

Study Protocol

Official Study Title

Comparison of Linear Versus Purse-String Skin Closure at Loop Ileostomy Reversal: A Randomized Controlled Trial

Brief Title

Comparison of Linear Versus Purse-String Skin Closure at Loop Ileostomy Reversal

ClinicalTrials.gov Identifier

NCT Number: Not yet Assigned

Unique Protocol ID HMC-QAD-RCT-3

Study Type Randomized Controlled Trial (RCT)

Study Sponsor / Conducting Institution Hayatabad Medical Complex (HMC)
Peshawar, Pakistan

Responsible Party: Principal Investigator

Principal Investigator: Dr. Gohar Ali Principal Investigator Department of Surgery Hayatabad Medical Complex, Peshawar, Pakistan

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Ethics Approval: Approved by Ethical Committee, Hayatabad Medical Complex, Peshawar Approval Number: HMC-QAD-F No. IREB-1680

Recruitment & Study Duration:

- **Estimated Enrollment:** 252 participants
- **Study Start Date:** June 2020
- **Primary Completion Date:** July 2025
- **Study Completion Date:** July 31, 2024

Study document date: May 5, 2020

1. Title

Comparison of Linear Versus Purse-String Skin Closure at Loop Ileostomy Reversal: A Randomized Controlled Trial

2. Background

Loop ileostomy reversal is a commonly performed surgical procedure for restoration of intestinal continuity. Although considered a minor operation, it is frequently associated with postoperative complications, particularly surgical site infection (SSI), which remains one of the most significant causes of morbidity.

Reported SSI rates following stoma closure vary widely from 4% to more than 20%. This variation is influenced by patient factors, bowel contamination, and surgical technique. Therefore, optimizing skin closure technique is essential to improve outcomes.

Two commonly used techniques are linear closure and purse-string closure. Linear closure involves primary approximation of skin edges, whereas purse-string closure allows partial opening for drainage, which may reduce bacterial accumulation and infection risk. However, evidence comparing these techniques remains variable, and no consensus exists regarding the optimal method.

3. Objectives

Primary Objective

To compare the incidence of surgical site infection (SSI) between linear and purse-string skin closure following loop ileostomy reversal.

Secondary Objectives

- To compare length of hospital, stay between both techniques
- To compare duration of surgery between both techniques
- To assess postoperative recovery outcomes

4. Study Design

- Study Type: Interventional (Clinical Trial)
- Study Design: Randomized Controlled Trial
- Allocation: Randomized
- Intervention Model: Parallel Assignment
- Masking: Open Label
- Primary Purpose: Treatment
- Study Setting: Single-center (Department of General Surgery, MTI-Hayatabad Medical Complex, Peshawar)

5. Study Population

Patients undergoing elective loop ileostomy reversal fulfilling inclusion criteria.

6. Eligibility Criteria

Inclusion Criteria

- Age 20–70 years
- Both genders
- ASA physical status I–II
- Elective loop ileostomy reversal patients
- Informed consent provided

Exclusion Criteria

- Active stoma site infection
- Emergency reversal cases
- ASA III or higher
- Patients refusing participation
- Inability to complete follow-up

7. Sample Size

A total of **252 patients** were included (126 in each group).

Sample size was calculated using expected SSI proportions from previous literature with 95% confidence and 80% power.

8. Randomization

Patients were allocated into two groups using **block randomization**:

- Group A: Linear skin closure
- Group B: Purse-string skin closure

Allocation was concealed prior to intervention.

9. Interventions

Group A: Linear Skin Closure

Conventional primary closure of the ileostomy reversal wound using interrupted or continuous suturing with complete approximation of skin edges.

Group B: Purse-String Skin Closure

Skin closure performed using purse-string technique, leaving a small central opening for drainage to reduce wound contamination.

10. Outcome Measures

Primary Outcome

- Surgical Site Infection (SSI) within **30 days after surgery**

Secondary Outcomes

- Length of hospital stay (days from surgery to discharge)
- Duration of surgery (minutes from incision to closure)

11. Data Collection

Data were collected using a structured proforma. Variables included:

- Demographics (age, gender, BMI)
- Comorbidities (diabetes, hypertension)
- ASA score
- Operative details
- Postoperative outcomes

Patients were followed during hospital stay and for **30 days postoperatively**.

12. Statistical Analysis

Data were analyzed using SPSS version 23.

- Continuous variables: mean \pm SD
- Categorical variables: frequency and percentages
- Independent t-test: comparison of means
- Chi-square test: comparison of proportions
- P value <0.05 considered statistically significant

13. Ethical Considerations

Ethical approval was obtained from the Institutional Review Board of MTI-Hayatabad Medical Complex, Peshawar. Informed consent was obtained from all participants. Patient confidentiality was strictly maintained.

14. Dissemination Plan

Results will be published in peer-reviewed surgical journals and presented at national and international conferences to improve evidence-based surgical practice.

15. Study Significance

This study aims to provide high-quality evidence regarding the optimal skin closure technique in loop ileostomy reversal. The findings may help reduce postoperative complications, improve wound healing, and optimize patient outcomes.

16. References:

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2. Gonzalez DO, Ambeba E, Minneci PC, Deans KJ, Nwomeh BC. Surgical site infection after stoma closure in children: outcomes and predictors. *J Surg Res.* 2017 Mar;209:234–41.
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11. Khokhar MA, Ahmad A, Rehman IU, Imtiaz T, Najeeb E, Haq MBU, et al. Outcomes of Purse-string versus Conventional Linear Suture Closure of the Skin Wound Following Ileostomy Reversal. *Journal of Islamabad Medical & Dental College.* 2024 Apr 15;13(1):137–42.

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