

**COMPARISON OF SEGMENTAL SPREAD OF THREE DIFFERENT DOSES OF 0.75% ROPIVACAINE ADMINISTERED IN LOWER THORACIC EPIDURAL SPACE IN PATIENTS UNDERGOING LOWER ABDOMINAL SURGERY: A RANDOMIZED PROSPECTIVE CLINICAL STUDY**Sujoy J. N<sup>1</sup>, Prakash B. C<sup>2</sup>**HOW TO CITE THIS ARTICLE:**

Sujoy J. N, Prakash B. C. "Comparison of Segmental Spread of three different Doses of 0.75% Ropivacaine Administered in Lower Thoracic Epidural Space in Patients Undergoing Lower Abdominal Surgery: A Randomized Prospective Clinical Study". Journal of Evolution of Medical and Dental Sciences 2014; Vol. 3, Issue 17, April 28; Page: 4539-4547, DOI: 10.14260/jemds/2014/2472

**ABSTRACT:** To provide adequate peri-operative thoracic epidural analgesia, it is important to determine the appropriate initial dosage of local anesthetics. To determine the proper dose, current study evaluated the effect of three different doses of 0.75 % ropivacaine, injected into lower thoracic epidural space, on the spread of analgesic segments and on hemodynamic variables. **METHODS:** The subjects were 90 patients between 18 to 60 years of age with ASA physical status I and II. Using an epidural catheter placed at site T<sub>9</sub> – T<sub>10</sub> intervertebral space, 0.75 % ropivacaine was injected as follows: Group A (n = 30, 5 ml), Group B (n = 30, 10 ml) and Group C (n = 30, 15 ml) sensory analgesia, motor blockade and hemodynamic variables were evaluated every 5 min for 25 min after the injection. **RESULTS:** Number of segments blocked were 5.48, 6.79 and 7.17 at 5<sup>th</sup> min. in Group A, B, C. respectively. At the end of 25<sup>th</sup> min, it reached 15.13, 15.50 and 16 segments. In the present study, there was no statistical difference in onset of sensory blockade at 5<sup>th</sup> min between three groups. But by 10<sup>th</sup> minute, the entire patient had detectable sensory blockade in all three groups. Motor Block onset was quicker and intensity was more in Group B and C as compared to Group A. More number of patients in Group B and Group C had hypotension and bradycardia when compared with Group A. **CONCLUSION:** To establish proper lower thoracic epidural analgesia with less hemodynamic changes, it is recommended to use 5 ml. of 0.75 % ropivacaine.

**KEYWORDS:** ropivacaine, Thoracic epidural analgesia.

**INTRODUCTION:** The use of thoracic epidural anesthesia in patients posted for major abdominal surgery provides not only pain control but also reduce respiratory complications, rapid recovery of bowel motility and hence reduce hospital stay.<sup>1</sup> Despite its wide spread use, the spread of local anesthetic in the epidural space is unpredictable.<sup>2</sup> Differences in anatomy, physiology and techniques to identify the epidural space makes extrapolation of data predicting spread of local anesthetics gathered during lumbar epidural anesthesia to thoracic epidural anesthesia was problematic.<sup>3</sup>

Many factors affect the spread of local anesthetic in epidural space. Among them, the site of injection, the mean mass of dry concentration and volume of drug are very important. Large number of studies has been done to determine the factors affecting the spread of local anesthetic in epidural space. A few studies done in lower thoracic epidural space have come up with inconsistent results since the choice of drug also influences the degree of sensory and motor block.

Ropivacaine is a long acting aminoamide local anesthetic. Ropivacaine with lower propensity for motor block and reduced potential for CNS toxicity and cardiotoxicity appears to be an ideal drug for epidural use<sup>4</sup>. This randomized study was designated to evaluate the effect of three different doses

## ORIGINAL ARTICLE

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of 0.75 % ropivacaine in low thoracic epidural area on sensory block, motor block, on hemodynamic variables, the incidence of improper block and whether the spread of ropivacaine in low thoracic area is cranial or caudal, linear or non-linear with increasing dose and volume of the drug.

The purpose of this study was to evaluate the effect of three different doses of 0.75 % ropivacaine, injected in the low thoracic epidural space, on the spread of analgesic segments, motor block, and sensory block and on hemodynamic variables.

**MATERIALS AND METHODS:** A randomized prospective single blind study was undertaken on 90 patients after local institutional ethics committee approval and informed written consent from patients posted for elective abdominal surgery. Patients with ASA physical status I and II, age 18 – 60 years were enrolled in this study. Patients with contraindications to neuraxial blocks, previous back surgery, diabetes mellitus, renal failure, severe cardiac and respiratory diseases were excluded.

Patients were divided into 3 groups and were randomly assigned to one of 3 groups using computer generated programme enclosed within opaque envelope to be opened just before the start of procedure. All patients had undergone pre-anesthetic evaluation and routine investigations. All patients were advised to fast for 6 hours for solid food. For each patient, table was kept ready for general anesthesia.

On arrival, standard monitoring, including ECG, pulse oximetry and automated non-invasive blood pressure were started. Ringer lactate solution was infused at a rate of 2 ml/kg/hr. after securing 18 G. cannula. Position selected for the procedure was sitting. Epidural catheter insertion site selected was T<sub>9</sub> – T<sub>10</sub> intervertebral space for all the patients. Following skin wheal with 2 ml of 2 % lignocaine, with the bevel directed cephalad, an 18 gauge tuohy needle was inserted. Midline approach with loss of resistance technique with air to identify the epidural space was used.

After negative aspiration of CSF or blood, a 20 gauge closed end epidural catheter with three side holes was inserted through the Tuohy needle in the cephalad direction, into the epidural space. In all patients, the catheter was introduced 3-5 cm beyond the tip of the Tuohy needle and was secured to the skin with a compressive dressing and the patient was placed supine.

Following negative aspiration for CSF and blood, 3 ml of solution containing 2 % lignocaine with adrenaline 15 mcg was administered through the epidural catheter as a test dose. After 3 min, if there was no evidence of inadvertent intravascular or intrathecal injection, the study drug was administered through the epidural catheter:

Group A received 5 ml of 0.75 % ropivacaine.

Group B 10 ml of 0.75 % ropivacaine.

Group C 15 ml of 0.75 % ropivacaine.

Study drug was administered over 2 minutes in fractionated doses as the spread of analgesia is minimally influenced by the spread of injection. Recording for systolic blood pressure, diastolic blood pressure, mean arterial blood pressure, heart rate, SPO<sub>2</sub> and motor blockade were done every 5 minutes for 25 minutes. Sensory analgesia is defined as insensitivity to pin prick test with sterile hypodermic needle in the cephalad and caudal direction in the mid clavicular line bilaterally.

The findings for the spread of the drug for sensory blockade were recorded 5<sup>th</sup> minute then every 5 minutes until 25 minutes after the injection of the drug. The most cephalad and the most caudal analgesic segments were noted.

## ORIGINAL ARTICLE

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Onset, degree of motor blockade were assessed using Bromage scale and RAM (Rectus Abdominis muscle) test. For all cases, surgical procedures were started after 25 minutes of epidural injection. Hypotension is defined as decrease in Systolic blood pressure about 20 % from the baseline value and was treated with intravenous crystalloid infusion and if not effective, 5 mg ephedrine or mephentermine was injected intravenously.

Bradycardia is defined as heart rate below 60 beats/minute and injection atropine 0.6 mg intravenously was administered.

After the study was over, further anesthetic management was adjusted according to the requirement of the surgery.

**STATISTICAL METHODS:** Descriptive and inferential statistical analysis has been carried out in the present study. Analysis of variance (ANOVA) has been used to find the significance of study parameters between three or more groups of patient's, Chi-square/fisher exact test has been used to find the significance of study parameters on categorical scale between two or more groups.

The statistical software namely SAS 9.2, SPSS 15.0, Strata 10.1, Medcalc 9.0.1, Systat 12.0 and R environment ver 2.11.1 were used for the analysis of the data. Microsoft word and excel have been used to generate graphs, tables etc.

**RESULTS:** There were no differences in age, weight, height, gender or ASA physical status distributions among the three groups (Table 1).90 patients were enrolled in the study and they successfully completed the study. The differences in the mean number of analgesic segments blocked among the 3 groups at each time period were studied. At the end of the 25<sup>th</sup> minute there was no significant statistical difference between 3 groups in the number of segments blocked. Tripling the volume of drug resulted in increase in number of segments blocked by only one segment (figure 1,Table 2).Onset of sensory blockade at different intervals were studied there was no statistical difference in the onset of sensory blockade at 5<sup>th</sup> minute with P value of 0.667.However,more number of patients had onset of sensory blockade by 5<sup>th</sup> minute in Group B and Group C when compaired to group A.But by 10<sup>th</sup> minute all the patients had detectable sensory blockade in all 3 groups (Table 3)Segmental dose requirement increased with increase in dose of 0.75%ropivacaine. Thus It is evident from the (Table 4) The dose requirement tripled with increase in number of segments blocked by only one dermatome. The median upper level of blockade was T<sub>5</sub> with range of T<sub>2</sub>-T<sub>4</sub> in group A, T<sub>4</sub> with range of T<sub>2</sub>-T<sub>8</sub> and T<sub>3</sub> with range of T<sub>1</sub>-T<sub>8</sub>in Group C.The median lower level of blockade was L<sub>4</sub> with range of L<sub>1</sub>-S<sub>5</sub> in group A,S<sub>1</sub> with range of L<sub>1</sub>-S<sub>5</sub> in group B and S<sub>3</sub> with range of T<sub>12</sub>-S<sub>5</sub> in group C . Thus in our study majority of the patients had sensory block from T<sub>5</sub>.L<sub>4</sub>in group A,T<sub>4</sub>-S<sub>1</sub> in group B and T<sub>3</sub>-S<sub>3</sub> in Group C. Extent of blockade was more in Group B and Group C due to more number of segments blocked in lumbosacral region.The distribution of analgesic spread was more towards cephalad than caudad in Group A at 25<sup>th</sup> minute. The analgesic spread at 25<sup>th</sup> minute in Group B was almost equal in cepalad and caudad direction.

It was demonstrated that at 25<sup>th</sup> minute in Group C the spread of the drug more toward the caudad. More number of patients in Group B and Group C when compared to Group A had Hypotension and bradycardia. Increasing the dose increased the number of patients having hypotension and bradycardia. In the study done, 16 patients had hypotension and were treated with injection ephedrine (3-6 mg) intermittent bolus intravenously. 13 patients had bradycardia and were

## ORIGINAL ARTICLE

treated with injection atropine 0.6 mg intravenously 4 patients had shivering and were treated with injection tramadol 50 mg intravenously (Table 5).

Variables	Group A	Group B	Group C	P Value
Age	41.86+8.73	37.93+11.18	37.3+11.72	0.242
Weight	55.53+8.38	56.33+8.29	56.23+6.84	0.912
Height	164.61+9.17	161.76+10.56	166.75+10	0.155
ASA Grade(I/II)	56.7/43.3	63.3/36.7	56.7/43.3	0.832
Gender(Male/Female)	66.7/33.3	53.3/46.7	76.7/23.3	0.162

Table 1: Demographic data

Age, weight, and height are expressed as mean (range or SD). ASA physical status, Gender are expressed as number of patients. No significant differences were found.

Variables	Group A 5 ml)	Group B (10 ml)	Group C (15 ml)	P Value
5 min	5.48 ± 2.84	6.79 ± 2.62	7.17 ± 2.71	0.067
10 min	9.83 ± 3.55	10.37 ± 3.00	11.13 ± 3.15	0.301
15 min	12.27 ± 3.36	12.80 ± 3.28	13.20 ± 3.98	0.596
20 min	13.67 ± 3.45	14.43 ± 3.94	15 ± 3.02	0.336
25 min	15.13 ± 3.10	15.5 ± 3.79	16.07 ± 2.82	0.538

Table 2: Analgesic segments blocked at different time interval

Data are presented as mean (SD).

Onset of Sensory Blockade Time (Min)	Number of Patients with Sensory Blockade			P Value
	Group A	Group B	Group C	
5	24 (80 %)	27 (90 %)	25 (83.3 %)	0.667
10	30 (100 %)	30 (100 %)	30 (100 %)	
15	30 (100 %)	30 (100 %)	30 (100 %)	
20	30 (100 %)	30 (100 %)	30 (100 %)	
25	30 (100 %)	30 (100 %)	30 (100 %)	

Table 3: Shows onset of sensory blockade at different time intervals

Data are presented as number of patients (n).

## ORIGINAL ARTICLE

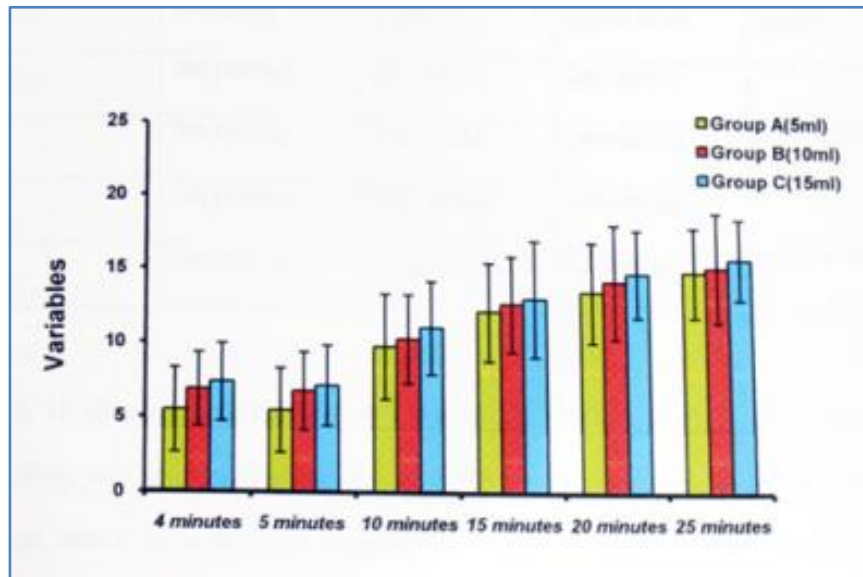
Variables	Group A (5 ml)	Group B (10 ml)	Group C (15 ml)
Dose/Segment (Mean) and Range	0.4 (0.23 - 0.63)	0.67 (0.47 - 1)	1.04 (0.71 - 3)
Dose/ Segment/ meter height (Mean & Range)	0.24 (0.16 - 0.39)	0.43 (0.29 - 0.58)	0.63 (0.42 - 1.7)
Upper level of analgesia and range	T <sub>5</sub> (T <sub>2</sub> - T <sub>4</sub> )	T <sub>4</sub> (T <sub>2</sub> - T <sub>8</sub> )	T <sub>3</sub> (T <sub>1</sub> - T <sub>8</sub> )
Lower Level of analgesia and Range	L <sub>4</sub> (L <sub>1</sub> - S <sub>5</sub> )	S <sub>1</sub> (L <sub>1</sub> - S <sub>5</sub> )	S <sub>3</sub> (T <sub>12</sub> - S <sub>5</sub> )

Table 4: Segmental dose requirement

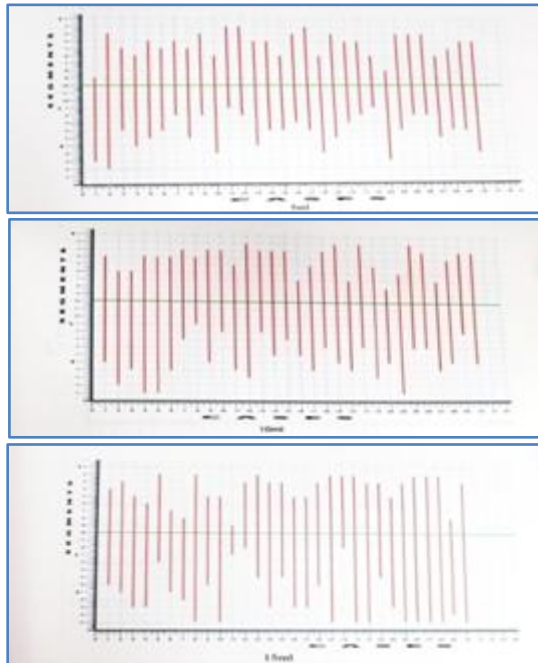
Complication	No. of Cases			
	Group A (n=30)	Group B (n = 30)	Group C (n = 30)	P Value
Hypotension	2 (6.7 %)	6 (20 %)	8 (26.7 %)	0.111
Bradycardia	2 (6.7 %)	5 (16.7 %)	6 (20 %)	0.413
Shivering	1 (3.3)	1 (3.3)	2 (6.7 %)	1

Table 5: Complications

Data are presented as number of patients



**Fig. 1: Number of analgesic segments blocked at different time intervals in 3 Groups**



**Fig 2: Depicts spread of drug in 25 minutes in Group A, Group B and Group C respectively**

**DISCUSSION:** Epidural anesthesia has been used as an anesthetic technique for decades. However, factors affecting the spread of sensory blockade remain unclear after epidural injection of local anesthetics. Factors affecting the distribution of neural blockade varies among individuals. Combination of several patients and technical factors may better aid in predicting local anesthetics dose requirements.

Ropivacaine is the first long acting, injectable local anesthetic to undergo testing in more than 20 years. Studies done by Dene Simpson et al found ropivacaine when compared to bupivacaine was equally potent in their ability to block C fibre activity, but ropivacaine was less effective in blocking larger ( $A\beta$ ) motor fibres.<sup>4</sup> Ropivacaine also has reduced potential for cardiac toxicity. The present study of thoracic epidural anesthesia for lower abdominal surgeries using 0.75 % ropivacaine was conducted in 90 patients divided into 3 groups.

The number of segments blocked were also significantly more in group C and group B when compared to Group A in the 5<sup>th</sup> minute. The spread of analgesic segments increased with increased volume of 0.75 % ropivacaine. However, in the current study, doubling or tripling the volume resulted in increased spread of the drug by only 1 segment and 2 segments higher respectively in the upper level of sensory blockade. Spread of the drug increased by 2 segments and 4 segments in caudal direction on an average.

It was expected that increasing the volume and dose will result in number of segments being blocked and also increases the incidence of hypotension and bradycardia. However, Woo young park et al reported that the total number of spinal segments anaesthetized was related to the total epidural dose, but not in linear manner<sup>5</sup>. Keneko. Et al demonstrated a lack of linear relationship between injected volume of local anesthetic and spread of epidural anesthesia.<sup>6</sup>

## ORIGINAL ARTICLE

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This study was conducted to evaluate the effectiveness of thoracic epidural anesthesia with regard to onset and extent of sensory analgesia, onset and quality of motor blockade. Effects on hemodynamic variable, incidence of improper block and whether the spread of ropivacaine in lower thoracic area is cranial or caudal, linear or non-linear with increasing dose and volume of the drug.

It has been reported that, as the dose of a local anesthetic increases, the onset of epidural block seems to get faster. Therefore, injecting a large volume is associated with rapid establishment of epidural analgesia. However, in the present study, more number of patients in Group B and Group C given 10 ml and 15 ml of 0.75% ropivacaine respectively had earlier onset of sensory block as compared to Group A (5 ml). All patients in the study had detectable sensory blockade by 10 minutes although more number of patients in Group B and C had detectable analgesia by 5<sup>th</sup> min.

In the present study, in Group A the spread of the drug was more cephalad. In Group B i.e., on doubling the drug dose the spread of the drug was almost equally distributed in both cephalad and caudad direction and on tripling the drug dose (Group C) the spread of the drug was more caudad direction. AK wahal et al found that caudal and cephalic spread of analgesic solution from the site of institution of epidural block between T<sub>6</sub> – T<sub>7</sub> intervertebral space was found to be in a ratio of 2:1 (Caudal: Cephalic).<sup>7</sup> Visser WA reported in their study, a more cranial spread of sensory block occurred in lower thoracic level of epidural anesthesia.<sup>8</sup> The patients height and age had small effect on spread.

Ropivacaine is known to spare motor fibres. In the present study according to Bromage scale, most of the patients in Group 'A' had partial block (30 % cases) or no block in 70 %. In contrast, Group B 40 % had partial block and 40 % had no block at all. In Group C, 80 % patient had partial to complete blockade. This implies that there was reduced incidence of motor blockade in Group A and Group B when compared to Group C.

The onset of action was faster in Group B and Group C by 25<sup>th</sup> minute, 85 % in Group A, 97 % in Group B and Group C had power less than 60 % (according to RAM test). Thus increasing the volume and dose had little effect on sensory blockade and extent yet had marked effect on the onset and intensity of motor block.

M conception et al suggested that satisfactory sensory anesthesia can be obtained with ropivacaine 0.5 % with minimal motor blockade<sup>9</sup>. Kerkamp et al reported in their study that 0.5 %, 0.75 % and 1 % ropivacaine with epinephrine provides adequate analgesia and motor blockade for abdominal surgeries.<sup>10</sup>

In the present study, there was significant decrease in mean arterial pressure and diastolic blood pressure at 5<sup>th</sup> minute between the groups. But there was no statistical significance between the groups at the 25<sup>th</sup> min. TH Gould et al advised to treat hypotension promptly and to minimize hemodynamic consequences, limit the segmental epidural block to T<sub>8</sub>–L<sub>1</sub> when possible<sup>11</sup>. Wm wahba reported that thoracic epidural given to achieve T<sub>4</sub> level will not result in derangement of ventilatory capacity, will have no effect on Functional Residual Capacity and cardiac output.<sup>12</sup> There was desaturation to levels below 85 % in all subjects studied.

No serious adverse events were noted in the study. The most common adverse effects were hypotension, bradycardia and shivering. There was no incidence of systemic toxicity in the current study.

It was expected that thoracic epidural anesthesia will be associated with high incidence of complications due to oblique and steep angulation of the spinous process. Reins M. Giebler et al

## ORIGINAL ARTICLE

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reported that the thoracic epidural catheterization for thoraco abdominal surgery was not associated with a high incidence of serious neurological complication<sup>13</sup>.

**CONCLUSION:** Lower thoracic epidural anesthesia with 0.75 % ropivacaine for abdominal surgeries provides good analgesia and muscle relaxation with minimal amount of drug. 0.75 % ropivacaine (5 ml) produces adequate analgesia and abdominal muscle relaxation with less degree of motor blockade in the lower limbs. In low thoracic epidural anesthesia, 15 ml of 0.75 % ropivacaine resulted in caudad spread of drug as compared to 5 ml. of 0.75 % ropivacaine.

- To establish proper perioperative lower thoracic epidural analgesia with less hemodynamic changes, it is recommended to use 5ml of 0.75% ropivacaine.

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## ORIGINAL ARTICLE

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