

Original Research Article

# A HOSPITAL BASED CLINICAL STUDY OF COMPARISON OF HEAVY LEVOBUPIVACAINE AND HEAVY BUPIVACAINE IN UROLOGICAL SURGERIES UNDER SPINAL ANAESTHESIA AT TERTIARY CARE CENTRE

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## ABSTRACT

**Background:** Levobupivacaine is an attractive alternative to racemic bupivacaine for spinal anesthesia due to the lower potential for cardio-toxicity and faster recovery profile. We performed this clinical trial to investigate the clinical efficacy and motor block of 0.5% levobupivacaine and 0.5% racemic bupivacaine in spinal anaesthesia for urological surgery requiring sensory block to at least the tenth thoracic (T10) dermatome.

**Materials and Methods:** This is a hospital based prospective study done on forty patients scheduled for elective trans-urethral resection of the prostate and/or bladder tumour. The patients were randomly assigned into one of two groups, receiving dextrose solution of either 0.5% levobupivacaine or 0.5% racemic bupivacaine intrathecally, according to a computer-generated randomization table.

**Results:** Our study showed that there were no significant differences between the levobupivacaine and bupivacaine groups for demographic data, baseline haemodynamic parameters, ASA classification or type of operation. There were no significant differences between the two groups in the quality of sensory and motor block or in haemodynamic change.

**Conclusion:** Levobupivacaine, having a lesser cardiovascular and central nervous system, was suggested as an alternative to bupivacaine.

**Keywords:** Heavy Levobupivacaine, Heavy Bupivacaine, Urological surgeries, Hemodynamic changes.

## INTRODUCTION

Spinal anaesthesia due to the sheer benefits of an awake patient, low drug costs, excellent intraoperative anaesthesia, prolonged and satisfactory postoperative analgesia, and quick patient turnover, seems to have become the preferred method of choice before general anaesthesia for lower abdominal, lower limb, pelvic, and perineum surgeries.<sup>[1]</sup>

Bupivacaine is the first amide-linked long-acting local anaesthetic that has edge of having longer duration of action than lignocaine. In the recent years, it's pure enantiomers such as ropivacaine [amides]

and levobupivacaine [amides], because of their decreased toxicity for the cardiovascular and central nervous systems, have been incorporated into clinical practice. Isobaric solutions have the extra benefit of not affecting the intrathecal dispersion of local anaesthetic during and after injection.<sup>[2]</sup>

The S (-) enantiomer of racemic bupivacaine, levobupivacaine, is less toxic to the heart and central nervous system than racemic bupivacaine.<sup>[2]</sup> Reports of levobupivacaine being used for epidural or brachial plexus anaesthesia suggested that it had the same clinical efficacy as Bupivacaine.<sup>[3]</sup> In subarachnoid block, levobupivacaine has similar effects to bupivacaine, and motor block reversion occurs early.<sup>[4]</sup> It causes differential neuraxial

blockade with motor function preservation at low concentrations, making it suitable for ambulatory surgery.<sup>[5]</sup>

At the time of designing this study there were only four published trials of intra-thecal administration of levobupivacaine. The results on clinical efficacy and motor block were not consistent.<sup>[6-9]</sup> The first publication was a non-comparative study using 0.5% levobupivacaine for lower limb surgery.<sup>[6]</sup> The second was a randomized controlled trial of 0.5% levobupivacaine versus racemic bupivacaine for spinal anaesthesia in hip replacement surgery.<sup>[2]</sup> The other two studies compared hyper-baric 0.25% levobupivacaine and 0.125% levobupivacaine with racemic bupivacaine.<sup>[7,8]</sup> No study had investigated 0.5% levobupivacaine for spinal anaesthesia for lower abdominal or urological surgery. Therefore, we performed this clinical trial to investigate the clinical efficacy and motor block of 0.5% levobupivacaine and 0.5% racemic bupivacaine in spinal anaesthesia for urological surgery requiring sensory block to at least the tenth thoracic (T10) dermatome.

## MATERIALS AND METHODS

This is a hospital based prospective study done on forty patients scheduled for elective trans-urethral resection of the prostate and/or bladder tumour were recruited after giving written informed consent at SSMCH, Jabalpur, M.P., India during one-year period.

The inclusion criteria were (i) age 50 to 80 years, (ii) ASA status 1-3, (iii) body weight 45-80 kg. The exclusion criteria were (iv) known hypersensitivity to amide local anaesthetic, (ii) contraindication to spinal anaesthesia.

The patients were randomly assigned into one of two groups, receiving dextrose solution of either 0.5% levobupivacaine or 0.5% racemic bupivacaine intrathecally, according to a computer-generated randomization table. Diazepam 5 mg was given orally at least two hours before surgery as premedication and an intravenous (IV) infusion of Hartmann's solution 10 ml/kg given immediately before spinal anaesthesia.

The insertion of the spinal needle was performed under aseptic conditions with the patient in left lateral position. A 25 gauge Quincke needle was used at L3/4 with a midline or paramedian approach. To standardize the technique, the second author (KM) performed all blocks.

The patients were turned supine immediately after injection of the spinal drug and were given supplementary nasal oxygen 2 l/min. Parameters monitored included (i) continuous electrocardiogram, heart rate and pulse oximetry, (ii) non-invasive blood pressure before the conduct of spinal anaesthesia, then every 2.5 minutes for 15 minutes and every 5 minutes thereafter, (iii) sensory block, which was monitored using loss of sensation to cold spray (ethyl chloride) every 2.5 minutes for 15 minutes after the initiation of spinal anaesthesia and at the end of operation, (iv) motor block, assessed according to a modified Bromage scale (0=no paralysis, able to flex hip/knees/ankles; 1=able to flex knees, unable to raise extended legs; 2=able to flex ankles, unable to flex knees; 3=unable to flex ankle, knee and hip) every 2.5 minutes for 15 minutes and at the end of the operation.<sup>9</sup>

The operation was started 15 minutes after the initiation of spinal anaesthesia if the level of sensory block had reached T10 or above. If the level of analgesia was inadequate, general anaesthesia was to be given.

Hypotension was defined as a systolic blood pressure less than 100 mmHg or a decrease of more than 30% from baseline and was treated with incremental doses of ephedrine 5 mg IV and/or intravenous Hartmann's solution. Bradycardia was defined as a heart rate <50 beats per minute and was treated with atropine 0.3-0.6 mg IV.

The onset of adequate sensory block was defined as the time interval from completion of the spinal drug injection to the achievement of a sensory block at T10. The incidence of motor block at the start and end of the operation and the addition of any sedative drug were recorded. At the end of surgery, the patient's satisfaction was assessed as good, fair or poor. The adequacy of anaesthesia was assessed as good, fair or inadequate by the attending anaesthetist.

## RESULTS

Our study showed that there were no significant differences between the levobupivacaine and bupivacaine groups for demographic data, baseline haemodynamic parameters, ASA classification or type of operation [Table 1 & 2]. There were no significant differences between the two groups in the quality of sensory and motor block or in haemodynamic change [Table 3 & 4].

**Table 1: Demographic data and baseline haemodynamic parameters**

Demographic variables	Heavy Bupivacaine	Heavy Levobupivacaine
Number of patients	20	20
Age (y)	66.9±10.24	67.8±11.51
Body weight (kg)	58.56±8.74	61.36±9.48
Body height (cm)	165.3±6.08	164.6±5.79
Baseline systolic blood pressure (mmHg)	139±20	148±22
Baseline heart rate (beats per minute)	74±12	72 ±13

Side-effects of anaesthesia were infrequent and minor. The incidence of hypotension was 5% (2/40)

with both cases in the bupivacaine group. Two patients (levobupivacaine group n=1 and bupivacaine

group n=1) experienced shivering. One patient in the bupivacaine group had nausea and vomiting. The efficacy of both levobupivacaine and bupivacaine was good. Anaesthesia was adequate and

patient satisfaction good in all cases. Two patients in the bupivacaine group and one patient in the levobupivacaine group required sedation with midazolam 1 mg IV in the intraoperative period.

**Table 2: ASA classification and type of operation**

	Heavy Bupivacaine	Heavy Levobupivacaine
ASA 1	3 (15%)	3 (15%)
ASA 2 & 3	17 (85%)	17 (85%)
transurethral resection of the prostate (TURP)	18 (90%)	17 (85%)
transurethral resection of the bladder (TURB)	2 (10%)	3 (15%)

**Table 3: Comparison of sensory block and motor block**

	Heavy Bupivacaine	Heavy Levobupivacaine
Time to achieve sensory block of T10 (min)	8.3±5	10.5±4
Highest level of sensory block	T8 (T3-T10)	T7 (T3-T10)
Motor block less than Bromage 3 at the start of operation	1 (5%)	2 (10%)
Motor block of Bromage 3 at the start of operation	19 (95%)	18 (90%)
Motor block less than Bromage 3 at the end of operation	1 (5%)	1 (5%)
Motor block of Bromage 3 at the end of operation	19 (95%)	19 (95%)

**Table 4: Comparison of hemodynamic effects**

	Heavy Bupivacaine	Heavy Levobupivacaine
Systolic blood pressure at 5 min (mmHg)	138±22	148±20
Systolic blood pressure at 10 min (mmHg)	134±24	142±23
Lowest systolic blood pressure (mmHg)	120±20	122±14
Heart rate at 5 min (beats per min)	74±16	76±18
Heart rate at 10 min (beats per min)	70±14	73±16

## DISCUSSION

The use of levobupivacaine for other routes of administration, including epidural anaesthesia and nerve plexus blocks, indicates that the anaesthetic potency of levobupivacaine is similar to racemic bupivacaine, although it produces more sustained sensory and motor block.<sup>[10,11]</sup> Lyons et al reported that the potency ratio of levobupivacaine to racemic bupivacaine was 0.98 for epidural analgesia for labour pain.<sup>[12]</sup> Levobupivacaine administered via these routes has the advantage of less cardiotoxicity should accidental intravascular injection occur. Since the dose of bupivacaine used in spinal anaesthesia is small, the issue of cardiotoxicity is less important. Nevertheless, investigation of the clinical effects of intrathecal levobupivacaine is important, because there is the possibility of accidental intrathecal injection during epidural anaesthesia. Furthermore, if levobupivacaine completely replaces racemic bupivacaine for other routes of administration, demand for racemic bupivacaine may drop, such that it may cease to be manufactured for economic reasons.

There are only a few studies involving intrathecal levobupivacaine. Burke et al conducted an open, non-comparative study of 0.5% levobupivacaine 3 ml for spinal anaesthesia for lower limb surgery in twenty patients.<sup>[6]</sup> The quality of anaesthesia was adequate in only 90% (18/20) of cases. They concluded that the spread of the 0.5% levobupivacaine solution was unpredictable. It was suggested that the variable sensory block might have been due to the hypo-baric property of 0.5% levobupivacaine at 37°C.<sup>[13]</sup> Glaser et al performed a prospective, randomized, double-

blind study comparing 0.5% levobupivacaine and racemic bupivacaine 3.5 ml for spinal anaesthesia for elective hip replacement.<sup>[2]</sup> They found similar clinical effects, including sensory and motor block. Most anaesthetists have extensive experience with intrathecal bupivacaine but the relative intrathecal potency for levobupivacaine, ropivacaine and bupivacaine is not known. The clinical use of levobupivacaine or ropivacaine as isobaric or hyperbaric solutions to replace racemic bupivacaine for spinal anaesthesia requires further evaluation. Levobupivacaine has been licensed for intrathecal use, but hyperbaric solutions of levobupivacaine or ropivacaine are not commercially available.

## CONCLUSION

We concluded that heavy 0.5% levobupivacaine can be used as an alternative to 0.5% racemic bupivacaine in spinal anaesthesia for urological surgeries when a sensory block to at least T10 is required. Levobupivacaine, having a lesser cardiovascular and central nervous system, was suggested as an alternative to bupivacaine.

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