STUDY PROTOCOL WITH STATISTICAL ANALYSIS PLAN

Tri-Radial Fascial Micro-Incision Technique for Difficult Gallbladder Extraction During Laparoscopic Cholecystectomy: A Prospective Randomized Controlled Trial

A prospective, three-arm, randomized controlled surgical trial

Item	Details
Brief Title	Tri-Radial Port Extension for Difficult Gallbladder Extraction
Acronym	TPE-LC
Protocol ID	BNSP-TPE-LC-2024-001
ClinicalTrials.gov NCT Number	To be assigned
Document Type	Study Protocol with Statistical Analysis Plan
Document Date	08 May 2026
Version	Registry Upload Version
Sponsor	BNS PATENGA Hospital, Bangladesh Navy
Responsible Party	Principal Investigator
Principal Investigator	Mohammad Tarequl Islam, MBBS, MCPS, FCPS, FACS
Study Site	BNS PATENGA Hospital, Patenga, Chattogram, Bangladesh
Study Period	January 2024 to April 2025
Final Follow-up	Twelve-month port-site hernia assessment completed in April 2026

Confidentiality Note: This document does not contain names, hospital registration numbers, contact details, or any other identifiable participant information.

Contents

1. Administrative Information

Field	Description
Official title	Tri-Radial Fascial Micro-Incision Technique for Difficult Gallbladder Extraction During Laparoscopic Cholecystectomy: A Prospective Randomized Controlled Trial
Short title	Tri-Radial Port Extension for Difficult Gallbladder Extraction
Interventional model	Parallel assignment, three arms, 1:1:1 allocation
Primary purpose	Treatment
Study phase	Not applicable
Study type	Interventional
Condition/focus	Difficult gallbladder extraction during laparoscopic cholecystectomy
Key words	Laparoscopic cholecystectomy; gallbladder extraction; tri-radial fascial micro-incision; Tareq's Port Extension; port-site extension; fascial extension; port-site hernia

2. Synopsis

Component	Protocol Summary
Study question	In patients with difficult gallbladder extraction during laparoscopic cholecystectomy, does tri-radial fascial micro-incision reduce bleeding severity and extraction time compared with vertical or horizontal fascial extension?
Population	Adults aged 18-70 years undergoing laparoscopic cholecystectomy for benign gallbladder disease with intraoperatively confirmed difficult extraction through the umbilical port.
Intervention	Tri-Radial Fascial Micro-Incision Technique, designated Tareq's Port Extension (TPE).
Comparators	Conventional vertical fascial extension and conventional horizontal fascial extension.
Primary outcomes	Extraction-site bleeding severity and specimen extraction time.
Secondary outcomes	Fascial extension length, 24-hour pain score, analgesic requirement, wound complications, cystic duct clip dislodgement, and port-site hernia at 12 months.
Sample size	156 randomized participants; 52 per arm.
Follow-up	From index surgery to 12 months after surgery.

3. Background and Rationale

Laparoscopic cholecystectomy is one of the most frequently performed abdominal operations and is the standard operative treatment for symptomatic gallstone disease. Major safety improvements in the procedure have focused on safe dissection of the hepatocystic triangle and prevention of bile duct injury. In contrast, the final phase of the operation, removal of the gallbladder specimen through the abdominal wall, remains less standardized.

Difficult gallbladder extraction is encountered when the specimen is large, thick-walled, inflamed, non-collapsible, or packed with large or multiple stones. In these situations, the specimen may not pass through a 10-mm umbilical fascial defect despite gentle traction. Surgeons commonly respond by extending the fascial opening vertically or horizontally, decompressing the gallbladder, fragmenting stones, using a retrieval bag, or combining several maneuvers.

Linear extension of the fascial defect may solve the immediate problem of extraction, but it can also concentrate mechanical stress along a single axis. This may lead to fascial-edge bleeding, tissue tearing, pain, or a larger defect requiring more careful closure. Horizontal extension at the infra-umbilical site may also encounter subcutaneous and small fascial-level vessels. Trocar-site hernia is uncommon but clinically important, and port size, fascial extension, and fascial closure technique are relevant technical factors.

The Tri-Radial Fascial Micro-Incision Technique was developed to provide a controlled, mechanically balanced method of fascial expansion. Rather than making a single long linear extension, three small radial micro-incisions are made around the existing port-site fascial defect. This creates a controlled cloverleaf-type expansion, improves working space around the specimen, and aims to reduce bleeding and tissue trauma. For consistency in reporting, the technique is designated Tareq's Port Extension (TPE).

4. Objectives and Hypotheses

4.1 Primary Objective

To compare TPE with conventional vertical and horizontal fascial extension techniques in terms of extraction-site bleeding severity and specimen extraction time during difficult gallbladder extraction.

4.2 Secondary Objectives

- To compare total fascial extension length among the three techniques.
- To compare postoperative pain at the umbilical port site at 24 hours.
- To compare analgesic requirement during the first 24 postoperative hours.
- To compare early port-site wound complications, including infection, seroma, and hematoma.
- To document cystic duct clip dislodgement during specimen extraction.
- To compare port-site hernia at 12 months.

4.3 Hypothesis

The study hypothesis is that TPE will reduce the severity of extraction-site bleeding and shorten specimen extraction time compared with conventional vertical and horizontal fascial extension, without increasing port-site complications.

5. Study Design

This is a prospective, single-center, randomized, parallel-group surgical trial with three intervention arms. Participants are randomized intraoperatively after difficult gallbladder extraction is confirmed. The allocation ratio is 1:1:1.

Arm	Intervention	Planned Sample
Arm 1	Vertical fascial extension	52 participants
Arm 2	Horizontal fascial extension	52 participants
Arm 3	Tri-radial fascial micro-incision / TPE	52 participants

6. Study Population

6.1 Inclusion Criteria

1. Adult patients aged 18 to 70 years.
2. Patients undergoing laparoscopic cholecystectomy for benign gallbladder disease.
3. Intraoperatively confirmed difficult gallbladder extraction through the umbilical port site.
4. Difficult extraction due to large gallbladder size, thickened gallbladder wall, large stone, multiple packed stones, or resistance at the fascial level.
5. Ability and willingness to provide written informed consent.
6. Willingness to attend follow-up for port-site complications and hernia assessment.

6.2 Exclusion Criteria

7. Conversion to open cholecystectomy before gallbladder extraction.
8. Suspected or confirmed gallbladder malignancy.
9. Uncorrected coagulopathy.
10. Pregnancy.
11. Previous major midline abdominal surgery affecting the umbilical port site.
12. Uncontrolled gallbladder perforation or major stone spillage before the extraction attempt.

13. Refusal to provide informed consent.
14. Inability or unwillingness to complete follow-up.

6.3 Definition of Difficult Gallbladder Extraction

Difficult extraction is defined as failure of the detached gallbladder specimen to pass smoothly through the 10-mm infra-umbilical fascial opening despite standard gentle traction, due to specimen bulk, large or multiple stones, thickened wall, poor collapsibility, or resistance at the fascial level. Only cases meeting this intraoperative definition are eligible for randomization.

7. Randomization and Masking

7.1 Randomization

Eligible participants are randomized in a 1:1:1 ratio using computer-generated block randomization. Randomization is performed only after difficult extraction is confirmed intraoperatively, because patients without difficult extraction do not require fascial extension and are not part of the study population.

7.2 Allocation Concealment

Allocation is concealed using sequentially numbered, sealed, opaque envelopes or an equivalent secure allocation system. The allocation is opened in the operating room after confirmation of difficult extraction.

7.3 Masking

The operating surgeon cannot be masked because the intervention is surgical and visible. Where feasible, postoperative pain assessment, wound assessment, and 12-month hernia assessment are performed by an outcomes assessor who is not the operating surgeon and is not informed of the assigned technique.

8. Interventions

8.1 Common Surgical Approach

All patients undergo standard laparoscopic cholecystectomy. The gallbladder specimen is removed through a 10-mm infra-umbilical midline port placed through a curved smile incision along the lower umbilical fold, with fascial entry over the linea alba. After complete gallbladder dissection and control of the cystic duct and artery, extraction is attempted through the umbilical port. If difficult extraction is confirmed, the allocated technique is applied.

8.2 Vertical Fascial Extension

In this arm, the umbilical fascial defect is extended vertically in the midline linea alba using a scalpel or scissors. The extension is limited to the minimum length required to permit specimen extraction. Decompression or stone manipulation may be performed as clinically required.

8.3 Horizontal Fascial Extension

In this arm, the umbilical fascial defect is extended transversely. The extension is limited to the minimum length required to permit specimen extraction. Decompression or stone manipulation may be performed as clinically required.

8.4 Tri-Radial Fascial Micro-Incision Technique / Tareq’s Port Extension

In this arm, three small radial micro-incisions are made at approximately the 12, 4, and 8 o’clock positions around the existing umbilical fascial defect. Each micro-incision is generally 2-4 mm and is directed radially outward. The incisions are kept within the linea alba and not extended laterally into

the rectus sheath. The intended effect is a controlled cloverleaf-shaped expansion that creates additional working space for suction, stone manipulation, and specimen retrieval. A blunt protective spacer such as a closed artery forceps may be placed between the gallbladder and the cutting instrument to reduce the risk of accidental gallbladder puncture.

8.5 Fascial Closure

After specimen extraction, the fascial defect is closed with interrupted delayed absorbable sutures according to standard surgical practice. Skin closure is performed according to surgeon preference.

9. Outcomes and Outcome Definitions

9.1 Primary Outcomes

Outcome	Definition	Time Frame
Extraction-site bleeding severity	Bleeding from the umbilical fascial extraction site categorized as minimal, moderate, or profuse according to predefined criteria.	Intraoperative, during specimen extraction
Specimen extraction time	Time in minutes from initiation of the assigned fascial extension technique to complete removal of the gallbladder specimen through the umbilical port site.	Intraoperative, during specimen extraction

9.2 Bleeding Severity Classification

Category	Operational Definition
Minimal	No active bleeding or minor oozing controlled by simple pressure, brief suction, or brief cautery without interrupting extraction.
Moderate	Active bleeding requiring additional hemostatic intervention such as repeated pressure, cautery, or focused hemostasis, but without major interruption of the extraction process.
Profuse	Brisk bleeding causing significant interruption of extraction or requiring prolonged hemostatic effort, suturing, ligation, or extension of exposure for hemostasis.

9.3 Secondary Outcomes

Outcome	Definition	Time Frame
Fascial extension length	Total length of fascial extension required to complete extraction, measured in millimeters.	Intraoperative
Postoperative pain score	Umbilical port-site pain measured by visual analog scale from 0 to 10.	24 hours after surgery
Analgesic requirement	Number of postoperative analgesic doses required within the first 24 hours.	Within 24 hours

Outcome	Definition	Time Frame
Port-site wound complications	Any port-site infection, seroma, hematoma, wound discharge, or wound dehiscence at the extraction site.	Up to 30 days
Cystic duct clip dislodgement	Any displacement or dislodgement of the cystic duct clip during specimen extraction.	Intraoperative
Port-site hernia	Clinically detected or ultrasound-confirmed hernia at the umbilical extraction site.	12 months

10. Follow-up Schedule

Visit/Time Point	Assessment
Preoperative	Eligibility screening, consent, demographic data, clinical history, planned laparoscopic cholecystectomy.
Intraoperative	Confirmation of difficult extraction, randomization, assigned intervention, bleeding severity, extraction time, fascial extension length, clip dislodgement.
24 hours	Pain score and analgesic requirement.
7-14 days	Wound assessment and early complications.
30 days	Port-site infection, seroma, hematoma, wound-related events.
6 months	Interim port-site assessment.
12 months	Clinical assessment for port-site hernia; ultrasound if clinically indicated or equivocal.

11. Safety Monitoring and Adverse Events

This study evaluates commonly used surgical variations of port-site fascial extension. The expected risks are those of standard laparoscopic cholecystectomy and port-site manipulation, including bleeding, wound infection, hematoma, seroma, pain, and port-site hernia. Adverse events are recorded from the time of randomization through the final follow-up visit.

- Any unexpected operative complication is documented in the operative record and study case report form.
- Any wound complication requiring antibiotics, drainage, readmission, or reoperation is recorded as an adverse event.
- Any port-site hernia detected during follow-up is recorded as a long-term adverse outcome.
- Serious adverse events are reported to the institutional authority according to local policy.

12. Statistical Analysis Plan

12.1 Analysis Population

The primary analysis will follow the intention-to-treat principle and include all randomized participants who receive one of the allocated fascial extension techniques. A per-protocol sensitivity analysis may be performed if there are major protocol deviations.

12.2 Descriptive Statistics

Continuous variables will be summarized as mean and standard deviation when normally distributed, or median and interquartile range when non-normally distributed. Categorical variables will be summarized as frequencies and percentages.

12.3 Primary Outcome Analysis

Extraction-site bleeding severity is an ordered categorical outcome with three levels: minimal, moderate, and profuse. The distribution of bleeding severity across the three intervention groups will be compared using chi-square testing. If expected cell counts are small, Fisher's exact test or exact methods will be used. An ordinal logistic regression model will be used to estimate the association between intervention group and higher bleeding severity, adjusting for relevant covariates.

Specimen extraction time is a continuous outcome. Between-group comparison will be performed using one-way ANOVA if assumptions are met. Tukey post hoc testing will be used for pairwise comparisons after a significant overall test. If assumptions are not met, a non-parametric Kruskal-Wallis test will be used, with appropriate pairwise comparisons.

12.4 Secondary Outcome Analysis

Fascial extension length, pain score, and analgesic requirement will be compared using ANOVA or non-parametric alternatives depending on distribution. Port-site infection, seroma, hematoma, clip dislodgement, and port-site hernia will be compared using chi-square or Fisher's exact test. Port-site hernia at 12 months will be analyzed descriptively and, if event numbers permit, by logistic regression.

12.5 Regression Models

Ordinal logistic regression will be used for bleeding severity. The model will include treatment group as the main predictor and may adjust for BMI, gallbladder neck diameter, stone size of 2 cm or more, acute cholecystitis, diabetes mellitus, and other clinically relevant covariates. Results will be reported as odds ratios with 95% confidence intervals for higher bleeding severity.

Multivariable linear regression will be used for extraction time. Covariates will include treatment group, BMI, gallbladder neck diameter, stone size of 2 cm or more, acute cholecystitis, and diabetes mellitus. Results will be reported as beta coefficients with 95% confidence intervals.

12.6 Missing Data

Every effort will be made to complete all primary and follow-up assessments. Missing data will be described by outcome and group. Complete-case analysis will be used for the main analysis if missing data are minimal. If missing data are substantial, sensitivity analysis will be considered.

12.7 Level of Significance and Software

All tests will be two-sided. A p-value less than 0.05 will be considered statistically significant. Statistical analysis will be performed using SPSS version 27.0 or a later validated statistical package.

13. Data Management and Confidentiality

Study data will be recorded in structured case report forms and transferred to a password-protected electronic database. Each participant will be assigned a study identification number. Names, hospital

registration numbers, phone numbers, and other direct identifiers will not be included in the analytic dataset. Access to the dataset will be restricted to authorized study personnel.

13.1 Individual Participant Data Sharing

De-identified individual participant data underlying the reported results may be shared upon reasonable request after publication of the main study results. Data sharing will require institutional approval and a signed data use agreement. Data will be available beginning 6 months after publication and will remain available for 5 years.

14. Ethics and Dissemination

The study will be conducted according to the principles of the Declaration of Helsinki and applicable institutional policies. All participants will provide written informed consent. The intervention arms compare accepted methods of port-site fascial expansion and a controlled radial modification intended to reduce surgical trauma. The expected risk is low and related to routine laparoscopic surgical care.

The study findings will be submitted for publication in a peer-reviewed surgical journal and may be presented at academic surgical meetings. The manuscript and any uploaded registry documents will not include identifiable patient information.

15. References

15. Strasberg SM, Hertl M, Soper NJ. An analysis of the problem of biliary injury during laparoscopic cholecystectomy. J Am Coll Surg. 1995;180(1):101-125.
16. Sgaramella LI, Gurrado A, Pasculli A, de Angelis N, Memeo R, Prete FP, et al. The critical view of safety during laparoscopic cholecystectomy. JSLS. 2020;24(4):e2020.00065.
17. Majid MH, Meshkat B, Kohar H, El Masry S. Specimen retrieval during elective laparoscopic cholecystectomy: is it safe not to use a retrieval bag? BMC Surg. 2016;16:64.
18. Mohamed HK, Abdelkhalek M, El Nakeeb A, et al. A systematic review and meta-analysis of bag extraction versus direct extraction for retrieval of gallbladder after laparoscopic cholecystectomy. Cureus. 2023;15(2):e35550.
19. Swank HA, Mulder IM, la Chapelle CF, Reitsma JB, Lange JF, Bemelman WA. Systematic review of trocar-site hernia. Br J Surg. 2012;99(3):315-323.
20. Owens M, Barry M, Janjua AZ, Winter DC. A systematic review of laparoscopic port-site hernias in gastrointestinal surgery. Surgeon. 2011;9(4):218-224.
21. Schulz KF, Altman DG, Moher D; CONSORT Group. CONSORT 2010 Statement: updated guidelines for reporting parallel group randomized trials. BMJ. 2010;340:c332.
22. Moher D, Hopewell S, Schulz KF, Montori V, Gotzsche PC, Devereaux PJ, et al. CONSORT 2010 Explanation and Elaboration: updated guidelines for reporting parallel group randomized trials. BMJ. 2010;340:c869.
23. La Regina D, Mongelli F, Cafarotti S, Saporito A, Ceppi M, Di Giuseppe M, et al. Use of retrieval bag in the prevention of wound infection in elective laparoscopic cholecystectomy: a meta-analysis. BMC Surg. 2018;18(1):102.