- **PROTOCOL TITLE**

Prospective observational study on the analgesic effectiveness of blocking the shoulder´s anterior capsule and the suprascapular nerve by the anterior approach versus blocking of the suprascapular and axillary nerves by the posterior approach in shoulder arthroscopy.

- **PROTOCOL CODE**

SHAC

- **PROTOCOL VERSION WITH DATE**

10/10/2023

ABSTRACT

• PROTOCOL TITTLE

Prospective observational study on the analgesic effectiveness of blocking the shoulder´s anterior capsule and the suprascapular nerve by the anterior approach versus blocking of the suprascapular and axillary nerves by the posterior approach in shoulder arthroscopy.

• PROTOCOL CODE

SHAC

• STUDY DESIGN

An observational study of paired cohorts, not randomized, is designed in two hospitals in northern Spain in the period between october 2023 and september 2024.

• MAIN AND SECONDARY OBJECTIVES

Main:

The measurement of pain intensity according to the numerical rating scale (NRS) at different times: preoperative and at the 1st, 2nd, 12th and 24th postoperative hours.

Secondary:

Postoperative opioid consumption and comparison of total cumulative consumption between the two groups.

It will also evaluated the degree of sensory and motor block, the easy of performance of the anesthetic technique, the degree of patient satisfaction and the record of short-term complications (first 24 hours post-intervention): hematoma, pruritus, nausea and/or vomiting.

• Study population and total number of subjects.

All patients consecutively scheduled for arthroscopic unilateral rotator cuff repair of the shoulder, who meet the inclusion criteria will be recruited for the study.

BACKGROUND AND JUSTIFICATION OF THE PROJECT

Arthroscopic shoulder surgery is related to a high incidence of postoperative pain, being rated as intense by 45% of patients in the immediate postoperative period (1). The management of these patients can be complex due to the high incidence of preoperative pain and its variability during the postoperative period, which is higher in patients undergoing rotator cuff repair surgery (2).

It is crucial to ensure adequate postoperative pain control in this type of intervention, especially in the context of major outpatient surgery. Adequate postoperative pain control can have several benefits, such as reducing hospital stay (3), accelerating postoperative rehabilitation (4), and improving long-term outcomes (5).

The PROSPECT guideline for rotator cuff repair surgery recommends associating a regional analgesic technique with a multimodal pharmacological approach to pain. (6).

Traditionally, the interscalene block has been considered the gold-standard for analgesia in shoulder surgery; However, its possible serious complications limit its use. Currently, most anesthesiologists choose to perform more distal peripheral nerve blocks of the brachial plexus (upper trunk block, supraclavicular block, infraclavicular block at the costoclavicular level, axillary nerve block...) which, although highly effective, continue to cause impairment. prolonged motor activity and are not free of complications (phrenic paralysis, transient nerve injuries, inadvertent vascular punctures...) (7).

Shoulder anterior capsular block (SHAC) has recently been described. It is a fascial block of the anterior capsule of the shoulder that aims to avoid motor impairment while maintaining optimal analgesic efficacy (8)(9). However, so far only anatomical and descriptive studies of small case series have been published. Therefore, this research work, with the objective of comparing the postoperative analgesic effectiveness of two regional analgesic techniques: the SHAC block associated with the suprascapular nerve block performed anteriorly vs. suprascapular and axillary nerve blocks performed posteriorly in operated patients. of the shoulder via arthroscopic procedures that cause intense postoperative pain.

STUDY HYPOTHESES

Two analgesic strategies included within the usual clinical practice will be compared for postoperative pain control after shoulder arthroscopy. With this study we want to compare the ultrasound-guided block of the suprascapular nerves and the shoulder joint capsule via the anterior route versus the ultrasound-guided block of the suprascapular and axillary nerves via the posterior route.

GOALS:

• **Main objective**

The measurement of pain intensity according to the NRS at different times: preoperative and at the 1st, 2nd, 12th and 24th postoperative hours.

• **Secondary objectives**

Postoperative opioid consumption and comparison of total cumulative consumption between the two groups.

It will also evaluated the degree of sensory and motor block, the easy of performance of the anesthetic technique, the degree of patient satisfaction and the record of short-term complications (first 24 hours post-intervention): hematoma, pruritus, nausea and/or vomiting.

STUDY TYPE

An observational study of paired cohorts, not randomized, is designed in two hospitals in northern Spain in the period between october 2023 and september 2024.

PROTOCOL

All patients will be trained preoperatively in pain assessment using a Numerical Rating Scale (NRS) from 0 (absence of pain) to 10 (maximum pain endured). All patients will receive the same anesthesia and analgesia protocol; fentanyl, propofol and rocuronium prior to intubation.

Anesthetic maintenance with 1 MAC of sevoflurane and boluses of muscle relaxant and fentanyl if there is an increase >20% in blood pressure or above baseline heart rate. The anesthetic protocol will include analgesia with 1 g of paracetamol and 50 mg of dexketoprofen every 8 hours and a bolus of 0.1 mg/kg of intravenous dexamethasone. When the patient reporte an NRS > 3 and functional impact, intravenous morphine will be administered at a dose of 0.04 mg/kg every 10 minutes until NRS < 3 in the PACU and tramadol 1 mg/kg in the ward. The nursing staff and the anesthesiologist in charge of the PACU will be blind to the block received by the patient in each study group.

Before general anesthesia, patients will be assigned to one of the study groups depending on the anesthesiologist responsible for performing the blocks.

SHAC + SSN Group (anterior approach): with the patient in the supine position and the arm placed in abduction and slight external rotation the ultrasound probe will be positioned in the transverse axis between the coracoid process and the humeral head. After identifying the tendon of the subscapularis muscle, a puncture will be performed in a lateral to medial plane and the local anesthetic will be deposited at two levels; one deep to the subscapularis tendon at the pericapsular level of the glenohumeral joint (5 ml of ropivacaine 0.2%), and another in withdrawal at about the level of the fascia that separates the subscapularis and deltoid muscles at a more superficial level (10 ml of 0.2% ropivacaine). Subsequently, the ultrasound probe will be positioned in the transverse axis at level with the neck to locate the suprascapular nerve through an anterior approach as it ran beneath the omohyoid muscle. After hydrodissecting the correct plane with saline solution 5 ml of 0.2% ropivacaine will be administered, depositing the local anesthetic under the lower belly of the omohyoid muscle.

SSN + AN group (posterior approach): with the patient in a sitting position and the arm placed in a neutral position, with slight internal rotation supported on the abdomen, the ultrasound probe will be positioned in the supraspinous fossa and a first puncture of the suprascapular nerve will be performed posteriorly, level with the supraspinous fossa. Next, the probe will be positioned at the level of Velpeau's quadrilateral and a second puncture of the axillary nerve will be performed, taking the posterior humeral circumflex artery as a sonoanatomical reference in the plane of intersection formed by the deltoid, triceps brachii, and teres minor muscles. After locating the planes by hydrodissection with saline solution 10 ml of 0.2% ropivacaine will be administered to each of the nerves.

MATERIAL AND METHODS

1.1 Definition of study subjects

The inclusion criteria: being over 18 years of age, ASA physical status I – III and having been scheduled for shoulder arthroscopy surgery.

The exclusion criteria: any contraindication for performing regional anesthetic techniques (infection at the puncture point, alteration of hemostasis, allergy to local anesthetics, patient refusal to participate in the study, inability to evaluate postoperative pain, known neuropathy of the operated limb and patients who required conversion to open surgery).

RECRUITMENT AND RECRUITMENT OF PARTICIPANTS

The anesthesiologist responsible for the operating room performed both the block of the anterior capsule of the shoulder and the suprascapular nerve via the anterior route and the blocks of the suprascapular and axillary nerves via the posterior route until the number of patients established in each of the groups is reached.

JUSTIFICATION OF SAMPLE SIZE

Because no work of this nature has been carried out previously, a sample size calculation will be not performed and all patients who underwent surgery in the 12 months that the study data collection will last were consecutively included in the study.

VARIABLES EVALUATED

The main variable will be the measurement of pain intensity according to the NRS at different times: preoperative and at the 1st, 2nd, 12th and 24th postoperative hours. As secondary variables, postoperative opioid requirements will be assessed in the form of intravenous morphine, measured in mg (only during the 2 hours of the patient's stay in the Postanesthesia Care Unit), and tramadol (mg) up to 24 hours postoperatively.

The degree of sensory block will be also assessed by a cold sensitivity test with a cotton swab dipped in cold water applied to the skin of the upper third of the arm, which will be graded with a sensitive scale going from 0 to 2 (2 being normal sensitivity to cold, 1 hypoesthesia and 0 anesthesia). The degree of motor block upon arrival at the PACU will be assessed by the movement of the arm using a simple numerical scale (0 = cannot raise the extended arm > 45º and 1 = can raise the extended arm > 45º), the ease of performance of the corresponding anesthetic technique by the anesthesiologist using a simple verbal scale (easy/medium difficulty/difficult), the appearance of adverse effects (postoperative nausea and/or vomiting, hematoma, pruritus, urinary retention), the degree of patient satisfaction (very satisfied, satisfied or dissatisfied) and the notification of complications related to the anesthetic techniques performed.

STATISTICAL ANALYSIS PLAN

Continuous quantitative variables will be expressed as mean and standard deviation and the results will be contrasted using the Student's T test if normality criteria will be met, failing which they will be expressed as median and range and contrasted using the Mann Whitney´s U. The qualitative variables will be expressed in absolute numbers and relative frequencies and the results of both groups will be contrasted using the Chi square. In addition, Fisher's test will be applied when necessary. Normality tests will be conducted for all continuous quantitative variables. The Kruskal-Wallis technique will be also employed with post-hoc application of the Bonferroni test for the analyses. The data will be processed using SPSS software version 19.0 (IBM Corporation, Armonk, NY, USA), assuming a p-value below 0.05 as significant.

SCHEDULE AND EXPECTED COMPLETION DATE.

The study will be carried out between october 2023 and june 2024.

ETHICAL-LEGAL ASPECTS

All data collected will be managed in accordance with the regulations established by Organic Law 3/2018, of December 5, on the Protection of Personal Data and guarantee of digital rights; such as 14/2007 of July 3, on Biomedical Research; such as the Standards of Good Clinical Practice, Declaration of Helsinki, as well as the Oviedo Convention.

The study protocol and all associated documentation will be submitted for evaluation to the CAEI of Galicia. Any modification to the initial approved protocol will be sent for re-evaluation.

Researchers assume the commitment to make public the results of their research, whether positive or negative.

Since this is an anonymous survey, informed consent will not be necessary.

RISKS.

Participation in this study does not imply an increased risk since it is a cross-sectional study, which will not interfere with the daily activities of the center in terms of clinical and therapeutic management of patients. The study will be carried out in accordance with local regulations and applicable laws and following internationally accepted ethical standards.

CONFIDENTIALITY OF THE INFORMATION COLLECTED IN THE CONTEXT OF THE STUDY.

The study research staff will ensure that the pseudonymization of participants is maintained. Which will be identified through a code in the electronic database, with all their information associated with this code and not with their personal data. This database will be stored on a service computer, access to which is password protected. Additionally, the database will also be protected by a password. This information will be stored securely and will only be accessible to members of the research team and authorized personnel.

The questionnaire to obtain the data will use the Microsoft Form platform and when the information is provided to the research team it will be coded and pseudonymized, making it untraceable and respecting the privacy of the data provided.

The person responsible for the processing and custody of the data will in all cases be the principal investigator of the study.

At the end of the study, the data will be stored in the institutional online repository of the Department of Health and Sergas RUNA for a minimum of 10 years, under a password that only the main researcher will have access to in Excel format that will be protected with a different password. also with only access for the main researcher.

In the future, if these data are required for subsequent studies, consent must be sought from the principal investigator.

COMMITMENT TO PUBLISH RESULTS

Researchers must make the commitment to make the results of their research public, whether positive or negative.

ECONOMIC REPORT AND SOURCE OF FINANCING

This project does not have financing.

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ANNEXES

INFORMED CONSENT

TITLE OF THE STUDY

Prospective observational study on the analgesic effectiveness of blocking the shoulder´s anterior capsule and the suprascapular nerve by the anterior approach versus blocking of the suprascapular and axillary nerves by the posterior approach in shoulder arthroscopy.

This document is intended to provide you with information about a **research study** in which you are invited to participate. This study was approved by the Galician Research Ethics Committee.

If you decide to participate in it, you must receive information from the researcher, read this document first and ask all the questions you need to understand the details about it. If you wish, you can take the document, consult it with other people, and take the time necessary to decide whether to participate or not.

Participation in this study is completely voluntary. You can decide not to participate or, it is accepted, change your mind by withdrawing consent at any time without giving any reason. We assure you that this decision will not affect your relationship with your doctor or the healthcare to which you are entitled.

What is the purpose of the study?

To collect information about the analgesic efficacy of anterior shoulder capsule and suprascapular nerve block versus posterior suprascapular and axillary nerve block in shoulder arthroscopy.

Why are they offering me to participate?

You are invited to participate because we want to know your experience and knowledge in analgesic management in the arthroscopic shoulder surgery to which you are going to undergo.

What does my participation consist of?

First of all, you will have answered some questions to determine if you meet the requirements of the study. Once you have been selected you will be informed of the procedure so you can collaborate in it. It will not involve collecting samples of biological fluids or performing tests in addition to those usual for good clinical practice. Once in the ante-operating room, we proceed to achieve an anxiolytic level with comfort for the patient to be able to perform the regional technique. Once a good anxiolytic level has been acquired, an ultrasound-guided puncture is performed and, through one or two punctures, for the administration of local anesthesia with the aim of blocking the aforementioned nerves. The fundamental objective is to achieve a good analgesic level without residual motor blockade. The patient may notice local discomfort derived from the diffusion of the local anesthetic, such as residual motor blockage or altered sensitivity, but these are usually temporary.

Your participation in the study will imply acceptance of completing questionnaires and using the results.

This data collection will be carried out by answering a questionnaire and does not imply any additional activity.

Your participation in it will involve completing questionnaires that would take about 10 minutes.

What discomforts or inconveniences does my participation have?

Your participation does not imply additional inconveniences to those of normal care practice except the time spent having to respond to a survey.

Will I get any benefits for participating?

You are not expected to obtain direct benefit from participating in the study. The research aims to discover unknown or unclear aspects about the clinical practice and care management of acute pain. This information may be useful in the future for other people.

Will I receive the information obtained from the study?

If you wish, you will be provided with a summary of the results of the study.

Will the results of this study be published?

The results of this study will be submitted to scientific publications for their dissemination, but no data that could lead to the identification of the participants will be transmitted.

How will the confidentiality of my data be protected?

The obtaining, processing, conservation, communication and transfer of your data will be done in accordance with the provisions of the General Data Protection Regulation (EU Regulation 2016-679 of the European Parliament and of the Council, of April 27, 2016) and the regulations Spanish on protection of personal data in force (Organic Law 3/2018, of December 5, on Protection of Personal Data and guarantee of digital rights).

The institution in which this research is carried out is responsible for the processing of your data, and may contact the Data Protection Delegate through the following means: email: dpd@sergas.es

The data necessary to carry out this study will be collected and stored in pseudonymized (encrypted) mode. Pseudonymization is the processing of personal data in such a way that they cannot be attributed to a data subject without the use of additional information. In this study, only the research team will know the code that will allow them to know their identity.

The regulations that regulate the processing of personal data give you the right to access your data, object, correct it, cancel it, limit its processing, restrict or request its deletion. You can also request a copy of these or for it to be sent to a third party (right of portability).

To exercise these rights, you can contact the Data Protection Delegate of the center through the contact methods indicated above or the main researchers of this study.

Likewise, you have the right to file a claim with the Spanish Data Protection Agency, when you consider that any of your rights has not been respected.

Only the research team and the health authorities, who have the duty to maintain confidentiality, they will have access to all the data collected by the study. Information that cannot be identified may be transmitted to third parties. In the event that any information is transmitted to other countries, it will be done with a level of data protection equivalent, at least, to that established by Spanish and European regulations.

At the end of the study, or the established legal period, the data collected will be kept anonymous for use in future research according to what you choose on the consent signature sheet.

Are there financial interests in this study?

The researcher will not receive specific remuneration for their dedication to the study. You will not be compensated for participating.

Thank you very much for your collaboration

CONSENT DOCUMENT FOR PARTICIPATION IN A RESEARCH STUDY

PATIENT'S WRITTEN INFORMED CONSENT

TITLE OF THE STUDY: PROSPECTIVE OBSERVATIONAL STUDY ON THE ANALGESIC EFFECTIVENESS OF BLOCKING THE SHOWLDER'S ANTERIOR CAPSULE AND THE SUPRASCAPULAR NERVE BY THE ANTERIOR APPROACH, VERSUS BLOCKING OF THE SUPRASCAPULAR AND AXILLARY NERVES BY THE POSTERIOR APPROACH IN SHOULDER ARTHROSCOPY

I, _____

□ I have read the information sheet that has been given to me.
□ I have been able to ask questions about the study.
□ I have received sufficient information about the study.
□ I have spoken with: _____
□ I have had sufficient time to adequately consider my participation in the study.
□ I understand that my participation is voluntary.
□ I understand that I can withdraw from the study:
.- whenever you want.
.- without having to give explanations.
.- without this affecting my medical care.

I freely give my consent to participate in the study and give my consent for the access and use of my data under the conditions detailed in the information sheet.

…….....
Signature of patients
Date: ____/____/____

…….....
Signature of researcher
Date: ____/____/____

……
Signature of the legal representative,
family member or person linked in fact
Date: ____/____/____

FORMULATION FOR REVOCATION OF INFORMED CONSENT

I, Mr/Mrs ..... with DNI…..... Through this channel I wish to inform my decision to withdraw from this research protocol for the following reasons:: (This section is optional and can be left blank if the patient so wishes)…… ……

on behalf of Mr/Mrs ……..……

……..... ……..... …….....

Signature of patients Signature of the legal representative, Signature of researcher

Date: ____/____/____ Date:____/____/____ Date:____/____/____