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COMPARISON OF ROPIVACAINE WITH ROPIVACAINE PLUS PERINEURAL DEXAMETHASONE ON BLOCK CHARACTERISTICS IN ULTRASOUND GUIDED SUPRACLAVICULAR BRACHIAL PLEXUS BLOCK

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ABSTRACT

Background- The aim of this study was to compare the effects on block characteristics of 0.5% Ropivacaine with 0.5% Ropivacaine and Dexamethasone in ultrasound guided Supraclavicular brachial plexus block.

Material and Methods- A prospective, double-blind, randomized, comparative study was conducted in 128 ASA I-II patients for surgeries of the elbow, forearm and hand, who were randomly assigned to receive 0.5% Ropivacaine or 0.5% Ropivacaine with 8mg Dexamethasone in supraclavicular brachial block using ultrasound and PNS guidance. The primary outcome was duration of analgesia; onset of sensory and motor block, duration of motor block, complications were secondary outcomes.

Result- The duration of analgesia and motor blockade were significantly prolonged in dexamethasone group. The mean time to onset of sensory and motor blocks were significantly shortened. The time to complete sensory block was not significantly different between the two groups.

Conclusion- Dexamethasone as an adjuvant hastens the onset and prolongs the duration of block significantly when added to Ropivacaine, without untoward effects. However the effect on time to complete sensory block is unsubstantial.

KEYWORDS : Dexamethasone, Ropivacaine, Supraclavicular Block, Ultrasound

INTRODUCTION-

Pain is the conscious interpretation of noxious stimuli, derived from the Latin "poena", meaning punishment. It exerts deleterious effects on systems like respiratory, cardiovascular, neuroendocrine and gastrointestinal[1] and is pivotal to be treated for a smoother transition to the pre-operative status.

Brachial plexus block remains the only substitute to general anaesthesia for surgeries of the upper limb and can be used effectively in patients with significant co-morbidities. When performed under ultrasound guidance, it provides extremely good nerve visibility, minimizes adverse effects and allows for the use of reduced volumes of drug perineurally. However intra-operative single shot blocks provide analgesia only for a short duration and do not effectively cover the post-operative period, leading to increased opioid consumption or inadequate treatment of pain.

Various adjuvants to brachial plexus block have been used to prolong the post-operative duration of analgesia. With most adjuvants, there has been a concern regarding their safety profile and side-effects.

Undesirable effects with single dose of Dexamethasone, a corticosteroid, seem to be minor and previous studies have demonstrated safe short term (<24 hour) use of dexamethasone[2]

The present study aims at comparative evaluation of dexamethasone added to ropivacaine and ropivacaine alone in supraclavicular brachial plexus block in terms of onset of sensory and motor block, post-operative duration of analgesia and motor block, and block related complications, if any, in the first 24 hours post surgery.

MATERIAL AND METHODS-

This was a prospective, randomized, comparative, double-blind study, conducted over a period of two years after obtaining clearance from the hospital ethical committee. Total 128 patients undergoing surgeries of the elbow, forearm and hand, American Society of Anaesthesiologist (ASA) grade I-II, aged 18-65 years, were enrolled after sample size calculation with the help of difference in mean method (using OpenEpi software) taking into consideration duration of analgesia as primary outcome at 95% confidence interval (α error) and at 90% power of study. The study by K.C.Cummings III et al[3] was taken as the reference article.

Patients with history of hypersensitivity to dexamethasone or local anaesthetics, neurological deficit involving the brachial plexus, infection at the site of injection, co-existing severe cardiovascular, respiratory, neurological diseases, or known contra-indications to steroids, and severe bleeding diathesis were excluded from the study The study protocol was explained to the patients and written informed consent was obtained after detailed pre-operative evaluation. Patients were randomized to receive 20 ml 0.5% ropivacaine (taking maximum allowable dose 250 mg) with 8 mg Dexamethasone (2ml) and 20 ml 0.5% ropivacaine with normal saline (2ml) into two groups of 64 each. Patients in group 1 received 0.5 % ropivacaine with distilled water (2ml) and patients in group 2 received Ropivacaine-Dexamethasone combination.

All patients were premedicated with Pantoprazole 40 mg and Ondansetron 4mg. An intravenous line was secured on the contra-lateral hand of patient and infusion of balanced salt solution started as per calculation of perioperative fluid requirement. Non-invasive blood pressure, pulse-oximeter and continuous ECG monitoring were initiated. Oxygen was administered at the rate of 2-3 L/min.

Patients were sedated with intravenous (IV) midazolam 1-2 mg and IV fentanyl 1-2 mcg/kg just prior to the induction of block.

Blocks were performed under strict aseptic precautions with 22 G, 50-mm insulated blunt Sonoplex needle under ultrasound guidance and confirmation with a nerve stimulator for precise localization. The patients were given supine position with the head turned to the contralateral side. The skin was disinfected and the transducer was positioned in the transverse plane immediately superior to the clavicle at approximately its midpoint. Once a cross-sectional view of the subclavian artery was obtained, the brachial plexus was identified as a collection of hypo-echoic oval structures (honeycomb) lateral and superficial to the artery.

1-2 ml of local anaesthetic was injected into the skin just lateral to the transducer; the block needle was inserted in-plane to the transducer towards the plexus, in a lateral-to-medial direction. Once the required motor response was obtained, current intensity initially at 1mA was gradually reduced to <0.5mA until the proper motor response was still elicited, and disappeared at 0.2mA. After documenting correct needle placement, study drug was injected following repeated negative aspiration for blood and air in 3 ml incremental doses, till a total volume of 20 ml was given.

Immediately after block placement, patients were evaluated every minute up to 30 mins for the onset of sensory and motor blockade, and thereafter for total duration of analgesia and motor blockade postoperatively. The time to requirement of first rescue analgesic within 24 hours of block was noted. Patients were also observed for any procedure related complications or toxicity of the injected drugs.

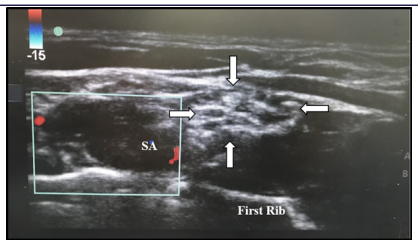


FIG 1 - Sonoanatomy at the supraclavicular level with the plexus looking like a bunch of grapes; SA- subclavian artery

In the event of a patchy action after 30 minutes of induction, patients were given general anaesthesia and such cases were excluded from the study.

The outcome measures were assessed by the principal investigator who was blinded to the drugs administered in the block. These included-

1. Sensory block characteristics- Time from injection to complete loss of sensibility to pin-prick was graded on a three point scale: where Grade 0= no loss of any sensation, Grade 1= loss of pin prick but intact touch (analgesia), Grade 2= loss of touch sensation (anaesthesia). Grade 1 was taken as the time to onset of sensory block and grade 2 as time to complete sensory block or surgical anaesthesia.
2. Motor block characteristics- Time from injection to reduction in motor power to 3 on the modified Lovett rating scale was taken as time onset of motor block. Time from injection to reduction in motor power to 0 on the modified Lovett rating scale was taken as time to complete motor block.

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 IMPAIREMENT
1	ALMOST COMPLETE PARALYSIS
0	COMPLETE PARALYSIS

3. Duration of analgesia- Time interval between brachial injection and first need of rescue analgesic by the patient. The duration of analgesia was noted according to 0-10 visual analogue score (VAS) for pain at 0 hour and then every hour for 24 hours. When the patients complained of pain, VAS was noted and rescue analgesic in the form of intravenous Diclofenac 75 mg was administered.
4. Duration of motor block- Time taken from onset to complete recovery of motor function was measured every hour for 24 hours.
5. Possible side effects included local anaesthetic toxicity, drowsiness, pruritus, nausea or vomiting, Horner's syndrome, phrenic nerve palsy, pneumothorax, respiratory depression were looked for in 24 hours post procedure

STASTICAL METHODS-

Comparison of quantitative variables between the study groups was done using Student t test for independent samples if normally distributed. Mann–Whitney U test was used for non-normally distributed quantitative data. For comparing categorical data, Chi square test was performed. Exact test was used instead when the expected frequency was less than 5. A probability value (p value) less than 0.05 was considered statistically significant.

RESULT-

The two groups were analysed for their demographic profile by comparing the age, weight, height, sex, and duration of surgery performed and were comparable [Table 1].

The hemodynamic variables between the groups were also comparable.

It was observed that the onset time of sensory block was significantly shorter in Group with Dexamethasone (Group 2) compared with the control group in which only local anaesthetic solution was given. The p value was calculated to be < 0.01 using the student test, while there was no statistically significant difference between the groups with respect to the time to complete sensory block (p value = 0.09). The onset time of motor block and time to complete motor block were significantly earlier in Group 2 with Dexamethasone compared with Group 1 [Table 2].

The administration of the block in these patients resulted in a rapid reduction of VAS compared with the baseline VAS scores. The increase in Mean VAS at rescue analgesia corresponded with the end of the concerned drug action. The mean duration of analgesia in our study for group 2 was 1073 minutes. Compared with group 1 (529 minutes), this duration to first rescue analgesic was significantly longer (p<0.01) [Graph 1].

Similar findings were noticed with respect to the duration of motor blockade where the mean total duration of 1087 minutes was significantly longer in group 2 compared with 467 minutes in group 1[Graph 2]. No complications were observed in either group.

Variables	Group	Mean	SD	p- value
Age (yrs)	**1**	35.05	10.38	**0.43**
	2	36.52	10.68	**NS**
Weight	**1**	67.56	9.22	**0.40**
	2	69.03	10.30	**NS**
Height	**1**	163.44	9.79	**0.93**
	2	163.59	10.62	**NS**
BMI	**1**	25.34	3.17	**0.41**
	2	25.81	3.34	**NS**
Duration of surgery (mins)	**1**	116.22	17.82	**0.83**
	2	116.88	17.17	**NS**

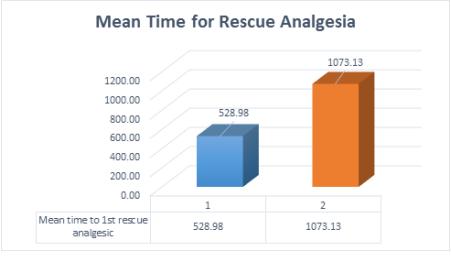
p<0.05 is significant, NS – not significant

Table 1- Demographic profile of both the groups with their Mean and SD

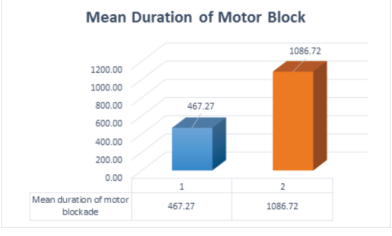
Block Characteristics	Group	N	Mean	SD	p-value
Onset of Sensory Block (mins)	**1**	64	6.05	0.97	**< 0.01**
	2	64	4.06	0.97	
Time to complete Sensory block (mins)	**1**	64	18.91	5.23	**0.09**
	2	64	17.31	5.33	
Onset of Motor Block (mins)	**1**	64	9.20	1.10	**<0.01**
	2	64	7.27	1.06	
Time to complete Motor block (mins)	**1**	64	24.03	4.75	**<0.01**
	2	64	20.84	6.72	

p<0.05 – Statistically Significant

Table 2- Intra-operative assessment of sensory and motor blockade



Graph 1- Comparing Mean time to 1st rescue analgesic between groups (minutes)



Graph 2- Comparing mean duration of motor blockade between groups(minutes)

DISCUSSION-

Suboptimal management of pain has both physical and psychological harmful effects. Hence the goal of post-surgical pain management should be to not only treat pain but also prevent it. As a method of perioperative pain relief, supraclavicular brachial plexus block is safe and feasible, allows day care anaesthesia, and can be utilised in

patients with contraindications to general anaesthesia, including patients with full stomach.

Strategies to prolong the duration of analgesia by increasing the dose of local anaesthetic are curtailed by their narrow therapeutic index. In some recent research, successful surgical anaesthesia and equivalent analgesic duration has been attained with volumes as low as 5 ml vis-à-vis standard volume[4,5,6].

Steroids as adjuvants to local anaesthetic solutions improve the quality of block and prolong the duration of analgesia. They exert anti-inflammatory effects via inhibition of phospholipase A2. Local application of methylprednisolone has been found to block transmission in nociceptive C-fibres but not in myelinated A-beta fibers[1]. The effect was reversible, suggesting a direct membrane action of steroids[1]. They alter the function of potassium channels in the excitable cells and this may be responsible for alteration of block characteristics when combined with local anaesthetics.

In our current study, we used ultrasound guidance to perform the block. Total 20 ml of local anaesthetic (0.5% ropivacaine) solution along with 2ml saline in group 1, and 2 ml dexamethasone in group 2 were chosen as the agents of choice. Six patients (four patients in group 1 and two patients in group 2) failed to achieve satisfactory levels of anaesthesia and required induction of general anaesthesia. They were excluded from the study. The 8mg dose of dexamethasone was selected as it is within the range of clinically used dose of postoperative nausea[7].

The mean onset of sensory block in minutes was 6.05 ± 0.97 and 4.06 ± 0.97 in group 1 and 2 respectively ($p < 0.01$). The mean time to complete sensory block was 18.91 ± 5.23 minutes and 17.31 ± 5.33 minutes ($p = 0.09$).

Thus the onset of sensory block was significantly shorter for group 2 but the time to complete sensory block was similar between the groups. The mean onset of motor block in minutes in group 1 and group 2 was 9.20 ± 1.10 and 7.27 ± 1.06 respectively ($p < 0.01$). The time to complete motor blockade for group 1 and 2 was 24.03 ± 4.75 minutes and 20.84 ± 6.72 minutes respectively. This difference was also statistically significant with $p < 0.01$. These results were comparable to the findings of other researchers[8,9].

However, Ali Movafegh et al found that the onset time of sensory and motor blockade was similar in both the groups[10]. This deviation could be explained on account of different methods of block assessment and block administration, dose of local anaesthetic, and different local anaesthetic agent.
Jaegar P et al assessed sensory block duration using five different measurement tools in bilateral saphenous nerve block to control for systemic effects of dexamethasone. They concluded that addition of 2 mg of dexamethasone to ropivacaine inconsistently and modestly prolonged block duration thus questioning the clinical efficacy after perineural administration[11].

In our study, the mean duration of analgesia in group 1 was 528.98 ± 40.02 minutes whereas in group 2 it was 1073.13 ± 54.15 minutes ($p < 0.01$). The mean duration of motor block in group 1 and group 2 were 467.27 ± 41.03 and 1086.72 ± 60.79 minutes respectively ($p < 0.01$). Both these data were highly significant statistically which showed that both the duration of analgesia and motor block were significantly prolonged compared to the control group.

Our results were similar to the study performed by Jadon A et al[12] with regards to duration of analgesia. They studied the effects of dexamethasone added to 0.5% ropivacaine in Interscalene block for arthroscopic shoulder surgery. They concluded that dexamethasone significantly prolonged duration of analgesia of ropivacaine during ISB used for arthroscopic surgeries of shoulder. However their study varied from ours in that they did not use ultrasound guidance to aid block administration and proved dexamethasone when mixed with ropivacaine did not alter other block characteristics including onset of sensory and motor blocks in interscalene block.

Neither were any signs of toxicity visible in any of the groups during our study period nor did the patients complain of any side effects.

Since we didn't compare the total rescue analgesic requirement, we cannot comment if dexamethasone reduces the total opioid or analgesic consumption. Moreover, the prolongation of motor blockade negatively affects early ambulation. The follow up period of 24 hours is too short to comment on the possibility of neurotoxicity with perineural dexamethasone. Since some recent studies have shown prolonged duration of analgesia with systemic administration of dexamethasone[13], the lack of a systemic control is an important limitation of this study.

CONCLUSION-

Perineural administration of dexamethasone to ropivacaine significantly prolongs the mean duration of analgesia and motor blockade in ultrasound guided supraclavicular block. It shortens onset of sensory and motor block and time to complete motor block. However, time to complete sensory block is not significantly affected.

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