Study Title: Umbilical Trocar Site Is the Usual Suspect for Trocar Hernia After Laparoscopic Cholecystectomy: A Prospective Study

NCT ID: Not yet assigned.

Date: April 15, 2025

CLINICAL STUDY REPORT (CSR)

Study Title: Umbilical Trocar Site Is the Usual Suspect for Trocar Hernia After Laparoscopic Cholecystectomy: A Prospective Study

Study Type: Prospective, randomized controlled trial

Study Duration: April 15, 2022 – June 15, 2024

Study Location: Umraniye Training and Research Hospital, Department of General Surgery

Principal Investigator: Ass. Prof. Dr. Tolga Canbak

ClinicalTrials.gov ID: Not yet assigned

1. Study Synopsis

Objective:

To evaluate whether the site of gallbladder retrieval (umbilical vs. epigastric) affects the incidence of trocar site hernia (TSH) following laparoscopic cholecystectomy (LC), and to identify risk factors for TSH.

Design:

Prospective, randomized, single-blind, controlled study with two parallel arms.

Participants:

110 patients undergoing elective LC for gallstone disease were randomized. After accounting for conversions and loss to follow-up, 100 patients (50 in each group) were included in the final analysis.

Intervention:

Standard 4-port LC performed. Gallbladder retrieved via either:

Group U: Umbilical trocar (10 mm)

Group E: Epigastric trocar (10 mm)

Primary Outcome:

Incidence of trocar site hernia at 12-month follow-up.

Secondary Outcomes:

Gallbladder retrieval time

Postoperative pain scores (VAS at 6 and 24 hours)

Risk factor analysis for TSH development

Key Results:

TSH occurred in 12% (6/50) of umbilical group and 10% (5/50) of epigastric group (P = 1.00).

All hernias were located at the umbilical site.

Epigastric retrieval was faster (P = 0.013) but associated with more early pain (P = 0.027).

Fascial widening was the only independent risk factor for TSH (OR = 4.08, P = 0.05).

2. Study Design

Randomization:

Performed via the Alea Randomisation mobile app. Allocation was sealed and revealed intraoperatively before specimen retrieval.

Blinding:

Patients were blinded. Surgeons were not blinded due to the nature of the procedure, but were unaware of group allocation until extraction.

Surgeon Consistency:

All surgeries were performed by three experienced general surgeons using standardized techniques.

Antibiotic Prophylaxis:

Intravenous cefazolin 2 g administered preoperatively.

3. Inclusion / Exclusion Criteria

Inclusion:

Age ≥ 18

Gallstone disease

No significant systemic comorbidities

Exclusion:

Age < 18

Conversion to open surgery

Acute cholecystitis

Prior common bile duct surgery

Presence of diastasis recti or umbilical hernia

4. Surgical Technique

Standard LC using:

10 mm umbilical camera port

10 mm epigastric port

Two 5 mm subcostal ports

Fascial closure was performed only at the umbilical site using polyglactin sutures.

Epigastric port sites were not sutured.

Gallbladder retrieval performed using a bag.

5. Postoperative Management & Follow-Up

Pain Control:

IV paracetamol and tramadol postoperatively. VAS recorded at 6 and 24 hours.

Discharge & Follow-up:

Routine discharge on Day 1 if no complications. All patients followed for 12 months.

Hernia Diagnosis:

Symptomatic patients evaluated with ultrasonography. Asymptomatic patients underwent scheduled USG at 6 and 12 months.

6. Statistical Analysis

- Data analyzed with SPSS v26 and RStudio.
- Categorical data were analyzed using Fisher's exact or Chi-square tests
- Continuous variables were compared using Student's t-test or Mann–Whitney U test
- Univariate and multivariate logistic regression performed to evaluate TSH risk factors.
- Significance threshold: $P < 0.05$

7. Results Summary

Demographics:

Age, BMI, and other baseline factors were comparable between groups.

Outcomes:

- Hernia rate: 6 in Group U, 5 in Group E (all at umbilicus)
- Retrieval time shorter in Group E ($P = 0.013$)
- Pain lower in Group U at 6h ($P = 0.027$)
- No difference in 24h VAS scores
- Multivariate Analysis:
- Fascial widening was the only independent predictor of TSH (OR = 4.08, $P = 0.05$)

8. Discussion

- All trocar site hernias (TSH) occurred at the umbilical site, regardless of extraction route.
- This confirms the umbilicus as the most vulnerable location for hernia development after
- laparoscopic cholecystectomy.
- Epigastric extraction avoided direct stress on the umbilical site and was associated with no
- hernias at the epigastric port.
- Gallbladder retrieval was faster via the epigastric route, offering operative efficiency.
- Early postoperative pain (6h) was slightly higher with epigastric extraction but not clinically
- limiting.
- Fascial widening during extraction was the only independent risk factor for TSH.
- These findings support preferential use of the epigastric port for specimen retrieval to
- minimize hernia risk.

9. Conclusion

While trocar site selection did not statistically alter the incidence of hernia, all hernias occurred at the umbilicus, highlighting its vulnerability. Fascial widening during extraction was a key modifiable risk factor. Epigastric retrieval may offer operative efficiency, but at a slight cost in postoperative discomfort.

10. Ethical Considerations

- Approved by the Clinical Research Ethics Committee of Istanbul University of Health
- Sciences, Umraniye Training and Research Hospital.
- All participants provided written informed consent.
- Study conducted in accordance with the Declaration of Helsinki.
- No funding received. No conflicts of interest declared.

STATISTICAL ANALYSIS PLAN (SAP)

Study Title: Umbilical Trocar Site Is the Usual Suspect for Trocar Site Hernia After Laparoscopic Cholecystectomy: A Prospective Study

Version: 1.0

Prepared by: Olgun ERDEM

Study Sponsor: Umraniye Research and Training Hospital

Principal Investigator: Ass. Prof. Dr. Tolga Canbak

1. Study Overview

This is a prospective, randomized, controlled clinical trial evaluating the incidence of trocar site hernia (TSH) in patients undergoing laparoscopic cholecystectomy, comparing gallbladder extraction via the umbilical versus epigastric port.

2. Study Objectives

Primary Objective:

To assess whether the site of gallbladder retrieval (umbilical vs. epigastric trocar) affects the incidence of trocar site hernia.

Secondary Objectives:

To compare postoperative pain levels at 6 and 24 hours between groups

To assess gallbladder retrieval time

To identify independent risk factors for the development of trocar site hernia

3. Endpoints

Primary Endpoint:

Incidence of trocar site hernia (clinical or ultrasonographic diagnosis within 12 months)

Secondary Endpoints:

- Gallbladder retrieval time (in seconds)
- Visual Analogue Scale (VAS) pain scores at 6 and 24 hours postoperatively
- Occurrence of fascial widening and its association with TSH

- Logistic regression model identifying independent risk factors for TSH

4. Analysis Populations

Intention-to-Treat (ITT):

All randomized patients, excluding those who converted to open surgery or were lost to follow-up.

Per Protocol (PP):

Patients who completed surgery and 12-month follow-up without major protocol deviations.

5. General Statistical Methods

- Statistical significance threshold set at $P < 0.05$ (two-sided).
- All statistical analyses will be performed using SPSS v26.0 and RStudio v4.2.0.
- Results will be reported with appropriate confidence intervals (CIs) and effect sizes when
- applicable.

6. Data Handling and Assumptions

Missing Data:

No imputation will be performed.

Patients lost to follow-up will be excluded from analysis of outcomes they did not complete.

Outliers:

Checked visually (boxplots, scatterplots).

No exclusions unless clinically justified.

Normality Testing:

Shapiro–Wilk test used for continuous variables.

7. Baseline and Demographic Comparisons

Descriptive statistics: mean ± SD for normally distributed data; median (min–max) for non-normal data; frequency (%) for categorical variables.

Comparisons:

- Categorical variables: Chi-square or Fisher's exact test

- Continuous variables: Student's t-test or Mann–Whitney U test depending on distribution

8. Primary Endpoint Analysis

Incidence of TSH:

Compared between the umbilical and epigastric groups using Fisher's exact test.

9. Secondary Endpoint Analyses

- Gallbladder retrieval time: Compared using Mann–Whitney U test (non-normal distribution
- anticipated).
- Postoperative pain scores (VAS at 6h and 24h): Assessed separately at both time points.
- Compared using Mann–Whitney U test.
- Exploratory regression analyses: Univariate logistic regression to identify factors associated
- with TSH Variables with $P < 0.2$ or known clinical relevance will be entered into a
- multivariate logistic regression model.
- Odds Ratios (OR), 95% CI, and P-values will be reported.

10. Subgroup Analyses

Subgroup analysis will be performed for patients in the umbilical extraction group to evaluate the impact of fascial widening on TSH incidence using logistic regression.

11. Software

All analyses will be conducted using:

- SPSS v26.0 (IBM Corp., Armonk, NY, USA)
- RStudio v4.2.0 (The R Foundation)