, just before the mesh implantation. The patient and the postoperative examiner were blinded to the kind of mesh. In the control group (PP) standard woven, heavy weight (80 g/m^2) polypropylene mesh was used (Surgipro®, Auto Suture).

In the two examined groups other materials were used: in group I (PTFE) polytetrafluoroethylene mesh (Mycromesh, W.L. Gore & Associates Inc.) and in group II (WN) a reinforcement patch, not knitted, not woven, made from polypropylene consolidated by heat sealing, low weight – 43 g/m^2 (Surgimesh® WN, Aspide Medical).

A standard case report form (CRF), described in the Polish Standard for Groin Hernia Repair, was used [9].

Table II. Types of hernia in the treated groups (numbers of patients)

Type of hernia according to Nyhus classification	total patients (patients in PP, ePTFE and WN group)
1	20 (7, 8, 5)
2	21 (7, 6, 8)
3a	23 (9, 7, 7)
3b	5 (1, 2, 3)
4a	3 (0, 1, 1)

The primary outcome measure was the chronic pain rate, the time of return to normal physical activity and quality of life (standard multidimensional questionnaire SF-36 adapted and validated in Polish language). Chronic pain was defined as pain of any kind at the site of the operation lasting longer than 3 months. Secondary outcome measures were recurrences, infection rate, seroma or haematoma formation. The follow-up examinations were performed 7 days, 3 months and one year after the surgery.

Standard *t* test and χ^2 test were used to assess the continuous and Mann-Whitney test for categorical data. Statistica 6.0 (Polish version, StatSoft Inc, Tulsa, USA) was used for statistical calculations. The minimum group size of 22 was calculated to achieve a study power of 90% with type I error rate (α) as 0.05. This calculation was based on the mean value (standard deviation) of bodily pain of the SF-36. In the group after mesh repair (own Polish data) the value of BP reached 40 ± 10. A 25% increase of the BP value was assessed to be clinically important.

Results

All of the patients completed the 3-month, and 96% one-year follow-up period. The mean pain score (VAS) measured on the 7th postoperative day was 4.36 in the PP group, 1.09 in the PTFE group and 1.2 in the WN group, and differed statistically between the PP and PTFE groups (p = 0.0001) and between the PP and WN groups (p = 0.00008). All the patients suffering from pain at that time were taking analgesics (metamizole sodium was administered *p.o.* in doses of 500 mg (max. 4 doses/day) on patients' requirement). After 3 months pain was present in 4 patients in the PP group (14%), 2 in the PTFE group (7%) and 1 patient in the WN group. Mean time of return to normal physical activity was 8.5 (PP), 8.5 (PTFE) and 7.5 (WN) days and did not statistically differ between groups (Table III).

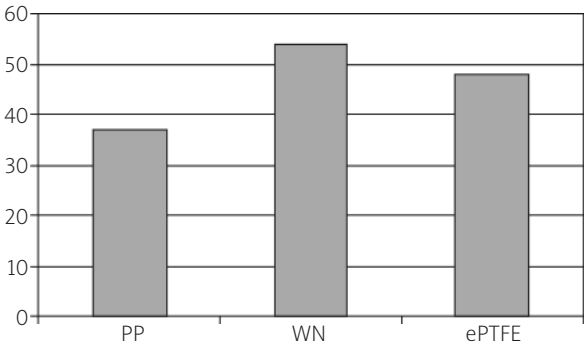

Figure 1. Bodily pain score of the SF-36 questionnaire after 1 year

The majority of SF-36 scores did not differ between groups. Some mentioned differences were in accordance with the baseline data. Only the level of physical (p = 0.035) and bodily pain on the 7th day was statistically lower in treated groups (Figure 1). This difference was not present after 3 months or one year.

No early superficial infections were observed, but in some cases due to the redness and local swelling of the wound removal of stitches was postponed until the 10th postoperative day (one in PP group, 4 in PTFE group). One mesh had to be removed due to deep infection of the ePTFE mesh. The patient was suffering from chronic pain (VAS 4 after 3 months). After 5 months at the time of the reparation a small (2 × 3 × 0.5 cm) abscess on the mesh site was found (not present in USG).

Recurrences after one year were not noted in any group. No other major complications were observed.

Discussion

Groin hernia surgery is one of the most frequently performed operations, and the Lichtenstein technique remains a gold standard because of good and repeatable results [10, 11]. This study shows that the use of thin polypropylene or ePTFE mesh can result in a similar or better recovery after hernioplasty. The concept of using other materials for groin hernia surgery to decrease chronic pain rate is quite new, and there are only a few trials on this topic [12, 13].

Table III. One-year follow-up results (PW – statistical difference between polypropylene and WN mesh, PG – statistical difference between polypropylene and ePTFE mesh)

		Polypropylene	ePTFE	WN	P if < 0.05
Time of hospital stay [hours] (mean, SD)		57.7 ± 19.3	48 ± 5.2	46.2 ± 10.5	PW = 0.003
Time to return to normal activity [days] (mean, SD)		8.5 ± 3.28	8.5 ± 2.6	7.5 ± 1.5	PG = 0.02
Recurrence (no. of patients)		0	0	0	
Redness of the wound (no. of patients)		1	4	0	
Infection (mesh removed)		0	1 (yes)	0	
VAS after 7 days [median (range)]		5 (0-9)	0 (0-6)	0 (0-5)	PW = 0.0001 PG = 0.00008
VAS after 3 month (no. of patients)	1-2	4	1	1	
	3-5	0	1	0	
	> 5	0	0	0	
VAS after 1 year (no. of patients)	1-2	1	2	0	
	> 2	0	0	0	

Implantation of lightweight composite meshes results in less postoperative pain, but a higher percentage of recurrence was also reported by Post and Weiss. Comparable results were achieved in this study with no increased recurrence rate for WN and ePTFE mesh. The low pain on the 7th day correlated with SF 36 scores in bodily pain. The number of patients with persistent pain after 3 months was lower in the PTFE and WN groups, which can possibly influence the epidemiology of those complications in a large study. In the population it can also reduce the time of rehabilitation and sick leave needed after hernioplasty. This confirms the findings of other clinical trials [12, 13]. On the other hand the cost of the examined material must be taken into account. However, this cost is not higher than that of the polypropylene pre-shaped devices (mesh-plug, PHS); the price of flat polypropylene mesh is still 3 to 4 times lower.

In the presented study we did not use antibiotic prophylaxis, because there were no clinical studies showing its advantages at the beginning of our study. The rate of infection was in accordance with other results, but the recently published trials revealed a need of such prophylaxis [14]. The value of such prophylaxis must also be taken into account due to the deep prosthetic infection that occurred in the ePTFE group. In light of the results the authors would recommend antibiotic prophylaxis in the case of implantation of ePTFE mesh. The redness and local swelling of the wound found in some cases (especially in the ePTFE group) did not influence patients' opinion about the procedure.

Conclusions

It is not easy to assess the potential social benefit of earlier rehabilitation in the postoperative period in a small study, but the theoretical advantage of another kind of implanted synthetic material can improve the quality of hernia repair in the coming years.

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