

## EFFECTIVENESS OF 0.2% ROPIVACAINE OR 0.2 % BUPIVACAINE DURING ULTRASOUND GUIDED AMBULATORY INTERSCALENE PLEXUS BLOCK FOR FROZEN SHOULDER MOBILIZATION

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### ABSTRACT

#### BACKGROUND

Interscalene Brachial plexus block has been utilized to provide analgesia for shoulder mobilization in frozen shoulder patients, but the associated motor blockade of the upper limb decreases the ability of the patient to do active physiotherapy. Several in-vitro studies have shown that Ropivacaine provided differential blockade with less motor weakness when compared to Bupivacaine. Hence, we designed this study to look at the motor and sensory blockade characteristics of the interscalene brachial plexus block when Ropivacaine or Bupivacaine were used as local anaesthetics.

#### MATERIALS AND METHODS

This randomised double blinded study was conducted in Karpagam Faculty of Medical Sciences and Research, Coimbatore, from November 2016 to November 2018. 60 patients who had frozen shoulder and who were planned for mobilization under anaesthesia were recruited. All patients were evaluated completely, and the procedure was done after obtaining informed consent. Under strict aseptic measure, interscalene catheter was introduced under the guidance of ultrasound and 20 ml of unlabelled local anaesthetic solution containing either 0.2% Ropivacaine or 0.2% Bupivacaine were injected. After satisfying discharge criteria, patients were ambulated to the physiotherapy department where blinded physiotherapist mobilized the shoulder joint. The sensory and motor onset time, degree and duration of motor blockade, quality and duration of shoulder analgesia were recorded.

#### RESULTS

Both Ropivacaine and Bupivacaine provided satisfactory analgesia (VAS score < 2) in all patients during shoulder mobilization. But the median degree of motor blockade (2 vs 2) and duration of motor blockade ( $222.4 \pm 88.4$  vs  $239.4 \pm 89.8$  minutes,  $P = 0.451$ ) were not less with Ropivacaine when compared to Bupivacaine. Similarly, the duration of analgesia ( $259.80 \pm 82.2$  vs  $273.00 \pm 89.5$  minutes,  $p = 0.554$ ) was comparable between the groups. The sensory onset was one minute earlier in Bupivacaine when compared to Ropivacaine ( $2.2 \pm 1.2$  vs  $3.2 \pm 1.9$  minutes,  $p = 0.017$ ) which was not clinically significant, but the motor onset time was comparable ( $6.7 \pm 3.4$  vs  $8.3 \pm 3.7$  minutes,  $p = 0.081$ ).

#### CONCLUSION

We conclude that 0.2% Ropivacaine provided effective analgesia for frozen shoulder mobilization but did not provided favourable sensory motor differential blockade over Bupivacaine 0.2% for frozen shoulder management.

#### KEY WORDS

Ropivacaine; Bupivacaine; Interscalene; Frozen Shoulder.

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#### BACKGROUND

Frozen shoulder is one of the commonest painful debilitating diseases of the middle and elderly population which can cause functional limitation in terms of performing basic activity of daily living. 2-3% of the general population and 2-5% of diabetic patients are affected by the frozen shoulder of which 6-17% of them have bilateral involvement. Pathologically frozen shoulder is characterised by inflammation of the synovial lining and fibrosis of the capsule within the shoulder joint.

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The primary treatment is focused on active and passive physiotherapy to regain the shoulder mobility at the earliest. The overall goal of treatment is to relieve pain, restore mobility and function.<sup>(1,2)</sup>

Many adjuvant therapies like oral analgesics,<sup>(3)</sup> oral and intra articular corticosteroid injection,<sup>(4)</sup> interscalene brachial plexus block<sup>(5,6)</sup> arthroscopic and open surgical capsular release have been tried to relieve the pain and increase the patient compliance for physiotherapy. Brachial plexus block is usually given at interscalene groove to provide sensory analgesia at the shoulder joint.<sup>(7)</sup> But the accompanying motor blockade impairs the ability of the patient to do the active physiotherapy. Several invitro studies have shown that Ropivacaine provides differential blockade with less motor weakness when compared to Bupivacaine<sup>(8,9)</sup> Hence we designed this study to look at the motor and sensory blockade characteristics of the interscalene brachial plexus block when Ropivacaine or Bupivacaine was used as local anaesthetics for frozen shoulder mobilization.

The aim of the study is to compare the interscalene brachial plexus block characteristics in terms of-

1. Onset time for sensory and motor blockade
2. Degree and Duration of motor blockade
3. Quality of analgesia during mobilization
4. Duration of shoulder analgesia,

When bupivacaine or ropivacaine is used as local anaesthetic for frozen shoulder mobilization.

**MATERIALS AND METHODS**

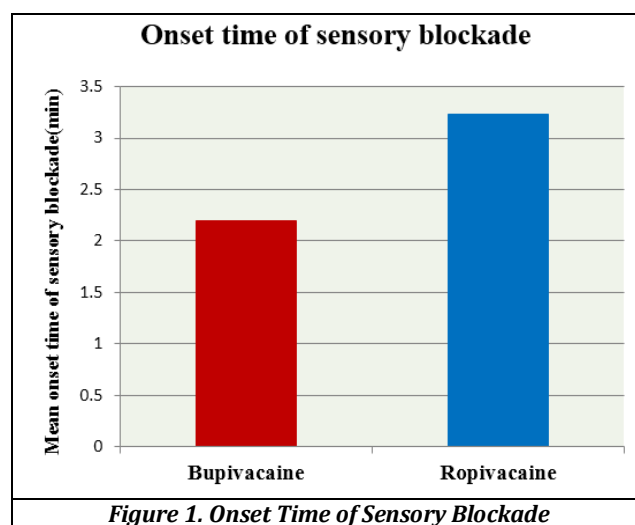
This Randomised Double blinded study was conducted at the Karpagam faculty of Medical sciences and Research from November 2016 to November 2018. After getting informed consent, 60 consecutive patients (30 for each group) who had been posted for ultrasound guided interscalene catheter placement for frozen shoulder mobilization were recruited for the study. The total number of patients attending the ortho department with the diagnosis of frozen shoulder in a year averages around 30 - 40 in our hospital which is evident from the registers. So we decided to choose 30 patients in each group leading to a total sample size of 60. Out of 60 patients, 30 patients received 0.2% Ropivacaine and 30 patients received 0.2% Bupivacaine. In both groups there were 14 male and 16 female patients respectively. This is a double blinded study, because local anaesthetic drug (20 ml of 0.2% Ropivacaine or 20 ml of 0.2% Bupivacaine) will be prepared by the anaesthesia technician and given to the anaesthesia provider as unlabelled. Here both anaesthesia provider and physiotherapist who records study parameters do not know the injected local anaesthetic, After thorough pre-anaesthetic assessment, the baseline range of motion for active and passive shoulder movements were recorded with a goniometer, the severity of pain during active movement was rated using a 10 point Visual analogue scale (0 = no pain, 10 = most severe pain) by physiotherapist. After recording the baseline ROM and VAS score, patients were wheeled in to the operating room. In the operating room after establishing the standard monitors (SpO2, ECG, NIBP) and intravenous cannula, the patients were randomized in to either one of the groups by selecting a closed envelope which contain a proforma numbered from 1 to 60. This number was passed on to an anaesthesia technician who will prepare 20 ml of 0.2 % unlabelled local anaesthetic solution containing either bupivacaine or ropivacaine according to the computerized randomization list. After randomization procedure was done and the drug spread was confirmed by the real-time ultrasound. Drug injection time was noted as a block time. Then every 2 minutes the sensory level was assessed by an ether-soaked gauze piece on C5 dermatome and motor blockade was assessed by loss of abduction at shoulder joint. Once the motor blockade was established patient was shifted to recovery room. At the end of one-hour effectiveness of the block was assessed by Bromage scale, 0 indicating no paralysis, 1 - able to flex the elbow and move the fingers but unable to raise the extended arms, 2 - unable to flex the elbow but able to move fingers, 3 - unable to move the arm, elbow and fingers. Then the patient is subjected to physiotherapy. During the manipulation the quality of analgesia was recorded on the VAS on each manipulation manoeuvre. After manipulation all patients were discharged home on a standard oral analgesic regimen which includes

paracetamol, NSAID at regular interval and a weak oral opioid such as Tab. Tramadol on demand basis. Patients were instructed to note the time when they were able to abduct the shoulder to record duration of motor blockade and perceive the shoulder pain to record the duration of analgesia from the block time. All data were recorded in the data collection proforma and entered in to the Master chart -MS Excel 2007. Statistical analysis was carried out using SPSS version 16. Parametric data was analysed with Unpaired 'T' test and the nonparametric data was analysed with Mann Whitney U test. 'P' value of < 0.05 was considered significant.

**RESULTS**

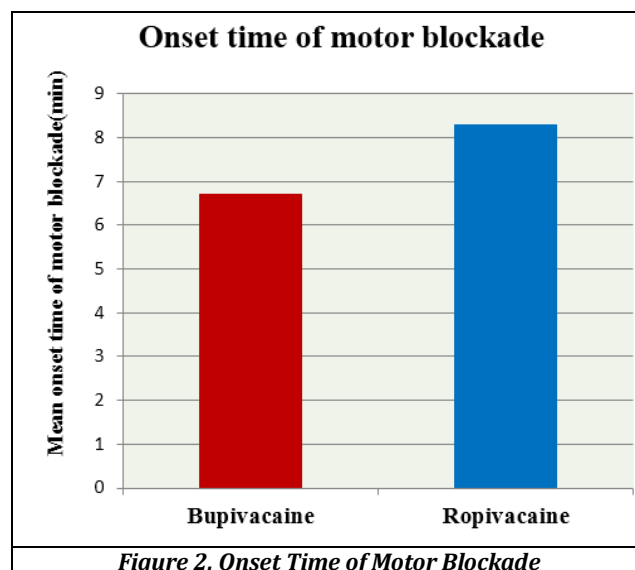
**(1) Onset Time for Sensory Blockade:**

The mean onset time of sensory blockade in group B was 2.2 ± 1.2 min and in group R was 3.2 ± 1.9 min. This finding was statistically significant (P value = 0.017) but not clinically significant. The results were depicted in figure 1.



**(2) Onset Time for Motor Blockade:**

The mean onset time for motor blockade in group B was 6.7 ± 3.4 min and in group R was 8.3 ± 3.7 min. When the two groups were compared, there was no significant difference in the time of onset of motor block (P value = 0.081). The results were depicted in figure 2.



**(3) Degree of Motor Blockade**

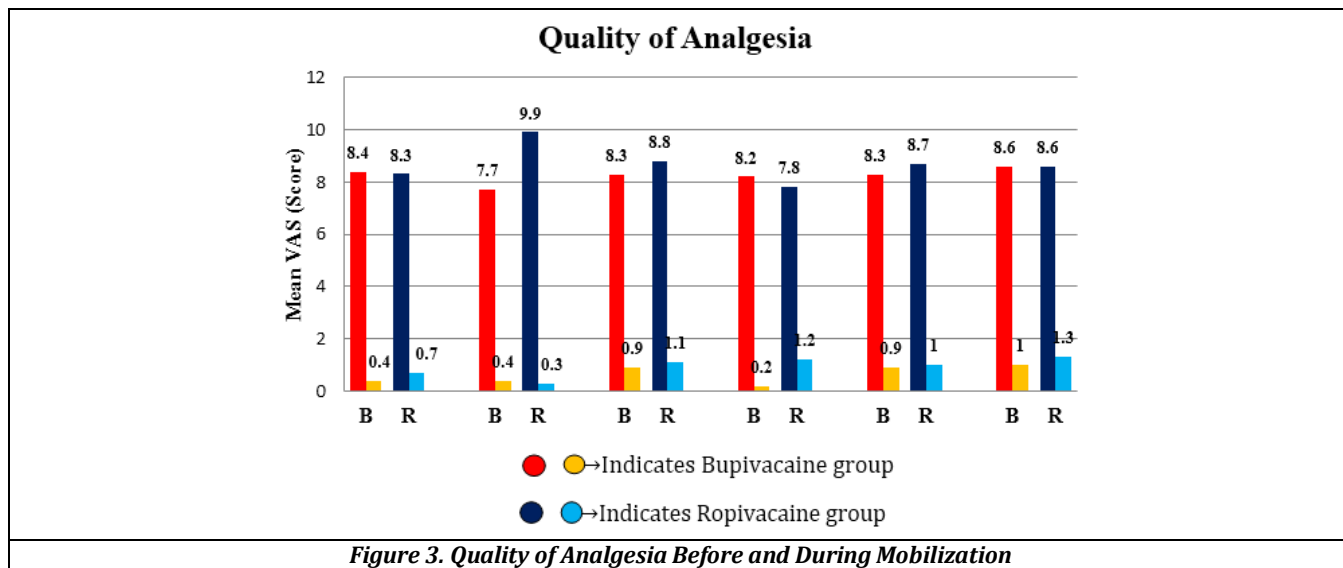
The median degree of motor blockade after one hour was comparable between the two groups and was not statistically significant. The results were shown in table 1.

Group	Bupivacaine (N=30)	Ropivacaine (N=30)	P-Value
Degree of Motor Blockade Median (Range)	2(2-3)	2(2-3)	0.200

**Table 1. Degree of Motor Blockade in Both Groups**

**(4) Quality of Analgesia**

An experienced physiotherapist who was not aware of the group allocation mobilized the shoulder joint and recorded quality of analgesia on a numerous rating scale during each mobilization manoeuvre. When the two groups were compared, there was no significant difference in the quality of analgesia. The results were represented in figure 3.

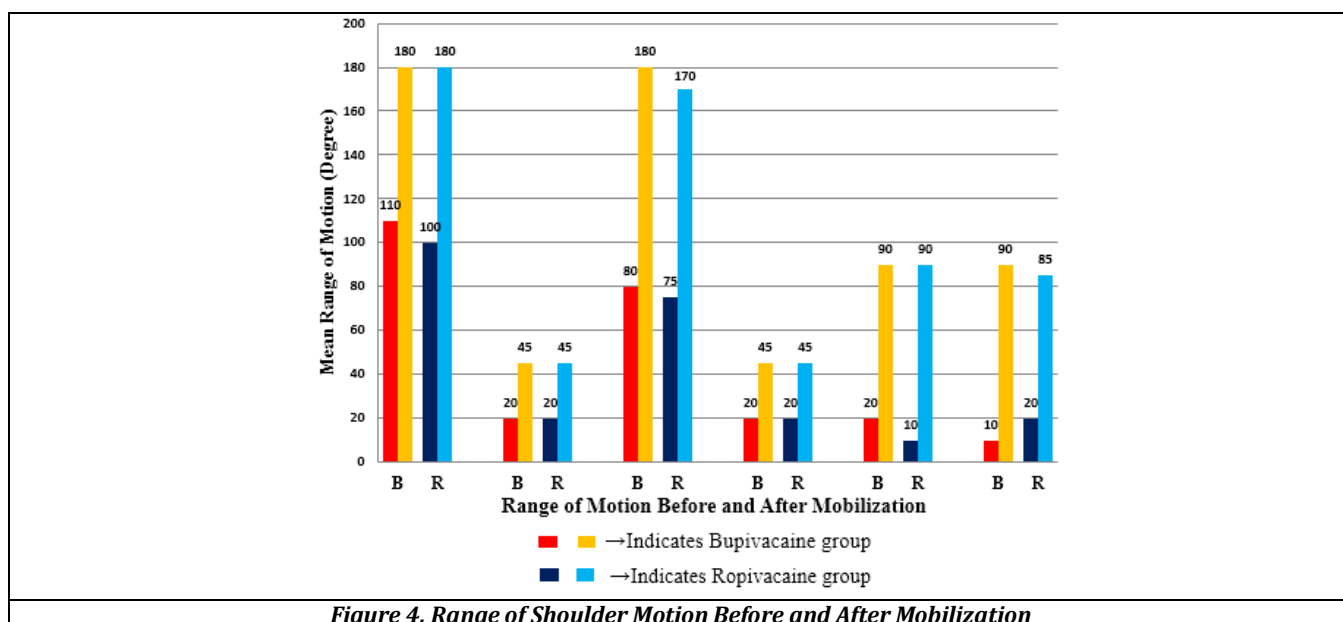


**Figure 3. Quality of Analgesia Before and During Mobilization**

- Respective taller bars indicate VAS score before mobilization.
- Respective smaller bars indicate VAS score during mobilization.

**(5) Range of Motion Before and After Mobilization**

An experienced physiotherapist has mobilized the shoulder joint after interscalene plexus block who was not aware of the group allocation has recorded the range of motion during each manipulation manoeuvre. There was significant improvement in the range of motion in both the groups after the end of mobilization, but it was not statistically different between the groups. The results were depicted in figure 4.

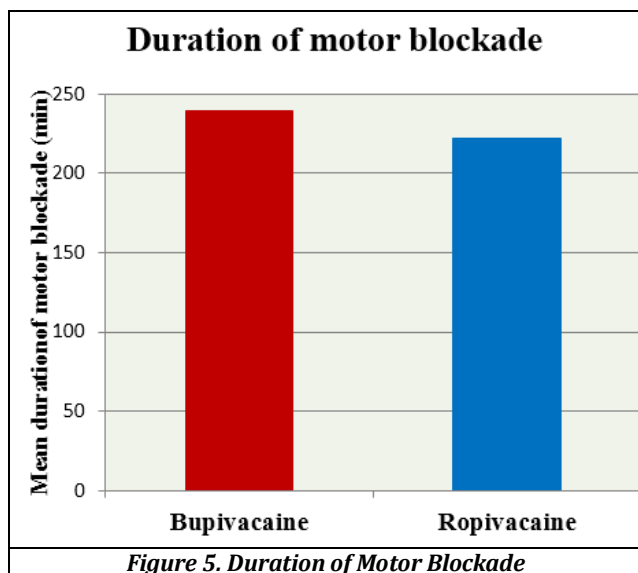


**Figure 4. Range of Shoulder Motion Before and After Mobilization**

- Respective smaller bars indicate ROM before mobilization.
- Respective taller bars indicate ROM after mobilization.

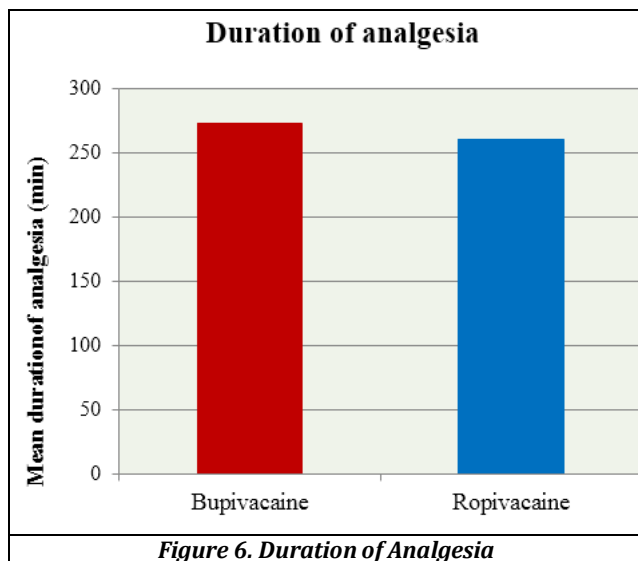
### (6) Duration of Motor Blockade

The mean duration of motor blockade in group B was  $239.4 \pm 89.8$  min and in group R was  $222.40 \pm 88.4$  min. When the two groups were compared, there was no significant difference in the duration of motor blockade (P value = 0.451). The results were depicted in figure 5.



### (7) Duration of Analgesia

The mean duration of analgesia in group B was  $273.00 \pm 89.5$  min and in group R was  $259.80 \pm 82.2$  min. When the two groups were compared, there was no significant difference in the duration of analgesia (P value = 0.554). The results were depicted in figure 6.



## DISCUSSION

In this randomized double blinded study, we recruited 60 patients who had frozen shoulder willing to undergo physiotherapy after Interscalene brachial plexus block and divided them randomly into two groups. Patients in group-R received 20 ml of 0.2% ropivacaine and patients in group-B received 20 ml of 0.2% bupivacaine for Interscalene brachial plexus block. We observed for sensory onset time, motor onset time, degree of motor blockade, duration of analgesia, quality of analgesia and duration of motor blockade. We

analysed the parametric data using unpaired-'t' test and non-parametric data using Mann-Whitney 'U' test.

Brachial plexus block for shoulder mobilization has been increasingly used because it provides ideal manipulation conditions like GA and prolonged analgesia after the procedure.<sup>(5,6,7)</sup> But in case of severe stiffness full range of motion cannot be attained in one sitting and patients needed more than one episode of mobilization and prolonged analgesia to facilitate active physiotherapy during recovery phase. The goal of frozen shoulder treatment can be achieved by providing effective analgesia for active and passive physiotherapy. Yilmazlar et al<sup>(6)</sup> mobilized three patients under Interscalene block and administered continuous catheter analgesia for 21 days to facilitate physiotherapy. All three patients were treated as in-patients. They concluded that continuous ISB provided sufficient analgesia and contributed to the recovery of shoulder function, but the ambulatory application of this technique has to be evaluated prospectively.

The analgesic efficacy of ropivacaine and bupivacaine had been extensively studied in the settings of labour analgesia.<sup>(10,11)</sup> Casati et al<sup>(12)</sup> studied the minimum local anaesthetic volume blocking the femoral nerve in 50% of cases with 0.5% Bupivacaine or 0.5% Ropivacaine and found that the volume needed for successful block was  $14 \pm 2$  ml in the Ropivacaine group and  $15 \pm 2$  ml in the Bupivacaine to produce equal effect. Similarly Hickey et al<sup>(13)</sup> compared the effectiveness of 0.25% ropivacaine and 0.25% bupivacaine in 44 patients receiving a subclavian perivascular brachial plexus block and found that the block characteristics were comparable between the two drugs.

The sensory motor differential blockade of Ropivacaine was very well demonstrated in spinal and epidural anaesthesia.<sup>(8,9)</sup> But the same results were not consistently reproduced in the peripheral nerve blocks.<sup>(13,14)</sup>

Introduction of ultrasound technology in regional anaesthesia enabled the clinician to deposit the local anaesthetic more close to the nerves which improved the efficacy of the block and decreased the complication rate.<sup>(15,16)</sup> Hence in our study we did all the ISB on ambulatory basis using 20 ml of 0.2% ropivacaine and 0.2% bupivacaine.

### Onset of Sensory Blockade

In our study the mean onset time of sensory blockade in group B was  $2.2 \pm 1.2$  min. And in group R was  $3.2 \pm 1.9$  min. This finding was statistically significant (p-value = 0.017) but not clinically significant. In the study conducted by McCrae et al the onset for pain relief after first dose of 0.5% bupivacaine was 12 min. and 18 min in 0.5% ropivacaine (P-value = < 0.05). When given for extradural analgesia during labour. In the study conducted by Wideside et al<sup>(17)</sup> the onset time for sensory block after 3 ml of intrathecal 0.5% ropivacaine was 5 min and for that of 3 ml of 0.5% bupivacaine was 2 min (p-value = 0.0046) they attributed the difference to baricity of the solutions used. Bupivacaine being more potent than ropivacaine at equal concentration provided earlier onset of sensory block. In the study conducted by Hickey et al the mean onset time for analgesia for ropivacaine 0.25% was  $19.2 \pm 22.2$  and for bupivacaine 0.25% was  $11.5 \pm 14.0$  at C5 dermatome when given for brachial plexus block. We

observed earlier onset of analgesia when compared to this study which could be because of USG guided block used in our study.

#### Onset of Motor Blockade

In our study mean onset time for motor blockade in group-B was  $6.7 \pm 3.4$  and in group-R was  $8.3 \pm 3.7$  min. when the two groups were compared, there was no significant difference in the time of onset of motor block ( $p$ -value = 0.08). In the study conducted by Hickey et al the onset time for motor blockade was  $12.2 \pm 8.3$  min in 0.25% ropivacaine group and  $14.8 \pm 13.4$  in 0.25% bupivacaine group when used in brachial plexus block. The difference was not statistically significantly ( $p$ -value >0.05).

#### Degree of Motor Blockade

In our study degree of motor blockade was 2-3 in both the groups with  $p$ -value of 0.200. In the study conducted by McCrae et al, to compare 0.5% bupivacaine and 0.5% ropivacaine for labour analgesia, the degree of motor blockade was assessed by Axelsson's quantitative method during isometric contraction. They found that 12 out of 20 patients in ropivacaine group and 11 out 20 patients in bupivacaine group come under degree 1 motor blockade. The difference was not statistically significant. One patient in each group was under grade 2 motor blockade and none of the patients in either group had severe motor blockade. They used a higher concentration of drug and a different assessment tool to assess the motor blockade. In our study we assessed the degree of motor blockade after one hour of drug injection.

#### Quality of Analgesia

In our study the mean baseline VAS scores ranged between 7.7 & 8.6 mm in bupivacaine group and ranged between 7.8 & 9.9 mm in ropivacaine group. After block the mean VAS score ranged between 0.2 and 1 mm in bupivacaine group, and ranged between 0.3 & 1.3 mm in ropivacaine group. There was significant decrease in VAS score in both the groups after block, but the difference between the groups was not statistically significant. In the study conducted by McCrae et al, quality of analgesia was evaluated using 100 mm VAS score before and after the epidural block. The mean VAS score before the drug dose were 84 mm in ropivacaine group and 69.5 mm in bupivacaine group and the mean VAS score 60 minutes after the block were 11.7 mm in ropivacaine group and 12.4 mm in bupivacaine group. This was comparable with the values achieved in our study.

#### Duration of Analgesia and Motor Blockade

In our study mean duration of analgesia in group-B  $273.00 \pm 89.5$  min and in group-R was  $259.8 \pm 82.2$  min. The mean duration of motor blockade on group-B was  $239.4 \pm 89.8$  min and group-R was  $222.4 \pm 88.4$  min. There was no significant difference between the two groups in duration of analgesia ( $p$ -value >0.05) and duration of motor blockade ( $p$ =0.451). In the study conducted by Hickey et al the duration of analgesia in shoulder was  $10.7 \pm 2.6$  hrs. in ropivacaine group and  $13.0 \pm 4.7$  hrs. in bupivacaine group. The duration of motor blockade was  $8.6 \pm 1.8$  hrs. in ropivacaine group and  $11.4 \pm 5.6$  in bupivacaine group ( $p$ -value >0.05). The prolonged duration of analgesia and motor blockade in their study could

be attributed to higher volume of drug used (40 ml) when compare to that in our study (20 ml).

#### CONCLUSION

Based on the results and the methodology employed, we have concluded that ropivacaine 0.2% provided effective analgesia for shoulder mobilization, but produced similar degree and duration of motor blockade when compared to bupivacaine 0.2% during the interscalene brachial plexus block for frozen shoulder mobilization.

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