Study Protocol

Comparison of the effect of erector spinae plane block versus perioperatively extrapleurally inserted catheter in postoperative pain control in minimally invasive cardiac surgery

1. Background and Rationale

Minimally invasive cardiac surgery aims to achieve early postoperative recovery and reduced hospital stay. However, thoracotomy-related pain can be substantial and may impair respiratory function and recovery. Regional analgesia techniques have therefore become an important component of enhanced recovery protocols in cardiac surgery.

The erector spinae plane block (ESPB) is a regional anesthesia technique providing multisegmental analgesia of the chest wall. In our institution, extrapleural analgesia (EPA) with a catheter inserted between the parietal pleura and the endothoracic fascia is routinely used. This study aims to compare these two techniques in patients undergoing minimally invasive coronary artery bypass surgery.

2. Objectives

The primary objective of this study is to compare postoperative pain intensity between continuous erector spinae plane block and extrapleural catheter analgesia in patients undergoing minimally invasive cardiac surgery.

3. Study Design

This is a prospective, single-center randomized controlled clinical trial conducted in accordance with the Declaration of Helsinki.

4. Study Population

Inclusion Criteria

• Age 18–70 years

• Scheduled for minimally invasive direct coronary artery bypass (MIDCAB) via thoracotomy

Exclusion Criteria

• BMI <18 or >30 kg/m^2

• Emergency or redo surgery

• Contraindication to regional anesthesia

• Psychiatric disorder

• Opioid addiction

• Chronic or neuropathic pain

• Patient refusal

5. Randomization and Blinding

Participants will be randomized in a 1:1 ratio to one of two postoperative analgesia strategies. The allocation sequence will be generated using computer-based random number generation with permuted blocks of variable size (4 and 8). Allocation concealment will be ensured using sequentially numbered opaque sealed envelopes opened only after written informed consent.

Participants and investigators responsible for outcome assessment will be blinded to treatment allocation.

6. Interventions

Group 1 – ESPB

A catheter will be inserted under ultrasound guidance into the erector spinae plane prior to induction of general anesthesia. Local anesthetic will be administered via the catheter perioperatively and postoperatively.

Group 2 – Extrapleural Analgesia

A catheter will be inserted by the surgeon between the parietal pleura and the endothoracic fascia before thoracotomy closure and used for continuous postoperative administration of local anesthetic.

7. Perioperative Management

All patients will undergo standardized general anesthesia and postoperative multimodal analgesia including paracetamol, metamizole and patient-controlled intravenous morphine.

8. Outcomes

Primary Outcome

Numerical Rating Scale (NRS) pain score at the surgical incision site 6 hours after the end of surgery.

Secondary Outcomes

- NRS pain scores at multiple postoperative time points
- Pain at chest tube insertion site
- Postoperative opioid consumption
- Spirometry parameters (FVC, FEV1)
- Incidence of postoperative nausea and vomiting
- Time to extubation
- ICU and hospital length of stay
- Block-related complications and adverse events

9. Sample Size Calculation

The planned sample size is 80 participants (40 in each study arm). The calculation was based on detecting a clinically meaningful difference in postoperative pain intensity between groups measured using the Numerical Rating Scale (NRS). A two-sided significance level of 0.05 and statistical power of 80% were assumed. This sample size also allows for potential dropout or protocol deviations.

10. Statistical Analysis

Continuous variables will be presented as mean ± standard deviation or median (interquartile range) depending on data distribution. Categorical variables will be presented as counts and percentages.

Between-group comparisons for continuous variables will be performed using the Student t-test or Mann–Whitney U test as appropriate. Categorical variables will be compared using the chi-square test or Fisher's exact test.

Repeated pain measurements over time will be analysed using repeated-measures analysis of variance or mixed-effects models as appropriate. A p-value <0.05 will be considered statistically significant.

11. Data Management

All collected data will be recorded in anonymised case report forms and stored in a secure institutional database. Participants will be identified only by a study-specific identification code. Access to the study database will be restricted to authorised study personnel.

Data will be handled in accordance with institutional policies and applicable data protection regulations. Only anonymised aggregated data will be used for statistical analysis and publication.

12. Ethics

The study was approved by the Ethics Committee of the General University Hospital in Prague (reference number 199/25 S-IV). All participants will provide written informed consent before enrolment.

13. Trial Registration

The study is registered in the ISRCTN clinical trial registry.