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Randomized controlled trial of fentanyl and tramadol as adjuvants to lignocaine for intravenous regional anesthesia for upper limb surgery

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Abstract

Background and Aims: Intravenous regional Anesthesia is safe, simple and cost effective compared to general anesthesia for upper limb surgeries and provides bloodless field. Aim-To compare the duration of postoperative analgesia and associated complications between IVRA with lignocaine-Fentanyl and Lignocaine-Tramadol.

Methods: In this Randomized controlled trial, 60 Patients in age group 20-60 years of ASA 1 and 2 undergoing surgeries of upper limb were selected. Postoperative analgesia was analysed by VAS Score and complications during first 24 hours were analysed. Mean duration of analgesia was also assessed. 0.5% lignocaine 40 ml + Fentanyl 0.1 mcg/kg (Group A) and 0.5% lignocaine 40 ml + Tramadol 1 mg/kg (Group B) were given to patients randomly assigned in two groups. Pulse rate, blood pressure, ECG, Oxygen saturation, respiratory rate, visual analog scale, time of first analgesic and total number of analgesics in 24 hours and any associated complications were noted throughout the procedure. Descriptive results were expressed as mean and SD. P value <0.05 was considered significant and P value < 0.01 was considered highly significant.

Results: Group B ($p < 0.001$) had greater duration of analgesia compared to group A. Group A ($p < 0.001$) had higher mean additional dosage requirement of analgesics.

Conclusion: Tramadol had significantly longer postoperative analgesia as compared to fentanyl added to lignocaine for upper limb surgery.

Keywords: IVRA, postoperative analgesia, duration of analgesia

Introduction

Relief of pain during surgery is one of the greatest objectives of anesthesia. IVRA – intravenous regional anesthesia is one of the useful and popular regional technique in anesthesia armamentarium. IVRA was first described in 1908 by the then professor of surgery Karl August Bier in Berlin. IVRA is safe, technically simple and cost effective compared to general anesthesia^[1] with success rates of 94 to 98% for upper and lower limb surgeries^[2]. It also provides bloodless field during surgery. Its limitations are systemic toxicity, tourniquet pain and inability to provide postoperative analgesia. To overcome these disadvantages many modalities have been tried with varying degrees of efficacy. Fentanyl, an opioid and tramadol, a weak opioid selective for mu receptor have been used here. Tramadol also acts on monoaminergic system by blocking the reuptake of nor epinephrine and 5-hydroxytryptamine at the alpha 2 adrenergic receptor level^[21]. AIM- 1. To compare the duration of postoperative analgesia between IVRA with lignocaine-Fentanyl and Lignocaine-Tramadol combination. 2. To assess associated complications in both the groups.

Materials and Methods

The present study was conducted at SVS Medical college, Mahabubnagar from October 2012 to September 2014 on 60 patients in the age group 20-60 years, ASA-grade 1 & 2 scheduled for either elective or emergency surgeries of upper limb after getting approval by the ethical committee and written informed consent from the patients. It was a Randomized controlled trial. All 60 patients were randomly allocated into Group A and Group B by computer generated randomization method. Patients with known history of hypersensitivity to any of the drugs used, history of hypertension/diabetes/valvular heart diseases/ischemic heart disease, peripheral vascular disease, patients with neurological disease, history of bronchospastic disease, patients with haemolytic disease, history of epilepsy were excluded from the study.

Pre anesthetic check-up was carried out pre operatively with a detailed history, general physical examination and systemic examination. Airway assessment and spinal column examination were done. Routine investigations were done. IV line was secured with 20 Gauge IV cannula on non operating hand and IV fluid was started, Patient was premedicated with Inj. Atropine 0.5 mg IV. After shifting the patient to the operation theatre, all the monitors were connected. A Vein on the dorsum of operating hand was usually selected, but if no veins were visible in that area, the most distal forearm vein was cannulated with 20 Gauge IV cannula. Two inflatable cuffs, appropriate for age and circumference were applied after proper padding beneath the two cuffs. The arm was exsanguinated with Eschmark bandage. If the limb was painful in the presence of fractures or gaping wound, the arm was exsanguinated by raising the limb above chest for 5 minutes. After exsanguination of limb, the proximal tourniquet was inflated to 100 mm Hg above systolic blood pressure. The tourniquet was tested for tightness and then eschmark bandage removed. The drug solution prepared by third person not involved in the study was injected, as both the patient and monitoring anaesthesiologist were blinded to the drug injected. Group A- 0.5% Lignocaine 40 ml + Fentanyl 0.1 mcg/kg, Group B-0.5% Lignocaine 40 ml + Tramadol 1 mg/kg. As per randomization, patients were given either drug solution A or B injected slowly over 2 minutes and then IV cannula on operative side was removed. After 10 minutes of drug injection the distal tourniquet was inflated to 100 mm Hg above systolic blood pressure and proximal cuff deflated. Throughout procedure pulse rate, blood pressure, ECG, oxygen saturation and respiratory rate were monitored. Pain was assessed by using visual analog scale of 0-10. A score of 0 was given for no pain and 10 for intolerable pain. If the patient had VAS of 5 or more, the patient was administered a dose of rescue analgesic Inj. Diclofenac 75 mg intramuscular. Patients were monitored every 15 minutes for the first hour, hourly for the next 24 hours. Time of first analgesic and total number of analgesics in 24 hours was noted. Maximum tourniquet time allowed was 90 minutes. Tourniquet was not deflated even if the procedure was over within 20 minutes. Between 20-40 minutes cuff was deflated for 5 seconds and reinflated immediately for 1 minute, was repeated twice and then tourniquet was deflated completely. After 40 minutes tourniquet was deflated completely as a simple manoeuvre. Any associated complications like perioral numbness, giddiness, tinnitus, nausea, vomiting, pain, skin rashes, hypotension, bradycardia, convulsions and cardiac asystole were noted. Postoperative analgesia was defined as time from inflation of tourniquet to the first analgesic dose requirement which was analysed by VAS scale. Associated complications from inflation to tourniquet to first 24 hours were noted.

Results

The data obtained was analysed using SPSS software version 17.0. Descriptive results were expressed as mean and SD of various parameters in different groups. Probability value (p value) was used to determine the level

of significance P value < 0.05 was considered as significant, P value < 0.01 was considered as highly significant. The mean age in group A was 40.87 and in group B was 40.96, there was no significant difference in the mean ages in two groups ($p>0.05$). The mean duration for onset of sensory blockade was significantly lower in group B compared to group A. The mean duration for onset of motor blockade was significantly ($p<0.001$) lower in group B compared to group A. Mean visual analogue scale for perception of pain was compared in both groups at fixed intervals it was observed that the mean VAS was significantly higher in group A where as the mean VAS score was significantly lower in group A.

Table 1: Comparison of patients according to onset of sensory block

Onset of sensory block in minutes	Group A No. of patients	Group A%	Group B No. of patients	Group B%
3-5	1	3.33	8	26.67
5.01-8	13	43.33	20	66.67
8.01-11	13	43.33	2	6.67
11.01-14	3	10	0	0
Total	30	100	30	100
Mean \pm SD	7.93 \pm 1.85		6.05 \pm 1.4	
T value= 4.4			P value <0.001	

In the present study it was observed that group B had a greater duration of analgesia compared to group A. 86.67% of patients in group B had analgesia for a duration of 7-12 hrs compared to group A where 80% of patients had analgesia for 0-6 hrs.

Table 2: Comparison of patients according to onset of motor block

Onset of motor block in minutes	Group A No. of patients	Group A%	Group B No. of patients	Group B%
8.01-11	2	6.67	15	50
11.01-14	16	53.33	15	50
>14.01	12	40	0	
Total	30	100	30	100
Mean \pm SD	13.32 \pm 1.57			
T value = 7.14			P value <0.001	

Table 3: Comparison of Mean duration of analgesia

Duration of analgesia hours	Group A No. of Patients	Group A%	Group B No. of patients	Group B%
0-6	24	80	1	3.33
7-12	5	16.67	26	86.67
13-18	1	3.33	2	6.67
19-24	0	0	1	3.33
Total	30	100	30	100
Mean \pm SD	5.83 \pm 2.19		9.23 \pm 2.44	
T value = 5.67			P value <0.001	

Mean additional dosage requirement in group A was significantly ($p<0.001$) higher compared to group B. There was no significant ($p>0.05$) statistical difference in the pattern of complications observed. In both the groups there was no significant ($p>0.05$) statistical difference in the occurrence of intraoperative side effects such as perioral numbness and tourniquet pain.

Table 4: Comparison of side effects in both the groups

Side effects	Group A No. of Patients	Group A %	Group B No. of Patients	Group B %
vomiting	1	3.33	1	3.33
nausea	3	10	3	10
pruritis	3	10	1	3.33
total	30	100	30	100
Chi square value=0.686			P value=0.71	

Table 5: Comparison of side effects intra operatively in both groups

Side effects	Group A No. of Patients	Group A %	Group B No. of Patients	Group B %
Perioral numbness	1	3.33	1	3.33
Tourniquet pain	1	3.33	1	3.33
total	30	100	30	100
Chi square value= 0			P value = 1.0	

Discussion

In the present study, we observed that:

1. Mean time to first analgesic in Lignocaine-Tramadol group was longer as compared to that in Lignocaine – Fentanyl group.
2. Total number of analgesic doses required in first 24 hours was significantly less in Lignocaine-Tramadol group as compared to that in Lignocaine-Fentanyl group.
3. The associated complications in Lignocaine – Fentanyl group was higher as compared to Lignocaine – Tramadol group but was not statistically significant.

Goel SN *et al.* [11] have compared the mean time to first analgesic and total number of analgesic doses required in the first 24 hours between Lignocaine – Tramadol group, Lignocaine - Ketorolac group and Lignocaine – Saline group. It was found that Lignocaine – Tramadol group was significantly better with longer pain free interval ($p < 0.05$). Also the number of analgesic doses required in the first 24 hours for Lignocaine-Tramadol group were significantly less as compared to Lignocaine - Ketorolac group ($P < 0.05$) and Lignocaine – Saline group ($P < 0.05$).

In our study Mean visual analogue scale for perception of pain was compared in both groups at fixed intervals it was observed that the mean VAS was significantly higher in group A.

In the present study it was observed that group B had a greater duration of analgesia compared to group A. 86.67% of patients in group B had analgesia for a duration of 7 – 12 hrs compared to group A where 80% of patients had analgesia for 0- 6 hrs. Mean additional dosage requirement in group A was significantly ($p < 0.001$) higher compared to group B. 66.67% of patients in group A required 3 doses of injection diclofenac and 20% patients required 4 doses of injection diclofenac to achieve sustained analgesia compared to group B where 50% patients required 2 doses and 46.67% patients required only one dose of injection diclofenac to achieve sustained analgesia post IVRA.

Fentanyl as an adjuvant to local anaesthetic in IVRA had associated disadvantages like pruritus, postoperative nausea, vomiting and shorter postoperative analgesia [4].

Tramadol, a racemic mixture, consisting of isomers with different spectrum of activity, is a weak opioid selective for the mu receptors. Tramadol has minimal respiratory

depression, stable haemodynamics, least postoperative nausea and vomiting and longer duration of action. Besides its opioid action, Tramadol also acts on monoaminergic system by blocking the re-uptake of norepinephrine and 5-hydroxy-tryptamine at the $\alpha 2$ -adrenergic receptor level [21].

Surgical trauma results in postoperative pain primarily by direct mechanical damage to the nerve endings. In addition inflammation causes release of endogenous chemical mediators, which activate nociceptors. If these nociceptive pathways are pharmacologically blocked by the so called preemptive analgesia prior to the surgical insult, the changes are diminished or prevented. Prolonged postoperative analgesia with Tramadol could be due to preemptive analgesia, other explanation being the prolonged action of the active metabolite of Tramadol, O-desmethyl Tramadol, which has longer half-life (7.6 ± 1.1 hours) than the parent drug [22], with half-life of 5.2 ± 0.9 hours and has analgesic action similar to the parent drug. Tramadol, with its dual mechanism of action appears to be an ideal agent to be used in IVRA.

Study by Armstrong P *et al.* [23] designed to investigate the effects of the addition of Fentanyl 2.5 μ g/ml-1 to 0.5% prilocaine during IVRA and found that Fentanyl had no potentiating effect on onset or duration of nerve blockade in IVRA, but it did cause an increase in nausea and potentiation of blockade *in vivo* which appears to be a central effect and have found an incidence of 20% dizziness and 46% nausea with the use of Fentanyl.

In our study to avoid the adverse central effect of Fentanyl, we used lower dose of Fentanyl with Lignocaine for IVRA which was less compared to the dosage used in the above study. It was observed that a total of seven patients experienced side effects when lignocaine + fentanyl was used to induce IVRA, vomiting was seen in 3.33% nausea, was seen in 10% and pruritus was seen in 10% of patients, compared to lignocaine + tramadol group where only five patients experienced side effects such as vomiting was seen in 3.33%, nausea was seen in 10% and pruritus was seen in 3.33% of patients. There was no significant ($p > 0.05$) statistical difference in the pattern of complications observed.

Tourniquet pain is generally considered the main factor limiting the duration of IVRA use. The mechanism of tourniquet pain remains unclear despite the role of A fibres and unmyelinated C fibres. It has been suggested that drugs with local anaesthetic activity added to LA solutions in IVRA may be of benefit to reduce tourniquet pain.

Goel SN *et al.* [11] in their study noted incidence of tourniquet pain intraoperatively in 26.6% of total patients. Langlois G *et al.* [12] noted in their study that VAS scores were similar between the control and Tramadol group. Acalovschi I *et al.* [20] in their study noted increased incidence of skin rash below the tourniquet level in Tramadol - Lignocaine group (9 patients) when compared with Lignocaine group (0 patient) ($p < 0.01$). Five patients in

Tramadol – Lignocaine group versus one patient in Lignocaine group complained of painful or burning sensation at the injection site ($p < 0.05$).

Tourniquet pain could be due to insufficient exsanguination of limb, as most of the patients had painful limb, this perhaps led to dilution of the IVRA drug which resulted in inadequate analgesia and hence tourniquet pain intraoperatively. This could have been avoided by simultaneous arterial compression while the extremity was being exsanguinated.

In our study, in both the groups there was no significant ($p > 0.05$) statistical difference in the occurrence of intraoperative side effects such as perioral numbness and tourniquet pain.

Santosh *et al.*,^[25] reported statistically significant delay in onset of motor block when used fentanyl as an adjuvant to lignocaine as compared with control group. Siddiqui *et al.*^[26], compared tramadol as an adjunct to lignocaine for IVRA with the control group and found that tramadol shortens the sensory block onset time which was statistically significant. Similarly Chakole *et al.*,^[27] compared tramadol as an adjunct to lignocaine for IVRA with the control group and found significantly shorter sensory block onset time in tramadol group. Tramadol modifies the action of lignocaine, providing shorter onset times^[20, 28].

The mean duration for onset of sensory blockade in our study was significantly lower in group B (Lignocaine-Tramadol) compared to group A (Lignocaine-Fentanyl). It was observed that 26.67% of patients in Group B (Lignocaine-Tramadol) could achieve sensory blockade after IVRA within 3 – 5 minutes compared to 3.3% in group A, 66.67% of patients in Group B (Lignocaine-Tramadol) could achieve sensory blockade after IVRA within 5.01 – 8 minutes compared to 43.3% in group A (Lignocaine-Fentanyl), 6.67% of patients in Group B (Lignocaine-Tramadol) could achieve sensory blockade after IVRA within 8.01 – 11 minutes compared to 43.3% in group A (Lignocaine-Fentanyl).

The mean duration for onset of motor blockade in our study was significantly ($p < 0.001$) lower in group B (Lignocaine-Tramadol) compared to group A (Lignocaine-Fentanyl). It was observed that 50% of patients in Group B (Lignocaine-Tramadol) could achieve motor blockade after IVRA within 8 – 11 minutes compared to 6.67% in group A (Lignocaine-Fentanyl), 50% of patients in Group B (Lignocaine-Tramadol) could achieve motor blockade after IVRA within 11.01 – 14 minutes compared to 53.3% in group A (Lignocaine-Fentanyl), 40% of patients in group A (Lignocaine-Fentanyl) required > 14 minutes to achieve a motor block.

From the above studies, by Siddiqui and Chakole, it was observed that onset of sensory blockade was earlier in the tramadol group compared to other additives used in their respective studies, which is similar to the results of our study and thereby supporting tramadol is superior to fentanyl in this aspect of onset of sensory and motor blockade.

Siddiqui *et al.*,^[26] when added tramadol as an adjuvant to local anaesthetic found improved perioperative analgesia and better tourniquet tolerance rendering operative conditions satisfactory similar to our study. From our study results it implies that the admixture of tramadol 1 mg/kg-1 with 40 ml of 0.5% Lignocaine in IVRA for upper limb surgeries has longer postoperative analgesia with minimal

side effects.

Limitations: -The dose of Fentanyl we used in our study was small. We used smaller dose to avoid CNS side effects associated with the use of Fentanyl.

-There is no significant difference between the two groups with associated complications like nausea, giddiness, burning sensation at injection site.

Conclusion

In the present study it was observed that group B (LIGNOCAINE + TRAMADOL) had a greater duration of analgesia compared to group A (LIGNOCAINE + FENTANYL). 86.67% of patients in group B (LIGNOCAINE + TRAMADOL) had analgesia for a duration of 7 – 12 hrs compared to group A (LIGNOCAINE + FENTANYL) where 80% of patients had analgesia for 0-6 hrs. Mean additional dosage requirement in group A (LIGNOCAINE + FENTANYL) was significantly ($p < 0.001$) higher compared to group B (LIGNOCAINE + TRAMADOL) 66.67% of patients in group A (LIGNOCAINE + FENTANYL) required 3 doses of injection diclofenac and 20% patients required 4 doses of injection diclofenac to achieve sustained analgesia compared to group B (LIGNOCAINE + TRAMADOL) where 50% patients required 2 doses and 46.67% patients required only one dose of injection diclofenac to achieve sustained analgesia post IVRA.

Based on the results obtained from our study we conclude that Tramadol as a component of IVRA had significantly longer postoperative analgesia as compared to Fentanyl added to Lignocaine for upper limb surgery.

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