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Original Article

Effect of Addition of Cisatracurium to Lignocaine versus plain Lignocaine for Intravenous Regional Anesthesia; A Quasi Experimental Study

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ABSTRACT

Objective: To compare the efficacy and safety of the addition of Cisatracurium to Lignocaine versusplain Lignocaine for IVRA.
Study Design: Quasi experimental study.
Place and Duration of Study: Combined Military Hospital, Rawalpindi Pakistan, from Jun to Dec 2023.
Methodology: Forty-four patients undergoing elective hand surgery were randomly assigned to two groups of 22 patients each. All demographic details were noted, all were briefed about VAS (0 to 10) for pain. Group 1 received Lignocaine 2%; Group 2 received Cisatracurium plus Lignocaine 2%. Standard technique was employed for IVRA. Following were assessed: onset and offset of sensory and motor block, quality of anesthesia using a numerical scale scored 1-4, postoperative pain using VAS measured at 5-minute,1, 2, 4, 8 hours and the time to first analgesic request.
Results: The onset times of sensory & motor blocks were significantly shorter (p=0.001 & p<0.001) and the regression times of sensory & motor blocks were prolonged (p=0.003 & p<0.001) in group B compared with the group A. The Cisatracurium group had better quality of anesthesia (p<0.001). Overall, lower mean VAS pain scores were recorded after tourniquet deflation and longer time to the first analgesic request (p<0.001) was recorded in Cisatracurium group post-operatively.
Conclusion: The addition of Cisatracurium to Lignocaine in IVRA, shortened the block onset times, prolonged the block offset times, improved the quality of anesthesia & decreased the post-operative pain & time to first analgesic requirement.

Keywords: Cisatracurium, Intravenous Anesthesia, Lignocaine, Regional.

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INTRODUCTION

Regional anesthesia has proved an important tool of modern anesthetic clinical practice. It has many advantages e.g., increased patient satisfaction, quick recovery, and enhanced safety.[1]

Intravenous regional anesthesia (Bier's Block) is a method of producing analgesia in the distal part of a limb by intravenous injection of a local analgesic solution into the vein of the same limb, while circulation to the limb is occluded by the application of tourniquet. This method of peripheral block was discovered by August Bier in 1908,[2] and was revived in 1963 by Holmes CMCK, who substituted Lignocaine for procaine.[3]

Intravenous regional anesthesia (IVRA) is most useful for surgery on arms but can be used for legs as well and is an effective method for providing anesthesia as well as a bloodless field during surgery. Intravenous regional anesthesia is easy to perform, reliable, and cost-effective, which makes it ideal for short operative procedures on the extremities.[4]

However, Intravenous regional anesthesia (IVRA) is not devoid of unwanted effects e.g., local anesthetic toxicity, delayed onset of action, poor muscle relaxation, tolerance of tourniquet time is short, rapid onset of post-deflation pain.[5]

Various techniques have been used to prevent and decrease these complications of IVRA. (a) The addition of a small amount of muscle relaxant to IVRA has been shown to provide good muscle relaxation in the arm.[6] The addition of different doses of Atracurium to Lignocaine for IVRA resulted in fast onset of sensory and motor block, a decrease in the severity of tourniquet pain, more satisfaction for the patients and surgeons without side effects from increasing Atracurium doses.[7] (b) Recently, use of

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improved forearm tourniquet technique has diminished tourniquet pain and potentially improved safety with the use of decreased local anesthetic volumes.[8,9] (c) In an attempt to improve perioperative analgesia and to shorten onset time of sensory and motor block, various drugs (Morphine, Fentanyl, Meperidine, Aspirin, Ketorolac, and Bicarbonate are among those agents) have been administered concomitantly with the local anesthetic in IVRA with controversial results.[10]

The ideal IVRA must have the following features: rapid onset, reduced intraoperative pain, and prolonged post–deflation analgesia in addition to minimum side effects. This study was undertaken to examine the possible clinical advantages of using muscle relaxant with IVRA.

METHODOLOGY

This Quasi Experimental study without any blinding technique was conducted according to the codes of the declaration of Helsinki. The study protocol was approved by the Ethical Committee/ Institutional Review Board of the Combined Military Hospital Rawalpindi, Pakistan (Ser No 446 of June 2023, ClinicalTrials.gov ID is NCT06214169). It was carried out at Department of Anesthesiology of Combined Military Hospital Rawalpindi from June to December 2023. The sample size was calculated using the WHO sample Size Calculator taking confidence interval 95%, margin of error 5%, mean motor block regression time for Control group as 4.5±2.31 minutes and motor block regression time as 17.8±9.5 minutes in the Cisatracurium group.[4] Nonprobability consecutive sampling technique was adopted.

Inclusion Criteria: All ASA physical status I & II patients between 20 to 55 years of age, scheduled for elective hand surgery (carpal tunnel, trigger finger, tendon release, fracture reduction and tendon repair) who gave informed written consent were included.

Exclusion Criteria: Patients with Raynaud disease, sickle cell anemia, or a history of allergy to any drug to be used were excluded. Also, patients who had bleeding tendency, on anticoagulant or antiplatelet therapy, significant cardiovascular, peripheral vascular or neurological disease were excluded.

A total of forty-four participants were randomly allocated into two groups according to the Block Randomization Principle. All eligible patients had equal chances of being placed in any of the two treatment groups without any specific patient preference. The two groups were Group 1(Plain lignocaine group) and Group 2(Cisatracurium + Plain lignocaine group). Blinding was adopted for participants and data collector (Figure).

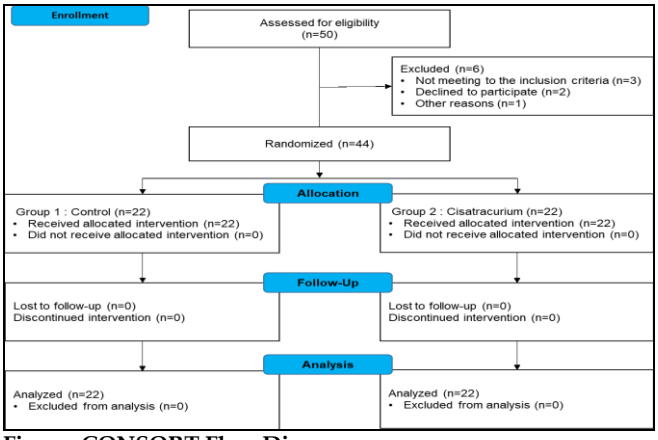

Figure: CONSORT Flow Diagram

All included patients were briefed about Visual Analogue Score (VAS) for pain, with scores from 0 to 10, where 0 = the absence of pain and 10 = worst possible pain. Patients age, gender, weight, pulse, blood pressure was recorded. On the day of procedure routine monitoring was established, including electrocardiography (lead II), non-invasive blood pressure and peripheral oxygen saturation. Then two cannulas were placed: one in a vein on the dorsum of the operative hand and the other in the opposite hand for IV Fluids and a double tourniquet was positioned on the upper operative arm. Patients were pre medicated with 0.07 mg/kg Midazolam intravenously. An infusion of 5% dextrose in 0.9% saline was begun in the normal limb. The operative arm was elevated for 2 min and was then exsanguinated with an Esmarch bandage. A pneumatic tourniquet was then placed around the upper arm, and the proximal cuff was inflated to 100 mmHg more than the systolic blood pressure to a minimum of 250 mmHg, and the bandage was removed. Circulatory isolation of the arm was verified by inspection, absence of a radial pulse, and a loss of the pulse oximetry tracing in the ipsilateral index finger. Patients were randomly allocated (according to Block Randomization Principle) into two equal groups (22 patients each): Group 1 (control group): IVRA was achieved using 3 mg/kg body weight Lignocaine 2% diluted with saline to a total volume of 40 ml. Group 2 (Cisatracurium group): IVRA was achieved using 0.01 mg/kg of Cisatracurium besylate plus 3 mg/kg

Lignocaine 2 % diluted with saline to a total volume of 40 ml. Sensory block was assessed by pinprick with a 22-gauge short-beveled needle, every 30 second. Patient response was evaluated in the dermatomal sensory distribution of the medial and lateral antebrachial cutaneous, ulnar, median, and radial nerves. Motor function was assessed by asking the subject to flex and extend his/her wrist and fingers; complete motor block was noted when no voluntary movement was possible.

Onset of sensory block was defined as the time elapsed from injection of the study drug to sensory block achieved in all dermatomes, and onset of motor block was defined as the time elapsed from injection of the study drug to complete motor block. After sensory and motor block onset, the operative tourniquet (distal cuff) was inflated to 250 mm Hg, the surgery was started. Heart rate, systolic and diastolic blood pressure and oxygen saturation were monitored by an automatic (NIBP) monitor before tourniquet application and then throughout the duration of surgery. The onset and regression times for sensory and motor blocks and the severity of intraoperative pain (tourniquet pain) were recorded. The severity of intraoperative pain was assessed using 10 cm VAS at 5, 10, 20, 30 minutes after tourniquet application where 0 = the absence of pain and 10 = worst possible pain. Patients with intraoperative VAS score more than 3 were given Fentanyl 1 ug/kg. Number of patients and total dose of Fentanyl were recorded. The tourniquet was not deflated before 30 min. At the end of surgery, the tourniquet was deflated gradually. Sensory recovery time (the time elapsed from tourniquet deflation to recovery of sensation in all dermatomes, determined by pinprick test) and motor block recovery time (the time elapsed from tourniquet deflation until movement of fingers) were recorded.

Postoperative pain was assessed by VAS at 5 minutes after tourniquet deflation and at 1, 2, 4, 8 hours postoperatively. Intramuscular diclofenac sodium 75 mg was administered if the VAS was more than 3 in the first 8 hours postoperatively. The first analgesic requirement time was also noted (the time elapsed from tourniquet release until first request for analgesic). Incidence of side effects such as tinnitus, dizziness, convulsions, gastric discomfort, muscle weakness and bleeding tendency were recorded.

Following the procedure's conclusion, the evaluation of anesthesia quality was conducted using a numerical scale as outlined: 4 = outstanding (no patient complaints); 3 = satisfactory (minor complaints without the necessity for additional analgesics); 2 = moderate (complaints necessitating supplemental analgesics); 1 = ineffective (block failure, requiring general anesthesia).

All the observations were recorded in specially designed data collection sheets and processed using computer-based software (SPSS version 26). Results were expressed as Mean±SD. Demographic data, duration of surgery, tourniquet times, sensory and motor block onset, and regression time and analgesic requirement were analyzed using Student's t test. Gender distribution was analyzed with Chi-square test. Quality of anesthesia was analyzed using the Mann-Whitney U test. *p*-values less than 0.05 were considered as statistically significant.

RESULTS

Forty-four patients who underwent hand surgeries under IVRA were randomly divided into two equal groups of 22 patients each. The mean age, sex, patient weight and duration of surgery were not different significantly between the two groups as shown in Table-I.

Table–I: Patients Characteristics (n=44)

Variables		Group 1 (n=22) (Mean±SD)	Group 2 (n=22) (Mean±SD)	*p*-value
Age (year)		35.55±8.70	39.73±7.94	0.10
Gender	Male	10(22.72%)	10(22.72%)	Not Significant
	Female	12(27.27%)	12(27.27%)	
Weight (kg)		72.95±7.83	75.09±7.25	0.35
Duration of surgery (min)		41.59±10.16	41.26±12.81	0.6

The onset time of the sensory block was significantly shorter for group 1 as compared to group 2 while the offset time of this block was significantly longer in group 2 when compared with group 1. The onset time of the motor block was significantly shorter in group 2 compared with the group 1. As regards the time to the first analgesic request, group 2 showed a significant longer time compared with the group 1. Also, the regression time of the motor block was significantly longer in group 2 compared with group 1 as shown in Table-II.

Table-III shows postoperative pain score as judged by VAS at 5 minutes after tourniquet deflation and at 1, 2, 4, 8 hours postoperatively. Analysis of these scores with Mann Whitney u test shows significant difference between the two groups at each of the times.

Table-II: The onset and regression of the sensory and motor blocks (n=44)

Variables	Group 1 (n=22) (Mean±SD)	Group 2 (n=22) (Mean±SD)	*p*-value
Sensory block onset time (min)	4.30±0.70	3.50±0.71	0.001*
Sensory block regression time (min)	3.41±0.55	4.02±0.75	0.003*
Motor block onset time (min)	5.98±1.07	4.11±1.02	<0.001*
Motor block regression time (min)	3.66±1.35	8.71±1.46	<0.001*
Time to the first analgesic request (hours)	1.41±0.55	2.07±0.57	<0.001*

(*): Indicates significant difference (p-value <0.05).

Table-III: Comparison of Postoperative Pain Score in the two Groups (n=44)

Parameters	Group 1 (n=22) Median (IQR)	Group 2 (n=22) Median (IQR)	*p*-value
Postop pain after 5 minutes	5.50 (3.00)	4.00 (1.25)	0.003
Postop pain after 1 hour	4.00 (1.25)	3.00 (1.50)	0.002
Postop pain after 2 hours	5.00 (2.00)	4.00 (2.00)	0.001
Postop pain after 4 hours	5.00 (1.00)	5.00 (1.00)	0.003
Postop pain after 8 hours	5.00 (0.25)	4.00 (2.00)	0.004

(*): Indicates significant difference (p-value <0.05).

No patient in the two groups reported any side effects throughout the study period except one patient in the group 1 who complained of mild tinnitus which disappeared spontaneously within few minutes.

DISCUSSION

Since the description of IVRA by Holmes CM in 1960s,[3] IVRA has rapidly increased in its usage by anesthetists in upper limb surgeries especially in ambulatory settings due to it being more favorable for the patient's recovery profile and having a shorter postoperative nursing care and hospital discharge time as proposed by V W Chan.[11] The major advantages in using IVRA include its simplicity, reliability, cost-effectiveness and high success rates[12] while the major limitation in the usage of IVRA is the tourniquet pain that occurs due to limb ischemia and the lack of post- operative analgesics.[13] Over the years, various adjuncts have been studied for the possibility of improving quality of anesthesia in IVRA to reduce time of onset of motor and sensory blocks and requirement of analgesia during and after the procedure. These adjuncts include opioids, muscle relaxants, alpha-2 receptor agonists and other local anesthetics like bupivacaine or general anesthetics like ketamine either individually or in combinations.[12,14] Our study used Cisatracurium as an adjunct to Lignocaine to check its possible effectiveness in increasing quality of anesthesia.

The results of our study show that the onset of sensory and motor block occurred earlier in the Cisatracurium group as compared to the control group and this difference was statistically significant (p<0.05). Study determining the effect of addition of Cisatracurium to Lignocaine conducted by Esmaoglu A *et al.,*[4] in Turkey gave similar results with significantly earlier onset of sensory and motor block. In the study, the quality of anaesthesia was notably superior in the Cisatracurium group compared to the control group. Moreover, In Egypt by (n=44)[15] in 2016 & Magdy H *et al.,*[16] in 2022, studied Atracurium added Lignocaine in IVRA, which similar to Cisatracurium is an intermediate-acting non-depolarizing neuro-muscular blocking agent.[17] They reported similar findings of early onset of sensory & motor block when Atracurium was added to Lignocaine in IVRA. N. Kurt *et al.,*[18] in 2002 reports significant early onset of only the sensory block at hand but not at tourniquet site and also no significant difference in onset of motor block with the addition of Atracurium.

Prippenow G *et al.,*[6] in Germany in 1985 reported no change in onset of sensory block while a significant earlier onset in motor block upon use of Pancuronium, which also belongs to the same group of non-depolarizing neuromuscular blocking agent as of Cisatracurium,[19] as an adjuvant to Lignocaine. This could have been concluded due to the relatively small sample taken in the research. However, Elhakim M *et al.,*[20] & Arafa M *et al.,*[21] both in their researches reported no significant change in onset of motor or sensory block in patients administered with Atracurium added Lignocaine as compared to patients administered with only Lignocaine so our results are in opposition to theirs with regards to onset of sensory and motor block.

A probable mechanism which might explain early onset of sensory and motor block is that Lignocaine potentiates effect of Cisatracurium, although the exact mechanism of potentiation is unknown, and so it causes early onset of sensory and motor block which has effect on intra-operative and post-operative analgesic requirements as Cisatracurium blocks the neuromuscular junction at motor end plate before limb ischemia can occur whereby reducing analgesia requirements or improving the quality of analgesia.[14]

Regarding offset, our study shows that early onset of both the sensory and the motor block is also accompanied by a late regression in group B and this difference is significant (p<0.05). This finding is in line with the study conducted by Mekkawy SM *et al.,*[15] in

which the regression of motor & sensory block by Lignocaine in which Atracurium was added has been shown to be late as compared to the control group.[17] In contrast to this, Esmaoglu A *et al.,*[4] concluded that Sensory block regression time did not differ between the two groups. However, the Cisatracurium group exhibited a statistically longer motor block regression time with lesser analgesic requirement. Similar findings of no significant change in regression of sensory block & late regression of motor block with Atracurium was studied by Magdy H *et al.,*[16] & Elhakim M *et al.,*[20] in their respective researches. Prippenow G *et al.,*[6] who studied the effect of addition of Pancuronium in Lignocaine also came to the same result of late regression of only the motor block in IVRA. With regards to regression of the sensory and motor block, the late regression of sensory block is helpful as it increases the time required before use of first analgesic is necessary after the procedure as has been demonstrated in our study where Group B required more time before use of first analgesic post-op as compared to group A and this difference was statistically significant (p<0.005). The late regression of motor block, however, is not desirable as prolonged hospital stays may result, and certain side effects associated with it can further complicate patient care.[22]

It is known that Cisatracurium undergoes degradation by temperature or pH dependent mechanisms also known as Hoffman degradation.[23] In IVRA, the limb ischemia which occurs, while the tourniquet is tied & due to the vasoconstrictor action of Lignocaine, causes metabolic acidosis and this acidosis reduces the Hoffman degradation that would have happened to Cisatracurium hence, causing later regression of sensory and motor block and allowing the components involved in IVRA to work in harmony.[18]

Our study also reported significant reduction in mean intra-operative pain VAS scores which also accompanied less use of intra-operative analgesia as compared to Group A. This difference was statistically significant. This is a good sign as it shows that effectiveness of IVRA increased after the addition of Cisatracurium and this caused less requirement of intra operative analgesia and hence sparing the patient from possible toxicity/ side effects of the analgesic & increasing the quality of anesthesia. This finding is also supported by Esmaoglu A *et al.,*[4] who used Cisatracurium & Magdy H *et al.,*[16] & Elhakim M *et al.,*[20] who used Atracurium in their studies reporting less pain during anesthesia and overall better operating conditions due to the accompanying muscle relaxation. However, opposing results were reported by Mekkawy SM *et al.,*[15] & N. Kurt *et al.,*[18] proposing no significant effect of Atracurium on tourniquet pain intra-operatively.

This study also reported an overall better mean post-operative VAS score across group B as compared to group A & a later use of first post-operative analgesic. This difference of better mean post-operative VAS score being statistically significant (p<0.05) lead to subsequent late administration of first analgesic and overall better quality of analgesia. This can be explained by the fact that addition of Cisatracurium allowed early motor block which reduces oxygen requirement of muscles and hence, less chance of limb ischemia which is postulated to be a cause of pain[24] and the longer duration of sensory block which means analgesic effect remains longer. Esmaoglu A *et al.,*[4] & Elhakim M *et al.,*[20] reported similar improvement in post-operative analgesia by addition of a non-depolarizing neuromuscular blocking agent .i.e. Cisatracurium & Atracurium respectively. Study conducted by Mekkawy SM *et al.,*[15] indicated that the postoperative VAS score was significantly lower up to 12 hours after the operation when Atracurium was combined with Lignocaine as compared to plain Lignocaine. However, there was no significant difference observed between the two groups 24 hours post-surgery. In opposition to this, Magdy H *et al.,*[16] & N. Kurt *et al.,*[18] concluded no significant difference in post-operative analgesia by the addition of Atracurium in Lignocaine during IVRA.

Esmaoglu A *et al.,*[4] who used Cisatracurium & Magdy H *et al.,*[16] who used Atracurium in their studies where use of Atracurium produced better quality of anesthesia with the study reporting less pain during anesthesia and overall better operating conditions due to the accompanying muscle relaxation. However, opposing results were reported by Mekkawy SM *et al.,*[15] proposing no significant effect of Atracurium addition to Lignocaine on the quality of anesthesia.

The only side effect reported in our study was one instance of dizziness This is significant as it showed that use of Cisatracurium as an adjuvant to Lignocaine in IVRA did not cause noticeable side effect or toxicity of anesthetic. Our finding is supported by other studies as well and no other studies have reported significant side effects on

addition of muscle relaxants to IVRA.[4,15,18,20] This provides an aspect of reducing the dose of anesthetic upon addition of adjuvant and more work needs to be done in this regard as very little work has been done to check dose adjustment of local anesthetic on addition of adjuvant.

The present study was limited by the use of a narrow dose range of Cisatracurium. We used only the recommended dose, and further comparison trials are therefore required to establish the optimal dose of Cisatracurium and its efficacy in augmentation of IVRA.

Furthermore, one of the major limitations of IVRA continues to be the lack of postoperative analgesia following tourniquet deflation. Trials to date have failed to identify an adjunct that provides consistent postoperative analgesia without an increase in minor side effects. Future studies should focus their investigations on novel adjuncts that can provide effective post deflation analgesia.

One of the strengths of the current study was a random allocation of participants and a lack of difference regarding demographic characteristics among the study groups; hence, the confounding impacts of such features were eliminated due to the homogeneity of the study groups.

CONCLUSION

In conclusion, the addition of Cisatracurium to Lignocaine in intravenous regional anesthesia shortened the sensory and motor block onset times, prolonged the sensory and motor block offset times, improved the quality of anesthesia & decreased the overall mean VAS pain score post-operatively & also prolonged the time to first analgesic requirement without causing clinical side effects.

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Authors' Contribution

Following authors have made substantial contributions to the manuscript as under:

MMI & SQAS: Data acquisition, data analysis, critical review, approval of the final version to be published.

MI & MRI: Study design, data interpretation, drafting the manuscript, critical review, approval of the final version to be published.

MRI & AS: Conception, data acquisition, drafting the manuscript, approval of the final version to be published.

Authors agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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