# Conservative Treatment of Lateral Epicondylitis

## Brace Versus Physical Therapy or a Combination of Both—A Randomized Clinical Trial

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**Background:** The authors evaluated the effectiveness of brace-only treatment, physical therapy, and the combination of these for patients with tennis elbow.

**Methods:** Patients were randomized over 3 groups: brace-only treatment, physical therapy, and the combination of these. Main outcome measures were success rate, severity of complaints, pain, disability, and satisfaction. Data were analyzed using both intention-to-treat and per-protocol analyses. Follow-up was 1 year.

**Results:** A total of 180 patients were randomized. Physical therapy was superior to brace only at 6 weeks for pain, disability, and satisfaction. Contrarily, brace-only treatment was superior on ability of daily activities. Combination treatment was superior to brace on severity of complaints, disability, and satisfaction. At 26 weeks and 52 weeks, no significant differences were identified.

**Conclusion:** Conflicting results were found. Brace treatment might be useful as initial therapy. Combination therapy has no additional advantage compared to physical therapy but is superior to brace only for the short term.

**Keywords:** tennis elbow; randomized controlled trial; treatment; brace; physical therapy; conservative

Lateral epicondylitis, or "tennis elbow," is a frequently reported condition in medical care. The complaint is characterized by pain over the lateral epicondyle of the humerus, which is aggravated with resisted dorsiflexion of the wrist.[5] The incidence in general practice is approximately 4 to 7 per 1000 patients per year with an annual incidence of 1% to 3% in the general population.[1,4] In the Netherlands, in approximately 10% of the patients the complaint will result in sick leave, for a mean period of 11 weeks.[20] Untreated, the complaint is estimated to last from 6 months to 2 years.[5,9,11] Several treatment options are available,[7] including an expectant policy, corticosteroid injections, orthotic devices, surgery, and physiotherapeutic modalities such as exercises, ultrasound, laser, massage, electrotherapy, and manipulations. In Dutch primary care, 21% of the patients with lateral epicondylitis are prescribed an orthotic device as a treatment strategy,[20] and many different types of braces and other orthotic devices are available for treating tennis elbow.[17] The main type is a band or strap around the muscle belly of the wrist extensors. Theoretically, binding the muscle with a clasp, band, or brace should limit expansion and thereby decrease the contribution to force production by muscle fibers proximal to the band.[8,21]

A recent trial by Smidt et al[15] compared physical therapy with an expectant waiting policy and corticosteroid injections. From the results of this trial, the authors con-

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PS planned and coordinated the data collection, analyzed the data, and wrote the article. WJJA designed the trial and supervised the planning, coordination, and collection of the data. GK participated in the collection of the data, and CvD contributed to the design of the trial and discussed clinical issues. All trialists contributed substantially in writing the article.

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cluded an expectant waiting policy to be the treatment of choice.

Despite the frequent use of braces, no definitive evidence is present in current literature concerning their effectiveness.[17] To provide this evidence, a randomized clinical trial was started, comparing effectiveness of a brace and a standardized physical therapy protocol for treatment of lateral epicondylitis in the short term, intermediate term, and long term.

## METHODS

### Setting

The trial was performed in an urban setting in the Netherlands. Inclusion was between January 1999 and May 2000. Patients were recruited by both general practitioners and primary care physical therapists and referred to our outpatient clinic. The hospital's medical ethics committee approved the study in July 1998.

### Patients

Patients were included in the study if, at time of presentation, they had clinically diagnosed lateral epicondylitis and complaints for at least 6 weeks. The diagnosis lateral epicondylitis was made if patients reported pain on the lateral side of the elbow, which was aggravated with both pressure on the lateral epicondyle of the humerus and resisted dorsiflexion of the wrist. Excluded were patients with bilateral complaints, with a clear decrease of pain in the previous 2 weeks, who had received any treatment for the lateral epicondylitis episode in the last 6 months before inclusion, and who were unable to fill out questionnaires.

### Study Design

Baseline assessments were undertaken by 1 medical doctor (GK) before randomization and were thus performed in a blinded setting. Assessments included patient characteristics, comorbidity, and baseline values of the outcome measures.

After retrieval of informed consent, patients were included in the trial by the medical doctor (GK) and subsequently randomized by a researcher (PS) using a computer program with minimization strategy for the duration of complaints (ie, ≤3 months; 3-6 months, and ≥6 months).[18,19]

### Treatment Strategies

Patients in the physical therapy group (group A) were treated according to a standardized protocol. During the 6-week intervention period, patients received a total of 9 sessions—3, 2, 1, 1, 1, and 1 session(s) per week, respectively—unless complaints had resolved before the end of these 9 sessions. Every session consisted of 7.5 minutes of pulsed ultrasound treatment according to the protocol by Binder et al.[3] Ultrasound is thought to enhance blood flow, increase membrane permeability, and alter connective tissue extensibility and nerve conduction.[3,12]

In addition, patients were treated by friction massage for 5 to 10 minutes.[6,12,20] When pain subsided, patients were instructed on a strengthening and stretching protocol by the physical therapist to perform at home twice daily.[12] All patients were provided an exercise diary in which the therapist described the number and type of exercises they were to do and in which they noted their compliance with this instructed program. The exercises were done in the physical therapy setting as well. This is to be sure that the exercises were performed in an adequate manner. The exercises were done in steps as described in Table 1. When a patient was able to perform an exercise step, he or she was allowed to perform the next step. Each exercise included 10 repetitions in 2 or 3 series. The exercise programs were performed 4 to 6 times daily at home. All participating physical therapists participated in a training session, received the protocol, and were visited by the researcher for a final question round.

TABLE 1
Progressive Exercise Program, Steps 1 to 4

| Step | Exercise[a] |
|---|---|
| 1 | Clenching fist strongly |
| | Resisted wrist extension |
| | Resisted wrist flexion |
| | Wrist rotation with a stick |
| | Toward the little finger |
| | Toward the thumb |
| | End: stretching at least 30 seconds to flexion and extension |
| 2 | Exercises against an elastic band for: |
| | Wrist extension |
| | Wrist flexion |
| | Wrist radial deviation |
| | Wrist ulnar deviation |
| | End: stretching as in step 1, 10 × 3 series, several repetitions daily |
| 3 | Combined wrist rotary movements using, for example, a table top as a support |
| | Upward resisted from below |
| | Toward the little finger |
| | Toward the thumb |
| | Downward resisted from above |
| | Toward the little finger |
| | Toward the thumb |
| | Pressing hand against a wall |
| | End: stretching as in step 2 |
| 4 | An occupational training program including: |
| | Softball compressing exercises |
| | Transferring buttons from 1 cup into another |
| | Twisting a towel into a roll |
| | Rotating hand on a table in both directions |
| | End: stretching as in step 2 |

[a] Each movement and exercise is performed while slowly counting to 8.

**Figure 1.** The brace that was used.

Patients in the brace group (group B) were provided with the brace immediately after randomization. The brace used was the Epipoint (Bauerfeind, Zeulenroda, Germany) (see Figure 1). Instructions on use and application were given immediately, using a standardized protocol. Patients were instructed to visit a physical therapist participating in the trial once during the first week of the intervention period, who, again, instructed the patient in the use of the brace according to the standardized protocol. No physical therapeutic treatment was applied in this 1 session. Patients were advised to wear the brace continuously during daytime for the 6-week intervention period. Activities causing pain despite the use of the brace were discouraged.

Patients in the combination group (group C) received the combination of both brace treatment and physical therapy.

Patients were withdrawn from the study if complaints deteriorated severely during treatment, according to the opinion of the patient's general practitioner.

### Outcome Assessment

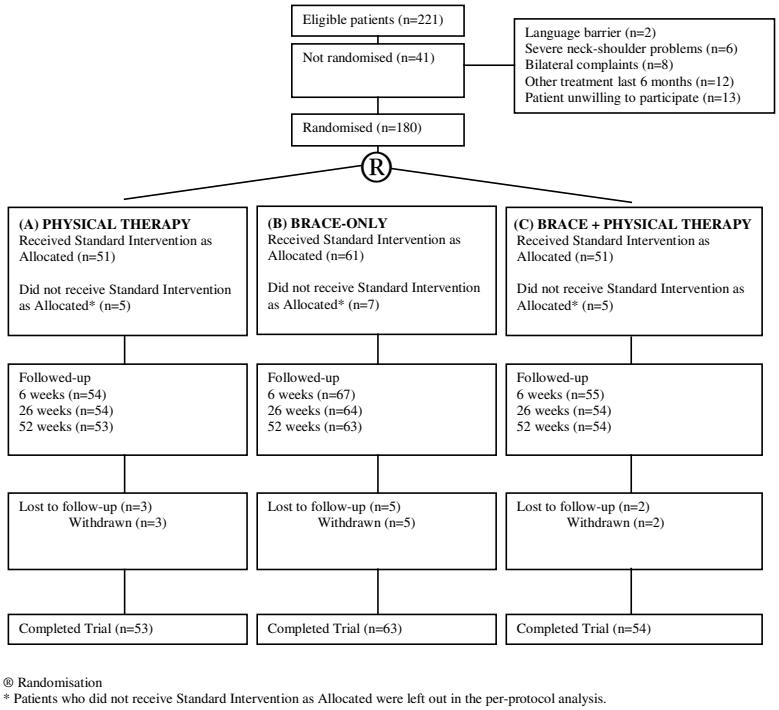
The blinded assessor (GK) assessed outcomes at 6 weeks and 1 year after randomization. In addition, a questionnaire was sent to patients at 26 weeks. Main outcome measures were the following: (1) a global measure of improvement compared to prerandomization, as assessed on a 6-point scale (1, *completely recovered*; 2, *much improved*; 3, *little improved*; 4, *not changed*; 5, *little worse*; 6, *much worse*). This measure was dichotomized: patients reporting to be completely recovered or much improved were noted as a "success"; (2) severity of the patient's complaints (11-point numeric scale, 10 indicating *severe complaints*); (3) score of pain intensity of the patient's most important complaint (11-point numeric scale, 10 indicating *severe pain*); and (4) modified Pain Free Function Questionnaire (PFFQ) describing 10 activities frequently affected in patients with lateral epicondylitis. Each activity was rated 0 to 4 by the patient (4 indicating *severe discomfort*), for a total score ranging from 0 to 40.[16]

Secondary outcome measures were the following: (5) inconvenience during daily activities (11-point numeric scale, 0 indicating *no inconvenience* and 10 *severe inconvenience*); (6) pain-free grip strength; and (7) maximum grip strength measured with a Jamar hand dynamometer (Sammons Preston, Bolingbrook, Illinois) in kilograms, assessed with the patient's elbow in extension. The mean of 3 measurements was calculated for both pain-free grip strength and maximum grip strength; (8) pressure pain at the lateral epicondyle as measured with a Pressure Threshold Meter (Pain Diagnostics & Treatment Inc., Great Neck, New York) in kilograms per $cm^2$. With this test, the blinded assessor gradually increased pressure on the common extensor tendon until the patient indicated discomfort. Again, the mean value of 3 measurements was calculated. The latter outcome measures (measures 6, 7, and 8) were reported as ratios of the maximum grip strength of the unaffected side. Satisfaction of the patient with the assigned treatment (11-point numeric scale: 0, *not satisfied*, to 10, *very satisfied*). In the analysis, all outcome measures were transformed to a 100-point scale to enable comparison between outcome measures. At follow-up visits, patients were asked to refer to prerandomization scores, which their previous scores showed. Blinding of assessment was optimized by instructing the patients not to inform the blinded assessor when they received treatment. After each follow-up examination, the assessor was asked to guess the allocation and give the reasons for this. Interobserver agreement on these outcome measures was found to be very good.[14]

## STATISTICAL ANALYSIS

The sample size was calculated based on the "global measure of improvement" at 6 weeks, analyzed as a dichotomous outcome measure. Calculation of sample size was based on the ability to detect a difference in success rate of 25% with the least effective treatment, giving the study 80% power and a 5% significance level.

Data were analyzed using both an intention-to-treat and a per-protocol analysis. Changes in scores over time were calculated for each patient by subtracting the results at baseline from those at follow-up. The differences in improvement between the groups with corresponding 95% confidence interval (95% CI) were computed and were compared using 1-way analysis of variance (ANOVA). Logistic regression was used to analyze dichotomous outcomes. Dichotomous outcomes were expressed in a relative risk (RR), an absolute risk reduction (ARR), and a number needed to treat (NNT). The NNT expresses the number of patients that need to be treated to prevent 1 bad outcome. It is the inverse of the ARR.[13]




® Randomisation
* Patients who did not receive Standard Intervention as Allocated were left out in the per-protocol analysis.

**Figure 2.** Flow diagram presenting the progress of the patients in the trial, including withdrawals and deviations from protocol.

Preplanned subgroup analyses on success rate and severity of complaints at short-term follow-up were conducted for duration of complaints, presence of neck/shoulder problems, previous episodes of tennis elbow complaints, and allocation to the therapy preferred by the patient.

## RESULTS

A total of 221 potentially eligible patients were examined and evaluated in our clinic. Of these, 41 were not included due to either unwillingness to participate in the study or because the patient did not meet the criteria; thus, 180 included patients remained (Figure 2). The baseline characteristics were well matched for all intervention groups (Table 2). At 6 weeks, 2 patients from group A and 1 patient from both group B and group C were lost to follow-up. These 4 patients all did not return for treatment by their physical therapist and did not respond to several letters. The blinded assessor was asked to guess the allocation of the 176 patients at 6 weeks follow-up and was correct for 73 (41%) patients ($\kappa = 0.12$) and was never certain of his guess.

### Short-Term Follow-up

On the primary outcome measure "success rate," no statistically significant differences were found between groups (see Tables 3 and 4).

### Brace-Only Versus Physical Therapy

When comparing results between physical therapy and brace only, 4 outcome measures statistically significantly differed. Outcomes (all converted to a 100-point scale) on decrease in pain for the patient's main complaint (mean difference [MD], 13; 95% CI, 3-21), PFFQ (MD, 7; 95% CI, 1-12), and satisfaction (MD, 9; 95% CI, 1-18) were in favor of physical therapy. Ability of daily activities was in favor of the brace-only group. Patients in the brace-only group showed less inconvenience (MD, 11; 95% CI, 1-21). Other outcome measures did not statistically significantly differ.

RR on success rate was 1.22 (95% CI, 0.9-1.7). The ARR was 0.11 (95% CI, 0.1-0.3) with an accompanying NNT of 9 (95% CI, 3-15) in favor of the physical therapy group.

### Brace-Only Versus Combination

Three outcome measures were identified to be statistically significantly different between the brace-only and combination group, in favor of combination treatment: outcomes on severity of complaints (MD, 11; 95% CI, 6-18), PFFQ (MD, 9; 95% CI, 2-15), and satisfaction (MD, 11; 95% CI, 3-19). No other outcome measures statistically significantly differed.

RR on success rate was 1.11 (95% CI, 0.8-1.5). The ARR was –0.06 (95% CI, 0.1-0.2), with an accompanying NNT of 17 (95% CI, 11-23) in favor of the combination group.

TABLE 2
Baseline Characteristics

| | Physical Therapy (n = 56) | Brace (n = 68) | Combination (n = 56) |
|---|---|---|---|
| Mean age in years (SD) | 43 (8) | 46 (11) | 47 (9) |
| Mean duration of complaints in weeks (SD) | 16 (16) | 23 (30) | 21 (37) |
| Sex, male % (n) | 48 (27) | 53 (36) | 50 (28) |
| Dominant arm affected % (n) | 77 (43) | 74 (50) | 71 (40) |
| Neck/shoulder complaints % (n) | 18 (10) | 25 (17) | 18 (10) |
| Primary outcome measures | | | |
| Severity of complaints[a] | 44 (18) | 47 (19) | 48 (17) |
| Pain most important complaint[a] | 72 (20) | 74 (18) | 72 (15) |
| Pain Free Function Questionnaire[b] | 48 (16) | 51 (17) | 52 (16) |
| Secondary outcome measures | | | |
| Inconvenience[a] | 59 (24) | 64 (21) | 60 (21) |
| Pain-free grip strength[c] | 45 (25) | 45 (27) | 42 (29) |
| Maximum grip strength[c] | 72 (27) | 67 (28) | 70 (27) |
| Pressure pain[d] | 51 (24) | 48 (23) | 39 (20) |

[a] Rated on numeric rating scales (0-10) and transformed into scores ranging from 0 to 100, 0 indicating *no complaints* and 100 indicating *severe complaints*.
[b] Questionnaire scores between 0 and 40; scores were transformed into scores from 0 to 100, 0 indicating *no complaints* and 100 indicating *severe complaints*.
[c] Pain-free grip strength and maximum grip strength are presented as a ratio of the maximum grip strength of the noninjured arm, multiplied by 100.
[d] Pressure pain threshold presented as a ratio of the pressure pain threshold of the noninjured arm, multiplied by 100.

### Physical Therapy Versus Combination

A statistically significant difference was identified only for increase in pressure pain threshold, in favor of combination therapy (MD, 13; 95% CI, 1-25).

RR on success rate was 0.90 (95% CI, 0.6-1.3). The ARR was 0.05 (95% CI, 0.2-0.1) with an accompanying NNT of 20 (95% CI, 15-25) in favor of the physical therapy group.

### Intermediate-Term Follow-up

On intermediate-term follow-up (mean, 26 weeks; SD, 3.1), no significant differences for any outcome measure were identified.

### Long-Term Follow-up

On long-term follow-up (mean, 51 weeks; SD, 4.2), no significant differences for any outcome measure were identified. At 1 year, the NNT favoring physical therapy compared to brace-only treatment is 33 patients (95% CI, 25-41). For physical therapy versus combination, the NNT was 50 (95% CI, 42-58), favoring the physical therapy group.

### Additional Treatment During Follow-up

In the physical therapy group, 21% of all patients received additional treatment for their tennis elbow complaints. In the brace-only group, 19% of all patients received additional treatment; in the combination group, 19% of all patients received additional treatment. This additional treatment consisted mainly of physical therapy sessions. Only 1 patient, in the brace-only group, underwent surgery for persisting complaints within 1 year. No differences were statistically significant (Table 5).

### Alternative Analyses

For the per-protocol analysis, a total of 17 patients who violated the treatment protocol were excluded. Similar results were found when compared to the intention-to-treat analysis.

Additional subgroup analyses carried out for duration of complaints, presence of neck/shoulder problems, previous episodes of tennis elbow complaints, and allocation to the preferred therapy showed no differences for subgroups.

## DISCUSSION

Comparing the different outcome measures, conflicting but explainable, results were found. Beneficial effects of physical therapy were found for pain, disability, and satisfaction but only over the short term. In contrast, brace-only treatment was superior on inconvenience during daily activities. No other outcomes showed statistically significant differences.

The hypothesized working mechanism of the brace is that it reduces the forces on the common extensor tendon and will therefore decrease the patient's pain during activities in which the extensor muscles contract. This was supported by the outcome measure "inconvenience during daily activities." The brace-only group was superior on this outcome measure when compared to physical therapy. The combination group showed a similar trend, but the difference was not statistically significant. This outcome shows a major advantage for use of the brace, with implications for daily practice and patient education. A contingent inca-

TABLE 3
Results at Follow-up: Mean Improvement (SD), Compared to Baseline

| | A Physical Therapy (n = 56) | B Brace (n = 68) | C Combination (n = 56) | Mean Differences in Improvement (95% CI) A-B | A-C | B-C |
|---|---|---|---|---|---|---|
| Success, % (n) | | | | | | |
| 6 weeks | 50 (28) | 40 (27) | 45 (25) | 10 (–7 to 27) | 5 (–15 to 25) | 5 (–12 to 22) |
| 26 weeks | 70 (39) | 72 (49) | 75 (42) | –2 (–18 to 14) | –6 (–24 to 12) | –4 (–20 to 12) |
| 52 weeks | 89 (50) | 85 (58) | 88 (49) | 4 (–7 to 15) | 1 (–8 to 16) | –3 (–14 to 8) |
| Severity of complaints[a] | | | | | | |
| 6 weeks | 16 (16) | 11 (16) | 22 (18) | 5 (–2 to 12) | –6 (–12 to 1) | –11 (–18 to –6)[f] |
| 52 weeks | 28 (19) | 31 (20) | 32 (21) | –2 (–10, 5) | –3 (–11,4) | –1 (–8,6) |
| Pain most important complaint[a] | | | | | | |
| 6 weeks | 31 (25) | 18 (23) | 24 (31) | 13 (3,21) | 7 (–4, 17) | –6 (–4,15) |
| 26 weeks | 42 (30) | 43 (26) | 47 (27) | –1 (–12,10) | –4 (–14,7) | –5 (–17,7) |
| 52 weeks | 60 (27) | 60 (28) | 58 (27) | 0 (–10,11) | 2 (–8,13) | 2 (–8,12) |
| Pain Free Function Questionnaire[b] | | | | | | |
| 6 weeks | 17 (14) | 10 (19) | 19 (17) | 7 (1,12)[f] | –2 (–8,4) | –9 (–15,–2)[f] |
| 26 weeks | 30 (19) | 30 (18) | 36 (18) | 0 (–6,7) | –6 (–12,1) | –6 (–13,1) |
| 52 weeks | 37 (16) | 40 (18) | 42 (20) | –3 (–9,3) | –5 (–12,1) | –2 (–9,5) |
| Inconvenience[a] | | | | | | |
| 6 weeks | 15 (27) | 26 (30) | 24 (27) | –11 (–21,–1)[f] | –9 (–18,1) | 2 (–8,13) |
| 26 weeks | 35 (32) | 40 (28) | 41 (25) | –5 (–17,7) | –6 (–18,6) | –1 (–11,10) |
| 52 weeks | 50 (27) | 53 (29) | 50 (35) | –4 (–14,7) | 0 (–10,10) | 4 (–6,14) |
| Pain-free grip strength[c] | | | | | | |
| 6 weeks | 18 (28) | 24 (29) | 27 (28) | –6 (–18,6) | –9 (–20,2) | –3 (–14,7) |
| 52 weeks | 53 (32) | 49 (31) | 54 (35) | 4 (–7,16) | –1 (–14,12) | –6 (–18,6) |
| Maximum grip strength[c] | | | | | | |
| 6 weeks | 16 (32) | 15 (27) | 12 (29) | 1 (–9, 12) | 4 (–6, 15) | 3 (–7, 14) |
| 52 weeks | 29 (28) | 30 (28) | 29 (26) | –1 (–11,9) | 0 (–10,10) | 1 (–8,11) |
| Pressure pain[d] | | | | | | |
| 6 weeks | 17 (37) | 22 (33) | 30 (30) | –5 (–18,8) | –13 (–25,–1)[f] | –8 (–20,4) |
| 52 weeks | 43 (39) | 41 (31) | 50 (26) | 2 (–11,14) | –7 (–18,4) | –9 (–19,1) |
| Satisfaction[a,e] | | | | | | |
| 6 weeks | 75 (20) | 66 (26) | 77 (19) | 9 (1,18)[f] | –2 (–9,9) | –11 (–19,–3)[f] |
| 26 weeks | 78 (20) | 71 (19) | 79 (15) | 7 (–1,14) | –1 (–9,5) | –8 (–15,1) |
| 52 weeks | 76 (19) | 75 (20) | 81 (18) | –2 (–22,2) | –5 (–12,2) | –7 (–14,4) |

[a] Rated on numeric rating scales (0-10) and transformed into scores ranging from 0 to 100, 0 indicating *no complaints* and 100 indicating *severe complaints*.
[b] Questionnaire scores between 0 and 40; scores were transformed into scores from 0 to 100, 0 indicating *no complaints* and 100 indicating *severe complaints*.
[c] Pain-free grip strength and maximum grip strength are presented as ratio of the maximum grip strength of the noninjured arm, multiplied by 100.
[d] Pressure pain threshold presented as ratio of the pressure pain threshold of the noninjured arm, multiplied by 100.
[e] For satisfaction, mean differences between groups were calculated, 0 indicating *not satisfied* and 100 indicating *very satisfied*.
[f] Statistically significant difference at the $P < .05$ level.

pacity to work might be favorably influenced by use of the brace, although patients might be able to continue their work.

Combination treatment showed no superior effectiveness when compared to physical therapy treatment only. It was, however, superior when compared to brace-only treatment over the short term. Therefore, physical therapy seems to have additional beneficial effects compared to brace-only treatment. However, the main question remains as to whether this surplus in effectiveness outweighs the extra costs of the physical therapy. Often, clinical relevance is expressed in the NNT.[13] With a risk difference of 3% and a corresponding NNT of 33 for cure at 1 year, there is, in our opinion, no place in tennis elbow treatment for the studied physical therapy protocol when long-term effects are aimed for. However, a NNT of 9 compared to brace-only treatment for cure at 6 weeks might indicate usefulness when a rapid recovery is required or wanted. Comparing combination and brace-only treatments, NNTs varied from 14 at 6 weeks to 100 at 1-year follow-up. With the small ARR and not significantly different RR, this seems not clinically relevant. Comparing physical therapy and combination, physical therapy was superior at 6 weeks and 1 year; combination was superior at 26 weeks. Again, ARRs were very small (2%-7%), RR did not statistically differ, and NNTs were relatively large.

TABLE 4
Relative Risk, Absolute Risk Difference, and Number Needed to Treat on Success Rate for All Treatment Strategies[a]

| | RR (95% CI) | ARR (95% CI) | NNT (95% CI) | NNT in Favor of |
|---|---|---|---|---|
| Brace-only versus physical therapy | | | | |
| 6 weeks | 1.22 (0.9 to 1.7) | –0.11 (0.1 to –0.3) | 9 (3 to 15) | Physical therapy |
| 26 weeks | 0.89 (0.5 to 1.6) | 0.03 (0.2 to –0.1) | 33 (27 to 39) | Brace only |
| 52 weeks | 1.26 (0.5 to 3.3) | –0.03 (0.1 to –0.2) | 33 (25 to 41) | Physical therapy |
| Brace-only versus combination | | | | |
| 6 weeks | 1.11 (0.8 to 1.5) | –0.06 (0.1 to –0.2) | 17 (11 to 23) | Combination |
| 26 weeks | 1.17 (0.6 to 2.2) | –0.04 (0.1 to –0.2) | 25 (16 to 34) | Combination |
| 52 weeks | 1.10 (0.4 to 2.8) | –0.01 (0.1 to –0.1) | 100 (89 to 111) | Combination |
| Physical therapy versus combination | | | | |
| 6 weeks | 0.90 (0.6 to 1.3) | 0.05 (0.2 to –0.1) | 20 (15 to 25) | Physical therapy |
| 26 weeks | 1.31 (0.7 to 2.4) | –0.07 (0.1 to –0.2) | 14 (8 to 20) | Combination |
| 52 weeks | 0.87 (0.3 to 2.4) | 0.02 (0.1 to –0.1) | 50 (42 to 58) | Physical therapy |

[a] RR, relative risk; CI, confidence interval; ARR, absolute risk reduction; NNT, number needed to treat to prevent 1 bad outcome.

TABLE 5
Additional Treatment After Intervention Period[a]

| | Physical Therapy (n = 53) | Brace (n = 63) | Combination (n = 54) |
|---|---|---|---|
| No additional treatment | 42 (79%) | 51 (81%) | 44 (81%) |
| Physical therapy | 12 (23%) | 10 (15%) | 13 (46%) |
| Elbow support * | 3 (6%) | 0 (0%) | 1 (2%) |
| Corticosteroid injection(s) | 4 (8%) | 4 (6%) | 5 (9%) |
| Pain medication | 2 (4%) | 0 (0%) | 4 (7%) |
| Surgery | 0 (0%) | 1 (2%) | 0 (0%) |

[a] Patients in the brace-only and combination groups were allowed to continue the use of their Epipoint brace. In this table, additional elbow supports were counted.

Thus, due to conflicting results and relatively small differences, the difference seems not clinically relevant.

A limitation of our trial was that no control group was included in our study. Comparison to no treatment would be simplified if so. However, the physiotherapy intervention and design of the study was comparable with a recently published trial by Smidt et al.[15] The results of the physiotherapy intervention in their study were strikingly similar to ours. Therefore, the results of this group can be interpreted against a control group (an expectantly awaiting policy). In Smidt et al's study, at 6 weeks there was a difference between physiotherapy and expectantly awaiting of 15%, at 26 weeks of 6%, and at 52 weeks of 8%, all in favor of the physiotherapy group.[15]

Another possible flaw might be the fact that patients were compliant in performing the exercises that they were instructed to perform. We tried to limit this by the exercise diaries patients were to fill out. Bias might have been introduced by patients not describing the correct number of exercises. Therefore, supervised physical therapy might have yielded different results.

In this trial, selection bias was prevented by randomization using a minimization strategy, which guarantees concealment of allocation. Blinding of outcome measures was adequate because the outcome assessor was never sure of his guesses concerning the patients' allocated treatment. The dropout rate was less than 6% after 1-year follow-up and thus kept to a minimum.

In the literature, limited evidence is present on the effectiveness of orthotic devices.[17] On the effectiveness of physical therapy strategies, the same conclusion can be drawn. Labelle and Guibert concluded that very limited evidence was present to draw definitive conclusions on the effectiveness of physical therapy strategies for tennis elbow complaints.[10] Recently, a new systematic review was undertaken that had similar conclusions.[14]

Not included in this latter review was a trial by the same author group, in which the content of the physiotherapeutic intervention was similar to ours.[15] The success rate for physical therapy at 6 weeks was remarkably similar to the success rate in our trial (47% and 50%, respectively), and it was the same for long-term follow-up: success rates of 91% and 89%, respectively. In the trial of Smidt et al,[15] the success rates for an expectantly awaiting policy were 32% at 6 weeks follow-up, 80% at 26 weeks follow-up, and 83% at 52 weeks follow-up. As in our trial for brace versus physiotherapy, the difference between physiotherapy and the expectantly awaiting policy in the Smidt et al trial was, however, not significant.

Over the intermediate term and long term, we showed that it is indifferent which therapy a patient received because no differences were present at those time points.

Also, no statistically significant differences were present between groups on additional treatment. This may partially be caused by the quite favorable natural course for tennis elbow.

Corticosteroid injections are a widely applied regimen as well. Their effectiveness, however, is controversial, and some think it is even harmful (causing relatively many recurrences).[2,15,16] Braces might thus be a good strategy to help wait out the natural course of tennis elbow complaints. The positive results for brace-only treatment on functional status should, however, be replicated in other well-designed trials to exclude the possibility that the favorable outcome on inconvenience during daily activities is based on chance.

For pain, disability, and satisfaction, physical therapy is more effective when compared to brace only over the short term. Combination treatment is more effective than brace only on 6 weeks follow-up for severity of complaints, disability, and satisfaction. Combination has no advantage over physical therapy only. At 26 weeks and 52 weeks, no differences were present between all studied regimens.

Therefore, for 1 outcome, knowing inconvenience in daily activities, brace treatment seemed useful as initial therapy. Although we advise conducting more studies under different circumstances, a brace as supportive treatment can be considered. It is a relatively cheap intervention, which helps wait out the natural course. When the patients do not show a pain-decreasing effect while using the brace, physical therapy can be considered, although added value is limited.

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