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Original Research Article

Comparative Study of 0.75% Hyperbaric Ropivacaine versus 0.75% Hyperbaric Ropivacaine with Clonidine for Lower Limb Surgeries under Spinal Anaesthesia

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Abstract

Background: Spinal anaesthesia remains a cornerstone technique for lower-limb surgeries, and optimizing the balance between rapid onset, prolonged analgesia, and hemodynamic stability continues to be an important area of clinical research.

Objective: To compare the onset, duration, and quality of sensory and motor blockade, along with hemodynamic stability and adverse effects, between 0.75% hyperbaric ropivacaine alone and 0.75% hyperbaric ropivacaine with clonidine in patients undergoing lower-limb surgeries under spinal anaesthesia.

Methods: This single-centre, prospective, randomized controlled study was conducted in the Department of Anaesthesia, ACS Medical College and Hospital, Chennai, from April 2023 to April 2025, after obtaining IHEC approval (Ref: 816/2023/IEC/ACSMCH).

Results: Both groups (n=60 each) were demographically and hemodynamically comparable at baseline, with similar age (38.7 ± 10.1 vs 39.3 ± 7.6 years), BMI (25.4 ± 4.4 vs 26.3 ± 5.1 kg/m²), and vitals ($p > 0.05$). After spinal anaesthesia, both groups showed transient reductions in heart rate and systolic blood pressure that returned to near-baseline by surgery end. Heart rate declined to 71.4 bpm in Group A and 75.5 bpm in Group B, while SBP reached nadirs of 109.0 mmHg and 103.5 mmHg, respectively. Group B exhibited significantly faster onset of sensory (4.1 min) and motor block (5.1 min), whereas Group L showed markedly longer sensory (263.8 min) and motor block (248.9 min) durations (both $p < 0.001$). Adverse events were more frequent in Group L (30.0% vs 8.3%, $p = 0.007$), mainly nausea, pruritus, and bradycardia, indicating a trade-off between prolonged analgesia and tolerability.

Conclusion: Adding clonidine to 0.75% hyperbaric ropivacaine under spinal anaesthesia significantly prolonged sensory and motor blockade and delayed analgesic requirement but increased adverse events, whereas ropivacaine alone achieved a faster onset with fewer side effects, supporting regimen selection based on the desired balance between duration and tolerability.

Keywords: Ropivacaine, Clonidine, Spinal anaesthesia, Lower limb surgery, Sensory and motor block, Hemodynamic stability.

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Introduction

Spinal anaesthesia is widely preferred for lower-limb surgery because it provides dense neuraxial blockade, reliable muscle relaxation, and reduced perioperative opioid exposure while permitting early mobilisation. Yet its sympathectomy can precipitate transient hypotension and bradycardia, mandating careful agent selection and haemodynamic monitoring.[1, 2] Ropivacaine, the pure S-enantiomer of propivacaine, offers a favourable safety profile – demonstrating lower cardiotoxicity and neurotoxicity than bupivacaine in animal, volunteer and clinical studies – while

producing adequate sensory block with comparatively less motor blockade, a feature attractive for day-case surgery.[3, 4] Formulation and baricity influence intrathecal spread. Hyperbaric ropivacaine yields more predictable cephalad spread than isobaric solutions and has been successfully employed for lower-limb and hip procedures.[5, 6] Randomised and comparative studies suggest that 0.75% hyperbaric ropivacaine provides effective surgical anaesthesia with acceptable haemodynamic stability and, in some settings, earlier motor recovery than bupivacaine.[7, 8] Nevertheless, spinal-induced hypotension remains a frequent event across neuraxial techniques, with incidence shaped by patient factors, dosing, positioning and vasopressor strategy.[9]

Alpha-2 adrenergic agonists are frequently added intrathecally to enhance block quality. Clonidine acts presynaptically and postsynaptically in the dorsal horn to inhibit nociceptive neurotransmission and reduces sympathetic outflow, thereby prolonging sensory block and postoperative analgesia when combined with local anaesthetics.[10] Randomised clinical trials show that small intrathecal doses of clonidine (30–45 µg) added to hyperbaric local anaesthetics can extend analgesia and improve block characteristics, though with a potential increase in bradycardia and hypotension due to augmented sympatholysis.[11] Contemporary observational and interventional studies further indicate that low-dose clonidine regimens may achieve a balance between prolongation of analgesia and haemodynamic tolerance.[12]

Comparative data specific to 0.75% hyperbaric ropivacaine – with and without clonidine – remain heterogeneous, and the optimal trade-off between onset time, duration of sensory/motor block and cardiovascular effects is still clinically debated. Moreover, because the risk of neuraxial-induced hypotension is modulated by technique and patient selection, rigorous characterisation of haemodynamic responses with specific intrathecal combinations remains pertinent for ASA I–II surgical populations.[2] Against this background, the present study aimed to assess and compare the onset, peak, and duration of sensory block; the time to achieve complete motor block and duration of motor blockade; the duration of effective analgesia; intraoperative hemodynamic parameters including blood pressure, heart rate, and oxygen saturation; and any intraoperative complications such as hypotension, bradycardia, nausea, or vomiting between the two groups.

Materials and Methods

This was a single centre, hospital-based, prospective, parallel, experimental study – randomized controlled study design – conducted in the Department of Anaesthesia, ACS Medical College and Hospital, Chennai, Tamil Nadu, India over a period of two years between April 2023 and April 2025. The study was approved by the Institutional Human Ethics Committee (IHEC) with reference number 816/2023/IEC/ACSMCH dated 10/04/2023. The participants (and their attenders) were given the Participant Information Sheet (PIS) in their native language, and its contents were verbally explained to ensure their understanding and satisfaction. Enrolment into the study proceeded upon receipt of written informed consent. Patients 18 to 60 years of age, of both gender, ASA I/II, undergoing lower limb surgery were enrolled. However, ASA III patients, patients with severe renal, hepatic, respiratory and/or cardiovascular diseases; known hypersensitivity to amide local anaesthetic drugs including the study drugs; coagulopathy, bleeding diathesis; infection at the site of injection; and patients with psychiatric illness were excluded.

Sample size was estimated for comparing two independent means using $n = 2[(Z\alpha/2 + Z\beta)^2 \sigma^2]/\Delta^2$. With two-sided $\alpha = 0.05$ ($Z\alpha/2 = 1.96$), power = 80% ($Z\beta = 0.84$), assumed SD (σ) = 3, and a detectable mean difference (Δ) ≈ 1.68 units, the required sample size was 60 participants per group (total N = 120). We used nonprobability sampling technique – convenience sampling/complete enumeration to enrol patients. Data were collected using a structured, pretested proforma. Each participant's comprehensive medical history was obtained, followed by a thorough physical examination and relevant investigations, including complete hemogram, random blood sugar, HbA1c, renal and liver function tests, blood grouping and typing, urine routine analysis, ECG, and ECHO where indicated.

Eligible patients were randomly allocated to either group using a closed-envelope technique. Before initiating the procedure, the anaesthesia machine was checked, and emergency equipment such as a functional laryngoscope, endotracheal tubes of various sizes, and resuscitation drugs were kept readily available. An intravenous line was secured using an 18-gauge cannula, and each patient was preloaded with 500 mL of Ringer's lactate. Baseline vital parameters (blood pressure, heart rate, and oxygen saturation) were recorded in the waiting area. In the operating room, continuous monitoring with ECG, non-invasive blood pressure (NIBP), and pulse oximetry (SpO_2) was established, and preoperative readings of heart rate, systolic and diastolic blood pressure, mean arterial pressure, and oxygen saturation were documented. Under strict aseptic precautions, subarachnoid block was performed at the L3–L4 interspace through a midline approach using a 25-G Quincke

spinal needle. After confirming free flow of cerebrospinal fluid, the study drug was administered as follows: Group B, 22.5 mg of 0.75% hyperbaric ropivacaine (3.0 mL); Group L, 22.5 mg of 0.75% hyperbaric ropivacaine + 30 µg of clonidine (3.2 mL). Patients were positioned supine with the table horizontal, and supplemental oxygen was delivered via a Hudson face mask. The time of spinal anaesthesia was recorded. Intraoperative vital parameters – blood pressure, heart rate, and oxygen saturation – were monitored every minute for the first 5 minutes, every 5 minutes up to 30 minutes, and every 15 minutes thereafter until the end of surgery. Additional readings were obtained at 15, 10, and 5 minutes before completion of the procedure and at the end of surgery.

The following parameters were assessed and recorded: (1) Sensory block – onset time, time to peak level (T6 dermatome), and two-segment regression time; (2) Motor block – onset time, time to maximum block (Bromage 3), and regression to Bromage 0; (3) Intraoperative haemodynamics and complications (hypotension, bradycardia, headache, backache, nausea, vomiting, or high spinal); and (4) Drug doses administered: ephedrine 3–6 mg IV and glycopyrrolate 0.2 mg IV boluses for hypotension (systolic < 90 mm Hg or > 25% drop from baseline) and bradycardia (heart rate < 60 bpm).

Rescue analgesia was provided with incremental doses of diclofenac 75 mg or tramadol 100 mg as required. Sensory block was evaluated by cold sensation along the mid-clavicular line using cotton swabs, starting immediately after positioning and repeated every minute until loss of cold sensation at T6. The duration of sensory block was defined from onset to regression to the S1 dermatome. Motor blockade was assessed using the Modified Bromage scale at one-minute intervals until achieving a score of 3, and onset was defined as the time to reach Bromage 1 after intrathecal injection.

Statistical Analysis: Statistical analysis was performed using two-sided tests with $\alpha=0.05$. Continuous variables were summarized as mean±SD (or median [IQR] when non-normal by Shapiro–Wilk). Between-group comparisons of single time-point continuous outcomes used the independent-samples t test (or Mann–Whitney U when assumptions were violated). Repeated hemodynamic measures (HR, SBP, DBP, MAP) were analysed using repeated-measures ANOVA. Categorical outcomes were compared using the χ^2 test or Fisher's exact test (when any expected cell <5). Analyses were conducted in SPSS v26 (IBM).

Results

Baseline characteristics were comparable between the two randomized groups (Group B and Group L; n=60 each). Mean age was 38.7±10.1 vs 39.3±7.6 years (p=0.701), height 159.5±6.5 vs 159.7±9.5 cm (p=0.850), and weight 64.5±10.0 vs 67.0±10.2 kg (p=0.835). Body mass index was similar (25.4±4.4 vs 26.3±5.1 kg/m²; p=0.305). Baseline vitals did not differ; pulse rate 83.0±11.6 vs 83.5±12.1 bpm (p=0.550), mean arterial pressure 94.1±5.2 vs 94.5±8.1 mmHg (p=0.650), and SpO_2 98.3±0.7% vs 98.5±0.7% (p=0.700). The duration of surgery was also similar (62.3±13.3 vs 63.4±18.4 min; p=0.710). No between-group difference reached statistical significance (all p>0.05).

Intraoperative trends showed a prompt fall in heart rate and systolic blood pressure after spinal anaesthesia in both groups, followed by gradual recovery toward baseline. Mean HR started higher in Group B than Group A (88.8 vs 81.4 bpm), reached its nadir around 10–20 min (71.4 bpm at 10 min in Group A; 75.5 bpm at 20 min in Group B), and rose again to 83.0 vs 89.2 bpm by the end of surgery. SBP was similar at baseline (127.7 vs 127.5 mmHg) but the mid-procedure decline was more pronounced in Group B; the lowest SBP was 103.5 mmHg at 15 min in Group B (−24 mmHg from baseline) versus 109.0 mmHg at 10 min in Group A (−19 mmHg).

Thereafter, SBP recovered, ending slightly above baseline in both groups (128.4 vs 130.8 mmHg). Both DBP and MAP showed similar temporal trends between the two groups following spinal anaesthesia. Baseline DBP values were nearly identical (73.7 mmHg in Group A vs 74.1 mmHg in Group B), followed by a gradual decline reaching the lowest levels around 10–15 minutes (63.5 mmHg vs 61.1 mmHg). Thereafter, DBP progressively recovered, reaching 75.7 mmHg and 76.5 mmHg at the end of surgery. Likewise, MAP values were comparable at baseline (91.7 mmHg vs 91.9 mmHg), fell during the first 15 minutes (78.8 mmHg vs 75.2 mmHg), and then steadily increased to near-baseline levels (93.3 mmHg vs 94.6 mmHg) by the end.

Across 120 patients (60/group), block onset was faster in Group B; sensory 4.1±0.8 vs 6.1±1.0 min (p=0.030) and motor 5.1±0.8 vs 7.0±1.0 min (p=0.020). In contrast, block duration was longer in Group L; time to first analgesia 263.8±9.1 vs 149.0±5.7 min (p<0.001) and motor block 248.9±10.2 vs 204.5±4.1 min (p<0.001). Adverse events were more frequent in Group L (30.0% vs 8.3%; p=0.007), with higher rates of nausea (13.3% vs 5.0%), pruritus (5.0% vs 1.7%), and bradycardia (11.7% vs 1.7%).

Overall, Group B achieved quicker onset, whereas Group L provided markedly prolonged sensory and motor blockade but with a higher adverse-event burden.

Table 1: Baseline characteristics of the study groups

	Group B N = 60	Group L N = 60	P value
Age (years), Mean (SD)	38.7 (10.1)	39.3 (7.6)	0.701
Height (cm), Mean (SD)	159.5 (6.5)	159.7 (9.5)	0.850
Weight (kg), Mean (SD)	64.5 (10.0)	67.0 (10.2)	0.835
Body mass index (kg/m2), Mean (SD)	25.4 (4.4)	26.3 (5.1)	0.305
Pulse rate (bpm), Mean (SD)	83.0 (11.6)	83.5 (12.1)	0.550
Mean arterial pressure (mmHg), Mean (SD)	94.1 (5.2)	94.5 (8.1)	0.650
SpO2 (%),Mean (SD)	98.3 (0.7)	98.5 (0.7)	0.700
Duration of surgery (minutes), Mean (SD)	62.3 (13.3)	63.4 (18.4)	0.710
*Statistically significant at p<0.05, SD, Standard deviation			

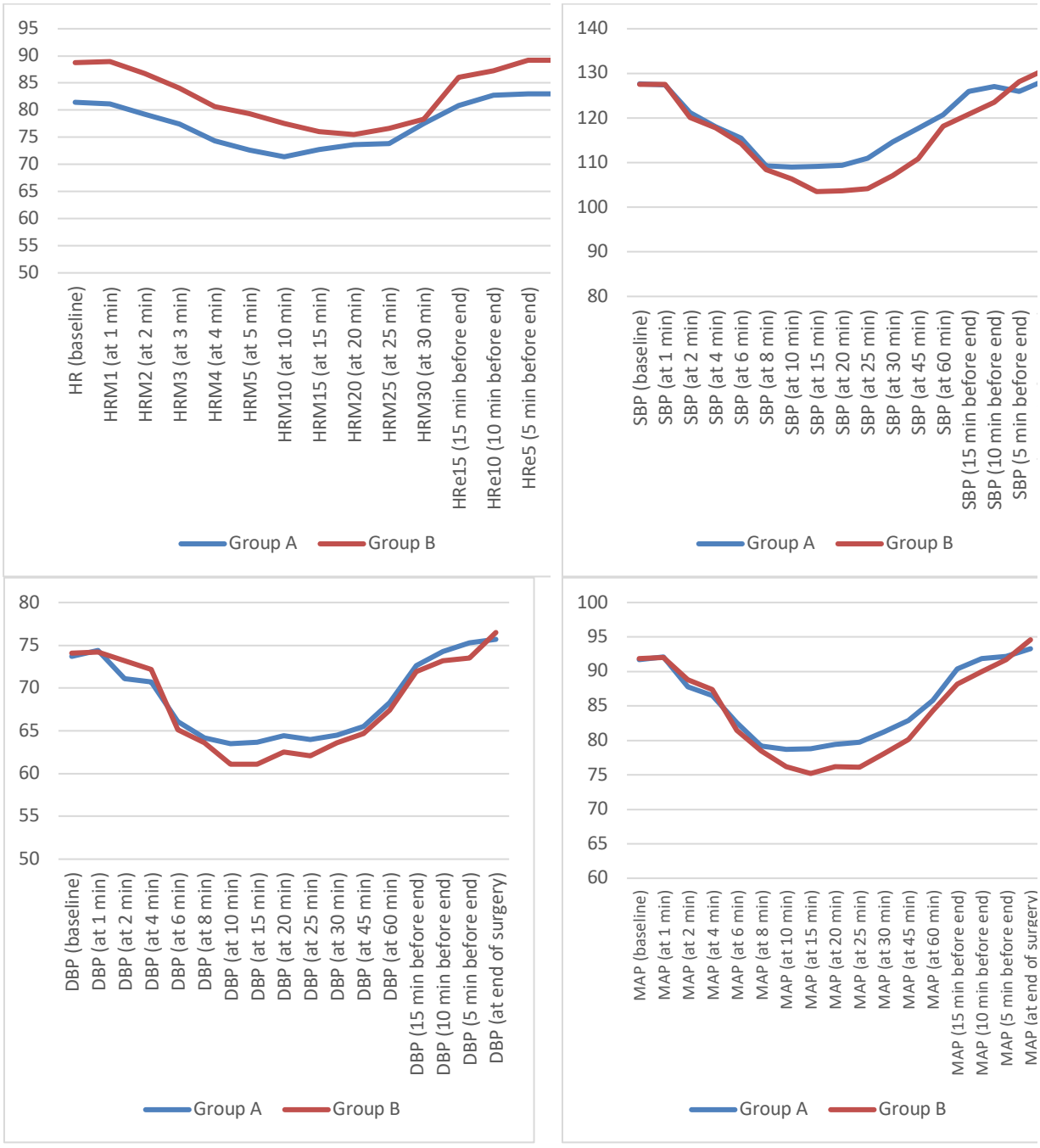

Figure 1: Comparison of study groups by heart rate, SBP, DBP and MAP

Table 2: Comparison of study groups by study outcomes

		Group B N = 60	Group L N = 60	P value
Onset of sensory block (minutes), Mean (SD)		4.1 (0.8)	6.1 (1.0)	0.030*
Onset of motor block (minutes), Mean (SD)		5.1 (0.8)	7.0 (1.0)	0.020*
Duration of sensory block (time to first analgesia requirement, minutes), Mean (SD)		149.0 (5.7)	263.8 (9.1)	<0.001*
Duration of motor block (minutes), Mean (SD)		204.5 (4.1)	248.9 (10.2)	<0.001*
Adverse events	Nausea	3 (5.0)	8 (13.3)	0.007*
	Pruritus	1 (1.7)	3 (5.0)	
	Bradycardia	1 (1.7)	7 (11.7)	
	Total	5 (8.3)	18 (30.0)	
*Statistically significant at p<0.05, SD, Standard deviation				

Discussion

The present randomized study demonstrated that both groups of patients undergoing lower-limb surgery under spinal anaesthesia were well matched at baseline, with no significant differences in age, height, weight, body mass index, pulse rate, mean arterial pressure, SpO_2 or duration of surgery (all $p > 0.05$). This comparability strengthens the internal validity of the subsequent findings. The intraoperative hemodynamic data revealed a typical pattern of sympathetic block following spinal anaesthesia;[13-15] an initial decline in heart rate and systolic blood pressure in both groups, followed by gradual recovery towards baseline. Notably, Group B exhibited higher baseline heart rate (88.8 bpm vs 81.4 bpm) and a more pronounced mid-procedure decline in SBP (nadir 103.5 mmHg, a drop of 24 mmHg) compared with Group A (nadir 109.0 mmHg, 19 mmHg drop). DBP and MAP followed similar trajectories in both groups. These patterns are consistent with prior work on Clonidine or other α_2-agonist adjuvants administered intrathecally (Margaritou (2003), Sagiroglu et al. (2009) and Sharma et al. (2024)), which have documented enhanced sympathetic blockade and associated hemodynamic changes.[16-18]

The block characteristics reveal a trade-off between rapid onset and prolonged duration. Group B achieved significantly faster onset of sensory (4.1±0.8 min vs 6.1±1.0 min) and motor blockade (5.1±0.8 min vs 7.0±1.0 min) compared to Group L (both $p < 0.05$), suggesting that the regimen used in Group B provides more rapid surgical readiness. Rapid onset is clinically desirable in busy operating environments, and comparable findings have been reported by Kujur et al. (2015) and Loannidou et al. (2002) when adding modest doses of clonidine to intrathecal local anaesthetic.[19, 20] Conversely, Group L exhibited substantially longer durations. The time to first analgesic request was 263.8±9.1 min vs 149.0±5.7 min ($p < 0.001$), and motor block lasted 248.9±10.2 min vs 204.5±4.1 min ($p < 0.001$). These findings align with the known potentiation of sensory and motor blockade by clonidine adjuvants and reflect the pharmacologic benefit of prolonged analgesia with minimal supplemental analgesic requirement.[16, 21] However, the benefit of extended blockade in Group L came at the cost of a higher incidence of adverse events (30% vs 8.3%, $p = 0.007$), including nausea (13.3% vs 5.0%), pruritus (5.0% vs 1.7%) and bradycardia (11.7% vs 1.7%). The increased rate of bradycardia in particular likely reflects enhanced sympatholytic effect of the adjuvant therapy and underscores the need for vigilant monitoring when prolonging blockade with α_2-agonists. Previous literature has similarly reported increased bradycardia and hypotension with intrathecal clonidine, although favourable analgesic outcomes may offset this in appropriately selected patients.[22]

From a clinical perspective, our data suggest that if the primary goal is rapid onset of block (for example, when time to surgical start is limited), the protocol used in Group B may be preferable. On the other hand, if prolonged analgesia and reduced need for rescue analgesics are prioritized – such as in longer procedures or where postoperative pain control is crucial – the regimen employed in Group L offers a distinct advantage. Modern trends in spinal anaesthesia increasingly emphasize the use of adjuvants to extend block duration and improve quality. For example, a review of intrathecal clonidine as an adjuvant found that it reliably prolongs sensory block when used with local anaesthetics such as bupivacaine or ropivacaine.[16, 18] The hemodynamic stability observed in both groups is reassuring; although there was a transient drop in HR and BP, neither group experienced severe hypotension or clinically significant instability, and recovery toward baseline was evident.

This suggests that the regimens were hemodynamically acceptable in ASA I/II patients undergoing lower-limb surgery. Nonetheless, the somewhat greater fall in SBP in Group B underscores that even modest modifications of intrathecal regimens can influence autonomic responses, reinforcing the importance of

intraoperative monitoring and readiness to intervene (e.g., fluid bolus, vasopressor) where needed. In relation to the literature, our findings resonate with earlier studies in several respects. One such study found that adding 30 µg clonidine to ropivacaine prolonged analgesia and improved blockade quality without significant hemodynamic compromise.[19] Another meta-analysis of α_2-agonists as intrathecal adjuvants reported enhanced duration of sensory block and analgesia but noted an increased incidence of bradycardia.[17] The present work adds to the cumulative evidence by directly comparing rapid onset versus prolonged duration outcomes within a single spinal-anaesthesia context, thus helping to refine adjuvant choice in real-world anaesthesia practice.

The present study had certain limitations that should be acknowledged. It was conducted as a single-centre trial with a relatively small sample size of 120 participants, which may limit the generalizability of the findings to broader surgical populations and higher-risk patients. The study included only ASA physical status I and II individuals undergoing lower-limb surgeries, thereby excluding elderly or medically complex patients in whom hemodynamic fluctuations may differ. Blinding of the anaesthesiologist performing the block was not feasible, introducing a potential element of observer bias in onset and regression time measurements.

The study period did not extend into the late postoperative phase, so delayed adverse effects and total postoperative analgesic consumption beyond the initial recovery period were not assessed. Furthermore, only a single fixed dose of clonidine (30 µg) and ropivacaine concentration (0.75% hyperbaric) were evaluated, precluding dose–response analysis or exploration of alternative concentrations or adjuvants.

Finally, biochemical markers of stress response or sedation scores were not measured, which could have provided additional insight into the systemic effects of the study drugs.

Conclusion

In conclusion, the present randomized controlled study demonstrated that both 0.75% hyperbaric ropivacaine alone and in combination with clonidine provided effective spinal anaesthesia for lower-limb surgeries, with comparable baseline and intraoperative hemodynamic stability.

The addition of clonidine significantly prolonged the duration of sensory and motor blockade and delayed the time to first analgesic requirement, thereby enhancing postoperative analgesia. However, this benefit was accompanied by a higher incidence of adverse effects such as nausea and bradycardia. Conversely, ropivacaine alone produced a faster onset of sensory and motor block with fewer side effects, making it more suitable when rapid recovery and hemodynamic stability are desired. Thus, while clonidine serves as an effective adjuvant for prolonging spinal anaesthesia, its use should be individualized based on surgical duration, patient comorbidities, and the need for extended postoperative analgesia.

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