Original Article

DOI: 10.7860/JCDR/2023/61135.17599

Anaesthesia Section

Two Dosages of Dexamethasone (2 mg and 4 mg) as Analgesic Adjuvant to Levobupivacaine in Ultrasound-guided Brachial Plexus Block in Upper Limb Surgery- A Randomised Clinical Trial

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ABSTRACT

Introduction: Perineural dexamethasone gives promising results in prolonging duration of analgesia in brachial plexus block. Doses between 1 to 10 mg have been used but the optimum dose is not yet settled.

Aim: To compare the analgesic efficacy of two low doses of dexamethasone in Ultrasonography (USG)-guided brachial plexus block for planned upper limb surgery.

Materials and Methods: A double-blind randomised clinical trial was conducted with 126 adult patients of either sex, randomised in equal numbers to 2 mg and 4 mg dexamethasone groups, the steroid being administered in conjunction with 0.5% levobupivacaine. Time to onset of sensory and motor blocks, duration of analgesia, duration of motor block, total consumption of analgesics in the first 24 hours postoperative period, haemodynamic parameters and features of neurotoxicity were compared. Tramadol 50 mg intravenous was permitted as analgesic. Stastistical Package for Social Sciences (SPSS) Version 24.0 was used for data analysis.

Results: No significant differences in onset of sensory and motor blocks were encountered. Duration of sensory block with 4 mg {median (Interquartile range); 1080 (915-1140) min} clearly exceeded that with 2 mg {840 (720-960) min} (p-value <0.001) dexamethasone. Duration of motor block was also greater with 4 mg dexamethasone {1080 (1020-1170) versus 870 (810-990) min} (p-value <0.001). Total analgesic consumption in first 24 hours was 225 (175-250) mg versus 100 (75-200) mg in 2 mg and 4 mg groups respectively (p-value <0.001). No features of neurotoxicity were encountered in either group.

Conclusion: Perineural dexamethasone 4 mg gives better results as analgesic adjuvant to bupivacaine compared to 2 mg in brachial plexus block for upper limb surgery without increasing adverse effects.

Keywords: Brachial plexus, Clinical trial, Nerve block, Regional anaesthesia

INTRODUCTION

Brachial plexus blocks for upper extremity surgery provide effective analgesia and reduce postoperative opioid consumption. Perineural catheters can improve duration of analgesia from local anaesthetics but carry problems of catheter migration, pump malfunction, leakage, etc., [1]. Therefore, many adjuvants (e.g., clonidine, dexmedetomidine, opioids, epinephrine) are added to the local anaesthetic in single shot regional technique with variable results [2-6].

The corticosteroid dexamethasone, as a non particulate injection, is a promising adjuvant in brachial plexus block and it has been shown that perineural dexamethasone prolongs analgesia by approximately 8-10 hours compared with placebo [7-9]. However, the administration of dexamethasone is not risk free and concerns have been raised regarding hyperglycaemia and surgical site infection [10]. These adverse effects are likely to be dose dependent. Owing to the potential toxicity concern, it may be beneficial to use low doses of dexamethasone, if these provide similar increase in analgesia duration compared to higher doses. Recent meta-analyses have suggested a ceiling dose of 4 mg for perineural administration [8,11].

The issue needs to be explored and settled in various regional blocks. The present study aimed to compare the effects of two relatively low doses (2 mg and 4 mg) of dexamethasone, used as adjuvant to 0.5% levobupivacaine, for supraclavicular brachial plexus block in patients undergoing upper limb orthopaedic surgeries.

MATERIALS AND METHODS

The study was conducted as an academic double blind randomised clinical trial, over one year from October, 2020 to September, 2021, in a tertiary care teaching hospital. The study protocol conformed to the Declaration of Helsinki and was duly approved by the Institutional Ethics Committee (Approval No IPGME&R/IEC/2020/288). The trial is registered with CTRI/2020/08/036177.

Inclusion criteria: Patients of either sex, aged between 18-65 years, of American Society of Anaesthesiologists (ASA) grade I or II, posted for upper limb surgery in the orthopaedics Operation Theatre (OT) under USG-guided supraclavicular brachial plexus block were included.

Exclusion criteria: Patients with coagulopathies (International Normalised Ratio of Prothrombin time >1.5), infection or injury at block site, compromised lung on contralateral side of block (like pneumothorax, haemothorax or pneumonectomy), history of hypersensitivity to local anaesthetics or dexamethasone and those not comfortable with Visual Analog Scale (VAS) scoring were excluded.

Sample size calculation: It was done with nMaster 2.0 software. Data were coded and recorded in Microsoft excel spreadsheet program. SPSS (IBM SPSS Statistics for Windows, Version 24.0. Armonk, NY: IBM Corp.) software was used for data analysis. Routine descriptive statistics have been presented, namely mean and standard deviation for numerical variables that are normally distributed, median and interquartile range for skewed variables

and counts and percentages for categorical variables. Intergroup comparisons for continuously distributed data were made using independent sample t-test. For skewed data, Mann-Whitney U test was used. Categorical variables were compared by Chi-squared test or Fisher's-exact test as appropriate. Statistical significance was set at p-value <0.05 for all comparisons.

Total 126 patients were screened, of whom one was excluded from data collection as the block failed. During the preanaesthetic check up, written informed consent was sought from eligible patients and they were familiarised with the 10 cm VAS for pain assessment. The left extremity of the graduated horizontal VAS scale represented complete absence of pain and the right extremity represented the worst pain imaginable.

Subjects were randomised into two study groups (Group A: 2 mg dexamethasone and Group B: 4 mg dexamethasone) using a computer generated random number list. Allocation concealment was done by the Serially Numbered Opaque Sealed Envelope (SNOSE) technique. The trial participants and investigators were both blinded to exact dose administered. Once an eligible patient was on the OT table and randomised, injection syringes were prepared by an OT technician with access to the randomisation code and specially instructed in this matter so that the dosing was not apparent to the anaesthesiologist investigator. The syringes were visually identical and contained study medication in 2 mL volume, namely levobupivacaine 0.5% with either 2 mg or 4 mg of the steroid. Hospital supply dexamethasone was used, each 1 mL containing dexamethasone sodium phosphate 4 mg along with methyl paraben (0.15% w/v) and propyl paraben (0.02% w/v). These preservatives are not known to cause neurotoxicity in the low concentrations used [12]. In the preoperative holding area, i.v. channel was made with 18G cannula and Electrocardiogram (ECG), Non Invasive Blood Pressure (NIBP) and pulse oximeter probes were attached, and the brachial plexus block procedure was explained to the patient.

Study Procedure

The patient was positioned supine on the OT table with head turned slightly to contralateral side, ipsilateral arm adducted, and shoulder depressed. The local site was prepared under aseptic precaution. USG machine was checked with a high frequency (0-18 MHz) linear array probe. Clavicle is the landmark for USG probe placement which was positioned in the supraclavicular fossa just superior to the midpoint of the clavicle. The probe was moved to locate the pulsating subclavian artery (anechoic round structure) and the area lateral and superior to the artery was explored to visualise the brachial plexus (bundle of hypoechoic round nodules). First rib and parietal pleura were seen as linear hyperechoic structure immediately lateral and deep to the artery. Anterior or posterior to the first rib was the hyperechoic pleura, with lung tissue deep to it. This structure was confirmed by observing a 'sliding' motion of the visceral pleura in synchrony with patient's respiration. The brachial plexus was typically visualised at 1-2 cm depth. Lignocaine 1% was infiltrated into the skin (2 mL) before peripheral nerve stimulation needle insertion. The needle was inserted from lateral side of the probe (1 cm) perpendicular to the skin to penetrate it and then at a shallow angle under the probe. It was advanced under USG guidance by in plane approach to reach the desired location. After eliciting desired motor response of the fingers at 0.5 mA and after repeated negative aspiration of blood, the local anaesthetic along with the adjuvant was injected. The drug was seen to spread around the brachial plexus.

Sensory block- The time of onset of sensory block was assessed by pin prick sensation every two minutes in the dermatomal areas supplied by three main nerves (median nerve, ulnar nerve, radial nerve) and graded as

- 0-no perception;
- 1-diminished perception; and
- 2-normal perception.

Motor block- Its onset was evaluated by loss of the ability to flex the hand and elbow against gravity every five minutes. Duration of motor block was recorded as duration to first movement, either abduction of the arm or ability to overcome gravity.

Duration of analgesia- It was determined as the time to first rescue analgesic within first 24 hours postoperative period, with VAS scoring being done every four hours. Ward nurse was instructed to give tramadol 50 mg by i.v. bolus, either when patient demanded or when the VAS score was found to be four. The total consumption of analgesic (tramadol) in first 24 hours postoperative period was also recorded. No other rescue analgesic was used.

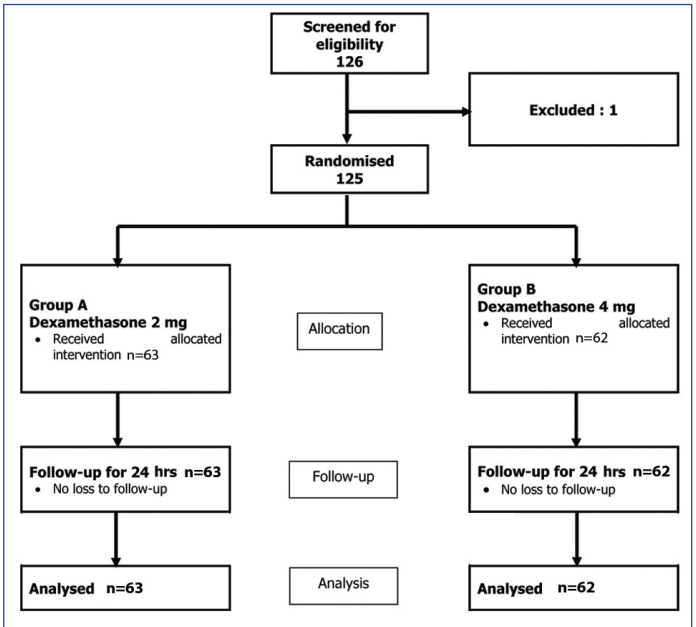
Haemodynamic parameters- Here, heart rate, systolic and diastolic blood pressure were recorded at four hours intervals for 24 hours and features of neurotoxicity (neuropathic pain, paresthesia, muscle weakness) were also assessed till 24 hours.

STATISTICAL ANALYSIS

It was calculated that 63 subjects would be required per group in order to detect a difference of 60 minutes (the minimum difference considered clinically meaningful) in this parameter between groups, with 80% power and 5% probability of type I error. This calculation assumed standard deviation of 120 minutes for the duration of postoperative analgesia (based on our earlier experience) and two-sided testing.

RESULTS

Total 126 patients were screened, of whom one was excluded from data collection as the block failed and general anaesthesia was given to the patient in group B. [Table/Fig-1] depicts the flow of patients through a Consolidated Standards of Reporting Trials (CONSORT) style flow diagram.



[Table/Fig-1]: Flowchart showing patient disposal in the study.

The baseline clinical and demographic parameters of the patients are depicted in [Table/Fig-2]. Evidently, the parameters were evenly matched at baseline.

From [Table/Fig-3] it is seen that there was no significant difference between the groups in terms of onset of sensory block as well as motor block. However, the duration of analgesia, as also duration of motor blockade, were significantly greater in group B. In terms of median values, analgesia duration was 360 minutes longer, while

Parameters	Group A (n=63)	Group B (n=62)	p-value
Age (years)			
Range	19-60	20-56	0.267
Mean±SD	38.4±11.66	36.3±9.47	
Median (IQR)	40.0 (28.0-46.0)	35.5 (29.0-42.0)	
Gender			
Male	32 (50.79%)	33 (53.23%)	0.859
Female	31 (43.21%)	29 (46.77%)	
ASA grade			
I	29 (46.03%)	30 (48.39%)	0.858
II	34 (53.97%)	32 (51.61%)	
Surgery type			
ORIF Left condyle	5 (7.94%)	6 (9.68%)	1.000
ORIF Left radius	17 (26.98%)	13 (20.97%)	
ORIF Left ulna	9 (14.29%)	6 (9.68%)	
ORIF Right both bones forearm	10 (15.87%)	9 (14.52%)	
ORIF Right condyle	9 (14.29%)	9 (14.52%)	
ORIF Right radius	6 (9.52%)	8 (12.90%)	
ORIF Right ulna	7 (11.11%)	11 (17.74%)	
Duration of surgery (minutes)			
Range	85.0-125.0	80.0-125.0	0.990
Mean±SD	103.2±11.37	103.2±11.31	
Median (IQR)	100.0 (95.0-110.0)	100.0 (95.0-110.0)	

[Table/Fig-2]: Comparison of demographic and baseline characteristics between study groups.
• ASA: American society of anaesthesiologists; IQR: Interquartile range; ORIF: Open reduction and internal fixation; SD: Standard deviation
• p-value in the last column is from independent samples t-test for age, Mann-Whitney U test for Duration of surgery, Fisher's-exact test for gender and ASA grade and Pearson's Chi-square test for surgery type; p-value <0.05 was considered to be significant

motor blockade was 210 minutes longer in the group B. The total rescue analgesic consumption is also summarised in [Table/Fig-3]. This was significantly lower in the higher dose dexamethasone group.

Parameters	Group A (n=63)	Group B (n=62)	p-value
Onset of sensory block (min)			
Range	5-12	5-12	0.577
Mean±SD	8.2±1.67	8.4±1.58	
Median (IQR)	8.0 (7.0-10.0)	8.0 (7.3-10.0)	
Onset of motor block (min)			
Range	10-18	10-18	0.229
Mean±SD	14.2±1.70	13.9±1.48	
Median (IQR)	15.0 (14.0-15.0)	14.0 (14.0-15.0)	
Duration of sensory block (min)			
Range	600-1110	810-1260	<0.001
Mean±SD	844.3±130.53	1057.7±123.39	
Median (IQR)	840 (720-960)	1080 (915-1140)	
Duration of motor block (min)			
Range	1660-1080	720-1350	<0.001
Mean±SD	884.1±112.50	1091.1±136.05	
Median (IQR)	870 (810-990)	1080 (1020-1170)	
Total analgesic use in first 24 h (mg)			
Range	75-350	50-250	<0.001
Mean±SD	215.9±65.11	126.6±64.95	
Median (IQR)	225 (175-250)	100 (75-200)	

[Table/Fig-3]: Comparison of block characteristics and additional analgesic use between the two study groups.
IQR: Interquartile range; SD: Standard deviation; p-value in the last column is from Mann-Whitney U test; p-value <0.05 was considered to be significant

There was no pain at four hours and eight hours, hence VAS score was not recorded. The two groups also differed significantly in terms of VAS score for pain from 12 hours following surgery, as shown in [Table/Fig-4].

VAS score for pain in the 24-hour postoperative period	Group A (n=63)	Group B (n=62)	p-value
4 hours			
Mean±SD	-	-	-
8 hours			
Mean±SD	-	-	-
12 hours			
Range	0.0-2.0	0.0-1.0	<0.001
Mean±SD	0.1±0.92	0.1±0.27	
Median (IQR)	1.0 (0.0-2.0)	0.0	
16 hours			
Range	1.0-4.0	0.0-4.0	<0.001
Mean±SD	2.8±1.46	1.0±1.16	
Median (IQR)	4.0 (1.0-4.0)	1.0 (0.0-2.0)	
20 hours			
Range	2.0-6.0	1.0-6.0	<0.001
Mean±SD	4.4±1.93	2.5±1.45	
Median (IQR)	6.0 (2.0-6.0)	2.0 (2.0-4.0)	
24 hours			
Range	4.0-6.0	2.0-6.0	0.043
Mean±SD	4.7±0.95	4.1±1.42	
Median (IQR)	4.0 (4.0-6.0)	4.0 (4.0-6.0)	
p-value for within group comparison over time	<0.001	<0.001	

[Table/Fig-4]: Change in Visual Analog Scale (VAS) score for pain in the study groups over time.
• VAS: Visual analog scale; SD: Standard deviation; IQR: Interquartile range
• Pain was absent in both groups for the first 8 postoperative hours
• p-value in the last column (intergroup comparison) is from Mann-Whitney U test
• p-value for within group comparison is from Friedman's analysis of variance; p-value <0.05 was considered to be significant

Heart rate and systolic blood pressure were essentially comparable between the two study groups throughout the duration of the study, while diastolic blood pressure was 4-6 mm lower in the group B (but well within the clinically normal range) for up to 150 minutes after surgery. These figures have not been shown. No neurological adverse effects were encountered in either group.

DISCUSSION

Perineural dexamethasone was first used clinically more than a decade ago and subsequently its use is supported by a myriad of clinical trials [13]. Recent reviews have suggested that perineural dexamethasone, compared to placebo, prolongs the duration of analgesia by over eight hours, when combined with long acting local anaesthetics, enabling patients a pain-free postoperative night [14,15]. The mechanism of action for this prolongation of block is not fully understood, but suggestions include a secondary effect of stimulation of glucocorticoid receptors located in neurons and increased expression of the inhibitory K^+-channels and thereby decreased excitability and transmission in nociceptive unmyelinated C fibres. It is also possible that part of the effect is mediated via localised vasoconstriction or systemic anti-inflammatory effects after absorption through the vasculature [15]. The meta-analysis by Kirkham KR et al., suggests, but does not confirm, a ceiling dose of 4 mg for perineural administration owing to potential neurotoxicity concerns [11]. The present study explored, through head-to-head comparison, this ceiling dose and half this dose to see whether the latter is equally effective, which would mean a further reduction in the neurotoxicity risk [16]. Levobupivacaine was a logical choice of local anaesthetic as it is long acting per se, has better safety profile than bupivacaine and has no issues of pharmaceutical incompatibility when mixed with dexamethasone.

Principal findings of this study were that 4 mg dexamethasone, compared to 2 mg, significantly increased duration of analgesia and motor blockade without appreciable difference in onset time of blocks, and decreased postoperative analgesic requirement in first 24 hours. Haemodynamic parameters were not significantly affected, and no neurotoxicity was encountered in either group.

Albrecht E et al., studied four doses of perineural dexamethasone-1,2,3 and 4 mg-together with 20 mL 0.5% ropivacaine for USG-guided interscalene brachial plexus block in shoulder arthroscopy under general anaesthesia and found duration of analgesia to be prolonged in a dose dependent manner with the 4 mg dose prolonging the duration by median nearly two hours compared to the 2 mg dose [16]. In the present study the sensory block was prolonged by median six hours and the motor block by three and a half hours. In contrast, Liu J et al., observed 1,2 and 4 mg doses of dexamethasone prolonged analgesia duration and motor blockade when added to 0.25% bupivacaine for supraclavicular brachial plexus nerve block to a statistically comparable extent [17]. Bravo D et al., performed a multicenter, randomised trial comparing 2,5 and 8 mg of perineural dexamethasone for USG-guided infraclavicular block in 360 patients undergoing upper limb surgery and concluded that these three doses provide clinically equivalent sensorimotor and analgesia duration [18]. The local anaesthetic they used was a combination of 1% lidocaine and 0.25% bupivacaine along with epinephrine 5 µg/mL. Woo JH et al., studied 144 patients undergoing shoulder arthroscopy under interscalene block and found 5 mg dexamethasone as the ceiling dose [19]. Therefore, results of the present study are partly in conformity with earlier studies.

Based on 33 randomised controlled trials, pooling a total of 2138 patients, Kirkham KR et al., in their meta-analysis concluded that 4 mg of perineural dexamethasone represents a ceiling dose that prolongs analgesia duration by a mean period of six and eight hours when combined with short-/intermediate-or long-acting local anaesthetics, respectively [11]. However, they opined that the quality of evidence is not entirely satisfactory and additional data are needed to explore the threshold for this effect, particularly with doses below 4 mg. This study fulfills such requirement and suggests that the 4 mg dose may be better without overt risk of toxicity. No placebo group was included as previous studies have conclusively shown that perineural dexamethasone as an adjuvant prolongs duration of postoperative analgesia in supraclavicular brachial plexus block [7,11,20] and it was considered unethical to do so.

In this study, there was no significant difference between the groups in terms of onset of both sensory and motor blocks. This contrasts with Knezevic NN et al., who in a meta-analysis with 1022 patients found that perineural dexamethasone added to local anaesthetic for brachial plexus block improved pain but delayed the onset of sensory and motor block and prolonged the duration of motor block [21]. Incidentally, they found smaller doses of dexamethasone (4-5 mg) were as effective as higher doses (8-10 mg) in prolonging the duration of postoperative analgesia. Increased duration of motor block with increasing dose of dexamethasone has been previously reported, but it is not clear whether this is a manifestation of local action on the neurons or a systemic effect [22].

The total rescue analgesic (tramadol in this case) used in the first 24 hours after operation, which reflects the quality of analgesia, was significantly less in the 4 mg than in the 2 mg dexamethasone group. VAS score was higher in the latter at 12,16,20 hours after giving the block indicating a better pain reducing effect over time.

Limitation(s)

Although no neurotoxicity was experienced, one important limitation of the study is that all the data were collected up to 24 hours. So, it cannot be concluded that perineural dexamethasone has no neurotoxic effects beyond this point. The dexamethasone used was not preservative free due to non availability of hospital supply. The patients belonged to age group of 18-60 years and therefore the results should not be extrapolated to extremes of age. The assessment of sensory and motor block was based on patient's perception which might have introduced some degree of assessment bias. Finally, point to note is that intravenous dexamethasone could have analgesic effect comparable to perineural injection leaving no need for the latter. Comparative evaluation of these routes of administration is required.

CONCLUSION(S)

This double-blind randomised clinical trial has shown 4 mg adjuvant dexamethasone to be better than 2 mg dose in prolonging postoperative analgesia when combined with 0.5% levobupivacaine for USG-guided supraclavicular brachial plexus block in patients undergoing upper limb surgeries without increasing toxicity.

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PLAGIARISM CHECKING METHODS: [Jain H et al.]
- Plagiarism X-checker: Nov 03, 2022
- Manual Googling: Dec 30, 2022
- iThenticate Software: Jan 06, 2023 (25%)

ETYMOLOGY: Author Origin

AUTHOR DECLARATION:
- Financial or Other Competing Interests: None
- Was Ethics Committee Approval obtained for this study? Yes
- Was informed consent obtained from the subjects involved in the study? Yes
- For any images presented appropriate consent has been obtained from the subjects. NA

Date of Submission: **Nov 01, 2022**
Date of Peer Review: **Dec 24, 2022**
Date of Acceptance: **Jan 07, 2023**
Date of Publishing: **Mar 01, 2023**