ORIGINAL ARTICLE

A comparison of intrathecal dexmedetomidine and fentanyl as an adjuvant to 0.5% levobupivacaine in the lower limb surgeries: A randomized double blind study

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Introduction: Spinal anesthesia is economic, easily administered and advantages of a minimal drug costs, awake patient and rapid patient turnover has made this the method of choice for many surgical procedures. In this research work, we describe to compare the combination of "levobupivacaine" (isobaric) with "fentanyl" versus "dexmedetomidine" in the low dosages for the various characteristics of the spinal blockade such as onset, duration, hemodynamic parameters, and side effect. **Material and Methods:** A double-blinded randomized study was done in 76 patients between 19 and 65 years of ASA Grades I and II under going lower limb surgeries divided in group 1-received 0.5% isobaric levobupivacaine 15 mg (3 ml) with dexmedetomidine (3 mcg in 0.5 ml) and Group 2–0.5% isobaric levobupivacaine 15 mg (3 ml) with fentanyl (15 mcg in 0.5 ml) intrathecally. **Results:** Onset of Sensory Blockade between Group 1 and Group 2 is 9.08 ± 0.73 and 4.09 ± 0.77 min, respectively. Mean Onset of Motor Blockade between Group1 and Group 2 is 11.4 ± 1.07 and 5.55 ± 0.54 min, respectively. Mean duration of sensory blockade between Group 1 and Group 2 is 196.03 ± 8.15 and 153.47 ± 4.67 min, respectively. Mean duration of motor block in min between Group 1 and Group 2 is 218.92 ± 9.76 min and 163.22 ± 4.64 min, respectively. **Conclusion:** Low dose of dexmedetomidine group has longer duration of sensory and motor block with prolonged post-operative analgesia. However, onset of sensory and motor block is earlier in fentanyl group.

KEY WORDS: Dexmedetomidine, fentanyl, levobupivacaine, lower limb surgeries, spinal anesthesia

INTRODUCTION

Spinal anesthesia is popular and commonly used worldwide. It is economic and easily administered and thus, commonly used procedure for the lower limb surgeries. The advantages of a minimal drug costs, awake patient and rapid patient turnover has made this the method of choice for many surgical procedures.[1] Post-operative pain is common problem during lower limb surgeries under spinal anesthesia because when spinal anesthesia has relatively limited duration of action when used only with local anesthetics. Thus, there is need for early analgesic intervention following surgery. So various adjuvants such as fentanyl, dexmedetomidine, clonidine, and midazolam have been experimented to lengthen the spinal anesthesia effect.[2]

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Racemic bupivacaine is one of the most common local anesthetics used for spinal analgesia and levobupivacaine is its S (-)-enantiomer.[3] Levobupivacaine has been introduced into clinical practice, and the clinical profile of spinal levobupivacaine has been evaluated in volunteers and in clinical

studies.[1] It has prolonged analgesia time duration with rapid recovery from the motor blockade. It has better safety profile, since it has less central nervous system and cardiac toxicity, lesser episodes of hypotension.[4] Levobupivacaine is also an effective local anesthetic agent with less systemic toxicity than racemic bupivacaine, but it has short post-operative analgesic duration.[5]

In few studies, adjuvants "fentanyl" and "dexmedetomidine" have been used in central neuraxial block to levobupivacaine in obstetric patients in varying doses. We have not came across any research work on the use of fentanyl and dexmedetomidine in the lower doses as an adjuvant or additive to intrathecal levobupivacaine. Hence, in this research work, we describe to compare the combination of "levobupivacaine" (isobaric) with "fentanyl" versus "dexmedetomidine" in the low dosages for the various characteristics of the spinal blockade under headings onset, duration and hemodynamic parameters, and side effect.

MATERIALS AND METHODS

After obtaining approval from institutional ethical committee, a double-blinded randomized study was conducted in Rohilkhand Medical College and Hospital, Bareilly. The study was registered in CTRI with CTRI number- CTRI/2021/09/036808. A thorough, well informed and written consent were taken from all patients before the procedure and patients of ASA Grades I and II posted for lower limb surgery between the age group of 19–65 years who were randomly divided into two groups using computer generated randomization technique each comprising 36 patients. Group 1, patient was given 0.5% of isobaric levobupivacaine 15 mg (3 ml) with dexmedetomidine (3 mcg in 0.5 ml) intrathecally, while in Group 2, 0.5% isobaric levobupivacaine 15 mg (3 ml) with fentanyl (l5 mcg in 0.5 ml) was given. Patients were explained about the procedure of spinal anesthesia. They were kept nil-per-oral for 6 h and Tablet Ranitidine 1 mg/kg and Tablet Alprazolam 0.25 mg was given orally, the night before surgery. On arrival in the operating room after application of routine monitors (non-invasive blood pressure measurement, electrocardiography, and pulse oximetry) and insertion of a peripheral 20 gauge intravenous cannula was done, patient was preloaded with RL solution 15 ml/kg. Antiemetic prophylaxis was given using Injection Ondansetron 0.08 mg/kg and Injection Ranitidine 1 mg/kg.

After disinfecting the skin and infiltrating with 2% lignocaine, lumbar puncture was performed at L3–L4 interspace with 26 gauge (Quincke needle) in sitting position. After obtaining CSF clear flow, Group 1 received preservative free 0.5% isobaric levobupivacaine 15 mg (3 ml) with dexmedetomidine (3 mcg in 0.5 ml) and Group 2 received isobaric 0.5% isobaric levobupivacaine 15 mg (3 ml) with fentanyl (15 mcg in 0.5 ml). Total volume, that is, 3.5 ml was given in each group intrathecally within 10 s.

After intrathecal injection, patient was immediately made in supine position. The effect of sensory and motor block was checked, for every 2 min for first 20 min, then every 3 min for next 30 min, then every 5 min for 40 min, then every 10 min for 60 min, and finally every 15 min until the sensory block has regressed to S1 dermatome. The patient was administered Injection midazolam 1 mg i.v. after spinal anesthesia. During the surgery the patient's pulse rate, systolic blood pressure, diastolic blood pressure, mean arterial pressure, and SpO_2 were recorded every 3 min for 15 min, then every 5 min for 30 min and then every 15 min until completion of the surgery. The level of sensory of the block was assessed in a caudal to cephalad direction with loss to pin prick sensation, and the unblocked reference point used were C5–C6 dermatome. The following parameters were noted: Time interval to the sensory blockade onset (i.e., time from intra-thecal injection of drug to complete loss of sensation to the pin pricking at T10 level) and duration of sensory block by regression to S1. Time taken to the onset of motor block was accessed by "Modified Bromage Score" (time interval taken to achieve of Bromage 2 from intrathecal injection). Motor blockade duration was noted as time from Bromage 3 to Bromage 2.

Sedation of the patient was assessed by the Ramsay sedation scale and shivering by A. W.A. Crossley and R.P. Mahajan Shivering Score.

Visual-analog scale score (VAS), shivering was assessed hourly till 6 h of post-operative period and at 12, 18, and 24 h postoperatively. 24 h PONV score was also assessed. Rescue analgesia will be given when VAS >4 and time for first rescue analgesia used was noted.

RESULTS

Spinal block was successfully achieved in all the patients and all patients enrolled for the study completed the study. Demographic parameters such as age, gender, and weight were comparable in both the groups [Table 1].

Mean onset of sensory blockade between Group 1 and Group 2 is 9.08 ± 0.73 and 4.09 ± 0.77 min, respectively, which is statistically significant [Graph 1]. Mean onset of motor blockade between Group 1 and Group 2 is 11.4 ± 1.07 and 5.55 ± 0.54 min, respectively, and is statistically significant [Graph 1 and Table 2].

Mean duration of sensory blockade between Group 1 and Group 2 is 196.03 ± 8.15 and 153.47 ± 4.67 min, respectively [Graph 2]. Mean duration of motor block in min between Group 1 and Group 2 is 218.92 ± 9.76 min and 163.22 ± 4.64 min, respectively, [Graph 2 and Table 2].

DISCUSSION

Spinal anesthesia is the most preferred technique in surgeries of the lower limb, because of easy and rapid induction, effective sensory, and motor blockade. Addition of adjuvant hasten the onset of sensory and motor blockade thereby prolonging the duration of anesthesia, adequate sensory and motor blockade with

Table 1: Demographic parameters

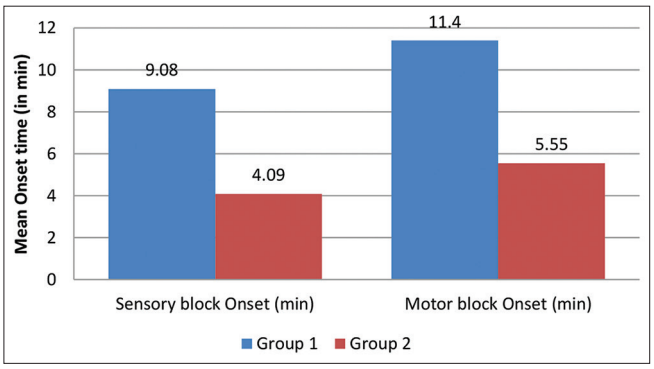
Parameters	Group 1	Group 2	*P*-value
Age in years	39.86±9.27	36.25±10.41	0.125#
Gender (Male/Female)	22/14	26/10	0.317#
Weight (in kg)	59.64±7.95	60.72±8.44	0.577#

#Statistically not significant

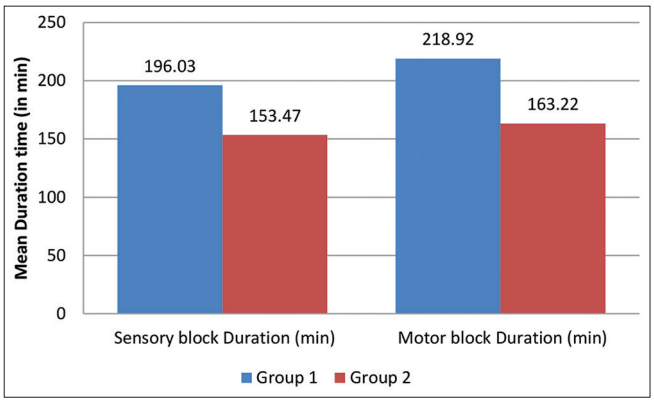
Table 2: Spinal block characteristics

Parameters	Group 1	Group 2	*P*-value
Sensory block Onset (min)	9.08±0.73	4.09±0.77	<0.001*
Motor block Onset (min)	11.4±1.07	5.55±0.54	<0.001*
Duration of sensory block(min)	196.03±8.15	153.47±4.67	<0.001*
Duration of motor block(min)	218.92±9.76	163.22±4.64	<0.001*

*Statistically significant



Graph 1: Onset of sensory blockade and motor blockade



Graph 2: Duration of sensory and motor blockade

better hemodynamic stability and minimum adverse effect. In this study, lower intrathecal doses of adjuvants dexmedetomidine and fentanyl were taken with levobupivacaine.

Our study showed that the mean time for onset of sensory and block was longer in the dexmedetomidine group as compared to fentanyl group. The study conducted by Bhure and Jagtap in 2019 found similar results to our study.[2] Rastogi *et al*. in 2020 also found that mean onset of sensory blockade is earlier in fentanyl group as compared to other groups similar to our study.[6] This could be attributed to more lipophilic nature of fentanyl due to which it rapidly transverses the dura and binds readily to the opioid receptors.

In our present study, the mean duration of sensory and motor-block was prolonged in dexmedetomidine group as compared to fentanyl group. Mahendru *et al*. in 2013 also found prolonged duration of motor block in dexmedetomidine group as compared to fentanyl group similar to our study.[7] The prolongation of motor block duration can be attributed to binding of alpha-2 receptor agonist to the motor neuron in the dorsal-horn. The minimal difference in the study can be attributed to high doses of adjuvants used with local anesthetics. Bhure and Jagtap in 2019 also found result similar to our study.[2] Li *et al*. in 2015 also found that duration of motor block was significantly longer in dexmedetomidine group as compared to fentanyl group similar to our study.[8]

The time to first analgesic requirement was prolonged in dexmedetomidine group when compared to the fentanyl group which can be attributed to better synergism of local anesthetics with alpha-2 agonist receptors.

CONCLUSION

As compared to 15 mcg of fentanyl, 3 mcg of dexmedetomidine may be used as an alternative adjuvant to intra-thecal isobaric levobupivacaine in elective lower limb surgery for longer duration of surgical procedures because of longer duration of sensory and motor blockade with better post-operative analgesia and similar hemodynamic stability. Hence, dexmedetomidine is an attractive alternative as intra-thecal adjuvant with levobupivacaine when compared with fentanyl. However, prolonged duration of motor-blockade with dexmedetomidine may be undesirable for short term surgical procedures or ambulation surgeries where fentanyl as an adjuvant can be preferred.

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