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COMPARISON BETWEEN ROPIVACAINE AND LEVOBUPIVACAINE IN AXILLARY BRACHIAL PLEXUS BLOCK-AN OBSERVATIONAL STUDY- IN A TERTIARY CARE CENTRE.

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ABSTRACT

Background: Regional anaesthesia techniques are an important part in the field of anaesthesiology. Axillarybrachial plexus block is one of the commonest & safest regional anaesthetic technique used for surgery of the hand, forearm and elbow.

Materials & methods: We have done a observational epidemiological study with longitudinal design among 60 numbers of age and sex matched patients (30 patients Ropivacaine group & 30 patients in Levobupivacaine group) underwent any surgery of upper limb. after cases fulfilling inclusion and exclusion criteria were taken up for the study with equal probability of allocation. After administration of the drugs, study subjects in both the group were observed at specific time interval for a period of 10 hours. Onset of sensory and motor block, duration of sensory & motor block, vitals and pain (was assessed by VAS score) was studied and compared between these 2 groups.

Results: The onset of sensory blockade & motor blockade, duration of sensory & motor block among the patients received Ropivacaine was shorter & significant statistically ($p<.05$) compared to levobupivacaine group. VAS Scores were comparable in both the groups

Conclusion: Ropivacaine has faster onset of sensory and motor blockade when compared with Levobupivacaine but But duration of both sensory and motor blockade was lesser than Levobupivacaine & provides satisfactory intra-operative &post-operative analgesia.

KEYWORDS : Ropivacaine, Levobupivacaine, axillary Brachial plexus block

INTRODUCTION

Regional anaesthesia techniques are an important part of the anaesthesiologist armamentarium. Axillary brachial plexus block is one of the commonest& safest regional anaesthetic techniques used for surgery of the hand, forearm and elbow. The conventional trans-arterial technique has potential drawback such as nerve injury due to needle trauma and intraneural injection as well as cardiovascular and central nervous system toxicity as a result of increase vascular uptake or accidental intravenous injection. Peripheral regional anaesthesia can be executed with nominal technological requirements using simple techniques.

Recently peripheral nerve block is gaining popularity over general anaesthesia as it is devoid of side effects intubation related and muscle relaxants and systemic haemodynamic changes. This type of anaesthesia is preferred in case of prolonged surgical procedures like orthopaedic, plastic reconstructive surgeries and in emergency surgeries where the patients are in full stomach,and in high risk patients. This technique provides anaesthesia as well as postoperative analgesia. The techniques which are commonly used for peripheral nerve block are; paresthesia, nerve stimulation and ultrasound technique.Recently ultrasound guided nerve locators is being introduced with higher rate of block success and quicker onset of action.[4,5]

The choice of local anaesthetic for a particular nerve block depends on the onset, duration, relative blockade of sensory and motor fibres, toxicity profiles and site specific risks.[6]Local anaesthetics may be deposited at any point along the brachial plexus, depending on the desired block effects like interscalene approach for shoulder and proximal humerus surgical procedures; supraclavicular, infraclavicular and axillary for surgeries distal to the mid humerus.[7]

The LAs which are most commonly used for peripheral nerve block are Bupivacaine, Ropivacaine and Levobupivacaine. The duration of motor and sensory block and post-operative analgesia provided by Ropivacaine is close to bupivacaine. The agent, Levobupivacaine is also significantly less cardiac and CNS toxic then the bupivacaine while still possessing a similar duration of sensory blockade. The Levobupivacaine has been shown to be safe, effective for epidural and spinal anaesthesia and also blockade of the brachial plexus.[8]

AIM AND OBJECTIVES

To compare the effects of Levobupivacaine and Ropivacaine in axillary brachial plexus block.

Primary objective:

Compare the efficacy of Levobupivacaine and Ropivacaine in axillary brachial plexus block.

Secondary objectives:

1. To compare the onset time, duration of sensory and motor blockade and any adverse effects following axillary brachial plexus block with 0. 5% Ropivacaine and o.5% Levobupivacaine.
2. To study the hemodynamic changes if any during intra-operative and postoperative period.

MATERIALS AND METHODS

Study type & design:

It was an observational analytical study with longitudinal design.

Study setting:

Department of Anaesthesiology, Agartala Government Medical College and G. B. Pant Hospital,

Study duration:

Study was conducted during October 2016 to September 2018.

Study population:

American Society of Anaesthesiologists(ASA) grade 1&2 underwent any surgery of upper limb .

Inclusion Criteria:

1. Patients belonging to ASA grade 1& 2.
2. Patient of either gender with age between 18 to 65 years.
3. Patient willing to participate in this study.

Exclusion Criteria:

1. Patients belonging to ASA grade 3& 4.
2. Patient agedless than 18 years or more than 65yrs.
3. Patient with h/o bleeding diathesis, neuromuscular disorder, morbid obesity (BMI >35.0)
4. Local site infection.
5. Patient having hepatic, renal or cardiovascular co morbidities
6. Patientnot willing to participate in this study.

Sample size:

Based on the data of previous 3 years, average 120 numbers of upper limbs surgeries take place in a year in AGMC. Of them approximately 48 cases (40%) may be performed under axillary brachial plexus block. Accordingly, the sample size in the study period of one and half years was (48+24) = 72. By exclusion criteria 12 cases were excluded from the study. So, calculated final sample size was (72-12) = 60.

Sampling technique:

Tossing a coin decision was taken for selection of the first patient and every alternative patient was allocated to the groups accordingly.

Techniques:
1. Interview of the study subjects
2. Observation of various clinical parameters by the researcher.

- **Test of sensory loss in the median, ulnar, radial, musculocu taneous nerve-** Yes/No

Sensory block was graded as follows;
Grade 0: No onset of sensory loss. Sharp pin prick felt.
Grade 1: Onset of sensory loss. Analgesia, dull sensation felt.
Grade 2: Loss of sensory sensation. Anaesthesia, no sensation felt.

- **Extent of motor blockade in the distribution of radial, ulnar, Median,musculocutaneous nerve-** Yes/No

Motor block was graded by modified Bromage scale.
Grade 0: No onset. Able to raise the extended arm to 900 for 2 seconds
Grade 1: Onset of motor loss. Able to flex the elbow and move the finger but unable to raise the extended arm.
Grade 2: Mild block. Unable to flex the elbow but able to move the finger.
Grade 3: Complete block. Unable to move the arm, elbow and finger

- **Post-operative pain intensity:** was categorized as no pain, mild pain, moderate pain and severe pain based on the scorning obtained from Visual analogue scale.

mild pain(0-3 cm), moderate pain (4-6cm), and severe pain (7–10cm).

- **Presence of nausea, vomiting-** Yes/No

Methods:
After proper PAC patients Heart rates (HR), blood pressure (BP), mean arterial pressure (MAP) were recorded before the procedure. Tab ranitidine 150 mg and Tab alprazolam 0.5mg ,Inj ondansetron 4 mg IV used as premedication. Preloading with IV fluid and multipara monitor attached, each patient was assigned into either of these group (age &sex matched) equally, group- 1 and group -2. Group -1 received 30ml 0.5% Ropivacaine and Group -2 received 30 ml 0 .5% Levobupivacaine.

The patients were positioned supine with the operative arm abducted at 90^0& externally rotated. After thorough skin preparation, the axillary artery was palpated as high in the axilla as possible. A 22 SWG(steel wire gauge) short bevel needle was inserted superior to axillary artery at 45^0 angle. By changing the direction of the stimulating needle, the nerves innervating the area where surgery was going to be performed (median. ulnar and radial nerves) identified and infiltrated.The position of the needle considered adequate when an output of lower than 0.5mA elicited a distal motor response in each individual nerve innervating the limb. In all patients, drugs first infiltrated as per the nerves innervating the surgical area. If only one of the main nerves (median, ulnar or radial) was implicated, 30ml of the drugs injected next to the nerve. If 2 or 3 nerves were involved, the concern drug was injected according to the following sequence: median, ulnar and radial nerve. When 2 or 3 nerves need to be blocked, the total volume of LA will be equally divided and injected in the proximity of the nerve. Evaluation of sensory and motor block was done every 5 minutes for 30 minutes or until onset of blockade noted and thereafter every 60 minutes till complete weaning from the block. When weaning occurred (VAS score 4-6), rescue analgesia was provided.

Heart rate, BP, MAP were recorded at 5, 10, 15, 30, 45, 60, 90, 120 minutes during peri-operative period and every 1 hours. post operatively till the complete weaning of the effects. Data were also recorded regarding any side effects related to anaesthetic drugs like presence of hypotension, bradycardia, hypoxia, nausea and vomiting. Patients were looked for these side effects and treated according to standard clinical practice.

Data analysis:
Chi-square test for categorical variables and student t test for continuous variable was applied to test significance. P value less than 0.05 was considered as statistically significant. Analysis of the data was done by IBM SPSS version 20.

RESULTS
After administration of the drugs, study subjects in both the group were observed at specific time interval for a period of 10 hours. Onset of sensory and motor block, duration of sensory & motor block, vitals and pain (was assessed by VAS score) was studied and compared between these 2 groups during this 10hours period. Data were collected using a pre-designed schedule.

- Among 60 study subjects 41.7% belonged to <30 years' age group followed by 28.3% in 30-40 years' age group and 16.7% in 41-50 years' age group. Rest 13.3% of the subjects belonged to >50 years' age group. Mean age was 34.7±12.6 years.
- Majority of the study subjects were males (73.3%) and 26.7% were females.
- The pre-operative parameters e.g. age, sex, body weight etc. were not statistically significant between the two groups in those parameters (p>.05).
- The onset of sensory blockade among patients received Ropivacaine was shorter (10.83±4.1mins) than patients received Levobupivacaine (14.00±3.5mins) & it was significant statistically (p<.05).
- The onset of motor blockade among patients received Ropivacaine was also shorter (15.33±4.5 mins) than patients received Levobupivacaine (18.17±3.8mins) & it was significant statistically (p<.05).
- Duration of sensory blockade was shorter (6.50±.938hours) in Ropivacaine group than Levobupivacaine group(7.53±1.00hours) & was found to be statistically significant(p<.05).
- Duration of motor blockade was also shorter (7.43±.817hours)in Ropivacaine group than Levobupivacaine group (8.73±. 907 hours) & was found to be statistically significant (p<.05).
- There was no significant change in vital parameters after administration of both the drugs when observed at specific time intervals.
- VAS Scores were comparable in both the group

Table 1: Comparison of onset of sensory block, motor block & duration of sensory & motor block in Ropivacaine and Levobupivacaine group

Parameter	Ropivacaine n=30	Levobupivacaine n=30	Test applied	t test value	p value
Onset of sensory block (In mins)	10.83±4.1	14.00±3.5	Independent sample t test	-3.1 (-5.1,-1.1)	.003
Onset of motor block (In mins)	15.33±4.5	18.17±3.8	Independent sample t test	-2.6 (-5.0,-66)	.01
Duration of sensory block (In hours)	6.50±.938	7.53±1.00	Independent sample t test	-4.1 (-1.5,-.53)	.0001
Duration of motor block (In hours)	7.43±.817	8.73±.907	Independent sample t test	-5.8 (-1.7,-.85)	.0001

Pain was assessed by Visual analogue scale (VAS).
Score7-10cm- Severe pain
Score 4-6cm- Moderate pain
Score0-3cm- Mild pain

VAS score upto 4hrs of drug administration was 0-3 in both the groups & there after upto 10 hrs was 4-6 in both the groups.

DISCUSSION
Several studies across the world have drawn the conclusion that both Ropivacaine and Levobupivacaine are safest alternative to Bupivacaine.

Sensory onset time was calculated from time of injection of drug to onset of dull sensation on any of the nerve distribution. Onset of sensory blockade was earlier (10.83±4.1 mins) in patients received Ropivacaine as a nerve blockade anaesthesia than in patients received Levobupivacaine (14.00±3.5 mins) and the onset of sensory blockade among patients received Ropivacaine was significantly earlier than patients received Levobupivacaine. Consistent with our study Kaur et al [9]in a study to compare the levobupivacaine with ropivacaine in axillary brachial plexus block among 50 patients reported that Onset of sensory block was observed from 5 min itself in Ropivacaine group as compared to bupivacaine group (10 min). But in contrast Jain S et al[10] in 2017 and Kulkarni SB et al[11] in a study with same drugs for supraclavicular brachial plexus block reported that onset of sensory

blockade (p=0.027) was Significantly earlier in group of patients receiving levobupivacaine compared to ropivacaine.Cappel leri et al[12] and Mankad et al[13] was reported sensory onset time was almost similar with that of Levobupivacaine and Ropivacaine group which is in contrast to our results.

Motor blockade onset time was calculated from time of injection of drugto when patient felt heaviness on abduction of arm at shoulder.The onset of motor blockade among patients received Ropivacaine was shorter (15.33±4.5 mins) i.e. rapid than patients received Levobupivacaine (18.17±3.8 mins) and this relation was significant statistically(P<0.05). In consistent with our study Mankad et al [13]and Cacciapuoti A et al [14] reported motor onset time was faster in ropivacaine group (9.50±2.403 mins and 14.0 ± 2.3 minrespectively) compared with levobupivacaine (12.33±2.54 mins and 17 ± 5 min respectively) with $P < 0.05$, which was statistically significant. Similar finding also found in other studies conducted by O LiisanttiLuukkonen J et al,[15] Susana et al[16], Kaur et al[17] . In contrast Mantauvalou et al[18] compared efficacy and safety of three local anesthetic agents namely bupivacaine,levobupivacaine and ropivacaine in patients undergoing abdominal surgery and showed that motor block onset was significantly faster in bupivacaine group almost same in levobupivacaine group (P<0.05) than in ropivacaine group.

Whiteside et al[19] who found the time to maximum degree of motor block in bupivacaine was significantly less (P<0.001) than ropivacaine group whereas Chung et al found that the both drugs ropivacaine and bupivacaine took similar time to complete motor block.[19,20]

A study by Heavner et al,[20] there was a rapid onset time of sensory blockade which is consistent with our study finding but slower motor blockade with ropivacaine than levobupivacaine, in contrast to our study finding.

In another study, both sensory and motor onset times were faster with 0.75% ropivacaine (7.5 ± 1.2 min and 14.0 ± 2.3 min, respectively) when compared with 0.5% levobupivacaine (10 ± 2.4 min and 17 ± 5 min, respectively), similar to our study result.

The difference in observations may be attributable to the anatomic location of the different nerve blocks, the technical procedure used, andthe different methods used to observe parameters such as analgesia and anesthesia.

Our study finding was in agreement with study by Susana et al, [21] who reported longer duration of sensory loss in Levobupivacaine group than Ropivacaine group.

Mankad et al[22] along with few other studies also reported finding in agreement with our finding, duration of motor block was shorter with ropivacaine when compared with levobupivacaine. In contrast few studies by DP Mc Glade and colleagues[23] reverse trend, viz. the duration of motor block was prolonged for ropivacaine when compared with levobupivacaine with statistical significance (p<0.05).

Mankad et al, [13] also reported that no significant changes wasfound in hemodynamic parameters between both the groups and in terms of hemodynamic stability, both groupswere comparable ($P > 0.005$) which was not significant.

Mageswaran and Choy et al [24]observed no significant difference in VAS score of pain among both the groups which is a similar findings in our study also.

CONCLUSION

The following conclusion can be made from the present study

- Ropivacaine has faster onset of sensory and motor blockade when compared with Levobupivacaine.
- But duration of both sensory and motor blockade was lesser than Levobupivacaine
- Ropivacaine provides stable haemodynamic profile similar to Levobupivacaine.
- It provides satisfactory intra-operative &post-operative analgesia comparable to Levobupivacaine.

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