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Original research

Factors predicting chronic pain after open mesh based inguinal hernia repair: A prospective cohort study

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HIGHLIGHTS

- 932 open mesh based hernia repairs were analyzed utilizing two regression models.
- Recurrence, complication, mesh weight, baseline VAS and age predict chronic pain.
- Recurrence, complication, mesh weight and baseline VAS predict intensity of pain.

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ABSTRACT

Introduction: Chronic postherniorrhaphy pain is the foremost setback of today's inguinal hernia repair. Finding predictors for it affects implants, operative techniques and allows for preventive measures.
Methods: Prospectively collected data from 932 outpatient open inguinal hernia operations between 2003 and 2010 were subjected to regression analysis. Visual analogue scale score (VAS) at least a year after operation and a measurement of chronic pain at one year were the target variables.
Results: Chronic pain was present in 99 (11.5%) patients one year after operation. Independent predictors for the occurrence of chronic pain were positively recurrence (Odds ratio, OR 6.77 vs. no recurrence, P = 0.005), complication (OR 5.16 vs. no complication, P = 0.002), mid-density mesh (OR 2.28 vs. lightweight mesh, P = 0.012), higher preoperative VAS score (OR 1.15, P = 0.006) and negatively higher age (OR 0.98, P = 0.027).
Predictors for a higher postoperative VAS score were recurrence (regression coefficient, RC, 1.49 vs. no recurrence, P = 0.001), complication (RC 0.76 vs. no complication, P = 0.016), heavyweight mesh (RC 0.50 vs. lightweight mesh, P = 0.046) and higher preoperative VAS level (RC 0.10, P < 0.001).
Conclusions: Recurrence, complication, mesh weight, preoperative VAS score and age are predictors for the occurrence chronic pain after open mesh based inguinal hernia repair. Recurrence, complication, mesh weight and preoperative VAS score are predictors of postherniorrhaphy VAS level.

1. Introduction

The era of open mesh repairs as the primary operative treatment for inguinal hernia has lowered recurrence to an acceptable level. Instead, chronic postherniorrhaphy pain has emerged as one of the most significant adverse effects. Pain has been pooled in reviews to be present in 10–12% of patients while single studies report ranges reaching 37% [1–3]. Factors contributing to postherniorrhaphy pain are complex and not well understood [4]. For example higher age, laparoscopy and lightweight mesh types have been found to be associated with lower prevalence of chronic postherniorrhaphy pain and reoperation, postoperative complications, higher preoperative pain levels and lower preoperative optimism with higher prevalence [5–7]. Such findings have been somewhat inconsistent. Variable results may have emerged from adding miscellaneous operative techniques in different proportions in the analysis. Also, some of the larger studies with the aim to find risk factors for pain are based on patient recollection of preoperative pain levels. In this study the prospectively collected details of several uniformly executed open inguinal hernia mesh repairs under the same setting

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were subjected to statistical analysis in order to find out which patient or operation related factors were associated with chronic postherniorrhaphy pain and higher postoperative VAS scores.

2. Materials and methods

The details of 932 open mesh based inguinal hernia repairs accumulated during the following prospective studies with chronic pain as primary end point, similar study design and uniform execution. These ambulatorily operated consecutively recruited adults who each went through a modification of the tension-free repair in a similar setting were treated as a cohort. Reporting follows the STROBE statement [8].

Between March 2003 and August 2004 consecutive adult patients (n = 228) in a single ambulatory unit were randomized to receive under local anesthesia unilaterally or bilaterally a heavyweight (Premilene®, 82 g/m^2; B. Braun, Melsungen, Germany), a mid-weight (Premilene LP®, 55 g/m^2; B. Braun) or a polypropylene-polyglactin lightweight composite mesh (Vypro II®, 35 g/m^2 after absorption; Ethicon, Hamburg, Germany) for a primary or recurrent inguinal hernia [9].

From June 2007 till May 2009 consecutive adult patients (n = 302) in three ambulatory units were randomized to receive under local anesthetic unilaterally or bilaterally a mid-weight polypropylene mesh (Optilene®, 60 g/m^2, B. Braun) secured in position either with absorbable sutures (3/0 Dexon®, United States Surgical, Norwalk, Connecticut, USA) or butyl-2-cyanoacrylate tissue glue (Glubran®; GEM, Viareggio, Italy) for a primary inguinal hernia [10].

Between February 2008 and January 2010 consecutive adult patients (n = 394) in two ambulatory units were randomized to receive under local, regional or general anesthesia unilaterally either a lightweight polypropylene mesh (Parietene Light™, 38 g/m^2; Covidien, Dublin, Ireland) secured with non-absorbable sutures (2/0 Prolene®; Ethicon, Somerville, New Jersey, USA) or a self-fixating polypropylene-polylactic acid (PLA) lightweight composite mesh (Parietene ProGrip™, 40 g/m^2 after absorption; Covidien) for a primary inguinal hernia [11].

Eligible were all at least 18 year old patients medically fulfilling the criteria of day case surgery without a previous mesh placement. In every operation incision, dissection, mesh trimming and slitting for the spermatic cord and its placement had followed according to the tension-free concept by Lichtenstein and Shulman [12]. In operations utilizing absorbing attachment, instead of permanent sutures, interrupted absorbable sutures or 1–2 drops of tissue glue had been applied along the inguinal ligament and over the conjoined tendon as well as between mesh tails. The self-fixating prefabricated mesh had been pressed into position as advised by Chastan [13]. Hernia sac had been usually resected. Large sacs had been inverted with absorbable sutures. In all procedures the iliohypogastric, ilioinguinal and genitofemoral nerves had been identified and preserved whenever possible but resected where visibly damaged. Outcomes had been obtained by clinical visits. Study 3 patients had additionally been sent symptom questionnaires 2–4 years after the operation. All patients had given written informed consent (Helsinki Declaration) and the local ethics committees (Central Hospitals Mikkeli, Päijät-Häme, North Karelia and Helsinki University) had approved the trials.

Analysis included the following patient, operation and implant related predictors: sex, body mass index (BMI, kg/m^2), age upon operation, preoperative inguinal pain in Visual Analogue Scale (VAS), hernia type (indirect, direct, combined, recurrent), mesh type (heavyweight, mid-weight, lightweight), attachment method (permanent sutures, absorbable sutures, glue, PLA microhooks), anesthesia method (local, regional, general), duration of operation, complication (visible nerve damage, bleeding, hematoma, infection, combinations), time to follow-up and 1-year hernia recurrence. The dependent variables were chronic pain (yes/no) one year after operation in one regression model and postoperative inguinal pain in VAS in the other. A 100 mm line on paper where the patient ticked the current inguinal pain served as the Visual Analogue Scale. Mesh weight cut off points were chosen according to Bellon: light (35–50 g/m^2), mid (50–80 g/m^2), and heavy (>80 g/m^2) [14]. The following were taken as indicative of chronic postherniorrhaphy pain at one year after operation: patient's yes-answer regarding bothersome pain in the operated groin, continuous need for pain medication due to pain in the operated groin and pain or VAS score >30 at rest. Choice of VAS >30 as threshold was based on the concept of analgesic success and the cut off points: no pain (<10 mm), mild (10–30 mm), moderate (31–70 mm) and severe pain (>70 mm) [15–17].

Statistical analysis was carried out with IBM SPSS Statistics 22.0® (IBM, Armonk, New York, USA). Mann-Whitney-U-test was utilized to test continuous variables in unrelated samples. Wilcoxon signed-rank test was applied to continuous variables in related samples. Predictor variables were entered simultaneously in a multivariate binomial regression model to find those that were independently associated with presence of chronic pain at 1 year. Additionally, the variables were subjected to a separate linear regression model to yield predictors for higher scores in postoperative VAS 1–4 years after operation. Missing data was considered random. The regression models omitted any incomplete sets of variable measurement. An α of 0.05 was chosen to mark statistical significance.

3. Results

Of the original 924 patients 698 (75.5%) had a complete set of measurements for the binomial regression model and 642 (69.5%) for the linear regression model. Fig. 1 displays patient numbers through the study.

At one year, 99 (11.5%) of responders (n = 862) experienced chronic pain: 19 (2.2%) used pain medication continuously, 65 (7.5%) had bothersome pain and 57 (6.6%) had at least moderate pain at rest. Overall, preoperative mean VAS score at rest was 28 and at follow-up 6, ($P < 0.001$) in those providing an answer on both occasions (n = 675). Tables 1a–1c provide information on VAS behavior from various perspectives. By the second follow-up point of study 3 patients, one hernia recurrence was reoperated and 4 more hernias explored laparoscopically because of eventually transient pain: their follow-up VAS values after the reoperation were low and reoperation had no effect on pain prediction models.

Table 2 presents results from multivariate binary logistic regression analysis for chronic postherniorrhaphy pain at one year for the predictors modelled simultaneously. Adjusting for the remainder of predictors, significant independent predictors for chronic pain were positively recurrence, complication, preoperative VAS level and mid-weight mesh as well as negatively age. Adding attachment type (as non-penetrative vs. penetrative) in the logistic regression model yielded: mesh type $P = 0.057$ where mid-weight mesh compared to lightweight mesh returned OR 2.21, 95% CI 1.15–4.26, $P = 0.017$. Fixation type was statistically insignificant (data not shown). Other model results were effectively same as with the original model.

Table 3 displays predictors for a postoperatively higher VAS score (included was 'time to follow-up') modelled in linear regression. Higher VAS scores were independently predicted from: higher preoperative VAS scores, recurrence, complication and heavyweight mesh as well as general anesthesia.