DOI: 10.7860/JCDR/2026/82181.22748

Research Protocol

Anaesthesia Section

Evaluate the Effect of Dexmeditomedine as an Adjuvant to 0.5% Bupivacaine in Ultrasound-guided Axillary Nerve Block: A Research Protocol

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ABSTRACT

Introduction: Effective perioperative pain management is a key component of enhanced recovery in upper limb surgeries. Ultrasound-guided Axillary Brachial Plexus Block (ABPB) is a reliable regional anaesthesia technique. Bupivacaine, a long-acting local anaesthetic, is commonly used for such blocks. Dexmedetomidine, a selective α2-adrenergic agonist, has been suggested to enhance block quality and prolong analgesia when used as an adjuvant.

Need of the study: However, there is limited evidence for forearm fractures comparing the efficacy of dexmedetomidine with bupivacaine versus bupivacaine alone in axillary blocks, highlighting the need for this study to establish its clinical benefit and safety profile.

Aim: To evaluate and compare the effect of dexmedetomidine as an adjunct to 0.5% bupivacaine and 0.5% bupivacaine without dexmedetomidine in ultrasound-guided axillary nerve block for forearm and hand surgeries.

Materials and Methods: A single-blinded randomised controlled study will be conducted at Jawaharlal Nehru Medical College and Acharya Vinoba Bhave Rural Hospital, Sawangi (Wardha), Maharashtra, from October 2025 to October 2026. Patients will be randomly allocated into two groups of 30 each: Group-BD will receive 20 mL of 0.5% bupivacaine with 0.2 mL dexmedetomidine, and Group-B will receive 20 mL of 0.5% bupivacaine with 0.2 mL saline. Sensory and motor block characteristics, duration of analgesia, pain scores, and complications will be recorded and analysed. The data will be analysed using the Shapiro-Wilk test for normality, independent sample t-test or Mann-Whitney U test for group comparisons, Chi-square or Fisher's exact test for categorical data. A p-value <0.05 will be considered statistically significant.

Keywords: Axillary approach, Forearm fracture, Perioperative pain

INTRODUCTION

Pain management is essential to the success of Enhanced Recovery After Surgery (ERAS) pathways, better healing and quicker postoperative recovery. Regional anaesthesia provides targeted pain relief, reducing the need for systemic medication, especially opioids, thereby enhancing patient comfort and satisfaction while minimising side-effects [1]. Regional anaesthesia entails the administration of a local anaesthetic agent in proximity to a peripheral nerve, thereby inhibiting afferent nerve signal transmission to achieve analgesia or anaesthesia. In contrast to general anaesthesia, it preserves the patient's consciousness. This technique offers multiple advantages, including the elimination of airway manipulation, decreased systemic drug exposure and associated adverse effects, expedited postoperative recovery, and superior postoperative analgesia [2].

The axillary approach to brachial plexus block is widely used for forearm and hand surgeries due to its simplicity, reliability, efficacy, and safety. It remains one of the most commonly utilised regional anaesthesia techniques in this context, offering effective and consistent anaesthetic outcomes with a favourable safety profile [3]. The advent of ultrasound guidance has further enhanced the precision and success rates of these blocks, minimising complications. Among the various techniques for brachial plexus blockade, the axillary approach is considered the safest due to its simplicity and consistent effectiveness. Ultrasound-guided ABPB can be performed using two main techniques: the Perivascular (PV) and Perineural (PN) approaches [4].

Bupivacaine, a potent local anaesthetic from the amide group, is known for its long duration of action and is commonly used in regional anaesthesia. Bupivacaine provides longer-lasting and more effective postoperative analgesia [5]. Previously, Ferraro LHC et al., showed that axillary blocks with 0.25% and 0.5% bupivacaine (equal drug mass) had similar plasma peaks, but 0.5% provided faster onset without increasing toxicity risk [6].

Dexmedetomidine is a highly selective α2-adrenergic agonist with sedative, analgesic, and sympatholytic properties. As an adjuvant in regional anaesthesia, it enhances nerve block quality by shortening onset, prolonging duration, and improving analgesia through nerve hyperpolarisation. Its benefits include reduced anaesthetic need, stable haemodynamics, minimal respiratory depression, and better postoperative recovery, making it a valuable and safe clinical adjunct [7]. A previous study revealed that adding dexmedetomidine to levobupivacaine in ABPB significantly shortens the onset time and prolongs both block duration and postoperative analgesia. However, it is associated with a higher incidence of bradycardia [8], highlighting the need for careful monitoring. Also, the study revealed that adding dexmedetomidine to bupivacaine provides faster onset, longer block duration, and prolonged postoperative analgesia with good safety [9].

Ultrasound guidance in axillary nerve blocks offers real-time visualisation, improving accuracy, success rates, and patient satisfaction while reducing complications compared to traditional techniques like nerve stimulation or landmark methods [10].

REVIEW OF LITERATURE

Achieving effective and balanced perioperative analgesia is crucial for enhancing patient comfort, minimising intraoperative stress, and promoting faster postoperative recovery, particularly in upper limb surgeries. Bupivacaine, a long-acting amide local anaesthetic, is

widely preferred due to its extended duration of sensory and motor blockade. Dexmedetomidine, a highly selective α2-adrenergic agonist, has garnered attention as an adjuvant for its ability to improve block quality, expedite onset, and prolong analgesic duration without significant hemodynamic compromise [11]. Hashim RM et al., (2019) compared the effects of dexmedetomidine (Group-DB), ketamine (Group-KB), and fentanyl (Group-FB) as adjuvants to bupivacaine in ultrasound-guided supraclavicular blocks. They found that the dexmedetomidine group exhibited the longest sensory and motor block durations, superior intraoperative analgesia, and more stable haemodynamics. Both dexmedetomidine and ketamine provided better postoperative pain relief compared to fentanyl, highlighting their effectiveness as adjuvants to bupivacaine [12]. Adinarayanan S et al., (2019) assessed dexamethasone (Group-A), dexmedetomidine (Group-B), and saline (Group-C) as adjuvants to bupivacaine in supraclavicular brachial plexus blocks. Their results showed that dexamethasone significantly prolonged sensory and motor block durations compared to dexmedetomidine, while both adjuvants substantially reduced postoperative morphine consumption in comparison to the control group, emphasising their opioid-sparing effects [13]. Manjunatha C et al., (2020) investigated the effects of adding dexmedetomidine to bupivacaine in ultrasound-guided supraclavicular blocks. They discovered that dexmedetomidine not only shortened the onset of sensory and motor blockade but also significantly extended the duration of analgesia, reinforcing its role as a valuable adjuvant for enhancing block efficacy [9].

Similarly, Sane S et al., (2021) demonstrated that the incorporation of dexmedetomidine into bupivacaine for supraclavicular blocks resulted in a quicker onset and longer duration of both sensory and motor blocks, while notably reducing postoperative pain scores, without causing major hemodynamic disturbances [14]. In a recent study, Iyengar SS et al., (2023) compared dexamethasone (Group-A) and dexmedetomidine (Group-B) as adjuvants to bupivacaine in ultrasound-guided infraclavicular blocks. They found that dexmedetomidine achieved a faster sensory onset, while dexamethasone produced longer durations of sensory and motor blocks, extended postoperative analgesia, and fewer drug-related adverse effects, highlighting the complementary benefits of both agents [15].

These findings underscore the importance of evaluating dexmedetomidine as an adjuvant to 0.5% bupivacaine in ultrasound-guided axillary nerve blocks for forearm and hand surgeries [16,17]. This approach is novel when compared to supraclavicular and infraclavicular techniques, providing better haemodynamic safety in the axillary approach. Ultimately, this contributes evidence that can optimise regional anaesthesia protocols for distal upper limb surgeries. This comparative study aims to evaluate the efficacy and safety of dexmedetomidine when combined with 0.5% bupivacaine in ultrasound-guided axillary nerve blocks for the forearm.

Primary Objectives: To evaluate the efficacy and safety of 0.5% bupivacaine with dexmedetomidine in ultrasound-guided axillary nerve blocks for forearm and hand surgeries.

To evaluate the efficacy and safety of 0.5% bupivacaine without dexmedetomidine in ultrasound-guided axillary nerve blocks for forearm and hand surgeries.

Secondary objectives:

To compare the efficacy and safety of 0.5% bupivacaine with and without dexmedetomidine in ultrasound-guided axillary nerve blocks for forearm and hand surgeries.

Null Hypothesis (H_0): Adding dexmedetomidine to 0.5% bupivacaine in ultrasound-guided ABPB has no significant effect on block onset, duration, quality, postoperative analgesia, or complication rates compared to bupivacaine alone.

Alternative Hypothesis (H_1): Adding dexmedetomidine to 0.5% bupivacaine in ultrasound-guided ABPB significantly improves block onset, duration, quality, and postoperative analgesia without increasing complications compared to bupivacaine alone.

MATERIALS AND METHODS

A randomised controlled study will be conducted at Jawaharlal Nehru Medical College and Acharya Vinoba Bhave Rural Hospital, located in Sawangi, Wardha, from October 2025 to October 2026. Patients with upper limb surgery who meet the eligibility requirements will be included in the research. They will receive a thorough explanation of the process and be asked for written agreement. Ethical clearance for the study is obtained from the Institutional Ethics Committee before commencement, with reference number Ref. No. DMIHER(DU)/IEC/2024/193. This study has been submitted for registration with the Clinical Trials Registry - India (CTRI). The reference number is REF/2025/03/101449. The CTRI confirmation number is currently under review and will be updated once issued. Before initiating any study-related procedures, including physical examinations, laboratory investigations, or administration of study-related medications, written informed consent will be obtained from each participant using the specified format. The study's nature, objectives, and significance will be thoroughly explained to both the patients and their families. For each case, all relevant outcome measures and findings will be systematically documented using a standardised proforma sheet.

Inclusion criteria:

1. American Society of Anaesthesiologists (ASA) physical status I and II;
2. Patient undergoing elective forearm and hand surgeries;
3. Patients aged between 18 and 60 years;
4. Patients who are willing to participate in the study.

Exclusion criteria:

1. Patient refusal;
2. Allergy to local anaesthetics and opioids;
3. Local infection at the site of the block;
4. Pregnant women;
5. Severe cardiopulmonary disease;
7. Patients with neurological deficits in the operating arm;
8. Bleeding disorders/patients on anticoagulants.

Sample size calculation:

$$n \geq \{(Z_{1-\alpha/2} + Z_{1-\beta})^2 \times (\sigma_1^2 + \sigma_2^2/r)\} / (\mu_1 - \mu_2)^2$$

Where:

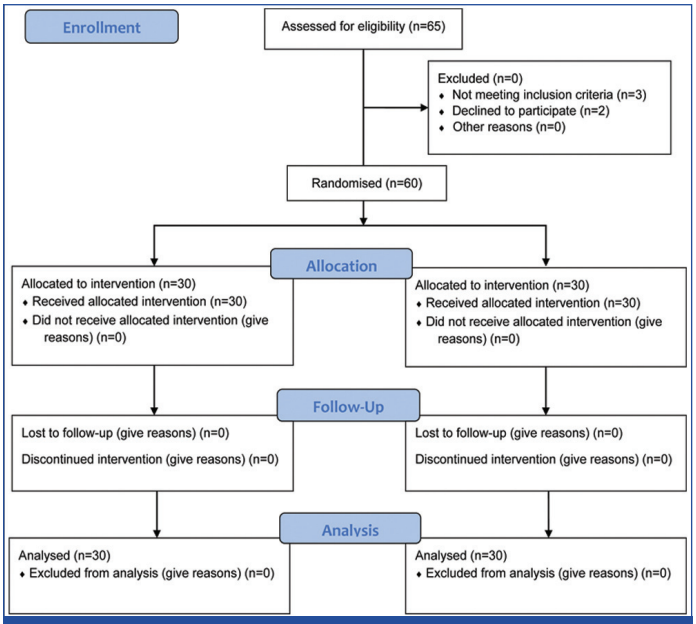
- $Z_{1-\alpha/2}$ is the Z value for the desired alpha level (two-tailed) at 99%
- $Z_{1-\beta}$ is the Z value for the desired power (1 - β) at 10%

Mean Visual Analogue Scale (VAS) score in Group-1 (μ_1): 1.6, Standard deviation in Group-1 (σ_1): 0.56

Mean VAS score in Group-2 (μ_2): 1.03, Standard deviation in Group-2 (σ_2): 0.60.(16)

Minimum sample size needed per group=27. However, with expected 10% attrition, inflate per group by 1/(1–0.10): $n_1 \approx 30$, $n_2 \approx 30$, total ≈ 60.

This study will include two groups, Group-BD and Group-B, with 30 patients in each. Both groups will receive an equal volume of medication, consisting of 20 mL of 0.5% Bupivacaine and 0.2 mL of adjuvant [Table/Fig-1]. Participants will be randomised 1:1 to Group-BD or Group-B using a computer-generated permuted block sequence (variable block sizes) prepared by an independent statistician. Allocation concealment will be ensured with Sequentially Numbered, Opaque, Sealed Envelopes (SNOSE) opened immediately before drug preparation. the patient will be blinded to group allocation. After opening the SNOSE.



[Table/Fig-1]: CONSORT flow diagram.

Demographic variables, including age, sex, weight, height, Body Mass Index (BMI), ASA physical status, and duration of surgery, will be recorded for all participants.

Before the procedure, each patient will undergo a thorough assessment to evaluate allergies, current medications, medical history, and comorbidities. The investigator will explain the entire procedure in understandable terms, address any concerns, and obtain informed written consent. Preoperative preparation will include ensuring adequate fasting status, reviewing medication instructions, and confirming adherence to pre-surgical protocols. During the procedure, the patient will be positioned in the dorsal decubitus posture with the arm abducted and externally rotated for optimal exposure of the axillary region. All essential materials, including the ultrasound machine, sterile probe cover, gloves, antiseptic solution, and local anaesthetic, will be arranged in advance. Continuous monitoring of vital parameters- Electrocardiography (ECG), non-invasive blood pressure, and pulse oximetry- will be maintained throughout. The axillary site will then be cleaned thoroughly using an antiseptic solution to maintain asepsis and minimise the risk of infection.

The procedure will be performed with proper alignment of the patient, operator, and ultrasound machine. A linear ultrasound probe will be placed in the axilla between the pectoralis major and biceps brachii to identify the axillary artery and surrounding nerves.

A 22-G needle will be used to inject 20 mL of 0.5% bupivacaine plus 0.2 mL of either dexmedetomidine (Group-BD) or normal saline (Group-B). The local anaesthetic will be deposited around the musculocutaneous nerve first, followed by anterior and posterior injections around the axillary artery to block the radial, median, and ulnar nerves. The block is assessed after 10-15 minutes, with successful anaesthesia indicated by loss of pinprick sensation and inability to flex or extend the wrist and fingers in the distributions of the median, ulnar, radial, and musculocutaneous nerves [18].

This structured approach will ensure consistent and safe delivery of ABPB with or without the addition of Dexmedetomidine.

During the procedure, all performance parameters will be systematically observed and recorded.

Outcomes

Imaging time will be measured from the moment the ultrasound probe is placed on the skin until all target nerves are clearly visualised.

Needling time will be noted from the first skin puncture to the completion of local anaesthetic injection, and execution time will be calculated as the total duration from probe placement to needle withdrawal. The number of needle passes will be counted each time the needle is completely withdrawn and reinserted or redirected.

Block success rate will be determined by the achievement of complete sensory and motor block within 30 minutes of injection without the need for supplemental anaesthesia.

Sensory block will be tested using a 3-point pinprick scale (2 = normal, 1 = dull, 0 = no sensation) [19].

Motor block assessment [20]: Motor block will be assessed using a modified Bromage scale for the upper limb:

- Grade 0: normal motor function with full extension and flexion of elbow, wrist, and fingers
- Grade 1: decreased motor strength, with ability to move only fingers
- Grade 2: complete motor block with inability to move elbow, wrist, and fingers

A block will be deemed unsuccessful if no analgesia is present at the surgical site 30 minutes post-injection.

The onset and duration of sensory and motor blocks will be evaluated every five minutes up to 30 minutes using a three-point pinprick scale and a modified motor scale until full recovery of sensation and movement

Pain Analysis

Pain will be continuously assessed during surgery using both objective and subjective indicators. The patient's facial expressions and haemodynamic changes, such as tachycardia (increase in heart rate >20% from baseline) will serve as early warning signs of inadequate analgesia. Additionally, pain intensity will be rated using a VAS ranging from 0 (no pain) to 10 (worst imaginable pain). A VAS score greater than 3 or signs of distress during surgery will be considered indicative of block failure, and supplemental analgesia or conversion to general anaesthesia will be provided as required.

If pain persists, moderate i.v. sedation (1-2 mg) and fentanyl (1 mcg/kg) will be administered. If ineffective, general anaesthesia will be given and the block will be considered failed.

During and after surgery, the following will be recorded: 1) Additional systemic medication required; 2) Conversion to general anaesthesia; 3) Adverse effects: local anaesthetic toxicity, Horner's syndrome, seizure, SpO_2 <90%, vascular puncture, dysrhythmias, and pneumothorax. Any vascular puncture detected by aspiration of blood or visible bleeding will be immediately documented. Patients will be closely monitored throughout the procedure and recovery for signs of Local Anaesthetic Systemic Toxicity (LAST), such as perioral numbness, tinnitus, dizziness, or arrhythmia, to ensure procedural safety and effectiveness [18,21].

A 24-hour follow-up to assess for complications like persistent paraesthesia or pneumothorax.

STATISTICAL ANALYSIS

Data will be analysed using R Studio version 4.3.3. Normality will be tested with the Shapiro-Wilk test. Continuous variables such as onset and duration of sensory and motor block, and VAS scores will be expressed as mean ± SD or median (IQR) and compared between groups using the independent sample t-test or Mann-Whitney U test, as appropriate. Categorical variables like incidence of side-effects will be presented as frequencies and percentages and analysed using the Chi-square test or Fisher's exact test when required. A p-value <0.05 will be considered statistically significant.

Activity	Months 1–3	Months 4–6	Months 7–9	Months 10–11	Months 12
Patient recruitment	Oct-Dec 2025	Jan-Mar 2026			
Data collection		Jan-Mar 2026	Apr-Jun 2026	Jul-Aug 2026	
Data analysis			Apr-Jun 2026		
Report writing and submission				Jul-Aug 2026	Sep-Oct 2026

[Table/Fig-2]: Gantt Chart for Study Timeline (1-year duration)

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PLAGIARISM CHECKING METHODS: [Jain H et al.]
- Plagiarism X-checker: Aug 22, 2025
- Manual Googling: Dec 04, 2025
- iThenticate Software: Dec 06, 2025 (14%)

ETYMOLOGY: Author Origin

EMENDATIONS: 7

AUTHOR DECLARATION:
- Financial or Other Competing Interests: None
- Was informed consent obtained from the subjects involved in the study? No
- For any images presented appropriate consent has been obtained from the subjects. NA

Date of Submission: **Jul 22, 2025**
Date of Peer Review: **Aug 24, 2025**
Date of Acceptance: **Dec 08, 2025**
Date of Publishing: **Apr 01, 2026**