Abstract

**Background:** The incidence of RTA is ever increasing has been associated with wide range of injuries. The present study aims to provide better anesthetic options for lower limb surgeries in order to improve intra as well as post-operative outcomes.

**Methodology:** Total of 100 Patients of ASA Grade I and II between the age of 18 and 60 years, undergoing lower limb orthopedic surgeries, were randomly allocated to one of the two treatment group. Patients in study group A receive 17 ml of 0.75% ropivacaine and 0.5mcg per kg of Dexmedetomidine (DXM), while study group B receives 17 ml solution of 0.75% ropivacaine and 1.5mcg per kg of DXM. Bromage scale was used to measure motor blocked and grades of sedation were evaluated using Ramsay sedation score. Peri and post block characteristics as well as hemodynamic parameters were recorded.

**Results:** The demographic profiles and the post op block characteristics of the patients in the two groups were comparable. The results of the study has shown that the addition of 0.5 mcg per kg of DXM to 17 ml solution of 0.75% ropivacaine not only prolongs the duration of analgesia but also provides desired sedation levels with peri and post-operative period hemodynamic stability during the surgical procedure.

**Conclusion:** Titrating optimum dose of DXM as epidural adjuvant with desired duration of sensory and motor block; peri and post operative analgesia; level & duration of sedation and hemodynamic stability, it is concluded by the study that 1.5 mcg dose of DXM gives no additional benefit over 0.5 mcg/kg dose, neither to the patients nor to the surgical team.

**Keywords:** Dexmedetomidine, adjuvant, hemodynamic stability.

1. **Introduction**

    Severe peri-operative as well as post-operative pain is commonly associated with orthopedic procedures.[1] Effective management of peri-and post-operative pain is an important component of postoperative recovery in orthopedic surgical procedures. It is known to blunt autonomic, somatic and endocrine reflexes with a resultant potential decrease in overall operative morbidity [2]

    Common practice is to treat peri-operative pain with poly-pharmacological approach, as no single agent has yet been identified to specifically inhibit nociception without associated side effects. [3] Different techniques and drugs have been studied over the years in order to prolong the duration of regional anesthesia while simultaneously enhancing postoperative pain relief.[4-6] Diverse classes of drugs such as epinephrine, midazolam, adenosine, magnesium sulfate, clonidine, dexmedetomidine (DXM) and neostigmine have been studied as adjuvant, in attempts to prolong analgesia and reduce the incidence of adverse events observed when opioids were used. [7,8] It has been reported by Bajwa et al [9] that the post-operative pain relief from epidural analgesia is superior to pain relief from IV opioids; therefore, epidural analgesia is now a well established anesthetic technique for lower limb surgeries.
The pharmacologic properties of α2 agonists have been extensively studied and have been employed clinically to achieve desired effects in regional anesthesia. Epidural administration of these drugs is associated with sedation, analgesia, anxiolysis, hypnosis and sympatholysis[10,11,12]. Though the studies have proven the supremacy of DXM over clonidine as adjuvant [9,13], however none of the studies titrate the optimum dose of DXM to achieve effective sedation, analgesia and stable hemodynamics during trans-anesthetic period. Therefore this study aims at comparing the block characteristics and hemodynamics effects of 2 different doses of DXM when used as adjuvant to epidural ropivacaine in lower limb orthopedic surgeries.

The incidence of road traffic accidents (RTA) is ever increasing of which large number of them require to undergo orthopedic lower limb surgeries. The present study aims to provide better anesthetic options for lower limb surgeries in order to improve intra as well as post-operative outcomes. This is an observational study which was carried out by Department of Anesthesiology, at one of the tertiary care service hospital which receives large number of poly-trauma cases.

1.1 Aim:
To study the effect of dexmedetomidine added to epidural ropivacaine in patients undergoing orthopedic lower limb surgeries.

1.2 Objectives:
1) To compare the additive effect of two different doses of dexmedetomidine to epidural ropivacaine.
2) To study the hemodynamic effects at two different concentrations of dexmedetomidine added to ropivacaine.
3) To recommend the optimum dose of dexmedetomidine as an adjuvant to epidural ropivacaine for orthopedic lower limb surgeries.

2. Material & methods
This study was approved by the Institutional Ethics Committee and written consent was obtained from all the participants. Patients of ASA Grade I and II between the ages of 18 and 60 years, undergoing lower limb orthopedic surgeries, during the study period of one year duration, were enrolled for the study. Patients with Hematological diseases, Bleeding or Coagulation abnormalities, Psychiatric diseases, Diabetes, H/o of drug abuse, unwilling patients and those with allergy to local anesthetics of the amide group were excluded from the study. A total of 23 patients were excluded from the study who were not meeting the inclusion criteria.

Total of 100 patients were randomly assigned to one of the two treatment group on a computer generated code using random number table. The patients in group 1 receive 17 ml of 0.75% ropivacaine and 0.5mcg per kg of Dexmedetomidine (DXM), while group 2 receives 17 ml solution of 0.75% ropivacaine and 1.5mcg per kg of DXM. The assignments were recorded and sealed within envelopes, with the anesthesiologists blinded to assignments. Epidural anesthesia was administered by one anesthesiologist and block characteristics, sedation level, hemodynamic changes were recorded by another anesthesiologist. The drugs for epidural anesthesia for the two study groups were prepared by third anesthesiologist.

In the operation theatre, patients were being attached to standard monitoring devices and baseline parameters were recorded. Epidural block was administered using 18G Toughy needle and catheter introduced. Bilateral pinprick method was used to evaluate and check the sensory level while modified Bromage scale [0=no block, 1=inability to raise extended leg, 2=inability to flex knee and 3=inability to flex ankle and foot] was used to measure motor block at 5 mins interval upto 30 mins of epidural drug administration. Following block characteristics were being recorded:

- Time of onset of sensory anaesthesia,
- Time to reach the highest level of sensory analgesia
- Highest dermatomal level of sensory analgesia achieved,
- Time of complete motor blockade and
- Time to two dermatomal regression of sensory analgesia.

Grades of sedation were evaluated using Ramsay sedation score [1=alert and wide awake, 2=arousable to verbal command, 3=arousable with gentle tactile stimulation, 4=arousable with vigorous shaking and 5=unarousable] every 15 min during the procedure.

Hemodynamic parameters were recorded every 5 min until 30 min and at 15 min interval, thereafter upto 60 min and then every 30 min till 180 min. Any hypotension (MAP falling <20%) were being treated with 3-6 mg of Inj Mephentermine given i.v bolus and heart rate <20% of baseline value was treated with 0.6 mg of i.v Inj Atropine. All the vital parameters were also recorded in the recovery room. Intraoperative fluids were given as per body weight and operative loss requirement.

Statistical analysis of the data was performed using the Z test, Analysis of Variance and chi square test as applicable. Variables are presented as mean ± SD. Categorical data are presented as number (%). p value less than 0.05 was considered as significant. Data were analyzed using the software package SPSS version 11.

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3. Results

In this study, the demographic profile of patients in the two groups were comparable with respect to mean age, body weight, ASA grade, gender ratio and duration of surgery with statistically non significant difference.

The study shows that DXM as an adjuvant in doses of 0.5 mcg per kg body wt lags behind 1.5mcg per kg of DXM when the initial block characteristics were compared. There was statistically significant difference with respect to the mean time of onset of sensory analgesia, mean time to reach highest level of sensory analgesia and the time taken to achieve complete motor blockade with p value < 0.05, howsoever the effectiveness of the peri-operative analgesia was very well comparable. (TABLE 1)

While analyzing mean Ramsay Sedation Score in the two groups, it was found that the mean sedation scores as well as duration of sedation were higher in the Study Group 2 which received 1.5 mcg dose of DXM as epidural adjuvant than Study Group 1.

When post op block characteristics were analyzed there was statistically significant difference in mean time taken for two dermatomal regression of sensory analgesia in the two groups, with comparatively greater time for dermatomal regression of sensory analgesia been offered in study group 2. Howsoever, the two groups were found comparable when time required to give first rescue top up of analgesic dose was analyzed at statistically non significant p value. This suggests that 1.5 mcg dose of DXM as adjuvant has no added advantage over 0.5mcg dose by offering increased duration of post op sensory analgesia.
4. Discussion

The positive anesthetic outcomes of any surgery include efficient intra and post operative analgesic management along with minimized side effects and hemodynamic interventions. This study aims at comparing the effects of two different doses of DXM when used as adjuvant to epidural ropivacaine in lower limb orthopedic surgeries and recommending the optimized dose of DXM in such surgeries.

In this study, the demographic profile of patients in the two groups were comparable with respect to mean age, body weight, ASA grade, gender ratio and duration of surgery with statistically non significant difference. The results of the study has shown that the addition of 0.5 mcg per kg of DXM to 17 ml solution of 0.75% ropivacaine not only prolongs the duration of analgesia but also provides desired sedation levels with hemodynamic stability during the surgical procedure.

There was statistically significant difference with respect to the mean time of onset of sensory analgesia, mean time to reach highest level of sensory analgesia and the time taken to achieve complete motor blockade with p value < 0.05, howsoever the effectiveness of the peri-operative analgesia is very well comparable. At the same time the minor delay in study group 1 with the onset of sensory analgesia is usually covered in the time utilized for positioning in orthopedic surgeries. Delay in achieving highest level of sensory analgesia and complete motor blocked in study group 2 does not in any way proved to be of hindrance for the surgery. When post operative block characteristics were analyzed it was found that 1.5 mcg dose of DXM as adjuvant has no added advantage over 0.5mcg dose by offering increased duration of post op sensory analgesia.

Concurrent review of duration of surgery on one hand and period of sedation on the other achieved by two different doses of DXM, reflects that the adequate sedation lasted during the entire duration of surgery in both the groups. Thus desired sedation levels were also being achieved by administering even the low doses of DXM, thereby not proving the supremacy of DXM in higher doses.

Previous studies have shown that the hypotensive effect of DXM persists in the intraoperative as well as in the post-operative period[14-16] This study also brings forth that DXM as an adjuvant in doses of 0.5 mcg per kg body wt has visible edge over than in doses 1.5mcg per kg when the hemodynamic parameters were compared and results were found to be statistically significant with p value < 0.05. 18% of patients in group 1 required atropine while 64% of patients in group 2 need to be given atropine to restore heart rate within 20% of acceptable range of baseline.

5. Limitations of the study

The present study has focused on orthopedic lower limb surgeries and hence the results may not be applicable to abdominal surgeries requiring higher level of sensory analgesia.

6. Conclusion

Titrating the optimum dose of DXM as epidural adjuvant with desired duration of sensory and motor block; peri and post operative analgesia; level & duration of Table 1: Summary of Comparison of the Study groups

<table>
<thead>
<tr>
<th>S No</th>
<th>Study Variables</th>
<th>Study Group 1 (n=50)</th>
<th>Study Group 2 (n=50)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>(a) Demographic profile</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>Age (yrs)</td>
<td>35.8 ± 5.01</td>
<td>38.3 ± 7.45</td>
<td>&gt;0.05</td>
</tr>
<tr>
<td>2</td>
<td>Weight (Kg)</td>
<td>68.33 ± 5.21</td>
<td>70.7 ± 7.60</td>
<td>&gt;0.05</td>
</tr>
<tr>
<td>3</td>
<td>ASA I/II</td>
<td>42/8</td>
<td>39/11</td>
<td>&gt;0.05</td>
</tr>
<tr>
<td>4</td>
<td>Gender ratio (Male/Female)</td>
<td>46/4</td>
<td>48/2</td>
<td>&gt;0.05</td>
</tr>
<tr>
<td>5</td>
<td>Duration of surgery (min)</td>
<td>96.7 ± 10.3</td>
<td>99.2 ± 12.1</td>
<td>&gt;0.05</td>
</tr>
<tr>
<td>(b) Initial Block characteristics</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>6</td>
<td>Time of onset of sensory analgesia at T12 (min)</td>
<td>16.7±3.6</td>
<td>12.1±2.7</td>
<td>&lt;0.05</td>
</tr>
<tr>
<td>7</td>
<td>Time to reach highest level of sensory analgesia (min)</td>
<td>42.8±7.6</td>
<td>38.3±5.4</td>
<td>&lt;0.05</td>
</tr>
<tr>
<td>8</td>
<td>Highest level of sensory analgesia reached</td>
<td>T8-T7</td>
<td>T7-T6</td>
<td></td>
</tr>
<tr>
<td>9</td>
<td>Time taken to achieve complete motor blockade (min)</td>
<td>48.8±6.1</td>
<td>43.2±5.3</td>
<td>&lt;0.05</td>
</tr>
<tr>
<td>(c) Post op block characteristics</td>
<td></td>
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</tr>
<tr>
<td>10</td>
<td>Time taken to achieve two dermatomal regression of sensory analgesia (min)</td>
<td>209.4±28.7</td>
<td>231.9±37.3</td>
<td>&lt;0.05</td>
</tr>
<tr>
<td>11</td>
<td>Time to first rescue top up (min)</td>
<td>441.6±23.8</td>
<td>451.2±29.6</td>
<td>&gt;0.05</td>
</tr>
<tr>
<td>(d) Hemodynamic parameters</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>12</td>
<td>Average change in MAP (mm Hg)</td>
<td>7.4±4.9</td>
<td>9.8±5.8</td>
<td>&lt;0.05</td>
</tr>
<tr>
<td>13</td>
<td>Average change in HR/min</td>
<td>5.8±1.1</td>
<td>8.1±4.8</td>
<td>&lt;0.05</td>
</tr>
<tr>
<td>14</td>
<td>Mean total dose of Mephentermine required (mg)</td>
<td>2.6±0.34</td>
<td>6.0±0.53</td>
<td>&lt;0.05</td>
</tr>
<tr>
<td>15</td>
<td>No. of patients intervention with atropine required</td>
<td>9</td>
<td>32</td>
<td>&lt;0.05</td>
</tr>
</tbody>
</table>
sedation and hemodynamic stability, it is concluded by the study that 1.5 mcg dose of DXM gives no additional benefit over 0.5 mcg/kg dose, neither to the patients nor to the surgical team. On the contrary, the very novel purpose of desired block characteristics, adequate sedation and hemodynamic stability offered by this drug of α2 agonists class are well being achieved at 0.5 mcg per kg body wt of DXM.

It is thus hereby recommended that Dexmedetomidine in dose of 0.5 mcg per kg body wt is an optimum dose as an adjuvant to epidural ropivacaine for orthopedic lower limb injuries.

References