COMPARISON OF TWO TECHNIQUES FOR THE TREATMENT OF CARPAL TUNNEL SYNDROME. RANDOMIZED CLINICAL TRIAL

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STUDY PROTOCOL

Objectives

To determine if the incidence of postoperative pillar pain is lower for either of the two surgical techniques being studied after 3 weeks and 6 months of follow-up
Secondary, to check if the post-surgical grip strength, pinch strength and Borton Carpal Tunnel Questionnaire (BCTQ) score are better for either of the two surgical techniques

Design

Randomised clinical trial.

Methods

Study variables

- Signs of compression of the median nerve: pain and paresthesias in the first three fingers and radial edge of the fourth finger, nocturnal paresthesias, thenar muscle atrophy, loss of opposition of the thumb. Durkan, Phalen, Tinel signs.
- *Pillar pain*: pain/sensation of allodynia in the area of the thenar and/or hypothenar eminence, hyperalgesia in the scar, pain when supporting the heel of the hand, dysesthesia at rest.
- Questionnaire: BCTQ (Boston Carpal Tunnel Syndrome Questionnaire).
- Grip strength and pinch strength with specific dynamometers

Inclusion criteria

1) Age > 18 years
2) Moderate-severe carpal tunnel syndrome
3) Symptoms that hinder the patient's daily activities
4) Have performed a correct conservative treatment without success

Exclusion criteria

1) Previous carpal tunnel syndrome surgery
2) Traumatic or congenital sequelae of the hand
3) Unable to understand the process and the tests to be performed

Design

The follow-up process was carried out in three visits (3 weeks and 6 months after surgery).
In the **pre-surgery visit**, we carried out: patient screening and recruitment, patient information and obtaining informed consent process, application of the **inclusion and exclusion criteria**, medical history and physical examination of the hand to reach the **clinical and exploratory diagnosis of carpal tunnel syndrome**, obtaining baseline values from the **BCTQ questionnaire**, obtaining baseline **grip** and **pinch strength** values. After that, patients were **randomly assigned** to one of two treatment groups. Once included in each study group, the specific **surgical operation** was carried out. Finally, in the **post-surgery visits (3 weeks and 6 months** post-surgery), we evaluated: clinical and

examination of the median nerve compression clinic, presence or not of **pillar pain**, post-operative BCTQ values and grip and pinch strengths.

STATISTICAL ANALYSIS PLAN (SAP)

To carry out the sample homogeneity study, the statistical Student t-tests for the quantitative variables and chi-square for the qualitative variables were used. For the analysis of the qualitative variables the chi-square statistical test was used. Mixed ANOVA was used using the patient as a random effect and using the visit and surgical technique as a fixed effect to analyse the absolute change in grip and pinch strength and the BCTQ score after 3 weeks and 6 months after surgery.

As for the data analysis, two new variables were created for the quantitative variables: the absolute change in grip strength, in pinch strength and in the BCTQ score and the relative change therein, performed by an absolute and percentage calculation (respectively) of the difference between values after 3 weeks from baseline and values after 6 months from baseline; i.e., comparing each patient with themself calculating the variation in these variables throughout the follow-up.

Finally, the Student's t-test was used to study the absolute and relative change in the grip and pinch strength and BCTQ values.