Ebenbichler GR, Erdogmus CB, et al. Ultrasound Therapy for Calcific Tendinitis of the Shoulder. New Engl J Med 1999;340:1533-8.

Design: Randomized clinical trial

Population/sample size/setting:

- 54 patients (mean age 52, sex distribution not specified) with 61 shoulders who completed treatment for calcific tendinitis at university Physical Medicine departments in Vienna and Germany; 63 patients were enrolled and 9 did not complete treatment
- Eligible if they had type 1 or 2 calcific deposits on Gartner classification with minimum diameter of 5.0 mm, at least 4 months of mild to moderate pain, or restricted range of motion of affected shoulder
- Excluded if they had previous surgery, needle aspiration, ultrasound, or shock-wave therapy for calcific tendinitis, glucocorticoid injection in shoulder in past 3 months, regular use of analgesics or anti-inflammatory drugs, or systemic disease associated with increased risk of calcification

Main outcome measures:

- Shoulders randomized to ultrasound (US) (24 sessions of 0.89 MHz frequency at intensity of 2.5 W/sq cm, 15 min/session, n=32) or 24 sessions of sham US (n=29)
- Treatments (real or sham) given 5times/week for 3 weeks, then 3times/week for 3 weeks
- Primary outcome was size of calcium deposit on x-ray at baseline, at six weeks, and at 9 month follow-up; Constant scores, subjective pain scores, and quality of life scores were secondary measures
- Calcium deposits improved or resolved in 15/32 US-treated shoulders and in 3/29 sham-treated shoulders at 6 weeks; at 9 months, resolution or improvement was seen in 20/31 US-treated shoulders and in 5/25 sham-treated shoulders
- At 6 weeks, US group had mean improvement of Constant score of 17.8 points, compared to only 3.7 in sham group; 75% of US-treated shoulders had Constant score of 90 or better, but only 34% sham-treated shoulders had Constant score of 90 or better
- At 9 months, improvement in Constant scores had equalized between groups (15.7 and 12.4 points for US and sham); 61% of US-treated shoulders had Constant score of 90 or better, compared with 48% of sham-treated shoulders
- For pain and quality of life scales, pattern of improvement was similar to that for Constant scores; the US group scored better at 6 weeks but group differences were not significant at 9 months

Authors' conclusions:

- Ultrasound therapy alleviates symptoms in short term
- In long term, symptoms may be self-limiting and improve independently of the change in the calcium deposit

Comments:

- Baseline description of population in Table 1 omits sex distribution
- US-treated group appears to have experienced a slight decline in Constant score between end of treatment at 6 weeks and final follow-up at 9 months; increase over baseline was 17.8 at 6 weeks and 15.7 at 9 months, while percent of patients with Constant score of 90 or better declined from 75% to 61%; some comment on this by authors would have been warranted
- Authors report that outcome was “unsatisfactory” for 7 shoulders on US group and 11 shoulders in sham group, but do not define criteria by which satisfactory outcome was judged
- Statistical test for change in calcium deposit was Fisher’s exact test; since the categories are ordered (unchanged/worse, improvement, resolution), a better test would have used this information and tested for ordered categories
- Reproduction of this analysis shows does not weaken but strengthens significance of radiographic changes; rather than p values of 0.003 and 0.002, the p values would be 0.001 and 0.001
- Even though numbers would have been very small, a discussion of the results in patients who had both shoulders treated would have been interesting

Assessment: Adequate for some evidence that in the setting of calcific tendinitis with restricted movement of the shoulder, ultrasound reduces calcium deposits and improves short term (at 6 weeks) function compared to sham ultrasound