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# Randomized controlled study of ultrasound therapy in the management of acute lateral ligament sprains of the ankle joint

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**Objective**: To determine the efficacy of a fixed dose of ultrasound energy to treat acute lateral ligament sprains of the ankle joint.
**Study design**: Double-blind randomised controlled trial.
**Setting**: Accident and Emergency department of University Teaching Hospital.
**Subjects**: Patients presenting at Accident and Emergency with ankle injuries.
**Intervention**: Ultrasound or placebo, and Tubigrip.
**Outcome measures**: Pain measured with visual analogue scales, swelling using a tape measure, range of movement using a fluid-filled goniometer, and weight bearing using two scales simultaneously.
**Results**: Patients in both groups improved symptomatically. There were no statistically significant differences between groups in any outcome measure. Within groups, statistically significant differences were detected in pain perceived, and range of movement (dorsiflexion).
**Conclusion**: At the dose and duration used, ultrasound therapy is no better than placebo in the management of lateral ligament injuries.

## Introduction

Ankle injuries are common, with a prevalence of 1 per 10 000 persons per day in the UK, and account for approximately 14% of all sports injuries.[1] Eighty-five per cent of ankle injuries are sprains, and 85% of these are sprains of the lateral ligament, which is the most injured single musculoskeletal structure in the body.[2] A proportion of patients with ankle injuries present at Accident and Emergency departments (A&E), accounting for up to 12% of the department's workload in some centres in the UK.[3] Ankle injuries cause morbidity, leading to days lost from work and leisure. The management of ankle sprains is an important consideration for medical staff and physical therapists, to whom such problems are often referred.

Injured ankles are painful and swollen, either on the injured side only, or, on both sides of the joint. Patients are often unable to bear weight on the injured limb, limiting their mobility. Treatments are aimed at reducing the inflammation and pain and may include analgesics, non-steroidal gels, ankle strapping, heat or cold therapy, interferential or pulsed electromagnetic radiation, short-wave diathermy, and ultrasound.[4]

Dyson suggested that ultrasound therapy improved both the rate and quality of healing[5] by possibly increasing the activity of polymor-

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phonuclear leucocytes, macrophages, fibroblasts and endothelial cells, all of which are involved in the early stages of repair for both soft and hard tissues. The same author also showed that following ultrasound therapy, there was an increase in intracellular calcium which suggested that mechanisms to reduce inflammation had been activated. This may also have beneficial effects on controlling pain.

Makuloluwe and Mouzas[6] reported that ultrasound therapy reduced pain associated with ankle injuries without offering details of their methodology or analysis of the data. Williamson and colleagues[3] carried out a randomized controlled trial comparing two similar groups who were treated with ice, wobble board plus real or sham ultrasound therapy, and reported no differences between the groups. The outcome measures chosen were subjective, limiting the value of the study.

This report presents the results of a randomized double-blind study which examined the role of ultrasound compared with placebo in the management of recent sprains of the ankle joint.

## Method

A randomized controlled study was carried out with patients assigned to either ultrasound therapy or placebo using a randomization code from the local department of Medical Statistics and Computing. All patients with inversion injuries of the ankle presenting consecutively to the A&E department at this centre were examined before having an x-ray of the injured ankle to exclude fractures, and admitted to the study if they met the following criteria.

Patients included had sustained injuries less than 100 hours prior to entry, were able to follow instructions, and were in the age range 14–65 years. Subjects were excluded from the study if they had a previous similar injury within 1 year, had sustained multiple injuries, were diabetic, had extensive varicose veins or had bony injuries rendering them unstable. All patients gave informed prior written consent to the study which was approved by the joint ethics subcommittee for the hospital.

### Treatment

A Med-link Module 72 (Electro Medical Supplies 1996, Greenham, UK) was used for ultrasound treatment (Figure 1). The system had two identical treatment heads, one of which was electronically disabled prior to start. The heads were labelled A and B and used as dictated by the randomization code for the study. The probes were tested to check the energy levels emanating from the transducers during the active phase and to ensure that no ultrasound energy was emitted during the sham phase by a certified and approved engineer from the hospital's Medical Engineering section. Neither the user (CSN) nor the patient was aware of whether the ultrasound machine was in its active or sham phases.

A treatment intensity of 0.25 W/cm$^2$ at a mark space ratio of 1:4 at 3 MHz was used. Treatment time was set at 10 minutes per session which allowed each area to be insonated for 2 minutes. An ultrasonic coupling gel recommended by the manufacturers was used. In practice, this gel was applied liberally to the skin under treatment with the transducer head held at right-angles to it. The head was moved in small overlapping circles to cover the area, taking care to keep the head in contact with skin all the time. Treatment was given on three consecutive days and patients were asked to attend a follow-up clinic 14 days after the last session.

Patients were advised to elevate the affected limb while resting, and weight bear on the injured foot when they were active. All patients were

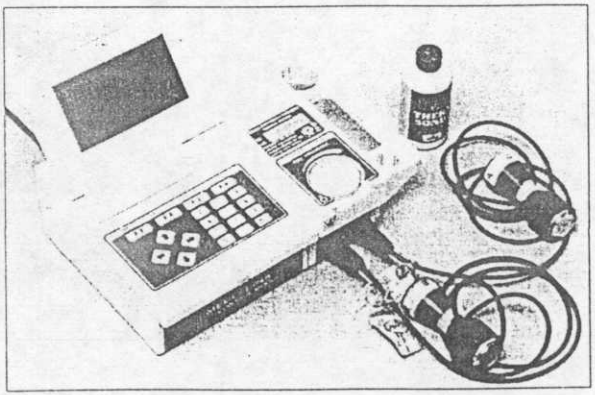

**Figure 1** The ultrasound machine used for treatment together with the real and dummy probes.

given suitably sized Tubigrip® (Seton, UK) to wear after treatment. Paracetamol was prescribed for those in need of analgesics.

### Outcome measures

Since pain, swelling and reduced mobility are major clinical features of ankle sprains, the outcome measures chosen to ascertain the effects of treatment were: a 10-cm linear visual analogue score (VAS) to assess pain, tape measurement of the ankle to determine swelling (Figure 2), range of ankle movement (ROM) to assess mobility, and simultaneous weighing on two identical bathroom scales with one foot on each to assess ability to weight bear. Both dorsiflexion and plantar flexion were recorded using a fluid-filled goniometer to determine ROM. All assessments were done by the same investigator (CSN) at all visits. Before recording VAS scores, patients were asked to walk a fixed 10-metre distance on all occasions.

The repeatability of the methods was determined by measuring the different parameter in a pilot prior to the main study. The pilot showed no significant differences between repeat measures as shown in Table 1.

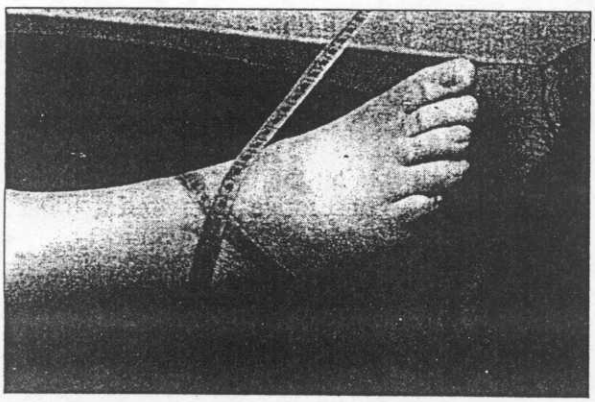

**Figure 2** Measurement of swelling using a tape measure.

## Results

The demographic details of the study group are presented in Table 2.

None of the patients reported tingling or other sensations in the affected areas during treatment. Seven patients (12.1%, 4 placebo group and 3 ultrasound group) failed to complete the study by not attending either the third or the final session. On enquiry, all of these reported that they had recovered fully and did not have the time to attend the study. Therefore, the data analysed includes only those 51 patients (87.9%) who com-

**Table 2** Demographic database

| | Group A (placebo) | Group B (ultrasound) |
|---|---|---|
| No. of patients | 29 | 29 |
| No. who completed the study | 25 | 26 |
| Male:female | 17:8 | 13:13 |
| Age range in years (mean) | 15–65 (50) | 14–63 (50) |
| Mean duration since injury | 24 hours | 24 hours |

There were no significant differences between the groups although there was a chance preponderance of males in the placebo group.

**Table 1** Results of pilot studies of measurements on healthy volunteers

| | Assessment no. 1 ($n$ = 10) | Assessment no. 2 ($n$ = 10) |
|---|---|---|
| Ankle circumference (cm) | | |
| Left ankle | 51.3 ± 1.2 | 51.3 ± 1.2 |
| Right ankle | 51.3 ± 1.2 | 51.3 ± 1.2 |
| % body weight bearing | 48.8 ± 2.3 | 49.0 ± 2.4 |
| Measurement of joint ROM (°) | | |
| Dorsiflexion | 20.1 ± 7.6 | 20.1 ± 7.6 |
| Plantar flexion | 25.4 ± 4.3 | 22.3 ± 5.6 |

Values are means ± 1 SD.
There were no statistically significant differences ($p$ = 0.05) between assessments for any of the measurements.

plied with the study in its entirety.

Patients in both the placebo as well as the ultrasound group improved during the study, showing remarkably less pain on days 2 and 3 (Figure 3). Reduction in swelling was also measured in both groups as shown in Figure 4. There was considerable improvement in dorsiflexion in both groups. Between the groups, there were no statistically significant differences in any outcome measure although within the groups, significant differences were detected as shown in Tables 3–5.

Percentage weight bearing measurements showed no statistical differences within or between groups and these data are presented in Table 5. At follow-up, patients in both groups reported improvement with less painful, less swollen ankles with better range of movements.

## Discussion

The aim of the study was to determine the efficacy of ultrasound to treat lateral ligament sprains from a randomized controlled study. Patients in both groups improved symptomatically during the study and this is resonant with the significant reduction in pain perceived. The other most notable significant change was increased dorsiflexion in both groups. Some significant changes were also measured in swelling in the placebo group, and in plantar flexion in the ultrasound group. Between groups, no statistically significant differences were measured in any of the objective measures. As the groups were comparable in every respect, the results permit the conclusion that at the dose and duration used in this study, ultrasound therapy is no better than placebo for the treatment of lateral ligament sprains.

Pain was significantly reduced in both groups on day 3 and at review ($p = 0.001$, $p < 0.001$

**Table 3** Pain perceived – VAS scores

| | Mean VAS score ± 1 SD (95% CI) | |
|---|---|---|
| Time point of assessment | Group A (placebo) | Group B (ultrasound) |
| Day 1 | 4.8 ± 2.6 (3.3, 6.2) | 4.9 ± 2.4 (2.7, 7.2) |
| Day 2 | 2.9 ± 1.7 (1.9, 3.9) | 3.3 ± 2.2 (2.1, 4.5) |
| Day 3 | 2.2 ± 2.1 (1.1, 3.1) | 1.9 ± 2.5 (0.9, 3.0) |
| Day 14 (review) | 0.7 ± 1.4 (0.1, 1.3) | 0.9 ± 1.4 (0.3, 1.5) |
| Day 2–day 3 difference | $p = 0.001$ | $p < 0.0001$ |
| Day 3–day 14 difference | $p < 0.0001$ | $p = 0.006$ |

The differences between groups were not statistically significant ($p > 0.05$, NS) although the within-group reductions in pain were highly statistically significant in both groups.

**Table 4** Swelling data

| | Mean ankle swelling (cm) ± 1 SD (95% CI) | |
|---|---|---|
| Time point of assessment | Group A (placebo) | Group B (ultrasound) |
| Day 1 | 53.1 ± 2.6 (51.6, 54.6) | 50.8 ± 2.6 (48.3, 53.2) |
| Day 2 | 53.0 ± 2.5 (51.6, 54.4) | 51.7 ± 2.2 (50.4, 52.9) |
| Day 3 | 52.3 ± 2.5 (51.2, 53.5) | 51.4 ± 1.9 (50.6, 52.3) |
| Day 14 | 51.6 ± 2.2 (50.6, 52.6) | 51.3 ± 2.5 (50.3, 52.3) |
| Day 2–day 3 difference | Increase $p = 0.57$ (NS) | Increase $p = 0.22$ (NS) |
| Day 3–day 14 difference | Decrease $p = 0.001$ | Decrease $p = 0.11$ (NS) |

The data are displayed from day of entry to day of review. The differences between groups were not significant. The reduction in swelling in the placebo group between end of treatment and review was significant ($p = 0.001$).

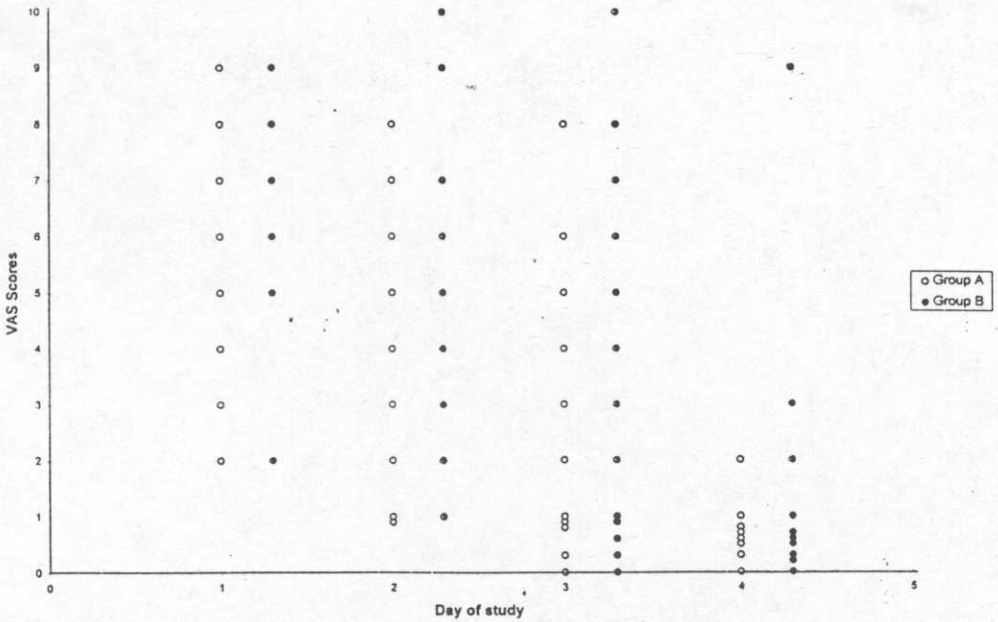


**Figure 3** Pain perceived as measured by VAS scores for both groups. Patients were reviewed on day 4. Since values overlapped, the number of dots may not correspond to the number of patients in the study. There were statistically significant differences within but not between groups as shown in Table 3.

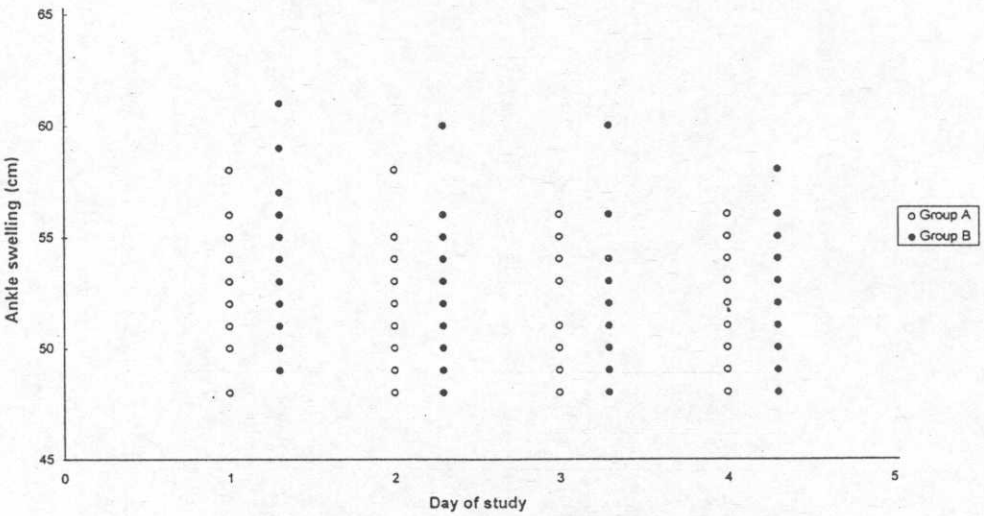


**Figure 4** Swelling measured by tape measure on days of the study including review (day 4) for both groups. Overlapping values may mean that the number of dots do not correspond to the total number in the study. There were no significant differences between groups. Within groups, there was a significant decrease in the placebo group at review only.

**Table 5** Results of range-of-movement and % weight-bearing measurements in the control group and the group receiving ultrasound treatment

| | Group A (placebo) | Group B (ultrasound) |
|---|---|---|
| Mean range of movement (°) – dorsiflexion[a] | | |
| Day 1 | 23.6 ± 11.3 | 14.3 ± 5.9 |
| Day 2 | 30.3 ± 9.3 | 25.9 ± 11.2 |
| Day 3 | 32.4 ± 10.7 | 29.6 ± 10.4 |
| Day 14 (review) | 38.6 ± 9.6 | 36.8 ± 11.1 |
| Mean range of movement (°) – plantar flexion[b] | | |
| Day 1 | 17.4 ± 8.3 | 18.4 ± 5.4 |
| Day 2 | 24.0 ± 10.1 | 22.5 ± 7.0 |
| Day 3 | 27.0 ± 12.5 | 29.4 ± 8.4 |
| Day 14 (review) | 31.7 ± 11.8 | 36.3 ± 11.0 |
| % bodyweight in the affected leg[c] | | |
| Day 1 | 40.4 ± 9.2 | 36.7 ± 11.0 |
| Day 2 | 44.9 ± 7.7 | 41.3 ± 5.9 |
| Day 3 | 43.0 ± 6.0 | 42.8 ± 5.7 |
| Day 14 (review) | 45.1 ± 4.6 | 44.7 ± 5.6 |

Values are means ± 1 SD.

[a] Within groups, the improvement between days 2 and 3 and days 3 and 14 were statistically significant ($p = 0.01$, $p < 0.0001$ for placebo and $p = 0.05$, $p = 0.005$ for the ultrasound group, respectively). Between-group differences were not significant at any time point.

[b] In the ultrasound group, the difference between days 2 and 3 and days 3 and 14 were both significant ($p = 0.008$ and $p = 0.01$, respectively). For the placebo group, the difference between days 2 and 3 was not significant, although the difference between days 3 and 14 was significant ($p = 0.02$). Between groups there was no significant difference at any time point.

[c] Differences between and within groups were not statistically significant at any time point.

placebo and $p < 0.006$ ultrasound). This is consistent with symptomatic improvements. Ankle swelling values were reduced at review (day 14), the reduction in placebo group being statistically significant ($p = 0.001$). The reduction in the ultrasound group was not statistically significant ($p = 0.05$, NS). Analysis of the ROM data showed significant increase in dorsiflexion in both groups ($p = 0.01$, $p < 0.0001$ placebo and $p = 0.05$, $p = 0.005$ ultrasound). Plantar flexion values increased significantly only in the ultrasound group (Table 5). Percentage of bodyweight was not significantly altered during the study in either group.

There were no statistically significant differences between groups, which suggests that the purity of blindness should be questioned. The only permissible control for ultrasound treatment is an identical probe that is disabled, i.e. one from which no energy is emitted when it is switched on, as used in this study. The ultrasound machine was tested by a competent authority and certified to meet the design constraints for this study. In use, neither patients nor operator could discriminate between the two different treatment heads and this satisfies us of the blindness in the study.

In use, the treatment heads were gently rotated over the skin surface which may increase lymph blood flow and drainage. Since this was common to both groups any effects should have been perceived by all. To elucidate whether probe rotation makes a difference, ultrasound treatment would have to be carried out with the ankle immersed in a water bath and this may be incorporated in a further study of the topic.

The study shows the VAS method is simple and reliable, which is in accord with many others. The fluid-filled goniometer technique for dorsiflexion measurements was reliable, and sensitive to changes in both groups. Ankle swelling, reliably measured using a tape, is simple but was found to be relatively insensitive. Surprisingly, there was no correlation between reduction in pain and swelling in our study. Both VAS recording and goniometer measurements of dorsiflexion are simple, easy to carry out in most circum-

stances and should be used as objective measures to assess ankle sprains in future studies.

In conclusion, this study has shown that at the dose and duration used, ultrasound therapy offers no benefits over sham ultrasound (placebo) in the management of lateral ligament sprains of the ankle joint. In the era of evidence-based medicine, it is important that simple treatment methods are studied in this manner, since the results will be beneficial to all.

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