Evaluation of the Efficacy of Procedural Sedoanalgesia and Infraclavicular Nerve Blockade on Analgesia in Forearm Fractures in the Emergency Department

1. Protocol

Trauma patients constitute a significant portion of emergency department visits. Forearm fractures are common upper extremity fractures in adult patients. A forearm fracture can present as an isolated radius fracture, an isolated ulna fracture, or a double bone radius-ulna fracture. Forearm fractures cause severe pain, both due to the fracture itself and during the reduction process. Pain management is crucial in emergency departments (ED). Therefore, multimodal approaches are available to reduce or eliminate pain during the reduction process. Procedural sedation and analgesia (PSA), which is widely used in emergency departments and effectively reduces pain, is particularly common. However, recent literature suggests the use of peripheral regional block techniques over the use of multiple nonsteroidal anti-inflammatory and/or opioid analgesics for pain palliation.

The aim of our study is to evaluate the success of reduction and pain palliation during the reduction process in patients with forearm fractures using PSA and ultrasound-guided infraclavicular nerve block (ICB). The secondary aim is to compare patient comfort, physician comfort, side effects, length of stay in the emergency department, and the need for pain medication after discharge between these two procedures, and to determine the most appropriate method. With this study, we aim to contribute to practical applications for achieving optimal pain control in patients with forearm fractures in emergency department settings.

PSA (Procedural Sedation and Analgesia) refers to the suppression of a patient's consciousness to maintain vital heart and lung functions while using sedative and dissociative agents combined with analgesics during a medical procedure, with the goal of preventing or minimizing the patient's awareness, response, and memory of the event. However, the use of sedoanalgesic drugs carries significant risks, such as respiratory depression or hypotension, and requires that every patient be monitored and observed at least until they return to a pre-sedation level of alertness. The need for the patient to stay in the emergency department for at least two hours and the requirement for staff to monitor the patient during this time present certain disadvantages, particularly in busy emergency departments. These concerns have led to the exploration of alternative approaches.

Ultrasound (US)-guided peripheral nerve blocks are alternatives used in pain management during the reduction of forearm fractures. These techniques are widely used in outpatient settings, orthopedic surgeries, and postoperative pain management in operating rooms. Peripheral nerve blocks involve the use of local anesthetics and are defined as the infiltration of peripheral nerves with local anesthetic agents to reduce motor output and sensory input. Nerve blocks are effective in pain control, act quickly, have low complication rates, and do not require prolonged observation. As a result, the use of peripheral nerve blocks in pain management is increasing in emergency departments.

Patients presenting with forearm fractures to the emergency department will be included in the study. The need for reduction at the time of presentation will be determined by orthopedic doctors. Patients who require reduction and have an ASA classification of ASA 1-2 (ASA: American Society of Anesthesiologists, Table-1) will be included in the study and followed up. The patients will be randomly divided into two groups: Group P, where reduction will be performed under Procedural Sedation and Analgesia (PSA), and Group B, where reduction will be performed under ultrasound-guided infraclavicular nerve block (ICB). Randomization will be done by assigning the first 5 patients to Group P and the next 5 patients to Group B (the procedures are described in detail below), and the following parameters will be evaluated:

Pain levels at the time of arrival, post-procedure but before reduction, and after reduction will be recorded using the Numeric Rating Scale (NRS). (NRS ranges from 0-10, with 0 representing no pain and 10 representing unbearable pain.)

The success of the reduction procedure will be assessed, noting whether additional reduction procedures were required, and the findings on control X-rays after each reduction (radial height, radial inclination, and volar tilt) will be recorded and evaluated by orthopedic doctors.

The length of stay in the emergency department will be recorded as the time from the patient's arrival to discharge.

Side effects/complications during the procedures will be recorded.

The need for rescue treatment during the procedure will be evaluated. If the NRS is above 5, the first-line rescue analgesic treatment will be 50 or 100 mg of tramadol IV, administered in 100 cc of normal saline over 15 minutes. If the pain remains above NRS 5, the second-line

treatment will be 50 mcg of fentanyl IV, administered in 100 cc of normal saline over 15 minutes.

The need for pain medication within 24 hours after discharge will be assessed by calling the patients.

Patient satisfaction will be recorded using a 5-point Likert scale (1: very poor, 2: poor, 3: fair, 4: good, 5: very good).

The same satisfaction survey will be administered to the orthopedic doctors who performed the reduction.

Procedures for the groups will be as follows before reduction: The PSA protocol for Group P will be performed by experienced emergency physicians who are skilled in sedation analgesia, advanced life support, and advanced airway management. The patient will be monitored by an experienced doctor or nurse during the sedation period until recovery. Emergency equipment will be readily available in case of any complications. The PSA protocol will include IV ketamine administered at a dose of 1-2 mg/kg. If the NRS remains above 5, additional doses of 0.25-1 mg/kg may be repeated every 5 to 10 minutes as needed. The decision to discharge the patient will be based on the modified Aldrete score, one of the recovery scoring systems.

The ultrasound (US)-guided infraclavicular nerve block protocol for Group B: The infraclavicular block (ICB) is a peripheral nerve block that anesthetizes the brachial plexus at the level of the cords. ICBs are used for anesthesia and/or analgesia during surgical or procedural interventions on the forearm, wrist, hand, and fingers. The block will be applied under ultrasound guidance as follows: The patient will be placed in a supine position, an intravenous (IV) line will be established, and the patient will be monitored. The patient's head will be turned to the side opposite the block site. The arm to be blocked will be adducted and placed in flexion across the patient's chest. After the block site is disinfected with povidone-iodine, a sterile linear ultrasound probe (the LOGIQ P9 ultrasound device currently used in our emergency department) will be placed longitudinally at the recommended site for the infraclavicular block . Once the axillary artery, vein, and the cords of the brachial plexus are visualized, a 22-gauge needle will be advanced in-plane with the ultrasound probe toward the 6-7 o'clock position relative to the artery. The lateral, medial, and posterior cords, containing hypoechoic nerve fascicles ("honeycomb" appearance), will be identified. First, 2 mL of saline will be injected; if the spread is appropriate, the local anesthetic (LA) solution, prepared by diluting 10 mL of 0.5% bupivacaine with 10 mL of normal saline to create 20 mL of 0.25% bupivacaine, will be injected in fractional doses with intermittent negative aspiration. The

spread of the local anesthetic within the brachial plexus will be observed as an expanding hypoechoic collection within the plexus. Fifteen minutes after this procedure, the level of anesthesia will be assessed using a cold-hot test, and reduction and casting will be performed

Inclusion Criteria:

Age 18 years and older
Diagnosed with a forearm fracture using standard radiography
Hemodynamically stable
No vascular or nerve injury
No infection in the skin or tissues where the needle will pass
Able to give written and verbal consent

Exclusion Criteria:

Allergy to drugs used for sedation analgesia and peripheral nerve block
Hemodynamically unstable
Patients with ASA 3-4 classification (for those in the PSA group)
Coagulopathy, liver or kidney failure
Patients with opioid, alcohol, or substance abuse
Skin infection or open wound at the site where local anesthetic will be applied
Pregnant or suspected of being pregnant
Those who do not give written and verbal consent

Sample Size: For the planned analyses in this study, the sample size calculation was based on the study by Tekin et al. titled 'Can ultrasound-guided infraclavicular block be an alternative option for forearm reduction in the emergency department? A prospective randomized study.' In that study, a 30% difference between the two groups was found to be significant, and thus, this article was used as a reference for our study. Based on this reference article, with an effect size of 0.5 (medium), an α level of 0.05, and a power of 0.80, it was determined that a total of 78 participants (39 in each group) would be sufficient. The sample size analysis was conducted using the GPower 3.1 program.

Volunteer recruitment for the study will be terminated once the total of 78 patients, as determined by the power analysis, is reached.

The study received approval from the Ankara Etlik City Hospital Ethics Committee on April 24, 2024 (approval code: AEŞH-EK1-2024-0040). However, patient recruitment has not yet started.

Volunteer Recruitment Start: September 1, 2024 [Expected]

Primary Completion: June 1, 2025 [Expected]

Study Completion: December 1, 2025 [Expected]

2. Statistical analysis

Statistical analysis will be performed using the SPSS 23.0 statistical software package. In the descriptive findings section, categorical variables will be presented as numbers and percentages, while continuous variables will be presented as mean ± standard deviation for normally distributed data and as median (minimum, maximum) for non-normally distributed data. The normality of the distribution of continuous variables will be assessed using the Kolmogorov-Smirnov test. Comparisons between groups for categorical variables will be evaluated using the chi-square test. For normally distributed quantitative variables, comparisons between the three groups will be made using the ANOVA test. For non-normally distributed quantitative variables, the Kruskal-Wallis test will be used. A p-value of < 0.05 will be considered statistically significant in this study

3. Informed Consent Form for Volunteers

Dear Volunteer,

In our Emergency Department, we are conducting an academic study titled "Evaluation of the Efficacy of Procedural Sedoanalgesia and Infraclavicular Nerve Block on Analgesia in Forearm Fractures in the Emergency Department," led by Dr. Emine Sarcan. The study aims to reduce pain in adult patients presenting to the emergency department with forearm fractures and to reposition displaced fractures without the need for surgery, using sedoanalgesia (mild sedation and pain relief) and regional anesthetic procedures. The objective is to assess the advantages of

these procedures, their effects on pain, the status of regional anesthesia, length of hospital stay, and the need for analgesics within 24 hours after discharge. The treatment to be applied during the initial presentation to the Emergency Department will be decided by your responsible physician. Patients will be divided into two groups: the first 5 patients will be assigned to Group P, and the other 5 patients will be assigned to Group B.

Patients in Group P will undergo procedural sedoanalgesia (PSA). PSA is defined as a state in which the patient's consciousness is suppressed, while maintaining vital heart and lung functions, to prevent or minimize the patient's awareness, response, and memory of the event during a medical procedure. Here, an intravenous line will be established, and the patient will receive 1-2 mg/kg of ketamine intravenously. The procedure will be performed when the patient is approximately asleep, and the patient will be monitored by the emergency doctor until fully awake.

Patients in Group B will receive a regional anesthesia called an infraclavicular block to reduce pain in the affected area. The block procedure will be performed under ultrasound guidance, inserting a 22 Gauge needle into the area around the fractured clavicle on the affected side, and 0.5% bupivacaine, a local anesthetic, will be administered. The procedure will be carried out after the forearm becomes numb. Before, during, and after the procedure, you will be asked to evaluate your pain on a numeric pain scale (0: no pain, 10: unbearable pain). No additional time is required to perform this study, and you will not be subjected to an experimental procedure.

During the procedure, there may be mild pain and minimal bleeding at the injection site. If you continue to experience pain during the procedure, tramadol 50 or 100 mg IV in 100 cc of normal saline will be administered as a first-line treatment over 15 minutes. If pain persists, the second-line treatment of 50 mcg fentanyl in 100 cc of normal saline will be given over 15 minutes intravenously. In case of any harm related to the research, the treatment and associated expenses will be covered by the responsible investigator, Dr. Emine Sarcan. Any developments during the research that may concern you will be promptly communicated to you or your legal representative. For additional information about the study or for any concerns regarding unwanted effects or other discomforts related to the study, you can contact Dr. Emine Sarcan at 0541-625-8585.

You may refuse to participate in this study. Participation in this research is entirely voluntary, and declining to participate will not result in any changes to the treatment provided to you. Furthermore, you have the right to withdraw your consent at any stage of the study.

II- Information on the Rights of the Volunteer

Dr. Emine Sarcan has informed me that a medical study will be conducted at the Emergency Medicine Clinic of Ankara Etlik City Hospital. I have been provided with the above information regarding this research and have been invited to participate as a "volunteer."

If I participate in this research, I believe that my personal information, which should remain confidential between me and the physician, will be treated with great care and respect during the study. I have been assured that my personal information will be meticulously protected when the research results are used for educational and scientific purposes.

I may withdraw from the study at any time without providing any reason. (However, I am aware that it would be appropriate to notify in advance if I decide to withdraw from the research to avoid putting the researchers in a difficult position.) Additionally, I can be excluded from the study by the researcher, provided that it does not cause any harm to my medical condition. I do not incur any financial responsibility for the expenses related to the research. No payment will be made to me. I am not obliged to participate in this research, and I may choose not to participate. I have not faced any coercion to join the study. If I refuse to participate, I understand that this will not affect my medical care or my relationship with the physician. I have comprehended all the explanations given to me in detail. After taking a certain time to think independently, I have decided to participate as a "volunteer" in this research project. I accept this invitation with great satisfaction and willingness.

A copy of this signed form will be given to me.

Participant's Name and Surname:

Signature:

Witness's Name and Surname:

Signature:

Physician Conducting the Interview

Name, Surname

Signature: