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Evaluation of the effect of Clonidine adjuvant with local anesthetic solution on the efficacy of Bier's block in upper limb surgeries

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Abstract

Background: Lidocaine remains an established local anesthetic agent of choice for intravenous regional anesthesia (IVRA), however widespread lidocaine use is contradicted by its short duration of action, hence different adjuvants have been used to counteract this issue. Clonidine when used with local anesthetic solutions produces a better analgesic effect in spinal, epidural or peripheral nerve blocks. This observation prompted us to conduct a prospective study and observe the effect of clonidine adjunct on the quality of block, particularly tourniquet time in intravenous regional anesthesia.

Methods: Sixty patients, of either gender, aged 18-65 years, ASA physical status I & II, undergoing upper extremity surgery expected to last one to one and half hours under Bier's Block were assigned randomly and blindly into two groups, group(I) received 40ml of 0.5% Lidocaine plus Clonidine (1µg/kg), and group(II) received 40ml of 0.5% Lidocaine plus Saline (1ml) for IVRA. Block characteristics, proximal and distal tourniquet time, and postoperative analgesia were evaluated.

Results: The duration of Proximal tourniquet tolerance (T1) was comparable between the two groups, (22.33± 1.762min for group 1, and 21.54± 2.749 min for group 2, ($p>0.05$). Distal tourniquet tolerance (T2) was however, better in the group receiving clonidine with lidocaine solution than in the group receiving plain lidocaine solution, 32.74±4.750min in group 1, compared to 26.64±3.689 min in group 2, ($p<0.0001$). VAS scores for tourniquet pain and pain in the extremity after tourniquet

deflation were significantly lower in clonidine group than in the plain lidocaine group. VAS at one hour after tourniquet deflation, 1.067±0.6915 in group 1, whereas it was, 2.900±1.398 in group 2, ($p<0.0001$). Similarly, pain score at two hours in group 1 was 1.367±0.7649, against 3.467±1.224 for group 2, ($p<0.0001$). The patients in the clonidine group experienced a prolonged pain free interval requiring no analgesia for 541.1±337.8 min as against 115.4±78.07 min in plain lidocaine group ($p<0.0001$).

Conclusion: the data shows a clear improvement in the quality of block in terms of tourniquet tolerance and postoperative analgesia by the addition of clonidine to 0.5% lidocaine solution used in IVRA.

Keywords: Bier's block, IVRA, anesthesia, upper limb surgeries, clonidine, lidocaine

Introduction

Bier's block or intravenous regional anesthesia (IVRA) was first described by August Bier in early twentieth century. Since the time of its introduction, this technique has stood the test of time and proved to be an effective means of providing regional anesthesia for short operative procedures performed on extremities. It is a simple, cost-effective, safe and trustable technique, with success rates between 94% and 98%. [1,2] Bier's block can be safely and effectively used in emergency surgeries when the patient is non-fasting, and it also finds a useful place in day care surgeries. [1] Despite being an excellent means of providing regional anesthesia, Bier's block, however is not totally devoid of limitations, some of the concerns include local anesthetic toxicity, delayed onset, inadequate muscle relaxation, torniquet pain, short duration of action, and poor postoperative analgesia.[3,4]

Lidocaine remains the standard local anesthetic agent of choice for intravenous regional anesthesia, however widespread lidocaine use is contradicted by its short duration of action, hence different adjuvants have been used to counteract this issue. Adjuvants used for this purpose include a wide range of drugs such as, opioids, muscle relaxant, neostigmine, nitroglycerine to name a few. [2] However, many of the adjuncts used in Bier's block including opioids and ketorolac have produced controversial results. [5,6] Hence, search for an appropriate adjuvant, devoid of serious unwanted effects continues.

Clonidine's analgesic effect is produced mainly by stimulation of α_2-adrenergic receptors located in the dorsal horn of the spinal cord, besides slowing down of action potential of C type unmyelinated nerve fibres.[7,8] Clonidine when used with local anesthetic solutions produces a better analgesic effect in spinal, epidural or peripheral nerve blocks. This observation prompted us to conduct a prospective study and observe the effect of clonidine adjunct on the quality of block, particularly torniquet time in intravenous regional anesthesia.

Materials & methods

The present study is a prospective, observational, cross sectional study, conducted in the Department of Anaesthesiology & Critical Care at, Govt. Bone and Joints Hospital, Barzulla, which is one of the associated hospitals of Govt. Medical College, Srinagar. The study was conducted over a period of two years. After obtaining approval from the hospital ethics committee on the study plan, written informed consent was obtained from all the patients included in the study.

Sixty patients, of both genders, aged 18-65 years, with ASA physical status I or II, planned for surgery on the forearm or the hand under Bier's block, were included in the study. Patients with history of peripheral vascular

disease, seizures, sickle cell anemia, neuro-deficits, infected operation site, patients with allergy to the test drugs, patients with cardiac conduction blocks or on anti-arrhythmic drugs, pregnant ladies, patients previously treated with opioids and patients who refused to participate in the study were excluded.

Local anesthetic solution was prepared by the anesthesiologist who was not a part of the study group.

Patients were randomly allocated to one of the two groups each of 30 patients using a standard randomization code.

Group (1) clonidine group N = 30. They received 40 ml of 0.5% lidocaine with 1µg/kg clonidine.

Group (2) control group N = 30. They received 40 ml of 0.5% lidocaine plus 1ml of 0.9% saline.

Anesthetic technique

No opioids or sedatives were administered to the patients in the preoperative period. On arrival to the operating room, standard monitoring devices were attached to record non-invasive blood pressure, heart rate and oxygen saturation during the procedure and till 2 hours after deflation of the tourniquet. A 22 gauge intravenous cannula was inserted in the most distal vein on the dorsum of the hand to be operated, it was used for injection of local anesthetic mixture, a separate venous access was established on the contralateral hand to allow administration of fluids and drugs.

Normal saline was given via intravenous cannula secured on non-operating hand before administration of IVRA solution.The double cuff pneumatic tourniquet was applied on the arm, to be anesthetized, with generous layers of padding beneath, ensuring that no wrinkles were formed. The arm was exsanguinated using Esmarch bandage, which was wrapped starting from distal towards the proximal portion of the arm. At this stage the proximal cuff was inflated to 250 mmHg. Complete cessation of arterial blood supply and venous return in this limb was confirmed by pallor of the hand, absence of radial pulse, and absence of plethysmography of pulse oximetry.

Esmarch bandage was removed. The local anesthetic IVRA solution was then injected slowly into the arm to be anesthetized over 1 min. Loss of sensation was confirmed by pin prick every 30 s to determine the sensory onset, and every 1 min after deflation of the tourniquet to determine sensory recovery time.

Motor activity was assessed every 30 s to determine onset of motor block, then every 30 s after deflation of the tourniquet to determine motor recovery time. It was examined by the ability of the patient to move his wrist or fingers.

When the complete sensory and motor block was established, surgery was allowed to start. Severity of pain at the tourniquet site was assessed using Visual Analogue Pain Scale (VAS) and when it was more than 6, the distal cuff was inflated with 250 mmHg followed by deflation of the proximal cuff.

Distal cuff was deflated only when the pain score at the site of its placement reached 10 or after 60 minutes of its inflation whichever was earlier, but not earlier than 20 minutes after injection of local anesthetic to avoid possibility of systemic toxicity.

Post procedure patients were monitored in the post anesthesia care unit for hypotension, bradycardia, tinnitus, numbness, dizziness or excessive sedation and were managed accordingly.

Statistical analysis

The data was subjected to statistical analysis using statistical software SPSS & Microsoft excel. The continuous variables were represented in terms of

descriptive statistical and categorical variables in terms of frequency and percentage. The categorical variables were also analyzed using Chi square, Mann-Whitney, U-test & Fisher's Exact test. All the results were discussed on 5% level of significance, i.e. p value less than 0.05 was considered significant.

Results

Sixty patients participated in the study, none of the patients were excluded and all of them were able to complete the study, they were randomly allocated into 2 groups, and the final data was subjected to analysis.

The baseline patient variables are summarized in Table 1. The number of cases in each group (30), mean age 39.9 ± 13.5 years Vs 41.4 ± 14.69 years; weight 64.63 ± 7.499 kg Vs 66.65 ± 7.31 kg; duration of surgery 30.33±6.66 mins Vs 29.7±5.559 mins were comparable between group 1 and group 2 respectively, as were the ASA class (I-II) and, site of surgical procedures.

Table 1: Baseline patient characteristics

Parameter	Group 1	Group 2	P value
Number of cases	30	30	-
Age (years)	39.9±13.5	41.4±14.69	0.5120
Weight (kg)	64.63±7.499	66.65±7.31	0.2570
ASA Class	I-II	I-II	-
Duration of surgery (minutes)	30.33±6.66	29.7±5.559	0.8132

The perioperative parameters are summarized in Table 2.The mean heart rate, arterial pressure, and oxygen saturation did not change significantly during the surgery, and there was no difference between the two groups intra-operatively as regards these parameters. None of the patients developed hypotension (systolic arterial pressure <80 mmHg), bradycardia (heart rate < 60 bpm), or hypoxemia (SaO_2 <90%). The average duration of proximal tourniquet tolerance time (T1) was 21.54± 2.749 min in Group 1, whereas in Group 2 it was 22.33± 1.762 min (P > 0.05).The mean distal torniquet tolerance time (T2) was 26.64±3.689 min in Group 1 and 32.74±4.750 min in Group 2 (p<0.0001), and the Total tourniquet time (TT) was 48.17±3.156 min in Group 1, whereas, in Group 2 it was 55.07±5.0857 min (p<0.0001).

Table 2: Perioperative parameters

Parameter	Perioperative phase	Group 1	Group 2	P value
Pulse (/min)	Pre-op	77.3±6.152	79.63±5.295	0.1960
	Intra-op	78.43±6.361	79.73±5.420	0.3934
	Post-op	79.43±4.500	80.33±4.929	0.0794
Systolic blood Pressure (mmhg)	Pre-op	122.3±1.172	121.4±1.031	0.206
	Intra-op	127.0±5.576	125.7±4.635	0.5104
	Post-op	125.6±6.322	124.3±4.865	0.6180
Diastolic blood pressure (mmhg)	Pre_op	79.55±4.904	80.83±5.478	0.5953
	Intra_op	77.27±3.930	79.63±5.295	0.0984
	Post-op	81.43±5.380	81.13±6.224	0.0615
Mean blood pressure (mmhg)	Pre-op	94.93±7.748	94.37±4.038	0.8688
	Intra-op	94.17±3.239	96.43±5.817	0.0970
	Post-op	96.07±3.965	95.87±5.144	0.0565
Proximal tourniquet time T1 (mins)	Intra-op	21.54±2.749	22.33±1.762	0.4407
Distal tourniquet time T2 (mins)	Intra-op	26.63±3.689	32.74±4.750	<0.0001
Total tourniquet time (TT) (mins)	Intra-op	48.17±3.156	55.07±5.085	<0.0001

The pain scores and duration of analgesia is summarized in Table 3. The average VAS score at one hour following block, was 2.900±1.398 in Group 1, and in Group 2 it was 1.067±0.6915 (p<0.0001). Similarly, VAS score at two hours was 3.467±1.224 in Group 1,and 1.367±0.7649 in Group 2 (p<0.0001). The average duration of postoperative analgesia was 115.4±78.07 min in Group 1, and 541.1±337.8 min in Group 2 (p<0.0001).

Table 3: Comparison of Pain Score and duration of analgesia

	Group-`1	Group-2	P- value
Pain score at 1 hour (VAS)	2.900±1.398	1.067±0.6915	<0.0001
Pain score at 2 hours (VAS)	3.467±1.224	1.367±0.7649	<0.0001
Total duration of analgesia (mins)	115.4±78.07	541.1±337.8	?0.0001

Discussion

Intravenous Regional Anesthesia (IVRA) has a long reputed history and a variety of local anesthetic agents have been used, however, lidociane remains the standard

local anesthetic agent for this technique. The ideal IVRA solution should have the features of low toxicity, decreased tourniquet pain, good muscle relaxation and prolonged post-operative analgesia. At present this may only be achieved by the addition of adjuvants to local anesthetic drug.

Clonidine has been added to local anesthetic solutions for various peripheral nerve blocks resulting in improved anesthesia and analgesia. The present study was undertaken to assess the efficacy of Clonidine as an additive to local anesthetic solution (0.5% Lidociane) for Intravenous Regional Anesthesia (IVRA).

Addition of 1µg/kg clonidine as a solution with lidocaine in IVRA has no significant effect on systolic, diastolic and mean blood pressure either intra operatively or after the deflation of tourniquet. There was no episode of hypotension (Mean BP < 80% of baseline), this is in agreement with the study by Gentili M et al[9], however hypotension has been reported by Kleinschmidt S et al[10] with 2µg/kg Clonidine when used both as a systemic drug as well as when used as an adjuvant to local anaesthetic solution in IVRA. Similarly, no significant difference was noted in preoperative pulse rates of the two groups (77.53+6.512 and 79.63+5.295 in Group 1, Group 2 respectively), the heart rates varied only marginally even during procedure (78.43+6.361, and 79.73+5.42 in Group 1 & Group 2 respectively) and after the deflation of tourniquet (79.00+4.50, and 80.33+4.929 in Group 1 & Group 2 respectively). Similar observations were made by Gentili M[9] and Reuben SS et al.[11] who also did not report any significant variations in heart rate while using clonidine in IVRA with lidocaine.

The average Proximal tourniquet time (T1) was similar among the two groups (21.54+2.749 min, and 22.33+1.762 min in Group 1, Group 2 respectively). Indicating that the proximal tourniquet tolerance time is not affected by the addition of clonidine with local anaesthetic solution. Distal tourniquet time (T2) was significantly increased in Group 2 (32.74+4.750 min), the duration of distal tourniquet (T2) in turn reflects tourniquet tolerance, which was appreciably better in clonidine group. The total tourniquet time (TT) was also prolonged in Group 2 (55.07+5.085 min), depicting a definitive improvement in tourniquet tolerance on addition of clonidine as an adjuvant to lidocaine solution in IVRA. Lurie SD[12] and Gentili M[9], reported an improved tourniquet tolerance in patients who received clonidine additive along with local anaesthetic solution in IVRA. A study by Gorgias NK et al.[13] also observed that total tourniquet tolerance was significantly increased in patients who received 1µg/kg clonidine mixed with lidocaine, however it was less than that achieved by addition of 0.1mg/kg ketamine to lidocaine solution, but use the of ketamine as an additive was associated with psycho-mimetic effects in 50% of recipients.

VAS scores at 1hr and 2 hrs also followed a favorable trend for clonidine group. The VAS was significantly less at 1 hour in Group 2 (1.067+0.695) compared to Group 1 (2.9+1.398) ($p<0.0001$). Similarly, at 2 hours the VAS was significantly less in Group 2 (1.36+0.7649) compared to Group 1 (3.467+1.224) ($p<0.0001$). A study by Reuben SS et al.[11] observed a similar trend and documented significantly low pain scores and lower analgesic requirement in patients receiving clonidine with lidocaine, indicating a residual analgesic effect of clonidine in postoperative period. These results differ from those of Kleinschmidt S et al.[10] who observed that addition of 2µg/kg Clonidine to 0.5% Prilocaine for IVRA produced no significant increase in post-operative

analgesia, however their study defined the duration of analgesia as the time from deflation of tourniquet until the patient reported “wound pain sensation”, which is most probably a more accurate reflection of regression of sensory anaesthesia than analgesic duration. The study by Kleinschmiet et al.[10] did not formally assess pain for more than 45 min after the deflation of tourniquet. In contrast we defined analgesic duration as the time from tourniquet deflation until a VAS score of more than 3 was reached.

Conclusion

The analysis of the data shows a clear improvement in the quality of block in terms of tourniquet tolerance and postoperative analgesia by addition of clonidine to 0.5% lidocaine solution used in IVRA.

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