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Original Article

Randomized Double-Blind Study to Compare Hemodynamic Profile of Intrathecal Hyperbaric Bupivacaine 0.5% Versus Hyperbaric Levobupivacaine 0.5% In Elderly Population Undergoing Infraumbilical Surgeries

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ABSTRACT

Background: Spinal anesthesia is widely used for infraumbilical surgeries in elderly patients because of its rapid onset, reliability, and reduced postoperative complications. However, age-related physiological changes predispose elderly patients to significant hemodynamic instability following spinal anesthesia. Levobupivacaine, the S (-) enantiomer of bupivacaine, has been reported to provide comparable anesthesia with improved cardiovascular safety. The present study compares the hemodynamic effects of intrathecal hyperbaric 0.5% bupivacaine and 0.5% levobupivacaine in ASA II and III elderly patients undergoing infraumbilical surgeries.

Materials and Methods: A prospective randomized double-blind interventional study was conducted on 70 elderly patients aged ≥60 years undergoing elective infraumbilical surgeries under spinal anesthesia. Patients were randomly allocated into two groups of 35 each. Group B received 3 ml of 0.5% hyperbaric bupivacaine, while Group L received 3 ml of 0.5% levobupivacaine intrathecally. Hemodynamic parameters including heart rate, systolic blood pressure, diastolic blood pressure, mean arterial pressure, oxygen saturation, incidence of hypotension, bradycardia, vasopressor requirement, sensory and motor block characteristics, and adverse events were recorded.

Results: Group B demonstrated a significantly greater reduction in systolic blood pressure and mean arterial pressure compared to Group L ($p<0.05$). Hypotension occurred in 14 (40%) patients in Group B compared to 7 (20%) patients in Group L. Vasopressor requirement was significantly higher in Group B (34.3%) than Group L (14.3%). Bradycardia occurred in 17.1% and 8.6% patients respectively. Sensory and motor block characteristics were comparable between groups.

Conclusion: Intrathecal levobupivacaine 0.5% provides effective anesthesia with superior hemodynamic stability compared to hyperbaric bupivacaine 0.5% in ASA II and III elderly patients undergoing infraumbilical surgeries.

Keywords: Spinal Anesthesia, Elderly Patients, Hemodynamic Stability.

INTRODUCTION

The elderly population undergoing surgical procedures has increased substantially owing to improved life expectancy and advances in healthcare.[1] Elderly patients frequently present with multiple comorbidities and reduced physiological reserve, making anesthetic management challenging. Spinal anesthesia remains a preferred technique for infraumbilical surgeries because it provides profound sensory and motor blockade while minimizing airway manipulation. [2,3]

Bupivacaine has long been considered the standard local anesthetic for spinal anesthesia. [4] However, profound sympathetic blockade associated with bupivacaine can result in significant hypotension and bradycardia, especially in elderly patients. Levobupivacaine, the pure S(-) isomer of bupivacaine, possesses reduced cardiotoxicity and neurotoxicity while maintaining equivalent anesthetic efficacy. [5]

The present study was undertaken to compare the hemodynamic profile of intrathecal hyperbaric bupivacaine 0.5% and levobupivacaine 0.5% in ASA II and III elderly patients undergoing infraumbilical surgeries.

MATERIALS AND METHODS

The present prospective randomized double-blind interventional study was conducted in the Department of Anaesthesiology of a tertiary care teaching hospital to compare the hemodynamic profile of intrathecal hyperbaric bupivacaine 0.5% and levobupivacaine 0.5% in elderly patients undergoing elective infraumbilical surgeries under spinal anesthesia. A total of 70 patients aged 60 years or older, belonging to ASA physical status II and III, were enrolled in the study after obtaining informed written consent. The participants were randomly allocated into two groups comprising 35 patients each. Group B received intrathecal hyperbaric bupivacaine 0.5%, while Group L received intrathecal levobupivacaine 0.5%. Patients with contraindications to spinal anesthesia, known allergy to local anesthetics, severe cardiac conduction abnormalities, coagulopathy, or infection at the puncture site were excluded from the study. Randomization was performed using a computer-generated random number sequence. To maintain double blinding, the study drugs were prepared by an anesthesiologist who was not involved in patient management or data collection, and both the patients and the investigators remained unaware of group allocation throughout the study period. Hemodynamic parameters and perioperative outcomes were recorded and analyzed. Statistical analysis was performed using SPSS version 24. Continuous variables were expressed as mean ± standard deviation and compared using the independent Student's t-test, while categorical variables were expressed as frequencies and percentages and analyzed using the Chi-square test. A p-value of less than 0.05 was considered statistically significant.

RESULTS

Table 1: Demographic Characteristics

Variable	Group B (n=35)	Group L (n=35)	p value
Age (years)	68.4 ± 5.8	69.1 ± 6.1	0.62
Male	22 (62.9%)	21 (60.0%)	0.80
Female	13 (37.1%)	14 (40.0%)	
Weight (kg)	64.8 ± 7.2	65.5 ± 6.8	0.67
ASA II	21 (60.0%)	20 (57.1%)	0.81
ASA III	14 (40.0%)	15 (42.9%)	

Table 1 shows the demographic and baseline characteristics of the study participants in both groups. The mean age of patients was comparable between Group B (68.4 ± 5.8 years) and Group L (69.1 ± 6.1 years) (p=0.62). Male patients constituted 62.9% of Group B and 60.0% of Group L, while female patients accounted for 37.1% and 40.0%, respectively (p=0.80). The mean body weight was similar in both groups, being 64.8 ± 7.2 kg in Group B and 65.5 ± 6.8 kg in Group L (p=0.67). With respect to ASA physical status, ASA II patients comprised 60.0% of Group B and 57.1% of Group L (p=0.81). The absence of statistically significant differences in age, gender distribution, body weight, and ASA status indicates that both groups were comparable at baseline.

Table 2: Hemodynamic Parameters:

Parameter	Group B	Group L	p value
Maximum fall in SBP (%)	28.4 ± 7.3	18.9 ± 5.8	<0.001
Maximum fall in DBP (%)	24.8 ± 6.4	16.7 ± 4.9	<0.001
Maximum fall in MAP (%)	26.5 ± 6.1	17.5 ± 5.2	<0.001
Lowest HR (beats/min)	58.2 ± 7.8	63.5 ± 6.9	0.004

Table 2 compares the hemodynamic changes observed following spinal anesthesia in both study groups. Patients receiving hyperbaric bupivacaine (Group B) experienced a significantly greater reduction in systolic blood pressure, with a maximum fall of 28.4 ± 7.3%, compared to 18.9 ± 5.8% in the levobupivacaine group (Group L) (p<0.001). Similarly, the maximum decrease in diastolic blood pressure was significantly higher in Group B (24.8 ± 6.4%) than in Group L (16.7 ± 4.9%) (p<0.001). The mean arterial pressure also showed a significantly greater decline in Group B (26.5 ± 6.1%) compared to Group L (17.5 ± 5.2%) (p<0.001). Furthermore, the lowest recorded heart rate was significantly lower in Group B (58.2 ± 7.8 beats/min) than in Group L (63.5 ± 6.9 beats/min) (p=0.004).

Table 3: Adverse Hemodynamic Events

Variable	Group B	Group L	p value
Hypotension	14 (40.0%)	7 (20.0%)	0.04
Bradycardia	6 (17.1%)	3 (8.6%)	0.29
Vasopressor use	12 (34.3%)	5 (14.3%)	0.04
Atropine use	5 (14.3%)	2 (5.7%)	0.22

Table 3 presents the incidence of adverse hemodynamic events in both study groups. Hypotension was observed significantly more frequently in Group B, affecting 14 (40.0%) patients, compared to 7 (20.0%) patients in Group L (p=0.04). Similarly, the requirement for vasopressor support was significantly higher in Group B, with 12 (34.3%) patients requiring intervention, whereas only 5 (14.3%) patients in Group L required vasopressors (p=0.04). Although bradycardia occurred more often in Group B [6 (17.1%)] than in Group L [3 (8.6%)], the difference was not statistically significant (p=0.29). Likewise, atropine administration was required in 5 (14.3%) patients in Group B compared to 2 (5.7%) patients in Group L, but this difference did not reach statistical significance (p=0.22).

Table 4: Block Characteristics

Variable	Group B	Group L	p value
Sensory onset (min)	3.1 ± 0.8	3.3 ± 0.7	0.28
Time to T10 level (min)	5.8 ± 1.2	6.1 ± 1.3	0.31
Motor block onset (min)	4.5 ± 0.9	4.7 ± 1.0	0.39
Duration of analgesia (min)	208 ± 28	201 ± 25	0.27

Table 4 compares the characteristics of sensory and motor blockade between the two study groups. The mean onset time of sensory block was 3.1 ± 0.8 minutes in Group B and 3.3 ± 0.7 minutes in Group L, with no statistically significant difference between the groups (p=0.28). Similarly, the time required to achieve the T10 sensory level was comparable, being 5.8 ± 1.2 minutes in Group B and 6.1 ± 1.3 minutes in Group L (p=0.31). The onset of motor block was also similar in both groups, with mean values of 4.5 ± 0.9 minutes and 4.7 ± 1.0 minutes in Groups B and L, respectively (p=0.39). Furthermore, the duration of postoperative analgesia was comparable between the groups, lasting 208 ± 28 minutes in Group B and 201 ± 25 minutes in Group L (p=0.27).

DISCUSSION

The present randomized double-blind interventional study compared the hemodynamic profile of intrathecal hyperbaric 0.5% bupivacaine and 0.5% levobupivacaine in ASA II and III elderly patients undergoing infraumbilical surgeries. The findings demonstrated that both drugs provided effective spinal anesthesia with comparable sensory and motor blockade characteristics; however, levobupivacaine was associated with superior hemodynamic stability, evidenced by a lower incidence of hypotension, bradycardia, and vasopressor requirement.

In the present study, patients receiving levobupivacaine exhibited better maintenance of systolic blood pressure, diastolic blood pressure, and mean arterial pressure throughout the intraoperative period. Similar findings were reported by Rachna Gupta et al.[6] who compared hyperbaric levobupivacaine and hyperbaric bupivacaine for infraumbilical surgeries and observed significantly lower mean arterial pressure values in the bupivacaine group after induction of spinal anesthesia, suggesting greater hemodynamic stability with levobupivacaine.

The lower incidence of hypotension observed with levobupivacaine in the present study is consistent with the findings of Chinthavali Sujatha et al.[7] who demonstrated a significantly lower occurrence of hypotension in patients receiving levobupivacaine compared with those receiving bupivacaine. They further reported increased requirements for ephedrine and atropine in the bupivacaine group, indicating a greater degree of cardiovascular depression associated with racemic bupivacaine.

Likewise, Nagesh Vangapalli et al. [8] reported that intrathecal levobupivacaine provided a higher degree of cardiovascular stability with a lower incidence of hypotension and bradycardia compared with hyperbaric bupivacaine in patients undergoing infraumbilical surgeries. Although sensory blockade and analgesic efficacy were comparable between groups, levobupivacaine demonstrated a superior safety profile with respect to hemodynamic parameters.

The present study also observed a significantly lower vasopressor requirement in the levobupivacaine group. This finding supports the observations of Chinthavali Sujatha et al. [7] who reported that patients receiving bupivacaine required more frequent administration of vasoactive agents such as ephedrine and atropine. Reduced vasopressor requirement is clinically important in elderly patients because repeated hypotensive episodes may predispose to myocardial ischemia, cerebral hypoperfusion, renal dysfunction, and delayed postoperative recovery.

Despite the differences in hemodynamic stability, sensory and motor block characteristics were largely comparable between the two groups in the present study. Similar observations were reported by Glaser et al. [9] who found that levobupivacaine and racemic bupivacaine were equipotent and produced similar onset times, durations, and qualities of

sensory and motor blockade. Fattorini et al. also reported no significant differences in spinal blockade characteristics between the two agents in patients undergoing orthopedic surgery. Furthermore, Sathitkarnmanee et al. [10] demonstrated comparable sensory and motor block quality between isobaric levobupivacaine and bupivacaine during lower abdominal and lower extremity surgeries.

Similarly, Lee et al. [11] found no significant differences in the quality of sensory or motor blockade and reported comparable hemodynamic changes between levobupivacaine and bupivacaine during transurethral resection procedures. Isha Yadav et al. [12] also observed no significant differences in sensory and motor block characteristics or electrocardiographic findings between the two drugs, supporting their overall safety and efficacy.

In contrast, some investigators have reported a slower onset and shorter duration of motor blockade with levobupivacaine. Rachna Gupta et al. [6] observed delayed onset of sensory and motor block and a significantly shorter duration of motor blockade in the levobupivacaine group, although they concluded that its improved hemodynamic profile made it a preferable alternative to bupivacaine. Similar observations were reported by Kunti Nayak et al. [13] who found slower onset but better hemodynamic stability and earlier postoperative recovery with levobupivacaine.

The superior hemodynamic profile of levobupivacaine may be explained by its pharmacological properties. Levobupivacaine is the pure S(-)-enantiomer of bupivacaine and possesses lower affinity for myocardial sodium channels, resulting in reduced cardiotoxicity and less depression of cardiac conduction. Additionally, its higher plasma protein binding decreases the concentration of free active drug in circulation, thereby reducing systemic toxicity. These pharmacological advantages contribute to improved cardiovascular safety while maintaining anesthetic efficacy. [14,15]

CONCLUSION

Intrathecal levobupivacaine 0.5% offers better hemodynamic stability than hyperbaric bupivacaine 0.5% in ASA II and III elderly patients undergoing infraumbilical surgeries. Levobupivacaine was associated with significantly lower incidences of hypotension and vasopressor requirement while providing comparable anesthetic efficacy. It may therefore be considered a safer alternative for spinal anesthesia in elderly high-risk patients.

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