A Clinical Study on the Efficacy and Tolerability of the Ultrasonic Therapy by Using Ultrasonic Machines of the Thailand Institute of Scientific and Technological Research

Rienporn Phoojaroenchanachai, M.Sc., Tassanee Hongsupangpunt, B.Sc., Oaythip Savetprasart, B.Sc., Pakdee Thiptawee, M.Sc.,

Department of Orthopaedic Surgery and Physical Therapy, Faculty of Medicine Siriraj Hospital, Mahidol University, Bangkok 10700, Thailand.

ABSTRACT

Objective: To examine the efficacy and tolerability of the ultrasonic (US) therapy by using the ultrasonic machines produced by the Thailand Institute of Scientific and Technological Research (TISTR).

Methods: Patients diagnosed with chronic musculo-tendinous pain were recruited from the outpatient clinic of Siriraj Hospital. Data from group 1 patients treated with the 4 TISTR-US developed machines were examined and compared with those from group 2 patients treated with a standardized and imported US machine. The self-reported levels of pain which are sought through use of visual analog scales (VAS) with pressure algometry before and after an 8-week course of treatment were obtained. Comparison was made between the groups, by using analysis of co-variance (ANCOVA, pre-and post-therapeutically as covariates).

Results: A total of 49 patients, aged 45.4 ± 15.8 years, participated. There were no significant differences between the 2 groups in the proportions of females, the proportion of muscular lesions, the proportion of elderly, the proportion of cases presenting with severe pain, the mean age, and the mean VAS. However, there were significantly lesser amounts of treatments (8.7 ± 4.0 vs. 11.3 ± 2.5 times, p = 0.002) in group 2 than group 1. After treatment, there were significant decreases of the mean VAS in both groups (4.4 ± 1.5 *vs.* 3.4 ± 1.5 for group 1 and 4.7 ± 1.8 vs. 3.3 ± 1.8 for group 2, respectively) ($p < 0.001$ for both groups). No significant differences were observed between the groups in the post-therapeutic VAS (3.4 ± 1.5 vs. 3.3 ± 1.8, $p = 0.90$). No side effects were reported.

Conclusion: Using of the TISTR-US developed machines in relieving patients' pain is clinically effective and tolerable.

Keywords: Pain; physical therapy, Thailand Institute of Scientific and Technological Research; ultrasound therapy

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It's generally acknowledged that ultrasound (US) therapy is effective for the reduction of pain, inflammation, relaxation of muscles and curing injured tissues i.e. muscle, tendon etcetera.[1-5] Moreover, the US wave is highly safe for patients and physical therapists, and is used widely in many developed countries.[6-8] In Thailand, the Ministry of Public health has announced that the US machine is one of physical therapy tools since 2520 B.E. The report on the basic physical therapy resources in the community hospitals has shown an increase in the requirements for the equipment.[9] However, most of the US machines are imported, hardly ever manufactured locally, and there are only the circuits that can be locally produced. Also the transducer, the heart of the machine, only needs to be imported. As a result, Thailand needs to spend a lot of money on this matter compared to the other countries. For the reasons mentioned above, the researchers from The Thailand Institute of Scientific and Technological Research (TISTR) and from Division of Physical Therapy, Department of Orthopaedic Surgery and Physical Therapy, Faculty of Medicine, Siriraj Hospital need to cooperate to

Correspondence to: Rienporn Phoojaroenchanachai
E-mail: phoorienporn@hotmail.co.th

invent and develop a completed US developed machine.

In general, there are only two major components of the US machine used in the physical therapy. Those are its head and the electronic circuits which function to send the electricity to the head that provide frequency greater than 800 kHz, but not more than 3 MHz which is high enough to get through the tissues.[10] The group of researchers from the TISTR had developed the technology to produce the piezo-electric device, the transducer that could transform the electricity into the sound waves. Therefore the institute can produce all parts of the ultrasonic machine locally with less budget. It has also passed the standard safety of the electricity equipment from the Thai Industrial Standard Institute no. 1325 - 2543 B.E. Additionally, the feature of the machine has been developed to be easy to access and control the same as the imported version. Hence, the single, US therapy model 4702 (UT4702) was standardized for all machines and initially produced in a way that is easily operated by physical therapists. However, the clinical evidence about treating patients with this US machine are insufficient.

Objective

The study was carried out to examine the efficacy and tolerability of the ultrasonic (US) therapy among patients presenting with pain which arose from musculo-tendinopathies by using of the US developed machines manufactured from the Thailand Institute of Scientific and Technological Research (TISTR).

MATERIALS AND METHODS

Study design

A singled blinded, therapeutic cohort was carried out between September 2004 and September 2005. Ambulatory patients, referred from orthopaedic surgeons at the Orthopaedic clinic, Outpatient Department, Siriraj Hospital with a diagnosis of chronic pain which originated from the musculo-tendinous problems were recruited. To receive treatments, patients had to transfer to the Outpatient Unit, Division of Physical Therapy, Department of Orthopaedic Surgery and Physical Therapy. Physical therapists assigned to each working day of the week readily took care of and consecutively followed up each patient by regular appointments until their condition was resolved. Upon arrival, records from the outpatient department were reviewed. Medical history associated with physical therapy was carefully elicited by interview by an assigned therapist. Previous and ongoing treatment received by each patient was noted. Each participant had a thorough physical examination which related to the given diagnosis by an assigned therapist. Contraindication to US therapy was looked for.[11] The diagnosis and the organ of involvement were recorded. The area of involvements and particular site of pain were precisely determined.

The study protocol which was approved by the Ethical Committee of Siriraj Hospital was explained to patients. Written informed consent was obtained. Inclusion criteria looked for patients of both sexes, aged $\geq$ 15 years, who had chronic musculo-tendinous pain attributed to muscle pain, myofascial pain syndrome and tendinitis. Chronic pain was defined by its onset which occurred $\geq$ 12 weeks.[12] Major exclusion criteria were 1) functional illiteracy (mental status insufficient to complete pain questionnaires), 2) treated and untreated central nervous system impairment that could affect the clinical evaluation, 3) pregnancy, 4) fever or recent infection, 5) history of intravenous drug abuse, 6) arterial/venous thrombosis related to the treatment site, 7) immuno-compromised host, 8) oncologic diseases during the past 5 years especially near the US treated site, 9) constitutional symptoms such as an unexplained weight loss, 10) patients with primarily inflammatory diseases or systemic vasculitis i.e. rheumatoid arthritis, systemic lupus erythematosus etc., 11) those who currently received systemic steroids, 12) pain possibly arose from neuropathies i.e. neuritis, disk syndrome, entrapment neuropathies, 13) acute event or any inflammatory response that could be attributed to acute processes i.e. recent trauma, acute infection, acute inflammatory process e.g. finding of warmness, redness, focal edema associated with the pain site, 14) inability to identify tender point, a reliable site for US treatment, 15) severe pain that needed analgesic drugs or alternative medical treatments e.g. herbal compression prior to receiving US therapy on the prearranged day, 16) patients who had an area of treatment which required larger than 2 times the transducer size (>12 cm^2).[11] To eliminate carry over effects from any previous therapy, those who had received non-steroidal anti-inflammatory agents, antidepressant, physiotherapy i.e. exercise therapy or hyper-thermal therapy within a week prior to the enrollment were not included. Patients who had recently received an intra-lesional injection with steroids, acupuncture, or traditional massage over the treated site were also excluded.

Despite various suggestions provided in classical textbooks on physical treatments[13], the consensus on the standardized method concerning the US application is lacking. Evidence based on well designed studies that one method of application outperforms another was not available. Therefore, a standardized US treatment protocol based upon routine physical therapy practices in the hospital was used. Each patient was carefully positioned, and a suitable application area for the piezo-electric head was sought out.[11] Proper dosage of US therapy was calculated according to the area of involvement. The area of treatment was cleaned with 70% alcohol and the US therapy was conducted through plain Siriraj conductor gel. One MHz of a continuous wave (CW) was chosen. An intensity of 0.5 - 1.5 watts/cm^2 with a US head moving technique was applied for 3 - 10 minutes per session of treatment. Fixed intensities of US wave were preferred for use during each visit until the study concluded. However, the intensity could be appropriately adjusted to each patient at the subsequent visits if patients were uncomfortable with the prescribed dosage. The designed regimen was aimed to alleviate the referred clinical conditions. A regular appointment was scheduled at twice a week. If a patient was unable to attend on the prearranged day, the visit could be rescheduled for the next day. A maximum of 14 visits scheduled in an 8-week course of treatment was used for the evaluation. Other hyper-thermal therapy, transcutaneous electrical nerve stimulation (TENS), mechanical traction or manual therapy was not allowed. Patients were prescribed daily home exercises and provided with standardized home exercise sheets. Compliance with home exercises was encouraged. Topical treatment with analgesic cream/balm or hot compression was allowed and patients were persuaded patients to incorporate these in the home program.

Four TISTR-US developed machines, ultrasonic therapy model 4702 (UT4702) (Fig 1), which had been manufactured and periodically validated their efficiency during, pre- and post-therapeutic application by the TISTR were used. All of these TISTR-US developed machines had been proven to possess a similar efficiency both before and after use in this study. The cooperating researchers had tested the

TABLE 1. Comparative study on the basic physical specifications of the machines.

Characteristics	TISTR-US machine	Imported US machine
Maximum intensity of the output in continuous wave (w/cm^2)	1.5 ± 10%	1.5
Frequency of the waves produced by the US head (MHz)	1.0 ± 10%	1.1 ± 5%
Maximum timer (Min.)	30	20
Effective radiation area (ERA) (cm^2)	3.8	4.0
Beam non-uniformity ratio (BNR)	Unknown*	<5
Electrical supplies of the machine	220v, 50 Hz	100-240v, 50/60 Hz

*Beam non-uniformity ratio (BNR) of the TISTR machine was not determined since the measuring machine was not available in our country (BNR unknown).

basic physical specifications of the machine (Table 1). Patients who received treatment using the TISTR-US developed machines were classified under group 1. The US machine which was operated by each physical therapist, was initially allocated by an independent research assistant using randomized numbers. After decoding, each of the US machines was operated by the same therapist until the study was concluded. Therefore, each of the TISTR-US developed machines was used separately by its assigned therapist. A standardized and periodically validated US machine, Therasonic 355 from the electro-medical supplies (Greenham, England) which had comparable basic specifications was used (Table 1). Patients who received treatment from the standardized US machine were then classified under group 2.

Routinely, physical therapists in our department were specifically allocated for each working day of a week. Since, there were four physical therapists participating in this study. On Monday, Wednesday, Thursday, and Friday they were responsible for treating eligible patients (group 1) by using the assigned TISTR-US developed machines. Using a randomized number, two of the participating therapists would alternately receive a standard US machine mentioned above to operate in treating patients referred from the orthopedists on Tuesday (group 2). Therefore, five working days of the week would be filled-up in this study. These patients were treated and followed by the same therapist until the study was concluded. Adequate allocation concealment was further enhanced by blinding to the medical staff and recruited patients which US machine would be use in the treatment.

The area of involvement at the first visit was marked and recorded as cm^2. The Intensity and duration of US treatment per session was recorded as watt/cm^2 and minutes, respectively. Dosage of given US waves, and total wattage, were then calculated from the multiplied factor of given intensities and effective radiation area (ERA). The outcome measures were completed by using the self-reported levels of pain which are sought through use of a non-divided horizontal 10-centrimeter scale, visual analog scales (VAS) with pressure algometry (PA) on the tender point.[14-16] The ends of the VAS were described with "none" and "unbearable", these words were translated in to Thai language. A pressure algometer (Baseline®, Italy) was used for VAS with PA determination. The method is to put the maximum weight which varied from 0.2 to 10 kg which patients could tolerate on the critical area (tender point) then let the patients mark on the VAS. Then, the therapist would apply on the marked scales. The size of the weight which was applied on the tender point must be in the same weight on the subsequent visits. The patient's pain levels before, during and after an 8-week course of treatment were obtained. Pain severity was defined. Patients with pain scores of 7.0 or more were defined as having severe pain. Those with scores from 3.0 to 6.9 were considered to have moderate pain. Those with scores of less than 3.0 were considered to have mild pain. To ensure an adequate sensitivity in detecting the efficacy of US therapy, patients who had had mild pain prior to receiving US treatment at the first visit were not included in the analyses. Treatments could be concluded prior to completion of the 8-week course of treatment if patients described themselves as "cured" and "none" on the VAS scale was marked during their subsequent visit. Side effects which occurred during, pre- and post-treatments were recorded.

Fig 1. Ultrasonic therapy model 4702 of the Thailand Institute of Scientific and Technological Research.

Sample size

To determine the required number of samples in this study, estimates of mean and standard deviation in the US therapy group were collected from a pilot study. Twenty-one patients presenting with similar clinical conditions and treated with a TISTR-US machine plus previous data on standard US therapy in our division between April 1, 2004, and September 31, 2004 were obtained. To determine the number of cases needed to demonstrate a statistical significance between pre- and post-US therapy, a sample size of 11 will have 80% power to detect a difference in means of 1.5 (e.g. a pre-therapeutic VAS, μ_1, of 6.49 and a post-therapeutic VAS, μ_2, of 5.00). Assuming a standard deviation of differences of 1.52, a paired t-test with a 0.05 two-sided significance level was exploited.

To determine the number of cases needed for the equivalence study, a larger sample size was required. When the sample size in each group is 22, a two group 0.05 one-sided t-test will have 80% power to reject the null hypothesis that the test and standard are not equivalent (the difference in the means, pre-and post-therapeutic VAS

TABLE 2. Clinical characteristics of the studied patients.

Patients' characteristics	All lesions (n = 69) n (%)	Group 1 (n = 45) n (%)	Group 2 (n = 24) n (%)	*p*-value[a]
Female	51 (73.9)	32 (71.1)	19 (79.2)	0.47
Elderly	13 (18.8)	10 (22.2)	3 (12.5)	0.26
Muscle pain in origin	36 (52.2)	27 (60.0)	9 (37.5)	0.08
Presenting lesions with severe pain at the first visit	30 (43.5)	16 (35.6)	14 (58.3)	0.07

[a]*p*-value between group 1 and group 2, [*]*p*-value considered significant at < 0.05, Elderly = aged ≥ 60 years, severe pain = pain that has VAS with PA ≥ 7.0

in group 1 - those in group 2, is 1.0 or farther from zero in the same direction) in favor of the alternative hypothesis that the means of the two groups are equivalent, assuming that the expected difference in means is 0 and the common standard deviation is 1.3.

Statistical analyses:

A Kolmogorov-Smirnov test was performed to identify the type of distribution. Results were demonstrated as mean ± standard deviation (SD) or percent (%) where appropriate. Statistical analyses were performed using Statistical Packages for Social Sciences (SPSS 9.0). Intention to treat analyses was performed. Comparison was made between the groups, by using analysis of co-variance (ANCOVA, pre-and post-therapeutically as covariates). Pearson's correlation study between the pre-and post- therapeutic VAS was performed. A p-value of less than 0.05 was considered statistically significant.

RESULTS

A total of 49 patients, 15 males and 34 females, aged 15 to 71 years agreed to join the study. Among females, 32 of them were married and worked at home. The mean age was 45.4 ± 15.8 years (47.5 ± 17.5 years in male and 44.5 ± 15.2 in female), and ranged from 15 to 71 years. The mean onset of pain was 19.0 ± 11.8 weeks (13.9 ± 4.0 weeks in male and 20.7 ± 13.0 weeks in female), and ranged from 12 to 48 weeks. Diagnosis given by the orthopedists on arrival were tendinitis, 33 cases, myofascial pain, 18 cases, muscle pain, 7 cases, spondylosis, 3 cases and osteoarthritis, 8 cases. The area of involvements included shoulder, 35 cases, hand, 9 cases, knee, 6 cases, leg and foot, 6 cases, back, 7 cases, elbow, 4 cases and neck, 2 cases. Among 35 patients presenting shoulder pain, one case was calcified tendinitis with a mild degree of restricted range of motion, 12 cases were supraspinatus tendinitis and 4 cases were biceps tendinitis. The rest were non-specified muscle pain. Thirteen patients had ≥ 2 lesions (7 patients in group 1 and 6 patients in group 2). Overall, 69 lesions, 36 muscles and 33 tendons in origins, were enrolled (Table 2). Distribution of each data was normal.

There were no significant differences in the mean age and onset of pain between group 1 and group 2 (44.3 ± 16.7 years vs. 49.8 ± 9.8 years, $p = 0.15$ and 18.8 ± 10.8 weeks *vs.* 19.5 ± 13.6 weeks, $p = 0.81$, respectively). There were no significant differences in the proportion of females, the proportion of elderly, the proportion of muscular lesion, the onset of pain and the degree of pain prior to treatment rated by VAS between group 1 and group 2 (Tables 2 and 3).

After treatment at the first visit, there were significant decreases of VAS from pre- to post- therapeutic levels (6.1 ± 1.7 to 4.7 ± 2.0 in group 1 and 6.8 ± 2.6 to 4.5 ± 2.5 in group 2, p <0.01 for both groups). There were no significant differences in the pain evaluated by VAS with PA post-therapeutically levels between group 1 and group 2 (4.7 ± 2.0 vs. 4.5 ± 2.5, $p = 0.76$). Characteristics of the US therapy given were also not different in the total wattage of US therapy and area of involvement between the group 1 and group 2 (Table 3). However, the intensity of US waves and the duration of treatment per session used in group 1 were higher than those in group 2 (Table 3). Moreover, pain improvement evaluated by the difference of pre- and post-therapeutic VAS with PA in those of group 2 were better than those of group 1 (2.3 ± 1.6 vs. 1.4 ± 1.4, $p = 0.02$) (Table 4).

After treatment at visit 2, pain evaluated either by pre- or post-therapeutic VAS with PA progressively declined (Fig 2). However, there were no significant differences in the improvement of pain evaluated by the differences between pre- and post-therapeutic VAS with PA between group 1 and 2 (Table 4). There were also no significant differences in the increment of changes in the VAS before rechecking at each following visit except visit 8 and 11 (Table 5).

After an 8-week course of treatment, there were significant decreases in the degree of pain rated by VAS

TABLE 3. Characteristics of pain and US therapy at the first visit (mean ± SD).

Characteristics of US therapy	All lesions (n = 69)	Range	Group 1 (n = 45)	Group 2 (n = 24)	*p*-value[a]
Onset of pain (weeks)	19.0 ± 11.8	12 - 48	18.8 ± 10.8	19.5 ± 13.6	0.81
Pre-therapeutic VAS with PA	6.4 ± 2.0	3 - 10	6.1 ± 1.7	6.8 ± 2.6	0.17
Post-therapeutic VAS with PA	4.7 ± 2.1	0 - 10	4.7 ± 2.0	4.5 ± 2.5	0.76
Intensity (watt/cm^2)	1.1 ± 0.3	0.5 - 1.5	1.1 ± 0.3	0.9 ± 0.3	0.01[*]
Area of involvement (cm^2)	7.9 ± 2.0	6 - 12	8.2 ± 2.2	7.4 ± 1.4	0.11
Duration of treatment (minutes)	4.9 ± 0.3	3 - 6	5.0 ± 0.2	4.8 ± 0.5	0.01[*]
Total wattage (watts)	4.1 ± 1.2	1.9 - 6	4.2 ± 1.1	3.7 ± 1.3	0.07

[a]*p*-value between group 1 and group 2, [*]*p*-value considered significant at < 0.05, area of involvement = total area covered by the technique of moving technique the piezo-electric head, total wattage = intensities x effective radiation area of the piezoelectric head

TABLE 4. Average decrement of the pre-and post-therapeutic VAS with PA during each visit (mean ± SD).

Visit number	All		Group 1		Group 2		*p*-value[a]
	N	Score	N	Score	N	Score	
1	69	1.7 ± 1.5	45	1.4 ± 1.4	24	2.3 ± 1.6	0.02*
2	69	1.1 ± 1.1	45	0.9 ± 1.0	24	1.4 ± 1.1	0.06
3	68	1.1 ± 1.0	45	1.0 ± 1.1	23	1.2 ± 0.8	0.54
4	65	0.9 ± 1.2	45	0.9 ± 1.0	20	1.0 ± 1.6	0.92
5	64	1.1 ± 1.2	45	0.9 ± 1.1	19	1.5 ± 1.2	0.08
6	63	1.1 ± 1.0	45	1.2 ± 1.1	18	0.9 ± 0.8	0.26
7	61	1.0 ± 1.1	45	1.0 ± 1.1	16	0.9 ± 0.8	0.26
8	60	1.0 ± 1.1	45	1.1 ± 1.0	15	0.7 ± 1.2	0.60
9	46	0.9 ± 1.3	35	0.9 ± 1.2	11	0.9 ± 1.4	0.20
10	38	1.2 ± 1.3	29	1.2 ± 1.3	9	1.1 ± 1.3	0.97
11	33	1.1 ± 0.9	25	1.2 ± 0.9	8	0.8 ± 1.0	0.80
12	29	1.0 ± 0.9	23	1.1 ± 0.9	6	0.7 ± 0.5	0.31
13	27	0.7 ± 0.8	21	0.8 ± 0.9	6	0.4 ± 0.5	0.32
14	23	1.0 ± 0.9	17	1.0 ± 1.0	6	0.8 ± 0.3	0.62
All	69	1.2 ± 0.8	45	1.1 ± 0.9	24	1.4 ± 0.8	0.15

[a]*p*-value between group 1 and group 2, [*]*p*-value is considered significant at < 0.05, N = number of patients remaining in the trial at each visit as treatments could be concluded prior to completion of the 8-week course of treatment if patient described themselves as "cured" and "none" on the VAS scale during their subsequent visit.

with PA in both groups (4.4 ± 1.5 vs. 3.4 ± 1.5 for group 1 and 4.7 ± 1.8 vs. 3.3 ± 1.8 for group 2, respectively) ($p < 0.001$ for both groups) (Table 6). There were no significant differences between group 1 and 2 in the degree of pain rated by VAS with PA post-therapeutically (3.4 ± 1.5 vs. 3.3 ± 1.8, $p = 0.90$) and the mean differences of pain decrement rated by VAS with PA between pre- and post-therapy (1.1 ± 0.9 vs. 1.4 ± 0.8, p = 0.15). There were no significant differences in the mean increments calculated from post- to pre-therapeutic VAS with PA. The intensities prescribed for patients in group 1 were higher than those in group 2. However, the total wattage using in each treatment session was also not significantly different between both groups (Table 6). The numbers of treatment sessions in group 1 were also higher than those in group 2 (11.3 ± 2.5 *vs.* 8.7 ± 4.0, $p = 0.002$) (Table 6). From the beginning until the end of the study, no adverse event was reported.

At visit 1 and for all visits, Pearson's correlation studies between the degree of pre-and post- therapeutic VAS with PA were performed (Fig 3 and 4). There were signficant correlation at r-value=0.75 after visit 1 and 0.86 after all visits, p <0.01 for both categories.

DISCUSSION

In this study, US wave is proposed as a pain reducing agent in the management of soft tissue disorders. At the end of the first visit, pain was immediately relieved after its treatment. The pain reduction reported following treatments with both US machines might result from an increase in nerve conduction velocity.[17-18] Thermal effects, rather than non-thermal effects, are known to elevate the pain threshold with only a small dosage such as 0.8 MHz US at 1.5 watts/cm^2/continuous wave.[19] A one-MHz of US wave with an average velocity in the studied soft tissues of 1,500 m/s at 1.1 ± 0.3 watts/cm^2/continuous wave (ranged 0.5-1.5 watts/cm^2) should have these analgesic effects. However, the alleviation of pain in patients who received US therapy using the standard US machine was better than those who received US therapy using the TISTR-US developed machines. A number of possibilities might be considered. A growing trend to have a higher number of cases presenting with severe pains was observed among patients who received US therapy using the standard US machine. Therefore, the likelihood of a higher degree of pain reduction increased compared to those who received US therapy using the TISTR-US developed machines. Moreover, the differences in US dosage used in treating patients with chronic pain may be a reason,[20] because, the TISTR-US developed machine has a smaller effective radiation area (ERA) than the standard US machine (3.8 cm^2 vs. 4.0 cm^2). Total wattage calculated from a multiplied factor of intensity and ERA of the piezo-electric head was analysed. Roughly, the higher intensities and the longer duration of treatment per session were given to patients in group 1 as compared to those in group 2. Patients who received US therapy using the standard US machine would probably get a lower dosage of US wave compared to those who received US wave from the TISTR-US developed machines. However, the calculated total wattages used in both groups of US therapy were not significantly different. These could be explained

TABLE 5. Average increment of the post-and pre-therapeutic VAS with PA during each visit (mean ± SD).

Visit number	All		Group 1		Group 2		*p*-value[a]
	N	Score	N	Score	N	Score	
2	69	0.8 ± 1.8	45	0.6 ± 1.6	24	1.1 ± 2.0	0.19
3	68	0.7 ± 1.3	45	0.7 ± 1.3	23	0.6 ± 1.1	0.75
4	65	0.8 ± 1.5	45	0.8 ± 1.5	20	0.8 ± 1.7	1.0
5	64	0.6 ± 1.3	45	0.6 ± 1.2	19	0.7 ± 1.5	0.78
6	63	1.0 ± 1.3	45	0.9 ± 1.2	18	1.4 ± 1.4	0.17
7	61	1.0 ± 1.2	45	1.0 ± 1.3	16	1.0 ± 1.1	1.0
8	60	0.8 ± 1.2	45	1.0 ± 1.2	15	0.3 ± 0.8	0.04*
9	46	0.5 ± 1.3	35	0.7 ± 1.1	11	0.1 ± 1.8	0.19
10	38	0.9 ± 1.6	29	1.0 ± 1.6	9	0.8 ± 1.6	0.75
11	33	0.7 ± 1.0	25	0.9 ± 1.0	8	0.1 ± 0.6	0.04*
12	29	0.7 ± 1.2	23	0.9 ± 1.1	6	0.0 ± 1.1	0.09
13	27	0.8 ± 1.2	21	0.8 ± 1.3	6	0.7 ± 0.8	0.86
14	23	0.4 ± 1.0	17	0.7 ± 1.1	6	-0.2 ± 0.4	0.07
All	69	0.8 ± 0.8	45	0.8 ± 0.9	24	0.9 ± 0.8	0.65

[a]*p*-value between group 1 and group 2
[*]*p*-value considered significant at < 0.05.
N = number of patients remaining in the trial at each visit as treatments could be concluded prior to completion of the 8-week course of treatment if patient described themselves as "cured" and "none" on the VAS scale during their subsequent visit.

TABLE 6. Characteristics of pain and US therapy: a summary from the first visit to the last visit (mean ± SD).

Characteristics	All lesions	Group 1	Group 2	*p*-value[a]
Averages of the pre-therapeutic VAS with PA	4.5 ± 1.6	4.4 ± 1.5	4.7 ± 1.8	0.54
Averages of the post-therapeutic VAS with PA	3.3 ± 1.6	3.4 ± 1.5	3.3 ± 1.8	0.90
Averages of decrement from pre- to post-therapeutic VAS with PA during each visit	1.2 ± 0.8	1.1 ± 0.9	1.4 ± 0.8	0.15
Averages of increment from post- to pre-therapeutic VAS with PA during each visit	0.8 ± 0.8	0.8 ± 0.9	0.9 ± 0.8	0.66
Intensity (watt/cm^2)	1.1 ± 0.3	1.1 ± 0.3	1.0 ± 0.2	0.03*
Averages of the total wattage used during each visit	4.2 ± 0.9	4.2 ± 1.0	3.9 ± 0.9	0.19
Number of treatment sessions	10.4 ± 3.3	11.3 ± 2.5	8.7 ± 4.0	0.002*

[a]*p*-value between group 1 and group 2, *p-value considered significant at < 0.05.

by the half value depth of penetration for the US wave which depended largely on the radius of the transducer head.[21] The effective radiation area of the TISTR-US developed machines was smaller than that of the standard US machine (3.8 cm^2 *vs.* 4.0 cm^2). Therefore, the energy given to produce similar thermal effects at the average depth and type of soft tissues among patients treated with the TISTR-US developed machines should be larger than those treated with the standard US machine. Also, the time applied to produce the above effects should be longer.

Despite the longer time used in patients treated with the TISTR-US developed machines at visit 1, the better improvement of pain evaluated by VAS with PA among patients treated with the standard US machine were still observed. Discrepancies between the dosages displayed on the machines and those given to the patients were then analysed. Such discrepancies could affect the studied outcomes and have been suggested as a possible reason why US treatments are believed to be ineffective in previous reports.[22] The TISTR had periodically measured all US machines output and reported that it rarely varied more than ±10% (personal communication). Therefore, these might not be a case. Likewise, the piezoelectric element that generates the US wave cannot vibrate uniformly; the ERA of the applicator is smaller than its geometric area.[11, 21] As a consequence, calculations of dosage based on geometric area may, in some cases, slightly understate the actual wattage per unit area applied relative to those using ERA. As the applicator needs to be kept moving to avoid hot spots, the area affected by US energy cannot be precisely determined and the dosage at a particular depth of tissue cannot be known. This beam non-uniformity ratio (BNR) should be as low as possible, between 2:1 and 6:1. The lower the BNR, the more even is the distribution of energy from the transducer, and the less risk there is of damage to tissues from areas of concentrated US energy.[21] The unknown specification of the BNR of the TISTR-US developed machines might contribute to the problem. Therefore, a study of the BNR of the TISTR-US developed machine is needed.

Although, the use of US continuous wave in chronic pain management programs is common, evidence supporting the use of US wave in these conditions is largely incomplete.[12, 23-27] It is rarely the sole modality of treatment. A 1995 American Physical Therapy Association position statement asserts that "Without documentation which justifies the necessity of the exclusive use of physical agents/modalities, the use of physical agents/modalities, in the absence of other skilled therapeutic or educational intervention, should not be considered physical therapy".[28] Therefore, treating patients with a combination of recommended modalities appropriate to each diagnosis i.e. therapeutic exercises, superficial heat with educational interventions to relieve and prevent further organ damage were unavoidable. Therefore, evaluation of the therapeutic response to US therapy might solely depend on immediate information after each treatment session. By contrast to the first visit, US therapy using the TISTR-US developed machines has a comparable efficacy on pain reduction as compared to that using the standard US machine during the following visits. Moreover, the characteristics of US therapy were similar to those mentioned above. It could be postulated that similar efficacy could be achieved if we treated patients presenting with a lower degree of pain by

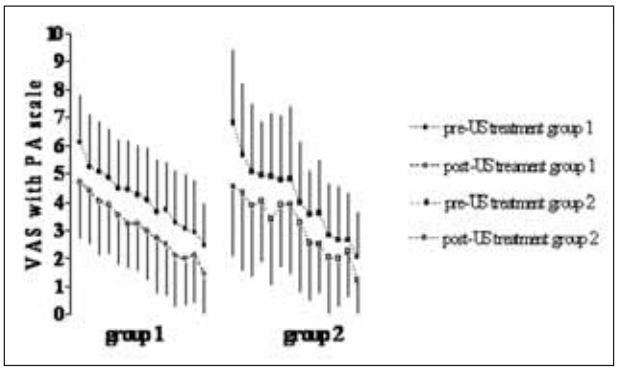

Fig 2. The observation on the improvement of pre-therapeutic VAS with PA after each treatment session with group 1 and group 2 (mean ± standard deviation).

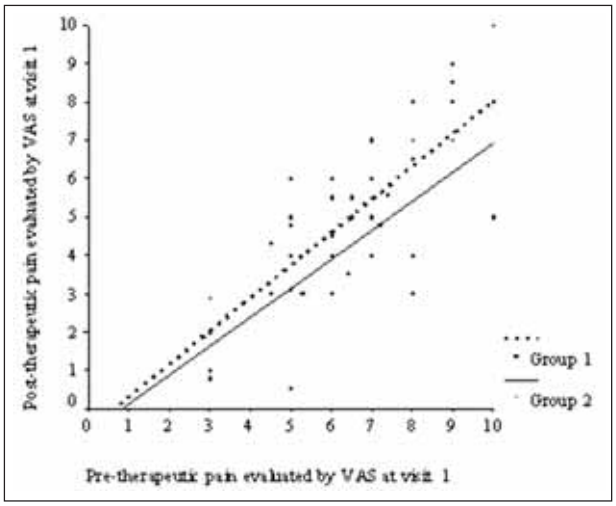

Fig 3. Correlation study between pre-and post-therapeutic VAS with PA during visit 1.

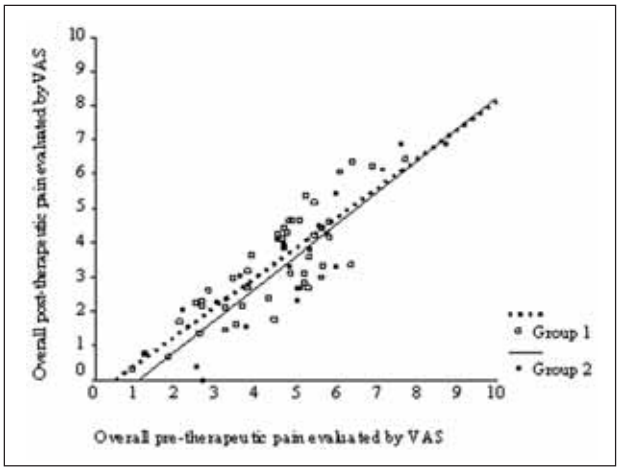

Fig 4. Correlation study between overall pre-and post-therapeutic VAS with PA.

using both groups of US machines (VAS of 6.1 ± 1.7 at the first visit vs. 5.3 ± 1.9 at the second visit, $p = 0.04$) (data not shown). These were supported by the correlation study between the degree of pre- and post-therapeutic VAS with PA at the first visit. Considering patients who received treatment using the TISTR-US developed machines, they could achieve a comparable post-therapeutic pain reduction to those who received treatment with the standard US machine when a patient with a lower level of pre-therapeutic pain was recruited. At a higher VAS with PA pre-therapeutically, patients in group 1 could not reach the same VAS with PA post-therapeutically as those in group 2 (Fig 3). Patients with overall VAS with PA evaluated pre- and post-therapeutically were subject to other co-existing interventions. Presenting with a similar degree of pre-therapeutic pain (scores < 7), patients who received treatment using the TISTR-US developed machines might not be able to reach a comparable level of post-therapeutic pain reduction compared to those who received treatment using the standard US machine (Fig 4).

After an 8-week course of treatment with the US equivalent machines from the TISTR the effectiveness in relieving patients' pain at a physical therapy clinic is effective and tolerable. According to the contradictory data that was observed from the first and the subsequent visits, we cannot exclude the possibility of the better quality of the standard US machine when compared to that of the TISTR-US developed machines i.e. the better response at the first visit, the achievement of pain reduction at a lower degree of pain evaluated by VAS with PA and the lower numbers of treatment sessions required (Table 5). However, patients in this study had a wide range of diagnoses. Furthermore, the many other interventions applied to the subjects in this study, including hot packs, educational program and various exercises, could be expected to obscure an effect of US therapy over a period. To definitely conclude this study, a well planned methodology, a study on the BNR, a limited type of soft tissue disorders and a larger sample size for an evenly distribution of the severity of pain are needed.

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