

A Comparison of the Intrathecal Isobaric 0.5% Levobupivacaine with Fentanyl and Isobaric 0.5% Ropivacaine with Fentanyl for Lower Abdominal and Lower Limb Surgeries: A Prospective Randomised Double Blind Controlled Study.

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ABSTRACT

Background: Spinal anaesthesia is an accepted and most convenient anaesthetic technique for lower abdominal and lower limb surgeries. Opioids have been used intrathecally as adjuvant for improvement in quality and extending the duration of spinal block. We conducted this prospective randomised double blind study to compare effects of intrathecal isobaric 0.5% levobupivacaine with fentanyl and isobaric 0.5% ropivacaine with fentanyl in spinal anaesthesia. **Methods:** After taking approval from institutional ethical committee, 80 patients of ASA grade I or II were randomly allocated into two groups. Group I received 3ml of 0.5% isobaric levobupivacaine with 25µg fentanyl and group II received 3 ml of 0.5% isobaric ropivacaine with 25µg fentanyl intrathecally. The level of sensory blockade and motor blockade was assessed. **Results:** The onset of sensory and motor blockade was earlier in group I as compared to group II. In group I sensory and motor blockade lasted significantly longer than group II. The duration of analgesia and time for rescue analgesia was prolonged in Group I as compared to Group II. **Conclusion:** Intrathecal 0.5 % isobaric ropivacaine-fentanyl combination provides satisfactory anaesthesia with shorter duration of motor blockade which is a desirable feature for early ambulation favouring day care ambulatory surgeries as compared to intrathecal 0.5% isobaric levobupivacaine-fentanyl combination which can be used in surgeries of longer duration.

Keywords: Fentanyl, Isobaric Levobupivacaine, Ropivacaine, Subarachnoid block.

INTRODUCTION

Spinal anaesthesia is an accepted technique for lower abdominal and lower limb surgeries. It produces complete analgesia with profound muscle relaxation, quiet respiration and small contracted bowel.^[1] Bupivacaine is the most commonly used local anesthetic in spinal anaesthesia. The last few years, its pure S-enantiomers, ropivacaine and levobupivacaine, have been introduced into clinical practice because of their lower toxic effects for heart and central nervous system.^[2]

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Ropivacaine a long-acting amide, first produced as a pure enantiomer, has been used for day care procedures as it provides adequate sensory blockade with early motor recovery.^[3] Levobupivacaine, an alternative to bupivacaine is known to have a safer pharmacological profile with lesser cardiac and neurotoxic adverse effects. The decreased toxicity of levobupivacaine is attributed to its faster protein binding rate. It has been shown to produce less hypotension intraoperatively.^[4,5] In recent years, use of intrathecal adjuvants like opioid analogues have gained popularity with the aim of prolonging the duration of block, improving success rate, patient satisfaction and reducing resource utilization compared with general anaesthesia and faster recovery.^[6] Fentanyl (a lipophilic opioid) has a rapid onset and short duration of action following intrathecal administration.^[7] It prolongs the duration and

reduces analgesic requirement in early postoperative period following spinal block.^[8,9] So, we conducted this prospective, randomized, double blind study with the aim of comparing the effect of isobaric levobupivacaine with fentanyl to isobaric ropivacaine with fentanyl with regards to sensory blockade, motor blockade and duration of analgesia in postoperative period.

MATERIALS AND METHODS

After approval from the institutional ethical committee, the present one year study was conducted in the department of anaesthesiology, Rohilkhand Medical College and Hospital, Bareilly starting from November 2015 to October 2016.

The study included 80 patients, ASA grade I or II, aged 18–65 years, of either gender. After taking informed written consent from the patients, demographic characteristics like age and sex of patients were noted and Preanesthetic Checkup was done, the day before surgery. Patients were explained about the procedure and about visual analogue scale. Tab ranitidine 150 mg and Tab alprazolam 0.25 mg were given night before surgery.

The randomization was done using a computer-generated sequence of numbers. The 80 patients were randomly divided into two groups: Group I received 3 ml of isobaric levobupivacaine 0.5% (15 mg) with 25 µg (0.5 ml) of inj. fentanyl (total volume 3.5 ml). Group II received 3 ml of 0.5% (15 mg) isobaric ropivacaine with 25 µg (0.5 ml) of inj. fentanyl (total volume 3.5 ml). An independent anaesthesiologist prepared the drug under all aseptic precautions.

In the operation theatre, all standard monitors were attached and baseline readings of heart rate, systolic and diastolic blood pressure, respiratory rate and SpO₂ were noted. Under all aseptic precautions, 25G quincke's spinal needle was inserted at L3-L4 interspace, after free flow of Cerebrospinal Fluid, study drug was injected slowly. The spinal needle was removed and the patient was placed supine to carry out the initial assessments.

Immediately after injection, sensory level was tested every 2 minutes by loss of pinprick sensation with 27G blunt hypodermic needle, checking in a caudal to cephalic direction until the highest level had stabilized for four consecutive tests, then every 30 minutes until regression of block to S1 segment. Motor blockade was tested using modified Bromage Scale. This was performed every 2 minutes until complete motor blockade and every 30 minutes until return of normal motor function.

The parameters that were observed included time of onset of sensory blockade, duration of sensory blockade, onset of motor blockade, duration of motor blockade and duration of analgesia. The

heart rate, systolic and diastolic blood pressure, arterial oxygen saturation and respiratory rate were also recorded. All the parameters were recorded just after giving spinal anaesthesia, at 2 minute intervals till 10 minutes, then at 5 minute intervals till 30 minutes and thereafter at 15 minute intervals till 180 minutes.

Hypotension was defined as decrease in systolic blood pressure by more than 20% from the baseline and was treated with injection mephentermine 6mg IV, the dose was titrated according to response. Bradycardia was defined as heart rate less than 50/minute and was treated with injection atropine 0.02mg/kg.

No of patients having nausea, vomiting and retention of urine were noted.

At the end of surgery patients were shifted to post anaesthesia care unit. Postoperatively sensory and motor blockade were checked every fifteen minutes till the sensory blockade regressed to S1 and motor blockade regressed to bromage zero.

Pain was assessed by using 10-point Visual Analog Scale (VAS) in which a score of "0" indicated "no pain" and a score of "10" "worst pain imaginable". When the patient's VAS score was >3, Inj. tramadol 1mg/kg was administered as a rescue analgesic.

The data was systematically collected, compiled and statistically analyzed after the completion of the study and summarized as mean ± standard deviation or as percentages. Numerical variables were normally distributed and were compared using Chi Square test for non-parametric data and Student 't' test for parametric data using SPSS software. P value of less than 0.05 was considered significant and less than 0.001 as highly significant.

RESULTS

Both the groups were comparable in terms of Age, Sex and ASA and no statistically significant difference was found (P>0.05) [Table 1].

The onset of sensory blockade was earlier in group I in comparison to group II (P<0.001) [Table 2].

The duration of sensory blockade was longer in group I in comparison to group II (P<0.001) [Table 2]. The highest sensory dermatome level reached was T6 level in both the groups, number of patients reaching the T6 sensory dermatome level block was comparable in both the groups and was statistically insignificant [Table 2].

The onset of motor blockade was faster in group I in comparison to group II (P<0.001) [Table 2]. The duration of motor blockade was longer in group I in comparison to group II (P<0.001) [Table 2].

The duration of analgesia was prolonged in group I in comparison to group II (P<0.001) [Table 2].

The mean heart rate was comparable in both the groups on starting of procedure. Pulse rate changes duration the entire intraoperative period was

statistically not significant in both the groups ($P > 0.05$) [Figure 1]

The mean systolic blood pressure, the mean diastolic blood pressure the mean mean arterial pressure, mean respiratory rate and mean SpO₂ at all the intervals in group I and II were comparable [Figure 2]. On comparing hypotension and bradycardia, no statistically significant difference was found.

DISCUSSION

In clinical practice, an ideal local anesthetic should combine rapid onset and long duration of action with minimal side effects. Among the various local anaesthetic drugs used now a days which include bupivacaine, ropivacaine and levobupivacaine, bupivacaine remains one of the most popular local anaesthetic agent because of its high potency and minimal neurological symptoms, but caution is required because of its toxicity profile particularly to the cardiotoxicity.^[2] Though cardiotoxicity is not of concern in subarachnoid blockade, the quality of sensory blockade, duration of motor blockade, haemodynamic changes and side effect profile are some consideration in selecting a drug for spinal anaesthesia.^[10] Levobupivacaine and ropivacaine, are safer alternative for regional anesthesia than its racemic parent with lower cardiotoxicity. The sensory and motor blockade characteristics of intrathecal ropivacaine and levobupivacaine are found to be inconsistent in various studies and the findings differ with varying doses of drug used in different studies.^[3]

Different adjuvants like clonidine, neostigmine, epinephrine and various opioids analogues (fentanyl, morphine etc) have been used as additives in spinal anaesthesia to improve the quality and prolong the duration of block along with better perioperative analgesia.^[11] Fentanyl (a lipophilic opioid) has a rapid onset and short duration of action following intrathecal administration. The co-administration of opioids reduces the total dose of local anaesthetics required for anaesthesia and significantly prolongs the duration of complete and effective analgesia without prolonging the duration of motor blockade. It prolongs the duration and reduces analgesic requirement in early postoperative period following spinal anaesthesia.^[6]

Till now, various studies have been done comparing the efficacy and safety of isobaric ropivacaine with fentanyl versus isobaric bupivacaine with fentanyl in spinal anaesthesia, but very few studies are available comparing the block characteristics of isobaric ropivacaine with fentanyl and isobaric levobupivacaine with fentanyl. So, we conducted a randomized double blinded study on 80 patients undergoing lower abdominal and lower limb surgeries under spinal anaesthesia to compare the efficacy of isobaric levobupivacaine with fentanyl and isobaric ropivacaine with fentanyl.

In our study, the mean onset of sensory blockade was faster in Group I (2.62 ± 0.95 min) when compared with Group II (3.39 ± 0.13 min). This observation is comparable to the study conducted by Varun et al.^[6] in which they compared 3 ml 0.5% isobaric bupivacaine plus 20 µg fentanyl and 3 ml 0.5% isobaric ropivacaine plus 20 µg fentanyl and found that time taken to achieve T10 level of

Table 1: Comparison of demographic profile

Parameters	Group I (n=40)	Group II (n=40)	P-value
Age (Years)	34.7 ± 11.5	34.33 ± 11.7	0.969
Gender (M/F)	37/3	33/07	0.310
ASA (I/II)	07/33	08/32	0.774

Table 2: Comparison of onset and duration of motor and sensory blockade and duration of analgesia.

variables	Group I(n=40)	Group II(n=40)	P-value
Onset of sensory blockade (Mins.)	2.62 ± 0.95	3.39 ± 0.13	0.001
Onset of motor blockade (Mins.)	3.53 ± 0.17	4.48 ± 0.10	0.001
Duration of sensory blockade (Mins.)	241.57 ± 1.87	196.28 ± 1.57	0.001
Duration of motor blockade (Mins.)	187.48 ± 12.12	160.75 ± 1.89	0.001
Duration of analgesia (Mins.)	249.59 ± 10.40	236.71 ± 16.10	0.001
Highest sensory dermatome level	T6	T6	0.711

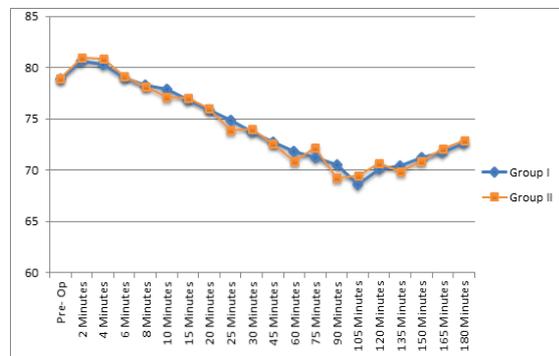


Figure 1: Comparison of mean Heart rate at different intervals (bpm).

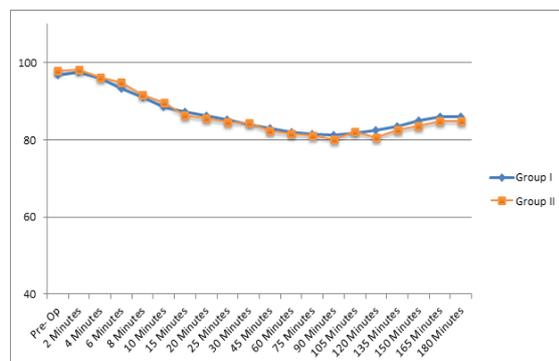


Figure 2: Comparison of mean MAP at different intervals (mm Hg).

sensory block was significantly more in ropivacaine fentanyl group as compared to bupivacaine fentanyl group. ($P < 0.05$) Indumathi et al.^[12] carried a study to compare the block characteristics and haemodynamic stability of intrathecal isobaric Ropivacaine and Levobupivacaine with Fentanyl and Magnesium as adjuvants for lower abdominal surgeries and observed that time to reach T10 dermatome was faster in levobupivacaine group compared to ropivacaine group which was statistically significant ($P < 0.001$), which is similar to our study. The result of our study is in accordance with the study conducted by Srilakshmi et al.^[2], where they found out that the onset of sensory blockade at T10 dermatome was achieved earlier in patients of levobupivacaine with fentanyl group than the patients in ropivacaine with fentanyl group which is similar to our study. Gunaydin et al.^[13] in their study, used 10 mg of isobaric bupivacaine and 15 mg isobaric ropivacaine with 20 µg fentanyl for elective caesarean sections. They concluded that both the drug solutions achieved T6 dermatome level but time to achieve sensory block till T6 level was significantly longer in ropivacaine group; which is comparable to our study. Breebaart et al.^[14] compared 10 mg isobaric levobupivacaine with 15 mg isobaric ropivacaine given intrathecally and found that the onset of sensory blockade was significantly faster for levobupivacaine group as compared to ropivacaine group. Since considering the fact that a different dose with no added adjuvant was used in their study, hence a slight difference can be noted in the onset of sensory block between that and our study.

In the present study, the mean duration of sensory blockade was longer in Group I (241.57 ± 1.87 min) when compared with Group II (196.28 ± 1.57 min) and was statistically significant (P value < 0.001). Our results are in accordance with the study conducted by Varun S et al.^[6]

Jagtap et al.^[15] compared 15 mg of 0.5% ropivacaine with 25 µg fentanyl and 15 mg of 0.5% bupivacaine with 25 µg fentanyl, and found out that the time to sensory regression to L1 dermatome was faster in the ropivacaine group compared with the bupivacaine group ($P = 0.36$) which is similar to our results. Mantouvalou et al.^[16] in their study found out that the duration of sensory block was 230 minutes, 240 minutes and 200 minutes respectively, while comparing 15 mg of isobaric levobupivacaine with 15 mg of isobaric bupivacaine and 15 mg isobaric ropivacaine. which is in accordance with our study. In a study of Chung et al.^[17] they noted that the time of regression of block to S1 was significantly longer in intrathecal bupivacaine group in comparison to ropivacaine group. The result of this study is similar to our study. Our study shows a slight contrast with Breebaart et al.^[14] which can be

explained due to the different dose of levobupivacaine used and also because no adjuvant was used in their study.

In our study, highest sensory dermatome level reached was T6 level in both the groups, number of patients reaching the T6 sensory dermatome level block was comparable in both the groups which is similar to the study done by Srilakshmi et al.^[2] and Varun et al.^[6]

In our study, the onset of motor blockade was faster in Group I (3.53 ± 0.17 min) than in Group II (4.48 ± 0.10 min). Our results are comparable to studies conducted by Indumathi et al.^[12] Mehta et al.^[18] and Srilakshmi et al.^[2]

Total duration of motor blockade was longer in Group I (187.48 ± 12.12 min) than in Group II (160.75 ± 1.89 min). Our study is in accordance with the study of Kolkta et al.^[19] in which they compared the equipotent doses of isobaric ropivacaine and isobaric bupivacaine (19.5 mg and 13 mg respectively) with fentanyl 20 µg., however the individual readings of motor block of ropivacaine group shows slight difference which may be due to the different dose of ropivacaine used. Our results are coinciding with the study conducted by Layek et al.^[20] in which the duration of motor block was significantly longer in group Bupivacaine when compared to group Ropivacaine in elective infraumbilical orthopedic surgery. ($P < 0.001$).

The results of our study are in agreement with the studies of Jagtap et al.^[15] Varun et al.^[6] and Lee et al.^[21]

In our study, the duration of analgesia was 249.59 ± 10.40 minutes in group I compared to 236.71 ± 16.10 minutes in group II ($P < 0.05$). These correlate well with the study done by Varun et al.^[6] Jagtap et al.^[15] Layek et al.^[20] Mantouvalou et al.^[16] and McNamee et al.^[22] but our study shows contrasting results when compared with Ogun et al.^[23] and Indumathi et al.^[12]

In our study, the baseline hemodynamic parameters i.e., mean heart rate, mean systolic blood pressure, mean diastolic blood pressure and mean arterial blood pressure were comparable in Group I and Group II at all the intervals since beginning ($P > 0.05$). Our result are also similar to the study done by Indumathi et al.^[12] Varun et al.^[9] Layek et al.^[20] and Srilakshmi et al.^[2] and show contrasting results with study by Erturk. E et al.^[24]

In our study, hypotension was observed in 12.5% of the cases in group I and 5% of the cases in group II. This observation is in accordance with results obtained by Jagtap et al.^[15] Vampugalla et al.^[25] Kolkta et al.^[19] In our study 5% of the patients of group I experienced nausea and vomiting, while it was 2.5% in group II. Similar results were observed in the study by Jagtap et al.^[15] and Vampugalla et al.^[25]

In our study, none of the patients experienced bradycardia and retention of urine which is also in accordance with the results of Vampugalla et al.^[25]

CONCLUSION

Intrathecal 0.5 % isobaric ropivacaine-fentanyl combination provides satisfactory anaesthesia with shorter duration of motor blockade which is a desirable feature for early ambulation favouring day care ambulatory surgeries as compared to intrathecal 0.5% isobaric levobupivacaine-fentanyl combination which can be used in surgeries of longer duration.

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