Unlocking the impact of foot-ankle exercises on clinical and plantar pressure outcomes in diabetic peripheral neuropathy: mediation analysis of an RCT

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Summary

This study explored the effects of a 12-week foot-ankle exercise program, delivered through the Sistema de Orientação ao Pé Diabético (SOPeD), on individuals with diabetic peripheral neuropathy (DPN). Sixty-two participants were randomized to either the intervention or usual care group. The program involved three weekly sessions focused on strengthening and stretching foot muscles. Outcomes (foot pain, function, and plantar pressure) and mediators (muscle strength, foot pain, foot function, ankle range of motion, and plantarflexion during gait) were assessed at baseline, 12 and 24 weeks. Mediation analysis showed significant indirect effects: reduced foot pain and improved plantarflexion at push-off mediated better foot function; enhanced foot function mediated reduced peak plantar pressure; and increased ankle range of motion mediated higher forefoot pressure–time integral. These findings highlight the pathways through which foot-ankle exercises improve function, reduce pain, and impact plantar pressure in DPN.

Introduction

Understanding how complex physical therapy interventions exert their effects is essential for effective implementation and better patient outcomes [1]. Foot-ankle exercises targeting modifiable risk factors, such as peak plantar pressure, ankle mobility, and muscle strength, may reduce ulcer risk and improve gait in diabetic peripheral neuropathy [2]. Mediation analysis, especially in randomized controlled trials, helps to uncover these pathways, providing insights into how these exercises influence clinical and plantar pressure outcomes [3]. Therefore, the aim of this study was to identify the causal pathways through which a 12-week foot-ankle exercise program improved foot function, pain, and plantar pressure during gait by examining key mediators of these effects.

Methods

A total of 62 participants with DPN were randomly assigned to either a web-based foot-ankle exercise program or usual care. Participants in the intervention group accessed the program through the SOPeD. The web-based program consisted of three exercise sessions per week over a 12-week period, totaling 36 sessions. Each session lasted between 20 to 30 minutes and focused on strengthening and stretching both extrinsic and intrinsic foot muscles. The intensity of the exercises was adjusted based on each participant's perceived effort, which was recorded in the software. The outcomes were peak pressure and pressure–time integral at the forefoot, foot pain, and foot function, and the mediators included hallux and toe strength, ankle range of motion, plantarflexion at push-off, ankle extensor moment, and foot pain and function. Outcomes and mediators were assessed at baseline, 12 weeks, and 24 weeks. Mediation models were tested using ordinary least squares regression with bias-corrected bootstrap confidence intervals to infer indirect effects. The original study protocol was approved by the Ethics Committee of the School of Medicine at the University of São Paulo (CAAE: 90331718.4.0000.0065) and was registered at ClinicalTrials.gov on July 8, 2019 (NCT04011267).

Results and Discussion

The mediation analysis showed significant indirect effects: foot pain (1.71, 95% CI: 0.21, 4.43) and ankle plantarflexion at push-off (0.45, 95% CI: 0.15, 0.74) mediated improvements in foot function, foot function (3.84, 95% CI: 1.04, 11.38) mediated reductions in forefoot peak pressure, and ankle range of motion (9.02, 95% CI: 2.47, 17.68) mediated increases in the forefoot pressure–time integral. We initially hypothesized that an improvement in foot strength could be a mediator of the reduction in the peak pressure and foot pain; however, our analyses showed that the small changes in foot strength did not significantly mediate the intervention's effects on reducing peak plantar pressure and foot pain. Future studies should consider including other physiological and psychological variables into the trial planning and thus in the multiple regression models to capture the full range of mediated effects on outcomes.

Conclusions

This study showcases the mechanisms underlying the effects of the SOPeD exercise program in reducing foot pain and enhancing ankle plantarflexion during push-off, which in turn mediated improvements in foot function in people with DPN. Additionally, we showed that an increase in the ankle range of motion mediated an increase in the pressure–time integral at the forefoot after 12 weeks of exercise.

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