

STUDY PROTOCOL

Effectiveness of custom-made foot orthoses vs heel lifts in children with Calcaneal Apophysitis (Sever disease): a randomized controlled trial

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Scientific Background

Calcaneal apophysitis (Sever disease) is a very common ailment present in the heel of children between 7 and 15 years old (1–5). Modern literature describes calcaneal apophysitis as a syndrome caused by overuse, resulting from the production of repetitive micro-traumas (3). Mechanical etiology relates the injury to the traction forces of triceps surae and plantar fascia on the calcaneus bony surface (3–6). The anatomical unit named ACPS describes the functional connection between the Achilles tendon, the calcaneus bone and the plantar fascia (6). There, the posterior trabecular calcaneal system works as a sesamoid bone between the fascia and the tendon fibers (6). Therefore, repetitive stress of the Achilles tendon and the plantar fascia is transmitted on the calcaneus surface affecting bone remodeling: creating perpendicular fibrous bands of cartilage in the secondary ossification center of the calcaneus (7). All this, in addition to repetitive impacts on the bony surface constitutes the focus of Sever's disease (5–8).

Sever disease, fortunately, is a benign ailment which disappears without exception after puberty when the secondary ossification center of the calcaneus is closed (9). Unfortunately, nowadays no evidence-based treatments are available (10). Nevertheless, conservative ones are the most commonly used; these include: sport activity modification, stretching and strengthening exercises and the application of podiatric strategies (heel-lifts and foot orthoses) (5,9–12).

Conservative strategies described in the foregoing paragraph are widely popular (10), but present a number of handicaps. Activity cessation means an increase of sedentary lifestyle, which is a major factor in obesity (13). The prescription of “off-the-shelf” heel-lifts is very widespread (9–12). These reduce pain levels because they elevate the heel, shortening distances between the triceps surae muscle and its insertion on the calcaneus (12). Unfortunately heel-lifts do not act completely on the mechanical etiology of Sever disease: ACPS traction and repetitive impacts (3,6,8). Heel-lifts only act on Achilles tendon traction, but lose both the effect of the plantar fascia and dissipating the impacts on the bony surface of the calcaneus (8,9).

Following this line, there are some studies in literature that have used orthoses to act both on ACPS and the repetitive impacts (8,11,12,14–16). Orthoses provide support in the medial arch (relaxing plantar fascia), include a heel-lift component and a wider support surface (dispelling impacts) (8,11,12,14–16). The available evidence reported the use of orthoses (8,11,14), but most of them were prefabricated and the studies reveal statistical analysis and methodological

concerns that limit the validity of the results reported (9,16,17). Nor studies have previously compare the use of “off-the-shelf” with custom-made orthotics (16).

Objective

The present research wanted to provide a pragmatic randomized controlled trial with an intervention period of 12 weeks, with the aim to compare heel pain perception in children with calcaneal apophysitis using a custom-made Ethyl Vinyl Acetate foot orthoses and “off-the-shelf” heel lifts. Therefore, it was hypothesized that the primary outcome, pain relief, would be significantly improved with the custom-made orthosis compared to the heel lift.

Design

The study was a parallel-group, randomized controlled trial with concealed allocation, blinding of investigators and assessors and intention-to-treat analysis. It examined the effect of custom-made foot orthoses and heel lifts in children with calcaneal apophysitis. Participants were enrolled at the time of Sever disease diagnosis. After baseline assessment, children were individually randomized to “custom-made foot orthoses” (experimental group) or “off-the-self heel lifts” (control group). Concealed allocation was carried out by having randomization performed by a third party who was not involved in the recruitment and treatment of the children. Eight permuted blocks were used to stratify randomization by BMI (20 versus > 20 kg/m 2), Lunge Test (35 versus $> 35^\circ$ of dorsal flexion), FPI (4 versus > 4) and by VAS score (74 versus > 74 mm) because these were considered as important risk factors associated with pain severity in Sever disease (2,14,18,19). A researcher who was unaware of the randomized group allocation measured the outcomes at baseline and 12 weeks later. The design of the present research was based on and executed according to the CONSORT Statement. The study was approved by the Ethics Committee of Clinical Research of Aragón (C.P.-C.I.PI16/0303)

Participants

All children with Sever disease diagnosis who came for an orthopaedic treatment at Podoactiva Headquarters Podiatric Clinic between September 2015 and April 2018 were assessed for study eligibility prior treatment application. Inclusion criteria included boys and girls between 9 and 12 years old diagnosed radiologically with calcaneal osteochondritis (10). Children were excluded if they: had suffered some trauma on the heel in the past 2 months; had received anti-inflammatory drugs and/or physical treatment for pain in the past 3 months; had presented

physical or neurological impairment; or were not interested. Informed consent form with parents' and children authorization was required to be part of the study.

Interventions

Before treatment application, all children received the following information about conservative strategies for pain reduction: triceps surae stretching, sport activity intensity reduction but no cessation and 10 minutes of ice application when pain exacerbation (10).

Each intervention (custom-made foot orthoses and heel lifts), consisted of a treatment period of 12 weeks. Both interventions were prescribed, designed and fabricated by a Podiatrist expert in orthopaedics, who was unaware of the randomized group allocations.

Experimental group

Children in the experimental group received as treatment intervention custom-made polypropylene foot orthoses (Podoactiva®, Spain). They were advised pragmatically to wear the orthoses at least 8 to 10 hours per day for the daily life and during sport activity.

Control group

Children in the control group received as treatment intervention an 8 mm "off-the-shelf" heel lift (Podoactiva®, Spain). They were advised pragmatically to wear the heel lifts at least 8 to 10 hours per day for the daily life and during sport activity.

Children were blinded to group allocation. Regardless to experimental or control group they received the same attention during the consultation and they were informed that the intervention given was adequate for their disease, before treatment application and after the follow-up.

Outcome measures

All the outcomes were obtained by an experienced and trained assessor who was blinded to group allocation. At baseline participant's weight and height were measured during each session with an Año-Sayol scale and stadiometer, respectively (Año-Sayol SL, Barcelona, Spain).

The primary outcome was Sever disease pain perception, which was determined by three ways: VAS, algometry and by the following question: "Do you have pain at sport activity?" which had

to be answered by YES or NOT (Sport Activity Pain dependent variable). The VAS is commonly used to measure pain perception (20), and has been used before to measure pain perception in children with calcaneal apophysitis (14,19). The VAS is described as a horizontal line 100 mm in length where at each end points the words “No pain” and “Worst imaginable pain” are placed (18,20). Participants were asked to mark the line at the point which best represents the level of pain intensity that they were experiencing (14). Algometry is commonly used to measure pressure-pain threshold (21). To perform the algometry, the Wagner FPX™ 25 Algometer (Wagner Instruments®, USA) was used. It had been used before in children with calcaneal apophysitis (10). To perform the algometry children were asked to lie down in prone position on the stretcher, with knee and ankle bent 90°. Then the algometer was positioned on the Achilles tendon insertion on the calcaneus. Three separate measurements were obtained and the average of them was taken as algometry value (10).

Secondary outcomes were to determine the values of the FPI and the Lunge Test in the children with Sever disease. The FPI was performed following the guidelines of Redmond et al (22). FPI is a 6-point tool for clinical assessment, which evaluates the multisegmental nature of foot posture in the three spatial dimensions. Each component of the test is graded between -2 and +2 (signs of supination or pronation), where neutral is graded with 0. Finally, a score range from -12 (highly supinated) to +12 (highly pronated) is obtained (22–24). Lunge Test is commonly used to determine shortness in triceps surae muscle (2,24). Restriction in the length of this muscle is considered when the dorsal flexion of the ankle is less than 38-35° (2,5,23,24).

Statistical analysis plan

Sample size estimation was based on the detection of a difference of 29% in the number of children with pain; and a mean difference of 0.39 or superior for the algometry and the VAS, between baseline and after the follow up based on a previous pilot study (2). Assuming a two-side α of 0.05, power of 80%, and a 10% drop-out rate, a sample size of 198 participants was required. Continuous variables were expressed as mean \pm standard deviation (SD) whereas qualitative variables were expressed as frequencies and percentages. Continuous data were checked for normality by Kolmogorov-Smirnov Test.

The baseline characteristics of the children were summarized using descriptive statistics and tabulated for comparison between intervention groups. Baseline characteristics were compared between included and excluded participants to analyze whether they were representative. Mann-Whitney U and T-Student Tests were used to compare continuous variables and the Fisher Test to compare dichotomous variables.

Differences between baseline and final assessment were performed using the average-to-average method. Mann-Whitney U Test was used to compare absolute and relative changes in algometry and VAS. McNemar Test was applied to calculate the improvement, which was positive when subjects changed from pain situation to no pain situation for the dependent variable Sport Activity Pain. Identifying treatment effectiveness after the follow-up was made by regression models. Linear regression was applied to quantitative variables, algometry and VAS, and logistic regression to dichotomous qualitative variables, association was measured in terms of odds ratio.

Statistical analysis of the outcomes was performed according to intention-to-treat principles compared the groups regarding pain perception evolution. For all tests, a two-sided p-value <0.05 was considered significant. The statistical analyses were performed using the SPSS software 22.0 for Windows (SPSS Ibérica, Madrid, Spain).

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