

## EFFECT OF ADDITION OF CLONIDINE OR FENTANYL TO INTRATHECAL HYPERBARIC ROPIVACAINE 0.75% IN LOWER LIMB SURGERIES: A RANDOMIZED CLINICAL STUDY

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### ABSTRACT

**Background:** Spinal anaesthesia emerged as a technique of choice for lower limb surgeries. Hyperbaric Ropivacaine 0.75% provides adequate intra-operative anaesthesia as compared to isobaric Ropivacaine. However, considering its shorter duration of action compared to commonly used Bupivacaine, patients encounter pain in early post-operative period warranting use of an adjuvant. This study aimed to compare effects of Fentanyl and Clonidine as adjuvant to hyperbaric Ropivacaine 0.75% on duration of sensory block, motor block and post-operative analgesia. **Materials and Methods:** Eighty patients of either sex aged 18-60 years scheduled to undergo lower limb surgery under spinal anaesthesia were included in study. Participants were randomly allocated to group RF and group RC. Participants in group RF received intrathecal 2.5ml hyperbaric Ropivacaine 0.75% + 25mcg Fentanyl (0.5ml) while participants in Group RC received intrathecal 2.5ml hyperbaric Ropivacaine 0.75% + 15mcg Clonidine (0.1ml) + 0.4ml normal saline. Primary outcome was to determine duration of sensory and motor block. Time of administration of first rescue analgesia was also included as primary outcome. The secondary outcomes were to determine time to onset of sensory and motor block, comparison of hemodynamic parameters and incidence of complications. **Result:** Both groups exhibited comparable demographic characteristics. Duration of sensory and motor block achieved was found to be more in group RC as compared to group RF and it was statistically significant ( $P < 0.05$ ). Time of first rescue analgesia requirement was also significantly more in group RC when compared to group RF ( $P < 0.05$ ). Time to onset of sensory and motor block was found to be significantly higher in group RF as compared to group RC ( $P < 0.05$ ). Hemodynamic measurements demonstrated no substantial variations between group RF and group RC at any time point. Finally, incidence of complications including hypotension, nausea and vomiting, bradycardia did not show any significant difference between the groups, however, incidence of pruritus showed statistically significant difference ( $P < 0.05$ ) with higher incidence in group RF as compared to group RC. **Conclusion:** This study demonstrated that intrathecal Clonidine with hyperbaric Ropivacaine 0.75% provides prolonged duration of sensory block, longer duration of post operative analgesia and hence, lesser number of rescue analgesia requirements. These findings advocate for use of Clonidine as adjuvant to hyperbaric Ropivacaine as equally safe and more efficacious adjuvant when compared to Fentanyl in spinal anaesthesia.

## INTRODUCTION

The most important role of an anaesthesiologist is ensuring analgesia throughout the intra-operative

period as well as extending this pain relief post-operatively. Regional anaesthesia, particularly spinal anaesthesia has emerged world-wide over the years as a technique of choice for lower limb surgeries due

to its reliability, cost effectiveness, excellent muscle relaxation and its potential to ensure prolonged post-operative analgesia.<sup>[1]</sup> Since the first administration of spinal anaesthesia, various drugs have been used over the period of time searching for an ideal drug that provides an excellent surgical anaesthesia, post-operative analgesia and also free of inadvertent side effects.

Bupivacaine, a local anaesthetic, belonging to amide class, is commonly used in spinal anaesthesia. Bupivacaine has a prolonged motor block and also, in high doses may lead to myocardial depression, heart blocks, dysrhythmias and toxicity of the central nervous system.<sup>[2]</sup> These days, necessity for early ambulation, quicker and complete recovery with minimal side effects is rising. Another local anaesthetic drug, Ropivacaine, a pure S-enantiomer of propivacaine is a popular in recent times due to its better safety profile over Bupivacaine with lower potential of neurotoxicity and cardiac toxicity.<sup>[3,4]</sup> It has low lipid solubility and blocks nerve fibres involved in pain transmission to a greater degree than those involved in motor function resulting in early recovery of motor function.<sup>[5]</sup>

Ropivacaine was approved for intrathecal route by European union in February 2004. Plain solution of Ropivacaine exhibits variable and less predictable effects resulting in either insufficient level of block level which remains inadequate for surgery or excessive cephalad spread resulting in dreadful side effects. Also, this preparation has shorter duration of action offering inadequate time for commonly performed surgical procedures.<sup>[6]</sup> To overcome these shortcomings, hyperbaric solutions were prepared after addition of dextrose to isobaric Ropivacaine. However, now-a-days hyperbaric preparation of Ropivacaine 0.75% is commercially available which has more predictable onset and intrathecal spread; and less interpatient variability after intrathecal injection.<sup>[7]</sup> It provides adequate intra-operative anaesthesia and has a shorter duration of action, making it an ideal agent for day care surgeries.<sup>[8]</sup> However, considering its shorter duration of action compared to commonly used Bupivacaine, patients encounter pain in the early post-operative period, necessitating the use of systemic drugs like non-steroidal anti-inflammatory drugs (NSAIDs) and opioids.

Considering this shortcoming with the use of hyperbaric Ropivacaine 0.75%, use of an adjuvant drug is looked-for. Various adjuvants are already used with hyperbaric Bupivacaine in spinal anaesthesia to improve quality of intra-operative anaesthesia as well as extending its effect for post-operative analgesia, most common being Fentanyl and Clonidine. Fentanyl, a lipophilic short-acting opioid, acts on  $\mu 1$  and  $\mu 2$  receptors. Since 1980, Fentanyl is in use as an intrathecal adjuvant. It facilitates reduction in dose of local anaesthetic by potentiating the afferent sensory blockade. When Fentanyl is used as an adjuvant in spinal anaesthesia, it provides good quality of intra-operative and post

operative analgesia with better hemodynamic stability. However, certain side effects including pruritus and urinary retention are associated with the use of opioids intrathecally.<sup>[9]</sup> Clonidine, which is a centrally acting partial agonist at  $\alpha 2$  adrenergic receptor is a non-opioid adjuvant used in spinal anaesthesia to improve the quality of anaesthesia and analgesia. Hypotension, bradycardia, sedation are some of its side-effects. When Clonidine is used at appropriate dose in spinal anaesthesia as adjuvant to isobaric Ropivacaine, it prolongs the duration of intraoperative anaesthesia and postoperative analgesia.<sup>[10]</sup>

Hence, hyperbaric Ropivacaine being a safer intrathecal anaesthetic and allowing early motor recovery as compared to Bupivacaine remains a preferred choice for lower limb surgeries. However, use of adjuvant is warranted with its use to overcome post-operative pain. This study aimed to compare the effects of Fentanyl and Clonidine as adjuvant to hyperbaric Ropivacaine 0.75% on duration of sensory block, motor block and post-operative analgesia.

## MATERIALS AND METHODS

This randomized double-arm parallel group, double-blind clinical study was conducted over 1 year at Maharaja Agrasen Medical College, Hisar following approval by the Institutional Ethical Committee. Before recruitment, the trial was registered on clinical trial registry of India with registration number CTRI/ 2023/ 10/ 058853. All participants gave written informed consent, confirming their agreement to participate in the study and authorizing the use of their anonymized data for research and educational purposes. The study followed the Declaration of Helsinki (2013) ethical guidelines and complied with Good Clinical Practice standards.

Study population involved 80 patients of either sex aged 18-60 years scheduled to undergo elective lower limb surgery under spinal anaesthesia. Patients with ASA PS 1 or 2 were included. Patients who refused for the procedure, having known drug allergy, pregnant patients, patients with BMI>30kg/m<sup>2</sup>, spine/ neurological disease, coagulation disorder, known cardiorespiratory disease or where the duration of surgery was less than 60 minutes were excluded from the study.

All patients were examined during the preoperative visit a day prior to surgery. Detailed clinical history along with physical examination was done. Routine and other investigations were carried out as per requirement. The purpose and protocol of the study were explained to the patients and informed written consent was obtained for the same.

On the day of surgery, in the pre-anaesthetic room, participants were randomized into two groups: Group RF and Group RC. Randomization and group allocation concealment were achieved using opaque, sealed envelopes enclosing numbers generated via

computer. The group allocation remained blind to the patients.

After shifting the patient in the operating room, all routine monitors, including ECG, heart rate (HR), systolic blood pressure (SBP), diastolic blood pressure (DBP), mean arterial pressure (MAP) and pulse oximetry (SpO<sub>2</sub>) were established and baseline readings were recorded. Intravenous access was established and patient was preloaded with 10mL/kg of Ringers Lactate solution. The study drug was prepared by the first anaesthesiologist in a sterile unlabelled syringe according to group allocation. For Group RF, 2.5ml hyperbaric Ropivacaine 0.75% + 25mcg Fentanyl (0.5ml) making total volume 3.0ml was prepared. For Group RC, 2.5ml hyperbaric Ropivacaine 0.75% + 15mcg clonidine (0.1ml) + 0.4ml normal saline making total volume 3.0ml was prepared.

Under all aseptic precautions, lumbar puncture was performed at L3-L4 intervertebral space in the sitting position using a 25G Quinckes spinal needle and the study drug was injected by the second anaesthesiologist, who remained blinded to the composition of the drug. Patients were placed supine immediately after the procedure and the operating table was maintained horizontal. The time of the intrathecal injection was noted.

The patient's assessment and observations were recorded by the second anaesthesiologist in the operating theater as well as in the recovery room and ward. Continuous monitoring of the HR, SpO<sub>2</sub>, and ECG was done. SBP, DBP and MAP were recorded every two minutes for the first 10 minutes, then at 5-minute intervals for 30 minutes and then every 15 minutes until the end of the surgery. In the postoperative period, these measurements were recorded every hour for 6 hours. A fall in SBP by 20% below the baseline was defined as hypotension and managed with Inj. Mephentermine 6 mg IV and a fall in HR to <50/min was defined as bradycardia and managed with Inj. Atropine 0.6 mg IV. If the onset of the sensory block did not occur even 20 minutes after the intrathecal injection of the study drug, plan of anesthesia was changed and general anesthesia was administered.

The sensory block was assessed by loss of sensation to pinprick using a 25G blunt needle along the mid-axillary line bilaterally every 2 minutes until two consecutive findings remained the same, i.e., the highest cephalad spread of the sensory block had occurred. The time of sensory block at T12 from time of intrathecal injection was noted as onset of the sensory block and the surgeon was allowed to start the surgery. The time of regression of the sensory block to S1 from time of onset was noted as the duration of the sensory block. The time of the first rescue analgesia was determined from the time of onset of sensory block until the patient demanded the first rescue analgesic and/or VAS >3 in the post-anesthesia care unit. The Visual Analogue Scale (VAS) was used, wherein 0 = no pain, and 10 = severe pain, every 15 minutes in the post-anesthesia

care unit. Rescue analgesia was given with Inj. Diclofenac 75 mg IV infusion.

Motor block was assessed according to the Bromage scale, i.e., Bromage 0: Patients able to move the hip, knee, and ankle; Bromage 1: Patients unable to move the hip but able to move the knee and ankle; Bromage 2: Patients unable to move the hip and knee but able to move the ankle; Bromage 3: Patients unable to move the hip, knee, and ankle. Motor block was assessed every 2 minutes. The onset of maximum motor block was defined as the time from the intrathecal injection of the drug to attaining Bromage scale 3. The duration of motor block was defined as the time taken from the onset of motor block to complete recovery of motor block, i.e., a Bromage score of 0.

The study's primary outcome was to determine the duration of sensory and motor block of the two groups. Time of administration of first rescue analgesia was also included as primary outcome. The secondary outcome of the study was to determine onset of sensory and motor block of the two groups. Comparison of hemodynamic parameters including HR, SBP, DBP, MAP and other complications such as hypotension, bradycardia, nausea, vomiting, shivering, and pruritus, if any during the intraoperative and postoperative periods were also recorded as secondary outcomes.

Sample size was estimated based on the study conducted by Priya L et al. comparing time for S1 regression (min) of sensory block between the two groups.<sup>[11]</sup> The sample size was calculated as 23 per group based on the following considerations: an  $\alpha$ -type-I error = 5% and 80% power of the study. Total eighty patients were recruited to overcome any possibility of dropping out and to increase power of the study.

Data related to demographic details and study parameters were collected from proforma and compiled on MS Excel spread sheet. Data analysis was conducted using Statistical Package for the Social Sciences (SPSS) statistics software version 21.0 (International Business Machines Corporation (IBM Corp), Armonk, NY, USA). Normally distributed numerical data including demographic details, time, blood pressure, and heart rate were summarized as mean (SD) and compared between groups using independent samples t-test. Categorical variables were expressed as frequencies and percentages and assessed using the Chi-square test. A P value of <0.05 was considered statistically significant.

## RESULTS

Out of 80 patients, who initially met the enrolment criteria, all patients participated. Further, from this cohort of 80 patients undergoing lower limb surgery under spinal anaesthesia, all patients completed the study and were subjected to final analysis. [Figure 1] Baseline demographic data including age, gender,

height, weight and BMI were comparable between the groups, with no statistically significant difference observed ( $P > 0.05$ ). [Table 1] Majority of the patients (58) belonged to ASA II, while 22 patients were ASA I. However, there was no significant difference between the groups regarding ASA grade. Duration of sensory and motor block achieved was found to be more in group RC as compared to group RF and it was statistically significant ( $P < 0.05$ ). The time of first rescue analgesia requirement was also significantly more in the group RC when compared to group RF ( $P < 0.05$ ) indicating longer duration of post-operative analgesia in group RC. Time to onset of sensory and motor block was found to be significantly higher in group RF as compared to Group RC ( $P < 0.05$ ). [Table 2]

The baseline values of HR, SBP, DBP and MAP in both the groups were comparable and the difference was statistically insignificant. All the hemodynamic measurements recorded after intrathecal injection including HR, SBP, DBP and MAP demonstrated no substantial variations between group RF and group RC at any time point ( $P > 0.05$ ). [Figure 2] Finally, incidence of complications including hypotension, nausea and vomiting, bradycardia did not show any statistically significant difference between the groups, however, incidence of pruritus showed statistically significant difference ( $P < 0.05$ ) with higher incidence in group RF as compared to group RC. [Table 3]

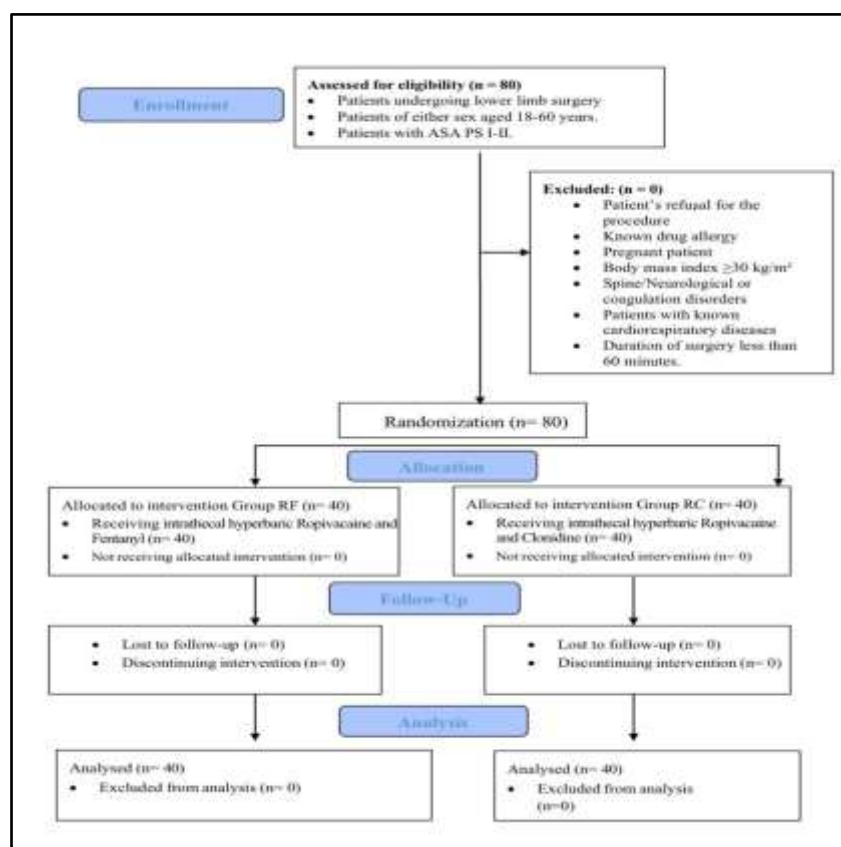


Figure 1: Consolidated Standards of Reporting Trials (CONSORT) flow chart

Table 1: Comparison of demographic variables between the studied groups

		Group RF (n=40)	Group RC (n=40)	P value
Age (years)		41.8 (10.2)	40.8 (10.5)	0.667
Gender	Male	21	24	0.499
	Female	19	16	
Weight (kg)		70.5 (4.2)	68.91 (3.7)	0.071
Height (m)		1.69 (0.05)	1.67 (0.05)	0.077
BMI (kg/m <sup>2</sup> )		24.42 (1.19)	24.77 (1.52)	0.255

Numerical data are expressed as mean (standard deviation); categorical data are expressed as count.



**Table 2: Operative and postoperative parameters**

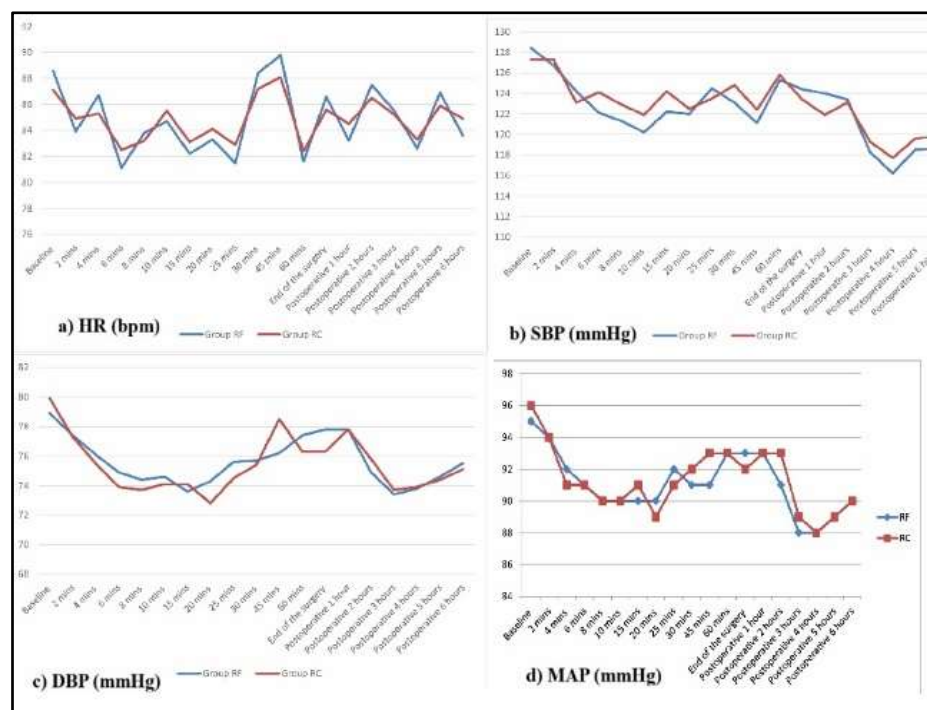
	Group RF (n=40)	Group RC (n=40)	P value
Duration of sensory block (Mins)	206.5 (22.05)	268 (20.7)	0.0001*
Duration of motor block (Mins)	168.6 (20.65)	210.65 (20.02)	0.0001*
Time to first rescue analgesic requirement (Mins)	302.6 (23.38)	384.7 (42.2)	0.0001*
Onset of sensory block to T12 (Mins)	2.8 (0.2)	2.21 (0.17)	0.0001*
Onset of motor block (Mins)	3.52 (0.21)	3.19 (0.43)	0.0001*

Numerical data are expressed as mean (standard deviation); \*Statistically significant

Categorical data are expressed as count; \*Statistically significant

**Table 3: Comparison of incidence of complications between the studied groups**

Complications	Group RF (n=40)	Group RC (n=40)	P value
Hypotension	1	2	0.261
Nausea/ vomiting	3	4	0.614
Bradycardia	1	1	1.0
Pruritus	5	0	0.020*



**Figure 2: Comparison of trend of hemodynamic parameters between the studied groups. a) HR=heart rate; b) SBP=systolic blood pressure; c) DBP=diastolic blood pressure; d) MAP=mean arterial pressure**

## DISCUSSION

Subarachnoid blockade is commonly used regional anesthetic technique for lower limb surgeries. Ropivacaine, a relatively safer local anesthetic is frequently used in this technique but carries some limitations including shorter duration of motor block; and earlier and higher doses of rescue analgesic requirement associated with its use. Higher doses of Ropivacaine can be used to avoid above limitations but it adds to higher chances of complications. Many studies have proven that intrathecal adjuvants like opioids, dexmedetomidine, midazolam, clonidine, fentanyl prolong the effect of spinal anaesthesia when combined with hyperbaric Bupivacaine or isobaric Ropivacaine. With the use of Fentanyl, side effects like pruritus, urinary retention, and respiratory depression are reported. Clonidine, commonly studied intrathecal adjuvant, is known for prolonging

sensory and motor block and post-operative analgesia. It has advantages like decreased post spinal shivering, emesis, sedation and pruritus. There is limited data on sensory and motor block characteristics when Clonidine and Fentanyl used as adjuvant to hyperbaric Ropivacaine 0.75%. The present study was conducted to assess the effect of addition of Clonidine or Fentanyl to intrathecal hyperbaric Ropivacaine 0.75% in patients undergoing lower limb surgeries under spinal anaesthesia.

The demographic characteristics of patients included in this study were comparable between Group RF and Group RC, ensuring minimal confounding variables that could influence the outcomes. Mean age of the patients in group RF and group RC was 41.8 (10.2) years and 40.8 (10.5) years respectively. Both the groups were comparable in terms of age-wise distribution. Mean height of the patients of group RF and group RC was 1.69 (0.05) m and 1.67 (0.05) m

respectively. Again, both the groups were comparable in terms of height-wise distribution. In a similar study conducted by Priya L et al., mean height of the patients in fentanyl group and clonidine group was reported as 166.73cm and 166.23cm respectively.<sup>[11]</sup> Height of the patient affects the intrathecal spread of the drug and comparable height between the two groups in this study nullifies height as a confounding factor. Mean weight of the patients of group RF and group RC was 70.54 (4.2) kg and 68.91 (3.7) kg respectively. In a study conducted by Bathari R et al. mean weight of the patients in the fentanyl group and clonidine group were reported as 61.65kg and 62.7kg respectively.<sup>[12]</sup> As dose of hyperbaric Ropivacaine used in both the groups was similar, comparable weight in between the groups excluded the effect of patients' weight on the outcome parameters. Mean BMI of the patients of group RF and group RC was 24.42 (1.19) kg/m<sup>2</sup> and 24.77 (1.52) kg/m<sup>2</sup> respectively. Obese patients are known to have more cephalad and rapid spread of intrathecal drug, however, in this study comparable BMI in between the groups facilitated reporting of unbiased results. Regarding gender distribution, 52.5% of the patients of group RF and 60% of the patients of group RC were males. This slight male predominance aligns with studies such as Sharan R et al. which documented similar trends.<sup>[13]</sup> The distribution may reflect healthcare seeking behavior or a regional variance between sexes. The uniformity in demographic characteristics supports the robustness of the study design, ensuring that any observed differences in outcomes are attributable to the intervention rather than demographic disparities. This study analyzed and compared the characteristics of sensory and motor block in terms of duration and onset between the group RF and group RC. Mean time to onset of sensory block to T12 among patients in group RF was 2.8 (0.2) minutes as compared to 2.21 (0.17) minutes in group RC. Although this difference was statistically significant, but clinically this was an insignificant difference. Our results were consistent with the results obtained by previous authors who also reported similar findings. In a study conducted by Sharan R et al., mean onset of sensory block to T10 in patients of fentanyl group and clonidine group was 5.94 minutes and 5.80 minutes respectively.<sup>[13]</sup> Attributed to the use of isobaric Ropivacaine, sensory onset was delayed in their study as compared to the results in the present study. Mean duration of sensory block in group RF and group RC was 206.5 (22.05) minutes and 268 (20.7) minutes respectively. Mean duration of sensory block was significantly higher in group RC as compared to group RF. Our results were in concordance with the results obtained by Priya L et al. who reported longer duration of sensory block (regression to S1) among patients of the clonidine group (148 minutes) in comparison to the patients of the fentanyl group (109 minutes).<sup>[11]</sup> Prolonged duration of sensory block while using Clonidine as an adjuvant can be attributed to its mechanism of action, where

Clonidine activates presynaptic  $\alpha_2$  receptors on the primary afferent nerve terminals, which inhibits the release of pro-nociceptive neurotransmitters like substance P.

Mean onset of motor block in group RF was 3.52 (0.21) minutes in comparison to patients of group RC where it was 3.19 (0.43) minutes. Again, the difference in onset time of motor block was statistically significant between the groups, but clinically the difference remained insignificant. Our results were in concordance with the results obtained by previous authors who also reported similar findings. In a study conducted by Sharan R et al., mean onset of motor block was comparable between the groups, 10.58 minutes and 10.78 minutes in clonidine and fentanyl group respectively but was longer when compared to this study.<sup>[13]</sup> Use of hyperbaric Ropivacaine in this study can be attributed to earlier onset of motor block as hyperbaric drug has more predictable and gravity-dependent spread, leading to more reliable block heights and earlier onset of sensory and motor block.

Mean duration of motor block in group RC was 210.65 (20.02) minutes, significantly higher in comparison to patients of group RF where it was 168.6 (20.65) minutes. Our results were in harmony with the results obtained by Bathari et al. who also reported similar findings.<sup>[12]</sup> In their study, duration of motor block was significantly higher among patients of the clonidine group (156 minutes) in comparison to the patients of the fentanyl group (128 minutes). Similar characteristics of motor block were noted in a study by Sagiroglu et al., who reported duration of motor block significantly higher among patients of clonidine group (162.6 minutes) in comparison to patients belonging to plain ropivacaine group (138 minutes).<sup>[10]</sup> In a study by Ogun et al., when a combination of 15mg ropivacaine and 30 $\mu$ g clonidine was administered intrathecally, the time to complete recovery of motor block was 153.2  $\pm$  19.9 min.<sup>[14]</sup>

Mean time to first analgesic requirement was 302.6 (23.38) minutes in group RF and was 384.7 (42.2) minutes among the patients of group RC. This difference is statistically and clinically significant indicating prolonged postoperative analgesia in group RC. Results of this study were aligned with the results obtained by Priya L et al., who also reported similar findings.<sup>[11]</sup> In their study, authors reported significantly higher time to first rescue analgesia requirement among patients of clonidine group (190.83 minutes) in comparison to the patients in fentanyl group (128.83 minutes) but overall, the analgesia duration was shorter than present study due to use of lower dose of isobaric Ropivacaine. In a study by Ogun et al., when combination of 15mg Ropivacaine and 30 $\mu$ g Clonidine was administered in women undergoing cesarean deliveries, the time to first request of rescue analgesia was seen to be 6.8  $\pm$  2.2 h.<sup>[14]</sup>

Hemodynamic parameters including HR, SBP, DBP and MAP were comparable in both the study groups

at different intraoperative and postoperative time intervals. This indicates hemodynamic stability and strengthens the safety profile of both the adjuvants. In the group RF, hypotension, nausea/vomiting, bradycardia and pruritus were seen in 2.5%, 7.5%, 2.5% and 12.5% of the patients respectively while in group RC, hypotension, nausea/vomiting, bradycardia and pruritus were seen in 5%, 10%, 2.5% and 0% of the patients respectively. Incidence of pruritus was significantly higher among patients of the group RF. In a study conducted by Sharan et al., hypotension was observed in five (10%) patients in clonidine group and two (4%) patients in fentanyl group, which was statistically insignificant ( $P > 0.05$ ).<sup>13</sup> Bradycardia was seen in three (6%) patients in clonidine group and one (2%) patient in fentanyl group, which was also statistically insignificant. In their study, there was no incidence of pruritus in clonidine group whereas six (12%) patients had pruritus in fentanyl group. The difference between two groups was statistically significant ( $P < 0.05$ ). Nausea/vomiting was seen in seven (14%) patients in clonidine group and eight (16%) patients in fentanyl group and the difference was statistically insignificant ( $P > 0.05$ ).

These results, coupled with the lack of any significant hemodynamic changes and complications in the current study, affirm that Clonidine and Fentanyl can be used as adjuvant to hyperbaric Ropivacaine 0.75% for lower limb surgeries. Future research should aim to expand the sample size and include diverse patient demographics yielding more generalized results. Additionally, integrating advanced hemodynamic monitoring systems in future studies could provide more precise data on subtle cardiovascular changes. These measures can enhance the evidence base for more efficient and safer anaesthesia.

This study had certain limitations. Only patients with ASA PS I and II were included, excluding those with cardiovascular disorders and respiratory disorders, which could affect the broader applicability of results. Furthermore, the study setting was a single institution, which may introduce bias related to local anaesthesia and surgical practices and protocols. Advanced monitoring tools for hemodynamic parameters, such as continuous blood pressure measurements were not utilized, possibly overlooking subtle cardiovascular changes. These factors should be considered when interpreting the study's findings and planning future research.

## CONCLUSION

From this study, it was concluded that hyperbaric Ropivacaine 0.75% when combined with Clonidine or Fentanyl provides adequate sensory and motor block for lower limb surgeries.

Intrathecal Clonidine with hyperbaric Ropivacaine 0.75% is better than Fentanyl in terms of prolonged duration of sensory block, longer duration of post-operative analgesia and hence, lesser number of rescue analgesia requirements.

Hemodynamic parameters varied less than 10% from baseline values and no significant difference in incidence of complications were reported except pruritus with both the drugs.

Thus, Clonidine as an adjuvant to hyperbaric Ropivacaine 0.75% is equally safe and more efficacious as compared to Fentanyl for patients undergoing lower limb surgery under spinal anaesthesia.

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