ORIGINAL RESEARCH PAPER

A COMPARATIVE STUDY OF EFFECTS OF FENTANYL & DEXMEDETOMIDINE AS ADDITIVES TO 0.75% ROPIVACAINE FOR EPIDURAL ANESTHESIA IN LOWER LIMB SURGERIES.

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AIM: To evaluate the clinical effects & adverse events when fentanyl & dexmedetomidine are used as additives to 0.75% ropivacaine for epidural anesthesia.

METHODS: Institutional ethical committee clearance was obtained. A total of 80 patients of both sex, aged 18-60 years, ASA grade I, II posted for elective lower limb surgeries were divided into two groups (n=40) by open label randomization method. Group RF received 1 μg/kg Fentanyl & group RD received 1 μg/kg Dexmedetomidine along with 15 ml ropivacaine 0.75% in both groups. Onset of complete motor & sensory blockade, duration of analgesia, two segmental dermatomal regression & adverse effects were recorded. Data was analysed using Fisher’s exact test & Chi-square test. Value of P<0.05 is considered significant and P<0.001 as highly significant.

RESULTS: The demographic profile was comparable in both the groups. Onset of sensory analgesia at T10 (10.04±0.86 vs 13.76±1.42) & onset of complete motor blockade (18.5±1.24 vs 20.4±1.32) was significantly earlier in RD group as compared to RF group. Duration of motor and sensory block was significantly longer in RD group (194.2. ± 20.73 and 150.42 ± 5.18 min) as compared to group RF (162.32 ± 22.38 and 122.4 ± 3.46 min). Incidence of bradycardia, hypotension & dry mouth was significantly higher in the RD group whereas incidence of nausea & vomiting was significantly higher in RF group with P<0.05.

CONCLUSION: Epidural anesthesia with dexmedetomidine as an additive to 0.75% ropivacaine is more effective with respect to earlier onset & prolonged duration of sensory & motor blockade when compared to fentanyl.

INTRODUCTION

Epidural anesthesia may be used for providing analgesia alone, adjunct to general anesthesia, as a sole technique for surgical anesthesia & post operative analgesia in lower abdominal and lower limb surgeries. Epidural anesthesia using bupivacaine was using since ages & it is highly cardiotoxic. The new amide local anaesthetic (LA) Ropivacaine was found to have minimal cardiovascular and central nervous system toxicity and longer duration of action.

Addition of adjuvants decreases the requirement of LA dose, hence side effects of LA will be minimised. Addition of fentanyl to ropivacaine in epidural helps in providing better analgesia and lesser systemic toxicity. But opioids has disadvantages of pruritus, nausea, vomiting and respiratory depression.

Dexmedetomidine, an alpha-2 adrenoreceptor agonist, which has got numerous beneficial effects when used through epidural route. It has been used as an effective adjuvant to ropivacaine for regional and central neuraxial blocks. It is a sympatholytic agent which decreases systemic sympathetic activity. It has a sedative effect, and it enhances the analgesic effect of all opioid analgesics.

METHODOLOGY:

This prospective randomized study was conducted after obtaining approval from the institutional ethics committee. Patients of ASA physical status I-II aged 18-60 years of either sex undergoing lower limb surgeries were included in this study. Patients refusing consent, coagulopathy, spinal anesthesia, fentanyl, ropivacaine were excluded from the study.

A total of 80 patients were divided into 2 Groups comprising of 40 patients each by allocating them a random number by a computer generated table.

- Group RF (Ropivacaine+Fentanyl) received fentanyl 1 μg/kg along with 15ml ropivacaine 0.75%.
- Group RD (Ropivacaine+Dexmedetomidine) received dexmedetomidine 1 μg/kg along with 15ml ropivacaine 0.75%.

Preanaesthetic evaluation and written informed consent was obtained and advised for nil per oral for 8 hours prior to surgery. All patients were premedicated with inj. pantoprazole 40 mg iv and inj. ondansetron 1 mg/kg iv 1 hour prior to surgery.

In the operation theatre, venous access was secured with 18G/20G cannula and preloaded with 10 ml/kg of lactated Ringer’s solution. All the baseline parameters were recorded which consisted of heart rate (HR), electrocardiography (ECG), non-invasive blood pressure (NIBP), and pulse oximetry (SpO2).

Patients in sitting position, under aseptic precautions lumbar epidural anesthesia was performed using 18G Touhy needle at L3-L4 interspace and epidural space was confirmed by loss of resistance technique. A test dose of 3 ml of 2% lignocaine with adrenaline was administered into epidural space and later epidural catheter was secured 5 cm into the epidural space and patients were placed in supine. The following solutions were randomly administered: 15 ml of 0.75% ropivacaine associated to 1 μg/kg of dexmedetomidine in group RD (n=40) and 1 μg/kg of fentanyl in group RF (n=40). The following parameters were observed after the administration of epidural anesthesia.

1. Onset of sensory analgesia at T10
2. Time to achieve complete motor blockade.
3. Time to regression to bromage scale 1.
4. Time to two segmental dermatomal regression
5. First feeling of pain/rescue analgesia.

Onset of sensory blockade at T10 level was noted by loss of painful stimuli by pinprick. Degree of motor blockade was...
noted using modified Bromage scale from 0 to 3 [Bromage scale 0: No motor block, 1 = inability to raise extended leg (able to flex knee); 2 = inability to flex knee (able to flex foot only); 3 = inability to flex ankle joint.] For quantification of pain, visual analog scale (VAS) score from 0 to 10 was used. Complications such as bradycardia, hypotension, pruritus, nausea, vomiting were documented & treated accordingly.

STATISTICAL ANALYSIS:
Data was compiled using statistical package for the social sciences (SPSS) version 15. Data are expressed in terms of mean ± standard deviation (SD) & percentage. Data were analyzed by student t test and chi square test. Based on Bajwa S, et al. [5] study by considering a probability level of 0.05 (α error) and power of 80%(1-β) yielded a sample size of 40 patients in each group. P-value <0.05 was considered significant and p-value <0.0001 was considered highly significant.

RESULTS:
Demographic data was statistically comparable among the two groups(Table 1).

Table 1: Demographic Data

<table>
<thead>
<tr>
<th>Variables</th>
<th>Group RD (Mean ± SD)</th>
<th>Group RF (Mean ± SD)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>45.4 ± 11.06</td>
<td>46.58 ± 11.25</td>
<td>0.84</td>
</tr>
<tr>
<td>Height (cms)</td>
<td>158.15 ± 7.54</td>
<td>159.4 ± 7.70</td>
<td>0.43</td>
</tr>
<tr>
<td>Weight (kg)</td>
<td>55.42 ± 19.32</td>
<td>56.64 ± 18.64</td>
<td>0.54</td>
</tr>
</tbody>
</table>

Data expressed in terms of mean ± standard deviation. Onset of sensory analgesia at T10 and onset of complete motor blockade was significantly earlier in RD group as compared to RF group. Duration of motor and sensory block was significantly longer in RD group as compared to RF group. Time to first rescue analgesia was longer. Duration of motor block was significantly longer in RD group as compared to group RF which was correlated with findings of Vasupalli R et al.[9] study. In our study incidence of side effects and complications like bradycardia, hypotension, dry mouth was 20%, 37.5%, 15% in RD group as compared to 7.5%, 20%, 2.5% in RF group respectively whereas the incidence of nausea, vomiting, shivering, pruritis was higher in RF group as compared to RD group.

CONCLUSION:
Dexmedetomidine is a better alternative to fentanyl as additive to 0.75% ropivacaine for epidural anesthesia as it provides earlier onset, prolonged duration of sensory and motor blockade and time to first rescue analgesia was longer.

REFERENCES:

In our study incidence of side effects and complications like bradycardia, hypotension, dry mouth in RD group as compared to RF group whereas the incidence of nausea, vomiting, shivering, pruritis was higher in RF group as compared to RD group (Table 3).

DISCUSSION:
Epidural analgesia offers superior pain relief and early mobilization especially when local anesthetic dose is combined with an adjuvant as compared to LA used alone.

The synergism between epidural administered LA and opioids was well established but there is a scarcity of literature regarding usage of combination of LA with dexmedetomidine through epidural route. In this study we have compared the effects of epidurally administered dexmedetomidine and fentanyl as additives to 0.75% ropivacaine.

Demographic profile in our study was comparable among both groups. In our study onset of sensory analgesia at T10 and onset of complete motor blockade was significantly earlier in RD group as compared to RF group which was correlated with findings of Vasupalli R et al.[9] study. In our study incidence of side effects and complications like bradycardia, hypotension, dry mouth was 20%, 37.5%, 15% in RD group as compared to 7.5%, 20%, 2.5% in RF group respectively whereas the incidence of nausea, vomiting, shivering, pruritis was higher in RF group as compared to RD group. Respiratory depression is not observed in both groups.

Table 2: Sensory and motor block variables.

<table>
<thead>
<tr>
<th>Variables</th>
<th>Group RD (Mean ± SD)</th>
<th>Group RF (Mean ± SD)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Onset of complete motor blockade (mins)</td>
<td>16.5±1.24</td>
<td>20.4±1.32</td>
<td>P&lt;0.0001</td>
</tr>
<tr>
<td>Onset of sensory blockade at T10 level (mins)</td>
<td>10.04±2.09</td>
<td>13.76±1.42</td>
<td>P&lt;0.0001</td>
</tr>
<tr>
<td>Time to regression to brolamge (mins)</td>
<td>194.2±20.7</td>
<td>162.3±22.4</td>
<td>P&lt;0.0001</td>
</tr>
<tr>
<td>Time to first rescue top up (mins)</td>
<td>330±21.08</td>
<td>234±21.84</td>
<td>P&lt;0.0001</td>
</tr>
<tr>
<td>Mean time for two segmental regression (mins)</td>
<td>150.4±5.18</td>
<td>122.4±3.46</td>
<td>P&lt;0.0001</td>
</tr>
</tbody>
</table>

Table 3: Side effects and complications

<table>
<thead>
<tr>
<th>Side effects</th>
<th>Group RD</th>
<th>Group RF</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bradycardia</td>
<td>08(20%)</td>
<td>03(7.5%)</td>
</tr>
<tr>
<td>Hypotension</td>
<td>19(37.5%)</td>
<td>08(20%)</td>
</tr>
<tr>
<td>Dry mouth</td>
<td>06(15%)</td>
<td>01(2.5%)</td>
</tr>
<tr>
<td>Nausea</td>
<td>05(12.5%)</td>
<td>14(35%)</td>
</tr>
<tr>
<td>Vomiting</td>
<td>01(2.5%)</td>
<td>06(18%)</td>
</tr>
<tr>
<td>Pruritus</td>
<td>00(0%)</td>
<td>03(7.5%)</td>
</tr>
<tr>
<td>Shivering</td>
<td>00(0%)</td>
<td>02(5%)</td>
</tr>
<tr>
<td>Respiratory depression</td>
<td>00(0%)</td>
<td>00(0%)</td>
</tr>
</tbody>
</table>

In terms of proportion there was higher incidence of bradycardia, hypotension, dry mouth in RD group as compared to RF group whereas the incidence of nausea, vomiting, shivering, pruritis was higher in RF group as compared to RD group (Table 3).