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Single blind study

A clinical single blind study to investigate the immediate effects of plantar vibration on balance in patients after stroke

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ABSTRACT

Summary: Balance disorder is a very common cause of disability in patients after a stroke. Vibration therapy is one of the physiotherapeutic modalities used to improve balance.
Objective: To investigate the immediate effects of plantar vibration on balance in patients with stroke.
Methods: In this single blind comparative study, 22 patients with stroke (8 females, 14 males; age 55.82 ± 11.87 years old) participated. Patients underwent treatment, first with the placebo vibration and 1 week later with active vibration (frequency 100 HZ, 5 min). Mini-BESTest score, Modified Modified Ashworth Scale for plantar flexor spasticity, and ankle dorsiflexion passive range of motion (PROM) were evaluated before and immediately after the placebo or active vibration.
Results: A significant clinical improvement in balance, ankle plantar flexor spasticity, and the ankle dorsiflexion PROM was observed following either placebo or active vibration. The improvements after active vibration were significantly greater for all outcome measures compared with placebo vibration. There was a large effect size (Cohen's $d = 0.85$) for balance after active vibration.
Conclusion: The vibration applied to the sole of the affected foot of patients after stroke was effective for improving balance, reducing ankle plantar flexor spasticity, and increasing ankle dorsiflexion PROM.

1. Introduction

Stroke is a sudden dysfunction in the central nervous system caused by abnormalities in the brain vessels lasting at least 24 h (Hosseini et al., 2012). Stroke is the second cause of death in the world (Di Carlo, 2009) and the most common cause of disability in adults (Tyson et al., 2006). Although many patients with stroke survive through appropriate emergency care and early treatment, they mostly suffer from motor, sensory, or cognitive disturbances (Choi et al., 2013; Lee et al., 2015).

Balance disorder is the most frequent deficit and a very common cause of disability in patients with stroke (Lendraitienė et al., 2017; Smania et al., 2008). The balance impairment not only increases the likelihood of falls, which can lead to high economic costs and social issues, but also reduce the individuals' confidence in their mobility, decrease the activities of daily living (ADL), and have negative impacts on quality of life of patients post-stroke (Shin et al., 2014; Seo et al., 2014; De Oliveira et al., 2008; Robertson et al., 2010; Lee, 2015).

The ability to maintain balance is essential for all functional activities. The control of balance is one of the most important factors in determining the independence in ADL and risk of falls following stroke (Miller et al., 2014). Therefore, using rehabilitation methods to improve balance and gait are crucial for the quality of life of patients with stroke and to reduce the ongoing cost of long-term care (Maguire et al., 2012).

Vibration is one of the techniques used for the treatment of balance disorders. The vibration can be applied in two forms: whole body vibration, and local vibration. The local vibration could be a

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useful tool to reduce spasticity, to facilitate muscle contraction for functional activity, and to stimulate the proprioceptive system to obtain an efficient motor control in functional activities (Murillo et al., 2014).

Plantar sensory receptors play an important role in balance (Lee et al., 2013). Application of vibration to the sole can stimulate its receptors and has profound and immediate effects on posture and balance (Rittweger, 2010). In a controlled study, the application of vibration to the plantar region improved the balance in elderly women (Wanderley et al., 2011).

There is no study on the effects of plantar vibration on balance in patients after stroke. Therefore, the purpose of the present study was to investigate the immediate effects of plantar vibration on balance in patients post-stroke.

2. Methods

2.1. Study design

The present study used a single blind comparative design. The approval of study protocol was obtained from the review board, and the Ethical Committee, School of Rehabilitation, Tehran University of Medical Sciences (TUMS). All patients or their caregivers gave written informed consent after an explanation about the study aims.

2.2. Participants

Twenty-two volunteers (8 females, 14 males; age 55.82 ± 11.87 years old) participated in this study. Subjects were recruited from the Physiotherapy Clinic for Stroke, School of Rehabilitation, TUMS, in Tehran, Iran. The inclusion criteria were: 1) spastic hemiplegia resulting from stroke; 2) at least 6 months duration from stroke onset; 3) age $\geq$18 years; 4) ankle plantar flexor MMAS spasticity score $\geq$1; 5) the ability to walk independently for at least six meters; 6) ability to understand and follow verbal commands. The exclusion criteria were: 1) subjects who took part in any kind of physical intervention to improve balance; 2) any other neurological disorder that affects balance; 3) taking drug that may affect balance or consciousness; 4) surgery of the lower limbs in the previous 12 months; 5) suffering from severe visual problem, hemianopia, and vestibular disorders.

2.3. Sample size

G*Power 3.1.3 was used to calculate the sample size with the Mini-BESTest as the primary outcome measure. The ANOVA, Repeated measures, within factors test, with input parameters of a small effect size 0.3, four measurements, $\alpha = 0.05$, and power = 0.80, produced a total sample size of 17 for one group. Considering 10% drop out, a total 20 patients were considered to recruit for this study.

2.4. Procedure

The present study was performed at the Physiotherapy Clinic for Stroke, School of Rehabilitation, TUMS. At baseline, after patients read and signed the written informed consent, the general characteristics including gender, age, weight, height, body mass index (BMI), affected side, duration of stroke since onset were recorded. The balance and the ankle plantar flexor spasticity were assessed using the Mini-BESTest, and the Modified Modified Ashworth Scale (MMAS), respectively. The ankle dorsiflexion passive range of motion (PROM) was measured by using an ankle biplane goniometer. The intervention was applied in two sessions; 1 placebo vibration session when no vibration was delivered, and 1 active vibration session. There was a 1-week interval between 2 treatment sessions. The measurements were taken before and immediately after the placebo vibration at first session, and after 1 week, the same measurements were performed at second session before and immediately after the active vibration.

2.5. Intervention

The vibration was applied by using a custom-made vibratory device (Erteashate Tebbie Iranian Co, Tehran, Iran). The device consisted of two vibrators fixed inside a box [dimension (width*-length*height, 30 * 45* 20 cm)] that its angle could be adjusted to the foot position. The top surface of the box had two panels for each foot through which the vibratory stimulation could be delivered (see Fig. 1). The subject was positioned supine on a bed with knees flexed, barefoot, and arms beside the trunk. Then, physiotherapist positioned the affected foot on the same plate as the vibratory device and secured it in place by three velcro straps. At first session, subjects received placebo vibration in which the sound was only made without vibration, set at a frequency of 100 Hz for 5 min. One week later, the subjects received the active vibratory stimulation, frequency 100 Hz, 5 min.

2.6. Assessment of the balance

The balance were assessed using the Mini-BESTest. The Mini-BESTest is a clinical balance test (Franchignoni et al., 2010) and consists of 14 items that evaluate four different balance subsystems ('Anticipatory postural adjustments', 'Postural responses', 'Sensory orientation', and 'Balance during gait'). Each item is scored from 0 (lowest level of function) to 2 (highest level of function) and the maximum total score is 28 (King and Hork, 2013). This test is a reliable and valid instrument for assessing balance performance in patients after stroke (Tsang et al., 2013; Dahl and Jørgensen, 2014). In this study, the Persian version of Mini-BESTest was used (http://www.bestest.us/test_copies/).

2.7. Assessment of the ankle plantar flexor spasticity

The ankle plantar flexor spasticity was assessed using the MMAS (Ansari et al., 2006). The MMAS is a reliable measurement tool for assessing plantar flexor spasticity which grades the spasticity level from 0 (no increase in muscle tone) to 4 (affected part rigid in

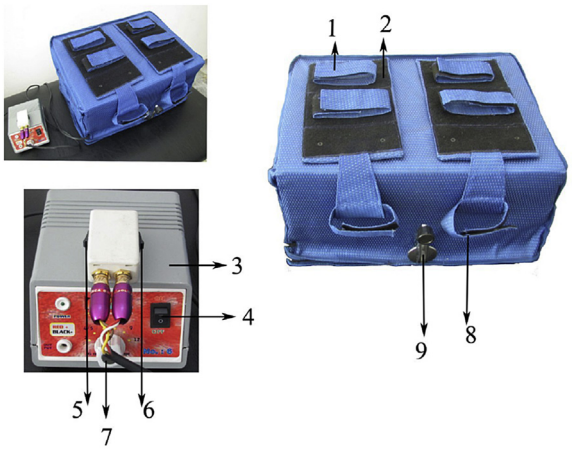

Fig. 1. Custom made vibratory device. 1) Foot strap; 2) Footplate; 3) Adaptor; 4) On/Off switch; 5) Right On/Off switch; 6) Left On/Off switch; 7) Voltage control switch; 8) Ankle strap; 9) Plate inclination handle.

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