Comparison of Combined Ultrasound-Guided Serratus Posterior Superior Plane and Transversus Thoracic Plane Blocks versus Conventional Analgesia for Postoperative Pain Control Following Coronary Artery Bypass Grafting: A Randomized Controlled Trial

Brief Title: Combined SPSP and TTP Blocks vs. Conventional Analgesia for Post-CABG Analgesia

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What is already known on this subject? AND

What does this study add?

Effective postoperative pain management after coronary artery bypass grafting (CABG) remains a clinical challenge. Inadequate analgesia is associated with poor respiratory function, delayed mobilization, and prolonged ICU/hospital stay. Systemic opioids — while widely used — carry risks of respiratory depression, nausea, vomiting, and delirium. Ultrasound-guided fascial plane blocks, including the **serratus posterior superior plane (SPSP) block** and the **transversus thoracic plane (TTP) block**, have each been studied as opioid-sparing adjuncts in thoracic surgery. Their **combined bilateral use in cardiac surgery** has not been evaluated in a prospective randomized trial.

This randomized controlled trial provides the first prospective Level I evidence for combined bilateral SPSP and TTP blocks in CABG. It quantifies **opioid-sparing effects**, **respiratory outcomes**, **hemodynamic stability**, and the early **recovery profile**, potentially establishing a multimodal regional strategy as a safer and more effective alternative to conventional opioid-based analgesia in this population.

INTRODUCTION

Coronary artery bypass grafting (CABG) requires a median sternotomy, which is associated with significant acute postoperative pain. Poorly controlled pain activates the sympathoadrenal axis, raising blood pressure, heart rate, and myocardial oxygen demand, and may precipitate postsurgical bleeding, myocardial ischemia, and hemodynamic instability [1]. Thoracic splinting and hypoventilation compound the problem, contributing to delayed tracheal extubation, extubation failure, reintubation, and respiratory complications that prolong ICU and hospital stay [1]. Persistent inadequate analgesia is also directly linked to the development of chronic post-sternotomy pain syndrome (PSPS), which affects 20–50% of CABG survivors [2].

Conventional pain management relies primarily on systemic opioids; however, these carry well-recognized adverse effects including respiratory depression, nausea, vomiting, ileus, urinary retention, and delirium. The modern fast-track cardiac anesthesia paradigm targeting extubation

within four to six hours of ICU admission has further exposed the limitations of opioid-centric regimens [3]. Neuraxial techniques such as thoracic epidural analgesia offer excellent pain control but carry a disproportionate risk of spinal hematoma in patients requiring full intraoperative anticoagulation, making them unsuitable for routine use in cardiac surgery [4].

Ultrasound-guided fascial plane blocks have therefore gained considerable traction as opioid-sparing adjuncts. The serratus posterior superior plane (SPSP) block targets the fascial plane deep to the rhomboid muscles overlying the serratus posterior superior muscle at the T2–T5 level; cadaveric dye studies have demonstrated consistent spread from C7 to T7, and clinical use has reported dermatomal blockade spanning the hemithorax [5]. The transversus thoracic plane block (TTPB) deposits local anesthetic into the fascial plane between the transversus thoracic muscle and the internal intercostal muscles, blocking the anterior cutaneous branches of T2–T6 and providing direct parasternal analgesia relevant to sternotomy incision pain [6,7].

Sternotomy-related pain encompasses both anterior (parasternal incision) and lateral components (chest drain sites, graft harvest sites). Neither block in isolation addresses both anatomical territories. Combining bilateral SPSP and TTP blocks could achieve comprehensive anterior and lateral chest wall coverage, potentially reducing opioid requirements and associated adverse effects. To date, however, this combination has not been evaluated in a prospective randomized trial in cardiac surgery. The present study tests the hypothesis that combined bilateral SPSP and TTP blocks are superior to conventional systemic analgesia alone in reducing postoperative opioid consumption after elective isolated CABG [8].

AIM OF THE WORK

To evaluate the efficacy of combined bilateral ultrasound-guided serratus posterior superior plane (SPSP) and transversus thoracic plane (TTP) blocks compared with conventional systemic analgesia for postoperative opioid-sparing analgesia in adults undergoing elective isolated coronary artery bypass grafting (CABG).

PATIENTS AND METHODS:

Type of study: A prospective, patient and outcome-assessor-blinded, randomized, controlled clinical trial, conducted in accordance with the Consolidated Standards of Reporting Trials (CONSORT) 2010 guidelines.

Study setting: After obtaining approval from the medical ethical committee in Ain Shams University and anaesthesia department Review Board (IRB) and after obtaining a written informed consent with explaining procedures, this study will be conducted in Cardiothoracic Academy Ain Shams University Hospitals. All patient data will be kept confidential.

Study period: Six months or until recruitment of the sample population.

Study Population:

Inclusion Criteria:

1. Adults aged 18–75 years.
2. Patients scheduled for elective isolated coronary artery bypass grafting (CABG).
3. American Society of Anesthesiologists (ASA) physical status III.
4. Ability to understand the study, provide written informed consent, and reliably report the numeric rating scale (NRS).

- **Exclusion Criteria:**

1. Emergency surgery or hemodynamic instability preoperatively.
2. Known allergy to local anesthetics or study medications.
3. Coagulopathy or uncontrolled bleeding risk or therapeutic anticoagulation that cannot be safely withheld per institutional guidelines.
4. Local infection or cellulitis at injection sites on anterior or lateral chest walls.
5. Pre-existing chronic pain syndromes requiring daily opioids or chronic opioid use/dependence.
6. Significant cognitive impairment, severe psychiatric disorder, or inability to reliably use pain scales.
7. History of prior thoracic surgery or major chest wall deformity that would distort anatomy or limit ultrasound window for blocks.
8. Pregnancy or breastfeeding.
9. Known contradiction for study participation as judged by the investigator (e.g., allergy to study adjuncts, anticipated need for prolonged postoperative sedation/ventilation).

10. Any other condition judged by the investigator to represent unacceptable risk or preclude study participation.
11. Patient refusal or withdrawal of consent.

Sample size:

Sample size was calculated using PASS 15 (NCSS, LLC; v15.0.10). Based on data from Shokri et al. [8] reporting median NRS pain scores at 24 hours of 2 [IQR 0–4] in the TTPB group versus 4 [IQR 0–4] in controls following cardiac surgery via median sternotomy, and applying the corresponding effect size to the primary endpoint of total opioid consumption at 24 h with a two-sided $\alpha = 0.05$ and 80% power, a minimum of 34 patients per group is required. Accounting for a 12% anticipated dropout/protocol-deviation rate, the target enrolment is 38 patients per group (n = 76 total). Accounting for a 15% dropout rate (to allow for block failure, protocol violations, or loss to follow-up), the final target sample size is 88 patients (44 per group).

Before first enrollment, the target sample size was expanded a priori to 50 patients per group (n = 100 total) to accommodate possible technical block failure and to improve precision of secondary outcome estimates. This provides approximately 91% power under parametric assumptions for the primary endpoint.

Randomization and blinding

Randomization

Eligible consenting participants will be randomized 1:1 to either the intervention group (combined bilateral SPSP + TTP blocks plus standardized analgesia) or the control group (standardized analgesia only), using a computer-generated permuted block sequence (block sizes of 4 and 6, randomly mixed) prepared by a statistician not involved in patient care or outcome assessment. Allocation concealment will be ensured by sequentially numbered, opaque, sealed envelopes (SNOSE). Envelopes will be opened in the preoperative area by the performing anesthesiologist immediately before the intervention, after induction of general anesthesia.

Blinding

Patients are inherently blinded, as blocks are performed under general anesthesia. All outcome assessors (ICU nursing staff, physiotherapists, data collectors, and statisticians) are blinded to group allocation and access only coded data. All study syringes and preparations are labelled "Study Injection" and handled solely by the performing anesthesiologist, who is the only unblinded individual and takes no part in postoperative outcome assessment, data collection, or analysis. The surgical team is not informed of group allocation; no local wound infiltration is

permitted in either group.

Study Interventions:

The study comparing the combination to systemic medications and not to separate administration?

Rationale:

Clinical Gap: While each block has been studied individually in thoracic and cardiac surgery, their combined use for comprehensive anterior and lateral chest wall coverage in CABG patients is underexplored.

Physiological Rationale: Sternotomy pain involves both anterior (parasternal) and lateral (harvest site, chest drains) components. Neither block alone covers both fully.

Comparative Clinical Relevance: The standard of care in many cardiac centers remains systemic opioid-based analgesia. To change practice, we must demonstrate superiority of the combined regional approach over current standard care, not just over single blocks.

Feasibility & Safety: Our study aims to provide Level I evidence for a multimodal regional strategy as a viable alternative to conventional opioid-based regimen.

Preoperative Assessment

Eligibility will be confirmed and written informed consent obtained during the preoperative clinic visit (24–72 h before surgery). Baseline comorbidities, current medications (including chronic opioids, anticoagulants, and antiplatelets with last dose date/time), allergy history, ASA status, and relevant laboratory values will be documented. Anticoagulant or antiplatelet agents will be withheld according to institutional guidelines, and coagulation parameters (INR ≤ 1.5; platelets $\geq 100 \times 10^9$/L) confirmed before proceeding with blocks.

Block Timing

Blocks will be performed after induction of general anesthesia and endotracheal intubation, *but before surgical skin preparation*. This timing (i) maintains patient blinding, (ii) allows block distribution before incision, and (iii) is clinically acceptable within the routine anesthesia

induction-to-incision interval in elective CABG, which commonly includes invasive line placement and transesophageal echocardiography. Total added block time is estimated at 20–30 minutes; this does not compromise surgical outcomes in elective cases.

Resuscitation Preparedness

Before initiating any block: active standard monitoring (ECG, NIBP, SpO_2), invasive arterial line monitoring, at least one large-bore IV cannula in situ, and Intralipid 20% with full resuscitation equipment at the bedside.

Ultrasound Equipment

Device: GE Vivid iq R3 Premium. Probe: high-frequency linear transducer (6–13 MHz). Sterile probe cover and sterile gel required. An in-plane needle approach is mandatory to maintain continuous visualization of the needle tip throughout injection.

Local Anesthetic Preparation and Dose Safety

Bupivacaine 0.25% plain (2.5 mg/mL) will be used for all blocks. The total dose must not exceed **2.5 mg/kg** without adrenaline. Dose must be calculated by patient weight before starting any block.

Standard bilateral dosing (patient weight ≥ 65 kg):

- TTP block (bilateral): 15 mL/side × 2 sides = 30 mL × 2.5 mg/mL = **75 mg bupivacaine**
- SPSP block (bilateral): 15 mL/side × 2 sides = 30 mL × 2.5 mg/mL = **75 mg bupivacaine**
- Combined total: 60 mL × 2.5 mg/mL = **150 mg bupivacaine**
- Safety check at 70 kg: 150 ÷ 70 = 2.14 mg/kg ✓ | at 65 kg: 150 ÷ 65 = 2.31 mg/kg ✓

Dose adjustment for patients < 65 kg: Reduce to 12 mL per site (total 48 mL × 2.5 mg/mL = 120 mg). For a 60 kg patient: 120 ÷ 60 = 2.0 mg/kg ✓. Alternatively, reduce concentration to 0.2% bupivacaine (2.0 mg/mL) at the same volumes. All dose calculations must be documented on the block record.

Block Techniques

A. Bilateral Transversus Thoracic Plane (TTP) Block

Purpose: Parasternal analgesia for sternotomy incision pain by blocking the anterior cutaneous branches of T2–T6 [7].

- Positioning: Supine. Anterior chest wall bilaterally exposed.
- Ultrasound landmarks: Parasternal region. Identify pectoralis major (superficial), internal intercostal muscle, and transversus thoracic muscle (deep to internal intercostal). Parasternal short-axis scan at the 2nd–4th intercostal space level.
- Needle: 22G, 50–80 mm echogenic block needle. In-plane approach (medial-to-lateral or lateral-to-medial, per operator preference).
- Injection: After negative aspiration and a 1 mL test dose, deposit **15 mL of 0.25% bupivacaine per side** in 3–5 mL increments with intermittent aspiration, confirming fascial spread (downward displacement of the pleura). Repeat on the contralateral side

B. Bilateral Serratus Posterior Superior Plane (SPSP) Block

Purpose: Analgesia of the lateral and posterolateral thoracic wall (lateral cutaneous branches of T2–T5), complementing the parasternal TTP block to achieve comprehensive bilateral chest wall coverage. In CABG, this addresses pain from chest drain sites and, where applicable, graft harvest sites [5].

- Positioning: Slight lateral tilt (15–20°) to expose the posterolateral thorax. Complete one side, then reposition for the contralateral side.
- Ultrasound landmarks: Identify trapezius (superficial), rhomboid major/minor, and the fascial plane deep to the rhomboids overlying the serratus posterior superior muscle at the T2–T5 vertebral level.
- Needle: 22G, 50–80 mm echogenic needle. In-plane lateral-to-medial approach.
- Injection: After negative aspiration and a 1 mL test dose, deposit **15 mL of 0.25% bupivacaine per side** incrementally, confirming fascial spread under continuous ultrasound guidance. Repeat on the contralateral side

Safe Injection Technique (Both Blocks)

- Aspirate before each 3–5 mL increment.
- Inject slowly (≤ 0.5 mL/second).
- Monitor ECG and invasive arterial pressure continuously throughout injection.
- Immediately stop injection and initiate the LAST protocol on any sign of intravascular injection.

Block Documentation

For each block performed, record: approach, level, side, needle gauge and length, total LA volume and concentration, total bupivacaine dose (mg and mg/kg), time of block completion, ultrasound image quality score, and any immediate complications.

Control Group: Conventional Systemic Analgesia

- Scheduled intravenous paracetamol 1 g every 6 hours from ICU arrival.
- Continuous intravenous fentanyl infusion commenced at 0.5 μg/kg/h once the patient emerges from anesthesia and NRS assessment becomes feasible. The infusion is weaned by 25% every hour prior to planned extubation and discontinued at extubation.
- Rescue intravenous morphine 2–3 mg every 10 minutes when NRS ≥ 4, titrated to NRS ≤ 3. Additional 1–2 mg boluses as required. Morphine withheld in the presence of excessive sedation, respiratory depression, or hemodynamic instability.

The continuous fentanyl infusion + rescue morphine regimen is applied identically in both groups. The sole difference is the presence or absence of the regional blocks. No additional regional blocks or surgeon-performed local wound infiltration are permitted in either group.

Standardized Intraoperative Management (Both Groups)

- Induction: Fentanyl 5–10 μg/kg, propofol (weight-adjusted), atracurium for neuromuscular blockade.
- Maintenance: Sevoflurane to target MAC; volatile agent concentration documented continuously.
- Hemodynamic goals: MAP 65–80 mmHg; vasopressors per institutional routine.
- Cardiopulmonary bypass: Managed per institutional protocol. On-pump vs. off-pump status, cross-clamp time, and total bypass time will be recorded as potential confounders.

• Total intraoperative opioid dose will be documented and converted to MME.

Monitoring and Safety

General Monitoring

- Continuous pulse oximetry (SpO_2) with active alarms throughout ICU stay.
- Continuous 5-lead ECG monitoring.
- Invasive arterial line for real-time blood pressure monitoring (placed before block performance).
- Sedation assessed every hour for the first 24 hours using the Richmond Agitation-Sedation Scale (RASS); thereafter per ICU routine.

Local Anesthetic Systemic Toxicity (LAST) Prevention and Management

All blocks will be performed by certified anesthesiologists with extensive ultrasound-guided regional anesthesia experience. The following LAST management protocol (per ASRA-ESRA guidelines) must be immediately accessible at the bedside:

- Stop injection immediately upon any suspicion.
- Airway management and high-flow oxygen.
- Seizure control: benzodiazepines (e.g. midazolam 2–5 mg IV).
- Intralipid 20%: bolus 1.5 mL/kg over 1 min; continuous infusion 0.25 mL/kg/min; repeat bolus if cardiovascular instability persists (maximum ~10 mL/kg in the first 30–60 min).
- Advanced cardiac life support.

Block-Related Complication Monitoring

- Pneumothorax: Post-block chest auscultation and continuous SpO_2 monitoring. Bedside lung ultrasound for any new desaturation or respiratory distress; chest X-ray if lung ultrasound is equivocal.
- Hematoma: Inspection of all block sites at 30 min, 6 h, and 24 h post-procedure.
- Infection: Strict aseptic technique throughout. Monitor for localized erythema, warmth, swelling, and discharge at all puncture sites for the duration of hospital stay.

Study outcomes:

Primary Endpoint

Total postoperative opioid consumption (intravenous morphine milligram equivalents, MME) accumulated in the first **48 hours after tracheal extubation**.

Secondary Endpoints

- NRS pain scores (0–10) at rest and on movement/coughing at: extubation (0 h), 6 h, 12 h, 24 h, and 48 h post-extubation.
- Time to first rescue analgesic (minutes from extubation).
- Time to tracheal extubation (minutes from end of surgery).
- PaO_2/FiO_2 ratio at 6 h and 24 h post-extubation.
- Incentive spirometry volume: Volume achieved with incentive spirometry in milliliters at 24 and 48 hours post-extubation. Assessed by a blinded physiotherapist or nursing staff using standardized technique.
- Incidence of pulmonary complications (atelectasis, pneumonia, reintubation) during hospital stay.
- ICU length of stay (hours from ICU admission to ICU discharge).
- Total hospital length of stay (days from surgery to discharge).
- Patient satisfaction with pain management at 48 h (Likert scale 1–5).
- Time to first ambulation (hours from extubation).

Safety Outcomes

- Block-related complications: pneumothorax, local hematoma, infection, nerve injury.
- Signs of LAST: CNS (tinnitus, circumoral numbness, metallic taste, agitation, seizure) and/or cardiovascular (arrhythmia, hypotension, cardiac arrest).
- Severe opioid-related adverse events: respiratory depression requiring naloxone, severe nausea/vomiting, delirium.

Assessment Timepoints

- Baseline: preoperative clinic visit, 24–72 h before surgery.
- Intraoperative: induction to end of surgery (including CPB period).

- Early postoperative/ICU: extubation (0 h), 6 h, 12 h, 24 h, and 48 h post-extubation.
- Hospital course: until discharge (ICU LOS, total hospital LOS, complications).

Variables Collected

Baseline/demographics: Study ID, randomization arm, age, sex, BMI, ASA class, comorbidities, current medications (chronic opioids, anticoagulants/antiplatelets with last dose date/time), baseline laboratory values.

Block-related data (intervention group only): Total bupivacaine volume, concentration, and dose (mg and mg/kg); approach, level, and side per block; block performance time; ultrasound image quality score; immediate complications.

Intraoperative data (both groups): Induction agents and doses; total intraoperative opioid dose (MME); on-pump/off-pump status; cross-clamp time; total bypass time; number of hypotension episodes requiring vasopressors; total vasopressor doses; time to ICU arrival.

Postoperative data (both groups): All primary and secondary outcomes listed in Section 6, recorded by blinded ICU nursing staff and data collectors using standardized case report forms (CRFs).

Data Management

Data will be entered into a secure, password-protected electronic database. Source documents will be retained at the study site for a minimum of 10 years. Patient identifiers will be replaced with unique study codes in the analysis dataset. Access will be restricted to authorized study personnel only. Serious adverse events will be reported to the REC within 24 hours of identification.

Statistical analysis:

Analysis Sets

- **Intention-to-treat (ITT):** All randomized participants analyzed according to their allocated group, regardless of protocol adherence. This is the primary analysis.
- **Per-protocol (PP):** Participants completing the study without major protocol deviations (e.g. failed or aborted block, crossover, missing primary outcome).

Restricted to patients with confirmed successful sensory blockade.

Primary Endpoint Analysis

Total **48-hour** postoperative opioid consumption (MME). Normality will be assessed by the Shapiro-Wilk test. The primary comparison will use the Mann-Whitney U test (Hodges-Lehmann median difference with 95% CI). An exploratory ANCOVA adjusting for intraoperative opioid consumption will be performed as a sensitivity analysis. Results will be reported as median difference with 95% confidence interval and corresponding p-value. Statistical significance is defined as two-sided $p < 0.05$.

Secondary Endpoint Analyses

- NRS pain scores at each timepoint: independent-samples t-test or Mann-Whitney U test; repeated measures analyzed with linear mixed-effects models (group, time, group × time interaction).
- Time to first rescue analgesic: Kaplan-Meier survival curves with log-rank test; adjusted hazard ratio via Cox proportional hazards regression.
- Binary respiratory outcomes (pulmonary complication, reintubation): chi-square or Fisher exact test; risk differences and risk ratios with 95% CIs.
- Continuous respiratory and recovery outcomes: t-test or Mann-Whitney U ± ANCOVA as appropriate.
- Patient satisfaction (Likert 1–5): Mann-Whitney U test.

Multiple Comparisons

Given the exploratory nature of secondary endpoints, no formal multiplicity adjustment will be applied to secondary analyses in the primary report. A Bonferroni-corrected threshold ($\alpha = 0.0033$) may be used for descriptive interpretation. Secondary outcomes will be presented with 95% confidence intervals and unadjusted p-values and interpreted as hypothesis-generating. This will be clearly stated in any resulting publications.

Statistical Software

All analyses will be performed using R (version 4.3.2; R Foundation for Statistical Computing, Vienna, Austria). Sample size calculation was performed using PASS 15 (NCSS, LLC, Kaysville, UT, USA).

REFERENCES

[1] Hamilton C, Alfille P, Mountjoy J, Bao X. Regional anesthesia and acute perioperative pain management in thoracic surgery: a narrative review. J Thorac Dis. 2022;14(6):2276–96.

[2] Kleiman AM, Sanders DT, Nemergut EC, Huffmyer JL. Chronic poststernotomy pain: incidence, risk factors, treatment, prevention, and the anesthesiologist's role. Reg Anesth Pain Med. 2017;42(6):698–708.

[3] Kelava M, Alfirevic A, Bustamante S, Hargrave J, Marciniak D. Regional anesthesia in cardiac surgery: an overview of fascial plane chest wall blocks. Anesth Analg. 2020;131(1):127–35.

[4] Balan C, Bubenek-Turconi SI, Tomescu DR, Valeanu L. Ultrasound-guided regional anesthesia — current strategies for enhanced recovery after cardiac surgery. Medicina (Kaunas). 2021;57(4):329.

[5] Tulgar S, Ciftci B, Ahiskalioglu A, Bilal B, Sakul BU, Korkmaz AO, Bozkurt NN, De Cassai A, Torres AJ, Elsharkawy H, Alici HA. Serratus posterior superior intercostal plane block: a technical report on the description of a novel periparavertebral block for thoracic pain. Cureus. 2023;15(2):e34582. doi:10.7759/cureus.34582.

[6] Ueshima H, Hara E, Marui T, Otake H. The ultrasound-guided transversus thoracic muscle plane block is effective for the median sternotomy. J Clin Anesth. 2016;29:83.

[7] Murata H, Hida K, Hara T. Transverse thoracic muscle plane block: tricks and tips to accomplish the block. Reg Anesth Pain Med. 2016;41(3):411–2.

[8] Shokri H, Ali I, Kasem AA. Evaluation of the analgesic efficacy of bilateral ultrasound-guided transversus thoracic muscle plane block on post-sternotomy pain: a randomized controlled trial. Local Reg Anesth. 2021;14:145–52. doi:10.2147/LRA.S338685.