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Local injection versus surgery in carpal tunnel syndrome: Neurophysiologic outcomes of a randomized clinical trial

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HIGHLIGHTS

- Both corticosteroid injections and decompressive surgery are clinically effective in reducing symptoms of carpal tunnel syndrome in the 12-months follow-up.
- Only surgery results in an improvement of the neurophysiological parameters in the 12-months follow-up.
- There is no correlation between clinical and neurophysiologic improvements.

ABSTRACT

Objective: The aim of our study was to characterize the neurophysiologic outcomes in a randomized clinical trial comparing local corticosteroid injection and decompressive surgery in idiopathic carpal tunnel syndrome.
Methods: Clinical and neurophysiologic assessments were done at baseline and 12 months after treatment. Four parameters were evaluated in the nerve conduction study (NCS): distal motor latency, motor amplitude, sensory conduction velocity and sensory amplitude. Statistic signification was established by the Student's *t* test, independent and paired samples, and Mann–Whitney test. Repeated measures analysis of variance was used by the three domains of symptoms. Correlations between the changes showed in clinical parameters and those evidenced by electromyography were calculated by the Pearson's test.
Results: Both groups of therapy were comparable at baseline. In 95 wrists, a second NCS was done 12 months post-treatment. Although clinical outcome improved in a similar way in both groups, we found statistically significant improvement in three (distal motor latency, sensory conduction velocity and sensory amplitude) of four neurophysiologic parameters only in the surgery group, when compared to baseline values.
Conclusions: Although local corticosteroid injection and decompressive surgery are clinically effective in reducing symptoms of carpal tunnel syndrome, only surgery results in an improvement of the neurophysiologic parameters, at 12-months follow-up.
Significance: Only decompressive surgery allows resolution of neurophysiologic changes. The symptoms of the syndrome are resolved with corticosteroid injections.

1. Introduction

Carpal tunnel syndrome (CTS) is a common condition, with a prevalence of 2.7% in the general population (Atroshi et al., 1999). Despite the high incidence of the condition, optimal therapy for mild to moderate CTS has not been fully defined. In routine clinical practice, corticosteroid injection (CI), decompressive surgery (DS) and splinting have been used, with a variable degree of success. There are scarce clinical trials comparing the different modalities of therapies in controlled and randomized conditions. Furthermore, very few studies have compared nerve conduction studies (NCS) before and after therapy. To date, the length of most of the NCS follow-up has been limited to a maximum of 6 months,

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after treatment (Padua et al., 1996; Aulisa et al., 1998; Demirci et al., 2002; Naidu et al., 2003; Hui et al., 2005).

In our randomized clinical trial (RCT) (Ly-Pen et al., 2005), data showed that CI and DS were similar in alleviating symptoms of primary CTS at one year follow-up. The objectives of the present study are to define the evolution of several parameters of NCS with CI or DS, and to assess whether clinical improvement observed after CTS therapy either with CI or DS correlates with a parallel improvement in the NCS. To our knowledge, this is the first RCT that characterizes the effects of CI and DS on NCS in CTS patients, with a follow-up of 12 months.

2. Patients and methods

2.1. Study design

The study was an open-label, prospective, randomly assigned, comparative clinical trial of CI versus DS in new onset idiopathic CTS (Trial Registration: Current Controlled Trials, www.controlled-trials.com, ISRCTN26264638). The study was performed in accordance to the Declaration of Helsinki principles. The Ethics Committee of University Hospital "Ramón y Cajal" reviewed and approved the study. Written informed consent was obtained from each patient before enrollment.

2.2. Study population

Eligible patients were at least 18 years-old, with suggestive symptoms of CTS (pain, tingling, burning, numbness, or some combination of those symptoms), in the fingers in the distribution of the median nerve, that may radiate to the forearm (Katz and Simmons, 2002), of at least three months of duration, and unresponsive to a course of at least two weeks of non-steroidal anti-inflammatory drugs and splints. Two hundred and seventeen wrists of 123 patients were evaluated. Exclusion criteria were clinical signs of severe motor impairment (such as atrophy of thenar eminence and/or muscle weakness), pregnancy, diabetes mellitus, hypothyroidism, inflammatory arthropathy, polyneuropathy, and previous CI or DS for CTS. All patients were evaluated by the same investigator (DLP). Patients with clinical diagnosis of CTS were invited to participate in the study and informed consent was requested. CTS was confirmed by NCS, according to Kimura (2001).

2.3. Treatment

All the surgical procedures were performed on an outpatient basis and carried out by the same investigator (ASO) by means of a limited palmar incision technique, previously described (Serra et al., 1997; Andrew Lee et al., 1998; Jugovac et al., 2002). Local CI were done by the same investigator (DLP), using a standard technique (Katz, 1994; Katz and Simmons, 2002). If symptoms did not disappear after the first injection, a second was given two weeks later.

2.4. Clinical endpoints

Patients were asked to assess their baseline values through a visual analogue scale (VAS) from 0 (no symptoms) to 100 mm (the most intense symptoms) for nocturnal paresthesias (np-VAS) in the distribution territory of the median nerve, pain (p-VAS), and overall self-perceived functional impairment (f-VAS). Visual analog scales for the three dimensions were obtained at baseline, 3, 6 and 12 months. The Disabilities of the Arm, Shoulder and Hand (DASH) questionnaire (Hudak et al., 1996) could not be used because it was not validated for the Spanish population when the study began (Rosales et al., 2002).

2.5. Nerve conduction studies

Nerve conduction studies (NCS) of both median and ulnar nerves, and median–ulnar comparison of the affected side were done by the same investigator (GDB) at baseline and at the 12-month follow-up. Skin temperature was measured before testing and hands with a temperature below 32 °C were warmed. Sensory and motor nerve conduction was studied using surface electrodes for stimulating and recording. The ground electrode was placed at the wrist. For median nerve motor conduction, stimulation was performed at the wrist and elbow, and the compound muscle action potential (CMAP) was recorded from the thenar eminence, with the active recording electrode placed over the belly of the abductor pollicis brevis and the reference electrode over the abductor pollicis brevis tendon, with the stimulating and recording cathodes 7 cm apart. For median nerve sensory conduction, antidromic stimulation was performed at the wrist and elbow, and the sensory nerve action potential (SNAP) was recorded with ring electrodes around the proximal (active) and distal (reference) interphalangeal joints of the third finger. The stimulating and recording cathodes were 14 cm apart. For ulnar nerve motor conduction, stimulation was performed at the wrist and above elbow; CMAP was recorded with the active electrode placed over the belly of the abductor digiti V muscle and the reference electrode over the tendon of this muscle. For ulnar nerve sensory conduction, antidromic stimulation was performed at the wrist and above elbow, and the SNAP was recorded with ring electrodes, the active around the proximal interphalangeal joint of the fifth finger, and the reference electrode around the distal phalanx of the finger. For the median-ulnar comparison, SNAP was recorded with ring electrodes at the ring finger, and median and ulnar nerve were stimulated at the wrist, both at the same distance (14 cm). In the motor studies, latencies were measured from the stimulus onset to the initial negative response, and amplitudes were measured from baseline to negative peak. In the sensory studies, latencies were measured from the stimulus onset to the initial negative response, and amplitudes were measured from peak to peak. The criteria for the diagnosis of CTS were: (a) a median distal motor latency (DML) from wrist to thenar, greater than 2 standard deviation (SD) of the normal mean (4.2 ms), with a difference of ulnar nerve distal motor latency greater than 2 SD above the mean (1.4 ms); or (b) a decrease of the median sensory conduction velocity under 2 SD from the normal mean (44 m/s), with a latency difference of ulnar nerve sensory potential greater than 2 SD above the mean (0.7 ms). The lower normality values of compound muscle action potential of median nerve, considered the mean less 2 SD, has been of 3.5 mV for the motor potential and of 19 μV for the sensory potential.

2.6. Statistical analysis

We analyzed the data according to the number of wrists that completed the study. The nerve conduction parameters, the outcome measures for severity of complaints, and the change scores (difference between baseline and follow-up) were calculated for each wrist separately. Statistic signification was established by the Student's t test, independent and paired samples, and Mann–Whitney test. Repeated measures analysis of variance was used for the three domains of symptoms. The associations between the changes in the nerve conduction parameters and the changes in the clinical outcome measures were assessed with Pearson correlation coefficients, because this scores followed a normal distribution, determined by Kolmogorov normality test. A strong correlation was arbitrarily defined as 0.7 or higher. All p values