



To Compare the Clinical Efficacy and Safety of 0.5% Hyperbaric LevoBupivacaine with 0.5% Hyperbaric Bupivacaine in Elective Infraumbilical Surgeries under Spinal Anaesthesia

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ABSTRACT

Background- The advantage of subarachnoid block(SAB)is that it can be used in an awake patient, minimal drug cost and rapid patient turnover has made subarachnoid block method of choice for lower abdominal, lower limb and perineal surgeries.

Aim- to compare the clinical efficacy and safety of 0.5% Hyperbaric Levobupivacaine with 0.5% Hyperbaric Bupivacaine inelective infraumbilical surgeries under spinal anaesthesia.

Methods and materials- This is arandomized double-blind study was conducted in order to compare the sensory and motor block characteristics of 0.5% Hyperbaric Levo bupivacaine with 0.5% Hyperbaric Bupivacaine for elective infraumbilical surgeries under subarachnoid block. Also hemodynamic parameters and any adverse effects like nausea, vomiting, bradycardia, hypotension, shivering, respiratory depression etc were noted. Patients aged between 18-70 years of either sex and ASA status 1 and 2 undergoing elective infraumbilical surgery under subarachnoid block were part of the study. Group L received 0.5% hyperbaric levobupivacaine 3.5 ml and Group Breceived 0.5% hyperbaric bupivacaine 3.5 ml intrathecally. Vitals were monitored preoperatively, intra operatively and post operatively until 24 hrs. Any adverse effects were noted during this period. Data was collected using pre designed proforma. After appropriate data filtration, the datasheet was analysed using graph and prism. P value of < 0.05 was considered statistically significant.

Results- the demographic data that is gender, Age, BMI, ASA status, spo2, preoperative vital

parameters were comparable throughout the study and their P value was not significant. In the levobupivacaine group (Group L),the meantime of onset of sensory block was 4.3 minutes as compared to 2.80 minutes in bupivacaine group (Group B) which was statistically significant ($p = 0.001$). Total duration of sensory block was higher in patients administered with bupivacaine (group B) (189.37 minutes) as compared to the mean total duration of sensory block in patients administered with levobupivacaine and the difference between two groups was statistically significant ($p = 0.001$). Time to reach the maximum height of sensory blockade was 10.26 minutes in the levobupivacaine group as compared to 9.23 minutes in the bupivacaine group.90% of patients in levo bupivacaine group had T8 level as maximum level of sensory blockade while 60% of patients in bupivacaine group had T6 as maximum level of sensory blockade. The difference between two groups was statistically significant ($p= 0.001$).The mean total duration of analgesia was statistically not significant. In the levobupivacaine group, the mean time of complete motor block significantly greater was 5.40 minutes in comparison to the mean time of complete motor block in bupivacaine group (3.90 minutes) ($p=0.001$).The duration of complete motor block was higher in the bupivacaine group (194.80 minutes) as compared to the mean duration of complete motor block in the levobupivacaine group (131.60minutes). The difference between two groups was statistically significant ($p =0.001$). Both findings imply that bupivacaine was comparatively better than levobupivacaine in terms of motor block characteristics. The intraoperative hemodynamic



parameters showed a statistically significant difference in both the groups. Heart rate among B & L groups displayed significant difference ($p > 0.05$). Intraoperative systolic blood pressure between 2 groups had significant differences at 3, 4, 5, 20, 25, 30 minutes respectively. Mean respiratory rate was significantly higher in group L than Bat all intervals except for 24th hr.

Conclusion- Our study results demonstrate that levobupivacaine provides excellent analgesia in terms of comparable block characteristics to bupivacaine. It also has better hemodynamic stability along with early return of ambulatory function with minimal postoperative complications.

Keywords- bupivacaine, regional anaesthesia, postoperative complications, spinal anaesthesia.

I. INTRODUCTION-

The development of regional anaesthesia started with the isolation of local anesthetics, the first being cocaine (the only naturally occurring local anesthetic). The first regional anesthetic technique performed was spinal anaesthesia, and the first operation under spinal anaesthesia was in 1898 in Germany by August Bier.

The central nervous system (CNS) comprises the brain and spinal cord. The term neuraxial anaesthesia refers to the placement of local anesthetic in or around the CNS. Spinal anaesthesia is a neuraxial anaesthesia technique in which local anesthetic is placed directly in the intrathecal space (subarachnoid space).

The advantage of subarachnoid block (SAB) is that it can be used in an awake patient, minimal drug cost and rapid patient turnover has made subarachnoid block method of choice for lower abdominal, lower limb and perineal surgeries. Subarachnoid block technique enables good cardiovascular stability and makes early discharge to home possible. It reduces surgical stress and attenuates increase in plasma catecholamines and other hormones. Regional anaesthesia gives intra and post operative pain relief with full preservation of mental status and normal reflexes(1). Autonomic, sensory and motor nerve fibers are blocked by spinal anaesthesia. It offers benefits like lesser blood loss, reduced incidence of venous thromboembolism, metabolic stress response to surgery, pulmonary compromise (2).

Bupivacaine (1-butyl-2', 6'-pipercol oxylydide), a pipe-coloxylydide derivative, synthesized in 1957 and introduced in clinical practice in 1963, is widely used. Bupivacaine is aracemic mixture of dextro(D)-is omer and levo(L)-isomer. The dextro-isomer of bupivacaine

is more cardiotoxic as compared to the levo-isomer. In 1979, a study reported an increased incidence of bupivacaine and cardiac arrest during regional anaesthesia(3). Bupivacaine is a long acting local anesthetic with a low therapeutic index due to cardiovascular toxicity (2). However, profound myocardial depression and even cardiac arrest can occur after accidental intravascular injection. Resuscitation from bupivacaine induced cardiovascular collapse has been found to be difficult and may be unsuccessful (4).

Levobupivacaine (S-1-buty 1-2-piperidy 1 for mo-2', 6'- xylidide hydrochloride), the pure S(-)-enantiomer of racemic bupivacaine, is a new long-acting local anesthetic that has recently been introduced in the clinical routine (5). S(-) enantiomer, 'levobupivacaine' has less negative inotropism and decreased affinity for cardiac sodium(2). Because of its significantly decreased cardiovascular and central nervous system toxicity, levobupivacaine seems to be an attractive alternative to bupivacaine(5).

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. Plain levobupivacaine has been shown to be isobaric with respect to cerebrospinal fluid and thus leads to more predictable drug spread, decreasing the incidence of hypotension and bradycardia. It also results in earlier motor recovery compared with racemic bupivacaine. These advantages make levobupivacaine an attractive alternative to racemic bupivacaine for spinal anaesthesia (6). So Levo bupivacaine has similar efficacy, but an enhanced safety profile as compared to bupivacaine in regional anaesthesia(7).

Hence, the purpose of this study is to assess the quality and duration of sensory and motor blockade of levobupivacaine and its toxic side effects, if any, compared to intrathecal bupivacaine in elective infraumbilical surgeries.

Aim- Aim of study is to compare the clinical efficacy and safety of 0.5% Hyperbaric Levo bupivacaine with 0.5% Hyperbaric Bupivacaine inelective infraumbilical surgeries under spinal anaesthesia.

II. METHODS AND MATERIALS-

STUDYDESIGN:-randomized double-blind study.

STUDY PLACE:- Study was conducted in the Department of Anaesthesiology and critical care, Chhattisgarh Institute of Medical Science, Bilaspur.

STUDY PARTICIPANTS:- Patients got pre-anaesthetic fitness for surgeries and posted in major



operation theatres for elective infraumbilical surgical procedures under spinal anaesthesia age group of 18-60 yrs.

STUDY DURATION:— Our study was started after getting permission from the institutional scientific and ethical committee and it was completed after the target sample size was achieved.

DATA COLLECTION PROCEDURE:— Data was collected using a data collection proforma.

SAMPLESIZE:—60(30 in each group)

ANTICIPATED BIAS-PLAN TO ADDRESS THE BIAS

Observation bias- blinding

Selection bias- randomization

Inclusion criteria-

- Patients willing to participate in the study.
- Patients between 18-60 yrs of age of either sex.
- ASA CLASS I and II.
- Patients undergoing elective infraumbilical surgery under spinal anaesthesia.

Exclusion criteria-

- Patient refusal.
- Any contraindication to neuraxial anaesthesia.
- Sensitivity or allergy to any of the study drugs.
- Patients with obvious spinal deformities.
- Patients with signs of raised intracranial pressure.
- Coagulopathy.
- Local infection at site of injection.
- Pregnant and lactating patients.

This study was conducted in the department of anaesthesiology and critical care unit CIMS, Bilaspur after approval from the institutional ethical committee. All patients were thoroughly examined and evaluated with regards to history, physical examination and investigations. A written informed consent was obtained from all the patients. All patients were premedicated with a tab. Alprazolam 0.5mg and tab Ranitidine 150 mg orally at bedtime on the previous night before surgery in the ward. Xylocaine sensitivity was done one night prior to surgery. They were kept nil orally for 6 hrs prior to surgery for solid food and 2 hrs for clear liquids. On the day of surgery, basal vital parameters (pulse, non-invasive Blood pressure, spo2) of all the patients were recorded in the operation theatre. Intravenous line was obtained with an 18 G cannula and preloading done with 500 ml ringer lactate. Monitoring was done using pulse oximetry, ECG, non-invasive blood pressure. Patients were allocated in 2 groups in the operation

theatre using sealed-envelope technique. Group L received 0.5% hyperbaric levo bupivacaine 3.5 ml intrathecally. Group B received 0.5% hyperbaric bupivacaine 3.5ml intrathecally.

The study drug was prepared by an anaesthesiologist, not involved in the study. Under all aseptic precautions lumbar puncture was done in sitting position at L3-L4 intervertebral space by midline approach using 25G Quincke's needle. After obtaining free and clear flow of cerebrospinal fluid, study drugs were administered slowly. Patients positioned supine immediately after completion of injection with the table in neutral position. Systolic blood pressure [SBP], diastolic blood pressure [DBP], mean arterial pressure. [MAP], respiratory rate [RR], SPO2, and heart rate [HR] recorded at zero minute, every 1 minute for 5 minutes, then 5 readings taken in 5 minutes interval and then every 15 minutes till completion of surgery after that vitals were monitored every 1 hourly for next 3 hours then 3 hourly for 24 hours.

The following parameters were studied: -

Assessment of sensory blockade: -

Sensory blockade was assessed every 2 minutes by pinprick method and time noted for the block to reach different dermatomal levels.

- Onset of sensory blockade:—This was taken as the time from the deposition of drug to the evidence of loss of pin prick sensation at T12 level.
- Maximum height of sensory block reached—was taken as the dermatomal level above which pinprick at 2 consecutive levels was identical.
- Time to reach maximum height of sensory blockade—was taken as the interval between the deposition of drug and the loss of pinprick sensation at the highest dermatomal level.

Assessment of onset and degree of motor blockade:—

Onset of motor block was noted as time taken from the drug deposition to the loss of power that is patient was not able to lift the legs assessed by modified Bromage scale every 2 minutes.

Modified Bromage scale:—

- Scale 0:—able to lift legs against gravity
- Scale 1:—able to flex knee but unable to flex legs
- Scale 2:—able to move feet but unable to flex knee
- Scale 3:—unable to move any joint



Quality of intraoperative anaesthesia was scored after completion of surgery assessed by the scoring system of Girish B.K et al (2):-

Quality of Intraoperative Anaesthesia included (QIPA) SCORE:-

- score0: No sensation at the site of surgery.
- Score1: Sensation at the site of surgery but no pain.
- Score2: Painful sensation at the site of surgery with supplemental analgesics.

Assessment of total duration of blockade-

Sensory- time elapsed from regression to S1 dermatome level from T12 which was tested by pin prick method after completion of surgery every 15 min.

Motor-time elapsed from onset of complete motor block to regression to modified bromage score 0 which was checked every 15 min after completion of surgery.

Total duration of analgesia:-

Time between highest level of established sensory block and first request to analgesic dose.

- Partial and incomplete effects of spinal anaesthesia as well as surgery duration more

than 3 hours was considered as drop outs from the study.

- Hypotension, defined as a decrease in systolic blood pressure less than 30% from baseline, was treated with IV ringer lactate bolus 5 ml/kg, if refractory to IV fluids IV Mephentermine was given in incremental doses. Bradycardia, <60 beats /min, when encountered was treated with IV Atropine given in small incremental doses. The patients were observed 24 hours for nausea, vomiting, and any complications.

DATA COLLECTION PROCEDURE:-

Data collected by using proforma.

VARIABLES

Independent variable-

- Age
- Gender
- ASA grade-I and II
- Socioeconomic Status
- Educational Standard
- Dependent variable-
- SBP, DBP, MAP
- Heart Rate
- SPO2
- Pulse Rate
- Respiratory Rate

LIST OF VARIABLES	MEASUREMENT PLAN
Time of onset and duration of sensory block	MINUTES
Time of complete motor block	MINUTES
Duration of complete motor block	MINUTES
Highest level of sensory block	DERMATOMAL LEVEL
Heart rate	PER MINUTE
Blood pressure	MM HG
Respiratory rate	PER MINUTE

STATISTICAL ANALYSIS PLAN:-

All the data were entered into a spreadsheet and using statistical package for social science SPSS version 22 for windows. Descriptive statistical methods were used to summarize the data. Student's t-test was used for continuous variables and chi-square test was used for categorical data. Statistical significance was considered to be present if p value was less than 0.05.

SAMPLE SIZE:-

Minimum Sample size determination:

Sample size 40 was derived from this following formula

For equivalent design, the following formula was applicable in our prospective study $N = 2 \times 2 \times P(1-P)$

Where, N=minimum sample size,

P=Prevalence rate (As per according 50%=.50, because it is unknown $1-P = 1-.50 = .50$, α = Level of significance, taken $(1 - \beta) =$ Power of test=80%

So, δ = The real difference between two treatment or clinical acceptance margin or error=20% (assumed) = .20, $Z_{1-\alpha}$ =Standard normal variable =1.64(from statistical table), $Z_{1-\beta}$ = 0.845 (From statistical table), Hence, $N = (1.64 + .845 / .20)^2 \times .50$

$= (2.49 / .2)^2 \times .25$

$= 38.59$

$N = 40$ (Round Figure)

The minimum sample size calculated was 40, therefore, as per our objective, there were two groups so I took 30+30= 60 samples of our study.



III. OBSERVATIONS AND RESULTS-

Our study comprised 60 patients who underwent elective infraumbilical surgeries under spinal anaesthesia divided into two groups, each comprising 30 patients. Group L was administered with 0.5% hyperbaric Levo bupivacaine 0.25% and group B was administered with 0.5% hyperbaric Bupivacaine. Each group had an equal number of patients—30 and constituted 50% of the study population, respectively.

Male and females are equal in both groups [15:15]. the distribution of patients according to gender was comparable across both groups, and the differences between the two groups were not statistically significant ($p = 1$).

The group L had 17 patients in the age group of 18 to 30 years as compared to 11 patients in the group B. In the age group of 31 to 45 years, 10 patients were in the group L, while 14 patients were in the group B. In the age group of 46 to 60 years, three (03) patients were in the group L while five (05) patients were in the group B. The difference between the two groups was not statistically significant ($p = 0.29$).

There are 24 patients in group L and 25 patients in group B were in the ASA I respectively. Only six (06) patients in group L and five (05) patients in group B belonged to ASA II. The difference was not statistically significant ($p = 0.74$).

Table 1:-Patients' distribution according to ASA Grade

ASA	Groups		□ 2,pvalue*
	Group L	Group B	
I	24 (80)	25 (83.3)	0.11, 0.74
II	06 (20)	05 (16.7)	
Total	30 (100)	30 (100)	

*p value <0.05 statistically significant; Chi-square test applied

The distribution of patients was comparable across two groups in terms of their body mass index. The difference between the two groups was not statistically significant ($p = 0.84$).

Table 2:-Patients' distribution according to body mass index (BMI)

Body mass index (BMI)	Groups		□ 2,pvalue*
	Group L	Group B	
Normal (18.5–22.9 Kg/m ²)	15 (50.0)	16 (53.4)	0.36, 0.84
Over weight(23.0–24.9 Kg/m ²)	09 (30)	07 (23.3)	
Obese(≥25 kg/m ²)	06 (20)	07 (23.3)	
Total	30 (100)	30 (100)	

*p value <0.05 statistically significant; Chi-square test applied

The comparison of pre-operative vital parameters between two groups. It can be seen that all vital parameters such as pulse rate, SBP, DBP, MAP, respiratory rate and oxygen saturation

(SpO₂) were comparable across both the groups and had no statistically significant difference between them pre-operatively.

Table 3:-Comparison of pre-operative vital parameters between two groups

Vital parameters	Group		T statistic, p-value*
	Group L	Group B	
Pulserate(in beats/min)	81.03 ± 10.38	81.30 ± 12.68	-0.09, 0.93
SBP (mm Hg)	127.43 ± 10.67	124.37 ± 9.88	1.15, 0.25
DBP (mm Hg)	79.80 ± 8.28	75.87 ± 7.49	-1.93, 0.06
MAP (mm Hg)	93.73 ± 9.42	91.73 ± 7.89	0.89, 0.38
Respiratory rate (in breaths/min)	13.60 ± 1.99	13.60 ± 1.67	00, 1
SpO ₂ (%)	98.27 ± 0.69	98.33 ± 0.71	-0.36, 0.71

* p value < 0.05 statistically significant; Independent samples t-test applied; SBP – Systolic blood pressure; DBP – Diastolic blood pressure; MAP – Mean Arterial Pressure; SpO₂ – Oxygen saturation



It can be seen that all vital parameters such as pulse rate, SBP, DBP, MAP, respiratory rate and oxygen saturation (SpO₂) were comparable across both the groups and had no statistically significant difference between them pre-operatively.

The comparison of sensory block characteristics in both the groups, the levobupivacaine group (Group L), the meantime of onset of sensory block was 4.3 minutes as compared to 2.80 minutes in bupivacaine group (Group B)

which was statistically significant ($p = 0.001$).

Total duration of sensory block was higher in patients administered with bupivacaine (group B) (189.37 minutes) as compared to the mean total duration of sensory block in patients administered with levobupivacaine and the difference between two groups was statistically significant ($p = 0.001$). Both findings imply that bupivacaine was comparatively better than levobupivacaine in terms of sensory block characteristics.

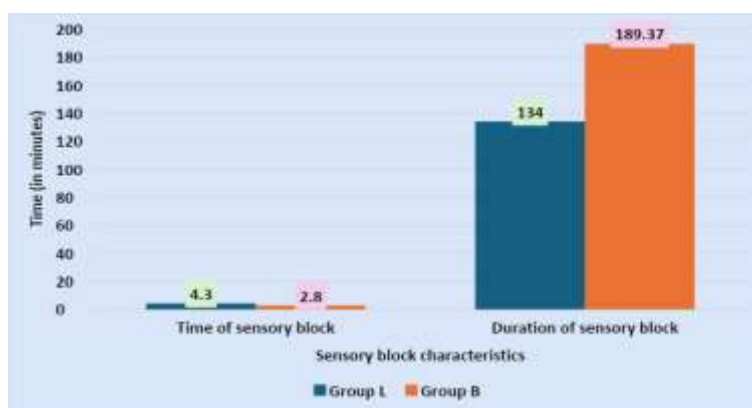


Figure 1:- Comparison of sensory block characteristics

The comparison of motor block characteristics in the present study. In the levobupivacaine group, the mean time of complete motor block was 5.40 minutes in comparison to the meantime of complete motor block in bupivacaine group (3.90 minutes). The difference between two groups was found to be statistically significant ($p = 0.001$).

The duration of complete motor block was

higher in the bupivacaine group (194.80 minutes) as compared to the mean duration of complete motor block in the levobupivacaine group (131.60 minutes). The difference between two groups was statistically significant ($p = 0.001$).

Both finding simply that bupivacaine was comparatively better than levobupivacaine in terms of motor block characteristics.

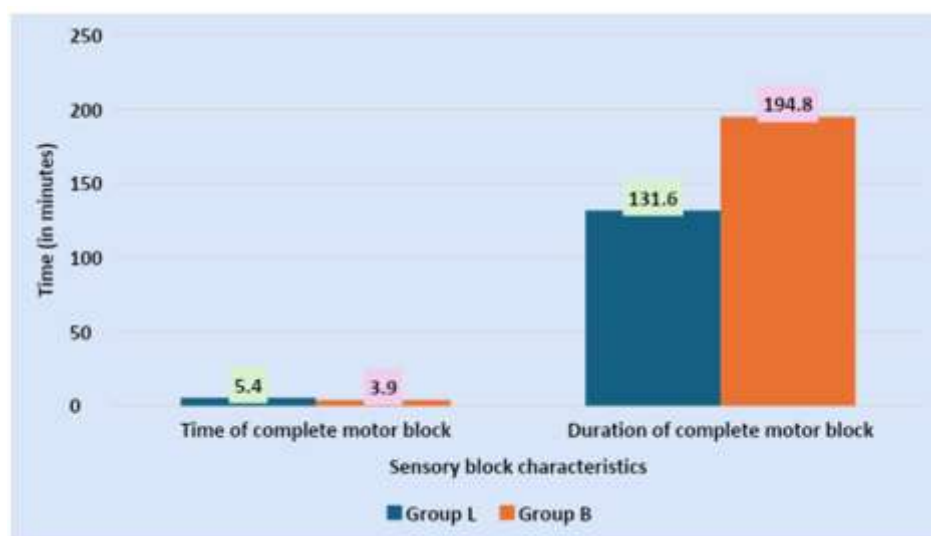


Figure 2:- Comparison of motor block characteristics



On comparing intraoperative heart rate (in beats/minute) between two groups at different time intervals. It can be seen that in both groups, the pulse showed variation at various time intervals. However, statistically significant difference was found between the two groups at any time intervals ($p > 0.05$) using an independent sample t-test except for at 3 minutes.

On comparing of the two study groups' intraoperative systolic blood pressure (in mm Hg). It can be seen that there was less volatility at different time intervals, with SBP showing minimal variation at various points in the period in both study groups. However, it was better in the patients who were administered with levobupivacaine than bupivacaine, and the difference between the two was statistically significant ($p < 0.05$) at 3, 4, 5, 20, 25 and 30 minutes respectively.

On comparing intraoperative diastolic blood pressure (DBP) among the two groups, it was found that mean diastolic blood pressure showed less variation and stayed in the range of 64 to 80mm Hg in group L. In group B, the mean diastolic blood pressure had more variability and oscillated between 65 to 80 mm Hg. The difference between the two groups was statistically significant at 4, 5, 10, 20, 25, 30, 60 and 135 minutes ($p < 0.05$).

On comparing intraoperative mean arterial pressure (MAP) among two groups. It can be seen that in both groups, mean arterial pressure declined in the first three minutes followed by it going gradually up in the follow-up period. The difference between two groups was found to be statistically significant at 3,10,15,20,25,30, 45, 60, 105, 135 and 150 minutes with levobupivacaine showing more MAP than bupivacaine group ($p < 0.05$).

On comparing intraoperative oxygen saturation (SpO₂) among two groups, no significant difference was observed in patients administered with bupivacaine as compared to levobupivacaine. The difference between two groups was not statistically significant.

On comparing post-operative heart rate among two groups. It varied from 72 beats per minute to 87 beats per minute in patients administered with levo bupivacaine. In patients administered with bupivacaine, it varied from 71 beats per minute to 85 beats per minute. The difference between two groups was statistically significant at all observed intervals except for at 24 hours ($p < 0.05$).

On comparing of post operative systolic

blood pressure among two groups at different time intervals. Among patients administered with levobupivacaine, systolic blood pressure varied from 121.40 mm Hg to 120.30 mm Hg while in patients administered with bupivacaine, it varied from 120.57 mm Hg to 119.20 mm Hg. The difference between the two groups was not statistically significant at anytime interval ($p > 0.05$).

On comparing post operative diastolic blood pressure among two groups, the difference was found to be statistically significant between two groups at 4 and 24 hours ($p = 0.03$).

On comparing of post operative mean arterial pressure (MAP) among two groups, the mean arterial pressure in the levo bupivacaine group was constantly stable throughout the observation period and it was similar in the bupivacaine group. The difference between the two groups was not statistically significant ($p > 0.05$).

On comparing of post operative respiratory rate among two groups, the mean respiratory rate in the levo bupivacaine group was higher than the mean respiratory rate in the bupivacaine group at all observed time intervals except at 24 hours. The difference between the two groups was statistically significant at all observed intervals ($p < 0.05$).

On comparing of complications among two groups in the present study, vomiting was present in two (02) patients in the bupivacaine group as compared to no patient in the levobupivacaine group. However, the difference between two groups was not statistically significant ($p = 0.49$).

Hypotension was present in three (03) patients in the levobupivacaine group as compared to six (06) patients in the bupivacaine group. The difference between two groups was not statistically significant ($p = 0.47$).

Bradycardia was present in only one (01) patient in the levobupivacaine group as compared to six (06) patients in the bupivacaine group. The difference between two groups was not statistically significant ($p = 0.10$).

Nausea was seen in five (05) patients in the bupivacaine group as compared to no patient in the levo bupivacaine group. The difference between two groups was not statistically significant ($p = 0.05$). Shivering as a complication was observed in only one (01) patient in the levobupivacaine group as compared to two (02) patients in the bupivacaine group. The difference between two groups was not statistically significant ($p = 1$).



Table 4 Comparison of complications among two groups

Complications	Groups		□ 2,p-value*
	Group L	Group B	
Vomiting			
Yes	00 (00)	02 (6.7)	Fisher's Exact,0.49
No	30 (100)	28 (93.3)	
Hypotension			
Yes	03 (10)	06 (20)	Fisher's Exact,0.47
No	27 (90)	24 (80)	
Bradycardia			
Yes	01 (3.3)	06 (20)	Fisher's Exact,0.10
No	29 (96.7)	24 (80)	
Nausea			
Yes	00 (00)	05 (16.7)	Fisher's Exact,0.05
No	30 (100)	25 (83.3)	
Shivering			
Yes	01 (3.3)	02 (6.7)	Fisher's Exact,1.00
No	29 (96.7)	28 (93.3)	
Total	30 (100)	30 (100)	

*p value < 0.05 statistically significant; Fisher's Exact test applied

The mean total duration of analgesia in the bupivacaine group was 200.23 minutes as compared to 198.97 minutes in the levo bupivacaine group. However, the difference between the two groups was not statistically significant ($p = 0.76$).

On comparing the level of maximum

sensory blockade between two groups. 90% of patients in levo bupivacaine group had T8 level as maximum level of sensory blockade while 60% of patients in bupivacaine group had T6 as maximum level of sensory blockade. The difference between two groups was statistically significant ($p = 0.001$).

Table 5:-Comparison of level of maximum sensory blockade between two groups

Level of maximum sensory blockade	Groups		□ 2,pvalue*
	Group L	Group B	
T6	03 (10)	18 (60.0)	20.52, 0.001
T8	27 (90)	10 (33.3)	
T10	00 (00)	02 (6.7)	
Total	30 (100)	30 (100)	

*p value < 0.05 statistically significant; Chi-square test applied

On comparing modified Bromage scale score between two groups. 63.3% of patients in levobupivacaine and bupivacaine group had score of three (03) on modified Bromagescale. 36.7% of patients in the bupivacaine group had a score of two (02) as compared to 26.7% of patients in the levobupivacaine group. The difference between two groups was not statistically significant ($p = 0.18$).

On comparing QIPA scoring between two groups. 66.7% of patients in levobupivacaine and bupivacaine group had score of zero (00) on QIPA scoring. 33.3% of patients in bupivacaine group had score of one (01) as compared to 30% of patients in the levobupivacaine group. The difference between two groups was not statistically significant ($p=0.59$).

IV. DISCUSSION-

Regional anaesthesia has several advantages over general anaesthesia in terms of reduced bleeding due to hypotension, better intraoperative and postoperative analgesia. It is used in awake patients, there are less requirements of parenteral opioids and decreased incidence of nausea and vomiting. There are also less incidences of venous thromboembolism, myocardial infarction, respiratory complications and renal failure in subarachnoid block.

Subarachnoid block is the current widespread popular anaesthetic technique available today. It has the definite advantage that a profound nerve block can be produced in a large part of the body by are latively simple injection of a small amount of local anaesthetic. An ideal anaesthetic



agent used in subarachnoid block should have rapid onset of action, intense analgesia, adequate motor blockade, long duration of action, adequate post operative analgesia and minimal cardiovascular change. Bupivacaine introduced by Ekenstam in 1957 seems to fulfill most of the requirements of an ideal local anaesthetic agent. It is a widely used local anaesthetic that has a prolonged action. Bupivacaine is more cardiotoxic than other local anaesthetics and has been associated with deaths when injected intravenously accidentally.

Levobupivacaine is the pure S () enantiomer of racemic bupivacaine, developed as an alter native anaesthetic agent to Bupivacaine. Levo bupivacaine has similar blocking properties and greater margin of safety due to reduced toxic potential.

We started our study with a null hypothesis that hyperbaric levobupivacaine is comparable with hyperbaric bupivacaine in sensory and motor block characteristics and concluded with the acceptance of the null hypothesis. We took 60 patients of the age group between 18-70 years, posted for various elective infraumbilical surgeries under spinal anaesthesia belonging to ASA physical status 1 and 2 for comparing 0.5% (3ml) Levobupivacaine and 0.5% (3ml) Bupivacaine.

In our study there were no statistically significant differences in terms of demographic properties or ASA grading, the mean age, spo₂, BMI, pre-operative vital parameters and gender of patients as in studies done by Girish B. Ket al.(1), Y.Y Lee et al.(4), Glaser et al.(5) and T. Sathikarnmanee et al.(21).

The first characteristic studied was the meantime of onset of sensory block. The onset of sensory block was taken as the time in minutes from the deposition of drug to the evidence of loss of sensation to pinprick at T 12 level. In the Levobupivacaine group (Group L), the mean time of onset of sensory block was 4.3 minutes as compared to 2.80 minutes in Bupivacaine group (Group B) which was statistically significant ($p = 0.001$). Our results can be compared with the studies done by Preeti Parasar et al.(2), A. Goyal et al.(3), Monica et al.(29).

Total duration of sensory block was higher in patients administered with Bupivacaine (group B) (189.37 minutes) as compared to the mean total duration of sensory block in patients administered with Levobupivacaine and the difference between two groups was statistically significant ($p=0.001$) as reported in studies done by Preeti Parasar et al.(2), A. Goyal et al.(3), Ajay sing h et al.(6) Guler et al.(28).

Time to reach the maximum height of

sensory blockade was 10.26 minutes in the Levobupivacaine group as compared to 9.23 minutes in the Bupivacaine group. The difference between two groups was statistically significant ($p=0.01$) similar to the studies done by Preeti Parasar et al. (2), Erdil et al.(20).

Maximum level of sensory block achieved in 90% of patients in Levobupivacaine group had T8 level as maximum level of sensory blockade while 60% of patients in Bupivacaine group had T6 as maximum level of sensory blockade. The difference between two groups was statistically significant ($p=0.001$) similar to studies done by Ayesha et al.(3), Hakan erbay et al.(17), Erdil et al.(20), Monica et al.(29).

The mean time of complete motor block in the Levobupivacaine group was 5.40 minutes in comparison to the mean time of complete motor block in Bupivacaine group (3.90 minutes). The difference between two groups was found to be statistically significant ($p = 0.001$) similar to studies done by Girish B. Ket al.(1), Hakanerbay et al.(17), Monica et al.(29).

The duration of complete motor block was higher in the Bupivacaine group (194.80 minutes) as compared to the mean duration of complete motor block in the levobupivacaine group (131.60 minutes). The difference between two groups was statistically significant ($p = 0.001$) comparable to the studies done by Girish B.K et al.(1), Ajay Singh et al.(6), Guler et al.(27). Both findings imply that bupivacaine was comparatively better than levobupivacaine in terms of motor block characteristics.

The comparison of modified Bromage scale score between two groups. 63.3% of patients in levobupivacaine and bupivacaine group had score of three (03) on modified Bromage scale. 36.7% of patients in bupivacaine group had score of two (02) as compared to 26.7% of patients in the levobupivacaine group. The difference between two groups was not statistically significant ($p = 0.18$) comparable with the studies done by Girish B.K et al.(1), Hakan Erbay et al.(17).

Comparison of intraoperative heart rate among two groups at different time intervals showed that in both groups, there was significant pulse variation. However, statistically significant differences were found between the two groups at all time intervals i.e from 0 min to 24hrs except for at 3 minutes, ($p > 0.05$) using an independent sample t-test similar to the study of Preeti Parasar et al.(2).

On comparing the intraoperative systolic blood pressure (in mmHg) in both the study groups, we found out that there was less volatility at



different time intervals, with SBP showing minimal variation at various points in the period. However, it was better in the patients who were administered with levobupivacaine than bupivacaine, and the difference between the two was statistically significant ($p < 0.05$) at 3, 4, 5, 20, 25 and 30 minutes as studies done by Preeti Parasar et al.(2).

On comparing intraoperative diastolic blood pressure (DBP) among the two groups, it was found that mean diastolic blood pressure showed less variation and remained in the range of 64 to 80 mm Hg in group L. In group B, the mean diastolic blood pressure had more variability and oscillated between 65 to 80 mm Hg. The difference between the two groups was statistically significant at 4, 5, 10, 20, 25, 30, 60 and 135 minutes ($p < 0.05$) similar to the study of Preeti Parasar et al.(2).

The comparison of intraoperative mean arterial pressure (MAP) among two groups showed that mean arterial pressure declined in the first three minutes followed by going gradually up in the follow-up period. The difference between two groups was found to be statistically significant at 3, 10, 15, 20, 25, 30, 45, 60, 105, 135 and 150 minutes with levobupivacaine showing more MAP than bupivacaine group ($p < 0.05$) in compliance with the studies done by Preeti Parasar et al.(2).

We also compared post operative heart rate in both the groups. It varied from 72 beats per minute to 87 beats per minute, and 71 beats per minute to 85 beats per minute in patients administered with levobupivacaine and bupivacaine respectively. The difference between two groups was statistically significant at all observed intervals except for at 24 hours ($p < 0.05$).

The comparison of post-operative systolic blood pressure among two groups at different time intervals showed that in the patients administered with levobupivacaine, systolic blood pressure varied from 121.40 mm Hg to 120.30 mmHg while in patients receiving bupivacaine, there was higher variation from 120.57 mm Hg to 119.20 mm Hg. However the difference between the two groups was not statistically significant at anytime interval ($p > 0.05$). The comparison of post-operative diastolic blood pressure gave a statistically significant difference between two groups at 4 and 24 hours ($p = 0.03$) in contrast to postoperative mean arterial pressure. The comparison of postoperative mean arterial pressure (MAP) among two groups gave a comparable result as it was constantly stable in both the levobupivacaine and bupivacaine group throughout the observation period. The difference between the two groups was not statistically significant ($p > 0.05$) at anytime interval similar to studies by Preeti Parasar et al.(2)

The mean total duration of analgesia in the bupivacaine group was 200.23 minutes as compared to 198.97 minutes in the levobupivacaine group. However, the difference between the two groups was not statistically significant ($p = 0.76$) like in studies by Girish B. K et al.(1), A.Goyal et al.(3), Ajay singh et al.(6), Hakan Erbay et al.(17), Guler et al.(27)

While comparing QIPA (Quality of intraoperative anaesthesia) scoring between two groups we found that 66.7% of patients in levobupivacaine and bupivacaine group had score of zero (00) on QIPA scoring. 33.3% of patients in the bupivacaine group had a score of one as compared to 30% of patients in the levobupivacaine group. The difference between two groups was not statistically significant ($p = 0.59$) similar to the study done by Girish B.K et al.(1), Ajay singh et al.(6).

Post operative complications like vomiting, shivering, post dural puncture headache and hypotension were comparable in both the groups and were statistically not significant. Similar Findings were seen in other studies also Ajay Singh et al.(6), Kopp SL et al.(14), Dasetal. (26).

The present study demonstrates that there is statistically significant difference between both the groups in terms of sensory and motor block characteristics, intraoperative and post operative hemodynamic parameters. The Levobupivacaine group offers less hemodynamic variability as compared to the bupivacaine group.

Based on our findings levobupivacaine seems to be an interesting alternative to bupivacaine for elective infraumbilical surgeries.

V. CONCLUSION-

Levobupivacaine, since its introduction into clinical practice, has been appreciated because of its lower degree of toxicity when compared to Bupivacaine. The early onset of sensory and motor blockade by hyperbaric Levobupivacaine can be used in short duration surgery where a rapid return of ambulatory function is desirable. Levobupivacaine with its almost similar block characteristics to bupivacaine can be advantage for high risk comorbid patients where minimal variation in hemodynamic parameters can be deleterious.

Therefore, we conclude that 0.5% hyperbaric Levobupivacaine can be used as a safer alternative to 0.5% hyperbaric Bupivacaine for infraumbilical surgeries.



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