Section: Anesthesia

Original Research Article

A PROSPECTIVE RANDOMISED STUDY COMPARING EFFICACY OF CLONIDINE VERSUS DEXMEDETOMIDINE AS AN ADJUVANT TO BUPIVACAINE IN SUPRACLAVICULAR BRACHIAL PLEXUS BLOCK FOR BOTH BONE FOREARM UPPER LIMB SURGERIES

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Received *: 12/11/2024*
Received in revised form *: 23/12/2024*
Accepted *: 08/01/2025*

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DOI: 10.70034/ijmedph.2025.1.34

Source of Support: Nil,
Conflict of Interest: None declared

Int J Med Pub Health
2025; 15 (1); 195-200

ABSTRACT

Background: Aim: Present study aimed to compare the analgesic efficacy of clonidine and Dexmedetomidine as local adjuvant to supraclavicular brachial plexuses block in both bone forearm upper limb surgeries

Material and Methods: Prospective double blinded randomized controlled study was conducted at Department of Anaesthesia in 60 ASA I & II patients aged 21-65 yrs. posted for both bone forearm upper limb surgeries. Group C (n=30) - 38ml of 0.25% bupivacaine and 100mcg clonidine, Group B (n=30) – 38 ml of 0.25% bupivacaine and 100 mcg Dexmedetomidine. Demographic data were recorded in both study groups age, sex, anthropometric parameters. study parameters like time of onset and duration of both sensory and motor block, duration of analgesia and number of rescue analgesia in 24 hrs were recorded in both the groups.

Results: Both the groups were comparable with respect to age and anthropometric parameters i.e. weight and height. Overall, 58.9% cases were males and 41.1% cases were females with no difference between study groups. Overall duration of sensory block and duration of motor block was also significantly longer in dexmed group as compared to clonidine. No difference was observed between the two groups in terms of pain till 4 hours after surgery. Pain scores were significantly lower in dexmed group as compared to clonidine group from 8th hour onwards till 24 hrs. ($p<0.01$). Mean time for duration of analgesia was significantly more in dexmed group cases as compared to clonidine group. Mean requirement of rescue analgesics in first 24 hours was also significantly lower in dexmed group. No difference was observed between study groups with regards to heart rate, SBP and DBP at baseline and also during the surgery.

Conclusion: We thus conclude that Dexmedetomidine when added to Bupivacaine in supraclavicular brachial plexus block, enhanced the duration of sensory and motor block and also the duration of analgesia as compared with clonidine.

Keywords: Bupivacaine, Dexmedetomidine, numerical rating scale.

INTRODUCTION

Upper limb surgeries are mostly performed under peripheral blocks such as the brachial plexus block. Peripheral nerve blocks not only provide intra-operative anaesthesia but also extend analgesia in the post-operative period without any systemic side-effects. There has always been a search for adjuvants to the regional nerve block with drugs that prolong the duration of analgesia but with lesser adverse effects. The search for the ideal additive continues, and led us to try the novel α2 adrenergic agonist, dexmedetomidine.

Alpha-2 adrenergic receptor agonists have been the focus of interest for their sedative, analgesic, perioperative sympatholytic and cardiovascular stabilizing effects with reduced anaesthetic requirements. Furthermore, various methods of administration, such as epidural, intrathecal and peripheral injections, have been tried either alone or in combination with another drug to prolong and intensify the anaesthesia.

Dexmedetomidine, a potent α2 adrenoceptor agonist, is approximately eight-times more selective towards the α2 adrenoceptor than clonidine. In previous clinical studies, intravenous dexmedetomidine resulted in significant opioid sparing effects as well as a decrease in inhalational anaesthetic requirements. In various animal studies, dexmedetomidine has been reported to enhance sensory and motor blockade along with increased duration of analgesia. In humans, dexmedetomidine has also shown to prolong the duration of block and post-operative analgesia when added to local anaesthetic in various regional blocks.[1,2]

Clonidine is a selective α-2 adrenergic agonist with some α-1 agonist property. In clinical studies, the addition of clonidine to local anaesthetics solutions improved peripheral nerve blocks by reducing the onset time, improving the efficacy of the block during surgery and extending post-operative analgesia. The effect of clonidine is dose related between 0.1 and 0.5 µg/kg. Clonidine possibly enhances or amplifies the sodium channel blockade action of local anaesthetics by opening up the potassium channels resulting in membrane hyperpolarisation, a state in which the cell is unresponsive to excitatory input.[3,4]

Very few studies compared dexmedetomidine with clonidine with respect to duration of block and post-operative analgesia. The current study was designed to test the hypothesis that dexmedetomidine when added as an adjuvant to local anaesthetic in supraclavicular brachial plexus block enhanced the duration of sensory and motor block and duration of analgesia as compared with clonidine.

MATERIALS AND METHODS

Prospective double blinded randomized controlled study was conducted at Department of Anaesthesia, Yashoda Hospital, a multi- super speciality hospital in Secunderabad, Telangana, in 30 patients of ASA Grade I and II inpatients of Yashoda hospital, Secunderabad, posted for both bone forearm upper limb surgeries. From September 2020 to May 2021.

Sample size:

Based on the previous studies and after discussing with the biostatistician, sample size was calculated using the formula,[5]

n =(α+ß)2*(sd12+sd22)

(µ1-µ2)2 where alpha= 1.9608

where (1-a)=(ß)=0.8416

sd1 = standard deviation of group A

µ1=mean group of A

µ2=mean of group B

n – 30

A computer generated random number list will be used to randomize people into two equal groups. A total of 60patients undergoing surgery in department of Anaesthesiology A written informed consent was taken from all the patients. They were randomly divided into 2 groups:

Group C (Bupivacaine + clonidine) – 30 patients – patients received 38ml of 0.25% bupivacaine and 100 mcg clonidine.

Group D (Bupivacaine + dexmedetomidine) – 30 patients -patients received 38 ml of 0.25% bupivacaine and 100 mcg Dexmedetomidine.

Allocation – group allocation will be concealed in sealed, opaque envelops.

Blinding – double blinding method where both observer and patient were unaware of the treatment carried out by a pain management nurse with prior education in postoperative analgesia.

Inclusion Criteria: Age more than 18, less than 65 years of either sexes, BMI 18-35 kg/m2, American Society of Anaesthesiologist (ASA) physical status 1 and 2 in patients scheduled for both bone forearm surgery.

Exclusion Criteria: Patients with chronic use of strong opioids (morphine, oxycodone), allergy to local anaesthetics or any drugs, contraindications for regional anaesthesia such as coagulopathy. with pre-existing neurological deficits in upper limb/ phrenic nerve with pre-existing lung disease (COPD, uncontrolled asthma), uncontrolled anxiety, cardiovascular disease, uncontrolled diabetes, schizophrenia or bipolar disorder, peripheral neuropathy, renal Impairment (Creatinine> 2.0 mg/dl), liver Impairment, palsy with history of chronic pain condition or daily intake of analgesics, pregnancy.

Preanaesthetic Evalustion

All the patients underwent thorough pre anaesthetic evaluation on the day prior to surgery. All systems were examined including the surface anatomy where the block was given and the procedure to be carried out was explained to the patients. They were informed the development of paresthesia. Patients were reassured to alleviate their anxieties. All the patients were kept nil per oral as per the fasting guidelines. Written informed consent was taken.

The following investigation were done as Blood investigations: Hb%, BT, CT, Urea, Serum creatinine, blood sugar, blood group and cross matching.

Urine: Albumin, sugar and microscopy

ECG and Chest x-ray PA view depending on the age & associated co-Morbidities

Other Investigations were done as per the Anaesthetic Requirements only.

Preliminaries: Written informed consent. Intravenous access -starting with 20 G intravenous cannula on contralateral upper limb under aseptic precautions. 2mg iv midazolam given before beginning of the procedure.

Monitoring for Pulse oximetry, Non-invasive blood pressure monitor on the opposite upper limb, respiratory rate, electrocardiography.

Supraclavicular Approach

The patient lie in supine position with the head facing away from the side to be blocked. Scanning with high frequency US probe (Ultrasound probe LOGIQ V5/V3 MHz probe, General Electric Medical system, Wisconsin, USA) is placed in the supraclavicular fossa superior to the clavicle and angled slightly toward the thorax. The subclavian artery should be easily identified. The brachial plexus appears as multiple hypoechoic disks just superficial and lateral to the subclavian artery. The needle is inserted lateral to the transducer in a

direction parallel to the ultrasound beam. The needle is advanced medially toward the subclavian artery until the tip is visualized near the brachial plexus just lateral and superficial to the artery.

After a careful aspiration Group C and Group D patients received respective dosage of drugs as discussed above. The block was performed using 20G, 100 mm short bevel needle (Jelco needle). After completion of the procedure, a sterile dressing was placed over the insertion site.

Sensory block was evaluated by doing pinprick test by using 3-point scale

0	Normal sensation
1	Loss of sensation of pinprick(analgesia)
2	Loss of sensation of touch(anesthesia)

Motor blockade was done using Bromage three-point score

1	Normal sensation
2	Decreased motor strength with ability to move fingers only
3	Complete motor block with inability to move fingers

Sensory and motor blocks were evaluated every 5 minutes until 30minutes after injection.

Numerical Rating Scale (NRS)

0 – no pain

1-3 - mild pain

4-6 - moderate pain

7-10 - severe pain

Statistical Analysis

All the collected data was entered in Microsoft Excel sheet. It was then transferred to SPSS ver. 17 software for statistical analysis. All the Quantitative data was presented as mean and standard deviation and compared using student's t-test. Qualitative data was presented as frequency and percentage and analysed using chi-square test. P-value of < 0.05 was considered as significant

RESULTS

Present study included a total of 60 patients scheduled for both bone forearm surgery. They were randomly divided into 2 study groups:

Overall, 58.9% cases were males and 41.1% cases were females with no difference between study groups.

Both the groups were comparable with respect to age and anthropometric parameters i.e. weight and height ($p>0.5$).

Mean time of onset (3.63 vs 5.37 mins; $p<0.01$) and completion (19.6 vs 22.7 mins; $p<0.01$) of sensory block was significantly faster in dexmed group as compared to clonidine group. Overall duration of sensory block was also significantly longer in dexmed group as compared to clonidine (520 vs 426 mins; $p<0.01$). [Table 1]

Mean time of onset (5.23 vs 6.43 mins; $p<0.01$) and completion (23.03 vs 25.77 mins; $p<0.01$) of motor block was significantly faster in dexmed group as compared to clonidine group. Overall duration of motor block was also significantly longer in dexmed group as compared to clonidine (503.37 vs 412.0 mins; $p<0.01$). [Table 2]

Pain was calculated using numerical rating scale measuring from 1 to 10. No difference was observed between the two groups in terms of pain till 4 hours after surgery. Pain scores were significantly lower in dexmed group as compared to clonidine group from 8th hour onwards till 24 hrs. [Table 3]

Mean time for first rescue analgesia was significantly more in dexmed group cases as compared to clonidine group (702.9 vs 601.4 mins; $p<0.01$). Mean requirement of rescue analgesics in first 24 hours was also significantly lower in dexmed group (1.07 vs 1.79; $p<0.01$). [Table 4]

Table 1: Mean age and anthropometric comparison among study groups

Variables	Group	N	Mean	SD	p- value
Age	C	30	39.30	12.91	0.186
	D	30	35.27	9.18	
Weight	C	30	66.50	6.44	0.319
	D	30	67.07	5.98	
Height	C	30	167.03	3.62	0.47
	D	30	166.57	3.61	

Table 2: Mean comparison of motor block parameters among study groups

Motor Block (mins)	Group	Mean	SD	p- value
Onset	C	6.43	0.73	<0.01
	D	5.23	0.77	
Complete block	C	25.77	1.01	<0.01
	D	23.03	4.12	
Duration	C	412.00	17.15	<0.01
	D	503.37	16.87	

Table 3: Mean comparison of pain score among study groups

NRS	Group	N	Mean	SD	p- value
4 hrs	C	30	0.00	0.00	NA
	D	30	0.00	00.00	
4 hrs	C	30	1.19	1.12	0.62
	D	30	1.83	0.84	
8 hrs	C	30	2.80	1.10	<0.01
	D	30	3.97	0.99	
12 hrs	C	30	4.77	1.30	<0.01
	D	30	6.21	1.70	
24 hrs	C	30	5.98	1.30	<0.01
	D	30	7.73	1.20	

Table 4: Mean comparison of time for first analgesia and dose of analgesics in first 24 hours

Analgesia	Group	Mean	SD	p- value
Time for first rescue Analgesia (mins.)	C	601.43	23.50	<0.01
	D	702.90	28.69	
Dose of analgesia in first 24 hours	C	1.79	0.32	<0.01
	D	1.07	0.07	

DISCUSSION

Supraclavicular brachial plexus block is a very popular mode of anaesthesia for various upper limb surgeries. This approach is superior due to its effectiveness in terms of cost, performance, margin of safety along with good postoperative analgesia. Supraclavicular approach gives the most effective block for portion of upper extremity that is carried out at the level of trunks of brachial plexus. The plexus is blocked where it is most compact i. .e. at the middle of brachial plexus, resulting in homogenous spread of anaesthetic throughout the plexus with a fast onset and complete block.[1]

There has always been a search for adjuvants to the regional nerve block with drugs that prolong the duration of analgesia but with lesser adverse effects. The search for the ideal additive continues, and led us to try novel α2 adrenergic agent like dexmedetomidine and selective α-2 adrenergic agonist like clonidine.

Dexmedetomidine, a potent α2 adrenoceptor agonist, is approximately eight-times more selective towards the α2 adrenoceptor than clonidine.[5] In previous clinical studies, intravenous dexmedetomidine resulted in significant opioid sparing effects as well as a decrease in inhalational anaesthetic requirements.[6] In various animal studies, dexmedetomidine has been reported to enhance sensory and motor blockade along with increased duration of analgesia. In humans, dexmedetomidine has also shown to prolong the duration of block and post-operative analgesia when added to local anaesthetic in various regional blocks.[7]

Clonidine was initially used for its antihypertensive properties. The central actions are mediated through α2adrenoceptors, which are situated at locus coeruleus and dorsal horn of spinal cord. But, specific peripheral effects of clonidine appear to be less obvious because α2 adrenoceptors are not present on the axon of the normal peripheral nerve.[8] There have been four proposed mechanisms for the action of clonidine in peripheral nerve blocks. These mechanisms are centrally mediated analgesia, α2 β adrenoceptor-mediated vasoconstrictive effects, attenuation of inflammatory response and direct action on peripheral nerve.[9] The direct action of clonidine on the nerve can be explained on the basis of a study conducted by Dalleet al.[10] They proposed that clonidine, by enhancing activity-dependent hyperpolarization generated by the Na/K pump during repetitive stimulation and increases the threshold for initiating the action potential causing slowing or blockage of conduction.

Both Dexmedetomidine and clonidine are α2 selective agonists. It is possible that they work in a similar manner and may indicate a class effect. Most studies carried out so far to prove the peripheral action of α2 agonists were animal studies. Keeping these facts in mind, we decided to compare the action of two α2 agonists, i.e. clonidine and dexmedetomidine with Bupivacaine in peripheral nerve blocks so that by increasing the duration of analgesia with a single shot block we can achieve a longer duration of post-operative analgesia without significant clinical side-effects.

The present study included a total of 60 patients scheduled for both bone forearm surgery. They were randomly divided into 2 study groups: Group C (Bupivacaine + clonidine) – 30 patients received 38 ml of 0.25 % bupivacaine and 100 mcg of clonidine and; Group D (Bupivacaine + dexmedetomidine) –

30 patients received 38 ml of 0.25 % bupivacaine and 100 mcg clonidine.

In our study both the groups were comparable with respect to age, gender and anthropometric parameters i.e. weight and height and showed no significance. The major findings in our study demonstrated that onset of sensory and motor blockade was faster in group D as compared to group C. Also the duration of sensory motor blockade and duration of analgesia is prolonged in group D as compared to group C.

In our study the mean time of onset of sensory block in group C (3.63 min) vs group D (5.37 mins) ($p<0.01$) and the mean time of onset of motor block in group C (5.23 min) vs group D (6.43 mins) $p<0.01$) of motor block was significantly faster in Dexmedetomidine group as compared to clonidine group. The findings of our study correlate with study,[11] where in group D which received Dexmedetomidine 1mcg/kg added to 35 ml of 0.25% bupivacaine and group C that received 35 ml of 0.25% bupivacaine with 1mcg/ kg clonidine added has shown faster onset of sensory and motor block. The mean time for onset of sensory block in group D (9.17±1.26) mins and group C (11.07±2.14) mins ($p<0.01$) compared to. mean time for onset of motor block in group D as (9.17±1.26) mins and that observed in group C as (11.07±2.14) mins ($p<0.01$). In another study.[12] that compared the efficacy of Dexmedetomidine and clonidine when 1 mcg/kg each (2ml) added to 38 ml 0f 0.25 % bupivacaine respectively showed faster onset of sensory and motor block.

In another study 75 patients aged from 20-60 yrs scheduled for upper limb surgery were divided into 3 groups – group 1 (0.5% ropivacaine + normal saline) group 2 (0.5% ropivacaine + clonidine), group 3 (0.5% ropivacaine + Dexmedetomidine). Group 3 showed early onset of sensory and motor block than group 2 and group 1 (group 3> group 2>group1). In another study,[13] 90 patients divided into 3 groups as group A (dexmed 1mcg/kg to 20 ml of 0.5% ropivacaine), group B (clonidine each of 1mcg/kg added to 20 ml of 0.5 % ropivacaine) and group C (placebo) with 2ml of normal saline to 0.5% ropivacaine. Group A showed faster onset of sensory and motor block compared to group B and group C. Studies,[14] showed statistically no difference in onset of sensory and motor block when Dexmedetomidine and clonidine were added to bupivacaine as adjuvant in supraclavicular brachial plexus block.

In our study duration of sensory block and motor block was significantly longer in dexmed group as compared to clonidine. The mean duration of sensory block in group D vs group C (520 vs 426 mins;($p<0.01$) while mean duration of motor block in group D vs group C (503.37 vs 412.0 mins; $p<0.01$). The findings of our study correlate with study,[15] where in group D received Dexmedetomidine 1mcg/kg added to 35 ml of 0.25% bupivacaine and group C that received 35 ml of 0.25% bupivacaine with 1mcg/ kg clonidine added has shown longer duration of sensory and motor block in group D compared to group C. Mean duration of sensory block in group D was (690 ± 87.41) mins and in group C was (470 ± 55) mins ($p<0.01$). The mean duration of motor block in group D was (353.17 ± 41.24) mins and in group C was (270.51 ± 51.61) mins ($p<0.01$). In a similar study,[13] clonidine and Dexmedetomidine added as an adjuvant to LA in supraclavicular brachial plexus block showed prolonged duration of sensory and motor in dexmed group Duration of sensory block and motor block was 227.00 ± 48.36 and 292.67 ± 59.13 min, respectively, in group C, while it was 413.97 ± 87.13 and 472.24 ± 90.06 min, respectively, in group D. In another study,[12] that compared which compared the efficacy of Dexmedetomidine and clonidine 1 mcg/kg each (2ml) added to 38 ml 0f 0.25 % bupivacaine showed prolonged duration of sensory and motor block.

In another study,[16] 75 patients aged from 20-60 yrs scheduled for upper limb surgery were divided into 3 groups – group 1 (0.5% ropivacaine + normal saline) group 2 (0.5% ropivacaine + clonidine) group 3 (0.5% ropivacaine + Dexmedetomidine). Group 3 showed prolong duration of mean sensory and motor block than group 2 and group 1 (group 3> group 2>group1). In another study,[17] 90 patients divided into 3 groups. group A (dexmed 1mcg/kg to 20 ml of 0.5% ropivacaine) group B (clonidine each of 1mcg/kg added to 20 ml of 0.5 % ropivacaine) and group C (placebo) with 2ml of normal saline to 0.5% ropivacaine. Group A patients had significant prolong duration of action of sensory and motor block compared to group B and group C.

In our study mean time for first rescue analgesia was significantly more in dexmed group cases as compared to clonidine group (702.9 vs 601.4 mins; $p<0.01$). pain was calculated using numeric ration scale measuring from 1 to 10. No difference was observed between the two groups in terms of pain till 4 hours after surgery. Pain scores were significantly lower in dexmed group as compared to clonidine group from 8th hour onwards till 24 hrs. ($p<0.01$). In study,[13] compared clonidine and dexmedetomidine as an adjuvant to local anaesthetic agent in supraclavicular brachial plexus block has shown that the duration of analgesia (time to requirement of rescue analgesia) in group D was 456 ± 97 min, while in group C, it was 289 ± 62 min. Statistically, this difference was significant ($P=0.001$). In study,[18] it was observed that duration of analgesia was 349.33 ± 42.91 min, significantly less in Group C compared to 525.33 ± 42.89 min in Group D ($P < 0.001$). In study,[17] also observed that duration of post-operative analgesia was significantly longer in Group-D as compared to Group-C (p-value<0.05). In study,[19] in meta-analysis observed that time before the need for analgesic requirements was significantly extended by 38.6 minutes, when dexmedetomidine was used as an adjuvant to local anesthetics (bupivacaine or ropivacaine).

No difference was observed between study groups with regards to heart rate, SBP and DBP at baseline and also during the surgery ($p>0.05$). In study,[13] also

observed no difference between study groups with regards to heart rate, SBP and DBP at baseline and also during the surgery (p>0.05). Similar results were seen in the studies by Zhang C et al,[19] and Dubey S et al.[18] Complications None of the patients in either groups had any side effects of drugs or

Thus to summarize, our study demonstrated that addition of dexmedetomidine to bupivacaine in supraclavicular brachial plexus block prolonged the duration of analgesia and improved the quality of anesthesia as compared to clonidine with comparable hemodynamic stability and incidence of side effects, thus making dexmedetomidine an attractive choice as an adjuvant to bupivacaine for supraclavicular brachial plexus block.

CONCLUSION

We thus conclude that Dexmedetomidine when added to Bupivacaine in supraclavicular brachial plexus block, enhanced the duration of sensory and motor block and also the duration of analgesia as compared with clonidine. Hence dexmedetomidine showed to have an upper edge over clonidine when used as adjuvant to Bupivacaine for brachial plexus block, and thus promises to be yet another addition to the already vast armamentarium of the present-day anesthetist.

Recommendations

We recommend use of supraclavicular brachial plexus block for suitable patients undergoing upper limb surgeries from mid humerus to finger tips distally. We would also recommend use of Dexmedetomidine as an adjuvant in supraclavicular block to increase the quality of block and duration of analgesia.

Limitations

Furthermore, studies to be needed to know the benefits or adverse effects of adding alpha 2 adrenergic agonists along with LA for producing the blockade. We did not monitor sugar levels intraoperatively and postoperatively. We did not record patient satisfaction scores regarding procedure.

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