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Comparison of 0.75% Hyperbaric Ropivacaine plus fentanyl versus 0.5% Hyperbaric bupivacaine plus fentanyl, given in lower abdominal and lower Limb surgery

Ankur Garg[1]*, Akash Gupta [2], Amisha Agarwal [3], Malti Agrawal[4]

[1,2]Asso. Professor, [3]Junior Resident Dept of Anaesthesia, Rohilkhand Medical College, Bareilly, Uttar Pradesh.

[,4]Professor and Head of Department on Anaesthesia, Rohilkhand Medical College, Bareilly, Uttar Pradesh

***Corresponding Author and reprint request to:** Dr. Amisha Agarwal, Junior Resident Dept of Anaesthesia, Rohilkhand Medical College, Bareilly, Uttar Pradesh. India

ABSTRACT

Background: Bupivacaine and Ropivacaine are the commonly used drugs in spinal anesthesia. The efficacy of these drugs along with adjuvant fentanyl, remains better but the question remains unsolved that whether bupivacaine plus fentanyl or ropivacaine plus fentanyl, which works better. Hence this study was undertaken to compare the efficacy, hemodynamic stability and side effects of these drugs for lower abdominal and lower limb surgeries.

Methods: This prospective randomized, control study was conducted among patients undergoing lower abdominal and lower limb surgeries in Rohilkhand Medical College Hospital, Bareilly for elective surgical procedures. Ninety four patients were included in the study with forty seven cases in group A (0.75% hyperbaric Ropivacaine-3ml plus 25mcg fentanyl) and forty cases in group B (0.5% hyperbaric bupivacine-3ml plus 25mcg fentanyl). Data analysis was done using SPSS version 17.

Results: Intrathecal 0.5% Hyperbaric bupivacaine plus fentanyl combination produces a significantly longer duration of analgesia, sensory block and motor block when compared

to intrathecal hyperbaricbaric ropivacaine plus fentanyl combination. Greater hemodynamic stability was observed in Ropivacaine plus fentanyl group.

Conclusion: Ropivacaine plus fentanyl provides a higher degree of hemodynamic stability plus allows early ambulation.

Key Words: Bupivacaine, Ropivacaine, fentanyl, spinal anesthesia

INTRODUCTION

Spinal anaesthesia is a common technique widely used for lower abdominal and lower limb surgeries. Bupivacaine and Ropivacaine are the commonly used drugs for this procedure. Bupivacaine, the most widely used local anesthetic agent, is a chiral compound [1] and racemic mixture of S (−) and R (+) enantiomers. Similarly Ropivacaine, which is an amide type local anaesthetic, also been used widely for spinal anaesthesia in recent days.[2] Although ropivacaine and bupivacaine are quite similar in structure, the former is relatively less toxic in terms of cardiovascular and central nervous systems effects [3] . To maintain the advantage of an intrathecal anaesthetic agent while improving intra and post operative analgesia, an analgesic adjuvant can be used.[4] Some studies have shown that intrathecal opioids can greatly enhance analgesia from subtherapeutic doses of local anaesthetic.[5,6] Fentanyl is an opioid that has shown to enhance the analgesic potency of ropivacaine and bupivacaine for spinal anesthesia. [7] Various studies have compared the efficacy and side effect profile of intrathecal bupivacaine and ropivacaine in different surgeries.[8,9,10] Whereas, there were only few studies which compared intrathecal use of hyperbaric ropivacaine and hyperbaric bupivacaine along with fentanyl as an adjuvant.[9] Hence, this study was undertaken to compare the efficacy,hemodynamic stability and side effects of intrathecal 0.5% hyperbaric Bupivacaine plus fentanyl and 0.75% hyperbaric ropivacaine plus fentanyl combination for lower abdominal and lower limb surgeries.

MATERIALS AND METHODS

This prospective randomized controlled trial was conducted among patients undergoing lower abdominal and lower limb surgeries, in Rohilkhand Medical College Hospital, Bareilly during for elective surgical procedures. Ninety four patients between the age group of 18-60 years, who belongs to American Society of Anesthesiologists (ASA) grade I and II were included in the study. Patients with any neuropathy, any known

allergy to local anaesthetics and patients with contraindication for spinal anaesthesia were excluded from the study. The study was approved by the ethical committee of this institution. Informed consent was obtained from the study participants before starting the study. The study patients were randomized and divided into two groups with forty seven participants in 3mL of 0.75% hyperbaric ropivacaine with 25 mcg fentanyl in group A and another forty seven participants in 3mL of 0.5% hyperbaric bupivacaine with 25 mcg of fentanyl in group B. Detailed history and the observations were documented in a proforma by the principal investigator. In the preoperative room, baseline recording of heart rate, respiratory rate, systolic blood pressure and conscious levels of the patients were noted. Spinal anesthesia was performed at the L2-3 inter-vertebral
space with the patient sitting, using the midline approach and a 25-gauge quincke's spinal needle. After completing spinal injection, patients was placed supine, continuous evaluation of sensory (with pin-prick method) and motor blocks for every 2 minutes for first 20 minutes, then every 5 minutes for 40 minutes, and then every 15 minutes until the sensory block has regressed to S1 dermatome and complete motor block regression. Patient was administered Inj. Midazolam 1mg IV after spinal anesthesia has been given. At the same observation times systolic and diastolic (DBP) and mean arterial (MAP) blood pressure values, heart rate and SpO2 was recorded. The extent of level of sensory block was assessed using the loss of pinprick sensation (24-gauge hypodermic needle); whereas motor block by modified Bromage scale.

Table1: Modified Bromage scale for lower limb [11]

Grade 0	**Full movement**
Grade 1	Inability to raise extended leg but can bend knee
Grade 2	Inability to bend knee but can flex ankle
Grade 3	No movement

Clinically relevant hypotension (defined as a decrease in systolic arterial blood pressure ≥30% from baseline values) was initially treated with a rapid IV infusion of 200 mL of

Ringer's lactate solution over a 10-min period. If this is found not to be effective, 6mg Mephentermin IV was administered. Occurrence of clinically relevant bradycardia (defined as heart rate reduction ≤50 bpm) was treated with 0.5 mg atropine IV. Any complications, side effects and adverse effects up to 24 hrs postoperatively were noted.

RESULTS

Our study was conducted on a sample of 94 patients classified as ASA I & II, aged from 19 to 60 years, who were undergoing surgeries on the lower abdomen and lower limbs. The participants were assigned randomly to two groups, namely Group A & Group B. The patients assigned to Group A were administered a combination of 0.75% Hyperbaric Ropivacaine (3 ml) and 25mcg Fentanyl. In Group B, a total of 47 patients were administered a combination of 0.5% Hyperbaric Bupivacaine & 25mcg Fentanyl, with a volume of 3 ml. The patients underwent spinal anaesthesia at the L2/L3 interspace utilising a 25G quince's spinal needle. After administering the Subarachnoid Block, an examination was conducted to assess the sensory blockade in terms of its onset, duration, peak sensory block, time to attain peak block, and regression of two segments. Similarly, the motor blockade was also examined in terms of its onset and duration. The heart rate & blood pressure (BP) were measured throughout the duration of the block. The sensory assessment was conducted utilising the pin prick method, while the motor assessment was performed employing the modified Bromage Score. The surgical readiness was operationally determined by the presence of pin prick sensation loss at or above the T10 dermatome level, accompanied by a modified Bromage Score of 2 or higher. The p-value was calculated to determine the level of statistical significance.

The mean weight of patients in Group A was 61.98 ± 13.97 kg, whereas in Group B it was 60.37 ± 14.95 kg. Group A consisted of 25 males and 22 females, whilst Group B consisted of 20 men and 27 females. The mean age in Group A 38.96 ± 12.39 and that of Group B was established to be 40.76 ± 11.34 There were no statistically significant differences seen in terms of age, sex, and weight between Group A & Group B.

Table 2: Characteristics of participants in each group

VARIABLES		GROUP A	GROUP B	p-value
AGE(years)		38.96 ±12.39	40.76 ± 11.34	0.128#
SEX	MALE	25	21	0.297#
	FEMALE	22	26	
WEIGHT(Kg)		61.98 ± 13.97	60.37 ± 14.95	0.448#

statistically insignificant

The demographic profiles exhibited similarities among both groups in my study. In Group A, the sensory block reached its highest point at T4 in 11 patients, at T6 in 20 patients, and at T8 in 16 patients. Conversely, in Group B, the sensory block peaked at T4 in 20 patients, at T6 in 16 patients, and at T8 in 11 patients. There was a statistically relevant difference in the mean initiation of sensory blockade between Group A and Group B ($p < 0.001$). The mean initiation of sensory blockade in the Group A was 7.25 ± 0.81 minutes, whereas in the Group B it was 4.13 ± 1.15 minutes. These findings indicate that the onset of sensory blockade was of longer duration in Group A as opposed to Group B. Between Group A & Group B, the difference was statistically significant in the mean start of motor blockage. ($p < 0.001$). The mean inception of motor blockade in Group A was 9.51 ± 1.68 minutes, whereas in Group B it was 5.54 ± 0.89 minutes. These findings indicate that the start of motor blockade was more long in Group A when opposed to Group B. There was a difference that was statistically significant in the time-duration of sensory block between group A and Group B (p value <0.001). The time span for sensory blockade in Group A was found to be 159.91 ± 14.06 minutes, whereas in Group B it was 188.28 ± 18.62 minutes. This points towards that the time-duration of sensory block was prolonged in Group B as opposed to Group A.

A statistically noteworthy difference was observed in the time duration of motor block between Group A & Group B (p value <0.001). The time duration of motor block in Group A was seen to be 150.02 ± 14.02 minutes, whereas in Group B it was 178.09 ±

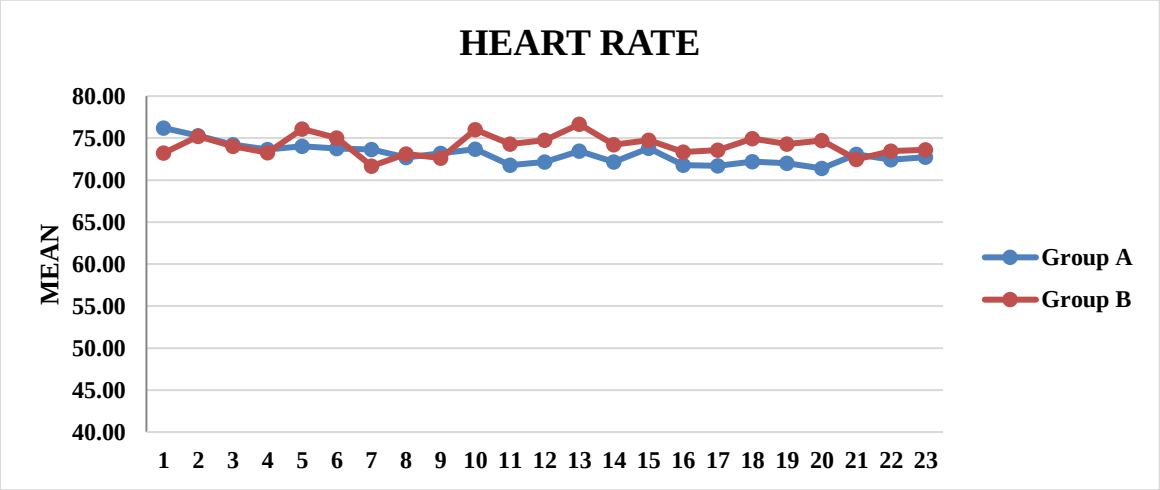
8.81 minutes. This notifies that the time duration for motor block was prolonged in Group B vs Group A.

Table 3: Clinical profile of participants in each group

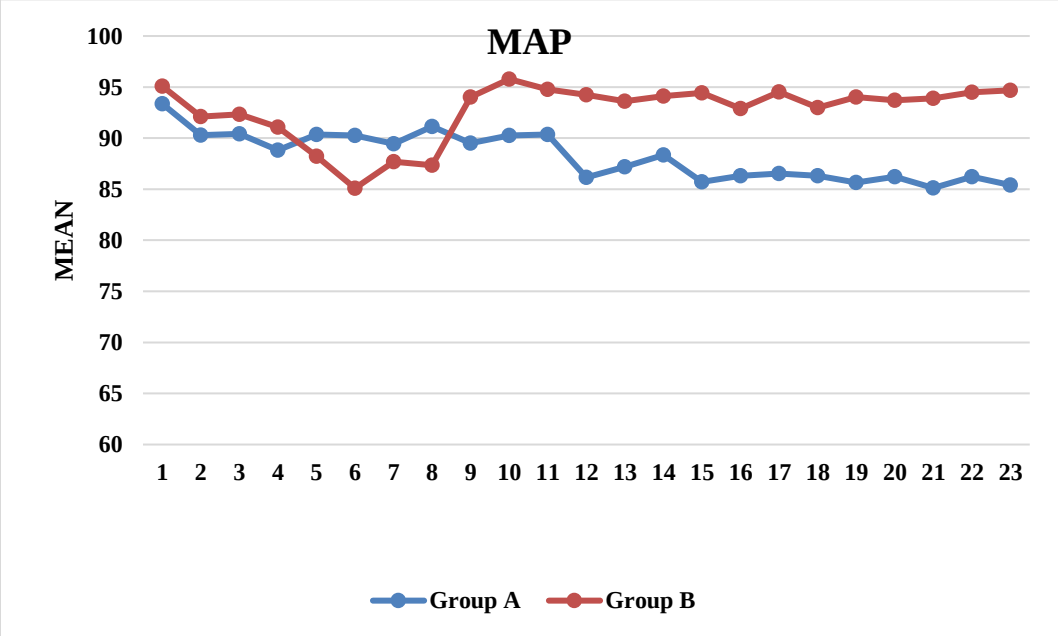
VARIABLES		GROUP A	GROUP B	p-value
Onset of sensory blockade(min.)		7.25 ± 0.81	4.13 ± 1.15	<0.001*
Peak height for sensory block	**T4**	11	20	0.096#
	T6	20	17	
	T8	16	10	
Onset of motor blockade(min.)		9.51 ± 1.68	5.54 ± 0.89	<0.001*
Duration of sensory blockade (min.)		159.91 ± 14.06	188.28 ± 18.62	<0.001*
Duration of motor blockade(min.)		150.02 ± 14.02	178.09 ± 8.81	<0.001*
Time for first rescue analgesia(min.)		199.21±15.06	212.28±17.30	<0.001*

* statistically significant # statistically insignificant

Insignificant variance in the mean heart rate was noted in Group A or Group B. There was a decrease in the mean systolic blood pressure observed which was statistically significant in group B following a 6-minute period of spinal anaesthesia,



Graph 1: Mean Heart Rate



Graph 2: Mean Arterial Pressure

The data in group A exhibited a consistent pattern with negligible fluctuations. There was a statistically notable decrease in the mean diastolic blood pressure observed in group B following a 6-minute period of spinal anaesthesia. The data in group A exhibited a consistent pattern with negligible fluctuations. There was a statistically considerable decrease in the mean of mean arterial pressure observed in group B following a 6-minute period of spinal anaesthesia. The data in group A exhibited a consistent pattern with negligible fluctuations.

DISCUSSION

In our study there was a statistically noteworthy difference in the mean onset of sensory blockade between Group A and Group B ($p < 0.001$). The mean onset of sensory blockade in Group A was 7.25 ± 0.81 minutes, whereas in Group B it was 4.13 ± 1.15 minutes. These findings indicate that the onset of sensory blockade was longer in Group A compared to Group B. There is a lack of substantial disparity seen in the initiation of sensory and motor block. Koltka et al [9].

In Group A, the sensory block reached its highest point at T4 in 11 patients, at T6 in 20 patients, and at T8 in 16 patients. Conversely, in Group B, the sensory block peaked at T4 in 20 patients, at T6 in 17 patients, and at T8 in 10 patients as. Lee et al.[10] conducted was a randomised double-blind comparison of ropivacaine-fentanyl and bupivacaine-fentanyl for spinal anaesthesia. The researchers observed that both groups achieved a comparable degree of sensory block. In the BF group, 80% of patients and in the RF group, 84% of patients successfully attained a sensory block extending up to the T6 level. In group BF, 16% of patients obtained a sensory block up to T8, whereas in group RF, 12% of patients reached the same degree of sensory block. Additionally, 4% of patients in both groups achieved a sensory block up to T10, indicating a similar outcome

In our study there was a statistically noteworthy difference in the time-duration of sensory block between group A and Group B (p value <0.001). The duration of sensory block in Group A was found to be 159.91 ± 14.06 minutes, whereas in Group B it was 188.28 ± 18.62 minutes. This indicates that the duration of sensory block was longer in Group B compared to Group A. Chung et al. [12].

The discrepancy was statistically remarkable in the mean initiation of motor blockade between Group A and Group B ($p < 0.001$). The mean start of motor blockade in Group A was 9.51 ± 1.68 minutes, whereas in Group B it was 5.54 ± 0.89 minutes. These findings indicate that the start of motor blockade was longer in Group A compared to Group B. Chung et al. [12] found Ninety-four percent of candidates in the RF group and

100% of candidates in the BF group had total motor block. In their study, reported that a comprehensive motor block was seen in all individuals who received one of the two amongst bupivacaine or ropivacaine during a caesarean section procedure.

The contrast was statistically remarkable in the extent of motor block between group A and Group B (p value <0.001). The extent of motor block in Group A was determined to be 150.02 ± 14.02 minutes, whereas in Group B it was 178.09 ± 8.81 minutes. This indicates that the extent of motor block was prolonged in Group B as compared to Group A. Koltka et al.[9], in study conducted by the authors examined the effects of equivalent doses of isobaric ropivacaine vs bupivacaine, both administered with fentanyl for subarachnoid block. The results indicated that the RF group had a shorter length of motor block, lasting 90 minutes, compared to the BF batch, which had a duration of 130 minutes. In the present research, the observed length of motor blockade in group RF was noted to be 158.82±24.55 minutes, which was comparatively lower than the period seen in group BF (180.50±50.84 minutes). However, it is crucial to observe that this difference was not statistically significant.

There was a statistically significant decrease in the mean diastolic blood-pressure observed in group B following a 6-minute period of spinal anaesthesia. The data in group A exhibited a consistent pattern with negligible fluctuations. There was a statistically relevant fall in the mean of mean arterial pressure observed in group B following a 6-minute period of spinal anaesthesia. The data in group A exhibited a consistent pattern with negligible fluctuations. Mc Namee et al. [13] found that hemodynamic parameters, including the pulse rate, systolic blood-pressure, and diastolic blood pressure, exhibited similar values in both groups. Furthermore, no significant changes in hemodynamic status were seen in either groups.

The mean time for first rescue analgesia was prolonged in Group B that is of 212.28 ±17.30min as opposed to Group A in which 199.21 ±15.06 min was the time seen in which the patient required rescue analgesia first. Layek et al [14]observed a similar

difference in the duration of analgesia of a mean of 360min in Group B and 245min in Group R.

CONCLUSION

Based on our research findings, it can be inferred that the administration of Ropivacaine with fentanyl intrathecally results in a shorter duration of motor and sensory blockade, a lower level of motor blockade, and a reduced time until the first urination, when compared to the use of Hyperbaric Bupivacaine. Furthermore, it exhibits greater hemodynamic stability. Therefore, the utilization of Hyperbaric Ropivacaine in conjunction with fentanyl for Spinal Anaesthesia presents a more favorable option for both lower abdominal surgeries & lower limb surgeries due to its ability to expedite the initiation of ambulation.

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