ORIGINAL RESEARCH PAPER

Anaesthesiology

"COMPARISON BETWEEN TRAMADOL AND DEXAMETHASONE AS AN ADJUVANT TO BUPIVACAINE IN SUPRACLAVICULAR BRACHIAL PLEXUS BLOCK: A RANDOMIZED CLINICAL STUDY"

KEY WORDS: Analgesia, Brachial plexus, Dexamethasone, Tramadol.

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ABSTRACT

Introduction: Brachial plexus block provides a superior and workable option to general anaesthesia for both routine and urgent upper limb procedures. The brachial plexus is densely packed at the level of the supraclavicular approach, which permits a single point injection that results in a dense sensory-motor blockage of the upper limb. The duration of sensory-motor blockage can be increased and its onset can be hastened by using local anaesthetics in conjunction with adjuvants. **Objective:** To compare the efficacy of dexamethasone and tramadol as adjuvants to bupivacaine in supraclavicular brachial plexus block for upper limb surgeries in terms of onset and duration of sensory-motor block and to observe any complication associated with block. **Material and method:** This double-blind, randomised clinical study was conducted on 60 patients, aged 18 to 65 years, posted for upper limb surgeries with ASA grade I and II. The patients were randomly divided into two groups. **Group D:** Bupivacaine 0.5%(1.5mg/kg)+ Dexamethasone (8mg), **Group T:** Bupivacaine 0.5% (1.5mg/kg)+ Tramadol (1mg/kg). The parameters observed were: onset and duration of sensory and motor block ,any intraoperative complication. **Results:** In present study,there is no statistical significant difference in their demographic parameter Age, Gender, ASA grading and weight among two groups. The mean onset time of sensory and motor block was faster in group D (5.53± 2.65 ,9.07 ± 2.79min) as compared to group T (11.03 ± 4.57, 11.77 ± 4.93 min) . The mean duration of sensory and motor block was prolonged in Group D (616.13 ±53.02, 557.77± 63.78 min) as compared to Group T(507.97 ±25.72, 417.13 ± 22.73 min). The duration of post-operative analgesia was longer in Group D (720min) as compared to Group T (540min). No adverse effect was observed during this study. **Conclusion:** Dexamethasone is more effective than Tramadol as an adjuvant to 0.5% bupivacaine 1.5mg/kg in Supraclavicular brachial plexus block.

INTRODUCTION

The purpose of this study is to compare the efficacy of Tramadol (1mg/kg) vs Dexamethasone (8mg) as an adjuvant to 0.5% 1.5mg/kg Bupivacaine in supraclavicular Brachial plexus block using nerve stimulation technique with respect to:

1. Primary Aim

a) To compare the onset and duration of sensory & motor blockade.

b) To compare the degree of intraoperative and post-operative analgesia.

2. The secondary aim

a) To Study intraoperative and post-operative complications.

b)To assess the patient's satisfaction with the block performed.

In contrast to general anaesthesia, the brachial plexus regional anaesthesia makes surgery possible on conscious patients by providing perfect intraoperative anaesthesia, analgesia, and muscle relaxation with fewer side effects, a reduced need for postoperative opioids, and a shorter hospital stay.**[5,7,3]**There are various approaches to block the brachial plexus, including the interscalene block(in the neck region), supraclavicular block(immediately above the clavicle),infraclavicular block(below the clavicle), and axillary block(in the axilla).**[6]**

Brachial plexus blockade without adjuvant abolishes the pain, but due to short duration, the challenge remains to increase the duration of analgesia with decreasing side effects. Various drugs have been used as an adjuvants with local anaesthetic to achieve quick, dense and prolonged brachial plexus block.[8] Morphine, pethidine, clonidine, dexmedetomidine, butorphanol, and midazolam are commonly used in conjunction with local anaesthetics for this purpose.Because morphine, pethidine, and butorphanol have been linked to side effects such as respiratory depression, heavy sedation, and a psychomimetic effect,drugs with few side effects are always looked for.

Dexamethasone has been studied as a local anesthetic adjuvant for peripheral nerve block. Dexamethasone attenuate the inflammatory mediators, reducing ectopic neuronal discharge and inhibit the potassium channel mediated discharge of nociceptive c fibers.It is effectively and widely administered for prophylaxis against post-operative nausea and vomiting. Dexamethasone, combined with bupivacaine prolonged the duration of both sensory and motor block.[11]

Similarly, Tramadol has been used as an adjunct to local anesthetic in brachial plexus block to extend the duration of post-op analgesia,as respiratory depression is not a major problem with their use.Tramadol is 4- 2phenyl-piperidine. Tramadol is an analgesic with mixed μ Opioid and non Opioid activity. It inhibits the reuptake of norepinephrine and serotonin from the nerve ending and potentiates the local anesthetics when mixed together in the peripheral nerve block. Tramadol is a unique opioid with two modes of action for inhibition of pain, i.e., an Opioid action mediated by the μ receptor and a non-opioid action mediated by α2-adrenergic and serotoninergic activity. [12] The monoaminergic activity of Tramadol inhibits the descending pain pathways, resulting in the suppression of nociceptive transmission at the spinal level. Tramadol also exhibits LA properties by blocking K+ channels. Clinically, intradermal administration of Tramadol provides local anesthesia for minor skin procedures. Many studies have characterized the effects of Tramadol as an adjuvant to LA in brachial plexus block. It has less respiratory depressant effect due to weak μ receptor.[12]

In this study, tramadol and dexamethasone were chosen as adjuvants to bupivacaine in brachial plexus block as they hasten the onset,prolong the duration of sensory ,motor blockade and post-operative analgesia without any significant side effects.[2]

MATERIALS AND METHODS

This double-blind, randomised clinical study was conducted at Rajindra hostpital Patiala from 16/9/2021 to 17/11/2022 . The ethics committee approval (No BFUHS/2K21p-TH/14752 dated 15/9/2021)and written informed consent from patients were obtained.

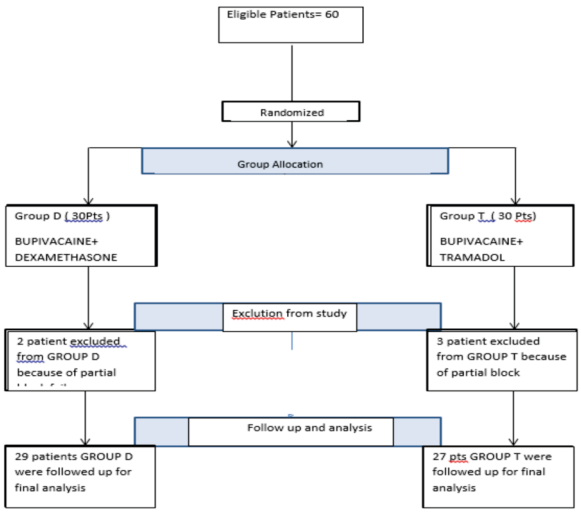
Inclusion criteria –

This study included 60 patients, aged 18 to 65 years of either gender, posted for upper limb surgeries with ASA grade I and II.

Exclusion criteria –

Patients refusal, history of allergy to multiple drugs, infection at the site injection and coagulopathy.

Table 1 : Consort Chart



60 patients were randomly divided into 2 groups of 30 each using computer generated randomization.

Group D: Bupivacaine 0.5%(1.5mg/kg) Plus Dexame thasone(8mg)

Group T: Bupivacaine 0.5% (1.5mg/kg) Plus Tramadol (1mg/kg)

Depending on the group assigned, an assistant who was not involved in the study would offer the investigator a syringe labelled with the patient's name and carrying the appropriate medication.

The parameters were then observed by a separate observer not involved in the investigation. The study's blinding was removed at the conclusion.

Pre anaesthetic check-up including detailed history, airway examination and thorough systemic examination was done on every patient. Fasting protocol was followed. Pre-medication with midazolam 0.02 mg/kg was given intravenously.

Anaesthesia technique

On the day of surgery, after shifting the patient to the operating room,all standard monitors were connected, which included NIBP, 5 lead ECG, pulse oximeter for monitoring vitals . Intravenous line was secured for intravenous fluid administration.

The brachial plexus block was carried out after thorough explanation of the procedure and emphasising the need for patient cooperation. Supraclavicular blockade was performed in supine position, with the head turned to the opposite side and the arm placed medially in adducted position. Skin and subcutaneous tissue was infiltrated with 2ml of 2% lignocaine at a point lateral to the subclavian artery where the clavicular head of sternocleidomastoid muscle joins the superior aspect of the clavicle. A 5cm 22G Insulated needle connected to a nerve stimulator, programmed with current 1.0 mA and frequency 2 Hz, was inserted through the wheal caudally and posteriorly until a muscle distal to deltoid was stimulated. Needle is further advanced slowly till twitches of hand and finger were achieved. Current was progressively reduced to 0.5 mA and if twitches continue, tramadol (1mg/kg) as an adjuvant to 1.5mg/kg 0.5% Bupivacaine is given in Group T and dexamethasone (8mg) as an adjuvant to 1.5mg/kg 0.5% bupivacaine is given in Group D .Drug was injected slowly with intermittent aspiration.[9,10]

Following parameters were observed after injecting anesthetic solution:

Primary Outcomes

1) Onset of sensory block:

Sensory onset was considered from the end of local anaesthetic administration to the establishment of score 1 on 3-point scale on all major peripheral nerves (ulnar, radial, musculocutaneous, and median). Complete Sensory block was considered as establishment of score 2 on 3-point scale which was assessed by pinprick using the blunt end of a 27-gauge needle at 2,4,6,8,10,15,20,25 and 30 minutes. Sensory block was graded with 3-point scale.

3-Pointscale[1]

- 0- sharp pain on pin prick.
- 1- dull pain on pin prick(Analgesia)
- 2- No pain perception of pin prick(anaesthesia)

2) Onset of motor block:

Motor onset is defined as the time interval from the administration of local anaesthetic to decreased motor strength or ability to move fingers only i.e. score 1 on Modified Bromage Scale. Complete motor block is defined as inability to move fingers .i.e .score 2 on Modified Bromage Scale. Motor block was measured at 2, 4, 6,8,10,15,20,25 and 30 minutes. Motor functions assessment was done with Modified Bromage Scale:

Modified BromageScale[4]

0- no block (normal function with full flexion and extension of elbow, wrist and fingers)

1- paresis (decreased motor strength with ability to move fingers only)

2- paralysis (complete motor block with inability to move fingers)(flexion at the elbow –musculocutaneous nerve, thumb abduction- radial nerve,thumb adduction- ulnar nerve, wrist flexion- median nerve)

3) Duration of sensory block:

The duration of sensory block was defined as the time interval between the end of local anaesthetic administration and the complete resolution of anaesthesia on all nerves (score 0 on 3-point scale). Patient was assessed every hour for pin prick sensation of the dermatome of the nerves anaesthetized.

4) Duration of motor block:

The duration of motor block is defined as the time interval between the end of administration of local anaesthetic and recovery of complete motor function of hand and forearm (score 0 on Modified Bromage Score). It was assessed and documented every hour.

5) Duration of analgesia

The duration of analgesia was taken from the time of onset of the block to the first complaint of pain (VAS>3). Intra-

operative and post operative pain was assessed using Visual Analogue Scale. Post operative follow up was carried out in the recovery and post operative ward. The duration of analgesia was noted according to 0-10 visual analogue score(VAS).

Visual analogue scale (0-10):
As shown in Fig-1
0- No pain
5-moderate pain
10-maximum pain.

In postoperative cases with (VAS>3), rescue analgesia in the form of non steroidal anti-inflammatory drugs (IM Diclofenac 1-1.5mg/kg) was given. The study was ceased after the first requirement of rescue analgesia.

In secondary outcome, in present study intended to observe intra-operative and post-operative complications as bradycardia, hypotension, hypoxemia, pneumothorax, diaphragmaticpalsy,hornersyndrome,pruritis,nausea and vomiting.

Patient's satisfaction:[13]
It was recorded at the end of the surgery as patient's satisfaction score:
1- Not satisfied, will not come to same hospital for same procedure
2- Satisfied but would have preferred another technique
3- Satisfied but would have preferred more analgesia
4- Well satisfied

Analysis was done in both groups.In our study 70% patient in Group D and 73.3% patients in Group T were well satisfied with block performed i.e score 4, while 30% patient in Group D and 26.7% patient in Group T was well satisfied i.e score 3.

Sample Size Calculation

$$n = \frac{2\,\sigma^2(Z_{1-\alpha/2} + Z_{1-\beta})^2}{\Delta^2} \text{ for each group}$$

The two independent groups to be compared were of equal size n, and were drawn from the population. Sample size was calculated by using the formula:
Alpha =0.05
$Z_{1-\alpha/2} = 1.96$
$Z_{1-\beta}$ =1.28155
Power =1-β =0.90
Sigma=0.39
Delta= 0.35D
$n = 26.09 \sim 26$

As our n=26, so in present study sample size is 30 for each group to increase the power of the study.

Statistical Analysis

RESULTS

The relevant data on each patient was entered into the proforma and also presented in the master chart. Data was compiled with the help of MS-Excel and analysis done with IBM SPSS 22 Version. Descriptive statistics was done for all data and were reported in terms of mean, S.D and percentages. Appropriated statistical tests of comparison were applied. Categorical variables were analyzed with the help of chi square test and Fisher Exact Test.Continuous variables were analyzed with t test and Mann whitney U test where applicable.Statistical significance was taken as p-value< 0.05, and p-value <0.001 was taken as statistically highly significant. The p value> 0.05 was taken as statistically non-significant.The observations were depicted in tables.

Demographic data:
Both groups were comparable in the terms of mean age, gender, ASA grade and weight (p-value was > 0.05) (As shown inTable/Fig 2).

Onset and duration of sensory, motor blockade and duration of Post-operative analgesia were faster in Group D as compared to Group T. These differences were statistically significant.The mean duration of sensory and motor blockade was maximum in Group D as compared to Group T .These differences were statistically significant(As shown inTable/ Fig. 5,6,7,8,9).

Hemodynamic parameters:(As shown in Fig/Table 10)
In our study the average heart rate was found to be 86.06±10.66 beats/min in Group D and 81.03± 10.56 beats/min in Group T.

The mean systolic BP was found to be 116.75±5.36mm of Hg in Group D and 116.88±6.58 mm of Hg in Group T .

The mean diastolic BP was found to be 76.01±5.82 mm of Hg in Group D and 76.37±6.64 mm of Hg in Group T.

The mean arterial blood pressure was found to be 84.38±20.57 mm of Hg in Group D and 84.78±20.99 mm of Hg in Group T.

The mean oxygen saturation was found to be 97.51±0.98% in Group D and 97.60 ±0.96% in Group T .

The mean respiratory rate was found to be 13.79±0.54/minute in Group D and 13.58±0.53/min in Group T.

There was no significant difference between both groups in terms of heart rate,systolic,diastolic and mean BP, oxygen saturation, and respiratory rate.(p value>0.05).

In present study, No episode of bradycardia, hypotension or hypoxemia was observed. Patient was satisfied with block performed.

DISCUSSION

Supraclavicular brachial plexus block is a common regional nerve block used to provide anaesthesia and analgesia for upper extremity surgery. It provides anaesthesia to the entire upper extremity in a quick, dense, and predictable manner. It is the most effective block for all parts of the upper extremity and is performed at the level where all the three trunks are densly packed postero-superior to subclavian artery. Adjuvants have been found to extend the duration of anaesthesia and analgesia. In present study, drugs used are 0.5% bupivacaine (1.5mg/kg) with tramadol(1mg/kg) in Group T and 0.5% bupivacaine (1.5mg/kg) with dexamethasone 8mg in Group D .Dexamethasone inhibits the transmission of nocioceptive C-fibers thus prolongs the duration of local anaesthetic block, whereas Tramadol is an opioid that inhibits the reuptake of norepinephrine and serotonin from nerve endings and thus potentiates the effect of local anaesthetic.

In this study, it is observed that adding dexamethasone to local anaesthetic causes early onset of sensory and motor blockade, as well as prolonging the duration of sensory,motor blockade, and post-operative analgesia when compared to the tramadol group. Our finding are in concordance with study conducted by **Shrestha BR et al. [2],Sudha shah et al. [11] ,Parteek singh et al. [12] and Amar Parkash kataria et al.These studies also concluded that** the onset of sensory-motor blockade was significantly earlier and the duration of blockade was prolonged in dexamethasone containing group as compared to tramadol. Study by **Shrestha BR et al.[2]** concluded that addition of 8mg dexamethasone to 0.5% bupivacaine (2mg/kg) for supraclaviclar plexus block shortens sensory block onset(16.76±2.34min vs 18.47± 2.03min), motor block onset (12.90±1.49min vs 13.93± 1.66min) and extends sensory – motor block duration as

compared to tramadol group.In this study, the drugs studied were 0.5% bupivacaine 2mg/kg+ Dexamethasone 8mg and 0.5% bupivacaine 2mg/kg + Tramadol (1mg/kg). Another study by **Sudha shah et al** [7] also concluded that the duration of analgesia was significantly higher in Group B (bupivacaine 0.5%(2mg/kg)+dexamethasone 0.15mg/kg) as compared to Group A(bupivacaine 0.5% (2mg/kg) + Tramadol(1mg/kg) (1023±161.01min vs 453.47±44.29min). The mean time for onset of a sensory block as well as motor block was significantly less in Group B containing dexamethasone as compared to tramadol group. Study by **Amar parkash kataria et al.**[11] also observed that dexamethasone when used as an adjuvant to bupivacaine decreased the onset of sensory and motor blockade and prolonged the duration of sensory and motor blockade as compared to tramadol group.Study by **Parteek singh et al.**[12] concluded that addition of dexamethasone prolongs the durations of sensory and motor block and duration of analgesia and improves the quality of anesthesia as compared with tramadol when injected with bupivacaine in supraclavicular brachial plexus block.

Both groups were comparable in terms of heart rate, mean arterial blood pressure, respiratory rate.There was no clinical or statistically significant difference amongst any of the groups as the p-value obtained was > 0.05. During the present study, no episode of bradycardia, hypotension, hypoxemia was observed in either of the group.

Limitation(s)

The block was not ultrasound-guided which could have helped use less volume and dosage of the local anaesthetic for achieving an adequate block.As the block was essentially landmark based, some room for inadequacy of block could have been avoided in the setting of more exactness of ultrasound guided approach.

CONCLUSION

The results of the present study conclude that Dexamethasone is more effective than tramadol as an adjuvant to LA (1.5mg/kg 0.5% bupivacaine) in supraclavicular brachial plexus block for upper limb surgeries. Further, the onset of sensory and motor block in the dexamethasone group was significantly faster with prolonged duration of sensory and motor block as compared to Tramadol group.

Table-1:Onset time and Duration of block of sensory, motor block, and duration of post-operative analgesia

Variables	Group D	Group T	Group I vs Group II
Onset of sensory block (in minutes)	5.53 ±2.65	11.03 ± 4.57	<0.001
Onset of motor block (in minutes)	9.07± 2.79	11.77 ± 4.93	<0.001
Duration of sensory block (in minutes)	616.13 ± 53.02	507.97 ±25.72	<0.001
Duration of motor block (in minutes)	557.77 ± 63.78	417.13±22.73	<0.001
Post-operative analgesia(in minutes)	720	540	<0.001

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