Achilles Pain Block

NCT 03316378

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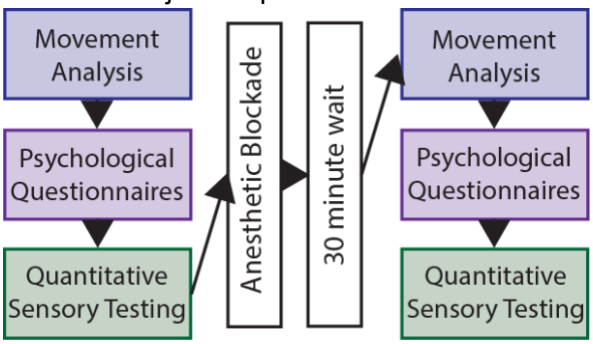
Study design

In this mechanistic, non-randomized controlled trial, all participants repeated testing twice in the following order within a single laboratory-based testing session: 1) pain-rating with activity, 2) movement analysis during high- and low-level tasks, 3) pain psychology questionnaires; 4) quantitative sensory testing (See figure below). The only difference in procedure between groups was that the AT group received an anesthetic injection after the first set of tests. For participants with bilateral AT the more painful side was designated the involved side for testing and injection. A sports medicine physician used sonographic guidance to inject 4 mL of 0.5% ropivacaine superficial and deep to the tendon to ensure coverage of the painful region. This dose was chosen based on clinical experience of the amount of ropivacaine needed to numb the area for minimally-invasive outpatient procedures. To minimize the risk of infection sterile technique was used, including sterile gloves, area of injection scrubbed, sterile gel, and a sterile transducer cover. The onset for ropivacaine was 10-20 minutes and pain relief lasted for 6-8 hours. Repeat testing began 30 minutes after the injection. Participants with AT were contacted 1-day and 1-week following testing to ask about any injection-related adverse events (e.g. increased pain, infection). All participants were contacted 1-week after testing to complete the pain catastrophizing scale (PCS).

Figure 1. All participants completed two sets of testing. The group with Achilles tendinopathy pain received a local anesthetic injection prior to repeat testing. The control group without Achilles tendinopathy pain did not receive an injection prior to the second set of testing.



Statistical Analysis

A priori power analysis determined that a sample size of 20 per group was needed to detect effect sizes (between groups≥0.91, between repeat tests≥0.68) less than or equal to published results for ankle power (mean difference= 0.9 W/kg, SD=0.9 W/kg)[1], kinesiophobia (minimal detectable change=5.6, SD=5.7)[2], and pressure pain threshold (group difference=171.8 kPA, SD=174.8 kPA) [3] with a power ≥80% and statistical significance defined as $P \leq 0.05$ (**Table 1**). Because 3 participants with AT had insufficient pain relief from the

anesthetic injection, an additional 3 participants were recruited per group to ensure adequate power, resulting in a final sample size of 46. Sample characteristics were compared between groups using independent samples t-test for parametric data, Mann-Whitney U test for non-parametric data, or Chi-square test for categorical data. Changes in Achilles tendon pain from pre-injection to post-injection were compared with Wilcoxon Signed Ranks tests. Mixed effects ANOVAs were used the examine the effects of group, time, and a group*time interaction for motor performance, pain psychology, and quantitative sensory testing. The type I error rate for the ANOVAs was maintained at 0.05 by using Bonferroni adjustment for multiple comparisons (3 tests for motor performance, 2 tests for pain psychology, 3 tests for quantitative sensory testing). Post-hoc comparisons were performed to examine significant interaction effects and p-values were adjusted using a Bonferroni adjustment for the number of time points compared (2 for TSK, 3 for PCS, 4 for quantitative sensory test). Pearson correlations examined relationships between the magnitude of change with an anesthetic injection of identified indicators of altered central processing in the AT group.

Table 1. Detectable effect sizes and published differences using proposed sample size and assumed SD

Primary outcome / *dependent variable*	Assumed SD	Detectable difference	Published difference
Specific Aim 1.1, n=40, between groups, *detectable effect size ≥0.91*			
PPT (Central sensitization)	174.8 kPa[3]	158.9 kPa	171.8 kPa[3]
TSK (Psychological factor)	5.7[2]	5.2	MDC= 5.6[2]
Ankle power (Motor control)	0.9 W/kg[1]	0.8 W/kg	0.9 W/kg[1]
Specific Aim 1.2, n=20, repeated measures, detectable *effect size ≥0.68*			
PPT (Central sensitization)	28%	19%	25.8%[4]
TSK (Psychological factor)	5.7[2]	3.8	MDC= 5.6[2]
Ankle power (Motor control)	0.9 W/kg[1]	0.6 W/kg	0.9 W/kg[1]

References

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3. Noehren B, Shuping L, Jones A, Akers DA, Bush HM, Sluka KA. Somatosensory and Biomechanical Abnormalities in Females with Patellofemoral Pain. *Clin. J. Pain.* Nov 26 2015.
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