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ORIGINAL RESEARCH ARTICLE

A Comparative Study of Hyperbaric Ropivacaine with Fentanyl and Hyperbaric Bupivacaine with Fentanyl in Subarachnoid Block for Lower Limb Surgeries

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ABSTRACT

Introduction: Subarachnoid block, commonly referred to as a spinal anaesthesia, is a highly effective regional anaesthesia technique that is simple to master. It provides dense sensory, motor and sympathetic block with very few adverse effects.

Spinal anaesthesia involves the deposition of local anaesthetic directly into the cerebrospinal fluid. The dense sensory and motor block produced by spinal anaesthesia necessitates a low amount of local anaesthetic, thus reducing the risk of systemic toxicity. Hyperbaric bupivacaine has been a standard choice for subarachnoid block (SAB), but hyperbaric ropivacaine has gained interest due to its potentially favourable safety profile. The addition of fentanyl as an adjuvant enhances the quality and duration of analgesia. This study aims to compare the efficacy and safety of subarachnoid hyperbaric 0.75% ropivacaine-fentanyl with hyperbaric 0.5% bupivacaine-fentanyl for lower limb surgeries.

Material and Methods: A prospective, randomized, single-blind, observational study was conducted on patients undergoing elective lower limb surgeries. Participants were divided into two groups: Group A received 2.8 mL hyperbaric ropivacaine (0.75%) with fentanyl (25 mcg), and group B received 2.8 mL hyperbaric bupivacaine (0.5%) with fentanyl (25 mcg). The onset and duration of sensory and motor blockade, hemodynamic parameters and adverse effects were recorded and analysed.

Results: Both groups achieved effective anaesthesia, but group A exhibited a slower onset and shorter duration of motor blockade compared to group B. Hemodynamic stability was significantly better in the ropivacaine group, with fewer instances of hypotension and bradycardia.

Conclusion: Hyperbaric ropivacaine with fentanyl provides effective anaesthesia with improved hemodynamic stability and a shorter motor blockade duration compared to hyperbaric bupivacaine with fentanyl. These findings suggest that hyperbaric ropivacaine may be a safer alternative in patients where hemodynamic stability is a concern, making it a valuable option for lower limb surgeries under SAB.

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INTRODUCTION

Central neuraxial blocks (CNBs) are widely used for lower limb and lower abdominal surgeries.[1,2] Intrathecal opioids are combined with local anaesthetics, as they synergistically intensify the sensory block and improve motor function.[3]

Since the use of cocaine in subarachnoid block (SAB) by August Bier in 1898, a number of other local anaesthetic had been used.[4] Among all of them, bupivacaine is the most used local anaesthetic for spinal anaesthesia because of its longer duration of action and lack of adverse neurological effects as seen with previous counterparts.

Hyperbaric ropivacaine 0.75% is known to have a lower toxicity profile compared to bupivacaine.[5] Its ability to provide a dense sensory but relatively lesser grade motor block makes it suitable for day care surgeries and early post-operative mobilization.[6] As a newer formulation, not many studies are available about its use in subarachnoid block.

The present study was conducted to compare the efficacy of hyperbaric 0.75% ropivacaine-fentanyl combination with hyperbaric 0.5% bupivacaine-fentanyl combination in subarachnoid block for lower limb surgeries.

MATERIAL AND METHODS

A prospective, observational, randomised, single blind study was conducted in the Department of Anaesthesia, SRMS-Institute of Medical Sciences, Bareilly, after taking written informed consent from the patient and prior approval of the Institute's ethical committee. The study was done in a total of 120 patients of ASA grade I and II of either sex in the age group of 18 to 60 years, divided into

two groups of 60 each, posted for lower limb surgeries under spinal anaesthesia. Patients with cardiovascular abnormalities, morbid obese and with a known hypersensitivity to the study drugs were excluded. Each patient underwent a thorough pre-anaesthetic evaluation before surgery. The patients were instructed to follow the ASA fasting guidelines, remaining nil per oral (NPO) before anaesthesia. As part of premedication, all participants were given tablet alprazolam (0.25 mg) the night before surgery.

Upon arrival in the operating room, IV access was established, and intravenous fluids were administered according to the Holliday Segar method. Standard non- invasive monitors were connected, and baseline parameters were recorded.' Pre-spinal hemodynamic parameters were documented. Spinal anaesthesia using drugs belonging to 'group A (2.8 mL 0.75% hyperbaric ropivacaine + 25 mcg Fentanyl) or group B (2.8 mL 0.5% hyperbaric bupivacaine + 25 mcg Fentanyl) were given under aseptic precaution in sitting position or lateral position depending on the restriction of movement (hip pathology), using a 25 G Quincke's needle and the patient was' made to lie supine.

'Hemodynamic parameters, including HR, SBP, DBP, MAP, SpO^2, were recorded post- spinal at every 5 minutes till 30 minutes and then every 10 minutes after 30 minutes till 3 hours. Sensory and motor block were recorded using the pin prick method and modified Bromage scale (Table 1), respectively, every 5 minutes post spinal till 60 minutes and then every 15 from 60 minutes to 300 minutes (5 hours).[7]

Table 1: 'Modified Bromage' scale[7]

Scale	*Description*
0	No motor block
1	Inability to raise extended leg; able to move knees and feet
2	Inability to raise extended leg and move knee; able to move feet
3	Complete block of motor limb

Side effects like hypotension, bradycardia, shivering, hypothermia, nausea and vomiting were documented perioperatively after spinal anaesthesia. Hypotension and bradycardia were defined as 20% decline from the pre-spinal value. They were addressed with intravenous injection of mephentermine 6 mg and injection of atropine 0.5 mg, respectively. They were not used for all 20% decline in pre-spinal value. After completion of surgery, patients were transferred to the post-anaesthesia care unit (PACU). In the PACU patient was monitored for 5 hours and then shifted to the orthopaedic ward.

The observed data were analysed using SPSS statistical software version. Qualitative data were analysed through frequency and percentage and quantitative data were

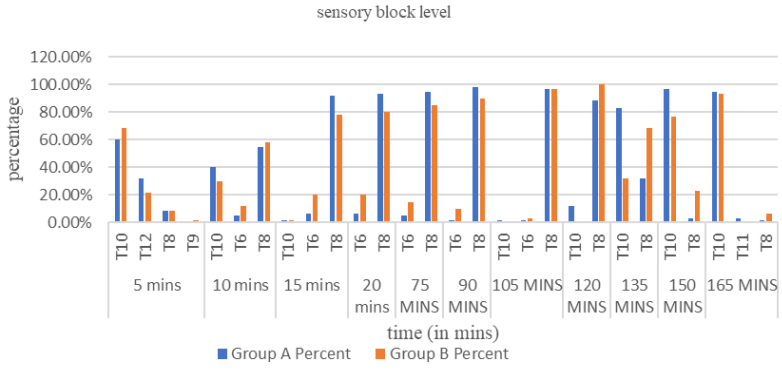

Figure 1a: Sensory block distribution at different interval

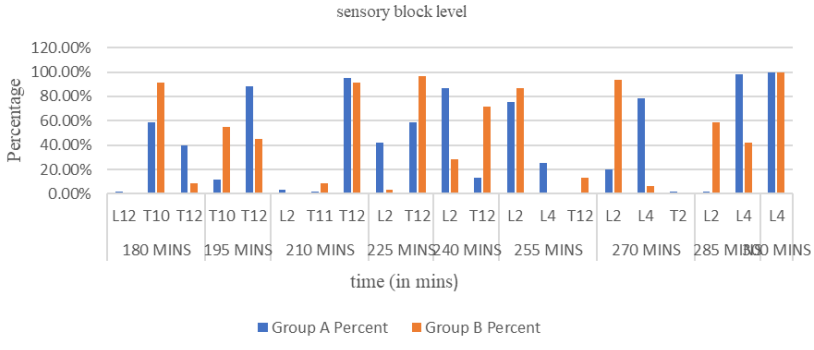

Figure 1b: Sensory block distribution at different interval

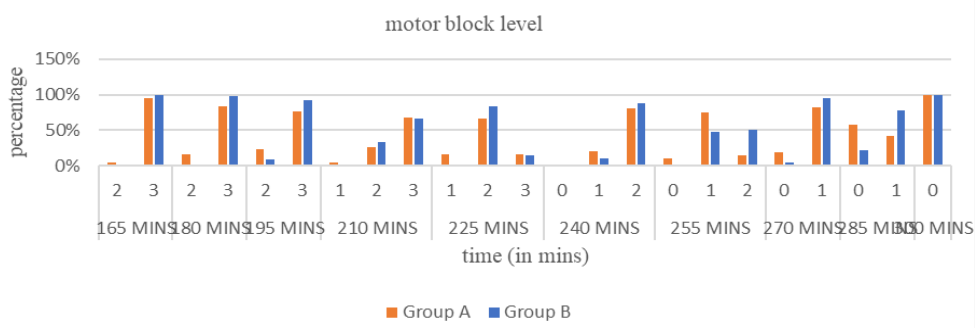

Figure 2: Motor block distribution at different interval

analysed through mean ± SD. An appropriate statistical test was applied to the same.

RESULTS

The study population was equally distributed between the two drug groups, A and B, with 60 participants in each group. Group A represents ropivacaine with fentanyl and group B represents bupivacaine with fentanyl. Both groups were comparable in terms of age, sex distribution, ASA classification, and duration of surgery, with group A having a mean duration of 159.75 ± 9.76 minutes and Group B having a mean duration of 157.75 ± 10.98 minutes.

By 15 minutes, the 'majority of patients in both groups experienced a sensory block (Figure 1a and b) at T8

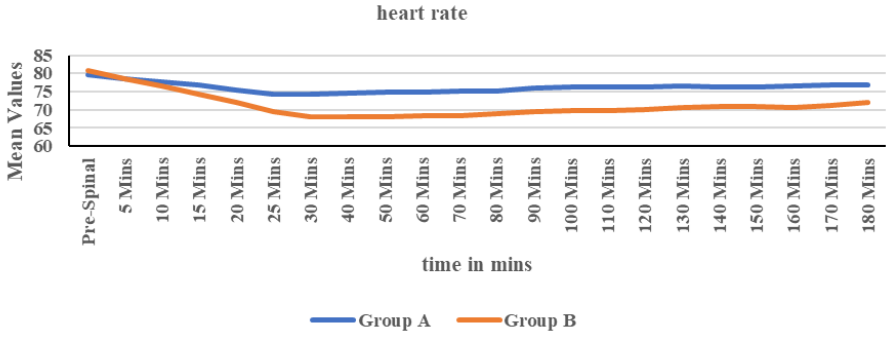

Fig. 3: 'Changes in heart rate between the two groups'

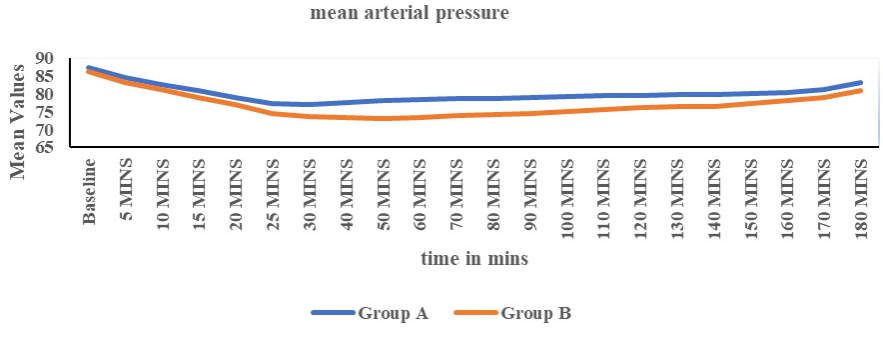

Fig. 4: 'Comparison of mean arterial pressure'

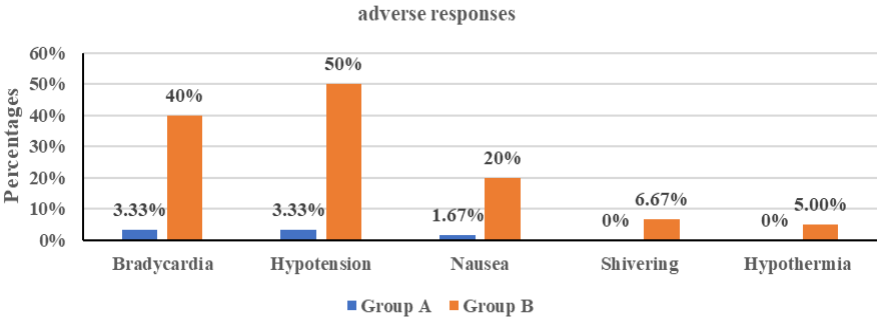

Fig. 5: Comparison of adverse responses

(91.67% in group A and 78.33% in group B, $p = 0.099$),' with a small proportion reaching T6. This trend continued further and between 30 and 60 minutes, the distribution remained stable, with T8 as the primary dermatome level in both groups. Group B exhibited a higher proportion of' T6 responses (20.00 *vs.* 6.67% in Group A, $p = 0.032$). Recovery of the sensory block started after 75 minutes, with Group A showing a faster regression to lower dermatomes, while Group B maintained the block at higher levels for longer durations.

At the 5 minute mark, the majority of patients in both groups exhibited a motor block (Figure 2) at grade 3, with 71.67% in group A and 70.00% in group B. However, group A had a higher proportion of patients at grade 1 (8.33%) compared to none in group B, resulting in a statistically significant difference ($p = 0.045$). From 15 to 150 minutes, all patients in both groups demonstrated a complete motor block at grade 3. Regression of block to lesser grade started by 165 minutes in group A (5%) and by 180 minutes in group B (1.67%), with a significant difference of ($p = 0.004$). Regression of the motor block continued, with a higher percentage of group A patients reaching lower motor block grades earlier. By 300 minutes both groups exhibited full motor recovery at grade 0.

From 25 minutes onward, 'a significant reduction in HR was observed in group B' (69.55 ± 11.47) compared to group A (74.37 ± 9.86, p 0.015). This trend continued at subsequent time points, with group B consistently showing lower HR values (Figure 3).

The comparison of systolic blood pressure (SBP) between drug Group A and B over time revealed significant differences beginning at 10 minutes post-baseline and persisting throughout the observation period. Significant differences began at 10 minutes, where group A recorded a higher SBP (117.05 ± 7.42) compared to group B (113.62 ± 7.59, $p = 0.014$) and this trend continued. From 25 minutes onward, a significant reduction in MAP was observed in group B, 74.5 ± 5.74 ($p = 0.020$), compared to group A, 77.1 ± 6.08, which became more pronounced later on. The most significant differences were observed between 40 minutes and 110 minutes, with highly significant *p-values* (<0.001) throughout this period (Figure 3).

Bradycardia was reported in 40.00% of participants in group B, compared to only 3.33% in group A (*p-values* < 0.001). Hypotension occurred in 50.00% of group B participants, a stark contrast to the 3.33% in group A (*p-values* < 0.001).'Nausea was observed in 20.00% of group B cases *versus* only 1.67% in group A, which was also statistically significant (*p-values* = 0.001). Shivering was noted in 6.67% of participants in group B, while none were reported in group A (*p-value* = 0.042). Hypothermia, while present in 5.00% of group B cases and none in group A, showed no statistically significant difference (*p-values* = 0.079) (Figure 4).

DISCUSSION

This study involved two groups of 60 patients each posted for lower limb orthopaedic surgeries. The groups were comparable in age, sex and ASA physical status. This study focused on the onset, duration and regression of motor and sensory blocks. Effects on haemodynamic parameters like blood pressure (SBP, DBP, MAP) and heart rate were compared. Also, side effects like hypotension, bradycardia, nausea, vomiting, shivering, and hypothermia were observed.'

By 10 to 15 minutes, the dominant sensory dermatomal level achieved was T8, with a smaller fraction reaching T6. A significant difference was observed ($p = 0.032$), as 93.33% of group A and 80.00% of group B exhibited sensory blocks at this level. Group B had a greater proportion of responses at T6 (20.00% vs. 6.67% in group A, $p = 0.032$). Group A exhibited a quicker decline to lower dermatomes, whereas group B retained the block at higher levels for an extended period. Kallio *et al* demonstrated comparable onset times for sensory block between the two drugs.[6] The time of onset for sensory block is consistent with the observation by Erturk *et al.* and Bigat *et al*.[8,9]

The degree of motor block onset in the lower limb was found to be slower in group R compared to group B by 5 minutes. This is in contrast to some of the early studies, which found that there was no difference in the onset time of motor block.[10,11] Regarding motor block regression from grade 3 to grade 0, it was significantly shorter in the ropivacaine group, which aligned with observations by Lee *et al*.[12]

Following the initial drop in systolic blood pressure (SBP) in both groups, group A exhibited a faster recovery compared to group B. Significant differences began at 10 minutes, where group A recorded a higher SBP (117.05 ± 7.42) compared to group B (113.62 ± 7.59 mm Hg), $p = 0.014$) and the trend continued and the difference widened. This trend is similar to Gupta *et al.'s* study, only 13.3% of patients in the ropivacaine group experienced hypotension, contrasting with 36.6% of patients in the bupivacaine group ($p = 0.01$).[13]

From 25 minutes onward, group B exhibited a significant reduction in MAP compared to group A.' The most pronounced differences occurred between 40 and 110 minutes, with highly significant *p-values* (<0.001) throughout this period. These findings of intraoperative hypotension requiring treatment with mephentermine are similar to studies conducted by Koltka *et al.* and Gupta *et al*.[14,13]

From 25 minutes onward, group B exhibited a significant reduction in HR compared to group A. At 25 minutes, the HR in group B (69.55 ± 11.47) was notably lower than in group A (74.37 ± 9.86, $p = 0.015$). While initial HR values were similar, group B demonstrated a progressive decline in HR compared to group A after 25 minutes, with statistically significant differences maintained throughout the monitoring period. This is similar to the findings of Varun *et al.*, who observed a greater reduction in HR in the bupivacaine group.[15]

Group B exhibited a significantly higher incidence of adverse responses compared to group A.

CONCLUSION

In this study, it was found that intrathecal ropivacaine with fentanyl provided effective spinal anaesthesia for lower abdominal surgeries. Although there was a significant difference in the upper level of sensory block, the overall quality of anaesthesia was comparable to that of bupivacaine with fentanyl. However, ropivacaine resulted in a shorter motor block duration and faster patient mobilization.

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