

# A Comparative Study on Intrathecal Hyperbaric and Hypobaric Bupivacaine in Unilateral Lower Limb Surgeries under Lumbar Sub-Arachnoid Block Held at Central Region of Kerala

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## ABSTRACT

### BACKGROUND

This study compared the characteristics of hyperbaric and hypobaric bupivacaine in patients undergoing unilateral lower limb surgeries under lumbar subarachnoid block with regard to their onset and level of sensory and motor blockades, haemodynamic stability, and recovery profile in terms of analgesic duration and motor recovery.

### METHODS

This is a comparative study. Two groups, each of 36 patients who satisfied American society of Anaesthesiologist (ASA) I & II aged 18 – 65 years, were observed intra operatively and during immediate post-operative period. Group 1 received 2.4 ml of 0.5 % bupivacaine (heavy) with operated limb in dependent position. Group 2 received 4 ml of reconstituted hypobaric bupivacaine 0.3 %, with the operated limb positioned in non-dependent position. Onset, level and duration of motor and sensory block, hemodynamic changes and duration of surgical analgesia were compared between groups.

### RESULTS

The level of sensory block attained in the hypobaric group was at T12 with maximum at T9, in the hyperbaric group it is variable and at higher level. Duration of sensory blockade was less with hypobaric. Motor block of modified Bromage scale 3 after 10 minutes was none in group 2 and 91.7 % in group 1. Significant fall in systolic blood pressure at 15 to 30 minutes and diastolic BP at 15 and 20 minutes was noted in hyperbaric group after subarachnoid block. There was significant percentage of change in systolic blood pressure from 4 to 70 minutes and mean arterial pressure (MAP) from 4 to 90 minutes in hyperbaric group. Duration of surgical analgesia in hypobaric group was longer compared to hyperbaric

### CONCLUSIONS

Intrathecal hypobaric bupivacaine showed better haemodynamic stability and longer duration of analgesia in comparison with hyperbaric bupivacaine in lower limb surgeries.

### KEYWORDS

Anaesthesia, Bupivacaine, Hypobaric, Subarachnoid Block

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## BACKGROUND

Many of the lower abdominal surgeries of short duration and most of the lower limb surgeries are often done under sub arachnoid block unless patients have co-morbid conditions which are contraindications for the procedure. Lumbar subarachnoid block (LSAB) is a simple, reliable and popular technique of anaesthesia. This form of neuraxial block gives adequate sensory and motor blockade and provides better haemodynamic control in most patients. Hyperbaric, hypobaric and isobaric preparations of local anaesthetics have been used for lumbar subarachnoid block. The common local anaesthetics used for central neuraxial blockade is lignocaine and bupivacaine. Lignocaine was synthesized by Nils Lofgren<sup>1</sup> and Lundqvist of Sweden in 1943 and used in clinical practice by Gordh<sup>2</sup> in 1948. The most common local anaesthetic preparation used for LSAB in our situation is hyperbaric bupivacaine which provides good motor and sensory blockade. Bupivacaine was synthesized by A F Ekenstam<sup>3</sup> and colleagues in 1957 and used for regional blocks in 1963 by Widman and L. J Telivuo.<sup>4</sup> The disadvantage of hyperbaric local anaesthetic preparation with respect to unilateral lower limb surgeries is that the drug needs to be administered with the affected side dependent, which may be painful and more difficult in patients with multiple fractures and elderly. Alexandre Faust<sup>5,6</sup> et al. in 2003 concluded that for total hip arthroplasty in lateral position, spinal hypobaric bupivacaine seems to be superior to isobaric bupivacaine in that it prolongs the sensory block on the operated side and delays the use of analgesics after surgery. So, if regional anaesthesia is chosen for surgical procedures involving hip or lower extremity, hypobaric spinal anaesthesia can be of help, since the patient need not lie on the painful site. The lower limb surgeries in elderly who are having co-morbidities is a challenge to anaesthesiologist because most of them experience detrimental alterations in haemodynamic intraoperatively. Hypobaric spinal anaesthesia is found to be better in terms of hemodynamic stability and greater post-operative analgesia and early recovery from motor blockade as well as return of bladder function. Multiple large series of spinal and epidural anaesthesia report that neurologic injury occurs in 0.03 to 0.1 % of all central neuraxial blocks.<sup>7</sup>

Transient neurologic symptoms (TNS) or transient radicular irritation (TRI) has also been emerged as a concern following neuraxial blockade. TRI is defined as pain, dysesthesia, or both, in the legs or buttocks after spinal anaesthesia. All local anaesthetics have been shown to cause TRI, although greater risk appears with lidocaine than with other local anaesthetics.<sup>8,9,10,11,12,13,14</sup>

Brown and Elman demonstrated that around 25 % of all surgical patients undergoing anaesthesia, regardless of the anaesthetic technique used, experience backache<sup>15</sup> and is more common after epidural than spinal.<sup>16</sup> Needle trauma, local anaesthetic irritation, and ligamentous strain secondary to muscle relaxation have all been proposed as possible explanations for backache. Caplan and associates identified 14 cases of sudden cardiac arrest in healthy patients after receiving spinal anaesthesia.<sup>17</sup> The cause is still poorly understood.

Veena R Shah et al. in 2008 compared the dose response characteristics of constant volume bupivacaine and found that small, diluted doses of bupivacaine for SAB can be used for ambulatory surgery.<sup>18</sup> Studies about wide usage of hypobaric are relatively few in literature even though it is practiced world over. The results of the study are promising even though done in a small sample and was not procedure specific.

The study aimed at comparing the characteristics of hyperbaric and hypobaric intrathecal bupivacaine in patients undergoing unilateral limb surgeries with regard to their onset and level of sensory and motor blockades, haemodynamic stability and recovery profile.

## METHODS

This prospective cohort study was conducted in a tertiary care hospital in central Kerala over a period of 1 year. After obtaining approval of Institutional Research and Ethical Committee, 72 patients aged 18 – 65 years, American Society of Anaesthesiologists physical status I & II (ASA PS I & II) of either sex, undergoing elective or emergency unilateral lower limb surgery under subarachnoid block were enrolled in this study. They were allocated in two groups of 36 patients each. A written informed consent in the local language was obtained from patient. Patients with known hypersensitivity to local anaesthetics and any other contraindications to spinal anaesthesia were excluded.

After pre anaesthetic check-up, thirty-six patients receiving preservative free hypobaric bupivacaine (Group 1) and thirty-six patients receiving hyperbaric bupivacaine (Group 2), were consecutively observed intra operatively and during immediate post-operative period extending up to three hours.

The preservative free hypobaric or hyperbaric bupivacaine solutions were prepared as follows.

**Hypobaric bupivacaine:** 3 mL of preservative free plain bupivacaine 0.5 % which is commercially available, diluted with 2 ml distilled water, to a total of 5 mL of which 4 ml (12 mg) is used for SAB; measured density was found to be 0.99751147 gml<sup>-1</sup> at 37° ± 5°C. Distilled water was taken from sterile distilled water ampoules with extreme aseptic precaution.

**Hyperbaric bupivacaine:** Spinal block with 12 mg (2.4 ml) of the commercially available hyperbaric 0.5 % bupivacaine (with 8 % dextrose in water) having a density of 1.02739384 g ml<sup>-1</sup> at 37° ± 5°C.

The densities of the study solutions were measured. The density, specific gravity and nativity were measured and calculated in a physical lab at National Institute of Technology, Kozhikode. Three measurements were done for each solution and the mean value considered.

The volume of drug given was 2.4 ml in patients receiving hyperbaric bupivacaine (Group 1) and 4 ml in patients receiving hypobaric bupivacaine (Group 2).

Monitors including non-invasive blood pressure, electrocardiogram and pulse-oximeter were attached, baseline readings were recorded and the monitoring continued throughout the intraoperative period. An

intravenous access secured in the non-dependent forearm and co-loading started with 500 ml of Lactated Ringer. 1 mg of midazolam was given intravenously as premedication. O<sub>2</sub> supplemented via face mask at 5 l/minute. Under aseptic precautions, lumbar subarachnoid block was performed at L3/4 or L4/5 interspace using 25 G Quincke needle with the patient in lateral position and the limb to be operated as nondependent in Group 2 and dependent in the Group 1. Once free flow of cerebrospinal fluid (CSF) was confirmed 15° Trendelenburg tilt was given and then 4 ml of hypobaric bupivacaine was injected slowly at approximately 0.1 ml/sec with the bevel of spinal needle pointing upward and caudad in group 2 and patients were kept in the same position (lateral decubitus with Trendelenburg) for 10 minutes before turning supine (if the surgery was planned in supine position). The lateral position was maintained if the surgery was planned in that position itself. If the block height ascended above T6, the Trendelenburg tilt was increased so as to restrict the level to T6. Otherwise, the initial degree of Trendelenburg tilt was continued for 20 minutes, after which the table was brought back to the horizontal position. Group 2 received 2.4 ml of hyperbaric bupivacaine in lateral decubitus position with the affected limb dependent.

Evolution of upper sensory block level on non-dependent side in case of hypobaric and dependent side in case of hyperbaric groups, noted every 5 minutes during first 20 minutes after LSAB. Maximal upper sensory block level and its onset time noted. Evaluation of degree of motor block using a modified Bromage scale every 5 minutes for 20 minutes. The surgery commenced once adequate level of block was achieved

Systolic blood pressure, diastolic blood pressure and heart rate were recorded every two minutes for the first 10 minutes, then every five minutes during surgery and every 15 minutes in the recovery room. Maximal decrease in these three parameters were recorded for the first one hour after LSAB.

The quality of block assessed according to the need for supplementary analgesia and in case of a failed spinal the subjects were given general anaesthesia and excluded from study. Haemodynamic status of the patient was maintained with IV crystalloids, medications which include vasopressors such as mephentermine in 3 mg increments if blood pressure falls > 20 % of baseline value and Inj. atropine IV 0.6 mg if heart rate decreased to < 50/minute.

After surgery, time to regression of sensory level to L2 was assessed every 15 minutes and, the degree of motor blockade was assessed every 15 minutes till Bromage score of 2 on both lower limbs. Duration of surgical analgesia is defined as the time between spinal injection and the first analgesic requirement for a pain score of > 3 on verbal numeric rating scale (ranging from 0 – 10 where 0 means no pain and 10 worst pain imaginable) at the operated site.

### Statistical Analysis

Data were entered in Microsoft Excel. Quantitative data was analysed using *t*-test and Mann-Whitney U test and qualitative data was analysed with chi square test. P value of < 0.05 was taken as significant.

## RESULTS

|                | Mean ± SD             |                        |
|----------------|-----------------------|------------------------|
|                | Hypobaric Bupivacaine | Hyperbaric Bupivacaine |
| Age            | 44.1 ± 14.2           | 39.5 ± 10.9            |
| Height (in cm) | 161.5 ± 8.1           | 164.2 ± 8.3            |
| Gender: male   | 24 (66.7 %)           | 19 (52.8 %)            |
| Female         | 12 (33.3 %)           | 17 (47.2 %)            |
| ASA PS: 1      | 29 (80.6 %)           | 28 (77.8 %)            |
| 2              | 7 (19.4 %)            | 8 (22.2 %)             |

**Table 1. Patients in the Two Groups Were Compared with Respect to Age, Sex, Height and ASA PS and Found no Significant Difference between the Groups**

|            |     | Hypobaric Bupivacaine |       | Hyperbaric Bupivacaine |      | Z#     | P     |
|------------|-----|-----------------------|-------|------------------------|------|--------|-------|
|            |     | Count                 | %     | Count                  | %    |        |       |
| 5 minutes  | T4  | 0                     | 0.0   | 1                      | 2.8  | 7.84** | 0.000 |
|            | T5  | 0                     | 0.0   | 1                      | 2.8  |        |       |
|            | T6  | 0                     | 0.0   | 8                      | 22.2 |        |       |
|            | T7  | 0                     | 0.0   | 11                     | 30.6 |        |       |
|            | T8  | 0                     | 0.0   | 10                     | 27.8 |        |       |
|            | T9  | 0                     | 0.0   | 4                      | 11.1 |        |       |
|            | T10 | 0                     | 0.0   | 1                      | 2.8  |        |       |
| 10 minutes | T12 | 36                    | 100.0 | 0                      | 0.0  | 7.52** | 0.000 |
|            | T4  | 0                     | 0.0   | 5                      | 13.9 |        |       |
|            | T5  | 0                     | 0.0   | 14                     | 38.9 |        |       |
|            | T6  | 0                     | 0.0   | 12                     | 33.3 |        |       |
|            | T7  | 0                     | 0.0   | 4                      | 11.1 |        |       |
|            | T8  | 0                     | 0.0   | 1                      | 2.8  |        |       |
|            | T10 | 25                    | 69.4  | 0                      | 0.0  |        |       |
| 15 minutes | T11 | 11                    | 30.6  | 0                      | 0.0  | 7.87** | 0.000 |
|            | T4  | 0                     | 0.0   | 6                      | 16.7 |        |       |
|            | T5  | 0                     | 0.0   | 16                     | 44.4 |        |       |
|            | T6  | 0                     | 0.0   | 11                     | 30.6 |        |       |
|            | T7  | 0                     | 0.0   | 3                      | 8.3  |        |       |
|            | T10 | 36                    | 100.0 | 0                      | 0.0  |        |       |
|            | T4  | 0                     | 0.0   | 6                      | 16.7 |        |       |
| 20 minutes | T5  | 0                     | 0.0   | 17                     | 47.2 | 7.56** | 0.000 |
|            | T6  | 0                     | 0.0   | 11                     | 30.6 |        |       |
|            | T7  | 0                     | 0.0   | 2                      | 5.6  |        |       |
|            | T9  | 10                    | 27.8  | 0                      | 0.0  |        |       |
|            | T10 | 26                    | 72.2  | 0                      | 0.0  |        |       |

**Table 2. Comparison of Sensory Blockade Level Based on Group**

# Mann-Whitney U Test \*\*: Significant at 0.01 level

| Group                  | Mean  | SD   | N  | t      | P     |
|------------------------|-------|------|----|--------|-------|
| Hypobaric Bupivacaine  | 144.3 | 13.7 | 36 | 9.83** | 0.000 |
| Hyperbaric Bupivacaine | 172.1 | 10.1 | 36 |        |       |

**Table 3. Comparison of Time Taken for Sensory Blockade Regression to L2 Based on Groups (Minutes)**

\*\*: Significant at 0.01 level

|            |   | Hypobaric Bupivacaine |       | Hyperbaric Bupivacaine |       | Z#     | P     |
|------------|---|-----------------------|-------|------------------------|-------|--------|-------|
|            |   | Count                 | %     | Count                  | %     |        |       |
| 5 minutes  | 1 | 36                    | 100.0 | 4                      | 11.1  | 7.39** | 0.000 |
|            | 2 | 0                     | 0.0   | 28                     | 77.8  |        |       |
|            | 3 | 0                     | 0.0   | 4                      | 11.1  |        |       |
| 10 minutes | 2 | 36                    | 100.0 | 3                      | 8.3   | 7.75** | 0.000 |
|            | 3 | 0                     | 0.0   | 33                     | 91.7  |        |       |
|            | 2 | 4                     | 11.1  | 0                      | 0.0   |        |       |
| 15 minutes | 3 | 32                    | 88.9  | 36                     | 100.0 | 2.04*  | 0.041 |
|            | 2 | 0                     | 0.0   | 0                      | 0.0   |        |       |
|            | 3 | 36                    | 100.0 | 36                     | 100.0 |        |       |
| 20 minutes | 2 | 0                     | 0.0   | 0                      | 0.0   | 0      | 1.000 |
|            | 3 | 36                    | 100.0 | 36                     | 100.0 |        |       |

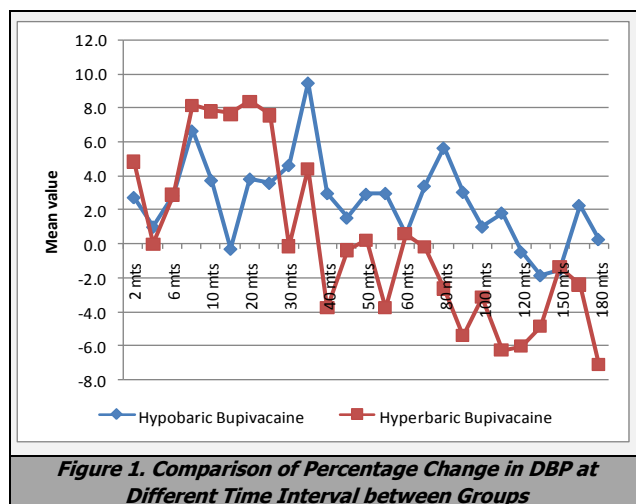
**Table 4. Comparison of Modified Bromage Scale Based on Group**

Whitney U Test. \*\*: Significant at 0.01 level, \*: Significant at 0.05 level

| Group                  | Mean  | SD   | N  | t      | P     |
|------------------------|-------|------|----|--------|-------|
| Hypobaric bupivacaine  | 317.1 | 29.2 | 36 | 6.69** | 0.000 |
| Hyperbaric bupivacaine | 257.5 | 44.7 | 36 |        |       |

**Table 5. Comparison of Duration of Surgical Analgesia Based on Group (Minutes)**

\*\*: Significant at 0.01 level



**Figure 1. Comparison of Percentage Change in DBP at Different Time Interval between Groups**

## DISCUSSION

Baricity of a local anaesthetic is an important factor in determining the block height because gravity causes hyperbaric solutions to flow downward in CSF to the most dependent regions of the spinal column, whereas hypobaric solutions tend to rise in CSF. This makes hypobaric solutions suitable for unilateral lower limb surgical procedures because the patient need not lie on the fractured extremity while being administered subarachnoid block. This study was an attempt to compare the differences in the characteristics of hypobaric and hyperbaric intrathecal bupivacaine in patients undergoing unilateral limb surgeries with regard to their onset and level of sensory and motor blockades, haemodynamic stability and recovery profile in terms of duration of surgical analgesia and motor recovery.

Rama Wason et al. in 2002 studied the effect of hyper, hypo and isobaric bupivacaine in patients undergoing knee arthroscopy in different volumes with same dose of the drug (6 mg) and found that the level of sensory analgesia, degree of motor block and duration of subarachnoid block were similar with low (1.2 ml hyperbaric) or high (3.4 ml hypobaric) volumes though the block was more unilateral with hypobaric or hyperbaric than isobaric solutions<sup>18</sup>

In our study, the sensory block attained at 5 minutes in the hypobaric group was T12 (100 %) but variable and at higher thoracic levels in the hyperbaric group (2.8 % at T4, 2.8 % at T5, 22.2 % at T6, 30.6 % at T7, 27.8 % at T8, 11.1 % at T9, 2.8 % at T10). The maximum sensory block height was T9 at 20 minutes with hypobaric and T4 at 5 minutes with hyperbaric. After 20 minutes of drug administration, 72.2 % of hypobaric group had upper level of sensory block at T10, whereas in 47.2 % of hyperbaric group it was at T5.

Time taken for sensory blockade regression to L2 after SAB was compared between the groups. Patients who received hypobaric bupivacaine had early regression of sensory block in this study. It was  $144.3 \pm 13.7$  minutes with hypobaric and  $172.1 \pm 10.1$  minutes with hyperbaric bupivacaine. The results showed statistically significant difference between two groups with a P value of 0.000.

Regarding motor blockade it was noted that achievement of motor blockade of modified Bromage scale 3 was delayed in hypobaric group in comparison with hyperbaric group. While 91.7 % of patients in group 1 achieved motor block after 10 minutes, it was none in group 2. (P value < 0.05). No difference in motor blockade was observed between the groups after 20 minutes (P value > 0.05). Regression of motor blockade to Bromage scale 2 was shorter in group 2 compared to group 1 ( $91.9 \pm 13.9$  vs  $158.2 \pm 31.3$  minutes respectively, P value < 0.05).

The difference in systolic blood pressure, diastolic blood pressure, mean arterial pressure and heart rate were monitored throughout the procedure and continued for 3 hours after subarachnoid block. Mean systolic blood pressure of  $117.9 \pm 17$ ,  $117 \pm 16.3$ ,  $117.8 \pm 16.4$ ,  $117.6 \pm 15.4$  mm of Hg was seen during 15, 20, 25, 30 and 35 minute intervals in hypobaric group while  $109.3 \pm 10.8$ ,  $104.8 \pm 11.9$ ,  $109.9 \pm 11.2$ ,  $109.6 \pm 11.8$ ,  $112.6 \pm 10.0$  observed in hyperbaric group (P value < 0.05). Mean diastolic blood pressure at 15 and 20 minutes of SAB, were  $71.9 \pm 14.5$  and  $70.3 \pm 13.4$  mm of Hg in hypobaric group and  $64.6 \pm 13.4$  and  $64.3 \pm 10.8$  mm of Hg in hyperbaric group (P value < 0.05), showing a significant decrease of diastolic BP in hyperbaric group.

The percentage of systolic and diastolic blood pressure variations between the groups were also analysed. Percentage of systolic blood pressure (fall from the mean value) were significant in hyperbaric group from 4 minutes to 70 minutes following sub arachnoid block (P value 0.000). Similarly, percentage change in mean arterial pressure from 4 minutes till 90 minutes of spinal anaesthesia was statistically significant (P value < 0.05) in the above group. This study could not find any difference in heart rate changes between the groups during anaesthesia.

Total duration of surgical analgesia was taken as the time between spinal injection and the first analgesic requirement for a pain score of > 3 on numerical rating scale (ranging from 0 – 10). The study compared the same between the groups and found prolonged duration of surgical analgesia in hypobaric group  $317.1 \pm 29.2$  minutes compared to  $257.5 \pm 44.7$  minutes in hyperbaric group which is statistically significant, with P value of 0.000. The prolonged duration is of advantage as it reduces the use of opioids and non-steroidal anti-inflammatory drugs (NSAIDs) in patients.

## CONCLUSIONS

Hypobaric bupivacaine gives the advantage of better positioning of a patient for performing lumbar subarachnoid block as the patient is not made to lie on the injured limb, but instead on the side of the healthy limb. The onset of sensory and motor blockade was found to be slow in the hypobaric bupivacaine group. The duration of sensory and motor blockade though found to be shorter in the hypobaric bupivacaine group, was adequate to cover the duration of surgery in all cases. Along with this, the statistically significant haemodynamic stability and longer duration of analgesia makes hypobaric bupivacaine a superior

alternative to hyperbaric bupivacaine for lumbar subarachnoid block in lower limb surgeries.

Data sharing statement provided by the authors is available with the full text of this article at jebmh.com.

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