DIRECT EFFECT OF FOCAL MUSCLE VIBRATION ON SPASTICITY

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ABSTRACT

Background: Stroke is one of the leading causes for disability worldwide. Undoubtedly, exercise therapy is a key element of stroke rehabilitation. Moreover, recently focal muscle vibration has been described as a useful therapeutic approach in the management of post stroke spasticity. Aim: The aim of this study is to investigate the immediate effects of focal muscle vibration on spasticity in post-stroke patients. Materials and Method: In this single-blinded pretest-posttest study, 12 patients were allocated to investigate the vibratory stimuli. After relaxing in a side lying posture, subjects received the interventions for 5 min in a single session with 60Hz frequency. The Modified Ashworth Scale and PROM parameters were recorded before and immediately after the intervention. Results: After using focal muscle vibration for a 5 min single session with 60Hz frequency, no significant difference was found in Modified Ashworth Scale and passive range of motion after the vibration application. Conclusion: Vibration therapy is a well-tolerated, effective and easy intervention to be used. Based on our results no significant difference was found using these parameters. So, further studies must be conducted with larger sample size, different frequency and time of application.

KEYWORDS: Spasticity; Stroke; Focal muscle vibration.

A- INTRODUCTION

Worldwide, Stroke is considered one of the leading causes of mortality and morbidity, functional impairments and disability in adults. However, spasticity is the most common
impairment and not inevitable condition in patients with stroke. It is following stroke and associated with different symptoms like: pain, soft tissue stiffness, and joint contracture, and may lead to abnormal limb posture, decreased quality of life, increased treatment cost, and increased caregiver burden (Baricich, Picelli, Molteni, Guanziroli, & Santamato, 2016).

It is a major disabling and common symptom in neurologic conditions such as post stroke hemiplegia.

Spasticity was first described by (Lance, 1980) as a motor disorder characterized by a velocity-dependent increase in tonic stretch reflexes (muscle tone), with exaggerated tendon jerks, resulting from hyper-excitability of the neurons involved in stretch reflex, as a component of the upper motor neuron syndrome.

It is common after stroke, with the prevalence ranging from 30% to 80% of stroke survivors. The incidence of spasticity among paretic patients has been reported to be 27% at 1 month, 28% at 3 months, 23% and 43% at 6 months, and 34% at 18 months after stroke (Opheim, Danielsson, Murphy, Persson, & Sunnerhagen, 2014).

In addition, American stroke association report that about 25 to 43% of survivors will have spasticity in the first year after their stroke. And it’s more common in younger stroke survivors. It’s also more common when the stroke is caused by a bleed (hemorrhagic).

Early detection and management of post-stroke spasticity may not only reduce complications, but may also improve function and increase independency in patients with spasticity. Management strategies include pharmacological agents, Surgery, Occupational, Physical Therapy, and exercise to cope with this physical burden. The physical management strategies for reducing spasticity and impairment are briefly muscle stretching, muscle strengthening, shock wave therapy, ultrasound therapy, cryotherapy, electrical stimulation, and vibration (Alp et al., 2018).

And because most people seek for noninvasive, non-aggressive treatments to relieve their complains and control spasticity, which is a common phenomenon seen in neurologic disorders and remarkable clinical feature in diseases caused by upper motor neuron lesions such as stroke, cerebral palsy, and spinal cord injury (Mukherjee & Chakravarty, 2010). They prefer physical therapy and its modalities because of its cost efficacy and less risky.
Therefore, Since the 1960s, the effect of vibration on reflexes and spasticity has been extensively investigated. This finding has led to the consideration of focal vibration as a potential therapy for spasticity.

Recently, several studies have investigated the antispastic effect of focal muscle vibration in patients with stroke (Caliandro et al., 2012; Liepert & Binder, 2010). In addition, it has also been reported that vibratory stimulation of the hemiplegic lower limb increased gait speed in stroke patients (Kawahira et al., 2004) and it is an effective modality which can be used in neurological rehabilitation (Sui, Shull, & Ji, 2014). Vibration based methods in either focal or whole body vibration (WBV) form have been used in healthy and patients populations to improve functional outcomes (Schlee, Reckmann, & Milani, 2012; Wanderley, Alburquerque-Sendn, Parizotto, & Rebelatto, 2011), but there are not many studies on focal intervention on lower region and most of the studies which conducted were focused on the upper limbs.

Therefore, the objective of the present study was to assess the effects of focal vibratory stimuli applied to the spastic lower region on patients after stroke. We postulated that spasticity of patients with stroke could be improved through the application of vibration directly to the affected region.

**B- Preview Studies**

Spasticity is a common phenomenon seen in neurologic disorders that result in loss of mobility and may produce pain due to muscle spasms. However, there are various physiotherapeutic interventions used for treating this symptom and focal muscle vibration is one of these modalities.

Few studies have been conducted to examine the effect of focal vibration therapy on spastic lower limbs in hemiplegic patients. One of these studies is a pretest-posttest study done by (Khalifeloo et al., 2018) which examined the effects of focal muscle vibration on balance impairments in 18 post-stroke patients. The vibration was applied to the plantar region of the more affected foot for 5 min in a single session using 100 Hz frequency. The results showed significant improvements in Modified Ashworth Scale, Passive Range Of Motion and Timed Up and Go Test meaning that fMV has an anti-spastic effect in addition to its positive effect on dynamic balance.
Another study was done by (Karimi-AhmadAbadi et al., 2018) also examined the immediate effects of using fMV on balance in stroke patients and found improvements in balance measured by Mini-Balance Evaluation Systems Test (Mini-BESTest), ankle plantar flexor spasticity measured by Modified Ashworth Scale, and ankle dorsiflexion passive range of motion (PROM). In this single blind comparative study patients (n= 22) underwent treatment with the placebo vibration at first and then 1 week later with active vibration (frequency 100 Hz, 5 min).

Moreover, in a case study done by (Ghotbi, Ansari, Naghdi, & Hasson, 2011) on a 72-year-old man with stroke to demonstrate the short-term effects of plantar vibration, reported beneficial effects on balance.

Furthermore, the anti-spastic effects of focal muscle vibration were also examined on upper limbs. (Costantino, Galuppo & Romiti, 2017) conducted a single-blind randomized controlled trial in 32 chronic post-stroke patients with upper-limb spasticity. The patients were randomized in two groups: treatment group and sham therapy group. The treatment protocol was applying a 300 Hz on triceps brachii and extensor carpi radialis longus and brevis muscles during voluntary isometric contraction. In addition, the application was for 30 minutes 3 times per week, for 12 sessions and they were evaluated before and after 4-week treatment. Significant improvements were found in grip muscle strength, pain, quality of life and decrease of spasticity was also recorded.

Additionally, in a study by (Annino et al., 2019), the participants (n= 34) demonstrated a reduction in upper extremity spasticity following (5 min SMV (30 Hz) + 30 min conventional physical therapy×3/wk×8 wk) in comparison to the control group. In this randomized controlled study, the participants were assessed at baseline and reassessed at the end of week 8 of treatment.

Another randomized controlled trial which included 36 post-stroke patients done by (Noma et al., 2012), found the direct application of vibratory stimuli has anti-spastic effects on the spastic upper limbs of post stroke patients. Participants were randomly allocated to the “Rest group”, and “Direct application of vibratory stimuli group”. After relaxing in a supine posture for 30 min, subjects received fMV of a 91 Hz frequency for 5 min. The MAS scores and F-wave parameters were recorded before, immediately after and 30 min after each intervention.
Lastly, a pilot randomized controlled trial, using a pragmatic double-blind, parallel-group study design by (Caliandro et al., 2012) studied the effect of focal vibration therapy in reducing upper limb spasticity. The participants were randomly placed into experimental (FMV (100 Hz) for 30 min (10 min/muscle) ×3/wk×1wk) and control groups (Placebo). The participants in both study and control groups showed a decreasing in the MAS scores (reduction in spasticity) of the upper extremity, however, with no significant difference between groups.

C- METHOD AND MATERIALS

1- Design
A clinical investigation with a single blinded pretest-posttest design was followed for this pioneering study which is approved by the ethical committee of Global University.

2- Participants
Twenty patients (males=10, females =10) who were diagnosed with stroke were initially recruited for this study. Among these, 12 (males =8, females 4) out of 20 patients fulfilled the selection criteria. During the intervention period three females were excluded because they did not meet the inclusion criteria, one patient has an amputated left leg, and the other two are not spastic patients. Five patients (males=3, females=2) dropped out of the study because of personal issues. The following inclusion and exclusion criteria were used (table 1).

Table 1: Shows the inclusion and exclusion criteria used in this study,

<table>
<thead>
<tr>
<th>Inclusion criteria</th>
<th>Exclusion criteria</th>
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<tr>
<td>(a) Spastic patient, (b) Age ≥ 40 years</td>
<td>(a) Participation in other treatment protocols for spasticity</td>
</tr>
<tr>
<td>(c) Duration since stroke ≥ 3 months</td>
<td>(b) Presence of conditions other than stroke leading to spasticity</td>
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<tr>
<td>(d) The study had included at least one measurement related to muscle spasticity</td>
<td>(c) History of lower-limb surgery within the previous year</td>
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<td>and published in English</td>
<td>(d) Cardiopulmonary complications</td>
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<td></td>
<td>(f) Uncomfortable feeling due to vibration application</td>
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<td></td>
<td>(g) Unwillingness for participation in the study.</td>
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<td></td>
<td>(e) Muscle pain in region to be tested</td>
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</table>

Before any data collection or any intervention all experiment procedures were explained to all patients and being sure that they well understand, then Patients signed a written informed consent that explained the protocol prior to data collection, and the ethical committee of global University approved this study.
To ensure masking, we did not reveal protocols and intervention order to clinical evaluators. Intervention allocation was recorded in a password protected document to maintain blinding. All data were measured by the same blinded evaluator before training began and at the end of the session.

3- Procedure
An extensive literature search was done using the following electronic databases: MEDLINE, PubMed, Cochrane Library and Physiotherapy Evidence Database (PEDro). In addition to search on focal muscle vibration in combination with stroke was generated to identify potential studies.

All study procedures were performed at Mohammed Khaled rehabilitation hospital and Dar Al Ajaza Al Islamia hospital in Beirut. Participants were interviewed to collect information including: age, sex, diagnosis (cerebral infarction or hemorrhage), duration since stroke onset, dominant hand and affected side. The height and weight were measured to calculate the body mass index (BMI \( \text{kg/m}^2 \) = weight [kg]/height [m2]). The outcome measures used are Modified Ashworth Scale (MAS) to identify the degree of spasticity using speed 2 which corresponds the free fall of a limb with gravity, and ankle PROM using a goniometer.

All measurements were taken before and immediately after treatment by two experienced physiotherapists other than authors, one of them performed all the assessments and the other one applied the vibration therapy.

4- OUTCOME MEASURES
The outcome measures were: The MAS and ankle PROM

4.1 Modified Ashworth Scale
Participants were lied down in supine position prior to testing. The physiotherapist used the ordinal MAS for rating gastrocnemius muscle spasticity from 0 (no increase in muscle tone) to 4 (affected part rigid) (Ansari et al., 2006; Ansari et al., 2008). The MAS has shown very good interpreter reliability for assessing spasticity.

4.2 Ankle PROM
The participant was in supine position on an examination table with the knee in extension. The 90° was defined as the neutral position for the measurements using an ankle biplane
goniometer (Bissell Health Care, model 7524, USA). Ankle dorsiflexion and plantar flexion from the neutral position was given either a positive or negative value (Ansari et al., 2006a).

5- INTERVENTION

A manual mechanical vibratory stimulation device was used to deliver the vibration stimuli to the gastrocnemius muscle region while the participant was in a side lying position, due to different cardiac problems that the patients suffer from which is a contraindication to apply the vibration prone. The device delivers vibration stimuli with frequencies ranging from 20–60 Hz.

The application of vibration was done by a physiotherapist, as the assessment was done before and recorded. And after a well explaining of the all experiment procedures to all patients and got a written informed consent from them.

The experiment was done in an isolated room with a bed which is suitable for all patients of different body weight, and was not too much high from the ground so the patient can sit and stand comfortably. First of all, vibration was applied to the intact leg of the patient for few second letting him to be familiar with the coming sensation on the affected leg. Then participant was asked to lie on an examination table in a side lying position, and the affected leg was up and the intact one is flexed down.

Participants received vibratory stimulation (60 Hz) to the gastrocnemius region especially to the belly of the muscle for 5 min session. The application was done by a physiotherapist who was blind to all study procedures. There was no pressure while application so all patients received the same stimuli. After vibration application the measurements were taken immediately and recorded.

D- RESULTS

This study aimed to investigate the effects of focal vibration therapy on spasticity in chronic hemiplegic patients. 12 individuals (8 M, 4 F, mean age 70 y/o) were eligible for participation, and they all completed the experimental and testing procedures. None of the subjects experienced discomfort before, during or after the interventions. The examinations were completed safely in all subjects.
Representation of data distribution

As shown in (figure 6) most of the patients who participate in the study were between (60-69) years, and (70-79) years as represent in percentage 41%. Which equals five patients in each category. While the smaller categories included patients their ages range between (50-59) and (80-89) and each of it equal 9% which correspond one patient in each category.

As shown in (figure 7) most of the hemiplegic patients were affected by their left side. And they were nine patients out of twelve and correspond 75%. While the rest of the patients were right side affected and equal to 25%.
As shown in (figure 8) the majority of the participants are male and equal 8 patients, and correspond 67%. While the rest of participants are 33%, which equals 4 females.

**Table 2: Paired t-test of the mean for PROM (DF & PF).**

<table>
<thead>
<tr>
<th></th>
<th>PROM PF Before</th>
<th>PROM PF After</th>
<th>Sig</th>
<th>PROM DF Before</th>
<th>PROM DF After</th>
<th>Sig</th>
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<tbody>
<tr>
<td></td>
<td>46.5</td>
<td>48.66667</td>
<td>0.262</td>
<td>-3.75</td>
<td>-9.25</td>
<td>0.157</td>
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The results show that the mean for both PROM DF and PF pre and post the intervention. As shown also both p–value are > 0.05 so difference is not significant.

**Table 3: Paired t-test of the mean for MMAS.**

<table>
<thead>
<tr>
<th>Modifiesd Ashworth Scale (Mas) Mean</th>
<th>Sig</th>
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<tbody>
<tr>
<td>BEFORE</td>
<td>AFTER</td>
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<tr>
<td>3.3</td>
<td>3.3</td>
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The results show that the mean for MAS before and after the intervention. In addition to the p-value which is > 0.05 so difference is not significant for MAS.

**E- DISCUSSION**

Spasticity is a frequently limiting problem in neurorehabilitation. It may restrict movements, impair dexterity and cause abnormal postures and pain, interfering with daily living activities (Duncan et al., 2005). Focal muscle vibration can be a useful tool in neurorehabilitation, as it is safe, well tolerated and easy to perform at bedside. Furthermore, it promotes neural plasticity with long-lasting motor recovery in chronic stroke patients (Marconi et al., 2011).

In this present study we used clinical evaluations to investigate the effect of fMV therapy applied using a manual mechanical vibration machine on spasticity in the calf muscles of chronic stroke patients.
Since there are not enough studies examining the clinical effectiveness of fMV in the management of lower limb spasticity in hemiplegic patients and due to the often inconsistent patient status in acute and sub-acute stages after stroke (Swayne et al., 2008), we decided to perform this pretest-posttest study in a group of chronic stroke patients with a stable clinical picture.

No significant changes were found in either Modified Ashwarth Scale or Passive Range of Motion among our results. These findings can be explained by several arguments including the limited time of exposure and the frequency used during application, as well as the use of a hand-held vibration device, which probably has poor inter- and intra-tester reliability. These possible factors will be discussed as following.

**Effects of parameters**

First of all, our intervention consisted of a single five-minute treatment session, while other studies used more treatment sessions and longer durations per session like (Costantino et al., 2017: 30 min (10 min/muscle) FMV×3/wk×6) and showed positive changes in Modified Ashworth Scale. However, in a study conducted by (Caliandro et al., 2012) the participants in both study and control groups (Placebo) received (fMV for 30 min (10 min/muscle) ×3/wk×1wk) and showed a decreasing in the Modified Ashworth Scale scores of the upper extremity but with no significant difference between groups.

On the other hand, (Khalifeloo et al., 2018) used a similar protocol to the one showcased in our study, but with a greater frequency (100 Hz) where the vibration was applied to the plantar region and showed significant improvements in terms of Modified Ashworth Scale, Passive Range of Motion and Timed Up and Go Test, whereas in this study, we used a 60 Hz vibration frequency applied on the gastrocnemius belly but no changes were found. However, lower frequencies were used in other studies (Annino et al., 2019: 30 Hz) for longer periods (3/wk × 8wk) and in combination with supervised physical therapy, but presented enhancements in Modified Ashworth Scale and Activities of Daily Living. Although some previous studies showed significant improvements in these variables regardless of the frequency used, it seems that these changes are related to either a longer duration of application, greater session numbers or the combination with other treatment strategies. So, in terms of using a low frequency vibration combined with a short time of application (5 min), we propose that a single 5 min session was not enough to produce a significant reduction in
lower extremity spasticity. However, the effective treatment protocol and dosage remain unclear.

The machine used
Moreover, in this study, we investigated the effectiveness of fMV therapy using a hand-held mechanical vibration device, whereas other authors used either mechanical (for example the so-called “ball” stimulator fMV (Caliandro et al., 2012; Marconi et al., 2011; Celletti et al., 2017), cylinder (Lee et al., 2014, Cody et al., 1998), etc.) or mechanoacoustic devices (Constantino et al., 2014) that use sound waves to activate mechanoreceptors. The ball stimulator fMV has a mechanical support that is rigidly anchored to the floor to ensure a good mechanical contact with tissue. In addition it has a mechanical arm which allows the transducer to be placed on the treatment site. As a result, there will be a better transmission of vibrations to the muscles since the soft tissues will be compressed. Moreover, in the cylindrical type of fMV, the vibrator was attached over the muscle or tendon using a small brace with a Velcro band. Furthermore in the mechanoacustic device used in the study done by (Constantino et al., 2014) has a compressor that delivers pressure in the range 0-400 millibar. The most notable weakness of the device we used is the fact that it is manual and the pressure may vary between users on one hand, and for the same user over different trials on the other. However, we tended to compensate this limitation by letting the same therapist do the intervention on all patients. Another issue is that the amplitude in this device was unknown and we could not measure it. Nevertheless, it is believed that the actual amplitude of the vibration is dependent on the tension of the device on the muscle, stiffness of the muscle or tendon, and the position of the vibrator with respect to the gravity. Thus, according to what have been discussed previously, it seems that also the characteristics of the vibration device may have a role in specifying the outcomes.

LIMITATIONS
The present results should be evaluated taking in consideration several limitations that should be acknowledged. First, the study was conducted with a small sample size and most of the participants were geriatrics which may have influenced the results in certain variables. Second, it was difficult to apply parallel pressure to all patients. Third, the amplitude could not be estimated. Fourth, no control or placebo group was included in the study to compare the post measures. Fifth, it was difficult to find a homogeneous group rehab and it was
difficult to have all patients at the same hospital, because of their cases and the difficulties in ambulation. Finally, few studies related to spastic lower limbs are available.

**F- CONCLUSION AND FUTURE PERSPECTIVES**

Vibration therapy is a well-tolerated, effective and easy intervention to be used in the field of neurorehabilitation. Based on the findings of our study, it seems that the application of vibration for a single 5 min session with a frequency of 60Hz have no significant effects on either MAS or PROM.

Therefore, further research is needed to characterize the effects, optimal frequency, best amplitude and duration of exposure to fMV in order to improve functionality in patients with neurological deficits.

Moreover, it is important to conduct more studies using other parameters with larger study population, including a control group, in the aim of verifying different effects of the vibratory stimuli either in isolation or combined with other interventions.

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