Abstract
Background and objective: Intravenous regional anesthesia (IVRA) for upper limb surgeries with traditional high dose of lidocaine can lead to life threatening side effects. In order to avoid these potential life threatening side effects, many modified techniques of IVRA have been attempted by using a low dose of lidocaine, muscle relaxant and opioid.

Method: The present study is carried out in sixty unpremedicated ASA Class 1 and 2 patients to compare the sensory and motor characteristics, cardio-respiratory parameters and side-effects during intra-operative and post-tourniquet deflation period between the patients who received 40 mL of 0.5% lidocaine alone (n = 30) and those who received a combination of 40 mL of 0.25% lidocaine with 0.05 mg fentanyl and 0.5 mg vecuronium (n = 30) in IVRA for upper limb orthopedic surgeries. The results were analyzed for statistical significance using a paired student t test.

Results: The difference between the two groups regarding the mean time of onset and complete sensory and motor block was statistically significant. But 15 minutes after the injection of anesthetic solution, there was complete sensory and motor block in both groups.

Conclusion: Although the short delay observed in the onset and attainment of complete sensory and motor block may theoretically delay the start of surgery for 10-15 minutes but clinically that time will be spent in the preparation of surgical field. So this combination can be used safely and effectively in intravenous regional anesthesia for upper limb orthopedic surgeries with reduced chance of local anesthetic toxicity.
Introduction

In this fast moving world, the number of road traffic accidents increases and so does the number of patients with upper limb trauma coming for various orthopedic surgical procedures. These patients often present a full stomach and, in addition, may have co-existing diseases, which make general anesthesia hazardous. The brachial plexus block can be employed for such upper limb orthopedic surgeries, but it requires technical skill. Furthermore, complications like pneumothorax, inadvertent intravascular injection or injury to nerves may occur. The technique has other problems like time consumption, delayed onset of analgesia and a chance of incomplete analgesia. Thus, a simple and effective technique like intravenous regional anesthesia (IVRA) or Bier’s block can be an alternative for upper limb surgeries.

Traditionally, lidocaine is used as 0.5% solution at the dose of 3 mg.kg⁻¹ in IVRA for effective anesthesia during upper limb surgeries. However, at this high dose, life threatening side effects such as convulsions, coma, cardio-respiratory depression and even cardiac arrest can occur due to accidental release of tourniquet during the procedure or deliberate release of tourniquet at the end of the procedure. In order to avoid these potential life threatening side effects, many modified techniques of IVRA have been attempted by using a low dose of lidocaine, muscle relaxant and opioid.

Given this background, the present study was carried out to evaluate the usefulness of addition of fentanyl (0.05 mg) and vecuronium (0.5 mg) to 0.25% lidocaine and to compare it with 0.5% lidocaine alone in intravenous regional anesthesia for upper limb orthopedic surgeries.

Methods

The institutional ethical committee approved the study and researchers obtained written informed consent from all patients.

This study was a randomized, prospective, comparative study. The study population consisted of sixty patients aged between 18 and 60 years belonging to ASA Class 1 and 2 scheduled for elective upper limb orthopedic surgeries. Patients with history of allergy to local anesthetics, highly nervous and uncooperative patients, patients with crush injury, open wounds, infection and cellulitis of the operative limb, patients with history of epilepsy, peripheral arterial disease, sickle cell disease, arteriovenous malformation and pregnancy were excluded from this study. Patients were randomly allocated into two groups of thirty each.

Group A (n = 30): received 40 mL of 0.5% lidocaine alone
Group B (n = 30): received 40 mL of 0.25% lidocaine with 0.05 mg fentanyl and 0.5 mg vecuronium.

A thorough preoperative evaluation was done and the patients were kept nil per oral overnight. We explained the procedure to ensure good cooperation. To the extent possible, we chose cases where the surgery was expected to be over before the maximum tourniquet time of the upper limb (lower than 90 minutes). None of the patients in this study received any premedication.

The patients were placed in supine position on a tiltable operation table. The intravenous line was secured on the non-operating upper limb with 20-gauge intravenous cannula for infusion of intravenous fluids. The patients were connected to standard monitors that included continuous electrocardiogram, pulse oximetry, and non-invasive blood pressure monitor. The baseline values were recorded. All the necessary equipment and emergency drugs were kept ready for resuscitation, in order to cope with any toxic and untoward reactions occurring during the procedure.

The venipuncture was done with 20-gauge intravenous cannula in the operative limb. After venipuncture, we performed exsanguination of the operative limb by elevating the limb above the body for two to three minutes and applied an Esmarch’s bandage starting from the tip of the fingers till the upper arm, where we applied the tourniquet, with due care for the intravenous cannula. We achieved vascular occlusion by application of double pneumatic tourniquet. We noted the time of inflation of proximal tourniquet. Before inflating distal tourniquet, we injected the local anesthetic drug into the operative limb through the 20-gauge intravenous cannula. The drug was injected slowly over 45 seconds to prevent leakage of the drug beyond the tourniquet. We inflated the distal tourniquet 2-3 minutes after the injection of the drug. After the inflation of distal tourniquet, the proximal tourniquet was deflated.

We assessed sensory and motor characteristics during the intra-operative and post tourniquet deflation period based on the following scale.

a. Sensory loss: We used a 0-2 scale to assess the sensory loss.
   0 = Sharp
   1 = Touch only (cannot appreciate pinprick)
   2 = Cannot feel touch

b. Motor loss: We used a 0-3 scale to assess motor block.
   0 = Ability to move the wrist against resistance
   1 = Inability to move the wrist against resistance
   2 = Inability to move the wrist and elbow against resistance
   3 = Inability to move the arm

The time at which patients were unable to perceive a pinprick (that is, sensory loss score 1) after the drug injection was considered as the time of onset of sensory loss and the time at which the patients were unable to perceive touch (that is, sensory loss score 2) after the drug injection was considered as the time of complete loss of sensation. The time at which patients were unable to move their wrist against resistance (that is, motor loss score 1) after the drug injection was considered as the time of onset of motor loss and the time at which patients were unable to move their arm (that is, motor loss score 3) after the injection of drug was considered as the time of complete loss of motor power. The tourniquet was released after surgery was over and, if surgery was completed in less than twenty minutes after the drug injection, the tourniquet was kept for a minimum period of twenty minutes. Before releasing the distal tourniquet, we noted duration of surgery and tourniquet time.
We studied sensory and motor characteristics in the post-distal tourniquet deflation period. We noted the time at which full sensation and full motor power returned (period of post-operative analgesia). The time from the release of distal tourniquet to the appearance of a sharp pain at the surgical site was considered as the time of return of full sensation. The time from the release of distal tourniquet to the time at which patients were able to move the wrist against resistance (that is, motor loss score 0) was considered as the time of return of full motor power.

The patients were observed for changes in pulse rate, blood pressure (systolic and diastolic), respiratory rate, oxygen saturation and electrocardiogram and also for side effects such as nausea, giddiness, diplopia and tourniquet pain during the intra-operative period and for 30 minutes after release of distal tourniquet.

The sample size for the study was based on a pilot study of 10 patients. The outcome of the pilot study indicated that a sample size of 30 in each group would give enough power of more than 85%. However, the results of the pilot study were not included in the results of the main study. Results were expressed as mean ± SD unless indicated otherwise. The results were analyzed for statistical significance using paired student t-test. Differences were considered to be statistically significant when P value was < 0.05.

**Result**

Both groups were statistically comparable with respect to demographic variables like age, sex and weight (Table 1). The mean tourniquet time was comparable in Groups A and B (54 ± 4 min and 55 ± 3 min, respectively) (Table 2). The mean time of onset of sensory loss in Group B (6.14 ± 0.78 minutes) was significantly longer than in Group A (2.22 ± 0.75 minutes); mean time of complete loss of sensation was significantly longer in Group B (12.25 ± 0.92 minutes) than in Group A (7.12 ± 0.75 minutes) (Table 2). The mean time of onset of motor block in Group B (8.35 ± 1.16 minutes) was longer than in Group A (4.17 ± 0.74 minutes); mean time of complete motor block in Group B (15.65 ± 0.94 minutes) was longer than in Group A (10.57 ± 0.81 minutes) (Table 2). There was no statistically significant difference between two groups with regards to the time of return of full motor power and the time of return of full sensation after deflation of distal tourniquet (Table 2).

No side effect was reported in the intra-operative period in either of the groups except that tourniquet pain was reported in two patients in Group A and none in Group B, but it was not statistically significant (Table 3). In post tourniquet deflation period, giddiness occurred in ten patients in Group A while none in Group B patients (P < 0.05, significant) and nausea occurred in one patient in Group B while none in Group A (statistically insignificant) (Table 3). There were no significant changes in cardio-respiratory parameters in either group.

**Discussion**

In this study, the difference between the two groups regarding the mean time of onset and complete sensory and motor block was statistically significant (P < 0.05). However, within fifteen minutes of anesthetic solution injection, there was complete sensory and motor block in both groups. Thus, the quality of anesthesia was comparable in both groups at fifteen minutes after injection of anesthetic solution. This roughly coincides with the usual time of start of surgery.

**Table 1 Demographic variables.**

<table>
<thead>
<tr>
<th>Variables</th>
<th>Group A</th>
<th>Group B</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>38.8</td>
<td>43.6</td>
<td>NS</td>
</tr>
<tr>
<td>Male: Female</td>
<td>24:6</td>
<td>20:10</td>
<td>NS</td>
</tr>
<tr>
<td>Weight (Kg)</td>
<td>52.6</td>
<td>56.8</td>
<td>NS</td>
</tr>
</tbody>
</table>

n: Number, NS: Not significant.

**Table 2 Sensory and motor characteristics.**

<table>
<thead>
<tr>
<th>Variables</th>
<th>Group A</th>
<th>Group B</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Time of onset of sensory loss (min)</td>
<td>2.22 ± 0.75</td>
<td>6.14 ± 0.78</td>
<td>0.0231</td>
</tr>
<tr>
<td>Time of complete loss of sensation (min)</td>
<td>7.12 ± 0.75</td>
<td>12.25 ± 0.92</td>
<td>0.0214</td>
</tr>
<tr>
<td>Time of onset of motor block (min)</td>
<td>4.17 ± 0.74</td>
<td>8.35 ± 1.16</td>
<td>0.0315</td>
</tr>
<tr>
<td>Time of complete motor block (min)</td>
<td>10.57 ± 0.81</td>
<td>15.65 ± 0.94</td>
<td>0.0354</td>
</tr>
<tr>
<td>Time of return of full motor power after release of tourniquet (min)</td>
<td>7.64 ± 0.83</td>
<td>7.48 ± 0.80</td>
<td>0.1245 NS</td>
</tr>
<tr>
<td>Time of return of full sensation after release of tourniquet (min)</td>
<td>11.93 ± 0.87</td>
<td>12.23 ± 0.73</td>
<td>0.0821 NS</td>
</tr>
</tbody>
</table>

Values are given as mean ±SD, NS: Not significant.

**Table 3 Incidence of side effects.**

<table>
<thead>
<tr>
<th>Variables</th>
<th>Group A</th>
<th>Group B</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intraoperative period</td>
<td>2/30</td>
<td>0/30</td>
<td>0.0950 NS</td>
</tr>
<tr>
<td>Tourniquet pain (Y/N)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Post-tourniquet deflation</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nausea (Y/N)</td>
<td>0/30</td>
<td>1/30</td>
<td>0.0811 NS</td>
</tr>
<tr>
<td>Diplopia (Y/N)</td>
<td>0/30</td>
<td>0/30</td>
<td>NS</td>
</tr>
<tr>
<td>Giddiness (Y/N)</td>
<td>10/30</td>
<td>0/30</td>
<td>0.0386</td>
</tr>
</tbody>
</table>

Y/N: Yes/No, NS: Not significant.
Study of 0.5% Lidocaine Alone and Combination of 0.25% Lidocaine with Fentanyl and Vecuronium in Intravenous Regional Anesthesia for Upper Limb Surgeries

after anesthetizing the patient. A similar study conducted by Sztark et al.² where pancuronium was used instead of vecuronium had also shown significant difference in the time of onset and complete sensory and motor block between two groups but there was no difference between the two groups twenty minutes after the injection of anesthetic solution.² Abdulla and Fadhil had conducted a study comparing lidocaine (100 mg) alone with a combination of lidocaine (100 mg), fentanyl (50 µg) and combination of lidocaine (100 mg), fentanyl (50 µg) and pancuronium (0.5 mg) in IVRA.³ They obtained successful analgesia in 100% of the cases with the combination of lidocaine, fentanyl and pancuronium in comparison with only 27% with the combination of lidocaine, fentanyl and only 13% with lidocaine alone.³ In our study, we compared the combination of fentanyl (0.05 mg), vecuronium (0.5 mg) and 0.25% lidocaine (100 mg) with the 0.5% lidocaine (200 mg) and noted 100% successful anesthesia in both the groups. Thus, we obtained the same quality of anesthesia as traditional high dose of lidocaine by using a combination of a nontoxic dose of lidocaine, low dose of vecuronium and fentanyl. As with the conventional method, the duration of postoperative analgesia was much less, even with the addition of fentanyl.

There were no significant side effects either group during intraoperative period. In the post tourniquet deflation period in the 0.5% lidocaine only group, patients showed significant incidence of giddiness that was not seen in any other group. This shows that a combination of opioid and muscle relaxants with low-dose lidocaine significantly reduces the incidence of potential local anesthetic toxicity. In addition, Abdulla and Fadhil had confirmed the safety of a combined solution of 100 mg lidocaine, 0.05 mg of fentanyl and 0.5 mg pancuronium, with the absence of side effects, by releasing the tourniquet pressure soon after administering the solution above.³

The precise role of opioid or muscle relaxant in IVRA is not clear. Opioid may possibly produce some degree of suppression of neural conduction and this may potentiate the effect of local anesthetic in IVRA.¹ Muscle relaxant may potentiate the local anesthetic by blocking muscle spindle activity, thus reducing muscle tone and spasm.²,³

In conclusion, both solutions can be used safely and effectively in intravenous regional anesthesia for upper limb orthopedic surgery. The addition of fentanyl and vecuronium to lidocaine helps in reducing lidocaine dose and, thus, lessening the potential local anesthetic toxicity in IVRA. The combined solution of fentanyl, vecuronium and 0.25% lidocaine has slower onset of sensory and motor block but it will not clinically delay the starting time of surgery.

Contribution by authors

Dr. Santhosh, MCB- Study design, conduct of the study, data collection, data analysis, and manuscript preparation.
Dr. Rohini Bhat Pai- manuscript preparation, editing.
Dr. Roopa S- manuscript preparation, editing.
Dr. Raghavendra P. Rao- editing.

References