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A DOUBLE-BLINDED RANDOMIZED CONTROLLED STUDY IN PATIENTS UNDERGOING FOREARM AND HAND SURGERIES TO STUDY THE EFFECT OF LOW DOSE DEXAMETHASONE AS AN ADJUVANT TO ROPIVACAINE IN AXILLARY BRACHIAL PLEXUS BLOCK"

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ABSTRACT: Introduction: Ultrasound-guided axillary brachial plexus block is commonly used for forearm and hand surgery. Perineural dexamethasone 8mg has proved to prolong the duration of analgesia, but studies with low doses of dexamethasone are scarce. Hence this study was designed to determine the duration of analgesia with 2 mg dexamethasone used perineurally with ropivacaine. **Methods:** Fifty-Eight patients scheduled for forearm and hand surgeries were included in our study and randomly allocated into two groups. Group R- Axillary Brachial Plexus Block given with 0.75% Ropivacaine 18 ml and 2ml NS and Group RD- Axillary Brachial Plexus Block given with 0.75% Ropivacaine 18 ml and 2 mg Dexamethasone making a total volume of 20ml. **Results:** Four patients were excluded because of block failure. The time of first rescue analgesia in Group RD was 515.74±11.07 minutes and in Group R was 452.78±14.76 minutes and was statistically significant. Onset of sensory block and motor block in Group RD was earlier than in Group R and duration of sensory and motor block was also longer in Group RD. In Group RD, the VAS score at 8th hour was higher in Group R with 4.63 ±0.49 Vs 2.19±0.48. VAS score at 10th hour was higher in Group RD with 5 ±0.62 Vs 1.22±0.97 in Group R. There was a significant difference in the doses of rescue analgesia between both the groups with p value<0.001 with Group R requiring higher doses of rescue analgesia in 24 hours. **Conclusion:** A combination of 0.75% Ropivacaine with low dose dexamethasone can be used safely as an adjunct to local anaesthetic in patients with higher safety profile and also provides marginal prolongation of postoperative analgesia.

INTRODUCTION: With the advent of ultrasound in recent years, ultrasound-guided axillary Brachial Plexus Block is commonly used for lower forearm and hand surgeries [1].

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But the limited duration of action of local anaesthetics can cause significant pain in the postoperative period, leading to increased consumption of opioids and prolonged hospital stay [2].

Bupivacaine is a commonly used drug for brachial plexus block. However, it has a slower onset of action is also cardiotoxic; hence should be used cautiously. Ropivacaine [3] S(−) enantiomer, unlike bupivacaine, is a racemic mixture, developed to reduce potential toxicity and improve relative

sensory and motor block profiles. It is structurally similar to bupivacaine with a similar duration of action. It is less cardiotoxic and neurotoxic than bupivacaine. Hence, lately, ropivacaine has become the preferred choice for brachial plexus block. Ropivacaine and bupivacaine provide surgical analgesia for 4 to 6 hours. There is no ultra-long-acting local anaesthetic or slow-release formulations available till date. So, there are studies where various additives [4] are used to prolong the duration of anaesthesia and also postoperative analgesia. These include fentanyl, tramadol, clonidine *etc*. Steroids, owing to their anti-inflammatory and analgesic effect are also used. Most recent studies indicate that dexamethasone used as an adjuvant to local anaesthetics augments the duration of postoperative analgesia.

Kirkham *et al* [5] in their review article stated that mechanism of action of perineural dexamethasone could be secondary to stimulation of glucocorticoid receptors located on the cell membranes of neurons, increasing the expression of inhibitory K+channels and thereby decreasing neuronal transmission in nociceptive unmyelinated C fibres. These actions are due to local vasoconstriction.

Various studies [6, 7, 8] have validated the use of perineural dexamethasone for prolonging the duration of analgesia. The use of dexamethasone may cause complications like hypergycemia, infection, impaired wound healing and neurotoxicity limiting its use in diabetics and immunocompromised patients. Dexamethasone has been associated with increase in postoperative blood glucose concentration in diabetic and non-diabetic patients [9]. So limiting the dose of steroids when used perineurally can minimize the side effects and broaden our spectrum of utility in diabetic patients with minimum side effects [10].

Many studies [10] which have proved that 8 mg dexamethasone, when used as an adjunct to local anaesthetics has prolonged the duration of analgesia compared to local anaesthetics used without any adjunct. But studies which have compared lower doses of dexamethasone as an adjunct to local anaesthetics are scarce [11, 12]. Our effort in this study is to find out whether dexamethasone used at a dose of 2 mg can prolong the duration of analgesia, when used as an adjunct to ropivacaine in axillary brachial plexus block in adult patients undergoing forearm and hand surgery. The study's primary objectives were to compare the duration of postoperative analgesia, defined as the interval between the onset of sensory block, and the initial use of rescue analgesia for surgical site pain. The secondary objective were to assess the onset and duration of sensory and motor block in minutes; cumulative dose of rescue analgesia in 24 hours and adverse effects such as nausea, vomiting, dysrhythmias, hypotension, convulsions, pruritus, jerking movements, and hypersensitivity reaction for the study drug.

MATERIALS AND METHODS: The study was designed as a Prospective Double-Blinded Randomised controlled trial and conducted in a 750 bedded teaching hospital. Institutional ethical committee approval was taken with the number IEC/127/2020-21. Patients aged 18 to 65 years of age of either sex, with ASA grade I and II, posted for forearm and hand surgeries under Axillary block were included in the study. Patients who refused to participate in the study, patients less than 18 years or more than 65 years, ASA grade III and IV, patients with a history of allergy to local anaesthetics, infection at the block site, history of convulsions, pre-existing neurological deficits, and coagulopathy were excluded. Written informed consent was taken from all the participants of the study.

Patients were shifted to the pre-operative holding area. Patient profile, diagnosis, proposed surgery, and pre-anaesthetic remarks were noted. Patients were randomized using computer-generated random numbers into 2 groups. Accordingly, the nurse in-charge of the pre-operative holding area attached an opaque sealed envelope to the patient's file chart noting the allocation of each patient to either of the groups.

Groups: Group R- Axillary Brachial Plexus Block given with 0.75% Ropivacaine 18 ml and 2ml NS making a total volume of 20ml Group RD- Axillary Brachial Plexus Block given with 0.75% Ropivacaine 18 ml and 2 mg Dexamethasone making a total volume of 20ml Patients were shifted to the operation theatre, 20 gauge intravenous cannula was inserted in the non-

operating arm and ringer lactate was started. Standard anaesthesia monitors were connected and baseline measurement of heart rate (HR), non-invasive arterial blood pressure (NIBP), peripheral oxygen saturation (SpO2), and respiratory rate was recorded before the start of the procedure. Junior anaesthesia resident opened the opaque sealed envelope and loaded the drug according to the group allotted.

The senior resident performed the block procedure and injected the local anaesthetic mixture. The patient was positioned in supine decubitus, with arm in 90 degree of abduction and elbow in flexion. Under strict aseptic precautions, a high-frequency linear probe (5-12 Hz) is placed in the transverse axis, over the axillary fold. The neurovascular bundle is localized 1-2 cm underneath the skin. Axillary artery is located as a spherical, pulsatile hypoechoic image not readily compressible **Fig. 1**. Median, ulnar and radial nerves were identified as oval or spherical hyperechogenic structures positioned around the artery. The radial nerve was identified between 4 and 6 o'clock position and 5ml of local anaesthetic mixture was deposited; median nerve was identified between 9 and 12 o'clock and 5ml of local anaesthetic mixture was pushed and ulnar nerve was identified between 12 and 3 o'clock position in relation to the axillary artery and 5 ml of local anaesthetic mixture was given after negative aspiration for blood. The musculaocutaneous nerve was identified separately between short head of biceps and coracobrachialis muscle and 5 ml of local anaesthetic mixture given with 21 gauge 1.5 inch neeedle by in-plane technique **Fig. 2.**

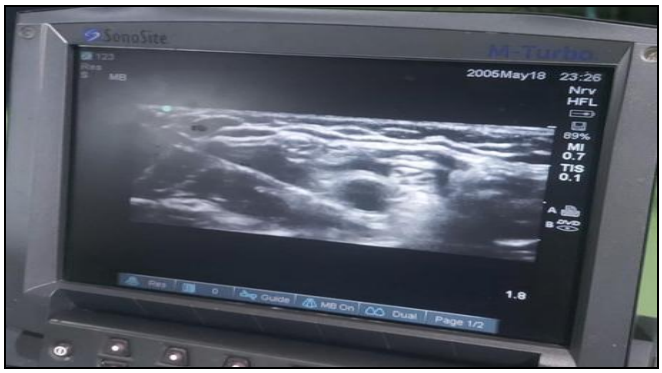

FIG. 1: AXILLARY BRACHIAL PLEXUS BLOCK WITH AXILLARY ARTERY IN THE MIDDLE SURROUNDED BY RADIAL, MEDIAN AND ULNAR NERVE AND NEEDLE SEEN IN THE PICTURE WITH 'IN-PLANE TECHNIQUE' OF NEEDLE INSERTION

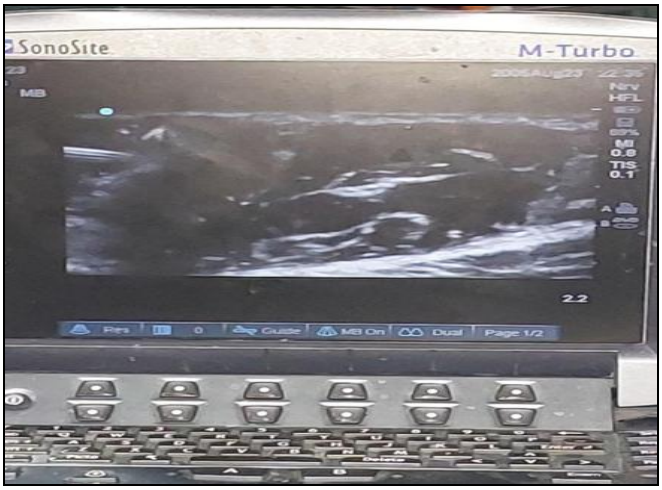

FIG. 2: MUSCULOCUTANEOUS NERVE SEEN IN CORACOBRACHIALIS MUSCLE

The time of onset of motor and sensory block was noted by the resident who performed the block, who was unaware of the group allocated. Onset of sensory block was defined as the time interval between the end of local anaesthetic injection and the complete sensory block (grade 2). Sensory function was assessed by the same observer every 2 minutes by pinprick in the distribution of the nerves (radial nerve, ulnar nerve, median nerve and musculaocutaneous nerve) Sensory block graded as

Grade 0- Sharp pin felt.

Grade 1- Analgesia (dull sensation felt).

Grade 2- Anaesthesia (no sensation felt).

Motor block was assessed by the same observer every 2 minutes till complete motor block was achieved after the drug injection. Motor block was determined according to a modified Bromage scale for upper extremities on 3-point scale. Onset of motor block was considered when there was Grade1 motor block.

Grade 0- Normal motor function with full flexion and extension of elbow, wrist and fingers.

Grade 1- Decreased motor strength with ability to move fingers only Grade 2- Complete motor blockade with inability to move the fingers.

The block was recorded as fail if at least Grade 1 motor and Grade 2 sensory were not achieved till 30 min from the time of injection or patient needed any supplementation with Inj Fentanyl > 50 mcg or conversion to General Anaesthesia.

Duration of sensory block was defined as the time interval between the end of local anaesthetic administration and complete resolution of sensory block (normal sensation or grade 0). Duration of motor block was defined as the time interval between the end of local anaesthetic administration and recovery of full power in the relevant muscle group (Grade 0). Pain was assessed using Visual Analogue Scale (VAS; 0-10) every 2 hours during the first 24 hours. Tab Tramadol, 100 mg oral, was given when the patient's VAS score was more than 4. The time interval between the end of local anaesthetic administration and the first analgesic request was recorded as the duration of analgesia. Total consumption of Tab tramadol in first 24 hours was noted. Duration of sensory and motor block and Visual Analogue Scale score were noted every 2 hours; the post-graduate incharge of the postoperative ward noted time of first rescue analgesic. He completed the proforma and handed over the proforma to the principal investigator.

Statistical Analysis: Sample Size was estimated by using the difference in Mean Duration of analgesia between RL Group and RLD group from the study by Aparna Pande *et al* [9] as 432±43.8 min and 386.4±40.2 min. Using these values at 99% Confidence limit and 90% power sample size of 26 was obtained in each group by using the below-mentioned formula and 'Med calc' sample size software [13]. With 10% non-response sample size of 26 + 2.6 ≈ 29 cases will be included in each group.

The Statistical software namely SPSS 22.0, and R environment ver.3.2.2 were used for the analysis of the data and Microsoft word and Excel have been used to generate graphs, tables *etc* [14, 15]. Descriptive and inferential statistical analysis has been carried out in the present study. Results on continuous measurements are presented on Mean ± SD (Min-Max) and results on categorical measurements are presented in Number (%). Significance is assessed at 5 % level of significance. The following assumptions on data is made, Assumptions: 1. Dependent variables should be normally distributed, 2 Samples drawn from the population should be random, Cases of the samples should be independent Student t test [16, 17] (two-tailed, independent) has been used to find the significance of study parameters on continuous scale between two groups (Intergroup analysis) on metric parameters. Leven`s test for homogeneity of variance has been performed to assess the homogeneity of variance. A t-test is a statistical test that is used to compare the means of two groups. It is often used in hypothesis testing to determine whether a process or treatment actually has an effect on the population of interest, or whether two groups are different from one another with the null hypothesis (H0) is that the true difference between these group means is zero and the alternate hypothesis (Ha) is that the true difference is different from zero.

Chi-square/ Fisher Exact test has been used to find the significance of study parameters on categorical scale between two or more groups, Non-parametric setting for Qualitative data analysis. Fisher exact test used when cell samples are very small. $P<0.05$ is considered significant

RESULTS: Fifty-eight patients were found eligible and included in the study. There were 29 patients in each group. There was no statistical difference between Group R and Group RD regrading age, sex, weight, ASA grading and duration of surgery **Table 1.**

TABLE 1: PATIENT DEMOGRAPHIC PROFILE AND DURATION OF SURGERY

	Group R	Group RD	P value
Age	44.40±12.82	40.77±11.78	0.284
Sex (M/F)	14/27	14/27	
Weight (Kg)	62.48±7.61	63.51±8.14	0.631
ASA grading (I/II)	12/15	16/11	
Duration of Surgery(min)	141.85±14.02	137.59±10.04	0.205

Group R- Group Ropivacaine, Group RD- Group Ropivacaine + 2mg Dexamethasone.

One patient in group R required conversion to general anaesthesia and another patient required Inj. Fentanyl > 50 mcg and thus excluded from statistical analysis. Two patients in group RD had partial block and required Inj Fentanyl > 50 mcg and excluded from the study **Fig. 3**. A total of fifty four patients completed the study.

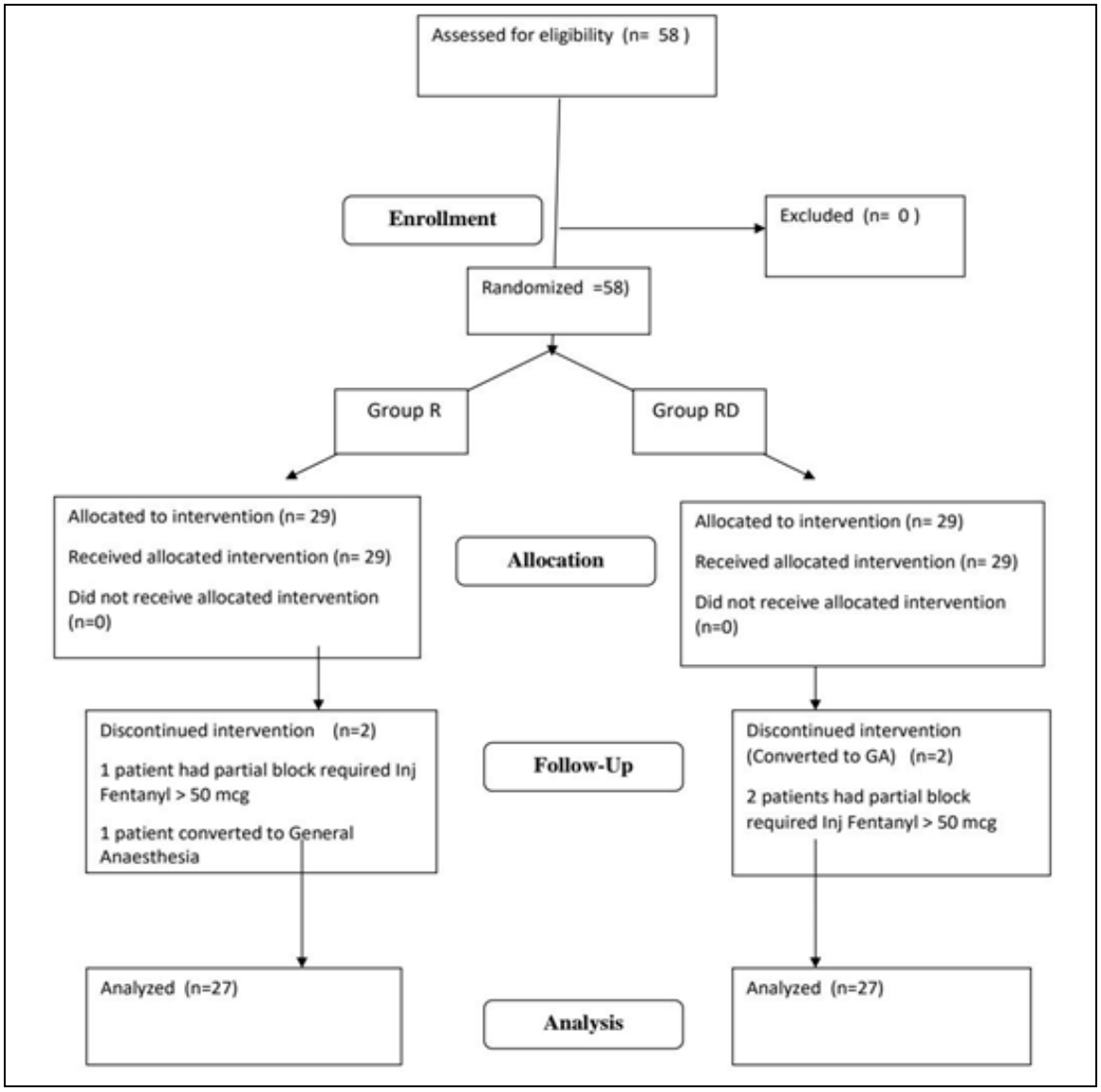

FIG. 3: CONSORT DIAGRAM

Onset of sensory block in Group RD was earlier than Group R (12.7± 0.91 min Vs 18.63±1.39 min) Onset of motor block was also earlier in Group RD than in group. R (16.04±1.32 min Vs 23.59±1.31 min). Both values were statistically significant. Duration of sensory and motor block was also longer in group RD as compared to Group R and was found to be statistically significant **Table 2.**

TABLE 2: COMPARISON OF STUDY VARIABLES ACCORDING TO PATIENTS COHORT IN TWO GROUPS

Variables	Group R	Group RD	Total	p Value
Onset of Sensory Block	18.63±1.39	12.7±0.91	15.67±3.21	<0.001**
Onset of Motor Block	23.59±1.31	16.04±1.32	19.81±4.03	<0.001**
Duration of Sensory Block	374.26±7.68	427.59±9.64	400.93±28.27	<0.001**
Duration of Motor Block	260.11±12.39	316.11±13.68	288.11±31.08	<0.001**

Group R- Group Ropivacaine, Group RD- Group Ropivacaine + 2mg Dexamethasone ** p<0.05 –significant.

Time of first rescue analgesia in Group RD was 515.74±11.07 minutes and in Group R was 452.78±14.76 minutes and was statistically significant **Fig. 4.** VAS score at 8th hour was higher in Group R with 4.63 ±0.49 Vs 2.19±0.48 in Group RD. VAS score at 10th hour was higher in Group RD with 5 ±0.62 Vs 1.22±0.97 in Group R. These values were statistically significant. Subsequently, it was observed that VAS at 2,4,12 and 24 hours were comparable between both the groups **Fig. 5.**

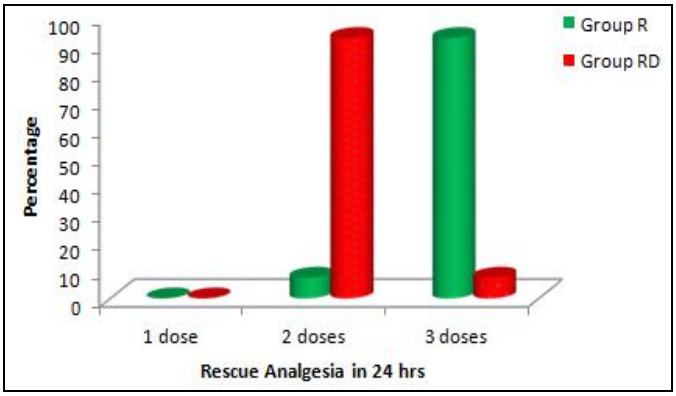

FIG. 4: NUMBER OF DOSES OF RESCUE ANALGESIA CONSUMPTION IN 24 HRS IN BOTH THE GROUPS

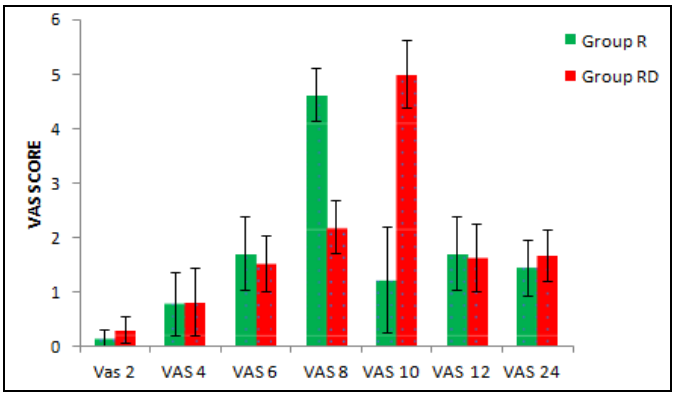

FIG. 5: VAS SCORING COMPARISON BETWEEN 2 GROUPS

In Group R, 25 patients required 3 doses of rescue analgesia and 2 patients required 2 doses of rescue analgesia. In Group RD required 25 patients required 2 doses of rescue analgesia and 2 patients required 3 doses of rescue analgesia in 24 hours. There was a significant difference in the doses of rescue analgesia between both groups with p value<0.001.

DISCUSSION: Ultrasound-guided Axillary brachial plexus block is being used for forearm and hand surgeries. Ropivacaine is becoming the preferred drug because of its safety profile. In our randomized controlled study, we used dexamethasone at a dose of 2mg as an adjunct to 0.75% ropivacaine. We concluded that 2mg dexamethasone hastens the onset of sensory and motor block, increases the duration, and delays the need for first-rescue analgesia. This low dose of dexamethasone gives a higher safety profile in high-risk patients with uncontrolled blood sugars, chronic renal failure, or immunocompromised conditions like malignancy. Here a combination of ropivacaine and a low dose of dexamethasone can be used without major side effects.

Santosh Kumar *et al.* [18] in a study used 8 mg dexamethasone as an adjunct to 0.5% ropivacaine and found that plain ropivacaine group required first rescue analgesia at 557 min and the group with ropivacaine with dexamethasone demanded rescue analgesia at 1179.4 min. Our study also found the time of first rescue analgesia in ropivacaine with dexamethasone 515.74 minutes compared to only the ropivacaine group 452.78 minutes. Although we used a lower dose of 2mg dexamethasone, the duration of action was prolonged compared to ropivacaine alone. In Santosh Kumar *et al.*, they have used 8 mg dexamethasone with ropivacaine. The duration of action is longer at 1179.4 min than 2mg dexamethasone in our study; we had a duration of action of 515 min. This demonstrates that dexamethasone, even in lower doses, when used as an adjuvant to ropivacaine prolongs the duration of action of ropivacaine.

Nibedita Pani *et al.* [19] compared 0.5% Levobupivacaine with 8 mg dexamethasone and found that onset of sensory and motor block was faster in dexamethasone group and mean duration of sensory (420.73 min) and motor block (306.80 min) was significantly longer in dexamethasone group as compared to the group without adjunct. The results of our study was also comparable with Nibedita Pani et al. In our study we used 2 mg dexamethasone as an adjuvant to ropivacaine and found faster onset of sensory and motor block and also had a longer duration of sensory(427.59 min) and motor block. (316.11 min). We can see that even low-dose dexamethasone of 2mg as an adjuvant to ropivacaine has hastened the onset and prolonged the duration of sensory and motor block in our study.

Darren Holland [20] compared the effect of intravenous and perineural routes of dexamethasone administration in a dose of 4 and 8 mg in interscalene brachial plexus block and concluded that compared with intravenous route, perineural dexamethasone in dose of 4 and 8 mg prolongs the mean interscalene block duration. But difference in mean block durations between 4 mg and 8 mg was not clinically significant, implying that dexamethasone at lower doses can also prolong

the analgesia's duration equivalent to that of 8 mg dexamethasone. In our study we used 2 mg dexamethasone and found increase in duration of block. According to the conclusions of Darren Holland *et al*, dose of dexamethasone will not matter as 4 mg dexamethasone and 8 mg dexamethasone had given similar duration of analgesia. Going further, even 2 mg dexamethasone in our study has prolonged the duration of analgesia compared to ropivacaine alone.

Youn Jin K *et al* [21] studied different doses of dexamethasone added to 0.5% ropivacaine where group I was control group and group II, III, IV contained 2.5mg, 5 mg and 7.5mg dexamethasone and he found that time of first analgesic request was significantly prolonged in Group III (mean 1380 min) and Group IV (mean 1150 min) compared to Group I (mean 720 min). In his results, he found that 5mg dexamethasone as an adjunct to ropivacaine prolonged the time of first analgesic request by 230 min as compared to group with 7.5 mg dexamethasone and by 660 min as compared to the control group. This study has shown longer duration of analgesia with lower dose of dexamethasone.

Aparna Pande *et al.* [9] studied low-dose dexamethasone 2mg as an adjunct to 0.5% ropivacaine and found a significant difference in the time of first analgesic request in dexamethasone group compared to the control group (432+/-43.8 min Vs 386.4+/- 40.2min). The onset of sensory and motor block was faster in dexamethasone group and overall analgesic consumption was also reduced in dexamethasone group. However, dexamethasone did not prolong the duration of motor block. In our study, low dose dexamethasone has hastened the onset of block and time of first recue analgesic but in contrast, our study has also shown an increase in duration of motor block. M. M. Vasconcelos *et al* used 6mg dexamethasone with 0.5% levobupivacaine with adrenaline (1:200000) for shoulder arthroscopic surgeries in interscalene block after general anaesthesia where a total of 74 patients were included in the study. These patients were followed up for 24 hours and found that block duration in dexamethasone group was 1440 min, and they did not require rescue analgesia in the first 24 hours. But in the group without dexamethasone, block duration was 1267±164 min and among the 34 patients, 24 patients required rescue analgesia within the first 24 hours. Panjainphum *et al* [23] comapared 2mg and 4 mg dexamethasone with local anaesthetic mixture of 20ml of 2% Lignocaine with 5mcg/ml adrenaline and 10ml of 0.5% bupivacaine. They found that mean analgesic duration in 2mg Dexamethasone group was 620 minutes and 4 mg dexamethasone group was 894 minutes compared to control group without adjuvant, which had a mean analgesic duration of 335 minutes and the values were statistically significant. Although they found that higher dose of perineural dexamethasone provides longer duration of analgesia, they also concluded even a low dose of dexamethasone added as an adjuvant to local anaesthetics will prolong the duration of analgesia as compared to local anaesthetics without adjuvant.

CONCLUSION: Dexamethasone added in a low dose of 2mg as an adjuvant to 0.75% ropivacaine hastens the onset of sensory and motor block and prolongs postoperative analgesia duration, reducing the requirement of postoperative opiod. Such a low dose of steroid can be used safely as an adjunct to local anaesthetic in patients with poor safety profile.

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CONFLICTS OF INTEREST: Nil

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