**Journal of Cardiovascular Disease Research**

**ISSN: 0975-3583, 0976-2833 VOL 14, ISSUE 12, 2023**

## Original Research Article

# A PROSPECTIVE STUDY OF EFFICACY AND CLINICAL PROFILE OF DEXMEDETOMIDINE AND FENTANYLAS AN ADJUVANT TO EPIDURAL ROPIVACAINE FOR POSTOPERATIVE PAIN RELIEF IN SPINE SURGERIES

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**Received: 04-12-2023 / Revised: 19-12-2023 / Accepted: 24-12-2023**

**Abstract**

**BACKGROUND:** Spine surgeries are commonly associated with moderate to severe postoperative pain which remains a great challenge for the anaesthesiologist to treat it. Multimodal analgesic techniques like parenteral analgesics or regional analgesia are commonly practiced. Use of intrathecal opioids before surgical closure provide effective postoperative analgesia without any major side effects. This study was designed to compare the analgesic efficacy of Ropivacaine and Dexmedetomidine (RD) with Ropivacaine and Fentanyl (RF) by giving these drugs by epidural administration in patients undergoing elective spine surgeries.

**MATERIALS AND METHODS:** This study done at Department of Anaesthesiology ,ESIC Medical College, Kalaburagi patients were randomly selected based on inclusion criteria and after obtaining written informed consent, patients were allocated into two equal groups.(RD & RF) and the data were analysed.

**RESULTS:** The onset of sensory analgesia was earlier in Ropivacaine Dexmeditomidine (RD) group (5.93±0.700 min) than Ropivacaine Fentanyl (RF) group(7.67±0.702 min), peak effect of analgesia was 12.07min for RD group and 13.13min for RF group, mean duration of analgesia was significantly longer in RD group than RF group(349.80± 8.124min vs 298.20±4.77min). Both groups showed haemodynamic stability. Visual Analogue Scale score between group RD and RF was1.79 and 2.31. Rescue analgesic requirement was less with RD group. Mean sedation score at various time intervals was significant between these groups. No episode of respiratory depression was noted in RD group.

**CONCLUSION:** Concluded from this study that epidural route provided adequate analgesia in both groups. However Dexmedetomidine seems to be a better alternative to Fentanyl as it provides early onset and establishment of sensory anesthesia prolonged postoperative analgesia lower consumption of postoperative rescue analgesia, comparablestable hemodynamics, andmuch better sedation levels.

**KEYWORDS:** Epidural analgesia, Ropivacaine, Dexmedetomidine, Fentanyl

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## Introduction

Spine surgeries are commonly associated with moderate to severe postoperative pain which is directly related to the invasiveness of the procedure. A large incision and manipulation of multiple vertebrae in spine surgeries contribute postoperative pain which remains a great challenge for the anaesthesiologist to treat it. Multimodal analgesic techniques like parenteral analgesics or regional analgesia are commonly practiced[1].

Conventional methods like intravenous or intramuscular analgesics are followed using opioids and non-steroidal anti-inflammatory drugs (NSAID's).The opioids, though potent analgesics, are associated with postoperative respiratory depression , nausea and vomiting, whereas less potent NSAIDs have limited use due to their renal and gastrointestinal side effects. The use of intrathecal opioids before surgical closure also provide effective postoperative analgesia without any major side effects[2].

The use of local anaesthetics with adjuvants like opioids and alpha agonists through an epidural catheter placed intraoperatively under direct vision at the end of the procedure, is an effective alternative method for controlling postoperative pain

Good perioperative analgesia is important to attenuate the surgical stress response. Epidural analgesia reduces the adverse physiological responses to surgery like hyperactive autonomic nervous system response, cardiovascular stress response, tissue breakdown, high metabolic rate, pulmonary dysfunction and immune system dysfunction[3].

By placing a catheter in the epidural space, continuous anaesthesia can be maintained for a long period of time . Epidural catheter can also be used to provide postoperative analgesia with lower concentrations of local anesthetic drugs alone or with adjuncts. Early postoperative mobilization and rehabilitation with minimal associated pain and discomfort is the most desirable feature in modern orthopedic surgeries[3]. This can be done by using a local anesthetic with lesser propensity of motor block.

Ropivacaine, the newer amide local anesthetic with minimal cardiovascular, central nervous system toxicity as well as lesser propensity of motor block has been used in this study. Traditionally opioids have been used as adjuvant to achieve the desired anesthetic effect with a lower dose of local anesthetic and superior analgesia.

Dexmedetomidine, is a new addition to the class of alpha-2 agonists, and a close congener of Clonidine, has been used for this purpose with many beneficial effects. Dexmedetomidine, is an imidazoline derivative, which is 1600 times more selective for alpha-2 receptors than alpha-1 receptors. It acts on both pre- synaptic and post- synaptic sympathetic nerve terminals and on the central nervous system thereby decreasing the sympathetic outflow and Norepinephrine release causing sedative, anti-anxiety, analgesic, sympatholytic effects. The anti nociceptive action is due to its effect at the spinal cord alpha -2 receptors[4].

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This study was designed to compare the analgesic efficacy of Ropivacaine with Dexmedetomidine and Ropivacaine with Fentanyl by their epidural administration in patients undergoing elective spine surgeries.

**MATERIALS AND METHODS:**

This study done at Department of Anaesthesiology, ESIC Medical College, Kalaburagi patients were randomly selected based on inclusion criteria and after obtaining written informed consent, patients were allocated into two equal groups.(RD & RF) and the data were analysed.

**Statistical analysis:** Descriptive statistics was done for all data and suitable statistical tests of comparison were done. Continuous variables were analyzed with the unpaired t test and categorical variables were analyzed with the Chi-Square Test and Fisher Exact Test. Statistical significance was taken as $P < 0.05$. The data was analyzed using EpiInfo software (7.1.0.6 version; Center for disease control, USA) and Microsoft Excel 2010.

**INCLUSION CRITERIA**

- Age: 20-65 years
- ASA: I & II
- Elective Surgeries
- Who have given valid informed consent.
- Lower thoracic below T8 and lumbosacral spine surgeries

**EXCLUSION CRITERIA**

- ASA III & IV
- Patients with heart block, Bradyarrthymia and Left ventricularfailure
- Hematological disease, Bleeding or coagulation abnormalities
- Psychiatric diseases, TB spine and any other permanentneurological disorders

**RESULTS**

Descriptive statistics was done for all data and suitable statistical tests of comparison were done. Continuous variables were analyzed with the unpaired t test and categorical variables were analyzed with the Chi-Square Test and Fisher Exact Test. Statistical significance was taken as $P < 0.05$. The data was analyzed using EpiInfo software (7.1.0.6 version; Center for disease control, USA) and Microsoft Excel 2010.

**Table 1: Group distribution (n=60)**

| Groups | Group Names | Intervention Used | Procedure |
|---|---|---|---|
| RD | Ropivacaine + Dexmedetomidine. | Post- operative epidural block with Ropivacaine and Dexmedetomidine. | In post-operative patients who are undergoing |
| RF | Ropivacaine + Fentanyl. | Post- operative epidural block with Ropivacaine and Fentanyl. | elective spine surgeries |

**Table 2: Age distribution (n=30 in Group RD and n=30 inGroup RF)**

| Age Distribution | RD Group | % | RF Group | % |
|---|---|---|---|---|
| ≤ 30 Years | 9 | 30.00 | 7 | 23.33 |

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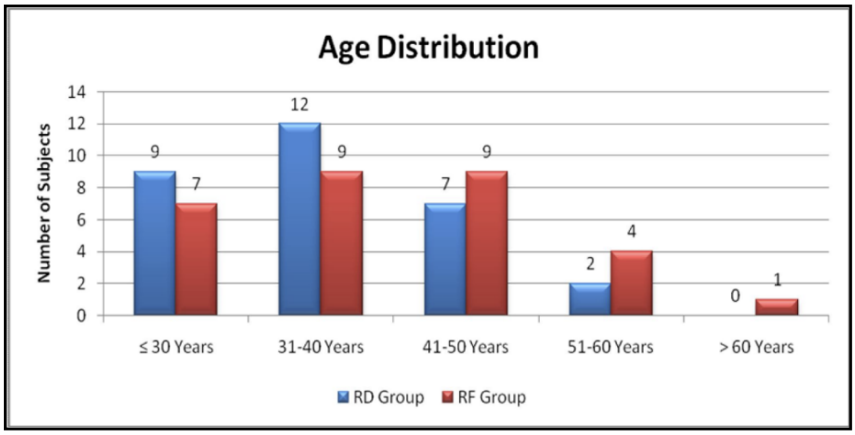
| | | | | |
|---|---|---|---|---|
| 31-40 Years | 12 | 40.00 | 9 | 30.00 |
| 41-50 Years | 7 | 23.33 | 9 | 30.00 |
| 51-60 Years | 2 | 6.67 | 4 | 13.33 |
| > 60 Years | 0 | 0.00 | 1 | 3.33 |
| Total | 30 | 100 | 30 | 100 |

| **Age Distribution** | **RD Group** | **RF Group** |
|---|---|---|
| N | 30 | 30 |
| Mean | 36.10 | 39.50 |
| SD | 10.83 | 11.02 |
| P value Unaired t test | | 0.233028 |




Majority of the Ropivacaine + Dexmedetomidine group patients belonged to the 31-40 years age group (n=12, 40%) with a mean age of 36.10 years. In the Ropivacaine + Fentanyl group patients, majority belonged to the same age group as Ropivacaine + Dexmedetomidine group (n=9, 30%) with a mean age of 39.50 years. The association between the intervention groups and age distribution is considered to be not statistically significant since p > 0.05 as per unpaired t test

**Table 4: Weight distribution**

| **Weight Distribution** | **RD Group** | **%** | **RF Group** | **%** |
|---|---|---|---|---|
| ≤ 50 kgs | 1 | 3.33 | 0 | 0.00 |
| 51-60 kgs | 5 | 16.67 | 9 | 30.00 |
| 61-70 kgs | 21 | 70.00 | 17 | 56.67 |
| 71-80kgs | 3 | 10.00 | 4 | 13.33 |
| Total | 30 | 100 | 30 | 100 |

| **Weight Distribution** | **RD Group** | **RF Group** |
|---|---|---|
| **N** | 30 | 30 |
| **Mean** | 66.23 | 65.47 |
| **SD** | 5.77 | 6.41 |
| **P value Unaired t test** | | 0.6282 |

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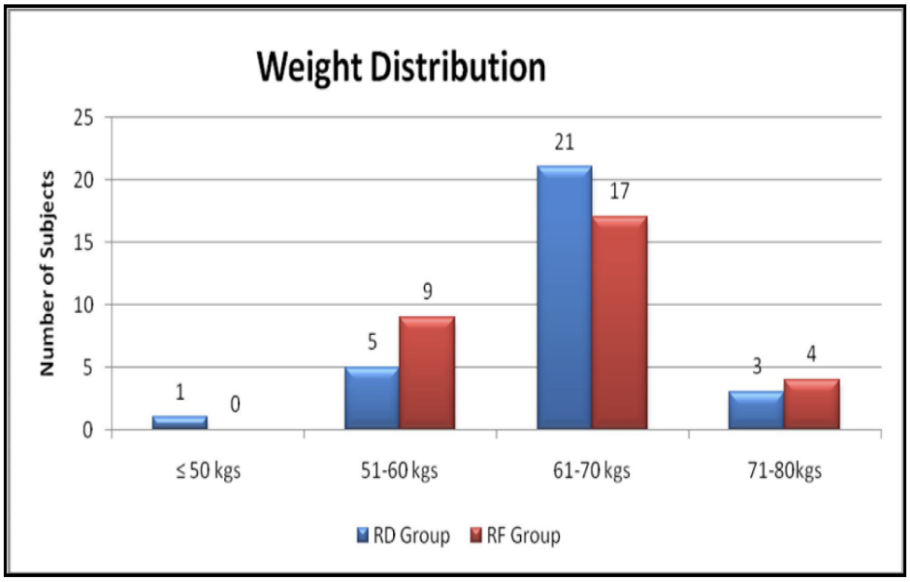


Majority of the Ropivacaine + Dexmedetomidine group patients belonged to the 61-70 kgs weight group (n=21, 70%) with a mean weight of
66.23 kgs. In the Ropivacaine + Fentanyl group patients, majority belonged to the same weight group as Ropivacaine + Dexmedetomidine group (n=17, 56.67%) with a mean weight of 65.47 years. The association between the intervention groups and weight distribution is considered to be not statistically significant since p > 0.05 as per unpaired t test.

**Table 5: ASA physical status classification**

| ASA Physical Status Classification | RD Group | % | RF Group | % |
|---|---|---|---|---|
| ASA I | 23 | 76.67 | 20 | 66.67 |
| ASA II | 7 | 23.33 | 10 | 33.33 |
| Total | 30 | 100 | 30 | 100 |
| P value Fishers Exact Test | | | 0.5675 | |

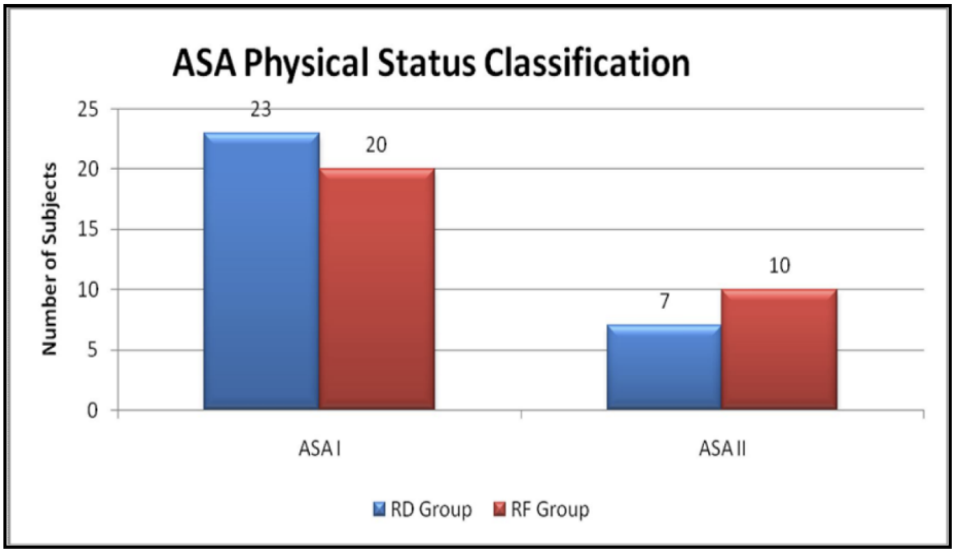

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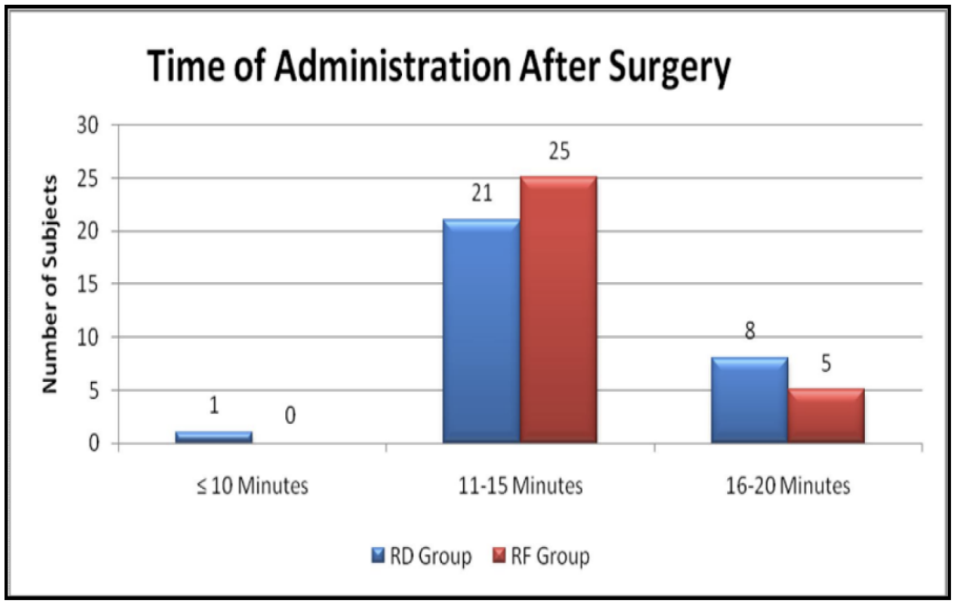
**Table 6: Time of administration of drug after surgery**

| Time of Administration ofdrug After Surgery | RD Group | % | RF Group | % |
|---|---|---|---|---|
| ≤ 10 Minutes | 1 | 3.33 | 0 | 0.00 |
| 11-15 Minutes | 21 | 70.00 | 25 | 83.33 |
| 16-20 Minutes | 8 | 26.67 | 5 | 16.67 |
| Total | 30 | 100 | 30 | 100 |

| Time of Administration After Surgery | RD Group | RF Group |
|---|---|---|
| N | 30 | 30 |
| Mean | 16.07 | 14.97 |
| SD | 2.63 | 2.04 |
| P value Unaired t test | | 0.0756 |




Majority of the Ropivacaine + Dexmedetomidine group patients belonged to the 11-15 minutes after surgery drug administration time group (n=21, 70%) with a mean time of administration after surgery of 16.07 minutes. In the Ropivacaine + Fentanyl group patients, majority belonged to the same class interval as Ropivacaine + Dexmedetomidine group (n=25, 83.33%) with a mean time of administration after surgery of 14.97 minutes. The association between the intervention groups and time of administration after surgery distribution is considered to be not statistically significant since $p > 0.05$ as per unpaired t test.

**Table 7: Drug Onset Time**

| Drug Onset Time | RD Group | % | RF Group | % |
|---|---|---|---|---|
| 4 Minutes | 6 | 20.00 | 1 | 3.33 |
| 6 Minutes | 20 | 66.67 | 12 | 40.00 |
| 8 Minutes | 3 | 10.00 | 8 | 26.67 |
| 10 Minutes | 1 | 3.33 | 9 | 30.00 |
| Total | 30 | 100 | 30 | 100 |

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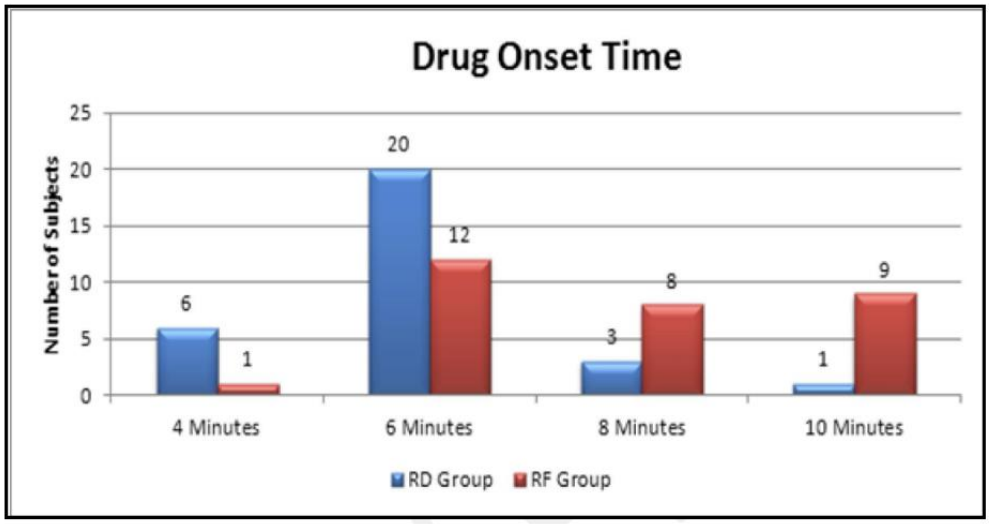
| Drug Onset Time | RD Group | RF Group |
|---|---|---|
| N | 30 | 30 |
| Mean | 5.93 | 7.67 |
| SD | 1.34 | 1.83 |
| P value Unaired t test | | 0.0001 |




By conventional criteria the association between the intervention groups and drug onset time is considered to be statistically significant since $p < 0.05$ as per unpaired t test. In simple terms, Most of the Ropivacaine + Dexmedetomidine group patients belong to 6 minutes drug onset time class interval (n=20, 66.67%) with a mean drug onset time of 5.93 minutes. Similarly in the Ropivacaine + Fentanyl group majority of the patients belonged to the 6 minutes drug onset time class interval (n=12, 40%) with a mean drug onset time of 7.67 minutes. This indicates that there is a true difference among intervention groups and the difference is significant with a p-value of 0.0001.

The mean drug onset time was meaningfully less in Ropivacaine + Dexmedetomidine intervention group compared to Ropivacaine + Fentanyl intervention group by a mean time of 1.73 minutes. This significant difference of 23% reduction in mean drug onset time among patients belonging to Ropivacaine + Dexmedetomidine intervention group compared to Ropivacaine + Fentanyl intervention group is true and has not occurred by chance.

In this study we can safely conclude that Post- operative epidural block with Ropivacaine + Dexmedetomidine results in significantly lowered drug onset time compared to Post- operative epidural block with Ropivacaine + Fentanyl when used in post-operative patients who underwent elective spine surgeries.

## DISCUSSION

Patients undergoing spinal surgeries experience severe pain in the postoperative period, which may increase the morbidity , incidence of complications and prolong postoperative rehabilitation. Postoperative pain therapy mainly consists of administration of oral or intravenous opioids in combination with non steroidal anti-inflammatory drugs, but it often

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results in insufficient pain control and side effects such as respiratory depression, nausea, and vomiting

Epidural anesthesia and analgesia have been shown to be superior to intravenous analgesia with respect to quality of pain relief, incidence of side effects, pulmonary, cardiac, and gastrointestinal dysfunction. Turner *et al.*[5], showed in an observational study that epidural catheters placed intraoperatively by the surgeon followed by infusion of local anesthetics with or without opioids were capable of providing good analgesia after posterior spinal fusion. Even when the epidural space was disrupted during surgery, local anesthetic that leaks out from epidural space acts like wound infiltration.

A good cooperation and communication is needed with the respective surgeon , who places the epidural catheter directly into the surgical field. It is easy to understand that surgeons are afraid of development of any kind of infection of the wound or the epidural space, especially after spine surgery, because even small hematomas are an excellent medium for bacteria. At first glance, a catheter directly placed in this area does not gain acceptance in the eyes of the surgeons, irrespective of the applied medication. Apart from dislodgement, the placement of an epidural catheter into a recently operated area in the vertebral column with epidural application of local anesthetics may include the problem of unpredictable absorption of the drug and motor blockade.

An ideal adjuvant should provide a longer duration of analgesia and better hemodynamic stability. There is a reduced requirement of analgesics with the use of an epidural adjuvant due to the property of augmentation of the local anaesthetic effects, thereby prolonging the duration of analgesia.

To avoid neuraxial opioid induced adverse effects such as respiratory depression, nausea, vomiting, urinary retention and pruritus, α-2 agonists are being used as an alternative epidural adjuvants. Introduction of this newer agent Dexmedetomidine has increased the scope of α-2 agonists usage in neuraxial blockade. Rapid onset of local anaesthetic action, longer period of analgesia and better cardiovascular parameters have widened the scope of usage of Dexmedetomidine epidurally.

In our prospective randomized control study, we compared the analgesic efficacy of Fentanyl 1µg/kg and Dexmedetomidine 1µg/kg which were added to 15 ml 0.2% Ropivacaine , by giving these drugs through an epidural catheter in 60 patients underwent elective spine surgeries. The efficacy of Dexmedetomidine verses fentanyl as an adjuvant in epidural analgesia was studied. The patients in both the groups with respect to age, weight, ASA Physical status did not show a statistically significant difference.

ONSET OF ANALGESIA

**Sukhminder jit singh bajwa** *et al* [6].,did a comparative study in 100 patients who underwent elective lower limb orthopaedic surgeries under lumbar epidural with Dexmedetomidine 1µg/kg and Fentanyl 1µg/kg added to Ropivacaine 0.75% as the study drug. In that study the onset time to reachT10 sensory level, was significantly shorter in group RD (7.12 ±2.44mon.) as compared to group RF(9.146±2.94).

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**MS Saravana babu *et al*.,** (2014)[7] conducted a prospective randomized study in 60 patients to evaluate the efficacy and clinical profile of Dexmedetomidine and Clonidine as an adjuvant to Ropivacaine, in epidural analgesia in spine surgeries by giving 20 ml of 0.2% Ropivacaine and 1 µg/kg of Dexmedetomidine (group RD) or 20 ml of 0.2% Ropivacaine and 2 µg/kg of Clonidine (group RC They observed that the addition of Dexmedetomidine to Ropivacaine as an adjuvant resulted in an earlier onset (7.33±1.76 min) of analgesia as compared to the addition of Clonidine (8.40±1.61 min

**Ajay Kumar Anandan *et al*.,(2014)[8]** conducted a study comparing Ropivacaine with Dexmeditomedine (RD) with Ropivacaine (R) in 30 patients and concluded that the onset was earlier in RD (3.60min.) compared with R group (4.60 min.).

In our study the onset of sensory analgesia was earlier in the RD group (5.93±0.700 min) than in the RF group (7.67±0.702 min). For onset of anaesthesia, the determinants are, diffusion through meningeal layers, penetration of neural tissue and distribution of the drug in various tissues. Dexmedetomidine being more lipophilic and having a favorable pKa produces an earlier onset of anagesia than fentanyl.

## PEAK EFFECT OF ANALGESIA

In **Sukhminder jit singh bajwa[9]** *et al* comparative study the time to reach peak analgesia was significantly shorter in RD group (13.38±4.48)compared to RF group(16.61±4.36)

The peak effect of analgesia in our study was at 12.07min. for RD group and at 13.13min. for RF group which is statistically not significant (Pvalue-0.1330) in our study.

## DURATION OF ANALGESIA

In **Sukhminder jit singh bajwa** *et al* [9] comparative study the mean duration of analgesia was longer (366.62±24.42min) in RD group than (242.16±3.86min) in the RF group thus promising the superior block characteristics of RD group than RF group

In the study conducted by **MS Saravana babu *et al*.,**[7] (2014) the duration of analgesia was also prolonged in Dexmedetomidine group (407.00±47.06 min) compared to Clonidine group (345.01±35.02).

**Mausumi Neogi *et al*., [10] (2010)** did a comparative study on paediatric patients undergoing elective inguinal herniotomy. They compared the efficacy of Clonidine 1 µg/kg and Dexmedetomidine 1 µg/kg as adjuvants to Ropivacaine for caudal analgesia.. They randomized the patients into 3 study groups, group R (Ropivacaine), group C (Ropivacaine
+ Clonidine), group D (Ropivacaine + Dexmedetomidine) and observed that, the mean duration of analgesia was 6.32±0.46 hours in group R, 13.17±0.68 hours in group C and15.26±0.86 hours in group D. . They concluded that the addition of both Clonidine and Dexmedetomidine with Ropivacaine administered caudally significantly increased the duration of analgesia

In **Ajay Kumar Anandan *et al*.,(2014)[8]** study comparing Ropivacaine with Dexmeditomedine (RD) with Ropivacaine (R) in 30 patients and concluded that the duration of analgesia was prolonged in RD (289min.) compared to R group (243 min). this

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results were correlated with our study.

**Sarabjit Kaur et al.,**[11] (2014) conducted a prospective, randomized double-blind study in 100 patients undergoing lower limb surgeries by randomly into groups receiving 150 mg of 0.75% Ropivacaine (Group A) and 150 mg of 0.75% Ropivacaine with Dexmedetomidine (1 μg/kg) (Group B). Two groups were compared with hemodynamic changesblock characteristics which included time to onset of analgesia at T10, maximum sensory analgesic level, time to maximum sensory and motor block, regression at S1 dermatome and time to the first dose of rescue analgesia. Significant difference was observed in relation to the duration of sensory block (375.20 ± 15.97 min. in Group A and 535.18 ± 19.85 min. in Group B [*P* - 0.000]), duration of motor block (259.80 ± 15.48 min in Group A and 385.92 ± 17.71 min in Group B [*P* - 0.000]), duration of post- operative analgesia (312.64 ± 16.21 min in Group A and 496.56 ± 16.08 min in Group B [*P* < 0.001]) and consequently low doses of rescue analgesia in Group B (1.44 ± 0.501) as compared to Group A (2.56 ± 0.67). They concluded that Epidural Dexmedetomidine as an adjuvant to Ropivacaine associated with prolonged sensory and motor block, hemodynamic stability, prolonged postoperative analgesia and reduced demand for rescue analgesics when compared to plain Ropivacaine. These study also concluded that addition of Dexmedetomidine to Epidural Ropivacaine prolongs the duration of action, and gives earlier onset of action of Ropivacaine.

## CONCLUSION

It can be concluded from this study that epidural route provided adequate effective analgesia in spine surgeries in terms of VAS score in both the groups. However, Dexmedetomidine seems to be a better alternative to Fentanyl as an epidural adjuvant as it provides comparable , early onset and establishment of sensory anaesthesia, prolonged analgesia in the post operative period, lesser consumption of post-operative rescue analgesics, stable haemodynamics and much better sedation levels.

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