

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.

Design: Meta-analysis of randomized clinical trials

Study question: Is extracorporeal shock wave therapy (ESWT) more effective than placebo ESWT in improving the symptoms and function in plantar fasciitis?

PICOS:

- Patient population: adults with at least 6 months of heel pain unsuccessfully treated with conservative care such as medications and physical therapy
- Interventions: ESTW of different levels of intensity
 - o Low-energy was defined as less than 0.1 mJ/mm²
 - o Moderate intensity was defined as 0.1-0.2 mJ/mm²
 - o High intensity was defined as > 0.2 mJ/mm²
- Comparisons: placebo ESWT
- Outcomes: Overall pain, morning pain, and function using the Roles and Maudsley (RM) score 12 weeks after the intervention
 - o 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
 - o RM score was apparently dichotomized so that success was a score of 1 or 2 and failure was a score of 3 or 4
- Study types: randomized controlled trials

Study selection:

- Databases included PubMed, Ovid, the Cochrane Library, EBSCO, Google scholar, and BioMed Central from 2002 to 2010
- Search was restricted to English language literature
- Study quality was assessed with the PEDro scale, which is an 11 point scoring system similar to the Cochrane Risk of Bias tool, awarding points for randomization, allocation concealment, blinding of patients and outcome assessors, good followup, and intention to treat analysis
 - o Two authors independently assessed articles on the PEDro scale

Results:

- The search yielded 368 publications, of which 11 were randomized trials which reported the relevant outcomes in a manner that lent itself to pooling data for meta-analysis

- 2 studies used low-intensity ESWT; 5 used moderate intensity, and 4 used high intensity ESWT
- For overall pain reduction, there was no difference between ESWT and placebo
- For morning pain reduction, ESWT was more effective than placebo, with a weighted mean difference (WMD) from 4 studies of 0.77 VAS points with a 95% CI from 0.25 to 1.30
 - o In a subgroup analysis, low intensity ESWT had no effect on pain, with a WMD of 0.50 VAS points but a 95% confidence interval which included 0
 - o The high intensity ESWT had a WMD of 1.00 VAS points with a 95% CI from 0.29 to 1.70
- Success of treatment was dichotomized by two studies of moderate intensity ESWT, one study using a 50% VAS reduction and the other using a 60% VAS reduction as a criterion of success
 - o The pooled results were in favor of ESWT, with an odds ratio of 0.65 and confidence intervals from 0.42 to 1.00
 - o This means that the odds of failure were 35% lower in the ESWT than with placebo treatment
- For activity pain, there was not a difference between ESWT and placebo
- The odds of adverse events were higher with ESWT than control for calcaneal pain (odds ratio of 8.19) and for erythema on calcaneal area (OR of 3.06), but the odds ratios were not elevated for local edema, paresthesia, or bruising

Authors' conclusions:

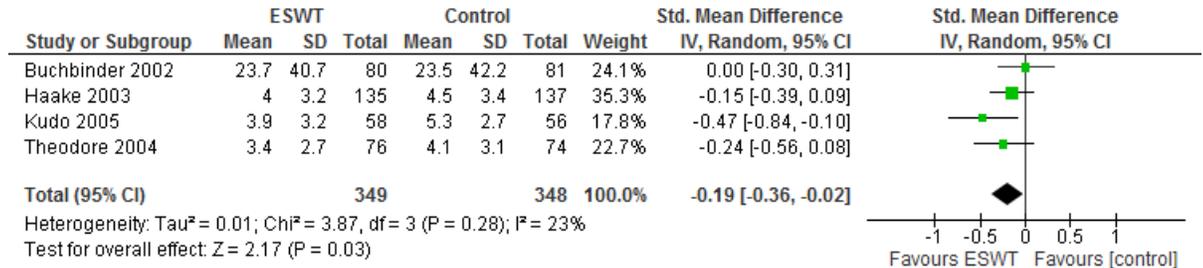
- The results provide evidence for the effectiveness of ESWT using moderate and high intensity in reducing pain and improving function in patients with chronic plantar fasciitis
- ESWT may reduce the need for surgery
- There were some limitations of the study because of a lack of uniformity in certain outcome measures, length of followup, and ESWT intensity

Comments:

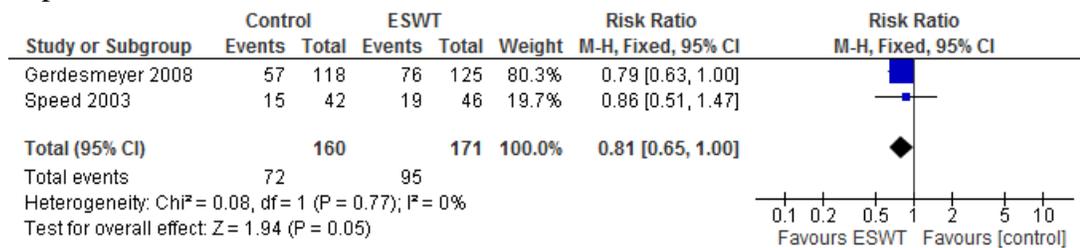
- There are several major errors in the way that data were pooled and analyzed
- The most serious error arises from pooling data with weighted mean differences on pain VAS, even though some studies used a 10 point scale and some used a 100 point scale; all meta-analyses were done in a way that treated a 5 point difference on a 10 point scale the same as a 5 point difference on a 100 point scale
- With the RevMan software used for the meta-analyses, it is easy, with the click of a mouse, to change from a weighted mean difference to a standardized mean difference

(SMD), which puts all studies on the same scale and eliminates the difficulty of using different scales in different studies

- For example, Figure 3 pools data from four studies for morning pain, and estimates a difference in favor of ESWT of 0.77 points, which is not clinically meaningful on a 10 point scale and is a nonexistent difference on a 100 point scale
- A SMD can be derived from the same four studies, and is estimated at 0.19 SD, which is just short of what is conventionally considered a “small” effect size of 0.2 SD



- Figure 4, supposedly showing an odds ratio of success in ESWT of 0.65, would be better expressed as a risk ratio, since an odds ratio inflates a treatment effect when the outcome of interest (treatment success or failure) is common
- The risk ratio for ESWT is 0.81, which represents a 19% reduction in the risk of treatment failure, a much more modest treatment effect; the fact that the confidence interval for the estimate of treatment effect touches the null value of 1.00 is also of importance



- The treatment effect in Figure 6 is similarly inflated with an odds ratio of 0.57, a 43% reduction of the odds of a poor functional outcome; the risk ratio is 0.74 with a 95% confidence interval between 0.64 and 0.87, a more modest 26% reduction in the risk of a poor functional outcome
- There is an additional error where the text does not match the figure: on page 615, the first paragraph refers to a WMD of 0.59 for activity pain, but the corresponding Figure 5 shows this to be an odds ratio, not a WMD
- Overall, the results do not support a clinically meaningful treatment effect of ESWT

Assessment: Inadequate for showing a favorable treatment effect of ESWT (wrong analyses and inflated estimates of treatment effects)