The efficacy of ultrasound in the treatment of musculoskeletal disorders

This issue of Critically Appraised Papers departs from the usual format. Structured abstracts of three recent high quality studies on the efficacy of therapeutic ultrasound for the treatment of musculoskeletal disorders are presented here. Commentators have been asked to comment on all three studies.

Ultrasound therapy is ineffective in the treatment of musculoskeletal disorders


Question: In patients with musculoskeletal disorders, can ultrasound improve pain, disability, range of motion or general recovery? Data sources: Studies were identified by searching MEDLINE, EMBASE and Cochrane databases and by citation tracking. Study selection: Selected studies were published full reports of controlled clinical trials, where at least one experimental group received active ultrasound. Studies were included if the patients had pain or reduced range of motion associated with musculoskeletal disorders and included one of the following outcome measures: proportion of patients recovered, pain, functional disability, range of motion. Data extraction: Two reviewers independently screened trials for eligibility and then rated each trial for methodological quality using the Amsterdam-Maastricht consensus list. Pooled effect sizes were calculated for homogeneous studies with high methodological quality. Where statistical pooling was not possible because of insufficient data, qualitative pooling was undertaken (“best evidence synthesis”). Results were presented separately for lateral epicondylitis, shoulder disorders, degenerative rheumatic disorders, ankle sprains, and temporomandibular or myofascial pain. A separate analysis was undertaken of the trials where ultrasound was provided in combination with exercise therapy. Main result: Thirty-eight trials were included in the review. In 11 of 13 high quality placebo-controlled trials there was no evidence of clinically important or statistically significant results. Statistical pooling was only possible for the lateral epicondylitis trials, where the difference between ultrasound and placebo treatment in proportion of subjects recovered was 15 per cent (95 per cent confidence interval -8 per cent to 38 per cent). This could be a chance difference and the authors did not regard this effect as clinically significant. The best evidence synthesis showed that ultrasound is ineffective for shoulder disorders and ankle sprains. There was insufficient evidence to judge the effectiveness for TMJ and degenerative rheumatic disorders. Ultrasound provides no additional benefit to exercise therapy. Conclusion: There is no evidence to support the use of ultrasound therapy singly or in combination with exercise therapy for musculoskeletal disorders.

Pulsed ultrasound and interferential therapy do not reduce shoulder pain or disability


Question: Do pulsed ultrasound and interferential therapies reduce shoulder pain and disability? Design: Randomised patient-therapist- and assessor-blinded trial with 12-month follow-up (subjects and therapists were blinded to ultrasound and its sham, but not to interferential and its sham). Setting: Seventeen physiotherapy practices in The Netherlands. Patients: One-hundred-and-eighty patients with shoulder pain or stiffness thought to originate from shoulder structures, but without complete rotator cuff tears, referred pain, fractures, surgery or systemic disease, and without exceptionally good or bad prognoses. To be eligible, subjects had first to comply with a two-week program of exercise therapy yet not have attained complete or near-complete recovery. All except one patient were followed up to one year. Intervention: Subjects were
randomised to active interferential (15 minutes, 4 KHz carrier, 60-100 Hz, intensity sufficient to produce paraesthesia but not pain or continuous muscle contraction) and active ultrasound (0.8 MHz, 20 per cent duty cycle, 2 min.cm⁻², intensity sufficient for tissues to absorb 50J.cm⁻² of energy), active interferential and sham ultrasound, active ultrasound and sham interferential, sham interferential and sham ultrasound, or no electrotherapy. Randomisation was concealed. All subjects performed active and passive exercise and stretching as tolerated. Twelve treatment sessions were given over six weeks. **Main outcome measures:** Outcomes were measured at three, six, nine and 12 months. The primary outcome was self-rated recovery on a seven-point Likert scale (“very much worse” to “very large improvement”). Secondary outcomes included severity of main complaint, the Shoulder Disability Questionnaire, and measures of pain intensity, physical impairment and shoulder mobility. **Main results:** The proportion of subjects experiencing a very large improvement in symptoms was nearly identical in groups receiving active and sham therapies. For example, at six weeks the difference in proportions between active and sham ultrasound favoured active ultrasound by 8 per cent (95 per cent CI -6 per cent to 23 per cent), and the difference in proportions between active and sham interferential favoured sham interferential by 1 per cent (95 per cent CI -13 per cent to 15 per cent). Between-group differences observed at three, six, nine and 12 month follow-ups in primary and secondary outcome variables were neither clinically important nor statistically significant. **Conclusion:** The addition of pulsed ultrasound or interferential therapy to an exercise program does not reduce shoulder pain, mobility or disability.

### Pulsed ultrasound reduces shoulder pain and disability due to calcific tendinitis


**Question:** Does pulsed ultrasound reduce pain and disability in patients with calcific tendinitis of the shoulder? **Design:** Randomised patient-therapist- and assessor-blind trial with nine-month follow-up. **Setting:** An outpatient clinic in a university physical medicine and rehabilitation medicine department in Austria. **Patients:** Sixty-three consecutive patients with radiographically-verified, clearly circumscribed calcific lesions, mild to moderate pain of more than four weeks duration or restricted range of motion, without systemic calcifying disease, not regularly using analgesia or anti-inflammatory medication, and not having been treated with ultrasound, shock-wave therapy, surgery or steroid injection. Eighty-seven per cent of subjects were followed to six weeks (cessation of treatment) and 80 per cent were followed for nine months. **Intervention:** Shoulders were randomised to receive either pulsed ultrasound (0.9 MHz, 20 per cent duty cycle, for 15 min at 2.5W.cm⁻²) or sham ultrasound. Randomisation was concealed. Twenty-four treatment sessions were given over six weeks. **Main outcome measures:** Outcomes were measured at six weeks (cessation of treatment) and nine months. The primary outcome was change in calcium deposits rated on a 3-point scale (no change or worse/at least 50 per cent reduction in area and density/complete resolution) by two independent blind radiologists. Secondary outcomes were measures of pain and disability (the 100-point Constant score and the 52-point Binder scale). **Main results:** At cessation of treatment, calcification had completely resolved in 19 per cent of ultrasound-treated shoulders and 0 per cent of sham-treated shoulders. This means that for every five shoulders treated with ultrasound rather than the placebo, one additional shoulder experienced complete resolution of the calcific lesion (95 per cent CI 3 to 19; all CIs are abstracter’s analysis). Ultrasound-treated shoulders had greater reductions in pain and disability (14.1 points more on the Constant scale, 95 per cent CI 5.1 to 23.1; 8.6 points more on the Binder scale, 95 per cent CI 3.5 to 13.7) than sham-treated shoulders. At nine-month follow-up, calcifications had resolved in a greater proportion of ultrasound-treated shoulders than sham-treated shoulders (42 per cent compared with 8 per cent) but measures of pain and disability were similar in the two groups. **Conclusion:** Pulsed ultrasound reduces shoulder pain and disability in people with painful calcific tendinitis of the shoulder.
Commentary 1

At the moment, two original studies and one systematic review dominate the debate on the use of therapeutic ultrasound. The debate is not new, but it has gained momentum since the Dutch Health Council concluded on the basis of this systematic review that “there is no scientific evidence for the use of ultrasound physiotherapy”. The ongoing discussion is obscured by fanatical believers on the one side and (almost as fanatical) scientists on the other side.

When looking at the presented studies, the overall conclusion should be that they are of outstanding quality. However, they show contradictory findings on apparently similar therapies and patients.

The study by van der Heijden et al, which uses a randomised, placebo-controlled factorial design, shows with scientific rigour that pulsed ultrasound for soft tissue shoulder disorders is not effective. The systematic review by van der Windt et al assessed seven studies on the effectiveness of ultrasound. The authors concluded that the majority of the ultrasound studies were of low quality. Clinical heterogeneity of study populations and insufficient data on outcome measures lead, in the absence of positive high quality studies, to the conclusion that there is no evidence that ultrasound is an effective treatment in shoulder disorders. But, just when we all thought the landscape was painted, Ebenbichler et al report a strikingly positive study of high quality that says pulsed ultrasound reduces pain and disability due to calcific tendinitis. Now what?

There are three options. The first is obvious: the fanatic believers will embrace Ebenbichler, slap him on the shoulder and say they were right all along. The second option is to add the Ebenbichler study to the systematic review (the study by van der Heijden et al was already included in the review) and see what happens. Adding one positive high quality study raises the overall validity score from 5.3 to 5.8 points (Ebenbichler gets 9 out of 10 points), and allows four instead of three studies to enter the best evidence synthesis. Remarkably, the evidence shifts from no effect to weak evidence of an effect. The last option is to look at the studies in detail. Ebenbichler et al have the most solid diagnosis: calcific tendinitis of the shoulder. The other studies in the review range from the rather vague “painful shoulder” to “shoulder disability”, “subacromial bursitis” and “rotator cuff lesions”; hinting at vastly different therapeutic consequences. Also, most studies are rather small (as is the one by Ebenbichler). Such studies may fail to detect effects because of lack of statistical power.

These and more detailed considerations suggest that it is too early to conclude that ultrasound works or does not work. The accumulated evidence, over a rather broad area of diseases, is mostly of low quality studies with heterogeneous samples and sparse outcome data. Bigger and better defined studies will hopefully solve the dilemma most systematic reviewers face today: there is a lot of fruit, but the combined fruit salad tastes awful.

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Reference


Commentary 2

Evidence-based practice (EBP) is described as a process arising from clinical questions. It combines the best available evidence from research with the clinical experience needed to interpret and implement the evidence (Sackett et al 1996).

This issue’s Critically Appraised Papers provide an opportunity to demonstrate EBP in action. Imagine you have a patient with shoulder pain and disability. He is referred specifically for ultrasound (US) but you are not so sure this is the best way to treat him and so you turn to the literature.

Your literature search reveals the three papers whose structured abstracts are presented here. The conclusions of these papers are contradictory. A systematic review and a randomised controlled trial (RCT) conclude that US is no better than a placebo, while another RCT concludes there is significant benefit.

The NHMRC suggest that evidence can be synthesised by constructing a “table of evidence” (NHMRC 2000) as outlined here from the abstracts provided.
### Table 1. Table of evidence.

<table>
<thead>
<tr>
<th>Guideline</th>
<th>Definition of Guideline</th>
<th>US for the Shoulder</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Level of evidence</strong></td>
<td>The type of study. Systematic reviews of RCTs and RCTs provide Level I and II evidence respectively.</td>
<td>Level I evidence that US is not effective.</td>
</tr>
<tr>
<td><strong>Quality of the evidence</strong></td>
<td>The methods used should ensure the study is as unbiased as possible. Trials should be randomised and blinded with adequate concealment of allocation and with all participants followed up.</td>
<td>All three studies are of high methodological quality. The systematic review included comprehensive searching, blinded assessment of trial inclusion and quality reporting of trials. Both RCTs have made all attempts to ensure blinding and have minimal withdrawals.</td>
</tr>
<tr>
<td><strong>Strength and precision of effect</strong></td>
<td>How big a difference is demonstrated between the treatment and control groups (effect size) and how accurate is the estimate of that difference likely to be (significance level and confidence intervals)?</td>
<td>The strength and precision of effect cannot be estimated for the systematic review as no formal meta-analysis (data pooling) was possible. In van der Heijden’s trial there is very little difference between groups for pain, function or mobility, and these differences are neither clinically or statistically significant. US clearly didn’t work. (Note that, as US was demonstrated to be of no additional benefit to exercise, the effect of exercise cannot be commented on from this trial). For the Ebenbichler trial there were large beneficial effects and the size of these effects was estimated with precision.</td>
</tr>
<tr>
<td><strong>Relevance</strong></td>
<td>How important is the research question? Were appropriate conflicting evidence in this case. The obvious difference between studies showing no effect for ultrasound and that showing a strong benefit is the study population. No benefit was demonstrated in an ill-defined mixed population of pain and/or restricted motion. In a population confirmed radiologically as having calcific tendinitis, US was effective.</td>
<td>Relevance can be used to explain the conflicting evidence in this case. The obvious difference between studies showing no effect for ultrasound and that showing a strong benefit is the study population. No benefit was demonstrated in an ill-defined mixed population of pain and/or restricted motion. In a population confirmed radiologically as having calcific tendinitis, US was effective.</td>
</tr>
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**The clinical answer:** if your patient has calcific tendinitis, use ultrasound in the dosage outlined by Ebenbichler. If your patient has a different shoulder disorder, it is likely that ultrasound is not effective. It is possible, however, that the mixing of varying shoulder disorders obscured benefit in particular diagnostic groups.

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**References**


Commentary 3

The three studies described in this issue’s Critically Appraised Papers present a troubling dilemma: a high quality systematic review and randomised controlled trial indicate that ultrasound is not effective for managing shoulder pain, but another high quality trial suggests a clinically important effect of ultrasound on a similar group of patients.

The Ebenbichler trial finds an effect that is large enough to be clinically worthwhile, although the size of the effect must be in some doubt because the authors report a mean reduction in pain that is greater than mean initial pain (which is impossible). The cost and inconvenience of the therapy (delivered five times per week for three weeks and then three times per week for three weeks, a total of 24 treatments) may not be acceptable to all patients, especially since the sham group had similar outcomes at nine-month follow-up.

It may be that the Ebenbichler trial finds an effect when the other studies do not because it has selected a homogeneous sample with calcific tendinitis (one report suggests these patients constitute about 7 per cent of all patients with shoulder pain; Speed and Hazelman 1999). It is tempting to think that ultrasound is effective for calcific tendinitis but not for other shoulder lesions. We are reluctant to accept this explanation for several reasons.

First, the role of calcific lesions in the production of shoulder pain is not clear. In fact the prevalence of calcific lesions in populations with and without shoulder pain is similar (Speed and Hazelman 1999), suggesting that the lesion may be an incidental finding. Second, we are concerned about the quality of blinding in the Ebenbichler study. In this study the ultrasound was switched off or on by an independent therapist prior to each treatment. This would appear to be an unsatisfactory method of blinding patients and therapists because there is the possibility of the independent therapist providing cues to the treating therapist, and the code would only need to be broken on one occasion to remove blinding for the rest of the study. In contrast van der Windt provide exemplary blinding (20 codes set by the manufacturer) and they explicitly tested the quality of blinding and found it to be high. Lastly, the findings of the Ebenbichler study are inconsistent with most of the many other randomised trials of ultrasound, almost all of which show no effect (see the van der Heijden review). It is disconcerting that one of the few other randomised trials to find any treatment effect (a trial of pulsed ultrasound for carpal tunnel syndrome) was by the same author and used a similar mechanism of blinding.

Clearly there is a need to replicate the Ebenbichler trial. Until that time we caution readers against concluding that pulsed ultrasound is effective for treatment of calcific tendonitis.

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Reference


Postgraduate and honours research

The School of Physiotherapy, University of South Australia, inadvertently omitted the following honours completions from the list published in the March 2000 issue of the Australian Journal of Physiotherapy.

BACHELOR OF APPLIED SCIENCE (Honours)

Bruland S: Correlation between change in dynamic plantar pressure and subjective outcome - a late analysis following displaced, intra-articular calcaneal fracture. (Supervised by L Chipchase)

Jarrett M: The feasibility of concurrently measuring diaphragm displacement using sonography and regional ventilation using Technegas. (Supervised by F Blaney)

Miles A: The effect of unilateral cutaneous foot anaesthesia on normal gait. (Supervised by A Warden-Flood)

Mueller K: The effect of local anaesthesia to the sole of the right foot during right single limb support in normal healthy adults as measured by the 3 space tracker. (Supervised by A Warden-Flood)

Phillips A: A comparison between static and dynamic measures of balance in elderly community dwellers: The concurrent validity of the Sharpe Sway Unit. (Supervised by S Mackintosh and M Sharpe)

Pontifex N: Effect of huffing and directed coughing on energy expenditure using indirect calorimetry in young asymptomatic subjects. (Supervised by M Williams)

Prideaux N: The effect of taping and bracing on the range of ankle inversion. (Supervised by R Gill)

Sypek S: The prevalence and morbidity of low back pain in Adelaide metropolitan taxi drivers. (Supervised by M Williams and M McEvoy)