International Journal of Current Advanced Research
ISSN: O: 2319-6475, ISSN: P: 2319-6505, Impact Factor: 6.614
Available Online at www.journalijcar.org
Volume 9; Issue 05(D); May 2020; Page No.22304-22309
DOI: http://dx.doi.org/10.24327/ijcar.2020.22309.4394

Research Article

EFFECTS OF THE TREATMENT OF CARPAL TUNNEL SYNDROME WITH SURGERY AND INJECTIONS ON THE MEDICAL OUTCOMES STUDY 36-ITEM SHORT FORM HEALTH SURVEY (SF-36).

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A R T I C L E I N F O

Article History:
Received 13th February, 2020
Received in revised form 11th March, 2020
Accepted 8th April, 2020
Published online 28th May, 2020

Key words:
Carpal tunnel syndrome; Quality of life; Medical Outcomes Study 36-Item Short-Form Health Survey (SF-36); steroid injection; sur

A B S T R A C T

Objective: To assess the effects of Carpal Tunnel Syndrome (CTS) treatment, with corticosteroid injection versus surgery on the punctuations of the Medical Outcomes Study 36-Item Short Form Health Survey (SF-36). Methods: Open, randomized clinical trial, comparing injection and surgery. CTS was confirmed by electro diagnostic testing. Each patient fulfilled a subjective evaluation of symptoms with a visual analogue scale of pain (VAS-p) and the SF-36 questionnaire, before treatment and at 3, 6 and 12-month after treatment. Statistic signification was established by the Student´s t test. Results: Sixty-five patients were eligible for the trial, with 30 patients randomly assigned to local infiltration and 35 to surgical decompression. There was no statistical difference between groups. Both groups improved significantly in the VAS-p compared with basal values at 3, 6 and 12-month follow-up. Basally, there were no statistical differences between both groups (including the eight SF-36 subscales). At 3-month follow-up both groups improved similarly. At 6-month follow-up, the surgery group had a significantly better punctuation for the general health perceptions subscale (66,0 vs 55,3; p = 0,026) and mental health subscale (74,3 vs 66,4; p = 0,021). At 12 months follow-up, the surgery group obtained a significantly better punctuation in the role-physical subscale (p = 0,041). Conclusions: In CTS treatment, both injection and surgery achieve significantly good punctuations on the Medical Outcomes Study 36-Item Short-Form Health Survey (SF-36). Despite this, surgery seems better in middle-term follow-up, in several subscales of SF-36.

INTRODUCTION

Carpal tunnel syndrome (CTS) is the most common peripheral nerve entrapment syndrome and one of the most frequent upper extremity disorders [Katz & Simmons, 2002]. A recent population-based study has established a prevalence of 2.7 % in general population Association [Atroshi *et al*., 1999a].

The most common symptoms are numbness and pain within the median nerve distribution that typically worsens at night [Katz & Simmons, 2002].

There are no universally accepted clinical and laboratory diagnostic criteria. It is commonly assumed, however, that electro diagnostic testing (EDT) support the diagnosis. The most widely used treatments of this condition are local injections of corticosteroids (I) and surgery (S). Both treatments have shown good symptomatic results at 1-year follow-up [Ly-Pen *et al*., 2005]. In spite of the importance of CTS (its high prevalence and incidence, the bothering symptoms affecting sleep and manual activities), there are few studies investigating CTS and its influence on quality of life [Atroshi *et al*., 1999b; Jensen *et al*., 2006].

Self-administered questionnaires for the assessment of symptom severity and functional status in CTS have been introduced and shown to be reliable and valid [Atroshi *et al*., 1999b; Jensen *et al*., 2006]. Most of these studies had been conducted in patients treated with S [Atroshi *et al*., 1999b; Besette *et al*., 1988; Gay *et al*., 2003; Galasso *et al*., 2011; São Romão Preto *et al*., 2015; Imaeda *et al*., 2006; Wang *et al*., 2020] and few of them with conservative treatments [Jensen *et al*., 2006; Boyd *et al*., 2005; Atroshi *et al*., 2013].

To our knowledge, the quality of life before and after randomised I and S treatment, had never been studied before.

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Objectives

The objective of this study was to assess the effects of the treatment of CTS either with I or with S on two scales: 1) a visual analogue scale of pain (VAS-p) and 2) the punctuations of the Medical Outcomes Study 36-Item Short Form Health Survey (SF-36)[Ware *et al*., 1980], adapted for the Spanish population [Alonso *et al*., 1995].

Patients AND Methods

Study design. This study was performed as a post-hoc analysis ofour previously published, 1-year prospective, randomised, open, comparative clinical trial of I versus S for new-onset CTS[Ly-Pen *et al*., 2005]. The study was conducted in accordance with the principles of the Declaration of Helsinki. The Ethics Committee of the University Hospital "Ramón y Cajal" reviewed and approved the study. Written informed consent was obtained from each patient before study enrolment. In patients with bilateral CTS, treatment assignments were made for individual wrists. An intent-to-treat analysis was performed according to the number of wrists randomly assigned to I or S[Ly-Pen *et al*., 2005].Only patients with a single wrist affected, or both wrists assigned to the same treatment (either I or S) were included in the present study.

Study population. Eligible patients were at least 18years old, had suggestive symptoms of CTS of at least 3months' duration, were consecutively referred by 26 general practitioners to a CTS unit specifically created for this study, had a presumptive diagnosis of CTS, and had been unresponsive to a course of at least 2 weeks of nonsteroidal anti-inflammatory drugs (NSAIDs) and splinting. Two hundred seventeen wrists in 123 patients were evaluated (See flow chart in Figure 1).

We excluded wrists with thenar atrophy, previous carpal tunnel release surgery, or previous local injection for CTS. As per protocol, we also ruled out patients who were pregnant or diagnosed with diabetes mellitus, hypothyroidism, inflammatory arthropathy, or polyneuropathy [Ly-Pen *et al*., 2005].The enrolment criteria were designed to represent the general population that seeks medical attention from their general practitioners because of new-onset CTS that is not associated with pregnancy and has been refractory to first-line treatment with NSAIDs and splinting. All patients were evaluated by the same investigator (DLP). After undergoing a complete clinical history and physical examination, patients with a clinical diagnosis of CTS (pain, tingling, burning, or numbness, or some combination of these symptoms, in the fingers in the distribution of the median nerve) [Atroshi *et al*., 2009a] were invited toparticipate in the study, and informed consent was requested.CTS was later confirmed in all cases by EDT, according to the criteria described by Kimura [Kimura, 2001].

A total of 163 wrists of 101 patients (93 women and 8 men) were enrolled. Eighty wrists were randomly assigned to S, and 83 wrists were randomly assigned to I.

For our purpose, 65 patients were chosen for the analysis of the quality of life (SF-36). Thirty patients were randomly assigned to local infiltration and 35 to surgical decompression. At baseline, there was no statistical difference between groups in terms of age, gender distribution, disease duration, VAS-p, EDT severity of CTS or any of the eight subscales of SF-36 questionnaire.

Outcomes. We used three outcomes to measure the effect of I and S. The first was the VAS-p, where each patient marked the severity of their pain, on a 100 mm continuous line, where "0" was no pain at all, and "100" was the maximum pain they could feel. The second was the Health-Related Quality of Life [Ware *et al*., 1980; Ware & Sherbourne, 1992], through the eight subscales of the Spanish validated SF-36 questionnaire [Alonso *et al*., 1995]. Both outcomes were assessed at baseline and at 3, 6, and 12 months after the end of each therapy. The SF-36 Health Survey includes one multi-item scale that assess eight health concepts [Atroshi *et al*., 2013; Kimura, 2001]: 1) limitations in physical activities because of health problems; 2) limitations in usual role activities because of physical health problems; 3) bodily pain; 4) general health perceptions; 5) vitality (energy and fatigue); 6) limitations in social activities because of physical or emotional problems; 7) limitations in usual role activities because of emotional problems; and 8) general mental health (psychological distress and well-being).

Treatment. All surgical procedures were performed onan outpatient basis by the same investigator (ASO) using alimited palmar incision technique, as previously described [Serra *et al*., 1997; Tarallo *et al*., 2014; Liawrungrueang & Wongsiri, 2020]. We chose this approach because it is the usualsurgical procedure for CTS decompression performed at ourunit.

Local steroid injections were performed by the same investigator (DLP) using a standard technique [Katz & Simmons, 2002; Ly-Pen *et al*., 2005]. Treated wrists were evaluated 14 days after the initial treatment. In the operated wrists, the main objective of this visit wasto examine the evolution of the scar. In the injected wrists, the protocol allowed a second injection if painhad not disappeared completely (i.e. score of 0 in the VAS-p). In both groups of treatment, a new follow-up visit was scheduled for about 3-month time after the procedure.

Statistical analysis

A statistical description of the patients was done, summarising the quantitative variables with the mean and standard deviation, or the median and interquartile range, in the case of asymmetric distributions.

The qualitative variables were summarised within the absolute and relative frequency. The results obtained in both groups of treatment were compared. The quantitative variables using students´ "t" for independent groups, or the Mann Whitney "U" for the non-parametric supposes.

The comparison among qualitative variables was done using the $\chi 2$ test, or the Fisher´s test when needed. The intragroup comparisons for quantitative variables at baseline and 12 months was performed by paired Student's test or its non-parametric equivalent Wilcoxon's test.

Intragroup comparisons of proportions were made using McNemar's test. We used a signification level of 0.05 and we calculated the confidence intervals to 95%. The statistic program used was SPSS 15.0

RESULTS

Fifty-six patients underwent S, in 24 of them the S was bilateral. Forty-nine patients received a single local injection; in 34 of them, the injection was bilateral.

Both S and I groups improved significantly in the VAS-p compared with basal values in the follow-up at 3, 6 and 12 months; there were no statistical differences between both groups (Table 1).

The SF-36 values also improved significantly in both groups. At 3-month follow-up, both groups improved in a similar way. At 6-month follow-up the S group had a significantly better scoring for the general health perceptions subscale (66.0 vs 55.3; p = 0.026) and mental health subscale (74.3 vs 66.4; p = 0.021). At 12-month follow-up, the S group obtained a significantly better scoring in the role-physical subscale (p = 0.041) (See Table 2).

Table 1 Visual analogic scale of pain in both arms of treatment: local injections and surgery (patients with bilateral wrist involvement, but not same treatment in both wrists, were not included in this study)

VAS-p (mm)	Injection	Surgery	p
Baseline	51.7	46	0.407
3 months	8,4	18,6	0,078
6 months	8,8	8,6	0,977
12 months	11	3	0,067

Table 2 Comparison of injection and surgery groups, SF-36, baseline, at 3,6 and 12-month follow-up

	Group Injection	Group Surgery	p
Number of patients			
- baseline	30	35	-
- 3 months	30	34	-
- 6 months	30	31	-
- 12 months	27	29	-
Physical functioning			
- baseline	65.5	67.8	0.698
- 3 months	73.8	72.8	0.855
- 6 months	73.8	76.6	0.621
- 12 months	74.4	77.1	0.648
Role – physical			
- baseline	38.3	4.,8	0.363
- 3 months	59.2	62.5	0.740
- 6 months	64.1	73.4	0.359
- 12 months	59.2	80.2	0.041
Bodily pain			
- baseline	38.9	38.5	0.948
- 3 months	59.2	54.0	0.366
- 6 months	60.5	66.2	0.395
- 12 months	60.7	69.7	0.171
General health perceptions			
- baseline	51.6	58.3	0.181
- 3 months	58.1	62.0	0.383
- 6 months	55.3	66.0	0.026
- 12 months	60.2	65.8	0.203
Vitality			
- baseline	51.7	54.0	0.666
- 3 months	58.8	59.7	0.850
- 6 months	56.3	65.0	0.059
- 12 months	59.8	65.2	0.265
Social functioning			
- baseline	70.4	77.8	0.241
- 3 months	80.4	82.0	0.772
- 6 months	82.9	87.5	0.358
- 12 months	82.9	89.2	0.196
Role – emotional			
- baseline	71.1	80.9	0.278
- 3 months	76.6	87.2	0.218
- 6 months	90.0	96.8	0.298
- 12 months	86.4	95.4	0.189
Mental health			
- baseline	58.2	64.4	0.233
- 3 months	65.5	69.0	0.439
- 6 months	66.4	74.3	0.021
- 12 months	67.7	74.9	0.054

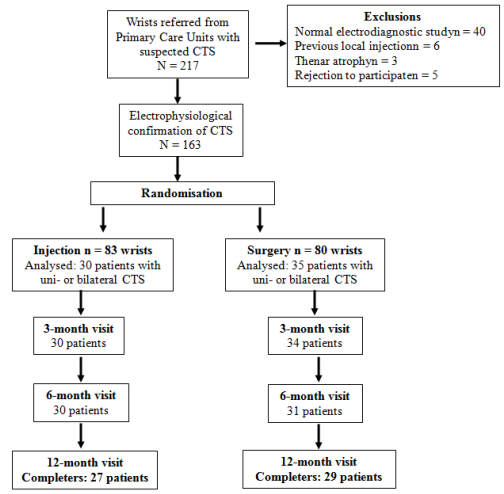

Figure 1 Flow chart of the study population. For current analysis, we only included patients with unilateral CTS or bilateral CTS with both writs assigned to the same treatment (either I or S)

DISCUSSION

As we demonstrated in the previous study [Ly-Pen *et al*., 2005], both treatments, I and S are similarly effective at 3, 6 and 12-month follow-up. Furthermore, our current analysis show that both I and S, achieve significantly good punctuations of the Medical Outcomes Study 36-Item Short-Form Health Survey (SF-36). At 3-month follow-up, both groups improved in a similar way. At 6-month follow-up, the surgery group had a significantly better scoring for the general health perceptions subscale (66.0 vs 55.3; p = 0.026) and mental health subscale (74.3 vs 66.4; p = 0.021).

At 12 months follow-up, the S group obtained a significantly better scoring in the role-physical subscale (p = 0.041).

Both therapeutic modalities are equally effective, but surgery seems better, in medium-term follow-up, in several subscales of SF-36.

There are several questionnaires designed to measure symptoms and functional status of patients with upper-extremity disorders, to compare the relative impact of treatments or their natural evolution. Awell-known one is the Disabilities of the Arm, Shoulder and Hand questionnaire (DASH) [Hudak *et al*., 2009]. Nevertheless, probably the most specific CTS' questionnaire, The Brigham and Women's Carpal Tunnel Questionnaire (BCTQ) may be more sensitive to small changes [Levine *et al*., 1993; Keith *et al*., 2009]; however, it is not designed to compare the effects of multiple conditions within a population, and gives a narrower view of disease activity [Keith *et al*., 2009]. Both questionnaires have demonstrated sufficiently responsiveness for use in outcome studies of CTS done 12 or more weeks after surgery [Gay *et al*., 2003].

The Medical Outcomes Study 36-Item Short-Form Health Survey (SF-36) is a general health status measure; it was developed in the USA for use in the Rand Corporation's Health Insurance Experiment [Ware *et al* 1980]. It has been translated into more than 120 languages and has been used around the world to gauge the health of local populations [Rosales *et al*., 2002]. Nevertheless, SF-36 was not designed to measure outcome of specific conditions [Ware & Sherbourne, 1992].

The SF-36 Health Survey had been used to assess general health status in samples of patients with a variety of diseases,

including CTS [Jarvik *et al*., 2009]. As it looks at a broadly based assessment of health, it may not be very responsive to changes in status related to CTS [Keith *et al*., 2009]. Almost of all the studies comparing pre and post-treatment in CTS, had been conducted with surgery [Atroshi *et al*., 1999b; Besette *et al*., 1988; Gay *et al*., 2003; Galasso *et al*., 2011; São Romão Preto *et al*., 2015; Imaeda *et al*., 2006; Wang *et al*., 2020].

Compared with the general population SF-36 norms, CTS patients have significantly worse scores for physical functioning, physical role, pain, vitality and the physical component summary before surgery [Cheadle *et al*., 1994].

The shortest follow-up was reported by Dominguez *et al*; 1-month post-surgery follow-up, their patients showed clinical improvement (measured by DASH & VAS), but SF-36 had no statistical changes [Domínguez *et al*., 2017]. Nonetheless, São Romão *et al*, 2 months after surgery, demonstrated that both Boston questionnaire and six parameters of the SF-36 improved, except physical role and general health perception [São Romão Preto *et al*., 2015].

Atroshi *et al* compared CTS patients with the general population SF-36 norms. He reported that CTS patients had significantly worse scores for physical functioning, physical role, pain, vitality, and the physical component summary before surgery. Three months post-surgery, theyshowed not only clinical improvement, but also SF-36 scores normalisation, except for physical role and the physical component summary [Atroshi *et al*., 1999b].

Gay *et al* reported that at 3-month follow-up, the most sensitive instrument to clinical change, as judged by effect size and standardized response means, was the Carpal Tunnel Questionnaire (effect size/standardized response means, 1.71/1.66). DASH questionnaire in second place (1.01/1.13), and SF-36 bodily pain (0.57/0.52) and role physical (0.39/0.39) subscales [Gay *et al*., 2003].

Imaeda *et al* studied their patients before and three months after surgery, with DASH (Japanese validated version), VAS-p, SF-36, and physical exam (objective assessment of grip strength, pinch strength and static two-point discrimination). At 3-monthfollow-up, DASH displayed the highest sensitivity to changes, followed by the VAS-p. All subscales of SF-36 were much less sensitive. Both grip and pinch strength remained unchanged [Imaeda *et al*., 2006].

In longer follow-up, Galas so *et al* published that at 6 months post-surgery, his patients improved all the three scales: Boston Carpal Tunnel Questionnaire, the historical-objective scale (Hi-Ob scale) and the SF-36 mental and physical summary scores[Galasso *et al*., 2011].

Wolny *et al* evaluated the overall health status of patients with mild to moderate forms of carpal tunnel syndrome (CTS) using 36-Item Short Form Health Survey (SF-36).His results showed that CTS affects the physical component of SF-36but not the mental component summary of overall health status [Wolny *et al*., 2017]

Our study has several strong points. It was the first study published in the literature, randomising CTS treatments either to I or S. After the diagnosis of CTS was confirmed by EDT, they were randomised either to treatment with decompressive surgery or to local injections [Ly-Pen *et al*., 2005]. It was designed from the beginning to include only newly diagnosed primary CTS in patients with suspicious symptoms, in an outpatient basis and in a Primary Care setting. In fact, all these patients were referred by general practitioners of our working area (Madrid Health Service, 4th Area. Province of Madrid). On the contrary, the vast majority of the other CTS studies have been designed and conducted in a secondary care setting. Likely, these patients had a longer evolution, other co morbidities and perhaps a more severe or advanced CTS than our naive patients [Andeu *et al*., 2013; Oteo-Álvaro *et al*., 2016]. Furthermore, patients that have done well in primary care with conservative therapies (not only local injections), did not need referring to secondary care, with the consequent selection bias. For this reason, our study may reflect much more realistically than other studies how primary CTS behaves in the general population.

We are aware of the limitations of the present study. This was a study randomising wrists, not patients. In this way, we had to rule out those patients with bilateral wrist involvement that both wrists did not fall into same treatment, either I or S.

Furthermore, when we conducted our study, both DASH and Boston Carpal Tunnel Questionnaire had not been validated in the Spanish population [Rosales *et al*., 2002; Oteo-Álvaro *et al*., 2016]. This is the reason why we had to use the VAS for pain.

Of course, we must exclude all studies involving work-related carpal tunnel syndrome where an economic compensation is involved. There is a strong evidence that these patients do worse, especially in claimants who remain disabled at six months after an injury that did not require hospitalization [Cheadle *et al*., 1994], and in a workers' compensation board claim despite greater use of treatment and comparable severity of disease [Sperka *et al*., 2008].

Acknowledgments

The authors are indebted to Dr Joseph Hogg, partner at Abbey House Medical Centre, for his critical review, helpful comments and careful English revision.

Declarations

Funding

No funding available. All authors declare no support from any organisation for the submitted work.

Conflicts of interest/Competing interests

The authors declare that they have no conflict of interest. No benefits in any form had been received or will be received from a commercial party related directly or indirectly to the subject of this article.

Ethics approval

All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards. This study was approved by the Ethics Committee of the University Hospital Ramón y Cajal (Trial Registration: Current Controlled Trials, www.controlled-trials.com, ISRCTN26264638).

Consent to participate

All patients signed informed consent before enrolling the study. No individual's personal data is included

Consent for publication

Domingo Ly, the corresponding author, has the right to grant on behalf of all authors, and do grant on behalf of all authors, an exclusive licence, on a worldwide basis, to permit this article (if accepted), to be published in your journal.

Availability of data and material (data transparency)

Please contact author for data requests.

Code availability (software application or custom code)
SPSS 15.0.

Authors' contributions

DLP attended and reviewed the patients, injected all patients of the injection group, collected data, wrote the paper and is the corresponding author. JLAS conceived, designed, coordinated the study and helped in data analysis and writing the paper. GdBB did the neurophysiological studies of all patients and assisted in the analysis of data. ASO operated all patients of the surgery group and helped in study design. MAS provided statistical consulting, helped in writing the paper, and analysed and interpreted the patient data. All authors read and approved the final manuscript.

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How to cite this article:

Domingo Ly-Pen *et al* (2020) 'Effects of the Treatment of Carpal Tunnel Syndrome with Surgery and Injections on the Medical Outcomes Study 36-Item short form Health Survey (sf-36).', *International Journal of Current Advanced Research,* 09(05), pp. 22304-22309. DOI: http://dx.doi.org/10.24327/ijcar.2020. 22309.4394

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