How to Cite:
Bekkam, G. J., Bano, I., Chandrika, B., & Tahseen, S. (2022). Comparison of 0.5% isobaric Levobupivacaine with 0.5% hyperbaric Bupivacaine in patients undergoing lower abdominal surgeries. *International Journal of Health Sciences*, *6*(S6), 6439–6449. https://doi.org/10.53730/ijhs.v6nS6.11012

Comparison of 0.5% isobaric Levobupivacaine with 0.5% hyperbaric Bupivacaine in patients undergoing lower abdominal surgeries.

Dr. Giridhar Janampet Bekkam
Assistant Professor of Anaesthesia Panimalar medical college hospital and research institute, Chennai

Dr. Ishrat Bano
Assistant professor of Anaesthesia, Panimalar Medical college hospital and research Institute, Chennai

Dr. B. Chandrika
Professor & HOD of Anaesthesia, Panimalar Medical college hospital and research Institute, Chennai

Dr. Sumaiya Tahseen
Assistant Professor of Anaesthesia, Panimalar Medical college hospital and research Institute, Chennai
*Corresponding author email: sumaiya.tahseen@gmail.com

Abstract---Background: Since more than a century ago, spinal anaesthesia has been a preferred approach for lower abdominal procedures. Local anaesthetics are selected primarily based on onset, duration, strength of sensory and motor block, and side effects. The aim of our study was to compare sensory and motor block characteristics, hemodynamic changes, and side effects following isobaric levobupivacaine (0.5%) and hyperbaric Bupivacaine (0.5%) in elective lower abdominal surgeries under spinal anesthesia. Materials and methods: A randomized, double-blind study was carried out on 60 patients of either sex, aged 18-60 years, ASA grade I or II scheduled for elective lower abdominal surgeries. Patients were divided into two groups of 30 patients each. Group L received 3 ml of 0.5% levobupivacaine, and Group B received 3 ml of 0.5% bupivacaine. We observed the characteristics of the sensory and motor blockade & side effects in both groups. Results: The mean time of onset of sensory block was 12.68±0.6 minutes in group L, while 7.22±0.7 minutes in group B. The mean time for total duration of sensory block was 211.1±8.2 minutes in group L, while 183.13±13.7 minutes in group B. Time for the total duration of motor block in group L was 198.76±8.4

minutes and in group B was 182.6±13.9 minutes. Statistically, significant difference was observed in total duration of sensory and motor block in both levobupivaciane and bupivacaine group ($p<0.01$). Stable haemodynamics and less side effects were observed in group L compared to group B. Conclusions: We observed that 0.5% levobupivacaine provided better hemodynamic stability, longer duration of sensory and motor block, and less side effects as compared to bupivacaine.

Keywords---levobupivacaine, Bupivacaine, motor blockade, sensory blockade.

Introduction

For lower abdominal surgery, spinal anaesthesia is a simple, affordable, and generally preferred approach because it quickly induces sensory and motor block, attenuates the stress response, and reduces thromboembolic episodes. Despite the fact that bupivacaine is the local anaesthetic that is most frequently used in spinal anaesthesia, there have been situations where an accidental intravascular injection of bupivacaine during an attempt at neuraxial anaesthesia led to a rapid cardiac arrest that was resistant to resuscitation. [1],[2] Amide local anaesthetics come in Levo S (-) and dextro R (+) stereoisomer forms and feature a chiral centre. Dextro form was discovered to be the most poisonous among the isomers. [3]. The increase in day care surgery has generated a need for a local anaesthetic with a faster onset and shorter duration of action, allowing early ambulation. Moreover, the development of Levobupivacaine, a novel long-acting amide[4] with a reasonably stable hemodynamic profile, was driven by the serious concern regarding the cardiotoxicity of bupivacaine.

The first levo enantiomer to be released, ropivacaine, had a stronger safety profile[5] than bupivacaine but was less potent[6] and was unable to replace bupivacaine. Levobupivacaine is a novel long-acting amide[3] with a somewhat stable hemodynamic profile as a result of the main worry regarding the cardiotoxicity of Bupivacaine. Levobupivacaine has a superior safety profile than bupivacaine and is virtually as potent[7]. [8] As seen with bupivacaine,[9] ropivacaine,[10] and levobupivacaine, hyperbaric local anaesthetic preparations are currently recommended for spinal anaesthesia because they generate an efficient sensory and motor block with an earlier onset than plain solution. [11] In order to examine the features of sensory-motor blocks, hemodynamic profiles, and side effects with similar doses of isobaric levobupivacaine and hyperbaric bupivacaine administered spinally to patients having lower abdominal surgery, we devised the current study

Material and Methods

After institutional ethical committee clearance and informed written consent had been taken from patients, the present study was carried out in the Department of Anesthesia, Panimalar medical college hospital and research institute, Chennai.

Study Design

A prospective, randomized, doubleblind, comparative study.

Study Population

Sixty patients of ASA I, II of either sex or ages between 18-65 yrs scheduled for elective lower abdominal surgery under spinal anaesthesia were enrolled in the study.

Exclusion Criteria

Were patients with coagulation disorders, on anticoagulants, patient refusal, spinal deformity, allergic to amide local anaesthetics, morbid obesity (body mass index >29 kg/m2), Systemic illness, musculoskeletal and psychiatric diseases that could make our technique difficult.

Randomization and group allocation

Sixty patients were randomly allocated into two groups of 30 each using sealed envelope method, depending on the drug regime used for spinal anaesthesia as follows: Group B: received 3 ml of 0.5% hyperbaric bupivacaine (15 mg). Group L: received 3 ml of 0.5% plain (isobaric) levobupivacaine (15 mg).

Spinal Anaesthesia Technique

Following arrival in the pre-anaesthetic room, intravenous access was secured and preloaded with 500 ml Ringer lactate and was briefed about the methods used for sensory and motor assessments. Standard monitoring were applied including containing non-invasive blood pressure (NIBP), electrocardiography (ECG), heart rate (HR) and pulse oximetry (SpO2). Baseline values were noted. With the patients in the sitting position, and under strict aseptic conditions, a lumbar puncture was performed in the midline at L3-L4 interspace, using Quincke 25G spinal needle. Correct needle placement was identified by free cerebrospinal fluid (CSF) flow. The study drug was given into subarachnoid space according to group allocation, and the patient was placed supine.

Data Recording

Sensory block was measured by the pinprick method[13] at 2, 4, 6, 8, 10, 12 and 15 minutes after drug injection to assess the time taken to reach T10 level, peak block height. Absence of sensation to pinprick was considered as the sensory block. Motor block was assessed based on modified Bromage scale as follows.[13]

0= no paralysis, able to flex hips, knees, ankles;
1= able to move knees but unable to raise extended legs
2=able to flex ankles, unable to flex knees;
3= not able to move any part of the lower limb.

Motor block was also assessed at 2, 4, 6, 8, 10, 12 and 15 minutes after spinal anaesthesia. Onset time of motor block (time to reach maximum Bromage score) was also recorded. Complete motor block was defined as interval between administration and to a Bromage score of 3. Intraoperative heart rate (HR) and non - invasive blood pressure (NIBP) was recorded initially at 2- minute interval for the first 10 min, after that every 5 minutes till the end of surgery. Intraoperative fluid and blood transfusion were given as per losses and maintenance required. Hypotension was defined as a decrease in the systolic blood pressure (SBP) of less than 100 mmHg and was treated with an injection of 6 mg Ephedrine IV and fluids. Bradycardia was defined as fall in HR less than 60 beats per min and was treated with atropine 0.6mg IV bolus.

Incidence of intraoperative hypotension, bradycardia, nausea, vomiting, or other side effects were noted and treated accordingly. Duration of surgery was defined as the time from the start of surgery up to the last suture. In post-anaesthesia care unit, for recovery characteristics, sensory and motor block were checked every 30 minutes till sensory regression to L1 and Bromage score returns to zero. Vital parameters (HR, NIBP) were also noted at the same intervals. Duration of analgesia was defined as time of the first complaint of postoperative pain and rescue analgesia in the form of Tramadol 100 mg IV was given as per institutional protocol. Statistical Analysis Quantitative data were presented as mean and standard deviation, and analyzed by using Student ttest. Qualitative data were presented as number (proportion or %). $P<0.05$ was considered statistically significant.

Results

Table 1 shows the age wise and weight wise distribution was similar in both the groups

Table 1
Comparison of demographic parameters

Demographic parameters	Group L (N=30)	Group B (N=30)
Age (Years)	37.64±6.84	36.38±8.62
Weight (Kgs)	55.62±4.92	56.54±6.72

Table 2 shows the mean time of onset of Analgesia was achieved earlier in group B and was statistically significant ($p<0.01$.

Table 2
Mean time of onset of Analgesia in Minutes

Group	Mean+SD	P-Value
Group L	12.68±0.6	0.02
Group B	7.22±0.7	

Table 3 shows the Mean duration of Analgesia was more in Group L and was statistically significant

Table 3
Mean Duration of Analgesia in Minutes

Group	Mean+SD	P-Value
Group L	211.1±8.2	0.04
Group B	183.13±13.7	

Table 4 shows the Onset of Motor blockade was achieved early in Group B and was statistically significant.

Table 4
Onset of Motor blockade

Group	Mean+SD	P-Value
Group L	8.60±0.9	0.02
Group B	4.56±0.6	

Table 5 shows the total duration of Motor Blockade was more in group L and was statistically significant.

Table 5
Total duration of Motor blockade

Group	Mean+SD	P-Value
Group L	198.76±8.4	0.01
Group B	182.6±13.9	

Table 6 shows the heart rate changes between the 2 groups at baseline, 3min, 5 min then every 5 min till 30 min. later Heart rate was recorded every 15 min till 90 min. Lesser decrease in Heart rate was was found in L group compared to B group.

Table 6
Heart rate changes in both groups

Parameter	Group B		Group L		P-value
	Mean	SD	Mean	SD	
HR Baseline	88.21	13.66	89.21	11.74	0.52
HR 3 min	87.24	14.44	85.72	12.93	0.24
HR 5 min	85.14	15.27	81.21	8.54	0.01
HR 10 min	80.23	12.76	77.12	8.76	0.23
HR 15 min	73.21	10.66	72.14	12.89	0.02
HR 20 min	76.21	10.35	71.01	11.09	0.01

HR 25 min	71.32	8.72	70.29	7.24	0.04
HR 30 min	75.21	9.28	69.23	8.06	0.04
HR 45 min	67.28	9.82	68.24	8.38	0.06
HR 60 min	68.32	9.07	68.34	8.31	0.02
HR 75 min	64.21	8.47	69.45	7.61	0.01
HR 90 min	62.24	8.06	68.42	7.29	0.02

Table 7 shows the systolic blood pressure changes between the 2 groups at baseline, 3min, 5 min then every 5 min till 30 min. later SBP was recorded every 15 min till 90 min. Lesser fall in SBP was observed in L group compared to B group.

Table 7
Systolic Blood pressure changes in both groups

Parameter	Group B		Group L		P-value
	Mean	SD	Mean	SD	
SBP Baseline	131.23	12.13	129.46	13.29	0.43
SBP 3 min	122.82	11.74	124.22	19.76	0.78
SBP 5 min	117.75	11.56	122.48	12.18	0.03
SBP 10 min	113.96	10.94	120.68	10.98	0.04
SBP 15 min	111.65	11.35	118.92	11.29	0.01
SBP 20 min	108.95	10.57	118.42	11.50	0.03
SBP 25 min	107.68	8.73	117.44	11.68	0.02
SBP 30 min	109.92	8.25	115.24	18.47	0.06
SBP 45 min	108.65	8.31	116.62	10.38	0.02
SBP 60 min	109.24	7.56	115.64	10.19	0.01
SBP 75 min	108.52	7.01	116.82	9.11	0.01
SBP 90 min	109.86	7.18	116.22	9.30	0.01

Table 8 shows the Diastolic blood pressure changes between the 2 groups at baseline, 3min, 5 min then every 5 min till 30 min. later DBP was recorded every

15 min till 90 min. Lesser decrease in DBP was observed in B group compared to L group

Table 8
Diastolic Blood pressure changes in both groups

Parameter	Group B		Group L		P-value
	Mean	SD	Mean	SD	
DBP Baseline	80.21	8.47	78.87	6.70	0.42
DBP 3 min	77.56	7.23	78.45	8.38	0.82
DBP 5 min	71.88	8.42	75.96	8.80	0.53
DBP 10 min	69.54	6.53	73.38	8.41	0.01
DBP 15 min	68.32	8.47	73.49	8.25	0.04
DBP 20 min	67.87	7.38	72.43	7.81	0.02
DBP 25 min	67.95	5.27	72.87	7.83	0.01
DBP 30 min	66.41	9.12	72.92	7.82	0.02
DBP 45 min	66.28	4.72	72.04	9.33	0.02
DBP 60 min	66.62	9.20	72.06	6.52	0.03
DBP 75 min	66.36	6.31	71.76	8.90	0.02
DBP 90 min	66.18	6.54	71.84	7.44	0.01

Table 9 shows the Mean arterial blood pressure changes between the 2 groups at baseline, 3min, 5 min then every 5 min till 30 min. later MABP was recorded every 15 min till 90 min. Lesser decrease in MABP was noted in L group compared to B group

Table 9
Mean arterial Blood pressure changes in both groups

Parameter	Group B		Group L		P-value
	Mean	SD	Mean	SD	
MAP baseline	89.14	11.91	90.21	11.26	0.03
MAP 3min	85.21	13.40	88.14	12.31	0.02
MAP 5 min	80.32	10.55	88.78	14.32	0.01

MAP 10 min	80.12	9.82	86.45	11.61	0.01
MAP 15 min	78.20	9.67	85.28	11.03	0.01
MAP 20 min	77.24	9.04	84.20	17.88	0.03
MAP 25 min	75.82	7.00	84.15	15.35	0.02
MAP 30 min	75.15	7.93	86.19	11.31	0.01
MAP 45 min	76.16	7.74	84.91	10.44	0.01
MAP 60 min	75.32	8.31	83.50	11.72	0.01
MAP 75 min	74.16	6.18	81.32	8.78	0.04
MAP 90 min	74.28	6.23	80.11	9.53	0.01

Table 10 shows the frequency of side effects between the 2 groups. 7 patients had hypotension in the B group whereas 1 patient in L group. 6 patients In the Bupivacaine group had bradycardia whereas 2 patients in the Levobupivacaine group. Total number of patients suffering from side effects is more in Bupithe vacaine group, compared to Levothe bupivacaine group.

Table 10
Frequency of side effects in both groups

Parameter	Group B	Group L
Hypotension	7	1
Bradycardia	6	2
Nausea/Vomiting	3	0
Shivering	2	0

Discussion

Our study compared isobaric levobupivacaine and hyperbaric bupivacaine for spinal anaesthesia in elective lower abdominal procedures on 60 patients divided into 2 groups of 30 patients each. After calculating the time intervals, they were examined for changes in heart rate, systolic blood pressure (SBP), diastolic blood pressure (DBP), mean arterial pressure (MAP), heart rate, time for the onset of sensory and motor block, and length of sensory and motor block. We discovered that compared to bupivacaine, levobupivacaine offers a longer duration of sensory block, motor block, and more hemodynamic stability. In our study, it was found that hyperbaric bupivacaine dramatically increase the onset of motor and sensory blockage. Similar results were also found by Sen H et al. in their investigation. [12] Another study found that when compared to isobaric levobupivacaine or isobaric ropivacaine, hyperbaric bupivacaine produced a faster start of clinically meaningful sensory and motor block. [13]

In comparison to isobaric levobupivacaine, Demarzio[14] et al. found faster onset, greater peak sensory level, and longer duration of the block using hyperbaric bupivacaine during caesarean. Isobaric levobupivacaine does not spread unpredictably high and levels of a sensory block are unaffected by a change in patient position, according to Gori et al's[15] description that the specific gravity of isobaric levobupivacaine is very close to C.S.F. It acts indifferently to gravitational forces both immediately after injection and later. This could be better than bupivacaine, which can spread unpredictably high. In a similar vein, Alley et al. (2002)[16] observed sensory onset of 18±6 min v/s 15±9 min p=0.30 for levobupivacaine and bupivacaine, respectively, when hyperbaric preparations of levobupivacaine and bupivacaine were examined. Hyperbaric bupivacaine had an onset time of 305±110 seconds compared to hyperbaric levobupivacaine's 345±134 seconds, according to Subasi et al.

When compared to isobaric levobupivacaine, hyperbaric bupivacaine caused more hypotension and bradycardia in our study, which is mostly attributable to the more cephalic distribution of hyperbaric solutions. When isobaric and hyperbaric preparations of bupivacaine or levobupivacaine were examined, it was shown that hyperbaric preparations were more likely to cause hypotension and bradycardia, which was linked to hyperbaricity. It is generally known that hyperbaric solutions increase peak levels but may also cause more bouts of bradycardia and hypotension. [20].

Conclusion

In our study it was observed that administration of either hyperbaric Bupivacaine or isobaric Levobupivacaine were well tolerated and provide comparable anesthesia for lower abdomen surgeries. Longer procedures may benefit from isobaric Levobupivacaine's ability to block sensory and motor pathways for a longer period of time. Hyperbaric bupivacaine's quick onset of sensory and motor blocking can be employed for the quick effect required in urgent procedures. We came to the conclusion that 3 ml of 0.5 percent hyperbaric Bupivacaine might be replaced with 3 ml of 0.5 percent isobaric Levobupivacaine as a safer spinal anaesthetic for lower abdomen procedures.

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