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

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ABSTRACT. To study the effect of pulsed ultrasound in shoulder pain, 35 patients were treated with pulsed ultrasound and 37 patients with placebo ultrasound in a double-blind design. The therapy was given during inpatient 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/cm². 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 addition 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. Several reports have claimed the value of continuous ultrasound in this condition (1, 7, 5), 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 media-


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pation 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 37–54 years) suffering from shoulder trouble of at least 2 months’ duration and with a painful arc between 40–130° of abduction, or with other painful movement plus pain in supraspinatus and/or patient’s version of shoulder 90° of abduction, 30° of horizontal abduction, and full internal rotation. Patients maintained position against downward resistance (9). Fifty-eight patients were X-rayed or牵引 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 ten- derness on biceps-sellae and pain in resisted elbow flexion), with prominent local tenderness over the acromio-

cavicular joint, with frozen shoulder (adhesive capsulitis) (restricted active and passive external rotation), with apparent capture 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 of postrotatory systems with bone or nerve lesions. Patients with inflammatory rheumatoid disease, and patients with associated compensation claims were also excluded.

All the patients found to fulfill 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 semiradiographic 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 EST300 machine (Electec Inc., Odense, Denmark) using Ultra-Phon ultrasonic coupling medium (Pharmaceutical Innovations Inc., Newark, New Jersey, USA). Before treatment the therapist chose a trans- ducer plug labeled either A or B according to the random group of patients. A technician, also responsible for the regular checking of the ultrasonic output of the machines, had made the other plug non-functioning. Apart from him, no other person knew which plug was manipulated.
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 (22 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).

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

<table>
<thead>
<tr>
<th>Sex/F/M</th>
<th>Ultrasound</th>
<th>Placebo</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Treatment period</td>
<td>6/29</td>
<td>5/32</td>
<td>NS</td>
</tr>
<tr>
<td>At 4 months</td>
<td>6/29</td>
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<td>At 12 months</td>
<td>5/25</td>
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<tr>
<th>Age</th>
<th>Ultrasound</th>
<th>Placebo</th>
<th>P-value</th>
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</thead>
<tbody>
<tr>
<td>Treatment period</td>
<td>66 ± 6</td>
<td>67 ± 9</td>
<td>NS</td>
</tr>
<tr>
<td>At 4 months</td>
<td>67 ± 6</td>
<td>67 ± 9</td>
<td></td>
</tr>
<tr>
<td>At 12 months</td>
<td>66 ± 6</td>
<td>69 ± 7</td>
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</tr>
</tbody>
</table>

| Use of NSAID* | Before treatment | 22 ± 34 | 16 ± 20 | NS |
|               | During treatment | 9 ± 22 | 8 ± 16 | |

| Use of steroidal injection* | Before treatment | 0 ± 0.7 | 0 ± 0.8 | NS |

| Use of physical therapy* | Before treatment | 4 ± 2.2 | 3 ± 2.2 | NS |

| Highest arc of abduction at entry (degrees) | 120 ± 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 ± 1.6 | 8 ± 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 pushed with an on-off-off ratio of 1:4, frequency 1.0 MHz, intensity 1.0–2.0 cm², pulse repetition rate 100 MHz, pulse duration 2 ms and radiating area 5 cm². 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 these questionnaires relevant to evaluating 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 aiming 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 imodium or anti-inflammatory medication at a minimum but drugs for pain disturbing sleep were given and registered (see Table II).

The study was approved by the ethics committee at the Perikhiria Rehabilitation Hospital.

**Table II. Subjective outcome at the discharge**

| Pain index of treatment period (1–5) | Before | After | 2.5 ± 0.7 | 2.5 ± 0.7*** |
| ADL-index of treatment period (2–10) | Before | After | 5.1 ± 1.0 | 4.2 ± 1.3*** |

NS: p > 0.05.
***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 adjunct 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 I. Clinical characteristics and physical findings in the patients
Mean ± SD except sex

<table>
<thead>
<tr>
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<tr>
<td>Sex F/M</td>
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<tr>
<td>Use of NSAID*</td>
<td>Before</td>
<td>22 ± 34</td>
<td>16 ± 20</td>
</tr>
<tr>
<td>Treatment</td>
<td>9 ± 22</td>
<td>8 ± 16</td>
<td></td>
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<tr>
<td>Use of steroid</td>
<td>Before</td>
<td>0 ± 0.7</td>
<td>0 ± 0.8</td>
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<tr>
<td>Injection*</td>
<td></td>
<td></td>
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<tr>
<td>Use of physical</td>
<td>Before</td>
<td>4.1 ± 2.2</td>
<td>3.8 ± 2.2</td>
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<tr>
<td>therapy*</td>
<td></td>
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<tr>
<td>Highest arc of</td>
<td>At treatment</td>
<td>130 ± 35</td>
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<tr>
<td>abduction at entry</td>
<td>Anesthesia</td>
<td>98 ± 32</td>
<td>96 ± 28</td>
</tr>
<tr>
<td>Arc of initial pain</td>
<td>At consent</td>
<td>1.3 ± 0.5</td>
<td>1.3 ± 0.6</td>
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<tr>
<td>during abduction at</td>
<td>Consent</td>
<td>16 ± 3</td>
<td>15 ± 3</td>
</tr>
<tr>
<td>entry (degrees)</td>
<td>Consent</td>
<td>8.1 ± 1.6</td>
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<td>NS: p &lt; 0.05</td>
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Manipulation affected only the function of the applicator head, with no difference in machine appearance. The treatment was pulsed with an on-off ratio of 1:4, frequency 1.0 MHz, intensity 1.0-1.0 cm, pulse repetition 100 mHz, pulse duration 2 ms and radiating area 5 cm². 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 the STAI, and pain before the treatment and at follow-ups (interval 3-14 for ADL and 4-20 for pain). From these questionnaires relevant to evaluate changes during the treatment period separate indexes were formed, with intervals 2-10 for ADL, and 1-5 for pain.

Other changes during the rehabilitation period were similar as possible for both the groups. They consisted of massage of neck and shoulder, 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 immobile or anti-inflammatory medication at a minimum but drugs for pain disturbing sleep were given and registered (see Table II).

The study was approved by the ethic committee at the Perikhir-Jyra Rehabilitation Hospital.

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

<table>
<thead>
<tr>
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<th>Ultrasound</th>
<th>Placebo</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pain index of treatment period (1-5)</td>
<td>3.5 ± 0.7</td>
<td>2.5 ± 0.7***</td>
<td>3.3 ± 0.7</td>
</tr>
<tr>
<td>ADL-index of treatment period (2-10)</td>
<td>5.1 ± 1.0</td>
<td>4.2 ± 1.3***</td>
<td>5.0 ± 1.1</td>
</tr>
</tbody>
</table>

* p < 0.01.
** p < 0.001.
*** p < 0.0001.

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 (3).

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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 group.
Ultrasound group | Placebo group
---|---
Before | After | Before | After
Highest arc of adduction (degrees) 130 ± 35 | 145 ± 25*** | 133 ± 31 | 146 ± 55***
Art of initial pain during abduction (degrees) 98 ± 32 | 113 ± 41** | 96 ± 28 | 109 ± 41*
Suprapatellar soft tissue pain score (0–5) 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 results of 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.

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ISOMETRIC MUSCLE STRENGTH AND MUSCULAR ENDURANCE IN NORMAL PERSONS AGED BETWEEN 17 AND 70 YEARS

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ABSTRACT
Isometric muscle strength was measured in 63 women and 65 men, randomly selected, aged 17–70 years, using Penn & Gleit’s1 hand-held dynamometers. Eight muscle groups as well as the hand grip strength were tested bilaterally. The muscular endurance was measured as time to exhaustion in the abduction of the shoulder and the flexors of the hip. Reference values for muscle strength and muscular endurance are given in the age groups 17–20, 20–29, 30–39, 40–49, 50–59 and 60–70 years of age. The mean strength of females was about 65–70% of that of the men, but when the results were related to weight, the differences almost disappeared. Both men and women seem to have the greatest muscle strength at the age of about 17–18. The strength is rather constant up to the age of about 40 years, after which a discrete decline is seen up to about 60, from where the decline is more obvious. Muscular endurance showed great variability between individuals. However, no decrease in endurance was seen in an age group. In lower reference limits of endurance, with the methods used, for arm abductors are maintained as being 3 minutes and for hip flexors, 90 seconds.

Key words: adults, muscle strength, muscle endurance.

INTRODUCTION
Assessment of neuromuscular functions and evaluation of isometric muscle strength is part of any routine neurological examination. The 0–5 scale designed by the Medical Research Council in Great Britain (MRC-scale) (23) gives only an estimation of muscle strength. This scale’s more accurate in severe weakness, but less so when normal and slightly decreased muscle strength is evaluated. There is a need for measurements of isometric muscle strength, not only for estimations. Measurements instead of estimations are, for example, to be preferred to follow the course of a neuromuscular disease and to evaluate the effect of physical therapy and other types of treatment. Reference values for muscle strength are especially needed to determine whether a pathologic mental muscle weakness is present or not in a person who complains of decreased muscle strength and endurance, but has no obvious weakness on manual muscle testing.

Some studies of isometric muscle strength have been reported in the literature with various kinds of myometers (1, 14, 28). Hand-held myometry, which is used in our study, has been used with different kinds of myometers mostly in children, but also in adults, and the methods have been found to be very reliable (2, 11, 26, 27). In children, the standard error of a single determination made by the same observer was found to be about 9% of the muscle strength. In children tested four times by four different investigators, the coefficients of variation of measurement error varied between 8% and 11% (5). Thus, the reproducibility of this method is acceptable for a method to be used in clinical practice.

The main purpose of this investigation was to obtain reference values for muscle strength and endurance at different ages for both men and women. Reference values for children in different ages have been published earlier (5).

Muscle strength as it is measured or estimated in routine clinical practice depends on nervous, muscular and biomechanical factors. The nervous factors include degree of cooperation, motivation, and ability to activate all motor units, and to do so with optimal frequency. The degree of central activation can only be evaluated in routine clinical practice. With techniques like the interpolating twitch technique (8), the degree of central activation of motor units can be measured in a few muscle groups, but this test is not used in routine practice. Great variation in results of three consecutive tests is.