



## COMPARATIVE STUDY OF EPIDURAL 0.75% ROPIVACAINE WITH DEXMEDETOMIDINE AND 0.75% ROPIVACAINE ALONE IN LOWER ABDOMINAL AND LOWER LIMB SURGERIES

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### ABSTRACT

**Background:** Epidural anaesthesia is one of the most common regional anaesthetic techniques used for lower abdominal and lower limb surgeries. The advantages of epidural anaesthesia being, it provides effective surgical anaesthesia and can meet the extended duration of surgical needs, provides prolonged post-operative analgesia, reduces the incidence of hemodynamic changes. Various adjuvants are being used with local anesthetics for prolongation of intra operative and postoperative analgesia in epidural block for lower abdominal and limb surgeries. Dexmedetomidine, the highly selective 2 adrenergic agonist is a new neuroaxial adjuvant gaining popularity.

**Aim:** To study the synergistic effect of adding dexmedetomidine to ropivacaine 0.75% in epidural anaesthesia for lower abdominal and lower limb surgeries.

**Materials and Methods:** One Hundred Patients scheduled for various lower abdominal and lower limb surgeries under epidural anesthesia participated in this study. They were assigned to: Control Group (n = 50), 15ml of 0.75% ropivacaine and Dexmedetomidine Group (n = 50), 15ml of 0.75% ropivacaine plus 0.6mcg. Kg<sup>-1</sup> of dexmedetomidine. The Following variables were studied: onset of sensory and motor block, duration of sensory and motor block, maximal dermatomal level of analgesia.

**Results:** Dexmedetomidine group had rapid onset of action (p<0.05), prolonged duration of sensory and motor block (p<0.05), postoperative analgesia (p<0.05), and determine more intense motor block (p<0.05). There was no difference in the maximal dermatomal level of analgesia.

**Conclusion:** Epidural Dexmedetomidine as an adjuvant to Ropivacaine is associated with prolonged sensory and motor block, hemodynamic stability, prolonged postoperative analgesia and reduced demand for rescue analgesics when compared to plain Ropivacaine.

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### INTRODUCTION

Intrathecal anaesthesia and epidural anaesthesia are the most popular regional anaesthesia techniques used for lower limb, lower abdominal surgeries. The advantages of epidural anaesthesia being it,<sup>1,2</sup> provides effective surgical anaesthesia and can meet the extended duration of surgical needs, provides prolonged post-operative analgesia, reduces the incidence of hemodynamic changes.

Different local anaesthetics are used for epidural anaesthesia,<sup>3</sup> most popular in India being Lidocaine and Bupivacaine. The drawback of lidocaine is its intermediate duration of action and the drawback of bupivacaine though long acting, is increased incidence of fatal cardiac toxicity after accidental intravascular injection, because of narrow cardiovascular collapse/central

nervous system toxicity (cc/cns).<sup>4</sup> For this reason there has been a search for alternative drugs with desirable blocking properties of bupivacaine but with a greater margin of safety. Ropivacaine and levobupivacaine are the newer long acting amide local anaesthetics which have a wide margin of safety compared to bupivacaine, with all its advantages.<sup>4</sup>

Recently Ropivacaine has been introduced and since Ropivacaine has all the advantages of bupivacaine with less cardiac toxicity,<sup>5</sup> it appears that it may be an ideal local anaesthetic for epidural anaesthesia. Various studies have found, Ropivacaine to be an effective local anaesthetic for epidural anaesthesia.<sup>6-9</sup> Richard Aurthur *et.al*,<sup>10</sup> in their comparative pharmacokinetics of bupivacaine and ropivacaine have found that when applied directly to an isolated vagus nerve preparation, ropivacaine was less potent than

bupivacaine in terms of conduction blocks of A fibers, but ropivacaine blocked A and C fibers to a greater extent than did bupivacaine. It is also been found that, lipid solubility of Ropivacaine is 2.9 compared with 3.9 of bupivacaine.<sup>11</sup> Hence in our study ropivacaine was selected as the study drug.

The fear of surgery, strange surroundings of the operation theatre, the sight and sound of sophisticated equipment and the masked faces of many strange persons makes the patient panic to any extent.

Sedation, stable haemodynamics and an ability to provide smooth and prolonged post-operative analgesia are the main desirable qualities of an adjuvant in neuraxial anaesthesia.

-2 adrenergic agonists have both analgesic and sedative properties when used as an adjuvant in regional anaesthesia. Dexmedetomidine is a highly selective  $\alpha_2$  adrenergic agonist with an affinity of eight times greater than clonidine. Various studies have shown that the dose of clonidine is 1.5 - 2 times higher than dexmedetomidine when used in epidural route. The anaesthetic and the analgesic requirement get reduced to a huge extent by the use of dexmedetomidine because of its analgesic properties and augmentation of local anaesthetic effects as they cause hyperpolarisation of nerve tissues by altering transmembrane potential and ion conductance at locus coeruleus in the brainstem.<sup>12</sup> The stable haemodynamics and the decreased oxygen demand due to enhanced sympathoadrenal stability make it a very useful pharmacologic agent.

Hence it would be ideal to compare 0.75% ropivacaine with dexmedetomidine and 0.75% ropivacaine alone in lower abdominal and lower limb surgeries.

Hence a study was undertaken to compare 0.75% ropivacaine with dexmedetomidine and 0.75% ropivacaine alone in lower abdominal and lower limb surgeries.

## METHODS AND MATERIALS

A study entitled "Comparative study of Epidural 0.75% Ropivacaine with Dexmedetomidine and 0.75% Ropivacaine alone in lower abdominal and lower limb surgeries" was undertaken in Kempegowda Institute of Medical Sciences (K.I.M.S) hospital, Bangalore during the period October 2011 and July 2013. The study was undertaken after obtaining ethical committee clearance as well as informed consent from all patients.

One hundred patients, scheduled for various elective lower abdominal and lower limb surgical procedures belonging to ASA class I and II were included in the study.

The study population was randomly divided using computer generated randomization numbers into two groups with 50 patients in each group:

1. Group R (n=50) - 15ml of 0.75% ropivacaine (Ropivacaine 0.75% preservative free – ROPIN 0.75% 20 ml ampoules – Neon laboratories India limited)
2. Group RD (n=50) -15ml of 0.75% ropivacaine + 0.6 $\mu$ g/kg of dexmedetomidine (inj.DEXTOMID-1ml=100mcg,1ml ampoule)

### Inclusion criteria for the study

1. Adult patients aged between 18 to 65 years of both sex.

2. Patients belonging to ASA class I and II posted for elective lower abdominal and lower limb surgical procedures.
3. Weight > 50 kgs
4. Height 150-180cms

### Exclusion criteria for the study

1. Patient refusal for regional anaesthesia.
2. Pregnancy and lactation.
3. Patients posted for Emergency surgeries.
4. Obese patient with BMI > 30.
5. Patients having:
  - A. raised intracranial pressure
  - B. severe hypovolemia
  - C. bleeding coagulopathy
  - D. local infection
  - E. uncontrolled hypertension/ diabetes mellitus
  - F. neurological disorder and deformities of spine
  - G. cardiac disease
  - H. hepatic disease
  - I. allergy to local anaesthetics and dexmedetomidine

## METHODS

A routine pre-anaesthetic examination was conducted on the evening before surgery. The patients were premedicated with tabl *et al* prazolam 0.5 mg and tablet ranitidine 150 mg orally at bed time on the previous night before surgery. They were kept nil orally 10 pm onwards on the previous night.

On the day of surgery, patient's basal pulse rate and blood pressure were recorded. A peripheral intravenous line with 18 gauge cannula after local anaesthesia was secured in one of the upper limbs. All the patients were preloaded with 500 ml of Ringer lactate 30 minutes prior to the epidural procedure. Multiparameter monitor was connected which records heart rate, non-invasive measurement of systolic blood pressure (SBP), diastolic blood pressure (DBP), mean arterial pressure (MAP), continuous electrocardiogram (ECG) monitoring and oxygen saturation (SPO<sub>2</sub>).

With the patients in sitting position under aseptic precautions, epidural space was identified by loss of resistance technique to air using 18G Tuohy needle via the midline approach at either L2-3 or L3-4 inter spinous space. An epidural catheter was threaded and fixed at 3 cms inside the epidural space. A test dose of 3 ml of 2% lignocaine with 1:200000 adrenaline was injected through the catheter after aspiration. After ruling out intrathecal and intravascular placement of the tip of the catheter, study drug was injected in increments of 5 ml. The patients were turned to supine position after 1 min.

Assessment of sensory and motor blockade were done at the end of each minute with the patient in supine position after completion of the injection of 15 ml of the study drug, which is taken as the starting time. The onset time for sensory and motor block, the maximum level of sensory block, intensity of motor block and sedation score were recorded.

Sensory blockade was assessed using a short bevel 22 gauge needle and was tested in the mid clavicular line on the chest, trunk and lower limbs on either side.

Motor blockade in the lower limbs was assessed using modified Bromage scale.

1. Able to perform a full straight leg raise over the bed for 5 sec
2. Unable to perform the leg raise but can flex the leg on the knee articulation
3. Unable to flex the knee but can flex the ankle
4. Unable to flex ankle but can move the toes
5. Unable to move toes (total paralysis).

Measurements of blood pressure, heart rate, and oxygen saturation will be recorded every 5 minutes till the end of 1hour and then every 15 minutes till the end of surgery

After the surgery, patients referred to the recovery room (PACU) post anaesthesia care unit where they remained until there was complete recovery of sensory and motor blockade. Epidural top up was given with 8ml of 0.2% inj.ropivacaine once the patient complains of pain. Postoperatively vital parameters will be recorded every 15minutes, and also duration of sensory and motor blockade.

**RESULTS**

Table 1 shows the mean age, weight, height and gender distribution in both the groups

**Table 1** Demographic Data of the Study Subjects

	Group R	Group RD	P Value
AGE in years(MEAN ±SD)	32.19 ± 11.1	32.8 ± 10.12	0.962
WEIGHT in kgs (MEAN ±SD)	58.64 ±5.17	56.10 ±6.11	0.27
HEIGHT in cms (MEAN ±SD)	170	169.3	
GENDER M/F	36/15	31/19	

**Table 2** Type of Surgeries in the Study Subjects

Type of Surgery	Group R		Group RD	
	Number of Patients	Percent	Number of Patients	Percent
Both Bones Leg Femur	13	26	12	24
Inguinal Hernioplasty	25	50	23	46
	12	24	15	30

**Table 3** Characteristics of Sensory and Motor Block in Both the Groups

	Group R	Group RD	p-value
Mean time for Onset of sensory block(min)	10.04±2.55	5.26±1.49	0.000
Mean time for Onset of motor block(min)	15.36±3.28	11.22±2.61	0.000
Mean duration of sensory block(min)	198.00 ±24.05	359.30 ±61.94	0.001
Mean duration of motor block(min)	149.00 ±14.21	233.70 ±15.36	0.001

The mean time of onset of sensory blockade in group R is 10.04±2.5 mins and in group RD is 5.26±1.49mins. There is highly statistical significant difference between the groups (p=0.000). The mean time taken for the onset of motor blockade is 15.36±3.28 mins in group R and 11.22±2.61 mins in group RD. There is statistical significant difference between the groups (p=0.000).

The mean duration of sensory block is 198.0±24.05 mins in group R and 359.30±61.94 mins in group RD. There is statistically highly significant difference between the groups (p=0.001). The mean duration of motor blockade is 149.00±14.21 mins in group R and 233.70±15.26 mins in group RD. There is statistically highly significant difference between the group (p=0.001)

Table 5 showing grade of motor blockade in both the groups. Number of patients with Bromage 2 was 15 in group R and 0 in group RD, whereas patients with Bromage 4 were 0 in group R and 16 in group RD.

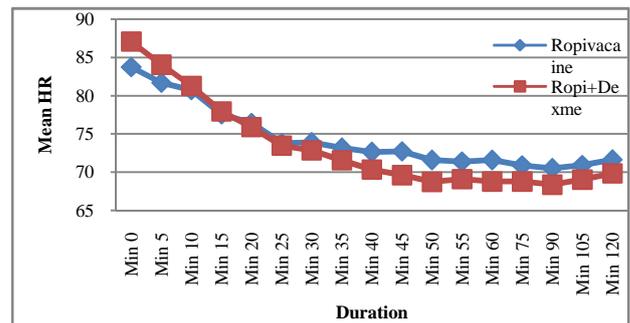
**Table 4** Maximum Level of Sensory Blockade Attained

Max sensory level	Group R (No. of patients)	Group RD (No. of patients)	p-value
T5	0	5	
T6	31	38	
T8	17	6	0.10
T10	2	1	

More intense motor blockade of Bromage 4 was found in patients in group RD compared to patients in group R, the p value being 0.001 is highly significant.

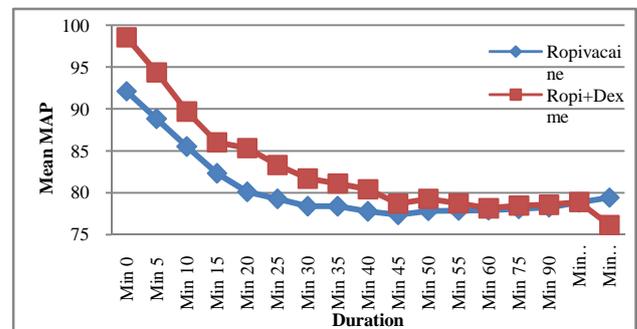
**Table 5** Grade of Motor Blockade

	Group R	Group RD	p-value
Bromage 2	15	0	<0.001
Bromage 3	35	34	0.35
Bromage 4	0	16	<0.001



**Figure 1** Graph showing mean heart rate (bpm) at various time intervals

There is no statistically significant difference in the mean heart rate between groups at various intervals. 4 patients in RD group developed bradycardia which was treated with inj.atropine0.6mg.



**Figure 2** Graph showing mean arterial pressure (mmHg) at various time intervals

There is no statistically significant difference in mean arterial pressure between both the groups.

**DISCUSSION**

In this study, the hypothesis that dexmedetomidine interacts with ropivacaine for epidural administration, improving the characteristics of anaesthesia was assessed.

In our study, the drugs selected for epidural anaesthesia were Ropivacaine and dexmedetomidine. Ropivacaine, has structural similarity to bupivacaine. Without cardiotoxic effects of bupivacaine, has been introduced to Indian market recently. Dexmedetomidine has been studied by various authors as an adjunct to epidural local anaesthetic.<sup>13-20</sup> Few studies have compared ropivacaine and dexmedetomidine for epidural anaesthesia in India. Hence ropivacaine and dexmedetomidine combination was selected for our study to compare with ropivacaine alone.

Presynaptic activation of alpha-2Adrenoceptor in the locus ceruleus inhibits the release of nor-epinephrine and results in the sedative and hypnotic effects.<sup>21</sup> In addition, the locus ceruleus is the site of origin for the descending medullospinal noradrenergic pathway, known to be an important modulator of nociceptive neurotransmission. Stimulation of alpha-2 adrenoceptors in this area terminates the propagation of pain signals leading to analgesia. Postsynaptic activation of alpha-2 receptors in the CNS results in decrease in sympathetic activity leading to hypotension and bradycardia.<sup>22</sup> Alpha -2 adrenoceptors present on primary afferent terminal (peripheral and spinal endings), in the superficial laminae of the spinal cord and within several brainstem nuclei have been implicated in the analgesia, supports the possibility of analgesic action of alpha agonist at peripheral, spinal and brainstem site.

According to the results, we found that there was a significant difference in the onset of sensory and motor block with the addition of dexmedetomidine to ropivacaine group compared to ropivacaine alone. It was found that, with the administration of dexmedetomidine, there was a significant increase in the duration of analgesia. There was also enhancement of the intensity of motor block and greater duration of blockade by dexmedetomidine. It provides better operative conditions and postoperative analgesia.

There was no difference between the two groups regarding the maximum sensory level attained. There was also no significant difference between groups with regard to occurrence of hypotension and bradycardia at any time of the study.

Hence addition of dexmedetomidine to ropivacaine provides better operating and haemodynamic conditions, with significant postoperative analgesia without increasing the morbidity.

## CONCLUSION

There is a clear synergism between dexmedetomidine and ropivacaine compared with plain ropivacaine in epidural anesthesia without increased morbidity.

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