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Intrathecal Dexmedetomidine vs Clonidine as Adjuvants to 0.75% Hyperbaric Ropivacaine in Patients Undergoing Elective Lower Limb Orthopaedic Surgeries: A Randomized Double-blinded comparative Study

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ABSTRACT

Background: Usually, adjuvant agents are added to intrathecal local anaesthetics to augment the quality of spinal anaesthesia and extend the duration of postoperative pain relief. Dexmedetomidine and clonidine, the α2-adrenergic agonists, have been investigated as potential adjuvants to ropivacaine in subarachnoid block.
Objectives: To compare the effects of intrathecal dexmedetomidine versus clonidine with 0.75% hyperbaric ropivacaine, on sensory and motor blockade, duration of postoperative analgesia, haemodynamic stability, and incidence of adverse effects.
Methods: The study enrolled 68 patients, randomly allocated into equal groups of 34 each, aged between 18 and 60 years, belonging to ASA physical status grade I or II, scheduled for lower limb elective orthopaedic procedures. Group RD received intrathecal 0.75% hyperbaric ropivacaine (3 ml) with dexmedetomidine 10 µg, whereas Group RC received 0.75% hyperbaric ropivacaine (3 ml) with clonidine 60 µg. Parameters including sensory and motor block characteristics, duration of analgesia, haemodynamic variables, and adverse effects were recorded and analysed.
Results: Group RD showed significantly earlier onset of sensory block (2.64 ± 0.37 min vs 3.46 ± 0.49 min) and motor block (4.38 ± 0.67 min vs 5.57 ± 0.70 min), and also showed significantly greater duration of sensory block (223.39 ± 18.57 min vs 204.51 ± 16.94 min), motor block (161.25 ± 13.52 min vs 149.93 ± 12.80 min), and postoperative analgesia (249.63 ± 18.50 min vs 231.81 ± 17.06 min) compared to Group RC. Haemodynamic parameters and the profile of adverse effects were similar between the two groups.
Conclusion: Adding intrathecal dexmedetomidine 10 µg to hyperbaric ropivacaine results in more rapid onset of anaesthesia and a prolonged duration of postoperative analgesia compared to clonidine, without causing clinically significant haemodynamic compromise.

Keywords: *Dexmedetomidine; Clonidine; Ropivacaine; Spinal anaesthesia.*

INTRODUCTION

Subarachnoid block is widely employed for orthopaedic procedures involving the lower extremities, owing to its rapid onset, intense neural blockade, and acceptable safety profile.[1, 2] The quality and extent of spinal anaesthesia are largely determined by the choice and dosage of the local anaesthetic agent. Ropivacaine, a long-acting amide local anaesthetic existing as a pure S-enantiomer, has been widely used due to its lower propensity for cardiotoxicity and neurotoxicity compared with bupivacaine.[1, 3]

The addition of adjuvant medications to intrathecal local anaesthetics is a well-established practice designed to intensify block quality and extending postoperative pain relief. In this context, α2-adrenergic agonists, mainly clonidine and dexmedetomidine, have been the subject of extensive investigation.[4] The analgesic mechanism of these agents involves their action on both presynaptic and postsynaptic receptors located in the dorsal horn of the spinal cord.[5]

Among the α2-agonists, dexmedetomidine exhibits a higher degree of receptor selectivity compared to clonidine. When administered intrathecally, it has demonstrated enhanced analgesic efficacy and prolongation of sensory block duration.[6, 7] Hence, the aim of the present study was to evaluate and compare the effects of dexmedetomidine and clonidine when used as adjuvants to hyperbaric ropivacaine in subarachnoid block for patients undergoing lower limb orthopaedic surgery.

OBJECTIVES

Primary Objective: To compare duration of postoperative analgesia.

Secondary Objectives:

- Onset and duration of sensory block
- Onset and duration of motor block
- Haemodynamic parameters
- Adverse effects if any.

MATERIALS AND METHODS

This was a double-blinded randomized comparative study, carried out at hospitals affiliated with Bangalore Medical College and Research Institute over the period from January 2023 to August 2023, following approval from the institutional ethics committee.

A total of sixty-eight patients, aged 18 to 60 years, belonging to ASA physical status grade I or II, and posted for elective lower limb orthopaedic surgery under spinal anaesthesia, were enrolled in the study. Written informed consent was obtained from all participants before their inclusion in the study.

Participants were allocated into two equal groups of 34 patients each using a computer-generated randomization table (http://www.randomizer.org). The local anaesthetic solution to be administered was drawn into a syringe labeled with the respective patient's serial number. Preparation and handing over of the study drug was carried out by an anaesthesiologist who was not involved in the conduct of the study.

Group Allocation

Group RD (n=34): Ropivacaine 0.75% 3 ml + Dexmedetomidine 10 µg
Group RC (n=34): Ropivacaine 0.75% 3 ml + Clonidine 60 µg

Procedure: All patients were kept nil per orally for a period of 8 hours prior to surgery. Tablet Ranitidine 150 mg and Tablet Alprazolam 0.5 mg were administered the night before the scheduled procedure.

On arrival to the operating room, intravenous access was secured and all patients received a preload of 10 ml/kg of Ringer's Lactate solution administered over 15 minutes. Non-invasive blood pressure monitoring, pulse oximetry, and three-lead electrocardiography were instituted, and baseline values of systolic blood pressure (SBP), diastolic blood pressure (DBP), mean arterial pressure (MAP), heart rate (HR), and oxygen saturation (SpO2) were documented.

Subarachnoid block was performed under strict aseptic precautions using a 25G Quincke Babcock spinal needle at the L3–L4 intervertebral space with the patient in the sitting position. Following confirmation of free cerebrospinal fluid flow, the prepared study solution was injected, after which patients were immediately repositioned to the supine posture and the time of spinal injection was recorded.

Assessment of Sensory Block: Sensory blockade was evaluated by testing loss of cold sensation bilaterally along the mid-clavicular line, beginning immediately after the patient was turned supine, until loss of pinprick sensation at the T10 dermatome was confirmed. Duration of sensory block was defined as the interval from completion of intrathecal injection to the return of sensation at the S1 dermatome.

Assessment of Analgesia: Duration of analgesia was defined as the time elapsed between intrathecal administration of the study drug and the first request for rescue analgesia (Injection Tramadol 50 mg intravenously), triggered when the patient reported pain corresponding to a Visual Analog Scale (VAS) score of 3.[8]

Assessment of Motor Block: Motor blockade was evaluated bilaterally using the Modified Bromage Scale.[9] Onset of motor block was defined as the time taken to achieve a Bromage score of 3 from the moment of intrathecal injection. Duration of motor block was recorded as the time from intrathecal injection until complete recovery, denoted by return to a Bromage score of 0.

Hemodynamic Monitoring: Hemodynamic parameters including HR, SBP, DBP, and SpO2 were recorded after the patient was repositioned supine, at one-minute intervals for the first three consecutive minutes, followed by five-minute intervals for the subsequent 15 minutes, and thereafter at 30-minute intervals until the conclusion of surgery. The need for vasopressor administration was also documented.

Sedation Assessment: Intraoperative and postoperative sedation levels were assessed using the Modified Ramsay Sedation Scale (RSS).[10]

Management of Complications: Hypotension, defined as a fall in SBP exceeding 20% from baseline, was managed with intravenous fluid administration and Injection Ephedrine 6 mg intravenously. Bradycardia, defined as a reduction in heart rate exceeding 20% from baseline, was treated with Injection Atropine 0.6 mg intravenously. Rescue analgesia in the postoperative period was provided as a slow intravenous injection of Tramadol 50 mg, administered upon the patient's request. Nausea and vomiting were managed with Injection Ondansetron 4 mg intravenously.

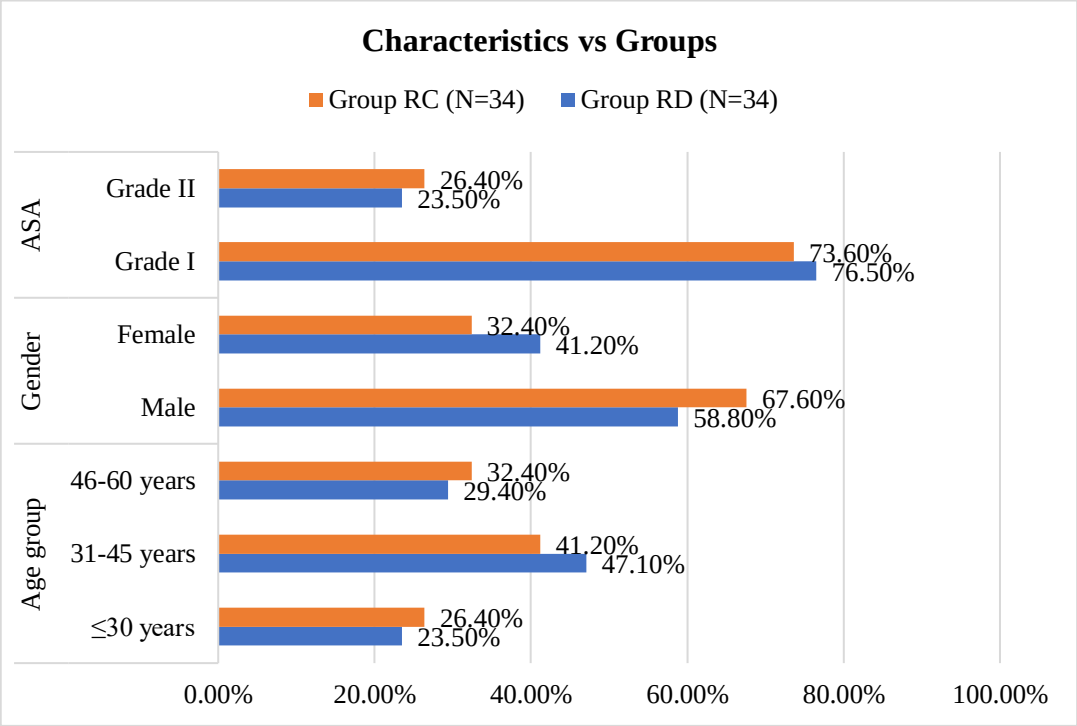
STATISTICAL ANALYSIS

Data were entered in Microsoft Excel and analysed using SPSS version 22. Continuous variables were expressed as mean ± standard deviation. Independent t-test was used for comparison between groups. Categorical variables were analysed using Chi-square or Fisher's exact test. A p-value <0.05 was considered statistically significant.

RESULTS

The groups were comparable with regards to the demographic characteristics (Graph 1).

Graph 1: Comparison of characteristics of the study subjects between the groups



The dexmedetomidine group demonstrated faster onset of sensory and motor block and significantly prolonged duration of sensory block, motor block and analgesia compared with the clonidine group. (Table 1)

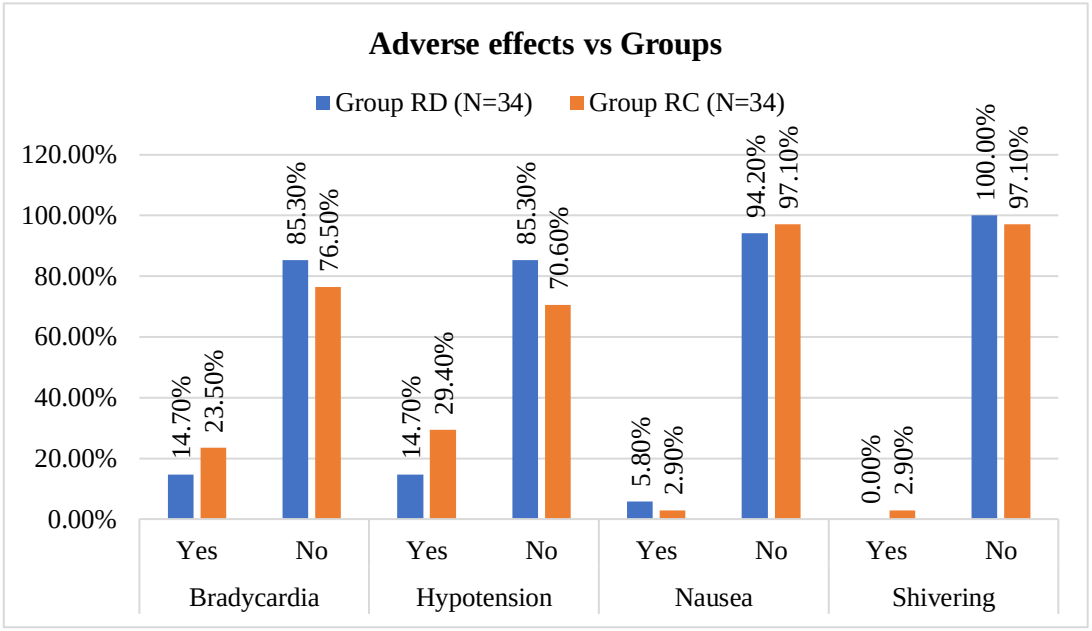
Table 1: Comparison of characteristics of sensory block, motor block and duration of analgesia between the groups

Parameter	Group RD (Dexmedetomidine)	Group RC (Clonidine)	P-Value
Onset of sensory block (min)	2.64 ± 0.37	3.46 ± 0.49	<0.001*
Time to maximum sensory block (min)	4.42 ± 0.61	5.75 ± 0.58	<0.001*
Duration of sensory block (min)	223.39 ± 18.57	204.51 ± 16.94	<0.001*
Onset of motor block (min)	4.38 ± 0.67	5.57 ± 0.70	<0.001*
Time to maximum motor block (min)	5.69 ± 0.42	6.41 ± 0.53	<0.001*
Duration of motor block (min)	161.25 ± 13.52	149.93 ± 12.80	<0.001*
Duration of analgesia (min)	249.63 ± 18.50	231.81 ± 17.06	<0.001*
Duration of rescue analgesia (min)	282.45 ± 21.89	260.77 ± 20.38	<0.001*

Throughout the observation period, subjects of both the groups maintained a nearly equivalent level of sedation, remaining oriented and responsive to commands.

No notable distinction was observed between the effects of Dexmedetomidine and Clonidine on heart rate, SBP & DBP during the observation period.

No statistically significant difference was found between the two groups concerning the adverse effects. (Graph 2)



Graph 2: Comparison of adverse effects among the subjects of both the groups

DISCUSSION

The findings of the present study indicate that dexmedetomidine, when used as an intrathecal adjuvant to ropivacaine, renders superior block characteristics compared to clonidine. Patients in the dexmedetomidine group showed earlier onset of both sensory and motor blockade, along with a more prolonged duration of postoperative analgesia.

These results are consistent with previously published literature reporting an enhanced analgesic profile with intrathecal dexmedetomidine as opposed to clonidine when combined with local anaesthetic agents.

In the present study, dexmedetomidine 10 mcg as an adjuvant to ropivacaine yielded superior quality of postoperative analgesia with a favourable adverse effect profile. This is in partial agreement with Krishnappa S M et al.,[1] who reported that a lower dose of 5 mcg dexmedetomidine combined with ropivacaine was sufficient to provide satisfactory postoperative analgesia with minimal side effects, suggesting that the higher dose employed in our study may offer further analgesic benefit.

Furthermore, hyperbaric ropivacaine combined with dexmedetomidine 10 mcg was observed to prolong sensory blockade and facilitate faster recovery of motor function, with minimal hemodynamic perturbations, findings that are consistent with those reported by Shashikala T K et al.[7]

The present study also demonstrated that Group RD exhibited more rapid onset and prolonged duration of both sensory and motor blockade, as well as a longer duration of analgesia in comparison with Group RC. These observations are corroborated by the findings of Sabu B et al.[11] and Kajur S et al.[4]

LIMITATIONS: The present study was limited by a relatively small sample size and its conduct within a single institutional setting. Validation of these findings would benefit from larger, multicentric trials encompassing a broader patient population.

CONCLUSION:

Intrathecal dexmedetomidine 10 µg combined with 0.75% hyperbaric ropivacaine produces faster onset of anaesthesia and significantly extends the duration of postoperative analgesia in comparison with clonidine, while ensuring haemodynamic stability throughout the perioperative period.

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Conflict of Interest: None

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