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Original Research Article

An observational comparative study of two different doses of intrathecal clonidine as adjuvant with hyperbaric ropivacaine in lower limb orthopedic surgeries

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Abstract

Background and Aims: Adjuvants are commonly added to local anaesthetics in subarachnoid block to prolong both aesthetic and analgesic duration. This study aimed to compare the effects of two different doses of intrathecal clonidine (30 µg and 50 µg) as adjuvants to hyperbaric ropivacaine in lower limb orthopaedic surgeries. The outcomes evaluated included hemodynamic changes, sedation levels, duration of analgesia, and sensory and motor blockade characteristics.

Materials and Methods: Ninety patients were randomly assigned into two groups. Group RC30 received 0.75% hyperbaric ropivacaine 3 mL combined with clonidine 30 µg, diluted with normal saline to a total volume of 3.5 mL. Group RC50 received 0.75% hyperbaric ropivacaine 3 mL combined with clonidine 50 µg, diluted with normal saline to achieve a total volume of 3.5 mL. The study compared the duration of analgesia, sensory and motor blockade, side effects, complications, and hemodynamic changes between the two groups.

Results: Group RC30 took a longer time to reach the highest spinal level (12.2 ± 1.26 min) compared to Group RC50 (11.8 ± 1.2 min, $P = 0.003$). Time to two segment regression was significantly longer in Group RC50 (148.10 ± 8.18 min) than in Group RC30 (102.5 ± 6.8 min, $P<0.001$). Sensory and motor blockade durations were also extended in Group RC50 (263.3 ± 9.2 min and 359.2 ± 18.1 min, respectively) compared to Group RC30 (215.78 ± 7.7 min and 300.27 ± 10.6 min, respectively, $P<0.001$). The duration of analgesia were significantly longer in Group RC50 (300.5 ± 18.2 min and 451.70 ± 18.2 min, respectively) compared to Group RC30 (289.9 ± 11.9 min and 363.8 ± 11.2 min, $P<0.001$). However, Group RC50 demonstrated a higher incidence of bradycardia and hypotension, which were effectively managed with standard therapeutic interventions.

Conclusion: Intrathecal clonidine at a dose of 50 µg provides superior analgesic effects compared to 30 µg but is associated with an increased risk of bradycardia and hypotension. Careful monitoring and timely interventions are crucial when using higher doses.

Keywords: Clonidine, Postoperative analgesia, Ropivacaine, Spinal anaesthesia.

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1. Introduction

In the practice of anaesthesia, managing intraoperative tension and anxiety is challenging, as these factors have several negative consequences on various bodily systems. Using only local anaesthetics for neuraxial analgesia often leads to inadequate analgesia and increased side effects.[1] Spinal anaesthesia, however, provides effective postoperative pain management, which is essential for minimizing adverse outcomes associated with surgical trauma.[2] It also ensures rapid and sufficient surgical anaesthesia, making it a widely used technique for abdominal surgeries, caesarean sections, urological procedures, and orthopaedic operations.[3]

Ropivacaine, a newer local anaesthetic, combines the anaesthetic potency and long-lasting effects of bupivacaine while offering a toxicity profile that is intermediate between bupivacaine and lidocaine. It has the added advantage of faster recovery. When used intrathecally, 15 mg of ropivacaine has been found to be three times more effective than 10 mg of bupivacaine, producing comparable motor and hemodynamic effects but offering slightly stronger

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anaesthesia.[4,5] Due to its efficacy, reduced tendency for motor block, and lower risk of central nervous system and cardiotoxicity, ropivacaine is a significant option for regional anesthesia. Additionally, it offers differential blockade, characterized by an increased separation between sensory and motor blockades.[4,5]

To achieve prolonged postoperative analgesia after subarachnoid block, adjuvants are often added to local anaesthetics intrathecally.[6] Among these, intrathecal clonidine, a selective partial α2-adrenergic agonist, has been widely used as an adjuvant in various surgical procedures.[7] Clonidine enhances postoperative analgesia by hyperpolarizing Aδ and C fibers in the spinal cord and inhibiting voltage-gated sodium channels.[8] It has been shown to provide potent analgesia without the adverse effects typically associated with opioids.[8,9] Furthermore, clonidine strengthens the sensory and motor blockade of local anaesthetics.[9]

Systemically, clonidine can induce sedation, hypotension due to central action, and bradycardia. It has numerous clinical applications, including premedication and postoperative analgesia when combined with local anaesthetics.[10,11] In light of these benefits, this study was conducted to compare the efficacy and safety of two doses of clonidine as an intrathecal adjuvant with hyperbaric ropivacaine in lower limb orthopaedic surgeries.

2. Materials and Methods

This observational study was conducted at a tertiary care centre after receiving approval from the ethics committee of the institution (SCIEC/ON/MEDI/BNPG21/ OCT/22/54). The study was done over a period of one and a half year and included 90 participants.

The sample size was calculated using OpenEpi software (version 3.03a) with a Type I error rate of 0.05, a Type II error rate of 0.2, a power of 80%, and a 95% confidence interval.[12]

The calculation was based on findings from Kakunje et al., where times to two-segment regression were 111.83 ± 14.35 minutes with 0.5% ropivacaine 12 mg, 124.00 ± 14.17 minutes with 0.5% ropivacaine 12 mg + clonidine 15 µg, and 157.00 ± 13.49 minutes with 0.5% ropivacaine 12 mg + clonidine 30 µg.[6] A total sample size of 90 patients was determined. Participants were randomly distributed into two groups. Patients in Group RC30 received 0.75% hyperbaric ropivacaine 3 mL combined with 30 µg clonidine, diluted with normal saline to a total volume of 3.5 mL. Patients in Group RC50 received 0.75% hyperbaric ropivacaine 3 mL combined with 50 µg clonidine, diluted with normal saline to a total volume of 3.5

Inclusion criteria for the study included patients aged 18 to 65 years who consented to participate, belonged to ASA Grade I or II, and had no known history of allergies, sensitivities, or reactions to ester or amide-type local anaesthetics. Patients were excluded if they were unwilling to participate, had arrhythmias, renal, hepatic, cardiovascular, or respiratory diseases, belonged to ASA Grade III or higher, were pregnant or lactating, had a known allergy to the study drugs, required supplementation with general anaesthesia, or had contraindications to spinal anaesthesia such as local infection, coagulation disorders, raised intracranial pressure, hemodynamic instability, or neurological disorders. Patients meeting the inclusion criteria were enrolled in the study. Patients fulfilling the above criteria were enrolled in the study (**Figure 1**).

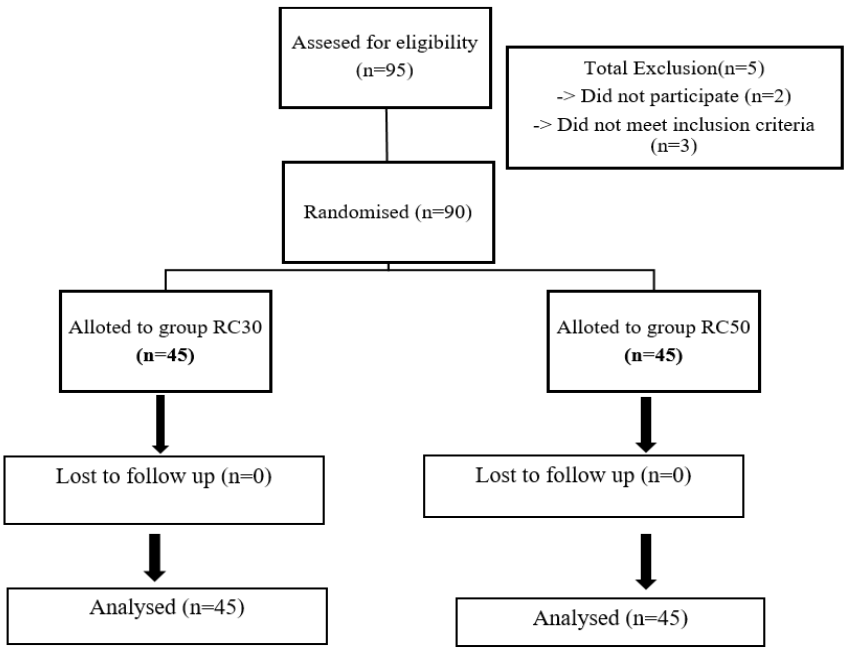

Figure 1: Consort flow diagram

Preoperative assessment included a detailed history, general examination to assess pallor, icterus, cyanosis, lymphadenopathy, clubbing, and edema, and a thorough evaluation of vital signs, including temperature, pulse rate, blood pressure, SpO_2, and respiratory rate. A systemic examination covering the cardiovascular, respiratory, and central nervous systems and per abdomen evaluation was performed. Routine preoperative investigations included complete blood count, random blood sugar, renal and liver function tests, serology, electrocardiography, chest x-ray, and any additional investigations as required. Patients were kept nil per oral (NPO) for six hours for solids and four hours for liquids, and written informed consent was obtained. Patients were also educated about the Visual Analogue Scale (VAS) for pain assessment, and intravenous lines were secured.

Preparation included arranging necessary equipment such as an anaesthesia workstation, 25G and 23G spinal needles, and emergency resuscitation equipment. Drugs prepared included glycopyrrolate, ondansetron, hyperbaric ropivacaine (0.75%), dexmedetomidine, clonidine, and emergency medications such as atropine, ephedrine, mephentermine, and lignocaine (2%). Intraoperatively, patients were connected to a multichannel monitor, and baseline vitals were recorded. Preloading was done with Ringer's lactate at 10 mL/kg, and premedication was administered using glycopyrrolate and ondansetron. Patients were divided into the two study groups, RC30 and RC50, based on their allocated treatment.

Sensory blockade was assessed using the pinprick method. Data collected included the time to sensory block onset (from spinal injection to the loss of sensation at the L1 level), the time to achieve the highest sensory block level, the time for regression by two segments, and the total sensory block duration (from spinal injection to the return of sensation at the L1 level).

Motor blockade was assessed using the Bromage scale, and data included the time to motor block onset (from spinal injection to Bromage grade I), the time to achieve the highest motor block level (grade III), and the total motor block duration (from spinal injection to the return to grade 0).[13]

Adverse effects, including bradycardia, hypotension, and respiratory depression, were monitored and managed. Bradycardia, defined as a heart rate below 60 beats per minute, was treated with 0.6 mg of intravenous atropine sulphate. Hypotension, defined as a systolic blood pressure decrease of 20% or more from baseline, was managed with 6 mg of intravenous mephentermine. Respiratory depression, defined as a respiratory rate below 10 breaths per minute, was treated with 100% oxygen.

Sedation was evaluated using a four-point sedation scale described by Chernik et al., with sedation scores recorded every five minutes for the first 15 minutes and then every 15 minutes until the end of surgery.[14] The scale included the following scores: 1 for spontaneous eye opening, 2 for response to verbal stimuli, 3 for response to physical stimuli, and 4 for no response.

Adverse effects were systematically documented on the Adverse Drug Reaction (ADR) form, and any complications that arose were managed accordingly.

Postoperatively, all patients vital signs were monitored, and the duration of sensory block and motor blockade were documented. Postoperative pain was observed using the VAS score, and both absolute and effective analgesia duration was documented. No. of rescue analgesia required in 24hrs was noted.

Postoperatively, patients' vital signs were monitored, and the duration of sensory and motor blockade was documented. Pain was assessed using the VAS, and the durations of absolute and effective analgesia were recorded (**Figure 2**).[15] Absolute analgesia duration was defined as the time from intrathecal injection to when VAS $\geq$ 1, while effective analgesia duration was the time from intrathecal injection to when VAS $\geq$ 4. The total number of rescue analgesia doses required within 24 hours was also noted, with each dose consisting of diclofenac sodium (1.5 mg/kg).

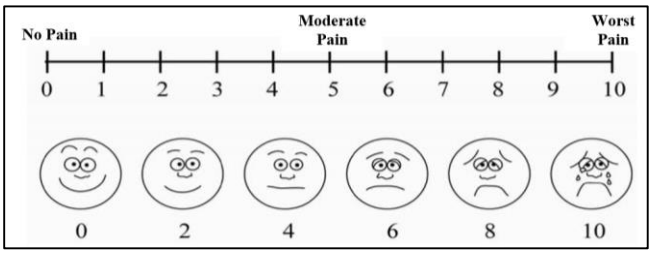

Figure 2: Visual analogue scale

2.1. Statistical analysis

Data were collected via a Case Record Form (CRF) and entered into MS Excel 2016, with analysis performed using SPSS Software version 26. Mean and standard deviation were used for continuous variables, and proportions for categorical variables. The t-test or ANOVA was applied to continuous variables, and the chi-square test was used for categorical variables. Statistical significance was set at a p-value < 0.05, with highly significant results defined as p-value < 0.001.

3. Results

Demographic characteristics were comparable between the two groups. The mean age in Group RC30 was 41.2 ± 12.6 years, while Group RC50 had a mean age of 44.04 ± 10.2 years (**Table 1**, p = 0.241).

Table 1: Mean age among both groups

Mean Age (years)	Group RC30	Group RC50	p-value
	41.2±12.6	44.04±10.2	0.241

Table 2: Gender wise distribution

Gender	Group RC30	Group RC50	p-value
Male	23	24	0.641
Female	22	21	

Table 3: ASA Grade wise distribution

ASA	Group RC30	Group RC50	p-value
I	20	21	0.536
II	25	24	

Gender distribution (Group RC30: 23 males, 22 females; Group RC50: 24 males, 21 females) and ASA status (ASA I: Group RC30: 20, Group RC50: 21; ASA II: Group RC30: 25, Group RC50: 24) showed no significant differences between the two groups, as analysed using the chi-square test (**Table 2** and **Table 3**, p = 0.641 and p = 0.536, respectively).

The time to achieve sensory blockade at L1, onset of motor blockade (Bromage Grade I), and onset of Bromage grade III did not differ significantly between the two groups. Group RC30 had a mean onset time of 3.07 ± 0.5 minutes for sensory blockade, while Group RC50 had 2.5 ± 0.26 minutes (p = 0.481). Similarly, for motor blockade onset, Group RC30 had 1.5 ± 0.3 minutes and Group RC50 had 1.06 ± 0.11 minutes (p = 0.234) (**Table 4**).

The time to achieve the highest sensory level was significantly shorter in Group RC50 (p = 0.003), and higher sensory levels (T4) were achieved more frequently in Group RC50 (31.1%) compared to Group RC30 (15.5%) (**Figure 3**, p < 0.001).

Table 4: Spinal blockade characteristics

	Group RC30		Group RC50		p-value (t test)
	Mean	(SD)	Mean	(SD)	
Onset of sensory blockade at L1 (min)	3.07	0.5	2.5	0.26	0.481
Onset of motor blockade bromage grade I (min)	1.5	0.3	1.06	0.11	0.234
Time to achieve highest level (MIN)	12.2	1.26	11.8	1.2	0.003
Onset of motor blockade bromage grade III (min)	3.1	0.59	3.012	0.63	0.942

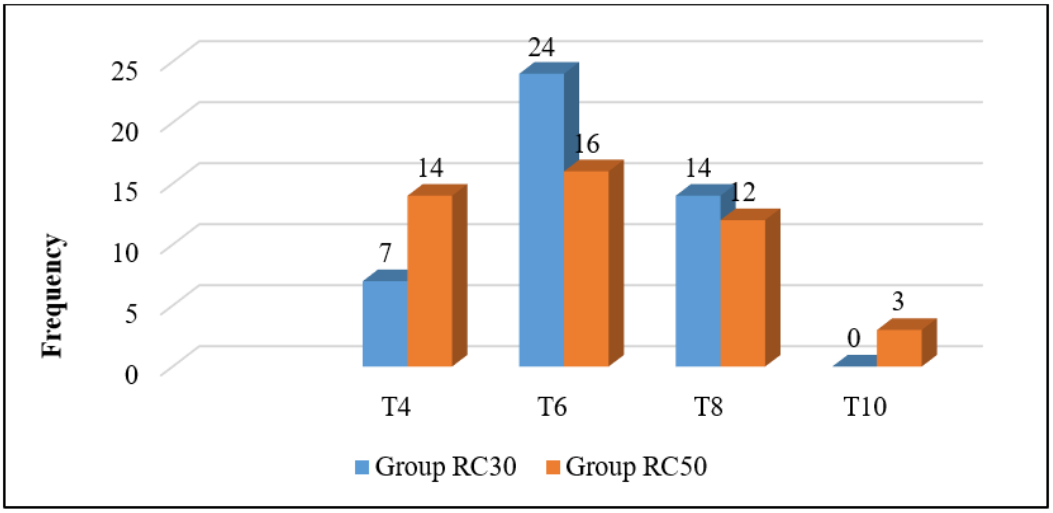

Figure 3: Highest level of sensory block achieved

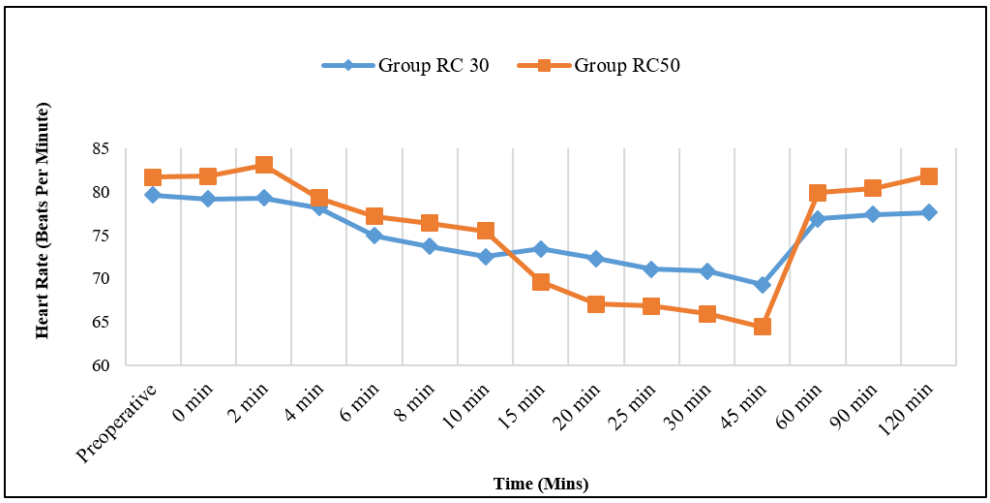

Figure 4: Intraoperative mean heart rate

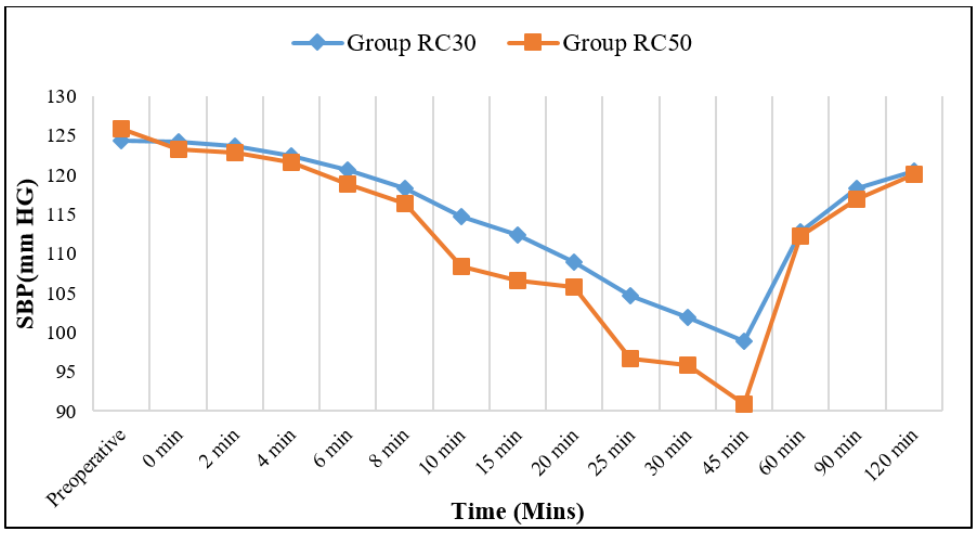

Figure 5: Intraoperative Systolic blood pressure

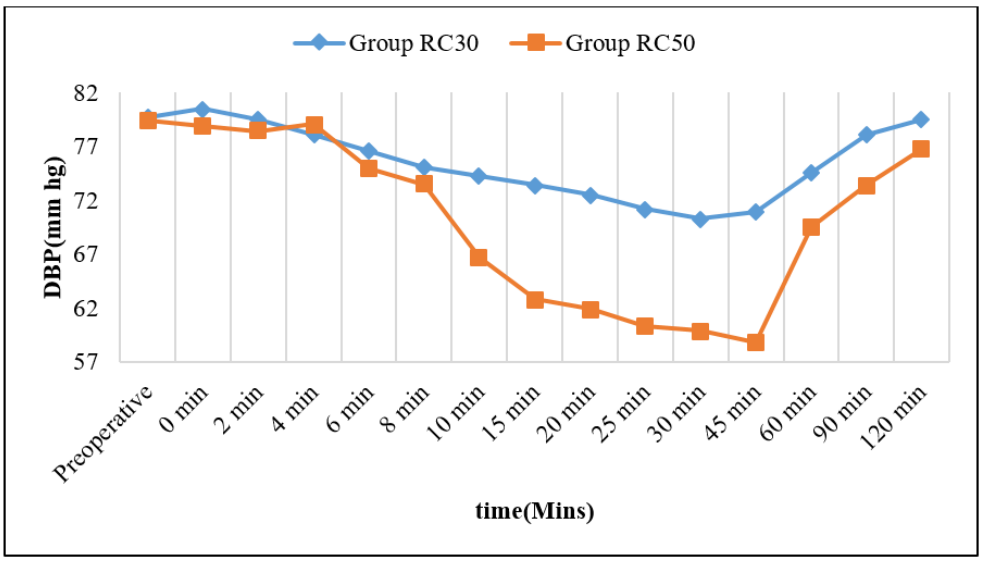

Figure 6: Intraoperative diastolic blood pressure

Significant differences in intraoperative systolic blood pressure ($p < 0.05$), diastolic blood pressure ($p < 0.05$), and heart rate ($p < 0.05$) were observed between the two groups during the period of 20 to 45 minutes post-injection. These differences were analysed using t-tests and are depicted in **Figure 4**, **Figure 5** and **Figure 6**.

Additionally, Group RC50 exhibited higher sedation scores compared to RC30 (**Figure 7**), with sedation being significantly greater ($p < 0.001$).

Group RC50 had a higher incidence of bradycardia and hypotension compared to Group RC30, as determined by the odds ratio analysis (**Figure 8**).

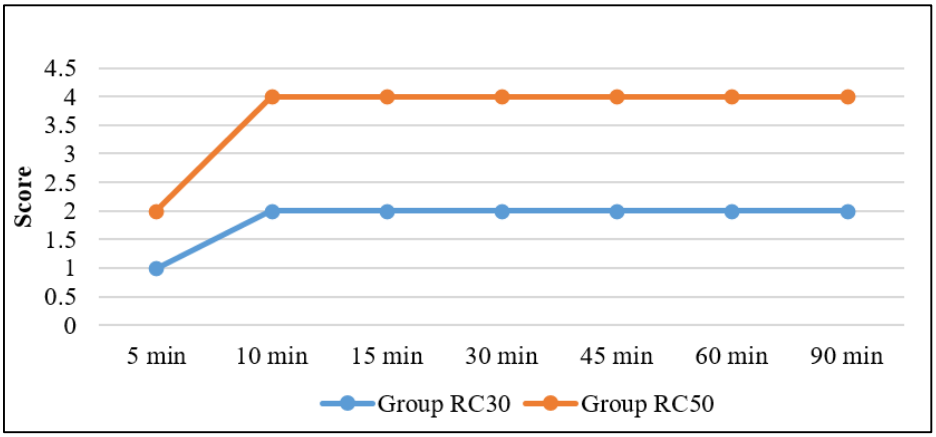

Figure 7: Sedation score

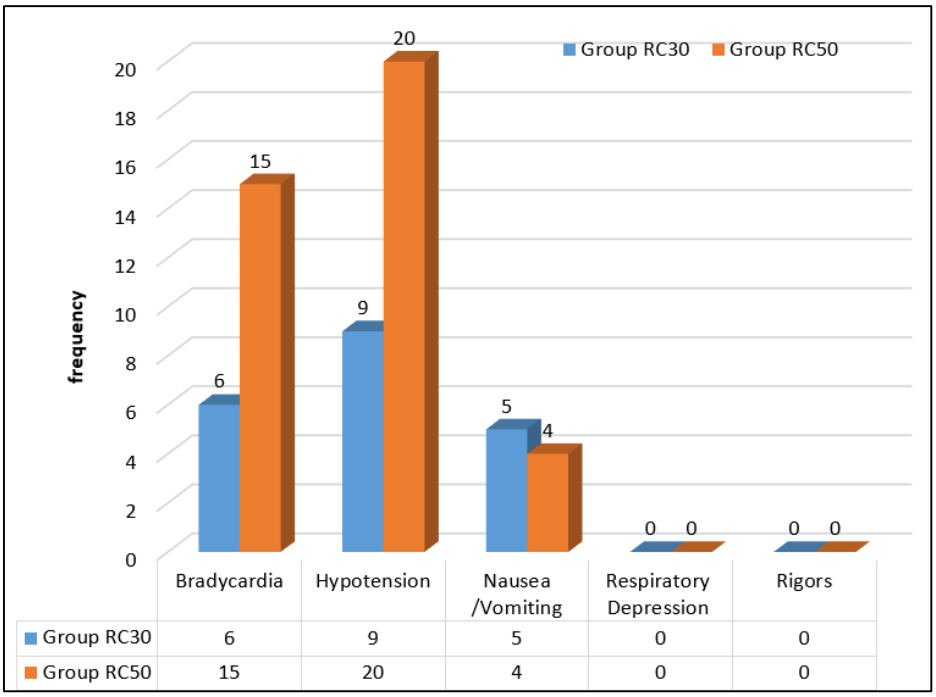

Figure 8: Intraoperative complications

Table 5: Duration of spinal blockade

	Group RC30		Group RC50		p value
	Mean	SD	Mean	SD	
Two segment regression (in mins)	102.5	6.8	148.1	8.18	P < 0.001
Motor blockade duration (in mins)	300.27	10.6	359.2	18.1	P < 0.001
Sensory blockade duration (in mins)	215.78	7.7	263.3	9.2	P < 0.001
Absolute analgesia duration (in mins)	289.9	11.9	300.5	18.2	P < 0.001
Effective analgesia duration (in mins)	363.8	11.2	451.7	18.2	P < 0.001

The duration of spinal blockade, including sensory and motor blockade, was significantly longer in Group RC50 compared to Group RC30. Group RC50 had prolonged sensory blockade (263.3 ± 9.2 minutes vs. 215.78 ± 7.7 minutes, p < 0.001), motor blockade (359.2 ± 18.1 minutes vs. 300.27 ± 10.6 minutes, p < 0.001), and absolute analgesia duration (300.5 ± 18.2 minutes vs. 289.9 ± 11.9 minutes, p < 0.001). Effective analgesia duration was also significantly longer in Group RC50 (451.7 ± 18.2 minutes vs. 363.8 ± 11.2 minutes, p < 0.001) (**Table 5**).

Table 6: Number of rescue analgesia required in 24hrs post operatively

Number of Rescue Analgesia Requirement	Group RC30	Group RC50	p-value
1	26	22	0.0309
2	19	23	

A statistically significant difference was found in the number of rescue analgesia doses required within 24 hours postoperatively. Group RC50 required more doses compared to Group RC30 (p = 0.0309) (**Table 6**).

4. Discussion

Spinal anaesthesia is a neuraxial blockade procedure in which a local anaesthetic is injected directly into the subarachnoid space. It is widely used for lower limb orthopaedic surgeries due to its simplicity, speed, reliability, and the advantages of early recovery and post-operative analgesia. Among the local anaesthetics used, ropivacaine is preferred due to its lower lipid solubility, offering a better safety profile with reduced central nervous system toxicity and cardiotoxicity. Additionally, α2-agonists, such as clonidine, when used intrathecally, can enhance the motor and sensory blockade duration through synergistic effects, due to their distinct mechanisms when combined with local anaesthetics.

The demographic information in our study, which included age, gender, weight, and ASA category, was statistically not significant (p >0.05) and comparable between the two groups. This is consistent with the findings of K Sri Hyndavi et al., who also observed no statistically significant difference in demographic data between groups receiving 15 µg and 30 µg clonidine with 0.5% hyperbaric ropivacaine for lower limb procedures (p > 0.05).[16]

In our study, time of sensory block initiation at L1 was found to be comparable i.e., 3.07 ± 0.5 minutes and 2.5± 0.26 minutes in Group RC30 and Group RC50 respectively, which was early for Group RC50 compared to Group RC30 and was not significant (P=0.481). Significant difference was there between time to achieve highest level which was earlier for Group RC50 (11.8 ± 1.2) minutes as compared to Group RC30 (12.2 ± 1.26) minutes (P=0.003). Time for 2 segment regression was longer with Group RC50 (148.1 ± 8.18) minutes as compared to Group RC30 (102.5 ± 6.8) minutes, (P<0.001) which was highly significant. Duration of sensory block was significantly longer in Group RC50 (263.3 ± 9.2) minutes compared to Group RC30 (215.78 ± 7.7) (p<0.001). These findings align with the study by Adlakha et al., where 50 µg clonidine resulted in a faster sensory block onset (2.35 ± 0.51 minutes) and a shorter time to reach the highest sensory segment (8.1 ± 1.21 minutes) when compared to the 30µg clonidine group (p = 0.002, p = 0.001, respectively).[17.] Similarly, Agrawal et al. observed a shorter time to reach the T10 spinal segment with 30 µg clonidine compared to 15 µg clonidine (12 ± 3.4 minutes vs. 12.8 ± 3.8 minutes, p = 0.032).[5]

In our study, the time to onset of motor blockade (Bromage grade I) was found to be comparable between the two groups. Specifically, Group RC30 had an onset of 1.5 ± 0.3 minutes, while Group RC50 had an onset of 1.06 ± 0.11 minutes. Although Group RC50 showed a faster onset, the difference was not statistically significant (p = 0.234). Similarly, the time to onset of complete motor blockade (Bromage grade III) was comparable between the groups. Group RC30 had a slightly delayed onset (3.1 ± 0.59 minutes) compared to Group RC50 (3.012 ± 0.63 minutes), with no significant difference (p = 0.942).

The duration of motor blockade was significantly prolonged in Group RC50 (359.2 ± 18.1 minutes) compared to Group RC30 (300.27 ± 10.6 minutes). This result indicates that Group RC50 experienced a longer-lasting motor blockade (p < 0.001).

These findings are in line with the study by Agrawal et al., which reported that the time to complete motor blockade (Bromage grade III) was similar between groups receiving 30 µg and 15 µg clonidine. The 30µg clonidine group reached complete motor blockade at 11 ± 3.1 minutes, whereas the 15µg clonidine group achieved it at 12 ± 3.4 minutes. However, the difference was not statistically significant. Additionally, the time for motor block regression was longer in the 30µg clonidine group (140.3 ± 39.3 minutes) compared to the 15µg clonidine group (128.3 ± 23.6 minutes), but the difference was not significant. The motor block duration was also longer in the 30µg clonidine group (165 ± 27 minutes), though the difference did not reach statistical significance (p > 0.05).[5.]

Adlakha et al. also reported comparable onset times for complete motor blockade (Bromage III) between two groups receiving 30 µg and 50 µg clonidine. The 50µg clonidine group showed a quicker onset (3.98 ± 0.78 minutes) compared to the 30µg clonidine group (4.78 ± 1.18 minutes), although the difference was not statistically significant. However, the duration of motor blockade was significantly longer in the 50µg clonidine group (186 ± 18.46 minutes) compared to the 30µg clonidine group (135 ± 15.39 minutes), with a highly significant result (p < 0.001).[17]

In terms of intraoperative complications, bradycardia and hypotension were more frequently observed in Group

RC50. Specifically, 13% of patients in Group RC30 experienced bradycardia, compared to 33.3% in Group RC50. Similarly, 20% of patients in Group RC30 had hypotension, compared to 44.4% in Group RC50. However, the incidence of nausea/vomiting was similar between the groups, with 11.1% of patients in Group RC30 and 8.8% in Group RC50 reporting these symptoms.

When examining heart rate, a statistically significant decrease was observed at 15, 20, 25, 30, and 45 minutes in Group RC50 ($p < 0.001$), compared to Group RC30, which remained stable during these periods. Similarly, systolic blood pressure and diastolic blood pressure decreased significantly in Group RC50 at these time points ($p < 0.001$), as compared to Group RC30. These results are in line with the findings of K Sri Hyndavi et al., who observed significant differences in heart rate, SBP, and DBP between the two groups after the 5th minute.[16.]

In the study by Kakunje et al., the effects of 15 µg and 30 µg clonidine as adjuvants to 0.5% hyperbaric ropivacaine were compared. In their study, heart rate was lower in the 30µg clonidine group compared to both the 15µg clonidine group and the control group from 20 to 120 minutes ($p < 0.05$). Additionally, the occurrence of hypotension and the need for mephentermine were higher with clonidine, and this effect was dose-dependent, with more hypotension observed in the 30µg clonidine group compared to the 15µg clonidine group. Bradycardia occurred more frequently with the addition of 30 µg clonidine.[6] Similarly, Agrawal et al. reported that clinically significant bradycardia occurred in 20% of patients in the 15µg clonidine group and in 30% of those in the 30µg clonidine group.[5.]

Regarding sedation scores, Group RC50 exhibited greater sedation compared to Group RC30, which is consistent with Adlakha et al., who found that sedation scores were higher in the 50µg clonidine group than the 30µg clonidine group.[17]

In terms of absolute analgesia, Group RC50 had a significantly longer duration (300.5±18.2 minutes) compared to Group RC30 (289.9 ± 11.9 minutes, $p < 0.001$). Similarly, the effective analgesia duration was significantly longer in Group RC50 (451.7±18.2 minutes) compared to Group RC30 (315.1 ± 37.6 minutes, $p < 0.001$). Interestingly, Group RC30 required more rescue analgesia in the first 24 hours post-operatively compared to Group RC50.

These findings align with those of Adlakha et al., who reported that the duration of absolute analgesia was significantly longer in the 50µg clonidine group (6.30 ± 1.45 hours) compared to the 30µg clonidine group (3.32 ± 1.80 hours, $p < 0.001$).[17] Similarly, Thakur et al. observed a significant prolongation in effective analgesia for the 30µg clonidine group compared to the 15µg clonidine group ($p < 0.05$).[18]

Our study also had few limitations. First, there was no placebo group, which restricts our ability to assess the true effects of clonidine compared to a neutral treatment. Second, we only included normotensive patients, which may limit the applicability of the findings to hypertensive individuals, where intraoperative hemodynamics could play a more critical role. Additionally, as this was a hospital-based study, the generalizability of the results may be limited to settings similar to ours.

5. Conclusion

Intrathecal Clonidine 50µg with hyperbaric ropivacaine is associated with an earlier onset and longer duration of both sensory and motor recovery. Postoperative analgesia is prolonged when 50µg clonidine is used as an adjuvant. However, the incidence of hypotension and bradycardia is also more with the 50µg clonidine, suggesting the need for careful monitoring of hemodynamic parameters in this group.

6. Source of Funding

Nil.

7. Conflict of Interest

There are no conflicts of interest.

8. Acknowledgement

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