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Ropivacaine Versus Bupivacaine in Interscalene Brachial Plexus Block -- Comparative Study

KEYWORDS: Bupivacaine, Ropivacaine, Interscalene brachial plexus block, visual analogue score.

Dr. G.Visala, M.D	Dr. G.Pratap Rao	Dr.C.Kailashnath Reddy
Associate Professor, Dept. of Anesthesiology, Kurnool Medical College, Kurnool.	Associate Professor, Dept. of Anesthesiology, Kurnool Medical College, Kurnool.	Professor, Dept. of Anesthesiology, Kurnool Medical College, Kurnool.

ABSTRACT ***Background:*** *In this study, we compared the efficacy of Ropivacaine with Bupivacaine to determine the suitability of each agent for interscalene brachial plexus block. Sixty patients undergoing elective orthopaedic upper limb surgery were divided into two groups. They were named as Group-R and Group-B. Group-R received 30 ml of Ropivacaine Hydrochloride 0.5% and Group-B received 30ml of Bupivacaine Hydrochloride 0.5%. Sensory and motor block onset time, duration of motor block, and duration of analgesia (VAS) were assessed during intra operative period and post operative period. Visual Analog Scale (VAS) scores were recorded at 0, 30 min, 45 min, 1 hr, 2hr, 3hr at regular one hour intervals up to 12 hrs and side effects were noted. Statistical Analysis: The observations obtained were recorded and tabulated. Statistical analysis was carried out using Students t-test and Chi-square test.* ***Results:*** *Onset time of sensory and motor block was shorter in Group-B when compared to Group-R and statistically not significant ($p > 0.05$). The duration of motor blockade was longer in Group-R and also statistically significant compared to Group-B ($p < 0.05$). The duration of analgesia in Group-R was longer compared to Group-B and also statistically significant ($p < 0.05$). We found that the patients who received Ropivacaine 0.5% had longer duration of motor blockade and longer duration of analgesia than the patients who received Bupivacaine 0.5%.*

1. INTRODUCTION

Brachial plexus block is one the most common regional anaesthetic procedures done for upper limb surgeries. The advent of new local Anaesthetics in clinical practice has renewed interest in studying the practical application for usage with minimal side effects.

Various local anesthetics have been used to produce brachial plexus block. Bupivacaine 0.5% is one of the most popular drugs used because of its higher potency and prolonged duration of action. One of the drawbacks of Bupivacaine is its cardiotoxicity especially when injected accidentally into the subclavian artery. The cardiotoxicity may be life threatening as the arrhythmias that are produced are resistant to all routinely used anti arrhythmics.

Ropivacaine[60] is a new amino amide local anaesthetic which has similar structure as Bupivacaine, has all its advantages but without any cardiotoxicity. Ropivacaine was introduced for regional anaesthesia in western countries in the 1990s. It has been recently introduced in India. Hence a study was undertaken to compare the routinely used Bupivacaine with recently introduced Ropivacaine for brachial plexus block for elective upper limb surgeries.

2. AIMS AND OBJECTIVES

The aim of the study is to assess and compare the safety and efficacy of intra-operative and post-operative analgesia between Bupivacine and Ropivacaine administered through interscalene brachial plexus block in patients undergoing elective orthopedic upper limb surgeries.

3. MATERIALS AND METHODS

A prospective randomized double blind study was undertaken to compare the sensory and motor blocking properties of 30 ml of 0.5% Ropivacaine and 30 ml of 0.5% Bupivacaine for interscalene brachial plexus block for elective upper limb orthopaedic surgeries. The study was undertaken after obtaining clearance from ethical committee in the department of Anaesthesiology and critical care, at Kurnool Medical College, Kurnool.

Sixty patients ASA class I and II were randomly divided into two groups. Each group consisting of 30 patients to receive interscalene brachial plexus block with 30 ml of 0.5% Ropivacaine (Group-R) and 30 ml of 0.5% Bupivacaine (Group-B).

Patients who were on anticoagulants, patients with severe renal, hepatic, respiratory, cardiac disease, neurological, psychiatric or neurological disorders, morbidly obese, pregnant women, patients with alcohol abuse or those with injury to any of the nerves of the upper limb were excluded from the study.Bilateral blocks were avoided.

After detailed pre-anaesthetic examination and investigations, the patients were kept nil orally 8hrs before surgery. All patients were pre medicated with Tablet Alprozolam 0.5 mg, Tablet Ranitidine 150 mg orally at night and Inj. Glycopyrrolate 4µgm/kg and Inj Ondansetron 4mg IV, given 5 minutes before surgery. All vital Data like Pulse rate, BP, Spo2, ECG were monitored

The interscalene brachial plexus block described by Winnie in 1970, is the most proximal approach to brachial plexus. It provides optimal anesthesia for surgeries on the shoulder, arm and forearm. In this technique, the patient lies supine with head turned to opposite side. A 22G needle of 4 cm is inserted in the interscalene groove, lateral to the sternomastoid and level with the cricoid cartilage. The needle is directed medially, caudally and posteriorly. Under aseptic pre cautions, 30 ml of local anesthetic solution is injected when paraesthesia or click is felt. If nerve stimulator is used, contractions should be sought in the shoulder, arm and forearm.

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The onset of sensory and motor blockade, quality of motor blockade, duration of sensory and motor blockade, adverse events and haemodynamic parameters were studied.

4. OBSERVATION AND RESULTS

The relevant data was collected and analysed by applying Student's t-test and chi-square test. Significance was assessed at 5% level of significance.

Table-1: Demographic data of the patients

	GROUP-B	GROUP-R	P-VALUE
AGE (Years)	36.43333 ± 14.868	35.0667 ± 11.313	0.69015161
SEX	1:2.3	1:1.7	0.78419123
WEIGHT(Kg)	55.90	55.16	0.58102171

Sensory Block:

The onset of sensory Block was 10.6333 ± 2.413.minutes in Group-B and 11.60 ± 2.0771 minutes in Group-R. The results were comparable in both the groups as the difference in the test was 1.6624 and was statistically not significant with a P-value of 0.1018. The onset of sensory block is given in Table-2.

Table-2: Time of onset of sensory block.

Sensory onset (min)	Group-B (n=30) Bupivacaine	Group–R (n=30) Ropivacaine
1-3	0	0
4-6	0	0
7-9	10	4
10-12	13	17
13-15	7	9

Duration of Analgesia (VAS Score)

The patients in Group-B at the end of 4 hours had a Visual analogue score of 25 and experienced mild pain. Patients in Ropivacaine group at the end of 4 hours had no pain. At the end of 4 hours data was analysed and found to be statistically insignificant. At the end of 4 hours no patient had rescue analgesia.

At the end of 5 hours patients in Group-B had a Visual analogue score of 39.44 ± 16.66 and required rescue analgesia. Patients in Group-R at the end of 5 hours, had no pain. At the end of 5-hours data was analysed and found to be statistically significant with P value of 0.03.

At the end of 6 hrs patients in Group-B had Visual analogue score of 56.66 ± 20.37, had moderate pain and required rescue analgesia. Patients in Group-R had Visual analogue score of 30.71 ± 9.75 at the end of 6 hrs, had mild pain did not require rescue analgesia. The patient data was analysed and found to be statistically significant with P value of 0.0016.

At the end of seven hours patients in Group-B had Visual analogue score of 27.14 ± 8.09 as these patients had received rescue analgesia earlier. Patients in Group-R had visual analogue score of 41.66 ± 18.25 and had moderate pain and required rescue analgesia. Data was analysed found to be statistically significant with a P value of 0.0299.

It was observed that Patients in Group-B required earlier rescue analgesia at the end of 5 hours while the patients in Group-R required analgesia at the end of 7 hours. The values when compared were statistically significant with P value < 0.05.

Table-3: Duration Of Analgesia (VAS Score value)

VAS score	Group-B (n=30) Bupivacaine	Group-R (n=30) Ropivacaine	't' value	'p' value	Inference
Immediate post operative	0	0			
30 min	0	0			
60 min	0	0			
2 hrs.	0	0			
3hrs.	0	0			
4 hrs.	25	0			
5 hrs.	39.44 ± 16.66	25 ± 0	2.30	0.03	HS
6 hrs.	56.66 ± 20.37	30.71 ±9.75	2.10	0.0016	HS
7 hrs.	27.14 ± 8.09	41.66 ± 18.25	2.11	0.0299	HS
8 hrs.	-	50.35 ± 25.65			HS

Table-3A: VAS Score No of patients in comparision between the groups B and R.

		20	25	30	35	40	45	50	55	60	65	70	75	Chi square	P value
4 hr	B		11												
	R		2												
5 hr	B			5	2	3		7	2	1					
	R		26												
6 hr	B	1	1	12	2		1	3	2	4		1	2	12.9731	0.225179
	R	7	4	9	5	4									NS
7 hr	B	2	11	14	2		1							11.5217	0.117423
	R	4	6	5	4			6	1	3					NS
8 hr	B	6	5											5.14829	0.27241
	R	8	8	12	1	1									NS

Motor block

The time of onset of motor block was 12.667 ± 3.516 in Group-B and 13.033 ± 3.746 in Group-R. When time of onset of block was compared between groups it was statistically not significant with p value of 0.697. The time of onset of motor block is given Table-4.

Table–4: Time to Onset of Motor Blockade

Motor Time (min)	Group-B (n=30) Bupivacaine	Group–R (n=30) Ropivacaine
1-3	0	0
4-6	2	1
7-9	3	4
10-12	6	9
13-15	14	10
16-19	5	3
19-22	0	3

Time of Complete Blockade

Time of complete blockade was 16.76 ± 3.42 minutes in Group-B, and 18.06 ± 3.60 minutes in Group-R. The values were statistically insignificant difference in both the groups with p-value of 0.157 as shown in Table-5.

Table-5: Time of complete blockade

Motor Time (min)	Group-B (n=30) Bupivacaine	Group-R (n=30) Ropivacine
0-5	0	0
6-10	0	0
11-15	9	5
16-20	17	17
21-25	4	8

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Duration of Motor Block

The duration of Motor block is 5.33 ± 0.571 hrs in Group-B and 7.23 ± 0.897 hrs in Group-R. The values when compared were statistically significant difference (p< 0.05) as given in Table-6.

Table-6: Duration Of Motor block

Duration (hrs)	Group-B	Group-R	t Value	P value
Mean	5.533333333	7.233333333	8.750866527	< 0.0001 S
SD	0.5713464637	0.897634183		

Hemodynamic parameters

The systolic Blood pressure in Group-B at 30minutes, 60 minutes and 90 minutes after the Block was 121.53 ± 6.22, 119.46 ± 6.25, 118.4 ± 6.52 respectively. The systolic blood pressure in Group-R at 30 minutes, 60 minutes and 90 minutes after the block were 124.13±6.40, 120.76 ± 6.344, 118.6 ± 6.24 respectively. When both the groups were compared at different time intervals the differences were found to be statistically insignificant. The changes in systolic blood pressure are given in the Table-7.

The diastolic blood pressure in Group-B at 30 minutes, 60 minutes and 90 minutes after the Block was 78 ± 4.06, 78.06±4.06 and 77.66 ± 4.30 respectively. The diastolic blood pressure in Group-R at 30 minutes, 60minutes and 90minutes was 79.33 ± 2.53, 79 ± 3.05 and 78.66 ± 3.45respectively. When both the groups were compared at different time intervals the differences were not statistically significant. The changes in diastolic blood pressure are given in Table-8.

Mean arterial pressure in Group-B at 30 minutes, 60 minutes and 90 minutes after the Block was 94.22 ± 3.09, 92.60 ± 4.63 and 93.23 ± 4.58 respectively. The mean arterial pressure in Group-R at 30 minutes, 60 minutes and 90 minutes 92.51 ± 4.86, 90.38 ± 4.01 and 91.90 ± 4.11 respectively. When both the groups were compared at different time intervals the differences were not found to be statistically significant. The changes in mean arterial pressure are given in Table 9.

Table–7: Intra Operative Changes in Systolic Blood Pressure

SBP	Group A	Group-B	t Value	PValue
30 min	121.5333333 ± 6.229702674	124.1333333 ± 6.409762669	1.628660409	0.11420178 **NS**
60 min	119.4666667 ± 6.257317555	120.7666667 ± 6.344605818	0.7990458956	0.42752392 **NS**
90 min	118.4 ± 6.526339207	118.6 ± 6.240026525	0.1213190907	0.90385764 **NS**

Table–8: Intra Operative Changes In Diastolic Blood Pressure

DBP	Group A	Group-B	t Value	P Value
30 min	78 ± 4.068381022	79.33333333 ± 2.537081317	1.439245834	0.16078821 **NS**
60 min	78 ± 4.068381022	79 ± 3.051285766	1.077032961	0.28592498 **NS**
90 min	77.66666667 ± 4.301830672	78.66666667 ± 3.457459036	0.9924241333	0.32511305 **NS**

Table-9: Intraoperative Changes in Mean Arterial Pressure (in mm Hg)

Time	Group-B (n=30) Bupivacaine	Group-R (n=30) Ropivacaine	't' value	'p' value	Inference
30 min	94.22 ± 3.09	92.51 ±4.86	0.341	>0.05	NS
60 min	92.60 ± 4.63	90.38 ±4.01	0.352	>0.05	NS
90 min	93.23 ±4.58	91.90 ±4.11	0.277	>0.05	NS

The changes in pulse rate in Group-B at 30 minutes, 60 minutes and 90 minutes after the Block was 86.13±2.515, 83.2±3.22 and 83.36±3.624 respectively. The pulse rate in Group-R at 30 minutes, 60 minutes and 90minutes 86.8±2.998, 84.266±3.473 and 83.733±4.322 respectively. When both the groups were compared at different time intervals the differences were not found to be statistically significant. The changes in pulse rate are given in Table-10.

Table–10: Intra Operative Changes In Pulse Rate

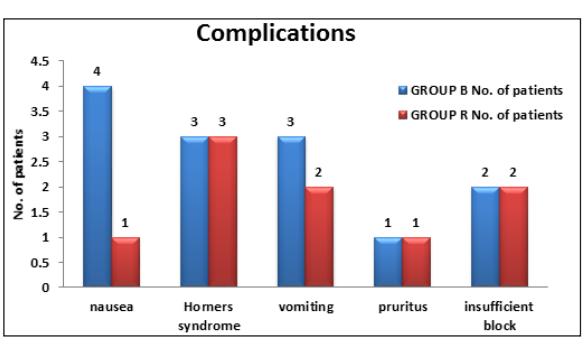
TIME	Group-B (n=30) Bupivacaine	Group-R (n=30) Ropivacaine	't' value	'p' value	Inference
30 min	86.13±2.515	86.8±2.998	0.9329	0.354	NS
60 min	83.2 ± 3.220623199	84.266 ± 3.473	1.233	0.222	NS
90 min	83.366 ± 3.624	83.733 ± 4.322	0.356	0.723	NS

Complications

Complications after the block in Group-B were nausea in four patients where as in Group-R in one patient only. Horner's syndrome is in three patients in both the groups B and R. Vomiting is observed in three patients in Group-B where as in only two patients in Group-R. Pruritus in one patient in both the groups B and R and insufficient block is in two patients in both the groups B and R as given in the Table-11.

Table–11: Complications

	GROUP-B		GROUP-R	
COMPLICATIONS	No. of patients	percentage	No. of patients	percentage
Nausea	4	13.33	1	3.33
Horners syndrome	3	10	3	10
Vomiting	3	10	2	6.67
Pruritus	1	3.33	1	3.33
Insufficient block	2	6.67	2	6.67



Surgical Procedures

All the surgical procedures were elective. Table-12 shows this distribution in both groups.

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Table –12: Distribution of Surgical Procedures

Surgical Procedure	Group-B (n=30) Bupivacaine	Group-R (n=30) Ropivacaine
Open Reduction + Pinning fracture humerus	11	13
Rotator cuff surgeries	12	6
Open Reduction Internal Fixation fracture radius	5	7
Tension Band Wiring Olecranon	1	2
Supracondylar fracture	1	2
Total	30	30

5. DISCUSSION

The present study to compare Ropivacaine 0.5% and 0.5% Bupivacaine for Interscalene Brachial plexus block using parasthesias as a guide was undertaken at Government General Hospital, Kurnool and various parameters were studied.

Sensory Block

The onset of sensory Block was 10 minutes in Group-B and 11 minutes in Group-R. The results were compared and were not statistically significant.

Similar observations were found in the studies conducted by Stephen M Klein et al[27].,Casati A[24], Misiolek et al.[36] where there was no statistically significant difference between the onset of sensory block among ropivacaine group and bupivacaine group which compares with our study.

Duration of Analgesia

Duration of analgesia in the studies conducted by various authors were as given in Table-13.

Table-13: Comparision of duration of analgesia by various authors

Authors	Ropivacaine	Bupivacaine
Laura Bertini et al.[29]	666 ± 174	666 ± 210
Casati et al.,[28]	642 ± 120	660 ± 144
Misiolek et al.[31]	450 ± 156	528 ± 192
Stephen M Klein et al., [24]	720 – 900	720 – 900
Raeder JC et al.[30]	720 ± 72	780 ± 78
Hickey R et al.[22]	780 – 840	540 – 660

The patients in bupivacaine group had received rescue analgesia at 360 minutes where as patients in Ropivacaine group had received rescue analgesia at 420 minutes. Phillipe Gautier and Catherine Vandepitte[32] had done a study using minimum anaesthetic solution of 5ml 0.75% Ropivacaine conducting Inter scalene block and found a block duration was 9.9 (5 to 19) hours. It is possible that Ropivacaine could produce a long duration sensory block which is in support of the findings done by Vanderpitt and Phillipe[32].

Motor Block

The onset of motor block in our study was studied at the shoulder and hand.The complete motor block was achieved in 18 minutes in ropivacaine group and 16 minutes in bupivacaine group. There was no statistically significant difference ($p > 0.05$) between the two groups regarding the time taken for complete motor blockade.

The duration of motor block is 5.33±0.571 hrs in Group-B and in Group-R the duration of motor block is 7.23±0.897 hrs. There was statistically significant difference ($p<0.05$)

93.33% of the patients in ropivacaine group and 93.33% in bupivacaine group had complete paralysis of both shoulder and hand which was not statistically significant, the same observation was made in the study conducted by Hickey et al.[22]

In our study, two patients in each group had insufficient block. We have used elicitation of paraesthesia as a method to identification to give the block. The chances of failure rate is high in this technique. Most of the authors in the study have used stimulating needles or ultrasound machine to locate the nerves under image guidance. The patients with insufficient block were given supplementation with Injection Ketamine Hydrochloride in the groups to complete the surgery. Casati et al[28] in their study showed that two patients in Ropivacaine group and seven patients in Bupivacaine group needed intraoperative supplementation with fentanyl to complete the surgery.

There were no complete failures of block in either group. There were no statistically significant difference between two groups in terms of overall quality of blockade.

Hemodynamic parameters include heart rate, systolic, Diastolic and mean Blood pressure were within physiological acceptable limits and when compared between Ropivacaine Group and Bupivacaine Group were statistically not significant and no patient required any intervention.

Complications

The complications that were seen in our study were nausea,Vomiting, Horners syndrome and Pruritus. The incidence of Horners syndrome and vomiting was equal in both the groups. The incidence of nausea was seen slightly more in Bupivacaine group. The patients in both the groups had no treatment for the above conditions.

6. Conclusion

There was no statistically significant difference in the onset of sensory and motor block, grade of motor blockade, overall quality of block, in both the groups, but the duration of sensory and motor blockade is prolonged in Ropivacaine group. Both groups had no adverse events or hemodynamic instability.

30 ml of 0.5%Ropivacaine and 30 ml of 0.5% Bupivacaine used in interscalene brachial plexus block produced satisfactory and comparable sensory and motor blockade. It is suggested that the lower cardiovascular toxicity of Ropivacaine with equal efficacy as Bupivacaine, may help in reducing the risks to the patient.

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