Effect of Focal Muscle Vibration on Pain, Mobility, Balance, and Sensation in Diabetic Peripheral Neuropathy

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INTRODUCTION

It is estimated that, of the world population in 2050 of 9.7 billion, 1/3rd will have diabetes and 50% of these individuals will be affected by Diabetic Peripheral Neuropathy (DPN) if there are no effective intervention for DPN. [1] DPN is the most common complication of diabetes, affecting approximately 50-70% of patients with diabetes.[2-3] DPN is characterized by loss of sensation in the lower extremities in a distal to proximal manner. In addition to the loss of sensation, patients with DPN also experience pain, lack of proprioception, loss of muscle strength, especially the toe and ankle extensors, lack of vibration perception, and kinesthesia.[4-6] The combined effects of the abovementioned symptoms of DPN cause impairments in the patients' balance, postural sway/stability, and functional mobility resulting in challenges for patients with DPN to ambulate safely without assistance. In addition to being a burden on quality of life (QoL), DPN also increases the health costs associated with diabetes significantly. The total annual cost associated with diabetes in the US in 2012, was reported $245 billion, of which 27% was attributed to DPN.[3]

Various pharmacological as well as non-pharmacological intervention strategies such as duloxetine, pregabalin, supplements (alpha-lipoic acid), transcutaneous electrical stimulation, spinal cord stimulation, whole body vibration (WBV), etc. have been studied to address the symptoms/impairments experienced by individuals with DPN [2], yet there is a lack of consensus among the results. Mechanical stimulation in the form of WBV has been shown to reduce acute pain, improve balance and dynamic stability, increase muscle strength, and improve glycemic control in individuals with DPN. [7-8] Thus, WBV proved to be an effective intervention for addressing all the symptoms of DPN. However, WBV has been associated with tissue inflammation and potential adverse effects on physiological systems such as the nervous and vascular systems. [9] The current commercially available WBV devices significantly exceed the ISO guidelines for safety.[10] Unlike WBV, focal muscle vibration (FMV) on specific muscles or tendons can easily be kept within safe limits. FMV is a non-invasive vibration therapy that entails applying a mechanical stimulus to a specific muscle/region of choice. [11] Researchers have established benefits of focal vibration on spasticity, muscle contraction for functional activity, motor learning in patients with neurological diagnoses, pain, balance and mobility in other diseases like stroke, spinal cord injuries, and multiple scoliosis. [11] The primary aim of this study was to examine the effects of short-term (4-weeks) FMV on pain, balance, and mobility in individuals with DPN. The secondary aim of this study was to assess whether baseline level of pain would affect the aforementioned effect of FMV.

METHODS

Design

We conducted a pilot single group pre-test post-test study. The study took place at the Technology for Occupational Performance (TOP) Laboratory within University of Oklahoma Health Sciences Center (OUHSC). This study was approved by the OUHSC Research Ethics Board.

Participants

Participants were recruited based on the following inclusion criteria: diagnosis of Type II Diabetes Mellitus and DPN for at least 1 year, aged 18 years and above, ability to ambulate independently, English-speaking, and have normal/corrected vision. Participants were categorized into three groups based on their baseline pain level as measured by Brief Pain Index – DPN (BPI-DPN) [12]: Mild pain (0-3), Moderate pain (4-6), and Severe pain (7-10).[13]

Equipment

We used a modified version of commercially available wearable focal vibration device (Myovolt™) for the intervention (Figure 1). The frequency of vibration produced by this device is 120Hz. Myovolt™ is registered with the U.S. Food & Drug Administration (Regulation Number: 890.5660) under the "therapeutic massager" category. Myovolt™ has been used as a muscle stimulation device in a similar way as sports massage. Studies using the device for athletes had reported positive effect on increasing peripheral blood circulation, reducing muscle soreness.

Procedure

The intervention involves patients wearing the Myovolt™ vibration device (Figure 1) on both legs and applying FMV to the following 3 muscles as shown in Figure 2 (left to right): tibialis anterior muscle group, distal quadriceps muscle/tendon, and gastrocnemius/soleus muscle tendon. Each session lasted ten minutes, with an intersession interval of 1 minute for one day, three days a week, for 4 weeks. The demographic was collected at the first visit. The outcome measures were pain as measured by BPI-DPN [12], balance assessed by Berg Balance Scale (BBS)[14], mobility as measured by the Timed Up-and-Go (TUG) and TUG-Cognitive[15], and sensation evaluated by the Semmes Weinstein Monofilament Test (SWMT) [16]. Those measures had been selected based on their previous usage in patients with DPN and established reliability and validity. All measurements were recorded at baseline and at end of the 4 weeks intervention.

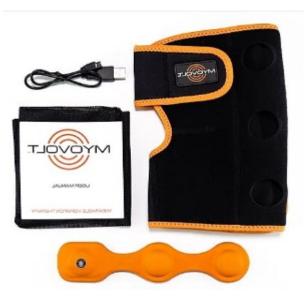

Figure 1. Myovolt wearable vibration device retrieved from https://www.myovolt.com/product-page/elbow

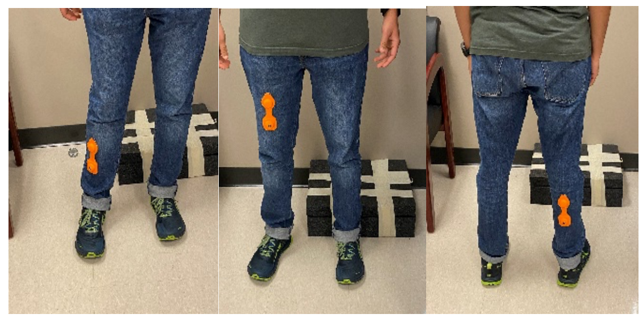

Figure 2. The three muscles where vibration is applied

Data Analysis.

Descriptive statistics were used on the demographic data and all the outcome measures. All the scores were tested for normality using the Kolmogorov-Smirnov test and paired *t*-tests and Wilcoxon signed-rank tests were used where applicable on the respective outcome measures to compare changes between baseline and post-intervention. The level of significance was set at a p value of .05 or less. Data analysis was carried out using MS Excel and SPSS.

RESULTS

13 participants completed both visits so far for the ongoing study. The demographic data was summarized in Table 1. FMV significantly ($p<0.05$) improved TUG, TUG cognitive, and SWMT score of left foot (Table 2).When we observed the groups with different pain levels, FMV significantly improved TUG for the moderate pain group ($p = 0.019$), and TUG cognitive for the mild pain ($p = 0.047$) and moderate pain ($p = 0.002$) group, and left foot SWMT in the mild pain group ($p = 0.049$). Improvements trending towards significance ($p<0.1$) were found in pain, balance for the moderate pain group, and the TUG for the mild pain group (Table 2).

Table 1. Patient Demographic Information

Patient Demographics	
Age (years)	65.69 (8.38)
Weight (lbs)	220.46 (70.19)
Height (inches)	66.58 (3.48)
Number of years with Diabetes	14.15 (6.94)
Sex (F/M)	9/4
Ethnicity	
Caucasian (n)	11
African-American (n)	1
Eurasian (n)	1

While looking at the sub-scales of BPI-DPN, FMV significantly improved the average pain ($p=0.03$), and the pain interference with walking ability ($p=0.06$), as well as pain interference with sleep ($p= 0.09$) (Table 3) were trending toward significance.

Table 2. Pain, Balance, mobility, and sensation scores before and after the 4-week vibration intervention (FMV) for the entire sample as well as each of the 3 groups based on the severity of pain

Patient Group and No. of patients (n)		All Patients n = 13	Mild pain group n = 5	Moderate pain group n = 6	Severe pain group n = 2
BPI-DPN	Pre	4.09 (2.49)	1.71 (1.25)	4.72 (0.86)	8.18
	Post	3.38 (1.60) ^	1.90 (1.53)	4.33 (0.60)	4.25
BBS	Pre	43 (11) ¥	44 (6)	40 (15)	51

	Post	46 (8)	42 (10)	47 (7) ^	54

Patient Group and No. of patients (n)		All Patients n = 13	Mild pain group n = 5	Moderate pain group n = 6	Severe pain group n = 2
TUG (s)	Pre	13.27 (4.33)	15.33 (4.32)	12.18 (4.70)	11.09
	Post	11.35 (3.52) *	12.90 (3.84) ^	10.74 (3.63) *	9.33
TUG Cognitive (s)	Pre	15.05 (5.14)	16.77 (6.52)	14.14 (4.86)	13.48
	Post	11.68 (3.62) **	13.08 (3.71) *	11.14 (3.78) *	9.78
SWMT Right	Pre	5 (3)	5 (3)	5 (3)	5
	Post	5 (3)	7 (3)	4 (3)	7
SWMT Left	Pre	5 (3)	5 (4)	5 (3)	4
	Post	6 (3) *	7 (4) *	5 (3)	7

***: p < 0.05, **: p<0.001, ^: Trending towards significance, ¥: not normally distributed**

Table 3. Item scores on BPI-DPN pre- and post-intervention, i.e. FMV in individuals with DPN.

BPI-DPN items	Pre	Post	p-value
Worst Pain¥	5.31 (3.45)	4.46 (2.54)	0.47
Least Pain¥	3.00 (2.86)	2.15 (1.28)	0.54
Average Pain	4.38 (2.36)	3.77 (2.17)	0.03*
Current Pain¥	2.77 (2.45)	2.54 (1.45)	1.00
General Activity	3.46 (3.36)	2.46 (1.76)	0.11
Mood	3.62 (3.28)	3.69 (2.93)	0.46
Walking ability¥	4.85 (3.00)	3.62 (1.45)	0.06 ^
Interference to Normal walking	4.54 (3.04)	4.08 (2.18)	0.31
Relationships¥	2.31 (3.30)	2.31 (2.25)	0.79
Sleep¥	6.08 (3.77)	4.92 (3.15)	0.09 ^
Enjoyment	4.69 (3.82)	3.54 (2.07)	0.10
Total Score	4.09 (2.49)	3.38 (1.60)	0.07

***: p < 0.05, ^: Trending towards significance, ¥: not normally distributed**

DISCUSSION

To our knowledge, this is the first study to examine if 4 weeks of at home FMV can improve pain, balance, functional mobility, and sensation in individuals with DPN. The preliminary findings confirm the hypothesis that FMV significantly improved TUG, TUG Cognitive, left foot SWMT, and the average pain sub-scale of BPI-DPN. At baseline most of the 13 participants had good balance with an average of 43 points, which is comparable to the BBS of 43.7 in individuals without DPN reported in a study by Timar et al. [17] Thus, in this study, the lack of significant improvement in the balance can be explained by the observed ceiling effect. Further, we noticed the large variation of the baseline balance score which could also the reason why the improvements in balance was not significant (Table 2). The trend towards significance in the pain interference with walking ability sub scale is consistent with the observed significant improvement in the mobility (TUG and TUG cognitive). Most of the participants reported using the FMV device right before sleeping and this explains the trend towards significance in the scores of pain interference with sleep. The trend towards significance in the overall pain score can be corroborated by the observed significant improvement in the average pain subscale of the BPI-DPN, which further supports our hypothesis that FMV reduces pain. These findings show the promising nature of FMV as an intervention for individuals with DPN. Also, since FMV is an in-home intervention, it can help to address the limitation of compliance when compared to interventions that are administered in a clinical setting, such as, WBV, spinal cord stimulation, exercise training, etc.

Akin to all pilot studies, there were some limitations in the study. Firstly, the sample size was small, However, this is an ongoing study and we are planning to recruit in total of 30 patients. Despite our current sample size of 13, we observed significant improvements on some of the outcome measures. Secondly, as a pilot study to examine the feasibility of FMV in patients with DPN, we did not have a control group, or comparison group with traditional exercise intervention, but, the data collected will be helpful for the effect size calculation, and the protocol could be used for guiding future study on effectiveness and efficacy of FMV in DPN.

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