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Original Research Paper

Anaesthesiology

A PROSPECTIVE RANDOMISED COMPARATIVE STUDY OF HYPERBARIC BUPIVACAINE VS HYPERBARIC LEVOBUPIVACAINE FOR SPINAL ANAESTHESIA IN INFRAUMBILICAL SURGERIES IN PATIENTS OF 60 YEARS AND ABOVE.

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ABSTRACT

Spinal anaesthesia is widely employed for infraumbilical surgeries due to its effectiveness and minimal airway management needs. While hyperbaric bupivacaine is commonly used, its cardiovascular and neurotoxic risks raise concerns in elderly patients. Levobupivacaine, the S-enantiomer of bupivacaine, has lower cardiotoxic potential and may offer a safer alternative. This prospective, randomised, comparative study evaluates the efficacy and safety of hyperbaric bupivacaine versus hyperbaric levobupivacaine in 60 patients aged 60 years and above undergoing infraumbilical surgeries under spinal anaesthesia. Participants were divided into two groups: Group B received 3 ml of 0.5% hyperbaric bupivacaine, and Group L received 3 ml of 0.5% hyperbaric levobupivacaine. Both groups achieved effective sensory and motor blockades, with no significant differences in onset or duration. However, from 30 minutes post-administration, Group B experienced more pronounced reductions in pulse rate and blood pressure compared to Group L. Levobupivacaine was associated with better hemodynamic stability and fewer cardiovascular changes. No differences in oxygen saturation were observed. The findings suggest that while both agents are effective, levobupivacaine may be more suitable for elderly patients due to its safer cardiovascular profile. Larger studies are needed to further validate these observations.

KEYWORDS :

INTRODUCTION

Spinal anaesthesia is a well-established and widely used regional anaesthetic technique, particularly for infraumbilical surgeries. Since its introduction by August Bier in 1898, spinal anaesthesia has gained widespread acceptance due to its efficacy, safety, and ability to provide profound sensory and motor blockade while minimizing systemic complications associated with general anaesthesia. The primary mechanism of spinal anaesthesia involves the administration of local anaesthetics into the cerebrospinal fluid (CSF), resulting in blockade of nerve conduction at the spinal cord level. This technique has several advantages, including avoidance of airway manipulation, reduced intraoperative blood loss, decreased opioid consumption, improved postoperative pain relief, early ambulation, and shorter hospital stays. Among the various local anaesthetics available for spinal anaesthesia, bupivacaine, a long-acting amide-linked local anaesthetic, has been widely used due to its reliable and prolonged sensory and motor blockade. However, concerns regarding its cardiotoxicity and neurotoxicity, particularly in high-risk populations such as the elderly, have led to the exploration of safer alternatives. Levobupivacaine, the S(-) enantiomer of racemic bupivacaine, has emerged as a promising alternative due to its similar anaesthetic efficacy but with reduced cardiotoxicity and neurotoxic effects.

Studies suggest that levobupivacaine has a lower affinity for cardiac sodium channels, reducing the risk of cardiac arrhythmias and myocardial depression compared to bupivacaine. Hyperbaric formulations of local anaesthetics offer more predictable onset, spread, and duration of the block compared to isobaric solutions, making them preferable for spinal anaesthesia. Hyperbaric bupivacaine remains the most commonly used local anaesthetic for spinal anaesthesia, but the recent availability of hyperbaric levobupivacaine has provided an alternative with potentially better safety outcomes. However, there is limited comparative data on the efficacy, onset, duration, and haemodynamic effects of hyperbaric levobupivacaine versus hyperbaric bupivacaine, particularly in elderly patients undergoing infraumbilical surgeries. Elderly patients undergoing spinal anaesthesia present unique physiological challenges due to age-related changes in the cardiovascular, respiratory, and nervous systems. Reduced autonomic reserve, increased sensitivity to anaesthetic agents, and diminished compensatory mechanisms make elderly patients more susceptible to hypotension, bradycardia, and prolonged drug effects. Hence, selecting an anaesthetic agent with minimal haemodynamic instability while ensuring adequate surgical anaesthesia is of paramount importance in this population. We conducted this study to compare hyperbaric 0.5% bupivacaine and hyperbaric 0.5% levobupivacaine in terms of their onset and duration of sensory and motor blockade, haemodynamic stability, and overall safety profile in patients aged 60 years and above undergoing infraumbilical surgeries under spinal anaesthesia.

MATERIALS AND METHODS

After approval from ethical committee, this prospective, randomized, comparative study was conducted with a total of 60 patients undergoing infraumbilical surgeries under spinal anaesthesia and were randomly assigned into two groups using a computer- generated randomization sequence: Group L (n=30) received 3 mL of 0.5% hyperbaric levobupivacaine, while Group B (n=30) received 3 mL of 0.5% hyperbaric bupivacaine. Informed consent was taken from each patient after which they underwent a detailed preoperative assessment, which included a thorough medical and surgical history, general physical examination, and systemic evaluation. Laboratory investigations were performed to assess the patient's fitness for spinal anaesthesia. Inclusion Criteria included Patients aged ≥ 60 years belonging to ASA Grade I and II patients undergoing infraumbilical surgeries under spinal anaesthesia. Exclusion Criteria includes refusal for spinal anaesthesia, ASA Grade 3 and 4 and contraindications to spinal anaesthesia. On the day of surgery, patients were kept nil per os (NPO) for six hours. After shifting to the operation theatre, standard American Society of Anaesthesiologists (ASA) monitoring was applied, including

Non-Invasive Blood Pressure (NIBP), Electrocardiogram (ECG), and Pulse Oximetry (SpO_2). Baseline vital parameters were recorded. An intravenous (IV) cannula was secured, and Ringer's lactate infusion was initiated as preload to reduce the risk of hypotension following spinal anaesthesia. Spinal anaesthesia was administered under strict aseptic precaution in the sitting position in L3-L4 interspace using a 25G Quinckie's spinal needle by either midline or paramedian approach . After confirming free cerebrospinal fluid (CSF) flow, the respective drug was injected slowly over 15 seconds, following which the patient was immediately positioned supine to allow uniform drug distribution.

The onset and progression of sensory blockade was assessed every two minutes using pinprick test until the block reached T6 level. Motor blockade was evaluated using the modified Bromage Scale. Haemodynamic parameters, including heart rate, blood pressure, and SpO_2, were recorded every five minutes for the first 30 minutes, followed by every 15 minutes until the end of surgery. Any adverse events, such as hypotension, bradycardia, nausea, vomiting, or shivering, were managed appropriately. Hypotension (SBP <90 mmHg or ≥20% decrease from baseline) was treated with IV fluids and Inj-mephentermine (3 mg IV bolus). Bradycardia (HR <50) was treated with Inj. Atropine 0.6mg IV ,shivering was treated with Inj. Tramadol (50 mg IV slow infusion) and nausea and vomit was treated with Inj. Ondansetron 4 mg IV. Postoperatively, patients were monitored in the post-anaesthesia care unit (PACU) until they regained adequate sensory and motor function. Sensory regression to L1 level and motor recovery to Bromage score 0 (Bromage 0- No block, Bromage 1- Partial Block, Bromage 2- Almost complete Block, Bromage 3- Complete Block) were recorded. Rescue analgesia was provided using IV Inj-paracetamol (1gm) when VAS score >4. The primary outcomes measured in the study included the onset time and duration of sensory and motor blockade, assessed using the pinprick test and Bromage Scale, respectively. Secondary outcomes included haemodynamic changes (heart rate, blood pressure, SpO_2), total duration of effective analgesia (time until first request for postoperative analgesia), and incidence of adverse effects such as hypotension, bradycardia, nausea, vomiting, and shivering. All collected data were recorded in a structured database and analysed using MedCalc Statistical Software. Categorical variables such as gender distribution, ASA classification, and incidence of adverse events were presented as percentages and compared using the Chi-square test. Continuous variables, including onset and duration of sensory and motor blockade and haemodynamic parameters, were expressed as mean ± standard deviation (SD) and compared using the independent Student's t-test. A p-value < 0.05 was considered statistically significant for all analyses.

RESULTS

The demographic characteristics of the patients in both groups were comparable, with no statistically significant differences in age, gender distribution, or ASA status. The mean age was 65.46 ± 5.27 years in Group L and 64.93 ± 4.60 years in Group B (p = 0.6797). Males constituted 76.67% of Group L and 66.67% of Group B, while females made up 23.33% and 33.33%, respectively (p = 0.3900). Most patients belonged to ASA Grade II (93.33% in Group L and 66.67% in Group B), with no statistically significant difference (p = 0.7344).

Distribution according to onset and duration of sensory blockade.

GROUP	ONSET (MIN) (MEAN ± SD)	DURATION (MIN) (MEAN ± SD)
GROUP L	4.5 ± 1.50	182.53 ± 29.49
GROUP B	3.9 ± 1.7	186 ± 27.74
P VALUE	0.1526	0.6405

Table. 1

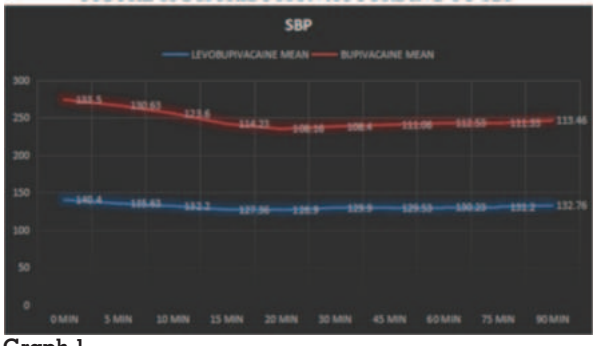
Table. 2

Distribution according to onset and duration of motor block

GROUP	ONSET	DURATION
GROUP L	3.46 ± 1.54	182.53 ± 29.49
GROUP B	2.96 ± 1.42	186 ± 27.74
P VALUE	0.1962	0.6405

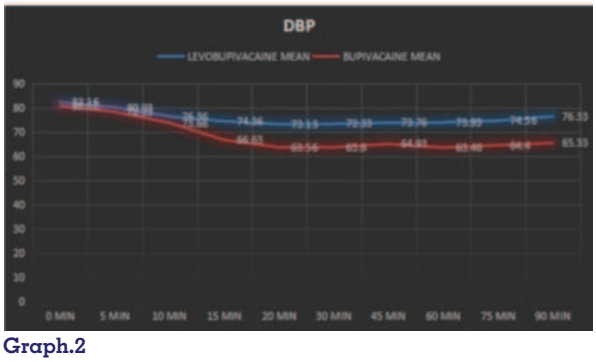
Regarding sensory blockade, the maximum level of sensory block achieved was higher in Group B, with 13.33% of patients attaining a T4 level compared to none in Group L (p = 0.0002). However, the onset time of sensory blockade was 4.5 ± 1.50 minutes in Group L and 3.9 ± 1.7 minutes in Group B, showing no significant difference (p = 0.1526). The total duration of sensory block was also comparable, with 182.53 ± 29.49 minutes in Group L and 186 ± 27.74 minutes in Group B (p =0.6405). Similarly, the onset time of motor blockade did not differ significantly between the two groups, with Group L achieving a motor block in 3.46 ± 1.54 minutes and Group B in 2.96 ± 1.42 minutes (p = 0.1962). The duration of motor blockade followed the same pattern, with 182.53 ± 29.49 minutes in Group L and 186 ± 27.74 minutes in Group B (p = 0.6405).

DISTRIBUTION ACCORDING TO SBP



Graph.1

DISTRIBUTION ACCORDING TO DBP



Graph.2

Table.3

DISTRIBUTION OF PATIENTS ACCORDING TO THE MAXIMUM SENSORY LEVEL ACHIEVED

MAXIMUM SENSORY LEVEL ACHIEVED	GROUP L		GROUP B	
	FREQUENCY	PERCENTAGE	FREQUENCY	PERCENTAGE
T4	0	0	4	13.33
T5	7	23.33	5	16.66
T6	13	43.33	9	30
T7	4	13.33	3	10

T8	5	16.66	5	16.66
T9	0	0	1	3.33
T10	1	3.33	3	10
P VALUE = 0.00024317				

Haemodynamic parameters were significantly different between the two groups. At 30 minutes, the heart rate in Group L was 78.26 ± 10.52 bpm, while in Group B, it was significantly lower at 71.66 ± 7.91 bpm (p = 0.0080). This trend persisted at 60 minutes, where the heart rate remained higher in Group L (77.96 ± 9.47 bpm) compared to Group B (71.63 ± 7.49 bpm, p = 0.0057). A significant difference was also observed in systolic blood pressure (SBP), with 129.9 ± 16.67 mmHg in Group L compared to 108.4 ± 10.9 mmHg in Group B at 30 minutes (p < 0.0001). Diastolic blood pressure (DBP) also showed a significant reduction in Group B (63.6 ± 7.87 mmHg) compared to Group L (73.3 ± 7.58 mmHg, p < 0.0001). The mean arterial pressure (MAP) at 30 minutes was 91.53 ± 9.55 mmHg in Group L, whereas it was significantly lower in Group B at 78.56 ± 8.36 mmHg (p < 0.0001). Oxygen saturation (SpO_2) remained stable in both groups throughout the study period. In terms of postoperative recovery, the time taken for sensory regression to L1 was 183.96 mins+ 1.436 minutes in Group L and 151.98+ 1.479 minutes in Group B, with no significant difference (p = 0.1621). The total duration of surgery was also comparable between the two groups, with the most common duration being 60-90 minutes (p = 0.0640). Adverse effects were more frequently observed in Group B. The incidence of hypotension was significantly higher in Group B (32%) compared to Group L (12%, p = 0.028). Bradycardia was also more common in Group B (20%) than in Group L (10%), though the difference was not statistically significant. Nausea and vomiting were reported in 16.67% of patients in Group B compared to 6.67% in Group L. Shivering was observed in 20% of patients in Group B compared to 13.33% in Group L.

DISCUSSION

Spinal anaesthesia remains the preferred technique for infraumbilical surgeries, particularly in elderly patients, due to its ability to provide profound sensory and motor blockade while avoiding the risks associated with general anaesthesia. However, the choice of local anaesthetic significantly influences the quality of anaesthesia, haemodynamic stability, and overall safety. This study aimed to compare 0.5% hyperbaric bupivacaine and 0.5% hyperbaric levobupivacaine in terms of their anaesthetic efficacy, haemodynamic effects, and postoperative recovery in patients aged 60 years and above undergoing infraumbilical surgeries. The demographic characteristics of the study population were comparable between the two groups, ensuring that any observed differences were attributable to the anaesthetic agent rather than patient-related factors. The mean age in Group L (levobupivacaine) was 65.46 ± 5.27 years, while in Group B (bupivacaine), it was 64.93 ± 4.60 years, with no statistically significant difference (p = 0.6797). Similarly, gender distribution (p = 0.3900) and ASA classification (p = 0.7344) were comparable, confirming the homogeneity of the study population.

The onset of sensory and motor blockade was slightly faster In Group B than in Group L, though the difference was not statistically significant. The onset of sensory blockade in Group L was 4.5 ± 1.50 minutes, whereas in Group B, it was 3.9 ± 1.7 minutes (p = 0.1526). The onset of motor blockade followed a similar pattern, occurring at 3.46 ± 1.54 minutes in Group L and 2.96 ± 1.42 minutes in Group B (p = 0.1962). These findings indicate that both drugs produce a comparable onset of action, allowing for timely surgical intervention. The maximum level of sensory blockade achieved was significantly higher in the bupivacaine group, with 13.33% of patients reaching the T4 level, whereas no patients in the levobupivacaine group attained this level (p = 0.0002). Despite this difference, the total duration of sensory blockade was similar in both groups, lasting 182.53 ± 29.49 minutes in Group L and 186 ± 27.74 minutes in Group B (p = 0.6405). The duration of motor blockade also showed no significant difference, with 182.53 ± 29.49 minutes in Group L and 186 ± 27.74 minutes in Group B (p = 0.6405). These results suggest that levobupivacaine provides an anaesthetic duration comparable to that of bupivacaine, making it a suitable alternative for infraumbilical surgeries. Haemodynamic stability is a critical concern in elderly patients undergoing spinal anaesthesia, as they are more susceptible to hypotension and bradycardia due to diminished autonomic reflexes. A significant difference was observed in heart rate (HR), systolic blood pressure (SBP), diastolic blood pressure (DBP), and mean arterial pressure (MAP) between the two groups. At 30 minutes post-spinal anaesthesia, the HR in Group L was 78.26 ± 10.52 bpm, significantly higher than 71.66 ± 7.91 bpm in Group B (p = 0.0080). This trend continued at 60 minutes, where HR remained higher in Group L (77.96 ± 9.47 bpm) compared to Group B (71.63 ± 7.49 bpm, p = 0.0057). Similarly, SBP at 30 minutes was significantly lower in the bupivacaine group (108.4 ± 10.9 mmHg) compared to 129.9 ± 16.67 mmHg in the levobupivacaine group (p < 0.0001). The DBP also showed a significant reduction in Group B (63.6 ± 7.87 mmHg) compared to Group L (73.3 ± 7.58 mmHg, p < 0.0001), and MAP was 91.53 ± 9.55 mmHg in Group L versus 78.56 ± 8.36 mmHg in Group B (p < 0.0001). These findings highlight that levobupivacaine provides superior haemodynamic stability compared to bupivacaine, reducing the incidence of hypotension and bradycardia. Postoperative recovery parameters were also evaluated. The time to sensory regression to L1 was 183.96 mins ± 1.436 minutes in Group L and 151.98 ± 1.479 minutes in Group B, with no statistically significant difference (p = 0.1621). The total duration of surgery was also comparable in both groups (p = 0.0640), indicating that both drugs provided an adequate anaesthetic duration for the required surgical procedures. Adverse effects were more frequently observed in the bupivacaine group, further reinforcing the safety profile of levobupivacaine. Hypotension was significantly more common in Group B (32%) than in Group L (12%), p = 0.028. Bradycardia occurred in 20% of patients in Group B, whereas it was 10% in Group L. Nausea and vomiting were reported in 16.67% of patients in Group B, compared to 6.67% in Group L. Shivering was also more frequent in Group B (20%) compared to Group L (13.33%). These findings support the hypothesis that levobupivacaine is associated with fewer adverse effects than bupivacaine, making it a safer option in elderly patients who are more vulnerable to haemodynamic instability and associated complications. The findings of this study are consistent with previous literature indicating that levobupivacaine provides a comparable anaesthetic effect to bupivacaine but with better haemodynamic stability and a lower incidence of side effects.

Studies suggest that the lower cardiotoxicity of levobupivacaine compared to racemic bupivacaine is due to its stereoselective properties, which reduce its affinity for cardiac sodium channels. This explains why patients receiving levobupivacaine experienced fewer cardiovascular complications despite achieving a comparable anaesthetic block. These results indicate that levobupivacaine can be used as an effective alternative to bupivacaine in elderly patients undergoing infraumbilical surgeries. While both agents provided adequate anaesthesia, levobupivacaine demonstrated a more favorable haemodynamic profile and a lower incidence of adverse effects, suggesting its potential as a safer option, particularly in patients with cardiovascular vulnerabilities.

CONCLUSION

This study demonstrated that both 0.5% hyperbaric bupivacaine and 0.5% hyperbaric levobupivacaine provide

effective spinal anaesthesia for infraumbilical surgeries in elderly patients. The onset, duration, and quality of sensory and motor blockade were comparable between the two groups, with no significant differences observed in the time to achieve adequate anaesthesia or its duration. However, levobupivacaine exhibited significantly better haemodynamic stability, as evidenced by higher blood pressure and heart rate values throughout the intraoperative period compared to bupivacaine. This suggests that levobupivacaine may be a preferable choice in elderly patients, who are at increased risk of hypotension and bradycardia following spinal anaesthesia. Furthermore, the incidence of hypotension, bradycardia, nausea, vomiting, and shivering was lower in the levobupivacaine group, reinforcing its superior safety profile. Given these findings, levobupivacaine emerges as a safer alternative to bupivacaine for spinal anaesthesia in elderly patients, offering comparable anaesthetic efficacy with reduced cardiovascular complications. Future studies with larger sample sizes and long-term follow-up are recommended to further validate these findings and establish levobupivacaine as the preferred agent for spinal anaesthesia in high-risk elderly populations.

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