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A comparitive study of ropivacaine 0.5% & ropivacaine 0.75% in ultrasound guided intrascalene brachial plexus nerve block

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Abstract
Background: A comparitive study of Ropivacaine 0.5% & Ropivacaine 0.75% in Ultrasound guided Intrascalene Brachial plexus nerve block
Materials and Methods: This is a prospective, randomised study conducted out on 100 patients of either sex, aged 18-60 years, ASA grade I and II scheduled for Upper Limb Surgeries.
Results: The effect of ropivacaine 0.5% and ropivacaine 0.75% in ultrasound guided intra scalene brachial plexus nerve block were similar in terms of duration of analgesia, duration of motor bloackade. Both the concentrations of ropivacaine showed insignificant variation in hemodynamic parameters as well and had similar side effects. All the results were insignificant statistically and have correlated well with the studies in reference.
Conclusion: On the basis of our study, conclusions were drawn that onset of action of sensory, motor block was similar in all the groups. Increasing the concentration of ropivacaine from 0.5% to 0.75% failed to improve onset as well as duration of sensory/motor block. Considering the greater toxicity potential and the cardiovascular effects of the bupivacaine, ropivacaine seems a good alternative for brachial plexus blocks at a concentration of 0.5% as well as 0.75%. Both the concentrations are equally efficacious.

Keywords: Ropivacaine 0.5% & 0.75%, upper limb surgeries

Introduction
Intrascalene brachial plexus block (ISBPB) is a nerve block given to patients who are undergoing surgery for the shoulder and upper arm. To block the brachial plexus, Injection of LA is given in the intrascalene groove between the anterior and middle scalene muscles. Earlier correct parasthesias of the target nerves were expected when touched by the needle and LA was injected slowly making sure it was not being injected intravascularlly or intrathecally. Later, nerve stimulators were used, but they are still not a reliable indicator of nerve proximity in several [1].

It has many dangers due to proximity to the nerve, vertebral artery, pleural dome, the cervical spinal cord, the carotid artery and IJV, and cause complications. The New technique of ultra sound helps us to enable the correct placement of block which is more safer and reliable method of nerve study. USG has been helpful in giving brachial plexus block, particularly after the introduction of high resolution and bigger probes. Before the era of USG, the nerves are found by placing the needle blindly in the nerve and now after the introduction of USG we can able to find the nerve easily. And we can able to give the block and the drug without any damage to other vital structures and other complications [2, 3].

The USG guided ISBPB has a quicker time of onset and extended time comparing the old nerve stimulation technique and it generates the more blockade and long duration of action with low doses of our desired anaesthetic drug. An USG guided approach can cause decrease in incidence of diaphragmatic hemiparesis [4]. But it does not decrease the incidence of post op neurological symptoms [5]. But the peri plexus technique to the ultrasound-guided ISB, which places the local anaesthetic drug in the space between middle scalene muscle and brachial plexus sheath, gives us the same level of blockade same as classic plexus approach in which the needle is kept in each nerve root to asses the level of blockade [6, 7].

And when we give the block outside the brachial sheath and with the help of USG we can help to reduce the risk of nerve injury through the peri plexus block [8].

There are some group of local anaesthetics which has increased and long duration of action like bupivacaine, which is mainly used for the blockade of brachial plexus.the bupivacaine has increased incidence of toxicity in the CNS and CVS due to which the anaesthesiologists are on the look for a newer drug which has lesser side effects in the CNS and CVS system but has the same effect as bupivacaine and also in the increasing time of blockade and due to which they have found a drug which is similar to bupivacaine as such frug is ropivacaine.

Ropivacaine, an amino-amide drug which has increased levels of toxin threshold but it causes decrease in the incidence of CNS and CVS system toxicity,and it causes decrease motor blockade and equal action of sensory blockade as compared to the bupivacaine.This has made the anaesthesiologists to change from the Bupivacaine to the Ropivacaine for all types of nerve blocks mainly due to the decrease in the CNS and CVS toxicity.but in terms of long term use of ropivacaine it showed that there is significant delay in the sensory blockade comparing to the bupivacaine and that is one of the main reason which is not used for the increase in the duration of the analgesia during post op period.

Materials and Methods

Study design: Randomised study.

Sample size: 100 patients.

Sample size calculation: Sample size was calculated using software Epi InfoTM [7], with the assumption of alpha error to be 5% and beta error to be 20% i.e. 95% confidence interval and 80% power of study. Assumption of exposed group taken to be 95% with 10% margin of error. Thus, a sample size of 100 patients was taken with 50 patients in each group.

Subjects & selection method: All participants were randomly divided into two groups (Group A and Group B) by a computer-generated randomization table.

Group A: Patients received Ropivacaine 0.5%30ml through USG Approach

Group B: Patients received Ropivacaine 0.75% through USG Approach

Inclusion Criteria:

1. Patients of either gender of Age group of 18 to 60 year.
2. ASA grade I -III.
1. BMI OF 18-30 kg/m^2.
2. Patients undergoing elective surgical procedure on upper limb of duration 1-4 hours.

Exclusion Criteria

1. Patient refusal.
2. Patients belongs to ASA grade 3 and 4.
3. Patients who are physically dependent on narcotics.
4. Patients with history of drug allergies.
5. Patients with head injury.
6. Patients with cardiac, pulmonary, hepatic and renal disorders.
7. Patients with peripheral neuropathy.
8. H/O Drug allergy

Technique methodology

Patients who were allotted to group A received 30ml of 0.5% ropivacaine through the Ultra Sound approach in the Intra scalene muscle. Group B received 30 ml 0.75% ropivacine through the Ultra Sound approach in the Intra Scalene muscle. After the instillation of the drug Heart rate, SBP, DBP, MAP, respiratory rate, Spo2, ETCO2 values were recorded. After Surgery patient was shifted to recovery room. Time to recovery was recorded. Complications were noted intraoperatively and post operatively. Time of onset of pain. Rescue analgesia:

Data recording

The following parameters were assessed Postoperatively, heart rate, Spo2, Blood Pressure, at 0, ½, 1, 2,4,6,12,24 hours. Other recordings were duration of analgesia, total number of doses and total amount of rescue analgesia given in 24 hrs, and any complications.

Statistical analysis

Data was presented as mean, standard deviation, median (range), or percentage, as appropriate. Study data was entered into the SPSS software (version 21, SPSS) and was analysed with the chi-square test for qualitative and student t-test for quantitative variables, between the trial and control groups, P values less than 0.05 was considered significant.

Results

Table 1A: Comparison of Mean Age of Patients±

(Mean±SD)	Group A (n=50)	Group B (n=50)	p-value	Significance
Age in years	35.04±9.98	35.2±9.76	0.936	NS

Statistical analysis shows no significant difference in average age among the two groups.(p value > 0.05)

Table 1B: Age Group Distribution

Age group	Group A		Group B	
	N	%	N	%
≤20 years	4	8	3	6
21-30 years	11	22	13	26
31-40 years	18	36	15	30
41-50 years	14	28	16	32
51-60 years	3	6	3	6
Total	50	100	50	100

Chi square value=0.71 P=0.95 NS

Table 2: Comparison of Gender Distribution of Patients

Gender	Group A		Group B		p-value
	N	%	N	%	
Male	29	58	31	62	0.28
Female	21	42	19	38	0.28
Total	50	100	50	100	

Chi square value=0.16 P=0.68 NS

In Group A there were 29 (58%) males and 21 (42%) females. Group B had 31(62%) males and 19 (38%) females. statistical analysis shows no significant difference in average taken for gender distribution among two groups. (p value > 0.05)

Table 3: Comparison of Mean Weight of Patients

Weight (Kg)	Group A (n=50)	Group B (n=50)	p-value	Significance
(Mean ± SD)	53.1±3.21	54.12±3.44	0.129	NS

Both the two groups were comparable in terms of mean weight (p-value >0.05).

Table 4: Comparison of Post-Operative Mean Heart Rate (HR) in Two Groups (MEAN±SD)

Study period (hours)	Pulse Rate (BPM) (MEAN±SD)		p-value	Significance
	Group A (n=50)	Group B (n=50)		
Baseline	81.4±8.96	81.9±6.72	0.753	NS
0	82.88±8.91	81.78±6.52	0.483	NS
0.5	80.7±5.8	81.72±6.48	0.409	NS
1	80.32±7.18	81.8±8.05	0.334	NS
2	78.76±8.75	80.28±7.3	0.348	NS
4	79.08±5.73	80.48±7.36	0.291	NS
6	79.44±7.81	79.92±8.71	0.772	NS
12	80.28±6.53	81.9±6.89	0.23	NS
24	79.64±6.49	81.58±6.05	0.125	NS

Baseline heart rate was comparable in the two groups, $p>0.05$ (unpaired t test). There was no significant difference in the meanheart rate between the two groups at any time interval, ($p>0.05$)

Table 5: Comparison of Post-Operative Mean SBP (mm Hg) in Two Groups (MEAN±SD)

Study period (hours)	Mean SBP (mmHg) (MEAN±SD)		p-value	Significance
	Group A (n=50)	Group B (n=50)		
Baseline	124.76±11.26	125.16±10.73	0.287	NS
0	122.48±12.48	123.86±10.45	0.284	NS
0.5	122.06±12.34	123.16±10.45	0.193	NS
1	121.56±12.03	122.84±10.23	0.314	NS
2	120.92±11.38	122.48±9.73	0.898	NS
4	120.58±11.05	122.16±9.6	0.653	NS
6	120.14±10.64	121.88±9.36	0.121	NS
12	119.26±10.28	121.44±9.02	0.159	NS
24	119.72±10.02	119.08±8.31	0.333	NS

At all time intervals, the p-value was > 0.05 (unpaired t test) and hence the difference in the SBP between the two groups were insignificant.

Table 6: Comparison of Post-Operative Mean DBP (mm Hg) in Two Groups (MEAN±SD)

Study period (hours)	Mean DBP (mmHg) (Mean±SD)		p-value	Significance
	Group A (n=50)	Group B (n=50)		
Baseline	84.14±4.66	84.12±8.21	0.988	NS
0	79.66±9.77	81.24±2.88	0.275	NS
0.5	79.8±12.08	80.48±3.93	0.706	NS
1	78.6±8.55	78.36±4.76	0.863	NS
2	75.4±5.32	76.2±4.5	0.419	NS
4	74.72±6.52	75.8±4.55	0.34	NS
6	75.72±5.7	75.14±4.46	0.572	NS
12	76.16±5.71	74.92±4.16	0.218	NS
24	75.24±4.53	75.88±4.19	0.465	NS

At all time intervals, the p-value was > 0.05 (unpaired t test) and hence on intergroup comparison the difference in the DBP between the two groups were insignificant.

Table 7: Comparison of Post-Operative Map (mm Hg) in Two Groups (MEAN±SD)

Study period (hours)	MAP (mm Hg) (MEAN±SD)		p-value	Significance
	Group A (n=50)	Group B (n=50)		
Baseline	97.68±3.98	97.8±6.73	0.914	NS
0	93.93±8.61	95.45±4.04	0.263	NS
0.5	93.89±10.31	94.71±4.53	0.607	NS
1	92.92±7.28	93.19±4.87	0.829	NS
2	90.57±4.45	91.63±4.67	0.251	NS
4	90.01±3.81	91.25±4.68	0.148	NS
6	90.53±4.22	90.72±4.59	0.827	NS
12	90.53±4.37	90.43±4.37	0.909	NS
24	90.07±3.9	90.28±4.18	0.792	NS

At all time interval, the p-value was > 0.05 (unpaired t test) and hence on intergroup comparison the difference in the MAP between the two groups were insignificant.

Table 8: Comparison of Post-Operative Mean SpO2 in Two Groups (MEAN±SD)

Study period (hours)	MEAN SpO_2 (MEAN±SD)		p-value	Significance
	Group A (n=50)	Group B (n=50)		
Baseline	99.96±0.2	99.98±0.14	0.562	NS
0	99.92±0.34	99.96±0.2	0.474	NS
0.5	99.98±0.14	99.94±0.24	0.312	NS
1	100±0	99.98±0.14	0.32	NS
2	99.98±0.14	99.96±0.28	0.656	NS
4	99.96±0.2	99.94±0.24	0.65	NS
6	99.96±0.2	99.92±0.4	0.524	NS
12	99.98±0.14	99.96±0.2	0.562	NS
24	99.94±0.24	99.92±0.27	0.699	NS

At all time interval, the p-value was > 0.05 (unpaired t test) and hence the difference in the SpO2 between the two groups were insignificant.

Table 9: Comparison of Mean Duration of Analgesia in Two Groups (MEAN±SD)

Interval (hours)	Group A (n=50)	Group B (n=50)	P value	Significance
Time of Onset (Sensory Blockade)	11.76±2.08	11.06±2.38	0.12	NS
Time of Onset (Motor Blockade)	12.06±2.17	11.54±1.97	0.213	NS
Duration of blockade	Group A (n=50)	Group B (n=50)	P value	Significance
Sensory blockade	332.06±53.58	341.6±39.79	0.315	NS
Motor Blockade	296.7±72.79	304.08±47.58	0.553	NS

Table 9: Comparison of Mean Duration of Analgesia in Two Groups (MEAN±SD)

	Group A (n=50)	Group B (n=50)	p-value	Significance
No of times analgesic required	2.16±0.65	2.4±0.93	0.137	NS

HS is highly significant

The mean number of analgesia was 2.16±0.65 min in group R with a range of 360 to 620 min. In group RD, the mean duration of analgesia was 2.4±0.93 min with a range 1-5. The difference in the mean duration of analgesia was statistically highly significant ($p<0.05$).

Table 10: Comparison of Post-Operative Mean Pain Score (VAS) in Two Groups (MEAN±SD)

Time interval (hours)	Mean Vas Score (MEAN±SD)		p-value	Significance
	Group A (n=50)	Group B (n=50)		
0	0±0	0±0		
0.5	1.28±0.45	0.46±0.5	<0.001	HS
1	1.78±0.42	1.24±0.43	<0.001	HS
2	2.18±0.39	1.78±0.42	<0.001	HS
4	2.92±0.27	2.08±0.27	<0.001	HS
6	2.92±0.27	2.08±0.27	<0.001	HS

Mean VAS scores were lesser in group RD than in group R at all the time intervals and were statistically highly significant ($p< 0.05$).

Table 12: Mean Amount (mg) of Rescue Analgesic Required in Two Groups (IN 24 Hours)

	Group A MEAN±SD (n=50)	Group B MEAN±SD (n=50)	p-value	Significance
Mean amount (mg) of rescue analgesic	111±37.85	93±32.36	<0.0001	HS

The mean total rescue analgesic consumption was low in group RD(150mg) as compared to Group R(84.38), and was statistically highly significant ($p< 0.05$).

Table 15: Comparison of Motor Blockade Score (RSS) in Two Groups

Time interval (hours)	Motor Blockade RSS score(MEAN±SD)		p-value	Significance
	Group R (n=40)	Group RD (n=40)		
0	2±0.49	2.18±0.66	0.126	NS
0.5	1.88±0.33	1.9±0.3	0.752	NS
1	1.88±0.33	1.9±0.3	0.752	NS
2	1.76±0.43	1.88±0.33	0.121	NS
4	1.76±0.43	1.88±0.33	0.121	NS
6	1.68±0.47	1.74±0.44	0.513	NS

Mean sedation score in postoperative period was found to be less than 2at all time interval, also on intergroup comparison the difference in the RSS between the two groups were observed to be statistically insignificant(p-value> 0.05) (Unpaired t test)

The mean total rescue analgesic consumption was low in group RD (84.0±24.62) as compared to Group R (151.5±38.6), and was statistically highly significant ($p< 0.05$).

Discussion

Opivacaine with a potentially improved safety profile when contrasted to bupivacaine [27, 28]. Human trials have demonstrated that less cardiac depression and fewer central nervous system effects when ropivacaine is injected TV. The fact that ropivacaine may offer less cardiac and neurologic toxicity with intravascular injection suggests a potential clinical advantage of this drug during neural blockade when large volumes of local anesthetic are required. This property may also enable the use of solutions with a higher concentration to enhance the speed of onset time and to prolong duration. However, if onset time and duration of neural blockade are not adequate, substitution for bupivacaine may not be appropriate. Currently, information about the onset time and duration of action of ropivacaine, when injected at the nerve. The selection of the optimal long-acting local anesthetic and concentration for interscalene brachial plexus block must take into consideration the available anesthetics, the time to onset, duration of blockade, and side effects of each drug and dose. A drug that has a fast onset, long duration, and minimal toxicity profile could be an advantage. Introduced recently, ropivacaine offers an alternative to bupivacaine for long-acting neural blockade. In a clinical practice, the choice and concentration of long-acting local anesthetics is only partially defined. Present study is a randomised controlled trial conducted among 100 patients

Group A-50 Patients (0.5% Ropivacaine)

Group B -50 patients (0.75% ropivacaine)

Demographic characters

Age

The mean age in group A is 40.18 and in group B mean age is 41.80.The two groups are comparable with respect to age. Statistical analysis shows no significant difference in average age among the two groups. (p value > 0.05). Sex In group A there were 31 (62%) males and 31 (62%) females. Group B had 36 (72%) males and 14 (28%) females. Statistical analysis shows no significant difference in average taken for gender distribution among two groups. (p value > 0.05). Mean duration of analgesia The mean duration of analgesia was 525.80±66.64 min in group A with a range of 360 to 620 min. In group B, the mean duration of analgesia was 746.60±93.78 min with a range of 510 to 845 min. The difference in the mean duration of analgesia was statistically highly significant ($p< 0.05$). Mean VAS Scores

Mean VAS scores were lesser in group B than in group A at all the time intervals and were statistically highly significant ($p< 0.05$). Mean total analgesic consumption The mean total rescue analgesic consumption was low in group B (150mg) as compared to Group A (84.38), and was statistically highly significant ($p< 0.05$). Adverse effects Shoulder pain was complained by two patients in Group B(5%) as compared to none of the patients in Group A. There were no adverse effects observed in patients in the perioperative period, neither CNS nor CVS adverse effects, and were comparable among the study groups. Haemodynamic parameters Both the groups are comparable with respect to systolic blood pressure, diastolic blood pressure, heart rate mean arterial pressure and SPO2. ($P> 0.05$). Mean sedation score

Mean sedation score in postoperative period was found to be less than 2 at all time interval, also on intergroup comparison the difference in the RSS between the two groups were observed to be statistically insignificant(p-value> 0.05). Comparison with other studies.

In the study done by Hickey *et al.* [29] there were no adverse effects. Klein *et al.* [13] and Chatrath *et al.* [30] compared 0.75% ropivacaine with clonidine and 0.5% bupivacaine with clonidine for infraclavicular block and reported that addition of clonidine to bupivacaine lead to early onset and prolonged duration of sensory and motor block with prolonged analgesia as compared to the addition of clonidine to ropivacaine. Sensory onset time was time approximately 5 minutes and motor was approximately 10 minutes in both the group which is much faster compared to our group and it can be explained that addition of clonidine

as an adjuvant potentiated the onset in their group compared to ours. Kaur *et al.* [31] compared ropivacaine with bupivacaine for axillary brachial plexus block and found that ropivacaine showed a better quality of analgesia with a shorter onset (5 min vs 20 min for 0.5% ropivacaine compared to 0.5% bupivacaine) and recovery time for both sensory and motor blockade in comparison to bupivacaine. Klein *et al.* (1998) [13], Conducted a double-blind, randomized study on 75 adult patients scheduled for outpatient shoulder surgery under interscalene block. They compared Bupivacaine and Ropivacaine to determine the optimal long-acting local anesthetic and concentration for interscalene brachial plexus block. They conclude that there was no clinically important difference in times to onset and recovery of interscalene block for bupivacaine 0.5%, ropivacaine 0.5%, and ropivacaine 0.75% and demonstrated a similar efficacy between equal concentrations of ropivacaine and bupivacaine. In addition, increasing the concentration of ropivacaine from 0.5% to 0.75% failed to improve the onset or duration of interscalene brachial plexus block.

Conclusion

On the basis of our study, conclusions were drawn that onset of action of sensory, motor block was similar in all the groups. Increasing the concentration of ropivacaine from 0.5% to 0.75% failed to improve onset as well as duration of sensory/motor block. Considering the greater toxicity potential and the cardiovascular effects of the bupivacaine, ropivacaine seems a good alternative for brachial plexus blocks at a concentration of 0.5% as well as 0.75%. Both the concentrations are equally efficacious

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