Scand J Rehab Med 20: 99–101, 1988

A COMPARATIVE STUDY OF CONTINUOUS ULTRASOUND, PLACEBO ULTRASOUND AND REST IN EPICONDYLALGIA

T. Lundeberg, P. Abrahamsson and E. Haker

From the Department of Physiology II, Karolinska Institutet, S-10401 Stockholm, Sweden

ABSTRACT. In this study the pain alleviating effects of continuous ultrasound treatment in epicondylalgia has been compared to placebo ultrasound and to rest. Of 99 patients 33 were randomly allocated to receive continuous ultrasound treatment, 33 to placebo ultrasound treatment and 33 were recommended only rest. The 66 patients treated were each given 10 treatments over 5 to 6 weeks. The condition was significantly improved in the group treated with continuous ultrasound in 36 %, in 30 % given placebo, and in 24 % of those recommended rest. A significant improvement was noted when the effect of continuous ultrasound was compared with rest, but continuous ultrasound treatment *was not* significantly better than placebo ultrasound.

Key words: epicondylalgia, pain, ultrasound, placebo.

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 range of clinical conditions there have been few reports of randomised, controlled clinical trials to evaluate its efficiency. In the few studies including a control group, there have only been moderate beneficial results (6, 9). Binder et al., using a control group, showed improved recovery when treating soft tissue lesions with *pulsed ultrasound* (3). The effect of *continuous ultrasound* was not studied. Therefore we have made a comparison of the effects of continuous ultrasound, placebo ultrasound and untreated controls in a group of patients suffering from epicondylalgia using similar procedures as used by Binder et al. (3).

PATIENTS AND METHODS

Patients

Ninety-nine patients suffering from epicondylalgia of at least one month's duration were included in the study. Patients with pain or point tenderness over the lateral epicondyle of the humerus were included (2). Their complaints also included aggravation of pain by dorsiflexion of the wrist against manual resistance with the elbow extended, dorsal elevation of the middle finger with the elbow extended, and resisted isometric extension of forearm. Patients with local arthritis of the elbow, generalised polyarthritis or neurological abnormalities in the affected arm were excluded, as were those with symptoms from the neck or thorax, or who had had steroid injections within the last 6 months.

The patients (63 men and 43 women) ranged in age from 21–68 years (mean 38 years). Fifty-two patients (53 %) attributed their symptoms to sport, forty-three (43 %) to housework and five (4 %) to elbow trauma. The patients were randomly allocated in three groups. Group A (n=33) were treated with continuous ultrasound treatment and instructed to rest. Group B (n=33) were given placebo ultrasound treatment and instructed to rest. Group C (n=33) received only instructions to rest.

Procedure

The two ultrasound units used were standardised initially and then every month. Output was checked before each treatment session on a simple underwater radiation balance. An on/off key introduced into the transducer circuit allowed mock insonation to be given to the placebo group without affecting the normal ultrasonic output when the key was turned on. The ultrasound head was applied to the patient's skin, using an ultrasonic coupling medium. The ultrasound treatment was given to the painful epicondyle and surrounding area (5×5 cm) and stimulation was carried out by continuous movement of the head (circular motion at a slow pace). The continuous ultrasound had a frequency of 1.0 MHz, intensity of 1.0 Wcm^{-2} and was applied for 10 min.

Ten treatments (two per week) were given over five to six weeks. A therapist not involved in treatment arranged a schedule allocating patients at random to either ultrasonic treatment, placebo treatment or rest. She was responsible for setting the transducer at the treatment sessions so that none of the patients, therapists or the physician could know the grouping.

All 99 patients were reviewed every fortnight. The follow up continued for another three months before patients were discharged or had alternative treatment.

At each visit the clinical assessment included: (A) a pain score using a 10 cm horizontal visual analogue scale; (B) assessment of pain and diminution of power when testing resisted wrist dorsiflexion compared to the normal wrist (0 = no pain, 1 = mild pain but normal power, 2 = moderate pain and reduced power, 3 = severe pain and absent power); (C) a weight test to assess ability to lift weights of 3, 2, and 1 kg with elbow extended and forearm pronated; (D) a test of grip strength made with elbow

Table I. *Overall outcome*
Satisfactory (+), unsatisfactory (−), ultrasound (U)

	At discharge		After 3 months	
	+	−	+	−
Cont. U	18	15	12	21
Placebo U	14	19	10	23
Rest	9	24	8	25

extended using a 300 mmHg spring coil gauge attached to a rubber bag preset to 25 mmHg, and using an average of three estimations. After completing their treatment or rest period the follow-up patients were asked to assess the results of their regime. The physician also judged the outcome.

It was considered a satisfactory outcome if the patient had full functional recovery and 75–100% reduction of tenderness and pain. At the end of the study patients either stopped or had alternative treatment.

Statistics

The χ^2-test with Yates' correction and the Wilcoxon rank sum test were used to analyse the objective outcome and the rate of recovery.

RESULTS

Twelve patients treated with continuous ultrasound (36%), 10 patients treated with placebo ultrasound (30%) and 8 who had been recommended only rest (24%) showed a satisfactory outcome on objective testing both at the end of treatment and during the 3-month follow-up (Table I). Contingency table analysis showed that the difference between the continuous ultrasound group and the rest group was significant ($p<0.01$). There was no significant difference, however, between the continuous ultrasound group and placebo ultrasound group.

Ten patients (six given continuous ultrasound treatment and four placebo ultrasound treatment) reported the outcome satisfactory, on completing treatment despite persistent disability on objective assessment. A follow-up after three months confirmed unsatisfactory results in these patients.

The three treatment groups showed no significant difference in the mean severity of any of the clinical variables at the time of entry to the study. Comparisons of the rate of recovery from time 0 to each follow-up visit (Wilcoxon's rank sum tests) confirmed a significant advantage for the continuous ultrasound over the rest group ($p<0.01$). This was not the case in the comparison of continuous and placebo ultrasound. Table II shows the reduction in the pain score, pain on resisted wrist dorsiflexion, pain on weight test, and the improvement of grip strength in extension, in the three groups at the 3-month follow-up. The duration of symptoms on entry, dominance of the affected arm, and treatment given before referral did not influence the outcome, but the patients who responded to ultrasound or placebo had had milder symptoms on entry than those who did not respond. Fluctuation (±20%) in the ultrasonic output was detected in the machine when it was subjected to checks on the underwater radiation balance before and after treatment.

DISCUSSION

The present study shows that there is *no* significant difference in recovery in patients with epicondylalgia receiving continuous ultrasound or placebo ultrasound treatment. When comparing continuous ultrasound with rest there was a significant difference in pain alleviation, indicating that treatment enhances recovery. The latter most likely reflected the benefits of careful supervision. Patients who had less severe symptoms generally responded better to treatment.

The patient's subjective assessment immediately after the completion of treatment is generally used to determine the efficacy of treatment. We found, as did Binder et al. (3), a definite discrepancy between the subjective and objective assessments. Review 12 weeks later showed better agreement.

Continuous ultrasound therapy, in the intensity of 1.0 Wcm^{-2}, is used extensively to reduce inflammation and enhanced tissue repair following a wide variety of soft-tissue injuries (1, 10), although, controlled studies offer little evidence to indicate that ultrasound has any anti-inflammatory activity.

Table II. *Mean improvement and standard deviations after 3 months in subjective pain (VAS), pain on resisted wrist dorsiflexion (WD), pain on weight test (WT), grip strength in extension (GS)*
Ultrasound (U)

	VAS	WD	WT	GS
Cont. U	2.8±0.3	0.8±0.08	0.8±0.06	39.4±3.8
Placebo U	2.4±0.3	0.8±0.05	0.4±0.04	40.2±3.1
Rest	2.1±0.5	0.6±0.12	0.5±0.04	36.2±4.3

No difference was found between ultrasound-treated and placebo groups in periarthritis or calcific tendinitis of the shoulder where the majority of patients in both groups improved (6, 9). In an animal model of acute inflammation, Goddard and colleagues found no anti-inflammatory acitvity (7). In a study by Hashish et al. (1986) it was shown that ultrasound at an intensity of 0.1 and 0.5 Wcm^{-2} might have an anti-inflammatory acitivity (8).

Pain relief following placebo treatment is a well-recognized phenomenon which may be due to changes in pain perception mediated by circulating opioids (5). Furthermore, it has been shown that there is a relationship between ACTH and cortisol levels and endogenous opioids indicating an anti-inflammatory activity of placebo as well (4).

In conclusion, continuous ultrasound is no better than placebo ultrasound in treatment of epicondylalgia. The beneficial effects obtained with treatment compared with rest may reflect the benefits of careful supervision and placebo effects.

ACKNOWLEDGEMENTS

This work was supported by grants from The Royal Swedish Academy of Sciences and Stiftelsen Clas Groschinskys minnesfond.

REFERENCES

1. Aldes, J. H.: Ultrasonic radiation in the treatment of epicondylitis. General Practitoner *13:*89–96, 1956.
2. Binder, A. I. & Hazleman, B. L.: Lateral humeral epicondylitis—a study of natural history and the effect of conservative therapy. Br J Rheumatol *22:*73–76, 1983.
3. Binder, A., Hodge, G., Greenwood, A. M., Hazleman, B. L. & Page Thomas, D. P.: Is therapeutic ultrasound effective in treating soft tissue lesions? Br Med J *290:*512–514, 1985.
4. Clement-Jones, V. & Rees, L. H.: Neuroendocrine correlates of the endorphins and enkephalins. In: Clinical Neuroendocrinology, vol. II, pp. 139–209. Academic Press, London, 1982.
5. Fields, H. L. & Levine, J. D.: Placebo analgesia—a role for endorphins? Trends Neuro Sci *7:*271–273, 1984.
6. Flax, H. J.:Ultrasound treatment of peritendinitis calcarea of the shoulder. Am J Phys Med *43:*117–124, 1964.
7. Goddard, D. H., Revell, P. A., Cason, J., Gallagher, S. & Currey, H. L. F.: Ultrasound has no anti-inflammatory effect. Ann Rheum Dis *42:*582–584, 1983.
8. Hashish, I., Harvey, W. & Harris, M.: Anti-inflammatory effects of ultrasound therapy: evidence for a major placebo effect. Br J Rheumatol *25:*77–81, 1986.
9. Mueller, E. E., Mead, S., Schultz, B. F. & Vaden, M. R.: Symposium on ultrasonics: a placebo-controlled study of ultrasound treatment for periarthritis. Am J Phys Med *33:*31–35, 1954.
10. Munting, E.: Ultrasonic therapy for painful shoulders. Physiotherapy *64:*180–181, 1978.

Address for offprints:

Dr T. Lundeberg
Dept. of Physiology II
Karolinska Institutet
104 01 Stockholm