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ORIGINAL ARTICLE

COMPATATIVE CLINICAL STUDY OF 0.5% ROPIVACAINE VERSUS 0.5% ROPIVACAINE WITH DEXAMETHASONE FOR INTERSCELENE BRACHIAL PLEXUS BLOCK IN PATIENTS UNDERGOING ELECTIVE UPEER LIMB ORTHOPEDIC SURGERIES: A RANDOMIZED CONTROLLED STUDY

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ABSTRACT: Regional anaesthesia in the form of interscalene brachial plexus block is often used for upper limb orthopedic surgeries. Bupivacaine is commonly used drug for brachial plexus block. Its cardiac and central nervous system toxic effects prompted the researchers to develop new drugs. Ropivacaine, a local anesthetic with similar and better safety profile, is newly introduced into the clinical practice. In an attempt to increase the duration of post-operative analgesia various adjuvant drugs are used along with local anesthetic agents with limited success. However, the glucocorticoid, Dexamethasone appears to be effective in prolonging the duration of analgesia using ropivacaine with the effect being stronger than ropivacaine alone. Hence the present study is undertaken to study the effect of adding Dexamethasone to Ropivacaine. **METHODS:** Sixty patients aged between 18-60 yrs. belonging to ASA 1/11 undergoing upper limb orthopedic surgeries under interscalene brachial plexus block using nerve stimulator, were randomly allocated to one of two groups. Group R received 28ml of 0.5% Ropivacaine plus 2ml of normal saline and Group RD received 28ml of 0.5% Ropivacaine plus 2ml of 8mg Dexamethasone. The onset and duration of sensory and motor blockade, quality of block, hemodynamic changes and side effects if any, were compared in both the groups. The results were analyzed for statistical significance (P) using student t test and ANOVA. **RESULTS:** There were no statistically significant differences with respect to onset of sensory and motor blockade and quality of motor block ($P<0.05$). The duration of sensory and motor blockade and duration of analgesia was statistically highly significant in both the groups. The duration of sensory blockade was 587.51±75.07 min. in R group and 755.14±89.15 min in RD group (P=0.00). The duration of motor blockade was 558.81±62.60 min in R group and 735.89±67.50 min in RD group (P=0.00). The duration of analgesia was 638.37±61.81 min in R group and 813.07±67.50 min in RD group (P=0.00). No adverse events/hemodynamic instability noted in either group. **CONCLUSION:** Addition of 8 mg of Dexamethasone to 0.5% Ropivacaine prolongs the duration of sensory, motor and duration of analgesia when compared with 0.5% Ropivacaine alone, for classical interscalene brachial plexus block in patient undergoing elective upper limb orthopedic surgeries.

KEYWORDS: Ropivacaine; Dexamethasone; Interscalene brachial plexus block.

INTRODUCTION: Regional anaesthesia in the form of interscalene approach to the brachial plexus is often used for orthopedic surgeries of the upper limb. It is often used either as an adjuvant to general anaesthesia or as the primary method of anaesthesia. With the introduction of newer and safer local anesthetics with better advantages, regional anaesthesia has taken over as the principle technique for upper limb surgeries. The use of interscalene block as the primary anesthetic technique avoids the complications associated with general anaesthsia.[1]

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There are many advantages.[2] of brachial plexus block for upper limb surgeries over general anesthesia, namely:

- Effective analgesia with good motor block.
- Awake patient.
- Extended post-operative analgesia.
- Early ambulation.
- Early resumption of oral feeding.
- Minimal number of drugs used so that polypharmacy is avoided.
- No airway manipulation.
- Less incidence of post-operative nausea and vomiting.
- Ideal operative conditions can be met.
- PACU and ward nurses particularly appreciate the use of regional anesthesia.

Various approaches.[2,3] of brachial plexus block have been used for upper limb surgeries, namely Interscalene approach, Supraclavicular approach, Infraclavicular approach and Axillary approach. The principal indication for an interscalene block is surgery on the shoulder or manipulation of the shoulder. 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 through T1) is often incomplete and requires supplementation at the ulnar nerve for adequate surgical anesthesia in that distribution.[4] Recent reports provide evidence that a low interscalene block (Below C6, just superior to clavicle) may provide sufficient anesthesia and analgesia for procedure of the lower arm.[5,6]

Long acting local anesthetic agent, Bupivacaine, is frequently used for brachial plexus anesthesia. Its cardiac and central nervous system toxic effects in some patients prompted the researchers to develop new local anesthetic agent with a profile similar to Bupivacaine without considerable side effects. One such possible replacement is Ropivacaine.[7] It is an amino-amide local anesthetic with higher toxic threshold produced less cardiac and central nervous system effects, less motor block and a similar duration of action of sensory analgesia compared to Bupivacaine. This favorable clinical profile has prompted many clinicians to switch from Bupivacaine to Ropivacaine for all types of neural blockade. However, with clinical use, it was discovered that Ropivacaine's latency of sensory analgesia was approximately two that of Bupivacaine, therefore it was not as effective in promoting prolonged post-operative analgesia.[7]

In an attempt to increase the duration of post-operative analgesia, various adjuvant drugs are used along with local anesthetic agents. Adjuvants include Epinephrine, Clonidine, Opioids, Ketamine and Midazolam. But all have met with limited success.[8] However, the glucocorticoid, Dexamethasone appears to be effective in prolonging the duration of analgesia from interscalene block using Ropivacaine, with the effect being stronger than Ropivacaine alone.

METHODOLOGY: The study was undertaken in K.R.Hospital attached to Mysore Medical College & Research Institute, Mysore after obtaining ethical committee clearance and informed consent form all patients.

Sixty patients posted for elective upper limb orthopedic 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.

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Group R (n=30) Received 28ml of 0.5% Ropicaine+2ml of normal saline.
Group RD (n=30) Received 28ml of 0.5% Ropicaine+2ml of Dexamethasone (8mg).

Total volume made up to 30ml, and the combination of Ropivacaine and Dexamethasone was physically compatible.

Inclusion Criteria: Adult patients of either sex, aged between 18 to 60 years belonging to ASA Class 1 and 11, without any co-morbid diseases, scheduled for elective upper limb orthopedic surgeries under classical interscalene brachial plexus block using nerve stimulator.

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 diseases and contralateral diaphragmatic paralysis).
- Pregnant and lactating patient.
- 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 the neck.

Pre-anesthetic evaluation was done on the evening before surgery. A routine examination was conducted assessing, the general condition of the patient, airway assessment by Mallampatti grading and rule of 1-2-3, nutritional status and weight of the patient. All the patients were premedicated with tab. Alprazolam 0.5mg and tab. Ranitidine 150mg orally at night before surgery and they were kept nil orally 6 to 8 hours before the surgery.

On arrival in the operating room, an 18 gauge intravenous cannula was inserted under local anaestheisa on the non-operating hand and an infusion of Ringer lactate was started. The patients were connected to multiparameter monitor (Star plus, Larson and uoubro) which records pulse rate, noninvasive blood pressure (NIBP), continuous electrocardiogram (ECG) monitoring and oxygen hemoglobin saturation (SPO2). The baseline values were recorded.

FOR THE BLOCK (PROCEDURE):

Equipments:

1. A portable tray containing sterile syringes of 10ml, 5ml, 2ml. Hypodermic needles of 22G and 24G: Bowl containing povidone iodine and spirit. Sponge holding forceps, towel clips and Study drugs.
2. B Braun nerve stimulator.
3. Insulated nerve stimulator needle of 5 cm length with extension tubing.
4. For emergency resuscitation necessary equipments, back up ventilation and drugs were kept ready.

One of the anesthesiologist not involved in the study prepared the local anesthetic solutions. The patient and observing anesthesiologist as well as physicians and nurses of the acute pain service were blinded to the study drugs.

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All the patients were premedicated with intravenous midazolam 1mg and 4mg ondansetron half an hour before the procedure.

The patients were placed in supine position with the head turned away from the side to be blocked. The interscalene groove was identified as described by Winnie. The posterior border of the sternocleidomastoid muscle identified and the interscalene groove was palpated by rolling the fingers posterolaterally from this border over the belly of the anterior scalene muscle. A line extending laterally from the cricoid cartilage intersecting the interscalene groove indicates the level of the transverse process of C6. Although the external jugular vein often overlies this point of intersection, it is not a constant or reliable landmark. The needle entry point will be, between the index and middle finger palpating the interscalene groove.

Under aseptic precautions, skin wheal raised with lidocaine 2% at the site of block. Classical interscalene brachial plexus block was performed as described by Winnie using 22G 50 mm insulated blunt needle (Stimuplex B. Braun needles) and B. Braun nerve stimulator. The positive electrode of the nerve stimulator was connected to the ECG electrode placed on the chest of the patient. The negative electrode is connected to the needle. The intensity of the stimulating current was initially set to deliver 1mA with impulse duration of 0.1ms. The needle was introduced perpendicular to the skin through the wheal. The needle is directed medially and caudally in the direction of the C6 transverse process.

A motor response to the stimulation was observed by identifying the deltoid muscle contraction. Then the current was gradually decreased to <0.5mA to get the muscle contraction and this was considered as evidence of proper needle position. The study drug was injected in 5ml increments, after a negative aspiration for blood. Following the injection, the 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.

After the block, the patients were evaluated every 1 minute for the assessment of, onset of sensory and motor block, quality of motor blockade, 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. After 30 minutes if the block was considered to be adequate, surgeons were allowed to start the surgery, if the block was considered to be inadequate, the patients were given general anaesthesia with endotracheal intubation.

During the surgery hemodynamic variables like pulse rate (PR), Systolic, diastolic and mean arterial blood pressure (SBP, DBP & MAP), oxygen saturation (SPO2) and ECG were monitored every 2^{nd}, 5^{th} and 20^{th} minutes till the completion of the surgery and every 60 minutes until complete recovery. 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. To evaluate the duration of analgesia and the duration of motor blockade, the 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 the Visual Analog Scale (VAS) scores and at VAS score of 5, the rescue analgesic, inj. Diclofenac sodium 75mg was given and the study was concluded. The patients were followed up for 24 hrs. For any side effects.

Adverse effects: Signs of cardiovascular system toxicity like changes in HR, BP rhythm and signs of central nervous system stimulation. Also looked for evidence of pneumothorax, nausea and vomiting, pruritus, jerking movements and Horner's syndrome.

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Complete failure and unsatisfactory blocks were considered as failures, converted to GA and were excluded from the study.

STATISTICAL ANALYSIS: The pilot study done revealed the required sample to be 30 in each group for avoiding skewness in time to first rescue analgesic, and the level of significance. Descriptive statistics, mean and standard deviation, were calculated. Independent samples t test compares means for two groups of cases. Repeated measures of ANOVA analyze groups of related dependent variables that represent different measurements of the same attribute.

All the statistical calculations were done through SPSS for windows (v 16.0)

$p>0.05$ is considered as statistically not significant.

$P<0.05$ is considered as statistically significant.

$P<0.01$ is considered as statistically highly significant.

RESULTS:

Sensory blockade	0.5% Ropivacaine (R group)	0.5% Ropivacaine+Dexamethasone (RD group)	P-value
Onset of Sensory block (Min)	3.59±1.24	3.46±0.99	0.675
Maximum Sensory blockade (Min)	11.29±1.95	10.57±1.50	0.128

Table 1: Onset and Maximum Sensory blockade in minutes Mean±SD)

Onset of Motor Blockade	0.5%Ropivacaine (R group)	0.5% Ropivacaine+Dexamethasone (RD group)	P-value
Paresis (Min)	5.62±1.41	5.46±1.10	0.631
Paralysis (Min)	15.48±2.47	14.82±2.47	0.317

Table 2: Motor block onset in minutes (Mean±SD)

Total duration of Sensory & Motor Blockade	0.5% Ropivacaine (R group)	0.5% Ropivacaine+Dexamethasone (RD group)	P-value
Sensory block (Min)	587.51±75.07	755.14±89.15	0.000
Motor block (Min)	558.81±62.60	735.89±67.50	0.000

Table 3: Duration of Sensory & Motor block in two groups in minutes (Mean±SD)

Duration of Analgesia	0.5% Ropivacaine (R group)	0.5% Ropivacaine+Dexamethasone (RD group)	P-value
(In minutes)	638.37±61.81	813.07±67.50	0.000

Table 4: Duration of Analgesia in two groups in minutes (Mean±SD)

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Quality of motor blockade	0.5% Ropivacaine (R group) Number	Percentage	0.5% Ropivacaine+Dexamethasone RD group) Number	Percentage
Paralysis (n)	27	90%	28	93.3%
Paresis (n)	3	10%	2	6.7%
No weakness	0	0	0	0

Table 5: Quality of motor blockade

Overall Quality of motor blockade	0.5% Ropivacaine (R group) Number	Percentage	0.5% Ropivacaine+Dexamethasone (RD group) Number	Percentage
Satisfactory block (n)	27	90%	28	93.3%
Unsatisfactory block (n)	3	10%	2	6.7%
Complete failure (n)	0	0	0	0

Table 6: Overall quality of block

P= 0.640. Not significant.

Hemodynamic parameters	0.5% Ropivacaine (R group)	0.5% Ropivacaine+Dexamethasone (RD group)	P-VALUE
Basal PR (per min)	78.6±5.78	78.6±5.28	0.711
Basal MAP(mm. Hg)	79.73±6.16	79.13±6.31	0.818
Basal SpO2 (%)	99.00±0.83	99.06±0.90	1.000
Post block Mean PR (per min)	78-80±6.16	78.73±6.22	0.941
Post block Mean MAP (mm Hg)	79.06±6.05	79.26±5.95	0.890
Post block Mean SpO2 (%)	99.03±0.92	99.03±0.86	0.822

Table 7: Comparison of Hemodynamic variables

P >0.05: No statistical difference

There were no statistically significant in demographic data, duration of surgery and duration of anesthesia within the groups. There were no statistically significant difference between the groups

with respect to the onset of sensory and motor block, quality of motor blockade and there were no adverse events/hemodynamic instability noted in either group. However, the duration of sensory, motor blockade and duration of analgesia was comparable and was statistically highly significant in both the groups.

DISCUSSION: After going through the relevant literature regarding the use of Dexamethasone as an adjuvant to local anesthetics, it was hypothesized that addition of dexamethasone to Ropivacaine for interscalene brachial plexus block, will be effective in prolonging the duration of analgesia.

Bupivacaine and Ropivacaine are being regularly used for brachial plexus block for upper limb orthopedic surgeries. Ropivacaine has a higher toxic threshold, produces less cardiac and central nervous system effects compared to Bupivacaine and hence selected for our study.

In an attempt to increase the duration of post-operative analgesia, various adjuvant drugs are used along with local anesthetic agents. Adjuvants include Epinephrine, Clonidine, Opioids, Ketamine and Midazolam.[8] But all have met with limited success and also there is an increase in the incidence of side effects. Dexamethasone, as an adjuvant appears to be effective in prolonging the duration of analgesia of interscalene brachial plexus block, with the effect being stronger with Ropivacaine.

There were two theories regarding as to how Dexamethasone prolongs the duration of local anesthetic induced analgesia. One theory is that steroids induce a degree of vasoconstriction, and hence act by reducing local anesthetic absorption. A second and more attractive theory holds that dexamethasone may act locally on nociceptive C-fibers (Via glucocorticoid receptors) to increase the activity of inhibitory potassium channels, thus decreasing their activity.

Despite the concern surrounding the 'off-label' use of perineural Adjuvants.[9] the safety profile of dexamethasone is promising. No trial has reported neurotoxicity attributable to dexamethasone.

Additionally, corticosteroids have a long history of safe use in the epidural space for the treatment of radicular pain arising from nerve root irritation [10] and dexamethasone specifically has been studied as an adjuvant to epidural local anesthetics.[11] the neurological risk if any, of dexamethasone thus appears to be small. In fact, the use of dexamethasone as an adjuvant to local anesthetics for nerve blocks is discussed in prominent textbooks. [12, 13] Systemic toxicity from a single dose of dexamethasone is also unlikely. It is effective.[14] and widely administered intravenously by anesthesiologists for prophylaxis against post-operative nausea and vomiting. Concerns about steroid induced hyperglycemia have been borne out in high-dose i.v. regimens. But have not been problematic in patients. Hence in our study Dexamethasone was selected as an adjuvant to Ropivacaine for studying the effectiveness in prolongation of the duration of analgesia.

CONCLUSION: Our study has shown that adding Dexamethasone 8mg (2ml) to 0.5% Ropivacaine 28ml for Classical Interscalene Brachial Plexus block prolongs the duration of sensory block, motor block and duration of analgesia. However, we did not find any 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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