Chew KT, Leong D, et al. Comparison of autologous conditioned plasma injection, extracorporeal shockwave therapy, and conventional treatment for plantar fasciitis: a randomized trial. PM&R 2013;5:1035-1043

Design: randomized clinical trial

Purpose of study: to compare the effectiveness of autologous conditioned plasma injection (ACP), extracorporeal shockwave therapy (ESWT) , and stretching exercise in patients with plantar fasciitis

Population/sample size/setting:

- 54 patients (29 men, 25 women, mean age 46) treated for plantar fasciitis at a sports medicine facility in Singapore
- Eligibility criteria were a clinical diagnosis of plantar fasciitis with at least 4 months of plantar heel pain, point of maximal tenderness on clinical examination over the medial tubercle of the calcaneus, and plantar fascia thickness of at least 4 mm on a baseline sonogram
- Exclusion criteria were arthritis, fractures, or tumors of the foot or ankle, rheumatoid arthritis, generalized polyarthritis, seronegative arthropathy, diabetes mellitus, neurologic impairments, lower extremity nerve entrapment, vascular abnormalities, prior operative treatment of the foot, or current pregnancy

Interventions:

- All patients had conventional therapy defined as instruction in an independent daily home exercise program, including lunge stretch of the gastrocnemius and soleus plus seated plantar fascia stretch by pulling the toes of the affected foot crossed over the opposite thigh
    - This program included 1-2 sessions with a physical therapist to learn the exercise routine
    - Instructions were to stretch 3 times a day, 3 times for each stretch , with 30 seconds at a time for each stretch
- In addition, all patients had referrals for orthotics evaluation when the treating physician identified biomechanical foot abnormalities
- Randomization was to ACP (n=19), ESWT (n=19) or conventional therapy alone (n=16)
    - ACP was done with venipuncture drawing of 10 ml of whole blood and centrifuged at 1500 RPM for 5 minutes, followed by drawing 3 ml of the cell-rich part of the tube and injecting it with a 23 gauge needle at the site of

plantar fascia thickening and tenderness at the medial calcaneal tubercle under ultrasound guidance
    - ESWT was done in two sessions one week apart with 2000 shock waves over a period of 10 minutes, beginning at 0.02 mJ/mm^2 and progressing to 0.42 mJ/mm^2 without local anesthesia

Outcomes:

- Followup was done at 1 month, 3 months, and 6 months after the interventions were done
- The primary outcomes were median change scores from baseline on pain VAS, on the ankle-hindfoot scale of the American Orthopedic Foot and Ankle Society (AOFAS), and on plantar fascia thickness at the medial calcaneal tubercle insertion site
- The conventional treatment group had slightly better VAS and AOFAS scores at baseline compared to the other two groups, and the final VAS and AOFAS scores were similar for all three groups, all of whom improved compared to baseline
- However, the analysis of change scores for pain VAS showed higher median change scores for the ACP and ESWT groups compared to the conventional group at one month (though the 3 and 6 month median change scores were not significantly different between groups)
    - The median change scores for ACP and ESWT groups were the same, 2.0 points, compared to 0.75 points for the conventional treatment groups
- For AOFAS change scores, the median changes were greater for ACP (10 points) and for ESWT (14.5 points) than for conventional treatment (0.5 points) at one month; at 3 months, the median change scores were 15 points, 21 points, and 5 points; at 6 months, the median change scores were 36 points, 28 points, and 15.5 points respectively
- No adverse events were reported an any of the groups

Authors' conclusions:

- ACP and ESWT were comparable in terms of pain relief and functional improvement as assessed by the AOFAS scores, and both were superior to conventional treatment alone
- The subjects were not blinded to treatment assignment, and this could have influenced their perceptions of their improvement, since two of the treatments could have been seen as involving high technology
- The patients did not keep a compliance log for their exercises or orthotic use, and they did not keep a pain medication use or activity log during the study
- ACP and ESWT may be considered in patients whose plantar fasciitis symptoma hae not responded to conventional treatments

Comments:

- The authors explained the difference in median change scores as likely arising from the superior effectiveness of ACP and ESWT compared to home stretching alone
- However, part of the difference could have been due to non-blinding and to the patients' expectations for greater effectiveness of an active intervention by a physician
- In addition, the conventional group had better baseline scores on the VAS and AOFAS scores, and some of the explanation for greater median change scores for the ESWT and ACP groups could have arisen from regression to the mean rather than from the effects of the treatments themselves
    - Normally, regression to the mean can be controlled by the choices in analysis of the data, where analysis of covariance, using the baseline scores as a covariate, is used to compare the final pain and function scores
    - It is possible that the authors decided that their data was not normally distributed enough to warrant use of this analysis
    - The distribution of the data in the graphs (Figure1 and 2, for example) does appear as if it could have been skewed, justifying the use of median scores rather than mean scores
    - The final VAS and AOFAS scores at 6 months are very similar between groups, and the final status of the three groups is very nearly the same for pain and function
- Together, the lack of blinding and the statistical artifacts which could lead to better change scores in the ESWT and ACP groups, are likely to be sufficient to explain much of the recorded differences in the median change scores
- For this reason, the superiority of ACP over conventional stretching is probably very limited, and its effectiveness is not yet shown

Assessment: inadequate for evidence of the effectiveness of autologous plasma for the treatment of plantar fasciitis