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Randomized clinical study evaluating the impact of mesh pore size on chronic pain after Lichtenstein hernioplasty

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ABSTRACT

Background: The primary aim of this study was to determine whether mesh pore size influences the rate of chronic pain at 6-mo follow-up. Another aim was to evaluate the rate of foreign body feeling and quality of life after inguinal hernia repair.

Methods: The patients were randomized into two study groups: the UM group received Ultrapro mesh (pore size 3–4 mm) and the OM group received Optilene LP mesh (pore size 1 mm). Pain scores were measured on a visual analog scale. The feeling of a foreign body was a yes-or-no question. Quality of life was evaluated using the Medical Outcome Study Short-Form-36 questionnaire.

Results: A total of 67 patients in the UM group and 67 patients in the OM group were investigated 6 mo after operation. There were no significant differences in the results of the pain questionnaire between the study groups. Of the patients, 46.3% in the UM group reported pain during different activities at 6-mo follow-up *versus* 34.3% in the OM group ($P = 0.165$). The feeling of a foreign body in the inguinal region was experienced by 47.8% of the patients in the UM group and by 31.3% of the patients in the OM group at 6-mo follow-up ($P = 0.052$; risk ratio 1.52, 95% confidence interval: 1.00–2.37). There were no significant differences in the quality of life according to the Short-Form 36 questionnaire between the two study groups at 6-mo follow-up. In both study groups, the quality of life scores improved after operation by most dimensions.

Conclusions: Differences in mesh pore size did not influence the rate of chronic pain. Although there was a trend for higher rate of foreign body feeling in the study group where a mesh with larger pores was used, we failed to find an explanation for this. The pore size of meshes investigated in this study did not affect the quality of life after inguinal hernia repair. Considering the fact that the quality of life improved significantly after operation, elective repair of symptomatic inguinal hernias should be undertaken as promptly as possible.

1. Introduction

There has been considerable debate about which meshes should be used in hernia surgery. In several studies, the use of lightweight mesh in inguinal hernioplasty reduced the rate of chronic pain [1–3] and foreign body feeling [1,3]. However, according to some studies, lightweight mesh has no advantages in reducing either chronic groin pain at the operation

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site after inguinal hernia surgery [4–8] or the rate of foreign body feeling [7].

Weyhe *et al.* [9] reported in their experimental study that the main determinant of biocompatibility was the pore size of mesh rather than the amount implanted. In the case of small pores, a dense scar plate will develop around the entire mesh. Larger pores are filled with local fat tissue and a scar net will form, resulting in the proper elasticity of the implant [10]. Loss of elasticity can lead to increased rate of chronic pain and foreign body feeling. Similar results from a rat model were also reported by Klinge *et al.* [11]. According to their study, increased pore size had a major impact on the biological response. In the case of mesh with small pores, the extent of foreign body reaction does not permit the ingrowth of the local tissue. If a mesh with large pores is used then large pores will guarantee preserving of elasticity and will hamper the bridging of inflammation across the pores [11].

The primary aim of the present monocenter, single-blinded, randomized clinical study was to determine whether usage of mesh with larger pores, compared with mesh with smaller pores, would result in decreased rate of chronic pain at 6-mo follow-up. Another aim was to evaluate the rate of foreign body feeling and the patient's quality of life after inguinal hernia repair.

2. Material and methods

All patients, aged ≥18 y and undergoing an elective inguinal hernia repair at the Surgery Clinic of Tartu University Hospital, from January 2011 to April 2012, were eligible to participate in the study. The inclusion criteria were age ≥18 y, unilateral primary reducible inguinal hernia, elective operation, and consent for participation in the study. The exclusion criteria were age <18 y, irreducible, strangulated, or recurrent hernia, inability to understand the questionnaire, and unwillingness to participate in the study. The study was approved by the Ethics Committee of the University of Tartu.

The patients were randomized to one of two study groups following restricted randomization procedures. Randomization was done using a set of sealed opaque envelopes, which were all prepared by one researcher (C.N.) before the beginning of the study. The envelopes were kept in an arranged location in the operating room. Before operation, the surgeon took randomly a sealed envelope that contained a label of mesh. The patients were blinded to which mesh they received. In the UM group, the patients received Ultrapro mesh; in the OM group, the patients received Optilene LP mesh. Ultrapro is a lightweight partially absorbable mesh consisting of polypropylene and polyglecaprone with a weight of 28 g/m^2 and a pore size of 3–4 mm (Ethicon, Hamburg, Germany). Optilene LP mesh is a monofilament polypropylene lightweight mesh with a weight of 36 g/m^2 and a pore size of 1 mm (BBraun, Rubi, Spain). A mesh with measurements 4.5 × 10 cm was applied, whereas Optilene LP mesh was commercially preshaped and Ultrapro mesh was shaped by the surgeon during the operation, using a stencil. The polypropylene 2-0 suture material was used for mesh implantation. A tension-free repair using the modified Lichtenstein technique was performed in both study groups. All nerves in the inguinal canal were identified and preserved when possible.

Follow-up examinations were performed at 7 d, 1 mo, and 6 mo after the operation.

The pre- and post-operative data were collected using standardized forms. The patient study form included demographic data, body mass index, duration of the disease, and operative data. Additionally, data about the method of anesthesia, type of hernia (direct or indirect), size of hernia, hernial sac handling, duration of operation, length of hospital stay, and the experience of the surgeon (trainee or staff surgeon) were collected.

All patients underwent a clinical examination for any evidence of wound problems and recurrent hernia at every postoperative follow-up visit. Postoperative analgesic consumption was also recorded.

The primary outcome measure of the present randomized study was the rate of chronic groin pain at 6-mo follow-up, taking into account all patients who reported pain during different activities (yes-or-no questions). The pain questionnaire was completed before the operation and during follow-up visits at week 1, month 1, and month 6. It included questions about pain at rest, on coughing, when rising from lying to sitting, and during physical effort and exercise (all yes-or-no questions). When the answers to these questions were positive, the pain scores were measured on a visual analog scale (VAS) ranging from 0 mm (no pain) to 100 mm (worst imaginable pain). A score <10 was graded as mild pain; a score of 10–50, as moderate pain; and a score >50, as severe pain. Such gradation has been used in earlier similar studies [12]. The analysis of the distribution of pain severity was based on the highest score on the VAS during different activities (at rest, on coughing, when rising from lying to sitting, and during physical effort and exercise). The patients were also asked whether the pain influenced their everyday activities.

Foreign body feeling and quality of life at 6-mo follow-up were the secondary endpoints.

Foreign body feeling was registered as a yes-or-no question.

Quality of life was evaluated using the Short-Form (SF)-36 questionnaire, which was completed by the patient before the operation and 6 mo after the operation. The SF36 questionnaire is a generic quality of life questionnaire, developed within the RAND Corporation Medical Outcomes study, which measures eight domains of health: general health, vitality, bodily pain, mental health, social functioning, physical functioning, emotional role, and physical role. The SF36 questionnaire's score of 100 represents the best possible health.

2.1. *Statistical analysis*

In our previous study, the rate of chronic pain in the group where also Optilene LP mesh was used was 47.8% [13]. In a study of Smietanski *et al.* [14] was the rate of pain (VAS >0) after inguinal hernia repair with Ultrapro mesh 21.2%. Based on previous research, to show that the difference in the rate of chronic pain for OM 48% *versus* UM 21% would be about 27% according to Fisher exact test at the 5% significance level (power 80%), a sample size of 56 patients was necessary. Considering the dropout rate of 5%, a minimum of 118 participants were needed for the study.