Is extracorporeal shockwave therapy for calcifying tendinitis of the rotator cuff associated with a significant improvement in the Constant-Murley score? A systematic review

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CRD summary
The review evaluated the effectiveness of extracorporeal shockwave therapy for calcifying tendinitis of the rotator cuff using the Constant-Murley score and found an improved score at 6 months, which suggested it was a useful nonoperative treatment. The extent to which the authors’ conclusions are reliable is unclear due to potential methodological flaws in the review process and limited evidence.

Authors' objectives
To evaluate the effectiveness of extracorporeal shockwave therapy for calcifying tendinitis of the rotator cuff using the Constant-Murley score.

Searching
PubMed and Cochrane Database of Systematic Reviews were searched for articles published between January 2003 and May 2008. Search terms were reported. The bibliography of each retrieved article was handsearched.

Study selection
Randomised controlled trials (RCTs) that evaluated the effectiveness of extracorporeal shockwave therapy (ESWT) for calcifying tendinitis of the rotator cuff compared to placebo using the Constant-Murley score (CMS) were eligible for inclusion in the review. (CMS is a simple standardised clinical method of assessing shoulder function with a maximum score of 100 points; more details of CMS were given.) The primary outcome measure was CMS six months after treatment. ESWT devices used in the included studies (where reported) were Orthima and OrthoWave. Energy per shock wave ranged from 0.28 to 0.55mm/mj². One study had a second intervention group that used a low energy shock wave of 0.08mm/mj². High-energy interventions used a range of 1,000 to 1,500 shock waves. The low-energy intervention used 6,000 shock waves. The number of treatments was two or four. The interval between treatments was either two weeks or four to seven days. One study had concomitantly administered treatment. Control groups used sham treatments. Participants had Gartner grade I or II calcifying tendinitis for a minimum of three to 10 months that had not responded to nonoperative treatment. Mean age ranged from 50.4 to 54.4 years. The proportion of males ranged from 38.6% to 41.3%.

The authors did not report how many reviewers performed the study selection.

Assessment of study quality
Methodological quality was assessed using the CONSORT statement for RCTs, a checklist of 22 items that included: randomisation (sequence generation, implementation and allocation concealment); blinding; intention-to-treat analysis; baseline data; and sample size.

The authors did not report how many reviewers performed the validity assessment.

Data extraction
Mean CMS and/or mean differences (MD) in CMS, with 95% confidence intervals (CI) when available, and the number of adverse events were extracted.

The authors did not report how many reviewers performed the extraction.

Methods of synthesis
A narrative synthesis was provided.
Results of the review
Three RCTs were identified (n=260, range 46 to 144): one double-blind and two single-blind. Quality scores for the three trials were 8, 10 and 19.

The authors reported that all trials showed a statistically significant improvement in mean CMS after ESWT when compared to placebo at six months (24.4, 32 and 30.7).

The highest-quality study (n=144) showed a significantly greater improvement in mean CMS for the high-energy ESWT group versus the low ESWT energy group six months after treatment (MD -16.0, 95% CI -22.9 to -10.8), the high-energy group versus the sham group (MD -24.4, 95% CI -31.0 to -17.8) and the low-energy group versus the sham group (MD -8.4, 95% CI -15.4 to -1.4).

The lowest-quality study (n=70) showed a significant improvement in the mean CMS in the (high) ESWT group (mean CMS 71) compared to the sham group (mean CMS 50) at the end of treatment (MD 21, p<0.001). The difference remained significant after six months, but there was a 66% loss to follow-up at six months in the sham group.

The third study (n=46) showed a significant difference (p<0.05) in mean CMS between the (high) ESWT and sham groups six weeks after treatment (74.3 versus 56.2), at 12 weeks (82.8 versus 57.3) and at six months (85.0 versus 54.3) and 12 months after treatment (88.0 versus 56.8).

Adverse events were reported for petechiae, bleeding, haematoma, erythema and initial pain.

Authors’ conclusions
Compared with placebo, ESWT was a useful nonoperative treatment modality for calcifying tendinitis of the rotator cuff.

CRD commentary
The review addressed a well-defined question in terms of interventions, study design and relevant outcomes; participants were less clearly defined. Relevant databases were searched, but authors sought only published studies and so some studies may have been missed. Publication bias was not assessed. Study quality was assessed using suitable criteria. It was unclear whether efforts were made to reduce error and bias in the review process. Relevant study details were reported. A narrative synthesis was performed, which appeared to be appropriate given the apparent heterogeneity between a limited number of small studies. In view of potential methodological flaws that arose from the review process and the limited evidence provided, the extent to which the authors’ conclusions are reliable is unclear.

Implications of the review for practice and research
Practice: The authors did not state any implications for practice.

Research: The authors identified a need for further well-designed RCTs to definitively assess the efficacy of ESWT for calcifying tendinitis of the rotator cuff. The design should conform to the CONSORT list. RCTS should be sufficiently large to demonstrate clinically relevant differences. Although future studies should continue to assess CMS to enable a comparison with other studies, use of other validated shoulder-specific and general health questionnaires should be considered.

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