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Intraoperative haemodynamic profile in patients undergoing lower limb and abdominal surgery under subarachnoid block using 0.5% hyperbaric levobupivacaine: an observational study

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ABSTRACT

Background: The aim of this study was to detect if intrathecal hyperbaric Levobupivacaine provided anaesthesia with more stable hemodynamic profile than 0.5% Hyperbaric Bupivacaine for lower limb and abdominal surgery.

Methods: This observational study was carried out on 60 Adult patients between 18-65 Years of age, in ASA I and II undergoing lower abdominal surgery. Subarachnoid block using 3.0 ml of 0.5% hyperbaric Levobupivacaine (15 mg) was used as anaesthesia for surgery. Vitals recorded first in operation theatre were taken as baseline and were compared with subsequent readings till closure to judge the fall in blood pressure. Frequencies of parameters falling more than 30% from baseline, amount of IV fluids, vasopressors administered and complications were recorded. The data collected was displayed as mean with a standard deviation and frequency with percentage. Statistical analysis was performed using in stat computer software.

Results: On analysis of the data it was found that fall in hemodynamic parameters was significantly lower in the Levobupivacaine group. It was observed that maximum onset of motor block was after 5 minutes, VAS after 4 minutes and loss of pinprick sensation was achieved at T-4 level after 4 minutes. Haemodynamic complications, which required therapeutic interventions, were hypotension (5%), bradycardia (3%), a total of 8%, who required urgent intervention as vasopressors and inotropes.

Conclusions: 0.5% Hyperbaric Levobupivacaine, has onset of action similar to other local anaesthetics used for subarachnoid block, but has better hemodynamic profile in comparison to Hyperbaric 0.5% Bupivacaine, the commonly used local anaesthetic agent used for Spinal Anaesthesia.

Keywords: Bradycardia, Hypotension, Levobupivacaine, Subarachnoid Block

INTRODUCTION

Role of subarachnoid block in conducting surgeries in lower abdomen and limbs is very important and undebatable. Anaesthesiologists find this regional technique safer and easier than General Anaesthesia, which is associated with complications of the various systems, some trivial and others serious. ¹⁻³ Despite being safe this technique is also associated with complications of the cardiovascular system, primarily hypotension. ⁴

These concerns are because of drugs used in administering subarachnoid block. Bupivacaine, the widely used local anesthetic in regional anaesthesia is available in a commercial preparation as a racemic mixture (50:50) of its two enantiomers, levobupivacaine, S(-) isomer and dextrobupivacaine, R(+) isomer.⁵⁻⁷

Severe central nervous system (CNS) and cardiovascular adverse reactions reported in the literature after inadvertent intravascular injection or intravenous regional

anesthesia have been linked to the R (+) isomer of bupivacaine. $^{8-11}$

This study was conducted to assess the pharmacological profile of the S(-) isomer of bupivacaine heavy, Levobupivacaine when administered via the intrathecal route.

METHODS

Institutional ethical committee clearance was obtained for the study. All adult patients in ASA grade I-II, between 18 – 65 yrs of age, undergoing lower abdominal and lower limb surgeries in operation theatre in this institute were included for the study. Written informed consent was taken from all the cases after explaining the procedure to be carried out on them.

Patients having allergy to local anaesthesia or to any of the study medications, psychiatric problems, height less than 145 cm, weight greater than 100 kg, patients suffering from COPD/Bronchial Asthma, patient refusal for subarachnoid block, any anomaly with the urogenital system, extremes of ages and coagulopathy were excluded.

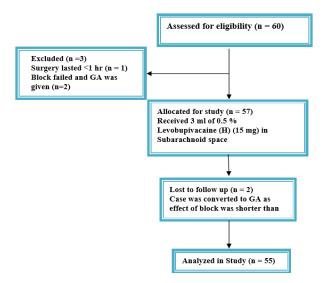


Figure 1: Consort flow diagram for patient eligibility.

All patients undergoing lower abdominal and lower limb surgeries were administered spinal anesthesia, 4 ml of hyperbaric levobupivacaine was made by adding 3 ml of 0.5% levobupicaine (15 mg) and 1ml of 25% Dextrose under strict asepsis. After taking the patient for surgery, vitals like blood pressure, electrocardiography, temperature, pulse oximetry and capnography was attached and was recorded. These readings were taken as baseline and were compared with vitals at time of administration of block, every two minutes till 10 minutes post block, at time of incision, every 5 minutes and at time of closure. Around 4.0 ml (15 mg) was given to all patients at L3-L4 level in left lateral position.

Post 10 minutes parameters were recorded every 5 minutes till closure and were averaged to compare it with baseline. If surgery finished in less than an hour or needed to be converted to GA then patients were excluded from the study. Total 60 patients were enrolled for this study. Patients were monitored and parameters were recorded by the independent observer.

All patients were given standard 1500 ml of Ringer Lactate as preload. The onset of a Sensory block by prick sensation at T4 Level, motor block using Bromage scale, hemodynamic status, amount of fluids infused, amount of vasopressor, atropine or any other drug required and complications were recorded. Results were analyzed using SPSS 20 statistical software.

RESULTS

Of the 60 patients included in this observational study three got excluded as the block failed in two and in one the surgery finished within an hour. Two more cases got excluded as the block got ineffective prematurely and the patient started perceiving pain and was given general anaesthesia. The other demographic parameters are mentioned in Table 1.

Table 1: Demographic profile of sample.

Demographic	Levobupivacaine group
Parameter	$(\mathbf{n} = 55)$
Age (yrs)	48.5
Gender (M/F)	19 / 36
Height (cms)	156.77
Weight (kgs)	52.26
ASA classI / II	47 / 8
Duration of surgery (min)	75.20

On analysis of demographic profile of the sample, maximum patients were female (M/F: 19/36) and patients undergoing gynaecological surgeries was high as high as 55%.

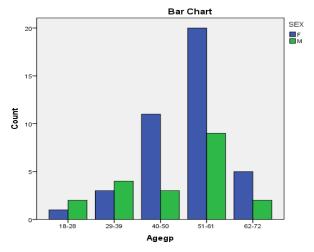


Figure 2: Age wise gender distribution of the sample.

The sample was of a relatively older age group and a low average height as 60% of the patients were mainly females from all age group but mostly in late menopausal stage (Table 2) as most of the surgeries were gynecological surgeries. The various surgeries carried out on the sample are mentioned in Table 2 below.

Surgeries of various specialities was represented in the sample. The baseline vital parameters were recorded and were taken as the reference value. More than 30% variation was considered as significant and was documented.

Hemodynamic stability of patients whose vitals fell more than 30% their frequency was recorded every 2 minutes till 10 minutes, at the time of incision and at the time of closure. It was observed that fall in hemodynamic parameters like Systolic BP, Diastolic BP Mean Arterial Pressure and heart rate fell significantly with after 4 minutes and continued till incision, after that it remained on decreasing trend till closure of the skin. Refer Table 3

- showing hemodynamic variation more than 30% than baseline.

Table 2: Surgeries carried out in the sample group.

Surgery	Total cases	Remarks
Total abdominal	20	Block failed in 2
hysterectomy	20	cases
Staging laparatomy	6	
On an mach manain	10	Early wearing off of
Open mesh repair		effect in 2 cases
Trans urethral	10	
resection of prostate	10	
Orchidectomy	4	
Eistula atomy	4	Surgery finished in
Fistulectomy		an hour in 1 case
Appendecectomy	4	
Others	2	
Total	60	

Table 3: Incidence of Hemodynamic instability after block till closure from baseline parameters.

	At Block	2 mins	4 mins	6 mins	8 mins	10 mins	At incision	At every 5 mins (Avg)	At closure
SBP	1	1	5	2	1	2	3	4	0
MAP	6	3	5	3	1	2	4	5	1
DBP	3	1	4	3	1	3	4	5	1
HR	2	2	7	5	1	3	5	6	1

Table 4: Onset of block assessment by using VAS, Bromage Scale and Pinprick sensation method.

Time of Onset of Block (VAS) (mins)	Frequency	Percentage
2	15	25
4	30	50
6	10	16
8	2	4
10	3	5
Total	60	100
Time of Orgat of Mator Plackage (mine)	Frequency of Bromage	Percentage of patients in each time
Time of Onset of Motor Blockage (mins)	scale less than 4	interval
2	25	41
4	27	45
6	8	14
8	0	0
10	0	0
Total	60	100
Time of Onset of Pin prick blockage (mins)	Frequency of patients	Percentage
2	17	29
4	21	35
6	18	30
8	2	3
10	2	3
Total	60	100

Onset of Subarachnoid block was measured using VAS (less than 4), Motor block- Bromage scale less than 4 and sensation to pin prick at T4-level. It was found that maximum onset of motor block was after 5 minutes, VAS after 4 minutes and Lost of pinprick sensation at T-4 level was after 4 minutes (Table 4).

Table 5: Adverse effects.

Adverse events	Frequency	Percentage
Hypotension	3	5
Bradycardia	2	3
Nil	55	92
Total	60	100

On assessment of haemodynamic complications:-hypotension- 3 (5%), bradycardia 2 (3%) i. e. total 5 (8%) were detected requiring therapeutic interventions (Table 5).

Total number of patients who required mephenteramine were 5% and those required atropine were 3%. 92% of patents required no intervention in form of drugs and they continued to be asymptomatic during the procedure. Limitations of this study was that baseline vitals were taken the when the patient came to the Operation theatre, which could itself be on the higher side than normal baseline because patient might be full of anxiety and apprehension on entering the OT, hence 30% from baseline was not intervened with any therapeutic intervention as patients were totally asymptomatic.

In other studies, carried out earlier with the usage of isobaric local anaesthetics and opioids the onset of blockade (10 - 12min) was more than that found in this study. The complication rate was lower than that of Bupivacaine.¹²

DISCUSSION

Central neuraxial blocks is one of the modalities for providing anaesthesia for surgery. These are techniques to administer Local Anaesthetics into the Epidural or Subarachnoid space to produce analgesia for surgery. 13,14 Although a very simple technique it is associated with complications, sometimes, which can be fatal. Anaesthesiologists have been searching for a local anaesthetic which can provide profound analgesia with minimal complications. In the search for such an ideal local anaesthetic enantiomers of existing ones have been discovered and researched extensively for their profile. Levobupivacaine pharmacological and Ropivacaine are some of these drugs that have been found off late.15,16

Levobupivacaine, a long-acting local anaesthetic, has been developed as an alternative to bupivacaine, after the numerous complications reported by its predecessor. Numerous researches have been carried out to assess the various advantages and disadvantages of the newer drug.

Levobupivacaine, a pure left isomer, seems to have less toxic effects on the central nervous system and the cardiovascular system than its counterpart, the racemic Bupivacaine. The decreased toxicity of levobupivacaine is attributed to its faster protein binding rate. However, the reduced toxic potential of the pure left isomer suggests their use in the clinical situations in which the risk of systemic toxicity related to either overdosing or unintended intravascular injection is high such as during epidural or peripheral nerve blocks. 19,20 But this high protein binding, does not only reduce its side effects, but also its potency and onset of blockade.

All these parameters were investigated in this observational study. The onset to the block was found to be between 4-5 mins and the complication rate of Hypotension (5%) and Bradycardia (3%) was much lower than its racemic compound Bupivacaine.²¹⁻²³ The interventions required in the study group was significantly lower than those required in the usage of Bupivacaine.

CONCLUSION

As per the findings of previous studies comparing bupivacaine vs ropivacaine and bupivacaine vs levobupivacaine, it was expected that Levobupivacaine would prove to be a better alternative to Bupivacaine. Yet surprisingly, in a study in the journal of Anaesthesiology in 2002, the two drugs had identical effective doses. Present study, while confirming the lower potency of levobupivacaine compared with bupivacaine, shows that laevobupivacaine when administered in a hyperbaric preparation has an early onset of sensory and motor blockade and fewer side effects in comparison to bupivaciane. 0.5% Hyperbaric Levobupivacaine, has onset of action lesser than other amides when used for Neuraxial Blocks, but has better haemodynamic profile in comparision to Hyperbaric 0.5% Bupivacaine and 0.75% Ropivacaine.

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Ethical approval: The study was approved by the

Institutional Ethics Committee

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