Original Article

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A comparative Study of Epidural Ropivacaine 0.75% Alone and Ropivacaine with Dexmedetomidine for Lower Limb Surgeries

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Abstract

Background: Ropivacaine in epidural anaesthesia provides good analgesia, lesser motor blockade and cardiac stability. Addition of adjuvants like dexmedetomidine provides longer duration of analgesia, prolonged motor blockade with adequate sedation. Our study compares Ropivacaine alone and in combination with dexmedetomidine on block characteristics, postoperative analgesia and sedation.

Methods: Following institutional ethical committee clearance and patients informed written consent Sixty patients (ASA I, II) aged 18 - 60 years of either sex posted for elective lower abdominal and lower limb surgeries were randomized into two groups, Group R and Group RD. The patients in group R received 19ml of 0.75% Ropivacaine with 1ml of normal saline and the patients in group RD received 19ml of 0.75% Ropivacaine with dexmedetomidine (1µg/kg) respectively. Both groups were compared with respect to onset and duration of sensory and motor blockade, intensity of motor blockade using modified bromage scale, maximum level of sensory blockade, sedation score, hemodynamic variations and adverse effects.

Results: The mean onset of sensory and motor block in group R was 11.36±3.03& 16.63±2.70 minutes, in group RD was 6.80±1.30 & 12.10±1.63 minutes respectively. Duration of sensory and motor block in Group R was 199.60±23.4 & 150±17.64 minutes and in group RD was 296.30±21.12 & 235.00±17.64 minutes respectively. The patients in Group RD had rapid onset of action, significant prolongation of motor and sensory block, intense motor block, better sedation score and postoperative analgesia ($p<0.05$).No significant hemodynamic changes in either group.

Conclusion: There is a clear synergism between dexmedetomidine and ropivacaine compared with ropivacaine in epidural anaesthesia without increased morbidity.

Keywords: Epidural; Dexmedetomidine; Motor block; Ropivacaine; Sensory block; Sedation.

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Introduction

Epidural blockade is a popularized technique to provide anaesthesia and adequate analgesia both during the surgical procedure as well as the post-operative period.[1] Epidural anaesthesia can be used as sole anaesthetic for procedures involving the lower limbs, pelvis, perineum and lower

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abdomen.[2] It has the ability to maintain continuous anaesthesia after placement of an epidural catheter, thus making it suitable for procedures of long duration. Epidural anaesthesia will also reduce need for intravenous analgesic agents in the post-operative period. The main advantage of epidural anaesthesia is to provide post-operative analgesia.[1-3]

Ropivacaine, long acting amide local anaesthetic derived from Bupivacaine is claimed to have lesser cardiovascular side effects than bupivacaine.[4,5] Ropivacaine has to be given in larger doses to achieve the analgesic and anaesthetic effects.[6] The addition of adjuvants like α-2 agonists, clonidine and dexmedetomidine can decrease the dose requirement and permit use of more diluted solutions for better analgesia and prevent side effects associated with larger doses of ropivacaine.[7] Dexmedetomidine is highly selective α 2 adrenergic agonist, The stable hemodynamic and the decreased oxygen demand due to enhanced sympathoadrenal stability make it a very useful pharmacological agent.[8-11] In the present study we have compared efficacy of ropivacaine 0.75% alone and ropivacaine with dexmedetomidine (1µg/kg) for lower abdominal and lower limb surgeries.[12]

Objectives of the study

To study the synergistic effect of adding dexmedetomidine to ropivacaine in epidural anesthesia for lower abdominal and lower limb surgeries regarding:[13]

1. Onset & duration of sensory blockade time.
2. Onset & duration of motor blockade.
3. Intensity of motor blockade.
4. Maximum level of sensory blockade.
5. Sedation.

Materials and Methods

After approval from the Institute ethical committee, as well as informed consent from all patients, a prospective double blind randomized clinical study was carried out on 60 adult patients scheduled for various lower abdominal & lower limb surgical procedures belonging to ASA class I and II. Patients were randomly divided into two groups of 30 each using computer generated random numbers, Group "R" (n =30) - 19 ml 0.75% Ropivacaine plus 1 ml normal saline and Group "RD" (n=30) – 19 ml 0.75% Ropivacaine plus dexmedetomidine (1µg/kg).

On the day of surgery patients basal pulse rate and blood pressure (mean), respiratory rate, SpO2 will be recorded, 18 G intravenous line secured. All patients will be preloaded with 20ml/kg of Ringer lactate 30 minutes prior to epidural procedure. Under all aseptic the subject will be given epidural block in sitting position in L2-3 or L3-4 space with 16 gauge Touhy needle and epidural space will be localized and confirmed by loss of resistance technique.[2] Epidural catheter will be secured 3-5 cm into the epidural space and confirmation for correct placement of the catheter done by injecting 3ml of 2% lignocaine hydrochloride solution containing adrenaline 1:200000. After 4-6 minutes of test dose, patients in group "R" will be administered 19ml of 0.75% Ropivacaine with 1ml of normal saline in incremental doses while the patients in group "RD" will receive 19ml of 0.75% Ropivacaine with 1µg/kg dexmedetomidine in incremental doses.[13,14]

Assessment of sensory and motor blockade were done at the end of each minute with the patient in supine position after completion of injection of 19 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 will be recorded. The bilateral pin prick method will be used to evaluate and check the sensory level while the modified Bromage scale (Table 1)[2] will be used to measure motor blockade. Analgesia was recorded by using VAS score at 5 min before epidural, at the start of surgery, and then, every 15-min interval till the surgery was over. Sedation score recorded with Ramsay Sedation Score (Table II).

Measurements of blood pressure, heart rate, and oxygen saturation will be recorded every 5 minutes till the end of 1 hour and then every 15 minutes till the end of surgery. Intra-operatively and post-operatively complications like fall in blood pressure, variation in heart rate, dryness in mouth, nausea, vomiting, urinary re-tension , excessive sedation were noted, treated and tabulated.

Onset of sensory blockade

Is taken as the time from the completion of the injection of the study drug till loss of sensation at T 10 level, assessed by loss of sensation to pin prick in the midline using a 22 gauge blunt hypodermic needle.

Onset of motor blockade

Is taken from completion of the injection of study drug till the patient develops modified Bromage scale grade 3 motor blockade.

Duration of motor block

Is taken from the time of injection till 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 S1 dermatome.

Statistical Analysis

The results of the study were statistically analyzed between the two groups. A sample size of 25 patients per group was determined through power analysis (α 0.05; β0.80). Considering the drop outs, 30 patients were selected for each group in our study. Statistical analysis was done using SPSS version 22; descriptive statistics was done by calculating mean. Results are expressed as the means and standard deviations. The interferential statistics (test of significance) was done using unpaired t-test and chi square test. 'P' value of >0.05 was considered as statistically insignificant & <0.05 was considered as statistically significant. (Table 5)

Results

Table I: Modified Bromage scale will be used to measure motor blockade.

Score	Patient Response
0	Full movement of legs and feet, with ability to raise extended leg.
1	Inability to raise extended leg, knee flexion is decreased, but full flexion of feet and ankles present
2	Inability to raise leg or flex knees, flexion of ankle and feet present.
3	Inability to raise leg, flex knee or ankle or move toes.

Table II: Ramsay Sedation Score (RSS).

Sedation Level	Description
1	Patient is anxious, agitated or restless, or both
2	Patient is cooperative, oriented, and tranquil
3	Patient responds only to commands
4	Patient responds to light glabellar tap or loud auditory stimulus
5	Patient has a sluggish response to light glabellar tap or loud auditory stimulus
6	No response

Table III: Demographic data.

Variables	Group R (Mean)	Group RD (Mean)	P Value
Age (years)	40.73	32.26	0.49
Sex	21/9	22/8	1.00
Height (cm)	166.9	168.57	0.19
Weight (kg)	63.26	61.06	0.22

Demographic data of both the study groups were comparable and statistically not significant (Table 3)

Table IV: Mean time for onset of sensory and motor block (In minutes).

Sl. No.	Group	Mean time for Sensory Onset	SD	p-Value	Mean time for Motor Onset	SD	p-Value
1	Group R	11.36	3.03	0.001	16.63	2.70	0.001
2	Group RD	6.80	1.30		12.10	1.63	

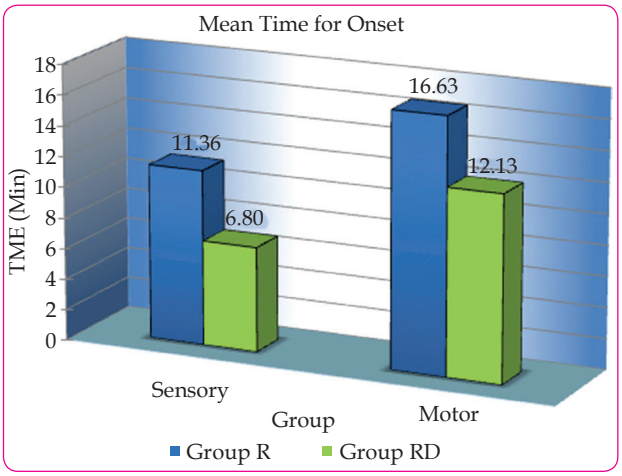

Fig. 1: Graph showing mean time for Onset of Sensory and Motor block (minute).

The mean time of onset of sensory in group R is 11.36 minutes, Group RD - 6.80 minutes. There is highly statistical significant difference between the groups (p=<0.001) (Table 4)

The mean onset time for motor in group R is 16.63 minutes and in Group RD it is 12.13 minutes. There is highly statistical significant difference between the groups (p 0.001). (Fig. 1)

Table V: Maximum level of Sensory Blockade achieved.

Sl. No.	Max. Sensory level	Group R (No. of Patients)	Group RD (No. of Patients)	p-Value
1	T5	0	3	0.52
2	T6	15	17	
3	T8	13	10	
4	T10	02	0	

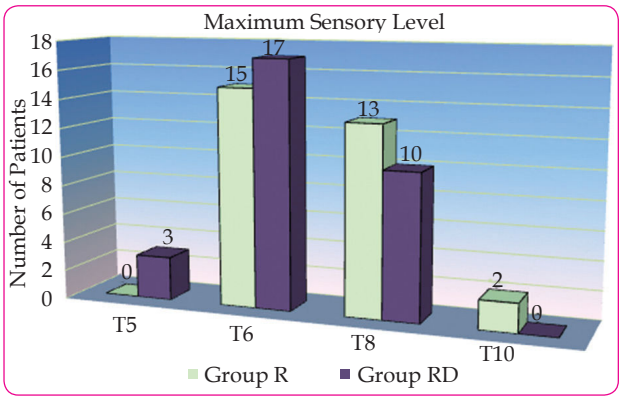

Fig. 2: Maximum level of sensory level achieved.

Maximum level of sensory blockade attained by the two groups, Group RD had the highest level of T5, and highest level in R group was T6. There is no statistical difference between the two groups (p=0.52) (Fig. 2)

Table VI: Grade of Motor Blockade.

Sl. No.	Bromage scale	Group R (No. of Patients)	Group RD (No. of Patients)	p-Value
1	Modified Bromage 1 (M1)	2	0	0.001
2	Modified Bromage 2 (M2)	15	13	1.00
3	Modified Bromage 3 (M3)	13	17	< 0.001

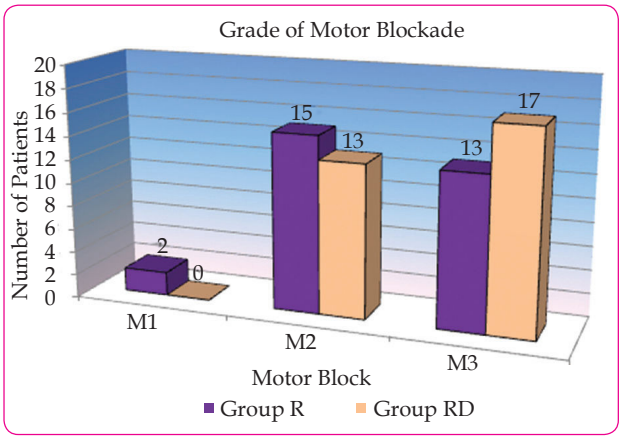

Fig. 3: Graph showing Grade of Motor blockade.

Number of patients with bromage 1 was 2 in group R, and 0 in group RD, where patients with bromage 3 were 17 in group RD, 13 in group R, more intense motor blockade of bromage 3 was found in patients in group RD. more intense motor blockade of bromage 3 was found in patients in group RD compared to patients in group R, the p value being <0.001 is highly significant.(Fig. 3) (Table 6)

Table VII: Sedation Score.

Sl. No.	Sedation Score	Group R (No. of Patients)	Group RD (No. of Patients)	p-Value
1	S1	11	0	< 0.001
2	S2	19	11	
3	S3	0	17	
4	S4	0	2	

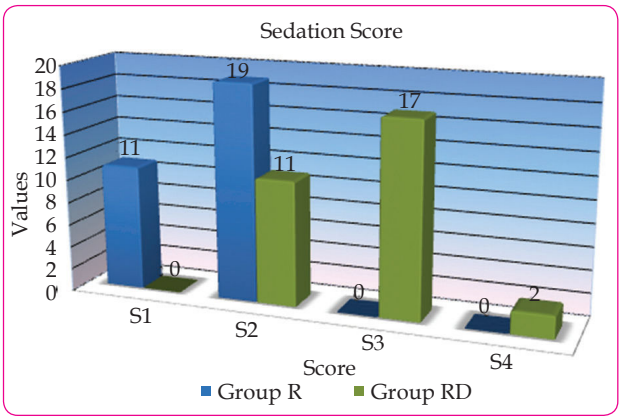

Fig. 4: Graph showing Sedation Score.

Group R the height score of 2, and the highest score in group RD was 4. Dexmedetomidine had highest scores compared to ropivacaine alone. There is highly statistically significant difference between the groups P (< 0.001). (Table 8)

Table VIII: Duration of Sensory and Motor Blocks (In Minutes).

Sl. No.	Group	Duration for Sensory Block	SD	P -Value	Duration for Motor Block	SD	P – Value
1	Group R	199.60	23.40	< 0.001	150.00	15.75	< 0.001
2	Group RD	296.30	21.12		235.00	17.64	

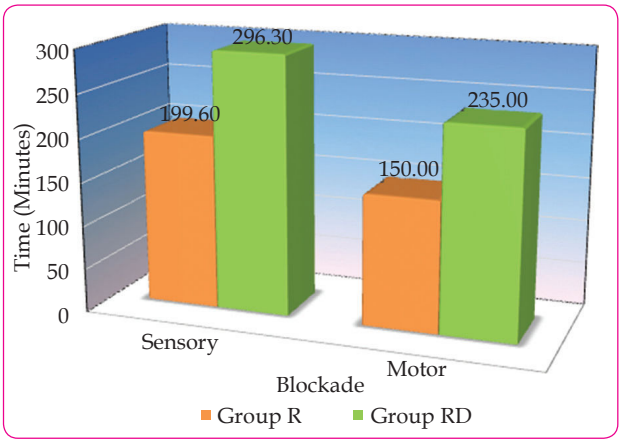

Fig. 5: Duration of Sensory and Motor Blocks (In Minutes).

The mean duration of sensory block in group R-199.60, in Group RD 296.The mean duration of motor blockade in group R 150 minutes, in group RD 235 minutes.There is statistically high significant difference between the groups (p<0.001). (Fig. 5)

Discussion

In our study we used epidural ropivacaine 0.75% alone and ropivacaine plus dexmedetomidine for lower abdominal and lower limb surgeries with major emphasis on onset of blockade, time to maximum sensory blockade, time to complete motor blockade, grade of motor blockade, sedation score, total duration of analgesia, time to complete motor recovery. Dexmedetomidine significantly extends the duration of sensory and motor block with better quality of postoperative analgesia as compared to Ropivacaine given alone.

Dexmedetomidine a novel α2 agonists produce pain relief through an opioid independent mechanism and proves to be a better alternatives to opioid for combination with local anaesthetic for analgesia during surgery.[8,9] Dexmedetomidine appears to exert analgesic effects at the spinal cord level and at supraspinal sites. The selectivity of Dexmedetomidine to alpha-2 receptors compared to alpha-1 receptors is 1620:1, whereas with clonidine it is 200:1. Dexmedetomidine act by binding to the presynaptic C-fibers and post synaptic dorsal horn neurons. They produce analgesia by decreasing the release of C-fiber transmitters and by hyperpolarisation of post synaptic dorsal horn neurons. The combined and synergestic action of local anaesthetics and α2 adrenergic agonists accounts for their prolonged analgesic properties.[10,11] The prolonged motor block may be the result of binding α2 adrenergic agonists to the motor neurons in the dorsal horn. Dexmedetomidine exerts synergistic actions with local anaesthetic agents.

Onset of analgesia (T10)

In our study the mean onset of analgesia in Group R was 11.36 ± 3.03, and in Group RD was 16.63±6.80. This shows that onset of anaesthesia was faster in group RD when compared to Group R ($p<0.001$); which was highly statistically significant. In a study Bajwa SJ and his colleagues, 2011,[14] a comparative evaluation of dexmedetomidine and clonidine in epidural anaesthesia, they found that onset of analgesia was shorter in RD group along with prolonged duration of analgesia when compared to RC group with mean onset of 8.52±2.36 and in RC group was 9.72±3.44 min.

Maximum sensory level

In our study the maximum level of sensory block in group RD was T5, and group R was T6. The range of block was very wide in both groups (T12-T5). The study conducted by Bajwa SI, Bajwa SK, Kaur J et al.,[15] showed maximum level of sensory block at T5-T6 level in group RD compared to T6-T7 in group RC which compares with our study.

Duration of sensory block

In our study duration of sensory block is longer with group RD compared to group R which is 296.30± 21.12 mins in group RD compared to 199.60 ± 23.40 mins in Group R this is statistically highly significant ($p <0.001$) Our study concurred with the study conducted by Bajwa SJ, Arora V, Kaur J et al.,[16] who observed the mean duration of analgesia to be 366.62±24.42 mins in group RD compared to 242.16 ±23.86 mins with in group RF which is highly significant

Motor block

The mean onset time for motor in group R - 16.63 minutes, in Group RD - 12.13 minutes. There is highly statistical significant difference between the groups (p 0.001). In our study motor blockade is assessed using modified bromage score and the onset was taken as soon as the patient developed Grade I motor blockade. Our study concurred with the study conducted by Bajwa SJ, Arora V, Kaur J et al.,[16] who observed the mean duration of analgesia to be 366.62±24.42 mins in group RD compared to 242.16 ±23.86 mins with in group RF which is highly significant.

Duration of motor block

In our study mean time to complete motor recovery (in min) was 150.00±15.75 in Group R, and 235.00±17.64 in Group RD. This shows that time to complete motor recovery was significantly longer in Group RD when compared to Group R ($P<0.001$). In a similar study with Bajwa SJ and his colleagues 2011,[15] mean time to two segment regression with RD group was 136.46 8.12 and 128.08 7.54 with RC group, time for first rescue analgesia was 342.88 29.16 with RD group and 310.76 23.76 with RC group. This shows that duration of sensory blockade was longer with RD group than with RC group. Hence it is highlighted that addition of additives like dexmedetomidine intensifies the motor blockade.

Sedation

Group R the height score of 2, and the highest score in group RD was 4. Dexmedetomidine had highest

scores compared to ropivacaine alone.[17,18] There is highly statistically significant difference between the groups i.e. P (< 0.001). Sedation represents an α2 adrenergic effect, because sedation from epidural clonidine can be reversed by the specific antagonist yohimbine in postoperative patients. The sedative-hypnotic effect of α2-adrenergic agonists is caused by actions on the locus ceruleus. Our results are in agreement with studies by Filos and his colleagues, in which dose-dependent sedation was observed.[19-20]

There was no significant difference in the HR, SBP, DBP, MAP, SPO2 during intraioperative & postoperative period up to 24hrs measured at regular intervals. No patients required any active intervention or had any side effects like nausea/ vomiting.

Conclusion

Dexmedetomedine group had rapid onset of action ($p<0.001$), prolonged duration of sensory and motor block ($p<0.001$), better sedation score ($p<0.001$) and more intense motor block .There was no difference in maximal dermatomal level of analgesia, was associated with side effects like bradycardia and hypotension which were not imposing a major problem in hemodynamic profile.

It can be concluded that Dexmedetomedine given epidurally with Ropivacaine produces synergistic effect of profound and prolonged duration of sensory blockade. Ropivacaine and dexmedetomidine can be a safe and effective agent for epidural blockade in lower abdominal and lower limb surgeries.

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