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"A COMPARATIVE STUDY BETWEEN ISOBARIC LEVOBUPIVACAINE WITH 5MCG DEXMEDETOMIDINE AND HYPERBARIC BUPIVACAINE FOR LOWER LIMB SURGERIES"

Anaesthesiology

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ABSTRACT

Introduction: Spinal anesthesia is the widely used mode of anesthesia for lower limb surgeries because of its profound muscle relaxation and analgesia. Bupivacaine being the drug of choice, is associated with serious cardiac toxicity. The Levo-enantiomer of bupivacaine can be a safer alternative with better cardiovascular safety. Dexmedetomidine, the highly selective alpha2 agonist drug used as an adjuvant in neuraxial anesthesia due to its prolonged and intense blockade with better post-op analgesia. **Objective:** In this study, we aimed to compare the hemodynamic changes, sensory, motor blockade and post-operative analgesia between 0.5% isobaric levobupivacaine with 5mcg dexmedetomidine and 0.5% hyperbaric bupivacaine in elective lower limb surgeries. **Materials And Methods:** 60 patients were randomized into two groups of 30 each. Group A patients received 2.5ml of 0.5% isobaric levobupivacaine + 0.5ml of 5mcg dexmedetomidine. Group B patients received 2.5ml of 0.5% hyperbaric bupivacaine + 0.5ml 0f normal saline. Onset, duration of sensory and motor blocks, time for maximum sensory and motor block, time for two segment sensory regression, post-operative analgesics requirement and hemodynamic parameters were recorded and analyzed. **Results:** It was observed that, the onset of sensory and motor blockade was significantly shorter in group A than group B ($p<0.001$), the time taken to achieve maximum sensory blockade and bromage 3 of motor blockade was shorter in group A than group B ($p<0.001$), the regression of the sensory block to S1 dermatome and bromage 0 was longer in group A than group B ($p<0.001$), the two dermatome regression time was longer in group A than group B ($p<0.001$), the post-operative rescue analgesic requirement time was longer in group A than group B ($p<0.001$). There was a statistically significant changes in pulse rate between two groups during first 60 minutes and no differences in systolic and diastolic blood pressure, mean arterial pressure and Spo2. **Conclusion:** We conclude that 0.5% isobaric levobupivacaine with 5mcg dexmedetomidine has an early-onset and prolonged duration of sensory and motor block and longer duration of post-operative analgesia than 0.5% hyperbaric bupivacaine, hence it is safer alternative for lower limb surgeries.

KEYWORDS

Isobaric levobupivacaine, Dexmedetomidine, subarachnoid block.

INTRODUCTION:

Spinal anesthesia is the preferred mode of anesthesia in patients undergoing lower limb surgeries, due to its cost effectiveness and ease of administration, unless contraindicated.

Levobupivacaine, the Pure S(-) enantiomer of bupivacaine causes less cardiovascular and neurological events. Increased protein binding and higher clearance explains cardiac stability of levobupivacaine[1].

The Position of the patient during and after the procedure has no effect on how widely an isobaric solution spreads in cerebrospinal fluid(CSF). Thus, intrathecal isobaric levobupivacaine does not spread unexpectedly high, and levels of sensory block after spinal isobaric levobupivacaine are unaffected by change in patient position following the injection.

However, using only local anesthetics is associated with relatively short duration of action, making early analgesic intervention necessary in the post-operative period. As a result, postoperative pain control is a significant issue.

A number of adjuvants, such as clonidine and midazolam, and others have been studied to prolog the effect of spinal anesthesia[2].

Dexmedetomidine, a highly selective alpha2 agonist is rapidly emerging as the choice of additive to spinal anesthesia in view of its property to provide analgesia and awake Sedation without respiratory depression along with a stable hemodynamics[3].Use in a dose of 5mcg (in 0.5ml volume) maximal beneficial effect of dexmedetomidine can be obtained[4-5].

In this study, we aimed to compare hemodynamics changes, sensory, motor block characteristics and post-operative analgesia between 0.5% isobaric levobupivacaine with 5mcg dexmedetomidine and 0.5% hyperbaric bupivacaine.

MATERIALS AND METHODS:

This was a prospective, randomized clinical trial conducted at basaveshwar teaching and general hospital, kalaburagi, Karnataka. After getting informed and written consent of the patients, 60 American Society of Anesthesiologists (ASA) grade 1 and 2 orthopedic patients between the ages of 20 to 60 years who were posted for elective lower limb surgeries were grouped randomly into two groups as Group A and Group B of 30 each.

- Group A - patients received, 2.5ml of 0.5% isobaric levobupivacaine + 0.5ml of 5mcg dexmedetomidine (total volume of 3.0ml)
- Group B – patients received, 2.5ml of 0.5% hyperbaric bupivacaine + 0.5ml of normal saline (total volume of 3.0ml)

Inclusion Criteria:

1. Patients aged between 20 and 60 years
2. ASA grade 1 and 2
3. Posted for elective lower limb orthopedic surgeries
4. Height 150-180cm
5. Weight 50-70kg

Exclusion Criteria:

1. Patient refusal
2. Patients using alpha 2 adrenergic receptors antagonists, angiotensin-converting enzyme inhibitors
3. Patients having absolute contraindication to spinal anesthesia

Careful preanesthetic check-up was carried out in all patients with detailed clinical history, general and systemic examination. After checking the informed consent overnight fasting for 8 hours done. On the day of surgery an intravenous line was secured with an 18-gauge cannula and patients were premedicated with injection ondansetron 0.1mg/kg, preloaded with ringer lactate solution 10ml/kg half an hour before spinal anesthesia. ECG, pulse rate(PR), automated noninvasive blood pressure (NIBP) and pulse oximetry(Spo2) readings were recorded.

All patients were placed in left lateral position, under strict aseptic

precautions lumbar puncture was performed at the level of L3-L4 through a midline approach using 25G quincke spinal needle and study drug was injected after confirmation of needle tip in the subarachnoid space by a free flow of CSF. Patients were made to lie down in the supine posture immediately after spinal anaesthesia with table flat. Then parameters like pulse rate, systolic blood pressure(SBP), diastolic blood pressure(DBP), mean arterial pressure(MAP), Spo2 and using a preformed structured proforma the following parameters were recorded.

1. Onset of sensory blockade at T10 level (tested using pinprick method).
2. Onset of motor blockade bromage>0 (quality of blockade was assessed by modified bromage scale).
3. Maximum dermatomal level of sensory blockade attained and time taken to achieve it.
4. Time taken to achieve bromage 3 of motor blockade.
5. Two segment sensory regression time.
6. Total duration of sensory and motor blockade.
7. Total duration of surgery, post-operative analgesia i.e, time to first request for analgesia by the patient.

Statistical Methods:

Descriptive and inferential statistical analysis has been carried out in the present study. Results on continuous measurements are presented on Mean SD (Min-Max) and results on categorical measurements are presented in Number (%). Significance is assessed at 5 % level of significance.

RESULTS:

The demographic profile for both the groups were comparable regarding age, sex, height, weight, ASA physical status and duration of surgery (Table.1).

Table 1: Demographic characteristics

Variables	Group A (n=30)	Group B (n=30)	P-Valve
Age(Years)	42.86 ± 19.8	41.30 ± 11.6	> 0.05
Sex(M:F)	18:12	19:11	>0.05
Height(cm)	156.40 ± 6.82	158.20 ± 7.19	>0.05
Weight(kg)	65.13 ± 13.4	64.42 ± 9.6	>0.05
ASA(1:2)	20:10	22:8	>0.05
Duration of Surgery	150 ± 13.30	146 ± 14.08	>0.05

The characteristics of block between the two groups were summarized in Table.2

Table 2: Comparison of sensory and motor block parameters in two groups

Variables	Group A (n=30)	Group B (n=30)	P-Valve
Onset of sensory block at T10 (min)	2.83 ± 0.5	3.25 ± 0.4	<0.001
Time taken to achieve maximum sensory block (min)	7.23 ± 1.04	10.00 ± 1.05	<0.001
Maximum level of sensory blockade attained	T5 (T4-T6)	T6 (T5-T7)	>0.05
Onset of motor blockade bromage>0 (min)	3.20 ± 0.60	4.00 ± 0.83	<0.001
Time taken to achieve bromage 3 of motor blockade	5.00 ± 0.53	8.00 ± 0.34	<0.001
Two segment sensory regression time (min)	100 ± 10.0	80 ± 8.03	<0.001
Duration of sensory blockade (min) (regression to S1 from highest sensory level)	310 ± 15.0	211 ± 10.0	<0.001
Duration of motor blockade (min) (regression time to bromage 0)	277 ± 11.03	183 ± 12.7	<0.001
Time at which rescue analgesia required (min)	230 ± 13.44	169 ± 10.45	<0.001

Block Characteristics:

The meantime for onset of the sensory blockade at T10 was 2.83 ± 0.5 minutes in Group A and 3.25 ± 0.4 minutes in Group B. There was a statistically significant difference between the two group regarding the onset of sensory blockade (P<0.001).The mean time taken to achieve maximum sensory blockade was 7.23 ± 1.04 minutes in Group A and 10.00 ± 1.05 minutes in Group B. There was a statistically significant difference between the two groups (P<0.001).

All the patients in both groups attained a block of T5 & T6 level respectively with no statistically significant difference between the two groups (P>0.05).

The meantime for onset of motor blockade bromage>0 was 3.20 ± 0.60 minutes in Group A and 4.00 ± 0.83 minutes in Group B. There was a statistically significant difference between the two groups (P<0.001).

The mean time taken to achieve bromage 3 of motor blockade was 5.00 ± 0.53 minutes in Group A and 8.00 ± 0.34 minutes in Group B. There was a statistically significant difference between the two groups (P<0.001).

The mean time for two segment sensory regression was 100 ± 10.00 minutes in Group A and 80 ± 8.03 minutes in Group B. There was a statistically significant difference between the two groups (P<0.001).

The total duration of sensory blockade (regression to S1 from highest sensory level) was 310 ± 15.0 minutes in Group A and 211 ± 10 minutes in Group B. There was a statistically significant difference between two groups (P<0.001).

The total duration of motor blockade (regression time to bromage 0) was 277 ± 11.03 minutes in Group a and 183 ± 12.7 minutes in Group B. There was a statistically significant difference between two groups (P<0.001).

The time at which rescue analgesic required was 230 ± 13.44 minutes in Group A and 169 ± 10.45 minutes in Group B. There was a statistically significant difference between two groups (P <0.001).

Hemodynamic Parameters:

Table 3: Comparison of pulse rate

Pulse rate (bpm)	Group A	Group B	P-Valve
Before induction	85.9 ± 5.7	84.3 ± 4.6	0.237
After induction	90.4 ± 3.7	89.7 ± 4.2	0.496
2 minutes	82.73 ± 5.5	83.26 ± 4.3	0.679
5 minutes	80.16 ± 2.3	81.79 ± 3.4	0.034
10 minutes	82.23 ± 5.7	80.76 ± 4.1	0.257
15 minutes	83.13 ± 5.0	79.15 ± 3.0	<0.001
20 minutes	84.23 ± 2.4	80.13 ± 3.2	<0.001
30 minutes	83.76 ± 4.3	80.10 ± 2.4	<0.001
60 minutes	84.37 ± 3.1	81.16 ± 2.41	<0.001
90 minutes	86.42 ± 3.7	83.93 ± 2.8	0.005
120 minutes	85.32 ± 4.3	88.37 ± 1.6	<0.001

(Table 3) shows the comparison of pulse rate in two groups of patients studied. There was a statistically significant change in the pulse rate between two groups during first 60 minutes.

Table 4: Comparison of systolic blood pressure

SBP (mmHg)	Group A	Group B	P-Valve
Before induction	130.86 ± 4.6	129.8 ± 8.6	0.555
After induction	126.60 ± 4.7	124.8 ± 4.6	0.139
2 minutes	118.30 ± 9.63	118.60 ± 4.3	0.877
5 minutes	116.00 ± 3.7	114.30 ± 2.1	0.034
10 minutes	118.85 ± 4.15	115.13 ± 3.8	<0.001
15 minutes	120.40 ± 2.3	118.00 ± 4.6	0.014
20 minutes	118.76 ± 3.4	114.32 ± 5.7	<0.001
30 minutes	120.23 ± 4.3	117.82 ± 3.2	0.017
60 minutes	123.43 ± 7.3	120.12 ± 3.7	0.032
90 minutes	125.40 ± 2.3	124.32 ± 3.8	0.189
120 minutes	128.30 ± 2.8	130.75 ± 3.2	0.003**

(Table 4) shows the comparison of mean SBP (mmHg) in two groups of patients studied. There was a statistically significant difference in systolic blood pressure at 10, 20 and 120 minutes between the groups.

Table 5: Comparison of diastolic blood pressure

DBP (mmHg)	Group A	Group B	P-Valve
Before induction	79.70 ± 10.83	80.90 ± 17.86	0.754
After induction	72.40 ± 8.00	68.70 ± 11.09	0.144

2 minutes	68.60 ± 9.40	70.10 ± 11.03	0.573
5 minutes	61.80 ± 12.66	73.10 ± 15.67	0.003**
10 minutes	63.80 ± 9.99	69.30 ± 12.08	0.060
15 minutes	67.20 ± 13.62	68.00 ± 12.48	0.813
20 minutes	63.40 ± 10.37	66.00 ± 10.46	0.338
30 minutes	64.70 ± 9.49	67.90 ± 11.39	0.242
60 minutes	59.75 ± 14.73	72.00 ± 8.60	0.110
90 minutes	69.00 ± 5.66	60.50 ± 12.02	0.461
120 minutes	67.67 ± 9.97	70.30 ± 14.02	0.647

(Table 5) shows the comparison of mean DBP (mmHg) in two groups of patients studied. There was a statistically significant difference in diastolic blood pressure at 10 minutes between the groups.

Table 6: Comparison of mean arterial pressure

MAP (mmHg)	Group A	Group B	P-Valve
Before induction	96.00 ± 9.14	95.10 ± 13.90	0.768
After induction	86.17 ± 9.38	86.71 ± 8.92	0.823
2 minutes	83.60 ± 10.35	84.20 ± 8.29	0.805
5 minutes	75.33 ± 13.53	73.27 ± 14.29	0.567
10 minutes	77.90 ± 10.07	80.50 ± 10.74	0.337
15 minutes	80.80 ± 16.13	79.20 ± 11.30	0.658
20 minutes	76.40 ± 12.38	79.30 ± 10.80	0.338
30 minutes	76.70 ± 8.62	80.20 ± 12.00	0.200
60 minutes	77.60 ± 8.99	84.88 ± 7.36	0.138
90 minutes	79.50 ± 12.02	78.00 ± 8.49	0.899
120 minutes	80.78 ± 9.38	79.20 ± 11.84	0.753

(Table 6) shows the comparison of MAP (mmHg) in two groups of patients studied. There is no statistically significant difference in mean arterial pressure between the groups.

Table 7: Comparison of Spo2%

Spo2%	Group A	Group B	P-Valve
Before induction	100.00 ± 0.00	100.00 ± 0.00	-
After induction	100.00 ± 0.00	100.00 ± 0.00	-
2 minutes	100.00 ± 0.00	100.00 ± 0.00	-
5 minutes	100.00 ± 0.00	100.00 ± 0.00	-
10 minutes	100.00 ± 0.00	100.00 ± 0.00	-
15 minutes	100.00 ± 0.00	100.00 ± 0.00	-
20 minutes	100.00 ± 0.00	100.00 ± 0.00	-
30 minutes	100.00 ± 0.00	100.00 ± 0.00	-
60 minutes	100.00 ± 0.00	100.00 ± 0.00	-
90 minutes	100.00 ± 0.00	100.00 ± 0.00	-
120 minutes	100.00 ± 0.00	100.00 ± 0.00	-

(Table 7) shows the mean Spo2% in two groups of patients studied. All the patients in both groups maintained 100% saturation.

DISCUSSION :

Levobupivacaine is a preferred local anaesthetic due to its more extended sensory block, lower cardiac and central nervous system toxicity[6]. Dexmedetomidine, the highly selective alpha2 agonist, when used as an adjuvant to local anaesthetics for neuraxial block, leads to 1. reduced onset time of sensory and motor block, 2. increased duration of sensory block, 3. delay motor regression, 4. Prolonged post-operative analgesia and reduced total dose of analgesic, 5. delayed need of first rescue analgesic, 6. decreased post-operative shivering[7].

There were few studies that compared isobaric levobupivacaine + dexmedetomidine with hyperbaric bupivacaine, we have compared and discussed our results with various studies.In our study, we compared sensory and motor characteristics between isobaric levobupivacaine with 5mcg dexmedetomidine and hyperbaric bupivacaine in patients undergoing elective lower limb surgeries. The demographic data in terms of age, height, weight, ASA status showed no statistical differences.

Lee YY et al,[8] concluded that 2.6ml of 0.5% levobupivacaine could be used as an alternative to 0.5% racemic bupivacaine in spinal anaesthesia for surgeries that requires a sensory block to at least T10.

Nayagam HA et al and Arati rai et al, concluded that dexmedetomidine in a dose of 5mcg is ideal for use as an additive in spinal anaesthesia.

In the present study the mean time taken for onset of sensory block at T10 was 2.83 ± 0.5minutes in Group A and 3.25 ± 0.4 in Group B. There was a statistically significant difference between two group (P<0.001). Similarly Esmaoglu et al,[9] had done a randomized controlled study comparing levobupivacaine (2.2 ± 0.7 minutes) and addition of dexmedetomidine to intra-thecal levobupivacaine (1.1 ± 0.3 minutes) and found that onset of sensory block was shorter in Group levobupivacaine with dexmedetomidine than in group levobupivacaine.

The mean time taken for onset of motor blockade was 3.20 ± 0.60 minutes in Group A and 4.00 ± 0.83 minutes in Group B, which shows statistically significant (P<0.001). Esmaoglu et al,[9] found statistically significant difference in the time taken for onset of motor blockade (bromage >0) was 3.5 ± 1.5 minutes in levobupivacaine group and 1.7 ± 0.6 minutes in levobupivacaine with dexmedetomidine group.

The mean duration of time at which rescue analgesia required in the present study was 230 ± 13.44 minutes in Group A and 169 ± 10.45 minutes in Group B, which shows statistically significant difference (P<0.001). Similarly in a study conducted by Gupta R et al,[10] the time for rescue analgesia in a control Group (Isobaric ropivacaine 0.75% 15mg) was 241.7 ± 21.67 minutes and in Group D it was 478.4 ± 20.9 minutes (Dexmedetomidine 5mcg added to 0.75% Isobaric ropivacaine).

CONCULSION:

We conclude that 0.5% isobaric levobupivacaine with 5mcg dexmedetomidine has an early-onset and prolonged duration of sensory and motor block and longer duration of post-operative analgesia than 0.5% hyperbaric bupivacaine, hence it is safer alternative for lower limb surgeries.

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