Research Article

Comparison of Efficacy and Hemodynamic Stability of 0.5 % Isobaric Levobupivacaine and 0.5% Hyperbaric Bupivacaine in Old Age Patients Posted For Lower Limb Surgery under Spinal Anaesthesia

Neepa Patel¹, Bhumika J Chaudhari², Pratik D Patel³, Malti Pandya⁴

¹Associate Professor, Department of anaesthesiology, SMIMER, Surat, India.

²Post graduate Student, Department of Anaesthesiology, SMIMER, Surat, India.

³Associate Professor, Namo Medical & Education College, Silvassa, India.

⁴Professor and HOD, Department of anaesthesiology, SMIMER medical college, Surat, India.

Corresponding Author: Dr Neepa Patel, Associate Professor, dept of anaesthesiology, SMIMER Medical college and Hospital, opposite Sahara Darvaja Surat-395010., India.

Email: drnpatelmd@gmail.com

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ABSTRACT

Background: Spinal anaesthesia, first introduced by August Bier in 1898, has evolved significantly with the introduction of bupivacaine and levobupivacaine. Bupivacaine is the most commonly used local anesthetic, while levobupivacaine and bupivacaine are equivalent but levobupivacaine have fewer cardiac side effects. Isobaric levobupivacaine is less toxicity and is used in various Anesthetic procedures. Geriatric patients are more susceptible to haemodynamic fluctuations due to changes in vertebrae structure, decreased cerebrospinal fluid volume, and nerve degeneration. This study aims to compare the safety profiles of hyperbaric bupiyacaine and isobaric levobupiyacaine in elderly patients during spinal anaesthesia for lower limb surgery. Materials and methods- The study was conducted at a tertiary health care center over a period of one year and six months, with 110 patients above 60 years of age, either sex, ASA grade III & IV, posted for lower limb surgeries. The total sample size was figured as 110 based on a previous study by Herrera R et $al.^{5}$ The study involved preanaesthetic evaluation, laboratory investigations, and informed consent from all study subjects. The patients were divided into two groups: Group B received a 0.5% 3 ml hyperbaric injection of bupivacaine intrathecally, and Group L received a 0.5% 3 ml isobaric injection of Levobupivacaine intrathecally. The patients were monitored using standard monitors such as pulse oximeter for saturation (SpO2), noninvasive blood pressure monitoring (NIBP), and electrocardiogram (ECG). Sensory and motor assessments were performed immediately after positioning supine and recorded as 0 minutes. The study also assessed the duration of motor blockade, Bradycardia, and hypotension. Postoperatively, hemodynamic parameters, duration of analgesia, and total duration of sensory and motor block were assessed every 2 hourly for 6 hours & 4 hourly till 24 hours. Result- The study compared the heart rate and blood pressure of two groups after spinal anesthesia. Both groups had similar baseline heart rates, but after spinal anesthesia, there was a significant difference in heart rate. Group B had greater pulse rate variability, indicating a statistically significant difference. Systolic blood pressure was comparable in both groups, but the decrease was greater in group B compared to group A. Mean arterial blood pressure was comparable in both groups, but Group B experienced a greater decrease. The onset time of sensory block at T10 level was comparable between groups, but the maximum sensory block level was different. The duration of sensory block was longer in Group B, while the total duration of analgesia was longer in Group B. Group B had greater pulse rate variability, but no significant difference in mean arterial pressure.

Conclusion- The study concluded that 0.5% isobaric levobupivacaine is more effective than 0.5% hyperbaric bupivacaine in elderly patients undergoing lower limb surgery due to its superior hemodynamic stability.

Keywords- isobaric levobupivacaine, intrathecal, old age, Hemodynamic stability, Bupivacaine, spinal anaesthesia, lower limb surgery

INTRODUCTION

The technique of spinal anaesthesia, which was first introduced by August Bier in 1898, has

made significant advances, particularly with the introduction of bupivacaine and

levobupivacaine. Bupivacaine, а local anaesthetic, has emerged as the most frequently used drug for spinal anaesthesia.^{7,8,5} The two isomers, levobupivacaine (S (-) isomer) and dextrobupivacaine (R (+) isomer), are equivalently effective local anaesthetics.⁴ However, the S isomer has a lower affinity for cardiac sodium channels, which results in fewer cardiac side effects.⁴ Isobaric levobupivacaine, a local anaesthetic that is distinguished by its less cardiovascular and neurological toxicity, has been used in spinal aesthesia, epidural anaesthesia, brachial plexus blocks, labour analgesia, postoperative pain therapy, and local infiltration.²¹ Geriatric patients with comorbidities who undergo major surgery under central neuraxial block are more susceptible to haemodynamic fluctuations as a result of changes in the anatomical structure of lumbar and thoracic vertebrae. decrease in cerebrospinal fluid volume and peripheral and central nerve degeneration.³ Hypotension and bradycardia are the consequences of sympathetic and motor blockade caused by subarachnoid block in elderly individuals. There is a scarcity of research that compares the safety profiles of hyperbaric bupivacaine and isobaric levobupivacaine in elderly populations.⁴ The objective of this study is to assess the sensory and motor blockade characteristics, as well as the haemodynamic characteristics, of equivalent dosages of hyperbaric bupivacaine and isobaric levobupivacaine during spinal anaesthesia for lower limb surgery in elderly patients.

AIM & OBJECTIVES

Aim was compare hemodynamic stability and efficacy using 0.5% isobaric levobupivacaine with 0.5% hyperbaric bupivacaine in lower limb surgery under spinal anaesthesia in old aged patients The primary objective was to compare hemodynamic profile between two groups. The secondary objective was to compare sensory and motor characteristics of two drugs

MATERIALS AND METHODS

After approval of the Institutional ethical committee the study was conducted at a tertiary health care center over a period of one year and six months, including one year for data collection and six months for data entry, analysis, and report preparation. The study design was a prospective observational study, with 110 patients above 60 years of age, either sex, ASA grade III & IV, posted for lower limb surgeries.

Sample size was enumerated using open EPI software (version 3.01). The total sample size was figured as 110 based on a previous study by **Herrera R et al.**⁵ Patients were divided into two groups: Group B and Group L by simple random sampling. patient Inclusion criteria included age >60 years, both sexes, ASA III & ASA IV, and posted for lower limb surgery.

Exclusion criteria included patient refusal, ASA I & ASA II, deformity in spine, patients with history of bleeding disorder or anticoagulant therapy, known hypersensitivity to amide local anaesthetics, pregnancy, operated case of spine surgery, psychiatric illness, BMI > 35, and spinal anaesthesia converted to general anaesthesia.

Pre-anaesthetic evaluation included a detailed history with emphasis on co-morbidities, previous medications, and surgeries. Laboratory investigations included routine haemogram, coagulation profile, renal function test & liver function test, random blood sugar, electro cardiogram, chest X-ray and investigations related to co-morbid conditions were carried out in all the patients.

Simple random sampling was used for randomization and group allocation, with each patient being assigned a number. Patients with odd numbers were assigned to group B, whereas patients with even numbers were assigned to group L. Informed consent was obtained from obtained from all the study subjects before the start of the study. Also patient were briefed about the technique of spinal anaesthesia and methods of sensory and motor assessments.

Patients were placed into two groups: Group B received (3 ml=15 mg) 0.5% hyperbaric injection of bupivacaine Intrathecally; Group L received (3 ml=15 mg) 0.5% Isobaric injection of Levobupivacaine Intrathecally.

Patients were shifted to OT and monitored using standard monitors such as pulse oximeter for saturation (SpO2), non invasive blood pressure monitoring (NIBP), and electrocardiogram (ECG). Spinal anesthesia was performed using a 25 gauge Quincke needle with a midline approach at L3-4 (determined by palpation of the bony landmarks). The surgical procedure was started 15min after initiation of the spinal injection, After spinal injection, the patients were turned

into a supine position with a pillow under their Head. Sensory and motor assessment was performed immediately after positioning supine and recorded as 0 minutes. Sensory level blockage was measured by pin prick in the midclavicular line on both sides with a blunt 24G needle every minute until no pain to pin prick was felt at T10 dermatome. Quality of motor blockade in the lower limb was graded using the modified Bromage scale. [1. Complete motor block (unable to move feet or knees), 2.Almost complete motor block (able to move feet only), 3. Partial block (just able to move knees), 4. Detectable weakness of hip flexion, 5. No detectable weakness of hip flexion while supine (full flexion of knees), 6. Able to perform partial knee bend] Surgical incision commenced when sensory level was at or above T10 dermatome. Onset of sensory blockade was defined as the time from the completion of the injection of study drug to the time when the patient did not feel the pin prick at T10 level. Time taken for maximum sensory blockade was defined as the time taken from the completion of the injection of study drug to the maximum sensory blockade attained. Maximum sensory block level achieved was defined as the level achieved after 20 min of completion of injection of local anaesthetic solution. Two segment regression time was defined as the time taken from injection of the first dose of local anaesthetic till the time when the maximum sensory level has receded by two segments

Onset of motor block defined as the time from spinal injection until Bromage score 2 was registered. Duration of motor blockade taken as the time from onset of motor block till the patient attained slight motor recovery to Bromage score 5 was noted.

Quality of motor blockade in the lower limb was graded using the modified Bromage scale. Duration of motor blockade was taken as the time from onset of motor block till the patient attained slight motor recovery to Bromage.

Bradycardia-pulse rate less than 60beats/min or if hemodyanamically unstable was treated with Inj. glycopyrolate 0.2mg IV. Hypotensiondecrease in systolic blood pressure less than 100 mmHg or less than 20% from baseline was treated with incremental boluses of Inj. ephedrine 6 mg IV. Supplementary oxygen through a face mask was administered during the surgical procedure. The duration of surgery in each case was noted. Postoperatively hemodynamic parameters, duration of analgesia and total duration of sensory and motor block assessed every 2 hourly for 6 hours & 4 hourly till 24 hours. In this study, the data were either quantitative data or qualitative data. For quantitative data descriptive statistics was presented by Mean and Standard Deviation. To analyze the data appropriate statistical tests were applied. For the comparison of the two groups, Independent Samples t-Test was used. For qualitative data, frequency count (N) and percentage were displayed in a tabular manner and assessed with chi-square test. For statistical analysis IBM SPSS (version 25) software and open EPI (3.01) was used.

RESULT

The demographic details of the patients were tabulated in table 1. The study compared the mean age, gender, height, and weight of 110 patients between two groups. The mean age in Group L was 70.5±9 years, while in Group M it was 67±8 years. There was no significant difference in age distribution between the two groups. In Group L, there were 54.5% males and 45.4% females, while in Group B, there were 54.5% males and 45.4% females. The mean height was 169±8.58 cm in Group L and 170±8.63 cm in Group B. The mean weight was 66±10 kg in Group L and 70±11.1 kg in Group B. there was no significant difference in gender, height and weight distribution between the two groups.

The mean duration of surgery in Group L was 109±26 minutes, while in Group B it was 109±28 minutes, with no statistically significant difference.

The graph 1 compares intraoperative heart rate between group L and group B. Both groups had similar baseline heart rate at various intervals throughout the surgery. However, after spinal anesthesia, there was a significant difference in heart rate after 10 minutes, 15 minutes, 20 minutes, 25 minutes, and 30 minutes. Group B had greater pulse rate variability from 10 minutes to 30 minutes, and this difference was statistically significant. None of the patients in either group required pharmacological intervention. The study highlights the importance of understanding the differences between heart rate and pulse rate variability during surgery.

Systolic blood pressure was comparable in both groups at the time of spinal anaesthesia, after,

every 5 minutes, every 30 minutes, and every 15 minutes up to the end of surgery. However, the decrease in systolic blood pressure was greater in group B compared to group A, with a statistically significant difference observed immediately after spinal anaesthesia, every 5 minutes, every 10 minutes, every 15 minutes, every 20 minutes, and at 60 minutes to 75 minutes. The mean diastolic blood pressure was also greater in group B compared to group L, with a statistically significant difference observed after spinal anaesthesia, every 5 minutes, every 10 minutes, every 15 minutes, every 20 minutes, and at 60 minutes to 75 minutes, every 10 minutes, every 15 minutes, every 20 minutes, and at 60 minutes to 75 minutes.

Graph 2 compares intraoperative mean arterial blood pressure between groups L and B at different intervals. Both groups showed comparable mean arterial blood pressure after SA. However, Group B experienced a greater decrease in mean arterial blood pressure compared to Group L, with a statistically significant difference (P<0.05). Similarly, oxygen saturation was comparable between Groups L and B at different intervals, but the difference was not statistically significant (P >0.05).

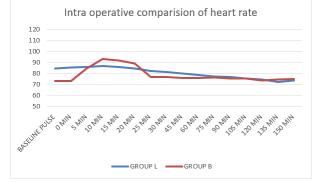
As shown in table 2 the study compared the onset time of sensory block at T10 level between two groups, Group B and Group L. The onset time was 4.9 ± 0.7 minutes in Group B and 7 ± 1 minutes in Group L. There was no statistically significant difference in the onset time of sensory block at T10 level between the two groups. The maximum sensory block level

was comparable between the two groups, with Group B having a maximum of T6 (58.2%) and Group L having a maximum of T8 (63.6%). It shows statistically significant difference between two groups. (P value 0.0001). The mean duration of time to achieve maximum sensory level was comparable between the two groups, with Group L having a mean duration of 9±1.3 minutes compared to Group B. The time for two segment regression was also comparable between the two groups. The mean duration of sensory block was longer in Group B (273±37 min) compared to Group L (249±39 min), which was statistically not significant. The total duration of analgesia was longer in Group B (288±37 minutes) compared to Group L (265±36 minutes). The difference was statistically significant with a p value of 0.000. The mean time of onset of motor blockade was longer in Group B $(6.04\pm0.7 \text{ minutes})$ compared to Group L (7.9±0.8 minutes). The mean duration of motor blockade was 284±37 min in Group B compared to Group L (276±38) minutes). the mean time of onset of motor blockade and duration of motor blockade were statistically insignificant.

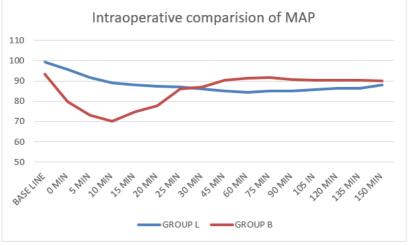
Group L and group B had comparable heart rates up to 24 hours post-surgery. However, Group B had greater pulse rate variability compared to Group L, indicating a statistically significant difference. Mean arterial pressure showed no significant difference. Oxygen saturation was not statistically significant between Group B and Group L during the postoperative period for 24 hours.

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	GROUP L		GROUP B		P VALUE
	MEAN	SD	MEAN	SD	
AGE (years)	70.56	9.62	66.92	8.75	0.0604
HEIGHT (cm)	169	8.58	170.01	8.63	0.605183
WEIGHT (kg)	66	10.00	70	11.12	0.049

Table 1: Demographic details of patients



Graph 1. Intra operative comparision of heart rate between two groups



Graph 2. Intra operative comparision of MAP between two groups

Table 2: Comparison of sensory	and motor blocade van	riables between two groups

Variables related to sensory and motor blockade	GROUP L	GROUP B	P VALUE
Sensory onset at t10(min)	7.02	4.98	0.655995
Time to achieve Maximum sensory Level(min)	9	6.98	0.659
Two segment Regression (min)	118.55	115	0.438287
Duration of sensory block (min)	249.44	273.55	< 0.000001
Total duration of analgesia (min)	265.64	288.55	< 0.000001
Time of onset of motor blockade(min)	7.93	6.04	0.679827
Duration of motor block (min)	276.91	284.55	0.095486

Table 3: Comparison of maximum sensory bloc	ock level achieved between the two groups
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Dermatome level	GROUP L		GR	GROUP B	
	Frequency	Percentag	je Frequency	Percentage	P value
Т6	2	3.6	32	58.2	<0.0001
T7	2	3.6	2	3.6	
T8	35	63.6	20	36.4	
T10	16	29.1	1	1.8	

DISCUSSION

As we know, the most popular procedure used on patients undergoing lower limb and lower abdomen procedures is spinal anaesthesia.4 However, the most frequent negative effects associated with this method include bradycardia and systemic hypotension.⁴ Particularly in elderly patients with diminished cardiac reserve, significant hypotension may be harmful.⁴ The gradual degeneration of peripheral and central nerves, alterations in the architectural arrangement of the lumbar and thoracic vertebrae, and a reduction in the volume of cerebrospinal fluid may all play a role in the development of sympathetic block in the elderly.⁴ The perfect subarachnoid block for the treatment of elderly in lower limb surgery is still elusive. The patients in our study were elderly and had various co-morbidities. The majority of patients who presented to our tertiary care

centre for lower limb surgery had femoral bone fractures.

The most common drug used for spinal anaesthesia is hyperbaric bupivacaine. A very novel long-acting local anaesthetic called levobupivacaine has pharmacological properties very similar to those of racaemic bupivacaine, although it is less harmful to the heart than racaemic bupivacaine.² Levobupivacaine has a lower affinity for sodium channels in the heart and is consequently less frequently linked to cardiovascular events.¹

There is little evidence comparing the therapeutic use of levobupivacaine and bupivacaine, or research evaluating the two medicines' safety in terms of dosage and local anaesthetic selection for elderly patients. As per previous studies like Herrera et al.¹, Naithini et

al.³, Balasubramanian et al.³, P Ture et al.²⁰ levobupivacaine was more effective than bupivacaine in hemodynamic and sensory & motor characteristics so we compare these two different local anaesthetics.

The study found no significant difference in age distribution between group L and group B, with the mean age of 70.56 years in group L and 66.92 years in group B, and no significant difference in heights or weights between the two groups.

Balasubramanian et al.³ found that heart rate variability was greater in group B compared to group L, with a statistically significant difference. similarly In our study heart rate variability(from 10 minutes to 30 minutes) was greater in Group B when compared to group L and the difference was statistically significant (p value 0.000). This contradicts Naithini et al.³ findings that pulse rate was not significantly different between the two groups. P ture et al.² study found a statistically significant lower pulse rate in group B compared to group L at 5 minutes, contradicting our findings. Herrera et al.¹ study found higher heart rate variability in group L compared to group B up to 30 minutes after spinal anaesthesia, also statistically significant.

The study found that group B experienced a greater change in SBP, DBP, and MAP from 1 minute to 20 minutes compared to group L, with a statistically significant difference (P value<0.05). This was similar to a Herrera et al.¹ study where group B had a significant increase in SBP and DBP. P ture et al.² also showed a significant decline in SBP from 5 to 60 minutes compared to group L, and a significant difference in DBP from 10 minutes to 45 minutes. However, no significant difference was found in the mean values of blood pressure and diastolic blood pressure between the two groups. Naithini et al.³ affirms when compared isobaric levobupivacaine, hyperbaric to bupivacaine caused more hypotension and bradycardia in study, which is primarily attributable to the more cephalic spread of hyperbaric solutions.

The study found no significant difference in surgery length between Group L and Group B, with an average of 109 minutes, consistent with previous studies by Erdil et al.⁴., R Duggal et al.⁶., and Balasubramanian et al.³

The study found that Group B experienced an early onset of sensory block (4.9 min) compared to Group L (7.02 min), but this difference was not statistically significant (p value >0.05). This finding is consistent with previous studies, such as Pture et al.², Erdil et al.⁴, Naithini et al.³, and Sathitkarnmanee et al.²⁵, which reported no clinical differences in spinal blockade features between isobaric levobupivacaine and isobaric bupivacaine. The comparatively short time to establish sensory block with bupivacaine appears to be an advantage for surgical procedures; nevertheless, in elderly patients, a quick increase in block level may be dangerous due to possible adverse effects on haemodynamic parameters

The study found that group B(58.2%) had a higher maximum sensory level T6 than group L (3.6%), while group L had a higher peak sensory level T8 (63.3%) although the difference was not statistically significant (P value 0.655). Peak sensory levels ranged from T8 to L1 (median T10) in group L, whereas in group B, it ranged from T4 to T8 (median T6). In a study by Naithini et al.³, 20% of patients in group B reached T6 sensory level, while 43% in group L did. In a study by Erdil et al.⁴, group bupivacaine had a significantly higher peak sensory block level compared to levobupivacaine group. However, adequate block level may be beneficial for elderly patients for haemodynamic stability. Gori et al²³. found that isobaric levobupivacaine, due to its close gravity to the central spinal fluid, reacts indifferently to gravitational forces, resulting in higher sensory block levels in Group B compared to Group L in a study.

The study found that the time to achieve maximum sensory level was faster in group B (6.98 min) than in group L (9 min), which was not statistically significant, similarly study by P ture et al². however, in Naithini et al³.'s study, the time to peak sensory level was significantly higher in group B. In R duggal et al⁶.'s study, the time to achieve maximum sensory level was longer in group B (9.2±5.5) min than in group L (8.1±1.7) min. This suggests that the longer time for levobupivacaine to reach its maximum level and adequate sensory blockage may contribute to greater hemodynamic stability in patients.

The study found that group B experienced a longer sensory block duration (273±37 min)

compared to group L (249 ± 39 min), a statistically significant difference (P value 0.000). This was consistent across various studies, including those by Naithini et al.³ and Duggal et al⁶., which also found a longer duration of sensory block in group B.

The two-segment regression durations were comparable between groups measuring 115±6 min in Group B and 118±6 min in Group L, with no significant difference (P value >0.05). However, a study by Erdil et al⁴ showed no significant difference in the duration of levobupivacaine and bupivacaine, while R Duggal et al⁶. showed a significant difference in the duration of two-segment regression between groups, with a difference of 72 minutes in group B and 54 minutes in group L. The study found that Group B had longer analgesia duration (288±37 minutes) compared to Group L (265±36 minutes), a statistically significant difference (P value 0.000). This finding was consistent with previous studies by Naithini et al³., while P ture et al.² found the total duration of analgesia in both groups to be statistically insignificant.

In our study, group B had a faster onset of motor block (6.04 min) than group L (7.93 min), but this difference was not statistically significant (P value 0.67). In a study by Naithini et al.³, hyperbaric bupivacaine significantly reduced the time it took to reach maximum motor block (6.731.23 min) compared to isobaric levobupivacaine (8.81.45 min), with a p-value of 0.001. Levobupivacaine took longer **REFERENCE**

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to reach its maximum blocking effect than bupivacaine did in a study with Erdil et al.⁴ which is (P value 0.05) statistically significant. In Group B, the average time of motor blockade was 284 minutes, compared to 276 minutes in Group L. The difference wasn't statistically significant. (P >0.05) Similarly the total duration of motor block was longer in group B (220 min) than in group L (216 min) in the study by P Ture et al.². but this difference was not statistically significant (P value 0.587). In numerous surgical procedures, Solakovic et

al.²⁷ compared the use of isobaric bupivacaine with hyperbaric bupivacaine. In addition, they claimed that isobaric solutions in spinal anaesthesia are useful for operations needing T10 or lower level.

In either study group, there was no instance of systemic toxicity or any other adverse event during the postoperative period.

CONCLUSION

This study concludes that 0.5% isobaric levobupivacaine has minimal effect on hemodynamic parameters, paces the time of onset at T10 sensory level and maximum sensory level achieved, with shorter duration of sensory blockade, motor blockade, analgesia and two segment regression time.0.5% isobaric levobupivacaine is preferable to 0.5% hyperbaric bupivacaine in elderly patients undergoing lower limb surgery due to superior hemodynamic stability.

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