Section: Anaesthesiology

Original Research Article

A COMPARATIVE STUDY TO EVALUATE THE EFFICACY OF DEXMEDETOMIDINE AND CLONIDINE AS INTRATHECAL ADJUVANTS IN SUBARACHNOID BLOCK FOR ELECTIVE LOWER LIMB PROCEDURES: A RANDOMIZED CONTROLLED TRIAL

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ABSTRACT

Background: Sub-arachnoid blockade is a widely used and reliable anaesthetic technique for lower-limb surgeries. Adjuvants such as α2-agonists prolong sensory and motor blockade and improve postoperative analgesia. This study aimed to compare Intrathecal Dexmedetomidine and Clonidine as adjuvants to hyperbaric bupivacaine for lower-limb surgeries in terms of onset, duration of spinal anaesthesia, time to two segment regression and haemodynamic stability.

Materials and Methods: Sixty adult patients of either sex, aged 18–50 years, belonging to ASA I and II, scheduled for elective lower-limb surgery under sub-arachnoid block, were randomly allocated into two groups (30 each). Group BD received 12.5 mg hyperbaric Bupivacaine(2.5ml) + 5 µg Prediluted Dexmedetomidine (0.5 ml), and Group BC received 12.5 mg hyperbaric Bupivacaine (2.5ml) + 30 µg Prediluted Clonidine (0.5 ml). The total intrathecal volume was 3 ml in both groups. The onset of sensory and motor block, duration of spinal anesthesia, time to two segment regression and hemodynamic variables were recorded.

Result: Demographic parameters were comparable. The onset of sensory and motor block was similar in both groups ($p > 0.05$). Duration of spinal anaesthesia was significantly longer in Group BD (303.66 ± 10.83 min) than Group BC (248.66 ± 7.76 min; $p < 0.001$). Time to two-segment regression was significantly prolonged with Dexmedetomidine (147.46 ± 9.16 min) compared with Clonidine (100.63 ± 4.90 min; $p < 0.001$). Mean Arterial Pressure and Heart Rate were comparable between groups throughout the intra-operative period. Both adjuvants are clinically relevant in regional anesthetic practice with minimal adverse effects after careful selection of patients.

Conclusion: In our study, Intrathecal Dexmedetomidine is associated with faster onset of sensory and motor blockade, delayed time to two segment regression with prolonged duration of spinal anaesthesia and comparable hemodynamic stability as compared to Intrathecal Clonidine.

INTRODUCTION

Spinal or sub-arachnoid block (SAB) remains one of the most dependable, cost-effective, and widely practised regional anaesthetic techniques for infra-umbilical surgeries. Its advantages include dense sensory and motor blockade, rapid onset, and predictable efficacy. Nevertheless, the duration of anaesthesia and postoperative analgesia provided by local anaesthetics alone, such as hyperbaric bupivacaine, is relatively limited. This constraint has encouraged the use of intrathecal adjuvants that prolong block duration, improve intra-operative stability, and extend postoperative pain relief without increasing adverse effects.[1,2]

Among various adjuvants, α2-adrenergic receptor agonists—specifically Clonidine and Dexmedetomidine—have gained considerable

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attention. These drugs exert their action through pre- and postsynaptic α_2-receptors in the dorsal horn of the spinal cord, leading to inhibition of nociceptive neurotransmission, hyperpolarisation of interneurons, and synergism with local anaesthetics.[3] Clonidine, a partial α_2-agonist, has long been recognised for its sedative and analgesic properties, whereas Dexmedetomidine, a highly selective α_2-agonist with an α_2:α_1 ratio of 1620:1 compared with Clonidine's 220:1, produces a more pronounced prolongation of sensory and motor blockade with minimal haemodynamic perturbation.[4,5]

Previous studies have compared either agent individually with opioids or with local anaesthetics alone; however, few randomised trials directly contrast their efficacy and safety profiles under similar clinical conditions.[6] Determining which α_2-agonist offers superior prolongation of spinal anaesthesia and postoperative analgesia, while maintaining haemodynamic stability, remains clinically pertinent.

The present randomised, double-blind study therefore aims to compare intrathecal Dexmedetomidine (5 µg) and Clonidine (30 µg) as adjuvants to 12.5 mg hyperbaric bupivacaine in adult patients undergoing elective lower-limb surgeries. The objectives were to assess onset of sensory and motor block, time to two segment regression, total duration of spinal anaesthesia, and haemodynamic stability.

MATERIALS AND METHODS

This prospective randomised double blinded study was conducted after approval of Medical Board of Ethics and proper signed consent from patients in Jawaharlal Nehru Medical College, AMU from November 2022 to November 2023. This study was registered in clinical trials (CTRI/2023/04/051460). Sixty adult patients, aged between 18 and 50 years, of either sex, belonging to the American Society of Anesthesiologists (ASA) physical status I or II, and scheduled for elective lower-limb surgeries under sub-arachnoid block were enrolled.

Exclusion criteria included patients with contraindications to spinal anaesthesia, history of hypersensitivity to study drugs, cardiac arrhythmias, uncontrolled hypertension, hepatic or renal dysfunction, coagulopathy, infection at the puncture site, or refusal to participate.

Patients were randomly allocated into two equal groups of 30 each by the sealed-envelope method:

- **Group BD:** received 12.5 mg (2.5 ml) of 0.5% hyperbaric bupivacaine + 5 µg Dexmedetomidine (diluted to 0.5 ml),
- **Group BC:** received 12.5 mg (2.5 ml) of 0.5% hyperbaric bupivacaine + 30 µg Clonidine (diluted to 0.5 ml).

The total volume administered intrathecally was 3 ml in each group.

Under strict aseptic precautions, spinal anaesthesia was performed at the L3–L4 interspace using a 23-G Quincke needle, with patients in the sitting position. After drug administration, patients were immediately placed supine. Standard monitoring (ECG, NIBP, pulse oximetry) was instituted and Heart Rate (HR), Mean Arterial Pressure (MAP), and SpO_2 were recorded at baseline, immediately after injection, and at 5-min intervals for the first 30 min, then every 15 minutes till 150 minutes or surgery gets over whichever is earlier.

Sensory block onset was defined as time from injection to loss of pinprick sensation at T8 dermatome, while motor block onset corresponded to the attainment of modified Bromage scale 3. Duration of spinal anaesthesia as the period from spinal injection to the first occasion when the patient complained of pain in the postoperative period. Time to two segment regression refers to the duration it takes for sensory block to regress by two dermatomal segments after reaching T8 level of block.

The motor level was assessed according to Modified Bromage score:

Bromage 0: The patient was able to move the hip, knee, and ankle;

Bromage 1: The patient was unable to move the hip, but able to move the knee and ankle;

Bromage 2: The patient was unable to move hip and knee, but able to move the ankle; Bromage 3: The patient was unable to move the hip, knee, and ankle.

Statistical Analysis and Sample Size: Statistical analysis of the data was done using Statistical Package for Social Science (SPSS 27.0 Evaluation version) after the completion of the study and used as per requirement. Based on a previous study (5), the sample size for the study was calculated for a hypothesized difference in the postoperative analgesia duration by 25% between the groups. We considered 80% power to be significant for our study and the sample was calculated for 95% confidence which gave a sample of 26 patients per group. However, we decided to recruit 30 participants per group. Data was expressed as means and standard deviation (SD). For categorical covariates (sex, ASA class), Chi-square test was used. Continuous covariates were compared using unpaired t test. The α level for all analysis was set at 0.05 and $p<0.05$ was considered statistically significant.

RESULTS

A total of 60 patients completed the study, 30 in each group. Both groups were comparable regarding age, sex distribution, body weight, ASA physical status, and duration of surgery ($p > 0.05$) as shown in Table 1. Thus, demographic characteristics did not confound the comparison between adjuvant drugs.

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Table 1: Demographic Characteristics, ASA grades and Duration of surgery

Variables	Group BD	Group BC	p-value
Age(years)	27.45±5.44	29.24±4.81	0.07
Sex (M:F)	24:6	21:9	0.37
ASA (I:II)	13:17	12:18	0.79
Duration of surgery(min)	108±44	98±46	0.38

Table 2: Comparison of Block Characteristics Between Dexmedetomidine (BD) and Clonidine (BC) Groups

Parameter	Group BD (Dex 5 µg)	Group BC (Clonidine 30 µg)	p-value
Sensory onset (min)	5.51 ± 0.91	5.61 ± 0.87	0.696
Motor onset (min)	6.18 ± 0.78	6.21 ± 0.82	0.850
Two-segment regression (min)	147.46 ± 9.16	100.63 ± 4.90	<0.001
Duration of spinal block (min)	303.66 ± 10.83	248.66 ± 7.76	<0.001

Block characteristics are summarised in Table 2.

The mean onset time of sensory blockade at T8 was comparable between the two groups (Group BD = 5.51 ± 0.91 min; Group BC = 5.61 ± 0.87 min; p = 0.696). Similarly, the onset of motor block, defined by attainment of modified Bromage scale 3, showed no significant difference (Group BD = 6.18 ± 0.78 min; Group BC = 6.21 ± 0.82 min; p = 0.850).

However, Duration parameters differed significantly. The total duration of spinal anaesthesia, defined as time from intrathecal injection to first complaint of postoperative pain was 303.66 ± 10.83 min for Group BD and 248.66 ± 7.76 min for Group BC (p < 0.001). Time to two-segment regression was significantly prolonged with Dexmedetomidine (147.46 ± 9.16 min) compared with Clonidine (100.63 ± 4.90 min; p < 0.001).

Intraoperative haemodynamic parameters (MAP and HR) remained stable and comparable between groups at all measurement intervals (p > 0.05). Minor, transient decreases in HR and MAP were observed within the first 15–30 min following sub-arachnoid block, but without clinical significance. The trends are shown in Figures 1 and 2, demonstrating parallel profiles of MAP and HR throughout the 150-minute observation period.

Minor adverse events—nausea, bradycardia, hypotension, or urinary retention—occurred sporadically and with similar incidence in both groups, with no statistically significant difference (p > 0.05).

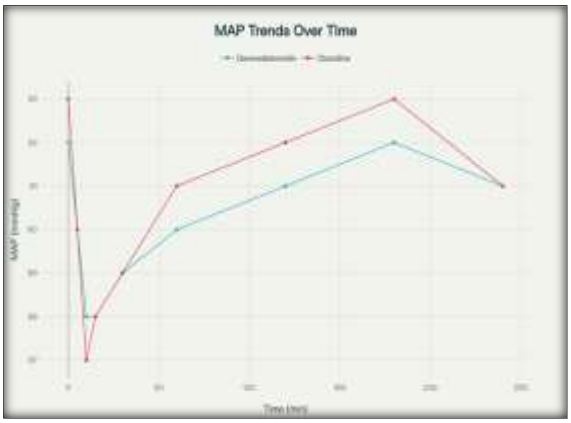

Figure 1: Mean Arterial Pressure (MAP) Trends Over Time

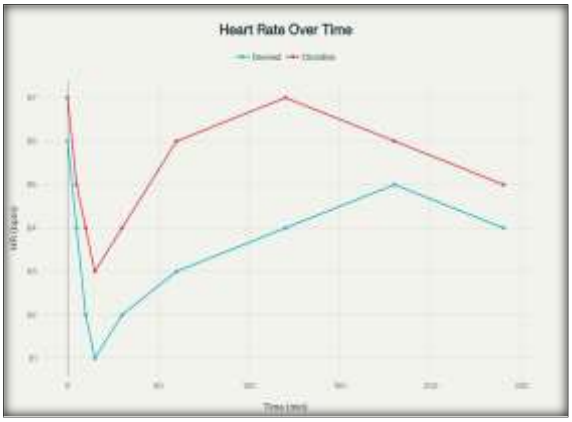

Figure 2: Heart Rate (HR) Trends Over Time

DISCUSSION

The present randomised, double-blind comparative study showed that adding 5µg dexmedetomidine has faster time of onset of sensory and motor block as compared to 30µg clonidine to heavy bupivacaine but the difference between both the group was statistically insignificant which was consistent with earlier work by Mahendru et al,[4] who reported that both agents exhibit a similar onset pattern when combined with bupivacaine.

Both groups in our study were comparable demographically, ensuring that observed differences were attributable to the pharmacodynamic profiles of the adjuvants rather than patient variability.

The result also demonstrates that the addition of intrathecal Dexmedetomidine (5 µg) to hyperbaric bupivacaine significantly prolongs total duration of spinal anaesthesia, and time to two-segment regression compared with Clonidine (30 µg), while maintaining stable haemodynamic parameters. The findings corroborate prior evidence suggesting the superior α_2-receptor selectivity and spinal efficacy of Dexmedetomidine as an adjuvant.[1-3] The key distinction lies in block duration: the Dexmedetomidine group demonstrated prolonged sensory and motor blockade, which can be attributed to its stronger α_2-adrenergic selectivity (α_2:α_1 ratio 1620:1) compared with Clonidine (220:1).[5]

The enhanced duration likely results from synergistic mechanisms at the spinal level. Dexmedetomidine inhibits C-fibre neurotransmission and

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hyperpolarises interneurons in the dorsal horn, leading to amplified and sustained suppression of nociceptive signals.[6,7] Clonidine acts through similar but less potent α_2-receptor pathways, explaining its comparatively shorter analgesic duration. Our results are consistent with Arora et al,[8] and Zhang et al,[9] who also observed that intrathecal Dexmedetomidine extends both sensory and motor block durations with total duration of spinal anesthesia more effectively than Clonidine.

This study also concluded that Time to two-segment regression was significantly prolonged with Dexmedetomidine compared with Clonidine which was supported by Eren G et al.[12]

Intraoperative haemodynamic stability, depicted in Figures 1 and 2, was maintained in both groups. Minor reductions in MAP and HR were expected, reflecting the sympatholytic effects of α_2-agonists, but no clinically significant hypotension or bradycardia occurred. These findings align with those of Tyagi et al,[10] and Rahimzadeh et al,[11] reinforcing the safety of Dexmedetomidine at low intrathecal doses.

Importantly, no major complications were encountered, indicating that both α_2-agonists are well tolerated as intrathecal adjuvants.

Collectively, these results reaffirm that Dexmedetomidine provides longer and more stable spinal anaesthesia compared with Clonidine, without compromising safety. The data thus support its preferential use as an α_2-agonist adjuvant in lower-limb surgeries requiring prolonged anaesthetic effect and postoperative comfort.

CONCLUSION

Intrathecal Dexmedetomidine (5 µg), when used as an adjuvant to hyperbaric bupivacaine (12.5 mg), provides a comparable onset of sensory and motor block, delayed two-segment regression, and prolonged postoperative analgesia compared with Clonidine (30 µg), while maintaining comparable haemodynamic stability and a favourable safety profile. The results of this study suggest that Dexmedetomidine is a superior α_2-adrenergic agonist adjuvant for sub-arachnoid block in elective lower-limb surgeries requiring extended anaesthesia and postoperative comfort.

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