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ORIGINAL ARTICLE

Effects of an isometric exercise training program on muscular strength, ankle mobility, and balance in patients with diabetic peripheral neuropathy in the lower legs in South Africa

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Abstract

Background Patients who suffer from diabetic peripheral neuropathy in the lower leg experience a greater risk of falls due to a decrease in strength of the lower extremities.

Methods Fourteen participants, diagnosed with diabetic peripheral neuropathy or nocturnal allodynia in either one or both extremities, volunteered to participate in this study. Participants were purposively selected from two private Podiatry practices based on their signs and symptoms, age, gender, and doctor's clearance to participate in any form of physical activity. Dependent variables included isometric muscle strength of the hip, knee and ankle, range of motion of the ankle in plantarflexion and dorsiflexion and an assessment of balance, which were measured pre- and post-intervention. The researcher developed a scientifically based exercise intervention program to target the entire kinetic chain, and to develop a standard isometric protocol for patients with DPN. The intervention program consisted of a combination of ankle, hip, and knee specific rehabilitation. The intervention took place 3 times a week for 45 min per session.

Results The Mann-Whitney test was used to evaluate the differences in dependent variables from pre- to post-intervention. The level of significance was set at $p<0.05$. Notable increases were observed in range of motion in ankle plantarflexion and in balance time in the intervention group, post-intervention.

Conclusions Although many of the changes noted were insignificant, the trends indicated an improvement in the intervention group over the 10-week intervention period. These improvements can be considered clinically important.

Keywords Diabetic autonomic neuropathy · Diabetic nerve pain · Distal polyneuropathy · Hyperglycemia · Peripheral neuropathy · Pressure air biofeedback system

Introduction

One of the main complications of diabetes mellitus (DM) is diabetic peripheral neuropathy (DPN) and can be classified as a decrease in sensation and proprioception in the distal extremities [1]. Diabetic neuropathy is a result of nerve damage caused by chronically uncontrolled high blood glucose levels and is a common complication of DM, affecting up to 50% of patients suffering from both types of diabetes [2]. Since DM frequently results in peripheral neuropathies, the result is associated with reduced muscle strength and balance, gait impairment, and decreased ankle stability [3, 4]. Hip alterations during walking occur due to a decrease in strength in the plantar flexion muscle group. Patients with DPN experience a decrease in movement during the late stance phase of gait. Due to the strength deficit, the patient will adapt a "hip strategy" [3], where the leg is pulled forward using the hip flexors instead of using the plantar flexor muscles to push forward (ankle strategy). This phenomenon is also known as the "slowness strategy" [3]. Diabetic sarcopenia is associated with systematic insulin resistance, which is related to mobility disorders and is associated with a decrease in muscle activation and a decrease in myofascial structures, leading to an increased fall risk in DM patients [5]. Approximately, 2.1% of

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the world's population suffer from DM [6], which currently affects over 420 million people worldwide [6, 7], with the prevalence of DM still increasing rapidly each year [8]. As a result, DM can have a major impact on one's quality of life due to high-risk complications that may be either chronic or acute [9–11].

In South Africa, the most common form of DM is type II, with less than 10% of reported cases being type I. In an audit conducted in 1997 of 300 people with DM in Cape Town, 27% had diabetic neuropathy [12], while in 2012, the SANHANES-1 report [13] indicated that, among individuals with diabetes, nearly half were unscreened (45.4%). An additional 14.7% were screened but undiagnosed, 2.3% were diagnosed but untreated, and 18.1% were treated but uncontrolled. With the current prevalence of DM in South Africa being unclear, the IDF estimated that, by 2025, 7.04% (3.5 million) of the total South African population will have DM and a further 1.5 million will be undiagnosed [14]. Thus, the prevalence of diabetes in South Africa appears to be increasing over time and it appears that a large proportion of individuals in South Africa may be susceptible to DPN and that more research needs to be conducted in this area.

The treatment of those diagnosed with DPN in South Africa, however, is inadequate and a course of action must be implemented to improve both its diagnosis and management [15]. It is well known that exercise training improves and increases muscle mass, decreases blood pressure, and improves glucose tolerance [16–18]. Early aerobic and resistance training intervention is of great benefit to DM patients, as it is an effective way to control blood glucose levels and enhance insulin action up to 72 h [2]. Improvements thereof lead to health-related quality of life. Further, a combination of lower limb muscle strengthening, balance, and proprioceptive rehabilitation improves range of motion, balance, muscular strength, and glycated hemoglobin in older patients with DPN [19–21]. Low-intensity exercise improves/enhances vascular and metabolic pathways, which decreases painful neuropathic symptoms and improves quality of life [22]. In other words, exercise is an excellent treatment modality for people with DPN. Therefore, the purpose of this research study was to evaluate the effectiveness of an exercise protocol that was developed for people with DPN and was different from the standard clinical protocol commonly used today.

Materials and methods

Design and sampling

The research design was a pre-test post-test study using quantitative methods. A single-blind approach was chosen as only the researcher knew which treatment the participants would receive, as this would have led to spurious results. The study was designed to evaluate muscular strength and flexibility of the ankle joint, as well as balance, to determine if an exercise intervention would be effective treatment for patients who suffer from DPN in the lower leg. Patient files were conveniently selected from two Podiatry practices to determine DM status. Those with a confirmed diagnosis of DPN were approached to be part of the study. Participants received an information leaflet and a consent form prior to the recruitment process of the study took place. Recruitment was strictly voluntary, and participants had the right to withdraw without penalty. Before signing the consent form, volunteers were assured that they had the right to withdraw from the study at any time without any penalties. The final study sample consisted of 14 participants, aged 18–80 years. The inclusion criteria for the study comprised DPN in one or both lower limbs, any age, male or female, any level on physical activity, and a pre-test health risk evaluation done by their doctor. Exclusion criteria included any current fracture(s) or any injury in the lower limb and any participant who suffered from foot ulcers.

Procedures

A total of 14 participants underwent pre- and post-intervention testing, which consisted of the following: range of motion of the ankle in plantar- and dorsiflexion using goniometry, a static balance test, using the stork stand test, and an isometric strength assessment of the muscles surrounding the hip (gluteus maximus, gluteus medius and gluteus minimus, piriformis, adductor magnus and the long head of the biceps femoris), knee (vastus lateralis, vastus medialis, vastus intermedius, and rectus femoris) and ankle (the tibialis anterior, extensor hallicus longus, extensor digitorum longus and the peroneus tertius [ankle plantarflexion], and tibialis posterior, peroneus longus, peroneus brevis, flexor hallucis longus and the flexor digitorium longus [ankle dorsiflexion] muscles) and joints using a pressure air biofeedback system. All 14 participants were then randomly divided into an intervention group and a comparison group. The process of randomization was based on previous diagnosis of diabetic peripheral sensory neuropathy in one or both lower limbs, participants' symptom severity, and a clinical assessment and diagnosis conducted by a Registered Podiatrist. Assessment tools utilized to diagnose neuropathy included a Tip-Therm, 28Hz Tuning Fork, 10g Semmes Weinstien Monofilament, 2-point discriminator, and a patellar hammer. The intervention group received a 10-week training program specifically designed by a clinical exercise specialist (biokineticist) for people with diabetic neuropathy. At the end of the study, the intervention training program was offered to the comparison group, so that they too could benefit from the study. The participants from both groups received the intervention programs along with the necessary rehabilitation equipment. Each exercise was explained and demonstrated in detail to all the participants. Due to the worldwide pandemic (COVID-19), the restrictions in place, and the severity of the disease, no long-term follow-ups could have been implemented, which restricted the time frame of the research and exercise intervention and follow-up.

Blood pressure

An aneroid blood pressure cuff and stethoscope were used to measure the participants' blood pressure before, during and after exercise to ensure the participant was not hypo- or hypertensive as these are both absolute indications to terminate any exercise training according to the ACSM [23–25]. The participant was asked to take a seat during the before and after exercise readings with their feet flat on the floor and legs uncrossed. The reading was recorded in millimeters of mercury (mmHg) and any false or abnormal measurements were noted and acted upon immediately.

Blood glucose

A Contour Plus® blood glucose analyzer was used to measure the participants' blood glucose levels. Blood glucose was measured before, during, and after exercise to monitor the participant's glycemic state. Blood glucose was measured 5 min before the exercise session took place, 5 min after the first set of exercises, and 5 min after the session was completed. The clinician strictly followed the universal health precautions for drawing blood [26] and always used medical gloves during the procedure. A single-use lancet was used to draw a sample of blood from the index finger, which was applied to the testing strip, according to the manufacturer's specifications. The reading was measured and recorded in millimoles per liter (mmol L^{-1}). The participant was informed about the results, which were explained and discussed immediately.

Ankle mobility

Ankle mobility (range of motion) was assessed in plantar and dorsiflexion. The participant was asked to sit upright on a plinth, with legs straight and both ankles slightly elevated over a rolled towel. For both plantarflexion and dorsiflexion, the researcher placed the fulcrum of the goniometer over the lateral malleolus with the proximal arm being placed along the fibula using the head of the fibula for reference.

Balance

The stork stand test was utilized to measure static balance. A static test was used as a dynamic test would have led to an increased risk of injury and/or pain and discomfort. The participants performed the stork stand test on both legs with their shoes removed and with their hands on their hips. The amount of time that the participant was able to stand on one leg was measured in seconds. The stork stand test is a valid and reliable test method to use to measure static balance for any age group.

Isometric muscular strength

The Pressure Air Biofeedback System® (PAB) was used to measure isometric muscle function. This device measures the force applied to an air bladder located inside the product. The device enables the clinician to test maximum isometric strength as well as fatigue performance patterns of the muscles. Assessing isometric muscular strength allows the clinician to evaluate the patient's maximum muscular strength within the patient's ROM capacity and the ability to produce sufficient strength in the various joints in particular movement patterns. Specific movements, such as hip extension (Fig. 1a), knee extension (Fig. 1b) and ankle-plantar (Fig. 1c), and dorsiflexion (Fig. 1d), were conducted.

Exercise intervention

For this study, the researcher developed an isometric exercise protocol for people with DPN, which was different from the standard isometric clinical protocol commonly used today, and designed to specifically target the entire kinetic chain, and to assist in developing an effective isometric protocol for patients with DPN that will help reduce fall risks. The program consisted of low intensity muscular strength training exercises, low intensity static and passive stretches, balance training and proprioceptive rehabilitation exercises to increase muscular strength, ROM and balance time and decrease fall risk. The 10-week intervention took place 3 times a week for 45 min per session and was divided in three categories: range of motion exercises, strengthening exercises, and balance and proprioception training exercises. All exercise sessions were conducted under strict supervision of the researcher. Progression of exercises was determined and adjusted according to each participant's individual progress. Where progression was needed, an increase in repetitions and intensity was made accordingly.

Results

A Mann-Whitney test was used to evaluate the differences in dependent variables from pre- to post-intervention. The level of significance was set at $p<0.05$. The only notable increases observed were for range of motion in the right ankle plantarflexion ($p=0.022$) and balance time ($p=0.018$) for the left and right leg in the intervention group after a 10-week follow-up assessment. However, a decrease in systolic (−9.09%) and diastolic blood pressure (−13.89%) and a

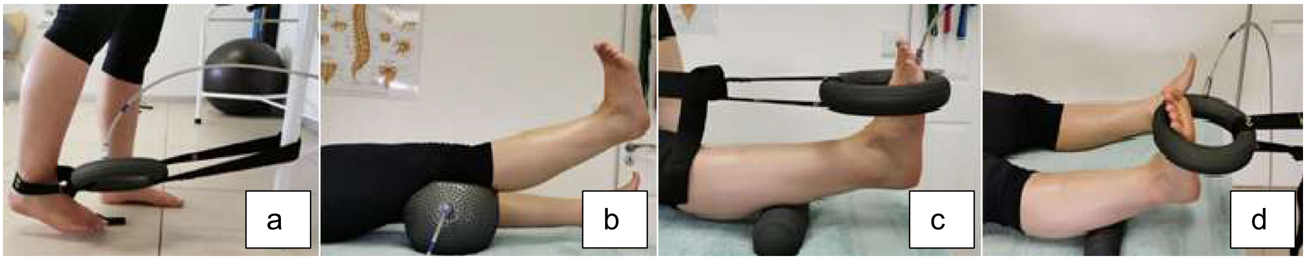

Fig. 1 Isometric muscle testing using the Pressure Air Biofeedback System. (**a**) Hip extension, (**b**) Knee extension, (**c**) Ankle-plantar flexion, (**d**) Ankle dorsiflexion

decrease in blood glucose levels (−17.89%) were observed post-intervention for the intervention group, which may be clinically important, as an increase in these variables was noted in the comparison group.An increase in plantarflexion, 8% (left) and 8% (right) and dorsiflexion 5.26% (left) and an 11.11% (right) increase in ROM for both left and right ankles, and balance time for both legs, 200% (left) and 159% (right) were observed in the intervention group post-intervention. The muscular strength variables showed a mix of an increase and decrease in strength post-intervention for the intervention group; however, they were insignificant. The strength test results observed in the comparison group post-intervention may also be clinically important. A summary of the expected and observed changes from pre- to post-intervention results is presented in Table 1.

Discussion

Diabetes mellitus is increasing rapidly worldwide each year and the prevalence of DPN is increasing along with the duration of DM [27]. It is predicted that in the year 2030, more

Table 1 A summary of the expected and observed changes from pre- to post-intervention

Variable	Expected change post-intervention (intervention group)	Observed change	
		Control group	Intervention group
Blood glucose (mmol L^{-1})	⬇	⬆ (37.84%)*	⬇ (−17.89%)
Systolic blood pressure (mmHg)	⬇	⬇ (−4.69%)*	⬇ (−9.09%)
Diastolic blood pressure (mmHg)	⬇	⬇ (−10.0%)	⬇ (−13.89%)
ROM plantarflexion (deg)			
Left ankle	⬆	⬇ (−4.62%)	⬆ (12.81%)
Right ankle	⬆	⬇ (−3.23%)	⬆ (8%)*
ROM dorsiflexion (deg)			
Left ankle	⬆	⬌	⬆ (5.26%)
Right ankle	⬆	⬆ (4.17%)	⬆ (11.11%)
Stork stand (s)			
Left leg	⬆	⬆ (77.65%)	⬆ (200%)*
Right leg	⬆	⬆ (2.95%)	⬆ (159%)*
Strength in extension (kg)			
Left knee	⬆	⬆ (22.78%)	⬇ (−10.65%)
Right knee	⬆	⬆ (2.95%)	⬆ (179.63%)
Strength in plantarflexion (kg)			
Left ankle	⬆	⬆ (41.67%)	⬆ (27.45%)
Right ankle	⬆	⬇ (−27.47%)	⬆ (31. 37%)
Strength in dorsiflexion (kg)			
Left ankle	⬆	⬇ (−41.07%)	⬇ (−31.43%)
Right ankle	⬆	⬇ (−34.88%)	⬇ (−17.24%)
Strength in extension (kg)			
Left hip	⬆	⬇ (−36.04%)	⬇ (−10.53%)
Right hip	⬆	⬆ (27.78%)	⬆ (22.92%)

Key: ⬆ increased; ⬇ decreased; ⬌ unchanged. *Significant at $p<0.05$

than 70% of people living with T2DM will reside in developing countries, and primary prevention of type II DM should be an urgent priority for such regions [28]. Proper assessments and intervention programs will guide clinicians to identify physical characteristics where improvements are required [29]. It is important for clinicians to understand the effect of DPN on muscular strength and balance, to be able to prescribe appropriate rehabilitation protocols to improve the quality of life of DPN patients [5]. Exercise training improves mitochondrial function, improving insulin sensitivity and glucose tolerance, and decreases blood pressure and increases muscle mass [17, 20]. Static range of motion/flexibility training is frequently used to increase joint mobility and flexibility and decrease the risk of any injury; balance and proprioceptive training decreases fall risk and improves postural stability in DPN patients [17, 20]. This pre- and post-intervention study was undertaken to evaluate the effectiveness of an isometric rehabilitation program for patients with DM, as there is a lack of currently researched protocols available for patients with DPN in South Africa. In this study, it was evident that a 10-week isometric rehabilitation program improved ankle range of motion (plantar- and dorsiflexion) and muscular strength of the surrounding musculature of the hip, knee, and ankle, and increased balance time. The researcher also found a non-significant decrease in blood pressure and blood glucose levels. These findings have important clinical implications for DPN patients as these improvements would improve quality of life of patients with DPN in South Africa. It has been shown that exercise positively affects blood glucose homeostasis, which improves due to structural remodeling of skeletal muscle as a result of the exercise intervention, and muscular strength/resistance training reduces systolic blood pressure in DPN patients [17, 20], which is supported by the findings in this study. Further, a combination of strengthening, balance, and proprioceptive rehabilitation will improve their gait patterns and decrease fall risk, leading to improved quality of life [20]. This study showed meaningful changes in objective measurements, and it appears to have been a clinically effective program for people with DPN in South Africa.

The total number of participants completing this study was affected by the following: COVID-19 restrictions, no clearance from a doctor to participate in any form of physical activity, noncompliance from participants and participants being medically booked off activities due to other chronic diseases/conditions. Therefore, a larger sample size would have increased the power of the study. Recommendations for future research include evaluations of isotonic muscle contractions of the entire kinetic chain, development and evaluation of isometric rehabilitation protocols based on the PAB® and to include the use of electromyography in the assessments of the distal musculature, to evaluate muscle function and to adapt specific rehabilitation exercises accordingly.

Conclusion

Individual, scientifically based rehabilitation protocols/interventions can be prescribed to DPN patients to improve muscular strength in the lower limbs and to improve overall muscular strength and endurance and improving functional capacity in the performance of daily living activities. The findings of this study indicate that an isometric evaluation and exercise program is effective in the treatment of DPN to evaluate and determine an effective treatment plan/intervention for patients with DPN, and to determine muscular strength deficits in both lower limbs in patients with DPN in South Africa.

Data availability Available

Code availability Not applicable

Declarations

Conflict of interest The authors declare no competing interests.

Ethics approval The study protocol was approved by the institution's Biomedical Research Ethics Committee (Ethics number: BM19/7/12).

Consent to participate Informed consent has been obtained from all the participants prior to the inclusion into the study.

Consent for publication The participant provided informed consent for publication of the images in Fig. 1a, b, c, and d.

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