Section: Miscellaneous

Original Research Article

COMPARISON OF ROPIVACAINE 0.2% AND LIGNOCAINE 0.5% INTRAVENOUS REGIONAL ANAESTHESIA (IVRA) IN UPPER LIMB SURGERIES

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ABSTRAC

Background: Upper limb surgeries require General Anaesthesia with controlled ventilation. To avoid General Anaesthesia, various regional techniques are tried. Intravenous regional anaesthesia (IVRA) is a safe and one of the reliable technique for providing anaesthesia as well as bloodless surgical field during surgeries. The objective is to evaluate the anesthetic efficacy, postblock residual analgesia and any toxicity of two local anesthetics (LA) agents Ropivacaine and Lignocaine.

Materials and Methods: 80 patients of age 18-60 years with ASA grade I & II, undergoing upper limb surgeries lasting for less than 90 minutes were randomly allocated into two groups. Group A received 40 ml 0.2% Ropivacaine and Group B received 40 ml 0.5% lignocaine for IVRA. Onset and regression of sensory and motor block were assessed by response to pinprick and by testing hand movements, respectively. Visual analog scores(VAS) were assessed intraoperatively and postoperatively.

Results: Adequate surgical anesthesia was provided with both ropivacaine and lignocaine. The mean sensory block onset and regression times were significantly delayed with ropivacaine as compared to lignocaine ($P < 0.05$). Postoperatively, the VAS was significantly lower in ropivacaine group in the first 90 min. None of the patients in any group showed any evidence of local anesthetic toxicity.

Conclusion: IVRA for upper limb surgery using 0.2% ropivacaine is a better option as compared to 0.5% lignocaine as it provides longer postoperative analgesia.

Keywords: IVRA; Bier's block; Ropivacaine; Lignocaine.

INTRODUCTION

Intra Venous Regional Anaesthesia (IVRA) is a regional anaesthetic technique commonly used in forearm surgeries. It was first introduced by a German surgeon August Gustav Bier in 1908 by injecting Procaine intravenously between two tourniquets.[1] He found that there was a rapid onset of anaesthesia between the tourniquets and a slower onset beyond the distal tourniquet. This technique gained more importance in the late 1960s after its reintroduction by Holmes.[2]

There have been many modifications to this technique over time, presently the use of double tourniquet with injection of drugs distal to the cuffs. Its use has been proved to have an advantage of faster recovery, shorter hospital stay, cost effectiveness and reduced nursing care requirements making it an ideal choice for Day care surgeries.[3] When IVRA is appropriately performed there is a 96-100% success rate.[4-6]

This technique has the advantage of rapid return of sensory and motor power at the end of surgical procedure allowing normal functioning of the operated limb and the surgeons are able to assess neurological status after surgery. This rapid recovery facilitates early discharge of patients.

IVRA is advantageous being reliable, easy to administer and cost-effective for short operative procedures of the extremities performed on an

ambulatory basis.[3] There are some disadvantages like delayed onset of action, poor muscle relaxation and rapid onset of pain at operative site after tourniquet is deflated.[7]

Various additives like Opioids, Muscle relaxants, Non steroidal antiinflammatory drugs (NSAIDs) such as Ketorolac,[8] Tenoxicam,[9] and Aspirin,[10] have been used to overcome these disadvantages to improve analgesia. There is a risk of local anaesthetic toxicity due to sudden release of large amounts of local anaesthetic as a result of leakage due to high venous pressure or accidental tourniquet failure past the inflated tourniquet. Due to the above mentioned effects it is desirable to limit the amount of local anaesthetic to a minimum.[11]

Since long time Lignocaine 0.5% was used for IVRA. Now new drug Ropivacaine is introduced into practice. Now it is time to compare the effectiveness of Ropivacaine 0.2% for IVRA as an alternative to Lignocaine 0.5%.

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.

Sample Size of Estimation

Formula of calculating sample size is

$n = [(Z_{\alpha/2} + Z_{\beta})^2 \times \{2(ó)^2\}]/ (\mu1 - \mu2)^2$

where

n = sample size required in each group,

μ1 = mean regression time in group A = 5.95 μ2 = mean regression time in group B = 5.82 ó = standard deviation = .2

Zα/2: This depends on level of significance, for 5% this is 1.96 Zβ: 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

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, Pagets 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.

The following parameters were observed intraoperatively:

1. Onset of sensory and motor block
2. Degree of sensory block using VAS
3. Duration of surgery
4. Side effects
5. Duration of blockade after cuff deflation: both sensory and motor time to first analgesic requirement was noted post operatively

Assessment of pain: Pain is a personal, subjective experience. There are three major psychological dimensions of pain sensory – discriminative, motivational affective and cognitive-evaluative. These categories of activity interact with one another to provide perceptual information on the location, magnitude and spatiotemporal properties of the noxious stimuli: motivational tendency towards escape or attack; and cognitive information based on past experience. All three forms of activity could then influence motor mechanisms responsible for the complex pattern of overt responses that characterize pain. Pain assessment should be ongoing, individualized and documented. The measurement of pain is important: to determine pain intensity, perception qualities and duration, to aid in diagnosis, to help decide on the therapy and to evaluate the relative effectiveness of different therapies.

Pain is subjective; changes in pain over time are difficult to interpret and have probably different meaning to each individual and there is no way to objectively quantify it. So the patient‟s self-report provides the most valid measure of the experience. The ideal pain measure should be sensitive, accurate, reliable, valid and useful for both clinical and experimental conditions and should be able to separate the sensory aspects of pain from the emotional aspects.

Visual Analogue Scale (VAS): VAS is most commonly a straight 100-mm line, that has the words "no pain" at the left most end and "worst pain imaginable" at the right most end. Patients are instructed to place a mark on the line indicating the amount of pain that they feel at the time of evaluation. The distance of this mark from the left end is then measured, and this number is used as a numeric representation of the patient‟s pain.

No pain → worst imaginable pain

Advantages

1. Sensitive to changes in a pain experience.
2. Its ease and brevity of administration and scoring.
3. Relatively easy to understand for most patients.
4. Its minimal intrusiveness.
5. Its greater sensitivity to detect intervention-based changes in pain.

Disadvantages

1. Its attempt in assigning a single value to a complex, multidimensional experience.
2. Assesses only one dimension (intensity) of a complex experience.
3. Has a ceiling at the upper most end.

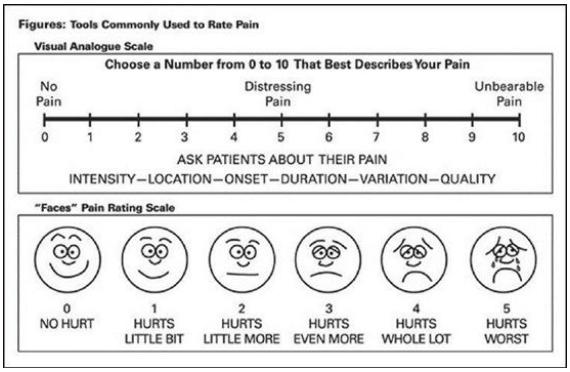

Figure 1: Visual Analogue Scale

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.

RESULTS

Table 1: Age distribution between two different groups

	Group A	Group B	p
Valid	40	40	
Missing	0	0	
Mean	32.225	35.775	
Std. Deviation	9.807	10.398	0.120 NS
Minimum	18.000	20.000	
Maximum	52.000	56.000	

Age category of the study population:

Age category	Group A	Group b	Total	Chi-square value	P value
18 to 20 years	5	1	6		
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	4.525	0.340
Total	40	40	80		

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 2: Sex distribution between both groups

	Group A	Group B	Total	Chi-square value	
Female	12	16	28	0.879	0.348
Male	28	24	52		
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.

Table 3: Sensory block onset in minutes

	Group	no's	Mean	SD	SE	T value	p value
Sensory block onset in minutes	A	40	5.225	0.716	0.113	8.089	<0.001
	B	40	3.850	0.802	0.127		

Based on independent t-test with a t-value of 8.089, a significant difference between the two groups was observed in the duration of onset in sensory block with a p value of <0.001. Group B had significantly lower duration of onset of sensory block in minutes with a mean value of 3.85 minutes. This difference can be deemed significant.

Table 4: Motor block onset in minutes

	Group	no's	Mean	SD	SE	T value	p value
Motor block onset in minutes	A	40	11.10	0.841	0.133	21.46	<0.001
	B	40	7.20	0.783	0.124		

Based on independent t test with a t value of 21.46, a significant difference between the two groups was observed in the duration of onset of motor block with a p value of <0.001. Group B had significantly lower duration of onset of motor block in minutes with a mean value of 7.20 minutes. This difference can be deemed significant.

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.

Intraoperative VAS score: Mann Whitney u-test was used for comparison of two groups on the estimated VAS score at different time intervals in the intraoperative period.

Table 5: VAS score

VAS score	Group		Over all score	Mean	SD	SE	Mann-Whitney U score	p value
At baseline	A	40	0	0.000	0.000	0.000	NA	NA
	B	40	0	0.000	0.000	0.000		
At 5th minute	A	40	0	0.000	0.000	0.000	NA	NA
	B	40	0	0.000	0.000	0.000		
At 15th minute	A	40	0	0.000	0.000	0.000	NA	NA
	B	40	0	0.000	0.000	0.000		
At 25th minute	A	40	0	0.000	0.000	0.000	NA	NA
	B	40	0	0.000	0.000	0.000		
At 40th minute	A	40	5	0.125	0.335	0.053	NA	NA
	B	40	0	0.000	0.000	0.000		
After release	A	40	4	0.100	0.304	0.048	380	<0.001
	B	40	25	0.625	0.490	0.078		
10 minutes after release	A	40	7	0.175	0.446	0.071	315	<0.001
	B	40	31	0.775	0.423	0.067		

Intra-operative VAS score: VAS score in intra-op period during baseline was nil for all the study population in both the groups. The total VAS score in both the study group during the intraop period was nil at baseline, 5th minute, 15th min, 25th min from baseline. At 40th minute the total VAS score in Group A was 5 and in group B it was 0.

Post-operative VAS scores: Mann Whitney u-test was used for comparison of two groups on the estimated VAS score at different time intervals during the postoperative period.

Table 6: Comparison of postoperative total VAS score between two groups at specified time intervals

VAS score	Group		Overall score	Mean	SD	SE	Mann- Whitney U score	p value
At 5th minute	A	40	24	0.600	0.545	0.086	554.5	0.004
	B	40	37	0.925	0.417	0.066		
At 15th minute	A	40	30	0.750	0.543	0.086	441	<0.001
	B	40	56	1.400	0.709	0.112		
At 30th minute	A	40	34	0.850	0.483	0.076	422	<0.001
	B	40	58	1.450	0.597	0.094		
At 45th minute	A	40	37	0.925	0.417	0.066	407.5	<0.001
	B	40	59	1.475	0.506	0.080		
At 60th minute	A	40	40	1.000	0.320	0.051	380	<0.001
	B	40	64	1.600	0.591	0.093		
At 75th minute	A	40	48	1.200	0.405	0.064	520	0.001
	B	40	62	1.550	0.504	0.080		
At 90th minute	A	40	56	1.400	0.496	0.078	800	1.000
	B	40	56	1.400	0.496	0.078		

The VAS score was significantly higher among study participants in group B after release with a p value of <0.001, similar was the case with 10th minute after release.

Sensory block regression time

Table 7: Comparison of sensory block regression time in minutes

Sensory block regression time	Mean (hours)	SD	SE	Mann Whitney U score	P value
Group A	6.26	0.83	0.132	1536	<0.001
Group B	4.3	0.64	0.103		

Based on Mann Whitney U score calculated for sensory block regression time a score of 1536 was obtained. Group B had a statistically significant sensory block regression time of 4.3 minutes when compared to group A.

Motor block regression time

Table 8: Comparison of motor block regression time in minutes

Motor block regression time	Mean	SD	SE	Mann Whitney U score	P value
Group A	4.38	0.76	0.121		
Group B	2.52	0.50	0.080	1558	<0.001

Based on Mann Whitney U score calculated for motor block regression time a score of 1558 was obtained. Group B had a statistically significant motor block regression time of 2.52 minutes when compared to group A.

DISCUSSION

In this study, we compared the two local anaesthetics, Lignocaine 0.5% versus Ropivacaine 0.2% in IVRA. Ropivacaine, a pure S(-) enantiomer and structurally related to bupivacaine, is a long acting amide LA agent. The S-enantiomers have been shown to substantially reduce systemic toxicity when compared to their racemic counterparts.

In our study, we used 0.2% ropivacaine as it has a potency of three times of lignocaine and is commercially available in this strength. Other workers have previously used 0.2 -0.375% in volunteer and patient studies 12-15. Ropivacaine has the analgesic potency of 0.6 times relative to bupivacaine. Clinically adequate dose of ropivacaine is associated with lower incidence of the motor block than bupivacaine as well as reduced potential for CNS toxicity and cardio toxicity. When used for IVRA, ropivacaine is an agent with a better safety profile than bupivacaine.[12] In our study, the onset times for sensory and motor blockade with lignocaine were faster than ropivacaine and were statistically significant, although clinically not much different.

Other authors who have studied onset times include Hartmannsgruber et al,[15] who did a comparison of ropivacaine 0.2% and lignocaine 0.5% for IVRA in volunteers. They found no significant differences for onset times of anesthesia.

In our study, the quality of anesthesia or intraoperative degree of pain relief was almost same in both the ropivacaine and lignocaine groups. The difference in VAS scores between the two groups in the intraoperative period was not statistically significant. The two groups were comparable and there was no significant difference in the quality of anesthesia in between the groups. Similar results were found by Atanassoff et al.[12] They showed that IVRA with 0.2% ropivacaine provides anesthesia of same surgical quality when compared with 0.5% lidocaine.

At the end of surgery, after deflation of the tourniquet, we checked the sensory block by pin-prick method in the distribution of the nerves. We observed that sensory regression in both the groups showed statistically significant difference with Lignocaine group having earlier mean sensory regression after deflation of tourniquet as compared to ropivacaine group. We observed that motor regression in both the groups also showed statistically significant difference with group lignocaine having earlier meant motor regression after deflation of tourniquet as compared to group ropivacaine.

Our results were similar to the Chan et al.[13] They found that sensory recovery in the high-dose ropivacaine group (1.8 mg/kg) was significantly longer than the low-dose ropivacaine (1.2 mg/kg) or lignocaine group (3 mg/kg). In motor recovery, they had similar findings with the high-dose ropivacaine group (1.8 mg/kg), where decreased grip strength was found to be sustained for 70 min as compared to complete recovery in the lignocaine group during the same period.

Asik et al,[16] also found sensory recovery to be significantly prolonged in both 0.2% and 0.25% ropivacaine groups as compared to 0.5% lignocaine (20.5 ± 4.6 min and 23.5 ± 4.8 min as compared to 3.5 ± 1 min). In present study, we found that the median Visual Analog Scores every 15 min for the first 90 min after the surgery were significantly lower in group ropivacaine as compared to the group lignocaine (P<0.05) for each point of time. Time to the first analgesic dose after tourniquet deflation was significantly higher in group ropivacaine of as compared to group lignocaine after surgery.

Our results were similar to the study of Atanassof et al,[12] who found significantly lower numerical pain scores at the time of post anesthesia care unit admission and a significantly longer time to the first analgesic in those receiving 0.2% ropivacaine

(median, 47 min; range, 27–340 min) as compared to 0.5% lignocaine (median, 34 min; range, 2–140 min). Peng et al,[17] also found that 0.375% ropivacaine provides superior postoperative analgesia when compared with 0.5% lidocaine when forearm IVRA is used. They found that verbal pain rating scores (VPRS) was significantly lower in the ropivacaine group in the first 60 min with significantly more patients in the ropivacaine group pain free (VPRS, 0) up to the first 90 min. More patients in lignocaine group requested analgesic in the first 2 h post block, and only patients in the lignocaine group required supplemental IV morphine in the recovery room. Asik et al,[16] also found significantly lower verbal numerical pain scores and longer time to the first analgesia in the 0.25% and 0.20% ropivacaine subjects as compared to 0.5% lignocaine (29.8 ± 4.9 min, 27.5 ± 7.3 min vs. 11.3 ± 3.9 min).

No signs and symptoms of central nervous system toxicity were observed in any group in our study. However, some authors have noticed some side effects when using the two agents. In volunteer patient studies, Hartmannsgruber et al,[15] and Chan et al,[13] both demonstrated an increased incidence of temporary dizziness, tinnitus, and light-headedness in the lignocaine groups as compared to ropivacaine group; however, these patients were not administered any sedation prior to, or during the procedure.

Asik et al,[16] identified an increased incidence of light- headedness, tinnitus, and metallic taste in patients receiving lignocaine as compared to ropivacaine. Niemi et al,[18] identified one patient with postoperative dizziness and blurry vision after receiving 0.5% prilocaine while none in ropivacaine group.

CONCLUSION

From the data and the statistical analysis of our study, it was concluded that Ropivacaine 0.2% when used in IVRA has slower sensory regression and longer postoperative analgesia and better hemodynamic stability. Hence it is a better alternative to Lignocaine 0.5% for use in IVRA.

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