Scand J Rehab Med 27: 105–108, 1995

PULSED ULTRASOUND TREATMENT OF THE PAINFUL SHOULDER
A RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED STUDY

Matti Nykänen

From the Punkaharju Rehabilitation Hospital, Punkaharju, Finland

ABSTRACT. To study the effect of pulsed ultrasound in shoulder pains, 35 patients were treated with pulsed ultrasound and 37 patients with placebo ultrasound in a double-blind design. The therapy was given during in-patient rehabilitation, 10–12 treatments over 3–4 weeks. Treatment time was 10 minutes, frequency 1.0 mHz, on-off ratio 1:4 and intensity 1.0 w/cm^2. Follow-ups were done after 4–12 months. No differences ($p < 0.05$) in outcomes were found between the groups after the treatment period or at follow-ups. These results discourage the adding of pulsed ultrasound therapy with the variables used to the conservative treatment of the painful shoulder.

Key words: shoulder pain, pulsed ultrasound, controlled clinical trial.

INTRODUCTION

Ultrasound has been used in the treatment of shoulder pain for decades. Some reports have claimed the value of continuous ultrasound in this condition (7, 11, 15), but the failure to randomize treatment and the lack of controls have cast doubt on their conclusions. Other studies which used control groups failed to prove any beneficial results (3, 5, 14).

Ultrasound can influence blood flow, the mediation of inflammation, leukocyte function, angiogenesis, collagen synthesis and collagen maturation, as recently reviewed (13). Many of these effects are due to the temperature elevation, but with the introduction of pulsed ultrasound, non-thermal effects are also shown to be present (4). However, the clinical significance of these non-thermal effects is unclear (10). Controlled clinical trials using pulsed ultrasound in treating lateral epicondylitis (epicondylalgia) have produced diverging results (1, 6, 12, 18). In this study, pulsed ultrasound was used to treat patients with painful rotator cuff in a double-blind placebo-controlled study design.

MATERIAL AND METHODS

The source population consisted of in-patient rehabilitation clients coming for a treatment period of 3–4 weeks from April 1987 to April 1989. Included in study were 73 patients (11 women, 62 men, aged 37–81 years) suffering from shoulder trouble of at least 2 months' duration and with a painful arch between 40°–120° of abduction, or with other painful movement plus pain in supraspinatus test (patient upright, shoulder 90° of abduction, 30° of horizontal adduction, and full internal rotation. Patient maintains position against downward resistance) (9). Fifty-eight patients were war cripples or veterans whose rehabilitation was financed by the State Accident Office. The rest were people suffering from musculoskeletal problems to whom the Finnish Social Insurance Institute had decided to finance an institutional rehabilitation period.

Patients with suspected biceps-tendinitis (prominent tenderness on biceps-sulcus and pain during resisted elbow flexion), with prominent local tenderness over the acromioclavicular joint, with frozen shoulder (adhesive capsulitis) (restricted active and passive external rotation), with apparent rupture of rotator cuff (marked weakness or inability of active abduction not due to pain) were excluded. Likewise excluded were patients with shoulder problems associated with hemiplegia, or cases of altered anatomy or function like posttraumatic states with bone or nerve lesions. Patients with inflammatory rheumatoid diseases, and patients with unresolved compensation claims were also excluded.

All the patients found to fullfil the study criteria were willing to participate, and after giving informed consent, the subjects were randomly assigned to groups A or B. Then the responsible physician made a clinical assessment including: 1) a goniometric measurement of abduction with recording of the starting point of possible painful arch, and 2) pain according to the supraspinatus test (9) (0 = no pain, 1 = mild pain, 2 = moderate pain, 3 = severe pain). This assessment was repeated at discharge.

Treatment was given with a EST301-machine (Escotec Inc., Oulu, Finland) using Ultra-Phone ultrasonic coupling medium (Pharmaceutical Innovations Inc., Newark, New Jersey, USA). Before treatment the therapist chose a transducer plug labelled either A or B according to the respective group of patients. A technician, also responsible for the regular checking of the ultrasonic output of the machines, had made the other plug nonfunctioning. Apart from him, no other person knew which plug was manipulated.

Table I. *Clinical characteristics and physical findings in the patients*

Mean ± SD except sex

	Ultrasound	Placebo	*P*-value
Sex F/M			
Treatment period	6/29	5/32	NS
At 4 months	6/29	4/31	NS
At 12 months	5/25	4/31	NS
Age			
Treatment period	66 ± 6	67 ± 9	NS
At 4 months	67 ± 6	67 ± 9	NS
At 12 months	66 ± 6	69 ± 7	NS
Use of NSAID*			
Before treatment	22 ± 34	16 ± 20	NS
During treatment	9 ± 22	8 ± 16	NS
Use of steroid injection*			
Before treatment	0.9 ± 0.7	0.9 ± 0.8	NS
Use of physical therapy*			
Before treatment	4.1 ± 2.2	3.8 ± 2.2	NS
Highest arc of abduction at entry (degrees)	130 ± 35	135 ± 31	NS
Arc of initial pain during abduction at entry (degrees)	98 ± 32	96 ± 28	NS
Supraspinatus test pain score at entry (0–3)	1.3 ± 0.5	1.3 ± 0.6	NS
Patient pain index at entry (4–20)	16 ± 3	15 ± 3	NS
ADL-index at entry (3–14)	8.1 ± 1.6	8.0 ± 1.6	NS

NS: $p > 0.05$.
* in arbitrary units.

Manipulation affected only the function of the applicator head, with no difference in machine appearance. The treatment was pulsed with an on-to-off ratio of 1 : 4, frequency 1.0 mHz, intensity 1.0 w/cm^2, pulse repetition rate 100 mHz, pulse duration 2 ms and radiating area 5 cm^2. The treatment time was 10 minutes. Ten to twelve treatments were given over 3–4 weeks during the in-patient rehabilitation period.

Before treatment, at the discharge, and after 4 and 12 months, the patients answered questionnaires about pain, activities of daily living, medication and other treatments received. Sum indexes were formed for ADL and pain before the treatment and at follow-ups (interval 3–14 for ADL and 4–20 for pain). From those questions relevant to evaluate changes during the treatment period separate indexes were formed, with intervals 2–10 for ADL and 1–5 for pain.

Other treatments during the rehabilitation period were as similar as possible for both the groups. They consisted of massage of neck and shoulders, and group gymnastics attempting to stretch and strengthen the humero-scapular and cervical musculature. During the treatment period, no other physical therapy or injections for shoulder pain was allowed. Patients were asked to keep analgesic or anti-inflammatory medication at a minimum but drugs for pain disturbing sleep were given and registered (see Table I).

The study was approved by the ethic committee at the Punkaharju Rehabilitation Hospital.

Statistics

Wilcoxon test was used for analyzing changes within a group and Kruskal-Wallis test for changes between the groups with the help of Systat program (Systat Inc. Evanston, IL, USA).

RESULTS

Seventy-two patients (35 in the ultrasound group and 37 in the placebo group) completed the treatment period (one patient suffered a fatal cardiac infarction after one week's treatment). At the 4-month follow-up, 67 responded (32 in the ultrasound and 35 in the placebo group) and at the one-year follow-up, 68 responded (30 and 37, respectively). Statistical comparisons showed the study groups to be similar in baseline clinical characteristics and physical findings (Table I).

Subjective outcome

After the treatment period, both groups showed a statistically significant beneficial change in pain index and ADL-index (Table II). This improvement was seen even at the one-year follow-up for the pain index in both groups, and in the ultrasound group for the ADL-index, too (Table III).

However, no statistically significant differences were observed between the groups of $p < 0.05$ after the treatment period or at follow-ups (Tables II and III).

Table II. *Subjective outcome at the discharge*

Mean ± SD

	Ultrasound group		Placebo group	
	Before	After	Before	After
Pain index of treatment period (1–5)	3.5 ± 0.7	2.5 ± 0.7***	3.3 ± 0.7	2.4 ± 0.9***
ADL-index of treatment period (2–10)	5.1 ± 1.0	4.2 ± 1.3***	5.0 ± 1.1	4.4 ± 1.4**

** = $p < 0.01$.
*** = $p < 0.001$.
Differences in change between the groups were NS ($p > 0.05$).

Clinical assessment

After treatment period about the same degree of favourable progress was seen in both ultrasound and placebo groups, without significant differences between the groups (Table IV).

DISCUSSION

Ultrasound therapy is a common adjuvant in the treatment of the painful shoulder. In the present study the patients felt significantly better for one year after inpatient treatment when ultrasound therapy was used as a complement.

However, with the chosen procedure there was no difference between the use of active or non-functioning transducer. The criteria for inclusion into the study aimed at collecting patients with long-standing but reversible pain in shoulder movements, types I and II in Neer's classification of impingement syndromes (16). Because most patients included were over 60 years old it is probable that other shoulder pathologies existed too, e.g. minor rotator cuff lesions which are known to be quite common in elderly people (2). Most of these, if symptomatic, are treated conservatively with usually acceptable results (8). Another quite common finding is arthrosis of the acromioclavicular joint. In this study no X-ray pictures were obtained but there are results suggesting that acromioclavicular arthrosis has no predictive value in determining outcome (17).

In the present study the overall response to the treatment was beneficial. It is possible that the general treatment with superficial heat and massage together with group gymnastics was capable of obscuring the possible differences between the true and placebo

Table III. *Results of the follow-up questionnaires*

Mean ± SD

		Before treatment	At 4 months	At 12 months
Pain index of follow-up (4–20)	A	16 ± 3	13 ± 5***	13 ± 5***
	B	15 ± 3	13 ± 4*	13 ± 4**
ADL-index of follow-up (3–14)	A	8.1 ± 1.6	6.9 ± 2.4**	7.0 ± 2.4*
	B	8.0 ± 1.6	7.4 ± 2.0^{NS}	7.3 ± 2.3^{NS}
Use of steroid injection[1]	A	0.9 ± 0.7	0.8 ± 0.6^{NS}	0.7 ± 0.5^{NS}
	B	0.9 ± 0.8	0.8 ± 0.5^{NS}	0.7 ± 0.7^{NS}
Use of physical therapy[1]	A	4.1 ± 2.2	3.1 ± 1.9^{NS}	3.3 ± 2.3^{NS}
	B	3.8 ± 2.2	3.5 ± 1.7^{NS}	3.4 ± 2.0^{NS}
Use on NSAID[1]	A	22 ± 34	17 ± 31^{NS}	14 ± 23^{NS}
	B	16 ± 20	17 ± 22^{NS}	15 ± 27^{NS}

* = $p < 0.05$.
** = $p < 0.01$.
*** = $p < 0.001$.
In each parameter the difference in change between the groups was NS ($p > 0.05$).
[1]In arbitrary units.
A = ultrasound group, B = placebo group.

Table IV. *Outcome of clinical assessment after treatment period*

Mean ± SD

	Ultrasound group		Placebo group	
	Before	After	Before	After
Highest arc of adduction (degrees)	130 ± 35	145 ± 27***	135 ± 31	146 ± 30**
Arc of initial pain during abduction (degrees)	98 ± 32	113 ± 41**	96 ± 28	109 ± 45*
Supraspinatus test pain score (0–3)	1.3 ± 0.5	0.8 ± 0.6***	1.3 ± 0.6	0.8 ± 0.7***

* = $p < 0.05$.
** = $p < 0.01$.
*** = $p < 0.001$.
In each parameter the difference in change between the groups was NS ($p > 0.05$).

ultrasound. Also the number of patients in this study was not sufficient to show a minor difference in outcomes. In addition, it cannot be excluded that different variables, e.g. higher dosage, higher frequency or both might have had an effect on the patients of the present study.

Ultrasound application requires constant presence of the therapist and is thus a manpower consuming modality. In view of cost-effectiveness it therefore seems that adding pulsed ultrasound to the in-patient rehabilitation program of the painful shoulder of the elderly is questionable.

ACKNOWLEDGEMENTS

The author is thankful to Docent Hannu Alaranta and Processor Martti Kormano for their constructive criticism and valuable comments on the manuscript. Thanks are also due to the whole staff for friendly co-operation, especially for doctors Jukka Honkanen and Timo Mononen.

REFERENCES

1. Binder, A., Hodge, G., Greenwood, A. M., Hazleman, B. L. & Page Thomas, D. P.: Is therapeutic ultrasound effective in treating soft tissue lesions: BMJ *290:* 512–514, 1985.
2. Cofield, R. H.: Current concepts review. Rotator cuff disease of the shoulder. J Bone Joint Surg [Am] *67:* 974–979, 1985.
3. Downing, D. S. & Weinstein, A.: Ultrasound therapy of subacromial bursitis. A double-blind study. Phys Ther *66:* 194–199, 1986.
4. Dyson, M., Pond, J. B., Joseph, J. & Warwick, R.: The stimulation of tissue regeneration by means of ultrasound. Clin Sci *35:* 273–285, 1986.
5. Flax, H. J.: Ultrasound treatment of peritendinitis calcarea of the shoulder. Am J Phys Med *43:* 117–124, 1964.
6. Haker, E. & Lundeberg, T.: Pulsed ultrasound treatment in lateral epicondylalgia. Scand J Rehabil Med *23:* 115–118, 1991.
7. Herrera-Lasso, I., Mobarak, L., Fernández-Dominguez, L., Cardiel, M. H. & Alcarcó-Segovia, D.: Comparative effectiveness of packages of treatment including ultrasound or transcutaneous electrical nerve stimulation in painful shoulder syndrome. Physiotherapy *79:* 250–253, 1993.
8. Itoi, E. & Talata, S.: Conservative treatment of rotator cuff tears, Clin Orthop *275:* 165–173, 1992.
9. Jobe, F. W. & Jobe, C. M.: Painful athletic injuries of the shoulder. Clin Orthop *173:* 117–124, 1983.
10. Lehmann, J. F. & de Lateur, B. J.: Diathermy and superficial heat, laser and cold therapy. *In* Handbook of Physical Medicine and Rehabilitation (eds. F. J. Kottke and J. F. Lehmann), pp. 238–367, Saunders, Philadelphia, 1990.
11. Lehmann, J. F., Erickson, D. J., Martin, G. M. & Krusen, F. M.: Comparison of ultrasonic and microwave diathermy in the physical treatment of periarthritis of the shoulder. Arch Phys Med *35:* 627–638, 1958.
12. Lundeberg, T., Abrahamsson, P. & Haker, E.: A comparative study of continuous ultrasound, placebo ultrasound and rest in epicondylalgia. Scand J Rehabil Med *20:* 99–101, 1988.
13. Maxwell, L.: Therapeutic ultrasound: its effects on the cellular and molecular mechanisms of inflammation and repair. Physiotherapy *78:* 421–426, 1992.
14. Mueller, E. R., Mead, S., Schultz, B. F. & Vaden, M. R.: Symposium on an ultrasonics:placebo-controlled study of ultrasound treatment for periarthritis. Am J Phys Med *33:* 31–35, 1954.
15. Munting, E.: Ultrasonic therapy for painful shoulders. Physiotherapy *64:* 180–181, 1978.
16. Neer, C. S. II: Anterior acromioplasty for the chronic impingement syndrome in the shoulder. A preliminary report. J Bone Joint Surg [Am] *54:* 41–50, 1972.
17. Petri, M., Dobrow, R., Neiman, R., Whiting-O'Keefe, Q. & Seaman, W. E.: Randomized, double-blind, placebo-controlled study of the treatment of the painful shoulder. Arthritis Rheum *30:* 1040–1045, 1987.
18. von Winterfeld, H. J.: Möglichkeiten der Gleichschall und Ultraschall-Behandlung der Epikondylitis humeroradialis. Z Ärtzl Fortbild *76:* 594–595, 1982.

Address for offprints:

Matti Nykänen, M.D.
Punkaharju Rehabilitation Hospital
58450 Punkaharju 2
Finland