

Comparison of onset and duration of sensory and motor blockade between equipotent doses of 0.75% plain ropivacaine and 0.5% plain levobupivacaine in lower abdominal surgeries under epidural anaesthesia - A one year hospital based randomized clinical study

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Epidural blockade unlike spinal anaesthesia, gives the clinician an opportunity to provide adequate anaesthesia for extended duration of surgical needs and enable excellent pain management well into the postoperative period. It provides better haemodynamic stability due to minimal sympathetic blockade. The present study used ropivacaine and levobupivacaine, which have recently been introduced for clinical use to compare the onset and duration of motor and sensory blockade in patients undergoing lower abdominal surgeries under epidural anaesthesia. The mean onset of sensory block in group R and group L were 17.93 ± 2.98 and 18.62 ± 3.09 minutes respectively; $p = 0.285$. The mean onset time of motor block was slightly longer in group L compared to group R (24.09 ± 3.07 vs 25.47 ± 4.13 minutes; $p = 0.076$). Mean duration of sensory block was slightly longer in group R compared to group L (196.78 ± 20.31 vs 189.0 ± 19.53 minutes; $p = 0.067$). The duration of post op analgesia was observed to be longer in group R (263.0 ± 22.77) in comparison to group L (253.78 ± 24.43). The duration of motor block was found to be lesser in group R (111.42 ± 16.70 min) compared to that in group L (118.53 ± 18.14 min), the difference being statistically insignificant ($p = 0.05$). It can thus be concluded that both 0.75% ropivacaine and 0.5% levobupivacaine when administered epidurally for elective lower abdominal surgeries, provide adequate and comparable sensory and motor blockade.

Keywords: Epidural; levobupivacaine; ropivacaine; analgesia; abdominal surgery

Introduction

The history of neuraxial anaesthesia goes back as far as the 19th century. Experiments by scientists like Corning, Bier, Pages and progressive research has led to its application in a variety of clinical situations.^{1,2} Epidural anaesthesia is more versatile than spinal anaesthesia, and has recently developed into the anaesthetic technique of choice for most of the abdominal and lower limb surgeries owing to its advantage of outstanding pain relief in the postoperative period.¹ It produces segmental blockade unlike spinal anaesthesia, thus providing better haemodynamic stability due to minimal sympathetic blockade.³

Bupivacaine, a racemic mixture of dextrobupivacaine and levobupivacaine, provides a long duration of action and a favourable ratio of sensory to motor neural block.⁴ But its use is limited by its cardiac and

central nervous system toxicity^{5,6,7,8} prompting research for newer drugs devoid of such side effects. Ropivacaine and levobupivacaine, claim benefits of more selective action on sensory fibres and reduced cardiac adverse effects.⁹

Ropivacaine, being less lipophilic than bupivacaine acts selectively on the pain-transmitting A δ and C nerves.^{10,11} Levobupivacaine too, due to less depressant effects on the myocardium, has emerged as a safer alternative with a superior pharmacokinetic profile.^{12, 13,14}

Considering that very few studies have compared levobupivacaine and ropivacaine for epidural anaesthesia, the present study was planned to compare the onset and duration of motor and sensory blockade in patients undergoing lower abdominal surgeries under epidural anaesthesia.



Materials and Methods

Patients aged between 20 to 60 years of either gender, belonging to ASA Grade I and II scheduled for elective lower abdominal surgeries under epidural anaesthesia were studied. Patients who denied consent, had contraindications to epidural, had pre-existing neurological deficits in the lower extremities, and cardio respiratory diseases, neurological or psychological disease, hepatic, or renal disease, bleeding diathesis were excluded from the study.

Sample size calculation

Using the results of previously conducted studies and standard statistical formula, time for duration of motor block is taken to determine the sample size. The formula used is;

$$\text{Sample size (n)} = \frac{2 \times (Z\alpha + Z\beta)^2 (\sigma^2)}{(X_1 - X_2)^2}$$

Level of significance is taken as 5%

Power of the test used is taken as 80%

Hence, $Z\alpha = 1.66$

$Z\beta = 0.84$

$X_1 = 185$

$X_2 = 225$

$\sigma = 75$

$$\text{Thus, } n = \frac{2[1.65 + 0.84]^2 \times 75^2}{(185-225)^2}$$

$n = 44$

Where:

- X_1 is duration of sensory block in levobupivacaine group
- X_2 is duration of sensory block in ropivacaine group

The minimum sample size obtained is 44. For the sake of consistent result n is taken as 45. There are two groups with 45 cases each.

After approval of Institutional ethical committee and informed consent, patients were randomized based on computer generated randomization table into one of the two groups.

- Group L – 15ml of 0.5% levobupivacaine
 - Group R – 15ml of 0.75% ropivacaine
- Study drugs were prepared in identical syringes with 15ml of 0.75% plain ropivacaine and 15ml

of 0.5% levobupivacaine by an anaesthesiologist not involved with subsequent administration and patient assessment. On confirming the patient's nil oral status, an intravenous access with 18 gauge cannula was secured and the patient was preloaded with Ringer's Lactate fluid at 10 ml/kg over 30 minutes. The patient was then shifted to operation theatre where monitors were attached and base line heart rate, blood pressure (systolic, diastolic, mean arterial blood pressure), respiratory rate and SpO₂ were recorded.

Under strict aseptic precautions, the skin and subcutaneous tissues at the L2-3 or L3-4 interspace were infiltrated with 2ml of 2% lignocaine. The epidural space was identified with patients in the lateral decubitus position by using an 18g Tuohy needle and a loss of resistance to air technique. Initial test dose of 3ml of 2% lignocaine with adrenaline was given after negative aspiration of blood or CSF, followed by injection of 15ml of either 0.5% levobupivacaine or 0.75% ropivacaine. Sensory blockade was assessed by using blunt end of a 27g needle. Adequate block to initiate surgery was a sensory block bilaterally to dermatome T10. The onset of sensory blockade was the time (in mins) at which there is loss of pain to pinprick at T10 level after complete injection of the study drug. Highest cephalad dermatomal sensory blockade achieved was noted. Duration of sensory blockade that is time from onset of sensory block till two segment regression from highest level of blockade and the duration of post-operative analgesia, that is the time from injection of study drug to the first supplemental analgesic administered were documented.

Onset, intensity of motor blockade and duration of motor blockade was tested bilaterally using *Modified Bromage scale*. Hypotension was defined as decrease in systolic BP by 30% from baseline values or a systolic BP less than 90mmHg and was treated with incremental intravenous boluses of mephentermine 5 to 10mg and a bolus administration of 250ml of ringer lactate solution over 10mins. Bradycardia was defined as decrease in heart rate less than 60 beats/min and was treated with intravenous atropine 0.6mg. Supplementary oxygen was given through face mask. All patients were observed and monitored for vital signs in the post



anaesthesia recovery room and in the ward until complete recovery from sensory and motor blockade and duration of post-operative analgesia and any side effects if present were recorded. Tramadol 100mg i.v. was given when patient complained of mild pain (VAS score > 3) and the time noted.

Statistical testing was conducted with SPSS version 17.0. Continuous variables are presented as mean ± SD, and categorical variables are presented as absolute numbers and percentages. The comparison of normally distributed continuous variables between the groups was performed using Student's t test. Nominal categorical data between the groups were compared using Fisher's exact test. P<0.05 was considered statistically significant.

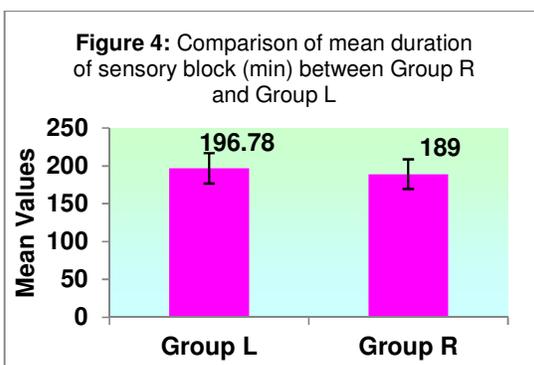
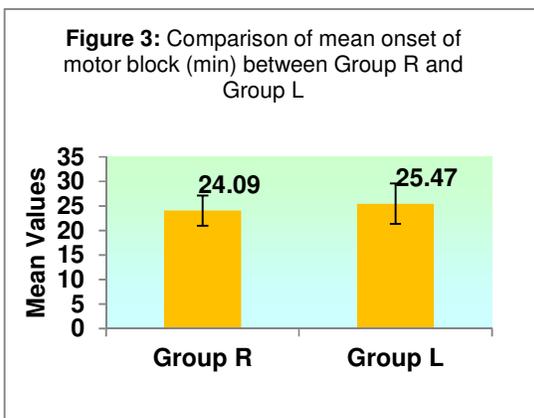
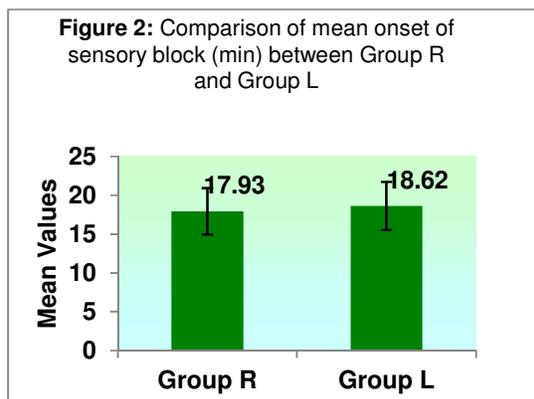
Figure 1: Modified Bromage Scale

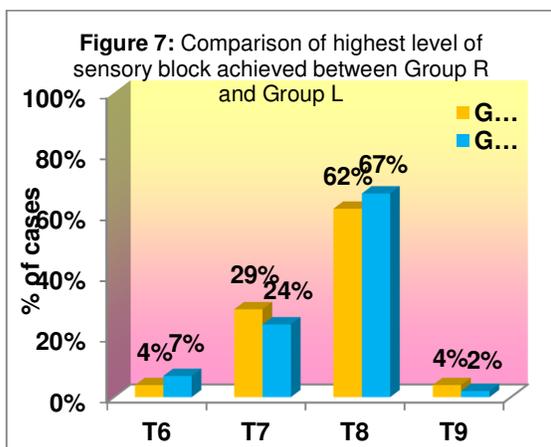
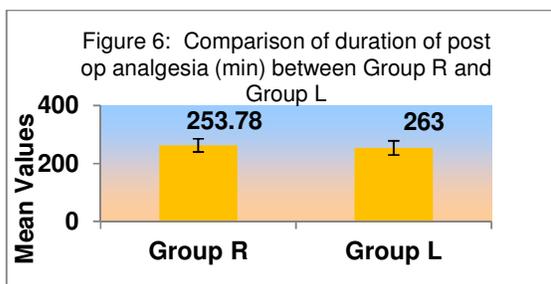
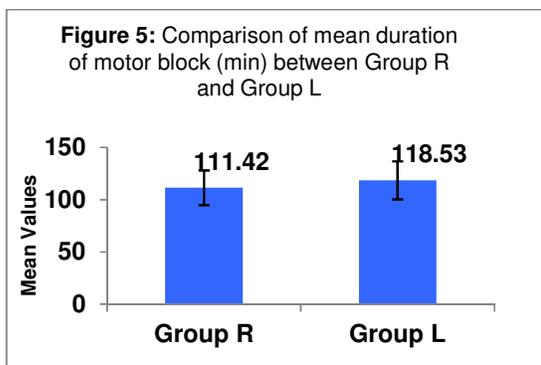
Scale	Criteria	Degree/Grade of block
0	Free movement of legs, feet with ability to raise extended leg	None
1	Inability to raise extended leg and knee flexion is decreased but full extension of feet and ankles are present	Partial 33%
2	Inability to raise leg or flex knees, but flexion of ankle and feet present	Partial 66%
3	Inability to raise leg, flex knee or ankle or move toes	Complete paralysis

Results

Both groups were comparable as regards the age, sex, anthropometric data. (p > 0.05). The mean onset of sensory block in group R and group L were 17.93 ± 2.98 and 18.62 ± 3.09 minutes respectively; p= 0.285. (Figure 2) The mean onset time of motor block was slightly longer in group L compared to group R (24.09 ± 3.07 vs 25.47 ± 4.13 minutes; p = 0.076). (Figure 3) Mean duration of sensory block was slightly longer in group R compared to group L (196.78 ± 20.31 vs 189.0 ± 19.53 minutes; p = 0.067). (Figure 4) The duration of motor block was found to be lesser in group R (111.42 ± 16.70 min) compared to that

in group L (118.53 ± 18.14 min), the difference being statistically insignificant (p=0.05). (Figure 5) The duration of post op analgesia was observed to be longer in ropivacaine group (263.0 ± 22.77) in comparison to levobupivacaine group (253.78 ± 24.43). (Figure 6) The number of patients that had a block level of T₇ and T₈ was 29% and 62% patients in group R compared to 24% and 67% in group L respectively (p = 0.857). (Figure 7) Only 4% patients in group R and 7% in group L attained a sensory block up to T₆, and 4% in group R. Thus the highest level of block achieved was similar in both groups.





Discussion

Neuraxial anaesthesia especially epidural anaesthesia greatly expands the anaesthetic armamentarium and provides better alternative to general anaesthesia when appropriate. It holds the added advantage of attenuating the stress of surgery by inhibition of sympathetic system activation. Local anaesthetics interact with the voltage-gated sodium-ion channels and reduce the peak permeability for sodium-ions of the axonal membrane, impeding the generation and propagation of action potentials in nerve fibres.⁴ Following an epidural injection, local

anaesthetics may diffuse into the paravertebral area through the inter vertebral foramina and block nerves distal to their dural sheaths, resulting in multiple para vertebral blocks. They may also diffuse across the dura into the subarachnoid space, where they act on nerve roots.^{3,14} Lastly, after diffusion through the dura, they act directly on the spinal cord.

The aim of our present study was to compare the effect of epidural 0.75% ropivacaine and 0.5% levobupivacaine for time of onset, highest level, duration of sensory block and onset and duration of motor block in patients posted for lower abdominal surgeries

In our study it was observed that the mean times for onset of sensory block in group R and in group L were similar to the results noted in a study conducted by Chun woo yang et al, which compared 20 ml of 0.5% ropivacaine (11.8 ± 8.6 min) and 20 ml of 0.5% levobupivacaine (15.5 ± 9.7 min) for caesarean sections.¹⁵

The R- and S- enantiomers of racemic bupivacaine have a different affinity for sodium, potassium, and calcium ion channels.⁷ Levobupivacaine which is the s- enantiomer, blocks the voltage sensitive sodium ion channels reversibly and exhibits increased cardiovascular and central nervous system safety and is considered a better alternative to bupivacaine.

Ropivacaine acts by reversible inhibition of sodium ion influx, and thereby blocks impulse conduction in nerve fibres. This action is potentiated by dose-dependent inhibition of potassium channels.

In our study, the mean time for onset of motor blockade for group R and group L was similar to the results noted in a study conducted by Chun woo yang et al where mean times for onset of motor blockade were (24.9 ± 13.3 min vs 31.0 ± 14.4 min) in Group R and Group L respectively.¹⁵

The mean duration of motor blockade in our study, was observed to be shorter in group R as compared to group L though it was statistically insignificant ($p=0.056$). The results of a similar study by Peduto et al, comparing epidural 0.5% levobupivacaine and 0.75% ropivacaine for lower limb surgery, found a duration of motor block



similar to results of our study which was much shorter with ropivacaine than with levobupivacaine (95 ± 48 min v/s 105 ± 63 min; $P = 0.86$).¹⁶ Casati A et al, in their comparison of 0.5% ropivacaine and 0.5% bupivacaine for interscalene brachial plexus block too observed similar time of onset and duration of pain relief in both groups.¹⁷

Another study conducted by Cacciapuoti A et al comparing 0.5% levobupivacaine, 0.75% ropivacaine and 0.5% racemic bupivacaine in brachial plexus block, found the onset of block to be similar for levobupivacaine and ropivacaine but delayed for bupivacaine.¹⁸

Another study conducted by Casati A et al for comparison of levobupivacaine, ropivacaine, and bupivacaine for epidural anaesthesia in orthopaedic surgeries revealed similar onset time of sensory block of 31 ± 16 minutes with levobupivacaine, 25 ± 19 minutes with bupivacaine, and 30 ± 24 minutes with ropivacaine ($p = 0.98$). Duration of post op analgesia was 214 ± 61 minutes with levobupivacaine, 213 ± 53 minutes with bupivacaine, and 233 ± 34 minutes with ropivacaine ($p = 0.26$)¹⁹

Conclusion

It can thus be concluded, that both 0.75% ropivacaine and 0.5% levobupivacaine when administered epidurally for elective lower abdominal surgeries, provide adequate and comparable sensory and motor blockade.

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