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The effectiveness of therapeutic ultrasound for musculoskeletal conditions of the lower limb: A literature review

Abstract

Background: Ultrasound is suggested as one of the treatment options available for soft tissue musculoskeletal conditions of the lower limb and to this end, the objective was to review the literature and evaluate the effectiveness of therapeutic ultrasound for musculoskeletal conditions of the lower limb.

Methods: A search of the literature published between 1975 and February 2009 was carried out. All studies that fulfilled the inclusion criteria were quality assessed and scored using the Critical appraisal skills programme (CASP) appraisal tool [1] for randomised controlled trials.

Results: Ten studies out of a possible fifteen were included in the review. Only one trial was considered to be high quality (score 16+), three medium quality trials (score 11-15) were identified and six trials were considered to be low or poor quality (score \leq 10). None of the six placebo-controlled trials found any statistically significant differences between true and sham ultrasound therapy.

Conclusion: This literature review found that there is currently no high quality evidence available to suggest that therapeutic ultrasound is effective for musculoskeletal conditions of the lower limb.

Keywords: Therapeutic ultrasound, musculoskeletal injuries.

Introduction

Ultrasound has been used as a therapeutic modality for over sixty years, mainly by physiotherapists to treat soft tissue injuries and is one of the most commonly used electrotherapy devices available within physiotherapy departments [2,3,4]. A comprehensive search of the literature has been unable to determine the extent of use of therapeutic ultrasound in podiatry clinics across the United Kingdom. Given that therapeutic ultrasound is suggested as one of the treatment options available for a variety of foot problems: to reduce oedema, relieve pain and mobilise collagen [5]; for the management of musculoskeletal conditions, acute sports injuries, soft tissue injuries and some inflammatory conditions [6]; and muscle spasm, contusion and localized inflammation and pain [7] it was therefore considered appropriate to conduct a literature

review with the intention of identifying how ultrasound works and what role it plays in current podiatric practice.

It is thought that despite evidence from laboratory studies *in vitro* and on animal models there is still minimal evidence to support a clinical beneficial effect; Robertson and Baker [8], Gam and Johannsen [9] and Van der Windt *et al.* [10] were unable to find sufficient evidence from well-designed controlled studies to recommend ultrasound as an effective therapeutic intervention. Watson [11] would argue that ultrasound is effective when applied appropriately and states that to achieve maximum therapeutic benefit there is a definite 'electrotherapeutic window', commonly missed due to incorrect application and dosage selection. He suggests that the correct frequency, intensity and pulse mode need to be selected for the specific structures, the tissue status and the intended therapeutic objective.

Methods

The following databases were electronically searched to identify all articles relevant to the review topic:

- ▶ MEDLINE (1966 to present)
- ▶ AMED
- ▶ CINAHL (1982 to present)
- ▶ SWETSWISE
- ▶ BMJ (British Medical Journal)
- ▶ EBSCO SPORTDiscus
- ▶ SCIENCE DIRECT
- ▶ EMBASE (1983 to present)
- ▶ The Cochrane Central Register of Controlled trials (CENTRAL)
- ▶ PEDro (Physiotherapy Evidence Database. Available from:

www.pedro.fhs.usyd.edu.au/index.html

The following journals were hand searched for relevant articles:

- ▶ Archives of Physical Medicine and Rehabilitation
- ▶ Foot and Ankle International
- ▶ Journal of Sport Rehabilitation
- ▶ Medicine and Science in Sports and Exercise
- ▶ Physiotherapy
- ▶ Podiatry Now
- ▶ The American Journal of Physical Medicine and Rehabilitation

- ▶ The British Journal of Podiatric Medicine
- ▶ The Foot
- ▶ The Journal of American Podiatric Medicine

Reference lists from all relevant articles and textbooks were searched for additional references and literature.

Search Terms

- ▶ Therapeutic Ultrasound
- ▶ Ultrasonic Therapy
- ▶ (Ultraso\$)
- ▶ Podiatry
- ▶ Foot
- ▶ Ankle
- ▶ Knee
- ▶ Patellar
- ▶ Ligament
- ▶ Plantar fasciitis
- ▶ Heel pain
- ▶ Achilles
- ▶ (Tendon\$ or tendin\$)

Inclusion criteria

Concurrent, randomised or quasi-randomised controlled trials published only in the English language were considered for qualitative analysis. Studies were confined to musculoskeletal injuries or conditions occurring in the lower limb and at least one treatment group must have received active ultrasound. Comparisons with sham or placebo ultrasound, other treatment modalities and comparisons between different ultrasound applications were included. Outcome measures considered were: Pain (visual analogue scale, ordinal scale, pain questionnaire), swelling, range of motion, general health, re-injury, adverse effects, objective assessment of function.

Exclusion criteria

Studies on wounds, pressure sores and leg ulcers were excluded from the review as were studies on asymptomatic individuals with no evidence of soft tissue injury of the lower limb.

Trials in which all participants received identical ultrasound treatment were excluded and due to the restrictions of the literature review, articles not in the English language and unpublished studies were excluded.

Data collection and analysis

The identified studies (table 1) [12-21], were reviewed and assessed by the author for trial quality using the Critical Appraisal Skills Programme (CASP) appraisal tool for randomised controlled trials [1]. For each component of the appraisal tool a score was allocated based on the information given and extracted from each individual study (table 2). Scores allocated were 2 (adequate/yes), 1 (can't tell/ inadequate) or 0 (No/unknown) with a maximum score of 20 available for each study. Trials scoring 16+ points were considered to be the highest quality, 11-15 points medium quality, 6-10 points low quality and 1-5 points poor quality. The CONSORT statement [22] was used as an additional guideline to assess the quality of the identified studies.

Results

The initial search yielded a total of fifteen studies five of which were excluded from the review (table 3) [23-27]. The literature search found that therapeutic ultrasound has been used for a number of lower-limb musculoskeletal conditions commonly encountered in podiatric practice such as ankle ligament injuries [13,16,17,18,20,21]; knee pain [12] and [19]; heel pain [15]; and Achilles tendon pain [14].

• *Effectiveness of therapeutic ultrasound*

Heel Pain: There is no evidence available to support the use of therapeutic ultrasound for the treatment of heel pain. Only one study was identified that attempted to evaluate the effectiveness of therapeutic ultrasound against placebo treatment [15]. Despite finding slightly greater improvements in the treatment group Crawford and Snaith failed to identify a statistically significant difference.

Achilles tendon pain: There is no evidence available to suggest that therapeutic ultrasound is effective for the treatment of Achilles tendon pain. Only one study was identified [14], which although a medium quality trial (12 points) was only a pilot study and small sample size (n=16). The study was a comparison of therapeutic ultrasound and eccentric calf muscle loading exercises, which lacked a control group and therefore the exact effect of ultrasound cannot be determined. It is interesting to note however, that the

results showed improvements in pain particularly in the ultrasound group during the first six weeks of treatment and also the patients own assessment of functional ability (FILLA) had increased in the ultrasound group over the twelve-week study period whereas it had decreased in the exercise group. The authors reported that although the results were not statistically significant, ultrasound was as effective as the eccentric loading exercises; eccentric calf muscle loading exercises are considered to be the gold standard treatment for Achilles tendon injuries [28] and based upon these findings the authors propose to carry out further research.

Ankle ligament injuries: There is only one trial of poor quality evidence to suggest that therapeutic ultrasound is effective for the treatment of acute lateral ligament ankle injuries [16]. They concluded that the use of ice packs and ultrasound therapy improved pain, swelling and function when compared to a treatment regime of immobilization and elastoplast. The lack of details of randomisation method, blinding, treatment protocol, control group and objective outcome measures were a few of the flaws apparent in this study and therefore little weight should be given to the results of this trial [29].

Only two of the six studies identified for ankle injuries were of medium methodological quality [17,18]. Both studies assessed the effectiveness of ultrasound with respect to similar outcome measures of pain, swelling, range of motion and ability to weight bear. Nyanzi *et al.* [17] found that although both ultrasound and placebo treatment groups improved symptomatically, only significant improvements were found for swelling within the placebo group and plantarflexion within the ultrasound group. No significant differences were found between the two groups.

Oakland [18] conducted a good-sized multi-centred trial that compared the use of therapeutic ultrasound with the topical NSAID felbinac. The effects of ultrasound treatment cannot however be determined by this study as there was no strict control group. Subjects received either ultrasound therapy with felbinac gel, sham ultrasound with felbinac gel or ultrasound with placebo gel. The authors acknowledged that a control group would have improved the quality and validity of the trial however it was deemed unethical and would have affected recruitment numbers. Although no statistical differences were found between the treatment groups, the authors concluded that the combination of ultrasound therapy and the topical NSAID might have provided additional benefit. In contrast to this, one recent study suggests that these two treatments have opposing modes of action [30], one pro-inflammatory and one anti-inflammatory and when used as a combination the effects of one would cancel out the effects of the other.

One low quality trial [16] with sample size (n=34) also found no statistically significant differences between three treatment groups of therapeutic ultrasound, placebo

ultrasound and no ultrasound. This trial suggests that the significant improvements found within the three treatment groups were the result of the additional therapies of ice packs, tubigrip and exercises. Williamson *et al.* [20] also found no statistical significance between groups treated with active ultrasound or sham ultrasound in conjunction with a physiotherapy programme. This was another trial, which despite a good sample size lacked detailed information, specifically randomisation methods, blinding procedure and ultrasound treatment provided. No information was given with respects to ultrasound dosage parameters therefore it is not possible to ascertain if appropriate dosages were applied and if this may have affected the results in any way.

Two trials identified found significant differences between therapy groups [13] and [16] however both trials scored low marks for quality assessment and therefore the validity of the evidence must be questioned. Bradnock *et al.* [13] compared traditional 'high frequency' ultrasound (3 MHz) with 'low frequency' (45 kHz) longwave ultrasound therapy and also included a third treatment group that received sham longwave ultrasound. The study compared the effects of each of the treatments immediately after one treatment using the Gaitway system to assess the spatio-temporal parameters of gait: length of stride, symmetry of swing phase duration, cadence and walking velocity. There was no long-term follow up. The authors reported that statistically significant improvements were recorded for the longwave ultrasound group compared to the 3 MHz 'high frequency' and sham ultrasound groups and also acknowledged that due to the immediacy of the treatment and assessment, the effects were likely to be purely analgesic and any longer term effects could not be ascertained because of the lack of follow up.

Although no dose response relationship has been identified for therapeutic ultrasound it could also be argued that the dosage used in this study was not appropriate and therefore any significant improvement was unlikely to be identified. This was unlike the previous studies that measured outcome for pain, swelling and range of movement and with respect to implications for clinical practice the results are questionable.

Knee injuries: There is only poor quality evidence available to suggest that therapeutic ultrasound is effective for the treatment of knee injuries, for example Antich *et al.* [12] concluded that a treatment regime of ultrasound and ice was more effective than ice alone, phonophoresis or iontophoresis for the treatment of pain associated with knee extensor mechanism disorders. Several flaws were identified within this study; the most obvious concern was that several types of knee extensor mechanism disorder were included for participation, the frequencies of which were not identified. The results were based on the patients' subjective percentage improvement and increase in hamstring and

quadriceps strength. The trial also lacked details of randomisation methods, blinding and dosage parameters of ultrasound treatment, further questioning the validity of the trial.

The highest quality trial identified [19] (17 points) aimed to investigate the efficacy of low intensity pulsed ultrasound (LIPUS) for the treatment of chronic patellar tendinopathy. They applied ultrasound at a much lower intensity than has traditionally been used (100 mW/cm² spaced-averaged, temporal-averaged intensity) which they report has been shown in recent studies to improve fracture healing. In this instance they found LIPUS to be of no additional benefit for the treatment of pain associated with patellar tendinopathy. The authors discuss at length the possible reasons for the absence of any beneficial effects of LIPUS ruling out the possibility that the sample size (n=37) was too small to detect any statistically significant effects. They also consider that LIPUS has been shown to be effective for the treatment of acute soft tissue injuries and therefore the absence of effect may be due to the chronic, recalcitrant pathophysiology of patellar tendinopathy.

Discussion

The results of this literature review indicate that there is little evidence to suggest therapeutic ultrasound is effective for the treatment of lower limb musculoskeletal conditions. Six placebo-controlled trials failed to detect any statistically significant differences between true and sham ultrasound therapy. Only one trial of low quality evidence [16] was identified to support the use of therapeutic ultrasound the findings of which must be questioned. The overall findings of the review are in agreement with other authors who have been unable to find any firm evidence that ultrasound is effective for musculoskeletal disorders. Gam and Johannsen [9] and Van der Windt [10] considered a variety of musculoskeletal disorders of the body (lateral epicondylitis, shoulder pain, rheumatic disorders and others) whereas this review was specific to the lower limb and incorporated the most current research available. It was evident from this review that more attention has been given to the production of higher quality studies in more recent years, which could be attributed to the emphasis placed by the CONSORT statement [24]. Higher quality research although limited has not produced any further evidence to support the use of therapeutic ultrasound.

The overall lack of evidence to support the use of ultrasound could be due to a number of confounding factors that create difficulties when conducting trials and result in no significant differences or clinical improvements identified.

- ***Methodological limitations of clinical studies***

In recent years all medical and health related professions have been encouraged to make treatment decisions based on the best available evidence which is considered to be

the randomised controlled trial (RCT), the 'gold standard' method of evaluation for treatment interventions [24]. Of the RCTs identified in this review the mean quality assessment score was 9.5 out of a possible 20 points. This shows that the majority of the trials were lacking in methodological quality, which increases bias, questions the validity of the results and provides little evidence upon which to make treatment decisions. The main flaws of the trials were lack of randomisation methods, small sample sizes, and lack of blinding. In some of the studies there was a general lack of details and information given, leaving many questions unanswered. This also makes future research difficult when attempting to reproduce trials for comparison and still does not explain why the medium/high quality studies that were identified failed to find any significant beneficial effects of ultrasound treatment. Other explanations for those results should therefore be investigated.

- ***Technical variables***

Inconsistencies have been previously identified between the intended and actual dosages of ultrasound [31-33], potentially affecting the therapeutic effect and the outcomes of trials. Of the studies identified, five reported that ultrasound machines were tested and calibrated during the study period [13,15,17,19,21] therefore this factor could be eliminated from these specific trials as a possible reason for lack of effect.

Ultrasound therapy is a combination of many different technical variables and each application has the potential for many possible combinations and outcomes. Therapeutic windows of opportunity are often referred to in areas of healthcare and are appropriate when considering ultrasound treatment to gain the maximum beneficial therapeutic effect [34]. Although a dose-response relationship has yet to be identified [35], it is generally accepted that the ultrasound dosage to be applied with respect to frequency, intensity, mode of delivery etc. will be dependent upon the condition or injury to be treated and the intended objectives of the treatment. It is possibly a little unrealistic to give one specific predetermined dose of ultrasound to a large group of patients and expect significant differences to be identifiable when no two subjects or their pathologies are identical.

- ***Complexity and variety of underlying pathologies***

The methods of the randomised controlled trial attempt to identify and analyse any group differences although it is still often difficult to find enough participants that present with similar pathologies for trial inclusion. The strict inclusion and exclusion criteria of high quality randomised controlled trials mean that the effects of the ultrasound treatment and thus the results of the trials are location-, tissue- and pathology- specific. This makes it difficult to incorporate the evidence into the clinical setting. An individual treatment

programme tailor made to the specific requirements of each patient is always going to be the most effective management plan however this is not achievable when conducting controlled trials as all patients need to receive identical treatments and in the case of ultrasound, identical dosages.

Basic ultrasound principles accept that different tissue types have different ultrasound absorptive abilities and more recently greater emphasis has been directed towards the reparative status of the tissues. Some of the current leading authors [34,36] and others suggest that the intensity of ultrasound applied should depend on the chronicity of the tissues involved. The only definitive way to determine this would be histopathological findings of tissue biopsy, which would be inappropriate and unethical under most circumstances. In the process of a clinical trial where one dosage of ultrasound is applied to all subjects, it has to be presumed that all subjects are presenting with similar conditions at similar stages of repair. This is unlikely to be the case and may result in negative outcomes through inappropriate dosages of ultrasound being applied.

- ***Co-interventions***

In clinical practice, ultrasound is rarely used as the sole treatment option and would normally be used in addition to other treatment modalities such as stretching/strengthening exercises, insoles/orthotics, heat/cold and other physical therapies as part of a treatment programme. The overall results achieved by the treatment programme may be due to the small effects created by each individual therapy, each on its own insignificant but when used adjunctively, result in significant improvements. It is possible that ultrasound is effective but in clinical trials the effects of this one treatment are so small they are not identified as significant.

- ***Outcome measures:***

Consideration should be given towards the most appropriate method to evaluate the effectiveness of therapeutic ultrasound; pain, range of motion and swelling have been tried and tested for their reliability however none of these outcome measures are able to measure healing quality. It is proposed that the effects of ultrasound are most beneficial if used in the early stages of the repair process result in stronger more elastic scar tissue [37] however, none of the clinical trials identified in this review reported the long-term effects of ultrasound therapy. A longer study period or follow up would enhance the quality of trials and may be able to identify a relationship between ultrasound treatment and recurrence of symptoms or re-injury. Appreciation is given to the fact that a longer study may affect recruitment numbers and create additional difficulties in conducting trials.

The pain VAS (visual analogue scale) was the primary outcome measure used in all the trials that failed to detect significant beneficial effects of ultrasound. Is this the most appropriate method of evaluation currently available? A number of different ways to evaluate treatment interventions within podiatry have been discussed by Farndon and Borthwick [38]. They report on the suitability of The Foot Health Status Questionnaire (FHSQ) to measure changes in foot health after a therapeutic or surgical intervention. This questionnaire or similar may be more appropriate than the VAS because a number of other factors are taken into consideration. Ultrasound therapy aims to enhance the healing process which ultimately will result in pain reduction but it is not the sole objective. Although the healing process is difficult to quantify, it may be that there are better methods currently available to evaluate the therapeutic effects of ultrasound.

- ***True lack of effect:***

Despite the large amount of literature and research available that has demonstrated a number of physiological effects of ultrasound *in vitro* [39-42] and on animal models [43-45] there is still little clinical evidence to suggest that it has the same effects on the human body. Zammit and Herrington [21] suggest that it has not been possible to directly translate the effects found in laboratory studies onto human healing because in clinical trials, the homeostatic effects of the human body moderate the effects of ultrasound application. This either suggests that ultrasound is unlikely to have an effect on the human body or it could indicate that ultrasound is effective but further research needs to be undertaken to identify the dose-response relationship.

The current trend for ultrasound appears to be research looking at the effects of ultrasound at much lower intensities (LIPUS). Warden [46] reviewed the benefits of LIPUS to aid fracture repair and stated that although there is little evidence available to support the use of ultrasound, it should not be discarded as a therapeutic modality. However, the attempt to transfer the findings of LIPUS to the study reviewed in this paper by Warden *et al.* [19] was unable to find any additional benefits when used for the management of patellar tendinopathy.

- ***Limitations of the review***

Due to the financial, time, word and reference restrictions unpublished articles and articles not written in the English language were not considered for this review. The inclusion of such articles may have altered the findings of the review although it should be considered that articles not submitted for publishing may be more likely to have found negative effects than positive effects and are therefore unlikely to have affected the overall findings of this particular paper. This review was also limited to musculoskeletal conditions

of the lower limb and does not take into consideration the effects of ultrasound treatment for other conditions such as wounds, ulcers and other complaints encountered in podiatric practice that may benefit from ultrasound therapy.

- ***Implications for podiatric practice***

This review was an attempt to establish the effectiveness of therapeutic ultrasound for the treatment of musculoskeletal conditions specific to the lower limb, to be used as a evidence based practice for podiatrists when considering treatment interventions for lower limb musculoskeletal conditions. It was not possible during the course of this review to obtain figures to show the availability and frequency of use of therapeutic ultrasound within podiatry, however the results do not support its current use as a part of evidence based practice.

As podiatrists other factors must be taken into consideration in addition to the best available evidence. Ultrasound therapy requires a course of treatments over a period of weeks. This can amount to a number of dedicated podiatry appointments and also a large amount of commitment from the patient. In addition to clinician time there are also the costs of ultrasound equipment purchase and maintenance, clinician training and any other adjunctive therapies involved in the treatment programme.

There are benefits and costs associated with most treatment options and those associated with ultrasound need to be carefully considered and compared to the alternatives before including it in a treatment programme. Podiatry clinicians currently using ultrasound should be considering if ultrasound treatment is the most appropriate treatment based on the current available evidence and also have a clear understanding of how ultrasound works and the therapeutic objectives they are trying to achieve.

- ***Future research***

This review has identified that there is still a lack of quality, well-designed, controlled ultrasound trials available and those reported to have adequate methods have failed to identify any significant beneficial effects. An initial proposal would be to ascertain the availability and frequency of use of therapeutic ultrasound within current podiatric practice. It would be beneficial to establish how widely ultrasound is currently used and the conditions it is used to treat. The continuation of *in vitro* research and studies on animal models suggests that ultrasound should certainly not be disregarded as a therapeutic modality but highlights the need for further high quality clinical evidence. Particular attention needs to be paid to the technical variables involved in ultrasound application

bearing in mind the specific therapeutic objectives, this may then help to establish a possible dose-response relationship.

Conclusion

There is currently no high quality evidence available to suggest that therapeutic ultrasound is effective for musculoskeletal conditions of the lower limb. There is a lack of well-designed randomised controlled trials within podiatry to assess the effectiveness of therapeutic ultrasound and further clinical research is needed to establish if this treatment modality provides any therapeutic benefit. Further research is also needed to ascertain the most appropriate outcome measure for ultrasound therapy. Higher quality randomised controlled trials are needed with longer periods of follow up if ultrasound is to remain as a therapeutic intervention used by podiatrists for musculoskeletal conditions of the lower limb.

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Table 1. List of included studies

Antich *et al.* (1986) [12]

Bradnock *et al.* (1995) [13]

Chester *et al.* (2008) [14]

Crawford and Snaith (1996) [15]

Makuloluwe and Mouzas (1977) [16]

Nyanzi *et al.* (1999) [17]

Oakland (1993) [18]

Warden *et al.* (2008) [19]

Williamson *et al.* (1986) [20]

Zammit and Herrington (2005) [21]

Table 2: Overall quality assessment scores

STUDY	QUALITY ASSESSMENT TOTAL SCORE (/20)	INJURY/CONDITION TREATED
Warden <i>et al.</i> (2008) [19]	17	Patellar tendinopathy
Nyanzi <i>et al.</i> (1999) [17]	15	Ankle sprains
Oakland (1993) [18]	13	Ankle injuries
Chester <i>et al.</i> (2008) [14]	12	Achilles tendon pain
Crawford and Snaith (1996) [15]	10	Heel pain
Zammit and Herrington (2005) [21]	10	Ankle sprains
Williamson <i>et al.</i> (1986) [20]	8	Ankle sprains
Bradnock <i>et al.</i> (1995) [13]	6	Ankle sprains
Antich <i>et al.</i> (1986) [12]	2	Knee extensor mechanism disorders
Makuloluwe and Mouzas (1977) [16]	2	Ankle sprains

Table 3: Characteristics of excluded studies

STUDY	REASONS FOR EXCLUSION
DaCruz et al. (1988) [23]	RCT of 28 subjects, presenting with Achilles paratendonitis. An evaluation of two different types of steroid injection. All patients received the same ultrasound therapy treatment therefore it was not possible to determine if therapeutic ultrasound was beneficial.
Klaiman et al. (1998) [24]	RCT of 49 subjects to compare phonophoresis and ultrasound for the treatment of musculoskeletal conditions. A broad range of different types of soft tissue injuries. Only 8 subjects presented with lower limb injuries, patellar tendonitis, plantar fasciitis and Achilles tendonitis. Only 4 of these received ultrasound treatment, all presenting with Achilles tendinitis.
Lowdon et al. (1984) [25]	RCT of 33 subjects to compare the effects of two types of heel pads on the treatment of Achilles tendinitis. All treatment groups received the same ultrasound therapy application.
Schwellnus et al. (1992) [26]	RCT of 17 subjects to determine the efficacy of deep transverse frictions for the management of iliotibial band friction syndrome. All treatment groups received identical ultrasound therapy application.
Turlik et al. (1999) [27]	RCT of 60 subjects to compare the efficacy of shoe inserts for the treatment of heel pain. All patients could request additional therapies that included therapeutic ultrasound. 2 patients requested ultrasound treatment.