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A CLINICAL STUDY COMPARING EFFICACY AND SAFETY OF INTRATHECAL 0.5% HEAVY BUPIVACAINE WITH FENTANYL AND 0.75% HEAVY ROPIVACAINE WITH FENTANYL IN LOWER LIMB SURGERIES.

Anaesthesiology

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ABSTRACT

Background: Subarachnoid block is the most commonly used anaesthesia technique for patients undergoing lower abdominal and lower limb surgeries. It is considered to be safe and superior to general anaesthesia. Various additives are added to spinal anaesthetic solution to minimize the hemodynamic variations and to prolong the surgical analgesia or postoperative analgesia. Fentanyl is one among those additives. **Methodology:** Prospective randomized double blinded study as per good clinical practice (GCP) guidelines by WHO. 60 patients aged between 18-60 years undergoing lower limb surgeries were enrolled in the study and were randomly divided into two groups of 30 patients each by using the computer-generated table. Group R received 3 ml of 0.75% hyperbaric ropivacaine with 25 mcg fentanyl and Group B received 3 ml of 0.5% hyperbaric bupivacaine with 25 mcg fentanyl. Spinal anaesthesia procedure was standardized. Onset and duration of sensory and motor blockade, level achieved, regression, hemodynamic parameters and side effects were compared between the two groups. **Results:** Both groups were comparable in terms of demographical data such as age, gender, ASA PS status, BMI and duration of surgery. The mean time for onset of sensory blockade, onset of motor blockade in our study were statistically not significant. It is seen that mean duration of sensory blockade in group R (128.5±10.60min) was significantly shorter when compared with group B (169.5±15.33 min). The estimated mean duration of motor blockade in group R(158±10.6min) was shorter when compared to group B(200±15.4min). Two segment regression time was significantly shorter with group R(119±12.7min) compared to group B(151±31.8min). The mean duration of first rescue analgesia requirement in group R(108±21min) is lower than in group B (135±26). VAS score was significantly lower (VAS< 4) in bupivacaine group than ropivacaine group. The incidence of complications was similar between two groups. **Conclusion:** Ropivacaine-Fentanyl provide reliable motor and sensory blockade with shorter duration of motor and sensory blockade without serious side effects allowing earlier mobilization.

KEYWORDS

Ropivacaine, Fentanyl, Bupivacaine, Subarachnoid block, Postoperative analgesia

INTRODUCTION

Subarachnoid block is the most commonly used anaesthesia technique for patients undergoing lower abdominal and lower limb surgeries. [1,2] It has rapid onset and provides dense sensory and motor blockade. It is considered to be safe and superior to general anaesthesia as airway manipulation, post operative nausea, vomiting and increased stress response can be avoided.[1] It provides good postoperative pain relief, early ambulation and postoperative discharge.[1,3,4] Lignocaine, Bupivacaine, Ropivacaine are some of the common local anaesthetic agents which has been administered intrathecally.[1] Of which, Lignocaine has shorter duration of motor blockade and found to cause transient neurological symptoms. Hence it has been withdrawn from clinical practice.[5,6] Bupivacaine and Ropivacaine are amino amide local anaesthetic agents. Bupivacaine has a butyl group whereas ropivacaine has a propyl group. Bupivacaine is the most commonly used local anaesthetic for the spinal anaesthesia. It produces adequate sensory and motor blockade. However, it has its own disadvantages such as cardiac toxicity, central nervous system toxicity,[1] prolonged motor blockade thus delaying discharge after ambulatory surgeries.[5,7] Ropivacaine is an amide local anaesthetic with low lipid solubility and high pKa, found to produce adequate sensory block with early motor recovery than bupivacaine.[5,8] The reason for less motor blockade is due to lipophilic nature of the drug.[9] It is considered less cardiotoxic when compared to bupivacaine.[5,10.] Ropivacaine is less likely to enter large myelinated motor fibers, thus producing less motor blockade.[11] Hence ropivacaine is found to have a good safety profile compared to bupivacaine.[6,12] There are various additives added to spinal anaesthetic solution to minimize the hemodynamic variations and to prolong the surgical analgesia or postoperative analgesia. Fentanyl is one among those additives. It is a synthetic opioid in the phenylpiperidine family. As there is insufficient information, this study was planned to compare the effects of addition of fentanyl to the 0.75% hyperbaric ropivacaine with addition of fentanyl to the 0.5% hyperbaric bupivacaine in terms of onset, recovery and safety characteristics in patients undergoing lower limb surgeries.

Aims And Objectives

Aim: To compare the efficacy and safety of intrathecal addition of fentanyl to 0.75% ropivacaine heavy and 0.5% bupivacaine heavy in lower limb surgeries.

Objectives: Primary objective is To compare the duration of sensory blockade, Secondary objectives are To compare the onset of sensory and motor blockade, to compare the duration of motor blockade, to compare the hemodynamic stability, to compare postoperative analgesia using VAS score, to compare the side effects – Nausea, vomiting, hypotension, bradycardia and shivering

Methodology

MATERIALS AND METHODS

The study was conducted in the Department of Anaesthesiology of Sri Lakshmi Narayana Institute of Medical Sciences, Puducherry, a tertiary teaching hospital in South India.

Prospective randomized double blinded study as per good clinical practice (GCP) guidelines by WHO. 60 patients aged between 18-60 years undergoing lower limb surgeries were enrolled in the study and were randomly divided into two groups of 30 patients each by using the computer-generated table. Group R received 3 ml of 0.75% hyperbaric ropivacaine with 25 mcg fentanyl and Group B received 3 ml of 0.5% hyperbaric bupivacaine with 25 mcg fentanyl. Spinal anaesthesia procedure was standardised. Onset and duration of sensory and motor blockade, level achieved, regression, hemodynamic parameters and side effects were compared between the two groups.

Sample Size:

The sample size was calculated using open epi software version 3.3 based on the duration of postoperative analgesia, expected difference of 45 min, expected SD of 60 mins with 95% confidence interval, 80% of power and alpha error < 0.05.

Inclusion Criteria: Patients posted for elective surgery, fit under ASA PS I and II **,** Age 18 – 60 years of Both gender, BMI - < 35 kg/m2 Height above 150 cm

Exclusion Criteria: Patient refusal for spinal anaesthesia, Pregnancy ,H/O coagulopathy, local site infection, allergic to local anaesthetics drug, Fixed stenotic valvular lesions, Inadequate spinal blockade

supplemented by other drugs,Pre-existing neurological deficit.

Study Procedure

Patients who satisfied the inclusion were explained about the nature of the study and the anaesthetic procedure and written informed consent was obtained from the patients. A pre-anaesthetic evaluation was performed at-least 24 hrs before the surgery. The patient was kept nil per oral according to NPO guidelines and T. pantoprazole 40mg was given the night before surgery. Surgery will be done under spinal anaesthesia. The patient was made supine immediately after giving spinal anaesthesia. After the block, vitals were monitored every min for 5 mins until 30 mins and thereafter every 30 min till the end of the surgery. Level of sensory blockade will be assessed by cold swab every min for 10 mins and thereafter every 5 mins for next 10 mins. The onset of sensory blockade is defined as the time taken for the blockade to reach T10 level and peak sensory level of blockade will be noted. After completion of the surgery, the sensory block will be tested at 15 min intervals to assess two segment regression from peak level and time taken to reach T10 noted. Motor blockade was assessed by Bromage scale every 3 mins up to 24 mins. (Bromage 0 – The patient is able to move hip, knee and ankle, Bromage 1 – The patient is unable to move the hip but is able to move knee and ankle, Bromage 2 – The patient is unable to move the hip and knee but able to move the ankle, Bromage 3 – The patient is unable to move the hip, knee and ankle.) The onset of motor blockade is defined as the time taken to reach the level of bromage scale 2. Motor blockade will be assessed every 15 mins from the end of the surgery till it becomes zero. Total duration of motor blockade was taken from the onset of blockade to completely recover from blockade (bromage scale 0). In the postoperative period, pain was assessed using VAS score.

First rescue analgesia was given when VAS ≥ 4 using Inj. Paracetamol 1gm iv. For shivering patient was given Inj. tramadol 25mg iv. All the data will be entered in the proforma and transferred to the excel sheet for further statistical analysis.

RESULTS

Table.1 : Onset Of Sensory Blockade

Outcome	Group R (n=30)		Group B (n=30)		P Value
	Mean	SD	Mean	SD	
Onset of Sensory blockade (min)	6.53	0.71	6.43	1.41	0.729

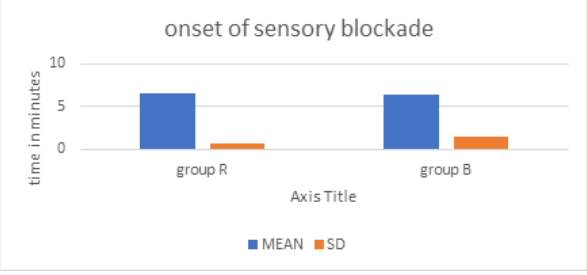

Fig.1

Table 2: Onset of Motor Blockade

Outcome	Group R (n=30)		Group B (n=30)		P Value
	Mean	SD	Mean	SD	
Onset of Sensory blockade (min)	15.172	4.722	17.0	5.813	0.1863

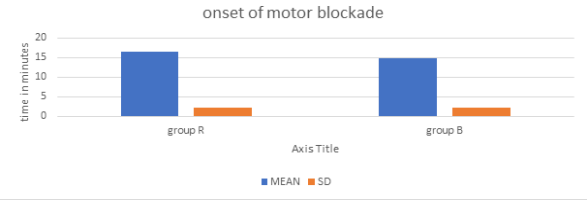

Fig.2

Table 3: Duration of 2 segment Regression:

Outcome	Group R (n=30)		Group B (n=30)		P Value
	Mean	SD	Mean	SD	
Duration of 2 segment Regression (min)	119	12.7	151	31.8	<0.0001

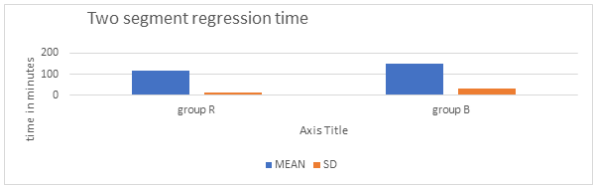

Fig.3

DISCUSSION

Subarachnoid block is preferred for lower abdominal and lower limb surgeries. Hyperbaric Bupivacaine is in use as an intrathecal local anaesthetic agent for many decades as it has lower incidence of transient neurological symptoms and cauda equina syndrome and thus it replaced lignocaine from clinical practice. Ropivacaine is an optically pure S-enantiomer form of parent chiral molecule p ropivacaine, belongs to pipecoloxylidide group of local anaesthetics. Ropivacaine has low lipid solubility, high pKa and thus results in lesser duration of blockade. Hyperbaric ropivacaine provided reliable level of sensory blockade and predictable onset and duration. [10,11] Intrathecal plain ropivacaine 15mg had a failure rate of 20% in abdominal surgeries41 and 16% failure rate in urological surgeries.[14] Studies with intrathecal bupivacaine has shown that addition of fentanyl increases the level and duration of sensory block, without altering the motor blockade characteristics.[15 16] Adjuvants or additives are often used with local anaesthetics for its synergistic effect by prolonging the duration of sensory-motor block and limiting the cumulative dose requirement of local anaesthetics.[10,12,13] This allows the use of lower dose of local anaesthetic solution which provided lower incidence of high block, hypotension and shorter duration of motor blockade. [15] Both groups were comparable in terms of demographical data such as age, gender, ASA PS status, BMI and duration of surgery. The mean time for onset of sensory blockade in our study in group R was 6.53±0.71min and 6.43±1.4 min in group B, which is statistically not significant which was in accordance with the study by Sheetal Jagtap et al[5] who conducted a comparative study using 0.5% isobaric ropivacaine-fentanyl with 0.5% isobaric bupivacaine fentanyl intrathecally and found that onset time for sensory block in group RF was 6.86 + 3.73 min and 7.07 + 2.99 min in group BF. Our study results correlated with this previous study. The degree of motor blockade was assessed by using Bromage score where a score of 2 or 3 indicates onset of motor blockade. The onset of motor blockade was rapid in both the groups with mean of 16.5±2.12min in group R and 14.9±2.16min in group B; these observations were statistically not significant ($p > 0.05$) and were comparable to previous studies by Mc Namee et al[16] and Shilpa Sree et al[17]. In our study, the duration of sensory blockade was assessed as the time taken by the block to reach T10 level from the maximum level. It is seen that mean duration of sensory blockade in group R (128.5±10.60min) was significantly shorter when compared with group B 79 (169.5±15.33 min). Similar findings were noted by Prajwal et al[1] who conducted a comparative study using 0.5% isobaric ropivacaine-fentanyl with 0.5% isobaric bupivacaine fentanyl intrathecally and found that duration of sensory blockade in group A was 132.08 + 16.39 min and 175.7 + 15.9 min in group B. Our study results correlated with this study and the results were statistically significant. ($p < 0.05$) Erturk et al[18] and Gudul et al [19]observed that in patients undergoing elective surgeries, duration of motor blockade with ropivacaine was shorter than bupivacaine which provided a better post operative recovery. Observations of our study correlated with the previous studies and has shown that the estimated mean duration of motor blockade in group R(158±10.6min) was shorter when compared to group B(200±15.4min) and the difference between the two groups was statistically significant. ($p < 0.05$). The upper level of sensory blockade was higher in patients of Group B than compared to Group R. In the studies conducted by Prajwal etal[1] and Malinovsky et al [14], the cephalad spread of sensory block was higher with bupivacaine compared to ropivacaine, similar to our findings. In our study motor block was assessed using bromage scale Maximum motor level block of 3 was achieved in all the patients in both groups R and B. The observations in our study were comparable to previous studies by Prajwal et al[1] ,McNamee et al [20] and Kallio et al [21]. Two segment regression time is defined as the time taken from the maximum level of sensory block attained till the sensation has regressed by two segments. It was significantly shorter with group R(119±12.7min) compared to group B(151±31.8min) fig.3. Similar observations were noted by Lee Y.Y et al[9] who conducted a comparative study using 0.5% isobaric ropivacaine-fentanyl with 0.5% isobaric bupivacaine fentanyl

intrathecally and found that two segment regression time in ropivacaine group was 99 (69-148) min and 115 (97-143) mins in bupivacaine group. Layek et al[22] who conducted a comparative study using 0.5% isobaric ropivacaine fentanyl with 0.5% isobaric bupivacaine fentanyl intrathecally and found that duration of first rescue analgesia requirement in group R was 85 (55-145) min and 120 (80-180) min in group B. The difference between the two groups was statistically significant. ($p < 0.05$). Our study also corroborated with similar findings with the mean duration of first rescue analgesia requirement in group R (108±21) min being lower than in group B (135±26) min and this was found to be statistically significant ($p < 0.05$). VAS score was significantly lower (VAS< 4) in bupivacaine group than ropivacaine group. Similar findings were noted by Layek et al[22] and noted a significantly higher time to request first rescue analgesia in patients who received bupivacaine than the patients who received ropivacaine and the difference between the two groups is statistically significant. ($p < 0.05$) We compared various cardiovascular and respiratory parameters between patients receiving intrathecal anaesthesia with either bupivacaine and fentanyl or ropivacaine and fentanyl for lower limb surgeries. Firstly, analysing heart rate, we observed no significant difference between the two groups at any point of time ($p>0.05$). These findings are consistent with previous studies done by Prajwal et 81 al1 and Lee Y.Y et al.[9] Regarding SBP and DBP, our findings revealed no significant statistical difference between the two groups at any time point. This result correlates with earlier studies conducted by Shilpa Sree et al[17] and McNamee et al.[20] Analysing SPO2 and RR, we found no significant difference between the two groups at any time interval ($p>0.05$). These findings align with previous studies performed by Prajwal et al1 and Lee Y.Y et al[9]

CONCLUSION:

This study compared the anaesthetic efficacy and safety of intrathecal addition of fentanyl to 0.75% ropivacaine heavy vs intrathecal addition of fentanyl to 0.5% bupivacaine heavy in lower limb surgeries. No significant disparities were observed in mean age, height, weight, or gender distribution between the two groups. Hemodynamic parameters such as heart rate and blood pressure did not significantly differ between the two groups, indicating hemodynamic stability with both agents. The study results show that the duration of motor blockade with the ropivacaine-fentanyl group was shorter than with the bupivacaine-fentanyl group. In conclusion, intrathecal ropivacaine with fentanyl provides adequate motor and sensory blockade. However, the duration of motor blockade will be shorter allowing early mobilization. Hence, it can be used as an alternative to intrathecal bupivacaine for ambulatory surgeries. However, further studies with larger sample sizes are appreciated to support the use of Ropivacaine with Fentanyl for ambulatory surgeries.

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