Comparative Evaluation of Efficacy of Intrathecal Isobaric Ropivacaine 0.75% Versus Isobaric Ropivacaine 0.75% with Dexmedetomidine for Infraumbilical Surgeries

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ABSTRACT

Background: Various adjuvants are being used for spinal anaesthesia. Dexmedetomidine hydrochloride is a newer alpha2 agonist with sedative, analgesic and anxiolytic properties. Ours was a comparative study of efficacy of intrathecal isobaric Ropivacaine 0.75% plain with adjuvant Dexmedetomidine for elective infraumbilical surgeries.

Materials & Methods: Prospective randomized study (May 2011- May 2013) on 60 patients of ASA 1-2, 18-60 years of either sex, 40-80kg with a random allocation to Group R (3.5 ml 0.75% isobaric Ropivacaine) and Group D (3.0 ml 0.75% isobaric Ropivacaine + 10 micrograms (0.1ml) Dexmedetomidine + 0.4 ml NS. Total volume 3.5 ml) was done.

Results: Group D patients had reduced dose, faster onset, significantly longer and effective sensory and motor blockade, hemodynamic stability, reduced demand of post-operative analgesics (P value < 0.05).

Conclusion: Addition of 10 micrograms Dexmedetomidine to intrathecal isobaric Ropivacaine 0.75% enhances sensory and motor blockade, offers hemodynamic stability and reduces demand of postoperative analgesics.

Keywords: Adjuvants, Dexmedetomidine Hydrochloride, Isobaric Ropivacaine 0.75%.

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INTRODUCTION

Spinal anaesthesia with a long acting anaesthetic such as Bupivacaine is the most commonly practiced technique of regional anaesthesia since many years¹, but the report of several cases of systemic toxic reactions after accidental intravenous injections of Bupivacaine², the need for an effective, long acting local anaesthetic with high therapeutic ratio has prompted researchers to develop new local anaesthetics. Isobaric Ropivacaine is a newer pure S enantiomer of amide local anaesthetic with lower potential for cardio toxicity and neurotoxicity. Various adjuvants like vasoconstrictors (epinephrine), opioids like fentanyl have been used to prolong the duration of spinal anaesthesia and to provide post-operative analgesia as well. These adjuvants have their own side effects and limitations.⁴ Dexmedetomidine hydrochloride is newer alpha 2 agonist with sedative, anxiolytic and analgesics effects via central and peripheral actions.⁵,⁶ So we designed a randomised prospective comparative study of clinical efficacy of isobaric Ropivacaine 0.75% plain and with an addition of Dexmedetomidine as an adjuvant for elective infraumbilical surgeries under subarachnoid block as regard the onset, duration of sensory block, degree of motor blockade as well as postoperative analgesia.⁷

METHODOLOGY

After obtaining an approval from institutional ethical committee and informed written consent, 60 ASA I-II patients of either sex, aged 18-60 years scheduled to undergo elective infraumbilical surgeries were enrolled in the study. Exclusion criteria were patients contraindicated to spinal anaesthesia, on therapy with adrenergic antagonists, calcium channel blocker, and/or ACE inhibitor. XST was done the night before surgery. On arrival to the operating room, a 20 G intravenous cannula was inserted and Ringer Lactate at 10ml/kg was started. All monitors were attached including pulse oximetry, non-invasive blood pressure, ECG limb lead II via GE Dash 4000 Multipara. All basic parameters were noted. Patients were randomly allocated into two groups. Group R: 30 patients in group R received plain 3.5 ml (26.25mg) of 0.75% isobaric Ropivacaine. Group D: 30 patients in Group D
received 3ml (22.5mg) of 0.75% isobaric Ropivacaine +0.1 ml (10 micro gram) Dexmedetomidine + 0.4 ml preservative free normal saline to make total volume of 3.5 ml. 25 G Quincke spinal needle was inserted in the midline at L2-3 or L3-4 inter-space in sitting position using aseptic precautions. The appropriate local anaesthetic solution was injected over 10-15 seconds. The drug was prepared by another anaesthesiologist as per instructions. The patient was placed supine immediately after injection. Bladder catheterization was performed only if surgically indicated. O2 supplied via nasal prongs at 2L/min. Mean arterial blood pressure (MAP) less than 60 mm Hg was considered to be significant hypotension and Inj. Mephentermine 6 mg increments was given intravenously. Pulse rate less than 50 beats per minute was considered to be significant bradycardia and was treated with Inj. Atropine sulphate 0.6 mg intravenously. Incidence of adverse effects, such as nausea, vomiting, shivering, desaturation, (SpO2@<95%), and respiratory depression were noted. The upper and lower spread of sensory block was assessed bilaterally by loss of pin prick sensation using 23 G hypodermic needle. It was assessed at 10-min post-injection and at 20-min interval for initial 30 min and then 30 min thereafter until two consecutive levels of sensory block were identical (fixation of the level), after which assessment was done every 60 min interval for first 12 hours after surgery. Then every 4 hourly for next 12 hours. Total duration was time taken for complete regression i.e. level below L1.
Degree of motor block was assessed by using Modified Bromage scale. Time of requirement of first rescue analgesic by visual analogue scale (VAS) was monitored by initially every 1 hourly for first 12 hours and then 4 hourly for next 12 hours. Inj. Diclofenac sodium (Dynapar) 75mg i.m. was given as a rescue analgesic when VAS >4. Total number of Inj. Diclofenac sodium required was noted.
Statistical analysis was done using MS excel 2003 (Data analysis Toolpark) and statistical software. Paired t test was used for between group’s comparisons, while for categorical variables; Unpaired t test was used. A difference with significance level <0.05 was considered statistically significant (*).
Table 1: Characteristic of sensory blockade

<table>
<thead>
<tr>
<th>Sensory (min)</th>
<th>Group R (n=25)</th>
<th>Group D (n=29)</th>
<th>T value</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Onset</td>
<td>4.19±1.91</td>
<td>1.89± 0.91</td>
<td>5.08</td>
<td>0.00012*</td>
</tr>
<tr>
<td>Max. Level</td>
<td>T6 (T4-T7)</td>
<td>14.48± 3.28</td>
<td>9.37± 3.78</td>
<td>5.30</td>
</tr>
<tr>
<td>Regression(L1)</td>
<td>127.4±22.03</td>
<td>197.72±18.95</td>
<td>12.46</td>
<td>0.00*</td>
</tr>
<tr>
<td>Duration</td>
<td>157.36±32.19</td>
<td>229.62±21.87</td>
<td>9.49</td>
<td>0.00*</td>
</tr>
</tbody>
</table>

Table 2: Characteristic of motor blockade

<table>
<thead>
<tr>
<th>Motor</th>
<th>Group R</th>
<th>Group D</th>
<th>T value</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Onset(min) Bromage III</td>
<td>5.04±2.28</td>
<td>2.65±0.96</td>
<td>4.85</td>
<td>0.0000*</td>
</tr>
<tr>
<td>Max (min) Bromage I</td>
<td>22.96±3.91</td>
<td>10.27±3.12</td>
<td>1.61</td>
<td>0.050*</td>
</tr>
<tr>
<td>Regression(min) Bromage II</td>
<td>157.2±41.63</td>
<td>233.41±61.29</td>
<td>5.40</td>
<td>0.000*</td>
</tr>
<tr>
<td>Complete regression(min) Bromage IV</td>
<td>198.2±46.38</td>
<td>274.96±20.62</td>
<td>5.04</td>
<td>0.000*</td>
</tr>
<tr>
<td>Duration</td>
<td>203±56.08</td>
<td>275.48±64.64</td>
<td>4.41</td>
<td>0.000*</td>
</tr>
</tbody>
</table>

Graph 3: Comparison of PR between two groups

Graph 4: Comparison of MAP between two groups
RESULTS
The groups were comparable with respect to age, weight and ASA physical status. There was no difference in type and duration of surgery. The results regarding characteristic of sensory blockade and motor blockade is shown graph 1 and graph 2 respectively. The results regarding comparison of PR and MAP between two groups is summarised in graph 3 and graph 4 respectively. VAS score is shown in graph 5.

DISCUSSION
Ropivacaine is a new long acting pure (S-enantiomer) amide local anaesthetic agent with a wide margin of safety than Bupivacaine but with shorter duration of sensory and motor action. Most commonly used alpha2 agonist as an adjuvant is clonidine but Dexmedetomidine affinity to alpha2 agonist is 10 times as compared to clonidine. We observed that addition of Dexmedetomidine to intrathecal isobaric Ropivacaine enhanced the onset and prolonged the duration of sensory and motor blockage. Our finding is supported by Hala EA Eid et al., 2011, who observed dose dependent prolongation of motor and sensory blockage with reduced analgesic requirement with increasing doses of intrathecal Dexmedetomidine (5,10,15 mcg). Al Ghanem et al., 2009 who concluded that addition of Dexmedetomidine produces more prolonged motor and sensory block seems to be alternative as an adjuvant to spinal bupivacaine in surgical procedures. Our both groups has intraoperative haemodynamic stability as regards with pulse rate and mean arterial pressure. Ropivacaine has been shown to be a better drug in terms of cardiovascular and haemodynamic control. Our study also coincides with Kanazi et al., 2006. We observed Grade III sedation in Group D patients and Grade I and II sedation in Group R patients. Dexmedetomidine produced better quality of sleep. In our study, we found that the analgesic effect of Ropivacaine was potentiated by Dexmedetomidine. In addition, Dexmedetomidine treated group required less postoperative analgesic in the first 24 hours after surgery. The mechanism of alpha2 agonist for intrathecal route is an additive or synergistic to the local anaesthetics. The local anaesthetics act by blocking sodium channels, whereas the alpha2 agonist acts by binding to presynaptic C-fibres and post-synaptic dorsal horn neurons. The analgesic action is by inhibition of release of C-fibre transmitters and by hyperpolarization of post-synaptic dorsal horn neurons. The antinociceptive effect may explain the prolongation of the sensory block. The prolongation of motor block of spinal anaesthetics may result from binding of alpha2 agonists to motor neurons in the dorsal horn. We did not observe any incidence of shivering in Dexmedetomidine group. The alpha2 agonists also have antishivering property. We observed four cases of bradycardia in Dexmedetomidine group managed with Inj. Atropine sulphate 0.6mg IV.

CONCLUSION
Isobaric 0.75 % Ropivacaine, a novel long acting local anaesthetic is a safer alternative to commonly used hyperbaric Bupivacaine for spinal anaesthesia. It can provide predictable and reliable anaesthesia. Addition of 10µg Dexmedetomidine with isobaric Ropivacaine 0.75% reduces the dose of local anaesthetic, enhances the onset, intensifies the sensory and motor blockade effectively, offers hemodynamic stability and significantly prolongs the duration of spinal anaesthesia. It also delays the time of requirement of first rescue analgesic and number of total analgesics required in the post-operative period. In conclusion, 10µg Dexmedetomidine seems to be an attractive alternative as an adjuvant to spinal Ropivacaine. It provides good quality intra operative anaesthesia, hemodynamically stable conditions, minimal and treatable side effects and excellent quality of postoperative analgesia.
REFERENCES

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