

# Factors associated with postoperative complications and hernia recurrence for patients undergoing inguinal hernia repair: a report from the VA Cooperative Hernia Study Group

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Manuscript received May 25, 2007; revised manuscript July 29, 2007

Presented at the 31st Annual Surgical Symposium of the Association of VA Surgeons, Little Rock, AR, May 10–12, 2007

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## Abstract

**Background:** We sought to determine perioperative variables predictive of complications or recurrence for patients undergoing surgical repair of inguinal hernias.

**Patients and Methods:** Using data from the Veterans Affairs trial, regression analyses were utilized to identify perioperative factors significantly associated with complications (overall, short-term and long-term), long-term pain, and to develop a risk model for recurrence.

**Results:** Recurrent and scrotal hernias were predictors for short term and overall complications, regardless of technique. Older age and higher Mental Component Score of the SF-36 were associated with higher risk of long term complications in the open group while prostatism and increased body mass index were the significant predictors in the laparoscopic group. Long-term pain complaints decreased as patient age increased in both groups. Patient and surgeon factors were predictive of recurrence but varied greatly depending on surgical technique.

**Conclusions:** Regardless of technique, scrotal and recurrent hernias were associated with a greater risk of complications and younger patients had more long-term pain. Predictors of recurrence vary based on surgical technique. © 2007 Excerpta Medica Inc. All rights reserved.

*Keywords:* Complications; Recurrence; Inguinal; Herniorrhaphy; Lichtenstein; Laparoscopic

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Repair of inguinal hernias is one of the most commonly performed general surgery procedures in the United States, with more than 750,000 inguinal herniorrhaphies performed every year [1]. The procedure is relatively safe and straightforward, however, recurrence and complications still occur at a significant rate [2]. Most recent literature on inguinal hernias has focused on the recurrence rate after various

types of repair and surgical techniques [3,4]. The number of preoperative and perioperative factors analyzed for correlation with hernia recurrence and postoperative complications has been limited. Most often these assessments focus on the role of surgical technique in determining the likelihood of complications and ignore other possible factors. The purpose of this report is to identify the risk factors associated with complications or recurrences in patients undergoing laparoscopic and open inguinal hernia repair. We present a risk-assessment model for hernia recurrence.

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## Patients and Methods

Over a 3-year period of time, a total of 2,164 men were enrolled in the Veterans Affairs Cooperative Studies Program Inguinal Hernia Trial: Tension-Free Inguinal Hernia Repair: Comparison of Open and Laparoscopic Surgical Techniques (Cooperative Studies Program #456). Of these, 1,983 underwent a randomly assigned surgical repair (laparoscopic vs open). The majority of patients (85%,  $n = 1,696$ ) were followed up for a minimum of 2 years postoperatively. Complication data were analyzed for all patients who underwent surgery. The patients who completed 2 years of follow-up evaluation formed the basis for our recurrence risk model. Inclusion and exclusion criteria, baseline characteristics of these patients, and the details of the 2 surgical techniques used in this study, as well as the primary results, were described previously [5,6]. All patients gave informed consent and the study was cleared through the institutional review boards at participating hospitals.

### *Preoperative factors*

Data were collected on patients' age, body mass index (BMI), ethnicity, employment status, marital status, education, physical activity level, health insurance, and caregiver status. In addition, at the time of entry into this trial (before surgery) all patients completed the Health-Related Quality of Life survey Short Form-36 version 2 (SF-36) [7]. SF-36, a widely used instrument to assess non-disease-specific health-related quality of life, can be summarized by 2 scores: a Physical Component Summary (PCS) and a Mental Component Summary (MCS). PCS and MCS scores both are standardized to a score of 50, with a standard deviation of 10. To facilitate interpretation, PCS and MCS scores were considered in 3-unit intervals (50–52, 53–55, and so forth).

### *Hernia factors, medical comorbidities, and surgical factors*

Information was collected regarding characteristics of the hernia, including symptoms, duration, size, recent enlargement, unilateral versus bilateral, ability to reduce, and recurrent versus primary. Data also were collected preoperatively on participants' comorbid conditions including cardiovascular, central nervous system, gastrointestinal, nutritional/immune, peripheral vascular (claudication), pulmonary dysfunction (severe chronic obstructive pulmonary disease), prostatism, diabetes requiring medication, nonsteroidal anti-inflammatory or anticoagulant use, smoking, alcohol consumption, and weight loss. Functional status (independent, partially, or total dependent) and American Society of Anesthesiology (ASA) classification were recorded before the procedure. Surgical factors included self-reported surgeon experience, type of anesthesia, size of mesh, and procedure performed (open anterior tension-free mesh repair [Lichtenstein] vs laparoscopic repair [either totally extraperitoneal laparoscopic or transabdominal preperitoneal]).

### *Complications and follow-up evaluation*

Complications were categorized by both timing and severity. Intraoperative complications were assessed on the

day of surgery and included excessive bleeding; injuries to bowel, bladder, vas deferens, nerves, or vascular structures; as well as anesthetic complications. The presence of a peritoneal defect over mesh after a laparoscopic inguinal hernia repair was considered an intraoperative complication. Short-term postoperative complications were assessed at the 2-week follow-up visit and included infection, hematoma, orchitis, seroma or hydrocele, pain of the groin or leg, and urinary tract problems (infection, retention, or hematuria). Long-term complications were assessed at 3 months and then at yearly intervals and included the same spectrum of complications as the short-term postoperative period. The overall complication rate was defined as the total number of unique patients with one or more intraoperative, short-term, or long-term postoperative complications divided by the number of patients available for evaluation at that time point.

Chronic pain patients were defined as having either groin or leg pain identified at any visit 3 or more months after the surgery. Chronic pain requiring treatment was defined similarly with the addition of specific medical or surgical treatment.

Complications that were present at the time of a follow-up visit were tallied for that time frame (short or long term). Patients may have had more than one complication recorded and had the same complication recorded more than once (ie, a single patient with a hematoma at both the 2-week and 3-month follow-up visit would be counted as contributing 2 complications, one each to short-term and long-term hematomas; however, this patient would contribute only a single end point to the overall complication rate).

### *Recurrence and follow-up evaluation*

Hernia recurrence was diagnosed at any follow-up appointment by a surgeon not involved in the initial repair. Follow-up appointments were at 2 weeks, 3 months, and at 1 and 2 years after surgery. Recurrences were confirmed by another surgeon, by ultrasound examination, or at surgery for repair.

### *Statistics: complication data*

Statistical analysis was performed based on the intention-to-treat principle. All statistical tests were 2-sided, and the statistical significance level was set at .05. Previous analysis of outcomes for patients in actual repair groups was not statistically different from intention-to-treat groups [5]. The relationship between surgical complication data and individual baseline variables was evaluated with the Pearson chi-square test or the Fisher exact test for categorical variables, and by using the Student *t* test for continuous variables. Multivariable best subsets logistic regression was applied to identify risk factors related to each type of complication outcome separately for each type of surgical approach (laparoscopic vs open). Baseline variables, including preoperative factors, hernia factors, medical comorbidities, and stratification variables of hernia type (primary/recurrent), and number of sides (unilateral/bilateral), all were included in the best subsets logistic regression model. Potential complication outcomes for multivariable modeling included intraoperative complications, short-term complications, long-term complications, overall complications, long-

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