Original Research Article

Randomized controlled study on comparative evaluation of 0.75% ropivacaine with 0.75% ropivacaine with dexmedetomidine in epidural anaesthesia in lower limb orthopaedic surgeries

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Abstract

Background: Regional anesthesia and analgesia has the potential to provide excellent operating conditions and prolongedpost operative pain relief. Epidural blockade is becoming one of the most useful and versatile procedures in modern anesthesiology. It is more versatile than spinal anesthesia. It can be used to supplement general anesthesia. It provides better postoperative pain control and more rapid recovery from surgery. **Aim:** To study the time of onset of action of ropivacaine0.75% and ropivacaine0.75% with Dexmedetomidine when administered epidurally. **Materials and Methods:** The prospective, randomized, comparative study was conducted on 60 patients aged between 18-55 years posted for lower limbsurgeries. Study compared the potentiating effects of epidurally administerd dexmedetomidine when combined with Ropivacaine in terms of haemodynamic changes, onset of sensory and motor blockade, duration of analgesia, intra-operative haemodynamic changes and complications/adverse effects. **Results:** There was no significant difference in age, weight and height between the two groups. The early onset of sensory analgesia to T10 level and early onset of motor blockade in Group RD is statistically significant pvalue<0.05 (p value<0.0001).The time taken to reach the maximum level of sensory analgesia in Group RD was statistically significant p value<0.05(p value<0.0001). The delayed recovery of motor blockade in Group RD was statistically significant p value<0.05 (p value <0.0001).Duration of analgesia is prolonged in Group RD which is statistically significant p value<0.05 (p value<0.0001).There was no statistically significant difference in the pulserate, systolic blood pressure and diastolic blood pressure between the two groups. **Conclusion:** when dexmedetomidine 1mcg/kg added as adjuvant to 0.75% Ropivacaine in epidural anaesthesia in lower limb orthopaedic surgeries resulted in earlier onset of sensory analgesia to T10 level and helped in achieving the complete sensory anaesthetic level in a shorter period as compared to ropivacaine.

Key Words: ropivacaine, dexmedetomidine.

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INTRODUCTION

Providing comfort to the patient byprevention and relief of pain and monitoring and maintenance of normalphysiology during the preoperative periodis the primary goalofan anesthetist.[1] Regional anesthesia and analgesiahasthepotential to provide excellent operating conditions and prolonged postoperative painrelief.[2] Epidural blockade is becoming one of the most useful and versatile procedures in modern anesthesiology. It is unique in that it can be placed atvirtually any level of the spine, allowing more flexibility in its application to

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clinical practice. It is more versatile than spinal anesthesia, giving the clinician the opportunity to provide anesthesia and analgesia, as well as enablingchronicpain management. It can be used to supplement general anesthesia, decreasing the need for deep levels of general anesthesia, therefore providing a more hemodynamically stable operative course. It provides better post operative pain control and more rapid recovery from surgery. For orthopaedic surgery, the provision of pain reliefenables early post operative mobilization acceleratesr ehabilitation and returntonormalfunction[3]. Aim of our study is to know the time of onset of actionofropivacaine0.75% and ropivacaine0.75% with Dexmedetomidine when administered epidurally and to study the duration of sensory and motor blockade, hemodynamic and respiratory effects and side effects by these drugs.

MATERIALS ANDMETHODS

A Prospective, randomized, double blind study was conducted on 60 patients of either sex (ASA I,II) between the age group of 18-55 yrs undergoing various lower limb orthopaedic procedures. Patients was randomly allocated into two groups of 30 patients each-GROUP R (Ropivacaine)-patients receiving 20 ml of 0.75% Ropivacaine 150mg epidurally n=30. GROUP RD (Ropivacaine with dexmedetomidine)-patients receiving 20ml of 0.75% Ropivacaine with dexmedetomidine 1mcg/kg. The study was conducted in Gandhi Hospital, Secunderabad after obtaining approval from institutional ethical committee. A written informed consent was obtained from each patient.Sixty patients aged between18 years and 55 years of (ASA I,II) of either sex undergoing lower limb orthopaedicsurgeries were included in the study.

Inclusion Criteria: Patients of age group 18-55 yrs of both sexe S, American society of Anaesthesiologists grade 1 and 2 physical status

Exclusion Criteria: Patients with age less than 18 yrs and more than 55 yrs**,** ASA III and IV. Pregnant woman**,** Any contraindications to epidural anaesthesia like hypotension, uncooperative patients, previous laminectomy, spine abnormality**,** Neurologic, cardiopulmonary or psychiatric disease, active liver, kidney disease. A Routine pre-anaesthetic was conducted on the evening day before surgery, assessing History and general condition of the patient Airway assessment by mallampati grading Nutritional status, height and weight of the patient A detailed examination of the cardiovascular system, respiratory system, central nervous system Examination of the spine. All patients in the inclusion criteria were visited on the previous day of surgery, and the procedure was explained to them. A detailed pre-anaesthetic examination was carried out and relevant investigations were advised. Baseline investigations were done in all patients. An informed valid written consent was taken from all the patients. premedication with Alprazolam 0.25mg and ranitidine 150mg was given orally the night before surgery. Patient was advised to maintain nil per oral status for 6 hrs. Pre-operatively pulse rate, Non-invasive systolic and diastolic blood pressure was recorded. In the operation room, a good intravenous access was secured and patients were preloaded with 20ml/kg body weight of Ringer lactate solution over 15-20 min. Multipara monitor was attached and baseline pulse rate, Non –invasive systolic blood pressure and diastolic blood pressure, oxygen saturation, ECG were recorded and monitoring was intiated.

Procedure: Patients were placed in sitting position and skin infiltration was given with 2ml of 2%lignocaine was performed. Then the epidural space was identified at L3-L4 inter space with a 18G Tuohy needle using the midline approach and a loss of resistance technique. After negative aspiration of blood,3ml of Lignocaine with 1:200000 Adrenaline test dose administered to exclude Intrathecal and intravascular placement of catheter. The study drug was given slowly in the epidural space over 2 min. All assessments were made by an anaesthesiologist who did not know the solution used. The study solution was revealed only at the end of the procedure.

Baseline pulse rate, systolic blood pressure and diastolic blood pressure were recorded. Pulse rate, systolic blood pressure, diastolic blood pressure every 5 min for the first 30 min, and there after every 15 min. Time to onset of sensory analgesia at T10 level. Time to onset and duration of Motor blockade, maximum level and duration of of sensory analgesia, Adverse effects and complications. Results were statistically analysed using unpaired t test and Fischer exact test. A p value <0.05 was considered as statistically significant. All the values are mentioned as mean standard deviation.

RESULTS

Table 1: Comparison of distribution between the two groups

Variables		GROUP R	GROUP RD	P VALUE
Age(yrs)	Mean	36.53	34.2	
	SD	10.80	9.79	0.384
Weight(kgs)	Mean	53.7	53.8	
	SD	5.618	5.026	0.942
Height(cms)	Mean	167.76	168.26	
	SD	2.635	3.215	0.512
Sex	Males	19	16	0.3119
	Females	11	14	

The average age in years was 36.53±10.80 in Group R and 34.2±9.79 in Group RD. There was no significant difference in age between the groups. The average weight

in kgs in Group R was 53.7±5.618 and in Group RD was 53.8±5.026.There was no significant difference in weight between the groups and two groups were comparable. The average height in cms in Group R was 167.7±2.635 and in Group RD was 168.26±3.215.There was no significant difference in height between the groups and two groups were comparable. Both groups had predominantly male population.

Table 2: Variables on sensory and motor analgesia in two groups

Variables		GROUP R	GROUP RD	P VALUE
Time to onset of sensory analgesia to T10 Level(min)	Mean	13.36	10.6	0.0001
	SD	2.498	1.428	
Time to maximum level of sensory analgesia(min)	Mean	21.36	13.06	0.0001
	SD	4.131	1.507	
Maximum duration of Sensory analgesia(min)	Mean	204.8	309.5	0.0001
	SD	8.6	11	
Time to onset of complete motor blockade(min)	Mean	22.7	15.26	0.0001
	SD	3.70	1.46	
Total duration of motor blockade(min)	Mean	133.9	215.86	0.0001
	SD	7.60	10.40	

The mean time to onset of sensory analgesia to T10 level is statistically significant (P value <0.05).The mean time to maximum level of sensory analgesia is statistically significant (P value <0.05). The mean to onset of complete motor blockade is statistically significant (P value <0.05).The mean time to total duration of motor blockade is statistically significant (P value<0.05). Mean time to maximum duration of sensory analgesia is statistically significant (P value<0.05).

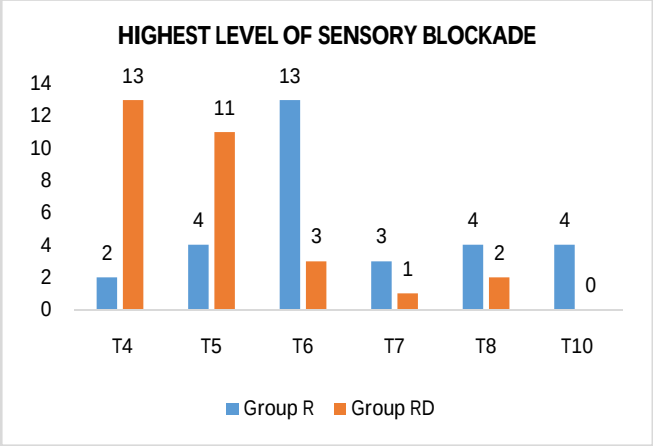

Figure 1: Highest level of sensory blockade

In patients of Ropivacaine group (Group R) 6% patients attained T4 level, 13%attained T5 level,43% attained T6 level,10% attained T7 level,13% attained T8 level, 13% attained T10 level. In patients of Ropivacaine and dexmedetomidine (Group RD) 43% attained T4 level,36.8% attained T5 level, 10% attained T6 level, 3% attained T7 level,6% attained T8.This implied that there was significant difference in highest level of sensory blockade compared in the two groups.

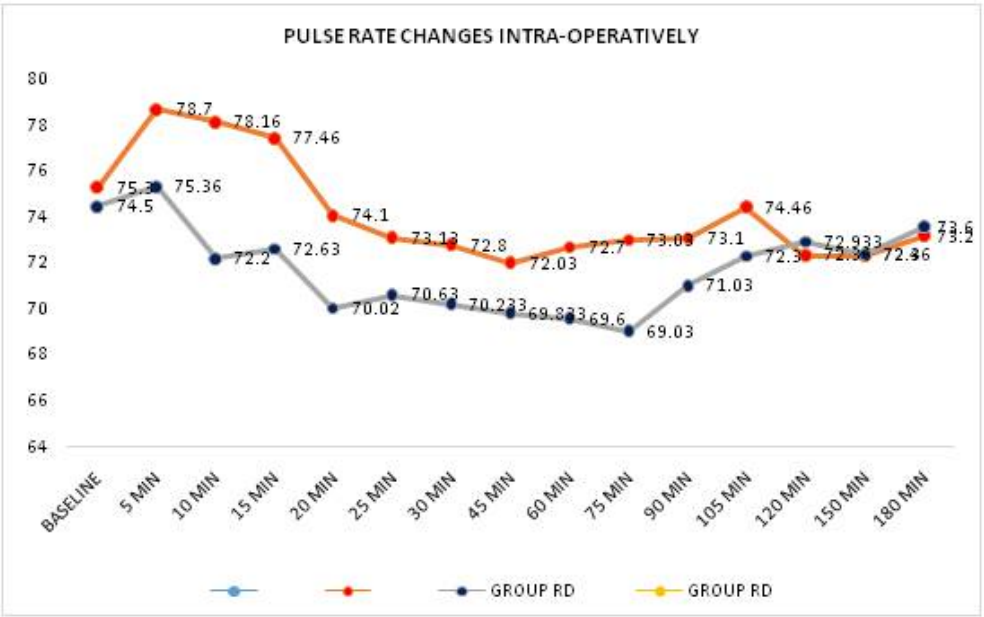

Figure 2: Comparison of pulse rate (beats per min) in the two groups

The mean pulse rate was compared between the two groups Group R and Group RD at 0,5,10,15,20,25,30,45,60,75,90,105,120,150 and 180 mins. There was no statistically significant difference between the two groups with respect to pulse rate when recorded at these time intervals.

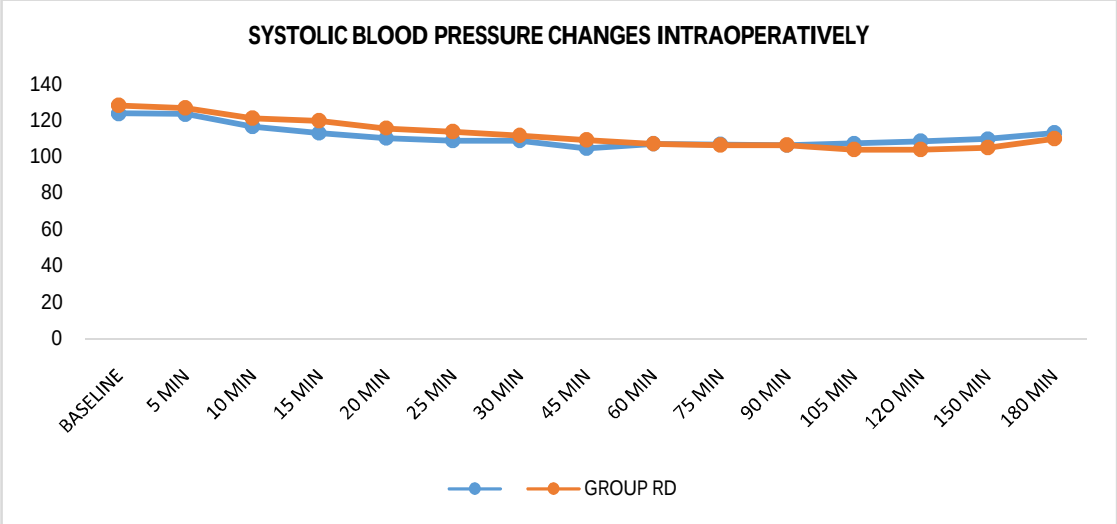

Figure 3: Comparison of systolic blood pressure (mm of Hg) changes in two groups-

The mean systolic blood pressure changes over the time intervals was compared between the two groups Group R and Group RD. It was found that systolic blood pressure did not differ between the groups.

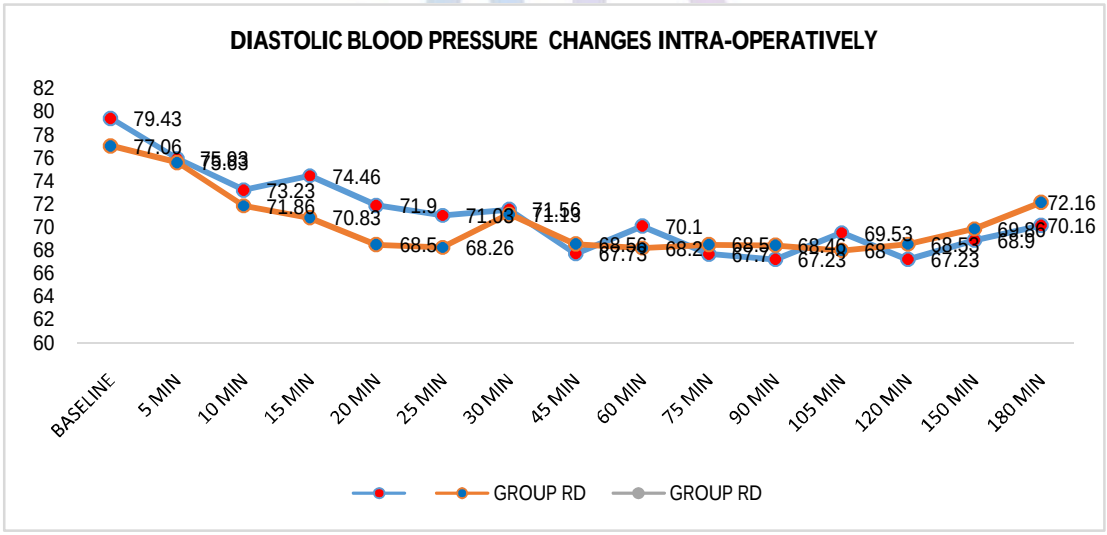

Figure 4: Comparison of diastolic blood pressure (mm of Hg) changes in two groups-

The mean diastolic blood pressure changes over the time intervals was compared between the two groups Group R and Group RD. It was found that diastolic blood pressure did not differ between the groups.

Adverse effects: In Ropivacaine group, 2 patients had nausea, and 2 patients had hypotension out of 30 during the intraoperative period. In Group RD 2 patients had nausea, 1 patient had hypotension, 2 patients had bradycardia out of 30 during the intraoperative period.

DISCUSSION

Epidural Anaesthesia and analgesia is considered by many as the gold standard technique for major surgery. It has the potential to provide complete analgesia for as long as the epidural is continued. Epidural techniques are particularly effective at providing dynamic analgesia, allowing the patient to mobilise and resume normal activities unlimited by pain. It also improves the postoperative outcome and attenuates the physiological response to surgery, in particular, significant reduction in pulmonary infections, pulmonary embolism, ileus, acute

renal failure and blood loss.[4]Previously Bupivacaine is a well established long acting local amide local anaesthetic which has been in use since 1957.It has been the most popular and widely used local anaesthetic agent for long surgical procedures. It is used to provide Intraoperative anaesthesia by intrathecal, epidural and caudal route, nerve blocks, field blocks, labour analgesia, postoperative analgesia. The major disadvantage is its potential for cardiotoxicity. A number of deaths have been reported due to cardiac arrest from regional anaesthesia with bupivacaine which appear due to inadvertent intravascular injection of drug. These deaths and subsequent recommendations of the food and drug administration provided the impetus to develop a new safer local anaesthetic.[5] Ropivacaine is a long acting regional anaesthetic which has been developed for the purpose of reducing the potential toxicity associated with Bupivacaine. It is developed as a pure S(-) enantiomer. R and S enantiomers of local anaesthetics have been demonstrated to have a different affinity for the different ion channels of calcium, potassium, sodium channels which results in a significant reduction of CNS and cardiac toxicity of the S (-) enantiomer to R (+) enantiomers. Ropivacaine is less lipophillic than bupivacaine and is less likely to penetrate the large myelinated motor fibres resulting in a relatively reduced motor blockade. Thus it has a greater degree of motor and sensory differentiation which is useful when motor blockade is undesirable.[6] Various adjuvants are being used with local anaesthetics for prolongation of intraoperative and postoperative analgesia in epidural block for lower limb orthopaedic surgeries and to minimize the adverse effects of high doses of local anaesthetics. The aipha 2 adrenergic agonists have analgesic properties when used as a adjuvant in regional anaesthesia. Dexmedetomidine, a newer and highly selective alpha 2 adrenergic agonist has evolved. The stable hemodynamics and the decreased oxygen demand due to enhanced sympathoadrenal stability make it a very useful adjuvant. The present study was conducted in the deparment of anaesthesiology at Gandhi hospital Musheerabad, secunderabad. In the present study the patients studied in the two groups did not vary much with respect to age, sex or weight and height. Majority of patients were in the age group between 18-55 yrs,with the mean age in yrs was 36.53±10.80 in Group R and 34.2±9.79 in Group RD. The mean sex distribution and the mean weight in the two groups were also identical. These parameters were matched in the two groups to avoid changes in intraoperative and postoperative outcome of patients. The average weights of the patients in Group R was 53.7±5.618 and in Group RD was 53.8±5.026.There was no significant difference in weight between the groups and two groups were comparable. The average height in cmsin Group R was 167.76±2.635 and in Group RD was 168.26±3.215.There was no significant difference in height between the groups and two groups were comparable.

Time to onset of sensory analgesia to T10 level-

The mean time to onset of sensory analgesia to T10 level in Group R was **13.36±2.498** and in Group RD was **10.6±1.428.**The early onset of sensory analgesia to T10 level in Group RD is statistically significant P value was <0.05 (0.0001).A prospective, randomized double blinded study was conducted by **Giri and Iqbal[7],**which included 60 adult patients, Addition of dexmedetomidine to ropivacaine as an adjuvant resulted in an earlier onset (8.52±2.36 minutes) of sensory analgesia at T10 level as compared to the ropivacaine alone (9.72±3.44 minutes).The difference was statistically significant.The results of these studies are in accordance to present study and comparable with our study.**Bajwa *et al*[8]**,conducted prospective randomized study was carried out which included 50 adult female patients between ages (44-65 yrs) the results of these studies are comparable with our study.Dexmedetomidine group has earlier onset compared to clonidine group.The difference was statistically significant.**Bajwa *et al*[9],**conducted prospective double blinded study on 100 patients of both gender aged (21-56yrs) Group RD had earlier onset of analgesia to T10 level compared to Group RF (7.12±2.44) vrs(9.14±2.94) the difference was statistically significant. This observation matches well with our study.

Time to maximum level of sensory analgesia: The mean time to maximum level of sensory analgesia in Group R was 21.36±4.131,and in Group RD was 13.06±1.507.The early onset to maximum level of sensory analgesia in Group RD is statistically significant p value<0.05(0.0001).In Group RD there is maximum sensory block level compared to Ropivacaine group. Bajwa *et al*[8],conducted prospective randomized study was carried out which included 50 adult female patients between ages (44-65 yrs) ASA I,II who underwent vaginal hysterectomies. In Group RD the time to maximum sensory block level is(13.14±3.96) vrs(15.80±4.86) and also maximum sensory block level in dexmedetomidine group compared to clonidine group which is statistically significant. This observation matches well with our study. Thimmappa *et al*[10], conducted a comparative study of epidural ropivacaine 0.75% alone with ropivacaine+clonidine and ropivacaine+dexmedetomidine for lower abdominal and lower limb surgeries. They conducted on 90 patients (ASA I,II) of age group 18-55 yrs of either sex. Group RD-19ml of 0.75% ropivacaine with 75mcg dexmedetomidine and observed that the time to maximum

sensory block level was faster in Group RD compared to Group RC and Group R (13.03±1.33) vrs (13.63±1.96) vrs (16.00±1.78) which are statistically significant.

Time to onset of complete motor blockade: The mean time to onset of complete motor blockade in Ropivacaine (Group R) was **22.7±3.70 min** and in Ropivacaine and dexmedetomidine (Group RD) was **15.26±1.46 min**. The mean to onset of complete motor blockade is statistically significant in Group RD compared to Group R.P value <0.05 (0.0001). Bhawana Rastogi *et al*[11],conducted a study by adding dexmedetomidine as an adjuvant to epidural 0.75% Ropivacaine in patients undergoing infraumbilicalsurgery. They conducted a study on 80 patients of 18-58 yrs of age of either sex had complete motor block in minutes(17.20±4.10 vrs 23.90±3.57) was significantly earlier in the ropivacaine with dexmedetomidinegroup. This observation matches well with our study. Thimmappa *et al*[10], conducted a comparative study of epidural ropivacaine 0.75% alone with ropivacaine+clonidine and ropivacaine+dexmedetomidine for lower abdominal and lower limb surgeries. They conducted on 90 patients (ASA I,II) of age group 18-55 yrs of either sex. Group RD-19ml of 0.75% ropivacaine with 75mcg dexmedetomidine and observed that establishment of complete motor block was earlier in Group RD (15.77±1.25 min) compared to Group RC(16.47±1.38 min) and Group R (21.37±2.13 min) which shows statistically significant. This observation supports the present study. Bajwa *et al*[8], conducted prospective randomized study was carried out which included 50 adult female patients between ages (44-65 yrs) showed onset time to complete motor block in Group RD was 17.24±5.16 min and in Group RC was 19.52±4.06 min, dexmedetomidine group had earlier onset of complete motor blockade compared to clonidine. This observation supports the present study.

Total duration of motor blockade: The mean time to total duration of motor blockade in Group R was 133.9±7.60 minand in Group RD was 215.86±10.40 min. The mean time to total duration of motor blockade is statistically significant p value<0.05(0.001).Thimmappa *et al*[10], conducted a comparative study of epidural ropivacaine 0.75% alone with ropivacaine+clonidine and ropivacaine+dexmedetomidine for lower abdominal and lower limb surgeries. They conducted on 90 patients. Group RD-19ml of 0.75% ropivacaine with 75mcg dexmedetomidine and observed that total duration of motor blockade was delayed in Group RD-213.83±17.30,and in Group RC-165.63±14.73 and in Group R-132.37±12.59 minutes. Total duration of motor blockade is prolonged in dexmedetomidine group which is statistically significant. This observation supports the present study. Sarabjitkaur *et al*[12], conducted a prospective randomized blinded study by adding dexmedetomidine as an adjuvant to 0.75% Ropivacaine in epidural anaesthesia in lower limb orthopaedic surgeries. They conducted in 100 patients of ASA (I, II) age group (20-65) yrs of either sex undergoing lower limb surgeries. Group RD-150mg of 0.75%Ropivacaine with dexmedetomidne 1mcg/kg. Motor recovery was delayed in Group RD 385.92±17.71 minutes compared to Group R 259.80±15.48 minutes which shows statistically significant. This observation supports the present study. Bhawana Rastogi *et al*[11],conducted a study by adding dexmedetomidine as an adjuvant to epidural 0.75% Ropivacaine in patients undergoing infraumbilical surgery. They conducted a study on 80 patients of 18-58 yrs of age of either sex observed that duration of motor blockade was 185.38±23.24 minutes in Group R and in Group RD was 362.13±72.9 minutes which is statistically significant, the results was in accordance to the present study

Maximum duration of sensory analgesia: The mean time to maximum duration of sensory analgesia in Group R was **204.8±8.6 minutes** and in Group RD was 309.5±11 minutes. The mean time to maximum duration of sensory analgesia is statistically significant p value<0.05(0.0001). Sarabjitkaur *et al*[12], conducted a prospective randomized blinded study by adding dexmedetomidine as an adjuvant to 0.75% Ropivacaine in epidural anaesthesia in lower limb orthopaedic surgeries. They conducted in 100 patients of ASA (I, II) age group(20-65) yrs of either sex undergoing lower limb surgeries. They observed that total duration of sensory block in Group R was 375.20±15.97 minutes and in Group RD was 535.18±19.85 minutes which shows statistically significant. This observation matches well with our study. Bhawana Rastogi *et al*[11],conducted a study by adding dexmedetomidine as an adjuvant to epidural 0.75% Ropivacaine in patients undergoing infraumbilicalsurgery. They conducted a study on 80 patients of 18-58 yrs of age of either sex they observed that duration of analgesia in Group R was 216.58±25.5 minutes and in Group RD was 429.25±90.4 minutes which shows statistically significant results.This observation matches well with our study. Thimmappa *et al*[10], conducted a comparative study of epidural ropivacaine 0.75% alone with ropivacaine+clonidine and ropivacaine+dexmedetomidine for lower abdominal and lower limb surgeries. They conducted on 90 patients (ASA I,II) of age group 18-55 yrs of either sex observed that duration of analgesia is prolonged in Group RD (291.33±27.79 minutes) compared to Group RC (261±17.68 minutes) and Group R (200.33±17.07

minutes) which shows statistically significant results. This observation matches well with our study.

Haemodynamic Parameters: In present study, baseline hemodynamic parameters were observed before giving the Epidural anaesthesia and for every 5 min for the first 30 min and thenevery15 mintill the end of surgery. It was observed that the changes in pulserate, systolic blood pressure and diastolic blood pressure throughout the intraoperative periodwas notclinically and statistically significant. Two patients out of thirty patients in Group R and one patient out of thirty in Group RD were observed to hypotension in the intra-operative period. The hypotension was responsive to fluid bolus and vasopressors. Salgado *et al*[13], conducted a study by adding dexmedetomidine as an adjuvant to 0.75%ropivacaine.They conducted on 40 patients scheduled for hernia repair, varicose vein surgeries under epidural anaesthesiathey observed that there was no statistically significant difference in heart rate, non invasive systolic blood pressure, diastolic blood pressure. This observation matches well with our study. Sarabjitkaur *et al*[12], conducted a prospective randomized blinded study by adding dexmedetomidine as an adjuvant to 0.75% Ropivacaine in epidural anaesthesia in lower limb orthopaedic surgeries they observed that there was no statistically significant difference in heart rate, non invasive systolic blood pressure and diastolic blood pressure.

CONCLUSION

From our study, we conclude that when dexmedetomidine 1mcg/kg added as adjuvant to 0.75% Ropivacaine in epidural anaesthesia in lower limb orthopaedic surgeries the following effects are seen-Addition of dexmedetomidine to ropivacaineas an adjuvant resulted in earlier onset of sensory analgesia to T10 level as compared to ropivacaine group Group R. Dexmedetomidine provided a higher dermatomal spread and also helped in achieving the complete sensory anaesthetic level in a shorter period in comparison to Ropivacaine alone. Group R Complete motor blockade was also achieved earlier in dexmedetomidine group Group RD in comparison to Ropivacaine Group R.Dexmedetomidine also increased the total duration of sensory analgesia in comparison to Ropivacaine group R. Duration of motor blockade is less in Ropivacaine(Group R) as compared to Ropivacaine and dexmedetomidine (Group RD).

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