Study Protocol and Statistical Analysis Plan

Official Study Title:

Impact of Two Minutes Delayed Supine Position Post-Spinal Compared With Immediate Supine Position in Geriatric Patients Undergoing Repair of Fracture Neck of Femur: A Randomized Controlled Trial

ClinicalTrials.gov Identifier:

Pending (Under PRS Review)

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Protocol of the study

This prospective, randomized, controlled, double-blind clinical trial was conducted at Sohar Hospital, from the period from January 2025 till January 2026, the study received an ethical approval: ID MOH/CSR/25/29207, a written informed consent was obtained from all participants or their legal guardians.

Geriatric patients (aged 65 years and above) scheduled for surgical fixation of fracture neck of femur under spinal anesthesia were eligible for inclusion. Exclusion criteria included: Contraindications to spinal anesthesia (e.g., coagulopathy, local infection, etc.), haemodynamic instability or baseline systolic BP < 90 mmHg, allergy to study medications, ASA 4 or morbidly obese patients.

Inside the operating room, all patients were connected to non-invasive blood pressure (NIBP), ECG, and pulse oximetry monitors, an average of two readings of systolic arterial blood pressure (SABP) and mean arterial blood pressure (MABP) was taken as the baseline parameters, then every 2 minutes for the first 20 minutes following spinal anaesthesia, then every 5 minutes until the end of surgery.

Under complete aseptic technique, spinal anaesthesia in the sitting position at the L3–L4 or L4–L5 interspace using a 25G Quincke spinal needle, 2.2 mL of 0.5% hyperbaric bupivacaine mixed with 0.3 ml (15 µg) fentanyl] was administered after free flow of cerebro-spinal fluid. Participants were randomly allocated into two equal groups using a computer-generated randomization sequence placed in sealed opaque envelopes; delayed supine group (group D) and immediate supine group (Group I) : in group D patients remained in the sitting position for two minutes post-spinal injection before being placed supine while in group I, patients were placed supine immediately after the spinal injection. The anaesthesiologist performing the block was aware of group allocation as well as the study protocol ; however another anesthetist who recorded vital signs, as well as the data analyst were blinded to group assignments.

All patients received fluid co-loading of 500 mL Ringer's lactate given within 30 minutes meanwhile spinal anaesthesia was performed, then patients were given fluid maintenance in a rate of $100 ml h^{-1}$. Hypotension defined as a decrease in systolic blood pressure of ≥25% from

baseline or a systolic pressure <90 mmHg was managed by a bolus dose of 250 mL Ringer's lactate plus 50µg phenylephrine if heart rate (HR) more than 60 beat/min or 5mg ephedrine if the HR is less than 60beats/min. boluses of vasopressors was repeated after 2 minutes if SABP did not reach the target of more than 90 mmHg and within 25% of basal both together. Bradycardia defined by HR less than 50 beats $^{-1}$min was managed by a bolus dose 200 µg of glycopyrrolate.

Primary and secondary outcomes

The number of hypotensive episodes in each group was recorded as the primary outcome, secondary outcomes included total dose of vasopressors (ephedrine or phenylephrine), incidence of bradycardia (HR < 50 bpm), amount of RL fluid. The time reaching 10th thoracic sensory block was assessed using facial expression during pinprick, while motor block was assessed by modified Bromage score (4): score 0= patient with full movement: able to move hip, knee, and ankle, score 1=patient is unable to move hip, but able to move knee and ankle, score 2 = patient is unable to move hip and knee, but able to move ankle And score 3 = patient has complete motor block ; unable to move hip, knee, or ankle, both were assessed at 2,4,6,18,10 minutes post-spinal.

Sample Size calculation and statistical Analysis

Assuming a 30% reduction in the incidence of hypotension, predicting the incidence of hypotension is about 50% (based on prior observational data), using a power of 80% and an α error of 0.05, the minimum sample size required was 45 patients per group. Categorical variables were analyzed using the chi-square or Fisher's exact test. Continuous variables were compared using the Student's t-test or Mann–Whitney U test, depending on data distribution. A p-value of <0.050 was considered statistically significant. Analysis was performed using IBM SPSS 25 version.