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A RANDOMIZED CONTROLLED DOUBLE BLIND COMPARATIVE STUDY OF ROPIVACAINE ALONE AND ROPIVACAINE WITH DEXAMETHASONE ON DURATION OF INTERSCALENE NERVE BLOCKS

Anesthesiology

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ABSTRACT

Background : The purpose of our study was to evaluate the effect of the addition of Dexamethasone 8 mg to 0.5% Ropivacaine 30 ml on duration of Interscalene Brachial Plexus Block in shoulder and upper arm surgeries.

Methods: In 60 patients scheduled for shoulder and upper arm surgeries that underwent nerve block , Block was performed with 0.5 % Ropivacaine 30 ml under the guidance of nerve stimulator. Patients were randomly allocated to receive the same volume (30 ml) of 0.5 % Ropivacaine with 2 ml normal saline (group R) , Dexamethasone 8 mg (2 ml) (group RD) as an adjuvant. A blind observer recorded vitals, onset and maximum time taken for sensory and motor blockade , duration of sensory and motor blockade , duration of analgesia , requirement of rescue analgesia (inj Diclofenac IM) , any complication , quality of blockade, VAS score at 0, 15 min, 30 min, 60 min, 90 min, 120 min or till completion of surgery intraoperatively and at 1 hr, 2 hr,3 hr, 4 hr, 5 hr, 6 hr, 12 hr, 18 hr and 24 hr, 48 hr post operatively.

Results: All patients had successful interscalene brachial plexus block. There were significant difference in duration of sensory , motor blockade, analgesia and rescue analgesic requirement.

Conclusion: The addition of Dexamethasone 8 mg to 0.5 % Ropivacaine 30 ml in Interscalene Brachial Plexus Block prolongs the duration of post operative analgesia significantly with significant prolongation in motor and sensory blockade and decrese in post operative analgesic requirement. There was not statistically significant difference in vitals, onset of sensory and motor blockade.

KEYWORDS

Analgesia, Interscalene Brachial Plexus block, Dexamethasone, Ropivacaine, Peripheral nerve stimulator

INTRODUCTION

Pain in the surgeries of shoulder and upper arm can be intense and may be difficult to manage especially in post operative period. To improve analgesia intraoperative as well as postoperative period and to facilitate early mobilization , peripheral nerve blocks as regional anaesthesia are often used . Recent advancements of use of peripheral nerve blocks in the practice of anesthesia for surgery of shoulder and arm , has attracted anesthesiologists particularly due to its safety, simplicity and almost complication free peri-operative period. The use of an interscalene block as the primary anaesthetic modality increases the proportion of patients suitable for post-anaesthesia care unit (PACU) bypass and decreases immediate postoperative pain[1].

The principal indication for an interscalene block is surgery on the shoulder and upper end of humerus. Blockade occurs at the level of the upper and middle trunks. Although this approach can also be used for forearm and hand surgery, blockade of the inferior trunk (C8, T1) is often incomplete and requires supplementation at the ulnar nerve for adequate surgical anaesthesia in that distribution[2]. Recent reports provide evidence that a low interscalene block (below C6, just superior to clavicle) may provide sufficient anaesthesia and analgesia for procedures of the lower arm[2,3].

Why Dexamethasone would prolong regional anaesthesia is a subject of much discussion. Steroids induce a degree of vasoconstriction, so one theory is that the drug acts by reducing local anaesthetic absorption. A more attractive theory holds that Dexamethasone increases the activity of inhibitory potassium channels on nociceptive C-fibres (via glucocorticoid receptors), thus decreasing their activity[4,5].

Ropivacaine is a long-acting amide local anaesthetic agent that is structurally related to Bupivacaine. It is a pure S(-)enantiomer, unlike Bupivacaine, which is a racemate, developed for the purpose of reducing potential toxicity and improving relative sensory and motor block profiles[6]. Ropivacaine causes reversible inhibition of sodium ion influx, and thereby blocks impulse conduction in nerve fibres[6]. This action is potentiated by dose-dependent inhibition of potassium channels[7].

MATERIAL AND METHOD:

The study was undertaken in Swaroop Rani Nehru Hospital associated to Motilal Nehru Medical college, Prayagraj (formerely Allahabad) during the period of one year after obtaining ethical committee clearance and written and informed consent from all patients. Sixty patients posted for elective upper limb orthopaedic surgeries were included in the study. The study population was randomly divided into 2 groups with 30 patients in each group (n=30) using shuffled, closed, opaque envelope method.

Group R (n = 30)- Received of 0.5% Ropivacaine 30 ml + 2 ml of normal saline

Group RD (n = 30)- Received of 0.5% Ropivacaine 30 ml + 2ml of Dexamethasone (8mg)

Total volume made upto 32 ml, and the combination of Ropivacaine and Dexamethasone was physically compatible. Adult patients of either sex, age between 18 to 60 years belonging to ASA class I and II, scheduled for elective upper limb surgeries under Interscalene Brachial Plexus Block using nerve stimulator. Under exclusion criteria patients with known hypersensitivity to study drugs, Infection at the site of block,patients with known coagulopathy (abnormal BT, CT) or patient on anticoagulants therapy, Patients with severe systemic disorder (respiratory, cardiac, hepatic, renal diseases neurological, psychiatric, neurovascular disorders and contralateral diaphragmatic paralysis), Pregnant and lactating patients, Patients with morbid obesity, Patients with systemic use of corticosteroids for 2 weeks or longer within 6 months of surgery and chronic opioid use (>30mg oxycodone equivalent per day), Patients with injury to any of the nerves of the upper limb, Patients having distorted anatomy of neck, Patients with partial or failed block were excluded from study.

All patients included in the study were premedicated with tab-Alprazolam 0.5mg and Tab-Ranitidine 150mg orally at night before surgery.

Next day on arrival of patients in the operating room, an 18 gauge intravenous cannula was inserted under local anaesthetic application on the non operating hand and an infusion of Ringer lactate was started. The patients were connected to multiparameter monitor which records pulse rate (PR), non invasive blood pressure, electrocardiogram (ECG) and pulse haemoglobin oxygen saturation (SpO_2). The baseline

vitals were recorded.

One of the anaesthesiologist not involved in the care or monitoring of the patient prepared the local anaesthetic study solutions. The patients and the observing anaesthesiologist as well as physicians and nurses of the acute pain service were blinded to the study drug used.

All patients were premedicated with i.v. 1mg midazolam and 4mg ondansetron half an hour before surgery. The patients were placed in the supine position with the head turned away from the side to be blocked. Interscalene brachial plexus block was performed as described by Winnie[8,9] using 22G 50mm insulated blunt needle [Stimuplex (B Braun) needles with extension tubing] and INMED nerve stimulator. The intensity of stimulating current was initially set to deliver 2mA with impulse duration of 0.1ms. The current was gradually decreased to <0.5 mA to get the muscle contraction and this was considered as evidence of proper needle position. The study drug was injected in 3ml increments, after a negative aspiration test, with repeat aspirations every 3ml. Following injection, area was massaged so as to help the solution to track along the plexus. Those patients posted for clavicular surgeries were supplemented with superficial cervical plexus block using 2% lidocaine with adrenaline 10cc along with classical interscalene brachial plexus block. During the time of injection the patients were observed for toxicity of the drugs and any other immediate complication of the block.

After the block was given, patients were evaluated every 1 minute for the assessment of, onset of sensory and motor blockade, quality of motor blockade, overall quality of the block, duration of sensory and motor blockade and hemodynamic variables. Assessments were carried out every 1 minute till the complete achievement of motor and sensory block.

During the surgery haemodynamic variables like Heart rate, mean arterial blood pressure, pulse oxygen saturation were monitored and recorded at 15 min, 30 min, 60 min, 90 min, 120 min or til the completion of surgery and after surgery at 1 hr, 2 hr, 3 hr, 4hr, 5 hr, 6 hr, 12 hr, 18 hr, 24 hr, 48 hr. Patients were monitored for any signs of cardiovascular or central nervous system toxicity (changes in HR/BP/rhythm/ signs of CNS stimulation) throughout the study. Any hypersensitivity reaction for the drugs, evidence of pneumothorax, and other adverse events were also monitored. To evaluate the duration of analgesia and the duration of motor blockade, patients were asked to document the time when incisional discomfort began and when the time full power returned to the shoulder respectively. In the post operative period, the pain is assessed using Visual Analog Scale (VAS) scores and at VAS Score > 3 , the rescue analgesic, inj Diclofenac 75mg IM was given and study was concluded. Patients were followed up for 48 hrs.

Definitions of study parameters:

- **Onset of sensory blockade:** is defined as the time from the completion of the injection of the study drug to the maximum sensory blockade attained (complete loss of sensation in all the dermatomes C_5-T_1).
- **Onset of motor blockade:** is defined as time from the completion of injection of study drug to to the maximum (complete) motor blockade attained in all the dermatomes C_5-T_1(LOVETT RATING SCALE-1 or 0).

Assessment of motor blockade

LOVETT RATING SCALE
6 - Normal muscular force
5 - Slightly reduced muscular force
4 - Pronounced reduction of muscular force
3 - Slightly impaired mobility
2 - Pronounced mobility impairment
1 - Almost complete paralysis
0 - Complete paralysis

For statistical purpose 0, 1 and 2 were considered as paralysis. 3, 4 and 5 were considered as paresis and 6 as no motor blockade.

- **Duration of sensory blockade:** Duration of sensory blockade is the time from the onset of sensory blockade to complete recovery of sensation in all the dermatomes.
- **Duration of analgesia:** is defined as the time from injection of study drug till the patient complains of pain (VAS score >3) at the site of surgery and receives the rescue analgesic.
- **Duration of motor blockade:** Duration of motor blockade is the time from the onset of motor blockade to complete recovery of motor power (LOVETT RATING SCALE-6).
- **Quality of overall block:** an overall assessment of quality of block will be made as a three point scale as follows

0- complete failure
1- unsatisfactory block(inadequate analgesia, inadequate relaxation, patients requiring general anaesthesia because of restless)
2- satisfactory block(complete sensory and motor blockade)

RESULTS

There were no statistically significant differences in the demographic profile of patients in either group in terms of age, body weights, or male/female (M/F) ratio (p > 0.05). The average age was 40.433 years in R group and 41.366 years in RD group. Youngest patient in our study was 23 years old and the oldest was 57 years old. The average body weights were 62.466 kgs in R group and 62.133 kgs in RD group. Both groups predominantly had male patients. Average height was 161.966 cm in Group R and 163.4 cm in Group RD.

Table 1: Onset Sensory Blockade in minutes (Mean ± SD)

Sensory Blockade	0.5% Ropivacaine (R group)	0.5% Ropivacaine + Dexamethasone(RD group)	P-value
Onset of Sensory Blockade (min)	11.133±1.306	10.466±1.502	0.0714

There was no significant difference between the two groups in terms of onset of sensory blockade (P value > 0.05). Onset of Sensory Blockade in Ropivacaine group was 11.133±1.306 min whereas in Ropivacaine+ dexamethasone group was 10.466± 1.502 min, which was not statistically significant.

Figure1: Onset of sensory blockade

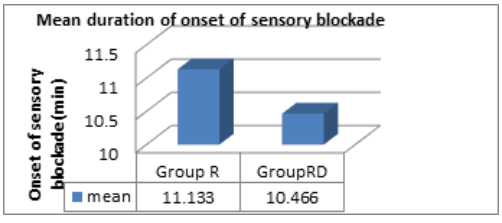

Table 2: Onset of Motor Block (min) (Mean ± SD)

Motor Blockade	0.5% Ropivacaine (R group)	0.5% Ropivacaine + Dexamethasone (RD group)	P-value
Onset of motor bockde(min)	15.433±3.036	14.833 ±2.547	0.4101

Onset of motor block was achieved in 15.433±3.036 min in R group and 14.833 ±2.547 min in RD group. There was no statistical significant difference between the two groups (p>0.05).

Figure 2: Onset of motor blockade

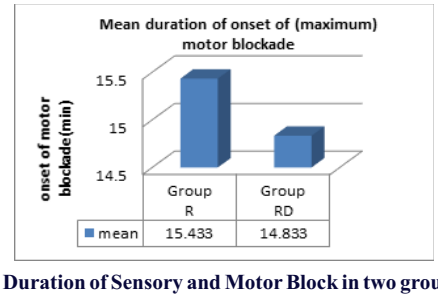

Table 3: Duration of Sensory and Motor Block in two groups (min) (Mean ± SD)

	Group R	Group RD	P-value
Duration of motor block (min)	558.833±57.844	735.833±58.133	0.0001
Duration of sensory block (min)	587.5±58.202	755.166±62.193	0.0001
Duration of analgesia (min)	638.333±60.973	813.166±64.667	0.0001

Duration of sensory blockade was 587.5±58.202 min in R group and 755.166± 62.193 min in RD group (P value = 0.0001) and duration of motor blockade was 558.833± 57.844 min in R group and 735.833± 58.133 min in RD group which were statistically highly significant (P value = 0.0001).

Duration of Analgesia was 638.333±60.973 min in R group and 813.166±64.667 min in RD group which was statistically highly significant(P value = 0.0001).

Figure 3: Comparison of duration of sensory and motor block and duration of analgesia in two groups

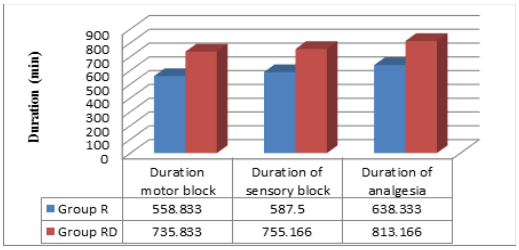

Table 4: Quality of motor block

	Group R	Group RD	P-value
Quality of motor block (Lovett scale)	0.666±0.711	0.666±0.660	1.000
Overall quality of block	satisfactory	satisfactory	

There were no statistical significant difference between the two groups regarding the number of patients developing complete paralysis of all the muscle groups of the upper limb. Patients with failed blocks were excluded from the study. There were no statistical difference in Haemodynamic parameters like pulse rate, mean arterial blood pressure and haemoglobin saturation (P>0.05).

Table 5: Requirement of Rescue analgesia

	Group R	Group RD	P-value
Requirement of rescue analgesia (inj. Diclofenac IM) mg	587.5±100.590	392.5±107.308	0.0001

DISCUSSION

Demographic data comparing age, sex, weight, height and duration of surgery shows no statistically significant differences (p > 0.05) between both the groups.

Changes in mean heart rate, mean arterial pressure, oxygen saturation were not statistically significant (p>0.005).

Onset time of sensory blockade:

In Ropivacaine group, onset of sensory Blockade was 11.133±1.306 min whereas in Ropivacaine+dexamethasone group, onset of sensory Blockade was 10.466±1.502 min, which was not statistically significant (P value = 0.0714). Similar observations were found in the studies conducted by Ganvit K S et al.,[12] and Kumar S et al.,[13] where there was no statistically significant difference between the onset of sensory blockade among Ropivacaine group and Ropivacaine+ Dexamethasone group which compares with our study.

Our study does not concur with the study conducted by Dar F A et al [10] who have found a significant difference between the two groups regarding the onset of sensory block.

Onset of Motor Blockade:

Onset of motor Blockade in Ropivacaine group was 15.433±3.036 min whereas in Ropivacaine+dexamethasone group, it was 14.833±2.547 min, which was not statistically significant (P value = 0.4101). Similar observations were found in the studies conducted by Ganvit K S et al[12] and Kumar S et al [13]., where there was no statistically significant difference between the onset of Motor blockade among Ropivacaine group and Ropivacaine+Dexamethasone group which concurs with our study. Similar study conducted by Dar F A et al [10] who have found a significant difference between the two groups regarding the onset of Motor block. Onset of Motor block has been defined by Modified Bromage scale. They have not separately studied the time taken for onset and maximum sensory blockade. In our study we have used Lovett Rating scale . Hence probably the difference and does not concurs with the study.

Duration of Motor and sensory blockade:

In our study, the duration of Motor blockade was 558.833±57.844 minutes in Ropivacaine group and 735.833±58.133 minutes in Ropivacaine+Dexamethasone group which was statistically highly significant (P value = 0.0001). The duration of Sensory blockade was 587.5±58.202 minutes in Ropivacaine group and 755.166±62.193 minutes in Ropivacaine+Dexamethasone group which was statistically highly significant (P value = 0.0001). The studies conducted by Ganvit K S et al [12] , Dar F A et al [10] and Kumar S et al [13] there were statistically highly significant difference in the duration of Motor and Sensory blockade between Ropivacaine and Ropivacaine+Dexamethasone group for brachial plexus block.

Hence our study concurs with the studies of Ganvit K S et al [12]., Dar F A et al [10] and Santosh et al [13] with respect to duration of motor and sensory blockade.

Duration of Analgesia:

In our study, the duration of analgesia was 638.333±60.973 minutes in Ropivacaine group and 813.166±64.667 minutes in Ropivacaine+ Dexamethasone group which was statistically highly significant (P value = 0.0001). The studies conducted by, Kawanishi R et al [11]., Ganvit K S et al [12] ., Dar F A et al [10] and Cummings KC et al [14] there was statistically highly significant difference in the duration of analgesia between Ropivacaine and Ropivacaine+ Dexamethasone group for brachial plexus block.

Hence our study concurs with the studies of Kawanishi R et al [11], Ganvit K S et al [12], Dar F A et al [10] ., Cumming K C et al [14], with respect to duration of analgesia.

Requirement of rescue analgesia:

Requirement of rescue analgesia (Inj. Diclofenac IM) in Ropivacaine group was 587.5±100.59 mg and in Ropivacaine + Dexamethasone group it was 392.5±107.30 mg which was statistically significant(P value = 0.0001).

Overall quality of block:

There was no statistically significant difference between two groups in terms of overall quality of blockade.

Hemodynamic parameters:

Hemodynamic parameters like heart rate , mean BP, and oxygen saturation were within normal limits during preoperative , intraoperative and postoperative period in both groups and were statistically insignificant (P value > 0.05).

Adverse events

The incidence of hematoma, pneumothorax, accidental intravascular injection, and Post block nausea, vomiting, convulsions, neuralgia were nil in either group. No patient required any intervention.

Limitation of the study: In our study we did not use ultrasound guide for the interscalene block. Ultrasound guided block would be more precise and requires small volumes of local anaesthetics.

CONCLUSION

Our study has shown that adding Dexamethasone 8 mg to 0.5% Ropivacaine 30 ml for Classical interscalene brachial plexus block prolongs the duration of sensory block, motor block and duration of analgesia. However we did not find any significant difference in the time taken for onset and time taken for maximum sensory and motor blockade by adding Dexamethasone to Ropivacaine. Dexamethasone did not improve the quality of motor blockade and overall quality of block with Ropivacaine.

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