COMPARATIVE EVALUATION OF ADDING CLONIDINE V/S DEXMEDETOMIDINE TO LIGNOCAINE DURING BIER'S BLOCK IN UPPER LIMB ORTHOPEDIC SURGERIES

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ABSTRACT: BACKGROUND AND AIMS: Intravenous regional anaesthesia is used for short procedures for upper limb and hand surgery. IVRA with adjuvants like opioids, NSAIDS, muscle relaxants increases the efficacy in terms of analgesic duration and quality of anaesthesia. We conducted this study for evaluation of adding clonidine with dexmedetomidine during bier's block in upper limb orthopedic surgeries. MATERIAL AND METHODS: Sixty patients of American society of anaesthesiologist (ASA) class I, II, III patients undergoing upper limb surgeries were enrolled. IVRA was established using 3mg/kg of 0.5% lignocaine diluted with saline to a total volume of 40ml to which 1µg/kg of clonidine in group I or 1µg/kg dexmedetomidine in group II was added. The sensory block and motor block onset and recovery, hemodynamic parameters sedation score, VAS score, doses of analgesic requirement, patient satisfaction score, surgeon satisfaction score were noted and recorded at 15min, 30min, 1hr, 2hr, 3hr, 12hr and 24hr time interval. RESULTS: Both like groups were comparable with respect to age, sex, weight, ASA grade, baseline hemodynamic vitals, duration of surgery and intra-operative and post-operative hemodynamic variables. Sensory block onset and recovery was 4.85 ±0.49 min and 5.9±0.66 min in group II (LD). Motor block onset and recovery was 10.91 ± 0.6 min and 6.83 ± 0.69 min in group I (LC) and 11.2 ± 0.59 min and 7.13 ± 0.57 min respectively in group II (LD). **CONCLUSION:** The addition of 1µg/kg of clonidine or 1µg/kg or 1µg/kg of dexmedetomidine to 3mg/kg of 0.5% of lignocaine is found to be effective, comparable in terms of onset and recovery of sensory and motor blockade, hemodynamically stable and without any side effects and complications.

KEYWORDS: Bier's block or IVRA, clonidine, dexmedetomidine, VAS score, sedation score.

INTRODUCTION: Bier's block is ideal for short surgical procedures of anticipated duration of 60-90 minutes on hand and forearm. It is an ideal technique for short operative procedures on extremities, performed on day care basis.¹ Regional anaesthesia has more to offer in orthopedic surgery than in any other surgical speciality.² Advancements in this field of IVRA have been primarily aimed at increasing the tourniquet tolerance, improving the overall quality of intra-operative, post-operative analgesia and reducing the drug related adverse effects.¹ Various local anaesthetic agents like lignocaine, bupivacaine, mepivacaine and procaine have been used for Bier's block. Prilocaine is used widely in Europe.³ Lignocaine remains the standard local anaesthetic agent for surgical procedures in many countries, especially North America.⁴ Several local anaesthetic agents that have been used are, opioids like fentanyl,⁵ pethidine,⁶ tramadol,⁶ NSAIDs like ketorolac,⁶ acetylsalicylate,⁶ lornoxicam,¹⁰ dexamethsone, butorphanol and muscle relaxants eg. Atracurium,¹¹ neostigmine¹² and ketamine. Lately magnesium¹³ have also been tried. However none of them have proved to be ideal. Recently, α-

2 adrenergic receptor agonists have been the focus of interest for their sedative, analgesic, perioperative sympatholytic and cardiovascular stabilizing effects in addition to their general anaesthetic sparing effects and ability to prolong local anaesthetic induced analgesia when used in regional blocks. ¹⁴ Clonidine is a centrally acting selective partial α -2 agonist. Activation of postsynaptic α -2 receptors in substantia gelatinosa of the spinal cord produces analgesia. ¹⁵ The addition of clonidine to local anaesthetic in IVRA have demonstrated reduced tourniquet pain and improved post-operative pain relief. Dexmedetomidine is a potent α -2 adrenoreceptor agonist. Dexmedetomidine-lignocaine mixture has been used recently to provide Bier's block and has been shown to improve the quality of anaesthesia, tourniquet pain and reduce post-operative analgesic requirement. ¹⁶ These reports suggest that dexmedetomidine would be a better adjuvant to lignocaine in providing bier's block than clonidine. However, there is no direct study till date directly comparing the two drugs as adjuncts to local anaesthestic in bier's block in patients of ASA grade I, II and III. Therefore the present study was carried out to evaluate the effects of adding either clonidine or dexmedetomidine to lignocaine for bier's block or IVRA.

MATERIAL AND METHODS: It was a prospective, randomized double blind study in which 60 patients in the age group of 18-65 years of either sex, with American Society of Anaesthesiologists (ASA) class, I II and III were admitted and scheduled for elective upper limb orthopedic surgeries were included after the approval of institution's ethical committee and taking the informed consent from the patient. Patients with coagulation disorder, unwilling for block, sickle cell anaemia, allergy to study drug were excluded from the study. They were randomly divided into two groups of 30 each as group I lignocaine clonidine (LC) and group II lignocaine dexmedetomidine (LD). Sample size was decided after consulting the statistician to get Power >85% taking into consideration the parameters of mean duration of analgesia. The interpretations of visual linear analogue scale were explained one day before the operation to the selected patients. This was carried out with 10 cm line. The first end mark '0' means 'no pain' and the end marked '10' means 'severe pain'. The patients were asked to mark the severity of pain experienced. All patients were given tab Alprazolam 0.25mg one night before operation. Sedatives were omitted on the day of surgery. Group I (LC): Clonidine as an adjuvant with lignocaine. Group II (LD): Dexmedetomidine as an adjuvant with lignocaine.

TECHNIQUE: Multipara monitor was applied and baseline ECG, pulse rate (PR), non-invasive systolic and diastolic blood pressure and peripheral arterial saturation (SPO₂), were monitored. Before establishing the anaesthetic block, two intra-venous cannulas were placed, one in a vein on the dorsum of the operative hand and the other in the opposite hand for crystalloid infusion. The operative arm was elevated for 3 minutes then exsanguinated with an Esmarch bandage. A pneumatic tourniquet was placed around the upper arm and the proximal cuff was inflated to 100 mmHg more than systolic BP to a minimum of 250 mmHg and the Esmarch bandage was removed. Circulatory isolation of the arm was verified by inspection, absent of radial pulse, and loss of pulse-oximetry tracing of the ipsilateral index finger. IVRA was established using 3 mg/kg of 0.5% lignocaine, diluted with saline to a total volume of 40ml to which 1 μ g/kg of clonidine or 1 μ g/kg dexmedetomidine was added. Drug was then slowly injected into in dwelling cannula and the patient warned that the limb may start feeling hot and the skin would take on mottled appearance. The sensory block onset was assessed by a pinprick method performed by a 25 G short bevelled needle at every 30 seconds

interval at forearm or hand or intact skin from the time of injecting drugs till the pinprick sensation was absent and it was taken as sensory block onset time. The sensation was tested in the dermatomal distribution of lateral, medial, antebrachial cutaneous, radial, median and ulnar nerve. The onset of motor block was defined as time elapsed from injection of local anaesthetic mixture till achieving a complete motor block. Motor function was assessed by asking the patient to flex and extend his/her wrist at 30sec intervals and complete motor block was achieved when no voluntary movement was possible. The distal tourniquet was inflated to 250 mmHg after the achievement of sensory and motor block. The proximal tourniquet was released and surgery was allowed to commence. Tourniquet was not deflated before 30 minutes even if the surgery finished and was not kept inflated for >1.5 hour. After the completion of surgery, tourniquet deflation was performed by the cyclic deflation technique. Cyclic deflation prevents release of drug in the circulation at one go so as to prevent the hemodynamic instability. Sensory and motor blocks were then tested and the regression times were noted. Sensory regression was assessed at these nerve sites at 2 minute interval after tourniquet deflation, till the pinprick score returned to the baseline value. Complete recovery of motor power assessed by asking patient to flex and extend his wrist and fingers at 30sec interval. Complete motor recovery was recorded when all voluntary movements were shown at the end of surgery and after removal of the tourniquet.

MONITORING: Continuous multipara monitoring was done to assess hemodynamic response. Readings were recorded every 5 minutes till the end of surgery and then 1 hourly till 6 hours. Pain (Tourniquet or post-operative) was assessed by using a 10 cm visual analogue scale (VAS). Inj. Butorphanol 0.5mg intravenous was given intra-operatively if patient complained of pain (VAS>3). An intramuscular dose of diclofenac sodium 75 mg was given post-operatively as and when required (VAS>3). Intra-operative butorphanol and post-operative diclofenac sodium consumption was recorded and the number of doses of diclofenac, were calculated. Sedation was assessed on a 1-5 numeric scale. Score was assessed as: 1-Completely awake, 2-Awake but drowsy, 3-Asleep but responsive to verbal commands, 4-Asleep but responsive to tactile stimuli, 5-Asleep and not responsive to any stimulus. The VAS for pain and sedation score was measured every 10 minutes during surgery, 15 minutes, 30 minutes and then in post-operative period at one hourly intervals till 4 hours and then every 4 hourly till 24 hours. Onset and regression time for sensory and motor blocks were noted.

PATIENT SATISFACTION SCORE: Patient satisfaction score was recorded post-operatively after 24 hours. It was coded as 5-Very satisfied, 4-Satisfied, 3-Neutral, 2-Dissatisfied, 1-Very dissatisfied. Any side effects or complications (systemic or local) were noted.

STATISTICAL ANALYSIS: The data from the present study were systematically collected, compiled and analyzed to draw relevant conclusions for the above mentioned parameters and patient's characteristics were compared using appropriate statistical tests, the non-parametric data were analyzed using the 'Chi-Square tests' and the parametric data were analyzed using the 'Unpaired "t" test'. The 'p-value' was determined to finally evaluate the levels of significance. The 'p-value' of <0.05 was considered significant and the 'p-value' of <0.001 was considered highly significant. The results were analyzed and compared to previous studies.

RESULTS: Both the groups were comparable with respect to age, sex, weight, ASA grade, baseline hemodynamic vitals, and duration of surgery, intra-operative and post-operative hemodynamic variables. Sensory block onset and recovery was 4.85±0.49 minutes and 5.9±0.66 minutes respectively in group I (LC) and 5.01±0.42 minutes and 6.2±0.56 minutes respectively in group II (LD). Motor block onset and recovery was 10.91±0.6 minutes and 6.83±0.69 minutes respectively in group I (LC) and 11.2±0.59 minutes and 7.13±0.57 minutes respectively in group II (LD). Both the groups were comparable with respect to onset and recovery of both sensory and motor block. The VAS score in intra-operative period was significantly higher in group I (LC) at 20 min, 30 min, 40 min and at 50 min time interval, than in group II (LD). During post-operative period VAS score was significantly higher at 15 min, 30 min, 1hr, 2 hr, 3 hr, and 12 hr and at 20 hr time intervals, in group I (LC) than in group II (LD). The mean rescue analgesia requirement in intra-operative period in group I (LC) was 0.367±0.49 doses, while none of the patients required any rescue analgesia in group II (LD). During post-operative period mean rescue analgesia requirement in group I (LC) was 3±0 doses, while in group II (LD), it was 2.23±0.43 doses, which was significantly higher in group I (LC) than in group II (LD).

The mean sedation score during intra-operative period in both the groups was equal and was 1 (completely awake). During post-operative period significantly higher sedation was observed at 15 min, 30 min and at 1 hr interval in group I (LC) as compared to group II (LD). The maximum sedation score achieved was 3 i.e. asleep but responsive to verbal commands. The mean duration of analgesia, based on the time for request of first dose of supplement analgesic, in group I (LC) was 2.8 ± 0.66 hr, while in group II (LD) was 8.67 ± 2.12 hr in group II (LD), which was significantly longer in group II (LD) as compared to group I (LC). The surgeon satisfaction score was equal in both the groups, which was 3(3-3) i.e. 'perfect'. The patient satisfaction was significantly higher in group II (LD) as compared to group I (LC). Quality of analgesia, as determined by the number of rescue analgesic doses during intra-operative and post-operative period, was better in group II (LD) than, as compared to group I (LC).

DISCUSSION: Intravenous regional anaesthesia is a safe and effective way to provide anaesthesia for hand and forearm surgeries expected for last less than 90mins. The main advantages of this technique are in its simplicity and reliability but with limitations such as lack of post-operative analgesia, tourniquet pain and limited tourniquet time. In an attempt to improve peri-operative analgesia various methods have been used which include systemic narcotics and non-steroidal anti-inflammatory drugs. However none of them have proven to be ideal, devoid of side effects that can be added to the local anaesthetic in Bier's block. Clonidine enhances peripheral nerve blocks of local anaesthetics by selectively blocking A δ and C fibres. Dexmedetomidine, a potent α_2 receptor agonist is approximately 8 times more selective towards α_2 receptors than clonidine. In present study we evaluated and compared the effects of adding either clonidine or dexmedetomidine to lignocaine for Bier's block in upper limb orthopedic surgeries. Baseline hemodynamic as mean pulse rate, mean systolic blood pressure, mean diastolic blood pressure and Spo₂ were comparable and found to be statistically insignificant in both the groups.

Dyck in a study observed that rapid dexmedetomidine intravenous administration produces abrupt bradycardia and hypertension until central sympatholytic effect dominates, resulting in a moderate decrease in both mean arterial pressure and heart rate from baseline.

No such hemodynamic changes were observed in our study, which could be due to the reason that in our study, we performed cyclic deflation technique during deflation after completion of surgery. 17

In our study, it was observed that in Group I (LC), mean onset of sensory block and the mean recovery time of sensory block in both the groups were found to be statistically insignificant. It was observed that mean motor block onset and mean motor block recovery in both the groups were found to statistically insignificant. Sensory block onset and recovery were 4.1+3.2min and 6.1 ± 2.3 min respectively while motor block onset and recovery 6.1 ± 3 and 6.2 ± 1.5 min respectively in clonidine group.

Esmaoglen in his study in 2005 on forty patients undergoing hand surgery, showed no significant difference in sensory and motor blockade using either $1\mu g/kg$ dexmedetomidine with 3mg/kg of 0.5% of lignocaine or 1ml saline with 3mg/kg of 0.5% of lignocaine in IVRA. Sensory block onset and recovery were 4.8 ± 2 and 4.5 ± 1.8 min respectively while motor blockade onset and recovery were observed to be 11 ± 4.6 and $5.4\pm1.7min$ respectively in dexmedetomidine group. Our results are in accordance with the results of these studies.

In our study, VAS score was measured at intervals of 10 min at 0, 10, 20, 30, 40, 50 minutes intra-operatively, at 0min, 15min, 30min, 1hr, 2hr, 3hr, 4hr, 8hr and at 4hr interval till 24hrs post operatively. Rescue analgesia in the form of 0.5 mg i.v of butorphanol, during intra-operative period and 75mg of diclofenac intramuscular during post-operative period was given if VAS score was >3. The VAS score was significantly higher at 20min, 30min, 40min, 50min, intra-operatively and 15min, 30min, 1hr, 2hr, 3hr, 12hr and at 20hr during post-operative period in group I (LC).

Abosedira MA in 2008 conducted a double blind study using either 1mcg/kg clonidine or 1mcg/kg dexmedetomidine with 3mg/kg of 0.5% lignocaine in IVRA. It was observed that the median VAS score was significantly lower in dexmedetomidine with lignocaine group than clonidine with lignocaine group in IVRA. 19

Alok in 2012 conducted a study with 1ml of Saline or 0.5mg/kg ketamine or 1mcg/kg of dexmedetomidine with 20ml of 1% lignocaine in IVRA. Post recovery mean VAS score was found to be 5.25±0.44min in lignocaine group, 3.21±0.41min in ketamine group and 3.21±0.41 in dexmedetomidine group. It was observed that addition of 1mcg/kg of dexmedetomidine-lignocaine in IVRA improves quality of anaesthesia, decreases post-operative recovery VAS score and decreases post-operative analgesic requirement. These results are in accordance with the result of these studies.²⁰

Gupta A in 2014 conducted a study with two different doses of dexmedetomidine as an adjunct to lignocaine in IVRA of upper limb surgeries and concluded that addition of $1\mu g/kg$ of dexmedetomidine to lignocaine for IVRA improves quality of anaesthesia and post-operative analgesia in comparison to $0.5\mu g/kg$ of dexmedetomidine.²¹

The mean total rescue analgesic consumption in the form of doses in both the groups were noted during intra-operative and post-operative period. Intra-operatively mean total rescue analgesic dose was.36±0.49 in LC combination group while none of the patient in LC required rescue analgesia intra-operatively. During post-operative dose of rescue analgesia in LC group was 3±0 and in group II (LD) was 2.23±0.43 which was statistically significant in group 1 (LC).

Sedation score intra-operative and postoperative period was done in the two groups with numeric sedation scale. The comparison was done at 10mins interval intra-operatively and at 0min,

5min, 15min, 30mins and at 1hr interval till 4hr. During post-operative-period comparison was done at 4hr interval till 24hrs. There was no sedation in the intra-operative period in both the groups. During post-operative period median sedation score at 15mins and 30 mins was higher in group II (LD). Sedation produced was higher in group II (LD) but short lived.

Our study was in accordance with the study done by Reuben who showed that there was no significant post-operative sedation for clonidine at dose of 1 μ g/kg used in IVRA. Gunes conducted a study in 2006 in which sedative effect of intravenous 1 μ g/kg of dexmedetomedine premedication administered 10 minutes before IVRA with 3 mg/kg of prilocaine was compared with IVRA with 1 μ g/kg of dexmedetomedine plus 3mg/kg of prilocaine. It was observed that adding 1 μ g/kg of dexmedetomedine to prilocaine in IVRA led to higher post-operative sedation score than dexmedetomedine intravenous premedication group. Our study was consistent with this study.

The mean duration of analgesia was 2.8 + 0.66 hours in group I (LC) and 8.67 + 2.12 hours in group II (LD). The difference was statistically significant between the two groups (p >0.05). Our study was in accordance with the study conducted by Swami SS who used 1 μ g/kg clonidine or 1μ g/kg of dexmedetomidine in 0.25% bupivacaine in brachial plexus block. He observed that dexmedetomidine when added to local anaesthetic in supraclavicular brachial plexus block enhanced duration of sensory and motor block and also the duration of analgesia. The time for rescue analgesia was prolonged in patients receiving dexmedetomidine.²³

No side effects like nausea, vomiting, hypertension, bradycardia and arrhythmias were observed in the study in both the groups. Quality of analgesia was determined by number of rescue analgesic doses given in intra-operative and postoperative period. In the intra-operative period 0.36 + 0.49 doses were given in the group I (LC) and no rescue analgesia in group II (LD). In the postoperative period 3+0 doses of rescue analgesia were given in LC group and 2.23 ± 0.43 doses of rescue analgesia in group II (LD). Quality of analgesia was found to be better in group II (LD) as compared to group I (LC). Surgeon satisfaction score between the two groups was found to be statistically non-significant and the mean patient satisfaction score in group I (LC) was 3.73 ± 0.21 and in group II (LD) was 4.46 ± 0.6 . The difference between two groups was statistically highly significant.

CONCLUSION: The addition of 1mcg/kg of clonidine or 1 mcg/kg of dexmedetomidine to 3mg/kg of 0.5% lignocaine is effective, comparable in terms of onset and recovery of sensory and motor blockade, hemodynamically stable and without any side effect and complications. However, group II mixture provides better quality of analgesia and longer duration of analgesia along with short lived post-deflation sedation.

Measured Parameter	Group I (LC)	Group II (LD)	p-value
Age(in years)	34.7±13.9	34.3±13.9	0.9
Weight (in kg)	67±5.6	68.8±4.9	0.17
Sex (M:F)	7:23	8:22	0.76
ASA grade (I:II:III)	16:11:3	14:14:2	0.7
Duration of surgery (in min)	41.63±6.9	40.57±7.8	0.58

Table 1: Demographic data

Measured Parameter	Group I (LC)	Group II (LD)	p-value
Sensory block onset	4.85±0.49	5.01±0.42	0.16
Motor block onset	10.9±0.6	11.02±0.59	0.66
Sensory block recovery	5.9±0.66	6.2±0.56	0.06
Motor block recovery	6.83±0.69	7.2±0.57	0.07

Table 2: Onset and regression of sensory and motor block

p-value>0.05; NS (not significant)

Time (min)	VAS Score		Sedation Score	
Time (min)	Group I (LC)	Group II (LD)	Group I(LC)	Group II (LD)
0	-	•	1(1)	1(1)
10	-	-	1(1)	1(1)
20	1(0-1)	0(0-1)*	1(1)	1(1)
30	2(1-3)	1(0-2)*	1(1)	1(1)
40	3(2-4)	1.5(1-2)*	1(1)	1(1)
50	3(2-4)	2(1-3)*	1(1)	1(1)
Table 3: Intra-operative VAS score and Sedation score				

VAS SCORE - *p-value<0.05; significant.

Measured parameters	Group I (LC)	Group II (LD)		
Intra-operative rescue analgesic requirement (dose)	0.36±0.49	0*		
Post-operative rescue analgesic requirement (dose)	3±0	2.23±0.43*		
No. of patients requiring rescue analgesia intra-operatively	11 (36.67%)	0*		
Duration of analgesia (hr)	2.8±0.66	8.67±2.12		
Surgeon satisfaction score	3	3		
Patient satisfaction score	3.73±0.21	4.46±0.6*		
Table 4				

*p-value<0.05: Significant

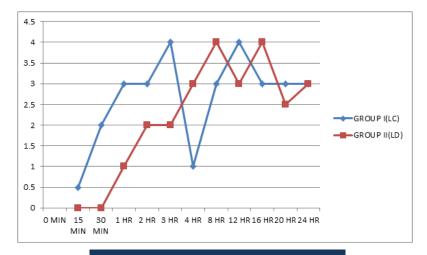


Figure 1: Post-operative VAS score

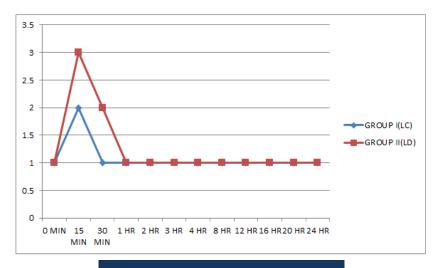


Figure 2: Post-operative sedation

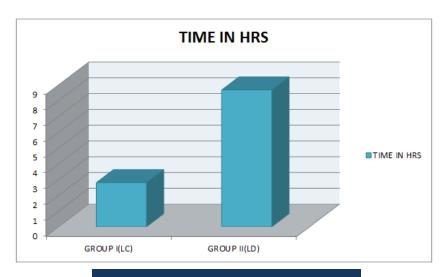


Figure 3: Total duration of analgesia

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