STUDY TITLE

ULTRASOUND-GUIDED PERCUTANEOUS TRANSVERSE CARPAL LIGAMENT SECTION VS OPEN SURGERY FOR THE SURGICAL TREATMENT OF CARPAL TUNNEL SYNDROME (CTS).

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3. SUMMARY

• **Title of the project:** ULTRASOUND-GUIDED PERCUTANEOUS TRANSVERSE CARPAL LIGAMENT SECTION VS OPEN SURGERY FOR THE SURGICAL TREATMENT OF CARPAL TUNNEL SYNDROME (CTS).

• **Principal investigator.**

- Manuel Castro Menéndez. F.E.A. Orthopaedic Surgery and Traumatology. University Hospital Complex of Vigo.

• **Centres where the study is planned to be carried out.** University Hospital Complex of Vigo

• **Design.** Prospective observational cohort study.

• **Main and secondary objectives:** To analyze the functional outcome of patients operated on for carpal tunnel syndrome (CTS) in a percutaneous ultrasound-guided manner and compare it with the results obtained by open surgery.

• **Primary endpoint:** Clinical and functional improvement using a specific questionnaire for CTS: Boston Carpal Tunnel Syndrome Questionnaire (BCTQ).

• **Population under study and total number of patients: Patients from** the CHUVI Health Area who have been diagnosed with Carpal Tunnel Syndrome and are going to undergo surgery at the centre from 1 February 2021 to 31 December 2021 by doctors

specialising in Orthopaedic Surgery and traumatology belonging to the CHUVI Upper Limb Unit.

• **Duration of patient enrollment:** From January 1, 2021 to January 31, 2024 (or until the calculated sample size is completed).

• **Calendar and expected date of completion of the study:** Febrary 2024 end of collection; between April and May 2024 analysis and dissemination of results.

4. BACKGROUND AND JUSTIFICATION OF THE STUDY

Surgical treatment for carpal tunnel syndrome consists of the transverse carpal ligament (LTC) section. The section of this ligament is usually done through a palmar skin incision. This technique is a common, simple, safe and effective procedure for the treatment of this pathology, but it is not exempt from complications such as the presence of painful palm scars, prolonged pain in the incision area, fatigue or weakness of the hand, periincisional pain (pillar pain) or prolonged convalescence time -return to previous activities-[1-3].

To try to minimize complications, percutaneous techniques have been developed. With these procedures, by not making an open incision through the palm, it is expected that the incidence of discomfort and tenderness in the palmar area will be reduced. In addition, it is also expected that there will be a decrease in postoperative morbidity, less time to return to work, and greater recovery of grip strength when this technique is used1,4-7. However, its risk-benefit ratio compared to that of open release remains controversial8-12. The risks to adjacent neurovascular structures inherent in these

percutaneous techniques remain one of the main factors preventing the acceptance of this technique4,13-15.

To minimize these risks, ultrasound has been used as a guide when performing these percutaneous techniques, since ultrasound makes it possible to perfectly visualize carpal tunnel structures when performing this release[1,12,16-18]. Ultrasound-guided percutaneous carpal tunnel release is a minimally invasive technique that has been developed over the last 20 years and has been shown to be effective and safe in several studies [1,8,19-21].

In our department, doctors from the Upper Limb Unit regularly use ultrasound for the diagnosis of upper limb pathology, as well as to perform local blocks when performing procedures under local anaesthesia. Due to the practice achieved with these procedures, ultrasound is being used as a support in other procedures such as the localization of foreign bodies, percutaneous release of CTS or the release of trigger fingers.

The aim of this study is to assess whether percutaneous release of the carpal tunnel guided by ultrasound provides, in our experience, more benefits than performing it through a short palmar incision.

5. HYPOTHESIS OF THE STUDY

Opening of the transverse carpal ligament percutaneously ultrasound-guided for the surgical treatment of carpal tunnel syndrome (CTS) has better results than opening by open surgery (palmar incision).

6. SPECIFIC AND SECONDARY OBJECTIVES OF THE STUDY

Main objective:

To analyze the functional results of the surgical treatment of CTS using percutaneous ultrasound-guided technique and to compare them with the results obtained by open surgery with a palmar incision.

Secondary objective:

To analyze the presence of complications (scar pain, pillar pain) and the pre- and postoperative difference in manual grip strength (measured with a JAMAR manual dynamometer) of surgical treatment of CTS using percutaneous ultrasound-guided technique and compare them with the results obtained by open surgery with a palmar incision.

7. DESIGN AND METHODS

Design:

Prospective observational cohort study.

Study population:

Patients in the CHUVI Health Area who have been diagnosed with CTS by a specialist in Orthopaedic Surgery and Traumatology at that centre, have undergone surgery for this pathology from 1 January 2021 to 31 January 2024, and meet the inclusion and exclusion criteria.

- Inclusion Criteria:

1.- Patient diagnosed with CTS by clinical examination and confirmed by complementary test (Electromyogram).

2.- Patients over 18 years of age.

3.- Patients who belong to the CHUVI Health Area.

4.- Patients with the capacity to consent and who agree to participate by signing the informed consent.

5.- Follow the guidelines and reviews set forth in the Consultation.

- Exclusion Criteria:

1- Patient who has previously undergone surgery for the same pathology in the same hand (recurrence).

2.- Patient incapacitated or unable to follow guidelines indicated by the Physician.

3.- Patient with associated pathology in the same hand for which he/she is going to be operated on in the same surgical act.

4- Patients with the presence of associated synovitis at the level of the flexor tendons of the hand to be treated.

- Sample size calculation.

Based on the study published by Kim et al23, who studied the minimum clinically important difference (MCID) for the Boston Carpal Tunnel Syndrome Questionnaire[22], and accepting an alpha risk of 0.05 and a beta risk of less than 0.2 in a bilateral contrast,

98 subjects in the first group and 98 in the second group are needed to detect a difference equal to or greater than 0.94 units. The common standard deviation is assumed to be 1. A follow-up loss rate of 10% has been estimated.

Procedure

Patients from the CHUVI Health Area diagnosed with the explained pathology, who meet the inclusion and exclusion criteria, and who are going to undergo surgery at the CHUVI by specialist doctors from the Orthopaedic Surgery and Traumatology Service belonging to the Upper Limb Unit, will be recruited. These patients will be informed of their pathology, and after signing the informed consent, surgery will be performed in the two proposed ways:

-Procedure A: ultrasound-guided percutaneous surgery.

-Procedure B: open surgery through a short palmar incision.

These two forms of surgical treatment are approved and used in our Service. The assignment to one or another surgical technique will be made based on the criteria of the physician who diagnoses the patient, as he or she does in his or her usual clinical practice, once the patient's clinical characteristics, pathology, and preferences have been heard.

Data will be collected from the patients included in the study in the preoperative consultation, intraoperatively and in the revision consultations that are usually carried out for this pathology 2 weeks after surgery, 6 weeks and 3 months.

In the preoperative consultation, the following will be collected:

1.- Grip strength of the hand measured with JAMAR manual dynamometer.

2.- Score of the specific questionnaire for the pathology of CTS: Boston Carpal Tunnel Syndrome Questionnair[22] (ANNEX 1).

Surgery will include:

1.- Time of surgical intervention

2.- Use or not of an ischemia cuff to perform surgery.

In the 2-week postoperative consultation, the following will be assessed:

1.- State of surgical wound.

2.- Presence of skin infection or other complication.

3.- Presence of pillar pain.

4.- Absence or presence of CTS (paresthesias or pain in the territory of the median nerve).

In the consultations that will be carried out 6 weeks and 3 months after surgery, the following will be assessed:

1.- Surgical incision status.

2.- Presence of skin infection or other complication.

3.- Presence of pillar pain.

4.- Absence or presence of CTS (paresthesias or pain in the territory of the median nerve)

5.- Grip strength of the hand measured with a JAMAR manual dynamometer.

6.- Score of the specific questionnaire for the pathology of CTS: Boston Carpal Tunnel Syndrome Questionnair[22] (ANNEX 1).

Data recording and management.

Potential candidates who meet the main characteristic of the study will be offered informed consent. Once the consent has been signed, a list of patients who meet the inclusion criteria and none of the exclusion criteria will be created.

The principal investigator (Dr Manuel Castro Menéndez) will be responsible for the collection and custody of the data and will ensure that the pseudonymisation of the participants is maintained. These will be identified through a code in the CRD and in the electronic database, all their information being associated with this code and not with their personal data.

The other members of the team as third parties involved in the statistical analysis of the data will only have access to the coded information.

Statistical analysis.

A descriptive analysis of the data will be carried out, presenting the qualitative variables with their absolute frequency and percentage, and the quantitative variables with their mean and standard deviation (SD) or median and percentiles if they do not conform to a normal distribution.

Initially, a univariate analysis will be performed to determine which variables could have an independent effect on functional outcomes (grip strength, and the validated questionnaire for CTS: Boston Carpal Tunnel Syndrome Questionnaire [22]).

To compare quantitative variables between the two groups, to assess whether there are differences and whether they are significant, the normality of the distribution of the data in each of the cohorts will be analysed and the parametric t-student test or the

non-parametric test (Mann-Whitney U) will be applied. For the comparison of the qualitative variables between the two cohorts, the Chi-square test will be used.

Subsequently, including as independent variables those that show significance in the univariate analysis or are of clinical interest, they will be included in multivariate regression models.

The data will be analyzed with the SPSS 22.0 Software and 0.05 will be considered as the α accepted significance level for all hypothesis tests.

8. ETHICAL AND LEGAL ASPECTS

Researchers undertake to respect the fundamental principles of the Declaration of Helsinki and the Council of Europe Convention on Human Rights and Biomedicine, as well as all current legislation related to the study.

The handling of the study's data, as well as its database, will comply with the requirements set out in Regulation (EU) 2016/679 and 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 data. and with Organic Law 3/2018, of 5 December, on the Protection of Personal Data and guarantee of digital rights.

The staff participating in the study will ensure that the anonymity of the participants is maintained. These will be identified through a code in the CRD and in the electronic database, all their information being associated with this code and not with their personal data. All documents will be stored securely and will only be accessible to members of the investigation team and authorized personnel.

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The study protocol and all associated documentation will be submitted for evaluation to the Galician ERC Network. Any modifications to the initial approved protocol will be forwarded for re-evaluation.

Informed consent

Study participants must sign an informed consent approved by the Network of Research Ethics Committees (CAEI) of Galicia before any of the study procedures are carried out. Patients will be provided with a study information sheet and one with informed consent. It will be clearly stated that the participant is free to withdraw from the study at any time and for any reason without affecting the treatment they will receive in the future and without any obligation to explain the reasons for their withdrawal.

Informed consent will be given to patients in the consultation once they are diagnosed with their pathology, meet the inclusion and exclusion criteria, their pathology is explained to them and participation in the study is offered.

9. IMPLEMENTATION PLAN

Inclusion: January 2021 to January 31, 2024.

Analysis and dissemination: Febrery 2024 to May 2024.

10. FINANCIAL REPORT / SOURCE OF FUNDING

The study has been approved by the Head of the Orthopaedic Surgery and Traumatology Service of the CHUVI.

There is no source of funding.

Date: December 1, 2020

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12.- ANNEX 1.- Validated Spanish version of the Boston Carpal Tunnel Syndrome Questionnair[22]

The following questions refer to the patient's symptoms on a typical day (24-hour period) during the past 2 weeks:

A. How severe is your wrist or hand pain at night?

1. I don't have pain in my wrist or hand2. I have mild pain3. I have moderate pain4. I have severe pain5. I have very severe pain

B. How often do you wake up during a typical night with wrist or hand pain (during the last 2 weeks)?

1. Never2. Once3. Two or three times4. Four to five times5. More than five times

C. Do you normally have pain in your hand or wrist during the day?

1. No2. I have mild pain3. I have moderate pain4. I have severe pain5. I have very severe pain

D. How often do you have pain in your wrist or hand during the day?

1. Never2. Once or twice3. Three to five times4. More than five times5. The pain is constant

E. How long did your last bout of pain last during the day?

1. I never have pain during the day2. 10 minutes or less3. 10-60 minutes4. More than 60 minutes5. The pain is constant throughout the day

F. Do you have numbness (loss of sensation) in your hand?

1. No2. I have mild numbness3. I have moderate numbness4. I have severe numbness5. I have very bad numbness

G. Do you have weakness in your hand or wrist?

1. No2. I have mild weakness3. I have moderate weakness4. I have severe weakness5. I have very serious weakness

H. Do you have a tingling sensation in your hand?

1. No2. I have mild tingling3. I have moderate tingling4. I have severe tingling5. I have very bad tingling

I. How serious is the numbness (loss of sensation) or tingling sensation at night?

1. I don't have numbness or tingling2. I have mild numbness or tingling3. I have moderate numbness or tingling4. I have severe numbness or tingling5. I have very bad numbness or tingling

J. How many times did you wake up during a typical night from numbness or tingling of the hand, in the last 2 weeks?

1. Never2. Once3. Two to three times4. Four to five times5. More than five times

K. Do you have difficulty grasping and using small objects such as keys or pens?

1. No2. I have mild difficulty3. I have moderate difficulty4. I have serious difficulty5. I have very serious difficulty

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Please answer all answers by circling a number that you think is appropriate.

ACTIVITY	No difficulty	Little Difficulty	Moderate difficulty	Severe difficulty	I can't do anything because of the symptoms
A.- Writing,	1	2	3	4	5
B.- Buttoning clothes,	1	2	3	4	5
C.- Holding a book while reading,	1	2	3	4	5
D.- Grab a phone,	1	2	3	4	5
E.- Open jars	1	2	3	4	5
,F:- Do household chores	1	2	3	4	5
G:- Carry shopping bags	1	2	3	4	5
H.- Bathing and dressing	1	2	3	4	5

Date: December 1, 2020