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Research Article

A double blind randomized study to assess the addition of clonidine to ropivacaine in supraclavicular brachial plexus block

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ABSTRACT

Background: The supraclavicular brachial plexus block provides anesthesia of the entire upper extremity in consistent and time-efficient manner. Ropivacaine is an amide, local anaesthetic agent, eliciting nerve block in brachial plexus. Clonidine as an adjuvant to ropivacaine enhances the quality and duration of analgesia when given epidurally or intrathecally. The aim of the present study was to assess the effect of adding clonidine to ropivacaine in supraclavicular brachial plexus block.
Methods: Sixty patients were randomly divided into two groups, Group C and R. Group C received 0.5% of ropivacaine with 1 ml normal saline while Group R received same amount of ropivacaine with 1 ml (equivalent to 100µg) of clonidine for supraclavicular brachial plexus block. The groups were compared regarding quality of sensory and motor blockade, duration of post-operative analgesia, intra and post-operative hemodynamic changes and sedation scores.
Results: There was a significant increase in duration of sensory and motor block and duration of analgesia in Group C as compared to Group R ($P<0.001$). There was no significant difference in mean onset time for sensory and motor blockade, the hemodynamic parameters (pulse rate, diastolic and systolic blood pressure)during and after surgery, sedation score post operatively in either groups ($P>0.05$).
Conclusions: Clonidine 100µg added to 0.5% ropivacaine for supraclavicular brachial plexus block, does not shorten the onset of sensory and motor blockade but the combination produced prolonged sensory and motor blockade, improved and prolonged duration of analgesia, thereby decreasing the need for systemic analgesics without any hemodynamic changes.

Keywords: Supraclavicular brachial plexus block, Ropivacaine, Clonidine, Sensory and motor block

INTRODUCTION

Blocking of supraclavicular brachial plexus during upper limb surgeries was found to be very effective in producing anaesthesia and analgesia. This type of peripheral nerve blocks provide intraoperative and postoperative analgesia without any systemic side-effects.[1] Ropivacaineis an amide, local anaesthetic agent, eliciting nerve block via reversible inhibition of sodium influx in nerve fibres. A clinically adequate dose of ropivacaine with its efficacy, lower propensity for motor block and reduced potential for CNS and cardiac toxicity than bupivacaine, appears to be an important option for regional anaesthesia for upper limb surgeries.[2] Concurrent administration of adjuvants like clonidine to local anaesthetics in brachial plexus block may enhance the quality and duration of analgesia. The purpose of our study was to determine the efficacy of clonidine as an adjuvant to ropivacaine for supraclavicular brachial plexus block in terms of onset, duration, degree of sensory and motor blockade, postoperative analgesia and any complications if produced.

METHODS

After receiving Institutional ethical committee approval and written informed consent, 60 patients aged between 18-60 years, ASA I or II patients scheduled for upper limb surgeries were included in the study.

Exclusion criteria were patients of ASA grade Ill, IV. Patients, coexisting severe cardiovascular, respiratory or neurological disorders, uncooperative and restless patients, infection at the site of block placement, past history of allergy to local anaesthetics, patients receiving oral anticoagulants, pregnant women and lactating mothers.

Patients, randomly allocated by computer generated randomisation list divided into two groups R and C. Group R (n=30) received 30 cc of 0.5% Inj. Ropivacaine hydrochloride+ 1ml of normal saline and Group C (n=30) received 30 cc of 0.5% Inj. Ropivacaine hydrochloride + Inj. Clonidine hydrochloride 100µg (preservative free) diluted to 1ml with normal saline.

Before the procedure, visual analogue scale (VAS) on 0-10 cm. was explained to the patient for the assessment of pain where 0 denotes no pain and 10 denotes worst unimaginable pain.

After the patient was taken on operation table, and monitored using pulse oximeter, cardioscope and noninvasive blood pressure monitor. An intravenous access was secured using an in-dwelling cannula of appropriate size. Oxygen supplementation was given using nasal cannula @ 2litres/min. Brachial plexus block was performed by supraclavicular approach.

Patient was positioned supine with head turned about 30 degree to contralateral side. After palpating the interscalene groove to its most inferior point, which is just posterior to the subclavian artery pulse, the latter can be felt in the plane just medial to the midpoint of the clavicle. A 22G, 50 mm stimuplex needle with the nerve stimulator was directed just above and posterior to the subclavian artery pulse and directed caudally at a very flat angle against the skin. The needle was advanced until the paraesthesia or flexion/extension of finger was noted. If contraction was still observed with the stimulator voltage decreased to 0.5mA, then patients in each group was given drugs accordingly.

If the rib was encountered without paraesthesia or if blood was encountered, the needle was withdrawn and the landmarks as well as the plane of needle insertion path were re-evaluated.

Patients were evaluated to determine the onset of motor and sensory blockade. Failure of loss of arm abduction or pain at surgical site after 30 min was considered to be block failure and hence general anaesthesia was given to those patients and thus was excluded from the study.

After evidence of successful motor and sensory block, surgery was performed. In case of prolonged surgeries general anaesthesia was given as the effect of brachial plexus block seemed to be weaning i.e. when the patient started complaining of pain at the site of operation.

Sensory block was assessed by the pin prick method. Assessment of sensory block was done at each minute after completion of drug injection in the dermatomal areas corresponding to median nerve, radial nerve, ulnar nerve, and musculocutaneous nerve until complete sensory blockade. Onset of sensory block was defined as a reduction of sensibility to 30% or less. Complete sensory block was considered when there was complete loss of sensation to pin prick. Quality of sensory block was be graded by Hollmen scale.

- 1=normal sensation of pin prick
- 2=pin prick felt as sharp pointed but weaker compared with same area in opposite limb
- 3=pin prick recognized as touch with blunt object 4=no perception of pin prick

Assessment of motor block was carried out at each minute until complete motor blockade after drug injection. Onset of motor blockade was defined as reduction of muscle power to Grade 3 or less. Complete motor block was defined as complete inability to move the limb and fingers (Grade 0). Quality of motor block was graded as

- 100%-no movement of the entire arm, forearm and hand against gravity – grade 0
- 66%-flexion and /or extension movement in the hand not in arm – grade 1
- 33%- flexion and/or extension movement in both hand and arm against gravity not against resistance – grade 2
- 0%- flexion and/or extension movement in both hand and arm against resistance – grade 3

The duration of sensory blockade was defined as the duration between injection of the drug and return of the pinprick sensation. The duration of motor blockade was defined as the duration between drug injections to complete return of motor power with movement of all upper limb joints.

Time interval for first rescue analgesic was defined as the time interval between the injection of the study drug to the time of first rescue analgesic (VAS>4).Patients were given Inj Diclofenac 75mg (IV) if the pain score by VAS >4. Sedation of the patient was assessed by sedation score and graded as 1=awake, 2=drowsy but responsive to command, 3=very drowsy responsive to pain, 4=unresponsive.

Postoperatively patients were monitored every hourly for 12 hours, then after 12 hours patients were shifted to

ward and they were asked to note the time of requirement of first rescue analgesic and parameters like pulse, BP, sedation score and Complications, if any were noted.

Statistical analysis

All the parameters were compared between the two groups. An unpaired 't' test was used to compare the demographic and intra operative hemodynamic variables, onset and duration of sensory and motor block and time for rescue analgesic requirement. For comparing gender ratio Pearson Chi-Square test was employed. Sedation scores and pain scores by VAS were compared by using Mann whitney test. Results with p value <0.05 was considered as statistically significant.

RESULTS

No statistical significant difference was observed when two groups were compared in case of gender participated in the study as shown in Table 1.

Age and weight were comparable between the two groups and no statistical significance was observed among them as shown in Table 2.

Table 1: Distribution of study group as per sex.

Group		Sex		Total
		Male	Female	
Group C	Percent	53.3%	46.7%	100.0%
Group R	Percent	63.3%	36.7%	100.0%
Total	Count	35	25	60
	Percent	58.3%	41.7%	100.0%

Table 2: Comparison of age and weight among study groups.

Variable	Group C			Group R			Unpaired t test	p value
	N	Mean	SD	N	Mean	SD		
Age (years)	30	35.47	10.30	30	34.77	10.27	0.264	0.793
Weight (Kg)	30	56.33	8.67	30	57.57	8.39	0.560	0.578

Insignificant statistical difference was noted in the duration of surgery and onset of sensory and motor blockade when compared between the groups as given in Table 3 and 4.

Table 3: Comparison of duration of surgery among study groups.

Duration of surgery in hours	Group C			Group R			Unpaired t test	p value
	N	Mean	SD	N	Mean	SD		
	30	2.00	0.54	30	2.13	0.72	0.812	0.420

Table 4: Comparison of onset of sensory and motor block among study groups.

Onset in minutes	Group C			Group R			Unpaired t test	p value
	N	Mean	SD	N	Mean	SD		
Sensory blockade	30	7.37	2.04	30	7.53	2.06	0.314	0.754
Motor blockade	30	13.13	2.53	30	14.40	2.62	1.905	0.062

Table 5: Comparison of duration of sensory blockade and motor blockade among study groups.

Duration in hours	Group C			Group R			Unpaired t test	p value
	N	Mean	SD	N	Mean	SD		
Sensory blockade	30	11.28	1.13	30	9.62	1.01	6.043	0.000
Motor blockade	30	9.02	1.09	30	7.65	0.82	5.495	0.000

Table 6: Comparison of introperative pulse rate at various time intervals among study groups.

Pulse rate (minutes)	Group C			Group R			Unpaired t test	P value
	N	Mean	SD	N	Mean	Std Dev.		
Pre-Op	30	79.97	7.91	30	81.63	10.21	0.707	0.482
0 min	30	79.83	8.44	30	82.43	10.48	1.058	0.294
5 min	30	79.93	6.90	30	83.27	10.64	1.440	0.155
10 min	30	80.43	6.27	30	82.60	10.26	0.987	0.328
15 min	30	80.33	5.59	30	81.17	9.93	0.400	0.690
20 min	30	80.53	5.98	30	80.97	9.45	0.212	0.833
25 min	30	79.70	5.95	30	79.80	10.23	0.046	0.963
30 min	30	78.67	5.36	30	82.17	8.95	1.838	0.071
60 min	30	78.67	6.10	30	82.97	9.02	2.163	0.035
90 min	28	79.64	6.67	27	82.63	10.27	1.284	0.205
120 min	20	79.65	6.06	21	81.33	9.11	0.693	0.493
150 min	9	78.44	5.39	12	83.42	10.61	1.281	0.215
180 min	3	81.67	6.51	5	90.80	10.06	1.385	0.215
210 min	0			3	94.67	10.07		
240 min	0			1	82.00			
270 min	0			0				
300 min	0			0				

Table 7: Comparison of intraoperative SBP at various time intervals among study groups.

SBP(mmHg)	Group C			Group R			Unpaired t test	P value
	N	Mean	SD	N	Mean	SD		
Pre-Op	30	117.47	8.69	30	119.17	11.33	0.652	0.517
0 min	30	117.27	8.53	30	119.53	10.40	0.923	0.360
5 min	30	116.77	8.21	30	119.67	11.04	1.154	0.253
10 min	30	118.03	8.12	30	119.13	11.54	0.427	0.671
15 min	30	118.07	7.83	30	117.57	11.84	0.193	0.848
20 min	30	119.87	15.92	30	119.03	10.13	0.242	0.810
25 min	30	116.77	6.77	30	118.17	10.96	0.595	0.554
30 min	30	116.87	8.07	30	120.90	10.46	1.672	0.100
60 min	30	116.70	6.88	30	118.93	11.21	0.930	0.356
90 min	28	117.75	8.09	27	119.22	11.58	0.548	0.586
120 min	20	117.95	5.58	21	119.19	11.39	0.439	0.663
150 min	9	118.44	5.68	12	123.67	11.85	1.216	0.239
180 min	3	120.33	7.51	5	125.60	18.08	0.469	0.656
210 min	0			3	132.00	6.93		
240 min	0			1	130.00			

Table 8: Comparison of intraoperative DBP at various time intervals among study groups.

DBP (mmHg)	Group C			Group R			Unpaired t test	P value
	N	Mean	SD	N	Mean	SD		
Pre-Op	30	80.47	4.31	30	82.43	7.30	1.270	0.209
0 min	30	80.80	4.31	30	83.67	6.98	1.899	0.061
5 min	30	81.27	4.72	30	84.37	7.42	1.915	0.058
10 min	30	81.27	4.80	30	84.27	7.46	1.837	0.069
15 min	30	80.97	4.69	30	83.43	6.94	1.614	0.112
20 min	30	80.60	3.85	30	82.87	6.57	1.631	0.108
25 min	30	80.57	5.51	30	83.33	6.30	1.798	0.075
30 min	30	82.03	5.55	30	84.83	6.45	1.789	0.077
60 min	30	80.53	4.81	30	83.60	7.43	1.883	0.063
90 min	28	81.29	4.96	27	84.26	8.18	1.624	0.108
120 min	20	80.20	4.91	20	84.55	8.39	2.001	0.053
150 min	9	79.33	3.64	12	85.42	8.24	2.059	0.053
180 min	3	80.67	4.51	5	91.80	8.67	2.021	0.090
210 min	0			3	95.33	7.57		
240 min	0			1	94.00			

Table 9: Comparison of post operative pulse rate at various time intervals among study groups.

Post-operative Pulse rate (hours)	Group C			Group R			Unpaired t test	P value
	N	Mean	SD	N	Mean	SD		
0 hour	30	79.43	7.23	30	82.13	9.54	1.236	0.222
1 hour	30	78.47	6.91	30	81.47	8.96	1.452	0.152
2 hour	30	78.53	7.30	30	81.13	8.85	1.242	0.219
3 hour	30	78.77	6.46	30	80.03	9.09	0.622	0.536
4 hour	30	77.73	5.18	30	79.57	7.76	1.076	0.286
5 hour	30	77.80	5.39	30	79.53	7.84	0.998	0.323
6 hour	30	78.60	5.37	30	78.40	6.99	0.124	0.902
7 hour	30	78.00	6.67	30	78.93	8.24	0.482	0.632
8 hour	30	77.87	6.22	30	79.30	9.58	0.687	0.495
9 hour	30	77.17	5.26	30	78.07	6.95	0.566	0.574
10 hour	30	77.60	5.54	30	77.73	7.34	0.079	0.937
11 hour	30	76.97	4.87	30	78.37	6.40	0.953	0.344
12 hour	30	76.77	4.93	30	77.97	6.47	0.808	0.422

Table 10: Comparison of post op SBP at various time intervals among study groups.

Post-operative SBP (mm Hg)	Group C			Group R			Unpaired t test	P value
	N	Mean	SD	N	Mean	SD		
0 hour	30	117.87	7.13	30	118.37	10.39	0.217	0.829
1 hour	30	116.63	6.05	30	117.50	9.65	0.417	0.678
2 hour	30	117.53	6.60	30	117.90	9.11	0.179	0.859
3 hour	30	116.90	6.78	30	117.57	9.42	0.315	0.754
4 hour	30	117.37	6.31	30	117.60	8.54	0.120	0.905
5 hour	30	117.10	6.51	30	118.30	7.75	0.649	0.519
6 hour	30	117.47	6.25	30	117.43	7.87	0.018	0.986
7 hour	30	117.70	5.83	30	118.07	8.44	0.196	0.846
8 hour	30	116.33	6.65	30	116.40	9.01	0.033	0.974
9 hour	30	116.83	6.90	30	115.93	7.66	0.478	0.634
10 hour	30	116.70	5.86	30	117.40	8.83	0.362	0.719
11 hour	30	117.60	6.04	30	117.07	7.84	0.295	0.769
12 hour	30	117.20	6.13	30	117.30	7.89	0.055	0.956

Table 11: Comparison of post op DBP at various time intervals among study groups.

Post-operative DBP (mm Hg)	Group C			Group R			Unpaired t test	P value
	N	Mean	SD	N	Mean	SD		
0 hour	30	80.63	4.63	30	82.97	7.04	1.516	0.135
1 hour	30	80.73	5.15	30	81.83	6.20	0.747	0.458
2 hour	30	80.37	5.18	30	81.60	5.18	0.922	0.361
3 hour	30	80.23	5.44	30	81.10	5.90	0.591	0.557
4 hour	30	79.83	4.28	30	81.30	5.88	1.104	0.274
5 hour	30	80.67	4.36	30	81.63	4.92	0.805	0.424
6 hour	30	81.03	3.35	30	82.20	5.57	0.983	0.330
7 hour	30	81.00	3.90	30	82.97	5.48	1.601	0.115
8 hour	30	80.90	4.47	30	81.97	5.74	0.803	0.425
9 hour	30	80.20	3.92	30	80.90	5.83	0.546	0.587
10 hour	30	80.60	4.81	30	81.80	5.02	0.945	0.348
11 hour	30	80.23	2.78	30	81.87	4.09	1.810	0.076
12 hour	30	80.13	4.03	30	81.37	4.17	1.164	0.249

Table 12: Comparison of time for first rescue analgesia among study groups.

Time for first rescue analgesia (hours)	Group C			Group R			Unpaired t test	p value
	N	Mean	SD	N	Mean	SD		
	30	14.48	1.31	30	12.58	1.11	6.051	0.000

The mean duration of sensory and motor blockade were statistically highly significant (p=0.00) in Group C compared to Group R as given in Table 5. No statistical significant difference was noted in the hemodynamic parameters (pulse rate, diastolic and systolic blood pressure) during and after surgery among the two groups as shown in Tables 6-11. The mean time for first rescue analgesia required post operatively was much longer in Group C as compared to Group R and the difference was significant(p=0.00) as shown in Table 12. Table 13 shows that both the groups had comparable VAS scores upto 6th hour postoperatively, but from 7th hour to 11th hour post operatively Group C had lower VAS score when compared to Group R. Though the difference was statistically significant (p<0.05) clinically there was no difference between the two groups.

Table 13: Comparison of post operative pain at various time intervals among study groups.

Post-operative pain	Group C			Group R			Mann Whitney Test	
	N	Mean	SD	N	Mean	SD	Z value	P value
0 hour	30	0.00	0.00	30	0.00	0.00	1.516	0.135
1 hour	30	0.00	0.00	30	0.00	0.00	0.747	0.458
2 hour	30	0.00	0.00	30	0.00	0.00	0.922	0.361
3 hour	30	0.00	0.00	30	0.00	0.00	0.591	0.557
4 hour	30	0.00	0.00	30	0.00	0.00	1.104	0.274
5 hour	30	0.00	0.00	30	0.07	0.25	0.805	0.424
6 hour	30	0.00	0.00	30	0.23	0.57	0.983	0.330
7 hour	30	0.07	0.25	30	0.63	0.93	1.601	0.115
8 hour	30	0.33	0.61	30	1.33	1.06	0.803	0.425
9 hour	30	0.87	1.07	29	2.38	1.24	0.546	0.587
10 hour	29	1.55	1.33	22	2.95	1.09	0.945	0.348
11 hour	26	2.15	1.19	14	3.36	1.01	1.810	0.076
12 hour	22	2.82	0.96	5	3.20	0.84	1.164	0.249

Table 14: Comparision of sedation scores among study groups.

Sedation score	Group C			Group R			Mann Whitney Test
	N	Mean	SD	N	Mean	SD	P value
0 hour	30	0.00	0.00	30	0.00	0.00	1.000
1 hour	30	0.00	0.00	30	0.00	0.00	1.000
2 hour	30	0.00	0.00	30	0.00	0.00	1.000
3 hour	30	0.00	0.00	30	0.00	0.00	1.000
4 hour	30	0.00	0.00	30	0.00	0.00	1.000
5 hour	30	0.00	0.00	30	0.07	0.25	1.000
6 hour	30	0.00	0.00	30	0.23	0.57	1.000
7 hour	30	0.07	0.25	30	0.63	0.93	1.000
8 hour	30	0.33	0.61	30	1.33	1.06	1.000
9 hour	30	0.87	1.07	29	2.38	1.24	1.000
10 hour	29	1.55	1.33	22	2.95	1.09	1.000
11 hour	26	2.15	1.19	14	3.36	1.01	1.000
12 hour	22	2.82	0.96	5	3.20	0.84	1.000

The sedation score was compared between the two groups and found they were not significant statistically as shown in Table 14.

DISCUSSION

The supraclavicular approach is considered the most efficacious brachial plexus block in upper limb surgeries that does not involve shoulder.[3] This is because the block is performed at the level of nerve trunks, where, almost the entire innervations of the upper extremity are confined to a very small surface area.[4]

Ropivacaine being a long acting pure S-enantiomer, structurally and pharmacologically related to bupivacaine but with less CNS and cardiovascular toxicity compared to bupavacaine.[5,6] It is less likely to penetrate large myelinated motor nerve fibers, resulting in a relatively reduced motor blockade.

Clonidine as an adjunct to local anaesthetic drugs in peripheral nerve blocks or plexus blocks has been used extensively. There have been four proposed mechanisms for the action of Clonidine in peripheral nerve blocks. These mechanism are centrally mediated analgesia,

alpha-2 adrenoreceptor mediated vasoconstrictive effects, attenuation of inflammatory response and direct action on peripheral nerve.[7]Clonidine possibly shows action by enhancing or amplifying the sodium channel blocking action of local anesthetics by opening up the potassium channels resulting in hyperpolarization.[8]

In our study the mean onset time for sensory and motor block was not shortened by addition of clonidine to ropivacaine. Similar results were obtained by El Saied et al. They found no significant difference in sensory and motor block onset time in each individual group ($p>0.05$).[9] The mean duration of sensory and motor block was significantly prolonged ($p<0.001$) by addition of clonidine to ropivacaine. These results are in consistent with the earlier studies.[4,10,11]

The time between the supraclavicular block administration and onset of pain (i.e. VAS >4) requiring the administration of a rescue analgesic, was measured as the duration of analgesia.The time for first rescue analgesia was increased in clonidine- ropivacaine group. This difference in pain scores was found to be statistically significant especially from 7th hour onwards to 11th hour ($p<0.05$).Similar results were observed by Chakraborthy et al and Casati et al.[11,12] Perineurally injected clonidine is thought to exert an analgesic effect through systemic absorption. Present study showed stable hemodynamics intra and post operatively with the use of clonidine. These reults are consistent with the findings of Eledjam et al[13] The present study did not reported any adverse hemodynamic effects that was comparable with the studies done by Casati et al.[12]

In the present study the patients did not receive any sedation before administration of the block. post operatively also no sedation was noted in both the groups. These results are similar with the earlier studies.[4,13,14] In this study no side effects were observed in both the groups. This could be due to lower dose of clonidine used in the study. From the results obtained, it was proved that clonidine-ropivacaine combination in supraclavicular brachial plexus block provides prolonged analgesia.

CONCLUSION

Our study concludes that clonidine 100µg when added to 30 ml of 0.5 % ropivacaine for supraclavicular brachial plexus block, does not hastens the onset of sensory and motor blockade but the prolonged sensory and motor blockade, improved analgesia, as manifested by lower pain scores and prolonged duration of analgesia, thereby decreasing the need for systemic analgesics without any hemodynamic changes.

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