ORIGINAL RESEARCH PAPER
Volume - 13 | Issue - 01 | January - 2024 | PRINT ISSN No. 2277 - 8179 | DOI : 10.36106/ijsr
INTERNATIONAL JOURNAL OF SCIENTIFIC RESEARCH

COMPARISON OF HEMODYNAMIC RESPONSE BETWEEN LEVOBUPIVACAINE AND BUPIVACAINE IN ORTHOPEDIC LOWER LIMB SURGERIES -A RANDOMISED DOUBLE BLINDED STUDY

Anaesthesia

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ABSTRACT

Background- Bupivacaine is the most commonly used local anesthetic drug in central neuraxial Blockade (spinal anesthesia). Newer Drug Levobupivicaine which is an S isomer of bupivicaine is being used popularly in wide range of surgical patients as it is less cardiotoxic and less neurotoxic with no changes in the potency when compared to Bupivacaine. As Both the drugs have similar arrhythmogenic effects on the cardiovascular system. However, there is no clear Literature regarding which drug is more Arrhythmogenic.Thus information about which drug is more arrhythmogenic and hemodynamically stable.This studywas aimed to detect the Hemodynamic responsiveness between the Hyperbaric levobupivicaine and Hyperbaric Bupivacaie.in patients posted for Lower limb fracture stabilisations **Methodology-** Based on previous studies 60 patients of either gender with ASA Grade 1 and 2 aged between 20 and 60 years were included in the study. Height between 150 to 170 cms,and weight between 50 to 100 kgs were enrolled in the study ..Patients were randomly assigned into two groups , GROUP A (n=30). who received Levobupivacaine (L) 15 mg of 0.5 % and Group B (n=30) who received Bupivacaine .The following parameters were recorded in the intraoperative period . Basal heart rate , blood pressure was recorded preoperatively and after spinal anesthesia at an intervals of 5min,10min,20min,30 min ,1hour and 2 hours. Adverse effects if any like vomiting , shivering ,bradycardia etc was noted during the entire study .statistical analysis unpaired student t test was performed among the variables. **Results-** Most of the patients in GROUP A varied in height between 163-179 meters .group (n=19, 63.3%) with the mean height of 166.80 meters. Most of the patients in group B belonged to the same height as group A(n=20,66.7%) with the mean height of 166.73 .There is no statistically significant difference (p>0.05) between the two groups with regard to the Height . In Group – B patients majority belong to the same height group as Group – A (n=20, 66.7%) with the mean height of 166.73 meters. The association between the intervention groups and height distribution is considered to be not statistically significant since P>0.05 as per student t- Test. to 66.90 The association between the intervention groups and mean heart rate is considered to be statistically significant since P<0/01 as per paired sample t- Test except at 5 minutes where there is no statistically significant difference. **Conclusion-** levobupivicaine appears to be better hemodynamically stable than the Bupivicaine and it can be a better alternative to the Bupivicaine

KEYWORDS

Levobupivicaine, Bupivicaine, Arrhythmogenic, Cardiostable

INTRODUCTION –

Bupivacaine (1-butyl-2',6'-pipecoloxylidide), a pipecoloxylidide derivative, synthesized in 1957 and introduced in clinical practice in 1963 (1)Studies have showen an increased incidence of bupivacaine and cardiac arrest during regional anesthesia (2)Bupivicaine has high affinity to bind to plasma proteins and it will not elicit clinical effects of toxicity until all all the protein binding sites are fully occupied (2)..Hyperbaric racemic bupivacaine is commonlybeing used for spinal anesthesia due to its high potency, long duration of action and combined motor and sensory blockade. However, the use of hyperbaric racemic bupivacaine in spinal anesthesia has some drawbacks. It has a high propensity to cause hypotension and bradycardia following intrathecal injection, and there is potential for cardiac toxicity due to the high affinity of bupivacaine to cardiac myocytes (3,4). Racemic bupivacaine is an equimolar mixture of dextro and levobupivacaine. Levobupivacaine has a lower affinity for cardiac sodium channels and greater plasma protein binding affinity compared with the dextro isomer; thus, reducing the risk of cardio-toxicity(5,6). Plain levobupivacaine has been shown to be isobaric with respect to cerebrospinal fluid (7) and thus leads to more predictable drug spread, decreasing the incidence of hypotension and bradycardia (8). studies have shown occurrence of irrreversible fatal ventricular fibrillation without warning signs during pregnancy(9) levobupivicaine is an amide local anaesthetic which is the s enantionmerof racemic bupivicaine which is less cardiotoxic. Levobupivicaine toxicity reports are rare. levobupivacaine had less of a negative inotropic effect and, at intravenous doses >75 mg, produced less prolongation of the QTc interval than bupivacaine(10). Fewer changes indicative of CNS depression on EEG were evident with levobupivacaine(10) .studies have shown The corrected QT interval (QTc) values increased significantly at 10 minutes after spinal block and at 10 min postoperatively in the bupivacaine group(10) .Erdil et al. (14) compared 1.5 ml of 0.5% levobupivacaine to 1.5 ml of 0.5% plain bupivacaine in elderly patients undergoing transurethral prostate surgery and found greater patient satisfaction with the use of levobupivacaine. Our aim of the study was to see whether levobupivicaine was more hemodynamically stable when used for subarachnoid block

MATERIALS AND METHODS –

After approval by the Institutional Ethical Committee, 90 patients aged between 50 to 70 years of either sex with American Society of Anesthesiologists (ASA) physical status I-II who were scheduled for fracture tibia fixation surgeries (short duration) under intrathecal anesthesia were enrolled in this prospective, double-blind, randomized comparative study with written informed consent. Patients with medical complications (uncontrolled hypertension, ischemic heart disease, valvular diseases, hypovolemia, septicemia, and coagulation disorders or on anticoagulant therapy), local infection at the site of the proposed puncture for spinal anesthesia, pregnancy, psychiatric disorders, height < 150cm and more than 170 cms, weightless than 50 and more than 100kgs and known case of hypersensitivity to the amide group of local anesthetics were excluded from the study

The selected patients were randomly allocated into two groups of 30 each by a random number table, prepared by another anesthetist outside the operating room, namely, group A (3 ML of 0.5% hyperbaric levobupivacaine), group B (3 mL of 0.5% hyperbaric bupivicaine). Preoperative and operative standards were followed as per hospital guidelines

Intervention–

After shifting the patient to the operating table, electrocardiogram, peripheral capillary oxygen saturation, and noninvasive blood pressure (NIBP) monitors were attached and baseline values of heart rate (HR) and blood pressure (BP) were noted. With the patient in the

sitting position, intrathecal anesthesia was performed under aseptic conditions after local infiltration of the skin with 2% lidocaine. Using 25 G Quincke's needle with a midline approach at L4-L5 or L3 –L4 depending on the better space the subarachnoid space was entered, with bevel pointing cephalad. Drug was injected slowly over 15 seconds without barbotage technique and after noting the free flow of cerebrospinal fluid (CSF). The patient was made to lie down supine after the injection with a pillow under their head and put in a neutral position. Thereafter, hemodynamic changes, which include pulse rate, systolic blood pressure (SBP), diastolic blood pressure (DBP), mean arterial pressure (MAP), and peripheral oxygen saturation (SpO2), were recorded every 5 min, 10 min, 20 min, 30 min, 1 hour,2hour until the end of the surgery(15).

Patients were followed up for eight hours in the postoperative ward monitored for nausea,vomiting, shivering, hypoxia (SpO2 < 90%), bradycardia, hypotension, or respiratory depression (respiratory rate < 8/minute). The incidence of hypotension (arterial blood pressure (BP) < 20% of baseline or MAP < 60 mmHg)was treated with injection ephedrine 3 mg IV, and bradycardia (heart rate< 50 beats/minute) was treated with injection atropine 0.6 mg IV stat. Nausea and vomiting were treated with injection ondansetron 4 mg IV. Shivering was treated with warm drapes and warm intravenous fluids.

Statistical Analysis –

Data was collected using a pre-approved Performa and then tabulated using the Microsoft Office® Excel software (Microsoft Corp., Redmond, WA, USA). The Statistical Package for the Social Sciences (SPSS) version 25 software for Windows (IBM SPSS Statistics, Armonk, NY, USA) was used to carry out the statistical analysis. Mean and standard deviation (mean±SD) were used to reflect quantitative variables, but frequency and percentage were used to reflect qualitative variables (including age, weight, height, body mass index, and ASA physical status. Hemodynamic variables such as heart rate, mean arterial pressure, systolic blood pressure, and diastolic blood pressure were analyzed using a paired sample t - test. Intergroup comparison was done using paired sample t test. Majority of patients of group A belonged to163-179 meters height group (n=19, 63.3%) with the mean height of 166.80 meters. In Group – B patients majority belong height group as Group – A (n=20, 66.7%) with the mean height of 166.73 meters. The association between the intervention groups and height distribution is considered to be not statistically significant since P>0.05 as per student t- Test. Majority of Group A patients had mean heart rate ranging from 83.27 to 79.70 between base line and 6- minutes preoperatively. Similarly majority of group b patients had mean heart rate ranging from 75.33 and 66.90 between base line and 90 minutes intra operatively. The association between the intervention groups and mean heart rate is considered to be statistically significant since P<0/01 as per paired sample t- Test except at 5 minutes which is not significantly different . comparison of systolic blood pressure was significant (p<0.01)between both the groups at baseline and 5 min .when compared clinically systolic blood pressure values are within 30% from the base line values in both the groups .diastolic blood pressure was comparable p>0.05 between both thr groups (group A and group B) through the surgery .when compared diastolic blood pressure are within 10% from the base line values in both the groups majority of group A patients had a mean arterial pressure ranging from 86.37mmHg to 82.87 mmHg between baseline and 60 min intraoperatively. similarly majority of group B patients had a mean arterial pressure ranging 99.17to75.20 between baseline and 60 min intraoperatively. mean arterial pressure is considered to be statistically significant since p<0.01 as per 2 tail unpaired t test .

TABLES –

Table 1 age, weight, sex distribution

S.NO	Demographic Profile	LevoBupivican (n=30)	Bupivican (n=30)	Statistical Significance
1	Age group (yr.)			
(a)	< 50 Years	3 (10.0)	0 (.0)	$\chi2$=6.250@ (p=0.100) df= 3
(b)	51 -60 Years	9 (30.0)	16 (53.3)	
(c)	61 - 70 Years	17 (56.7)	14 (46.7)	
(d)	> 70 Years	1 (3.3)	0 (.0)	
	Total	30 (100.0)	30 (100.0)	
2	Mean age &SD (yr.)	61.20±11.687	61.37±4.958	t =0.072@; p=0.943
3	Mean Height &SD	166.80±8.582	163.73±4.201	t =1.756@; p=0.084
4	Mean Weight &SD	73.80± 11.633	69.93 ± 7.786	t =1.513@; p=0.136
4	Sex			
(a)	Male	13 (43.3)	16 (53.3)	$\chi2$=0.601@ (p=0.438) df= 1
(b)	Female	17 (56.7)	14 (46.7)	
	Total	30 (100.0)	30 (100.0)	

@ -Not significant

Table No. 2

Heart Rate		Baseline	5 min	10min	20 min	30 min	60 min
LevoBupivican	N	30	30	30	30	30	30
	Mean	86.53	85.90	83.27	81.83	81.47	79.70
	SD	13.017	11.701	12.622	9.447	9.808	9.285
Bupivican	N	30	30	30	30	30	30
	Mean	67.40	81.83	75.33	70.07	68.23	66.90
	SD	10.288	17.544	15.164	10.834	9.358	7.058
t-value		6.316**	1.056@	2.202*	4.484 **	5.347 **	6.011 **
P value Unpaired t Test		0.000	0.295	0.032	0.000	0.000	0.000

@ -Not significant; **significant at 0.01 level; *significant at 0.05 level;

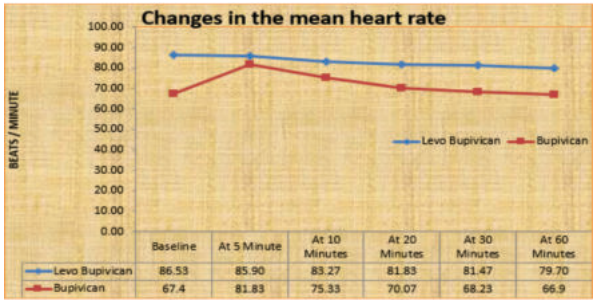

Table No. 3

mean systolic blood pressure		Base line	5 min	10min	20 min	30 min	60 min
Levo Bupivican	N	30	30	30	30	30	30
	Mean	128.4	126.43	120.87	120.63	121.53	120.73
	SD	16.437	16.094	15.525	14.282	11.428	11.688
Bupivican	N	30	30	30	30	30	30
	Mean	162.3	141.03	126.37	113.53	110.4	114.57
	SD	12.066	18.836	19.418	17.242	14.885	16.567
t-value		9.106 **	3.228**	1.212	1.737	3.249* *	1.666
P value Unpaired t Test		0.000	0.002	0.231	0.088	0.000	0.101

@ -Not significant; **significant at 0.01 level; *significant at 0.05 level;

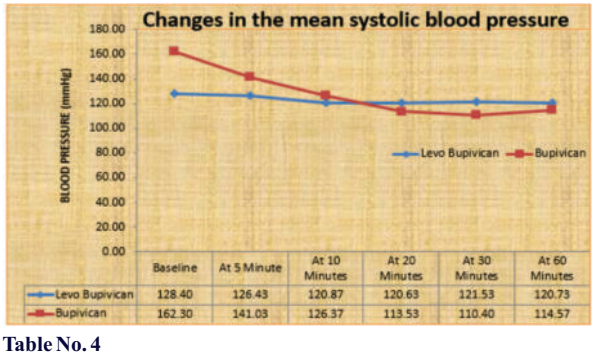

Table No. 4

mean diastolic blood pressure		Baseline	5 min	10min	20 min	30 min	60 min
Levo Bupivican	N	30	30	30	30	30	30
	Mean	84.20	82.47	80.97	80.97	79.90	80.17
	SD	10.59	8.37	9.79	8.32	6.22	5.41

Bupivican	N	30	30	30	30	30	30
	Mean	85.23	77.03	74.33	72.77	74.17	75.57
	SD	7.61	8.35	7.54	6.08	7.51	5.84
t-value		0.434@	2.517*	2.940 **	4.359 **	3.221 **	3.165
P value Unpaired t Test		0.666	0.015	0.005	0.000	0.002	0.002

@ -Not significant; **significant at 0.01 level; *significant at 0.05 level;

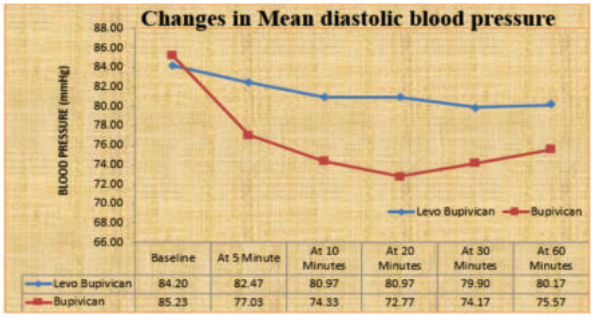

Table No. 5

Mean arterial pressure		Baseline	5 min	10 min	20 min	30 min	60 min
LevoBupivican	N	30	30	30	30	30	30
	Mean	86.37	85.50	81.83	82.17	82.77	82.87
	SD	17.35	15.66	13.71	13.12	11.77	11.89
Bupivican	N	30	30	30	30	30	30
	Mean	99.17	91.93	84.83	79.33	74.70	75.20
	SD	12.05	10.60	9.27	8.39	7.07	6.11
t-value		0.434@	2.517 *	2.940 **	4.359 **	3.221 **	3.165
P value Unpaired t Test		0.666	0.015	0.005	0.000	0.002	0.002

@ -Not significant; **significant at 0.01 level; *significant at 0.05 level;

DISCUSSION –

in this study, we compared levobupivacaine with bupivacaine in terms of hemodynamic stability and also any adverse effects associated with their use. We conducted our study with a dose of 3 mL of 0.5% of each drug, and our study findings were comparable with several studies (5 - 6) using the same dose. We noted that patients who received levobupivicaine were hemodyamically more stable. In our study, the incidence of hypotension was significantly less with the use of levobupivacaine than with bupivacaine . This finding is similar to that of Erdil et al. (14) who found a 10% incidence of hypotension with levobupivacaine and 30% with bupivacaine. Bupivacaine, being a more potent local anesthetic than levobupivacaine (16), may cause greater sympathetic blockade, resulting in greater incidence of hypotension.). None of the group of patients had bradycardia (less than50. There was very low incidence of hypotension and nausea with the use of levobupivacaine.

CONCLUSION –

0.5%levobupivicaine heavy is more hemodynamically stable compared with 0.5%bupivicaine heavy hence it can be used as a safer alternative to bupivicaine

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