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COMPARISON OF ANESTHETIC AND ANALGESIC EFFECT OF ISOBARIC 0.5% ROPIVACAINE VERSUS LEVOBUPIVACAINE WITH FENTANYL AS ADJUVANT IN LOWER LIMB SURGERIES UNDER SPINAL ANESTHESIA- A RANDOMIZED DOUBLE-BLIND, INTERVENTIONAL STUDY

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ABSTRACT

Background: Spinal anesthesia is a widely used technique for lower abdomen and lower limb surgeries. We used opioids as an adjuvant to attain a dense block and increase the duration of surgery. The purpose of the study is to compare the anesthetic and analgesic effects of intrathecal isobaric 0.5% ropivacaine-fentanyl versus isobaric 0.5% levobupivacaine-fentanyl in patients undergoing lower limb surgeries. **Material and methods:** This prospective randomized double-blind interventional study was carried out in ASA I and II, aged 18 to 60 years. Injection Isobaric ropivacaine (0.5%) 2.5 ml with injection fentanyl 0.5 ml (25 µg) intrathecally in group A (n=30) and Inj. Isobaric levobupivacaine isobaric (0.5%) 2.5 ml with injection fentanyl 0.5 ml (25 µg) intrathecally in group B (n=30) was used. The sealed envelope method was used for group allocation. **Results:** Both groups' demographic and hemodynamic data were comparable. There was a faster onset of sensory and motor block in the levobupivacaine group than in the ropivacaine group with fentanyl, and the result was statistically significant. (P value <0.001). Two-segment regression mean time was statistically significant between groups (P value > 0.008). Sensory and motor block durations were shorter in the ropivacaine than in the levobupivacaine with the fentanyl group. There is a statistically significant difference between the two groups' time to first-dose rescue analgesia. **Conclusion:** We deduce in our study that using intrathecal 2.5 ml of 0.5% ropivacaine with 0.5ml fentanyl (25 micrograms) helps in early ambulation and can be used in day-care lower limb surgeries when compared with levobupivacaine.

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INTRODUCTION

Subarachnoid block (SAB), is a popular and common anesthetic procedure practiced worldwide and was first performed by August Bier (1898), by injecting cocaine into the cerebrospinal fluid of a patient [1]. Studies have shown that the resumption of the different physiologic functions was more rapid, with reduced hospital stay and greater compliance when abdominal and gynecologic surgeries were performed under spinal anesthesia than with general anesthesia.

It has inherent advantages like intense motor and sensory blockade, muscular relaxation and reliability, and avoidance of complications of general anesthesia like poly-pharmacy, postoperative respiratory depression, nausea and vomiting, drowsiness, etc. Many local anesthetic agents have been used in spinal anesthesia since their introduction. Among them, Ropivacaine was first used clinically in 1992. It provides a shorter duration of sensory and motor block than bupivacaine and may be of particular use in daycare surgeries. Ropivacaine is effective in providing surgical anesthesia for patients undergoing total hip replacement, transurethral resection of the prostate, lower abdominal or lower limb surgery, and cesarean section [2].

Levobupivacaine, a pure S (−) enantiomer of bupivacaine is a long-acting amide local anesthetic that produces a differential neuraxial block, that is, early onset and prolonged duration of the sensory block with shorter duration of motor block and lower cardiac toxicity [3]. Levobupivacaine has been widely used in ambulatory surgeries after the development of the low-dose spinal anesthesia technique.

Intrathecal opioids enhance sensory block without prolonging motor and sympathetic block. Among them, Fentanyl has a rapid onset of action, binds strongly to plasma proteins, and potentiates the afferent sensory blockade, thus reducing the dose of local anesthetics. The study aims to compare the anesthetic and analgesic effects of intrathecal isobaric ropivacaine fentanyl versus isobaric levobupivacaine fentanyl in patients undergoing lower extremity surgery.

MATERIALS AND METHODS

The present study enrolled 60 patients between the ages of 18 and 60 years of both genders, American Society of Anesthesiology Grade (ASA) I and II, undergoing lower limb surgery with a subarachnoid block in a tertiary care hospital who were treated after approval the ethics committee and the research review committee of the institution. Written informed consent was obtained from all patients and subjects were divided into 2 groups of 30 each by the sealed envelope method. It was a hospital-based, double-blinded, randomized, interventional study. Patients not willing to participate in the study, patients with a history of hypersensitive reactions to local anesthetics and with medical complications such as anemia, heart disease, severe hypovolemia, shock, septicemia, and hypertension, patients on anticoagulant therapy and a history of coagulation disorders, any local infection at the proposed site of puncture for spinal anesthesia, patients with neurological and psychiatric disorders and If the optimal effect of anesthesia was not achieved by spinal anesthesia were excluded from the study.

The study was conducted in the following two groups of patients.

Group A – 30 patients received an injection of isobaric ropivacaine, 2.5 ml (0.5%) with an injection of fentanyl, 0.5 ml (25 μg) intrathecally.

Group B – 30 patients received an injection of isobaric levobupivacaine, 2.5 ml (0.5%) with an injection of fentanyl, 0.5 ml (25 μg) intrathecally.

The pre-anesthetic check-up was done a day before the surgery that included the complete medical, surgical, and personal history of the patient and any known drug allergy. General and systemic examination. Vital parameters like Blood Pressure, pulse, temperature & respiratory rate, and weight were recorded. The entire procedure was explained to the patient and informed written consent was taken.

After confirming overnight fasting, the patient was taken to the operation table, connected to monitors, and baseline vitals like BP, pulse rate, and respiratory rate was recorded. An adequate size cannula was taken and fluid started. Under all aseptic precautions, spinal anesthesia was performed at the $L_3 – L_4$ inter-vertebral space, with the patients in a sitting position. The drug was prepared by another anesthetist.

A volume of 3 ml of the drug was injected over 30 seconds through a 25-gauge spinal needle. The intrathecal drug composition was depending upon the group to which the patient belonged. The patient was placed in the supine position. Oxygen

(4L/min) was administered via a face mask. Vitals were checked every 5 minutes for 30 minutes and after that every 10 minutes till the end of the surgery and then every 60 minutes for 12 hours postoperatively.

Hypotension, defined as a decrease in systolic blood pressure by more than 30% from baseline or a fall below 90 mmHg, was treated with incremental IV doses of Mephentermine 5 mg and IV fluid as required. **Bradycardia**, defined as heart rate <60 bpm, was treated with IV Atropine 0.6 mg. **Respiratory depression** was defined as a respiratory rate less than 8 breaths per minute and/or oxygen saturation less than 90% in room air.

Sensory Block: **The onset of sensory block** was defined as the time from the intrathecal injection of the study drug to the time taken to achieve the sensory block till T10. This was assessed by pin prick test bilaterally in mid-clavicular line by using 25G hypodermic needle. The level of sensory block was assessed every 2 minutes till the T10 level of the block was reached.

The Time to achieve highest level of sensory block was noted from intrathecal injection to achieve highest level of sensory block. **Regression of sensory block** was defined as the time taken for the sensory block to regress up to 2 segments of dermatome from highest level achieved sensory block. **Postoperatively sensory block** was tested every 30 minutes till 4 hours. **Grading of Sensory Blockade –** Sharp pain (0), Touch sensation only (1) and no touch sensation (2)

Motor Blockade – Motor block was assessed using the Modified Bromage scale. **Onset of motor block** was defined as the time from intra-thecal injection of the study drug to the time taken to achieve complete motor block by. **Duration of motor block** was assessed by recording the time elapsed from the maximum to the lowest Modified Bromage score (1-6). Time taken to reach Modified Bromage 1 was recorded.

Total duration of Analgesia: Time from intrathecal drug administration to patient's first demand of rescue analgesia (On VAS 3). Patients were allowed to receive rescue analgesic on VAS score of 3. Intramuscular Inj. Diclofenac (75mg) was given as rescue analgesic. Time from the intra-thecal injection to the first administration of rescue analgesic (total duration of analgesia) was noted. Patient was monitored for 24hrs for any adverse effects.

RESULTS

Table 1: Demographic Profile (Mean ± SD)

	Group A	Group B	P value
Age (Yrs)	34.9±11.1	32.7±9.58	0.401 (NS)
Gender (M:F)	25:5	28:2	0.424 (NS)
Weight (Kg)	66.3±9.1	65.2±6.2	0.588 (NS)
Height (Cm)	165.7	165.6 3.4	0.876 (NS)
ASA Grade I:II	29:1	30	1.0 (NS)

Table 2: Characteristics of Subarachnoid Block in both the groups.

Block characteristic	Group A	Group B	P value
The onset of Sensory*	10.59±1.2	6.04±0.7	<0.001
The onset of Motor *	14.13±1.5	10.31±0.8	<0.001
Duration of Sensory*	139.8±8.0	197.4±23.1	<0.001
Duration of Motor*	126.4±6.7	173.0 11.4	<0.001
Total duration of analgesia*	305.3±31.9	389.0 ±28.1	<0.001
Two-segment sensory regression time*	90.7±6.7	94.8±4.8	0.008
Level of highest sensory block (T8)	27	30	.237
Level of highest sensory block (T10)	3	0	

*(mean±sd)

Table 3: Side effects

	Group A	Group B	P value
Hypotension	5(16.7%)	5(16.7%)	1.0*
Bradycardia	0	3(10%)	0.237#
Nausea	3(10%)	5(16.7%)	0.706#
Vomiting	2(6.7%)	5(16.7%)	0.424#

*Chi-Square test | #Fisher Exact test

DISCUSSION

Spinal anesthesia, a common technique in anesthesia practice, has got inherent advantages like intense motor and sensory blockade, good relaxation, reliability, avoiding side effects of multiple drugs used in general anesthesia, no postoperative respiratory depression, nausea, vomiting, drowsiness, etc. Safely administered in patients with systemic diseases where general anesthesia and endotracheal intubation can be hazardous. Levobupivacaine, pure S(−) enantiomer of racemic bupivacaine. Because of its significantly decreased cardio-vascular and central nervous system toxicity, levobupivacaine

seems to be an attractive alternative to bupivacaine. Ropivacaine is an S-enantiomer, amide local anesthetic, with low lipid solubility, which blocks nerve fibers involved in pain transmission Aδ and C fibers to a greater degree than those controlling motor functions Aβ fibers [4].

Both groups' demographic and hemodynamic data were comparable and the results were insignificant. (Table 1). As shown in Table 2, in our study we found that the difference in the mean onset time of sensory and motor block was faster in the levobupivacaine with fentanyl than ropivacaine with fentanyl group and was statistically significant (P value of <0.001) and results were comparable with the study conducted by Priyank Samar et al [4]. The mean highest level of sensory block achieved in our study was T-8 dermatome in both groups and was similar to the study conducted by Girgin NK, et al [5].

In our study, we observed that the mean duration of sensory and motor block was shorter in group A and was statistically significant. The mean duration of sensory block in Group A was 139.8 ± 8.0 min and in Group B was 197.4 ± 23.1 min (p-value < 0.001). Similarly, the mean duration of the motor block in Group A was 126.4 ± 6.7 min and in Group B was 173.0 ± 11.4 min (p-value < 0.001). Vampugalla PS, et al [6] observed that ropivacaine achieved a shorter duration of sensory and motor blockade when compared to L-bupivacaine. Thus, ropivacaine was beneficial for short-duration ambulatory surgeries of the lower abdomen and lower limb. They observed fentanyl when used as an adjuvant potentiates the duration of the sensory block. The mean duration of motor blockade was also shorter in group A. In Priyank Samar, et al [4] study the mean duration of sensory and motor blockade was also found shorter in the ropivacaine with fentanyl group.

As shown in table 2, the mean time to two-segment regression in Group A was 90.7 ± 6.7 (min) and in Group B was 94.8 ± 4.8 (min) (p-value > 0.008). Similar results were obtained by kulkarni et al [7].

The mean duration of 1st dose of rescue analgesia was 305.3 ± 31.9 minutes in Group A and 389.0 ±28.1 minutes in group B, which was longer in group B compared to group A and were statistically significant. Kim et al [8] supported our study by concluding intrathecal ropivacaine offered shorter analgesia compared with intrathecal levobupivacaine. Joginder Pal et al [9] observed the addition of fentanyl to levobupivacaine leads to prolonged postoperative analgesia. Akhtar N, et al [10] supported our study by saying the addition of fentanyl to intrathecal ropivacaine produces adequate analgesia and also prolongs the total duration of postoperative analgesia. McNamee et al[11], found that the time to first rescue analgesic was significantly shorter in the ropivacaine group (median 3.4 hours) than in the bupivacaine group (median 4.9 h) with P<0.001 which also coincides with our study.

Rescue analgesia was given as intramuscular Inj. diclofenac (75 mg) when patients experienced pain (VAS score of 3). The mean total dose of analgesic required in group A (2.2) was higher than that in group B (1.9) and was found to be statistically significant. The mean VAS score in group A was 0.13 ± 0.35 at 4 hours, 1.13 ± 0.35 at 5 hours, and 3.00±0.00 at 6 hours. In group B, the mean VAS score was 0.00 ± 0.00 at 4 hours, 0.27 ± 0.45 at 5 hours, 1.10±0.31 at 6 hours, and 3.00±0.00 at 7 hours. The differences among the groups were found to be statistically significant (p<0.001).

In group A and group B, 5 patients experienced hypotension, and patients were treated by giving fluid and injection of mephentermine 6 mg intravenously. The findings observed were not statistically significant. Hypotension in both groups at any point in time coincided with the findings of Layek A, et al[12]. In our study, no patient developed bradycardia in group A while 3 patients developed bradycardia in group B. Bradycardia was treated by giving an injection of Atropine 0.6 mg intravenously. It was statistically not significant.

In the present study, the hemodynamic parameters (Mean pulse rate, mean systolic blood pressure, mean diastolic blood pressure, and mean arterial blood pressure) in the two groups both intraoperatively and postoperatively were statistically non-significant. Our results coincide with K Koltka et al[13] they observed that the groups in their study did not differ in hemodynamic parameters in the operating room. 3 patients developed nausea and 2 patients developed vomiting in group A. Whereas 5 patients developed nausea and vomiting in group B. This was also statistically not significant as depicted in table 3.

CONCLUSION

In our study, we observed the total duration of sensory and motor blockade is shorter with ropivacaine and fentanyl than with

levobupivacaine and fentanyl that helps in early ambulation, and appropriate for use in day care surgeries. Furthermore, fentanyl potentiates sensory duration

FINANCIAL ASSISTANCE
Nil

CONFLICT OF INTEREST
The authors declare no conflict of interest

AUTHOR CONTRIBUTION
Sampat Rathod and Trishala Jain planned the study, did the literature survey and collected the data. Chetali helped in designing the manuscript and collecting the data. All the authors helped in proofreading and reviewing the final manuscript

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