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Original Article

Effects of whole-body vibration therapy on perception thresholds of type 2 diabetic patients with peripheral neuropathy: a randomized controlled trial

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Abstract. [Purpose] The aim of this study was to investigate the effect of whole-body vibration training on perception thresholds in type 2 diabetic patients with peripheral neuropathy. [Subjects and Methods] Fifty-nine patients with diabetic neuropathy participated in the study. They were randomly divided into the experimental group (n=29) and the control group (n=30). The experimental group performed whole-body vibration training, whereas the control group performed only lower body training in the same posture without using whole-body vibrator for 6 weeks. Perception threshold variables were measured to examine the effect of training. [Results] Warm and cold pain thresholds did not show significant changes in both groups before and after training. Vibration perception threshold showed significant improvement in the experimental group. [Conclusion] Our findings suggest that whole-body vibration training can improve vibration perception threshold of type 2 diabetic patients with peripheral neuropathy.

Key words: Diabetes, Whole-body vibration, Perception threshold

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INTRODUCTION

Type 2 diabetes is a metabolic disorder closely related to aging¹⁾. The International Diabetes Federation estimates that there will be approximately 642 million diabetics by 2040²). More than 90% of diabetic patients have type 2 diabetes, and 94 million of the elderly are aged between 65 and 79 years²).

Diabetes itself is a problem, but more problems are caused by secondary diseases such as cardiovascular and metabolic diseases³⁾. Diabetic complications mainly include circulatory disturbances resulting from ischemia and hypoxia in peripheral tissues due to inappropriate blood glucose control⁴). Typical complications include vascular complications, such as diabetic retinopathy and nephropathy, and neuropathy and diabetic foot^{3, 4)}.

Diabetic neuropathy is a common complication that occurs in more than half of diabetic patients, causing disturbance of balance due to central and peripheral nervous system transmission disturbances⁵⁾. Loss of sensory perception delays response time to the stimulus and reduces muscle-nervous system response⁶⁾. The lack of inherent receptive sensory feedback from the lower limb leads to posture instability⁷⁾. Diabetic neuropathy patients are at increased risk of falls^{5, 8)}. Therefore, treatment and management of neuropathic diabetes mellitus aims to improve peripheral nerve senses as well as blood glucose control⁹⁾.

Whole-body vibration (WBV) has been used in patients with neurological or musculoskeletal disorders as a new and effective intervention method to improve physical function 10, 11). WBV recently has been applied to improve the strength and balance of diabetic patients^{12, 13)}, but it is yet to be applied as a therapeutic method for improving sensation.

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The effect of WBV is manifested by muscle contraction, facilitation of sensory inputs, and stimulation of proprioceptive receptors. A few studies have tried to improve perception threshold with WBV^{14–16}). One study found that the vibro-tactile threshold decreased after 48 hours of short-term WBV application in healthy adults, but the acute response of a single WBV increased¹⁵). Therefore, the need for longer interventions is being discussed to improve tactile threshold¹⁵). Another study reported that WBV in healthy adults reduced plantar foot sensitivity and improved balance control¹⁶).

Perception threshold has been previously used to screen for neuropathy, and it is important to identify the effect of WBV on perception threshold in patients who are at risk of neuropathy, such as patients with diabetes.

The aim of this study was to verify the effect of 6-week WBV training on perception thresholds of neuropathic diabetic elderly.

SUBJECTS AND METHODS

We recruited 78 type 2 diabetic elderly people who participated in the exercise program at the K-Welfare Center in Republic of Korea. Inclusion criteria were age of 65 years and older, one or more falls within the past 12 months, and diabetic peripheral neuropathy diagnosed by a physician. Exclusion criteria were presence of musculoskeletal abnormality, inability to stand independently, neurological impairment, and a Mini-Mental State Examination score of less than 24.

We explained each subject all the experimental procedures and got their written consent. All experiments were

conducted with the confirmation of institutional review board of Sahmyook University. This study was a single-blinded randomized controlled trial. Sixty subjects who met the selection criteria were randomly divided into two groups, the experimental group (n=30) and the control group (n=30), using Random Allocation Software (version 2.0) (Fig. 1).

The experimental group performed WBV training using whole body vibrator for 11 minutes per session 3 times a week for 6 weeks, whereas the control group performed lower body training in the same posture without using the whole-body vibrator for 11 minutes per session 3 times a week for 6 weeks. WBV training was performed under the supervision of a physical therapist by using a vibration platform (Galileo 2000, Novotec Medical GmBH, Germany). The subject stood on the platform with his/her feet barefoot shoulder width and stared at the front. The subject bent the knee a little (30°), so that vibration did not reach up to the head. To prevent falls, the subject held the railing. Anyone who felt fatigue or dizziness during training had a rest. The training was performed at a frequency of 12 Hz and amplitude of 1–3 mm. The training comprised of 3×3 -min bouts of WBV with 1-min intervals between bouts. The control group was trained at the same time, position, and frequency as the experimental group but without WBV.

Thermal perception thresholds, including warm and cold thresholds, were assessed by a thermal sensory analyzer (TSA-II, MEDOC, Ramat Yishai, Israel). Thermal thresholds were derived using a feedback controlled Peltier stimulator with a 9 cm² contact area. A modified Marstock protocol ('method of limits' protocol in the TSA-II software) was used to determine warm and cold stimuli detection thresholds. The protocol started with the thermal probe comfortably strapped to the test site for 1 min at an adapting temperature of 32°C. Thereafter, the temperature was increased (or decreased in separate blocks of trials) at a rate of 1°C/s until the subject pushed the response button to indicate that he/she felt the warm and the cold pain stimuli. At that point, the probe temperature returned to the adapting temperature for an inter-stimulus interval of 6–10 s before the next stimulus. The threshold was taken as the median temperature at the time of the button press of 4 trials.

Vibratory thresholds were additionally measured using a vibratory sensory analyzer (VSA-3000, Medoc, Minneapolis, MN, USA). This computerized device vibrated at a constant frequency (100 Hz), with amplitude increasing from 0 to $25\mu m$. The vibrator head was placed over the skin at a constant force pressure and the patient was asked to press a signal-button immediately at the first perception of vibration. The vibratory threshold, expressed in micrometers, was defined as the mean of 5 consecutive trials. Vibration perception threshold (VPT) was quantified using the "method of limits," a protocol in which repeated increasing vibratory stimulation is applied to the plantar aspect of the dominant great toe. Subjects pushed a button on a hand-held indicator as soon as they detected vibration.

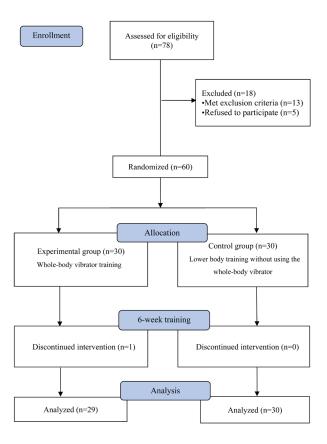


Fig. 1. Experimental flow diagram according to CONSORT

Table 1. General characteristics of the subjects

| | All | Experimental group | Control group |
|--------------------------------------|-----------------|--------------------|-----------------|
| | (N=59) | (n=29) | (n=30) |
| Age (years) | 71.8 ± 4.0 | 71.3 ± 3.7 | 72.1 ± 4.3 |
| Height (cm) | 163.4 ± 8.2 | 164.8 ± 6.8 | 161.9 ± 9.3 |
| Weight (kg) | 61.8 ± 8.3 | 62.7 ± 7.4 | 60.9 ± 9.1 |
| BMI (kg/m^2) | 6.8 ± 2.1 | 23.1 ± 2.4 | 23.1 ± 1.8 |
| Gender (male/female) | 37/22 | 19/10 | 18/12 |
| History of falls(Yes/No) | 39/20 | 20/9 | 19/11 |
| Medication (Yes/No) | 41/18 | 21/8 | 20/10 |
| Exercise (regular/non-regular) | 17/25 | 1/11 | 16/14 |
| Perceived general health (Fair/Poor) | 46/59 | 16/34 | 30/25 |
| Duration of diabetes (years) | 15.9 ± 6.8 | 15.4 ± 7.1 | 16.3 ± 6.7 |
| Hemoglobin A1c (%) | 8.4 ± 1.1 | 8.5 ± 1.1 | 8.2 ± 1.1 |
| MMSE (points) | 25.8 ± 1.1 | 25.8 ± 1.2 | 25.7 ± 0.9 |

BMI: body mass index; MMSE: mini mental state examination

Values are expressed as mean \pm standard deviation.

Table 2. Comparison of perception thresholds between experimental and control group (N=59)

| | | Experimental group | Control group |
|----------|----------|----------------------------|-----------------|
| | | (n=29) | (n=30) |
| CPT (°C) | Pre | 10.7 ± 5.7 | 11.5 ± 5.7 |
| | Post | 10.9 ± 6.8 | 10.6 ± 3.1 |
| | Pre-Post | 0.3 ± 6.6 | -0.9 ± 6.1 |
| HPT (°C) | Pre | 50.7 ± 6.7 | 51.6 ± 8.5 |
| | Post | 48.2 ± 9.6 | 48.5 ± 9.5 |
| | Pre-Post | -2.5 ± 10.8 | -3.1 ± 13.6 |
| VPT (mm) | Pre | 45.4 ± 16.8 | 41.1 ± 19.2 |
| | Post | 35.7 ± 17.6 | 40.1 ± 19.2 |
| | Pre-Post | $-9.7 \pm 17.3^{*\dagger}$ | -1.0 ± 7.6 |

CPT: cold pain threshold; WPT: warm pain threshold;

VPT: vibration perception threshold

Values are expressed as mean \pm standard deviation.

These examinations were performed double-blinded. First, the switch of the stimulator was manipulated by a physician (not the person performing the sensory testing session). Secondly, the patients did not experience any sensory or motor sensation at stimulator switching, and therefore could not detect it. This test, as a measure of physical mobility, has good intrarater and interrater reliability (r=0.90 and 0.84, respectively)¹⁷).

All statistical analyzes were performed using 19 version of SPSS statistical package. The Shapiro-Wilks test was used to check for normality, and all values were normally distributed. Independent t-test and χ^2 test were performed for comparisons of general characteristics of participants between the two groups, and paired t-test was conducted to compare general characteristics of participants before and post WBV training. Statistical significance was defined as p value<0.05.

RESULTS

The total number of subjects in this study was 59 (experimental group=29, control group=30). One participant dropped out of the experimental group due to personal reasons. The attendance rate of training sessions was over 90%. Table 1 shows the general characteristics of subjects in the study. There were no significant differences between the two groups.

Thermal perception threshold was evaluated as the warm pain threshold (WPT), cold pain threshold (CPT), and VPT. WPT and CPT did not show significant changes in both groups before and after training. VPT showed significant improvement in the experimental group (p<0.05) but not in the control group. There was a significant difference between the groups in the pre-post change (p<0.05) (Table 2).

DISCUSSION

The purpose of this study was to investigate the effect of whole-body vibration on WPT, CPT, and VPT to improve sensory

^{*}means significant difference within group.

[†]means significant difference between groups.

threshold in patients with diabetic neuropathy. In the present study, the WPT and CPT did not change after intervention, and VPT significantly improved in the whole-body vibration group.

In this study, the mean age of patients was 70 years or older. The duration of diabetes mellitus was over 15 years and mean HbA1c was more than 8.4%, suggesting that diabetic complications such as neuropathy are progressing. Progression of neuropathy depends on the duration and severity of diabetes mellitus. The longer the duration of the disease, the more severe the neuropathy is¹⁸. Compared with subjects in J Pfützner, et al.¹⁹ and O Kalter-Leibovici, et al.²⁰ papers, CPT and HPT of the subjects in this study had similar values of 10.7 and 50.7, respectively, but VPT was 45.4, indicating that the degree of diabetic complication, neuropathy, was more severe.

In this study, WPT and CPT showed no significant changes after intervention. It is thought that vibration stimulation in WBV training did not affect temperature receptors.

When a diabetic patient is trained, the body decomposes glucose to supply energy, which causes blood glucose to drop. In addition, as blood circulation in the body increases, the amount of glucose and insulin delivered to the muscles increases, resulting in increased glucose levels in the peripheral tissues. As a result, insulin sensitivity is increased, and microcirculation, perfusion rate, and peripheral sensory function are improved^{4, 21)}. This physiological mechanism seems to be effective in improving peripheral sensory function of WBV of this study. In this study, VPT decreased by 21% in the experimental group after WBV.

Tactile receptors require time to adapt to vibration²²⁾. MA Hernandez-Mocholi, et al.¹⁵⁾ found that tactile threshold increased after a single WBV session but the 48 hours of short-term WBV, requiring longer intervention. A 6-week intervention period in this study was thought to play a key role in increasing sensitivity of native receptors and lowering threshold of tactile receptors by providing the body with the opportunity to adapt to repeated vibration input.

Tactile receptors of the sole and proprioception are important sensory mechanisms for posture control that provide feedback and feedforward information²³). Lack of this sense limits movement correction, and inaccurate movement leads to a lack of normal sensation and vice versa^{23, 24}). These senses play an important role in balance and walking²⁴). Future research will need to further focus on balance and gait improvement through sensory enhancement of patients with diabetic neuropathy through WBV training.

The limitation of this study is that it does not clarify the mechanism of the unfavorable effect of WBV training on the temperature sensation. In addition, there are no studies on perception thresholds affected by intervention, and the results of this study could not be compared.

This study confirmed the improvement in VPT by applying WBV to elderly patients with diabetic neuropathy, and it is thought to be a cornerstone for patients with sensory impairment.

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