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Chapter VII

Manipulation of the wrist for treatment of tennis elbow
A randomised clinical trial

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Abstract

Background Tennis elbow is a common entity. Several conservative treatment strategies, with varying success rates, have been described. The aim of this randomized clinical study was to compare the effectiveness of two physiotherapeutic protocols: (1) manipulation of the wrist versus (2) ultrasound, friction massage and a muscle stretching strengthening protocol, for treatment of tennis elbow.

Methods Thirty-one patients with tennis elbow complaints were included in the trial. Patients were randomly allocated to either treatment. Three patients were lost to follow-up, leaving twenty-eight patients for analysis. Follow-up at three and six weeks took place in a research clinic. Analysis was performed using independent t-tests, Mann-Whitney tests, and Fisher exact tests.

Results Statistically significant differences were found for two outcome measures, both in favor of manipulation. At three weeks, success rate in the manipulation group was 62%, compared to 20% in the ultrasound, friction massage and muscle stretching strengthening group (RR 3.1 95% CI 1.0-9.2). At six weeks, improvement for pain during the day as assessed on an eleven-point numeric scale was 5.2 (±2.4) in the manipulation group, compared to 3.2 (±2.1) in the ultrasound, friction massage and muscle stretching strengthening group (p<0.05).

Conclusions Manipulation of the wrist demonstrates to be more effective to ultrasound, friction massage and muscle stretching strengthening for treatment of tennis elbow at short-term follow-up. However, results need replication in a large-scale randomised clinical trial.
Introduction

Tennis elbow is characterized as pain at the lateral side of the elbow, aggravated with movements of the wrist, palpation of the lateral side of the elbow or by contraction of the extensor muscles of the wrist. The incidence of tennis elbow in Dutch general practice is approximately 4-7 per 1000 patients a year with a peak incidence in the fifth decade. Tennis elbow is a self-limiting complaint: when untreated the symptoms will usually resolve in eight to twelve months. Several treatment strategies have been described, including a wait-and-see policy by providing only advise to patients, corticosteroid injections, orthotic devices, surgery, and physical therapeutic modalities such as muscle stretching and strengthening exercises, ultrasound, laser, massage and electrotherapy.

Manipulation has frequently been used for treatment of back- and neck complaints and is thought to (1) unbuckle motion segments that have undergone disproportionate displacement and (2) cause relaxation of secondary muscle hypertony. These mechanisms are thought to be associated with distribution of abnormal stresses within the joint, resulting in pain, restriction of motion and potentially inflammation.

The aim of this randomized clinical pilot study was to compare the effectiveness of manipulation of the wrist to the effectiveness of a protocol using friction massage, ultrasound and a muscle stretching strengthening program for treatment of tennis elbow complaints with the hypothesis that there is no difference in effectiveness of both physiotherapeutic interventions.

Methods

Between April 2000 and August 2000, patients were recruited for inclusion by ten general practitioners in a city in the Netherlands and referred to our research clinic if diagnosed by their general practitioner with lateral epicondylitis, according do the Dutch Guidelines for General Practitioners: pain on the lateral side of the elbow, which aggravated with both pressure on the lateral epicondyle of the humerus and resisted dorsiflexion of the wrist. Patients were finally included by a clinical assessor (PD) if they had clinically diagnosed tennis elbow, with complaints being present for at least six weeks and no longer than six months. Exclusion criteria were no limited range of motion, according to the clinical assessor; bilateral complaints; a definite decrease in pain for the last two weeks, as described by the patient; severe neck/shoulder problems likely to cause or maintain the elbow complaints (as assessed by the clinical assessor); treatment for the current episode; and inability to fill out questionnaires. The study was approved by the hospital’s medical ethics committee. However, since it was a pilot study, and not intended to find statistically significant differences, the number of requested patients was arbitrarily set at 30 patients.
The clinical assessor undertook baseline assessments before randomisation. Assessments included patient demography, co-morbidity, and baseline values of the outcome measures. After obtaining informed consent, patients were included in the trial. After inclusion, essential patient data were transferred by telephone to an independent researcher (PS), who drew a numbered sealed envelope. Patients were randomized over two treatment groups: (1) manipulation (2) ultrasound, friction massage and muscle stretching strengthening. The researcher (PS) informed the physical therapist concerned, who would call the patient for a first treatment session. Patients were asked not to discuss their treatment with the clinical assessor. Thus, the clinical researcher remained unaware of the allocated treatment, throughout the trial.

**Patients and methods**

A total of thirty-eight potentially eligible patients was referred for inclusion in the study (Figure 1). Seven patients were not included: three patients had complaints for a too short period of time, two patients had double-sided complaints and two patients had severe neck/

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**Figure 1. Flow diagram presenting the progress of the patients in the trial, including withdrawals and deviations from protocol.**

- **Eligible patients**
  - Not randomised (n=7)
    - Complaints < 6 weeks (n=3)
    - Severe neck-shoulder problems (n=2)
    - Bilateral complaints (n=2)
  - Randomised (n=31)

- **MANIPULATION**
  - N=15
    - Drop-out (n=2)*
      - Travel distance too far (n=2)
    - Followed-up
      - 3 weeks (n=13)
      - 6 weeks (n=13)
    - Completed Trial (n=13)

- **US, FRICTION, MUSCLE STRETCHING, STRENGTHENING**
  - N=16
    - Drop-out (n=1)*
      - Unsatisfied with allocated treatment (n=1)
    - Followed-up
      - 3 weeks (n=15)
      - 6 weeks (n=15)
    - Completed Trial (n=15)

© Randomisation
* Patients withdrawn from study before completion of treatment.
Manipulation of the wrist for treatment of tennis elbow

shoulder pathology. Therefore, thirty-one patients were randomized. Three patients were not willing to continue participation in the study, and were regarded as drop-outs: two patients from the manipulation group claiming after two and three sessions that the distance to the physical therapy practice was too far, and one patient from the ultrasound, friction massage and muscle stretching strengthening group who was not satisfied with the allocated treatment after one session. The remaining twenty-eight patients were evaluated on an intention-to-treat basis.

Figure 2a–d - The manipulation: The wrist is manipulated from the neutral position (a,b) to maximal dorsaflexion (c,d)

Treatment

Ultrasound, friction massage and muscle stretching, strengthening.

Patients in this group were treated by a standardized protocol. This exact protocol was used in a previous large trial on tennis elbow. During the six weeks intervention period, patients underwent a total of nine sessions. The first week three sessions, the second week two sessions
and the remaining four weeks one session per week. Every session consisted of a 7.5 minutes pulsed ultrasound treatment (sonopuls 590, Enraf Nonius®). Pulsed ultrasound (20% duty cycle) was given with an intensity of 2W/cm². In addition, patients were treated by friction massage for approximately ten minutes. When pain subsided, patients were instructed a strengthening and stretching protocol by the physical therapist to perform at home twice daily. These exercises were intensified in four steps. Patients were instructed to use the elbow to their pain-threshold. In case complaints had resolved, treatment was stopped.

**Manipulation**

Patients were treated two times per week with a maximum of nine treatments in six weeks, all by the same physical therapist (EB), experienced in this manipulative procedure. As soon as complaints resolved, treatment was stopped. A therapeutic session consisted of a number of manipulative maneuvers. The manipulative maneuver is a thrust technique and was performed as follows (figure 2): the patient rested his forearms on a table with the palmar side of his hand facing down. The therapist sat at a right angle to the patients’ affected side and the scaphoid bone between his thumb and index finger. He consolidated this grip by placing the thumb and the index finger of his other hand on top of them. The therapist then extended the patient’s wrist dorsally at the same time the scaphoid bone is manipulated ventrally. Duration of a treatment was approximately fifteen minutes. No restrictions in use of the arm were imposed.

No previous description of this maneuver was found in literature.

**Outcome assessment**

Outcome was assessed at three and six weeks after start of the treatment. Primary outcome measure was patients assessment of ‘global measure of improvement’ assessed on a six-point scale with verbal descriptives (1. completely recovered; 2. much improved; 3. slightly improved; 4. not changed; 5. slightly worse; 6. much worse). This measure was dichotomized: a success was defined before the start of the study as much improved or completely recovered, based on previous studies.

Other outcome measures were a) severity of their main complaint b) pain at the moment of examination c) pain during the day and d) inconvenience during daily activities (all scored on an eleven-point numeric scale)

Secondary outcome measures were e) Pain-free grip strength (PFGS) and f) maximum grip strength (MGS) (grip strength was measured in kilograms with a Jamar hand dynamometer (PGB, Bussum, the Netherlands) and was expressed both as mean improvement and improvement in a ratio of injured arm / non-injured arm;

  g) Pressure pain (PP) at the lateral epicondyle was measured in kg/cm² with a Pressure Threshold
Manipulation of the wrist for treatment of tennis elbow

Meter (Pain diagnostics & treatment inc., Great Neck, NY 11023, USA) and expressed both as mean improvement and improvement in ratio injured arm / non-injured arm. In addition, h) dorsiflexion and the range flexion-extension of the wrist was measured using a goniometer.

To ascertain if blinding was adequate, the clinical assessor was asked to guess the allocation (manipulation or ultrasound, friction massage and muscle stretching strengthening) of the included patients at six weeks follow-up.

Statistical analysis

Data were analyzed using SPSS version 10.0. Differences in continuous outcome measures were compared using independent t-tests in case of normal distribution. In case the distribution was not normal, the Mann-Whitney test was applied. Dichotomous outcomes were analyzed using the Fisher-exact test.

Results

The baseline characteristics of the two groups were similar regarding initial demographic and outcome measurements, except for the male/female distribution and duration of complaints (table 1), though differences were not statistically significant at the \( \alpha = 0.05 \) level.

<p>| Table 1 - Baseline characteristics |
| Manipulation versus Ultrasound, friction massage and muscle stretching strengthening |</p>
<table>
<thead>
<tr>
<th>Characteristic * †</th>
<th>Manipulation</th>
<th>US,FM,MS‡</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of patients</td>
<td>13</td>
<td>15</td>
</tr>
<tr>
<td>Mean age, years (SD)</td>
<td>46.3 (8.4)</td>
<td>47.5 (11.5)</td>
</tr>
<tr>
<td>Duration of complaints, wks (SD)</td>
<td>14.2 (12.3)</td>
<td>9.3 (6.1)</td>
</tr>
<tr>
<td>Sex (male/female)</td>
<td>9/4</td>
<td>6/9</td>
</tr>
<tr>
<td>Dominant arm affected (%)</td>
<td>76.9</td>
<td>73.3</td>
</tr>
<tr>
<td>Pain patient’s main complaint, NRS (SD)</td>
<td>6.4 (1.6)</td>
<td>7.3 (1.5)</td>
</tr>
<tr>
<td>Pain at the moment, NRS (SD)</td>
<td>3.9 (2.7)</td>
<td>4.4 (2.8)</td>
</tr>
<tr>
<td>Pain during day, NRS (SD)</td>
<td>6.3 (1.3)</td>
<td>6.3 (1.4)</td>
</tr>
<tr>
<td>Inconvenience, NRS (SD)</td>
<td>6.7 (2.4)</td>
<td>7.3 (1.4)</td>
</tr>
<tr>
<td>Pain Free Grip Strength, kg (SD)</td>
<td>19.7 (10.7)</td>
<td>15.9 (11.0)</td>
</tr>
<tr>
<td>Maximum Grip Strength, kg (SD)</td>
<td>33.5 (13.7)</td>
<td>28.1 (14.4)</td>
</tr>
<tr>
<td>Ratio PFGS/MGS n,i, (SD)</td>
<td>0.5 (0.3)</td>
<td>0.4 (0.3)</td>
</tr>
<tr>
<td>Pressure Pain, kg/cm² (SD)</td>
<td>2.0 (0.5)</td>
<td>1.7 (0.2)</td>
</tr>
</tbody>
</table>

* NRS: Numeric Rating Scale (0-10)
† n.i.: non-injured arm
‡ US,FM,MS Ultrasound, Friction Massage and Muscle Stretching Strengthening protocol
At three weeks, our primary outcome measure differed statistically significant between groups, in favor of the manipulation treatment. On global measure of improvement eight of thirteen patients were either much improved or completely recovered in the manipulation group, compared to three from fifteen patients in the ultrasound, friction massage and muscle stretching strengthening group. The accompanying relative risk was 3.1 (95% confidence interval 1.0-9.2).

Decrease in VAS-scores for pain for the most important complaint, pain at rest, pain during the day and inconvenience all showed a similar positive trend for the manipulation treatment, though differences were not statistically significant (table 2).

At six weeks follow-up, decrease in score for pain during the day differed statistically significant between groups. The mean decrease in the manipulation group was 5.2 (SD 2.4) compared to 3.2 (SD 2.1) in the ultrasound, friction massage and muscle stretching strengthening group. All other outcome measures showed a similar trend positive for the manipulation, however, differences were not statistically significant (table 2).

At three and six weeks, for range of motion no statistically significant differences were identified in mean improvement per group or improvement between groups (table 3).

The average number of sessions to reach a successful result ('much improved' or 'completely recovered') was an average of 6.6 manipulation sessions and 9.0 physical therapy sessions. This difference was not statistically significant (Mean difference 3.4 95% CI -6.2 , 9.7)

Concerning guessing the allocated treatment, the clinical assessor was correct for 39% of the patients (less than chance).

Table 2 - Results
Manipulation of the wrist versus Ultrasound, friction massage and muscle stretching strengthening

<table>
<thead>
<tr>
<th>Outcome measure</th>
<th>3 weeks</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Manipulation</td>
</tr>
<tr>
<td>Global improvement, number of patients (%)</td>
<td>8/13 (62%) ()</td>
</tr>
<tr>
<td>Pain main complaint, mean decrease NRS (SD)</td>
<td>2.6 (1.7)</td>
</tr>
<tr>
<td>Pain at the moment, mean decrease NRS (SD)</td>
<td>1.9 (2.7)</td>
</tr>
<tr>
<td>Pain during day, mean decrease NRS (SD)</td>
<td>2.6 (2.6)</td>
</tr>
<tr>
<td>Inconvenience, mean decrease NRS (SD)</td>
<td>3.0 (3.2)</td>
</tr>
<tr>
<td>Pain Free Grip Strength, mean increase, kg (SD)</td>
<td>5.8 (11.1)</td>
</tr>
<tr>
<td>Maximum Grip Strength, mean increase, kg (SD)</td>
<td>1.8 (10.0)</td>
</tr>
<tr>
<td>Ratio PFGS/MGS, mean increase (SD)</td>
<td>0.1 (0.2)</td>
</tr>
<tr>
<td>Pressure Pain (PP), mean increase, kg/cm² (SD)</td>
<td>0.7 (1.0)</td>
</tr>
<tr>
<td>Ratio PP/PP, mean increase (SD)</td>
<td>0.2 (0.3)</td>
</tr>
</tbody>
</table>

SD Standard Deviation * n.i.: non-injured arm † NRS (0-10): 0 = no complaints, 10 = severe complaints ‡ Significant differences ($\alpha\leq0.05$) between groups $\|$ US.FM.MS Ultrasound, Friction Massage and Muscle Stretching Strengthening protocol
Table 3 - Results Range of Motion measurements (in degrees)

<table>
<thead>
<tr>
<th></th>
<th>Injured arm</th>
<th>Non-injured arm</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Manipulation</td>
<td>US,FM,MS*</td>
</tr>
<tr>
<td>Dorsal Flexion</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline</td>
<td>63.0 (8.3)</td>
<td>60.5 (7.4)</td>
</tr>
<tr>
<td>3 weeks</td>
<td>64.5 (8.1)</td>
<td>63.0 (8.3)</td>
</tr>
<tr>
<td>6 weeks</td>
<td>62.0 (8.8)</td>
<td>64.6 (8.1)</td>
</tr>
<tr>
<td>Range</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline</td>
<td>110.9 (16.3)</td>
<td>112.2 (9.4)</td>
</tr>
<tr>
<td>3 weeks</td>
<td>112.9 (17.4)</td>
<td>113.9 (9.4)</td>
</tr>
<tr>
<td>6 weeks</td>
<td>118.6 (16.4)</td>
<td>121.2 (13.0)</td>
</tr>
</tbody>
</table>

* US,FM,MS  Ultrasound, Friction Massage and Muscle Stretching Strengthening protocol
Note: none of the possible calculable differences are statistically significant on the p=0.05 level.

Alternative analyses

A worst-case analysis was performed for the success rate and pain during the day for at 3 and 6 weeks follow-up. For the patients lost to follow-up the last observation carried forward method was applied, meaning baseline measurements in our case. Statistical significant differences were no longer present with p-values >0.2 for all calculated outcomes.

Also, a post-hoc power-analysis was performed on success rate at 3 weeks as outcome measure and α =0.05. This resulted in a power of 0.68 (β 0.32).
Discussion

This study shows that manipulation of the wrist might have additional treatment effects compared to ultrasound, friction massage and muscle stretching strengthening for treatment of tennis elbow over the short-term. For global improvement at three weeks and decrease in the score for 'pain during the day' at six weeks, a statistically significant difference (p=0.05) in favor of manipulation was found.

All other outcome measures show a similar trend, favoring manipulation, although no significant differences were identified. This is most likely due to the small number of patients included, resulting in a low power. A post-hoc power analysis showed the power of this small-sized study to be 0.68 (80.32), as calculated using the success rate at 3 weeks (α 0.05). This will have inflated the chance of a type II error in our study. The small size and resulting low power of the study implies that caution has to be applied in drawing definitive conclusions on effectiveness between both strategies compared. In addition, a worst case analysis showed no statistical significant differences.

The number of outcome measures might have inflated type I error in our trial. However, this was limited by a priori deciding the hierarchy in our outcome measures. In addition, outcome measures all addressed different, both patient-oriented and non patient-oriented, dimensions. Another shortcoming of the study is that only short-term effects are described. Although often patients are mainly interested in a fast recovery, effects over the long-term might be less distinctive due to, for example, recurrence of complaints. In a recent trial by Hay et al. comparing corticosteroid injections with NSAIDs, the initial advantage of injections subsided at long-term follow-up.

The manipulation was performed by an experienced therapist. Therefore, the results might be overestimated, compared to what may be expected in with implementation on a larger scale with less experienced therapists. Patients in the manipulation group were not limited in daily activities, while in the ultrasound, friction massage and muscle stretching strengthening group activities were restricted to the pain threshold. Therefore, the effectiveness of the manipulation might be caused by difference in co-interventions. Concerning baseline characteristics, differences between groups were present for the male/female distribution and duration of complaints. This may have introduced bias, however, gender has not been reported to be a prognostic factor and duration of complaints was longer in the manipulation group and effectiveness may therefore even be underestimated.

There is no international indexed literature on manipulation of the wrist for treatment of tennis elbow. In contrast, stretching of the forearm muscles as part of the treatment for tennis elbow,
Manipulation of the wrist for treatment of tennis elbow

has been reported frequently\textsuperscript{16,20}. To achieve effective stretching, the wrist joint is moved to the endpoint of joint movement. A secondary effect of this stretching might be based on the unbuckling of disproportionate displaced motion segments. Also, the so-called Mills’ manipulation is described which, however, is aimed at manipulation of the elbow joint\textsuperscript{15}.

Despite its broad application, the working mechanism of manipulation is poorly understood. Manual therapy is used quite often for spine and peripheral joints, in spite of the inability of clinicians to accurately diagnose an impairment at which a manipulation is targeted. In low back pain and neck pain, spinal manipulation is thought to unbuckle motion segments that have undergone disproportionate displacements and relax secondary hypertonic muscle by sudden stretching\textsuperscript{11-13} The secondary muscle hypertony in patients with low back pain will cause a limited range of motion to protect against sudden movements. Pain in these patients can be elicited by palpation on the insertion of these para-vertebral muscles.\textsuperscript{21}

Authors have come up with following rationale for the effectiveness of manipulation for tennis elbow. This rationale, however, has several flaws with should be notified. Solveborn et al. reported on limited range of motion of the wrist in patients with tennis elbow, when compared to the uninjured arm\textsuperscript{22}. It is our hypothesis that in tennis elbow patients, a disproportionate displacement within carpal bones leads to secondary hypertonic forearm-muscles. This will lead to a limited range of motion of the wrist and pain at the insertion of the extensor muscles, presenting as tennis elbow. By treating the cause, the secondary symptoms being the insertion tendinopathy, are likely to resolve spontaneously. It is important to realize that adequate measurement of such a supposed displacement is extremely difficult achieve. An additional limitation is the precise measurement of the extension deficit, which can be felt by an experienced therapist, but is difficult to objectify adequately.

Thus, to clarify the exact working mechanism, further biomechanical research is required.

The advantage of the manipulation of the wrist is the potential effectiveness over the short-term and the ability for the patient to maintain his daily activities without restrictions. In addition, manipulation might be more direct cost-effective due to a reduction in the number of treatments. Considering the relatively high prevalence of the injury, this might implicate a major cost reduction on population level.

The promising results of this trial need replication in a large-scale randomized clinical trial. The trial should be sufficiently powered and should compare manipulation of the wrist to the most commonly used and potentially effective conservative treatment strategies for tennis elbow. Validated outcome measures should be used and evaluated over short-term, intermediate-term
and long-term. More treating therapists should be included and inter-performer variability should be studied. In addition to the analysis of the effectiveness of the compared treatment strategies, a cost-effectiveness analysis should be incorporated in the trial, since reduced costs are an important advantage of the manipulative treatment. The analysis should concentrate on both direct and indirect costs.

Acknowledgements

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Reference List

Manipulation of the wrist for treatment of tennis elbow
