COMPARISON OF HYDRODILATION RESULTS AT DIFFERENT VOLUMES IN ADHESIVE CAPSULITIS BY PHASES

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PROTOCOL

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COMPARISON OF HYDRODILATION RESULTS AT DIFFERENT VOLUMES IN ADHESIVE CAPSULITIS BY PHASES

DEPARTMENT: M. PHYSICS AND REHABILITATION

1. Starting hypothesis

Adhesive capsulitis (AC) is a very common condition seen in Physical Medicine and Rehabilitation clinics. In most cases, its progression is self-limiting. However, during this time, the patient experiences pain and daily functional disability.

The diagnosis depends primarily on clinical data focused on pain and both active and passive functional limitation. The use of imaging tests is more aimed at ruling out pathologies that can cause similar symptoms.

Until recently, treatment focused on oral medication, corticosteroid injections for pain, and physical therapy (PT) to prevent further shoulder limitation. With the advent of the hydrodilation (HD) technique, the progression of the disease can be shortened.

Although this type of technique is increasingly used, its protocolization as a second-line treatment has not yet been possible. The wide variability in the performance of the technique may be one of the reasons. Within this variability, the volume required to consider this technique optimal is a matter of debate.

Initial hypothesis: Patients with AC, depending on the stage of development, who receive high-volume HD as treatment, obtain better results in the Shoulder Pain and Disability Index test (SPADI), the visual analogue scale (VAS) and the joint range of motion (ROM) at the first, third and sixth month of therapy, compared to patients who receive low-volume HD in the general population.

2. Background and previous results

AC, also known as frozen shoulder, is defined as a condition in which a “global limitation of active and passive movement of the shoulder progressively develops, which may or may not be associated with pain, without other radiographic findings to justify it” (1). The prevalence of this pathology is around 2 - 5% in the general population (2), with an age of onset between 40 - 60 years (3) and being up to four times more frequent in women (2,4).

Regarding the historical course of this disease, the clinical picture was first described in 1872 by Duplay. Codman later named it "frozen shoulder" in 1934 (5). Neviaser later named it AC in 1945 (6) and described its pathophysiological process.

This disease, with an average duration of 1-3 years (3), is a self-limiting process (4,5) that can be divided into three (2,4) or four (5,6) main phases, depending on the literature.

> **1st Freezing Phase (0–9 months):** Increasing diffuse and disabling pain, mostly at night, associated with mild stiffness. This phase includes the pre-freezing phase (0–3 months), with symptoms of very mild pain and stiffness.
>
> **2nd Stiffness Phase (9–15 months):** Significant stiffness across all ranges of motion, accompanied by a progressive decrease in pain.
>
> **3rd Thawing Phase** (15–24 months): Gradual return of joint balance without associated pain.

Among the predisposing factors are gender due to estrogens (7), diabetes mellitus due to hyperglycemia (8) and thyroid diseases (9), all of them related to the creation of a chronic proinflammatory state that favors the appearance of AC. This chronic inflammation promotes the presence of inflammatory cells such as fibroblasts, B lymphocytes, cytokines, interleukins such as IL-6 or tumor necrosis factor alpha, which in turn from a histological point of view favor the appearance of fibrosis, proliferative synovitis and capsular thickening (2,4).

The pathological findings appear to be related to the phases of AC, with hypervascular and hypertrophic synovitis with fibroplasia and perivascular scarring being more common in phase 1; and hypercellular tissue accompanied by extensive fibroplasia but with a thin synovial membrane and without hypervascularity or synovitis being more common in phase 2. (10)

At present, the general consensus regarding the diagnosis of AC is a section still to be developed due to its difficulty (11). This has been based so far on fundamentally clinical aspects such as pain, and limitations of the ROM (3–5,12). The limitation of ROM both in active and passive is a data considered pathognomonic (2,4), with a limitation of external rotation (ER) (3–5) and abduction (ABD) (12) mainly. However, in a pathology in which the clinical stage in early phases seems to be associated with the need for shorter recovery times (13), as concluded in the systemic review by Schiltz M et al, its diagnosis should be based on more precise “diagnostic tools” in addition to a clinical pillar (12).

Currently, the two most commonly used diagnostic imaging tests to rule out pathologies that may resemble AC (rotator cuff tendinopathies, acromioclavicular osteoarthritis, labral injury, etc.) (2) would be magnetic resonance imaging (MRI) and ultrasound (US).

Regarding MRI, although there is no consensus yet, this test provides parameters that may be useful in cases of contradictory exploration (14). However, if we think about the long

waiting lists, the need for several appointments to associate clinical symptoms with images and perhaps the most devastating data associated with the study carried out by Dimitris MD et al in which it is stated that "the routine use of shoulder MRI scans in patients with AC but without suspicion of an additional pathology may not be indicated", because "37 MRIs were necessary to change a single therapeutic plan" (15) makes us think that MRI may not be the diagnostic tool we are looking for.

Quite the opposite occurs with the use of ultrasound. The possibility of performing it at the same time as the consultation, the high availability for many specialties, the low cost and the good diagnostic accuracy (11) make this test a great possibility of diagnostic support in AC. Within the ultrasound parameters related to AC, the measurement of the thickness of the axillary recess (AR) is a piece of data that, as shown in the study by Byung Chan L et al, seems to correlate significantly with pain, functionality and ROM (16). The average scores that are taken as a reference to determine whether or not AC may exist, would be to find, together with clinical data, an AR of ≥ 4 mm, although more studies are needed to demonstrate this (11,16,17).

We now focus on possible treatments. Previously, the concept of "benign neglect" (13) was used, which referred to allowing the disease to progress given its self-limiting nature. However, other conservative treatments are now emerging that may be useful in AC. These include physical therapy, intra-articular corticosteroid injections, suprascapular nerve block, and HD (2,13,18–20).

Focusing on the latter, the procedure was first described in 1965 by Andren and Lundberg (21). HD consists of an ultrasound-guided procedure in which a volume of fluid (saline, anesthetic and corticosteroid) is injected to cause expansion of the joint capsule, which is already rigid (19,22).

As early as 2008, Cochrane concluded that HD was a useful tool in AC, but that it did not provide improvement in terms of pain and disability for more than 3 months (23). The medium- to long-term role of this technique remains a topic of discussion due to the enormous "evidence gap" that exists (24).

Most of the studies reviewed for this study show a heterogeneous pattern regarding the results of this technique and its comparison with intra-articular injections. Some of them conclude that HD has "comparable efficacy to intra-articular corticosteroid injections" (25). However, studies are beginning to appear that demonstrate its long-term benefits, such as the study by Sofía Dimitri-Pinheiro et al., which concludes that "it is effective in improving shoulder pain and increasing disability... with benefits lasting up to 2 years" (26).

The difficulty in finding consistent results using this technique may arise from its lack of protocolization. This is why this essay focuses on various points of conflict.

The first of these is the differences in relation to the volume needed to achieve optimal capsular expansion. A study carried out in 2020 by Jang Hyuk Cho concluded that the optimal volume to achieve such expansion was around 18 ml (27). This amount of volume,

or close to it, appears in later studies on HD (28,29). However, we also find later studies where they talk about “variable volumes” (26), and even higher volumes, typically 30-40 ml (30), or like the one carried out by Magdalena Pimenta et al in which it is discussed that a volume of up to 47 ml (31) allows capsular expansion without risk of rupture, data related to worse results (27,31).

The combined use or not of other therapies with HD, such as suprascapular nerve block (SSNB) and PT, are also topics of interest, however their use is increasingly common and seems to be little discussed. In the case of SSNB, its use has been associated with additive improvements in both pain and shoulder function (18,32), being in many cases "a valuable complementary therapy" (33). In the case of PT, its use in the first line of treatment (20) is more than established in clinical practice. Most studies show that PT is a very useful complementary treatment (34).

The second important point, not so much due to the scientific discussion, but rather due to the absence of this variable in the reviewed studies, is the lack of stratification by phase of the disease. Considering the relationship between clinical phases and pathological findings, the fact that studies on HD from 2019 to the present are reviewed and most do not differentiate these results according to the phase of AC (18,22,25,26,29–31) does not make much sense. Only in the study by Fabio Vita et al. in 2024 is a differentiation made between the results obtained in both phase 1 and phase 2 (28). If we take into account everything previously stated, the variability between HD techniques, the lack of phase stratification in the results, the diagnostic difficulty and above all “high quality scientific work” (35), it is normal that the most repeated conclusion is the need to carry out more studies in order to be able to protocolize this treatment (18,20,25,30).

3. Main and secondary objectives

1. Primary Objective:

- To demonstrate the variability in SPADI, VAS, and ROM results among patients receiving HD at different volumes.

2. Secondary Objectives:

- To determine whether there are differences in time to physical therapy discharge among patients receiving HD at different volumes.
- To determine whether the overall results differ when stratified by AC stage.
- To determine the mean values that AR can present in AC.

4. Study design

Design: A parallel block randomized clinical trial with triple blinding is proposed.

Study population, variables and inclusion-exclusion criteria

Inclusion Criteria:

- Patients aged 30-70 years.
- Shoulder pain lasting more than 3 months.
- Limited ROM, both active and passive.

Exclusion Criteria:

- Lidocaine + test with improved ROM. (4)
- Conditions that preclude treatment (active cancer, tissue infection, oral anticoagulant therapy, cardiac arrhythmias, etc.)
- Previously receiving HD treatment in less than 1 year.
- Stage 0 or 3 AC.
- Non-adherence to the FST program, with attendance rates exceeding 20%.
- Presence of conditions that can cause similar symptoms, such as acromioclavicular osteoarthritis, labral injury, massive rotator cuff tear, or rheumatic diseases.
- Intra-articular corticosteroid injections for less than 2 months.

Clarifications regarding diagnosis and staging by phases

In order to establish consistent diagnostic criteria and facilitate staging of AC, the selection process will be based on the following points.

Regarding the diagnosis, the ROM limitation must be affected in two planes, one of which must be the RE and/or ABD. These ROMs will be considered limited if they are reduced by 30% or more (3,22,36,37).

If there is any doubt as to whether the limitation may be due to a blockage caused by the patient to prevent pain, a lidocaine test will be performed (3,4). This consists of injecting 5–10 cc of 1% lidocaine into the subacromial space to facilitate passive examination of the joint. It will be considered positive if a release of ROM and a reduction in pain are found after its use.

Staging in phases will be performed according to the information provided in section 1.1 Background and justification. Patients in stage 1 will be considered those in whom the predominant symptom is pain accompanied by limited ROM, and patients in stage 2 will be those in whom limited ROM predominates over pain. Patients with intermediate symptoms, in whom both pain and limited ROM are present, will be classified based on the chronology of the disease, with the midpoint between the two stages being considered at 9 months of disease progression.

Variables to take into account:

- **SPADI** (22,38,39).

The Shoulder Pain Disability Index is a widely used outcome measure that provides information about shoulder pain and limitations.

  - Pain Scale

How severe is the pain? 0 = no pain and 10 = the worst pain imaginable.

- At its worst?
- When lying on that side?
- When reaching for something on a high shelf?
- When touching the back of your neck?
- When pushing with the affected arm?

- Disability Scale:

How much difficulty do you have? 0 = no pain and 10 = the worst pain imaginable.

- Washing your hair.
- Washing your back.
- Putting on a T-shirt or sweater.
- Putting on a button-down shirt.
- Putting on your pants.
- Placing an object on a high shelf.
- Carrying a heavy object weighing 4.5 kilograms.
- Reaching out of your back pocket.

Then, pain and disability are separately recorded, and a percentage of impairment is combined.

This index has demonstrated "good internal consistency, convergent validity, and reliability" in its Spanish version, making it one of the most reliable measurement instruments in the field of shoulder disorders today.

- **VAS** (28,40,41).

The VAS "is a validated subjective measure for acute and chronic pain." It allows for the measurement of pain intensity with maximum reproducibility.

It consists of a 10-centimeter horizontal line, with the extreme expressions of a symptom at each end. To the left (0) is the absence or lowest intensity, and to the right (10) is the highest intensity. The patient is asked to mark the point on the line that indicates the intensity. The minimally detectable differences for the symptom level to be acceptable are 2 to 3 points.

- **ROM** (21,42).

Range of motion assessment is a basic practice in the study of shoulder pathologies, especially in the case of AC. ROM should be measured, both actively and passively.

The ROMs that will be assessed actively and passively will primarily be flexion, abduction, external rotation (with the arm at 90° of abduction, by asking the patient to show us the palm of their hand), and internal rotation (with the arm at 90° of abduction, by asking the patient to show us the back of their hand). All of these are measured with the PLURIMETER inclinometer.

The measurement will be performed with the patient actively seated, and if limitations are found, the patient will be placed supine to eliminate the influence of gravity.

- **LATTINEN** (43)

The Latineen test is a widely used tool for pain assessment, validated in Spain as a tool to measure the degree of pain in patients with chronic pain. This scale consists of five items scored from 0 to 4:

1. Pain intensity.
2. Pain frequency.
3. Analgesic use.
4. Degree of disability.
5. Hours of sleep.

Although this test is widely used in chronic pain conditions, its use in AC is not very common. However, we believe it can provide important data such as analgesic medication intake. This is why we consider its use appropriate.

- **AR SIZE** (16,44)

It will be measured using ultrasound with a longitudinal section of the AR. The patient will be placed supine with the shoulder abducted at 90° and the elbow flexed.

- **TIME FROM START TO END OF PHYSIOTHERAPY.**

The following criteria will be established for discontinuing PT treatment:

- Failure to improve ROM by 15% after full HD after 16 sessions.
- Recovery of full ROM after 4 sessions.
- Increased pain that precludes PT.
- Maximum of 24 PT sessions.

Variables	Initial Consultation	Intervention	1 Month	3 Months	6 Months
Age	×				
Gender	×				
Previous Treatments	×				
Diseases					
Time Since Clinic Start	×				
AR Size	×		×	×	×
SPADI	×		×	×	×
VAS	×		×	×	×
ROM	×		×	×	×
Lattinen			×	×	×
PGI - I					×
CGI - C					×
Time from Start to End of FST			↔	↔	↔
HD Repetition				↔	↔

Table 1: *Variables collected chronologically according to successive consultations*

Interventions

Type of intervention

- - HD technique with a 20 ml volume.
- - HD technique with a 40-50 ml volume.

Assignment to interventions

The allocation process will be pre-established and random. This assignment will be carried out using an algorithm created in an Excel database. This assignment will be known only to Javier Muñoz (JMP), who will safeguard the information until the end of the study to avoid interfering with the results obtained and thus avoiding potential bias.

Execution of interventions

It is proposed to perform HD techniques at different physiological saline solution (SSF) volumes. To do this:

- First, an ultrasound-guided suprascapular nerve block (SSNB) will be performed with 4 ml of 0.25% anesthetic + 0.5 ml of corticosteroid in the suprascapular notch.

- - After 15 minutes of the SSNB, ultrasound-guided HD will begin. To do this, the patient will be placed in a lateral decubitus position on the unaffected arm. The arm to be treated will be positioned at the patient's side without forcing its extension. The joint cavity will then be approached posteriorly, introducing a spinal needle in the ultrasound plane between the humeral cortex and the labrum. The joint cavity will then be confirmed by introducing physiological saline solution and observing its reflux by pushing the plunger. Subsequently, 5 ml of 0.25% anesthetic + 0.5 ml of corticosteroid will be introduced, and then the corresponding predetermined volume will be topped up with saline solution.

- Variability in the volume used in each HD is a constant within this technique. The volumes proposed above, as explained in section *2. Background and previous results,* are those used to obtain optimal results, without posing any risk to the patient, as they do not involve any change in the usual practice of this technique.

- Finally, gentle release manipulations will be performed passively without forcing pain.

PT protocol after HD

PT treatment will begin 3 to 5 days after HD. The patient will visit twice a week.

Patients will be treated exclusively with manual techniques and kinesitherapy. They will be given manual techniques to release joint balance and will be instructed on exercises adapted for both the gym and home use. Exercises that cause pain will be avoided.

- Active kinesitherapy: 4 sets of 10 repetitions (rest between 30 seconds and 1 minute between sets) twice a week.

- Manual therapy:

  - Fascial release of the cervical and scapular areas. Axial and lateral coaptation tractions with a strap.
  - Mobilization with manual resistance through all ranges of motion.
  - Post-isometric stretches through all ranges of motion, emphasizing restrictions. - 5-second contraction with repetitions of 5 times for each muscle group.

Risks and discomfort of interventions

The techniques used and medications described above are included within approved and approved indications for use in our setting. This type of technique is a common treatment for your condition.

Regarding the potential risks that may be encountered, we state the following:

Frequent

- Infiltration may cause mild local reactions such as redness and pain, which disappear within a few days without the need for additional therapeutic measures. Early, transient facial flushing is common.
- Adverse effects associated with corticosteroids may occur (elevated blood glucose, elevated blood pressure, and subcutaneous tissue atrophy).

Uncommon

- Allergic reactions (ranging from minor symptoms to anaphylactic reaction) to any of the injected components. Therefore, if you know of any known allergies, you should inform your doctor before administration.
- Tendon injury, including rupture, near the injection site. Infection at the injection site.
- Temporary depigmentation of the injected area.

Risks related to the patient's clinical condition.

- It is essential to ensure that there is no pregnancy in women of childbearing age.
- This treatment is contraindicated in patients with pacemakers, infections, or tumors located in the injection site.

Benefits of Interventions

The potential benefits of this type of therapy focus on pain reduction and a return to functionality as close to the patient's previous condition as possible. All of this, therefore, would entail indirect benefits such as reduced painkiller use, improved sleep, and so on.

It's possible that you won't obtain any health benefits at all.

Alternative Treatments

Available alternatives include oral medication, physical therapy alone, and debridement surgery.

Financial Expenses and Compensation

You will not have to pay for medications or specific study tests. Your participation in the study will not incur any additional costs beyond your usual clinical practice.

The technique performed is a standard procedure in the clinical practice of this type of pathology**.**

Sample size (22,38)

Two studies using the SPADI scale in AC were used for the sample calculation. An average was calculated using the necessary values (standard distribution and minimum difference to be detected) for this calculation. Therefore:

Accepting an alpha risk of 0.05 and a statistical power greater than 0.8 in a two-tailed contrast, 16 subjects are required in group 1 and 16 in group 2 to detect a difference equal to or greater than 15 units. The common standard deviation is assumed to be 14. A 20% loss to follow-up rate has been estimated.

Work plan

The recruitment and results collection process will consist of the following phases:

1st Recruitment and Interventional Treatment (JMP) Phase: In this first phase, patients referred to the Physical Medicine and Rehabilitation Service will attend an initial screening consultation to confirm the diagnosis of AC and that they meet the established inclusion/exclusion criteria.

In this initial consultation, the protocol will be explained to the patient, the specific informed consent form will be signed, and the variables listed in Table 1 will be collected. Subsequently, patients will be scheduled for the Interventional Rehabilitation Consultation for H. The necessary variables will be collected again, and they will be referred to FST through the mechanisms and means created for this purpose.

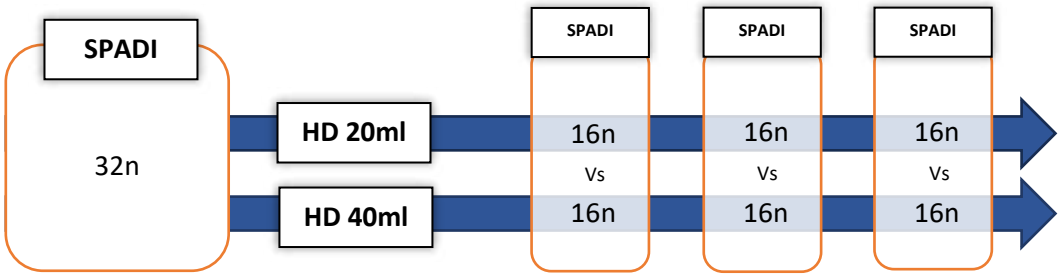
2nd Physical Therapy Treatment Phase (Amin Wahab (AW) and Francisco Espinosa (FE)): Referred patients will begin the FST program in less than 3-5 days. The FST start and discharge date will be recorded according to pre-established criteria.

3rd Review Phase (Ana Belén Jiménez (ABJJ)): Periodic reviews will be conducted at 1, 3, and 6 months after the intervention to collect the corresponding variables.

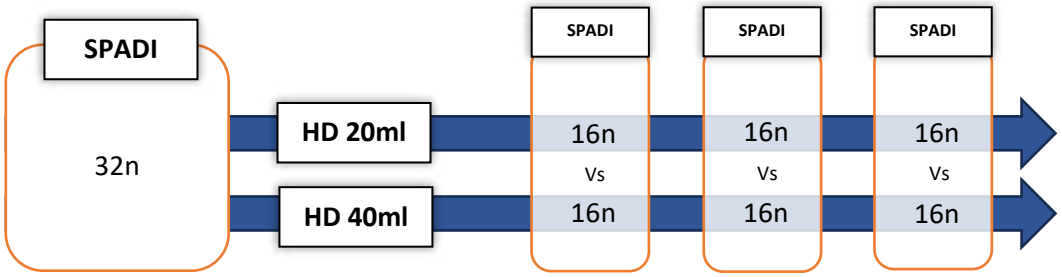
4th Phase: The collected information will be synthesized and entered into SPSS software to obtain results. The following actions will be carried out:

Primary outcomes: SPADI, EVA, ROM, Lattinen.
Grouping outcome: 20 ml HD vs. 40 ml HD

AC phase I



AC phase II



- For an independent data design:

  - 2 groups: Student's t-test or Mann-Whitney U-test.
  - More than 2 groups: Analysis of variance or Kruskal-Wallis H-test.

- For a paired data design:

  - 2 groups: Student's paired t-test or Wilcoxon test.
  - More than two groups: Repeated measures analysis of variance or Friedman test.

Pearson's Linear Correlation Coefficient (r) will be used to correlate two quantitative variables. A test (Bonferroni, Finner, etc.) will always be used for multiple comparisons to correct the "p" value. Multiple Linear Regression Analysis will be used for multiple analyses.

All contrasts will be two-tailed, and those with a P <0.05 will be considered significant. Data will be collected, processed, and analyzed using SPSS v.24.

Masking

The study is planned as a triple-blind study, with only the allocation information, as described in the previous section, known to JMP. No other team member, neither the patient nor the statistician, will have any knowledge of the treatment assignment.

Data collection and management

The data obtained from the reviews conducted during the study will be stored in the Diraya system. From there, JMP will enter the data into a database, without patient identification, in the SPSS.24 program. This database will be given to the statistician for obtaining and interpreting the results.

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Limitations of the study

The following limitations may arise when performing the following study:

1. Poor patient adherence to the study, resulting in losses.
2. Increased waiting times.
3. Inability to perform the technique with the predetermined volumes.

Ethical aspects

Data confidentiality will be respected at all times, through anonymization of the database by a person external to this project, in accordance with Regulation (EU) 2016/679 of the European Parliament and of the Council of April 27, 2016, on the protection of natural persons with regard to the processing of personal data and on the free movement of such data (General Data Protection Regulation). Furthermore, the project will be subject to the standards of good clinical practice and will comply at all times with the ethical precepts contained in the Declaration of Helsinki, always ensuring compliance with Organic Law 3/2018 on the protection of personal data. The ultimate goal is to respect and safeguard the rights to privacy, image, and information, accessing only information relevant to the study and separating information in a way that prevents patient identification.

The results obtained will be published through normal channels of scientific dissemination, regardless of the results obtained.

Amendments to the protocol

Modifications to the initial protocol will be reported as soon as possible to the Provincial Research Ethics Committee of Córdoba, by submitting the new protocol highlighting the changes made with respect to the old one, with the aim of confirming that the established changes do not represent a reduction in the ethical principles of said study nor alter its purpose.

Declaration of interests

This study does not present any opportunistic interests on the part of the team members who accessed the data.

Both the data entered into the SPSS database and the results obtained will be in the public domain and may be accessed by anyone upon request. These data will not contain any identifying information and will therefore be completely anonymous.

Additional and post-study care

This type of technique is commonly used in the Physical Medicine and Rehabilitation Department, so if the problem is not resolved or an issue arises, treatment will be provided according to the established procedures within the department.

Patients who show improvement will be scheduled for a one-year appointment in their discharge report, so they can return in the event of a relapse. Patients who have not improved will be referred to the Upper Extremity Trauma Unit due to the exhaustion of therapeutic options in our department.

Dissemination Policy

The results of the study will be communicated to clinical stakeholders and discussed in communications at scientific events and through publications in peer-reviewed scientific journals. The final results will also be communicated to healthcare professionals involved in the care of these patients through the Andalusian Health Service's internal communication channels.

Necessary Resources

The study will be conducted in the Physical Medicine and Rehabilitation Department of Reina University Hospital. Hospital resources, such as consultations, ultrasounds, and physiotherapy rooms, will be required.

This study is not funded.

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