CALCIFYING TENDINOPATHY OF THE ROTATOR CUFF: BARBOTAGE VS SHOCK WAVES

BOTCH (5775)
19/6/24

PROYECT BOTCH

HURS

RESEARCH PROJECT – BOTCH (5775) - Version 3 (19/06/2024)

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DEPARTMENT: PHYSICAL MEDICINE AND REHABILITATION

1. Starting assumptions

Calcifying tendinitis (CT) of the rotator cuff is one of the most common pathologies in the clinical practice of Med. Physical Medicine and Rehabilitation. It is based on the accumulation of calcium hydroxyapatite, causing inflammation, pain and functional impotence.

The use of ultrasound in consultation has favored the diagnosis, classification and treatment in some cases. Regarding their classification, they are classified in 3 grades according to Bianchi Martinoli's classification.

For their treatment, rest, anti-inflammatory drugs (NSAIDs) and kinesitherapy are the first-line treatments. But in resistant cases, other therapies such as extracorporeal shock waves (ESWT) and or ultrasound-guided barbotage (US-PICT).

Currently, the use of these last two therapies tends to have better results in ultrasound types II and III. However, the results obtained with each treatment have not been compared.

Given the current situation regarding waiting times, knowing in which cases one or the other therapy should be indicated is very useful in order to avoid overloading the system and to give the patient the best possible treatment in the shortest possible time.

Starting hypothesis: Patients with CT, in its different degrees, who have received US-PICT as treatment, obtain the same VAS differences at 1 month, 3 months and 6 months as patients who received ESWT as treatment in the population.

2. Background and previous results

Shoulder pain is a very frequent complaint among adults. A large number of these are due to TC with prevalences close to 8%, especially in women aged 30 - 60 years (1).

Of the risk factors that we can assume, many consider that "hormonal abnormalities and/or autoimmune diseases such as hypothyroidism, diabetes mellitus and rheumatoid arthritis" (2) play an important role in the development and chronicity of TC (3).

The natural course of CT pathogenesis is currently incomplete. As discussed in the starting hypothesis, calcium hydroxyapatite deposition is the pathophysiological basis of CT. This deposit, as opposed to the first theories that described its appearance due to tendon degeneration, is not currently supported (4).

In this pathology, what is known is the evolutionary course passing through 3 phases according to Uhthoff et al: (5)

1. Pre-calcified → 2. Calcified (edema and pain) →3. Post-calcification

For diagnosis, physical examination and imaging-based tests are strictly enforced and among them, radiography and ultrasound of the rotator cuff are the gold standard tests. Thanks to the use of these tests, two classifications have been created that relate to the evolutionary course described above.

Radiological classification by Gärtner and Heyer (6)

1. Circumscribed, dense, in formation.
2. Dense/translucent, circumscribed/cottony outline
3. Cloud-like and translucent, in resorptive phase.

Ultrasound classification by Bianchi Martinoli (7)

1. Type I: hyperechoic foci with good acoustic shadowing.
2. Type II: hyperechoic foci with a slight acoustic shadowing.
3. Type III: isoechoic with tendon, without acoustic shadowing.

The symptomatology of this disease has great variability among patients. If we speak of general numbers, 50% of the patients recover spontaneously or following conservative guidelines in the first 3 months and 20% during the first year. The remaining 30% develop repeated pain for months in periods exceeding several years (8).

Having explained the most relevant data on which CT is based, we focus on treatment. The initial therapy, being a self-limited disease, is focused on symptomatology control with anti-inflammatory drugs and oral analgesics, being able to resort to glucocorticoid injections in the rotator cuff in those cases in which inflammation is observed. As explained above, there is a large percentage of patients whose CT is limited, but the question is what about the remaining 50%? It is in these patients, with CT refractory to treatment, where therapies such as ESWT or US-PICT appear.

The use of ESWT has been for many years a controversial practice in relation to its use in CT due to the lack of studies. Following the study published by Gerdesmeyer et al, in which it was shown that even with low energy ESWT it was possible to dissolve these calcifications (9) , its use and new publications have been encouraged.

All deriving in 2016, when the SETOC (Spanish Society of Shock Wave Treatments), was able to include CT as an approved standard indication for the use of high energy ESWT.(10).

Regarding the use of US-PICT, there are multiple studies that support this practice. They recognize it as "an effective and safe treatment in CT, since it produces a significant clinical and radiological improvement"(7). A study carried out in the year 2022, which retrospectively sought to study the results of this technique, culminated demonstrating a significant improvement in pain in patients treated with this technique (11).

Few studies have been conducted to determine which type of therapy is most effective in each case, with very mixed conclusions. In the 2014 systemic review by Louwerens et al, it was shown that both the use of high-energy ESWT and US-PICT are effective treatments in chronic cases of TC for patients with symptomatology longer than 6 months, however it gave greater effectiveness to ESWT.(12) However, Yang-Soo Kim, MD et al, in 2014 published a randomized study which concluded that "ultrasound-guided needling treatment was more effective in restoring function and short-term pain relief." (13)

The aim and desire of this study goes a bit further and is outlined below.

3. Main and secondary objectives

1. Main objective:

- The main objective is to compare the mean differences in VAS at 1 month, 3 months and 6 months according to the treatment received, US-PICT or ESWT in patients with TC according to the evolutionary stage of the lesion based on the Bianchi Martinoli classification.

2. Secondary objectives:

- To know if there are variations in functionality with the Latinen test, joint balance (ROM), PGI and CGI.
- To protocolize an attitude towards this type of pathology.
- To favor the use of hospital resources.

4. Design of the study

Design: We propose to conduct a **prospective experimental longitudinal analytical block randomized clinical trial.**

<u>Study population, variables and inclusion-exclusion criteria.</u>

Inclusion criteria:

- Patients aged 30 - 60 years.
- Omoalgia lasting more than 3 months.

- Radiographic and ultrasound visualization in both planes of calcification.
- Sizes > 5 millimeters (mm).

Exclusion criteria:

- Patients not meeting inclusion criteria.
- Presence of another evident cause of pain (joint degeneration, capsulitis, rotator cuff tendon ruptures...).
- Patient who has previously received ESWT or US-PICT.
- Contraindication of therapies: infection, drug allergies, cancer....

Variables to take into account:

- Age: years
- Sex: male/female
- Type of therapy: ESWT/barbectomy
- Endocrine/rheumatologic diseases: hypothyroidism, diabetes mellitus and rheumatoid arthritis.
- Number of calcifications
- Size of calcifications: mm
- Previous treatments: Yes/ No
- Location of calcification: Supraspinatus, subscapularis, and infraspinatus.
- ROM: Flexion, abduction, and external and internal rotation (º).

- **Visual analgesic scale (VAS)**: initial, at 1, 3 and 6 months.

- Latineen test: initial, at 1, 3 and 6 months of each test variable and final score.

Correlation of VAS levels and Latineen test: (14)

VAS of 0 - 2.5 → IL = 6 VAS of 2.5-5 → IL=10 VAS of 5-7.5 → IL 13 VAS of 7.5-10 → IL =14

- **Patient Global Impression of Improvement Scale (PGI-I)**

- **Global improvement impression scale (CGI - GI)**

Sample size

Accepting an alpha of 0.05 and a beta of 0.2 in a bilateral contrast, 28 subjects in each arm are required to detect a difference equal to or greater than 3 units on the VAS scale. A standard deviation of 5 is assumed. A loss-to-follow-up rate of 20% has been estimated.

Work plan

The protocol carried out was as follows:

1st Phase : in this first phase, patients will be collected according to the criteria set out above for a period of **12 months**. During this time, the patients will be explained the two possible treatments to be received and after signing the appropriate informed consent, **they will be divided into groups according to treatment (ESWT vs US-PICT) stratifying according to the Bianchi Martinoli classification: (I/II or III).** The decision for each

treatment will be made randomly, **dividing the patients in a 1:1 ratio** according to whether they come to the initial consultation and the previous patient has received one or the other treatment.

The variables indicated above and in the table of variables will be collected from these patients.

	ESWT	US-PICT
Type I	14n	14n
Type II/III	14n	14n

In relation to **ESWT**, these will be given using a **15 mm transmitter in continuous mode with pressure at 3 bar, frequency 12Hz and 3000 impacts.** The number of sessions will be between 4 - 8 according to the patient's clinical condition with a rest between sessions of 5 to 10 days.

US-PICT will be performed with 1 session in which the following actions will be performed:

- First, a **suprascapular nerve block** will be performed with corticosteroid and anesthetic (3 ml of bupivacaine) in an ultrasound-guided manner.
- Then **the calcification will be infiltrated** with 5 ml of local lidocaine and preloaded physiological saline solution under ultrasound guidance.
- Finally, **repeated suctioning** with physiological saline will be performed to extract the calcium in an echoguided manner.

The inclusion of patients in the study will be carried out by Dr. Javier Muñoz.
The barbotomy technique will be performed jointly by Dr. Javier Muñoz, Dr. Sebastian Acosta and Dr. Fiorella Piaggio.
The ESWT technique will be performed by Fst. Diego Gomez Flores.

2nd Phase: Subsequently, 3 revisions will be carried out. One at 1 month, 3 months and another at 6 months after the end of therapy. In these, the variables will be taken again as indicated in the table of variables.

Initial consultation	1 month	3 month	6 month
Age Gender Type of therapy Diseases Number of calcifications Size Previous treatment Location ROM (measurement with goniometer) VAS_{in} Latineen Test	ROM (measurement with goniometer) VAS_{1m} Latineen Test	ROM (measurement with goniometer) VAS_{3m} Latineen Test	ROM (measurement with goniometer) VAS_{6m} Latineen Test PGI – I CGI - GI

Table of variables

3rd Phase: The information collected will be synthesized and entered into the SPSS program to obtain the results. For these the following actions will be carried out:

- 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:

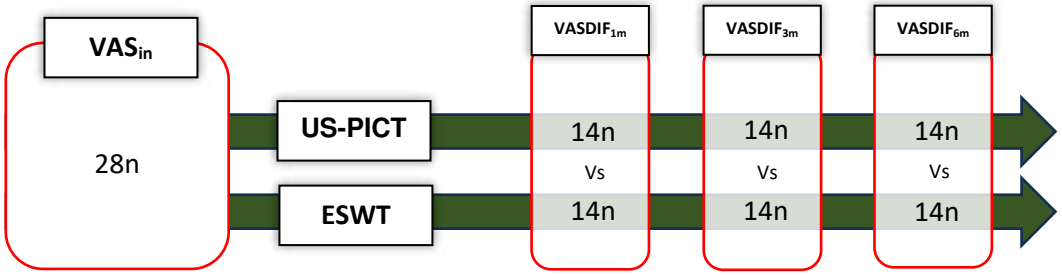
  - 2 groups: Student's t-test for paired data or Wilcoxon test.
  - More than two groups: Analysis of variance for repeated measures or Friedman's test.

A new variable VAS difference (VASDIF) will be created later, with the data obtained, according to the following formula in order to evaluate the variation with the initial VAS levels.

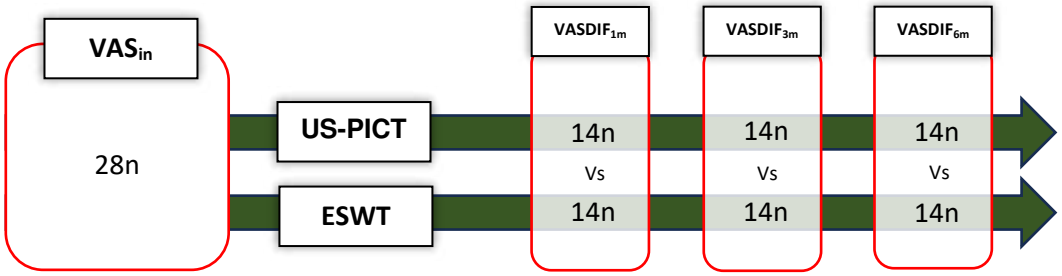
$$\mathbf{VAS_{in} - VAS_{xm} = VASDIF_{xm}}$$

Main variables: VAS,Test de Latineen y variables, PGI y CGI.
Variable agrupadora: ESWT Vs US-PICT

Type I calcifications



Type II/III calcifications



All contrasts will be bilateral and those where P<0.05 will be considered significant. Data will be collected, processed and analyzed with SPSS v.21 statistical software.

Limitations of the study

In order to be able to carry out the following study, the following limitations can be found.

1. Poor adherence to the study by the patients causing losses.
2. Increased waiting times due to ESWT saturation.

Ethical aspects

It will be respected at all times, through data anonymity in the base by a person external to this project, the confidentiality of these, in accordance with Regulation (EU) 2016/679 of the European parliament and of the council of 27 April 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). Likewise, the project will be subject to the rules of good clinical practice and will comply at all times with the ethical precepts contained in the Helsinki declaration, always ensuring compliance with the organic law 3/2018 on the protection of personal data. With the ultimate aim of respecting and safeguarding the rights of privacy, image and information, accessing only and exclusively to information that is relevant to the study and separating the information so that it is not possible to identify patients.

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

Resources required

The study will be carried out at the Physical Medicine and Rehabilitation Services of the Hospital Universitario Reina. Hospital resources will be necessary for the tests to be ordered.

The database will be created using the SPSS v.21 statistical program and the data will be obtained from the Diraya clinical database.

This study does not have any economic funding.

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