Dr. Isa Cuce

NCT04938037 UNİQUE PROTOCOL ID: 2021/353

05.05.2020

Comparison of Spinoglenoid Versus Suprascapular Notch Approaches for Ultrasound-Guided Distal Suprascapular Nerve Blocks for Shoulder Pain: A Prospective Randomized Trial

Study Design and Patients

The present study was conducted in a prospective, randomized, double-blind fashion at a tertiary-care university hospital in Kayseri, Turkey, from June 2021 to August 2022. The Consolidated Standards of Reporting Trials (CONSORT) guideline was used as the reference for the standardization of the data reported in this study. Ethical approval for the study was obtained from the Erciyes University Clinical Research Ethics Committee (approval date: May 05, 2020; approval number: 2021/353). The study was also registered at ClinicalTrials.gov (NCT04938037). The research adhered to the Ethical Principles for Medical Research Involving Human Subjects outlined in the World Medical Association's Declaration of Helsinki, as revised in 2013. A written informed consent form approved by the ethics committee was signed by each participant who agreed to participate in the study.

All patients over the age of 18 who had chronic shoulder pain of any specific etiology (duration >3 months), had a visual analog scale (VAS) score above 4 despite conservative treatment, and gave informed written consent were screened for eligibility for the study. Exclusion criteria were previous fractures or surgery around the shoulder, receipt of any injections to the affected shoulder in the last 3 months, chronic pain due to other diseases such as malignancy, cervical radiculopathy, hemiplegia, or uncontrolled diabetes or hypertension, coagulopathies, local infection over the shoulder region, or allergy to local anesthetics.

The clinical diagnosis of chronic shoulder pain for each included patient was determined by physical examination and radiologic imaging technique (magnetic resonance imaging [MRI] or ultrasound [US]).

Patients were randomized into two groups: Group 1 received SSNB at the spinoglenoid notch level, while Group 2 received SSNB at the suprascapular notch level. Stratified randomization was performed in four blocks based on age and gender. Group allocations were made (using sealed envelopes) by our medical secretary. The assigned numbers were presented to the physician at the time the procedure was performed. The patients and the physician assessing the outcomes were blinded to the group assignments, but the physician who performed the injections could not be blinded.

Procedures

All injections were administered by a single experienced physician specializing in musculoskeletal injections who used the linear transducer (LA3-16AD) of the Samsung HM70A Plus US device (Seoul, South Korea). The same injection solutions were prepared for both groups and consisted of 1 mL of methylprednisolone acetate (40 mg/mL) and 5 mL of 0.5% bupivacaine for the SSNB.

For SSNB at the level of the spinoglenoid notch, the patients were positioned on a stretcher in the lateral decubitus position between the US device and the physician. The patient's hand on the side of the injection was placed on the contralateral shoulder. The transducer was positioned on the glenohumeral joint, parallel to the inferior border of the spina scapula, and then shifted medially to visualize the spinoglenoid notch. After sterile prep, a 20G 3.5-inch needle was advanced, using an in-plane technique, into the spinoglenoid notch. A lateral-medial needle insertion was used so that the intended target of the final needle tip was at the medial wall of the spinoglenoid notch.

For SSNB at the level of the suprascapular notch, the technique described by Harmon et al.(1) was used. In brief, the patient was positioned seated between the physician and the US equipment. The patient's injection-side hand was placed on the shoulder on the opposite side. To view the suprascapular notch, the transducer was positioned above the acromion, parallel to the spina scapula, and then gently adjusted medially. After sterile prep, a 20G 3.5-inch needle was advanced into the suprascapular notch.

One week after the injection, all patients received a prescribed exercise regimen to be performed in their own homes. The exercise routine encompassed self-stretching, joint mobility exercises, and strength-building activities. A designated physical therapist demonstrated the exercises to each patient individually, and an exercise booklet was provided to assist them.

Finally, the patients were advised to use paracetamol (500 mg) and/or naproxen (750 mg), if necessary. They were asked not to take analgesics at or 1 day before the follow-up points, as it could affect the clinical outcome measures.

Outcome Measures

All patients were evaluated for primary and secondary outcome measures before injection (baseline) and at 1, 4, and 12 weeks after injection by an investigator blinded to the injections. The primary outcome measure of the study was the Shoulder Pain and Disability Index (SPADI), while the secondary outcome measures were visual analog scale (VAS) scores, active range of motion of the shoulder (ROM), pressure pain thresholds (PPT), and treatment satisfaction. All adverse events that occurred during the procedure and at a follow-up visit were recorded.

Primary outcome measure: The Shoulder Pain and Disability Index is a shoulder-specific index consisting of 13 items that assess shoulder pain and disability on two different scales. Each item is scored between 0 and 10, and the resulting score is converted into a 100-point scale separately for pain, disability, and total score. Increased SPADI scores indicate an increase in patients' shoulder-related pain and disability. Patients with a reduction in the total SPADI score of 18 points or more from baseline to week 12 (the last follow-up) were considered treatment successes. (2). The SPADI has been shown to be valid and reliable in Turkish (3).

Secondary outcome measures: The VAS (0–10 range) was evaluated in each patient for night and activity. An additional VAS assessment was performed 1 h after the injection. Active

shoulder ROM measurements of the patients were performed using a standard manual goniometer. Measurements were made in the supine position, and active forward flexion (FF), abduction (US), internal rotation (IR), and external rotation (ER) were measured. The IR and ER measurements were made with the shoulder abducted at 90°. The PPT measurements were obtained over the middle deltoid, upper trapezius, infraspinatus, and tibialis anterior muscles using a 1 cm diameter probe from an electronic digital display algometer (Commander Echo® Algometer, JTECH Medical, Midvale, UT, USA). Measurements were taken directly on the skin and vertically, and the patient was instructed to stop when the feeling of pressure first turned into a feeling of pain and discomfort. Three measurements were taken from each region, and the average of the last two measurements was recorded. The PPT values were expressed as kilograms per square centimeter (kg/cm^2). A low PPT value represents a decrease in the pain threshold and, therefore, increased sensitivity. A 5-point Likert scale was used to evaluate the patients' overall satisfaction with the treatment (1= extremely dissatisfied, 2= dissatisfied, 3=neutral, 4= satisfied, and 5= extremely satisfied).

The patients' compliance with the exercise program was queried at the 4th and 12th weeks after the injection. The patients were asked to choose between "Never did," "I did it occasionally," and "I did it regularly." Finally, they were asked how much they used the paracetamol (500 mg) and naproxen (750 mg) that had been sent home with them after the injection at the 1^{st}, 4^{th}, and 12^{th} weeks. The total amount of drug used was recorded.

Statistical Analyses

The sample size required for the research was calculated via a website (http://statulator.com/SampleSize/ss2M.html). In a previous study, the Minimal Clinically Important Difference (MCID) value for SPADI ranged from 8 to 13 points (2). We established our research hypothesis that the clinical results of SSNB at the level of the spinoglenoid notch would not be non-inferior to SSNB at the level of the suprascapular notch. Accordingly, when the non-inferiority margin is -9 and the standard deviation is 15.3; With 80% power and type 1 error 0.05, 36 patients in each group should be recruited. Assuming a 10% dropout rate, 40 patients were planned for each group.

The collected data were statistically analyzed using IBM SPSS ver. 22.0 (IBM Corp., Armonk, NY, USA). All analyses were performed according to the "intention to treat" principle, and the missing data were completed using the single imputation method. The Shapiro-Wilk test, as well as histograms and QQ plots, were used to test whether the data were normally distributed. Analysis results were presented as mean ± standard deviation for numerical data and as numbers and percentages for categorical data. For numerical data, the differences between groups were compared using the independent samples t-test or the Mann–Whitney U test. Categorical data were analyzed using chi-square tests or Fisher's exact test. In addition, the differences (Δ) between the baseline value of the outcome measures and the values at the follow-up time points were calculated and included in the intergroup comparison. The Friedmann test was used for intragroup comparisons of the changes in outcome measures from baseline to follow-up times. The post hoc Dunn-Bonferroni test was then used for

pairwise comparisons of follow-up times. A P value less than 0.05 was considered statistically significant.

1- Harmon D, Hearty C. Ultrasound-guided suprascapular nerve block technique. *Pain Physician.* 2007; 10:743-746.

2- Roy JS, Macdermid JC, Woodhouse LJ. Measuring shoulder function: a systematic review of four questionnaires. *Arthritis Care Res.* 2009; 61:623-632.

3- Bumin G, Tüzün EH, Tonga E. The Shoulder Pain and Disability Index (SPADI): Cross-cultural adaptation, reliability, and validity of the Turkish version. *J.Back Musculoskelet.* 2008; 21:57-62.