TO STUDY AND COMPARE THE EFFECT OF DEXMEDETOMIDINE AND FENTANYL AS AN ADJUVANT TO LEVOBUPIVACAINE IN INTERSCALENE BRACHIAL PLEXUS BLOCK FOR HUMERUS SURGERY: A PROSPECTIVE RANDOMIZED DOUBLE-BLIND CONTROLLED STUDY

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Abstract
Introduction: Interscalene brachial plexus block provides complete and reliable anaesthesia for surgery of humerus as well as analgesia for postoperative period. Many studies are being done for the search for an adjuvant which when added to a local anaesthetic, prolong the duration of postoperative analgesia. Therefore we compared the effect of fentanyl and dexmedetomidine on postoperative analgesia when added to levobupivacaine for Interscalene brachial plexus block.

Material and Methods: In this prospective study, 90 patients were randomly allocated to 3 groups: Group C (n=30) received 30 ml of 0.5% levobupivacaine, Group D (n=30) received 30 ml of 0.5% levobupivacaine + dexmedetomidine 1 μg/kg, Group F (n=30) received 30 ml of 0.5% levobupivacaine + fentanyl 1 μg/kg. The duration of blockade and analgesia were assessed for all the three groups.

Observations: Demographic profile was comparable in all the groups. The onset of sensory and motor block and duration of analgesia and motor block were enhanced in Group D and Group F as compared to Group C. The mean pulse rate and mean arterial pressure were slightly lower in dexmedetomidine group than in other two groups.

Results: Compared to the use of levobupivacaine alone for interscalene brachial plexus block, addition of 1 mcg/kg dexmedetomidine or 1 mcg/kg fentanyl to levobupivacaine enhanced the onset of blockade as well as increased the duration of blockade and post-operative analgesia. Also, the blockade characteristics were better improved with addition of dexmedetomidine to levobupivacaine than addition of fentanyl to levobupivacaine without increasing incidence of any unwanted side-effects.

Keywords: Interscalene brachial plexus block, Levobupivacaine, Fentanyl, Dexmedetomidine.

Introduction
Peripheral nerve blocks are cost effective anaesthetic techniques which provide excellent anaesthesia and analgesia in addition to avoiding airway instrumentation and the adverse hemodynamic consequences of general anaesthesia. For this reason, interest in regional anaesthesia is growing rapidly all around the world.¹

The interscalene brachial plexus block is performed at the level of the trunks of brachial plexus and hence blocks the entire sympathetic, sensory and motor innervations of the upper extremity. This block provides satisfactory surgical conditions with complete sensory and motor blockade. Currently bupivacaine is the most frequently used local anaesthetic because of its long duration of action.²,³ Local anaesthetics may produce systemic toxic reactions affecting brain and heart.⁴ Concerning with the cardiovascular toxicity profile of bupivacaine, levobupivacaine having the same pharmacological profile,⁵ has begun to gain importance over bupivacaine for peripheral nerve blocks. Dexmedetomidine, a centrally acting alpha 2 agonist, mainly used to provide ICU sedation, is now also being used as adjuvant to local anaesthetics for peripheral nerve blocks. Opioids like fentanyl are being used concomitantly with local anaesthetics for providing improved quality of anaesthesia as well as post-operative analgesia. The purpose of this study was to compare dexmedetomidine with fentanyl when added to levobupivacaine in interscalene brachial plexus block, for humerus surgery, in aspect of blockade characteristics and duration of post-operative analgesia.

Materials and Method
This prospective, randomized, double blind controlled study was carried out on 90 patients of American Society of Anaesthesiologist (ASA) I or II; aged 20–50 years, of either sex, undergoing humerus plating to be done under interscalene brachial plexus block. The patients were randomly assigned to one of the following 3 groups using computer generated random number table:

Group C (n=30): 30 ml of 0.5% levobupivacaine
10 ml of 2% lignocaine with adrenaline

Group D (n=30): 30 ml of 0.5% levobupivacaine + dexmedetomidine 1 μg/kg
10 ml of 2% lignocaine with adrenaline
Group F (n=30): 30 ml of 0.5% levobupivacaine + fentanyl 1 μg/kg

10 ml of 2% lignocaine with adrenaline

Patients excluded from the study were those who refused for procedure, on alpha/beta agonist or antagonist therapy, with bleeding disorders, any known hypersensitivity to local anaesthetic drugs, local infection at the injection site and pre-existing peripheral neuropathy.

On arrival in the operation room, baseline pulse rate, blood pressure, ECG and oxygen saturation were recorded. Ringer's lactate was connected to an intravenous line in the unaffected limb. The procedure was explained to the patient and the head turned away to the opposite side by 30 to 40°. After aseptic preparation of the skin, interscalene brachial plexus block was performed by an experienced anaesthesiologist who was blinded to the three treatment groups. Block was performed using a Plexynon nerve stimulator and Locoplex nerve stimulating needle 20 G, 50-mm-long was used to elicit the muscle twitch. The end motor response was a muscle twitch either in pectoral, deltoid or in the ulnar nerve region with a current of 0.4 to 0.5 mA. The drug was injected with intermittent negative aspiration. Pulse rate and blood pressure were recorded at 5, 10, 15, 30, 45, 60, 90, 120, 180, 360, 480 and 720 minutes after the block. Onset of sensory and motor blockade was observed at every 2 minutes after completion of drug injection. Assessment of sensory block was done by pin prick method and by comparing with the corresponding areas of the other arm. Sensory block graded as:

Grade 0: Sharp pin felt
Grade 1: Analgesia, dull sensation felt
Grade 2: Anaesthesia, no sensation felt.

The motor block was determined by using modified Bromage scale.

0 = can lift extended arm, 1 = inability to raise extended arm, but can bend elbow, 2 = inability to bend elbow, but can flex wrist and fingers, 3 = No movement

If patient complained of pain during the intraoperative period, they were supplemented with I.V. inj. midazolam (0.02 mg/kg) and inj. fentanyl (1 μg/kg) or if required were given general anaesthesia. These patients were excluded from the study. Rescue analgesia given was Inj. tramadol 100 mg as infusion in 100 ml normal saline and total number of doses of rescue analgesia given were noted.

The motor block duration was calculated from the end of local anaesthetic administration till the complete recovery of motor function of the hand and forearm. Pain scores were recorded at 30, 60, 90, 120, 180, 360, 480 and 720 minutes from the time of block. Assessment of pain was done using numerical pain scale between 0 – 10. Side effects and complication if any during injection, operation or postoperative period were recorded and treated accordingly.

**Statistical Analysis**

Statistical package for the social science (SPSS 17.0) was used for statistical analysis of the data. Chi-square, Anova test and Tukey post hoc test were used. P< 0.05 was considered as statistically significant and p>0.05 was considered as not significant.

**Results**

The group were comparable with respect to age, weight and sex ratio (p>0.05) (Table 1).

The time of onset of sensory and motor blockade was (14.59 ± 3.18) and (21.49±3.30) minutes in Group C, (5.10 ± 2.38) and (11.21 ± 2.25) minutes in Group D and (10.70 ± 3.39) and (16.53 ± 4.38) minutes in Group F. The difference between the three groups was statistically significant with (p < 0.05) at 95% confidence interval.

The mean duration of analgesia (sensory) for Group C was (619.53 ± 149.48) minutes, for Group D it was (1062.18 ± 183.28) minutes and for Group F it was (778.63 ± 138.15) minutes. The mean duration of motor blockade was [(549.19 ± 128.31), (903.17 ± 182.49) and (638.0 ± 125.18)] minutes for Group C, Group D and Group F respectively (Table 2). The difference in the duration of analgesia and duration of motor blockade was statistically significant (p< 0.05).

The pulse rate and mean arterial pressure (MAP) in Group C, Group D and Group F were comparable in preoperative, intra operative and post operative period (Graph 1and2). The mean pulse rate and MAP were slightly lower in Group D than in Group C and Group F and the difference being statistically significant (p <0.05).

**Table 1: Demographic Data between Three Groups**

<table>
<thead>
<tr>
<th>Parameters</th>
<th>Group C (Mean ± SD)</th>
<th>Group D (Mean ± SD)</th>
<th>Group F (Mean ± SD)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>35.15±11.01</td>
<td>36.63 ± 12.22</td>
<td>37.15 ± 11.12</td>
<td>&gt;0.05</td>
</tr>
<tr>
<td>Weight (kg)</td>
<td>56.31±6.7</td>
<td>57.34 ± 15.93</td>
<td>56.10 ± 15.33</td>
<td>&gt;0.05</td>
</tr>
<tr>
<td>Gender (M/F)</td>
<td>16/14</td>
<td>17/13</td>
<td>18/12</td>
<td>&gt;0.05</td>
</tr>
</tbody>
</table>

**Table 2: Comparison of sensory and motor block onset time, duration of motor block and duration of analgesia**

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Group C (Mean ± SD)</th>
<th>Group D (Mean ± SD)</th>
<th>Group F (Mean ± SD)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Onset time to sensory block (mins)</td>
<td>14.59 ± 3.18</td>
<td>5.10 ± 2.38</td>
<td>10.70 ± 3.39</td>
<td>&lt;0.05</td>
</tr>
<tr>
<td>Duration of motor block (mins)</td>
<td>21.49±3.30</td>
<td>11.21 ± 2.25</td>
<td>16.53 ± 4.38</td>
<td>&lt;0.05</td>
</tr>
<tr>
<td>Duration of analgesia (sensory)</td>
<td>619.53 ± 149.48</td>
<td>1062.18 ± 183.28</td>
<td>778.63 ± 138.15</td>
<td>&lt;0.05</td>
</tr>
<tr>
<td>Duration of analgesia (motor)</td>
<td>549.19 ± 128.31</td>
<td>903.17 ± 182.49</td>
<td>638.0 ± 125.18</td>
<td>&lt;0.05</td>
</tr>
</tbody>
</table>
Discussion

In this study, we found that addition of inj. dexmedetomidine 1mcg/kg led to earlier onset of both sensory and motor blockade and prolonged duration of analgesia compared to 0.5% levobupivacaine used alone. Also, the addition of Dexmedetomidine to levobupivacaine led to a significant improvement in the onset and duration of blockade and prolongation of analgesia compared to the addition of fentanyl. An earlier onset of motor and sensory block in Group F compared to Group C may be related to the peripheral effects of fentanyl. The lipid solubility of fentanyl may have a perineural effect and also fentanyl is supposed to have a local anesthetic action which might be responsible for quicker onset and establishment of complete block. In their study under supraclavicular block, showed that time of onset of blockade was shorter in Dexmedetomidine group (P < 0.001).

In their study under supraclavicular brachial plexus block and concluded that onset of blockade was quicker in patients receiving either fentanyl or dexmedetomidine as adjuvant to local anaesthetic.

The prolonged anesthetic and analgesic effect shown by fentanyl could be due to its anti-nociceptive action by activation of endogenous and exogenous opioid receptors present in the peripheral nervous system. Another cause could be due to the action of fentanyl in the substantia gelatinosa after its axonal transport during perineural injection. The mechanism by which dexmedetomidine produce analgesia and sedation is not fully understood. Peripherally, alpha 2 agonists reduce release of nor epinephrine and produce analgesia by causing alpha 2 receptor-independent, inhibition of nerve fibre action potential. Centrally, analgesia and sedation caused by α2 agonists occurs by inhibition of release of substance P in
the nociceptive pathway and by activation of alpha 2 adrenoceptors in the locus ceruleus.\textsuperscript{15,16}

Aliye Esmaoglu et al.\textsuperscript{17} in their study concluded that duration of analgesia and motor block was prolonged with addition of dexmedetomidine to 0.5% levobupivacaine in forearm and hand surgery under axillary brachial plexus block.

The study by Soma C Cham et al.\textsuperscript{18} concluded that duration of analgesia and motor block was prolonged in patients receiving either dexmedetomidine or fentanyl as adjuvant to 0.5% ropivacaine in comparison to ropivacaine used alone. Also, the duration of analgesia and motor block was significantly increased in dexmedetomidine group than in other two groups.

The mean pulse rate and MAP were slightly lower in Group D than in Group C or Group F. Bradycardia and hypotension were seen in some patients in group D but none in group C or group F.

In study done by Aliye Esmaoglu et al.,\textsuperscript{17} heart rate level were found to be significantly lower in dexmedetomidine group than in levobupivacaine group except the basal measurement (P < 0.05).

Soma C. Cham et al.\textsuperscript{18} also reported bradycardia in patients of dexmedetomidine group.

The mean pain score were recorded and compared at 30, 60, 90, 120, 180, 360, 480 and 720 minutes from the time of block. The mean pain score was slightly lower in Group D and group F than Group C at 480 and 720 minutes. However, pain scores were significantly lower in dexmedetomidine group when compared to fentanyl group. Inj. tramadol 100 mg as infusion in 100 ml normal saline was given to patients when numerical pain scores were found to be more than 4.

The number of boluses of rescue analgesic needed in first 24 hrs of post operative period was lower in Group D and Group F than Group C. Also the number of rescue analgesic needed was lower in dexmedetomidine group as compared to the fentanyl group.

Anjan Das et al.\textsuperscript{19} in their study found that patients of dexmedetomidine ( added as adjuvant to ropivacaine) group required significantly less number of rescue analgesics in first 24 hours of post operative period than the patient in ropivacaine group (P < 0.01).

**Conclusion**

From the results of the present study it can be concluded that the addition of 1 mcg/kg of fentanyl or 1 mcg/kg dexmedetomidine as an adjuvant to levobupivacaine, in interscalene brachial plexus block, prolongs the duration of both sensory and motor block and also shortens the latency (onset) period. However, dexmedetomidine prolongs the duration of motor block and postoperative analgesia much greater in comparison to fentanyl.

**References**