Original Article

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Anaesthesia Section

Comparative Evaluation of the Effect of Clonidine and Dexmedetomidine as Adjuncts to Lignocaine in Intravenous Regional Anaesthesia in Forearm and Hand Surgeries- A Randomised Clinical Study

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ABSTRACT

Introduction: Intravenous regional anaesthesia for forearm and hand surgeries, which is one of the safe, cost-effective and rapid onset anaesthesia is less popular nowadays, because of its lesser postoperative analgaesia and tourniquet pain.

Aim: To compare dexmedetomidine and clonidine as an adjuvant to 0.5% lignocaine to study block characteristics, tourniquet pain and postoperative analgaesia in forearm and hand surgeries.

Materials and Methods: This randomised clinical trial was conducted in Acharya Vinoba Bhave Rural Hospital (Tertiary Care Hospital), Wardha, Maharashtra, India, from September 2019 to September 2021 on 70 patients posted for forearm and hand surgeries. The patients were divided into two groups of 35 each. Group C received clonidine 1 mcg/kg with 40 mL of 0.5% lignocaine preservative free. Group D received dexmedetomidine 1 mcg/kg with 40 mL of 0.5% lignocaine preservative free. Independent samples t-test was used for evaluation of demographic data, haemodynamic data, block characteristics, duration of surgery and tourniquet, onset of tourniquet pain, duration of analgaesia and intraoperative and postoperative analgesic requirement.

Results: Onset of sensory and motor block was faster with dexmedetomidine group (1.60±0.60 min and 2.77±0.81 min) when compared to clonidine group (3.57±0.74 min and 6.40±1.26 min). Duration of analgaesia was significantly longer in group D (345.23±44.52 min) compared to group C (205.14±37.76 min), sensory and motor regression was delayed with group D (7.69±0.72 min) as compared to group C (6.40±0.85 min). There was no significant adverse effect noted in both the groups.

Conclusion: Dexmedetomidine is an excellent adjuvant when added to lignocaine for Intravenous Regional Anaesthesia (IVRA) in terms of block quality, postoperative analgaesia, and adverse effects.

Keywords: Adjuvant, Motor block, Postoperative analgaesia, Sensory block

INTRODUCTION

For any forearm and hand surgeries we have various options of anaesthesia to provide, like general anaesthesia, peripheral nerve block, intravenous regional anaesthesia [1]. Advantages of general anaesthesia include greater acceptance by patients, duration can be prolonged for more than 2 hours, greater muscle relaxation and secured airway, this is even acceptable in haemodynamically unstable patients. However, there are associated complications like airway instrumentation, respiratory complications, at risk of barotrauma, deep vein thrombosis, pulmonary embolism and it also comes with postoperative discomfort [2].

Peripheral nerve block has been commonly used nowadays for surgeries of extremities. Advantages of this technique include longer duration of analgaesia with least effect of haemodynamics. Disadvantages are chances of nerve injury, it being time consuming as technical expertise is needed, and requirement of equipment like nerve stimulator or ultrasound machine [2].

August Karl Gustav Bier, a German surgeon in 1908, described Intravenous Regional Anaesthesia (IVRA) (Bier's block) for the first time. Even though it was effective, because of the advent of the brachial plexus block, IVRA lost its popularity. Then in the 1960s Charles Holmes made IVRA popular by improving the technique and substituting lidocaine for prilocaine. Now even after 100 yrs it remains popular for short procedures of extremities [3]. The exact mechanism of action of IVRA is not known. When a local anaesthetic is injected it diffuses into the small nerves in the skin blocking conduction [2].

The benefits of IVRA is that it allows us to get a bloodless anaesthetic field with less procedural skill. It is considered as safe, less time consuming, cost effective, and reliable with rapid onset of analgaesia. It has a high success rate of 94-98%. It is popular because of rapid recovery of function which aids for rapid ambulation after surgery [3].

There are certain disadvantages of IVRA includes application of a pneumatic tourniquet throughout the procedure can cause tourniquet pain, the duration of surgery is limited by time during which the tourniquet could be safely inflated, minimal postoperative analgaesia, and the chance of local anaesthetic toxicity is high if tourniquet is not inflated properly [3].

To overcome these disadvantages few advancements have been made, mainly aimed to improve the quality of intraoperative and postoperative analgaesia to improve tourniquet tolerance.Various modalities have been adopted like altering the concentration and volume of local anaesthetics. Different local anaesthetics (ropivacaine and chlorprocaine) have been tried and modification of tourniquet techniques. To mitigate tourniquet pain and to improve intraoperative and post operative analgaesia various drugs has been used. Alpha 2 adrenergic receptor agonist is the focus of interest to improve the quality of analgaesia perioperatively [4]. Clonidine, an

alpha 2 adrenergic receptor agonist, has sympatholytic, sedative and cardiovascular stabilising effects. This as an adjuvant to local anaesthetic and it has shown to prolong the duration of analgaesia and also improves tourniquet pain by blocking selectively A Δ and C fibres [5].

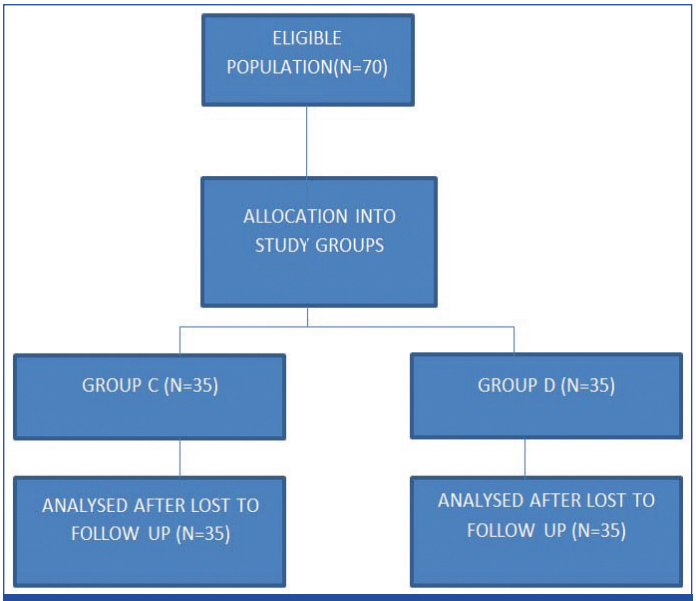
Dexmedetomidine, a powerful alpha 2 receptor agonist, is more selective than clonidine for alpha 2 receptors. Other than the sympatholytic effect of dexmedetomidine it has antihypertensive, anxiolytic, sedative and analgesic effects [6].

The aim of the study was to compare the effects of adding clonidine or dexmedetomidine to lignocaine for IVRA in forearm and hand procedures as an adjuvant to intravenous (i.v) lignocaine 0.5%.The primary outcome measures were to compare and study the duration of analgaesia when clonidine and dexmedetomidine were added as adjuvant to i.v. lignocaine 0.5% in IVRA. The secondary outcome measures were to compare and study the onset of sensory and motor block, incidence of tourniquet pain, haemodynamic changes, postoperative analgaesia and adverse effects.

MATERIALS AND METHODS

This randomised clinical trial was conducted in Acharya Vinoba Bhave Rural Hospital (Tertiary Care Hospital), Wardha, Maharashtra, India, from September 2019 to September 2021 on 70 patients posted for forearm and hand surgeries. Institutional Ethical Committee clearance obtained (Ref Number: DMIMS (DU)/IEC/SEPT/8372). Informed consent were obtained from the patients.

Sample size calculation: Sample size was calculated using the open epi app. The sample size was calculated from values of previous study [4]. Using α level of 0.05 and β level of 0.90 to produce a desired power of 90% using two-sample mean test (Satterthwaite's t-test) assuming unequal variance. Enrollment of 32 patients in each group was required according to the calculation. Considering possible dropouts 35 patients in each group and a total of 70 were taken up in the study [Table/Fig-1].



[Table/Fig-1]: Consolidated Standards of Reporting Trials (CONSORT) flowchart.

Inclusion criteria: Age group 20-60 years of both sex, surgeries lasting for less than 1-1.5 hrs, American Society of Anaesthesia (ASA) grade I and II, patient undergoing forearm and hand surgery, both elective and emergency were included in the study.

Exclusion criteria: Patients with peripheral vascular disease, hypersensitivity to local anaesthetic agents, coagulation disorder, patients with sickle cell trait or any haemolytic diseases, local infection, haemodynamically unstable patients, any neurological diseases, anticipated difficult airway patients were excluded from the study.

There were 70 patients, 35 in each group -

- Group C: Clonidine 1 mcg/kg with 40 mL of 0.5% lignocaine preservative free
- Group D: Dexmedetomidine 1 mcg/kg with 40 mL of 0.5% lignocaine preservative free.

Data Collection

Independent samples t-test was used for evaluation of demographic data, haemodynamic data, block characteristics,. duration of surgery and tourniquet, onset of tourniquet pain, duration of analgaesia and intraoperative analgesic requirement.

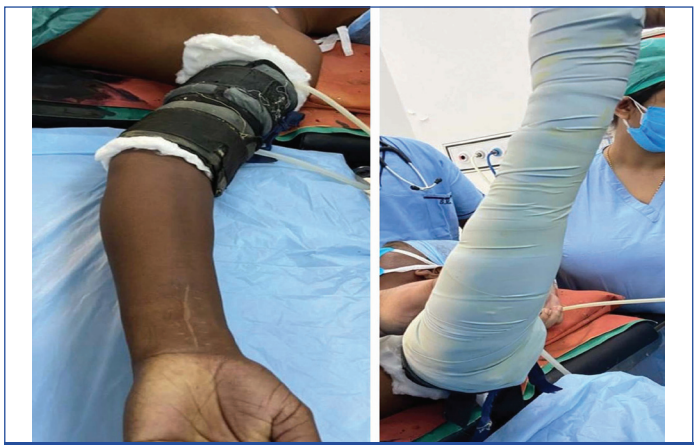
A thorough preoperative evaluation was done in preoperative visit and the nature of procedure along with its complications was explained and written informed consent was obtained. Visual Analogue Scale (VAS) scoring system was explained before the surgery 0 as 'no pain' and 10 as 'worst pain'.

Study Procedure

Lignocaine 0.5% was constituted by adding 30 mL normal saline to 10 mL of 2% preservative-free lignocaine.

On the day of surgery, 8 hours of NBM was confirmed, antibiotic was given before shifting the patient to the Operation Theater (OT). In OT patients baseline non invasive blood pressure, pulse rate, Electrocardiogram (ECG) was recorded. A 22-gauge i.v. cannula was secured into the distal vein of the operating limb [7]. One more i.v. cannula was secured in non operating hand to administer drug or fluids, if needed in case of emergency. Two tourniquets were tied over the cotton pad in the arm of operating limb [Table/Fig-2].

Operating arm was exsanguinated using the Esmarch bandage and the arm was kept elevated for 2 minutes [Table/Fig-3]. Proximal tourniquet inflated to 100-150 mmHg above the patient's systolic blood pressure. Pulse oximetry was used for radial artery pulsation confirmation. A 40 mL of test solution was injected slowly over 180 sec by an anaesthesiologist who was blinded to the study drug [8]. The sensory block was assessed by pinprick every 30 sec and sensory onset was evaluated in dermatomal distribution. Motor onset was checked by asking the patient to do some voluntary movements. Sensory and motor onset was noted. Onset of sensory block was noted from administering study drug to absence of pinprick sensation in required dermatome. And onset of motor block was noted from injection of drug to absence of motor movements. After achieving sensory and motor block distal cuff was inflated and then proximal cuff was deflated.



[Table/Fig-2]: Proximal and distal tourniquet.
[Table/Fig-3]: Exsanguinated with esmarch bandage. (Images from left to right)

Parameters monitored: Basic haemodynamic parameters were monitored before induction like Mean Arterial Pressure (MAP), Heart Rate (HR), it was monitored before tourniquet inflation and also at 5, 10, 15, 20 and 40 min after the injection of study drugs.

Hypotension was treated with i.v. ephedrine and bradycardia (>20% decrease from baseline) was treated with i.v. atropine 0.6 mg.

Tourniquet pain scores: The Tourniquet pain scores was assessed by:

- VAS between 0 and 10 (0- "no pain" and 10- "worst pain imaginable") [9].
- Sedation by Modified Ramsay sedation score [10] before tourniquet application and after the injection of anaesthetic drug.

Intraoperatively, intravenous inj. paracetamol 15 mg/kg was given for tourniquet pain if needed. The tourniquet was not inflated for more than 1hr 30 mins and it was not deflated before 30 mins, even if the procedure was short. Sensory and motor recovery time was recorded. The VAS score was recorded 30 min after tourniquet deflation and at frequent intervals for 24 hrs. Patients were given 15 mg/kg i.v paracetamol once they complained of pain in the postanaesthesia care unit. The duration of analgaesia was taken as the time between tourniquet release and first rescue analgaesia. If there was no usage of inj.paracetamol for 24 hrs, then duration of analgaesia was considered as 1440 min [3].

Patient and surgeon satisfaction: This was Patient and surgeon satisfaction was also recorded as:

- Very satisfied-5
- Satisfied-4
- Neutral-3
- Dissatisfied-2
- Very dissatisfied-1.

All the measurements were performed by an anaesthesiologist who was blinded to the medication administered. All complications and adverse effect were recorded.

STATISTICAL ANALYSIS

Data were entered in Microsoft excel software and analysed using STATA software version 12.0 (manufactured by Stata Corp LP, College station, Texas). Independent samples t-test was used for evaluation of demographic data, haemodynamic data, block characteristics, duration of surgery and tourniquet, onset of tourniquet pain, duration of analgaesia and intraoperative analgesic requirement. For all the statistical interpretation p-value <0.05 was considered as significant.

RESULTS

With respect to the basic demographic parameters of both the groups were comparable [Table/Fig-4].

The mean time required for onset of sensory block (min) was faster in group C compared to group D.Time required for the regression of sensory and motor block was faster in group C [Table/Fig-5].

Demographic data	Group C (n, %)	Group D (n, %)	p-value
Age group (years)			
21-30	10 (28.57%)	6 (17.14%)	χ^2=6.413, df=3, p-value=0.0931
31-40	13 (37.14%)	7 (20%)	
41-50	5 (14.29%)	6 (17.14%)	
51-60	7 (20%)	16 (45.71%)	
Gender			
Male	23 (65.7%)	22 (62.86%)	χ^2=0.062, df=1, p-value=0.8033
Female	12 (34.29%)	13 (37.14%)	
American Society of Anaesthesiologists grade			
I	27 (77.14%)	27 (77.14%)	-
II	8 (22.86%)	8 (22.86%)	

[Table/Fig-4]: Demographic data.
p-value <0.05 was considered as statistically significant

Variables	Group C (Mean±SD)	Group D (Mean±SD)	p-value
Onset of sensory block (min)	3.57±0.74	1.60±0.60	<0.05
Onset of motor block (min)	6.40±1.26	2.77±0.81	<0.05
Regression of sensory (min)	5.37±0.94	6.63±0.77	<0.05
Regression of Motor block (min)	6.40±0.85	7.69±0.72	<0.05

[Table/Fig-5]: Distribution of patients according to onset and regression of block.
p-value <0.05 was considered as statistically significant

The duration of surgery, tourniquet pain and duration of tourniquet time was statistically not significant. However, the total duration of analgaesia in group D was significantly longer than group C [Table/Fig-6].

Variables	Group C (Mean±SD)	Group D (Mean±SD)	p-value
Duration of surgery (min)	41.71±9.72	44.60±9.24	0.2074
Tourniquet pain	6.31±15.75	1.31±7.78	0.0985
Duration of tourniquet time (min)	49.77±7.65	52.14±7.30	0.1893
Duration of analgaesia (min)	205.14±37.76	345.23±44.52	<0.05

[Table/Fig-6]: Distribution of patients according to Duration of surgery and tourniquet pain and time.

The difference observed in pulse rate and MAP among the both groups at various time intervals was not statistically significant [Table/Fig-7]. After distal tourniquet deflation, there was a slight drop in mean pulse rate and MAP in group D which was statistically significant when compared with group C, but not significant enough that it required treatment.

Variables	Group C (Mean±SD)	Group D (Mean±SD)	p-value
At baseline			
Pulse rate (per minute)	78.77±7.71	78.46±8.08	0.8682
Mean arterial pressure (mmHg)	72.86±5.91	74.06±6.83	
After inflation of tourniquet			
Pulse rate (per minute)	76.46±7.31	78.26±7.14	0.3010
Mean arterial pressure (mmHg)	72.03±5.43	75.03±6.28	
At 5 minutes			
Pulse rate (per minute)	74.71±6.95	76.83±6.40	0.1898
Mean arterial pressure (mmHg)	71.54±6.07	74.06±6.85	
At 10 minutes			
Pulse rate (per minute)	74.14±6.11	76.46±7.37	0.1575
Mean arterial pressure (mmHg)	71.11±5.81	73.86±6.86	
At 15 minutes			
Pulse rate (per minute)	75.40±6.73	76.37±7.42	0.5681
Mean arterial pressure (mmHg)	71.23±5.56	73.43±6.06	
At 20 minutes			
Pulse rate (per minute)	76.74±6.53	76.74±8.29	1
Mean arterial pressure (mmHg)	72.77±5.57	73.14±6.36	
At 40 minutes			
Pulse rate (per minute)	78.89±6.69	77.97±7.16	0.5829
Mean arterial pressure (mmHg)	73.46±6.07	72.51±6.10	
After distal tourniquet deflation			
Pulse rate (per minute)	80.97±7.63	75.03±7.20	0.0013
Mean arterial pressure (mmHg)	74.94±6.03	69.71±6.08	

[Table/Fig-7]: Distribution of patients according to pulse rate.
p-value <0.05 was considered as statistically significant

The pain experienced by the group C (205.14±37.76 mins) patients was early as compared to group D (345±44.52 mins). While studying the complications it was observed that among the group C one patient had hypotension and from group D one had bradycardia. There were no sedation, dry mouth, nausea, vomiting or urinary retention in any of the patients.

The patient's satisfaction was more among group D (62.86% were satisfied) as compared to group C (34.29% were satisfied). The Surgeon's satisfaction score was better in the group D (88.57% were satisfied) as compared to group C (82.86% were satisfied) but the difference observed was not statistically significant [Table/Fig-8].

Variables	Group C (n, %)	Group D (n, %)	Statistics
Patient satisfaction score			
Very satisfied	0	2 (5.71%)	χ^2=10.066, df=3, p-value=0.0180
Satisfied	12 (34.29%)	22 (62.86%)	
Neutral	21 (60%)	11 (31.43%)	
Dissatisfied	2 (5.71%)	0	
Very dissatisfied	0	0	
Surgeon satisfaction score			
Very satisfied	0	0	χ^2=0.467, df=1, p-value=0.4943
Satisfied	29 (82.86%)	31 (88.57%)	
Neutral	6 (17.14%)	4 (11.43)	
Dissatisfied	0	0	
Very dissatisfied	0	0	

[Table/Fig-8]: Distribution of patients according to patient satisfaction and surgeon satisfaction.
p-value <0.05 was considered as statistically significant

DISCUSSION

The technique of IVRA has been significantly improved and simplified since August Bier's historical "Venous Anaesthesia" was published. It's great for ambulatory or short operative surgeries on the extremities that need only a few minutes of surgery. The inability to administer postoperative analgaesia is a disadvantage of this approach [11].

Thakur A et al., studied different doses of dexmedetomidine (0.5 mcg/kg and 1 mcg/kg) in axillary brachial plexus block. They found that mean duration of analgaesia was more with 1 mcg/kg than 0.5 mcg/kg without any significant side effects. So, 1 µg/kg as a dose for dexmedetomidine was considered [12].

To improve the quality of anaesthesia by IVRA and postoperative analgaesia various additives like opioids, muscle relaxants, NSAIDs, ketamine and lornoxicam have been studied but satisfactory results appear to be less [7,13].

This study was carried out to find the action of dexmedetomidine and clonidine with respect to duration of analgaesia, onset of sensory and motor, regression of sensory and motor and its side-effects. It was found that onset of sensory and motor was faster and duration of analgaesia was prolonged with dexmedetomidine with minimal side-effects.

In group C, only two patients had onset of sensory block within 2 mins, 33 patients had onset of sensory block between 3-5 mins. Whereas in group D only two patients had onset of sensory block between 3-5 mins all other patients had onset within 3 mins.The mean time required for onset of sensory block (min) among group D patients was earlier compared to group C. About 29 patients from group D had faster onset of motor block within 1-3 mins but none in group C. In group C all patients had onset of motor block from 5-8 mins. Time required for the onset of motor block in group D was shorter compared to group C.

Sardesai SP et al., conducted a similar study comparing clonidine 1 µg/kg and dexmedetomidine 1 µg/kg as adjuncts to 0.5% lignocaine in biers block. They found that onset of sensory block in dexmedetomidine group was earlier (4.28±1.23 min) compared to clonidine group (6.18±1.07 min). Similarly, onset of motor block was 11.27±1.66 min in group C and 8.63±1.86 min in group D, suggesting that onset of motor block was faster in dexmedetomidine group than in clonidine group. In this study, onset of motor block was much earlier i.e within 1-3 mins. But study showed faster onset of sensory and motor in dexmedetomidine group [3]. Hence, results of this study correlates with the present study findings.

Rayan AA and El Sayed AA, investigated the efficacy of dexmedetomidine in IVRA by giving it as an adjuvant to LA (0.5 mcg/kg) and intravenous systemic infusion (1 mcg/kg). Onset of sensory block when dexmedetomidine added as adjuvant was faster compared to plain lignocaine group and dexmedetomidine infusion group. They found that there was faster onset of motor block (12.3±3.5 min vs 14.6±4.9 min) when dexmedetomidine was added as an adjuvant to LA as compared to systemic infusion. The result coincides with the findings of this study [13].

In group D, only one patient complained of tourniquet pain, in group C, five patients complained of tourniquet pain, even though group D showed less tourniquet pain compared to the other, it was statistically not significant in the present study. In group C almost 17 patients had regression of sensory block within 5 mins, rest of the patients also had regression within 7 mins. Whereas, in group D only two patients had regression of sensory block within 5 mins. It was seen that the time required for regression of sensory blocks was more in group D as compared to group C and the difference observed was statistically significant. None of the patients in group D and C had regression of motor block within 5 mins. Total 34 patients in group D regression within 7-9 mins, but only 15 patients from group C had regression of motor block within 7-9 mins.

So, the time required for regression of motor block was more in group D as compared to group C and the difference observed was statistically significant. These findings were similar to the study conducted by Sardesai SP et al., [3].

Abdelkader AA et al., studied and evaluated the addition of dexmedetomidine 0.5 mcg/kg to lidocaine in IVRA and found that regression time for sensory block was 5.3±0.7 min in group L and 7.65±1.3 min in group LD showing prolonged effect in dexmedetomidine group. Mean while, regression time of motor block was 3.8±0.8 min in lidocaine group vs 6±0.7 min in dexmedetomidine group suggesting prolonged regression time of motor block in dexmedetomidine group, where p-value <0.05, which is statistically significant. Hence, their results are consistent with the findings of the present study [14].

There was no significant change in mean pulse rate and mean arterial pressure among the group C and group D patients. After the deflation of distal tourniquet there was a slight drop in MAP in group D which was statistically significant when compared with group C, but not significant enough that it required treatment, which resolved on its own [Table/Fig-7].

Tourniquet pain was assessed by using Visual Analogue Scale (VAS) of 0-10. A score of 0 was given for no pain and 10 for intolerable pain [15]. Rescue analgaesia was given when VAS ≥3. In group C (6.31±15.75) patients experienced pain compared to group D (1.31±7.78). It was observed that pain experienced by the group C patients was early as compared to group D and the difference observed in pain on VAS was statistically significant in the present study.

Nasr YM and Waly SH, studied haemodynamic changes following administration of dexmedetomidine to lignocaine in IVRA, found that there was fall in blood pressure and heart rate with dexmedetomidine group after the release of tourniquet, which was similar to the present findings [16].

Subramanya V et al., studied dexmedetomidine 0.5 mcg/kg with lignocaine for IVRA, they used VAS score for assessing the postoperative pain. In their study they found that patients in the dexmedetomidine group had less pain in the first 6 hours after deflation of tourniquet compared to only lignocaine group which was consistent with the current study. The total duration of analgaesia was considered from deflation of distal tourniquet to patient receiving rescue analgaesic [17].

The average total duration of analgaesia among the group C patients was more among group D patients when compared to group C

and the difference observed was statistically significant [Table/Fig-5] which was similar to the study conducted by Sardesai SP et al., [3].

Dexmedetomidine and clonidine have been compared in various other studies. Kasirajan G, studied the effect of clonidine 1 mcg/kg and dexmedetomidine 1 mcg/kg as adjuncts to ropivacaine in caudal analgaesia found that the dexmedetomidine group had a longer duration of postoperative analgaesia [18]. Swami SS et al., compared dexmedetomidine 1 mcg/kg and clonidine 1 mcg/kg as an adjunct to local anaesthesia in supraclavicular nerve blocks. They found that the duration of analgaesia was more in group D compared to group C, which was consistent with the current study [19].

Patient satisfaction score and surgeon satisfaction score was more among group D compared to group C in the present study. Sardesai SP et al., in their study they found that patient satisfaction was significantly higher in Group D, which showed similar results like the present study [3].

Complications: The expected complications were hypotension, bradycardia, sedation, dry mouth, nausea, vomiting and urinary retention. While studying the complications it was observed that among group C one patient had hypotension and one had bradycardia from group D.

According to the study by Sardesai SP et al., they did not observe any side-effects like sedation, hypotension or bradycardia in both clonidine and dexmedetomidine group [3]. Chatrath V et al., compared clonidine 1 mcg/kg and dexmedetomidine 1 mcg/kg in IVRA, they observed that haemodynamic parameters were stable and no side-effects were noted which was similar to this study [20].

Limitation(s)

In this study patients requiring tourniquet for more than 90 minutes were not included. The efficacy of α receptor agonists was not compared with other group of drugs like opioid, NSAIDs, muscle relaxants.

CONCLUSION(S)

Dexmedetomidine is an excellent adjuvant when added to lignocaine for IVRA, in view of their block quality which includes both sensory and motor onset and regression, postoperative analgaesia and it also has minimal side effects. Hence, it is recommended to use dexmedetomidine as an effective adjunct to lignocaine for IVRA.

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