

moderate evidence that low-energy ESWT is not effective in treating chronic noncalcific rotator cuff tendonitis.¹

Needle aspiration of the calcific deposits and/or lavage under ultrasound or image-intensifier control have also been successful. The study by Krasny et al examines the use of this technique in conjunction with high-energy ESWT, versus ESWT alone. Strengths include well defined inclusion/exclusion criteria, 1 center with a single shock-wave device, clinically relevant outcome measures, and adequate follow-up. Appropriately, only patients with Gartner and Simons types I and II deposits were included, as type III are more likely to resolve spontaneously. The orthopedic surgeon assessing clinical and radiologic outcomes was blinded to treatment group, but because the nature of the intervention (ultrasound-guided needling) it was not possible to blind the patients.

Some aspects of the study could be modified in future trials. The sample size was relatively small (40 in each group). Gerdesmeyer et al² calculated that their sample of 144 patients had 90% power to find a 15% difference in the primary outcome as compared with sham treatment, given an α level of 0.025. Comparison with other studies would be facilitated by reporting the total energy flux density used for each patient and examining the cost-effectiveness of the combined therapy, because the additional need for a radiologist for the ultrasound-guided needling adds to the financial cost of ESWT. The group receiving only ESWT also had more pain during treatment, but received the local anesthetic in a slightly different location. This could be controlled for in future trials.

Nevertheless, the study adds to current knowledge about the use of ESWT for soft tissue conditions. It is becoming increasingly evident that high-energy ESWT is effective in creating tissue changes, even with a single application, whereas low-energy ESWT has a predominantly analgesic effect, requiring more treatment sessions. Practitioners should

be cognizant of the mechanisms of action and desired effects before prescribing ESWT therapy.

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Is Acupuncture or Ultrasound Therapy More Efficacious for Impingement Syndrome?

Johansson KM, Adolfsson LE, Foldevi MOM. Effects of acupuncture versus ultrasound in patients with impingement syndrome: randomized clinical trial. *Phys Ther*. 2005;85:490-501.

Objective: To compare the efficacy of acupuncture and continuous ultrasound therapy, in addition to home exercises, for patients with impingement syndrome.

Design: Randomized controlled trial with blinded assessment and follow-up for 12 months. Sample size was calculated to be sufficient to show a difference between groups ($\beta = 0.80$, $\alpha = 0.05$) with a difference of 30% in the proportion of improved patients.

Source of funding for the original study: County Council of Östergötland and Linköpings Universitet, Sweden.

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Setting: Patients were referred from 3 urban primary healthcare centers in Sweden between March 1997 and June 2000.

Participants: General practitioners and physical therapists referred patients with probable impingement syndrome ($n = 173$) for a standardized clinical examination by the research physical therapist and confirmation by radiologic findings. Eligibility criteria were 30 to 60 years of age; history of pain in the proximal lateral aspect of the upper arm, especially during arm elevation; a positive Neer impingement test (after subacromial injection of anesthetic); and ≥ 2 months' duration of the current episode. Two of the following inclusion criteria had to be positive: Hawkins-Kennedy impingement sign; Jobe supraspinatus muscle test; and painful arc between 60 and 120 degrees of active abduction. Exclusion criteria were a history of malignancy, arthritis, skeletal abnormalities, previous surgery, fractures, dislocation, or joint instability in the shoulder area; suspicion of frozen shoulder, problems from the cervical spine, ruptured rotator cuff, or acute subacromial bursitis; and previous treatment with the study therapies or corticosteroid injection during the previous 2 months. None of the 85 patients (mean age, 49 y; regular exercisers, 82%; women, 69%) who were included on clinical criteria were excluded by radiologic examination.

Intervention: All patients were assigned to home exercises. Acupuncture ($n = 44$) comprised 30-minute treatment sessions, twice per week for 5 weeks, with standardized needle placements by physical therapists trained to locate the 4 local and 1 distal points, using 0.30-mm diameter, 30-mm long needles. The needle was rotated a few times until the patient reported de qi (radiating paresthesia) or the needle position was adjusted until de qi was experienced. Further stimulations were done after 15 and 30 minutes. Standardized continuous ultrasound ($n = 41$) comprised 10-minute sessions, twice per week for 5 weeks, at a frequency of 1 MHz and spatial-average intensity of 1 W/cm².

The transducer head was moved in small circles covering an area of 8 to 10 cm² inferior to the anterior and lateral part of the acromion. Calibration of the equipment was checked. For the first half of the 5-week treatment period exercises taught by the physical therapist comprised many repetitions of pain-free low-intensity exercises to improve motion in the rotator cuff. In the fourth and fifth weeks patients were to add strengthening exercises with the arm in a position that avoided impingement.

Main Outcome Measure: The main outcome measure was a composite of 3 shoulder assessment scales, the Constant-Murley Shoulder Score, the Adolphson-Lysholm Shoulder Score, and the University of California at Los Angeles End-Result Score (composite score, 0 to 100, worst to best). Patients were assessed at the end of treatment and after 3, 6 (81% follow-up), and 12 months (76% follow-up).

Main Results: Patients in both groups improved ($P < 0.0001$). Among those adhering to the study protocol, the mean scores from all 4 assessments showed greater efficacy for acupuncture ($P = 0.045$) than for ultrasound (mean baseline and 12-mo scores, acupuncture, 61 and 93, and ultrasound 63 and 89). In intention-to-treat analysis the groups did not differ (12-mo scores, acupuncture, 88 and ultrasound, 85). The groups did not differ in compliance with exercises or use of pain medications, and no adverse effects were reported.

Conclusion: Acupuncture treatment for shoulder impingement syndrome, in combination with home exercises, was more efficacious than ultrasound and exercises in improving shoulder scores among participants who complied with treatment.

In departing from our usual practice, 2 commentaries on a single abstract follow. The 2 pieces complement one another and will, we hope, broaden perspectives on an important aspect of the management of shoulder impingement—Lawrence Hart, Journal Club Editor.

COMMENTARY

There is little rigorous evidence for the efficacy of therapy interventions for shoulder impingement syndrome. The study by Johansson et al, however, meets many of the methods criteria for a robust intervention design. Patients were suitably randomized and there was no statistical difference between groups on salient variables at baseline. The participants and the setting are well described, and the inclusion and exclusion criteria are clearly defined, judicious, and reproducible. The authors provide detailed descriptions of the study's 3 therapeutic maneuvers, which are all feasible and commonly used in various combinations in clinical practice. Compliance is monitored. The overall reproducibility and applicability of the treatments are sound and the generalizability of the study results is relevant to most clinicians.

Measurement of study outcomes is important. Johansson et al combine 3 different scales with varying representation of functional traits. Their composite score does not clearly relate the study results to everyday practice and means little to the reader in terms of specific clinical consequences. The combined scale would have contained some repeated items, which can negatively affect the content validity of the test.¹ The validity and reliability these scales may have individually was also no longer applicable.

The intention-to-treat analysis (all study patients) showed no differences between groups. The second analysis excluded participants who did not adhere to the study protocol. This did show a significant difference between the acupuncture and the ultrasound groups. By omitting noncompliant participants and dropouts in this analysis Johansson et al run the risk of negating randomization, increasing bias, and overestimating clinical effectiveness.² On the other hand, there is value in knowing that compliance might be an important factor in the effectiveness of acupuncture.

Because little is known about the natural history of shoulder

impingement syndrome, it is difficult to determine how much improvement could be attributed to the interventions and how much to natural healing. A factorial design with a no-intervention control arm would have allowed the authors to differentiate the effectiveness of each therapy, as well as to determine the effectiveness of combining therapies.³ Johansson's study provides some support for combining acupuncture with exercise in participants who comply with treatment. The effectiveness of this approach in clinical practice will remain equivocal until further controlled studies are carried out.

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COMMENTARY

Johansson et al attempted to discern whether there is a difference between ultrasound and acupuncture in the treatment of impingement syndrome. Both ultrasound and acupuncture are now commonly used adjuncts to active exercise in the treatment of shoulder pathology. Both modalities are intended to decrease pain and stimulate healing but their physiologic effects differ. Ultrasound uses a high-frequency sound wave that has both mechanical and thermal effects on the target tissues. Modern acupuncture stimulates the peripheral nervous system using small needles at standardized acupuncture

points, with the goal of activating pain suppression mechanisms in the central nervous system. The investigators cited 2 studies that cast doubt on the efficacy of ultrasound in any musculoskeletal disorder, thus they sought a better treatment with a different mechanism of action.

The methods of the study were appropriate. The participants were randomized to the treatment groups, and were diagnosed using commonly accepted impingement tests; the exclusion criteria were strict enough to eliminate more complicated cases with multiple sources of pain. The observers were blinded, and standardized functional outcome measures were used to gauge improvement. The groups were treated for the same number of sessions and had identical exercise programs.

The rationale for the choice of acupuncture points was that they were "in accordance with common practice" and included large intestine (LI) 4, 14, and 15, lung (L) 1, and triple warmer (TW) 14. With the exception of LI 4 and 14 (whose effects on shoulder pain would likely be through stimulation of the radial nerve), these points correlate with subacromial structures including the rotator cuff, deltoid, biceps, and branches of the axillary nerve. No rationale was given for the ultrasound parameters, but one would assume from the protocol that the goal was a thermal effect on the subacromial tissues. The application of both modalities mirrors the typical application in clinical practice.

The exercise program did not reflect best practice. The authors state that rotator cuff weakness is only one of many possible causes of impingement syndrome, yet their exercise program focused on rotator cuff weakness exclusively. The strength and co-ordination of the scapular stabilizers, scapular dynamics during movement, postural control, and core stability have all been implicated in subacromial impingement, yet these factors were not addressed in either the diagnosis or treatment of the study participants. The deficiencies of the program, however, would have affected each group equally.

The results of the study state that although both groups improved, the acupuncture group showed greater improvement. The authors admit that in the absence of a control group, the true magnitude of treatment effect was difficult to ascertain, and that the improvements in both groups were probably attributable to both treatment effect and natural history. Perhaps a future study design could compare the difference between treatment of impingement that includes a more global approach (including scapular stability and posture) and the same treatment with the addition of acupuncture. This would provide a better measurement of the benefits of acupuncture in treating shoulder disorders.

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Is There a Better Mouth Guard for Preventing Concussion in Contact Sports?

Barbic D, Pater J, Brison RJ. Comparison of mouth guard designs and concussion prevention in contact sports. A multicenter randomized controlled trial. *Clin J Sport Med.* 2005;15:294–298.

Objective: To compare the effectiveness of the WIPSS Brain-Pad mouth guard with other mouth guards for preventing concussion among varsity football and rugby players.

Design: Cluster-randomized controlled trial during 1 playing season. Number of participants (610 participants in 12 teams) was calculated to

be able to show a difference at the 0.05 level with a 50% reduction in concussions from an estimated 15% per season.

Setting: Universities in Ontario, Canada, during the 2003 football and rugby playing season (September 3 to November 17).

Participants: Players from 5 universities in 4 male football teams (394 players), 4 male rugby teams (129), and 4 female rugby teams (123) were recruited (81% inclusion rate) by team therapists, trainers, and sport medicine physicians, and randomized by team. Eligibility criteria were ≥ 16 years of age, physically able to participate in contact sports, and no known history of seizures or similar neurologic conditions. Players with previously diagnosed concussions were not excluded (intervention arm, 35.1% and control arm, 33.3%). At baseline participants in the study arms did not differ in age (mean, 21 y), height, weight, or years of playing experience (mean, 6.5 y).

Intervention: Players in the intervention arm were assigned to use a WIPSS Brain-Pad mouth guard through the season, at no cost. This is a 2-layered boil-and-bite mouth guard that creates and maintains a separation of the temporomandibular joint, which might be expected to reduce acceleration forces entering the cranium when the chin is struck. Players in the control arm were to continue their usual mouth guard practices (59% used a generic boil-and-bite guard and 15% reported no mouth guard use). Compliance with mouth guard use was recorded by the team athletic therapists and by the investigators during unannounced site visits. Mean compliance during the season was 70% for the intervention arm (range by team, 69% to 80%) and 74% (range, 69% to 98%) for the control arm.

Main Outcome Measures: The main outcome measure was the incidence of diagnosed concussion in the 2 study arms. A concussion event was defined by the American Academy of Neurology (AAN) Concussion Guidelines. Events were recorded in an injury report binder by a team therapist, trainer, or physician who was already

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