Original Research Paper

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# PROSPECTIVE INTERVENTIONAL STUDY OF COMPARISON BETWEEN EPIDURAL ANAESTHESIA PLAIN 0.75% ROPIVACAINE AND 0.75% ROPIVACAINE WITH DEXMEDITOMIDINE IN LOWER ABDOMINAL AND LOWER LIMB SURGERIES

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**ABSTRACT** **1.1 AIMS:** The aim of the study is to identify the benefits of adding Dexmedetomidine 0.6mcg/kg to Ropivacaine 0.75% for epidural analgesia for surgeries involving lower abdomen and lower limb, and to observe the onset of sensory and motor blockade, duration of analgesia, and sedation score. **1.2 BACKGROUND:** Studies indicate that regional anesthesia has numerous advantages for lower abdominal and lower limb surgeries when compares to general anesthesia. Hence distinct varieties of regional anesthetics are being used for epidural anesthesia. When looking into regional anesthesia it was learned that ropivacaine was the preferred regional anesthesia for its long-acting effect and lower the cardiotoxic action in comparison to Dexmedetomidine. Whereas in comparison to ropivacaine, Dexmedetomidine has an additional effect, along with prolonging the action and sedative effect its neuroprotective effect is mediated by activation of alpha 2 adrenergic receptor subtype [2]. After looking at the individual benefits of Ropivacaine, and Dexmedetomidine, this study aims to see the potential benefits of the combined effects of these two drugs. **1.3 OBJECTIVE**: To study the onset of action, duration of sensory and motor blockade, and any hemodynamic variations, level of sensory and motor blockade. **1.4 METHODS:** The Patients were randomly allocated to two groups and each group consisted of 50 patients 1) Group R -15ml of 0.75% Ropivacaine 2) Group RD- 15ml of 0.75% Ropivacaine + 0.6µg/kg of dexmedetomidine. **1.5 RESULTS:** The study concluded that adding dexmedetomidine as an adjuvant to Ropivacaine for epidural anesthesia reduced the time to onset of action, and increased the duration of sensory blockade. Patients were calm, with sedation scores of 3 and 4 in RD Group, and did not require extra sedation. Patients were hemodynamically stable in both groups.

**KEYWORDS :** Dexmedetomidine, Epidural, Ropivacaine, Motor block, Sensory block.

**1.7 STATISTICAL ANALYSIS:** For this study, a quantitative research approach was used to analyse the data. Descriptive statistics such as mean and standard deviation were used in the analysis, whereas inferential statistics such as t-test, and ANOVA were used to address the research question. The chi-square test was applied to check the statistical significance at alpha 0.05.

## 2] LIST OF ABBREVIATIONS USED

| | |
|---|---|
| ASA | →American Society of Anesthesiologists |
| DBP | →Diastolic Blood Pressure |
| ECG | →Electrocardiogram |
| HR | →Heartrate |
| Hrs | →Hours |
| IV | →Intravenous |
| Kg | →Kilograms |
| MAP | →Mean Arterial |
| Pressuremcg(µ) | →Microgram |
| ml | →Milliliter |
| mg | →Milligrams |
| min | →Minutes |
| mmHg | →Millimeter of Mercury |
| % | → Percentage |
| SPO2 | →Oxygen saturation |

## 3] INTRODUCTION:

The most common regional anaesthesia techniques used for lower abdomen and lower limb procedures are intrathecal and epidural anesthesia. Epidural anaesthesia has the advantage of providing good surgical anaesthesia and allows longer surgical procedures since prolonged postoperative analgesia minimizes the risk of hemodynamic alterations [3].

Ropivacaine, with newer amide local anaesthetics, is considered to have a better tolerability profile for cardiovascular tissues and has been indicated as an alternative to bupivacaine [4, 1]. Ropivacaine is the first single and enantiomer-specific compound that has a reduced risk of cardiotoxicity, neurotoxicity, and rapid recovery of motor function [5, 6]. The unfriendly atmosphere in operation theatre with huge instruments, sounds of monitor, and anxiety of surgery and anaesthesia can make the patient uncomfortable. Our aim of adding adjuvant was to combat the above apprehension by providing some amount of sedation, stable hemodynamics, and the ability to provide prolonged anaesthesia. Commonly opioids are used as an adjuvant to local anaesthetics but they are associated with a number of undesirable side effects including delayed respiratory depression, urinary retention, pruritis, hemodynamic instability, nausea, and vomiting [7]. Dexmedetomidine is a more selective alpha 2 adrenoreceptor agonist and has recently been used as an adjuvant to intrathecal local anaesthetics [8, 9, 10]. Intrathecal alpha2 receptor agonists are found to have antinociceptive action for both somatic and visceral pain [11]. Alpha 2 adrenergic agonistic action of dexmedetomidine has a synergistic effect on local anaesthetic through prolongation of the sensory block by depressing neurotransmitter release from C fibers of the spinal cord leading to hyperpolarization of postsynaptic dorsal horn neurons [12]. It has also been found that Dexmedetomidine has less incidence of nausea and vomiting compared to fentanyl when used as an adjunct [13]. Hence, we compared 0.75% ropivacaine with dexmedetomidine 0.6mcg/kg and 0.75 % ropivacaine plain.

## 4] MATERIAL AND METHODS

The study used a quantitative research approach to compare 0.75% ropivacaine with dexmedetomidine 0.6mcg/kg and 0.75 % ropivacaine plain. The study included 100 patients ASA I and II belonging to the age group of 18-65yrs who were posted for elective abdominal and lower limb surgeries and the study was conducted at Basaweshwar Teaching and General Hospital Kalaburgi. Before the study was conducted an institutional ethical committee clearance was obtained and the patients were well-informed about the study and their consent was taken. For this study patients were randomly distributed into two groups. Group R consisted of patients that received only ropivacaine 0.75% 15ml epidurally as a bolus, while Group RD consisted of patients who received ropivacaine 0.75% +

0.6microgram/kg of dexmedetomidine epidurally as a bolus. Each group was assigned, 50 patients.

**Statistical Analysis:**
For this study, a quantitative research approach was used to analyse the data. Descriptive statistics such as mean and standard deviation were used in the analysis, whereas inferential statistics such as t-test, and ANOVA were used to address the research question. The chi-square test was applied to check the statistical significance at alpha 0.05.

**4.1 Selection Criteria For Patients**
**Inclusion Criteria:**
Adult patients aged between 18 and 65 years old, of either sex, weight > 50 kgs, height between 150 and 180 cms, American Society of Anesthesiologists (ASA) class I and II posted for elective lower abdominal and lower limb surgical procedures.

**Exclusion Criteria:**
Pregnancy and lactation**,** Obese patients with BMI>30**,** patients who have known allergies to any of the test drugs, patients with coagulation disorders or on anticoagulant drugs, patients with cardiac disease (heart block, premature ventricular contractions, significant bradyarrhythmias, left ventricular failure), and patients with respiratory diseases, and patient refusal for regional anaesthesia.

**4.2 Procedure:**
Epidural space was identified with loss of resistance to air technique at L2-L3/L3-L4 level in sitting position using 18G Tuohy needle. After confirming the correct position of the catheter, the patient was turned to the supine position. Five minutes after the test dose, in the absence of any adverse squeal, 15ml of the study drug was given at a rate of 1ml/3sec through the catheter. After giving 15 ml of the study medication, which was taken as the starting time, the sensory blockade was assessed by pinprick sensation and the motor blockade was assessed by Bromage scale when the patient was lying supine. The maximal level of sensory and motor block, as well as the onset time, was recorded. The sedation score is based on a five-point scale, shown in Table I.

**TABLE I:**
**Five point scale for sedation scoring**

| | |
|---|---|
| 1 | ALERT AND WIDE AWAKE |
| 2 | AROUSABLE TO VERBAL COMMANDS |
| 3 | AROUSABLE WITH GENTLE TACTILE SENSATION |
| 4 | AROUSABLE WITH VIGOROUS SHAKING |
| 5 | UNAROUSABLE |

The assessment of sensory and motor blockade levels achieved was performed by a senior resident who was blind as to the study protocol and drug(s) administered.

**4.3 Sedation scoring as per (Five-point scale):**
Vitals which included blood pressure, heart rate, and SpO2 were measured at 5-minute intervals for the first hour and subsequently at 15-minute intervals until the end of the procedure. Intraoperative and postoperative complications like fall in blood pressure and variation in heart rate were noted. Hypotension is defined as a reduction of systolic blood pressure of more than 30% from basal systolic blood pressure or SBP less than 90 mmHg and is treated with an increased rate of intravenous fluid and, if needed, injection mephentermine 3 mg (I.V) given in increments. Bradycardia (<60 beats/min) was treated with injection Atropine 0.6 mg ((I.V).

Patients were referred to PACU (POST ANAESTHESIA CARE UNIT) after surgery, where they remained until the sensory and motor blockade was completely removed. Vital parameters were recorded every 15 minutes, and the duration of sensory and motor blockade and any adverse effects were recorded.

The onset of sensory blockade: is taken as the time from the completion of the injection of the study drug until loss of sensation at T10 level.

The onset of motor blockade: it is taken from the completion of the injection of the study drug until the patient develops a modified Bromage scale grade 1 motor blockade.

**Duration Of Motor Block:** is taken from the time of injection until the patient attains complete motor recovery (Bromage 0).

**Duration Of Sensory Block:** is taken from the time of injection till the patient complains of pain at the T10 dermatome.

**5. RESULTS:**
The data was analysed to observe the effects of using Ropivacaine and Dexmedetomidine 0.6mcg/kg to Ropivacaine 0.75% for epidural analgesia for surgeries involving lower abdomen and lower limb, and to observe the onset of sensory and motor blockade, duration of analgesia, and sedation score. The effect of drugs between the group R and group RD based on age-wise distribution was observed. The mean and standard deviation score for group R was 42.78± 3.69. Whereas the group RD has a mean and standard deviation score of 40. 66 ±13.55. The t =.778 and p>.005 indicated that there was no statistically significant difference in the effect of drug between the group R and group RD based on the age of participants.

**OBSERVTIONS**
**FIGURE NO 1: Multiple bar diagram represents age wise distribution of patients in Group R and Group RD**

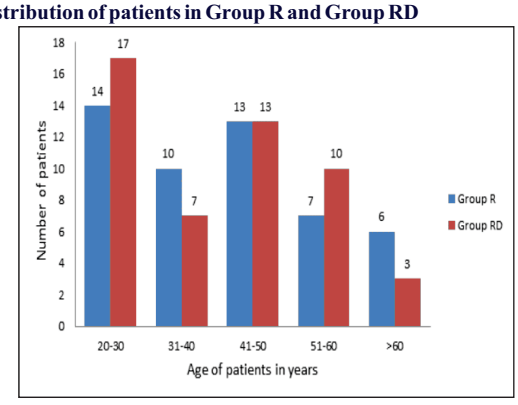


**FIGURE NO 2: Multiple bar diagram represents sex wise distribution of patients in Group R and Group RD**

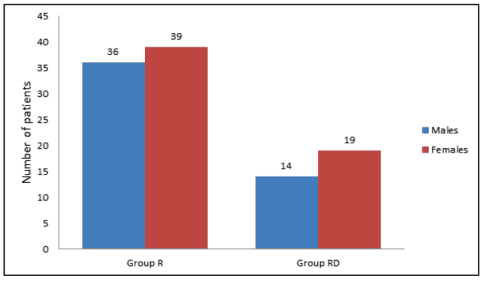


**FIGURE NO 3: Multiple bar diagram represents type of surgery wise distribution of patients in Group R and Group RD**

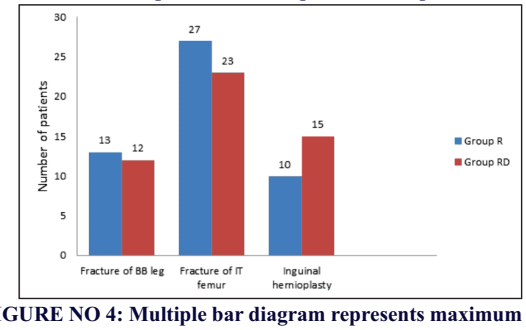


**FIGURE NO 4: Multiple bar diagram represents maximum level of sensory blockade attained in Group R and Group RD**

**FIGURE NO 5: Multiple bar diagram represents comparison of intensity of motor blockade between Group R and Group RD**

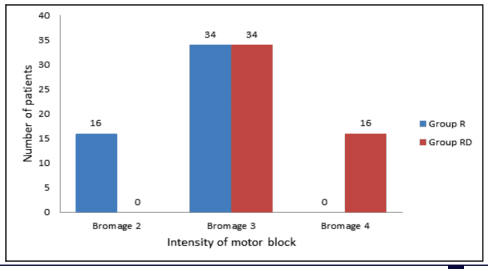

**FIGURE 6: Multiple bar diagram represents comparison of duration of sensory and motor blockade between Group R and Group RD**

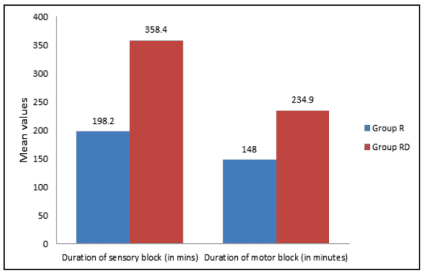


**FIGURE 7: Multiple bar diagram represents comparison of sedation between Group R and Group RD**

## 6. DISCUSSION

Dexmedetomidine is a new alpha 2 agonist which has got numerous beneficial effects when used through the epidural route. Adding dexmedetomidine to local anesthetics provided a better sedation score good analgesia and early mobilization and more hemodynamic stability. Dexmedetomidine when given intravenously shows a rapid distribution phase with a half-life of 6 minutes and causes profound hypotension, bradycardia, nausea, and dry mouth. Dexmedetomidine when given epidurally did not cause any hemodynamic instability or other side effects that is why in this study we preferred using dexmedetomidine 0.6mcg/kg epidurally.

Ropivacaine supports their use in clinical situations where the risk of systemic toxicity are related to either overdosing or unwanted intravascular injection is high, such as during epidural or peripheral nerve blocks [14]. Ropivacaine has been shown to have increased therapeutic safety in laboratory animals and human volunteers [15]. Ropivacaine when used for epidural has been well tolerated [16,17,18] at higher concentrations Ropivacaine have similar blocking activity as other local anaesthetic agents [19,20,21]. Dexmedetomidine can be helpful because it is a relatively selective alpha 2 agonist with sympatholytic, sedative, amnestic, and analgesic properties [22]. There was statistically no difference with the level of sensory blockade which was around T6 in both the groups in most of the patients. Coskuner I et al studied the effect of dexmedetomidine on the duration of anesthesia and wakefulness in epidural block [23]. Saravia P.F.S. et al studied the synergistic effect between dexmedetomidine and ropivacaine 0.75% in epidural anesthesia [24]. Lopez SAO et al studied the epidural dexmedetomidine in regional anesthesia to reduce anxiety [25].

In our study, the duration of sensory blockade was around (358.40+61.92) in the RD Group and (198.20+21.98) in the R Group. So, adding dexmedetomidine to local anesthesia significantly provided more postoperative analgesia. Bromage scale 3 and 4 were achieved in most cases in the RD Group which indicates the addition of dexmedetomidine increased the intensity of blockade which was statistically significant with a p-value of $p<0.001$. SJS Bajwa et al conducted a comparative study between dexmedetomidine and clonidine in epidural anesthesia and concluded that dexmedetomidine is a better adjuvant than clonidine in epidural anesthesia as far as patient comfort, stable cardiorespiratory parameters, intraoperative and postoperative analgesia is concerned [26].

Viera AM, Schnaider TB et al concluded that the association of clonidine or dexmedetomidine to 0.75% Ropivacaine induces analgesia and sedation at 2 and 6 hours after anesthesia recovery [27] Epidural Dexmedetomidine did not affect onset time for the upper level of anesthesia in the study conducted by SaraivaSalgedo et al [28]. It is observed that the addition of clonidine or dexmedetomidine to bupivacaine prolongs caudal analgesia in children with no significant hemodynamic changes or side effects [29]

In our study Group, RD had a better sedation score and required no additional sedation, and was hemodynamically stable with no incidence of respiratory depression.

Sedation score in our study it was observed that group R had sedation score of score S1 and S2 in 16 and 32 patients respectively whereas in group RD 0 patients of score S1,15 patients of score S2,29 patients of score S3 and 4 patients of S4, there was a statistically significant difference in sedation score in both groups. Our study showed that patients were well sedated and comfortable in group RD as per [FIGURE 7] In our study mean time of onset of analgesia at T10 is10.26±2.69 in group R and 5.36±1.49 in group RD, This is statistically highly significant ($p<0.001$). In our study the maximum level of sensory block in group R was T6 and in group RD was T5. The range of blocks was very wide in both groups (T12- T5). In our study [FIGURE NO 4] FIGURE NO. 4, the duration of sensory block is longer with Ropivacaine + Dexmedetomidine group compared with Ropivacaine group. It is 358.40±61.92 mins with ropivacaine + Dexmedetomidine group compared to 198.20 ± 21.98 mins with ropivacaine group. This is statistically highly significant ($p<0.001$). The onset of motor blockade was assessed using a modified Bromage scale and onset was taken as soon as the patient developed grade 1 motor blockade. The onset of motor blockade was 15.52 ± 3.29 min in group R and 10.26 ± 2.69 mins in group RD. This is statistically significant. In our study it was found that group RD produced more intense motor block than group R. Maximum number of patients in each group had a motor blockade of Bromage scale 3 in group R,16 patients had Bromage scale 2 motor blockade but whereas in group RD 16 patients had a motor blockade of Bromage 4. A motor blockade of Bromage 4 was 0 in group R this shows very highly significant ($p< 0.001$) of the motor blockade in both the groups as per [FIGURE NO 5] The duration of motor block in group RD is 234.94±56.45 mins compared to 148.58 ±14.58 in group R. The duration of the motor block with RD group is more prolonged than with group R, which is statistically highly significant ($p<0.001$) as shown in [FIGURE NO 6].

## CONCLUSION:

According to the findings of this study, there was a statistically significant difference at the beginning of sensory and motor blockade in the Ropivacaine and Ropivacaine + dexmedetomidine groups. The dexmedetomidine and ropivacaine groups had more intense motor blockage than the ropivacaine group. When Ropivacaine and dexmedetomidine are used instead of Ropivacaine, the sensory block lasts longer. Incidence of hypotension and bradycardia were almost negligible in both groups. Hence it is found that adding dexmedetomidine to ropivacaine produces a synergistic effect leading to prolonged motor and sensory blockade.

### Summary:

A prospective interventional study was undertaken to evaluate the sensory and motor blocking properties of epidurally administered 15ml of Ropivacaine 0.75% and dexmedetomidine incomparison with Ropivacaine 0.75% alone in lower abdominal and lower limb surgeries.

One hundred patients between the ages of 18-65 years belonging to ASA I and II posted for elective lower abdominal and lower limb surgeries were randomly divided into two groups. The groups, each consisting of 50 patients, epidurally received 15 ml of Roipvacaine 0.75% (group R) and 15 ml Roipvacaine 0.75% and dexmedetomidine 0.6µg/kg (group RD) respectively. Patients who had contraindications for epidural anesthesia, patients posted for emergency surgery, patients whose height is less than 150cms and more than 180cms, pregnant patients, and patients with BMI > 30 were excluded from the study. In both the groups' epidural space was identified in sitting position using the loss of resistance technique and the epidural catheter was introduced for 3 cms inside. After negative aspiration for blood and CSF, test dose with 3 ml of lignocaine 2% with adrenaline, 15 ml of the study drug was given in sitting position and the patient was put in the supine position. The onset, maximum level, and duration of sensory and motor blockade and hemodynamic parameters were studied.

### Ethics Approval And Consent To Participate:

This study was approved by the institutional ethics committee on 29/10/2018 at 11 AM in MahadevappaRampure medical college council hall with IEC. Reg. NO: ECR/889Inst/KSA/2017.

### Human And Animal Rights:

No animals were used in the research. All human research procedures were followed in accordance with the ethical standards of the committee responsible for human experimentation (institutional and national),and with the Declaration of Helsinki(1975), as revised in 2013(http://ethics.iit.edu/ecodes/node/3931).

### Consent For Publication:

Consent was obtained from all patients to be involved in the study.

### Availability Of Data And Materials:

Not applicable

**Funding:**
We have not received any funds from any of the agencies.

**Conflicts Of Interest:**
The authors declare no conflict of interest, financial or otherwise.

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