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"Comparative Study Of Intrathecal Isobaric Levobupivacaine With Fentanyl Versus Isobaric Levobupivacaine With Buprenorphine In Elective Lower Limb Orthopaedic Surgeries"

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ABSTRACT
BACKGROUND:
Spinal anesthesia is one of the most widely used regional anesthesia technique, providing adequate sensory as well as motor blockade. Hyperbaric racemic bupivacaine is one of the most frequently used long acting agent for intrathecal anesthesia. But adverse effects like profound myocardial depression and even cardiac arrest can occur after accidental intravascular injection.With the introduction of levobupivacaine, the pure S (-) enantiomer of bupivacaine, a safer alternative to racemic isomer of bupivacaine is available– which has lower cardio and neuro toxic effects.
The addition of opioids such as buprenorphine, morphine and fentanyl and other adjuvants like clonidine to local anesthetics have a favorable effect in regional anesthetic techniques.Previous studies have compared the anaesthetic and recovery profiles of levobupivacaine and also analysed the effects of addition of adjuvants individually. However, there is lack of literary evidence in anesthesia practice that compares the addition of the buprenorphine to levobupivacaine with fentanyl for intrathecal anesthesia. Hence we attempted this in the current study.
METHODS
A Prospective randomized study was conducted in sixty patients aged 18-75 years undergoing elective lower limb orthopaedic surgeries under spinal anaesthesia over a period of one year after dividing them into two groups:
GROUP 'A':3.5 ml of 0.5% levobupivacaine(isobaric) with 0.5ml(25mcg) of fentanyl
GROUP'B': 3.5 ml of 0.5% levobupivacaine(isobaric) plus 0.3ml (90 mcg) of buprenorphine
RESULTS
The study demonstrates that 0.5% isobaric levobupivacaine with fentanyl (25 mcg) and combination of 0.5% isobaric levobupivacaine with buprenorphine (90 mcg) administered intrathecally provides comparable onset of sensory and motor block, duration of motor block and hemodynamic stability with minimal side effects. Addition of buprenorphine (90 mcg) prolongs the duration of sensory blockade. Addition of fentanyl increased the level of sensory block achieved.
CONCLUSION
use of adjuvants with intrathecal local anaesthetics is advisable for patients undergoing spinal anaesthesia in order to achieve higher level of block and to achieve longer duration of block.

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I. Introduction:

In the last two decades, regional anesthesia has emerged as an important and safer alternative to general anesthesia as it offers effective anesthesia and adequate muscle relaxation with rapid onset of action with fewer adverse effects. Spinal anesthesia provides adequate sensory as well as motor blockade.[1,2]

Hyperbaric racemic bupivacaine is one of the most frequently used long acting agent for intrathecal anesthesia however, adverse effects like profound myocardial depression and even cardiac arrest can occur after accidental intravascular injection.[3]

With the introduction of levobupivacaine, the pure S (-) enantiomer of bupivacaine, a safer alternative to racemic isomer of bupivacaine is available– which may have lower cardio and neuro toxic effects. Both levobupivacaine and racemic bupivacaine have been used effectively as long acting local anesthetics intrathecally with good sensory as well as motor blockade. Because of its significantly low side effects, levobupivacaine

appears to be a safer alternative. Similarly, the potential for CNS toxicity is lower with levobupivacaine as compared to bupivacaine.[4, 5, 6] It has been stated that its faster protein binding rate reflects a decreased degree of toxicity and studies done have supported that it has lesser cardiovascular and central nervous system toxicity than bupivacaine.[7, 8 10]

Results from previous studies have shown that the addition of opioids such as buprenorphine, morphine and fentanyl and other adjuvants like clonidine to local anesthetics have a favorable effect in regional anesthetic techniques.11, 12 Fentanyl is a phenyl piperidine derivative, synthetic opioid agonist which is 75– 125 times more potent, 800 times more lipid soluble and it has faster onset of action and relatively short duration of action compared to morphine. Neuraxial fentanyl when added with local anaesthetics has been shown to increase the anaesthesia period for the surgery Neuraxial buprenorphine when used along with local anesthetics have been shown to help reduce the requirement of local anesthetics while also helping to prolong analgesia in the immediate postoperative period. Buprenorphine which is a partial Mu opioid agonist and Kappa and delta antagonist is one of the most commonly used adjuvants with levobupivacaine for spinal anesthesia.[11]

There are several studies in the past that have compared the anesthetic and recovery profiles of levobupivacaine and also analyzed the effects of addition of adjuvants individually. However, there is lack of literary evidence in anesthesia practice that compares the addition of the buprenorphine to levobupivacaine with fentanyl for intrathecal anesthesia. Hence we attempted this in the current study.

II. METHODOLOGY:

Inclusion Criteria

a) Adults between 18 to 75 years of age.
b) Body mass index of 18 to 28
c) ASA 1-2
d) Posted for elective hip or lower limb orthopedic surgeries.
e) Surgeries less than 4hrs

Exclusion Criteria

a) Any hypersensitivity to local anesthetics.
b) Emergency surgeries.
c) Bleeding diathesis.
d) Infections at the injection site.
e) Known congenital abnormalities of lower spine or vertebral column

PLAN OF STUDY:

A Prospective randomized study was conducted in sixty patients aged 18-75 ,meeting the inclusion criteria years undergoing elective lower limb orthopaedic surgeries under spinal anaesthesia over a period of one year after dividing them into two groups using block randomisation using a computer generated random sequence.
GROUP 'A':3.5 ml of 0.5% levobupivacaine(isobaric) with 0.5ml(25mcg) of fentanyl
GROUP'B': 3.5 ml of 0.5% levobupivacaine(isobaric) plus 0.3ml (90 mcg) of buprenorphine

METHOD OF STUDY:

After adequate preparation of the patient, standard monitoring was established ,IV lines were secured and the groups were administered their respective study solution by inserting 25-G Quincke Babcock spinal needle at lumbar vertebral interspace using midline approach with patient in sitting position.

Patients were made to lie down in the supine posture immediately after the subarachnoid injection of the study drug, keeping the table flat. All patients were given supplementary oxygen through a Hudson's Mask at 6 L/min. Patients were monitored at 2 minutes and 5 minutes interval for first 20 minutes, and then every 10 minutes till the end of the surgery and postoperatively every half hour till 4 hours after spinal anaesthesia.

Parameters observed:

1. Heart rate (HR), Electrocardiography (ECG), Noninvasive blood pressure (NIBP), Oxygen saturation (SpO2), Respiratory rate (RR).
2. Time for onset of analgesia was assessed by loss of sensation to temperature bilaterally along mid clavicular line to cold saline in a test tube. Motor blockade was assessed using modified Bromage score (39) . Time for onset of sensory blockade at L1 level, time for onset of motor blockade was noted. Maximum height of sensory blockade attained, total duration of sensory blockade, total duration of motor blockade was recorded.
3. Any intraoperative and postoperative side effects and complications were noted

(Onset of sensory blockade: time taken from the completion of the injection of the study drug till the patient did not feel cold sensation at T10 dermatome.

Maximum height of sensory blockade achieved: the maximum sensory blockade attained at 20 mins from the time of completion of injection of study drug.

Duration of sensory block: the time taken from the onset of sensory blockade at T10 level till the sensory level receded to below L1 dermatome level.

Onset of motor blockade: was defined as the time taken from the completion of the injection of the drug till the patient achieved motor blockade of Bromage score 3.

Quality of motor blockade: was assessed according to modified Bromage score.)

Modified Bromage score (42) 1) Complete block (unable to move feet or knees). 2) Almost complete block (able to move feet only). 3) Partial block (just able to move knees). 4) Detectable weakness of hip flexion while supine (full flexion of knees). 5) No detectable weakness of hip flexion while supine. 6) Able to perform partial knee bend

Duration of motor blockade: the time taken from the onset of motor blockade of Bromage score 3 till the complete recovery of motor blockade to Bromage score 6. Hypotension was defined as systolic BP (SBP) less than 90mmHg or diastolic blood pressure (DBP) less than 60mmHg, mean arterial pressure (MAP) less than 65mmHg and was treated with increased rate of intravenous fluids and vasopressors (inj. Phenylephrine 60mcg IV) bolus.

Bradycardia was defined as heart rate less than 45 beats/min and was treated with injection atropine 0.6mg IV bolus

III. RESULTS

The study demonstrated that 0.5% isobaric levobupivacaine with fentanyl (25 mcg) and combination of 0.5% isobaric levobupivacaine with buprenorphine (90 mcg) administered intrathecally provides ***comparable*** onset of sensory and motor block, duration of motor block and hemodynamic stability with minimal side effects.

However significant difference was found in terms of mean sensory duration and maximum sensory level achieved while using the two drugs.

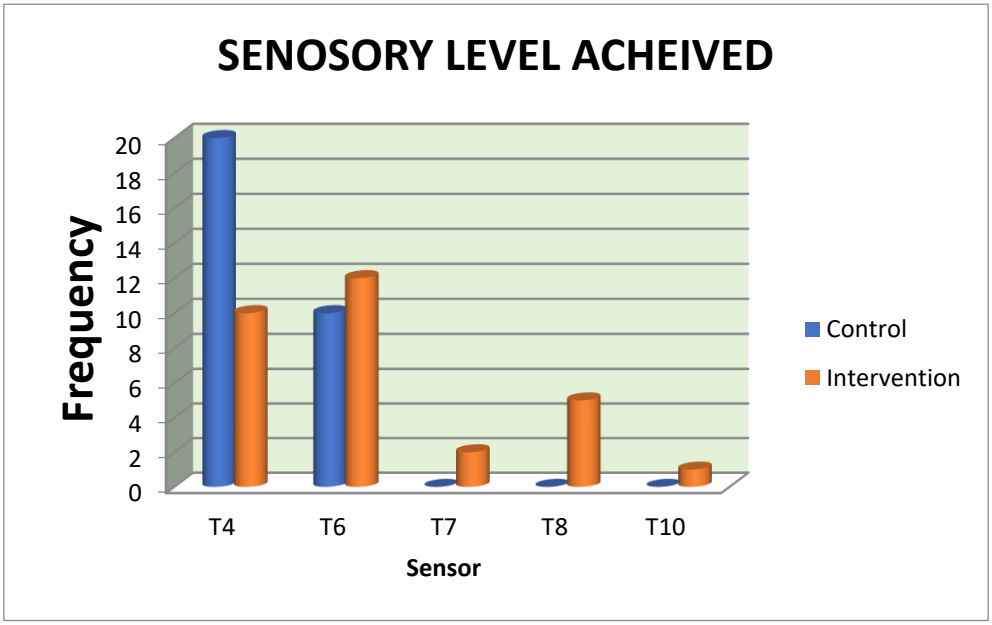
Mean Sensory Duration Comparison between two groups

Group	**Mean SENSORY BLOCKADE DURATION**	**SD**	**p value**
A	285.27	13.50	
B	309.00	14.65	**<0.001**

Mean Sensory Duration in Group A was 285.27 ± 13.5 and in Group B was 309 ± 14.65.There was a significant difference in mean Sensory Duration comparison between two groups (P value <0.001). This was one of the positive findings of this study.

MAXIMUM SENSORY LEVEL ACHIEVED:

	Group			
SENOSORY LEVEL ACHIEVED	A	B	Total	**p value**
T4	20	10	30	0.021
T6	10	12	22	
T7	0	2	2	
T8	0	5	5	
T10	0	1	1	
Total	30	30	60	



No statistical test was applied- due to 0 subjects in the cells

In Group A, 66.67% had T4 and 33.33% had T6. In Group B, 33.33% had T4, 40.00% had T6, 6.67% had T7, 16.67% had T8 and 3.33% had T10.

Majority in group A achieved T4 and T6 was achieved by most in B group.

There was a difference in the maximum level of sensory blockade noted in the two groups. Sensory block height was more in patients who received fentanyl as an intrathecal adjuvant in the dose of 25 mcg.

Thus,Addition of buprenorphine (90 mcg) prolongs the duration of sensory blockade. Addition of fentanyl increased the level of sensory block achieved.

IV. DISCUSSION:

The aim of the study was to evaluate the sensory and motor blocking properties, hemodynamic variations, and side effects if any, of isobaric levobupivacaine 0.5% 3.5 ml(17.5 mg) plus 25 mcg fentanyl(0.5ml) and isobaric levobupivacaine 0.5% 3.5 ml(17.5 mg) with buprenorphine 90 mcg(0.3 ml).

The data was entered into MS Excel spreadsheets and analysis was carried out. The procedures involved were transcription, preliminary data inspection, content analysis, and interpretation. For analysis, descriptive and inferential statistics were used. The statistical analyses were done by using PSW software version 21.0.

The major findings of the study were as follows:

Maximum sensory block achieved: In our study we found a *significant difference* in maximum level of sensory block achieved with the addition of two different opioids, fentanyl and buprenorphine intrathecally. Majority of the patients in A group achieved the level of T4 (66%) while only 33% of the patients reached T4 level in B group.

The findings were in concurrence with the study of Joginder pal attri et al comparing intrathecal fentanyl (25mcg) with levobupivacaine and plain levobupivacaine, both at 10 mg; the maximum level achieved was T6 in the group with the addition of fentanyl and T8 in levobupivacaine alone. This shows the although addition of the fentanyl increased the level achieved, the dose of the local anesthetic used is equally important in achieving a higher sensory blockade as seen with our study which used 17.5mg of levobupivacaine compared to their 10mg.[12]

Total duration of the sensory block: In the study, the total duration of the sensory blockade is defined as regression to the L1 level and it was found that there was a *statistically significant* difference between the two groups in the duration of sensory block. In group levobupivacaine with fentanyl, the duration was 285.27±13.5 minutes. While in group levobupivacaine with buprenorphine, it was 309±14.6 minutes

This finding was in concurrence with the study of Kamal, Davis et al which compared intrathecal buprenorphine (75 mcg) and fentanyl (25 mcg) with bupivacaine (1.8 ml) in cesarean section also showed statistically significant increase in the duration of analgesia in buprenorphine group (317±54 minutes) compared to the 214±35 minutes in the fentanyl group. This outcome is comparable to our finding.[13]

The other parameters that were compared such as Onset of motor blockade, Duration of motor blockade, Hemodynamic variations, complications observed in our study such as bradycardia, hypotension requiring

vasopressor, sedative effect due to the opioids, shivering, pruritus, nausea and vomiting *did not vary significantly* between the two groups.

V. CONCLUSION:

our study demonstrates that 0.5% isobaric levobupivacaine with fentanyl (25 mcg) and combination of 0.5% isobaric levobupivacaine with buprenorphine (90 mcg) administered intrathecally provides comparable onset of sensory and motor block, duration of motor block and hemodynamic stability with minimal side effects. Addition of buprenorphine (90 mcg) prolongs the duration of sensory blockade. Addition of fentanyl increased the level of sensory block achieved.

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