Yin M-C, Ye J, et al. Is Extracorporeal Shock Wave Therapy Clinical Efficacy for Relief of Chronic, Recalcitrant Plantar Fasciitis? A Systematic Review and Meta-Analysis of Randomized Placebo or Active-Treatment Controlled Trials. Arch Phys Med Rehabil 2014;95(8):1585-93.

Design: meta-analysis of clinical trials

Study question: In patients with chronic plantar fasciitis, is extracorporeal shock wave treatment (ESWT) effective compared to other interventions?

PICOS:

- Patient population: adults over 18 with at least 6 months of symptoms from plantar fasciitis
    - Trials of patients with specific pathologic changes such as fracture, inflammation, or trauma, were excluded
- Interventions: ESWT at any level of intensity
- Comparisons: conservative treatments such as shoe inserts, oral analgesics, night splints, stretching, steroid injections
    - Any of these was used as a control intervention provided that only 1 comparison was made in the included study
    - Studies comparing different forms of ESWT were also excluded
- Outcomes: pain relief using a VAS scale; function using the Roles and Maudsley (RM) score
    - RM is subjective pain and function score where 1 = excellent, no pain, full movement, full activity; 2 = good, occasional discomfort, full movement, and full activity; 3 = fair, some discomfort after prolonged activity; and 4 = poor, pain limiting activities
    - RM score was dichotomized so that success was a score of 1 or 2 and failure was a score of 3 or 4
    - The “midterm” results were the focus of the primary analyses, defined as followup at least 6 months after treatment but less than 2 year after, which is considered “long term”
- Study types: both randomized and quasi-randomized scores were eligible for inclusion

Study selection:

- Databases included PubMed, EMBASE, the Cochrane Central Resister, and Evidence-Based Medicine Reviews through April 2013
- 2 authors independently evaluated articles for meeting selection criteria, and assessed methodologic quality using the Jadad scale, which has a maximum score of 5 (1 for random sequence generation, 1 for allocation concealment, 1 for blinding of

participants and personnel, 1 for blinding of outcome assessment, and 1 for satisfactory outcome data with low attrition

Results:

- 23 RCTs were identified, and 7 with 550 patients were selected as having met inclusion criteria
    - 11 lacked a clear definition of successful treatment standards; 2 compared different forms of ESWT; 3 studies used a local anesthetic in the ESWT group
- All trials mentioned randomization; 5 had allocation concealment and 5 had double blinding while 1 had single blinding
- The authors separately estimated the effects of low intensity and high intensity ESWT, defining low intensity as delivering energy < 0.20mJ/mm^2 with high intensity as > 0.20 mJ/mm^2
- "Success rates" were defined differently by different authors, but the definitions were not greatly different; some set a requirement of a 60% improvement in outcome scores, and others set a requirement of 50% improvement
    - For 5 trials of low intensity the overall success rate of ESWT was greater than for control (relative success rate 1.69, 95% CI from 1.37 to 2.07)
    - For the high-intensity studies, the overall success rate was not better in ESWT than for control (relative success rate 1.16, 95% CI from 0.86 to 1.56)
- Pain relief was more effective for ESWT than for control in the low intensity studies; the difference (on a 10 point VAS) in the change of pain scores after baseline was 1.51 points (95% CI from 0.77 to 2.26)
    - Only one of the high-intensity studies compared changes in pain scores between ESWT and control, with a difference in favor of ESWT of 1.41 points (95% CI from 0.57 to 2.23)
- Function was reported in 5 trials with 423 patients, with RM success dichotomized as described above
    - For low intensity ESWT, the relative success rate for function was 1.41 with 95% CI from 1.08 to 1.82
    - For high intensity ESWT the relative success rate for function was 1.33 with 95% CI from 0.94 to 1.9
- Adverse events were reported in 2 studies, but it appeared that no serious adverse events occurred

Authors' conclusions:

- The midterm results for ESWT show strong statistical evidence for its efficacy in the treatment of chronic plantar fasciitis
- There were differences in the focus of the included studies with respect to the standard for success (pain on taking the first steps in the morning, pain with daily

activities, heel pain with local pressure), and only one study used the American Orthopedic Foot and Ankle Society (AOFAS) score to define treatment success
    - Such nonuniform evaluation criteria may cause bias during evaluation
    - The between-group difference between ESWT and control was not statistically significant in 4 of the included trials
- Low intensity ESWT appears to be superior to high intensity ESWT, which contradicts the conclusions of another meta-analysis by Dizon et al 2013, but the authors are unable to provide further practical information in this regard
- The long term efficacy of ESWT remains unknown due to a lack of data

Comments:

- The comparison of low and high intensity ESWT is problematic
    - The discussion section suggests that low intensity is superior to high intensity ESWT
    - This inference would require that analytic methods for indirect comparisons be used, since there were no head to head comparisons of low and high intensity doses, and these methods were not applied to the data
- One of the studies appears to be an outlier, as seen in Figure 4, which compares the success rates of ESWT versus control for low intensity doses and has an I^2 of 66%
    - Ibrahim 2010 shows a success rate of 100% for the ESWT group, which is much greater than for the other four studies in the figure
    - Removing Ibrahim from the analysis eliminates the heterogeneity, but does not greatly reduce the success ratio; instead of a ratio of 1.69 as in the figure, the ratio is 1.43 (confidence interval from 1.15 to 1.77)
- A funnel plot is mentioned to test publication bias, but there are too few studies to make a funnel plot informative, and there is no purpose in doing one
- In the meta-analysis figures, the axes are inadvertently reversed; “favours control” should be “favours experimental” and vice versa
- Pain relief appears to be close to the minimal clinically meaningful amount; for low dose ESWT, the effect size is 1.51 points, which is a fairly small effect size
- Overall, the pooled effects of ESWT are not impressive; the authors’ conclusion that it is “worthy of recognition” is vague and debatable
- The Dizon meta-analysis, referred to by the authors, is also problematic and is evaluated elsewhere

Assessment: Inadequate for evidence that ESWT has a clinically meaningful effect on plantar fasciitis pain or function (small pooled effect sizes) at low or at high intensity

Reference:

Dizon JN, Gonzalez-Suarez C, et al. Effectiveness of extracorporeal shock wave therapy in chronic plantar fasciitis: a meta-analysis. Am J Phys Med Rehabil. 2013;92(7):606-20.