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COMPARISON OF FRACTIONATED DOSES AT TWO DIFFERENT INTERVALS IN SPINAL ANESTHESIA WITH HYPERBARIC ROPIVACAINE IN PATIENTS UNDERGOING INFRAUMBILICAL SURGERIES

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ABSTRACT

Background: Spinal anesthesia (SA) with a bolus dose has a rapid onset but may precipitate hypotension. Bupivacaine is commonly used; however, ropivacaine, having less cardio-neurotoxic potential than bupivacaine, may prove more beneficial in spinal anesthesia in a fractionated dose. The current study aimed to compare fractionated doses at two different intervals in spinal anesthesia with 0.75% hyperbaric ropivacaine for the characteristics of sensory and motor block in patients undergoing infra-umbilical surgeries.

Material and Methods: After clearance from the Institutional Ethics Committee, the study was carried out in 102 patients. Patients were randomly allocated into three groups of 34 each. Group BD, Group F60, and Group F120. In group BD, a single bolus dose of 3.3 ml with 0.75% hyperbaric ropivacaine was given. In group F60 and group F120, after injection of the initial two-thirds dose (2.2 ml) of 0.75% hyperbaric ropivacaine, the syringe was kept attached to the spinal needle for 60 sec and 120 sec, respectively, following which the remaining one-third dose (1.1 ml) was given. Onset time of sensory block and motor block, intraoperative hemodynamics, and adverse effects were recorded.

Results: The onset of sensory and motor block, time to reach maximum height of sensory block, and complete motor block were faster in the F60 group and F120 group compared to the bolus dose group. The duration of sensory and motor block was also prolonged in the F120 group compared to the F60 group and bolus dose group, with statistical significance among all three groups. The patients belonging to the F60 group and F120 group were more hemodynamically stable compared to the bolus dose group. Except for one patient from group F120 who had vomiting, none of the patients had any adverse effects. Postoperative VAS scores were statistically significant among all three groups at 30 min and 60 min.

Conclusion: The results of this study show that 0.75% hyperbaric ropivacaine, when injected intrathecally in fractionated doses with a time interval of 60 seconds and 120 seconds, produced earlier onset and prolonged duration of sensory and motor block along with hemodynamic stability for infraumbilical surgeries.

Keywords: Hyperbaric Ropivacaine, Fractionated Doses, Spinal Anesthesia, Infraumbilical Surgeries.

INTRODUCTION

Spinal anesthesia is the most effective technique that provides rapid and reliable anesthesia for patients undergoing lower abdominal surgeries.[1] Ropivacaine is a long-acting amide local anaesthetic agent and was first produced as a pure enantiomer. Ropivacaine is less lipophilic than bupivacaine; this

has a decreased potential for central nervous system toxicity and cardiotoxicity.[2] Ropivacaine enantiomers exist in two different spatial configurations and are present in equal amounts in a racemic solution. They are optically active and can be differentiated by their effects on the rotation of the plane of polarized light into dextrorotatory [clockwise rotation (R+)] or levorotatory [counterclockwise rotation (S-)] stereoisomers.[3] The R (+) and S (-) enantiomers of local anesthetics have different affinities for various ion channels of sodium, potassium, and calcium. This results in a significant reduction in the central nervous system (CNS) and cardiac toxicity (cardiotoxicity) of the S(-) enantiomer compared to the R(+) enantiomer.[4] The pure S(-) enantiomers of bupivacaine, levobupivacaine, and ropivacaine were thus introduced into clinical anesthesia practice.[3] Ropivacaine is less likely to penetrate large myelinated motor fibres, leading to relatively mild motor blockade.[4,5] Ropivacaine is a long-acting regional anesthetic that is structurally related to bupivacaine. It is a pure S(-) enantiomer, unlike bupivacaine, which may be a racemate, developed to reduce potential toxicity and improve relative sensory and motor block profiles.[6,7] Compared with plain ropivacaine, hyperbaric ropivacaine produces more predictable and reliable sensory and motor blocks, with a faster onset.[8,9] In 1908, Barker described the use of dextrose to increase the density of local anesthetic solutions over CSF to be administered into the subarachnoid space.[10,11] Spinal anesthesia (SA) with a bolus dose has a rapid onset but may precipitate hypotension. Previous studies using bupivacaine in fractionated doses demonstrated prolonged spinal anesthesia with good hemodynamic stability. [12,13] Ropivacaine, which has less cardio-neurotoxic potential than bupivacaine, may be more beneficial in spinal anesthesia in fractionated doses. No study has compared the time-gapped fractionated dose of heavy ropivacaine with a single bolus dose of ropivacaine in spinal anesthesia. Therefore, we aimed to study and compare fractionated doses at two different intervals in spinal anesthesia with 0.75% hyperbaric ropivacaine for sensory and motor block characteristics in patients undergoing infra-umbilical surgeries.

MATERIALS AND METHODS

This prospective, observational study was done in the Department of Anesthesiology, Kakatiya Medical College and MGM Hospital, Telangana. Institutional Ethical approval was obtained for the study. Written and informed consent was obtained from the patients participating in the study after explaining the nature of the study in the vernacular language.

Inclusion Criteria

1. Patients posted for elective infraumbilical surgeries under spinal anesthesia.
2. The ASA physical status I and II
3. Age from 18 to 60 years.
4. BMI ≤ 30 Kg/m^2
5. Patients voluntarily signed the consent.

Exclusion Criteria

1. Those who are not willing to participate in the study.
2. Patients with uncontrolled pre-existing diseases.
3. Any contraindication to spinal anesthesia.
4. Severely altered mental status.
5. Spine deformities or a history of laminectomy.
6. Pregnant and lactating women.
7. Bleeding or coagulation test abnormalities.

Study Population: The minimum sample size was determined based on the comparison of the average value of outcomes between groups. Cohen's d method is used to arrive at the number of patients (n), by taking effect size (d) =0.7, power =80% and 95% confidence limit. This gave a sample size of 34 patients in each group.

Randomization: Sample size was n=102 patients. Patients were randomly allocated into three groups of n=34 in each group. Group BD (Bolus dose), Group F60 (Fractionated dose at 60-second interval), and Group F120 (Fractionated dose at 120-second interval). Randomization into one of the three groups was done before initiating the study by a computer-generated random number table with a sealed opaque envelope technique.

Study groups: Group BD (34): A single bolus dose of 3.3ml-0.75% hyperbaric ropivacaine was given over 15-20s. Group F 60 (34): Patients received two-thirds (2.2ml) of a fractionated dose of 0.75% hyperbaric ropivacaine, followed by one-third (1.1 ml) dose after 60 seconds. Group F120 (34): Patients received two-thirds (2.2ml) of a fractionated dose of 0.75% hyperbaric ropivacaine followed by one-third dose (1.1ml) after 120s. Total volume of study drug administered was 3.3 ml-0.75% hyperbaric ropivacaine.

Preoperative Evaluation and Preparation: A Thorough and detailed pre-anesthetic checkup was done on the day before surgery. Patients were informed about the study procedure, and written informed consent was obtained. A visual analogue scale to score the pain was explained to the patients. Patient's history, general physical examination, systemic examination, and investigations were documented. Patients were kept nil by mouth for 6 hrs for solids and 2 hrs for clear liquids before surgery. All patients were premedicated with Tab ranitidine 150 mg orally the night before surgery and in the morning on the day of surgery. Take Alprazolam 0.5mg orally the night before surgery.

In The Operating Room, after checking the identity, patients were shifted into the operating room, and the following monitors were connected. Electrocardiogram (ECG), Non-invasive blood pressure (NIBP), Pulse oximetry (SPO_2), IV access was secured with an 18G cannula under local anaesthesia, and all patients were preloaded with 10-15 ml/kg Ringer's lactate over 10 min before the spinal block.

Lumbar puncture: With the patient in a sitting position under local anesthesia, a 25-gauge Quincke needle was introduced into the subarachnoid space at the L3-L4 or L4-L5 level
through the midline approach. The position of the needle was confirmed by gentle aspiration of CSF. After aspiration of cerebrospinal fluid, injection of Ropivacaine 0.75% was performed according to the respective groups BD, F60, and F120. In group BD, a single bolus dose of 3.3 ml-0.75% hyperbaric ropivacaine was given over 15-20s. In group F60, after injection of the initial two-thirds dose (2.2 ml) of 0.75% hyperbaric ropivacaine, the syringe was kept attached to the spinal needle for 60 sec, following which the remaining one-third dose (1.1ml) was given. In group F120, after injection of the initial two-thirds dose (2.2 ml) of 0.75% hyperbaric ropivacaine, the syringe was kept attached to the spinal needle for 120 sec, following which the remaining one-third dose (1.1 ml) was given. In both groups (group F60 and group F120), the rate of injection of the drug was 0.2 ml/s. Immediately after the injection of the drug, the patient was positioned supine. Oxygen was supplemented with a face mask at a rate of 3 L/min.

Sensory block characteristics: Sensory block was assessed by loss of cold sensation with a spirit swab along the midclavicular line bilaterally every two minutes till the fixation of the sensory level.

The following parameters were recorded in all patients

1. Onset time of sensory block to the T10 dermatome.
2. Maximum block height attained by the cold swab method.
3. Time to reach maximum sensory block.
4. Regression time to S2 dermatome.

Motor block characteristics: Motor block was assessed by the Modified Bromage scale every two minutes till the fixation of the motor block. The following parameters were recorded in all patients.

1. Onset time of motor block (Inj of intrathecal drug to Modified Bromage 1).
2. Time taken to achieve complete motor block (Inj. of intrathecal drug to Modified Bromage 3).
3. Time to regression Modified Bromage 0.

Hemodynamic parameters: Hemodynamic parameters like heart rate (HR), systolic blood pressure (SBP), diastolic blood pressure (DBP), mean arterial pressure (MAP), and SPO2 were recorded at baseline, 5 min, 10 min, 15 min, 30 min, 45 min, and 60 min after block and then every 15 min till completion of surgery. Hypotension was defined as systolic blood pressure <90 mmHg and was treated with the injection of ephedrine 0.06mg/kg given IV and repeated when needed. The number of hypotensive episodes and ephedrine used were recorded for each patient. Bradycardia was defined as HR of < 50 beats/min and was treated with IV atropine 0.6 mg. Complications like hypotension, bradycardia, nausea, vomiting, shivering, and respiratory depression were recorded.

The pain was assessed with the visual analogue scale every 30 min post-operatively for the first 2 hr, then hourly up to 6 hr. The duration of analgesia was defined as the time from intrathecal injection till the first demand for rescue analgesic when the visual analogue scale was≥4. The patient was given an intravenous injection of tramadol 2 mg/kg intravenously as a rescue analgesic.

Statistical Analysis: All the parameters recorded were analyzed and uploaded to Microsoft Excel and analyzed by SPSS version 25 in Windows format. The continuous variables were denoted as mean, standard deviation, and percentage. The qualitative data were calculated using the Chi-square test, and values of p (<0.05) were considered significant.

RESULTS

The demographic and baseline characteristics of the cohort are given in Table 1. A critical analysis of the table showed that most of the characteristics of the cohort were comparable, including the duration of surgery across the three groups (BD, F60, F120). Because the p-values were greater than 0.05, there were no statistical differences between groups, indicating that the groups were well matched for comparison of results, and no confounding factors existed between the groups, which could interfere with outcomes. Age ranged from 43 to 46 years across groups, and BMI values were similar (24–25 kg/m²). ASA class I patients predominated in all groups, ensuring comparable surgical risk profiles.

Table 1: Demographic and baseline characteristics of study groups

Characteristic	Group BD (n=34)	Group F60 (n=34)	Group F120 (n=34)	p-value
Age (Years)	46.29 ± 11.25	44.88 ± 10.96	43.67 ± 10.47	0.61
Gender, n (%)				
Male	12. (35.3%)	7 (20.6%)	2.0 (58.8%)	0.24
Female	22 (64.7%)	27 (79.4%)	2.1 (61.8%)	
ASA Physical Status, (%)				
	27 (79.4%)	21 (61.8%)	2.0 (58.8%)	0.15
	7 (20.6%)	13 (38.2%)	14 (41.2%)	
Height (cm)	157.82 ± 6.1	159.68 ± 8.0	157.9 ± 7.0	0.48
Weight (kg)	63.09 ± 8.5	63.29 ± 8.8	62.24 ± 9.7	0.87
BMI (kg/m^2)	24.82 ± 2.4	24.32 ± 2.8	24.35 ± 2.7	0.68
Duration of Surgery	98.20 ± 38.8	109.85 ± 32.9	101.91 ± 33.3	0.38

Sensory Block Characteristics of the cohort are presented in Table 2. There were noticeable variations in all the major sensory parameters (p = 0.001). Onset to T10: Fractionated dosing (F60 and F120) produced a quicker onset (3.334.51 min) than BD (4.19 min), which implies a quicker rate of sensory block evolution with slower fractionated injection. Time to Maximum Height of block: F60 and F120 reached maximum block height faster (5.22 - 5.37 min) compared to BD (7.52 min), and once again, showed better block efficiency with fractionation. Regression to S1: The sensory block duration was found to be longer at F60 (213 min) and F120 (242 min) than at BD (199 min), and it was concluded that the duration of the injection interval had a positive effect on the duration of the sensory block. Maximum block height: Higher-level block (T6) was more commonly obtained in F120 (35.3%) and F60 (23.5%) than in BD (5.9%). On the other hand, the T10 dominance in BD was the greatest (47.1) and in F120 the lowest (8.8). These results suggest that longer fractionated dosing, particularly at 120 seconds, offers a greater, faster, and prolonged sensory block.

Table 2: Sensory Block Characteristics

Parameter	Group BD (n=34)	Group F60 (n=34)	Group F120 (n=34)	p-value
Onset to TIO (min)	4.19 ± 0.87	3.51 ± 0.48	3.33 ± 0.52	0.001*
Time to Max Height (min)	7.52 ± 1.2	5.22 ± 0.9	5.37 ± 0.99	0.001*
Regression to SI (min)	199.45 ± 15.68	213.35 ±23.84	242.4 ±21.87	0.001*
Max Sensory Block Height, n (%)				
T6	2 (5.9%)	8 (23.5%)	12 (35.3%)	0.01*
T8	16 (47.1%)	18 (52.9%)	19 (55.9%)	0.75
TIO	16 (47.1%)	8 (23.5%)	3 (8.8%)	0.001*
*Significant				

Table 3 shows the characteristics of the Motor Block after anesthesia. There was a significant variation in motor block onset and progression between groups (p = 0.001*). The onset of motor block was the quickest in the F120 group (3.48 min) and the slowest in the BD group (4.15 min). The time to complete the motor block was much less in fractionated (5.44–5.94 min) than in BD (7.65 min). Resolution Motor block followed the same pattern of sensory regression, with the longest F120 (230 min), then F60 (207 min) and BD (193 min), the shortest duration. These findings indicate that fractionation of the dose not only quickens the motor block development but also increases its duration, with the most significant impact on the interval of 120 seconds.

Table 3: Motor Block Characteristics

Parameter	Group BD (n=34)	Group F60 (n=34)	Group F120 (n=34)	p-value
Onset of Motor Block (min)	4.15 ± 0.64	3.63 ± 0.66	3.48 ± 0.37	0.001*
Time to Complete Block (min)	7.65 ± 1.3	5.94 ± 1.01	5.44 ± 1.2	0.001*
Resolution of Motor Block (min)	192.92 15.8	207.81 ± 18.9	230.1 ± 25.3	0.001*
* Significant				

Table 4 shows the hemodynamic variables and complications recorded in the cases of the study. Baseline hemodynamics were found to be similar across the groups (HR, SBP, DBP). This shows that there was a similarity in the physiological state of the groups before intervention. Nevertheless, the need for ephedrine was greatly different in each group (p = 0.01). Hypotension was the most frequent in Group BD (26.47%), and the least in F120 (2.94%). This is in line with the theory that slow dosage-controlled limits acute sympathetic blockage. There was a low incidence of bradycardia and vomiting that was not significant between groups. Altogether, fractionated dosing, especially with a 120-second interval, was correlated with an increased level of hemodynamic stability and decreased vasopressor use.

Table 4: Hemodynamic Parameters, Vasopressor Requirement, and Complications

Parameter	Group BD (n=34)	Group F60 (n=34)	Group F120 (n=34)	p-value
Baseline Heart Rate (bpm)	78.77 ± 11.93	78.94 ± 11.2	81.94 ± 14.21	0.5
Baseline SBP (mmHg)	143.35 ± 16.0	144.5 ± 12.1	146.1 ± 12.4	0.7
Baseline DBP (mmHg)	84.12 ± 9.52	85.59 ± 7.26	86.82 ± 5.02	0.33
Ephedrine Required, n (%)	9 (26.47%)	4 (11.76%)	1 (2.94%)	0.01
Total Ephedrine Dose(mg)	3.67 ± 1.32	3 ± 0.2	3.0 ± 3.0	0.58
Complications, n (%)				
Hypotension (SBP<90 mmHg)	9 (26.47%)	4 (11.76%)	1 (2.94%)	0.74
Bradycardia (HR<50 bpm)	3 (8.82%)	1 (2.94%)	1 (2.94%)	0.43
Vomiting	0 (0%)	0 (0%)	1 (2.94%)	0.36

Pain after surgery (VAS Scores) was not found to be significantly different in the groups as given in Table 5. It was also observed that the (VAS) score of pain continued to rise after the operation as anticipated; however, the trend was the same in all the groups. Although minor differences were noted in each group at different intervals, the values did not reach the level of significance. This indicates that while fractionation affects onset, height, and duration of block, it does not significantly alter postoperative pain perception within the measured period.

Table 5: Postoperative Pain Assessment (VAS Scores)

Time Point	Group BD (n=34)	Group F60 (n=34)	Group F120 (n=34)	p- value
30 min	0.00 ± 0.00	0.08 ± 0.51	0.00 ± 0.00	0.37
60 min	0.00 ± 0.00	0.08 ± 0.51	00.0 ± 0.00	0.37
90 min	0.70 ± 1.03	0.91 ± 1.05	0.97 ± 0.99	0.54
120 min	1.82 ± 0.57	1.73 ± 0.89	1.67 ± 0.80	0.73
180 min	1.85 ± 0.92	2.11 ±1.2	2.05 ± 1.01	0.55
240 min	2.41 ± 1.25	2.14 ± 1.45	1.91 ± 1.08	0.27
300 min	2.58 ± 0.85	2.41 ± 0.85	2.61 ± 0.73	0.53
360 min	2.82 ± 0.79	2.70 ± 0.67	2.38 ± 0.88	0.06

DISCUSSION

Subarachnoid block is one of the most commonly used anaesthetic techniques for lower extremities and lower abdominal surgeries because of its simplicity, rapid onset of action, intense analgesia, and relatively fewer complications. Spinal anesthesia (SA) with a bolus dose has a rapid onset but may precipitate hypotension.[14] When we inject local anesthetic infractions with a time gap, it provides a dense block with hemodynamic stability and also prolongs the duration of analgesia.[15] These advantages make fractionated dosing an appealing option, especially in modern anaesthetic practice. As the number of operations performed in the ambulatory settings increases, we intended to find an appropriate drug that will provide a faster onset and faster recovery without compromising anaesthetic efficacy. Ropivacaine is a long-acting amide local anaesthetic agent and was first produced as a pure enantiomer. Ropivacaine is less lipophilic than bupivacaine, and therefore, the reduced lipophilicity is additionally related to decreased potential for central nervous system toxicity and cardiotoxicity. Ropivacaine enantiomers exist in two different spatial configurations and are present in equal amounts during a racemic solution. They are optically active and may be differentiated by their effects on the rotation of the plane of a polarized light into dextrorotatory [clockwise rotation (R+)] or levorotatory [counterclockwise rotation (S-)] stereoisomers. R (+) and S (-) enantiomers of local anaesthetics are demonstrated to possess different affinity for various ion channels of sodium, potassium, and calcium; this leads to a big reduction in central nervous system (CNS) and cardiac toxicity (cardiotoxicity) of the S (-) enantiomer as compared with the R (+) enantiomer. Ropivacaine is less likely to penetrate large myelinated motor fibres, leading to relatively reduced motor blockade. Hyperbaric ropivacaine produces more predictable and reliable sensory and motor blocks, with faster onset than plain ropivacaine.[16]

Limited studies till now have been undertaken to compare the fractionated dose versus bolus dose injection with hyperbaric bupivacaine for spinal anesthesia for patients undergoing elective caesarean section. The present study has been undertaken to compare fractionated doses at two different intervals in spinal anesthesia with hyperbaric ropivacaine in patients undergoing infra-umbilical surgeries. A prospective, controlled, randomized, observational study was planned and conducted in the Department of Anaesthesiology, Critical Care and Pain Medicine. One hundred two patients of American Society of Anesthesiologists (ASA) physical status Grade I and Grade II of either sex aged between 18 and 60 years were randomly allocated into 3 Groups. The random number sequence was generated before initiating the study. Subarachnoid block was performed in the sitting position. Hyperbaric ropivacaine was prepared with 3 mL of 0.75% ropivacaine and 0.3 mL of 25% dextrose. Group BD received a single bolus dose of 3.3 ml 0.75% hyperbaric ropivacaine over 15–20s. Group F60 patients received an initial two-thirds (2.2 ml) fractionated dose of 0.75% hyperbaric ropivacaine followed by one-third (1.1 ml) dose after 60 s. Group F120 patients received an initial two-thirds (2.2 ml) fractionated dose of 0.75% hyperbaric ropivacaine followed by one-third dose (1.1 ml) after 120 s. Total volume of study drug was 3.3 mL of 0.75% hyperbaric ropivacaine.

Hansen TG et al,[2] and Kuthiala G et al,[3] compared bupivacaine and ropivacaine spinal block characteristics and safety profile and concluded that ropivacaine had a better safety profile than bupivacaine. Sell A et al,[17] conducted a study to determine the minimum effective local anaesthetic dose and concluded that the MLAD of ropivacaine is 12.8 mg. So, we decided to use 15 mg of ropivacaine for spinal anaesthesia. McLeod GA,[10] determined that the density of local anaesthetics decreases with temperature and increases with the addition of dextrose, supporting our use of hyperbaric ropivacaine. Djeno IT et al,[18] found a statistically significant difference in block characteristics between hyperbaric and hypobaric solutions. Gupta R et al,[1] reported that hyperbaric ropivacaine produces a more rapid and adequate block than isobaric ropivacaine. Additional studies by Casati A

et al,[19] and Luck F.J et al,[20] supported the clinical efficacy of hyperbaric ropivacaine.

In our study, the onset of sensory block was earlier in group F120 (3.33 min) and group F60 (3.51 min) when compared to the bolus dose group (4.19 min). The onset of motor block was earlier in group F120 (3.48 min) and group F60 (3.63 min) than in group BD (4.15 min). The time to reach the maximum height of sensory block was earlier in group F60 (5.22 min) and group F120 (5.37 min) compared to group BD (7.52 min). The mean time to regression of sensory block below S2 level was shortest in group BD (199.45 min), intermediate in group F60 (213.35 min), and longest in group F120 (242.40 min). Similarly, the mean resolution of motor block was shortest in group BD (192.92 min), followed by group F60 (207.81 min), and longest in group F120 (230.10 min). Hemodynamic parameters showed that patients in group F60 and group F120 had higher mean SBP, DBP, and MAP at all time points, with fewer patients requiring ephedrine compared to the bolus group. Incidence of bradycardia and other adverse effects was minimal. Postoperatively, pain intensity measured by VAS was lowest in group F120 at all time intervals. Finally, an extensive search of the literature revealed that there were no studies evaluating fractionated dosing at 120 seconds and 60 seconds with 0.75% ropivacaine in infraumbilical surgeries, indicating the novelty of our study.

Limitations of our study: Most patients expressed satisfaction with the quality of postoperative analgesia. However, we did not analyse this data in our study.

CONCLUSION

Within the limitations of this study, intrathecal 0.75 % hyperbaric ropivacaine given as fractionated doses (with 60- or 120-s intervals) produced faster onset and a higher peak of both sensory and motor block, longer total block duration, and better haemodynamic stability than the same dose administered as a single bolus.

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