Efficacy of paracetamol when added as an adjunct to lignocaine in intravenous regional anaesthesia- A prospective randomised double blinded study

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<u>Abstract</u>

Background: Intravenous regional anaesthesia (IVRA) using Lignocaine is a safe, reliable, and cost-effective technique for providing anaesthesia as well as a bloodless field during upper limb surgery. It has been postulated that the site of action in IVRA is probably by blockade of small nerves or possibly nerve endings and not the major nerve trunks. Aim: In this study we evaluated the effects of Paracetamol on the onset of sensory and motor block time, sensory and motor recovery time and the requirement of postoperative analgesia. **Methods:** Sixty patients undergoing upper limb extremity surgeries were randomized into two groups .IVRA was achieved by injecting 10 ml of 2% Lignocaine with 30 ml of Paracetamol to a total of 40 ml in Group 1(n=30) and 10 ml of 2% Lignocaine with 30 ml of Normal saline to a total of 40 ml in Group 1(n=30) and 10 ml of 2% Lignocaine with 30 ml of Normal saline to a total of 40 ml in Group 1 (p < 0.001). Intraoperative VAS scores were significantly lower in Group 1 (p< 0.05). Intraoperative Fentanyl consumption was 8.33 ± 21.82 mcg in Group 1 and 38 ± 37.82 mcg in Group 2, the number of patients requiring Fentanyl was 4 and 17 respectively (p< 0.001). The postoperative analgesic requirement was lower in Group 1 with 9 patients and was 25 patients in Group 2 (p< 0.001). Conclusion: The administration of Paracetamol as an adjunct to Lignocaine in IVRA was found to be efficacious and it provided significant shortening in the onset of sensory block, a decrease in the intraoperative analgesic requirement and an improvement in the postoperative analgesia with a reduced need for analgesics in the postoperative period.

Key Words: Intravenous regional anesthesia, Lignocaine, Paracetamol, Postoperative Pain

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INTRODUCTION

Intra Venous Regional Anaesthesia (IVRA) is a regional anaesthetic technique commonly used in forearm surgeries. It was first introduced by a German surgeon August Gustav Bier in 1908 by injecting Procaine intravenously between twotourniquets¹. He found that there was a rapid onset of anaesthesia between the tourniquets and a slower onset beyond the distal tourniquet. This technique gained more importance in the late 1960s after its reintroduction by Holmes². There have been many modifications to this technique over time, presently the use of double tourniquet with an injection of drugs distal to the cuffs. Its use has been proved to have an advantage of the faster recovery,

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shorter hospital stays, cost-effectiveness and reduced nursing care requirements making it an ideal choice for Daycare surgeries³.When IVRA is appropriately performed there is a 96 - 100% success rate⁴⁻⁶. This technique has the advantage of the rapid return of sensory and motor power at the end of surgical procedure allowing normal functioning of the operated limb and the surgeons are able to assess neurological status after surgery. This rapid recovery facilitates early discharge of patients. IVRA is advantageous being reliable, easy to administer and cost-effective for short operative procedures of the extremities performed on an ambulatory basis3.There are some disadvantages like the delayed onset of action, poor muscle relaxation and rapid onset of pain at the operative site after the tourniquet is deflated⁷. Various additives like Opioids, Muscle relaxants, NSAIDs such as Ketorolac.8 Tenoxicam9 and Aspirin¹⁰ have been used to overcome these disadvantages to improve analgesia. There is a risk of local anaesthetic toxicity due to the sudden release of large amounts of local anaesthetic as a result of leakage due to high venous pressure or accidental tourniquet failure past the inflated tourniquet. Due to the above-mentioned effects it is desirable to limit the amount of local anaesthetic to a minimum¹¹.In previous studies, IVRA with Paracetamol was shown to improve the overall quality of the block, early onset of motor block, reduced tourniquet pain, delayed recovery of motor and sensory block, low intraoperative pain scores and decreased analgesic requirements both during the intraoperative and postoperative period. The ideal IVRA solution should have a rapid onset of action, require less amount of local anaesthetic, reduce tourniquet pain and prolong postdeflation analgesia. This may be achieved by the addition of adjuncts to the localanaesthetic. Paracetamol added as an adjunct to Lignocaine has been shown to provide decreased tourniquet pain, increased anaesthesia quality and decreased postoperative analgesic consumption.

AIM

To determine the efficacy of Paracetamol when added as an adjuvant to Lignocaine for IVRA.

MATERIALS AND METHODS

This randomized double-blinded study was conducted in the Department of Anaesthesiology, PSG Institute of Medical Sciences, Coimbatore in ASA I and II patients posted for upper limb surgeries from August 2013 – March 2015.The study group patients were assigned into two groups as Group 1 and Group2, comprising of 30 patients each. IVRA was performed using 10 ml of 2%Lignocaine with 30 ml of Paracetamol in Group 1 patients and 10 ml of 2%Lignocaine with 30 ml of Normal saline in Group 2.

Inclusion Criteria:

ASA I and II patients, aged between 20-60 yrs, Upper limb extremity surgeries of duration not exceeding 60 minutes. Exclusion Criteria: a history of allergy to local anaesthetics, expected duration of surgery more than 60 minutes, Raynaud's disease, Sickle cell anaemia, Coagulation disorders. Simple randomization was done and assigned into two groups (with 30 patients in each group as Group -1 and Group - 2). According to ASA starvation guidelines patients were kept nil per oral status overnight and pre-medicated with Tablet Ranitidine 150 mg and Tablet Diazepam 5 mg the night prior to surgery and on the morning of surgery. Anaesthesia machine safety checklist including resuscitation equipment, emergency drugs and tourniquet equipment were kept ready before the patient arrived in the operating room (OR). Starvation status and surgical consent confirmed in the preoperative room before the patient was shifted inside the operating room. Preinduction monitors like ECG leads, Noninvasive blood pressure (NIBP)cuff and pulseoximeter were connected and baseline readings noted. All the patients were explained about the Visual Analogue Scale (VAS) prior to the start of the procedure. Vital signs like MAP, HR, and SpO2 were recorded before and after application of a tourniquet and monitored continuously during the procedure at 5, 10, 15, 20, 30,40, 50 minutes interval till the release of a tourniquet. The pain was assessed using a 10cm visual analogue scale. If the patient reported a VAS > 4, rescue analgesic of 1 mcg/kg Fentanyl was intravenously given and the requirement for analgesics was recorded.

RESULTS

In this study, 60 patients were selected after considering the inclusion and exclusion criteria. Consent was obtained from all the 60 patients and was divided into2 groups with 30 patients in each group. Group 1 received 30 ml of Paracetamol and 10 ml of 2% Lignocaine (preservativefree (PF)). Group 2 received 30 ml of Normal Saline and 10 ml of 2% Lignocaine (preservative-free (PF)). In our study, after reviewing the literature we selected the study group in the age between 20 - 60 years. The mean age distribution in our study was 42.87±11.57 in Group 1 and 39.37±13.04 in Group 2. Out of 60 patients in our study, the sex distribution was 18:12 (Male: Female)in Group 1 and 16:14 (Male: Female) in Group 2.In our study, we used a double pneumatic tourniquet placing the first tourniquet on the proximal portion of the extremity to be operated and the second tourniquet distal to the proximal one. Group 1 patients in our study had very negligible intraoperative pain / discomfort during the procedure, but

Group 2 patients reported with pain intraoperatively, presumably tourniquet pain. In our study, the meantime of onset of sensory block was 5.60± 1.58 minutes in Group 1 and 7.13 ± 1.59 minutes in Group 2 patients. The p-value<0.001 shows there is a statistically highly significant difference between the two groups in terms of the time of onset of sensory block. In our study amongst patients in Group 1, the average onset of motor block time was 8.70± 2.52 minutes and in Group 2 it was 12.27 ± 2.79 minutes. The p-value < 0.001 shows that there is a statistically significant difference among the two groups in terms of the time of onset of motor block. In our study, the sensory recovery time was 7.60 ± 1.102 minutes in Group 1and 5.60 ± 1.610 minutes in Group 2. The p-value<0.001 showed that there is a statistically highly significant difference with regard to the onset of the sensory recovery time between the two groups. In our study, the motor recovery time was 8.90 ± 2.13 minutes in Group 1 and 10.37 ± 2.498 minutes in Group 2. The pvalue 0.018 showed that there is a statistically significant difference between the two groups in terms of motor recovery time. In our study, 4 patients out of 30 required Fentanyl consumption intraoperatively in Group 1 and 17 patients out of 30 in Group 2 and proved to be statistically significant. In our study, the mean Fentanyl consumed was 8.33±21.82 micrograms in Group 1 and 38±37.820 micrograms in Group 2, p-value<0.001 showed that there

is a statistically significant difference between the two groups in terms of Fentanyl consumption as rescue analgesic intraoperatively. The mean VAS pain score intraoperatively was 2.17±1.62 in Group 1 and 3.80±2.36 in Group 2. The p-value 0.003 showed that there is a statistically significant difference in the intraoperative VAS score between the two groups. Out of 30 patients in each group in our study, 9 patients required analgesia following tourniquet deflation in Group 1 and 5 patients in Group 2; which was statistically significant between the two groups with p-value< 0.05.Out of 30 patients in each group in our study, surgeon satisfaction grade was excellent in 14 patients in Group 1 and 6 patients in Group 2. The grade was good in16 patients of Group 1 and 24 patients of Group 2. There was a statistically significant difference between the two groups as the pvalue is 0.028 (which is < 0.05) with regard to surgeon satisfaction in our study. Out of 60 patients in our study, 7 patients from Group 1 and 2 patients from Group 2 gave excellent grading (Grade 1), 18 patients from Group 1 and 14 patients from Group 2 gave good grading (Grade 2) and 5 patients from Group 1 and 14patients from Group 2 gave moderate grade (Grade 3). There was a statistically significant difference between the two groups as p is0.023 (<0.05) with regard to patient satisfaction in our study.







Figure 1: ASA grading distribution Figure 2: Onset of the sensory block (mins)

Figure 3: Onset of the Motor block (mins) Figure 4:Sensory recovery time

Figure 5: Motor recovery time; Figure 6: Fentanyl Consumption; Figure 7: Postoperative analgesic requirement

DISCUSSION

In our study, we investigated whether the addition of Paracetamol to IVRA solution decreased tourniquet pain, intraoperative use (Fentanyl) and enhanced the sensory and motor block duration by increasing the quality of IVRA. However, in our study we also demonstrated a decrease in postoperative pain score and analgesic requirement. Elhakim M and Sadek RA¹² carried out IVRA on patients between 25 - 55 years. Palecha S et al¹³ used IVRA on patients above 20 years of age. Sanjay Kherde *et al*¹⁴ used the age group of 15 - 55 years in his study. Tourniquets are used in IVRA to restrict the drugs from entering beyond the cuff into the systemic circulation causing untoward consequences. It is also used to provide analgesia and motor blockade distal to the tourniquet. Chandrashekara PM et al15 used single rubber latex bandage as a tourniquet above the site of surgery. He noted the tourniquet pain and discomfort in surgeries that prolonged for more than 40-50 minutes. Holmes C et al¹, Sorbie C and Chancha P¹⁶ and Janardhan et al¹⁷ used double tourniquet with the second tourniquet placed on the anaesthetized portion of the extremity distal to the proximal one to prevent tourniquet pain and discomfort. Intravenous regional anaesthesia technique is successful when there are proper tourniquet placement and adequate exsanguination1.Holmes C et al1 and Chandrashekara PM et al^{15} achieved exsanguination either by simple gravity draining method or by using Esmarch bandage and combined both in some cases. Blond L et al¹⁸ showed there was a 69% reduction in blood volume in the limb after exsanguinations using Esmarch bandage. The observation of the present study is in accordance with regards to the meantime of onset of the sensory block by Myoung Jin Ko and Jeong Han Lee *et al*¹⁹. He reported a similar statistically significant difference in his IVRA study, in patients who received 40 ml of 0.5% Lignocaine in one group and 0.5% Lignocaine diluted with intravenous Acetaminophen 300 mg to a total volume of 40ml. The observation of the present study is in

accordance with the observations of Sen H. Kulahci Y et al^{20} who stated the similar statistically significant difference in theirs tudy population with the meantime motor block onset, mean time of sensory block recovery time, mean time of motor block recovery time. This observation was in accordance with observation obtained in Sen H et al²⁰ where intraoperative VAS scores were seen at 20 and 30 minutes were significantly lower in Group 2 which was 10 ml 3mg/kg Lignocaine with 300mg Paracetamol similar to the present study. Post deflation analgesic requirement in a study done by Sen H et al²⁰ and Myoung Jin Ko et al¹⁹ where they showed a statistically significant difference between the two groups with а p value < 0.005 using Diclofenac and Tramadol respectively.

CONCLUSION

To conclude from our study, that the administration of Paracetamol as an adjunct to Lignocaine in IVRA, was found to be efficacious and it provided significant shortening in the onset of sensory block, a decrease in the intraoperative analgesic requirement and an improvement in the postoperative analgesia with a reduced needf or analgesics in the postoperative period.

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