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CLONIDINE VERSUS DEXMEDETOMEDINE AS AN ADJUVANTS IN BRACHIAL PLEXUS BLOCK: A COMPARATIVE RANDOMIZED DOUBLE BLINDED PROSPECTIVE STUDY

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Abstract

Background: Ultrasonography(Usg) is the POINT OF CARE need in today's practice of medicine. What makes it trendy is its under vision opportunity, precision, vigilance and the most important being SAFETY. With ultrasound guided blocks adding an adjuvant like beta agonists to local anaesthetics will further reduce the anxiety and offer sedation to high risk patients for whom brachial plexus block (BPB) will be an better option compared to general anaesthesia and its complications. Aim: To study such adjuvants which is been extensively used in today's anaesthesia practice, i.e clonidine and dexmedetomedine with respect to BPB to observe the efficacy and potentiation in terms of a)Duration of motor and sensory blockade, b)Reduction of demand analgesia for NSAID'S, c)Total postoperative opioid need, d)Sedation score, e)Adverse events such as bradycardia, hypotension, loss of airway reflexes which needs treatment. Methodology: Patients recruited into 2 groups with one study drug allotted to each group. Surgery contemplated as per standard protocol using brachial plexus block with local anaesthetic mixture using Ropivacaine(2mg/kg) and lignocaine with adrenaline(4ml/kg) along with either dexmedetomedine or clonidine(1mcg/kg) under ulrasound guidance. Performance time and sedation score assessed intraoperatively along with hemodynamics. Postoperatively total analgesia and motor blockade duration, patient satisfaction score assessed and compared. Results: Demographics, hemodynamics, ultrasound performace time, intraoperative monitoring were all comparable amongst both groups. Total analgesia is typically prolonged with respect to Dexmedetomedine group(13.75 hours vrs 11.34 hours) and motor blockade which was dense was observed in clonidine group (12.85 hours versus 11.48 hours), both of which are statistically significant with p value <0.001 and 0.009 respectively. Conclusion: Using ultrasound and adjuvants will definitely enhance the efficiency of regional anaesthesia in today's evidence based patient centered practice.

Keywords: Dexmedetomedine better for postoperative analgesia, clonidine versus dexmedetomedine for postop analgesia, ultrasound guided block for safety and precision.

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Introduction

Ultrasonography is the POINT OF CARE need in today's practice of medicine. What makes it trendy is its under vision opportunity, precision, vigilance and the most important being SAFETY.

USG(ultrasonography) has made its way into anaesthesiology via REGIONAL ANAESTHESIA. One such vastly used regional technique for intraoperative anaesthesia and postoperative analgesia is UPPER LIMB-BRACHIAL PLEXUS BLOCK.

BPB(brachial plexus block) by giving dense motor blockade and sensory analgesia not only provides excellent conditions for surgeons to operate but also takes off the need of intubation and its response and risks of general anaesthesia in High risk patients of ASA-3 & 4 physical status

Although LA drugs are the main agents facilitating sensory and motor blockade, the adjuvants excels in prolonging/potentiating the analgesia and motor blockade, especially in postoperative period. This further reduces the sympathetic response and hence lessens morbidities, lessen the need of OPIOIDS, need of NSAID'S requirement PERIOPERATIVELY.

Most commonly used adjuvants currently for BPB are clonidine and dexmedetomedine. Both being alpha 2 agonists, dexmedetomedine is about 8 times higher selective to clonidine at alpha 2 receptors 2. Hence they act by activating alpha 2 receptors on sympathetic preganglionic neurons that mediate reduction in norepinephrine release, overall effect being sympatholysis resulting in analgesia, sedation, hypotension and bradycardia. Both the drugs are used rampantly today in view of there ability to maintain airway reflexes in conscious sedation 2.

The main drawbacks of regional techniques are pain at puncture site, fear of needles and recall of procedure. These factors stress the need of sedation which offers analgesia, anxiolysis and amnesia.

So we planned to study such adjuvants which is been extensively used in today's anaesthesia practice i.e clonidine and dexmedetomedine with respect to BPB to observe the efficacy and potentiation in terms of:

- A) Duration of motor and sensory blockade
- b) Reduction of demand analgesia for NSAID'S
- c) Total postoperative opioid need.
- d) Sedation score
- e) Adverse events such as bradycardia, hypotension, loss of airway reflexes which needs intervention. (morethan 20% of baseline reading)

Common features amongst the study drugs which helped us to choose these drugs so that there can be efficient blinding

- 1.Same group of drug-alpha 2 agonists
- 2. Transparent nature
- 3.Common actions analgesia, motor blockade, prolongation of sensory and motor blockade of Local Anaesthetics, central sympatholytic action.
- 4.Sedation
- 5. Common Cardiovascular effects- bradycardia, hypotension

Methodology

After obtaining hospital ethical committee clearance, 35 patients each are recruited into 2 groups, one being Group D and Group C.

Prospective Randomized Double Blinded 2 Arm study was planned, with blinding both observer and patient blind to the study.

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Patients undergoing upperlimb surgeries who are of ASA 1-2 physical status are explained the study in PAC and after patients consent for the study pts were recruited. Patients are given random sealed envelops, which are handed over to the block performing anaesthesiologist, who will open the sealed envelop and prepares and give the drug written in the group allotted envelop.

Patients are maintained on 6 hours NPO for solids, 2 hours for clear liquids. Antiaspiration prophylaxis are given with rantidine 50mg iv and metaclopramide 10mg iv as per hospital protocol 1 hour prior to planned procedure.

Patients are received in OT, reviewed for any fresh complaints, confirmed NPO status.

Monitors connected, baseline vitals noted and entered into chart.

Block performing anaesthestist prepares the envelope assigned drug which will be blinded to patient and to the observer who will be assessing the effects post blockade.

Patients is made to lie in supine position with neck turned to opposite side of operated upper limb.

Under strict asepsis, block site painted and draped with betadine solution. Sterile set opening time noted till preparartion of drug by performing anaesthesiologist.

Needle port site skin infilterated with 2% lignocaine. Ultasonography performed to obtain satisfactory field, Imaging time noted from onset of observation to obtaining satisfactory field. Brachial plexus block performed by supraclavicular approach and axillary approach with pajunk block needle is used to perform block connected to 200cm extension which is connected to 20ml syringe containing study drug.

Drug used- 0.75% ropivacaine 15ml + 2% lignocaine with adrenaline(5mcg/cc i.e 1 in 2,00,000 conc) 15ml+ dexmedetomedine(1mcg/kg)+ NS to make total drug volume 50ml in GROUP-D Drug used-0.75% ropivacaine 15ml+2% lignocaine with adrenaline(5mcg/cc i.e 1 in 2,00,000 conc) 15 ml+clonidine (1mcg/kg)+NS to make total drug volume 50ml in GROUP-C.

Time from needle insertion into last drug injection is noted as performance time.

Onset time of sensory blockade is assessed following blockade-loss of pinprick pain sensation(clock time)

Onset of motor blockade is assessed following blockade-loss of extension/flexion against resistance/movement of fingers.

Sensory blockade grade

0-intact sensations

1-analgesia

2-anaesthesia

Motor blockade grade

0-no motor block

1-decreased purposeful movements

2-complete motor blockade with not able to move fingers

Modified Wilson sedation score

1-oriented, eyes may be closed but can respond to command like telling his name and place

2-eyes may be closed, arousable only to command-name, please open eyes.

3-arousable to mild physical stimulation(earobe tug)

4-unarousable to mild physical stimulation

Patients are assessed every 15minutes intraoperatively and postop every 15mints for first 2 hours(if surgery duration is <2 hours) and the 6th hourly till 24 hours.

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During postoperative period

- a) duration of sensory and motor blockade
- b) demand analgesia
- c) opiod /NSAID need
- d) Need of airway manipulations
- e) sedation score
- f) patient satisfaction are noted.

Inclusion Criteria

- 1. Adult Male and females Patients of age 18-60yrs belonging to ASA 1-2 physical status.
- 2.Patient scheduled for upperlimb surgery willing to participate in study under regional anaesthesia.

Exclusion Criteria

- 1.ASA -3 and above physical status patients.
- 2.Patients allergic to LA.
- 3. Patient not willing to take up regional blocks, lost for follow up.
- 4. Coagulation abnormalities, on antiplatelets.
- 5. Patients with contraindications for study drugs.

Statistical analysis

Data were analyzed using SPSS software version 18.0 (SPSS Inc. Released in 2009. PASW Statistics for Windows, Version 18.0. Chicago: SPSS Inc.). The continuous variables were analyzed using descriptive statistics (mean and SD). The categorical variables were analyzed using frequency and percentage. The normalcy of the data was checked by applying the Kolmogorov-Smirnov Test.

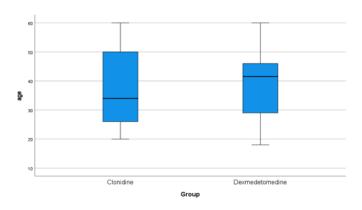
Baseline comparisons between the groups were carried out using students' t-test for the data of continuous variables following normal distribution and Mann Whitney U test for variables not following a normal distribution. Chi-square test for testing the difference in the percentage distribution of categorical variables between the group. The baseline, during, and post a comparison of HR, SBP, and DBP between the groups was carried out using repeated measures of ANOVA (RM ANOVA) test. Bonferroni multiple comparisons test was used to compare the pairwise differences. Two-tailed P value < 0.05 was considered statistically significant at a 5% level of significance.

Demographics were comparable amongst both the groups except the change with respect to height where Group D (dexmedetomedine-with 155.53cm) had higher limits than (Group Clonidine (group 1)with 128.87cm which is statistically significant as shown in table 1 and table 2 below.

Table 1: Demographics of study participants

		Group		Total	
		1	2		
sex	Male	19	23	42	
		45.2%	54.8%	100.0%	
	Female	19	15	34	
		55.9%	44.1%	100.0%	
Total		38	38	76	
P value	0.356				

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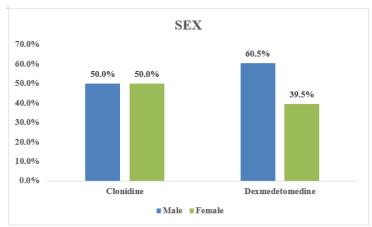


Figure 1: Comparison between sex and Groups

Table 2: Demographics of study participants

variables	group(N = 38 in each)	Mean	Std. Deviation	P value
Age	1	38.74	13.02	0.91
	2	39.05	12.45	
Weight	1	61.03	8.38	0.32
	2	63.05	9.28	
Height	1	128.87	66.82	0.03
	2	155.53	37.31	
BMI	1	22.87	2.45	.491
	2	23.26	2.52	

Haemodynamic variables are also comparable among both the groups as shown in table 3.

Table 3: Mean arterial BP comparision amongst both groups

	Mean	Std. Deviation	P value within the group	P value between the group
BMAP1(group 1)	92.66	8.842	< 0.001	0.877
IMAP1	86.58	9.226		
RMAP1	83.18	7.843		
BMAP2(group 2)	93.53	8.968	< 0.001	
IMAP2	86.16	7.398		
RMAP2	83.53	7.678		

Recovery VAS score charting reveals a good number of patients of Group C are having mean score around 2(n-23) and maximum pain score is 3(n-2) whereas Group D patients has mean score of 1(n-29) but the maximum pain score is 4 where a patient complained of some discomfort at the needle insertion site.

Sedation score intraoperatively was higher in Clonidine group with 3 divisions of assessment that is Score 1 where patient is conscious, spontaneous eye closing and opening present and easily arousable, Score 2 where patient is sleepy and needs loud call for waking up, Score 3 where patient is deeply sedated and needs physical stimulation for alerting as detailed in Table 4.

Table 4:	Sedation	score of	both	groups
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	SEI	Total			
	1	2	3		
Group C	1	19	18	38	
	2.6%	50.0%	47.4%	100.0%	
Group D	6	16	16	38	
	15.8%	42.1%	42.1%	100.0%	
Total	7	35	34	76	
P Value = 0.139					

Nature or duration of surgery hasn't influenced much towards VAS or sedation score.

Onset of sensory blockade assessed by pinprick(2.96 minutes vrs 3.65 minutes) and onset of motor blockade by push, pull, lift tests reveals early blockade with respect to dexmedetomedine group(1.68 minutes vrs 2.26 minutes) over clonidine group which is statistically not significant. Total analgesia is typically prolonged with respect to dexmed group(13.75 hours vrs 11.34 hours) and motor blockade which was dense was observed in clonidine group(12.85 hours versus 11.48 hours),both of which are statistically significant with p value <0.001 and 0.009 respectively as depicted in table 5.

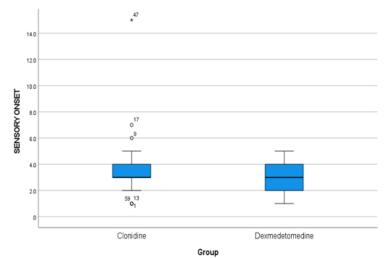


Figure 2: Comparison between Sensory onset and Groups

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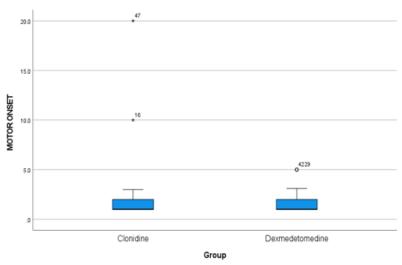


Figure 3: Comparison between Motor onset and Groups

Table 5: Onset of sensory and motor blockade,total analgesia and motor blockade duration, preparation time, injection time, performance time and drug volume

comparison of both groups

Parameter	Group	Duration in	Standard	P value
	allocated	minutes	deviations	
DURATION	1	92.76	30.15	0.809
	2	94.47	31.25	
SENSORY ONSET	1	3.65	2.22	0.110
	2	2.96	1.07	
MOTOR ONSET	1	2.26	3.32	0.855
	2	1.68	1.00	
TOTAL	1	11.34	2.45	<0.001*
ANALGESIA				
	2	13.75	2.55	
TOTAL MOTOR	1	12.85	2.48	0.009*
	2	11.48	1.92	
PREP TIME	1	6.21	1.39	0.613
	2	6.32	1.36	
IT	1	3.87	1.77	0.674
	2	4.052	1.96	
PERFORMANCE	1	10.07	3.63	0.619
TIME				
	2	9.40	2.22	
DRUG VOLUME	1	25.76	2.61	0.549
	2	26.11	2.70	

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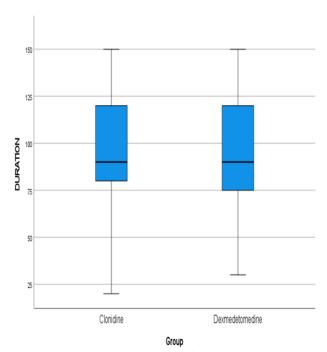


Figure 4: Total duration of sensory analgesia in both groups

What was observed classically was the difference in the tolerance for pain among rural and urban population. Few of rural patients had good tolerance for pain where there total analgesia lasted for morethan 24 hours and few urban patients had minimal tolerance where surgery which held totally calm during intraoperative period had patients complaining of some discomfort otherthan operative area in the recovery room and median period around 6 hours postoperatively. Exception to such findings in urban was an young boy of 19 years with supracondylar fracture elbow saying no pain or no discomfort even during discharge time. Since the difference among rural and urban population was less with rural patients being 8 and 6 in group 1 and group 2 we couldn't conclude regarding above findings. A study amongst such difference would better conclude the findings.

Review literature

- 1. In the article of Archana tripathi,khushboo sharma J Anaesthesiol clin pharmacol.2016 julsep;32(3): 344-348 Duration of analgesia was 349.33+/- 42.91 minutes significantly less in group Clonidine compared to 525.33 +/- 42.89 minutes in group Dexmedetomedine with Quality of anaesthesia was significantly better in dexmed group- p value< 0.001
- 2. In the article Sruthi arunkumar, V R Hemanth kumar Saudi J Anaesth. 2015 oct-Dec; 9(4): 404-408 Onset(8.53+/- 1.81 versus 11.93+/- 1.96) and duration of sensory blockade(316+/- 31.5 versus 281+/-37) is better significantly in dexmed group,, whereas no significant change noticed in motor blockade duration(15ml ropin)
- 3. Similarly in Swami SS,keniya VM,Ladi SD, Rao R.Comparision of dexmedetomedine and clonidine as an adjuvant to local anaesthesia in supraclavicular brachial plexus block: A randomized prospective study,IJA sep 3; 56-243-9 2012, Quality of block-grade 4 reached in 24 patients compared to 12,,grade 1 in 1 patient in clonidine group
- 4. Vania kanvee *et al.*;A Comparative study of clonidine and dexmedetomedine with ropivacaine.JRMDS,volume 3,issue 2-june 2015 concluded in there study that Duration of sensory(540 versus 346.8) and motor blockade(586 versus 386.4) as well as post op analgesia(559 versus 372) were prolonged in dexmed group than clonidine group

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- 5. contrast to above studies and our study , Bafna U *et al.* in comparision of clonidine and dexmedetomedine as an adjunct to 0.5% ropivacaine in supraclavicular brachial plexus block: A prospective randomized double blind and controlled study. J recent adv pain 2015, Sensory and motor block onset times were shorter in dexmedetomedine group(4.9 +/-1.08 minutes than in ropivacaine alone group(12.2+/-3.16minutes) /Ropivacaine+ 2mcg/kg clonidine group(10.7+/-4.05).but regarding the quality of block was higher in dexmedetomedine group compared to other groups-mean pain scores 0.25+0.439 compared to 2.65+/-0.48 and 1.275+/-0.45, which even our study dexmed group had.
- 6. Kathuria S *et al.* in dexmedetomedine as an adjuvant to ropivacaine in supraclavicular brachial plexus block. saudi J Anaesth 2015;9:148-54.As an adjuvant shortens sensory(9.75+/-4.23) compared to (22.20+/- 8.62) and (14.55+/-8.39) as well as motor block onset time(18.75+/-6.37)as compared to 39.05+/-16.38 and 30.15+/-14.52) prolongs sensory(789 versus 451 and 670 minutes) and motor block(754 versus 387 and 612 minutes) duration

Conclusion

Use of ultrasound as we said earlier being rampant now, can help us to come down with the dose of drug used, volume of drug needed to effectively block the plexus compared to nerve stimulator guided or anatomic landmark guided. Total analgesia is typically prolonged with respect to dexmed group(13.75 hours vrs 11.34 hours) and motor blockade which was dense was observed in clonidine group(12.85 hours versus 11.48 hours),both of which are statistically significant with p value <0.001 and 0.009 respectively.

Though we dint had statistically significant difference among both group with respect to performace time or volume as this study uses Ultrasonography as a common mode for performing procedure and hence we cannot conclude upon the same.

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