Study Protocol

Official Study Title

Comparison of Vicryl Versus Prolene for Midline Rectus Sheath Closure After Elective Laparotomy

Brief Title

Comparison of Vicryl Versus Prolene for Midline Rectus Sheath Closure

ClinicalTrials.gov Identifier
NCT Number: *Not yet assigned*

Unique Protocol ID
HMC-RECTUS-2019

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

Study Document
Study Protocol

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

Recruitment & Study Duration:

- **Estimated Enrollment:** 152 participants
- **Study Start Date:** April 2024
- **Primary Completion Date:** October 2024
- **Study Completion Date:** October 2024

Study document date: May 5, 2024

Comparison of Vicryl Versus Prolene for Midline Rectus Sheath Closure After Elective Laparotomy

Brief Summary:
This study aims to compare the incidence of surgical site complications, including Surgical site infections (SSI) and wound dehiscence following midline rectus sheath closure using either polyglactin 910 (Vicryl®) or polypropylene (Prolene®) in elective laparotomy. The study will evaluate outcomes over a 30-day postoperative follow-up period.

Objectives:

- **Primary Objective:**
  To compare the **rate of SSI** between patients undergoing midline rectus sheath closure with **Vicryl® versus Prolene® sutures**.
- **Secondary Objectives:**
  To compare the Incidence of Wound dehiscence within 30 days
  Postoperative pain**,** assessed using the Visual Analog Scale (VAS).
  Other complications.

Background & Rationale:
Abdominal wall closure technique and choice of suture material play a crucial role in determining postoperative outcomes following laparotomy. Previous studies have reported variable rates of SSI and wound dehiscence and others complications depending on the type of suture material used. However, evidence remains inconsistent regarding the optimal suture choice for elective midline laparotomy closure.

This randomized controlled trial is designed to evaluate whether Vicryl® (delayed absorbable) or Prolene® (non-absorbable) sutures provide superior clinical outcomes, thereby guiding evidence-based surgical practice.

Study Design:

- Interventional, randomized, parallel-group, open-label clinical trial study.
- Allocation: Randomized 1:1 to either Vicryl® or Prolene®.
- Number of Arms: 2

Arms & Interventions:

1. **Vicryl Arm:** Midline rectus sheath closure performed using **polyglactin 910 (Vicryl®)** suture with a **continuous mass closure technique**.
2. **Prolene Arm:** Midline rectus sheath closure performed using polypropylene (Prolene®) suture with a continuous mass closure technique.

Outcome Measures:

- **Primary Outcome:** SSI within 30 days postoperatively.
- **Secondary Outcomes:** Incidence of wound dehiscence, postoperative pain (VAS scale), incidence of incisional hernia at 30 days.

Eligibility Criteria:

Inclusion Criteria:

- Age 18 to 70 years
- Patients undergoing elective midline laparotomy
- Ability to provide written informed consent

Exclusion Criteria:

- Emergency laparotomy
- Previous abdominal mesh placement
- Immunocompromised patients
- Pregnant women

Ethics:

- Approved by Institutional Review Board, HMC (HMC-QAD-F No. IREB-1680)
- Written informed consent obtained from all participants

Data Management:

- Data recorded in secured database and standardized proforma
- Patient identifiers removed for any shared datasets.
- SPSS V23. Is used for data entry.

References:

1. Kunju RD, Thakkannavar V, K SM, G SH, Netto A, J S, et al. A clinical study of continuous and interrupted fascial closure in emergency midline laparotomy at a tertiary care centre. International Surgery Journal. 2017 May 24;4(6):2014–7.

2. Frassini S, Cobianchi L, Fugazzola P, Biffl WL, Coccolini F, Damaskos D, et al. ECLAPTE: Effective Closure of LAParoTomy in Emergency—2023 World Society of Emergency Surgery guidelines for the closure of laparotomy in emergency settings. World Journal of Emergency Surgery. 2023 July 26;18(1):42.

3. Lakshmi G, Ravimohan TR. Post Laparotomy Abdominal Wound Dehisence – A Study in Tertiary Care Hospital. IJCMR [Internet]. 2018 Nov [cited 2025 Nov 5];5(11). Available from: https://www.ijcmr.com/uploads/7/7/4/6/77464738/ijcmr_2208_v1.pdf

4. Usman Ali Rahman, Muhammad Adil Iftikhar, Mohammad Zia Ul Miraj, Maliha Javaid Butt, Iftikhar Ahmed, Humaira Yousaf. Incidence of wound dehischence and factors causing wound dehiscence in patients undergoing laparotomy in a newly established surgery department at a tertiary care hospital. TPMJ. 2023 Oct 5;30(10):1225–9.

5. Alam I, Amin S, Iqbal S, Samad M, Tahir R. THE FREQUENCY OF WOUND DEHISCENCE IN ADULTS UNDERGOING MIDLINE EXPLORATORY LAPAROTOMY IN A TERTIARY CARE HOSPITAL IN PESHAWAR. NORTHWEST JOURNAL OF MEDICAL SCIENCES [Internet]. 2025 Sept 30 [cited 2025 Nov 4];4(3). Available from: https://njms.pk/index.php/njms/article/view/595

6. Akbar F, Khan M, Ahmad N, Abbas S, Khan N. Comparison of Laparotomy Wound Dehiscence (LWD) Rate Using Interrupted X-Suture Technique vs Continuous Suture Technique in Rectus Sheath in Emergency Laparotomy. Journal of Saidu Medical College Swat. 2021;11(3):133–6.

7. Walming S, Angenete E, Block M, Bock D, Gessler B, Haglind E. Retrospective review of risk factors for surgical wound dehiscence and incisional hernia. BMC Surg. 2017 Feb 22;17(1):19.

8. Helgeland J, Tomic O, Hansen TM, Kristoffersen DT, Hassani S, Lindahl AK. Postoperative wound dehiscence after laparotomy: a useful healthcare quality indicator? A cohort study based on Norwegian hospital administrative data. BMJ Open. 2019 Apr 3;9(4):e026422.

9. Patel SV, Paskar DD, Nelson RL, Vedula SS, Steele SR. Closure methods for laparotomy incisions for preventing incisional hernias and other wound complications. Cochrane Database Syst Rev. 2017 Nov 3;11(11):CD005661.

10. Huang Q, Li J, Lau WY. Techniques for Abdominal Wall Closure after Damage Control Laparotomy: From Temporary Abdominal Closure to Early/Delayed Fascial Closure-A Review. Gastroenterol Res Pract. 2016;2016:2073260.

11. Diener MK, Voss S, Jensen K, Büchler MW, Seiler CM. Elective midline laparotomy closure: the INLINE systematic review and meta-analysis. Ann Surg. 2010 May;251(5):843–56.

12. Fortelny RH. Abdominal Wall Closure in Elective Midline Laparotomy: The Current Recommendations. Front Surg. 2018;5:34.

13. Pandey S, Singh M, Singh K, Sandhu S. A Prospective Randomized Study Comparing Non-absorbable Polypropylene (Prolene®) and Delayed Absorbable Polyglactin 910 (Vicryl®) Suture Material in Mass Closure of Vertical Laparotomy Wounds. Indian J Surg. 2013 Aug;75(4):306–10.

14. Declaration of Helsinki. In: Wikipedia [Internet]. 2025 [cited 2025 Aug 23]. Available from: https://en.wikipedia.org/w/index.php?title=Declaration_of_Helsinki&oldid=1305632486

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