

Comparison of Hemodynamic Parameters during Ropivacaine 0.2% And Lignocaine 0.5% Intravenous Regional Anaesthesia (IVRA) In Upper Limb Surgeries

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ABSTRACT

Objective: To compare the **Hemodynamic Parameters** during Ropivacaine 0.2% and Lignocaine 0.5% for IVRA
Methods: This Prospective Randomized study was conducted at Bapuji Hospital and Chigateri General Hospital attached to J.J.M Medical College, Davangere, Karnataka. Duration of study was two years. **Result:** Based on individual t test value calculated for systolic blood pressure at baseline, 5th min, 15th min, 25th min, 40th min, after release and 10mins after release there was no statistical significance noted between the two study groups for systolic blood pressure. Based on individual t test value calculated for diastolic blood pressure at baseline, 5th min, 15th min, 25th min, 40th min, after release and 10mins after release there was no statistical significance noted between the two study groups for diastolic blood pressure. Based on individual t test value calculated for mean arterial pressure at baseline, 5th min, 15th min, 25th min, 40th min, after release and 10mins after release there was no statistical significance noted between the two study groups for mean arterial pressure. Based on individual t test value calculated for oxygen saturation at baseline, 5th min, 15th min, 25th min, 40th min, after release and 10mins after release there was no statistical significance noted between the two study groups for oxygen saturation. **Conclusion:** There was no statistical significance noted between the two study groups for Heart rates, systolic blood pressure, diastolic blood pressure, mean arterial pressure and oxygen saturation.

Keywords: *Hemodynamic Parameters, Heart rates, systolic blood pressure, diastolic blood pressure, mean arterial pressure and oxygen saturation.*

INTRODUCTION

IVRA is advantageous being reliable, easy to administer and cost-effective for short operative procedures of the extremities performed on an ambulatory basis¹. There are some disadvantages like delayed onset of action, poor muscle relaxation and rapid onset of pain at operative site after tourniquet is deflated.²

Despite vast clinical experience and success with IVRA, the site and mode of action of Local anaesthetic (LA) agent in IVRA are still controversial. It is possible that the local anaesthetics acts at two levels. First at the level of the nerve endings and secondly at the level of the nerve trunks themselves. Cardiac arrest and circulatory overload commonly occur. It is believed that there is shift of blood volume into central

circulation causing an increase in systemic vascular resistance and this leads to a transient rise in systolic blood pressure and central venous pressure.³

Tourniquet pain is detected 30 – 60 minutes post inflation by gradual rise in arterial blood pressure and heart rate. Tourniquet deflation causes redistribution of circulating volume back into the limb and causes post ischemic reactive hyperaemia.

Accumulated circulating metabolites are released back into systemic circulation and leads to a transient fall in arterial blood pressure and central venous pressure.^{4,5}

MATERIALS AND METHODS

This Prospective Randomized study was conducted at Bapuji Hospital and Chigateri General Hospital

attached to J.J.M Medical College, Davangere, Karnataka. Duration of study was two years.

Ethical Approval

The study protocol was approved by the Institutional Ethics Committee of J.J.M. Medical College, Davangere. The study was conducted in accordance with the Declaration of Helsinki.

Informed Consent

Written informed consent was obtained from all participants before enrolment in the study.

Sample Size Of Estimation

Formula of calculating sample size is

$$n = [(Z\alpha/2 + Z\beta)^2 \times \{2(\sigma)^2\}] / (\mu_1 - \mu_2)^2$$

where

n = sample size required in each group,

μ_1 = mean regression time in group A = 5.95 μ_2 =

mean regression time in group B = 5.82 σ = standard deviation = .2

$Z\alpha/2$: This depends on level of significance, for 5% this is 1.96 $Z\beta$: This depends on power, for 80% this is 0.84

By substituting

$$n = 37$$

Considering a drop out rate of 8%

Sample size in each group = 40

Sample size 80

Outcome Measures

Primary Outcome

- Heart rate
- Systolic blood pressure
- Diastolic blood pressure
- Mean arterial pressure
- Oxygen saturation

Secondary Outcomes

- Adverse effects
- Local anaesthetic toxicity
- Tourniquet tolerance
- Need for rescue analgesia

Inclusion Criteria:

1. Adults between age 18 to 60 years of both sex
2. ASA grade 1 and 2
3. Posted for upper limb surgeries
4. Without coagulation disorders

Exclusion Criteria:

1. Known case of allergy to local anaesthetics
2. Patients with cardiovascular and neurological abnormalities
3. Pregnant women
4. Surgical duration more than one and a half hours (exceeding the tourniquet time)

5. Coagulation disorders.

METHOD

After obtaining approval from ethical committee and after obtaining written informed consent, 80 patients of either sex in the age group of 18-60 years with ASA I & II classification scheduled for upper limb surgeries lasting for less than 90 minutes were included in this study.

Patients with history of allergy to local anaesthetics, sickle cell disease, Raynaud's disease, scleroderma, local infection, Paget's disease were excluded from this study. Pre-anaesthetic evaluation was done.

All patients fasted overnight or for a minimum of 6 hours. The patients underwent various types of surgeries like open reduction with wire fixation, and plate and screw fixation, ganglion excision etc. The patients were randomly allotted in two groups of 40 each using closed envelope technique.

- Group A – received 40 ml 0.2% Ropivacaine for IVRA
- Group B – received 40 ml 0.5% Lignocaine.

All patients were premedicated with inj midazolam 0.02mg/kg intravenously 30 minutes before surgery. Resuscitation equipment and drugs were kept ready. The Initial pulse rate, blood pressure and arterial oxygen saturation were recorded and then continuous monitoring was done throughout the procedure.

A 22 G cannula was placed intravenously as distal as possible in the dorsum of the hand to be anaesthetized. Venous access was established in the non-operating limb as well using a 20 G cannula to allow administration of fluids and drugs if necessary. After testing the tourniquet equipment for any leaks, the double lumen tourniquet was applied on the arm with generous layers of padding, ensuring that no wrinkles are formed and the Tourniquet edges do not touch the skin. Limb exsanguination was done by Esmarch bandage or limb elevation at 90° for 3 minutes. The proximal tourniquet was inflated to at least 100 mm Hg higher than the patient's systolic blood pressure and to maximum of 250 mm Hg. Circulatory isolation of operating limb was confirmed by oligemia, absence of ulnar and radial pulses, and loss of pulse oximeter tracing. Group A patients received 0.2% Ropivacaine and Group B Patients received 0.5% Lignocaine; the volume of the anaesthetic drug was 40ml in both the groups. After achieving surgical anaesthesia, the distal tourniquet that overlies part of the anaesthetized arm was inflated and the proximal one was deflated. After that the surgeons were allowed to proceed.

Intraoperatively, Pulse rate, Blood pressure, Respiratory rate, SPO2 and signs of local anaesthetic toxicity were monitored regularly. The cuff was not deflated until 30 minutes after injection of the local anaesthetic, even if the surgery was completed before 30 minutes and not inflated for more than 90 minutes. Cuff deflation was done in cycles with

deflation/inflation times of less than 10 seconds until patient no longer shows signs of systemic toxicity.

Statistical Analysis

Statistical analysis was performed using Statistical Package for the Social Sciences (SPSS) version 26.0. Chi-square test and independent „t“ test was used for

analysis. “p value of <0.05” was considered to be statistically significant in this study and “p value of <0.001” was considered to be statistically highly significant. Effect size (Cohen's d) and 95% confidence intervals were calculated for all primary outcomes.

RESULTS

P value for age category based on fisher’s exact test was 0.340. No significant difference between samples of two groups in terms of category of age group was found.

Table 1: Age category of the study population

Age category	Group A	Group b	Total	hi-square value	P value
18 to 20 years	5	1	6	4.525	0.340
21 to 30 years	14	14	28		
31 to 40 years	12	12	24		
41 to 50 years	8	9	17		
51 to 60 years	1	4	5		
Total	40	40	80		

P value based on chi-square test – 0.348(NS). There was no significant difference in the sex category of the study population between the two groups.

HEMODYNAMIC PARAMETERS

Table 2: Heart rate (beats/min)

Heart rate	Group		Mean	SD	SE	t value	p value
At baseline	A	40	78.075	5.841	0.924		0.420
	B	40	76.975	6.278	0.993		
At 5 th minute	A	40	78.075	5.841	0.924		0.420
	B	40	76.975	6.278	0.993		
At 15 th minute	A	40	78.450	5.747	0.909	0.506	0.614
	B	40	77.800	5.743	0.908		
At 25 th minute	A	40	78.675	5.806	0.918	0.893	0.375
	B	40	77.525	5.715	0.904		
At 40 th minute	A	40	78.650	5.829	0.922	1.479	0.143
	B	40	75.175	13.666	2.161		
After release	A	40	78.575	5.656	0.894	1.432	0.156
	B	40	75.225	13.673	2.162		
10 minutes after release	A	40	78.375	5.692	0.900	1.273	0.207
	B	40	75.425	13.506	2.135		

Heart rates noted at various time intervals showed no significant difference between the two study groups.

Systolic Blood Pressure

Table 3: Comparison of Systolic blood pressure between two groups at specified intervals

Systolic blood Pressure	Group		Mean	SD	SE	t value	p value
At baseline	A	40	115.500	8.373	1.324	0.114	0.910
	B	40	115.250	11.128	1.759		
At 5 th minute	A	40	115.500	8.373	1.324	0.114	0.910

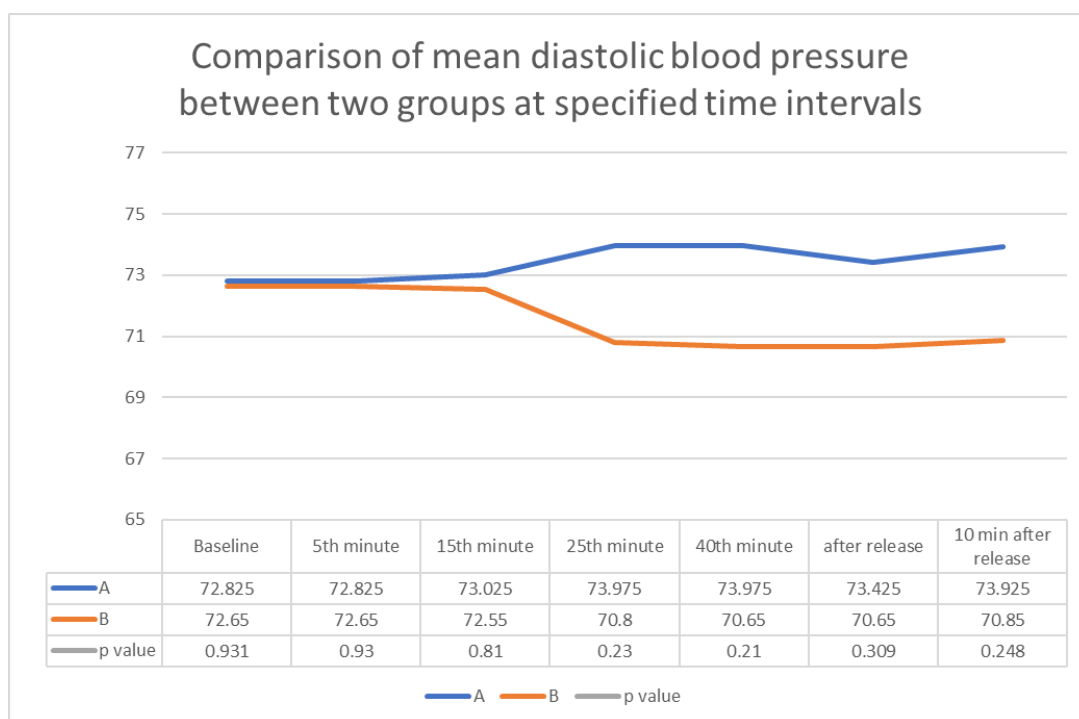
	B	40	115.250	11.128	1.759		
At 15 th minute	A	40	115.850	8.574	1.356	0.190	0.850
	B	40	115.450	10.198	1.612		
At 25 th minute	A	40	115.650	8.496	1.343	0.954	0.343
	B	40	112.200	21.233	3.357		
At 40 th minute	A	40	115.450	8.339	1.318	0.884	0.379
	B	40	112.250	21.321	3.371		
After release	A	40	115.750	8.366	1.323	0.983	0.329
	B	40	112.200	21.257	3.361		
10 minutes after Release	A	40	115.350	8.245	1.304	0.507	0.614
	B	40	113.600	20.225	3.198		

Based on individual t test value calculated for systolic blood pressure at baseline, 5th min, 15th min, 25th min, 40th min, after release and 10mins after release there was no statistical significance noted between the two study groups for systolic blood pressure.

Diastolic Blood Pressure

Based on individual t test value calculated for diastolic blood pressure at baseline, 5th min, 15th min, 25th min, 40th min, after release and 10mins after release there was no statistical significance noted between the two study groups for diastolic blood pressure.

Graph – 1: Comparison of mean diastolic blood pressure between two groups at specified time intervals



Mean Arterial Pressure:

Comparison of mean arterial pressure between the two groups at specified time intervals.

Table – 4: Comparison of mean of mean arterial pressure between two groups at specified intervals

Mean arterial pressure	Group		Mean	SD	SE	t value	p value
At baseline	A	40	87.050	6.179	0.977	0.130	0.897
	B	40	86.850	7.511	1.188		
At 5 th minute	A	40	87.050	6.179	0.977	0.130	0.897
	B	40	86.850	7.511	1.188		
At 15 th minute	A	40	87.300	6.241	0.987	0.298	.766

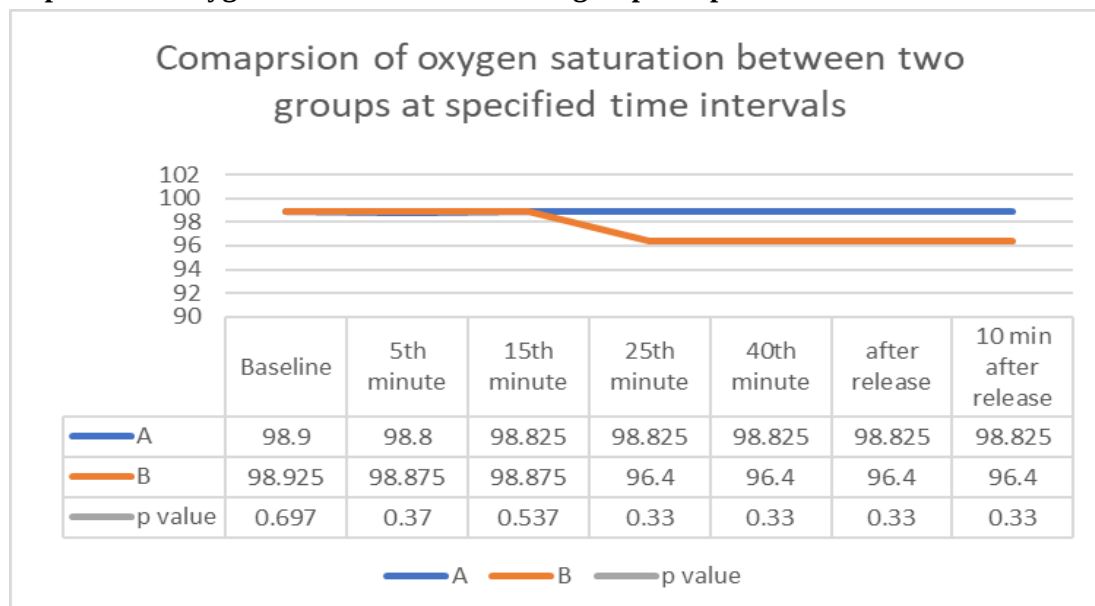
	B	40	86.850	7.223	1.142		
At 25 th minute	A	40	87.867	6.247	0.988	1.23	.219
	B	40	84.600	15.455	2.444		
At 40 th minute	A	40	87.800	6.190	0.979	1.248	.216
	B	40	84.517	15.444	2.442		
After release	A	40	87.533	6.309	0.997	1.142	.257
	B	40	84.500	15.570	2.462		
10 minutes after release	A	40	87.733	6.284	0.994	1.003	.319
	B	40	85.100	15.364	2.429		

Based on individual t test value calculated for mean arterial pressure at baseline, 5th min, 15th min, 25th min, 40th min, after release and 10mins after release there was no statistical significance noted between the two study groups for mean arterial pressure.

Oxygen Saturation

Based on individual t test value calculated for oxygen saturation at baseline, 5th min, 15th min, 25th min, 40th min, after release and 10mins after release there was no statistical significance noted between the two study groups for oxygen saturation.

Graph – 2: Comparison of oxygen saturation between two groups at specified time interval



DISCUSSION

IVRA was first introduced by August Bier in the year 1908. This technique is commonly known as Bier's block in commemoration of its founder. IVRA is a simple technique, easy to perform, providing adequate analgesia intraoperatively and decreased postoperative analgesic requirements, while the circulation is occluded. It can be performed in extremities requiring surgical intervention where general anaesthesia may be contraindicated either due to their comorbid conditions or inadequate fasting status.

IVRA technique provides a simple, easy application, cost effective and time saving anaesthesia which makes it as a day care procedure resulting in early discharge allowing them to resume normal activities at the earliest.

Many local anaesthetic agents like Procaine, Mepivacaine, Bupivacaine, Ropivacaine and Prilocaine have been used, but Lignocaine has been popularised as it was found to have less complications when compared with other agents. This technique has the disadvantages of local anaesthetic toxicity, tourniquet pain and inadequate postoperative analgesia. These factors have been overcome by changing the local anaesthetics used, modifying the technique and adding additives to local anaesthetics.

Atanassoff *et al*⁶ studied the times from injection of LA to surgical incision and found that it was longer for ropivacaine (15 ± 4 min) than for lignocaine (12 ± 4 min) which, however, was not statistically significant. Peng *et al.*⁷ found that onset time of anesthesia (8.0 ± 4.1 min vs. 6.5 ± 2.9 min for ropivacaine and

lignocaine groups, respectively) and motor block were similar in forearm IVRA.

Hartmannsgruber *et al.*⁸ also had similar results. They observed that sensory recovery was prolonged by up to 30 min in those who received 0.2% ropivacaine as compared to 0.5% lignocaine. In motor block regression, they found that 0.2% ropivacaine resulted in decreased grip strength for up to 30 min in comparison to 0.5%. The difference in the sensory regression and motor regression between ropivacaine and lignocaine was statistically significant.

Atanassoff *et al.*,⁶ also found a prolonged sensory recovery by approximately 19 min, on average, with the use of ropivacaine as compared to lignocaine. The difference in the sensory regression in between ropivacaine and lignocaine was statistically significant.

Limitations

This was a single-centre study with a relatively small sample size. Long-term postoperative outcomes and patient satisfaction were not evaluated. Therefore, multicentre studies with larger sample sizes are recommended.

Strengths of the Study

The randomized prospective design, standardized anaesthetic protocol and objective haemodynamic assessment strengthen the validity of the present study.

Future Recommendations

Future multicentre randomized controlled trials with larger sample sizes are recommended to evaluate long-term outcomes and postoperative analgesia.

CONCLUSION

There was no statistical significance noted between the two study groups for Heart rates, systolic blood pressure, diastolic blood pressure, mean arterial pressure and oxygen saturation.

Data Availability Statement

The datasets generated and analysed during the current study are available from the corresponding author on reasonable request.

Conflict of Interest

The authors declare no conflict of interest.

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Authors' Contributions

Jyothi R: Conceptualization, study design, patient recruitment, data collection, and manuscript drafting.

Rajani R. Kunthe: Methodology, supervision, data interpretation, critical revision of the manuscript, and final approval of the manuscript.

Pachha Priya: Statistical analysis, data interpretation, manuscript editing, overall supervision, and corresponding author responsibilities.

All authors have read and approved the final version of the manuscript and agree to be accountable for all aspects of the work.

Abbreviations

IVRA – Intravenous Regional Anaesthesia

ASA – American Society of Anesthesiologists

LA – Local Anaesthetic

HR – Heart Rate

SBP – Systolic Blood Pressure

DBP – Diastolic Blood Pressure

MAP – Mean Arterial Pressure

SpO₂ – Peripheral Oxygen Saturation

IEC – Institutional Ethics Committee

SPSS – Statistical Package for the Social Sciences

SD – Standard Deviation

SE – Standard Error

CI – Confidence Interval

CTRI – Clinical Trials Registry–India

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