Effect of Addition of Clonidine (75µg) to Isobaric Ropivacaine (0.75%) on Spinal Blockade Characteristics

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ABSTRACT
BACKGROUND: Ropivacaine, a new amino amide local anesthetic has an improved safety profile over Bupivacaine. Aims and objectives: The objective of this study were to observe the effect of addition of clonidine to isobaric ropivacaine on spinal blockade characteristics, hemodynamics and postoperative analgesia. MATERIALS AND METHODS: A randomized, double blind, prospective study comprised of 60 adult patients of ASA status I/II scheduled for lower limb orthopedic surgeries. They were divided into groups of 30 each and Group R patients received 0.75% isobaric ropivacaine (22.5mg) + 0.5ml normal saline while Group RC patients received 0.75% isobaric ropivacaine (22.5mg) + clonidine75µg (0.5ml) intrathecally. The onset and regression time of sensory and motor block, hemodynamic changes and complications were recorded. RESULTS: The onset sensory and motor block was early in Group RC compared to group R (98.66±45.37 v/s 124.66±48.86 seconds) and (120.16±55.77 v/s 157±81.41 seconds, p<0.05). The duration of sensory and motor blockade was significantly prolonged in Group RC (159±23.54 v/s 240.66±48.86 seconds) and (120.16±55.77 v/s 157±81.41 seconds, p<0.05). All patients remained hemodynamically stable in both the groups. The addition of clonidine provided longer duration of analgesia. CONCLUSION: Addition of clonidine to intrathecal isobaric ropivacaine shortens the onset and prolongs the duration of sensory and motor block and postoperative analgesia without affecting the other parameters and complications. Keywords: Spinal anaesthesia, Ropivacaine, Clonidine, Orthopaedic surgeries

INTRODUCTION
Ropivacaine, a new amino amide local anesthetic introduced into clinical practice in 1996, is the S-(+)- enantiomer of 1-propyl 2, 6 pipercolo-xylidide. It is less cardio toxic (Stefania Leone 2008)¹,²,³ and has low lipid solubility which blocks nerve fibers involved in pain transmission (Aβ fibers) and produces shorter duration of sensory and motor block and lesser intensity of motor block than Bupivacaine. (D A McNamee 2002)⁴ Hence various adjuvants are used to enhance the blockade. Clonidine, a selective partial agonist of α₂ - adrenoceptors is being extensively evaluated for the control of pain and has proven to be a potent analgesic, free of undesirable side effects associated with opioids and other drugs. The purpose of this study was to evaluate the effect of addition of Clonidine 75µg to isobaric Ropivacaine 0.75% on onset and duration of sensory and motor blockade, hemodynamics, duration of postoperative analgesia and any complications.

MATERIALS AND METHODS
This prospective, randomized, double blind, comparative clinical study conducted after the approval from institutional ethical committee, comprised of 60 patients of either sex, aged 18 to 60 years of ASA classification I/II undergoing femur surgeries. Patient refusal / unable to understand VAS score, uncooperative patient/with psychiatric illness, history of allergy to drug, patients taking antihypertensive treatment, any other contraindication for spinal anesthesia and pregnant patients were excluded from the study. All patients received tablet diazepam 0.2mg/kg, orally on previous night. An informed written consent was taken. Preloading was done with Ringer lactate 10ml/kg 30 minutes prior to induction. In sitting position, intrathecal block was given in L₂-L₃ or L₃-L₄ space with 23 G Quincke’s spinal needle under all aseptic condition. Patients were randomly divided into two groups.Group RC - Inj. isobaric ropivacaine 0.75% 3ml + Inj. clonidine 75µg (0.5ml) and Group R - Inj. isobaric ropivacaine 0.75% 3ml + Inj. normal saline(0.5 ml). Total volume injected was 3.5ml in both the groups. Immediately after the spinal blockade, they were made supine and various parameters for characteristics of spinal blocks were assessed. The anaesthesiologist performing the block was blinded to the study drug and recorded the data. Sensory block was checked by pin prick method using 23G...
hypodermic needle. Parameters like onset of sensory block (loss of sensation at the level of L1 dermatome), highest sensory level (noted after 30 minutes), and duration of sensory block (time interval from onset to when sensation felt at L1 dermatome again) were noted. Motor block was assessed by Bromage scale. Onset of motor block (time to attain Bromage grade I), maximum Bromage grade (noted after 30 minutes) and duration of motor block (time interval from onset to when Bromage grade become 0 again) were noted. Level of sedation was assessed on four points scoring system. 

Score 0: Awake: Eyes opens spontaneously
Score 1: Mild: Drowsiness/Eyes open on command
Score 2: Moderate: Eyes open when shaken
Score 3: Deep: Loss of verbal contact/Eyes open on pain with difficulty

Vital parameters like pulse, blood pressure, SpO2, and sedation score were monitored. Recording of data was done at 2, 5, 10, 20 and 30 minutes after giving the block, then every 15 minutes till 1 hour and every 30 minutes till end of surgery. Oxygen (2 L/min) was administered via a mask if \( \text{SpO}_2 \leq 90\% \). Hypotension, defined as a decrease of systolic blood pressure by \( \geq 30\% \) from baseline or a fall below 90 mmHg, was treated with incremental IV doses of ephedrine 5 mg and IV fluid as required. Bradycardia, defined as heart rate \( < 50 \) /min, was treated with IV atropine 0.3 mg. Patients were monitored for various intraoperative complications like bradycardia, hypotension, respiratory depression, nausea and vomiting, excessive sedation, dryness of mouth etc. Postoperatively pain assessment was done by VAS and the duration of Absolute analgesia (time taken from intrathecal injection to feeling of first sensation at site of surgery) and of Effective analgesia (time taken from intrathecal injection to first rescue analgesia at VAS \( \geq 4 \)) were noted. Injection dicyclofenac sodium 75 mg was given intramuscularly as rescue analgesia and doses of rescue analgesic required in 24 hours was compared in both the groups. Data obtained were tabulated and analysis of variance (ANOVA) of the data for the various parameters was done using using Medcalc software. Data was expressed as mean and standard deviation (SD). Student’s paired t-test for intra group comparison and unpaired t-test for intergroup comparison were used. For categorial co- variates (sex, ASA class, highest level achieved) Fisher exact test and Chi square test were used. The significance of ANOVA was considered significant if \( P \) value is \( < 0.05 \) and highly significant if it is \( < 0.001 \).

RESULTS

Both the groups were demographically comparable. The mean time for onset of sensory block (98.66\( \pm 45.37 \) v/s 124.66\( \pm 48.86 \) seconds) and motor block (120.16\( \pm 55.77 \) v/s 157\( \pm 81.41 \) seconds) was faster in group RC than group R. In majority cases, maximum sensory level achieved was T6-T8 in group R and T4-T6 in group RC (\( p \leq 0.001 \)). Except 1 patient in group R, all patients had motor blockade of Borage grade III. Compared to group R, duration of sensory blocks (159\( \pm 23.54 \) v/s 240.66\( \pm 42.01 \) minutes) and motor block (188.83\( \pm 25.65 \) v/s 299\( \pm 43.37 \)minutes) was prolonged in group RC. (Table 2)

Table 1: Demographic Data

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Group R</th>
<th>Group RC</th>
<th>( p ) value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age in Years (MEAN ( \pm SD ))</td>
<td>36.23( \pm 13.10 )</td>
<td>35.23( \pm 11.0 )</td>
<td>( &gt;0.05 )</td>
</tr>
<tr>
<td>Sex (Male:Female)</td>
<td>25:5</td>
<td>27:3</td>
<td>( &gt;0.05 ) *</td>
</tr>
<tr>
<td>ASA Grading (I : II)</td>
<td>17:13</td>
<td>18:12</td>
<td>( &gt;0.05 ) #</td>
</tr>
<tr>
<td>Mean Duration of Surgery (Minutes)</td>
<td>106.5( \pm 33.96 )</td>
<td>114( \pm 21.43 )</td>
<td>( &gt;0.05 )</td>
</tr>
</tbody>
</table>

* Fisher’s Exact test  # Chi-Square test

The duration of absolute (370.16\( \pm 54.33 \) v/s 219.33\( \pm 30.47 \)minutes) and effective (455.33\( \pm 56.06 \) v/s 279.83\( \pm 36.23 \)minutes) analgesia in Group RC was prolonged than in group R and difference was statistically highly significant. (Graph 4) The requirement of rescue analgesic was less in group RC (1.73\( \pm 0.44 \) v/s 2.53\( \pm 0.77 \)) during 24 hours period. (Table 2)

Table 2: Characteristics of spinal block

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Group R</th>
<th>Group RC</th>
<th>( p ) value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Onset of sensory block (seconds)</td>
<td>124.66( \pm 48.86 )</td>
<td>98.66( \pm 45.37 )</td>
<td>( &lt;0.05 )</td>
</tr>
<tr>
<td>Peak sensory level achieved</td>
<td>T4:T6:T8:T10 : 2: 10: 15 : 3</td>
<td>T4:T6:T8:T10 : 9 : 12 : 6 : 3</td>
<td>( &lt;0.05 ) #</td>
</tr>
<tr>
<td>Duration of sensory block at L1 level (minutes)</td>
<td>159( \pm 23.54 )</td>
<td>240.66( \pm 42.01 )</td>
<td>( &lt;0.001 )</td>
</tr>
<tr>
<td>Onset of motor block Bromage grade 1(seconds)</td>
<td>157( \pm 81.41 )</td>
<td>120.16( \pm 55.77 )</td>
<td>( &lt;0.05 )</td>
</tr>
<tr>
<td>Time to achieve maximum Bromage grade (seconds)</td>
<td>597.5( \pm 204.61 )</td>
<td>315( \pm 197.78 )</td>
<td>( &lt;0.001 )</td>
</tr>
<tr>
<td>Duration of motor block at bromage grade 0(minutes)</td>
<td>188.83( \pm 25.65 )</td>
<td>299( \pm 43.37 )</td>
<td>( &lt;0.001 )</td>
</tr>
<tr>
<td>Duration of absolute analgesia (minutes)</td>
<td>219.33( \pm 30.47 )</td>
<td>370.16( \pm 54.33 )</td>
<td>( &lt;0.001 )</td>
</tr>
<tr>
<td>Duration of effective analgesia (minutes)</td>
<td>279.83( \pm 36.23 )</td>
<td>455.33( \pm 56.06 )</td>
<td>( &lt;0.001 )</td>
</tr>
<tr>
<td>Number of rescue analgesic (IN 24 HOURS)</td>
<td>2.53( \pm 0.77 )</td>
<td>1.73( \pm 0.44 )</td>
<td>( &lt;0.001 )</td>
</tr>
</tbody>
</table>

# Chi-Square test

As shown in the graphs 1 and 2, there is significant fall in pulse rate and blood pressure in both the groups but was within the limit of 30% of preoperative values. All patients in Group R were alert whereas in Group RC, 15 patient’s drowsy and 13 patients were able to respond when shaken. (Graph 3) In group RC, 3 patients (10%) had bradycardia, 2 patients (6.66%) in group R had hypotension compared to 4 patients (13.3%) in group RC. 3 patients (10%) had dryness of mouth in group RC, but did not require any treatment. No
Addition of Clonidine (75µg) to Isobaric Ropivacaine

other perioperative complications observed in both the groups.

**Figure 1: Changes in Mean Pulse rate**

![Graph showing changes in mean pulse rate](image1)

**Figure 2: Changes in Mean BP**

![Graph showing changes in mean blood pressure](image2)

**Figure 3: Sedation Score**

![Graph showing sedation score](image3)

**REFERENCES**


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