Original Paper • DOI: 10.2478/rjaic-2021-0011 • RJAIC 2021;28(2);63-70

Romanian Journal of Anesthaesia and Intensive Care

COMPARISON OF TWO DIFFERENT DOSES OF DEXMEDETOMIDINE ADDED TO LIGNOCAINE IN PATIENTS POSTED FOR UPPER LIMB ORTHOPEDIC SURGERY UNDER INTRAVENOUS REGIONAL ANAESTHESIA

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Abstract

***Background:** Intravenous regional anaesthesia (IVRA) is a dependable and safe technique specific anatomical knowledge is not required. The present research aimed to evaluate the effects of dexmedetomidine in combination with lidocaine and to compare the onset of motor and sensory block and evaluate the postoperative analgesia, as well as the side effects.*

***Methods:** A prospective randomized controlled double-blinded study was conducted on 90 patients assigned randomly into three equal groups,. Group (I) received only lidocaine 2% 3mg/kg for Bier block. Group (II) received lidocaine 2% 3mg/kg with plus dexmedetomidine 0.25 µg/kg for Bier block. Group (III) received lidocaine 2% 3mg/kg plus dexmedetomidine 0.5 µg/kg for Bier block.*

***Results:** Postoperative VAS was lower in a statistically significant way in the group III patients than those in groups I and II and this followed a reduction in the analgesic requirement in group III.*

***Conclusions:** The combination of dexmedetomidine 0.5 µg/kg with lidocaine 2% (3mg/kg) when applying intravenous regional anaesthesia (IVRA) allowed improved postoperative analgesia. Furthermore, the combination reduced onset time, extended recovery time for sensory/motor blocks and did not affect the incidence of intra-operative and post-operative complications.*

Keywords

Dexmedetomidine • lignocaine • upper limb orthopedic surgery • intravenous regional anaesthesia

Introduction

Dexmedetomidine is a short-acting, selective, α2-adrenergic receptors agonist. It does have antihypertensive, anxiolytic, sedative/hypnotic and analgesic properties in addition to its sympatholytic action. [1]. It is approximately 8 times more selective to α-2 adrenoceptors than clonidine. It reduces anaesthetic demand by up to 90% and provokes analgesic effect in patient [2]. It has been used effectively for procedures such as brachial blocks and IVRA, in conjunction with local anaesthetics. [3].

The interactions with the central nervous system CNS and the adrenergic receptors α-2 of the spinal cord mediate the primary physiological actions of dexmedetomidine via the stimulation of the parasympathetic outflow and the inhibition of sympathetic outflow. [4] It provides a unique mechanism of action that provides sedation and anxiolysis through receptors in the locus coeruleus and primary analgesic effects and enhancement of analgesia induced by opioids via the activation of α-2 adrenergic receptors within the spinal cord's dorsal horn and the inhibition of the release of P substance, and attenuation of the stress response with no significant respiratory depression [5].

The goal of this study is to compare use of 2 doses of dexmedetomidine (0.25 µg/kg and 0.5 µg/kg) in addition to lignocaine in IVRA for upper limb orthopedic operations.

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Material and Methods

This is a prospective controlled randomised double-blinded study performed in Menoufia University Hospital from 3/2020 till 3/2021. Informed and written consents have been obtained from the patients after acquiring permission of the medical and ethical committee of Menoufia University. The study was conducted on ASA classes I and II patients of both sexes aged 20 - 70 years old scheduled for forearm and hand surgery lasting for about 60 minutes.

The exclusion criteria: Patients with known hypersensitivity to any study medications- Patients with neurological and severe peripheral vascular diseases. Patients with whom the utilization of a tourniquet would be be impossible or contraindicated. Patients suffering from haemolytic diathesis especially hypertension, diabetes mellitus, epilepsy or sickle cell anaemia as well as cardiovascular diseases such as cardiac arrhythmias, myocardial infarction, altered mentation and heart block. Patients indergoing procedures longer than 90 minutes will also not be taken into consideration. Therapy using ACE inhibitors, adrenergic receptor and calcium channel blockers . Patients with impaired liver function.

The allocation of the patients to one of these three groups was random, using a sealed envelope technique. **Group I:** Subjects were administered 3 mg/kg of 2% lignocaine (maximum dose 300 mg) only diluted with normal saline 0.9% to have the final volume 30 ml. **Group II:** Subjects were administered 3 mg/kg of 2% lignocaine (maximum dose 300 mg) in addition to dexmedetomidine 0.25 **µg**/kg diluted with normal saline 0.9% to have a total volume 30 ml. **Group III:** Subjects received 3 mg/kg of 2% lignocaine (maximum dose 300 mg) in addition to dexmedetomidine 0.5 **µg**/kg diluted using saline 0.9% to have a total volume 30 ml.

Dexmedetomidine was used in form of (Precedex®**) Vial 200µg/2ml and Lignocaine was used in form of (Lidocaine Hydrochloride «**Debocaine" 2%) Vial 20mg/ml.

Preoperative evaluation and preparation:

1) Evaluation of patients was carried out within 2 weeks through: taking case histories properly, full laboratory investigation and clinical testing: including complete blood count, coagulation profile, and any other needed investigations.
2) Preaanesthetic preparation and premedication: Midazolam 1 or 2 mg I.V was given to all patients

Assessment of sensory blockade

Evaluation of the sensory block was made at every minute using hypodermic needle after completing injection of the drug in the dermatome areas corresponding to median nerve (thenar eminence), radial nerve (first web space), and ulnar nerve (hypothenar eminence) until complete blockade of sensory input. Sensory block was graded with Hollmens Scale [6].

Assessment of motor blockade

Evaluation of motor block was done via the same observer every minute until total motor blockade post injecting the drug. The blockage was then calculated using a modified Bromage scale [7] for upper limbs.

After achieving complete sensory and motor blocks, deflation of proximal cuff followed the inflation of the distal cuff to 250 mmHg, to prevent discomfort caused by tourniquet in each case.

During the operation, the tourniquet's pressure was checked and kept at 250 mmHg. After the surgery's completion, the tourniquet cuff was deflated using a repeated deflation and reinflation method.

Quality block assessment: The grade of overall blockade was evaluated according to the grading given by Ware R.J [8].

Pain assessment: The pain score was noted by utilizing visual analogue pain scale (VAS), postoperatively [9], from 0 to 10 (where 0 meant no pain and 10 meant maximum severe pain). Patients were asked to indicate on the line where pain was being

Analgesic requirements (milligrams): Ketorolac was given IV as rescue analgesic at VAS values more ≥4 or with first request for analgesics. The moment in time, was noted, at which the first analgesic dose was required. The total dose of ketorolac given to the patients postoperatively was calculated and elaborated statistically.

Duration of analgesia: Duration of postoperative analgesia was recorded starting at the deflation of tourniquet until VAS score of sedation assessment: Sedation score was accomplished using Ramsay sedation scale [10].

Any related side effects occurring at any time of the study were spotted, recorded and treated accordingly. Cases with any surgical or anesthetic complications were omitted out of the study.

Sample size: MedCalc® **version 12.3.0.0 program Ostend, Belgium** was utilised for calculations of sample size. This statistical calculator was based on 95 % confidence interval and power of the research 80 % with α error 5 %.

Statistical analysis: The data recorded was analysed using SPSS version 20.0 (Inc., Chicago, Illinois, USA). Quantitative data were reported as mean± standard deviation (SD). Qualitative data were stated as percentage and frequency. These following tests were done: A one-way analysis of variance (ANOVA) was used when there is a comparison between over two means with Post Hoc test: Least Significant Difference (LSD) was utilised for numerous comparisons between different variables. Kruskal Wallis test: was used for multiple comparisons of groups in a non-parametric data. Mann Whitney U test was used for two-group comparisons

in non-parametric data. Chi-square (x^2) significance test was utilised for comparing proportions among qualitative parameters. The confidence interval was set to 95% and the error margin accepted was set to 5%. P value ≤0.05 was considered significant.

Results

No statistically significant differences were found between the groups regarding their demographic data such as age and sex and regarding American Society of Anesthesiologists (ASA) classification and surgery duration. (Table 1)

Regarding heart rate, no statistically significant differences were found between groups. (Figure 1)

Regarding mean arterial pressure, there was no statistically significant difference found among groups at preoperative, 5 min. after starting of surgery, before tourniquet switch over, after tourniquet deflation at 5min., after tourniquet deflation at 10min. and after tourniquet deflation at 15min. (Figure 2)

Regarding respiratory rate there were no statistically significant difference between groups at preoperative, 5 min. post starting the surgery, before the switch over of tourniquet, after tourniquet deflation at 5min., after tourniquet deflation at 10min. and after tourniquet deflation at 15min. (Figure 3)

Regarding sedation score, no statistically significant difference was found among groups (after tourniquet deflation) but regarding VAS score and duration of analgesia, there was statistically significant difference found between groups. Moreover, regarding doses needed of analgesic, there was statistically significant difference between groups in 2nd dose, 3rd dose and 4th dose and there was statistically significant difference between groups according to their total dose (ketorolac mg/kg). (Table 3)

Regarding complications, there was no statistically significant difference between groups. (Table 4)

Discussion

In agreement with our study, Nilekani et al., compared between two groups of 30 patients each. In their study Group C as a (control group) was given 40ml 0.5% lignocaine solution and Group D (dexmedetomidine group) was given 0.5µg/kg of dexmedetomidine in addition to 0.5% lignocaine up to a total volume of 40ml. This study concerned patients of ASA physical status, I and II of either sex, from the age of 18 up to 60 years, scheduled for orthopaedic surgery of the upper extremity with statistically insignificant difference according to age, sex and ASA physical status. Also, AboEl-Enin et al., [12] in their study compared the effect of adding dexmedetomidine 0.5 mcg / kg to lignocaine with lignocaine alone in IVRA in 60 patients aged between 20-60 years with statistically insignificant differences in terms of age [12].

The results of our study agree with Sathe et al. [13] who concluded that adding dexmedetomidine in IVRA cause no significant change in blood pressure or heart rate, as they compared two groups:- in G1 25 patients were given lignocaine (3 mg/kg) to total volume with no adjuvant in IVRA and in G2 25 patients were given (1 mcg/kg) dexmedetomidine as an additive to lignocaine (3 mg/kg) to total volume in IVRA.This study found that differences in intraoperative blood pressure and intraoperative heart rate were statistically insignificant. Also, this was in correspondence with the results obtained by Subramanya et al., [14] who reported that the hemodynamic variables (HR and MAP) were comparable among both groups wich they studied during the whole study period, Group L administered

Table 1: Comparison among groups according to demographic data.

Demographic data	Group I: Control (n=30)	Group II: Dex 0.25 µg/kg (n=30)	Group III: Dex 0.50 µg/kg (n=30)	Test	p-value
Age (years)					
Range	20-70	21-70	20-69	$F = 0.935$	0.397
Mean ± SD	41.54 ± 7.06	39.04 ± 6.92	40.60 ± 7.47		
Sex					
Male	23 (76.7%)	26 (86.7%)	24 (80.0%)	$x^2 = 1.015$	0.602
Female	7 (23.3%)	4 (13.3%)	6 (20.0%)		
ASA					
I	21 (70.0%)	22 (73.3%)	19 (63.3%)	$x^2 = 0.726$	0.696
II	9 (30.0%)	8 (26.7%)	11 (36.7%)		
Duration of surgery (min)					
Range	28-60	25-59	27-58	$F = 0.930$	0.399
Mean ± SD	43.84 ± 7.45	41.21 ± 7.30	42.86 ± 7.89		

Using: F-One Way Analysis of Variance; x^2: Chi-square test p-value>0.05 NS

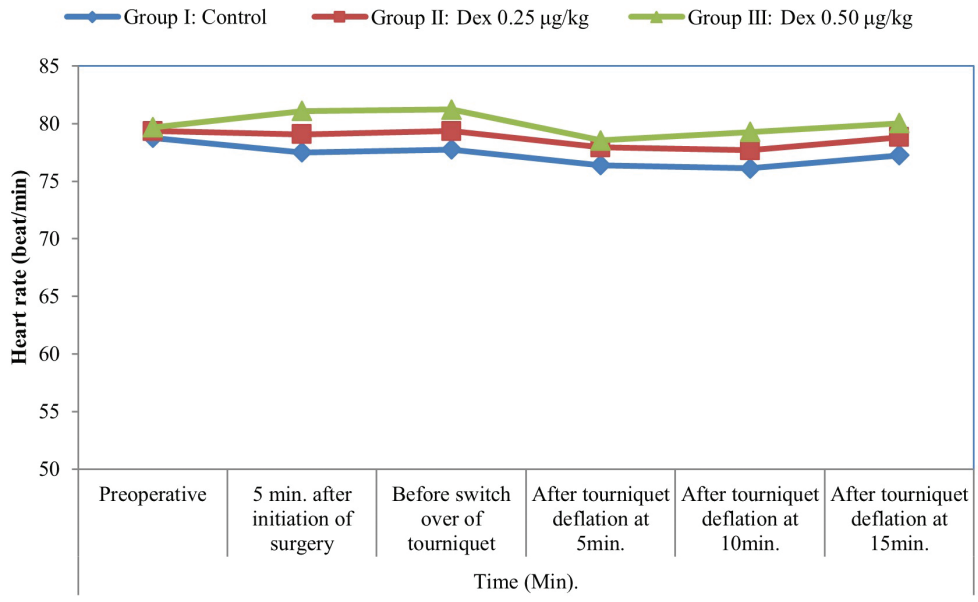

Figure 1. Comparison between groups according to heart rate (beat/min).

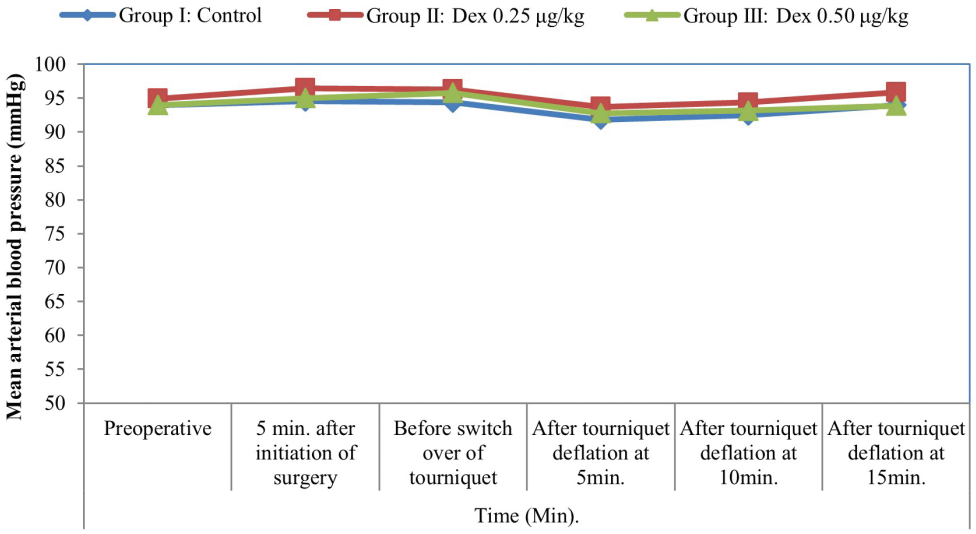

Figure 2. Comparison between groups according to mean arterial blood pressure (mmHg).

40 mL of 0.5% preservative-free lignocaine while Group LD administered 40 mL of 0.5% preservative-free lignocaine with 0.5 **µg**/kg body weight dexmedetomidine. They also noticed transient increases in HR and a fall in MAP following tourniquet deflation in both groups. That was also similar to what reported by Nilekani et al., [11] who noted that the heart rates in each group stayed similar during the intraoperative duration. Although bradycardia was observed in three individuals from Group D at minute 40 after the inflation of the tourniquet, it was extremely transient and normalised before administration of atropine. No postoperative episodes of bradycardia were noted in either group. And no hypotension episode was recorded in either group throughout or post surgery, according to the mean arterial pressure. Also, Jewlikar and Suryawanshi [15] reported that pulse rate and mean arterial blood pressure in their Group LD (30 patients with 200mg of 0.5% lignocaine and 0.5µg/kg dexmedetomidine diluted with saline up to a total volume of 41 ml) were lower than their Group L (30 patients with 200mg of 0.5% lignocaine diluted with saline upto a total volume of 41 ml), throughout after 15 mins. But there was no evidence of bradycardia or hypotension (P>0.05).

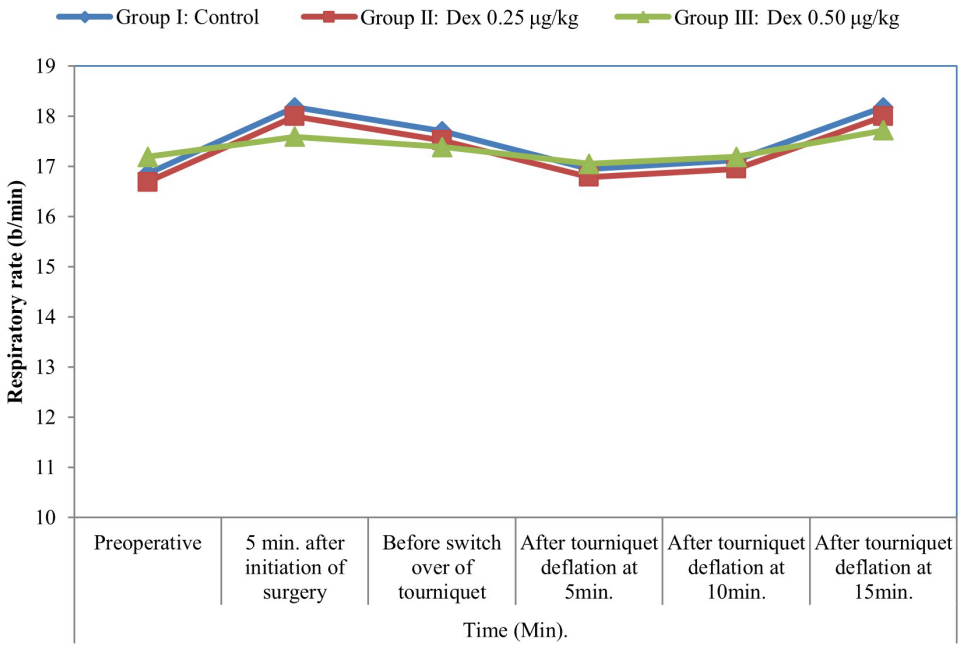

Figure 3. Comparison between groups according to respiratory rate (b/min).

Table 2: Comparison between groups in terms of block and mean duration of tourniquet time.

Block (min)	Group I: Control (n=30)	Group II: Dex 0.25 µg/kg (n=30)	Group III: Dex 0.50 µg/kg (n=30)	Test	p-value
Onset of sensory block (min)	4.96 ± 0.90	3.92 ± 0.92[a]	1.06 ± 0.35[ab]	*F* = 206.345	<0.001**
Onset of motor block (min)	12.80 ± 2.16	10.69 ± 2.20[a]	5.34 ± 1.16[ab]	*F* = 122.649	<0.001**
Quality of block					
Excellent	15 (50.0%)	24 (80.0%)	26 (86.7%)		
Good	8 (26.7%)	4 (13.3%)	3 (10.0%)	x^2 = 13.219	0.040*
Fair	5 (16.7%)	2 (6.7%)	1 (3.3%)		
Poor	2 (6.7%)	0 (0.0%)	0 (0.0%)		
Mean duration of tourniquet time (min)					
Mean ± SD	52.77 ± 4.58	55.06 ± 5.20	54.28 ± 4.82	1.712	0.187

Using: F-One Way Analysis of Variance; x2: Chi-square test Post HOC test, LSD: a: significant difference with group I: control; b: significant difference with Group II: Dex 0.25 p-value>0.05 NS; *p-value <0.05 S; **p-value <0.001 HS

Sathe et al, [13] agreed with the outcomes of the present study. They reported that adding dexmedetomidine as an additive to IVRA hastened onset of motor and sensory block. They discovered that onset of sensory analgesia was significantly quicker in their G2 Group (1.96 mins) in comparison with G1 Group (3.56 mins); (p value < 0.05), while onset of motor block in was significantly faster in their G2 Group (3.82 mins) when compared with G1 Group (5.76 mins); (p value < 0.05). Also, Jewlikar and Suryawanshi [15] reported that the mean time of onset of sensory block in their Group L was (3.83 ± 1.88) minutes and in Group LD was (3.23 ± 1.85) minutes, (P<0.05). The mean time of onset of motor block was (16.37 ± 2.92) in Group L and (15.33 ± 2.25) in Group LD (P<0.05). Quality of sensory block was (3.57 ± 0.51) in Group L and (3.77 ± 0.43) in Group LD, (P<0.05). Quality of motor block was (3.57 ± 0.50) and (3.67 ± 0.55) for Group L and LD respectively, (P<0.05).

In the study from Nilekani et al., [11] the onset of motor and sensory block was reported to be quicker among Group D in comparison with Group C (sensory block onset p-value=0.001, motor block onset p-value=0.034) this was similar to our result.

Table 3: Comparison between groups according to sedation score (after tourniquet deflation), VAS score duration of analgesia, doses needed of analgesic and total dose of ketorolac.

Sedation score (after tourniquet deflation)	Group I: Control (n=30)	Group II: Dex 0.25 µg/ kg (n=30)	Group III: Dex 0.50 µg/ kg (n=30)	Test	p-value
After 20 min	2 (1-4)	2 (1-4)	2 (1-4)	1.713	0.207
After 40 min	1 (1-3)	1 (1-3)	1 (1-3)	1.117	0.186
After 60 min	1 (1-2)	1 (1-2)	1 (1-2)	1.440	0.173
VAS score					
After 1 hr	1 (0-3)	1 (0-2)	0 (0-1)	1.679	0.201
After 2 hrs	3 (1-5)	2 (1-4)[a]	1 (0-2)[ab]	2.338	0.016*
After 3 hrs	5 (1-5)	3 (1-4)[a]	1 (1-2)[ab]	2.189	0.013*
After 4 hrs	4 (2-6)	3 (2-5)[a]	2 (1-4)[ab]	2.099	0.012*
After 5 hrs	5 (3-7)	4 (3-5)[a]	3 (1-4)[ab]	2.015	0.006*
Duration of analgesia				**F-test**	
Mean ± SD	108.27 ± 55.00	174.20 ± 67.08[a]	331.53 ± 78.27[ab]	86.746	<0.001**
Doses needed of analgesic				1.713	0.207
After 40 min	1 (1-3)	1 (1-3)	1 (1-3)	1.117	0.186
After 60 min	1 (1-2)	1 (1-2)	1 (1-2)	1.440	0.173
VAS score				**x^2**	
1st dose	30 (100.0%)	30 (100.0%)	30 (100.0%)	0.000	1.000
2nd dose	30 (100.0%)	26 (86.7%)	17 (56.7%)	19.291	<0.001**
3rd dose	18 (60.0%)	12 (40.0%)	0 (0.0%)	25.200	<0.001**
4th dose	5 (16.7%)	0 (0.0%)	0 (0.0%)	10.588	0.005*
Total dose (Ketorolac mg/kg)				**F-test**	
Mean ± SD	83.75 ± 7.54	68.61 ± 6.18[a]	47.42 ± 4.27[ab]	264.587	<0.001**

Using: H-Kruskal Wallis test; p-value>0.05 NS

Table 4: Comparison between groups according to complications.

Complications	Group I: Control (n=30)	Group II: Dex 0.25 µg/kg (n=30)	Group III: Dex 0.50 µg/kg (n=30)	*x2*	p-value
Dry mouth	1 (3.3%)	2 (6.7%)	3 (10.0%)		
Bradycardia	0 (0.0%)	1 (3.3%)	2 (6.7%)		
Tinnitus	0 (0.0%)	1 (3.3%)	2 (6.7%)	8.280	0.407
Perioral numbness	0 (0.0%)	1 (3.3%)	2 (6.7%)		
Nil	29 (96.7%)	25 (83.3%)	21 (70.0%)		

Using: x2: Chi-square test; p-value>0.05 NS

In accord with our study Subramanya et al., [14] reported that most of patients in Group LD had very good quality of block as compared to Group L, in whom the majority had average quality of block requiring intraoperative supplemental fentanyl analgesia.

The intraoperative fentanyl consumption was found to be 35.30±27.797µgs in group C in comparison with 16.00±27.241µgs in group D as reported by Nilekani et al. (p-value=0.009) [11], which delivered the best quality block in dexmedetomidine group which was the same as our results.

A.Esmaoglu et al., [16] in a study found that adding dexmedetomidine to lignocaine didn't affect the sensory and motor blocks onset times which doesn't agree with our study. The insignificant difference may be due to limited procedures for only carpal tunnel release or tendon release. In correspondence with Sathe et al., [13], they reported that the postoperative sedation score according to the Ramsey scale was comparable in both the control and study groups. In the postoperative period, all the patients in both the groups were cooperative, alert, oriented and tranquil with sedation score of 2/6. They

concluded that the addition of dexmedetomidine in IVRA does not cause any intra operative and postoperative sedation after deflation of the tourniquet. In concordance with our study, Nilekani et al., [11] reported that sedation scores in both groups were found to be similar . Contrary to our result, Subramanya et al., [14] reported that sedation scores were similar among the two groups at all periods of time, except for the first 2 hrs post-tourniquet deflation, during which participants in Group LD were more sedated than Group L ($P < 0.001$).

A. Esmaoglu et al., [16] found, in a study they conducted, higher levels of sedation score postoperative in the dexmedetomidine (1 **µg**/kg)group than in the control group. We suggested that this difference was caused by the higher dose of dexmedetomidine than we used in our study. Pain is perceived by the sufferer solely as it is a subjective phenomenon. Because of the variations in the pain relief mechanism of the neuro endocrine system, males need more pain killers than women. Postoperative pain is caused by the surgical trauma along with inflammation and damage initiation in the afferent neuron. Pogatzki-Zahn et al., [17] discovered that inefficiently treated postoperative pain may result in problems and a lengthy recovery. Development of a chronic pain state is associated with uncontrolled acute pain that leads to poor quality of life. Proper pain treatment leads to shorter hospital stays, lower hospital expenses and more satisfaction among patients.

In accord with our result Sathe et al., [13] reported that total duration of postoperative analgesia in G2 is significantly longer than G1. Addition of dexmedetomidine as an adjuvant to IVRA prolongs the duration of postoperative analgesia significantly (25 mins in G1 verses 234 minutes in G2). Also the duration of postoperative analgesia in the Nilekani et al., [11] study was noticed to be extended in group D 388.53±104.71 minutes in comparison with group C 200.5 ± 55.86 minutes (p-value=0.009), furthermore, the occurrence of tourniquet pain was less recurrent. Subramanya et al., [14] also reported that extent of postoperative analgesia was more prolonged in patients in Group LD (30.16± 4.04) ($P < 0.001$) compared to Group L (7.3±1.48).

Subramanya et al., [14] agreed with our results as they reported less total diclofenac (mg) used postoperatively in group LD (100±35.95) than in group L (197±36.75).

In accord with our results, Sathe et al., [13] came across a few complications. two out of 25 patients in G2 had hypotension and one out of 25 patients in G2 had bradycardia after release of the tourniquet. They reported that the incidence of complications in both groups was not statistically significant. They concluded that addition of dexmedetomidine as an adjuvant to IVRA does not give rise to any significant complications.

The Subramanya et al., [14] study reported two patients in Group LD who developed bradycardia requiring atropine administration. None of the patients in any group developed hypotension or hypoxemia during surgery or during the first 24 hr postoperatively.

The side effects in the Jewlikar and Suryawanshi [15] study were observed immediately after the release of the tourniquet for 2-3 minutes in the lidocaine group only. In group L, two patients had light-headedness (6.7%), and one had tinnitus (3.3%), the total incidence was 10% and no one required any treatment. None of patients in LD group had experienced any side effects ($P>0.05$).

Conclusions

The addition of dexmedetomidine 0.5 µg/kg to lidocaine 2% (3mg/kg) during intravenous regional anaesthesia (IVRA) delivered and enhanced postoperative analgesia. Additionally, this combination lowered onset time, extended recovery time of sensory/motor blocks and didn't affect the incidence of intraoperative and postoperative complications.

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