

Clinical Science

# Risk factors for umbilical trocar site incisional hernia in laparoscopic cholecystectomy: a prospective 3-year follow-up study

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## Abstract

**BACKGROUND:** Trocar site incisional hernia (TSIH) is a common complication after laparoscopic cholecystectomy. The aim of this study was to evaluate the prevalence of TSIH and analyze the influence of several risk factors for this complication in a prospective series.

**METHODS:** From 2007 to 2008, a prospective observational study with 3 years of follow-up was performed including all consecutive patients with cholelithiasis who underwent elective laparoscopic cholecystectomy. A multivariate analysis was performed to identify risk factors for TSIH.

**RESULTS:** Overall, 241 patients were included. During a median follow-up period of 46.8 months, 57 patients (25.9%) were diagnosed with umbilical TSIH by physical exam or ultrasound. The multivariate analysis revealed that incision enlargement (odds ratio [OR], 14.17; 95% confidence interval [CI], 3.61 to 55.51;  $P < .001$ ), wound infection (OR, 5.62; 95% CI, 2.35 to 13.42;  $P < .001$ ), diabetes mellitus (OR, 2.79; 95% CI, 1.05 to 7.37;  $P = .0038$ ), and obesity (OR, 2.71; 95% CI, 1.28 to 5.75;  $P = .009$ ) contributed to the risk for developing a TSIH.

**CONCLUSIONS:** Umbilical TSIH is highly prevalent. This study identified several factors that could be useful to introduce preventive measures in high-risk patients.

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The introduction of laparoscopic surgery in 1987 and its widespread use in the past 20 years has dramatically increased the number of patients undergoing this surgical approach. Any new technique is associated with the

development of new complications, and trocar site incisional hernia (TSIH) is possibly the most common in laparoscopic surgery.<sup>1</sup>

Although this complication can cause significant morbidity, it is frequently underdiagnosed. To date, the prevalence of TSIH was believed to range from 1.50% to 1.80%,<sup>1-4</sup> but it is commonly accepted<sup>1,5</sup> that without medium-term to long-term follow-up, most cases will remain undiagnosed. Therefore, the true prevalence may be higher.

The authors declare no conflicts of interest.

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There are few recommendations in the literature on how TSIH should be avoided or minimized, and the real impact of TSIH and its causal factors should be determined in prospective studies. Identifying which patients will be at risk for TSIH could be of paramount importance to establish preventive measures or a special follow-up schedule. However, to date, there have been insufficient prospective series with a long-term follow-up to allow the impact of this complication to be analyzed.

The aims of the present study were to evaluate the prevalence of TSIH and to analyze the influence of several risk factors for this complication in a prospective series.

## Methods

### Inclusion and exclusion criteria

A population-based prospective observational study was performed including all consecutive patients with cholelithiasis who underwent elective laparoscopic cholecystectomy from 2007 to 2008 at our institution. Exclusion criteria consisted of conversion from laparoscopy to an open procedure and the finding of unexpected acute cholecystitis during the intervention.

### Surgical technique

Six experienced surgeons participated in the study, and all performed the same technical procedure to enter the abdomen and the same closure technique. At the beginning of surgery, a supraumbilical transverse skin incision followed by an open technique with a vertical incision along the midline were performed. Next, a 12-mm Hasson trocar was inserted and an additional 2 or 3 more bladeless trocars (5 mm at the lower right quadrant, 10 mm at the upper left quadrant, and 5 mm, if required, at the epigastrium) were introduced.

Only the umbilicus incision was closed in all cases with same technique: a hand-sewn interrupted suture with a variable number of stitches according to length of the incision. A medium-term absorbable synthetic polyglycolic acid polymer (size 0), using a 30-mm atraumatic hook needle, including all layers of the abdominal wall was used. In cases in which umbilical incision needed to be enlarged, the closure technique was the same. Skin closure was performed using metallic staplers in all cases.

No antimicrobial prophylaxis was used. In all patients, the gallbladder was removed through the umbilical incision without a protection bag.

### Management of trocar site wound

Standard management of trocar site incisional wound was carried out in all patients. Postoperative dressing was removed earlier (24 hours after surgery), and we advised patients that they could shower safely 48 hours after

surgery and that the use of topical antimicrobial agents for surgical wounds has not been recommended apart from surgeon recommendation. Surgical staples were removed during the first office visit (7 days after surgery).

### Study variables

The following variables were recruited prospectively: age, gender, diabetes mellitus, obesity (body mass index [BMI]  $>30 \text{ kg/m}^2$ ), fascial incision enlargement to remove the gallbladder from the abdomen, and the preexistence of an umbilical hernia. In addition, trocar location, trocar size, and the occurrence of postoperative port site wound infection were registered prospectively.

Wound infection was defined according to the internationally accepted definition of the Centers for Disease Control and Prevention<sup>6</sup> and attending to 2 criteria: a positive culture and/or a finding of infection in the surgeon's opinion.

### Follow-up

The main end point of the study was a postoperative diagnosis of TSIH. In all patients, a thorough physical examination was performed checking specifically for signs suggestive of a TSIH at day 7, 1 month, 1 year, and 3 years after the intervention. The diagnosis was performed clinically, but if the examiner suspected a TSIH but could not confirm it by physical examination, abdominal ultrasound was carried out.

All patients received instructions on the clinical signs of TSIH and were told to contact the team if they developed these signs outside the follow-up schedule described.

This study was approved by the institutional review board, and informed consent was obtained from the patients.

### Statistical analysis

All results and variables were introduced in a specially designed database. Continuous variables are presented as means and ranges and categorical variables as absolute numbers or percentages. Chi-square tests were used to compare differences in categorical variables (Fisher's exact tests were used as needed), and Student's *t* tests were used for continuous variables. Univariate analysis and multivariate logistic regression analysis were performed to identify independent predictive causal factors for the development of TSIH. Adjusted odds ratios (ORs) were calculated using logistic regression. Variables achieving statistical significance in the univariate analysis were considered for multivariable analysis. ORs with 95% confidence intervals (CIs) are presented for each studied variable. Differences were considered to be significant at the 5% level. All *P* values reported are 2 sided. Statistical analyses were performed using SPSS version 17.0 (SPSS, Inc, Chicago, IL).

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