

I would like to submit the following study protocol “Comparative assessment of postoperative effect dexmedetomidine and fentanyl as an adjuvant to heavy bupivacaine in spinal anaesthesia in lower limb vascular surgeries”

This study discussed postoperative effect of using intrathecal dexmedetomidine and fentanyl as an adjuvant to heavy bupivacaine in lower limb surgeries on pain intensity, analgesic requirement and shivering.

Sincerely,

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Comparative assessment of postoperative effect dexmedetomidine and fentanyl as an adjuvant to heavy bupivacaine in spinal anaesthesia in lower limb vascular surgeries

Background

Spinal anaesthesia is an excellent choice of numerous operating procedures. This is due to its effectiveness, rapid onset of action, easy to implement, patient stayed awake, and minimal drug cost.⁽¹⁾

It is also beneficial for patients with chronic airway disorders, reducing the risk of pulmonary aspiration and vomiting in patients with full stomach, as well as its fewer adverse effects, and speedy patient turnover.^(2,1)

In lower abdominal and lower limb surgeries, spinal anaesthesia is still the primary option.⁽³⁾ The resultant nerve block is sufficient for patient welfare, while motor block eases the surgeon's work. Moreover, it grants efficient pain relief in the early post-operative period.⁽²⁾

Yet, postoperative analgesia is a most important dilemma.⁽⁴⁾ Thus, additional pain control is essential after spinal anaesthesia effect fades. Consequently, effective analgesia is crucial to accelerate rehabilitation and return to proper functional ability. Post-operative analgesia can be accomplished by numerous approaches specifically systemic opioid and non-opioid, local wound infiltration and peripheral nerve blocks, each approach have its own advantages and drawbacks.⁽²⁾

Different adjuvants have been added to local anaesthetics in spinal anaesthesia such as adrenaline, midazolam, clonidine, neostigmine, magnesium, and ketamine to extend the analgesic effect duration and to decrease the prevalence of adverse actions, but no one had been reputable in daily clinical practice.^(2,4,5)

Administration of opioids intrathecal such as fentanyl, morphine, and buprenorphine, allows decrease dose of the local anesthetic drug, augment analgesic effectiveness, and reduces probable toxicity and cardiovascular adverse consequences of local anesthetics.^(5,6)

Dexmedetomidine is a novel central alpha2-agonist that was approved by the FDA in 1999. It has sedation, anxiolytic, analgesic and sympatholytic effect that depress cardiovascular reflexes in perioperative interval.⁽⁶⁾

Thus, this study will be conducted for assessment of the effectiveness of addition 4 µg Dexmedetomidine to hyperbaric Bupivacaine intrathecally in lower limb surgeries.

Aim

This clinical comparative study aiming to evaluate postoperative effect of using intrathecal dexmedetomidine and fentanyl as an adjuvant to heavy bupivacaine in lower limb surgeries on pain intensity, analgesic requirement and shivering.

Patients and Methods

After approval of medical institutional ethical committee, 40 patients of American Society of Anaesthesiologists (ASA) physical status 1 or 2, aged between 20-60 years will be incorporated in this prospective randomized controlled study.

Inclusion Criteria

- 1- The patient aged range from 20 to 60 years
- 2- ASA 1 and 2
- 3- Patient prepared for elective lower limb surgeries.
- 4- Either sex male or female.

Exclusion Criteria

- 1- Patient refusal.
- 2- Patient has absolute contraindication to spinal anaesthesia.
- 3- Patients with ASA 3 or more
- 4- Patients taking ACE inhibitor, adrenergic receptor antagonist and calcium channel blocker.
- 5- Patients with head injury and polytrauma.

An informed written consent will be taken from all the providers.

Patients will be divided into the following groups using randomizer software.

Group D: patients will receive 3 mL volume of 0.5% hyperbaric bupivacaine and 4 µg dexmedetomidine in 0.5 mL of normal saline intrathecal (dexmedetomidine 100 µg/mL will be diluted in 12.5 ml preservative-free normal saline, 0.5 ml will be withdrawn)

Group F: patients will receive 3 mL volume of 0.5% hyperbaric bupivacaine with 25 µg fentanyl (0.5 mL) intrathecal.

In preoperative room area: clinical history and examination will be evaluated, and then non-invasive BP and heart rate will be measured and recorded as baseline values.

Technique and measurement

- Patients will be moved to operation table, 18G IV access is inserted and secured.
- Preloading begins 15 minutes before spinal anaesthesia administration with ringer lactated 20ml/kg.
- Intraoperative monitoring involves NIBP, pulse rate, ECG, SPO2
 - Patients are divided randomly into two groups by using randomizer software.
 - Baseline vital signs will be measured.
 - Under strict aseptic technique, after the local infiltration with 2% lignocaine, lumbar puncture is done using 25 G Quincke spinal needle, at L 3 – L 4 space after free flow of CSF is verified. Instantly after spinal injection, the patient is placed in a supine position with a cushion supporting shoulders and head. O2 (4-6L/min) is provided throughout face mask.

Post-operative measurement will be collected from instant recovery room to time of the first analgesia dose administrated in the ward

Pain will be assessed firstly every 1 hour for first 4 hours and subsequently till the patient required analgesia by means of “Visual Analogue Scale”, It is a lined scale, entails a 10 cm line attached at one end by a marker such as “No pain” and the other end by “Worst pain comprehensible”. Patient just make mark on the line to denote the intensity of pain. ⁽⁶⁾

First analgesic requirement time is defined as from the time of spinal injection to the time the patient requires analgesia. The rescue analgesic used is Tramadol 50mg IV for visual analogue score of more than 4.

The incidence and intensity of shivering will be also assessed postoperatively in the recovery room using the method of Tsai and Chu as follows: ⁽⁵⁾

0, no shivering

1, peripheral vasoconstriction without visible shivering

2, muscular activity in only one muscle group

3, muscular activity in more than one muscle group

4, shivering involving the whole body.

Complications will be noted post-operative

- Nausea, vomiting, pruritis.
- Incidence of respiratory depression defined as respiratory rate less than 9 /min and SpO₂ less than 90% on room air, will be noted, it will be treated with Oxygen (2 L/min) will be administered via a mask.
- Hypotension (> 20% fall of baseline blood pressure or systolic blood pressure of <100mmHg.) will be treated with bolus dose of 6 mg ephedrine intravenously
- Bradycardia (pulse rate < 60 bpm), will be treated with 0.3- 0.6 mg atropine intravenously

Reference

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