## **Original Research Article**

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## Comparison between isobaric levobupivacaine 0.5% and hyperbaric bupivacaine 0.5% in spinal anesthesia in lower limb surgeries and lower abdominal surgeries in adult patients

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### ABSTRACT

**Background:** The aim of our study was to compare sensory and motor block characteristics and hemodynamic changes following intrathecal hyperbaric bupivacaine (0.5%) and isobaric levobupivacaine (0.5%) in elective lower limb and lower abdominal surgeries.

**Methods:** 60 patients of either sex, aged 18-60 years, ASA grade I or II scheduled for elective lower abdominal and lower limb surgeries were randomized into two groups, group B (n=30) and group L (n=30) and received either 3 ml of intrathecal hyperbaric bupivacaine or isobaric levobupivacaine intrathecally.

**Results:** The mean time of onset of sensory block at shin of tibia in both the groups was comparable i.e. levobupivacaine  $(1.19\pm0.2 \text{ minutes})$  and bupivacaine (1.1+0.2 minutes). The mean time for total duration of sensory block was  $211.1\pm8.2$  minutes in group L, while  $193.13\pm13.7$  minutes in group B. Time for total duration of motor block in group L was  $198.76\pm8.428$  minutes and in group B was  $182.6\pm13.989$  minutes. Statistically significant difference was observed in total duration of sensory and motor block in both levobupivaciane and bupivacaine group (p<0.0001). Patients in group L were hemodynamically more stable with significantly less decrease in pulse rate, systolic blood pressure and diastolic blood pressure as compared to group B.

**Conclusions:** We observed that 0.5% isobaric levobupivacaine provided better hemodynamic stability, longer duration of sensory and motor block as compared to bupivacaine.

Keywords: Anesthesia, Bupivacaine, Levobupivicaine, Spinal

### **INTRODUCTION**

Regional anesthesia is preferred mode for lower limb and lower abdominal surgeries as it offers benefits like lessor blood loss, reduced incidence of venous thromboembolism, metabolic stress response to surgery, pulmonary compromise.<sup>1</sup> Autonomic, sensory and motor nerve fibers are blocked by spinal anesthesia.<sup>2</sup> Bupivacaine is long acting local anesthetic with a low therapeutic index due to cardiovascular toxicity.<sup>3</sup> But its S(-) enantiomer, 'levobupivacaine' has less of negative inotropism and decreased affinity for cardiac sodium channels, offering an improved safety profile.<sup>4</sup> The spread of isobaric solution in cerebrospinal fluid does not depend upon the patient's position during and after the injection. Thus, intrathecal isobaric levobupivacaine does not spread unexpectedly high, and levels of sensory block after spinal isobaric levobupivacaine are unaffected by the change in patient position following the injection.<sup>5</sup> Hyperbaric solutions may cause sudden cardiac arrest after spinal anesthesia because of the extension of the sympathetic block.<sup>6,7</sup> Isobaric solutions are favoured due to their less sensitive to position issue properties The purpose of this study was to compare sensory and motor

block characteristics, intraoperative hemodynamic changes following intrathecal hyperbaric bupivacaine (0.5%) or isobaric levobupivacaine (0.5%) in elective lower abdominal and lower limb surgeries.

### **METHODS**

After approval from institutional ethical committee, 60 patients of either sex belonging to ASA grade I or II. aged 18 to 60 years weighing 50-90 kg undergoing elective lower abdominal and lower limb surgeries were included. This prospective, randomized controlled study was conducted in M. P. Shah medical college, Jamnagar Gujarat over a period of one years (December 2015-December 2016) and patients were divided into two different groups namely, group B (n=30) and group L (n=30) who either received 3 ml of intrathecal hyperbaric bupivacaine or intrathecal isobaric levobupivacaine. Patients having active skin diseases over spine region or injuries of spine, convulsions, hydrocephalus, coagulation disorders, having significant neurological disease with deficit motor or sensory and those having drugs, refusal, hypersensitivity to pregnant or uncooperative patients were excluded. Preanaesthetic checkup was done and the procedure of sub-arachnoid block was explained to the patient and written informed consent was obtained. In the operation theatre, 18 G intravenous cannula was secured and Ringer's Lactate (500 ml) started. All standard ASA monitors were attached and baseline heart rate (HR), systolic, diastolic blood pressure (SBP and DBP) and mean arterial pressure (MAP) were recorded. Patients were premedicated with glycopyrrolate 0.2 mg intravenous (i.v.) slowly, midazolam 1 mg i.v. slowly, ondansetron 4 mg i.v. slowly before procedure. Under strict aseptic precautions, lumbar puncture was performed with 25 gauge quinckes spinal needle at L<sub>3</sub>-L<sub>4</sub> intervertebral space using midline approach with patient in sitting position. Patients were positioned supine immediately after the administration of either intrathecal agent. Patients were randomly divided into two groups using computerized random table before starting of procedure and the selected drug was blinded to the anesthesiologist performing the procedure and taking recordings of the same to reduce bias. Onset of sensory block was taken as time interval from complete injection of local anesthetic agent to the achievement of complete loss of sensation at shin of tibia. Time taken to achieve complete sensory blockage at L<sub>1</sub> and T<sub>10</sub> was also noted. Time to achieve maximum sensory level was noted using 25 gauge hypodermic needle by pin prick method as 0 having no sensation, 1 as sense of dull pressure and 2 as sharp pain. The motor block was assessed using modified bromage scale- 0 (no paralysis), I (inability to raise extended legs), II (inability to flex the knee) III (inability to flex ankle) and the onset time was recorded as the time from injection and achieving modified bromage scale I. Complete motor block was evaluated as time taken to achieve modified bromage scale III. Total duration of block was evaluated from onset to complete recovery of motor block.

Hemodynamic parameters (HR, SBP, DBP, MAP) and oxygen saturation were recorded immediately after injection (0 minute) and then at 1, 2, 5, 10, 15, 30, 60, 90, 120, 150 and 180 minutes after injection of anesthetic agent. During the procedure all the patients were infused with appropriate quantity of intravenous fluid guided by these hemodymanic parameters. Patients were considered hypotensive when MAP decreased to less than 25% from baseline and were treated with ephedrine 6 mg intravenously, dose titrated according to response. If HR decreased to less than 60 beats per minutes, atropine 0.02 mg/kg was given intravenously. Complications such as nausea, vomiting, bradycardia, hypotension, shivering, headache was noted and treated appropriately. All patients were shifted to recovery room at the end of surgery and monitored.

Statistical analysis was done using statistical package for social sciences (SPSS 16). Qualitative data was analysed using chi square test and quantitative data using unpaired t-test. P value <0.05 was considered statistical significant. Sample size was calculated as 30 per group to detect 10% difference in hemodynamic parameters.

### RESULTS

The demographic profile for both the groups was comparable in terms of age, weight and male/female ratio (Table 1). Mean time of onset of sensory block at shin of tibia in group L (isobaric levobupiviacaine) was 1.19±0.2 minutes, in group B (hyperbaric bupivacaine) was 1.1+0.2 minutes which was comparable. The mean time of sensory block at L<sub>1</sub> level in group L was 7.83±0.7 minutes and in group B was 3.07±0.4 minutes. Thus sensory block at L<sub>1</sub> level was achieved earlier in group B and was statistically significant (p<0.001). Similarly, mean time for sensory block to reach T<sub>10</sub> level was 12.68±0.6 minutes in group L and 7.22±0.7 minutes in group B, this difference was also statistically significant. The total duration of sensory block was significantly longer (211.1±8.2 minutes) in group L as compared to group B (193.13±13.7 minutes) p<0.001 (Table 2).

# Table 1: Mean demographic data in group Land group B.

Particulars	Group L	Group B	P value
	Mean±SD	Mean±SD	
Age (years)	34.4±8.9	37.4±9.8	p>0.05
Weight (kg)	61.1±7.0	$64.8 \pm 7.8$	p>0.05
Gender male/female	24/6	25/5	p>0.05

Time of onset of motor blockade (Modified Bromage Scale- I) was statistically significant and earlier in group B ( $4.56\pm0.6$  minutes) as compared to group L ( $8.6\pm0.9$  minutes) in group B. But, time for complete motor blockade (Modified Bromage scale III) was longer in group L ( $15.91\pm0.7$  minutes) as compared to group B ( $11.72\pm0.8$  minutes) and this difference was significant (p<0.001). Time for total duration of motor block in

group L was 198.76±8.428 minutes (longer) and in group B was 182.6±13.989 minutes which was highly significant (Table 2).

### Table 2: Comparison of sensory and motor blockade.

Particulars	Group L Mean±SD	Group B Mean±SD	P value
Onset of sensory block at shin of tibia (min)	1.19±0.2	1.10±0.2	0.137
Sensory block at L1 level achieved (min)	7.83±0.7	3.07±0.4	< 0.001
Sensory block at T10 level achieved (min)	12.68±0.6	7.22±0.7	<0.001
Maximum sensory level achieved (min)	23.03±0.7	19.54±1.1	< 0.001
Total duration of sensory block (min)	211.10±8.2	193.13±13.7	< 0.001
Onset of motor blockade by Modified Bromage Scale- 1(min)	8.60±0.9	4.56±0.6	<0.001
Complete motor blockade achieved by Modified Bromage Scale-3 (min)	15.91±0.7	11.72±0.8	<0.001
Total duration of motor block (min)	198.76±8.4	182.6±13.9	< 0.001

### Table 3: Comparison of pulse rate.

Pulse rate per	Group L	Group B	P value
minute	Mean±SD	Mean±SD	
Before premedication	87.9±5.7	86.3±4.6	>0.05
<b>Before induction</b>	93.3±5.7	$92.2 \pm 4.8$	>0.05
After induction (0 min)	93.1±5.6	92.26±4.8	>0.05
1 min	91.53±5.3	90.133±4.9	>0.05
2 min	89.73±5.3	86.63±5.0	>0.05
5 min	88±5.5	$80.96 \pm 5.1$	< 0.001
10 min	86±5.7	$76.06 \pm 5.3$	< 0.001
15 min	84.56±5.8	71.7±4.8	< 0.001
30 min	83.13±6.0	$67.76 \pm 4.1$	< 0.001
60 min	82.23±5.7	66.1±4.1	< 0.001
90 min	81.52±6.0	$65.25 \pm 4.0$	< 0.001
120 min	$82.66 \pm 5.4$	65.71±2.4	< 0.001
150 min	81.12±6.1	65.5±1.6	< 0.001
180 min	80.5±6.2	66±1.6	< 0.001

Gradual decrease in HR from basal value till the end of surgery was observed in both the groups but in group L, decrease was from  $87.9\pm5.7$  to  $80.5\pm6.2$  beats per minute while in group B, from  $86.3\pm4.6$  to  $66\pm1.6$  beats per minute. This decrease was statistically significant after 5

min of injection of drug up to completion of surgery with lessor decrease in heart rate in group L as compared to group B (Table 3).

### Table 4: Comparison of systolic blood pressure.

Systolic blood	Group L	Group B	P value
pressure (mmHg)	Mean±SD	Mean±SD	
Before premedication	124.86±4.6	123.8±4.6	>0.05
<b>Before induction</b>	$124.86 \pm 4.6$	123.8±4.6	>0.05
After induction 0 min	124.6±4.5	123.73±4.5	>0.05
1 min	123±4.7	122.73±4.6	>0.05
2 min	121.4±4.6	120.33±4.3	>0.05
5 min	$120.53\pm5.1$	$117.06 \pm 4.7$	< 0.05
10 min	$119.06 \pm 5.0$	113.6±4.6	< 0.001
15 min	118.2±5.1	111.4±4.3	< 0.001
30 min	117.46±5.7	$109.06 \pm 3.5$	< 0.001
60 min	$116.46\pm5.4$	$108.46 \pm 3.4$	< 0.001
90 min	$116.69 \pm 5.2$	$108.4 \pm 2.1$	< 0.001
120 min	119.11±3.8	109.71±2.7	< 0.001
150 min	$118.75 \pm 3.5$	110.5±3.5	< 0.05
180 min	118±4.6	$108.66 \pm 1.8$	< 0.05

#### Table 5: Comparison of diastolic blood pressure.

Diastolic blood	Group L	Group B	P value
pressure (mmHg)	Mean±SD	Mean±SD	
Before premedication	78.06±4.2	79.6±4.0	>0.05
<b>Before induction</b>	$78.06 \pm 4.2$	79.6±4.0	>0.05
After induction 0 min	78.0±4.2	79.6±4.1	>0.05
1 min	76.73±3.9	78.66±3.9	>0.05
2 min	74.86±3.6	76.33±3.6	>0.05
5 min	74±3.1	72.73±3.2	>0.05
10 min	72±3.0	69.86±2.3	< 0.05
15 min	70.86±3.0	68.2±2.2	< 0.001
30 min	70.53±2.7	66.53±2.2	< 0.001
60 min	$70.2 \pm 2.5$	65.93±2.4	< 0.001
90 min	$70.08 \pm 2.1$	66.2±1.5	< 0.001
120 min	70±1.3	67.14±0.9	< 0.001
150 min	70±1.4	66.5±0.8	< 0.05
180 min	69.5±1.6	68±1.6	>0.05

Fall in mean SBP was observed in both the groups ( $124.86\pm4.6$  mmHg to  $118\pm4.6$  mmHg in group L and  $123.8\pm4.6$  mmHg to  $108.66\pm1.8$  mmHg in group B). This was statistically significant after 5 minutes, 10 minutes till 120 minutes after injection of drug with lessor fall observed in group L than group B (Table 4).

We observed fall in mean DBP from baseline  $78.06\pm4.6$  mmHg to  $69.5\pm1.6$  mmHg in group L and  $79.6\pm4.0$  mmHg to  $68\pm1.6$  mmHg in group B. It was statistically significant after 10 minutes, 15 minutes till 120 minutes,

150 minutes and insignificant at end of surgery. Also, less decrease in DBP was noted in group L than group B (Table 5).

There was fall in MAP from baseline  $93.6\pm3.7$  mmHg to  $85.6\pm2.4$  mmHg in group L and  $94.3\pm3.7$  mmHg to  $81.5\pm1.6$ mmHg in group B. Though there was fall in mean arterial pressure, it was statistically significant after 5 minutes till the end of surgery (Table 6).

Mean arterial	Group L	Group B	P value
pressure (mmHg)	Mean±SD	Mean±SD	
Before premedication	93.67±3.7	94.33±3.7	>0.05
<b>Before induction</b>	93.67±3.7	94.33±3.7	>0.05
After induction 0 min	93.53±3.5	94.31±3.7	>0.05
1 min	92.15±3.6	93.35±3.6	>0.05
2 min	90.37±3.4	91.0±3.4	>0.05
5 min	89.51±3.2	87.51±3.1	< 0.05
10 min	87.68±3.1	$84.49 \pm 2.6$	< 0.001
15 min	$86.64 \pm 3.2$	$82.6 \pm 2.5$	< 0.001
30 min	86.17±3.2	80.71±2.3	< 0.001
60 min	85.62±3.1	$80.11 \pm 2.4$	< 0.001
90 min	$85.60 \pm 2.8$	$80.28 \pm 1.4$	< 0.001
120 min	86.37±1.6	81.33±1.3	< 0.001
150 min	86.25±1.9	81.16±1.2	< 0.001
180 min	85.67±2.4	81.56±1.6	>0.05

### DISCUSSION

Our study was conducted to compare isobaric levobupivicaine and hyperbaric bupivacaine for spinal anesthesia in elective lower abdominal and lower limb surgeries. We found that isobaric levobupivicaine provides longer duration of sensory block, motor block and more hemodynamic stability as compared to hyperbaric bupivacaine. The mean time of onset of sensory blockade to reach shin of tibia,  $L_1$  and  $T_{10}$  level using both the local anesthetics was comparable and similar observations were made by other investigators.<sup>8,9</sup>

Similar study in which patients received either 13.5 mg hyperbaric bupivacaine or 13.5 mg isobaric levobupivacaine for transurethral endoscopic surgery, found that the speed of onset and offset of motor and sensory blockade were significantly quicker with hyperbaric bupivacaine.<sup>10</sup> Also another study concluded that hyperbaric Bupivacaine produces an earlier onset of clinically significant sensory and motor block as compared to isobaric levobupivacaine or isobaric ropivacaine.<sup>11</sup> In our study, we found that onset rate (at shin of tibia) was earlier with hyperbaric bupivacaine  $(1.10\pm0.2)$ minutes) as compared to isobaric levobupivicaine (1.19±0.2 minutes) but was not statistically significant.

In our study, we observed that hemodynamic parameters such as HR, SBP, DBP and MAP decreased after intrathecal administration of anesthetic agents in both the groups. But this decrease was significantly more with hyperbaric bupivacaine. In contrast to our study other author found statistically significant hypotension. More cephalic spread of the block and rapid increase in block level explains the higher incidence of significant hypotension with hyperbaric bupivacaine but they have used higher dose of drug (3.25 ml each).<sup>8</sup> Other studies show no difference between SBP of patients receiving these two agents but they used agents with comparable baricity i.e. both drugs were either isobaric or hyperbaric.<sup>12,13</sup>

None of the patients from either groups developed respiratory difficulty or fall in SPO<sub>2</sub> below 90% throughout the surgery. There was no incidence of headache, nausea, vomiting, hypotension, bradycardia, chest pain, coughing, convulsions and respiratory depression, and procedure related complications in either groups in our study.

### CONCLUSION

Intrathecal administration of either hyperbaric Bupivacaine or isobaric levobupivacaine were well tolerated and provide comparable anesthesia for lower abdomen and lower limb surgeries. Longer duration of sensory and motor blockade by isobaric levobupivacaine can be advantageous for surgeries of longer duration. The rapid onset of sensory and motor blockade by hyperbaric bupivacaine can be used for rapid effect necessary in emergency surgeries.

We concluded that 3 ml of 0.5% isobaric levobupivacaine can be used as a safer alternative to 3 ml 0.5% hyperbaric Bupivacaine in spinal anesthesia for lower abdomen and lower limb surgeries.

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