



## Original Research Article

# Comparative evaluation of levobupivacaine-fentanyl and ropivacaine - fentanyl in epidural anaesthesia in lower limb orthopaedic surgeries in elderly patients

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## ABSTRACT

**Background:** Epidural blockade with levobupivacaine and ropivacaine, the two new long-acting local anaesthetics, have been preferred in elderly due to low cardiac and central nervous system toxicity.

**Materials and Methods:** A randomized prospective study was conducted on 100 patients having age 60-85 yr of ASA physical status I, II and III admitted for elective lower limb orthopaedic surgeries under epidural anesthesia. Patients were randomly divided into two groups, Group A received epidural levobupivacaine 0.5% (13ml) and Group B received ropivacaine 0.75% (13ml), both with fentanyl 100 µg (2ml). Time of onset, peak level and time to attain peak level of the sensory block & time of regression upto two segment along with duration of analgesia were noted. Onset time and duration of motor block, hemodynamics and adverse effects were also compared in the two groups.

**Results:** Onset time of sensory block in group A was  $5.74 \pm 0.66$  minutes, while it was  $5.68 \pm 0.62$  minutes in group B. Maximum sensory block was attained in  $8.58 \pm 0.81$  minutes in group A and  $8.52 \pm 0.84$  minutes in group B.  $134.2 \pm 8.10$  minutes were taken for two segment regression in group A, while the time taken in group B was  $134 \pm 10.88$  minutes. Motor blockade mean onset time was  $20 \pm 3.35$  minutes and  $20.2 \pm 3.64$  minutes in group A and group B respectively. The mean duration of motor block in group A was  $248.4 \pm 13.60$  minutes and  $247.8 \pm 13.29$  minutes in group B. The mean duration of analgesia was  $382 \pm 18.63$  minutes in group A, while it was  $382.4 \pm 15.98$  minutes in group B. Results were comparable with regards to sensory and motor blockade parameters, hemodynamics and adverse effects.

**Conclusion:** Both 0.5% levobupivacaine and 0.75% ropivacaine with fentanyl as adjuvant are effective and comparable for epidural anaesthesia in elderly patients with regard to sensory and motor block characteristics along with similar hemodynamic profile.

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## 1. Introduction

Epidural anaesthesia is the anaesthesia of choice in elderly patients in various surgeries where general or spinal anaesthesia carries a risk. It provides extended postoperative analgesia and facilitate early ambulation.<sup>1,2</sup> In elderly patients age related degenerative changes in central and peripheral nervous system as well as in the anatomical configuration of lumbar and thoracic spines lead to decrease in size and compliance of epidural space affecting the pharmacokinetics and pharmacodynamics of local anaesthetics.<sup>3,4</sup>

Majority of studies have compared the clinical efficacy of levobupivacaine or ropivacaine with bupivacaine. Although Bupivacaine is the most commonly used drug for regional anaesthesia but it is associated with number of side effects like unwanted motor blockade, neurotoxicity and cardiotoxicity.<sup>4,5</sup> Therefore, new and safer anaesthetic agents ropivacaine and levobupivacaine have been introduced and are commonly used nowadays.<sup>6</sup> We designed a study to compare 0.5% levobupivacaine or 0.75% ropivacaine with fentanyl as a common adjuvant with regard to their sensory and motor block characteristics along with hemodynamic parameters in elderly patients undergoing epidural anaesthesia for lower limb orthopaedic surgeries.

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## 2. Materials and Methods

The present double-blinded randomised prospective study was conducted in a tertiary care centre enrolling 100 ASA physical status I, II and III patients between 60-85yrs undergoing lower limb surgeries under epidural anaesthesia. After obtaining approval from ethical committee and written informed consent, patients were randomized according to computer generated random numbers into two groups with 50 patients in each group. Group A received 13 ml of 0.5% levobupivacaine with 2ml of 100  $\mu$ g fentanyl and Group B received 13 ml of 0.75% ropivacaine with 2ml of 100  $\mu$ g fentanyl. Exclusion criteria were refusal to give consent, abnormality of spine, altered coagulation profile, local skin infection, neurological disorders and other contraindications for epidural anaesthesia.

Patients were explained in detail about the procedure of the study during the preanaesthetic visit and were advised overnight fasting. After shifting the patient to the OT, preloaded with 10 ml/kg of Ringer lactate. Baseline hemodynamic parameters were recorded after attaching routine monitors (ECG, NIBP, pulse oximeter). Local anaesthesia was given with the patient in sitting position using 2 ml of 2% lignocaine at L3-L4 interspace. Epidural space was identified with loss of resistance (LOR) technique using 18 G Tuohy's needle and epidural catheter was advanced 3-4 cm into the epidural space. After negative aspiration for blood and CSF, a test dose of 3 ml of 2% lignocaine with adrenaline was given. Then, the study drug solutions of 15ml prepared by the anaesthesiologist who was not involved in study was given over 3 minutes (T-0). The person performing the procedure and carrying out the observation was blinded to drug solutions injected. The patient was turned supine and O<sub>2</sub> was administered via venturi mask. The following parameters were observed intraoperatively.

Sensory block was assessed by bilateral pinprick method using 27-gauge hypodermic needle every 1 minute for first 10min and thereafter every 10min, till two segment regression, thereafter every 30 min to record the duration of analgesia. The time elapsed from epidural administration of drug (T0) to the loss of pin prick sensation at T10 level was taken as the time of onset of sensory block. Peak level, time to attain peak level and time taken for regression of sensory block by two segments was recorded.

Onset of motor blockade was defined as the time from epidural administration of study drugs (T-0) till patient develops Bromage scale grade 1 motor blockade and assessed at 5-minute interval till first 30minutes. Subsequently, the duration of motor block was observed every 15 minutes till 90 minutes and then every half-hourly till complete recovery of motor blockade. The Modified Bromage Scale:<sup>7</sup>

1. No motor block
2. Unable to flex the hip [hip blocked]

3. Unable to flex the knee [hip and knee blocked]
4. Unable to flex the ankle [hip, knee and ankle blocked]

Duration of analgesia is defined as the time taken from T0 to till the patient complain of pain at site of surgery and demands rescue analgesia.

Non invasive blood pressure (systolic, diastolic and mean), heart rate and peripheral oxygen saturation (SpO<sub>2</sub>) were monitored continuously and recorded every 5 minutes after administering the epidural injection (T0) till 30 minutes and subsequently every 10 minutes. If systolic blood pressure dropped to less than 20% of baseline or < 90 mm Hg, the patient was assumed to be in hypotension and was treated with intravenous fluids. Bradycardia (defined as HR < 60 bpm or 20% fall from baseline) was treated with intravenous 0.5 mg atropine sulfate. Adverse effects like bradycardia, hypotension, nausea, vomiting, urinary retention, pruritus and shivering were recorded and treated.

At the end of study, all the data were collected and analyzed statistically using IBM SPSS statistics (version 22.0). Numerical data were expressed as mean+standard deviation and analysed using independent paired or unpaired 't' test while nonparametric data were compared using Chi square test. For skewed data or scores, Mann-Whitney U-test was used. Statistical significance was taken as 'p' (<0.05).

The minimum sample size required for the study was calculated to be n=37 with Type 1 error of 0.05 and Type 2 error of 0.2 and estimated power of study was 80%.

## 3. Results

Both the groups were comparable with regards to the age, weight, ASA classification and duration of surgery.

The sensory block parameters of both the groups are shown in Table 2.

The sensory block onset in group A was 5.74±0.66 minutes and 5.68±0.62 minutes in group B.

Maximum height of sensory blockade obtained was at the level of T6 in 64% and 76% of the patients in groups A and B respectively. The difference found was statistically not significant (p >0.05).

The time to achieve peak sensory level was 8.58±0.81 minutes and 8.52±0.84 minutes and the time taken for the sensory block to regress by two segments was 134.2±8.1 minutes in group A, while it was 134±10.88 minutes in group B, and were comparable in both the groups. The duration of analgesia was comparable in the two groups (382 ± 18.63 minutes in group A and 382.4 ± 15.98 minutes in group B).

The time to achieve the onset of motor block was 20±3.35 minutes and 20.2±3.64 minutes and the duration of motor block was 248.4±13.60 minutes and 247.8±13.29 minutes in groups A and B respectively. There was no statistically significant difference found in both the groups.

**Table 1:**

Parameters		Group A	Group B	p value	Significance
Age (years)		65.00 ± 6.70	65.94 ± 6.88	0.725	NS
Weight (kgs)		68.36±4.31	69.14±4.10	0.357	NS
ASA physical status	I	39(78%)	43(86%)	0.298	NS
	II	11(22%)	7(14%)		
Duration of surgery (min)		151.1± 46.93	135.5± 48.98	0.107	NS

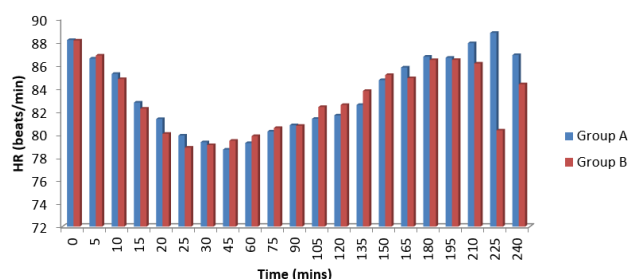
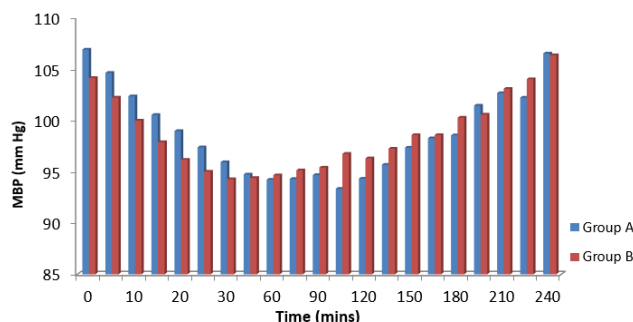
**Table 2:** Sensory block parameters

Sensory block parameters		Mean ± SD		P value	Significance
		Group A	Group B		
Time of Onset of sensory block in minutes		5.74 ± 0.66	5.68 ± 0.62	0.642	Non-significant
Highest level of sensory block	T4	15(30%)	8(16%)	0.248	Non-significant
	T6	32(64%)	38(76%)		
	T8	3(6%)	4(8%)		
Time to attain maximum sensory level(min)		8.58 ± 0.81	8.52 ± 0.84	0.717	Non-significant
Time to two segment regression(min)		134.2 ± 8.10	134 ± 10.88	0.917	Non-significant
Duration of analgesia (min)		382 ± 18.63	382.4±15.98	0.910	Non-significant

**Table 3:** Motor block parameters

	Group A	Group B	P value	Significance
Time of onset of motor block(min)	20 ± 3.35	20.2 ± 3.64	0.775	NS
Duration of motor block (min)	248.4±13.60	247.8±13.29	0.820	NS

Hemodynamics were comparable in the two groups at different time intervals (Figures 1 and 2). Intraoperative adverse events were also comparable in both the groups (Table 2).

**Fig. 1:** Heart Rate(beats/min)**Fig. 2:** Mean Blood Pressure(mm Hg)

#### 4. Discussion

Epidural blockade provides complete analgesia for as long as epidural is continued hence making it gold standard for major lower limb surgeries.<sup>8,9</sup> The addition of adjuvants in epidural anaesthesia accelerates the onset of sensory blockade and also decreases the effective dose of local anesthetic agent (dose sparing effect) that is required in elderly patients.<sup>10</sup>

In the present study, we found that there was no significant difference ( $p > 0.05$ ) between 0.5% levobupivacaine and 0.75% ropivacaine so far as onset, peak level and time to attain peak level and time to two segment regression were concerned.

Chandran et al also found statistically insignificant difference in onset of sensory block which was 6.24 minutes with 0.75% ropivacaine and 6.92 minutes with 0.5% bupivacaine in lower extremity orthopaedic surgeries.<sup>11</sup> Concepcion et al also observed the onset of sensory block faster with increasing concentration of ropivacaine from 0.5% to 1%.<sup>12</sup> Kumar et al compared 20ml ropivacaine 0.75% with levobupivacaine 0.5% in abdominal and lower limb surgeries in epidural anaesthesia. They also found that the difference between the two groups with regard to onset and duration of sensory block, the time to attain peak level of sensory block and time to two segment regression of sensory block as well as to onset and duration of motor block was insignificant. Similar results were observed in the present study.<sup>13</sup>

**Table 4:** Complications

Adverse events	Group A	Group B	Chi Square	P value	Significance
Bradycardia	7	5	0.38	0.54	NS
Hypotension	9	4	2.21	0.14	NS
Nausea	5	5	0	1	NS
Vomiting	4	2	0.71	0.40	NS
Urinary retention	0	0	0	0	NS
Shivering	5	5	0	1	NS
Pruritis	1	1	0	1	NS

In the present study, the peak level of sensory blockade at T6 was achieved in 64% patients in Group A and 76% of the patients Group B. There was statistically no significant difference between the two groups ( $p > 0.05$ ). Similar results were observed by Jain et al where they compared 0.5% levobupivacaine with 0.5% racemic bupivacaine along with 100µg of fentanyl in lower limb orthopaedic surgeries. In both the groups highest level of sensory block achieved was T6 in 63.3% and 60% respectively.<sup>14</sup> However in contrast to our study Zaric D et al observed that the maximal cranial spread of 20ml of 1%, 0.75% and 0.5% ropivacaine was T9, T8 and T10, respectively during epidural analgesia.<sup>15</sup> Our study showed the lesser time to achieve peak level of sensory block which might be due to addition of fentanyl 100mcg as adjuvant in elderly patients. Mischa et al observed the effects of age on neural blockade and hemodynamic variations after epidural block of 15ml of 1% ropivacaine and observed that with advancing age the highest level of analgesia increased, as was observed in our study.<sup>16</sup>

In the present study, time of onset and the duration of motor blockade was also comparable in both the groups. A study conducted by Jain K et al also found no significant difference in the onset and duration of motor block where they compared epidural 0.5% levobupivacaine with 0.5% racemic bupivacaine using fentanyl 100µg as common adjuvant in lower limb orthopaedic surgeries.<sup>14</sup> Similar results were observed by Peduto et al who found that both the groups were comparable with regard to time of onset of motor block on using 0.5% levobupivacaine and 0.75% ropivacaine for lower limb surgery.<sup>17</sup>

In our study the duration of analgesia was 382 + 18.63 minutes in group A and 382.4 + 15.98 minutes in group B which was statistically comparable. Chandran et al also observed no significant differences in the block parameters in both groups however ropivacaine was associated with relatively longer duration of analgesia.<sup>11</sup> Jain K et al compared 15ml of epidural 0.5% levobupivacaine with 0.5% racemic bupivacaine using fentanyl 100µg as common adjuvant in lower limb orthopaedic surgeries and found both the drugs were comparable with regard to duration of analgesia ( $p > 0.05$ ).<sup>14</sup>

The difference in hemodynamic parameters and various side effects was statistically insignificant in both the groups.

In our study bradycardia was observed in 7 patients in group A and 5 patients in group B. Hypotension was observed in 9 patients in group A and 4 patients in group B. Similar results were also observed by Concepcion M et al,<sup>12</sup> Kumar et al,<sup>13</sup> Jain et al,<sup>14</sup> Kopacz et al,<sup>18</sup> Rastogi et al,<sup>19</sup> Gautam et al<sup>20</sup> and Bardsley H et al.<sup>21</sup>

## 5. Conclusion

Both 0.5% levobupivacaine and 0.75% ropivacaine with fentanyl as adjuvant are effective and comparable for epidural anaesthesia in elderly patients with regard to sensory and motor block characteristics along with similar hemodynamic profile. Keeping in view the better safety profile of these drugs as compared to bupivacaine, they might be preferred in elderly patients in lower limb orthopaedic surgeries.

## 6. Conflict of Interest

None.

## 7. Source of Funding

None.

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