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Single-center, single-blinded, randomized study of self-gripping *versus* sutured mesh in open inguinal hernia repair

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ARTICLE INFO

Article history:
Received 29 August 2014
Received in revised form
30 August 2014
Accepted 12 September 2014
Available online 18 September 2014

Keywords:
Inguinal hernia
Self-gripping mesh
Lichtenstein hernioplasty
Chronic pain
Foreign body feeling
Quality of life

ABSTRACT

Background: The primary aim of the present study was to evaluate whether usage of self-gripping mesh in open inguinal hernia repair, compared with standard Lichtenstein repair with sutured mesh, could result in a decreased rate of chronic pain at 6-mo follow-up. The secondary outcome was to evaluate foreign body feeling and the quality of life after inguinal hernia repair.

Methods: The patients were randomized into two study groups as follows: the OLP group received Optilene LP mesh and the PPG group received self-gripping Parietex ProGrip mesh. Pain scores were measured on a visual analog scale. Foreign body feeling was registered as a yes or no question. Quality of life was evaluated using the Medical Outcome Study Short-Form 36 questionnaire.

Results: A total of 75 patients in the OLP group and 70 patients in the PPG group were included in the analysis. According to the primary end point, 45.3% and 31.4% of the patients in the OLP group and PPG group experienced pain during different activities at 6-mo follow-up, respectively ($P = 0.092$). Per secondary end point, 22.7% in the OLP group and 40% in the PPG group reported foreign body feeling at the operation site at 6-mo follow-up ($P = 0.031$, risk ratio 0.57, 95% confidence interval 0.29–1.07). There were no significant differences in any domain of quality of life according to the Short-Form 36 questionnaire between the two study groups at 6-mo follow-up, except for the social functioning domain ($P = 0.035$). In the OLP group, the quality of life scores improved significantly after operation in all domains except for general health and mental health. In the PPG group, the quality of life scores improved significantly after operation in the domains of bodily pain, physical functioning, and physical role.

Conclusions: Self-gripping mesh compared with standard Lichtenstein operation has no advantages in reducing chronic pain 6-mo after surgery. The rate of foreign body feeling was higher in the self-gripping mesh group. Scores of bodily pain, physical functioning, and physical role improved significantly in both study groups after hernia surgery.

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http://dx.doi.org/10.1016/j.jss.2014.09.017

1. Introduction

Although the well-known mesh material polypropylene was developed 60 y ago [1] and more than 166 different meshes for hernia repair are in the market [1], with more than 20 million prosthetic meshes used worldwide each year [2], we do not yet know the parameters of an ideal mesh. After the widely used alloplasty in inguinal hernia surgery, the most common complication is chronic pain whose rates reach up to 51.6% [3].

Different mesh characteristics have been studied, among them weight of mesh has probably gained the most attention. Considering the high rate of chronic pain after inguinal hernia surgery, which can have serious socioeconomic impacts; also other mesh characteristics should be studied.

There are different hypotheses regarding what can cause chronic pain after inguinal hernia surgery. One possible reason for development of groin pain is nonabsorbable sutures, which are used for fixation of the mesh in Lichtenstein hernioplasty. Other fixation solutions like tissue glue and absorbable sutures have been investigated to reduce the rate of chronic pain [4–6].

The aim of the present single-blinded, randomized study was to evaluate whether usage of self-gripping mesh in open inguinal hernia repair, compared with standard Lichtenstein repair with sutured mesh, results in a decreased rate of chronic pain at 6-mo follow-up. Second, we aimed to evaluate foreign body feeling and the patient's quality of life after inguinal hernia repair.

2. Material and methods

All patients scheduled for inguinal hernia repair at the Clinic of Surgery of Tartu University Hospital, Department of General Surgery, from January, 2012–June, 2013, who met the inclusion criteria were eligible to participate in the study. Eligible patients were adults aged ≥18 y with unilateral primary reducible inguinal hernia, providing consent for participation in the study. Patients <18 y and patients with irreducible, strangulated, or recurrent hernia were excluded. Also patients who were unable to understand the questionnaire or who were unwilling to participate in the study were excluded. The study was approved by local ethics committee.

The patients were randomized to one of two parallel study groups. Randomization was done using a set of sealed opaque envelopes, which were all prepared by one investigator (C.N.) before commencement of the study. The envelopes were kept in an arranged location in the operating room. Before operation, the surgeon took a sealed envelope randomly that contained a label of mesh. The patients were blinded to which mesh they received. In the OLP group, the patients received Optilene LP mesh (B. Braun Medical, Tallinn, Estonia); in the PPG group the patients received Parietex ProGrip mesh (Covidien, Tallinn, Estonia). Optilene LP mesh is a monofilament polypropylene lightweight mesh with a weight of 36 g/m^2 and a pore size of 1 mm. Parietex ProGrip mesh is a partially absorbable monofilament mesh consisting of polyester and polylactic acid with a weight of 74 g/m^2 before resorption and 38 g/m^2 after resorption and a pore size of 1.1 × 1.7 mm. Parietex ProGrip mesh has microgrips across the mesh surface area, which ensure gripping between muscle fibers and the connective tissue. The resorption time of polylactic acid is 12 mo [7]. Both meshes are commercially preshaped. Optilene LP mesh with measurements 6 × 14 cm and Parietex ProGrip with measurements 8 × 12 cm were used. A tension-free hernioplasty, using the Lichtenstein technique, was performed in the OLP group. The polyprolylene 2/0 suture material was used for mesh implantation. In the PPG group, the inguinal canal was prepared and the wound was later closed as in the standard Lichtenstein operation. The mesh was placed in position in the inguinal canal, the flaps were closed around the cord, and pressure was applied to the mesh for fixing it. All nerves in the inguinal canal were identified and preserved when possible in both study groups.

The patients were examined after 7 d, 1 mo, and 6 mo.

The preoperative and postoperative data were documented using standardized forms. The data included demographic data, body mass index, duration of the disease, method of anesthesia, type of hernia (direct or indirect), size of hernia, hernial sac handling, mesh used, duration of operation, length of hospital stay, and experience of the surgeon (trainee or staff surgeon).

The patients were examined for any evidence of wound infections, hematomas, seromas, and recurrent hernia at every postoperative follow-up visit. The patients were inquired about postoperative analgesic consumption.

The primary end point of this 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. The pain questionnaire 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 patients' response to the questionnaire was 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 less than 10 was graded as mild pain, a score 10–50, as moderate pain, and a score more than 50, as severe pain. Such gradation has been used in similar studies [8]. 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). Data about whether pain influenced the patients' everyday activities were recorded as well.

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

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

Quality of life was evaluated using the Short-Form 36 (SF36) questionnaire, which was completed 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 as follows: general health, vitality, bodily pain, mental health, social functioning, physical functioning, emotional role, and physical role. The SF36 questionnaire's score 100 represents the best possible health [9].