

To Compare The Efficacy of Adding Clonidine Versus Adding Dexmedetomidine as an Adjunct to 0.25% Bupivacaine in Supraclavicular Brachial Plexus Block.

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ABSTRACT

Background: Brachial plexus blockade is a technique used for providing anaesthesia and post-operative analgesia for upper limb surgeries. Among the various approaches, supraclavicular approach is considered safest and most effective. Addition of adjuvants, not only prolongs the analgesic effect but also improves the quality of anaesthesia. Aim And Objectives –The study was undertaken to compare between Clonidine and Dexmedetomidine as adjuvants to 0.25% Bupivacaine in Supraclavicular Brachial Plexus block. **Methods:** The study was conducted in Gandhi Hospital, Secunderabad after obtaining approval from institutional ethical committee and written informed consent from each patient. Sixty patients aged 18-50 years undergoing upper limb surgeries were included in the study. Patients were randomly divided into two groups of 30 patients each. Group C (Clonidine) – received conventional supraclavicular brachial plexus block with 40 ml of 0.25% Bupivacaine and 0.5 µg/kg of Clonidine. Group D (Dexmedetomidine) – received conventional supraclavicular brachial plexus block with 40ml of 0.25% Bupivacaine and 0.5 µg/kg of Dexmedetomidine. The onset of sensory and motor blockade were noted. Intra-op haemodynamics, post-op pain and side effects were assessed at regular intervals. **Results:** The duration of analgesia is prolonged with Dexmedetomidine as compared to Clonidine with no significant difference either in onset of sensory and motor blockade or in hemodynamic variables. The only side-effect observed was hypotension in Clonidine group. **Conclusion:** We conclude that Dexmedetomidine has prolonged duration of analgesia with no side effects as compared to Clonidine.

Keywords: Brachial plexus block, Clonidine, Dexmedetomidine, Perioperative analgesia.

INTRODUCTION

Pain is an unpleasant sensation associated with significant psychological and physiological changes during surgery and post-operative period. This can be overcome by the use of suitable drugs and techniques. Regional anaesthetic techniques have specific advantages both for anaesthesia and as analgesic supplements for intraoperative and postoperative care. Brachial plexus blockade is a time tested technique for providing anaesthesia and post-operative analgesia for upper limb surgeries. There are different approaches but the ones frequently employed for blocking the brachial plexus include.^[1]

- Supraclavicular approach
- Infraclavicular approach
- Axillary approach
- Interscalene approach

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Among the various approaches of brachial plexus block, supraclavicular approach is considered safest and most effective. Bupivacaine is commonly used local anaesthetic for brachial plexus block and many other regional anaesthesia techniques. Duration of peripheral nerve block anaesthesia depends on the dose of local anaesthetic, its lipid solubility, its degree of protein binding and use of vasoconstrictors like epinephrine. To prolong the duration of analgesia various drugs have been studied as adjuvant to local anaesthetic solution and techniques like the continuous catheter placement in the plexus have evolved. These adjuvant drugs ideally are expected to prolong the analgesic effect without causing any systemic side effects. Novel adjuncts studied include opioids, clonidine, neostigmine, and tramadol.

Clonidine and Dexmedetomidine are partial and selective alpha-2 agonists. They are being studied and used in regional anaesthesia practice as adjuvant to local anaesthetic (LA) agents for a long period of time. Widespread presence of alpha -2 receptors in the brain, spinal lamina and peripheral nerves and their role in pain modulation explains the analgesic

and LA sparing action of these agents. In clinical studies, the addition of clonidine to local anaesthetic solutions improved peripheral nerve block characteristics by reducing the onset time, improving the efficacy of the block during surgery and extending postoperative analgesia. Dexmedetomidine has shown greater affinity as an alpha-2 adrenoceptor agonist than clonidine.

Clonidine, the first developed and the most known α_2 -agonist is considered as a partial α_2 – agonist since its α_2/α_1 selectivity is 200:1 while the α_2/α_1 selectivity of Dexmedetomidine is 1620:1 and hence it is 8 times more powerful α_2 – adrenoceptor agonist than clonidine and is considered as a full α_2 adrenoceptor agonist.^[2]

Hence, the study is attempted to evaluate the efficacy of adding Clonidine (0.5 $\mu\text{g}/\text{kg}$) to 0.25% Bupivacaine Hydrochloride when compared to adding Dexmedetomidine (0.5 $\mu\text{g}/\text{kg}$) to 0.25% Bupivacaine Hydrochloride in Classical Supraclavicular brachial plexus block.

Technique and its Complications

The patient is placed in a supine position, with the head turned away from the side to be blocked.^[3] After appropriate preparation and raising a skin wheal, the anaesthesiologist stands at the head end of the patient facing the patient's foot. A 22G, 4cm needle is directed in a caudal, slightly medial, and posterior direction until a paraesthesia or motor response is elicited or the first rib is encountered. If the first rib is encountered without elicitation of a paraesthesia, the needle can be systematically walked anteriorly and posteriorly along the rib until the plexus or the subclavian artery is located. Location of the artery provides a useful landmark; the needle can be withdrawn and reinserted in a more posterolateral direction that usually results in a paraesthesia or motor response.^[4] On localization of the brachial plexus, aspiration for blood should be performed before incremental injections of a total volume of 40 ml of solution.

Complications

- 1) Neurological Complications
- 2) Vascular Complications
- 3) Myotoxicity
- 4) Pulmonary complications –Incidence following supraclavicular block is 0.5% to 6.1 %52.
- 5) Unintended local anaesthetic destinations- The reported incidence is 20-90%.

MATERIALS AND METHODS

Source of data - The study was conducted in Gandhi Hospital, Secunderabad after obtaining approval from institutional ethical committee. A written informed consent was obtained from each patient. Sixty patients aged between 18 years and 50 years undergoing upper limb surgeries were included in the study.

Method of collection of data - The patients were randomly divided into two groups of 30 patients each – Group C (Clonidine) – was given conventional supraclavicular brachial plexus block with 40 ml of 0.25% Bupivacaine and 0.5 $\mu\text{g}/\text{kg}$ of Clonidine. Group D (Dexmedetomidine) – was given conventional supraclavicular brachial plexus block with 40ml of 0.25% Bupivacaine and 0.5 $\mu\text{g}/\text{kg}$ of Dexmedetomidine.

Inclusion Criteria

The following patients were included in the study –

1. Patients of age between 18 and 50 years of both sexes.
2. Patients with American Society of Anaesthesiologists grade 1 and 2 physical status.
3. Patients posted for various Upper limb elective surgeries.

Exclusion Criteria

Patients with the following features were excluded from the study –

1. Patients with age less than 18 years and more than 50 years.
2. Patients with history of hypersensitivity to local anaesthetics.
3. Significant bleeding or coagulation abnormalities in the patient.
4. Patients with mental impairment.
5. Patients with peripheral neuropathy.
6. Patients with significant pre-existing systemic diseases.
7. Vulnerable patients (i.e. children, pregnant women, cognitively impaired) were excluded from the study.
8. Patients with baseline heart rate less than 65 bpm.
9. Patients with Blood pressure less than 100/60 mm of Hg.
10. Patients with known allergy to Dexmedetomidine, Clonidine and Bupivacaine were excluded from the study.
11. Patients with failed Supraclavicular brachial plexus block.

Preliminaries Included

- 1) Written informed consent and baseline investigations.
- 2) Intravenous access – with 18G intravenous cannula on the contra lateral upper limb.
- 3) Pre-medication – Injection midazolam 1 mg was given intravenously before the procedure.

Drug combination given after eliciting paraesthesias was –

In group C – 20 ml of 0.5% Bupivacaine + 20 ml of normal saline + 0.5 $\mu\text{g}/\text{kg}$ of Clonidine.

In group D–20 ml 0.5% Bupivacaine + 20 ml of normal saline + 0.5 $\mu\text{g}/\text{kg}$ of Dexmedetomidine.

Monitors: Pulse oximetry, Non-invasive blood pressure monitor on the opposite upper limb, respiratory rate, electrocardiography. Crash trolley is kept ready for emergency.

Procedure performed and the onset of sensory blockade and motor blockade were noted. Intra-operatively, haemodynamics were monitored at regular intervals. Following completion of surgery, the patients were monitored to assess the quality and duration of post-operative analgesia. Thus, the patients were asked to classify analgesia as no pain, mild pain, moderate pain or severe pain every hour for the first 6 hours and then again at 8 and 10hrs. At the time of each subsequent assessment, patients were observed and/or questioned about any subjective and/or objective side effects (sedation, nausea, vomiting or respiratory depression, neurological injury).

Definitions of Parameters

Onset of sensory blockade – defined as interval between the time of injection of test drug to reduction of pain at the site of surgery or loss of sensation to pin prick at the site of surgery.

Onset of motor blockade – defined as interval between time of injection of drug to development of motor weakness in the blocked limb.

Duration of analgesia – defined as interval between onset of analgesia/sensory blockade to the time patient first complains of pain at wound site.

Failure of block – it is defined as inadequate or patchy analgesia even after 30 mins of the drug administration. Depending on the effectiveness of the block the patient was administered sedative & analgesic in the form of IV midazolam & Injection Fentanyl. In case of complete failure general anaesthesia was administered and the case was excluded from the study.

Grading of sensory blockade

I = No difference

II = Some difference but pin prick still sensed in blocked arm

III = No prick sensation in blocked arm

Grading of motor blockade (Bromage 3 point score)

0 = normal motor function with full flexion and extension of elbow, wrist and fingers,

1 = decrease motor strength with ability to move fingers and/or wrist only

2 = complete motor blockade with inability to move fingers

Following nerves were tested for motor block

- Musculocutaneous nerve-by flexion of arm,
- Radial nerve by extending the flexed arm & wrist,
- Median nerve by asking the patient to flex the wrist and also opposing the thumb to 2nd & 3rd fingers,
- Ulnar nerve by flexing 4th & 5th fingers.

Baseline hemodynamic parameters were recorded, then after giving the block parameters were recorded every 5 mins for first 30 mins, then every 10 minutes till the end of surgery.

Statistical Analysis

Results were statistically analysed using Unpaired t test and Fisher exact test. A 'p' value of <0.05 was considered as significant. All the values are mentioned as Mean ± Standard Deviation.

RESULTS

The prospective, randomized, comparative study was conducted in the Department of Anesthesiology, Gandhi Hospital, Secunderabad on 60 patients.

Age and Weight Distribution

The average age was 33.13 ± 9.179 years in group C, and 31.4 ± 8.295 years in group D. Youngest patient in the study group was 19 years and oldest was 50 years. The average weights of the patients were 67.66 ± 8.38 kgs in group C and 69 ± 9.505 kgs in group D respectively. There was no significant difference in age and weight between the two groups.

Sex Distribution

Both groups had predominantly male population, accounting for nearly $\frac{3}{4}$ of the total study population in each group.

Onset Of Sensory and Motor Blockade

Table 1: Onset of sensory and motor blockade in the two groups

		Sensory blockade			Motor blockade		
		Group C	Group D	P Value	Group C	Group D	P Value
Time taken for the onset (min)	Mean	6.8300	7.0600	0.5755	11.1300	11.2300	0.8600
	SD	1.7200	1.4300		2.2500	2.2300	

The mean time of onset of sensory blockade in group C was 6.83 ± 1.72 min. In group D it was 7.03 ± 1.43 min. The slight delayed onset of sensory blockade in group D was however not statistically significant.

The mean time of onset of motor blockade was 11.13 ± 2.25 in group C when compared to 11.23 ± 2.23 in group D. This was not clinically or statistically significant.

Duration of Analgesia

The mean time for duration of analgesia was $357 \pm$

37.62 min in group C whereas in group D the mean was 489.66 ± 59.91 min. This was statistically significant with a p value of <0.0001.

Table 2: Duration of analgesia in the two groups

		Group C	Group D	P Value
		Duration of analgesia (min)	Mean	
	SD	37.6200	59.9100	

Hemodynamic Parameters

Table 3: Comparison of Pulse rate (beats per min), Systolic blood pressure and Diastolic blood pressure (in mm of Hg) in the two groups

	Pulse rate			Systolic blood pressure			Diastolic blood pressure		
	Group C (MEAN±SD)	Group D (MEAN±SD)	P Value	Group C (MEAN±SD)	Group D (MEAN±SD)	P Value	Group C (MEAN±SD)	Group D (MEAN±SD)	P Value
Baseline	81.6±8.6	78.3±9.46	0.1647	125 ± 9.07	124.5±10.7	0.8463	77.6±6.02	78.8±7.72	0.5046
5 MIN	81 ± 9.5	77.9±10.5	0.2354	124 ± 8.28	122.4± 8.9	0.4744	76.6±4.65	78.8± 7.02	0.1578
10 MIN	81 ± 9.2	77.9 ± 9.83	0.2123	123.4±10.2	122 ± 8.90	0.5536	76.9±5.86	77.6± 7.14	0.6796
15 MIN	81.1±9.4	78.7 ± 9.09	0.3179	123 ± 11	123 ± 9.08	1.000	76.7±5.78	77.1± 7.39	0.8162
20 MIN	81 ± 8.2	78.4 ± 8.79	0.2410	122 ± 10.6	121.9±10.1	0.9702	76.0 ± 6.5	76.0± 7.45	1.0000
25 MIN	80.9±7.5	78.2 ± 9.98	0.2426	121 ± 11.5	121 ± 10.3	1.0000	76.0±6.20	77.3± 7.40	0.4638
30 MIN	80.3±7.9	80.3 ± 7.96	0.2661	122 ± 11.9	121.7± 8.1	0.9095	74.7±7.31	76.6± 5.48	0.2593
40 MIN	79.5±7.1	77 ± 7	0.1743	124 ± 11	122.7± 5.3	0.5497	77 ± 5.7	74.9 ± 4.5	0.1187
50 MIN	80 ± 5.2	77.73±4.54	0.0769	124 ± 7.8	123.9± 3.9	0.9651	76 ± 4.7	76.6± 3.82	0.5529
60 MIN	81 ± 8.6	77.8 ± 8.05	0.1422	123 ± 13.5	121.2± 7.9	0.5311	75.0±6.60	76.2± 6.04	0.4655
70 MIN	80 ± 7.2	78.5 ± 4.46	0.3360	122 ± 10	122.53 ± 5	0.7961	77 ± 3.7	75.2± 4.60	0.0931
80 MIN	78 ± 6	75.83±5.11	0.1370	122 ± 6.64	124.2± 4.6	0.1357	76 ± 3.6	75.4± 4.32	0.5355
90 MIN	80 ± 6.95	78.2 ± 8.73	0.3806	124 ± 11.7	121.1±10.7	0.3202	76.5±6.75	79.2± 11.2	0.2628
100 MIN	78 ± 5.4	77.26±6.86	0.6442	124 ± 7.1	123.5± 5.9	0.7809	75 ± 4.6	75.3± 4.26	0.7741
110 MIN	77 ± 3.7	75.8 ± 5.44	0.3219	123 ± 5.4	124.7± 3.9	0.1617	74 ± 3.7	75.8± 4.68	0.1038
120 MIN	79 ± 7	76.03±5.85	0.0798	125 ± 7.9	124.3± 5.3	0.7014	74.5±4.31	76.2± 4.51	0.1410

There was no statistically significant difference in the pulse rate, systolic blood pressure and diastolic blood pressure between the two groups during all the periods of study.

Adverse Effects

In Group C, only three patients out of thirty patients had hypotension at 25 – 30 min of intra-operative period. No such adverse effect was seen in Group D. There were no other adverse effects observed. This was analysed using Fisher's exact test which provided a 'p' value of 0.2373 which is not statistically significant.

Table 4: Comparison of Adverse effects between the two groups

	Hypotension	No adverse effect	Test	P Value
Group C	3	27	Fisher's Exact test	0.2373
Group D	0	30		

DISCUSSION

Patient satisfaction, a growing demand for cost effective anaesthesia and a favourable postoperative recovery profile have resulted in increased popularity for regional techniques. Brachial plexus block is an easy and relatively safe procedure for upper limb surgeries. Supraclavicular approach to brachial plexus block is associated with rapid onset and reliable anaesthesia.^[5,6] Lanz et al. showed that blockade of the brachial plexus with a technique directed near the first rib (at the level of trunks and divisions of brachial plexus) provides the most reliable, uniform and predictable anaesthesia for upper extremity.^[7] Hence it is one of the most popular techniques used for upper limb blocks. Supraclavicular approach has been routinely used in our institution for upper limb surgeries and it has proven to be a safe technique as well.

Currently available local anaesthetics can provide analgesia for limited period of time when used as single injection.^[8] To extend the analgesia period beyond the operating rooms, various methods have been tried, like continuous infusion of local anaesthetics via indwelling catheters, use of different additives in local anaesthetics. Increasing the volume (dose) of LAs may prolong the duration of analgesia, but may also increase the risk of LA systemic toxicity. A variety of perineural adjuvants, including buprenorphine, clonidine, dexamethasone, magnesium, and midazolam, have been used to prolong the duration of analgesia of nerve blocks with varying degrees of success.^[9]

Clonidine is known to produce antinociception and to enhance the effect of local anaesthetic when administered intrathecally and epidurally. Three possible mechanisms for this interaction have suggested.

- First Clonidine blocks conduction of C and A δ fibers and increases potassium conductance in isolated neuron in-vitro and intensifies conduction of blockade of local anaesthetic .
- Second Clonidine may cause local vasoconstriction in clinical setting, thereby reducing vascular removal of local anaesthetic surrounding neural structure.
- Finally it has become evident that analgesic whether administered systemically or locally can enhance peripheral blockade.

Dexmedetomidine and clonidine are both α selective agonists. It is possible that they work in a similar manner and may indicate a class effect. Keeping this fact in mind, it was decided to compare the action of two α agonists, i.e. clonidine and dexmedetomidine with bupivacaine (0.25%), in peripheral nerve blocks so that by increasing the duration of analgesia with a single shot block, a longer duration of postoperative analgesia can be achieved without significant clinical side effects and hence we can avoid continuous catheterization.

A total of 60 patients within the age group of 18 – 50 were included in the study, 30 in each group. The patients were then randomized to one of two groups Group C and Group D using a computer generated randomization table. The sample size was comparable in demographic data and duration of surgery. The two groups were comparable in age and weight distribution. Both the groups had a predominant male population accounting for nearly ¾ th of the study group.

Onset of sensory and motor blockade

The mean time of onset of sensory blockade in group C was 6.83 ± 1.72 min. In group D it was 7.03 ± 1.43 min. The slight delayed onset of sensory blockade in group D is however not statistically significant. The p value was >0.05 (0.5755). A prospective, randomized, double blind, placebo-controlled study was conducted by Chakraborty S et al to assess the efficacy of Clonidine as an adjuvant to Bupivacaine (Group A) in brachial plexus block.^[10] Group B - received Bupivacaine with normal saline. The mean onset of sensory block (group A 6.2 ± 0.78 min, group B, 8.7 ± 1.01 min) and motor block (group A, 10.6 ± 1.36 min; group B, 18.1 ± 1.35 min) was significantly faster in group A than in group B ($P < 0.001$). These results are comparable with our study. Sarita S Swami et al, conducted a randomised double blind prospective study to compare Dexmedetomidine and Clonidine as an adjuvant to local anaesthesia in Supraclavicular brachial plexus block.^[11] Onset of sensory block was faster in Group D than in Group C, while onset of motor block was faster in Group C than in Group D, but the difference was not statistically significant. This observation matches well with our study.

Esmaglu et al added dexmedetomidine to levobupivacaine for axillary brachial plexus block and showed that it shortens the onset time of both sensory and motor block, prolongs the duration of block and the duration of postoperative analgesia.^[12] However, in our study, we found that onset of sensory and motor block was a little faster with Group C as compared with Group D, but it was statistically insignificant. The duration of analgesia in Group D was longer than in Group C, and it was statistically significant with a p value of <0.0001 . This observation supports the present study.

Duration of Analgesia

In present study the mean time for duration of analgesia was 357 ± 37.62 min in group C whereas in group D the mean was 489.66 ± 59.91 min. This was statistically significant with a p value of <0.0001 . A randomised double blind, prospective study was done by Sarita S Swami et al, to compare Dexmedetomidine and Clonidine as an adjuvant to local anaesthesia, there was significant increase in duration of analgesia in Group D (456.12 ± 97.99 min) as compared with Group C (289.67 ± 62.50

min).^[11] The difference was statistically significant with a p value of <0.001 . This observation supports our study.

In 2004 Hutschala D et al conducted a study to determine whether Clonidine added to Bupivacaine enhances and prolongs the analgesia after brachial plexus block via a local mechanism.^[13] They concluded that admixture of clonidine to bupivacaine plus epinephrine prolongs and enhances brachial plexus blockade. Lower plasma concentration of clonidine for block treatment strongly suggests a local effect.

Chakraborty S et al performed a randomized double blind placebo-controlled trial, in which it was concluded that addition of a small dose of clonidine to 0.5% bupivacaine significantly prolonged the duration of analgesia without producing any clinically important adverse reactions other than sedation.^[10] This observation supports our study in terms of prolongation of duration of analgesia.

Haemodynamic Parameters

In present study, it was observed that the changes in pulse rate, systolic blood pressure and diastolic blood pressure throughout the intraoperative period was not clinically and statistically significant. Three patients out of thirty patients in group C were observed to have hypotension at 25-30 min of intra-operative period. The hypotension was responsive to fluid bolus and vasopressors. This event of hypotension was not observed in group D and all the patients had a stable haemodynamic profile throughout the surgery. Hemodynamic parameters remained stable at all times in most of the patients both intraoperatively and postoperatively in our study. Stable hemodynamics was also reported by Singelyn et al and Bernard et al while using clonidine in BPB.^[14,15]

Bernard et al evaluated effects of adding 30-300 mcg Clonidine to local anaesthetic for brachial plexus block and found it is hemodynamically safe upto 150 mcg.^[15]

Singelyn F et al performed a study to assess the minimum dose of clonidine required to prolong the duration of both anaesthesia and analgesia after axillary brachial plexus blockade.^[14] They concluded that the dose of clonidine required to prolong significantly the duration of both anaesthesia and analgesia after axillary brachial plexus blockade is 0.5-1 microgram/kg and that, at this dose, clonidine may be used without important reported side effects even in outpatients.

Harshavardhana H S et al compared Efficacy of Dexmedetomidine to Clonidine added to Ropivacaine in Supraclavicular Nerve Blocks and observed that the mean time of onset of sensory and motor block was earlier in dexmedetomidine group as compared to clonidine group, though the difference was not statistically significant.^[16] The mean duration of sensory and motor block in

dexmedetomidine group was significantly prolonged ($p < 0.001$) in compare to clonidine group. Hence findings in the above study supports the observations made in the present study.

Limitations of the Study –

The present study incorporated a conventional paraesthesia technique for block. A US guided study would demonstrate the spread of local anaesthetic. Ultrasound should therefore be used as a dynamic tool to follow the spread of the local anaesthetic.

CONCLUSION

From our study, we conclude that when Clonidine (0.5 $\mu\text{g}/\text{kg}$) and Dexmedetomidine (0.5 $\mu\text{g}/\text{kg}$) are used as adjuvants to Bupivacaine (0.25%) in Supraclavicular brachial plexus block the following effects are seen –

- 1) The duration of analgesia is prolonged with Dexmedetomidine as compared to Clonidine.
- 2) No significant difference in onset of sensory and motor blockade is seen.
- 3) No significant difference in hemodynamic variables in two groups (Pulse rate, Systolic BP, Diastolic BP) is seen.
- 4) Only three patients in group Clonidine had hypotension as adverse effect. It was managed by fluid boluses and vasopressors. Hypotension was not observed in group D. No other side effects were observed in both the groups.

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