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RANDOMISED COMPARATIVE STUDY OF DIFFERENT DOSES OF DEXAMETHASONE AS AN ADJUVANT TO ROPIVACAINE IN SUPRACLAVICULAR BRACHIAL PLEXUS BLOCK IN UPPER LIMB SURGERY.

Anaesthesiology

Jasmeen Chowdhary MBBS, MD Senior Resident Government Medical College Jammu.

Naine Bhadrala* MBBS, MD Assistant Professor Government Medical College Jammu. *Corresponding Author

Jameel Hussain Consultant Anesthesia Government Medical College Jammu.

ABSTRACT

BACKGROUND: Upper limb surgeries below the shoulder joint are mostly performed under peripheral blocks such as the brachial plexus block. Peripheral nerve blocks not only provide intra-operative anesthesia, but also extend analgesia in the post-operative period without major systemic side-effect by minimizing stress response and using minimal anesthetic drugs.The present study evaluated the effects of different doses of dexamethasone as an adjuvant to 0.75% ropivacaine in producing desired peripheral nerve blockade.

MATERIAL AND METHODS:-90 patients posted for upper limb surgeries were selected randomly after taking informed written consent into three groups(30 patients of ASA I and II in each group) . Group I –received 28 ml of 0.75% ropivacaine +2ml of normal saline, Group II received 28ml 0.75% ropivacaine + 1 ml dexamethasone(4mg) + 1 ml normal saline and Group III– received 28ml 0.75% ropivacaine+2ml dexamethasone(8mg). Total volume of the drug kept was 30 ml in all the groups.The onset of sensory and motor blockade and duration of sensory and motor blockade were assessed.

RESULTS: The demographic profile were comparable in all the three groups.The onset of sensory and motor block were similar among the three groups. The duration of sensory and motor block and time to first analgesic use were significantly longer and the total need for rescue analgesics was lower in group II &III ($P < 0.05$) than group I .The duration of motor and sensory block were comparable between group II and group III. Post-operative VAS value at 12 h were significantly lower in group II &III($P < 0.05$). The systolic blood pressure, diastolic blood pressure, mean arterial pressure, and heart rate showed no significant differences among three groups without any appreciable side effects.

CONCLUSION: Addition of different doses of dexamethasone to supraclavicular brachial plexus block increases the sensory and motor block duration and time to first analgesic use, and decreases total analgesic use with no side-effects.No significant difference was seen between high and low dose of dexamethasone.

KEYWORDS

dexamethasone ,ropivacaine and supraclavicular block

INTRODUCTION

Brachial plexus block is an excellent method for attaining optimal operating conditions for upper limb surgeries by producing complete muscular relaxation, maintaining haemodynamic stability and the associated sympathetic block. They also provide extended postoperative analgesia with minimal side effects. In addition, it offers a better preservation of mental functions in elderly; decreased risk of aspiration due to intact pharyngeal and laryngeal reflexes; avoids difficult intubation; decreases postoperative complications associated with intubation and provides better postoperative analgesia without undue sedation facilitating early mobilization and discharge[1].

Various local anesthetics alone or in combination with different adjuvants have been tried to prolong the duration of postoperative analgesia for a long time but have met with limited success. Bupivacaine is a well-established long-acting regional anesthetic, which like all amide anesthetics has been associated with cardiotoxicity when used in high concentration or when accidentally administered intravascularly. Hence, there is a need for a drug that can have all the advantages of bupivacaine without its cadiotoxicity. Ropivacaine is a long-acting regional anesthetic that is structurally related to bupivacaine. It is a S(−) enantiomer, unlike bupivacaine, which is a racemate, developed for the purpose of reducing potential toxicity and improving relative sensory and motor block profiles.

Various adjuncts (epinephrine, dexamethasone, tramadol, sodium bicarbonate, clonidine, dexmedetomidine, tramadol, buprenorphine, dexamethasone , midazolam) have been added to enhance the effect of single injection local anaesthetic peripheral nerve blockade, with varying results. Perineural dexamethasone appears to prolong the duration of analgesia after brachial plexus block when combined with the local anaesthetics lidocaine, mepivacaine and bupivacaine [2]. Other benefits include improved visual analogue pain scores, decreased peri.operative opioid use and decreased nausea and vomiting.

Studies suggest its addition can impressively prolong the duration of block with minimal side effects. It has been suggested that dexamethasone may prolong the duration by increasing the activity of inhibitory potassium channels on nociceptive C fibres or by causing vasoconstriction via glucocorticoid receptors mediated nuclear transcription modulation. Dexamethasone suppression of inflammatory mediators including prostaglandins (PGE2), may also play a role. Therefore,we carried out the present study to compare the effects of 4 mg dexamethasone versus 8 mg dexamethasone as an adjuvant to 0.75% ropivacaine in producing desired peripheral nerve blockade and post operative analgesia.

MATERIALS AND METHODS

After local Hospital Ethical Committee approval and an informed written consent, 90 adult patients of ASA grade I and II, aged 18 to 60 years, scheduled for upper limb surgery via supraclavicular block were recruited in this prospective, randomized double blinded study over a period of one year. No analgesic drug or sedative premedication was given. Exclusion criteria included ASA grade >II, patients with known case of hypersensitivity reaction to dexamethasone and local anaesthetic, patients with abnormal coagulation parameters or on anticoagulation therapy, local infection at the site of proposed puncture for supra-clavicular block, patients with a history of peptic ulcer disease, diabetes mellitus, hepatic or renal failure, pregnant women and peripheral neuropathy,patients refusal .

After securing an IV access, an infusion of Ringer Lactate was started. In the operating room standard monitors including Electrocardiograph, Non-Invasive Blood Pressure and Pulse oximeter were placed. All baseline parameters were recorded. Patients were randomly allotted into three equal groups; –. Group I –received 28 ml of ropivacaine + 2ml of normal saline ,Group II- received 28ml 0.75% ropivacaine+ 1 ml dexamethasone(4mg) + 1 ml normal saline and Group III – received 28ml 0.75% ropivacaine+2ml dexamethasone(8mg). Total volume of the drug kept was 30 ml in all the groups.Study drug was given by an anesthesiologist who did not participate in the study .

Patient were pre-medicated with Inj. Midazolam 0.05mg/kg. Patient was positioned supine with the head to the opposite side. The midclavicular point, subclavian artery pulsation and external jugular

vein was identified. A point 2 cm above the mid-clavicular point and just lateral to the subclavian artery pulsation identified ,a 24 G needle 1.5 inch needle was inserted via classical approach of supraclavicular block and after eliciting paraesthesia and confirming negative aspiration of blood, keeping the needle in the same position, the 30 ml of the study medication was injected slowly while ruling out intravascular injection intermittently.

The above assessment was carried out by the principal investigator, who was blinded to the drugs administered in the plexus block. The study drug was prepared by an operation theatre technician not involved in the care or monitoring of the patients. The patients and the observing anesthesiologist and nurses were blinded to the study drug used. The following parameters were studied

SENSORY BLOCK was assessed by pinprick test using a 3-point scale:
0 = normal sensation,
1 = loss of sensation of pinprick (analgesia), and
2 = loss of sensation of touch anesthesia)

MOTOR BLOCK was assessed by Bromage 3- point scale:
0: Normal motor function with full flexion and extension of elbow, wrist and fingers.
1. Decreased motor strength with ability to move fingers and/or wrist only
2. Complete motor blockade with inability to move fingers

The onset time of sensory and motor blockade is defined as, the time between the last brachial injection of local anaesthetic to the total abolition of pinprick response in all nerve distributions; and complete paralysis respectively (unable to lift the hand against gravity).

Sensory and motor blockade were assessed every 2 min after completion of injection until 30 min and then every 30 min after the end of surgery until first 12 h, thereafter hourly until the block had completely worn off.

Sensory blockade of each nerve was assessed by pinprick.
The duration of sensory block was defined as the time interval between the onset of sensory block and the need for first rescue analgesia.

The duration of motor block was defined as the time interval between the onset of motor block and complete recovery of motor functions Pain was assessed using the Visual Analogue Scale (VAS;0-10) every 60 min during first 24 h.Injection diclofenac sodium (rescue analgesic) 75 mg was given intramuscularly when VAS ≥4..The number of injection diclofenac given to each patient during first 24 h of the post-operative period was recorded.

Hypotension defined as a decrease in MAP >20% of the baseline or fall in systolic blood pressure <90 mmHg which was treated with intravenous Mephentermine 3 mg.

Bradycardia defined (heart rate <50 beats per minute) was treated with intravenous atropine 0.5mg.

In case of failed block, general anesthesia was administered and those patients were excluded from the study. Possible side effects of brachial plexus block:Incidence of drowsiness, pruritus, nausea/vomiting, Horner's syndrome, phrenic nerve palsy, pneumothorax, respiratory depression, and signs and symptoms for local anesthetic toxicity were looked for and noted, if any.

The data was analyzed using computer software Microsoft Excel and IBM SPSS version 16.0 for Windows. Mean and standard deviation (SD) was calculated and reported for quantitative variables. The statistical difference in mean value was tested using paired't' test and independent't' test. ANOVA (analysis of variance) was also performed to evaluate statistical significance in more than two groups. A p-value of <0.05 was considered as statistically significance.

RESULTS

A total of 98 patients were screened. Two patients refused to cooperate after enrollment .Supraclavicular block failed in 4 patients and 2 patients were disqualified due to protocol violation. All the groups were comparable with regard to age, weight, height, gender, and duration of surgery (**Table 1**).

TABLE 1: DEMOGRAPHIC DATA

Patients characteristics	Mean+SD (n=30)			P value
	Group I	Group II	Group III	
Age	30±8	31±9	28±10	0.60
Height	157.73±2.81	157.95±2.95	157.23±2.75	0.68
Weight	64.73±4.77	65.60±5.57	65.95±5.26	1.45
ASA I/II	31/4	27/8	29/6	0.95
Duration of surgery	106±12.81	108.73±15.81	110.73±16.56	0.38

Values are mean±standard deviation
ASA-American Society Of Anesthesiologist physical status
<0.05= statistically significant.

The mean onset of sensory and motor blockade in group I was 9.55±1.40min and 18.53±1.61min respectively,group II was 10.06±1.41min`and 19.02±1.55min respectivey and group III was 9.71±1.28min and 19.35±1.50min respectively.The difference in onset of sensory and motor block in all the three groups came out to be statistically insignificant among all the groups.The duration of sensory and motor block in group I was 19.35±1.50min and 390±20.51min respectivel,group II was 740.48±21min and 455.81±42.57min respectively and group III was 760.65±30.87min and 437.20±34.1min respectively. (**Table 2**).

Table 2: Sensory & Motor characteristics

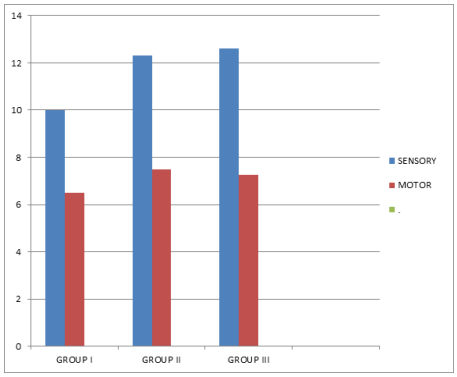
	Group I (n=30)	Group II (n=30)	Group III (n=30)	P – value		
				Group I & II	Group I & III	Group II & III
Time to Peak sensory block (min)	9.55± 1.40	10.06± 1.41`	9.71±1.28	0.3	0.31	0.43
Time of peak motor block(mins)	18.53± 1.61	19.02± 1.55	19.35±1.50	0.09	0.2	0.1
Duration of sensory block(mins)	622.87 ±31	740.48 ± 21	760.65±30.87	<0.01	<0.01	0.3
Duration of motor block (mins)	390± 20.51	455.81 ± 42.57	437.20±34.1	<0.01	<0.01	0.35

P value less than 0.05 is considered stastistically significant.

The difference between group I and group II was statistically significant and between I and II also statistically significant results were found.The results wre comparable between group II and III.Similarly the duration of motor block was comparable between group II(455.81±42.57min) and group III(437.20±34.1min) but statistically significant than group I(390±20.51min) The total need for rescue analgesics and post-operative VAS value at 12 h were significantly lower in group II &III($P < 0.05$).We found no significant difference between low and high dose of dexamethasone with regard to onset and duration of sensory and motoar block. Duration of analgesia was taken as time from the onset of sensory blockade to the reappearance of pain.

The mean duration of analgesia (sensory block) was longer in Group II(740.48±21min) and Group III(760.65±30.87min) as compared to group (622.87± 37 min) versus 557.25 ± 58.99 min), which was highly statistically significant(<0.01)[Fig.1]

Figure 1 : DURATION OF SENSORY AND MOTOR BLOCK



The systolic blood pressure, diastolic blood pressure, mean arterial pressure, and heart rate showed no significant differences among three groups without any appreciable side effects Side Effects: None of our patients complained of any side effects nor any sign of toxicity was visible in both the groups during the study period.

DISCUSSION

Supraclavicular blocks are performed at the level of the brachial plexus trunks. Here, almost the entire sensory, motor and sympathetic innervations of the upper extremity are carried in just three nerve structures (trunks), confined to a very small surface area. Consequently, typical features of this block include rapid onset, predictable and dense anesthesia along with its high success rate. Local anesthetics alone for supraclavicular brachial plexus block provide good operative conditions but have a shorter duration of postoperative analgesia. Hence various drugs such as opioids,[3] clonidine,[4] neostigmine, dexamethasone,[5] midazolam,[6-8] sufentanil,[7] etc., were used as adjuvant with local anesthetics in brachial plexus block to achieve quick, dense and prolonged block, but the results are either inconclusive or associated with side-effects. Ropivacaine provided better operating conditions, but the duration of analgesia is rarely maintained for more than 4-6 h. Addition of steroid to local anesthetics eff ectively and significantly prolongs the duration of analgesia Corticosteroids have all been studied previously in an attempt to prolong the duration of analgesia after peripheral nerve blockade with varying degrees of success.[8,9] However, the glucocorticoid dexamethasone appears to be effective in a small number of preclinical[10,11] and clinical[12] studies. More recent studies indicate that 8 mg dexamethasone added to perineural local anesthetic injections augment the duration of peripheral nerve block analgesia.[13] Dexamethasone is very potent and highly selective glucocorticoid, its potency is about 40 times that of hydrocortisone. Clinical uses of dexamethasone are for treatment of many inflammatory and autoimmune condition Use of steroids as adjuvant to local anaesthetic drug in brachial plexus block is gaining popularity. Steroids have nerve block prolonging effects by blocking transmission of nociceptive myelinated c-fibres and suppressing ectopic neuronal discharge. They are also thought to alter the function of potassium channels in the excitable cells. Thus, dexamethasone was selected as an adjuvant to local anaesthetic (ropivacaine) in this study because it has been reported to prolong duration of action of local anaesthetics with no respiratory depression [4].

In the present randomized, double blinded study, on comparison of heart rates, systolic and diastolic blood pressure in all the groups at different time intervals, no statistically significant difference was observed. None of the patients had bradycardia or tachycardia, hypertension or hypotension following administration of dexamethasone along with local anaesthetic agent. Our findings corroborated with that of Choi et al., Persec et al., and Shreshtha et al., who also found no significant difference in haemodynamic parameters on addition of dexamethasone to LA [14,15,16]. Despite the concern surrounding the 'off-label' use of perineural adjuvants,[17] the safety profile of dexamethasone is promising. None of our study patient complained of neurotoxicity or any other complaints attributable to dexamethasone, although our sample size was insufficient to detect rare outcomes and we did not follow our patients beyond 24 h.

Shrestha et al., Islam et al., and Biradar et al.[11-12] found that addition of dexamethasone leads to significantly faster onset of action and prolonged duration of analgesia for brachial plexus block, without any unwanted side effects [8]. However, Movafegh et al., observed that the onset times of sensory and motor block were similar on adding dexamethasone to Lidocaine in Axillary Brachial Plexus Blockade [14]. But the duration of sensory (242±76 versus 98±33 min) and motor (310±81 versus 130±31 min) blockade were significantly longer in thedexamethasone than in the control group ($p < 0.01$).Similarly in our study,we also observed that onset of block was similar to control group but the duration was significantly prolonged in patients receiving dexamethasone.

Our study is also corroborated with Tandoc MN et al 2011., showed in a prospective randomized study in patients undergoing shoulder surgery using interscalene block with 0.5% bupivacaine (40 mL) were assigned randomly to one of three groups: control patients, "Group C," who received no additive; low dose,(Group L) who received additional dexamethasone 4 mg; and high dose, (Group H) who received dexamethasone 8 mg in addition to 0.5% bupivacaine. Postoperative analgesia was assessed. It was concluded that the addition of dexamethasone to bupivacaine significantly prolonged the duration of the motor block and improved the quality of analgesia following interscalene block. There was no difference in the duration of analgesia and motor block between low-dose and high-dose dexamethasone[18]similarly we also found that there is no added advantage of using 8mg of dexamethasone over 4mg of dexamethasone with ropivacaine.

CONCLUSION

The addition of dexamethasone to ropivacaine significantly prolonged the duration of the sensory and motor block and improved the quality of analgesia following supraclavicular block and the requirement of postoperative analgesia was much reduced.There was no difference in the duration of sensory and motor block between low and high dose of dexamethasone.So, dexamethasone 4mg added to ropivacaine is sufficient to prolong the duration of block and higher doses have no added advantage.

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