A randomized controlled (intervention) trial of ischemic compression therapy for chronic carpal tunnel syndrome

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Study Design: Randomized clinical trial.

Objective: The aim of this study was to evaluate the effect of ischemic compression therapy in the treatment of chronic carpal tunnel syndrome.

Method: Fifty-five patients suffering from carpal tunnel syndrome were randomized to two groups. Thirty-seven patients received 15 experimental treatments which consisted of ischemic compressions at trigger points located in the axilla of the shoulder, the length of the biceps muscle, at the bicipital aponeurosis and at the pronator teres muscle in the hollow of the elbow. Eighteen patients received the control treatment involving ischemic compression on trigger points located in the deltoid muscle, supraspinatus muscle and infraspinatus muscle. Of the 18 patients forming the control group, 13 agreed to receive the experimental treatments after the 15 control treatments. Outcome measures included a validated 18-question questionnaire to assess the severity of symptoms and functional status in carpal tunnel syndrome, and a quantification of the patients’ perceived improvement, using a scale from 0% to 100%. Outcome measures evaluations were completed at baseline, after 15 treatments, 30 days following the last treatment, and 6 months later.

Results: For the disability questionnaire, a significant reduction of symptoms was noted only in the experimental group. In the experimental group the outcome at baseline was 33.5 (SD, 10.3); after 15

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Méthodologie : essai clinique randomisé.

Objectif : le but de la présente étude est d’évaluer l’effet de la compressothérapie ischémique dans le traitement du syndrome du canal carpien chronique.

Méthode : Cinquante-cinq patients souffrant du syndrome du canal carpien ont été séparés aléatoirement en deux groupes. Trente-sept patients ont reçu 15 traitements expérimentaux, qui consistaient en des compressions ischémiques à des points gâchettes situés dans le creux axillaire de l’épaule, le long du biceps, à l’aponévrose bicipitale et au muscle rond pronateur situé dans le creux du coude. Dix-huit patients ont reçu le traitement contrôle, qui comprenait des compressions ischémiques sur des points gâchettes situés dans le muscle deltoïde, le muscle sus-épineux et le muscle sous-épineux. Des 18 patients du groupe contrôle, 13 ont accepté de recevoir les traitements expérimentaux à la suite des 15 traitements contrôles. Les mesures des résultats incluent un questionnaire validé de 18 questions servant à évaluer la gravité des symptômes et les capacités fonctionnelles relativement au syndrome du canal carpien, ainsi qu’une quantification des améliorations perçues par les patients, au moyen d’une échelle allant de 0 % à 100 %. Les évaluations mesurant les résultats ont été effectuées au niveau de base, après 15 traitements, 30 jours après le dernier traitement et six mois plus tard.

Résultats : du côté du questionnaire sur l’invalidité,
Intervention

Carpal tunnel syndrome (CTS) is one of the most common and most clinically significant of all nerve entrapment syndromes.\(^1\) Numbness and paresthesia along the distribution of the median nerve in the hand, i.e., the thumb, index, major and half the ring finger are common symptoms related to CTS. Symptoms and concurrent discomfort often peak at night and may wake the patient several times. To ease pain and discomfort, the patient will shake the affected hand(s) and flex the fingers vigorously.\(^2\)

Point prevalence of CTS is estimated at 2.7% and it is typically diagnosed in adults over the age of 30.\(^3\) The symptoms generally originate from a nerve compression occurring when the median nerve runs through a fibrous or fibro-osseous tunnel or switches direction around a fibrous or muscular band.\(^2,4\)

Forty-seven percent of CTS cases can be related to the patient’s occupation. Over the last decades, there has been a major increase in work-related CTS cases.\(^5,6\) Compression or entrapment may be present at a number of sites along the median nerve.\(^7,8\) To describe such phenomenon, Leahy uses the expression “the whole nerve syndrome”.\(^7\)

Conservative allopathic treatment usually includes wrist support, change in activities and anti-inflammatory medication. If symptoms are not relieved by a conservative approach within a six-month period, cortisone injections may be used. Wrist surgery (carpal tunnel release) is considered where symptoms remain pronounced and treatments it was 18.6 (SD, 7.0). The control group outcome at baseline was 36.3 (SD, 15.2); after 15 treatments it was 26.4 (SD, 9.9) and after the crossover (15 control treatments plus 15 experimental treatments) 20.2 (SD, 12.2). A significant between group difference (P < 0.021) was noted in the patients’ perceived improvement after 15 treatments: 67 (SD, 26) percent and 50 (SD, 25) percent respectively for the experimental and control groups.

Conclusion: This practice-based clinical trial suggests that myofascial therapy using ischemic compression the length of the biceps, at the bicipital aponeurosis, at the pronator teres and at the subscapularis muscles could be a useful approach to reduce symptoms associated with the carpal tunnel syndrome. Patients’ perceived improvement in functional capacities persisted over a 6-month period.

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Key words: chiropractic, myofascial trigger points, ischemic compression, carpal tunnel syndrome, randomized clinical trial

Une diminution significative des résultats n’a été remarquée que chez le groupe expérimental. Pour le groupe expérimental, le résultat au niveau de base était de 33,5 (écart-type : 10,3); après 15 traitements, il était de 18,6 (écart-type : 7,0). Le résultat du groupe contrôle au niveau de base était de 36,3 (écart-type : 15,2); après 15 traitements, il était de 26,4 (écart-type : 9,9) et après le traitement croisé (15 traitements contrôles et 15 traitements expérimentaux) de 20,2 (écart-type : 12,2). Une différence significative entre les groupes (p < 0,021) a été notée dans la perception qu’ont les patients de leur amélioration après 15 traitements : 67 % (écart-type : 26) et 50 % (écart-type : 25) respectivement pour le groupe expérimental et le groupe contrôle.

Conclusion : Cet essai clinique fondé sur la pratique suggère que la thérapie myofasciale au moyen de compressions ischémiques le long du biceps, à l’aponévrose bicipitale, au muscle rond pronateur et aux muscles subscapulaires pourrait s’avérer un moyen utile de réduire les symptômes associés au syndrome du canal carpien. L’amélioration des capacités fonctionnelles, telle que perçue par les patients, a persisté pendant 6 mois.

(JCCA 2010; 54(3):155–163)

Mots clés : chiropratique, point gâchette myofascial, compressions ischémiques, syndrome du canal carpien, essai clinique randomisé.
motor and sensitive functions decline.\textsuperscript{4,9} There are three main reasons why patients agree to undergo surgery for CTS: (1) relief of night pain (36\% of surgical patients), (2) relief of hand numbness (21\%), (3) relief of daytime pain (13\%).\textsuperscript{10}

Furthermore, almost a third of the patients who have undergone CTS surgery experience persistent or recurrent symptoms after surgery and report that the initial improvement associated with carpal tunnel surgery is lost within less than two years.\textsuperscript{10} The most significant discomfort described by patients after carpal tunnel surgery is pain in the area of the scar, and a weakened hand.\textsuperscript{10} On average, two years following surgery, 30\% of patients characterize their results as being poor to medium.\textsuperscript{11}

\section*{Natural history of CTS}
When CTS is not treated surgically, the symptoms usually disappear after nine months in the case of one half of those patients who do not move on to a surgical procedure. However, 22\% of such patients continue to have symptoms eight years later.\textsuperscript{12}

Self-rating scales represent the most valid assessment method for CTS.\textsuperscript{13} When clinical symptoms are not conclusive and common CTS diagnostic procedures are unable to confirm the presence of median nerve compression, it may be necessary to use electrodiagnostic procedures.\textsuperscript{13–15} These procedures are rarely appropriate for initial CTS assessment, but are essential when it comes to pre-surgery examinations.\textsuperscript{13–15}

Carpal tunnel syndrome is commonly treated in chiropractic. In 1988, the number of cases of CTS declared by various specialists broke down as follows: chiropractors (23\%), specialists in internal medicine (19\%), neurologists (14\%), and family physicians (9\%).\textsuperscript{5}

A CTS survey study involving 254 physicians was carried out in 74 outpatient sentinel practices in 30 US states and three Canadian provinces. The authors of the study collected data from 552 CTS patients.\textsuperscript{16} Of this number, 23.5\% were women, 70.4\% were aged between 30 and 49, and 61.4\% said that their work involved physical strain or repetitive movements. Clinicians determined that 43.1\% of these cases were caused by the work itself. These practitioners rarely used electrodiagnostic procedures, preferring conservative initial treatment such as wrist support and anti-inflammatory medication, while cortisone injections were rarely used.\textsuperscript{16} Another study showed that 40\% of 125 CTS sufferers who received conservative treatments over a period of 30 months said that they were willing to put up with their low-level residual symptoms for the rest of their life.\textsuperscript{17}

\section*{Rationale for using ischemic compression therapy in the treatment of carpal tunnel syndrome}
Since, in patients suffering from carpal tunnel syndrome, the median nerve is more than twice (2.1 times) its normal size when it enters the carpal tunnel,\textsuperscript{18} the authors of the present trial hypothesized that part of the cause of the related oedema could be noxious myofascial sites along the median nerve course. Along its course, part of this nerve enters the axilla of the shoulder, runs immediately adjacent to the biceps, and descends within the hollow of the elbow under the pronator teres muscle and the bicipital aponeurosis. Other authors suggest that compression or entrapment may be present at a number of sites along the median nerve.\textsuperscript{7–8} In the present trial, the clinicians found hypertonicity and trigger points (TrPs) along the biceps of every participant. Trigger points in the hollow of the elbow were also present in all cases. It was suspected that eliminating the trigger points located along the median nerve course would diminish the CTS symptoms with or without normalizing the size of the median nerve.

Figure 1 illustrates the trigger point locations along the biceps, at the bicipital aponeurosis and in the pronator teres muscle. In skeletal muscles the blood flow is extremely variable and it is tied to the activity level. At rest, only 25\% of their capillaries are open.\textsuperscript{19} With exercise the blood flow can increase up to 10 times, at which point almost all the capillaries open up to admit more blood.\textsuperscript{19} In the present trial, the affected biceps (principally) was in partial and continual contraction because of TrPs. It is known that TrPs in a muscle cause a partial contraction.\textsuperscript{20,21} This contraction state results in higher consumption of oxygen and glucose. However during the night, with blood flow being much less, the supply of oxygen and glucose diminishes and lactic acid then accumulates and accentuates the contraction state. The authors of the present trial speculate that, during the night, the median nerve being more irritated, the patient is awakened by increased numbness and pain in the hand. Shaking the arm vigorously increases the blood flow, eliminates the lactic acid, and consequently the biceps relaxes partially, the median nerve is less irritated and the numbness and pain diminish.
Our primary hypothesis of interest was that private clinic patients with CTS who are treated with ischemic compression on TrPs localized along the biceps, in the axilla and in the hollow of the elbow would exhibit more significant reduction in the severity of symptoms and improvement in functional status in comparison with patients treated with ischemic compression on TrPs localized in the deltoid, supraspinatus and infraspinatus muscles.

Methods

Participants
This prospective randomized clinical trial was conducted in a private clinic located in Trois-Rivières, Québec. The study was approved by the ethics committee of the Université du Québec à Trois-Rivières.

An advertisement was placed in a local newspaper on three different occasions offering CTS sufferers the opportunity to take part in this research project. The first 55 eligible patients were included in the study and underwent a course of 15 chiropractic treatments at a rate of three treatments per week (see Table 1). Thirty-seven patients received the experimental treatment; eighteen were given the control treatment (see Patient Flowchart). Patients accepted into the study were required to read and sign an informed consent form.

Randomization procedure
Each subject was randomly assigned to either the experimental group or the control group at a 2:1 ratio using a table of random numbers. Sixty numbers (2/3 even, 1/3 odd) were mixed in an envelope, and an independent research assistant drew a number for each participant, who was then allocated accordingly.

Treatment protocols
All the patients included in this study presented multiple trigger points (TrPs) and taut bands along the biceps and at the bicipital aponeurosis. TrPs at the pronator teres muscle were also common clinical findings, but were not present in two patients. Twenty patients had TrPs in the axilla of the shoulder. All patients were examined for TrPs in these four areas while in a supine position, the arm supine and spread along the body or, in the case of the axilla of the shoulder, the hand of the patient under his head.

Patients were advised to stop any treatments other than that provided by the chiropractor treating their CTS. During the treatment, at each visit, pressure was applied for 5–15 seconds to each of the identified trigger points. Thumb tip pressure (one thumb over the other) was then applied for 5 seconds every 2 cms, along the biceps. For the TrPs located in the hollow of the elbow (pronator teres, biceps aponeurosis) and in the axilla (subscapularis), the pressure was maintained for 15 seconds. Trigger points were treated using a light pressure, which was gradually increased until it reached the participant’s maximum pain tolerance level. The patients were blinded to treatment allocation and therefore did not know whether they were in the control or the experimental group.
Seventeen patients received 15 control treatments consisting of ischemic compressions of latent or active trigger points located in the posterior region of the clavicle (supraspinatus area), on the deltoid (anterior and lateral region), and on the center of the shoulder blade (infra-spinatus area). Since TrPs are often found in these locations, this control treatment would appear plausible to the patient and the authors believed that it would not induce significant clinical changes as concerned CTS symptoms. Following the control treatment phase of the study, the 18 patients who received fifteen control treatments were offered the opportunity to receive fifteen further treatments. They were still blinded to the kind of treatment they would receive. Thirteen agreed to continue with the treatment and, this time, only the experimental treatment was given.

Outcome measures

In order to quantify the severity of symptoms and the functional status of patients, a standard validated questionnaire specific to patients suffering from CTS was used. The scales used in this questionnaire are highly reproducible (Pearson correlation coefficient, R = 0.91 and 0.93 for severity of symptoms and functional status, respectively) and internally consistent (Cronbach alpha, 0.89 and 0.91 for severity of symptoms and functional status, respectively). This type of questionnaire was chosen because carpal tunnel patients generally consult their clinicians due to the severity of the symptoms experienced and the difficulty they have in carrying out normal daily tasks. The first part of the questionnaire defines the functional status of the patient while carrying out eight daily activities. The second part, using 10 simple questions, defines the severity of the symptoms experienced by the patient. All participants completed the questionnaire before and after the treatment protocol. A numerical scale where patients could rate their perceived improvement from 0% to 100% was also used. For the experimental group the questionnaire and numerical scale were also completed 30 days after the last treatment and 6 months later. For the control group, the questionnaire and the numerical scale were also completed after the crossover. The questionnaires were filled in without the assessor being present.

Statistical analysis

To test the effects of experimental treatment over the Time, a repeated-measures one-way ANOVA was performed. The same analysis was completed to test the cross-over effect in the control group. When a main effect of Time was observed for the experimental group, post hoc comparisons were performed using Tukey tests. A t-test for independent samples was used to compare the perceived improvement percentage between the control and experimental groups after 15 treatments. For all analyses statistical significance was set at $p < 0.05$.

Results

All 55 participants received the initial fifteen treatments and completed the questionnaires as intended. Fifty-five patients were randomly assigned to one of the two treatment groups. The t-test showed no statistically significant difference between the two groups’ baseline characteristics (see Table 2).

The experimental group symptoms and functional status scale questionnaire mean scores (and standard deviations) were 33.5 (SD, 10.3) at baseline; 18.6 (SD, 7.0)
Table 2  Baseline characteristics of the experimental and control groups. ( ) = SD

<table>
<thead>
<tr>
<th>Group</th>
<th>N</th>
<th>Gender</th>
<th>Age</th>
<th>Symptoms duration (years)</th>
<th>Disability score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Experimental</td>
<td>37</td>
<td>11M; 26F</td>
<td>46 (6.7)</td>
<td>4.3 (2.9)</td>
<td>33.5 (15.2)</td>
</tr>
<tr>
<td>Control</td>
<td>18</td>
<td>10M; 8F</td>
<td>47 (7.2)</td>
<td>2.4 (3.1)</td>
<td>36.3 (10.2)</td>
</tr>
</tbody>
</table>

Patients Flowchart

- Assessed for eligibility (N = 55)
- Enrolment
- Excluded (N = 0)
- Randomized
  - Allocated to intervention, experimental group (N = 37)
    - Received intervention (N = 37)
    - Assessment after 15 treatments (N = 37)
    - Assessment 30 days after the treatments (N = 37)
    - Assessment 6 months after the treatments (N = 37)
  - Allocated to interventions, control group (N = 18)
    - Received intervention (N = 18)
    - Assessment after the 15 treatments (N = 18)
    - Cross-over (N = 13)
      - Received the experimental treatment (N = 13)
    - Assessment after 30 treatments (N = 13)
after 15 treatments; 17.5 (SD, 6.1) thirty days following
the last treatment, and 20.7 (SD, 7.4) at 6 months. The
experimental group maintained a significant reduction in
the symptoms and functional status scale questionnaire
scores at both follow-up evaluations (One-way ANOVA:
F (3, 108) = 39.2, p < 0.0001). Conversely, the repeated-
measure ANOVA yielded a significant decrease for the
control group only after the cross-over: 36.3 (SD, 15.2)
at baseline; 26.4 (SD, 9.9) after 15 placebo treatments;
and 20.2 (SD, 12.2) after the cross-over (One-way ANO-
VA: F (SD, 2, 24) = 10.1, p < 0.001). Figure 2 illustrates
the symptoms and functional status scale questionnaire
changes in both groups throughout the trial. Mean (SD)
 improvement in the symptoms and functional status scale
questionnaire are presented in Table 3.

A significant difference (p < 0.021) was noted between
the two groups regarding the perceived improvement
scores after 15 treatments. The mean perceived percentage
of improvement was 67 (26) and 50 (25) for the experi-
mental and control groups respectively. Table 4 presents
the mean scores from the perceived improvement numerical
scale for both groups throughout the experiment.

Discussion
In this study, patients’ symptoms associated with CTS
improved in the majority of patients who received is-
chemic compression therapy in the axilla of the shoul-
der, the length of the biceps, at the bicipital aponeurosis
and at the pronator teres muscle. The data from the two
questionnaires showed an improvement in both groups,
but the improvement was significantly greater in the ex-
perimental group than in the control group. Moreover,
a significant reduction in pain and improved functional
status were noted after the crossover (75% improvement)
when the participants in the control group received the

<table>
<thead>
<tr>
<th>Table 3</th>
<th>Mean (SD) improvement in severity of symptoms and functional status (%)</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>15 treatments</td>
</tr>
<tr>
<td>Experimental (N = 37)</td>
<td>42 (21)</td>
</tr>
<tr>
<td>Control (N = 18)</td>
<td>26 (18)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Table 4</th>
<th>Mean (SD) score from the perceived improvement numerical scale (%)</th>
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<tr>
<td></td>
<td>15 treatments</td>
</tr>
<tr>
<td>Experimental (N = 37)</td>
<td>67 (26)</td>
</tr>
<tr>
<td>Control (N = 18)</td>
<td>50 (25)</td>
</tr>
</tbody>
</table>

Figure 2  Mean (SE) symptoms and functional status scale questionnaire scores for the experimental and control groups throughout the trial. The top set of bar graphs is for the experimental group and the bottom is for the control group.
A randomized controlled (intervention) trial of ischemic compression therapy for chronic carpal syndrome

experimental treatment. Even though the study protocol included 15 treatments, many patients (89%) in the experimental group reported improvement within six treatments. They either said so spontaneously or when asked by the clinician during the 6th visit. In this study, only ischemic compression therapy was used, but one may suppose that the results could be improved if such therapy was combined with ergonomic recommendations per se.\textsuperscript{23} No side effects were reported during the treatments, except for a slight sensitivity reported by a small number of patients after the first few treatments.

The most pathognomonic symptom of myofascial pain syndrome is the presence of pressure-sensitive palpable nodules that reproduce the chief complaint: they are called trigger points.\textsuperscript{24} These TrPs may be located in muscles, ligaments, tendons, fascias and articular capsules.\textsuperscript{25} Ischemic compressions are amongst the most popular methods of treatment used by chiropractors for patient care of the myofascial pain syndrome. The National Board of Chiropractic Examiners 2005 Job Analysis reported that over 91% of chiropractors use trigger point therapy for passive adjutant care.\textsuperscript{26}

Overuse of the biceps can cause myofascial irritations and subsequent hypertonicity. Gerwin\textsuperscript{22} claims that a myofascial trigger point refers to a zone of intense pain in a hardened muscle band that triggers pain when mechanically stimulated by plucking it manually. He added that there is a segmental hyper-contraction within the muscle fiber. The present authors speculate that the hypertonicity of the biceps, pronator teres and subscapularis muscles can irritate the median nerve and may cause local oedema. Consequently, the nerve may be pinched when it runs through the narrow space of the carpal tunnel, and this would result in numbness and impairment of distal motor and sensory functions. The longer this process lasts (months-years), the more severe the neuropathy becomes, causing muscular weakness in the hand. We would argue that eliminating the TrPs along the median nerve relaxes the muscles and removes a source of irritation to the median nerve.

The treatment of the whole median nerve was used effectively in a case study by Leahy.\textsuperscript{7} The median nerve may be damaged along its whole length, from its root, between the cervical vertebrae, down to and including the wrist.\textsuperscript{5} According to Bonebrake et al.,\textsuperscript{27} conservative treatment of CTS is intended to lessen muscular and fibrous restriction. In their study, treatment was applied along the whole median nerve and, amongst other techniques, they used ischemic compression. In a recent trial by George,\textsuperscript{28} five patients suffering from CTS were treated three times weekly for two weeks using the Active Release Technique (ART) with a protocol designed to affect the median nerve. Using the Boston Questionnaire, they concluded that ART offered a significant reduction of the symptom severity and improvement of the functional status of the patients.

Davis\textsuperscript{29} published a randomized clinical trial that showed a significant improvement in CTS syndrome amongst the patients. Myofascial massage along the median nerve was used with the chiropractic group but, since there were other modalities involved, the authors could not assess which was the active component of their intervention.

Limitations of the study

The total number of participants was small and there were only two treating chiropractors. The number of patients in the control group was small, compared with the number of those in the treatment group. The reason for this was that the treating clinicians found it difficult to construct a practice-based study that provided a group with what they considered would be a near placebo treatment. There was only a short-term follow-up comparison of the two group results and therefore it is unclear whether the results reported in this study would persist beyond the point of treatment cessation. The compression sites treated by the clinicians were considered very important on the basis of clinical experience, though very few others have treated these sites in the context of carpal tunnel syndrome. Finally, the control group was crossed over immediately after the 15 initial control treatments. In the absence of a wash-out period, a potential nonspecific effect of the placebo intervention could have carried over into the active treatment period among those patients who did participate in the crossover portion of the study.

Conclusion

This practice-based (pragmatic) clinical trial suggests that myofascial therapy using ischemic compression along the biceps, at the bicipital aponeurosis, at the pronator teres and at the subscapularis muscles could be a useful approach to reducing symptoms associated with the carpal
tunnel syndrome. Patients’ perceived improvement in functional capacities persisted over a six-month period. This last observation is based only on the before-and-after analysis of within group data. Future research on CTS should include a larger number of participants, a parallel placebo treatment group and long-term assessments.

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