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PULSED ULTRASOUND TREATMENT IN LATERAL EPICONDYLALGIA

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ABSTRACT. This study was carried out to explore the pain-alleviating effect of pulsed ultrasound in lateral epicondylalgia. Forty-five patients were consecutively assigned at random to two groups for pulsed ultrasound or placebo. The parameters for ultrasound were 1 MHz; 1 : 4; 1 W/cm^2. Each session was for 10 min, two to three times weekly, ten treatments in all. Follow-ups were done after three and twelve months. The statistical analysis showed no significant differences in relation to subjective or objective outcomes between the groups after the treatment period or at the follow-ups. Our results do not support the use of pulsed ultrasound treatment with the chosen parameters in lateral epicondylalgia.

Key words: epicondylalgia, tennis elbow, ultrasound, pain, placebo.

Pain is the outstanding symptom in tennis elbow (8) or "lateral elbow syndrome" (2), which is a condition associated with improper or exessive use of the elbow. Whether this condition is caused by an inflammatory reaction is not settled. It appears to be multifactorial in origin, while the clinical picture is fairly uniform (2–4, 13, 17). Furthermore, only 5% of the people suffering from tennis elbow actually play tennis, and therefore, the condition may rather be referred to as lateral epicondylalgia (8, 15).

Ultrasound has been used as a therapeutic agent in physical medicine for decades, but although it has been claimed valuable in the treatment of a wide variety of pain conditions there have been few reports of randomized, controlled clinical trials to evaluate efficacy.

Previous studies of continuous ultrasound treatment in epicondylalgia (10) and shoulder pain (5, 12) have failed to prove beneficial results for the relief of pain. When using pulsed ultrasound in lateral epicondylalgia, the results are contradictory (1, 14, 19). In a comparative study of continuous ultrasound and pulsed ultrasound, the pulsed ultrasound was favoured (17).

The aim of this study was to explore the pain-alleviating effect of pulsed ultrasound in lateral epicondylalgia using similar procedures and the same dose of treatment as Binder et al. (1) and Zachrisson-Forsell (19).

PATIENTS AND METHODS

Patients

Fifty-four patients suffering from lateral elbow pain were examined and evaluated at the clinic during a period of 7 months. The patients were either self-referred or referred by their physician or physiotherapist. Patients were included if they had pain over the lateral epicondyle at two or more of four tests and pain for at least one month. The diagnostic criteria used were: (1) *Palpation of the lateral epicondyle.* (2) *Resisted wrist extension.* Position: shoulder flexion, 60 degrees, elbow extended (not supported); forearm pronated; wrist extended about 30 degrees. Pressure was applied on the dorsum of the second and third metacarpal bones in the direction of flexion toward the ulnar side to prove involvement of the extensor carpi radialis brevis and longus. (3) *Passive stretching of the extensor muscle group.* Position: elbow extended, forearm pronated, maximal wrist palmar flexion. (4) *Resisted finger extension.* Position: 60 degrees of shoulder flexion, elbow extended, forearm pronated, fingers extended. Resisted extension was applied manually on digiti II to V to prove involvement of the extensor indicis, the extensor digitorum, and the extensor digiti minimi. Resistance applied on digitus III was the middle-finger test.

Patients were excluded who demonstrated the following: (1) Dysfunction in the shoulder, neck, and/or thoracic region; (2) Local arthritis or generalized polyarthritis; (3) Neurologic abnormality; (4) Radial nerve entrapment (9, 11).

Forty-five patients who met the criteria of lateral epicondylalgia were consecutively assigned at random to two groups. Two patients "dropped out" during the treatment period; one because of illness unrelated to the elbow; the other was on medication without out knowledge. Forty-three patients (23 men and 20 women) completed the study; they were all limited to unilateral epicondylalgia.

Group A: the pulsed ultrasond group, had 21 patients (11 men and 10 women) with a mean age of 50.3 years (range 34 to 67 years), and a median duration of pain of 8 months (range 2 to 60 months).

Group B: the placebo group, had 22 patients (12 men and 10 women) with a mean age of 48.3 years (range 33.7 to 67.2

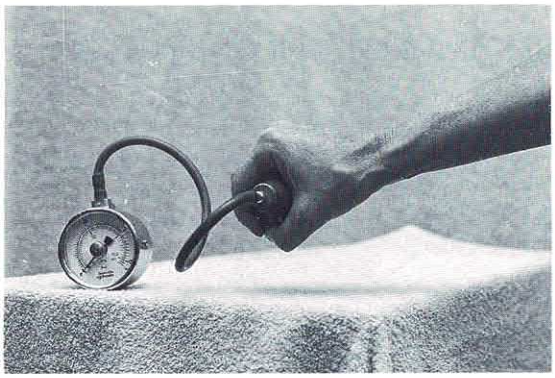

Fig. 1. Test position of the Martin Vigorimeter.

years), and a median duration of pain of 9 months (range 1 to 60 months).

Details were recorded of profession, onset of pain, pain at night, pain at rest, character of pain (dull or shooting), time of sick listing, workload and involvement in monotonous and repetitive movements. Furthermore, they were asked about activities worsening the pain (e.g. brushing teeth, shaking hands, grasping, and lifting) and rotatory movements of the arm (e.g. using a screwdriver, knitting, handwriting, driving a car, and flexion and/or extension of the elbow). Affected arm, cause of pain, and previous treatment are presented in Table I.

All the patients were informed that two modes of treatment were to be tried out and that no fee was to be charged. No other treatments or drugs were to be used during the month before the trials began and throughout the study. They were instructed to "use the arm but avoid painful movements".

METHODS

Two Sonicator 705 were used. The parameters were: frequency, 1.0 MHz; puls ratio, 1:4; intensity, 1.0 W/cm^2; pulse repetition rate, 100 Hz; pulse duration, 2 ms; effected radiated area, 5 cm^2. Two machines were available and they were standardized initially and then every month. One of the machines allowed mock insonation to be given to the placebo group. No difference in machine appearance was observed either by the assistant who carried out the treatments or by any other persons involved in the study. The output of the machines were controlled every day on a simple underwater radiation balance. Using an ultrasonic coupling medium, the ultrasound was applied with a slow gliding rotating movement over the lateral epicondylar area.

The patients were treated for 10 min two to three times weekly, and given ten treatments in all. Follow-ups were done at the clinic after 3 and 12 months. The pulsed ultrasound/placebo ultrasound code was broken only after the follow-ups.

Evaluation

One of the authors, unaware of the treatment schedule, examined the patients before and after the treatment period and at the follow-ups. In addition to the four diagnostic criteria (*tests 1 to 4*), the patients were evaluated in further four tests.

In tests 5 and 6, the patients were tested as to whether pain could be produced at the lateral aspect of the epicondyle by isometric pronation and supination of the forearm. The test position was elbow flexed 90 degrees and supported with the forearm in between pronation and supination.

In the vigorimeter test, test 7, grip strength was measured. Thorngren & Werner (16) used the Martin vigorimeter to determine the ratio dominant to the nondominant hand to 1.07 ± 0.11. According to this result, the value of the nonaffected arm can serve as a parameter in evaluating the pain-free grip strength. The vigorimeter is a dynamometer with a rubber balloon which is compressed in the hand. The air-pressure within the balloon is registered in kilopond per square centimeter (1 kp/cm^2 = 98.1 kPa) on a manometer. In our study, a medium sized balloon was used.

The patient was seated comfortably, shoulder 60° in between flexion and abduction, elbow extended, forearm pronated with 20° dorsiflexion of the wrist, holding the balloon with the connection tube protruding between thumb and index finger. The patients were instructed to squeeze the balloon and to stop pressure when any kind of pain was experienced over the lateral epicondyle (Fig. 1).

The reading was not visible to the patient. If the mere position of the arm caused pain, this was noted as zero, and no pressure was exerted. Otherwise, the mean value of three consecutive estimations was calculated in kPa. The pain threshold when gripping was noted before and after the ten

Table I. *Affected arm, cause and previous treatments*

A = ultrasound group, B = placebo ultrasound

	Group		
	A+B	A	B
No. of pat.	43	21	22
Affected arm			
Right	36	19	17
Left	7	2	5
Dominant arm			
Right	41	21	20
Left	2	0	2
Cause			
Work	14	9	5
Sport	14	6	8
Other activities	24	12	12
Unknown	7	4	3
Previous treatment			
Steroids	20	9	11
Laser	12	5	7
Ultrasound	11	6	5
Acupuncture	4	0	4
Other treatments	10	6	4
Untreated	13	6	7

Table II. *Test schedule. Pre-treatment values*

The number of patients denotes how many of them being positive at the different tests

Test scedule	No. of pat.
1. Pain at epicondyle	43
2. Resisted wrist extension	37
3. Stretching of the Extensor muscle	15
4. Middle finger test	36
5–6. Resisted pronation/supination	21/16
7. Vigorimeter test	43
8. Lifting 1–4 kg	17/33/35/36

treatments and at the follow-ups. The post-treatment values were compared to those obtained at the pre-treatment evaluation, and the median values of the differences were calculated.

Test 8 was the lifting test. Sitting in the position described above, the patient was also required to lift four different weights, 1, 2, 3, and 4 kg, with grip diameters of 2.5 to 3 cm. Pain over the epicondyle was recorded as present or absent. All the tests were performed bilaterally, and the number of patients positive at the different tests is presented in Table II.

After the tenth treatment and at the follow-ups all eight clinical tests were repeated, and, moreover, a subjective assessment completed the clinical examination.

A scale of 1 to 5 was shown to the patients, indicating: 1=excellent, 2=good, 3=improved, 4=slightly improved, and 5=unchanged or worse. They were asked, "How do you assess your pain today compared to the pre-treatment condition?" The patients indicated the score that most adequately reflected their present condition.

Statistics

Correlation analysis, the Mann-Whitney U-test of two independent samples, and chi-square test were used for the statistical analyses.

RESULTS

All the 43 patients completed the study and the three months follow-up. At the one year follow-up, five in the ultrasound group and six in the placebo group had withdrawn due to insufficient pain alleviation.

Subjective outcome. Eight patients in the ultrasound group and ten in the placebo group reported an excellent or a good result (1 and 2 on the verbal scale), eight and seven patients respectively reported improved (3 on the scale) and five patients in each group reported slightly improved, unchanged or worse (4 and 5 on the scale). No significant differences were observed between the groups after the treatment period or at the follow-ups.

Objective outcome. In both the ultrasound and placebo groups the vigorimeter test did show about the same increase of the pain-free grip strength after ten treatments and at the follow-ups (Table III).

The patients in the two groups had similar pre-treatment conditions. There was no significant difference between the groups in relation to profession, onset of pain, pain at night, pain at rest, character of pain, time of sick listing, workload, involvement in monotonous and repetitive movements, activities worsening the pain, affected arm, cause, and previous treatment. There was no correlation between the pre-duration of pain or any of the other observed parameters, and the increase of the pain-free grip (vigorimeter test). No side effects were reported during or after the treatment period.

DISCUSSION

The present study shows that there is no significant difference in recovery between pulsed ultrasound and placebo ultrasound. Both groups improved throughout the study, which may reflect the spontaneous recovery known to occur and/or local compression arising from the ultrasound head applied on and around the affected epicondyle. Also the placebo effects should be taken into account.

In spite of a similar procedure of treatment, contradictory results of pulsed ultrasound in lateral epicondylalgia have been reported. The parameters in one study, not favouring the pulsed ultrasound, were 1 MHz; 1 : 4; 0.8 W/cm^2 (10 treatments, 5 min) (19) and in the other study, reporting enhanced recovery of pulsed ultrasound, the parameters were 1 MHz; 1 : 4; 1–2 W/cm^2 (12 treatments, 5–10 min) (1). The procedures used in these two studies were similar to those

Table III. *Evaluation of the vigorimeter test (kPa)*

	Pre-tr.	10 tr.	3 months	1 year
A) Ultrasound	24	18	32	53
B) Placebo	35	16.5	29	47
	NS	NS	NS	NS

Pre-tr. = The median values of the Vig. test of the two groups were calculated before the first treatment. Because of the wide range, the median values were used. The differences between the post-treatment and the pre-treatment values were calculated after 10 treatment, 3 months and 1 year, and the median values obtained were compared. NS = non significant.

used in our study, 1 MHz; 1:4; 1 W/cm^2 (10 treatments, 10 min). The result in the present study support the findings obtained by Zachrisson-Forsell (19). A similar non-significant pain relieving effect has also been reported in a study using continuous ultrasound in lateral epicondylalgia (10).

Injuries treated by physiotherapists involve soft connective tissue, i.e. tissue located in the dermis, joint capsules, ligaments, and tendon. The repair of such tissue consists of three overlapping stages: acute inflammation, proliferation, and remodelling. During the acute inflammation, platelets, and mastcells become activated releasing substances initiating tissue repair (6). It has been demonstrated in vivo by Fyfe-Chatel that a single pulsed ultrasound treatment can stimulate the release of histamine from mastcells by degranulation, if the treatment is given during the first 24 hours. Given later, the opposite effect was reported (7). However, our patients had a duration of pain of at least one month; this may partly explain the lack of difference in outcome between the pulsed ultrasound and placebo.

In conclusion, our results do not support the use of pulsed ultrasound in lateral epicondylalgia with the chosen procedure.

This work has been approved by the ethics committee at the Karolinska Institutet.

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