
Design: randomized clinical trial

Purpose of study: to compare the effectiveness of trigger point dry needling versus sham dry needling in patients with plantar heel pain

Population/sample size/setting:
- 84 patients (44 men, 40 women, mean age 56) treated for plantar heel pain at a university gait studies program in Melbourne
- Eligibility criteria were age 18 or older, plantar heel pain (plantar fasciitis) for at least one month, first-step pain 20 mm or more on a 100 mm VAS, and no previous history of dry needling or acupuncture
- Exclusion criteria were potential contradictions to dry needling, fractures or infection of the heel, inflammatory disorders, and treatment for plantar heel pain in the past four weeks

Interventions:
- Randomization was to either dry needling (n=41) or sham dry needling (n=43) of trigger points which were identified in all patients with essential criteria
  - A tender point within a taut band of skeletal muscle
  - A characteristic pattern of referred pain
  - A local twitch response elicited on dry needling of the taut band
  - Patient recognition of pain on sustained compression over the tender point
- Each group had one 30 minute session per week for six weeks, using a curtain across the thoracic spine to maintain blinding of the patients
- Dry needling group was treated with acupuncture needles which were inserted into the muscle according to the number of trigger points identified in the muscle, the responsiveness of the patient’s toleration for needle insertion, and the degree of post-needle soreness for a specific muscle
  - Following insertion, the needle was partly withdrawn and then repeatedly advanced, after which it was left in place for five minutes
  - For the sham group, a sham needle was removed from its packaging to simulate removal of an actual acupuncture needle; the sham needle inside its guide tube was placed on the skin overlying the trigger point and the needle was taped to simulate needle insertion, then manipulated with an up and down motion several times, after which the practitioner pretended to remove the needle and disposed of a real needle in a sharps container

Outcomes:
Followup was done at 2, 4, 6, and 12 weeks.
The primary outcome was measured at six weeks, and included (1) first step pain on getting out of bed, using a 100 mm VAS where 0 is the best score and 100 is the worst, and (2) the pain subscale of the Foot Health Status Questionnaire (FHSQ) on a 100 point scale where 0 is the worst score and 100 is the best.

Several secondary measures were also taken, including the foot function and general foot health subscales of the FHSQ, the physical and mental scales of the SF-36, and self-reported magnitude of change on a 15 point Likert scale where +7 means “a very great deal better” and -7 means “a very great deal worse”.

For the primary endpoint of the FHSQ pain subscale, the authors powered the study to detect a minimal important difference (MID) of 13 points between groups and a MID of 19 points on the 100 mm pain VAS.

Both groups showed decreased pain at 6 weeks when the primary outcome was ascertained, but there were significant differences that favored dry needling over sham needling for the pain VAS:

- The dry needling group had a mean VAS of 67.7 at baseline and a VAS of 28.6 at 6 weeks
- The sham group had a mean VAS of 58.5 at baseline and a VAS of 38.3 at 6 weeks
- The group difference, adjusted for differences in baseline VAS scores, was 14.4 points (95% confidence interval from 0.3 to 23.5 points).

There were also differences at 6 weeks on the FHSQ in favor of dry needling:

- The dry needling group had a mean FHSQ pain of 32.9 at baseline and a FHSQ of 63.0 at 6 weeks
- The sham group had a mean FHSQ of 40.2 at baseline and a FHSQ of 55.7 at 6 weeks
- The group difference, adjusted for differences in baseline FHSQ scores, was 10.0 points (95% confidence interval from 1.0 to 19.1 points).

For the secondary endpoints of function on the FHSQ and for general foot health on the FHSQ, there were no differences between groups at 6 weeks.

Adverse events were transient and were related to needle site pain, which occurred in 70 dry needling appointments (32%), but in only 1 sham needling appointment.

There were no differences between groups in how believable and convincing the treatment appeared to the patients.

The most frequently treated muscles were the gastrocnemius, soleus, quadratus plantae, and abductor hallucis.

Authors’ conclusions:

- At the end of 6 weeks, there were statistically significant differences in the primary end point between dry needling and sham needling.
However, for both the pain VAS and the pain subscale of the FHSQ, the group differences were less than the MID which the study was looking for, since the MID for the FHSQ was 13 points (observed difference of 10.0 points) and was 19 points (observed difference of 14.4 points).

- The 95% confidence intervals for the group differences did include the MID for both the pain VAS and the pain FHSQ.
- The value of Cohen’s d (which detects the group differences in terms of standard deviations--SD), the value of d was 0.49 SD for first-step VAS pain and was 0.33 SD for the FHSQ.
- A value of 0.5 SD is considered a moderate effect size for Cohen’s d, and dry needling could have a moderate benefit on first-step pain by this criterion.

The benefit in terms of pain must be considered in relation to the high frequency of needle-related pain, which happened in one third of dry needling sessions but did not occur in the sham group.

The benefits may be due to nonspecific elements of the treatments in addition to specific effects on known pain pathways such as local blood flow and substance P.

Comments:

- The authors point out some limitations, including the lack of power to detect differences in foot function and the lack of blinding of the practitioner who did the needling or sham needling.

- Some of the exclusion criteria lack adequate definition.
  - “potential contraindications to dry needling” is not defined.
  - “treatment for plantar heel pain in the previous 4 weeks” is not defined and could include prescribed exercises such as stretching or the use of over-the-counter orthotics in the shoe.

- The source of the MID of 19 mm for first step pain was Landorf et al 2010, and that MID had a confidence interval from 13 to 25 mm; Landorf’s MID used for purposes of comparison is itself an estimate with some uncertainty surrounding it, and the value of Cohen’s d may provide an additional perspective on the effect size.
  - By convention, a value of d of 0.2 is small, a value of 0.5 is moderate, and a value of 0.8 is large.
  - The effect size measured by the authors for first step pain is moderate by these considerations.
  - However, the value of d for the FHSQ was 0.33, which is between a small and moderate effect size by the same conventional interpretation.

- The lack of an effect on the FHSQ functional scores probably shows an additional limitation on the usefulness of dry needling.

- Dry needling was painful in one third of the sessions in which it was used; it is not clear whether this was because one third of patients had pain with each session and
two thirds had no discomfort at all, or whether every patient had pain with one third of the sessions they attended, or some other mixture

- The frequent discomfort with the dry needling would be of concern to practitioners considering options for patients with plantar heel pain
- The overall usefulness of dry needling from the results of this study would appear to be quite small and of dubious clinical importance

Assessment: adequate for some evidence that in the setting of plantar fasciitis, six weekly sessions of dry needling have a small benefit for pain in the first steps in the morning, no measurable effects on foot function, and frequent local pain during the treatment sessions in which dry needling is used

Reference: