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COMPARATIVE STUDY OF INTRATHECAL DEXMEDETOMIDINE (5 MCG) AND CLONIDINE (50 MCG) AS ADJUVANTS TO 0.75% HYPERBARIC ROPIVACAINE IN LOWER LIMB SURGERIES.

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ABSTRACT

Background & Aim: Adjuvants in spinal anaesthesia improve block characteristics and extend postoperative analgesia. Dexmedetomidine and clonidine, both α_2 -adrenergic agonists, are widely used for this purpose. This study aimed to compare the efficacy of intrathecal dexmedetomidine (5 μ g) and clonidine (50 μ g) as adjuvants to 0.75% hyperbaric ropivacaine in lower limb surgeries. **Methods:** Fifty-four ASA I–II patients undergoing elective lower limb surgeries under spinal anaesthesia were randomly allocated into two groups. Group RC received 3 mL of 0.75% hyperbaric ropivacaine with clonidine 50 μ g, while Group RD received 3 mL of 0.75% hyperbaric ropivacaine with dexmedetomidine 5 μ g. Onset of sensory and motor block (Modified Bromage Scale), duration of block, time to first rescue analgesia, haemodynamic parameters, and adverse events were assessed. **Results:** Group RD showed a faster onset and significantly prolonged sensory and motor block duration ($p < 0.001$), with delayed need for rescue analgesia compared to Group RC. Haemodynamic parameters remained stable in both groups, and adverse effects were minimal without significant intergroup differences. **Conclusion:** Both dexmedetomidine and clonidine are effective intrathecal adjuvants to hyperbaric ropivacaine. Dexmedetomidine provides superior block quality and prolonged analgesia with a comparable safety profile, making it a preferable choice for extended lower limb surgeries.

KEYWORDS : Hyperbaric ropivacaine, Dexmedetomidine, Clonidine, Spinal anaesthesia, Postoperative analgesia

INTRODUCTION:

Spinal anaesthesia is preferred for lower limb surgeries because it avoids airway manipulation, reduces drug requirements, provides superior postoperative analgesia, enables earlier return of gastrointestinal function, decreases postoperative nausea and vomiting, and facilitates faster ambulation and discharge.(1,2) It offers rapid onset with effective sensory and motor blockade, fewer cardiovascular and respiratory complications, and better suppression of the neuroendocrine stress response, improving perioperative pain management.(3)

Hyperbaric local anaesthetic solutions prolong motor blockade and allow faster recovery. Although bupivacaine is commonly used, its cardiotoxic and neurotoxic potential has shifted interest toward ropivacaine, which has a favourable pharmacological profile—rapid onset, reliable blockade, shorter recovery, and superior cardiovascular safety.(4) The equipotent dose ratio of bupivacaine to ropivacaine is $\sim 1:1.3$, with 0.5% bupivacaine equivalent to 0.75% ropivacaine.(5)

Adjuvants such as clonidine and dexmedetomidine are often added to local anaesthetics to enhance spinal block quality and duration. Dexmedetomidine, a highly selective α_2 -adrenergic agonist, prolongs intra- and postoperative analgesia, reduces shivering, and attenuates the surgical stress response.(6) Clonidine, another α_2 -agonist, potentiates local anaesthetic action on A δ and C fibres, prolonging sensory blockade and the pain-free period in a dose-dependent manner.(6)

Comparative data on 0.75% hyperbaric ropivacaine with clonidine (50 μ g), using a 10:1 dose ratio versus dexmedetomidine (5 μ g) remain limited in the Indian population. Thus, this study was aimed primarily to compare the efficacy in terms of duration of analgesia, duration of sensory and motor blockade, time to first postoperative rescue analgesia, and incidence of postoperative nausea and vomiting, secondarily haemodynamic stability and adverse effects based on literature. ⁽⁷⁾ We hypothesised that both adjuvants would be effective, but dexmedetomidine would provide a longer duration of sensory and motor blockade. The primary outcome was duration of analgesia; secondary outcomes were intraoperative haemodynamic changes, time to first postoperative rescue analgesia, and incidence of postoperative nausea and vomiting.

Methodology:

This prospective, randomized study was conducted after obtaining approval from the Institutional Ethics Committee (Approval No.:

JSS/MC/PG/2046/20/2023-24) and registration with the Clinical Trial Registry of India (CTRI/2024/04/065890). Written informed consent was obtained from all participants. Patients aged 18–65 years, ASA physical status I–II, of either gender, scheduled for lower limb surgery under spinal anaesthesia were included. Exclusion criteria were contraindications to spinal anaesthesia, allergy to local anaesthetics, spinal deformities, bleeding disorders, and ASA physical status III or above.

Considering the standard deviation of 51.61 for Group 1 & 48.65 for Group 2 and mean differences as 38 from the pilot study, the calculated effect size came upto 0.7580. With 5% Alpha error and 80% power. The calculated sample size came upto 27 per group. Considering the dropouts we considered the sample size to be 27 in each group. Hence we observed a total of 54 subjects.

All patients underwent pre-anaesthetic evaluation and were instructed to fast for at least 6 hours for solids and 2 hours for clear liquids. On the day of surgery, intravenous (IV) access was secured with an 18G cannula, and baseline measurements of non-invasive blood pressure, electrocardiography, and pulse oximetry were recorded. With the patient in the sitting position, lumbar puncture was performed at the L2–L3 or L3–L4 interspace using a midline approach with a 25G Quincke spinal needle. After confirming free cerebrospinal fluid flow, 3 mL of the study drug was injected intrathecally at a rate of 0.2 mL/sec.

Sensory block onset time was defined as the time from intrathecal injection to loss of pinprick sensation at the T10 dermatome, assessed every minute at the anterior axillary line. The maximum height of the block was recorded, and two-segment regression time was defined as the time taken for the sensory block to regress two dermatomes from its maximum height. Total sensory block duration was the time from onset at T10 to the first report of postoperative pain. Motor block was assessed using the Modified Bromage Scale, with onset defined as the time to reach grade 3, regression as the time to return to grade 1, and total duration calculated as the interval between these two points.

Haemodynamic parameters, including heart rate, systolic, diastolic, and mean arterial pressure, and oxygen saturation were recorded at baseline, every 5 minutes for the first 30 minutes, and every 10 minutes thereafter until the end of surgery. Sensory and motor block assessments continued at 30-minute intervals postoperatively until full recovery. Hypotension, defined as a $\geq 20\%$ decrease in mean arterial pressure from baseline, was treated with IV mephentermine (6 mg) and fluids. Bradycardia, defined as a $\geq 20\%$ decrease in heart rate from

baseline, was treated with IV atropine (0.6 mg). Postoperative nausea and vomiting were also recorded.

Data were entered into Microsoft Excel and analysed using SPSS version 23 (IBM SPSS Statistics, Somers, NY, USA). Categorical variables were expressed as frequencies and percentages, and compared using the Chi-square test or Fisher's exact test for 2×2 tables. Continuous variables were expressed as mean ± standard deviation and compared using the independent samples t-test. A p-value <0.005 was considered statistically significant.

RESULTS

A total of 54 patients aged 18–65 years were included.

Table1: comparison of baseline characteristics of the study participants

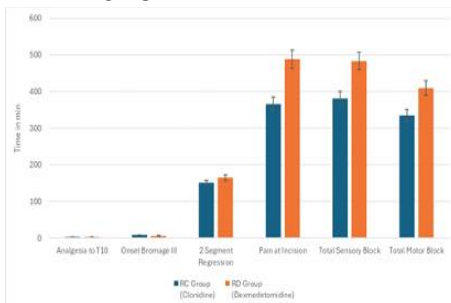
Parameter	Group RC (Clonidine)	Group RD (Dexmedetomidine)	t/ χ^2 value	p-value
Age	45.15 ± 12.14	40.07 ± 12.26	1.53	0.132
Sex (F/M)	6 (22.22%) / 21 (77.78%)	9 (33.33%) / 18 (66.67%)	$\chi^2=0.83$	0.362
Height (cm)	165.59 ± 6.9	164.99 ± 7.74	0.63	0.531
Weight (kg)	65.22 ± 7.6	65.22 ± 11.04	0	1
BMI	23.59 ± 2.66	23.78 ± 3.48	-0.22	0.827
ASA Grade (I/II)	13 (48.15%) / 14 (51.85%)	17 (62.96%) / 10 (37.04%)	$\chi^2=1.2$	0.273

There is no clinical significance in any of the following parameters above.

Table2: comparison of outcome variables between two groups

Parameter	Group RC (Clonidine)	Group RD (Dexmedetomidine)	t/ χ^2 value	p-value
Analgesia to T10 (min)	3.65 ± 0.52	3.30 ± 0.54	2.45	0.00175
Onset Bromage III (min)	8.77 ± 1.38	6.73 ± 1.36	5.47	<0.001
2 Segment Regression (min)	150.81 ± 6.31	164.52 ± 7.74	-7.14	<0.001
Pain at Incision (min)	366.3 ± 28.4	488.4 ± 28.7	-15.7	<0.001
Total Sensory Block (min)	381.07 ± 1.85	482.67 ± 28.68	-12.32	<0.001
Total Motor Block (min)	334.7 ± 25.34	409.6 ± 34.3	-8.78	<0.001

There is a significant change in analgesia time to T-10, Onset of motor and sensory blockade, 2 segment regression time, Total sensory and motor blockade time and pain at incision site time which showed group RD was better than group RC.



Haemodynamic Parameters also showed no clinical significance in both groups.

DISCUSSION

Spinal anaesthesia is the preferred technique for lower limb surgeries due to reduced airway manipulation, superior postoperative analgesia, rapid onset, and effective sensory–motor blockade.^(1,3) Hyperbaric solutions offer faster onset and more predictable block characteristics compared to isobaric preparations, with fewer incidences of hypotension and block failure.⁽¹⁰⁾ Although hyperbaric bupivacaine is widely used, its potential cardiotoxicity⁴ has led to increased use of ropivacaine, which has a favourable safety profile and reliable block quality.⁽⁴⁾ The addition of α_2 -adrenergic agonists such as clonidine and

dexmedetomidine further enhances block duration and postoperative analgesia.⁽⁶⁾

In this study, we compared 0.75% hyperbaric ropivacaine with either clonidine 50 μ g (Group RC) or dexmedetomidine 5 μ g (Group RD) in elective lower limb surgeries. The groups were demographically comparable. RD demonstrated a significantly faster onset of sensory block, longer two-segment regression time, and prolonged total sensory and motor blockade compared to RC ($p < 0.001$ for all). These findings are consistent with earlier work by Rajan et al., Priya Kishani et al., Desai et al., and Kujur et al., all of which reported superior onset and duration profiles with dexmedetomidine over clonidine.^(7,11–13)

Our results showed a mean sensory onset at T10 of 3.30 ± 0.54 min in RD versus 3.65 ± 0.52 min in RC, aligning with previous studies where dexmedetomidine produced faster block initiation. —(1012) The two-segment regression time was significantly longer in RD (164.52 ± 7.74 min) than RC (150.81 ± 6.31 min), corroborating earlier reports.^(12,13) Similarly, total sensory and motor block durations were prolonged with dexmedetomidine, consistent with findings from multiple comparative studies.^{—(1114)} These findings highlight dexmedetomidine's superior ability to hasten the establishment of effective anesthesia, which is consistent with previous reports suggesting its higher α_2 -adrenergic receptor affinity and synergism with local anesthetics. This study supports the analgesic superiority of dexmedetomidine when used intrathecally, in line with earlier studies demonstrating its role in attenuating nociceptive transmission at the spinal level.⁽¹⁵⁾

Hemodynamic parameters, including MAP, heart rate, and SpO₂, remained stable in both groups, with no significant differences. This supports previous evidence that intrathecal dexmedetomidine at 5 μ g is well tolerated and does not cause clinically significant cardiovascular or respiratory adverse effects. Despite its greater efficacy, dexmedetomidine did not compromise hemodynamic stability in this study, aligning with safety outcomes reported elsewhere.^(12,13)

Overall, our findings suggest that intrathecal dexmedetomidine (5 μ g) combined with hyperbaric ropivacaine provides faster onset, prolonged sensory–motor blockade, and longer postoperative analgesia than clonidine (50 μ g), without increasing adverse effects.

The superior efficacy of dexmedetomidine over clonidine as an intrathecal adjuvant can be attributed to its pharmacological profile. Dexmedetomidine possesses a much higher $\alpha_2:\alpha_1$ receptor selectivity ratio (~1600:1) compared to clonidine (~200:1), resulting in more potent activation of α_2 -adrenergic receptors in the dorsal horn of the spinal cord and thereby producing greater inhibition of nociceptive neurotransmitter release such as substance P and glutamate.⁽¹⁷⁾ Its higher lipophilicity further facilitates rapid penetration into neural tissue, accounting for the faster onset and prolonged duration of both sensory and motor block.⁽¹⁶⁾ In addition, dexmedetomidine exerts supraspinal actions through the locus coeruleus, contributing to sedation and enhanced analgesic synergy with local anesthetics.⁽¹⁷⁾ From a hemodynamic standpoint, dexmedetomidine provides greater cardiovascular stability due to its balanced sympatholytic effect and better preservation of baroreceptor reflexes, which prevent excessive hypotension or bradycardia often associated with clonidine. Furthermore, dexmedetomidine more effectively attenuates perioperative catecholamine release, leading to smoother intraoperative hemodynamics. These mechanisms explain the overall superior clinical profile of dexmedetomidine observed in our study.⁽¹⁸⁾

The present study has certain limitations. The sample size, though adequate for primary outcome assessment, was relatively small for evaluating rare adverse effects. The study also restricted the dose of adjuvants to a single fixed level; dose–response relationships were not explored. Additionally, long-term outcomes such as recovery profiles and patient satisfaction scores were not assessed.

CONCLUSIONS:

Intrathecal dexmedetomidine (5 μ g) with 0.75% hyperbaric ropivacaine in elective lower limb surgeries provided a faster onset and prolonged duration of sensory and motor blockade, along with extended postoperative analgesia, without significant cardiovascular or respiratory side effects. These findings support its role as a safe and effective adjuvant for spinal anaesthesia in procedures requiring prolonged analgesia.

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