

# The efficacy of 0.75% ropivacaine by epidural neuroaxial blockade for lower abdominal surgeries

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## Abstract

The feasibility of injecting a local anaesthetic by the epidural route was first demonstrated by the French Urologist Cathelin in 1901. However, for many years caudal rather than lumbar epidural blockade was the preferred method for epidural anaesthesia. A thorough pre-anaesthetic check-up was done for all patients, a day before surgery. Patients were evaluated for any systemic diseases. No special investigations were required pertaining to the study. Basic investigations like haemoglobin, total and differential WBC count, bleeding and clotting time, HIV and HBs Ag, ECG and urine routine investigations were carried out for all the patients. Written informed consent was obtained before the surgery after explaining the patients about the drug and Epidural anaesthetic procedure. The highest level of sensory block achieved was T 5 with a range of T 5 - T 8. The mean time taken to reach highest level of sensory block was  $29.77 \pm 4.94$  minutes. 83.3% of the patients achieved the highest level between 20 to 35 minutes. The total duration of motor block was assessed when the pt could raise the extended leg on both sides and in the present study, the mean total duration of motor block was found to be  $263.58 \pm 21.19$  minutes

**Key Word:** Ropivacaine, epidural neuroaxial blockade, lower abdominal Surgeries

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Received Date: 19/06/2018 Revised Date: 18/07/2018 Accepted Date: 10/08/2018

DOI: <https://doi.org/10.26611/1015726>

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Accessed Date:  
13 August 2018

## INTRODUCTION

The principal function of anaesthesiologist in patient care is not only to save lives, but also to relieve pain and suffering. Pain was often considered to be a punishment for committed sins or a form of religious suffering. It is possible to perform all surgical procedures under general anesthesia. But, general anaesthesia has its own

disadvantages and limitations in terms of its use in patients with cardio-respiratory diseases and in certain situations like asthmatic's coming for lower abdominal surgeries. Therefore regional anaesthesia is preferred. The need for specialized post operative monitoring and care is minimal with regional than general anaesthesia. Regional techniques may also decrease the length of hospital stay<sup>1</sup>. Epidural anaesthesia is superior to Spinal as the desired level of block levels can be achieved with less significant haemodynamic disturbances and top-up doses of local anaesthetics and analgesics can be given. The feasibility of injecting a local anaesthetic by the epidural route was first demonstrated by the French Urologist Cathelin in 1901. However, for many years caudal rather than lumbar epidural blockade was the preferred method for epidural anaesthesia. The introduction of Tuohy needle for epidural use in 1949, along with recognition due to anatomical difficulty of caudal block has become increasingly popular over

caudal block.<sup>2,3</sup> Bupivacaine – a pipercoloxylidide derivative synthesized in 1957 by Ekenstam and introduced in clinical practice in 1963 is widely used local anaesthetic agent by epidural route. It is a racemic mixture of the dextro and levo stereoisomers. However the dextro enantiomer makes Bupivacaine a more cardiotoxic drug. In 1979 Albright published an alarming editorial in which he described occurrence of cardiac arrest during regional Anaesthesia with Bupivacaine.<sup>4,5</sup> Bupivacaine depresses the rapid phase of depolarization ( $V_{max}$ ) in Purkinje fibres and ventricular muscle. The rate of recovery from a use dependent block is slower in Bupivacaine treated papillary muscles. This slow rate of recovery results in an incomplete restoration of  $Na^+$  channel availability between action potentials. These effects explain the arrhythmogenic potential of Bupivacaine.<sup>6</sup> Research for a local anaesthetic with less potential for cardiotoxicity was needed. There was a need for a local anaesthetic agent with less potential for cardiotoxicity. These findings generated laboratory research program, which was aimed at identifying a local anaesthetic with a similar clinical profile but with less cardiotoxicity than Bupivacaine. Ropivacaine is an amino local anaesthetic agent. It is the monohydrate of the hydrochloride salt of 1-propyl-2', 6'- pipercoloxylidide and is prepared as the pure enantiomeric form. This drug was first registered for clinical use in 1996. Ropivacaine blocks nerve fibres involved in pain transmission to a greater degree than those controlling motor function. The very slow reversal of  $Na^+$  channel blockade after a cardiac action potential, which is a hallmark of bupivacaine, is considerably faster with ropivacaine. The physico-chemical properties of Ropivacaine suggest that its rate of onset (related to pKa) is similar to that of Bupivacaine, and that its absolute potency (Lipid solubility) and duration of effect (Protein binding) is slightly less compared to Bupivacaine. Ropivacaine has slightly rapid plasma clearance and shorter elimination half life than that of racemic Bupivacaine.<sup>8</sup> In view of these potential advantages of Ropivacaine over racemic Bupivacaine this drug has gained popularity in clinical practice in most of the developed countries. This present prospective clinical study is intended to evaluate the onset, duration of analgesia and intensity of motor block of 0.75% preservative free epidural Ropivacaine for lower abdominal surgeries.

## METHODOLOGY

### Pre anaesthetic examination and preparation:-

A thorough pre-anaesthetic check-up was done for all patients, a day before surgery. Patients were evaluated for any systemic diseases. No special investigations

were required pertaining to the study. Basic investigations like haemoglobin, total and differential WBC count, bleeding and clotting time, HIV and HBsAg, ECG and urine routine investigations were carried out for all the patients. Written informed consent was obtained before the surgery after explaining the patients about the drug and Epidural anaesthetic procedure. All patients were given Tab. Diazepam 10mg orally on the previous night of surgery at bed time as pre-medication.

### Preparation in operation theatre

Anaesthesia machine was checked. Appropriate size endotracheal tubes, laryngeal mask airways as appropriate for weight, working laryngoscope with medium and large sized blades, stylet and working suction apparatus were kept ready before the procedure. Emergency drug tray consisting of atropine, adrenaline, mephenteramine, dopamine were also kept ready.

### Anaesthetic technique and monitoring

Once the patient's nil oral status was confirmed, patient were shifted to operating room and were preloaded with Ringer's Lactate fluid @ 10 ml/kg over 30 to 60 minutes after securing an intravenous access with 18 gauge IV Cannula. All the patients were connected to Philips Intellivue MP 20 monitor and base line Heart rate, Blood Pressure (systolic and diastolic, Mean arterial blood pressure) and SpO<sub>2</sub> were recorded. Patients were put in left lateral position and under strict aseptic precautions and local anaesthesia infiltration, L2-L3 lumbar epidural space was identified by loss of resistance to air technique using 18G Tuohy's needle. If, there was any technical difficulty in appreciating L2-L3 space, L3-L4 lumbar epidural space was attempted. After identification of epidural space, epidural catheter was inserted upto 5 cm inside the space and position of catheter was confirmed by negative aspiration for blood and CSF. Then sterile dressing is applied and the epidural catheter was secured in place with tape. A test dose of 3ml of 2% lignocaine with adrenaline (1:2,00,000) was given through the epidural catheter. 5 minutes after test dose, in the absence of any adverse sequelae, the patient was positioned in the supine position and 15 ml of study drug (preservative free Ropivacaine 0.75%) was injected through epidural catheter intermittently over 3 minutes. The time at which epidural injection of the study drug was completed was considered as zero ( $t=0$ ). Surgery was allowed to commence when adequate sensory blockade was achieved for that particular surgery. All the patients were given Oxygen @ 4L/min through plain face mask. No intravenous analgesics or opioids were given during the procedure. After injecting the study drug in to the

epidural space, following clinical assessments were made from time zero,

### A. Sensory blockade

Onset of sensory blockade was assessed by pin prick method at S1, L1, T10 and T6 dermatomal levels from time zero. The sensory block was assessed bilaterally by pain to pinprick every minute till 10 minutes and later every 2 minutes till sensory blockade level was established at all 4 dermatomal levels and then every 15 minutes until the first hour had elapsed, then every 30 minutes interval until the complete recovery from sensory blockade. Time to achieve highest level of sensory block, time required for 2-segment regression from highest cephalad spread, time required for regression to T10 dermatome and total absence of the sensory block at any dermatomal level were assessed and recorded.

### B. Motor blockade

Motor block was assessed by modified Bromage scale. Onset time, intensity of motor blockade and duration of motor blockade was tested bilaterally using modified Bromage scale (Proposed by Bromage and modified by Logan-Smith) In our study, following data were analysed: Patient demographic variables: onset, duration and regression of both sensory and motor blockade. Data were expressed as mean and standard deviation and presented through tables and charts.

## RESULTS

**Table 1:** ASA physical status distribution

Age group (Yrs)	ASA grade I		ASA grade II		TOTAL	
	No	%	No	%	No	%
20-30	8	15.1	0	0.0	8	13.3
31-40	25	47.2	4	57.1	29	48.3
41-50	18	34.0	2	28.6	20	33.3
51-60	2	3.8	1	14.3	3	5.0
TOTAL	53	100.0	7	100.0	60	100.0

In ASA physical status distribution, 53 patients belonged to ASA grade I and 7 patients to ASA grade II. 81.6% patients were in the age group of 31 to 50 years.

**Table 2:** Duration of surgery

Time (Min)	No of patients	%
85-110	24	40.0%
111-135	7	11.7%
136-160	8	13.3%
161-185	21	35.0%
<b>TOTAL</b>	<b>60</b>	<b>100.0%</b>

The site of placement of epidural catheter was in L<sub>2</sub> – L<sub>3</sub> interspace for 53 patients and L<sub>3</sub>-L<sub>4</sub> space due to technical reasons, for 7 patients.

- From the injection of drugs into the epidural space the mean time interval to the beginning of surgery was  $23.41 \pm 7.0$  minutes.
- The mean duration of surgery was  $134.3 \pm 33.71$  minutes.

**Table 3:** Highest level of sensory block achieved

Highest level of sensory block achieved	No of patints	Percent
T 5	6	10.0%
T 6	45	75.0%
T 7	4	6.6%
T 8	5	8.4%
Total	60	100%

In the present study, the highest level of sensor block achieved was T<sub>5</sub> in 8.4% of patients (5 patients out of 60) with a range between T<sub>5</sub> – T<sub>8</sub>. Majority (75%) of patients achieved T<sub>6</sub> dermatomal level.

**Table 4:** Time to reach highest level of sensory block

Time (in Min)	No of patients	Percent
20-25	11	18.3%
26-30	29	48.3%
31-35	10	16.7%
36-40	9	15.0%
41-45	1	1.7%
Total	60	100.0%

The highest level of sensory block achieved was T 5 with a range of T 5 - T 8. The mean time taken to reach highest level of sensory block was  $29.77 \pm 4.94$  minutes. 83.3% of the patients achieved the highest level between 20 to 35 minutes

**Table 5:** Onset of sensory Block - S1

Onset (in Min)	No of patients	Percent
10-15	2	3.3%
16-20	26	43.3%
21-25	12	20.0%
26-30	16	26.7%
31-35	4	6.7%
Total	60	100.0%

In the present study the time of onset of sensory block was assessed for 4 dermatomal level .ie.S<sub>1</sub>, L<sub>1</sub>, T<sub>10</sub> and T 6 using pin prick method with a 23G hypodermic needle. The mean onset time for sensory block at S<sub>1</sub> dermatomal level was  $22.9 \pm 5.01$  minutes in the present study.

**Table 6:** Block Regression

Block Regression	Time Range (mins)	Mean	SD
2-Segment from Maximal cephalad spread	175-225	209.03	22.75
Regression to T 10	200-325	273.4	23.57
Complete regression ( Total Duration )	350-475	406.25	23.22

The regression of sensory block level was assessed as follows,

1. The time required for the sensory block to regress by two dermatomal segments from the highest level of sensory block achieved.
2. Time required for the sensory block to regress up to T<sub>10</sub> dermatomal segment.
3. Time until there is no sensory block present at any dermatomal level .ie. total duration of sensory block.

The mean time required for two segment regression of sensory block from maximal cephalad spread was 209.03 ± 22.75 minutes. 76.7% of the patients had two segment block regression between the time range of 175 to 225 minutes. For sensory block to regress to T<sup>10</sup> dermatomal level, the mean time taken was 273.4 ± 23.57 minutes. Most of the patients ie. 90% of them had sensory block regression between the range of 226 to 300 minutes. The mean total duration of sensory block was found to be 406.05 ± 23.22 minutes.

**Table 7:** Onset time for Bromage scale-Grade 1

Time (Min)	No of patients	Percent
10-13	16	26.7%
14-17	20	33.3%
18-21	21	35.0%
22-24	3	5.0%
Total	60	100.0

The degree of motor blockade was assessed using Modified Bromage scale. All the patients achieved Bromage scale 1 and 2 and only 4 patients achieved Bromage scale 3. Bromage scale 1 was achieved in all patients with a mean time of 15.98 ± 3.38 minutes. Majority of patients (95%) developed this in the time range of 10 to 21 minutes.

**Table 8:** Onset time for Bromage scale-Grade 2

Time (Min)	No of patients	Percent
22-24	6	10.0%
25-29	25	41.7%
30-34	23	38.3%
35-39	6	10.0%
Total	60	100.0%

The mean onset time for Bromage scale 2 was found to be 29.31 ± 3.78 minutes. 90% of the patients achieved Bromage 2 scale between 22 to 34 minutes.

**Table 9:** Total duration of Motor block

Time (Min)	No of patients	Percent
200-225	2	3.3
226-250	16	26.7
251-275	26	43.3
276-300	15	25.0
301-325	1	1.7
Total	60	100.0

The total duration of motor block was assessed when the pt could raise the extended leg on both sides and in the present study, the mean total duration of motor block was found to be 263.58 ± 21.19 minutes.

## DISCUSSION

The primary aim of our present clinical study was to evaluate the anaesthetic effect of 0.75% preservative free Ropivacaine given through epidural route for lower abdominal surgeries and to find out whether the haemodynamic changes caused by the study drug in different lower abdominal surgeries are within safe limits when used epidurally. In the present study, we measured the onset of action, maximum level and total duration of sensory block, Degree of motor blockade and it's duration, Duration of sensory block with respect to two segment regression, Haemodynamic changes and side effects, if any. In the present study, the onset of sensory block for different dermatomal levels were tested. We found that the mean time of onset of sensory block at S1, L1, T10 and T6 were 22.9±5.01 mins, 8.48±3.18 mins, 13.4±3.88 mins and 29.5±3.33 mins respectively. The highest level of sensory block achieved was T5 dermatomal level and mean time to reach highest cephalad level was 29.77±4.94 minutes. When time required for regression of sensory block was measured, we observed that mean time for two segment regression from highest cephalad spread was 209.03±22.75 minutes and the mean time for sensory block regression to T 10 segment was 273.4 ± 23.57 minutes. The mean time for complete regression of sensory block .ie.total duration of sensory block was 406.25± 23.22 minutes.

In the study conducted by Bendan.T., Finucane and *et al*, they found similar results for sensory onset, sensory distribution and total duration of sensory block and results were comparable with our present study<sup>9</sup>. In another study conducted by C.P.J.Morton and *et al*, they observed that onset of sensory block at S1 , T10 and T6 were 20 mins (range of 5-13), 10 mins (range of 5-18) , 15 mins ( range of 5-38) respectively which were similar and comparable with our study.<sup>10</sup> In the study conducted by DusankaZaric, KjellAxelsson and *et al* observed that for 0.75% ropivacaine group, the onset of sensory block was 9 ±0.9 minutes and time for regression to two dermatomes from highest cephalad level was 203 ± 20.3 minutes which were similar and comparable with our study.<sup>11</sup> The study conducted by Tuttle. AA, Katz and *et al* (Rop-9), the total duration of sensory block was 404±62 minutes which was similar to our results. Study done by J.A.Katz, Phillip.O. Bridengaugh and *et al* also showed that mean time for two segment regression from highest cephalad spread

was  $180 \pm 30$  minutes for 0.75% ropivacaine group which was comparable with our study.<sup>12</sup> In our present study, only 4 patients, i.e. 6.66% of total patients achieved Modified Bromage scale grade 3 in motor blockade assessment. The mean time of onset of Modified Bromage scale degree 1 and 2 were  $15.98 \pm 3.38$  minutes and  $29.31 \pm 3.78$  minutes respectively. The total duration of motor blockade was  $263.58 \pm 21.9$  minutes. The motor block onset and duration were similar and comparable with the study conducted by Brendan. T, Filnucane and *et al*. In the study conducted by Tuttle AA, Katz and *et al*, the time for motor block onset was  $12 \pm 3$  minutes and duration of motor block was  $310 \pm 65$  minutes which were comparable with our study results.<sup>12</sup> In another study conducted by C.P.J.Morton and *et al*<sup>10</sup>, the onset of Bromage scale I motor block and Bromage scale 2 motor block was 18 mins (range of 6-45) and 26 mins (range of 11-45) respectively which were comparable with our study. In the present study, it was notable that we found marked separation between the effect of sensory and motor block (total motor block was  $263.58 \pm 21.19$  minutes and total sensory block was  $406.25 \pm 23.22$  minutes). This shows that 0.75% Ropivacaine provides analgesia in the post-operative period even after motor function returns. All the haemodynamic parameters were monitored and recorded and there were no significant changes with 0.75% Ropivacaine from base line values. Maximal decrease in Heart rate, Systolic blood pressure, Diastolic blood pressure and Mean arterial blood pressure occurred at  $26.08 \pm 4.22$ ,  $30.41 \pm 4.04$ ,  $26.08 \pm 4.22$  and  $26.08 \pm 4.22$  respectively. Only 3 patients required InjMephenteramine due to fall in MAP of less than 60 mm of Hg. Otherwise, all the 60 patients were haemodynamically stable throughout the anaesthetic procedure which were comparable with many other studies. There were little changes in oxygen saturation as measured by pulsoximeter and respiration in the present study which were similar to many studies conducted by other investigators. In our study, incidence of side effects were minimal. Only 2 patients had vomiting, 6 patients had shivering and 3 patients had hypotension (MAP <60 mm of Hg). Hypotension was treated with InjMephenteramine 6 mg. All the patients were pre-loaded with Ringer's Lactate @ 10 ml/Kg over 30 – 60 minutes period before the beginning of anaesthetic procedure. The mean requirement of Crystalloids during intra operative period was  $1000 \pm 220$  ml. In the present study, 15 ml of 0.75% preservative free Ropivacaine was given epidurally for 30 male patients undergoing different lower abdominal surgeries. It was observed that 0.75% Ropivacaine is an effective long acting local anaesthetic agent. The onset

of sensory block was quiet faster and was similar and comparable with studies conducted by other investigators. The duration of motor blockade is far less than the sensory blockade which may help the patients in giving post-operative relief from pain even after return of motor function and this drug may be a better choice for day care and ambulatory surgeries. In this study, all the patients were haemodynamically stable throughout the anaesthetic procedure with minimal cardiovascular changes from the pre-block values and minimal side effects.

## CONCLUSION

With 0.75% preservative free Ropivacaine, the mean onset time of sensory block for S<sup>1</sup>, L<sup>1</sup>, L<sup>10</sup>, and T<sup>6</sup> dermatomal levels were  $22.9 \pm 5.01$  mins,  $8.48 \pm 3.18$  mins,  $13.4 \pm 3.88$  mins and  $29.5 \pm 3.33$  mins respectively. The maximum cephalad spread was T5 dermatomal level and mean time to reach maximum cephalad spread was  $29.77 \pm 4.94$  minutes.

The mean duration of sensory blockade and motor blockade were  $406.25 \pm 23.22$  minutes and  $263.58 \pm 21.19$  minutes respectively. The motor blockade time was far less than the sensory blockade. Only 6.66% of the total patients achieved the Modified Bromage scale 3.

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Source of Support: None Declared  
Conflict of Interest: None Declared

