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A PROSPECTIVE, RANDOMIZED DOUBLE BLIND STUDY TO EVALUATE THE EFFICACY OF INJ. DEXAMETHASONE (8mg) AS AN ADJUVANT TO 0.375% BUPIVACAINE IN ULTRASOUND GUIDED SUPRACLAVICULAR BRACHIAL PLEXUS BLOCK IN PATIENTS UNDERGOING SURGERIES ON THE UPPER LIMB BELOW THE SHOULDER JOINT.

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ABSTRACT

Introduction: The supraclavicular brachial plexus block has proven to be an important, safer and effective alternative to general anesthesia in surgeries of upper extremity. This study was conducted to study the effect of addition of dexamethasone to bupivacaine for brachial plexus blockade in adult patients posted for upper limb surgeries.

Methodology: This prospective randomized double blind clinical study was conducted on 50 patients of age 18 to 70 years and ASA I/II posted for upper limb surgeries below shoulder joint.

Control group S (n=25) received
- Inj. bupivacaine 18ml
- Inj. Normal saline 2ml

Study group D (n=25) received
- Inj. bupivacaine 18ml
- Inj. Dexamethasone 2ml (8mg)

Total volume: 20ml. Both the groups were demographically comparable.

Results: Onset of sensory effect was 3.92±1.41 minutes in group D and 4.56±1.38 minutes in group S. ($p>0.05$)
Onset of motor effect was 6.56±1.32 minutes in group D and 6.84± 0.85 minutes in group S. ($p>0.05$)
Mean duration of sensory blockade was 10.09 ±1.22 hours in group D and 6.53± 0.6 hours in group S. (<0.001)
Mean duration of motor blockade was 8.54±0.92 hours in group D and 7.45±0.74 hours in group S. (<0.001)
Total duration of analgesia was 17.01±1.13 hours in group D and 8.30±1.95 hours in group S ($p<0.001$).

Conclusion: Dexamethasone added to bupivacaine for brachial plexus block did not alter the onset time of sensory or motor blockade but prolonged the duration of sensory and motor blockade along with total duration of postoperative analgesia.

KEYWORDS :

INTRODUCTION

The process of alleviating pain and suffering during surgical procedures with the help of using various modalities of anesthetic techniques and drugs was scientifically known before the middle of nineteenth century, though ingenious methods were used from time to time. Throughout the ages, man has diligently sought for the alleviation of pain. The interventions in anesthetic pharmacology and technique removed the barriers and led to rapid progress in surgical procedures.

The ability to modulate and interrupt the sensory warning, pain anywhere in the nerve pathway forms the basis of peripheral neural blockade. Brachial plexus block is a valuable and safe alternative to general anesthesia in upper limb surgeries.

Peripheral neural blockade has emerged as comprehensive anesthetic care from intraoperative pain management to post operative and chronic pain management. Interrupting the acute pain can help in limiting the development of chronic pain syndromes. Another advantage is that the pain free patient has better mobility.(1,2)

Regional anesthesia works well when local anesthetic is put in the right place in the right volume. The first brachial plexus block was performed under direct visualization after surgical exposure by Halsted in the year 1885. The technique has slowly evolved from landmark guided percutaneous localization of brachial plexus to use of electrical nerve stimulation and ultrasound guidance. The use of ultrasound to guide localization and anesthetizing brachial plexus allows limiting of complications.

Various approaches to brachial plexus block have been used for upper limb surgeries namely:
1.Interscalene approach
2.Supraclavicular approach
3.Infraclavicular approach
4.Axillary approach etc.

Various steroids have been used for this purpose but Dexamethasone, a synthetic glucocorticoid, has highly potent anti-inflammatory property without mineralocorticoid activity. Previous studies have shown that dexamethasone as an adjuvant, have no significant neurotoxicity and elevation of blood glucose concentrations. Various studies have shown that addition of dexamethasone to local anesthetics prolonged duration of blockade in peripheral nerves. These authors believe that there is a causal relationship between suppression of inflammation and remarkably longer duration of action (3,4)

The aim of the study is to evaluate the efficacy of Inj. Dexamethasone (8mg) as adjuvant to 0.375% Bupivacaine in ultrasound guided supraclavicular brachial plexus block in patients undergoing surgeries on the upper limb below the shoulder joint with respect to
1. Onset of sensory blockade and motor blockade
2. Duration of motor blockade & sensory blockade
3. Total Duration of analgesia.

MATERIALS AND METHODS

Study area:
Department of Anesthesiology and Critical care, CARE hospitals, Banjara Hills, Hyderabad.

Study design:
"A Prospective, double blind, randomized comparative study"

Inclusion criteria:
1. Patients of age group 18-70 years.
2. Patients with ASA grade I and II.
3. Patients who are scheduled to undergo Upper limb surgery below shoulder joint (both elective and emergency surgery).

Exclusion criteria:
1. Patients who are not willing to give consent for participation in the study.
2. Patients with:

3. AS A Grade III and IV.
4. Any bleeding disorder and patient on anticoagulants.
5. Severe respiratory disease.
6. Neurological deficit involving brachial plexus.
7. Local infection at the injection site.
8. History of allergy to local anesthetic.
9. History of peptic ulcer disease, uncontrolled diabetes mellitus, hepatic or renal failure (contraindication to steroids).
10. Pregnant women.

Duration of study:
The duration of study was from June 2017 to November 2017

Sample size:
A total of 50 patients belonging to ASA I/II, were enrolled in the study to satisfy the sample power of 85%, and a 95% Confidence interval (alpha-0.05).

Sampling Technique & Study Groups:
Patients were randomly allocated using shuffled sealed opaque envelope technique into one of the following two groups depending upon the drugs they were to receive for brachial plexus block.

Group- D: (n=25) Patients received -
- Inj. bupivacaine 0.375% 18 ml
- Inj. Dexamethasone 8mg 2ml

Total volume made up to 20ml.

Group- S: (n=25) Patients received -
- Inj. bupivacaine 0.375% 18ml
- Inj. Normal Saline 2ml.

Total volume made up to 20ml.

Double Blinding Technique:
The study drugs were prepared by an anesthesiologist who was involved in randomization of the patient and not involved further in the study. Thus the observer and the patient were blinded to the study drug.

PROCEDURE INSIDE OT:
After all essential monitors were applied, a wide bore I.V. cannula was secured and an infusion of Dextrose Normal Saline was started at a rate of 10ml/kg body weight.

Premedication: Inj. Ondansetron 0.1mg/kg IV, Inj. Midazolam 0.01mg/kg IV.

Procedure of the supracla vicular block (5,6):
The patient was placed in supine position with head rotated towards the non operative side. The area surrounding the clavicle on the desired site was sufficiently prepared by cleaning with antiseptic solution and sterile drape. The transducer probe was covered with Tegaderm(3M) ,dipped in povidone iodine solution and positioned in the transverse plane immediately superior to the clavicle at approximately its midpoint. The transducer was tilted caudally to obtain a cross-sectional view of the subclavian artery. The brachial plexus was seen as a collection of hypoechoic oval structures lateral and superficial to the artery.

PARAMETERS MONITORED:
The following parameters were monitored after giving the block.
1. Sensory block:
   a) Onset time
   b) Peak time
   c) Total duration
2. Motor block:
   a) Onset time
   b) Peak time
   c) Total duration
3. Total duration of post operative analgesia.
4. Haemodynamic parameters: Change in Heart Rate (HR), Systolic Blood pressure (SBP), Diastolic blood pressure (DBP), Mean arterial pressure (MAP), oxygen saturation (SpO2), Respiratory rate and Electrocardiogram were monitored.
5. Side effects and complications like pneumothorax, intra-arterial injection, hematoma, Horner's syndrome, bradycardia, and hypotension.

OBSERVATIONS AND RESULTS

Table 1 Demo Graphic Data

Parameter	GroupD	GroupS	Pvalue
Number of patients	25	25	
Age(in years,Mean±SD)	34.24±13.04	34.76±13.93	>0.05
Sex(Male:Female)	19:6	17:8	>0.05
Weight(in kg,Mean±SD)	61.16±6.63	60.52±4.64	>0.05
AS A status(I:II)	18:7	18:7	0.05

The number of patients in either group were 25.The mean age of patients was 34.24± 13.04 years in Group D and 34.76±13.93 years in Group S (P value=Not Significant). The ratio of Male to Female was 19:6 in Group D and 17:8 in Group S (P value=Not Significant). The mean weight of patients was 61.6±6.63kg in Group D and 60.52±4.64k g in Group S .The ratio of ASA I:II status of patients was 18:7 in both Group S and Group D (P value=Not Significant).Thus both the groups were comparable to each other with out significant difference.

Table 2 Onset Time Of Sensory Block

On set Time (inminutes)	GroupD(n)	GroupS(n)	P-Value
1-2	7	3	p>0.05
2-4	6	7	
4-6	12	15	
6-8	0	0	
8-10	0	0	
10-12	0	0	
Mean±SD	3.92±1.41	4.56±1.38	

Table 3 Peak Effect Time Of Sensory Block

Time(inminutes)	GroupD(n)	GroupS(n)	Pvalue
4-6	2	0	p>0.05
6-8	11	9	
8-10	12	15	
10-12	0	1	
12-14	0	0	
14-16	0	0	
Mean±SD	8.36±1.35	9.00±1.08	

Table 4 Total Duration Of Sensory Block

Time in hours	Group D(n)	Group S(n)	Pvalue
4-6	0	9	<0.001
6-8	0	15	
8-10	15	1	
10-12	9	0	
12-14	1	0	
Mean±SD	10.09±1.22	6.53±0.64	

The mean duration of motor block was 8.45 ± 0.921 hrs in group D and 7.45± 0.74hrs in group S the p value being < 0.01. Thus the total duration of motor block was significantly prolonged in group D compared to group S.

The total duration of postoperative analgesia was 17.01 ±1.13 hrs in group D and 8.30±1.95 hrs. in Group S, the p value being < 0.001. Thus total duration of postoperative analgesia was significantly longer in group D patients compared to Group S patients.

(VAS SCORE ≥ 4) : On inter – group comparison:
By the end of 6th hour: 7 patients (28%) required rescue analgesia in Group S while none of the patients required rescue analgesia in group D.

By the end of 7th hour: 14 patients (56%) in Group S required rescue analgesia none of the patients required rescue analgesia in group D.

By the end of 12th hour: 25 patients in Group S (100%) required rescue analgesia and none of the patients in group D.

By the end of 16 hours: Only 7 patients (28%) required rescue analgesia in group D. All patients in Group S (100%) required rescue analgesia.

By the end of 18 hours: Only 19 patients (76%) required rescue analgesia in group D. All patients in Group S (100%) required rescue analgesia.

By the end of 24 hours : 25 patients (100%) required rescue analgesia in group D.

Thus, rescue analgesia started from 6th hour post – operatively in Group S and at the endof 12th hour all patients in Group S had received their rescue analgesia.

While in group D, rescue analgesia started from 16th hour post – operatively and at the end of 24 hours all 25 patients required rescue analgesia.

Thus, requirement of rescue analgesia was much earlier in Group S as compared to group D (p 0.05=significant).

DISCUSSION

A wide variety of receptors mediate anti-nociception on peripheral sensory axons therefore, administering appropriate adjuvants along with local ane sthetics on

Peripheral nerves may have analgesic benefit and reduce systemic side effects. There are a wide variety of adjuvants like opioids, neostigmine, ketamine, sodium bicarbonate , buprenorphine, alpha-2 agonists like clonidine, Dexmedetomidine, steroids etc being used in clinical practice.

In this study we aimed to evaluate additional anesthetic and analgesic effects of the steroid, Dexamethasone along with local anesthetic in brachial plexus block.

This study was a randomized prospective double-blinded comparative study carried out at CARE Hospitals, Banjara hills, Hyderabad

Fifty patients of ASA I and II between ages of 18-70 years were included and divided into two groups (group D and group S). Group S received brachial plexus block with 18ml of 0.375% Bupivacaine with 2ml of saline and Group D received 18ml of 0.375% Bupivacaine combined with Dexamethasone 8mg(2ml).

Age, weight and Sex have been shown to be comparable in both groups using student's t-test.

The exact dose of dexamethasone to be used in peripheral nerve block has not been described. Dexamethasone was used in doses of 4mg and 8mg and was found to be safe without any adverse effects.

In Movafegh A et al[7] (2006), Biradar et al[8] (2013), El Hamid et al[9] (2016) Akkaya et al[10] 2014, have used 8mg of Dexamethasone without any side effects. Hence 8 mg dexamethasone has been used as an adjuvant in supraclavicular brachial plexus block in this study.

CONCLUSION

We conclude from our study that, bupivacaine 0.375% with dexamethasone (8mg) when compared to bupivacaine 0.375% alone in supraclavicular brachial plexus block showed:

1. Prolonged duration of sensory and motor block.
2. Prolonged duration of postoperative analgesia.
3. No difference in onset and peak effect time of both sensory and motor block between the groups.
4. No incidence of complication like pneumothorax, hypotension, and bradycardia were observed in either group.

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