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ORIGINAL ARTICLE

A Comparative Evaluation of Hyperbaric Levobupivacaine Versus Hyperbaric Bupivacaine for Elective Infraumbilical Surgeries Under Spinal Anaesthesia

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Abstract

Levobupivacaine, the S (-) enantiomer of bupivacaine, is known for its reduced cardiotoxicity and central nervous system side effects. The present study was conducted to compare the anesthetic efficacy and safety profiles of two local anesthetic agents—hyperbaric levobupivacaine and hyperbaric bupivacaine—in patients undergoing elective infra-umbilical surgeries. A total of 100 patients classified as ASA Physical Status I–II were randomly assigned to receive subarachnoid block with either hyperbaric levobupivacaine or hyperbaric bupivacaine. Group L (n = 50) received 3 ml of 0.5% hyperbaric levobupivacaine (15 mg), while Group B (n = 50) received 3 ml of 0.5% hyperbaric bupivacaine (15 mg). The onset and duration of sensory and motor blockade, recovery characteristics, hemodynamic changes, and adverse effects were compared between the two groups. The onset of sensory block was faster in Group B compared to Group L. The time for two-segment regression and duration of motor blockade were significantly longer in Group B. However, Group L demonstrated greater hemodynamic stability than Group B. Overall, 0.5% hyperbaric levobupivacaine (15 mg) produced satisfactory sensory and motor blockade with stable hemodynamic parameters and fewer adverse effects than an equivalent dose of hyperbaric bupivacaine. Therefore, hyperbaric levobupivacaine may be considered a safer and effective alternative for subarachnoid block in infra-umbilical surgeries.

Keywords: Levobupivacaine, bupivacaine, infra-umbilical surgeries, hemodynamic stability

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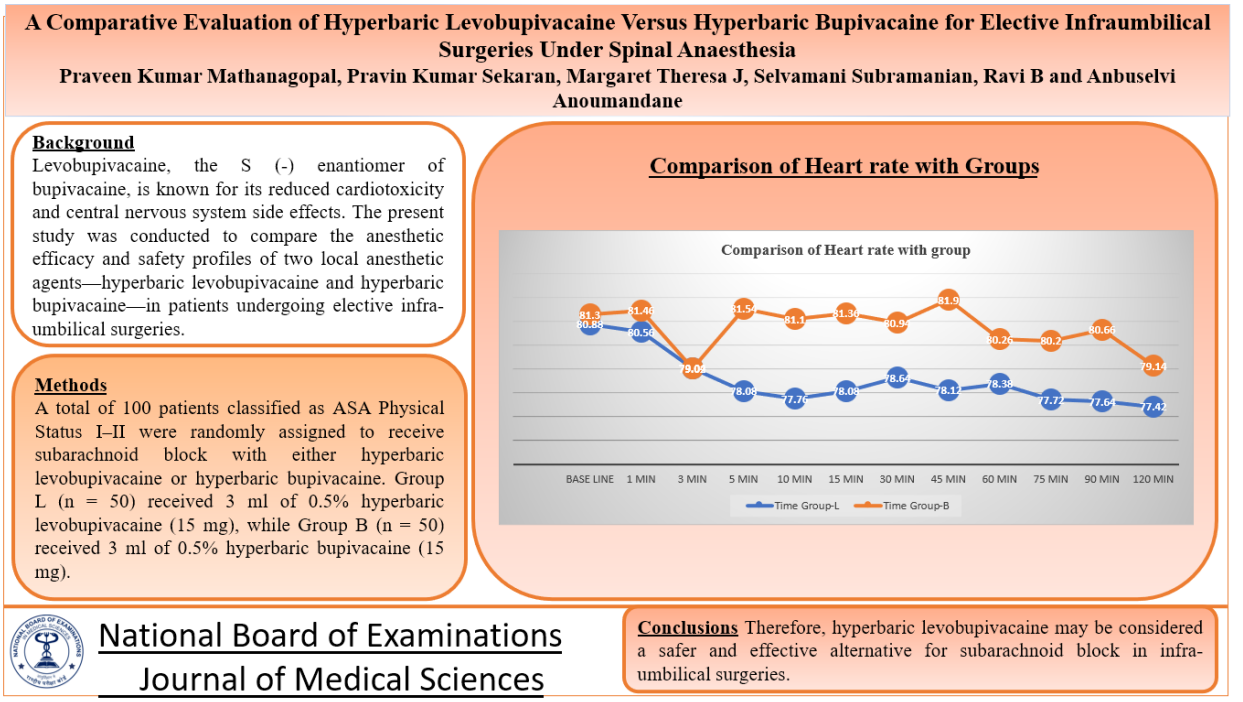
Graphical Abstract



Introduction

Spinal anaesthesia is a fundamental anaesthetic technique extensively utilized in infra-umbilical surgeries, which include lower limb orthopaedic procedures, urological operations and various gynaecological interventions. The primary advantages of spinal anaesthesia include a rapid onset of action, predictable and dense sensory and motor block, reduced postoperative pain, and lower incidence of systemic side effects compared to general anaesthesia [1]. Among the various local anaesthetics used in spinal anaesthesia, bupivacaine has long been regarded as the gold standard due to its favourable pharmacokinetic profile, which includes a prolonged duration of action suitable for lengthy surgical procedures [2]. However, It is associated with a significant risk of cardiotoxicity and neurotoxicity, particularly in higher doses or accidental intravascular administration. To mitigate these risks, levobupivacaine, the S-enantiomer of bupivacaine, has been developed and introduced into clinical practice. Levobupivacaine exhibits a similar pharmacokinetic and pharmacodynamic profile to racemic bupivacaine but with a significantly lower incidence of cardiotoxicity and central nervous system toxicity. This improved safety profile is due to the stereo-selectivity of levobupivacaine, which binds less avidly to cardiac sodium channels compared to the R-enantiomer found in racemic bupivacaine [3,4]. Comparative study between hyperbaric levobupivacaine and hyperbaric bupivacaine shall demonstrate levobupivacaine can provide comparable sensory and motor block characteristics with an improved safety profile.

Materials and Methods

This prospective randomized controlled study was conducted in one hundred patients undergoing elective infra-umbilical surgeries under subarachnoid block in a tertiary care hospital. The study

period was from July 2022 to February 2024. The hundred patients were randomly allocated to either one of the two group using sealed envelope technique.

Sample size calculation

All the data collected from the selected cases were systematically entered into a master chart. Statistical analysis was performed using Microsoft Excel and SPSS version 28.0. The software was utilized to calculate frequencies, percentages, ranges, means, and standard deviations. Statistical tests such as the Chi-square test, Friedman test, and t-test were applied, and corresponding p-values were obtained. A p-value of less than 0.05 was considered statistically significant.

Inclusion criteria

- Patients aged between 25 and 50 years
- Body weight ranging from 40 to 80 kg
- Classified as ASA Physical Status I or II
- Scheduled for elective infra-umbilical surgeries

Exclusion criteria

- ASA I II patients
- BMI > 35
- Severe renal, hepatic, respiratory and cardiovascular diseases
- Known hypersensitivity to amide local anaesthetic drugs and study drugs
- Coagulopathy and bleeding diathesis
- Infect ion at the site of injection.

Results

The study compared several parameters including hemodynamic stability, onset and duration of sensory and motor blockade, two-segment regression time, incidence adverse events, and the requirement of ephedrine between the two groups. The onset of sensory block occurred more rapidly in Group B compared to Group L. The time to achieve two-segment regression was significantly longer in Group B than in Group L. Similarly, the duration of motor block was extended in Group B. Overall, Group L demonstrated greater hemodynamic stability than Group B (Figure 1).

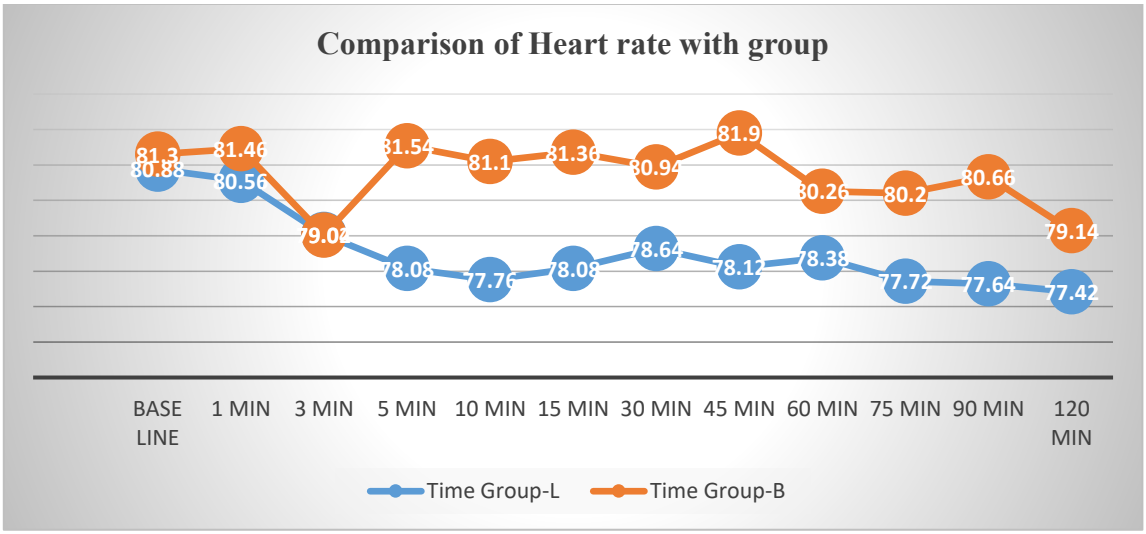


Figure 1. Comparison of Heart rate with Groups

The figure above illustrates the comparison of heart rate between the groups using an unpaired t - test. Despite the relatively lower heart rates observed in Group-L, the obtained p-value of greater than 0.05 indicates that there is no statistically significant difference between the groups. Therefore, they are considered comparable in terms of heart rate (Figure 2).

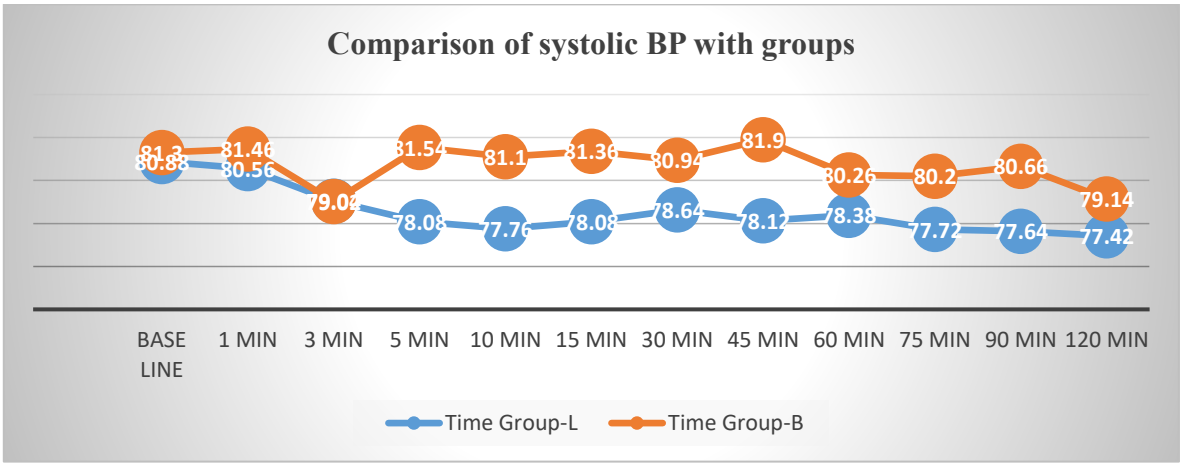
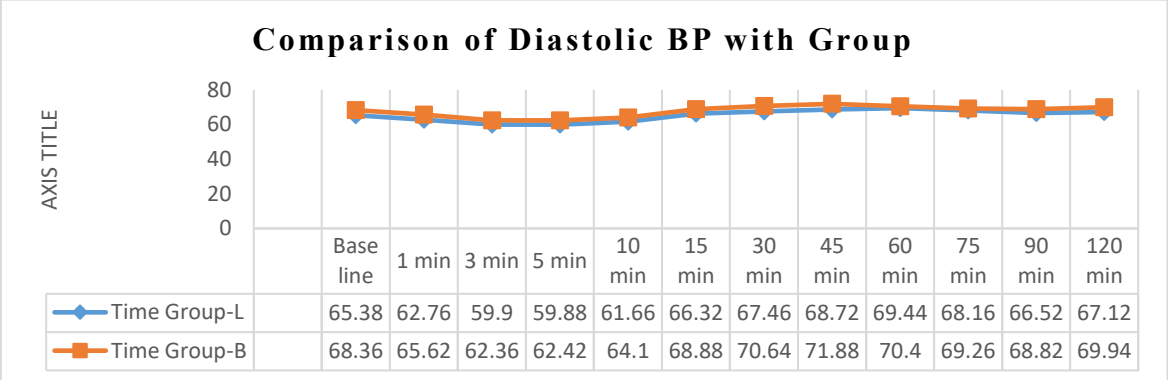


Figure 2. Comparison of Systolic BP with Groups

The table above presents the comparison of systolic blood pressure (SBP) between the groups using an unpaired t -test. Despite the relatively lower SBP observed in Group -L, the obtained p-value of greater than 0.05 indicates that there is no statistically significant difference between the groups. Therefore, they are considered comparable in terms of SBP.



	Base line	1 min	3 min	5 min	10 min	15 min	30 min	45 min	60 min	75 min	90 min	120 min
Time Group-L	65.38	62.76	59.9	59.88	61.66	66.32	67.46	68.72	69.44	68.16	66.52	67.12
Time Group-B	68.36	65.62	62.36	62.42	64.1	68.88	70.64	71.88	70.4	69.26	68.82	69.94

Figure 3. Comparison of Diastolic BP with Groups

The table above illustrates the comparison of diastolic blood pressure (DBP) between the groups using an unpaired t -test. Despite the DBP being relatively lower in Group -L, the obtained p-value of greater than 0.05 indicates that there is no statistically significant difference between the groups. Therefore, they are considered comparable in terms of DBP (Figure 3).

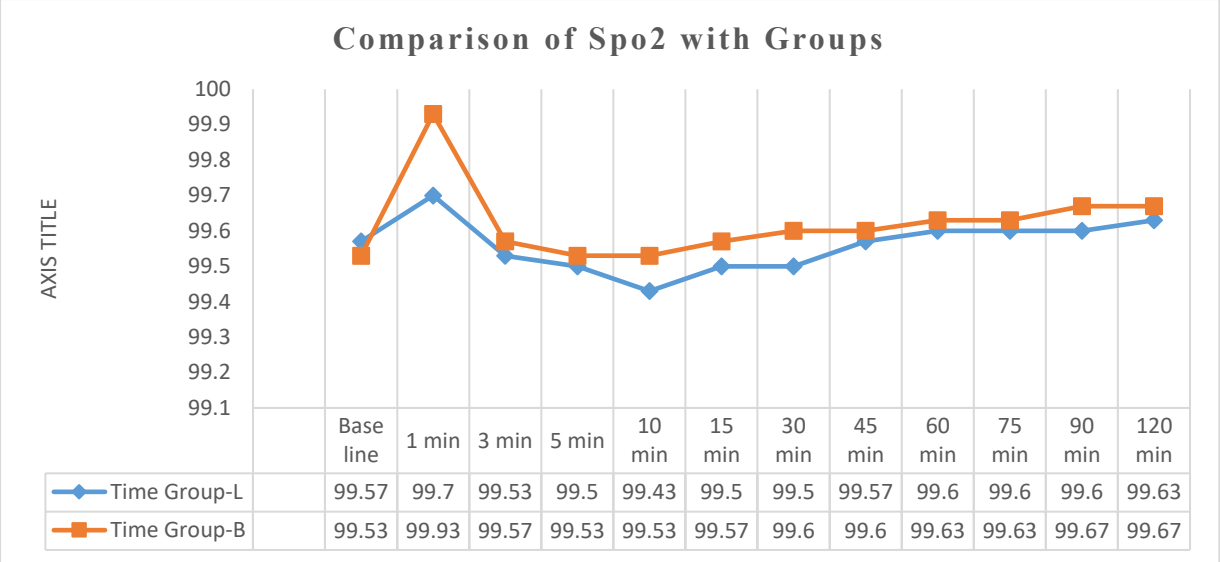


Figure 4. Comparison of spO2 with Groups

The above table shows comparison of spO2 with Groups by Unpaired t -test: a p-value>0.05, which is not a statistically significant difference and therefore, they are not comparable (Table 5).

Table 5. Comparison of Onset of Sensory blockade (minutes)

Onset (Sensory)	**Group**	
	Group -L	**Group- B**
Mean	2.45	1.88
SD	0.47	0.47
P Value	< 0.0001	
P<0.05, Hence highly significant		

The above table shows comparison of Onset of Sensory Blockade with Groups by Unpaired t - test with p<0.0001 which shows high statistically significant difference between the onset of Sensory Blockade with Groups. Group-B had significant early onset of act ion compared to Group L (Table 6).

Table 6: Comparison of Time for peak Sensory blockade

Duration (Sensory)	**Group**	
	Group -L	**Group- B**
Mean	11.77	13.27
SD	2.24	3.20
P Value	< 0.0078* HS	
P<0.05, Hence highly significant		

The above table shows comparison of Time for peak Sensory Blockade (minutes) with Groups by Unpaired t -test with p=0.0078 which shows high statistically significant difference between the mean time for maximal Sensory Blockade with the Groups. Group-L had significant early onset of maximal sensory blockade (Table 7).

Table 7: Comparison of Two Segment Regression Time for sensory block

Time for 2SR	**Group**	
	Group -L	**Group- B**
Mean	73.20	77.50
SD	6.29	5.27
P Value	0.0003* HS	
P<0.05, Hence highly significant		

The above table shows comparison of time for Two Segment Regression time with Groups by Unpaired t -test shows a p=0.0003, which shows high statistically significant difference between the mean duration for Two Segment Regression Time with the Groups. Group-L had significantly earlier two segment regressions than Group B (Table 8).

Table 8. Comparison of Onset of Complete Motor blockade

Onset (Motor)	**Group**	
	Group -L	**Group- B**
Mean	4.18	2.83
SD	0.7	0.59
P Value	< 0.0001* HS	
P<0.0001, Hence highly significant		

The table above illustrates the comparison of the onset of motor blockade between the groups using an unpaired t -test. The obtained p-value of 0.0001, which is less than 0.05, indicates a highly statistically significant difference in the onset of motor blockade between the groups. Specifically, Group -B exhibited a significantly earlier onset of complete motor blockade compare d to Group-L (Table 9).

Table 9. Comparison of Duration for maximum Motor Blockade

Duration of maximum motor blockade	**Group**	
	Group -L	**Group- B**
Mean	11.70	6.78
SD	1.97	1.42
P Value	<0.0001	
P<0.0001, Hence highly significant		

The above table shows comparison of duration for maximum motor blockade in minutes with Groups by Unpaired t- test with a p<0.0001 which shows high statistically significant difference between the mean duration of motor blockade with the Groups. Group-L had significant longer time for achieving maximum motor block (Table 10).

Table 10. Comparison of Regression Time for motor block

Duration of maximum motor blockade	**Group**	
	Group -L	**Group- B**
Mean	101.82	138.99
SD	17.17	29.13
P Value	<0.0001* HS	
P<0.05, Hence highly significant		

The table above displays the comparison of the regression time for motor blockade between the groups using an unpaired t - test. The obtained p-value of less than 0.0001 indicates a highly statistically significant difference in the mean duration for the regression time of motor blockade between the groups. Specifically, Group-B demonstrated a significantly longer time for regression of the motor blockade compared to Group-L (Table 11).

Table 11. Comparison of dose of ephedrine used

Duration of maximum motor blockade	**Group**	
	Group -L	**Group- B**
Mean	10.20	23.40
SD	3.77	3.38
P Value	<0.0001* HS	
P<0.0001, Hence highly significant		

The above table shows comparison dosage of ephedrine used for correcting hypotension within Groups by Unpaired t -test shows a $p<0.0001$, which shows high statistically significant difference. There is higher consumption of Ephedrine in Group -B (Table 12).

Table 12. Complications

Complications	Group-L	Group-B	Chi square	P-Value
Hypotension	**4**	**11**	**3.8**	**0.049**
Bradycardia	**2**	**6**	**2.17**	**0.14**
Headache	**1**	**1**		**-**
Nausea	**2**	**8**	**4**	**0.04**
Vomiting	**1**	**2**	**0.34**	**0.55**
High spinal block	**0**	**0**		
Total spinal block	**0**	**0**		

For the complication of hypotension, Group B exhibits a higher frequency compared to Group L (11 vs4), resulting in a Chi -square value of 3.8 and a p-value of 0.049. This indicates a statistically significant association between the group and the occurrence of hypotension. In the case of bradycardia, although Group B again demonstrates a higher frequency, the difference is not statistically significant, with a Chi -square value of 2.17 and a p-value of 0.14.Regarding nausea, vomiting, and itching, Group B shows higher frequencies compared to Group L. Notably, nausea and itching exhibit statistically significant associations with the group, as indicated by Chi -square values of 4 and 0.34, respectively, and corresponding p-values of 0.04 and 0.55.

Discussion

This randomized prospective control study done in 100 patients of age 25-50 years scheduled for elective infra-umbilical surgeries. The key parameters evaluated included intraoperative hemodynamics, onset and duration of sensory and motor blockade, time for two-segment regression sensory blockade and motor blockade, as well as the incidence of adverse effects and the required dose of ephedrine for managing hypotension.

In the present study, the onset of sensory blockade was observed to be 2.45±0.47 minutes with Levobupivacaine and 1.88±0.47 minutes with Bupivacaine. Notably, the onset of sensory blockade was significantly prolonged with Levobupivacaine compared to Bupivacaine at the equivalent dosage (15 mg). However, there was no statistically significant distinction in the duration taken for the sensory blockade to extend to the T10 dermatome level between the two drugs (4.73±0.9 minutes with Levobupivacaine and 4.74±1.14 minutes with Bupivacaine). Lee et al. [5] conducted a dose-effect study comparing racemic bupivacaine and levobupivacaine in patients undergoing

urological surgery. They found nearly equivalent clinical profiles and hemodynamic effects with 2.6 ml of 0.5% of both drugs. The time for peak sensory blockade was 11.77±2.24 minutes with Levobupivacaine and 13.27±3.20 minutes with Bupivacaine. This difference in early onset of sensory blockade with Levobupivacaine was statistically significant. In the present study, two-segment regression time was 73.20±6.26 minutes with Levobupivacaine and 77.50±5.27 minutes with Bupivacaine. The two-segment regression time was significantly longer with Bupivacaine with p value of <0.05 which is comparable with study conducted by Gautier et al [6] showed early two segment regression times with Bupivacaine.

Present study showed the onset of complete motor blockade was 4.18±0.7 minutes with Levobupivacaine and 2.83±0.59 minutes with Bupivacaine. The onset of motor blockade was significantly longer with Levobupivacaine. Similar rapid onset of motor blockade was seen in the study by Vanna et al [7] (3.9 min vs 3 min). In the present study the time for peak motor blockade was 11.7±1.97 minutes with Levobupivacaine and 6.78±1.42 minutes with Bupivacaine. This difference in early onset of motor blockade with Bupivacaine was statistically significant. The motor blockade regression time was 101.82±17.17 minutes with Levobupivacaine and 138.99±29.13 minutes with Bupivacaine. The motor blockade regression time was significantly longer with 0.5% Bupivacaine, which signified longer duration of motor blockade with Bupivacaine than Levobupivacaine. Similar prolonged motor blockade with Bupivacaine was seen in the study by C. Glaser et al [8] (280 min vs 284 min) Whereas Fattorini et al [9] reported prolonged motor duration with Levobupivacaine (256 min vs 245 min) The effects of baricity on block characteristics have been inconsistent in the literature. Therefore, we cannot solely at tribute the differences in sensory and motor block between the two groups in our study to the difference in baricity.

The present study showed no statistically significant changes in the hemodynamic parameters (heart rate, blood pressure and oxygen saturation) between both the groups. However, it was seen that the mean heart rates and blood pressures were found to be lower in the Group-L. Both the parameters were within the 20% range of the baseline parameters, except for some patients having hypotension (systolic blood pressure <90 mm Hg) in 8% with Levobupivacaine and 22% with Bupivacaine especially after 3 minutes and 5 minutes of administering the subarachnoid blockade.

The fall in the heart rates (Bradycardia defined as a heart rate <60 beats/minute) was seen in 2(4%) patients in Levobupivacaine group; while it was seen in 6 (12%) patients in Bupivacaine group. Though there were instances of bradycardia, none of the patients required Atropine supplement for bradycardia. A similar trend was seen in the blood pressure as well (systolic, diastolic and mean arterial pressure). The blood pressure in Group-L was lower than that of group-B, however these differences were not statistically significant between the groups. Ephedrine was supplemented for hypotension, besides giving boluses of crystalloid solution. Both the groups were comparable in the oxygen saturations.

In the preset study the incidence of Bradycardia was 4% in Group-L and 12%

in Group-B; nausea was 4% in Group-L and 16% in Group-B and vomiting, itching was seen in 2% in Group-L and 4% in Group-B). The incidence of bradycardia and vomiting was however not statistically significant. In regional anaesthesia for caesarean sections, nausea and vomiting can arise from various factors. A primary reason is the reduction in cerebral blood flow resulting from hypotension induced by the anaesthesia. Additionally, the level reached by the nerve block can contribute to nausea and vomiting, either through an increase in block level or inadequate cover age of structures affected by peritoneal stretching during surgery. The lower incidence of nausea observed in the levobupivacaine group in our study may be attributed to the fact that the doses administered achieved adequate blocks while causing less hypotension, thereby minimizing the risk of nausea and vomiting.

The incidence of hypotension was 8% in Group -L and 22% in Group-B. The incidence of hypotension was however highly statistically significant. Hypotension is a common complication associated with spinal anaesthesia. Various strategies have been employed to mitigate hypotension, including preoperative hydration with crystalloid or colloid solutions. Fattorini et al [9] observed better cardiovascular stability with levobupivacaine compared to bupivacaine, despite similar sensory and motor block characteristics. Similarly, Parpaglioni et al [10] reported a significant decrease in hypotension incidence with levobupivacaine in caesarean sections. The variations in reported hypotension rates a cross studies may be attributed to differences in the definition of hypotension, with some studies considering a 25% decline in systolic blood pressure from baseline values, while others, including ours, used a 20% decline from the baseline pressure as the threshold. In the current study, ephedrine was given in increments of 3 - 6mg to correct hypotension. The mean dose of ephedrine used was 10.2±3.77 mg with Levobupivacaine and 23.4±3.38 mg with Bupivacaine. There was significantly higher requirement of Ephedrine for correcting hypotension following subarachnoid block with Bupivacaine.

Conclusion

To conclude duration of sensory block and motor block in patients receiving 0.5% Hyperbaric Levobupivacaine was less when compared to patients receiving 0.5% Hyperbaric Bupivacaine. Onset of sensory and motor block was slow compared to the Bupivacaine group. Incidence of complications like Hypotension and Bradycardia were less in Hyperbaric Levobupivacaine group when compared to Hyperbaric Bupivacaine group. So Levobupivacaine being a safer local anaesthetic agent can be considered as a suitable alternative to bupivacaine for spinal anaesthesia in infra-umbilical surgeries

Statements and Declarations

Conflicts of interest

The authors declare that they do not have conflict of interest.

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