Original Article

Intrathecal Dexmedetomidine Versus Fentanyl as Adjuvants to Hyperbaric Bupivacaine for Lower Limb Orthopaedic Surgery: A Randomised Double-Blind Study

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Abstract

Background: Adjuvants are added to intrathecal bupivacaine to prolong spinal anaesthesia and postoperative analgesia. Fentanyl is the most widely used, but its effect is short. Dexmedetomidine, an α2-adrenoceptor agonist, may give a longer block. The aim is to compare intrathecal dexmedetomidine and fentanyl as adjuvants to 0.5% hyperbaric bupivacaine for onset and duration of sensory and motor block, postoperative analgesia, haemodynamics and adverse effects in lower limb orthopaedic surgery. **Material and Methods:** Sixty ASA physical status I–II adults aged 18–50 years were randomised in a double-blind manner to receive 12.5 mg of 0.5% hyperbaric bupivacaine with dexmedetomidine 5 µg (Group D, n = 30) or fentanyl 25 µg (Group F, n = 30). Onset of sensory block to T10 and of Bromage 3 motor block, two-segment regression, complete motor recovery, sensory regression to S1, time to first rescue analgesic, visual analogue scale (VAS) pain scores, haemodynamics and adverse effects were recorded. **Results:** Onset of sensory block was similar (11.6 ± 0.6 vs 11.6 ± 0.8 min; p = 0.86), and onset of motor block was slightly faster with fentanyl (10.8 ± 0.6 vs 11.1 ± 0.7 min; p = 0.04). All measures of block duration were longer in Group D (p < 0.001): two-segment regression 125 ± 12 vs 77 ± 8 min, complete motor recovery 423 ± 8 vs 149 ± 8 min, and sensory regression to S1 475 ± 12 vs 182 ± 6 min. The first rescue analgesic was required at 256 ± 13 min in Group D and 167 ± 8 min in Group F (p < 0.001), and VAS scores were lower in Group D from 4 to 24 hours. Adverse effects were few and similar in the two groups. **Conclusion:** Compared with fentanyl 25 µg, intrathecal dexmedetomidine 5 µg added to hyperbaric bupivacaine markedly prolonged sensory and motor block and postoperative analgesia, without more haemodynamic or other adverse effects.

Keywords: Dexmedetomidine, Fentanyl, Bupivacaine, Spinal anaesthesia, Adjuvants, Postoperative analgesia, Orthopaedic surgery.

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Introduction

Spinal anaesthesia with hyperbaric bupivacaine is the most common technique for lower limb orthopaedic surgery. It is simple, reliable and avoids airway instrumentation, but a single injection of bupivacaine gives limited postoperative analgesia. Adjuvants are therefore added to prolong the block and improve its quality.

Lipophilic opioids such as fentanyl act on µ-opioid receptors in the dorsal horn and are widely used. Intrathecal fentanyl prolongs sensory block and improves intraoperative analgesia without prolonging motor block or delaying discharge.[1,2] but its effect lasts only a few hours and it can cause pruritus, nausea and, rarely, respiratory depression.[3]

Dexmedetomidine is a highly selective α2-adrenoceptor agonist. Intrathecally, it acts on presynaptic receptors to reduce release of nociceptive transmitters and on postsynaptic receptors to hyperpolarise dorsal horn neurones. Small doses (3–5 µg) prolong sensory and motor block with little haemodynamic effect.[4,5] Several trials have compared intrathecal dexmedetomidine with fentanyl in lower abdominal, gynaecological, obstetric and lower limb surgery.[5–12] and a meta-analysis concluded that dexmedetomidine gives longer sensory and motor block and analgesia.[13] Few of these trials were in orthopaedic patients, and doses and outcome definitions vary. We therefore compared intrathecal dexmedetomidine 5 µg and fentanyl 25 µg as adjuvants to hyperbaric bupivacaine in patients undergoing lower limb orthopaedic surgery.

Materials and Methods

Study design and ethics: This prospective randomised comparative study was conducted at the Institute of

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Anaesthesiology and Critical Care, Madras Medical College and Rajiv Gandhi Government General Hospital, Chennai, India. The study was approved by the Institutional Ethics Committee of Madras Medical College (approval no. 11012021, dated 5 January 2021; EC Reg. No. ECR/270/Inst./TN/2013/RR-16). Written informed consent was obtained from all patients.

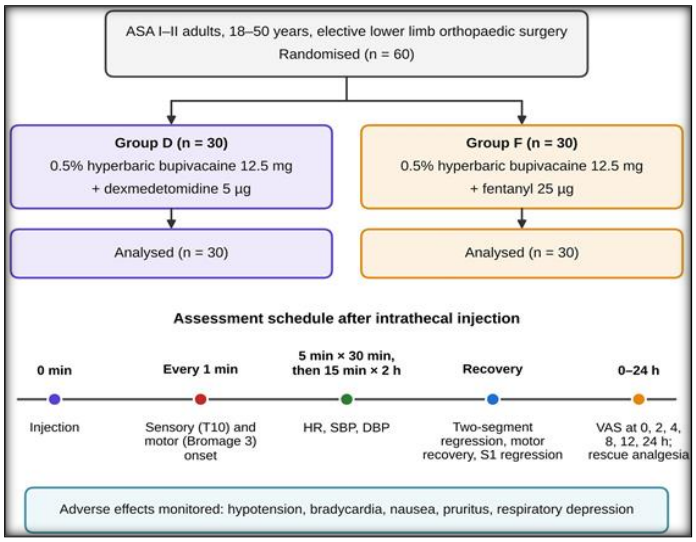
Participants: We included patients aged 18–50 years, of American Society of Anesthesiologists (ASA) physical status I or II, scheduled for elective lower limb orthopaedic surgery under spinal anaesthesia. Exclusion criteria were haemodynamic instability; cardiovascular, respiratory, hepatic, renal, endocrine, neurological or psychiatric disease; coagulopathy; local infection at the injection site; allergy to local anaesthetics; morbid obesity; an anticipated difficult airway; emergency surgery; and refusal to participate.

Sample size: The sample size was based on the trial by Safari et al,[10] who reported a duration of sensory block of 185.5 ± 27.5 min with intrathecal dexmedetomidine 5 µg and 158.9 ± 29.7 min with fentanyl 25 µg added to hyperbaric bupivacaine. To detect a difference of this size (26.6 min, pooled standard deviation 28.6 min) with a two-sided α of 0.05 and 80% power, 19 patients were required in each group. Thirty patients were enrolled in each group to allow for dropouts, which gave a power of about 94% for this difference.

Randomisation and allocation concealment: Sixty patients were randomly allocated to Group D or Group F in a 1:1 ratio using a computer-generated randomisation sequence with variable block sizes of 4 and 6, prepared before recruitment began. Allocation was concealed in sequentially numbered, opaque, sealed envelopes, which were opened only after eligibility had been confirmed and informed consent obtained.

Blinding: An independent anaesthesiologist who was not involved in patient assessment or outcome recording received the allocation and prepared the study drug in identical syringes with the same final volume and coded labels. The intrathecal injection was given by an anaesthesiologist blinded to group allocation. Patients and the investigator who recorded sensory block, Bromage scores, VAS scores, haemodynamics and adverse effects were also blinded. Data were analysed using coded group assignments, and the allocation code was revealed only after the statistical analysis was complete.

Intervention: Group D received 2.5 mL of 0.5% hyperbaric bupivacaine (12.5 mg) with dexmedetomidine 5 µg, and Group F received 2.5 mL of 0.5% hyperbaric bupivacaine (12.5 mg) with fentanyl 25 µg. The study design and assessment schedule are shown in [Figure 1].



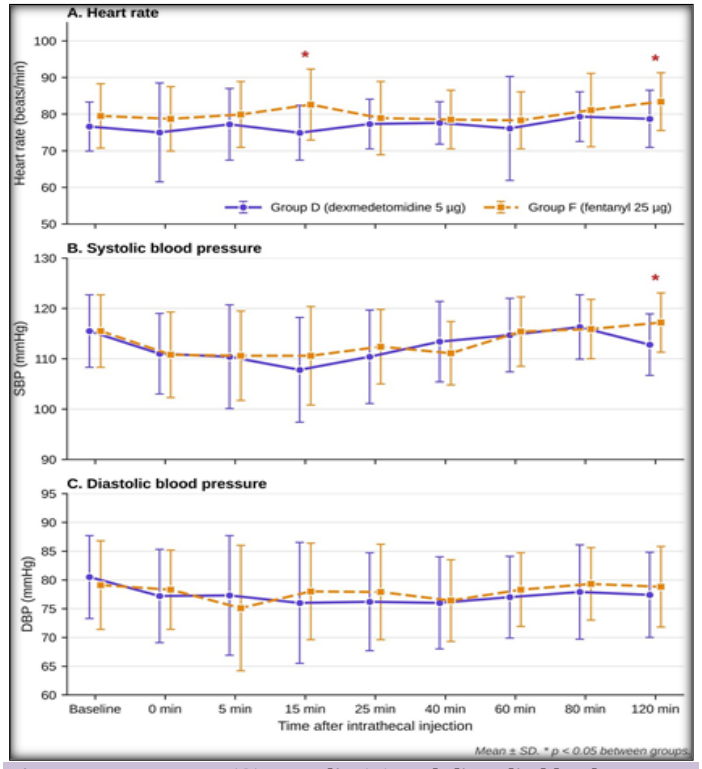


Figure 1: Heart rate (A), systolic (B) and diastolic blood pressure (C) after intrathecal injection (mean ± SD).

Postoperative pain: VAS scores were identical in the two groups at the end of surgery and at 2 hours. From 4 hours onward they were lower in Group D ($p < 0.001$), and the difference widened over time: at 24 hours the mean score was 6.0 in Group D and 9.5 in Group F [Table 5, Figure 4].

Results

Table 1: Postoperative VAS scores

Time after surgery	Group D	Group F	p value
0 h	2.00 ± 0.00	2.00 ± 0.00	1.00
2 h	2.37 ± 0.49	2.37 ± 0.49	1.00
4 h	3.63 ± 0.49	4.43 ± 0.68	<0.001
8 h	5.43 ± 0.50	6.47 ± 0.57	<0.001

12 h	5.43 ± 0.50	8.23 ± 0.63	<0.001
24 h	6.00 ± 0.00	9.50 ± 0.51	<0.001

Values are mean ± SD. Mann–Whitney U test.

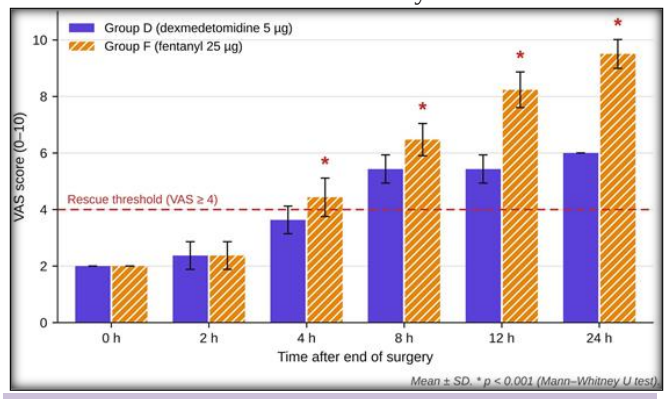


Figure 4: ?.

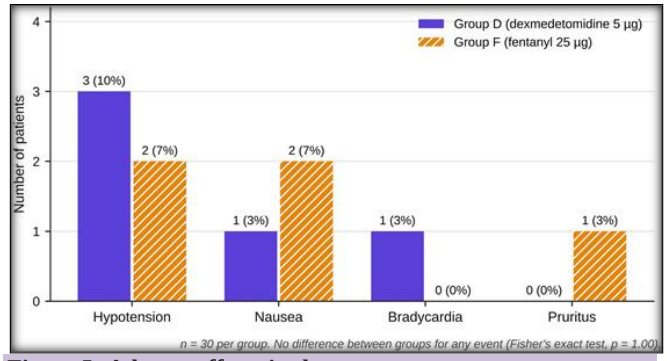


Figure 5: Adverse effects in the two groups.

Discussion

In this trial, adding dexmedetomidine 5 µg rather than fentanyl 25 µg to intrathecal hyperbaric bupivacaine produced a much longer block: sensory regression to S1 was delayed by nearly 5 hours, complete motor recovery by about 4.5 hours, and the first rescue analgesic by about 90 minutes. Onset of sensory block was the same in both groups, and motor block developed marginally faster with fentanyl. Haemodynamic changes and adverse effects were few and similar.

The longer block with dexmedetomidine is consistent with its mechanism. By acting on presynaptic and postsynaptic α2-receptors in the dorsal horn and, at higher concentrations, by blocking C and Aδ fibres, it augments the local anaesthetic effect of bupivacaine for longer than fentanyl, whose lipophilicity leads to rapid clearance from the cerebrospinal fluid.[4,5] Our durations are close to those of Gupta et al., who found sensory regression to S1 at 476 ± 23 min with dexmedetomidine and 187 ± 12 min with fentanyl, and two-segment regression at 120 vs 76 min, in lower abdominal surgery.[5] In lower limb orthopaedic surgery, Rahimzadeh et al. reported two-segment regression times of 149 and 89 min.[7] Patro et al., Khosravi et al. and Safari et al. also found longer sensory and motor block with dexmedetomidine.[8–10] The meta-analysis by Sun et al. confirmed longer sensory and motor block and analgesia with dexmedetomidine than with fentanyl.[13]

Onset times were similar in our study, in agreement with Gupta et al. and Mahendru et al., who found no difference in the onset of sensory or Bromage 3 motor block between dexmedetomidine and fentanyl.[5,6] The faster motor onset with fentanyl in our patients, about 20 seconds, was statistically significant but clinically unimportant.

VAS scores were lower with dexmedetomidine from 4 hours after surgery, and rescue analgesia was required later. These findings agree with previous studies.[5,9,11] Fentanyl added to bupivacaine improves intraoperative analgesia, but its postoperative effect is short and does not increase with dose.[12] The persistent difference in VAS to 24 hours suggests that the longer initial block delayed the onset of severe pain, but VAS scores of 6 to 9 at 12 and 24 hours in both groups indicate that the postoperative analgesic regimen was inadequate.

Haemodynamic stability was similar in the two groups. HR was lower with dexmedetomidine at 15 and 120 minutes and SBP at 120 minutes, but the differences were small and only one patient needed atropine. With 5 µg intrathecally, the systemic sympatholytic effect of dexmedetomidine is small; bradycardia becomes more frequent at higher doses.[14] Gupta et al. and Patro et al. also found no meaningful haemodynamic differences between dexmedetomidine and fentanyl.[5,8] Pruritus, a typical opioid effect, occurred in only one patient given fentanyl.

This study has limitations. It was a single-centre study with 30 patients per group. Surgery lasted longer in Group D, and the patients underwent a range of orthopaedic procedures. The prolonged motor block with dexmedetomidine (about 7 hours) may delay mobilisation and discharge, which we did not assess. Mean arterial pressure, sedation scores and urinary retention were not analysed, and only one dose of each adjuvant was studied.

Conclusion

Intrathecal dexmedetomidine 5 µg added to hyperbaric bupivacaine produced substantially longer sensory and motor block and postoperative analgesia than fentanyl 25 µg in lower limb orthopaedic surgery, with similar onset, haemodynamic stability and adverse effects. Dexmedetomidine is a suitable adjuvant when prolonged spinal anaesthesia and analgesia are wanted, although its long motor block should be considered when early mobilisation is planned.

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Conflicts of interest

There are no conflicts of interest.

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