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Original research

Standard polypropylene mesh vs lightweight mesh for Lichtenstein repair of primary inguinal hernia: A randomized controlled trial

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HIGHLIGHTS

- During Lichtenstein with polypropylene mesh, the worst characteristics can be chronic pain.
- In order to prevent such kind of difficulties, the usage of lightweight mesh is recommended.
- The usage of the LW mesh was associated with less feeling of foreign body than that of the HW mesh.
- Thepoint listed above can be considered as an advantage of LW mesh rather than HW mesh.

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ABSTRACT

Purpose: The aim of the present clinical study was to compare early and late outcomes after inguinal hernia repair with the heavyweight mesh (HW) and lightweight mesh (LW) during a 3 year follow-up period. **Methods**: 226 patients were randomized into LW and HW mesh groups, both of which underwent unilateral primary inguinal hernia repair via the Lichtenstein technique. Wound complications (infection, hematoma, seroma), hernia recurrence, pain and feeling of foreign body in inguinal area were determined in patients. Pain was measured by visual analogue scale. **Results**: No statistical difference has been found between LW and HW groups by wound complication ($P = 0.80$). One case of hernia recurrence has been mentioned in both groups one year after hernioplasty. But there was no detectable difference between the two groups. No significant difference has been found between LW and HW groups by frequency of chronic pain 7 days, 1 and 3 months, 1, 2, and 3 years after surgery. As for the feeling of foreign body in groin it is similar in both groups after 1 and 3 months. Level of feeling of foreign body was significantly lower in LW group 1, 2, and 3 years after surgery, than in HW group ($P = 0.03$, $P = 0.02$, $P = 0.02$, respectively). **Conclusion**: Our research shows no significant difference in wound complications, hernia recurrence and chronic pain after Lichtenstein hernioplasty, by using of LW and HW meshes. The usage of the LW mesh was associated with less feeling of foreign body than that of the HW mesh, what can be considered as prevalence of LW mesh hernioplasty.

1. Introduction

Inguinal hernia repair is one of the most frequently performed operations in general surgery. Tension-free mesh repair currently is the gold standard in inguinal hernia surgery. Currently the Lichtenstein method is one of the most popular techniques [1]. Usage of prosthetic materials decreased the frequency of hernia recurrence, although the chronic pain and feeling of a foreign body in inguinal area after surgery is still considerable problem – it worsens the level of patients' quality of life [2–4].

The incidence of chronic pain after inguinal hernioplasty varies from 9 to 52% and the feeling of a foreign body occurs in around 40% of patients [3,5,6]. The pain may be caused by damage to the inguinal nerves, but these complications may be due to the foreign body reaction against the mesh which results in an inflammatory response and scar tissue formation [5,7]. The reaction on foreign

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body is depend on the type and volume, as well as the size of pores and web-structure of synthetic prosthesis. Taking into consideration this fact, nowadays partially absorbable lightweight meshes (LW) are being used instead of heavyweight polypropylene meshes (HW). Low mass, decreased content of foreign body and large pores are characteristic for LW [8–10].

According to the current researches usage of LW meshes for inguinal hernioplasty decreases the frequency of chronic pain [11–13], at the same time several articles don't confirm the fact [14,15]. It's worth mentioning, that the risk of hernia recurrence might be increased in case of using LW meshes [16].

The aim of the present clinical study was to compare early and late outcomes after inguinal hernia repair via the Lichtenstein technique with the heavyweight mesh (HW) and lightweight mesh (LW) during a 3 year follow-up period.

2. Methods

From January 2008 to April 2011 patients over 18 years of age who underwent elective surgery for unilateral primary inguinal hernia via the Lichtenstein technique were enrolled in the study. The patients were operated at the General Surgery Department of Kiphshidze Central University Hospital. The inclusion criteria were a unilateral primary inguinal hernia requiring operative treatment and patient's approval to participate in the study. The exclusion criteria were bilateral hernia, irreducible hernia, recurrent hernia, strangulated hernia, a patient's preference for either mesh type, or a patient's refusal to participate in the study. The basic principle for this study was one unit, one surgeon trained in the standard Lichtenstein technique and the use of LW and HW meshes. The patients were assigned to one of the two groups: the LW group or the HW group. The randomization (by simple random sampling) of patients to each of the two groups described above was done before the surgical intervention. The assignment of patients to the specific groups was performed by the clinical manager not involved in the surgical procedures. The study participants were blinded regarding the type of the mesh used in the surgical intervention. The Lichtenstein hernioplasty was performed according to the original description of the technique [17]. The nerves in inguinal canal were identified and preserved when possible. In the HW group, a monofilament polypropylene mesh with a weight of 82 g/m^2 and pore size 0.8 mm (Prolene, Ethicon, Somerville, New Jersey) was used. The LW mesh in this study was Ultrapro (Ultrapro, Ethicon, Somerville, New Jersey), a large pore composite mesh (polypropylene and poliglecaprone, Monocril) (weight = 28 g/m^2, pore size 3 mm). In both groups, 8 × 12 cm mesh was applied. Polypropylene 2/0 monofilament suture material was used for mesh implantation.

Several preoperative factors were studied, which included sex, age, body mass index, occupation, tobacco use, risk groups by American Society of Anesthesiologists (ASA) and comorbidities, and site of hernia. Patients with ASA groups 4 and 5 were excluded from the study.

Among the intraoperative factors, the following were evaluated: type of hernia, anesthesia method (local, general), and duration of the operation. Prophylactic antibiotics were not used in all patients. We were using it only in patients with concurrent disorders. In these instances, 1.5 g cefuroxime was used intravenously 30 min before the operation.

Among the postoperative data, the following were studied: postoperative days at the ward (hospital stay), sick-leave days, and complications. The latter were divided into two groups: early and late complications. The early complications included wound infection, hematoma, and seroma. The late complications included chronic pain in the inguinal region, the feeling of a foreign body and hernia recurrence. Pain scores were measured on a Visual Analogue Scale (VAS), ranging from 0 (no pain) to 10 (worst imaginable pain).

After discharge from the hospital, all patients were examined after 1 week, 15 days, and 1 month at the outpatient department by the same surgeon who performed the operation. Also, these patients were examined 3 month, 1, 2, and 3 years after the operation date. The examinations were performed by surgeons who had not been participating previously in this study. They were paying attention to the pain in the inguinal region, to the feeling of a foreign body and the presence of hernia recurrence. The pain questionnaire included questions regarding pain at rest, on coughing, while climbing steps and during physical activity.

3. Statistical methods

Descriptive statistics methods were used to characterize each variable. Comparison of continuous variables was performed by independent samples *t*-test or the Mann–Whitney *U* test according to the normality of the variables. Categorical variables were evaluated by two-tailed Chi-square test or Fisher's exact test where appropriate. The threshold for statistical significance was set to $P < 0.05$. Statistical tests were performed by SPSS 16.00 (SPSS Inc., Chicago, IL).

4. Results

From January 2008 to April 2011, 328 patients underwent inguinal hernia repair via Lichtenstein technique. Among these patients, 226 were randomized in two groups equally (113 patients in each group). All of these patients underwent the allocated operations. Information about 28 patients was lost during the time observation: among them – 19 patients were not coming for examination, 7 patients were died during observation period (the causes of death were all non-hernia surgery related), in 2 patients developed recurrence of hernia. Subsequently 102 patients from HW group and 96 – from LW group were consecutively examined during 3 years after surgical operation. The data of this investigation is analyzed on this article (Fig. 1).

Both groups were similar by preoperative (sex, age, body mass index, tobacco use, American Society of Anesthesiologists risk groups, comorbidities, site of hernia, and occupation) and intraoperative (type of hernia, anesthesia, prophylactic antibiotics, and operation time) factors. No statistically significant differences were found between the groups by these factors (Table 1, Table 2).

Regarding the postoperative data, no statistical difference has been found ($P = 0.35$) between groups by postoperative time spent at the ward (hospital stay), and by sick-leave days ($P = 0.15$). In the LW group, 8 early complications (wound infection, hematoma, seroma) were observed (8.3%), in the HW group – 10 early complications (9.8%). The difference did not statistical significant ($P = 0.80$). One case of hernia recurrence was marked in each group after 1 year of surgery. But there was no detectable difference between the two groups (Table 3).

As for frequency of inguinal pain the difference was not statistically significant between LW and HW groups 7 days, 1 and 3 month and 1, 2 and 3 years after surgery. There was no detectable difference between the two groups according to average VAS scores too (Table 4).

The difference was not statistically detectable between LW and HW groups concerning the feeling of a foreign body 7 days, 1 and 3 months after operation. Statistical significant difference ($P = 0.03$) was found in the data of feeling of a foreign body 1 year after surgery: the symptom was mentioned in 6 (6.3%) patients in LW group and 17 (16.7%) patients in HW group. 2 years after surgery the same symptom was detected in 2 (2.1%) patients in LW group