Gerdesmeyer L, Wagenpfiel S, et al. Extracorporeal Shock Wave Therapy [ESWT] for the Treatment of Chronic Calcifying Tendonitis of the Rotator Cuff. JAMA 2003;290: 2573-2580.

Design: Randomized clinical trial

Study question: is ESWT more beneficial than sham ESWT in the setting of calcific tendinitis?

Population/sample size/setting:

- 144 patients (mean age 50, 57 men, 87 women) with calcific tendinitis treated at 7 sites in Germany and Austria
- Eligible if they were over 18, had 6 months of pain from idiopathic calcific tendinitis, resistant to conservative treatment, had calcific deposits of 5 mm or more in diameter on x-ray that were Type I (homogenous with well-defined borders) or Type II (heterogeneous with sharp outline)
- Excluded if they had rotator cuff tear or subacromial bursitis (on sonogram or MRI), rheumatic/connective tissue disease, glenohumeral or acromioclavicular arthritis, previous shoulder surgery, previous unsuccessful ESWT, Type III calcification (cloudy and transparent)

Main outcome measures:

- Block randomization with block size of 48 into high-energy ESWT (n=48), low-energy ESWT (n=48), or sham ESWT (n=48)
- High-energy and low-energy groups received the same total acoustic energy, but high-energy group received 1500 waves of .32 mJ/mm^2, with low-energy receiving 6000 shocks of .08 mJ/mm^2 ,all groups treated in 2 sessions 14 days apart
- Main outcome was change in mean Constant-Murley Score (CMS) between baseline and 6 months after treatment; success defined as 30% increase in CMS from baseline; failure defined as needing additional therapies except for physiotherapy and acetaminophen (e.g., surgery, steroid injection, NSAID)
- Secondary outcomes were 3 and 12 month CMS, VAS pain scores, and size of calcific deposits on x-ray
- Baseline CMS for high-energy, low-energy, and sham ESWT was 60, 62.7, and 64.2 respectively; these improved by 31, 15, and 6.6 points at 6 months
- Percent with 30% improvement were 89%, 41%, and 17% respectively
- Calcific deposits disappeared at 12 months in 86%, 37%, and 25% of high-energy, low-energy, and sham ESWT respectively
- Pain requiring IV analgesics during ESWT was recorded in 8 high-energy patients, 2 low-energy patients, and 1 sham ESWT patient

Authors' conclusions:

- ESWT has a beneficial effect on calcific tendinitis; high-energy appears to have an advantage over low-energy, but threshold energy is not defined

- Follow-up at 6 months was nearly complete, but high attrition after that means that results beyond that must be interpreted with caution

Comments:

- A substantial baseline imbalance in sex composition between groups is not noted by authors; male/female composition of high-energy, low-energy, and sham groups are 13/35, 16/32, and 28/20 (chi-square with 2 degrees of freedom=10.9, p=.004)
- Response rates are not stratified by or adjusted for sex; this would be important when a large baseline difference is present, whether it arose by chance or by unrecognized selection bias
- Selection bias was tested for using Berger-Exner test, which is most applicable with trials with restricted randomization in which there is a good chance that allocation concealment will be compromised by knowledge of block size and previous allocations (through loss of blinding)
- A block size of 48 is very large, and is practically equivalent to unrestricted randomization, making the Berger-Exner test unlikely to be relevant to questions of selection bias for this study
- It appears that size of calcification may not be correlated with symptoms; the sham group had the smallest baseline calcification diameter but the best CMS

Assessment:

- Adequate for some evidence that ESWT may be provide functional benefits in the setting of calcific tendinitis, and may reduce the size of the calcific deposits as well