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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Ain Shams University

Faculty of Medicine

Ethical Committee of Scientific research

Informed consent form for patients who are invited to participate in the research

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

Effective postoperative pain management after **coronary artery bypass grafting (CABG)** remains a clinical challenge, as inadequate analgesia is associated with poor respiratory function, delayed mobilization, and prolonged ICU/hospital stay.

Conventional systemic analgesia (mainly opioids and adjuncts) is widely used but carries risks of **respiratory depression, nausea, vomiting, constipation, and delirium**, especially in cardiac surgical patients.

Regional anesthesia techniques have gained attention as opioid-sparing strategies.

The **serratus posterior superior plane block** provides analgesia to the lateral chest wall, while the **transversus thoracic plane block** targets anterior chest wall innervation. To date, most studies have evaluated these blocks individually, and evidence regarding their **combined use in cardiac surgery** is very limited.

This **randomized controlled trial** is to assess the combined use of **ultrasound-guided serratus posterior superior and transversus thoracic plane blocks** for pain control after CABG. Demonstrates whether the

combination of anterior and posterior chest wall coverage provides superior analgesia compared with conventional systemic analgesia alone.

Provides evidence on **opioid-sparing effects, respiratory outcomes, hemodynamic stability, and recovery profile** in the early postoperative period. May establish a novel, effective, and safer **multimodal regional anesthesia strategy** for patients undergoing CABG, potentially improving both pain outcomes and postoperative recovery.

Place of work:

After obtaining approval from the medical ethical committee in Ain Shams University and anaesthesia department Review Board (IRB). 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.

Number and Selection of participants:

88 Participants will be randomized into one of two groups using a computer-generated randomization sequence: Group A (Block Group n= 44), Group B (Conventional Analgesia group n= 44).

Plan of the work:

After your consent achievement and fully explained about the steps of research, the patients will be subjected to the following:

Randomization and blinding

- **Randomization**
  - Allocation ratio: **1:1** (Combined SPSP + TTP block group vs Conventional analgesia group).
  - Method: **Computer-generated random sequence** using permuted block randomization to preserve balance.
  - Allocation concealment: **Sequentially numbered, opaque, sealed envelopes (SNOSE)** prepared by an investigator not involved in

patient care or outcome assessment. Envelopes opened in the preoperative area by the anesthetist performing the intervention immediately before block placement.

- **Blinding**
  - **Double-blind design**: Patients and outcome assessors (data collectors, ICU staff recording pain scores, statisticians) will be blinded to group allocation.
  - Study syringes/preparations will be labelled "study injection" and handled by the block performer only.

- **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 II–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. Patient refusal or withdrawal of consent.

Method:

Study Interventions:

<u>Preoperative interventions</u>

Pre-enrolment / screening

- Confirm eligibility; obtain written informed consent in preoperative clinic. Document comorbidities, medication (opioids and anticoagulants), allergy history, ASA status, and labs.

Pre-block checks

- Ensure coagulation status meets institutional safety thresholds (e.g., INR ≤ 1.5, platelets $\geq 100 \times 10^9$/L).
- Review anticoagulant/antiplatelet timing; withhold according to institutional guidelines prior to blocks.
- Place standard monitors (ECG, NIBP and SpO_2). Prepare resuscitation and LAST kit (intralipid 20% available).
- Intravenous access: at least one large-bore IV and arterial line placement under local anesthesia.

Block timing

- **Perform blocks after induction of general anesthesia and endotracheal intubation but before surgical preparation** (to allow block distribution and maintain blinding).

Ultrasound equipment and settings

- Device: **GE Vivid iq R3 Premium**.
- Probe: **High-frequency linear transducer** (e.g., 6–13 MHz) for superficial/intermediate plane visualization.
- Use **sterile probe cover and sterile gel** for the block.
- Needle visualization: in-plane approach preferred to keep needle tip visible throughout.

Block techniques

Local anesthetic

- **Bupivacaine 0.25% plain**.
- Maximum dose safety: adhere to institutional/weight-based limits (≤ **2.5 mg/kg** plain bupivacaine). Calculate total dose pre-procedure. Consider using 0.25% to reduce risk of LAST.

A. Transversus Thoracic Plane (TTP) block

- Purpose: parasternal analgesia for sternotomy pain (targets anterior cutaneous branches).
- Positioning supine. Expose anterior chest.
- Ultrasound landmarks: parasternal region, identify pectoralis major, internal intercostal muscle, transversus thoracic muscle deep to internal intercostal (or plane between internal intercostal and transversus thoracic muscle). Use parasternal short-axis scan at level of 2nd–4th intercostal spaces.
- Needle: 22G, 50–80 mm stimulating or echogenic blockneedle. In-plane medial-to-lateral or lateral-to-medial depending on operator comfort.
- Injection: after negative aspiration and test dose, inject **15 mL of 0.25% bupivacaine per side** slowly in aliquots (e.g., 3–5 mL increments) with continuous aspiration and observation for spread in plane with downward movement of pleura ***(Matura et al 2016).***

B. Serratus Posterior Superior (SPSP) block

- Purpose: analgesia of lateral thoracic wall (lateral cutaneous branches), complements parasternal coverage. For median sternotomy pain, it is used to cover lateral expansion and graft harvest site.
- Positioning: slight lateral tilt; expose posterolateral thorax.
- Ultrasound landmarks: identify latissimus dorsi, rhomboid major/minor, serratus posterior superior plane (deep to rhomboids above T2–T5 level).
- Needle: 22G, 50–80 mm, in-plane lateral-to-medial.
- Injection: after negative aspiration, deposit **15 mL of 0.25% bupivacaine per side** in the chosen plane (total volumes adjusted to not exceed safe mg/kg). Inject incrementally and watch for fascial spread.

Total LA volume example (bilateral TTP + bilateral SPSP):

- TTP: 15 mL × 2 = 30 mL of 0.25% = 75 mg bupivacaine.
- SPSP: 15 mL × 2 = 30 mL of 0.25% = 75 mg bupivacaine.
- **Total = 50 mL of 0.25% (90 mg)**
- 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.

Safety injections technique

- Aspirate before each 3–5 mL injection. Inject slowly (≤ 0.5 mL/sec). Monitor for signs of intravascular injection (sudden heart rate changes, ECG changes). Keep lipid emulsion (20%) readily available.

Documentation

- Record approach, level, side, needle type, total LA volume and concentration, time of block, and any immediate complications.

Intraoperative management (standardized)

Anesthesia induction and maintenance (standardized across groups)

- Induction: fentanyl (e.g., 5–10 μg/kg depending on institutional practice), propofol per protocol, atracurium for muscle relaxation.
- Maintenance: sevoflurane to target MAC per clinician. Keep anesthetic plan consistent between groups. Document volatile concentration or propofol infusion rates.
- Hemodynamic goals: standard institutional targets (MAP 65–80 mmHg unless clinical indication). Use vasopressors per routine.
- Cardiopulmonary bypass: manage per routine, record on-pump vs off-pump details, cross-clamp and bypass times. Record intraoperative opioid doses (fentanyl, morphine) precisely.

Intraoperative analgesia standardization

- Limit intraoperative supplemental opioids to protocol-defined boluses (e.g., fentanyl 1–2 μg/kg) to avoid large intergroup differences.
- No additional regional blocks or local infiltration by surgeon.

Postoperative interventions (standardized analgesia and rescue)

Immediate postop (ICU)

- All patients to receive standardized multimodal analgesia unless contraindicated:
    - **Paracetamol (acetaminophen) 1 g IV every 6–8 h scheduled**, starting on arrival to ICU.

Rescue analgesia algorithm

- If NRS ≥4 at rest or on demand: give IV morphine bolus 2–3 mg q5–10 min until NRS ≤3 (max per protocol), then allow PCA.

Monitoring&safety

1. **General Monitoring**

- **Continuous pulse oximetry (SpO_2):**
    - Detects hypoxemia early.

- Keep alarms active.

- **Continuous (ECG):**
  - For arrhythmia detection, especially important since both bupivacaine and opioids can cause rhythm disturbances.
- **Sedation&responsiveness checks:**
  - Use a standardized sedation scale (e.g. Richmond Agitation-Sedation Scale [RASS]).
  - Assess **every hour for the first 24 hours**, then as per ICU routine.
  - Purpose: to detect over sedation from opioids or neurological toxicity from local anesthetic.

2. Monitoring for Local Anesthetic Systemic Toxicity (LAST)

- **What to look for:**
  - Early CNS signs: tinnitus, circumoral numbness, metallic taste, agitation, dizziness.
  - CNS excitation progressing to seizures.
  - Cardiovascular signs: arrhythmias (bradycardia, ventricular tachycardia, fibrillation), hypotension, cardiac arrest.
- **Action if suspected:**
  - Stop injection immediately.
  - Call for help/resuscitation team.
  - Follow **LAST treatment protocol**:
  - Airway management, oxygenation, seizure control (benzodiazepines).
  - **Intralipid 20% therapy** (per ASRA guidelines):
  - Bolus: 1.5 mL/kg over 1 min.
  - Continuous infusion: 0.25 mL/kg/min.
  - Repeat bolus if CV instability persists; maximum ~10 mL/kg in first 30–60 min.
  - Advanced cardiac life support.

3. Monitoring for Block-Related Complications

- **Hematoma:**
  - Inspect block site for swelling, bruising, or bleeding.
- **Infection:**
  - Fever, redness, swelling, warmth, discharge at puncture site.

- **Pneumothorax:**
  - Monitor for sudden desaturation, decreased breath sounds, hypotension.
  - Confirm with bedside ultrasound or chest X-ray if suspected.

Study outcomes:

Primary Endpoints:

- **Total opioid consumption** (intravenous morphine milligram equivalents) in the first 48 hours.

Secondary Endpoints:

- **NRS pain scores** at predefined time points: immediately on extubation (0 h), 6 h, 12 h, 24 h, 48 h.
- **Time to first ambulation** (hours from extubation).
- **Time to first rescue analgesic** (minutes from extubation).
- **Respiratory outcomes:** time to extubation, incentive spirometry volumes (if used), PaO_2/FiO_2 ratio at 6 and 24 h, incidence of pulmonary complications (atelectasis, pneumonia, reintubation) during hospital stay.
- **Time in ICU and total hospital length of stay** (hours/days).
- **Patient satisfaction** with pain control at 48 h (Likert scale 1–5).
- **Adverse events / safety outcomes:** block-related complications (local hematoma, infection, pneumothorax), signs of local anesthetic systemic toxicity (LAST), and severe opioid-related events (respiratory depression requiring naloxone).

Benefits to the individual and the community

Demonstrates whether the **combination of anterior and posterior chest wall coverage** provides superior analgesia compared with conventional systemic analgesia alone.

Provides evidence on **opioid-sparing effects, respiratory outcomes, hemodynamic stability, and recovery profile** in the early postoperative period. May establish a novel, effective, and safer **multimodal regional anesthesia strategy** for patients undergoing CABG, potentially improving both pain outcomes and postoperative recovery.

Conducting the consent:

The consent will be given to the legal guardian or the patient by the investigators. Literate individuals will be left to read the consent followed by its explanation by the investigators, while illiterate individuals will have the consent read and explained to them as well.

Risks and complications:

- **Transversus Thoracic Plane (TTP) Block:**

  - **Pneumothorax:** Rare.
  - **Hematoma:** Lower risk due to minimal vascular structures in parasternal region.
  - **Local anesthetic systemic toxicity (LAST):** If large volumes are injected intravascularly.
  - **Block failure/inadequate spread:** Leading to insufficient analgesia.

- **Serratus Posterior Superior (SPSP) Block:**

  - **Pneumothorax:** Lower risk compared to deeper thoracic blocks.
  - **Hematoma:** Uncommon; minimal superficial vessels.
  - **LAST:** As with all regional techniques.
  - **Nerve injury:** Rare, due to superficial plane.
  - **Inadequate coverage:** May not fully cover all dermatomes needed for sternotomy.

- **Expected Side Effects of Combination:**

  - **Increased risk of LAST:** Due to larger total local anesthetic volume.
  - **Cumulative risk of pneumothorax:** Two separate needle passes on each side.
  - **Prolonged block performance time:** May extend anesthesia preparation phase.

- **Monitoring & Minimization Strategies:**

All study-related procedures will be conducted under the supervision of an expert, certified anesthesiologist with extensive experience in regional and general anesthesia.

- **LAST Prevention & Monitoring:**
  - Adhere to maximum safe dose of bupivacaine (≤ 2.5 mg/kg).
  - Use incremental injection with frequent aspiration.
  - Continuous ECG and hemodynamic monitoring for 30 minutes post-block.
  - Immediate availability of lipid emulsion (20% intralipid) and resuscitation equipment.
- **Pneumothorax Monitoring:**
  - Post-block chest auscultation and SpO_2 monitoring.
  - Bedside lung ultrasound if desaturation or respiratory distress occurs.
- **Hemodynamic Monitoring:**
  - Invasive arterial line for real-time blood pressure monitoring.
  - Vasopressor readiness.
- **Infection & Hematoma Prevention:**
  - Strict aseptic technique.
  - Post-procedure site inspection.
- **Standardized Rescue Protocol:**
  - Clear criteria for intervention (e.g., oxygen, chest tube, vasopressors).

Reimbursements in cases of risks and complications:

There are no reimbursements in case of complications, but the patients will be treated in the hospital.

Alternatives to participating:

In case of refusing to participate in this research. The patients will receive the standard management protocol only.

Confidentiality:

You will deal in complete confidentiality, and no one has the right to read your patient medical information except the main researcher. After the

research is complete, you will be informed regarding your patient `s research results and further information regarding your patient `s health status.

Right to refuse or withdraw:

Any participant doesn`t have to take part in this research if he/she or want. They may also stop participating at any time. If you have read this form and have decided to let your patient to participate in this study, please understand that your patient's participation is voluntary, and you have the right to withdraw your consent or discontinue participation at any time without penalty or loss of benefits to which your patient is otherwise entitled. Your decision whether or not to participate in this study will not affect your patient's medical care. Individual privacy will be maintained in all published and written data resulting from the study.

Contact information:

If you have any questions, concerns or complaints about this research, its procedures you should ask one of the following researchers:

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Certificate of Consent:

Name of Participant …….

Signature of legal guardian (Thumbprint of participant if illiterate)
…….

Date: ……

I have accurately read or witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Name of researcher: ……

Signature of researcher: ……

Date: ……

This proposal has been reviewed and approved by the Ethical committee of scientific research, whose task it is to make sure that research participants are protected from harm. If you wish to find about more about the Ethical Committee of scientific Research, contact:

Name: ……

Address ……

Telephone ……