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ORIGINAL RESEARCH

Low Vibrational Training as an Additional Intervention for Postural Balance, Balance Confidence and Functional Mobility in Type 2 Diabetic Patients with Lower Limb Burn Injury: A Randomized Clinical Trial

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Purpose: Burn injury with pre-existing diabetes has poorer outcomes and complications. Balance and functional mobility are disturbed in diabetic patients with burn injury which increase the risk of total morbidity. The aim of the current study was to evaluate the impact of vibrational training as an additional intervention on postural balance, balance confidence and functional mobility in type 2 diabetic patients with lower limb burn injury.

Patients and Methods: Thirty-eight type 2 diabetic patients of both sexes with healed lower limb burn were randomly assigned into two equal groups: the vibration group and the control group. The vibration group received whole body vibration (WBV), 3 sessions a week for 8 weeks, in addition to the selected exercise program (balance exercises and resisted exercises), while the control group only received the selected exercise program. Biodex Balance System was used to assess the dynamic balance score, the Activities-specific Balance Scale to assess balance confidence and the timed up and go test to assess the functional mobility. All measurements were obtained before and at the end of the study after 8 weeks of treatment.

Results: Marked improvement in all dynamic balance indices; overall stability index, antero-posterior stability index and medio-lateral stability index, balance confidence and the functional mobility were obtained in both the vibration and the control groups ($P< 0.05$), whereas post-treatment comparison between groups revealed a statistically significant difference in favor of the vibration group in all measured variables.

Conclusion: Based on the results of the current study, it is possible to conclude that adding WBV training for an 8-week duration to a selected exercise program (balancing and resisted exercises) seems to be effective; in improving postural balance, balance confidence, as well as improving the functional mobility in type 2 diabetic patients with lower limb burn injury.

Keywords: burn injury, postural balance, vibrational training, functional mobility, resisted exercises

Introduction

The main concern of burn injury rehabilitation has shifted from survival to optimizing functional outcomes and speeding up work return. Lower limbs (LL) are considered from the most commonly burned body parts, and resulting in many potential complications, including pain, contractures, scars, altered sensations, muscle weakness, and postural balance impairment.[1–3]

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Burn injury combined with a pre-existing disorder worsens and seriously affects the clinical outcomes in hospitalized patients. Diabetes is one of the most common premorbid conditions among hospitalized patients and it raises the risk of poorer outcomes and complications.[4,5] Furthermore, diabetic patients are at an increased risk of burn injuries.[6,7]

Diabetes mellitus (DM) is the most common metabolic disorder and is becoming more prevalent not only in developing countries but also in developed countries, with a total prevalence of 8.8% all over the world.[8] Similar to burn injuries, DM has a negative impact on different systems, leading to cardiovascular problems, peripheral neuropathies, immune system impairments, delayed wound healing, vascular damage, and musculoskeletal impairments.[9,10]

Balance impairment is the main concern in diabetic patients as it may be associated with an increased risk of morbidity. In many clinical studies, it has been reported that DM affects both static and dynamic balance by its negative impact on the structures and functions of the vestibular system by damaging mechanoreceptors in the sole of the foot, affecting proprioception, reducing balance confidence and causing LL muscle fatigue.[11–13] Moreover, approximately 60–70% of diabetic patients complain of diabetic peripheral neuropathy, which is the main cause of foot ulceration, impairs balance and balance confidence, alters one's gait, and increases the risk of falling due to sensory and motor nerve impairments that delay the rehabilitation and functional recovery after traumatic events such as burn injury. The risk of accidental fall or fall-related injuries increases in diabetic individuals by 2.5 times compared to age-matched controls. Both balance and functional mobility are disturbed in diabetic and burned patients which makes diabetic patients with burn injury at a high risk of total morbidity.[14–18] Therefore, during assessment as well as the plan of treatment; physiotherapists need to consider the impacts of burn injury and DM on the vestibular system, balance, risk of falls and the functional mobility. Many physical therapy modalities and interventions can improve balance and physical function, either in diabetic patients or burned patients.[2,19–21]

Whole body vibration (WBV) transmits a low-amplitude, high-frequency mechanical stimuli through the body which is generated by a vibrating platform.[22,23] Vibrational training has a beneficial effect on balance through augmenting neuromuscular activation of LL muscles. Previous studies found that vibrational training has a profound impact by significantly improving muscle strength as well as balance and functional mobility in both diabetic patients with peripheral neuropathy and burned patients.[22–28]

Although many previous researches have approved the beneficial impacts of WBV on diabetic and burned patients separately.[25–28] To the best of our knowledge, there is a lack of clinical trials about the effect of WBV in burned patients with pre-existing diabetes. Therefore, the current study aimed to evaluate the impact of WBV as an additional intervention on postural balance, balance confidence and functional mobility in type 2 diabetic (T2DM) patients with LL burn injury. We hypothesized that both WBV and the selected exercise program (balance exercises and resisted exercises), may improve balance, balance confidence and functional mobility in burned patients with pre-existing diabetes.

Patients and Methods

Trial Design

A randomized, single-blind, controlled trial was conducted at the Outpatient Clinic of the Faculty of Physical Therapy Cairo University and some licensed rehabilitation centers for one-year period from May 2019 to July 2020. Diabetic patients with LL burn were recruited from tertiary hospitals of Cairo University.

Participants

Thirty-eight T2DM patients of both sexes (18 males and 20 females) with healed LL burn and with the following inclusion criteria: 1) age of the patient was ranged from 35 to 55 years; 2) weight range 60–85 kg, height 155–170 cm; 3) total burned surface area (TBSA) was 20–35% measured by the rule of nines; 4) the burn cause was thermal; 5) burn depth, partial-thickness burn injury; 6) at least 3 months after burn injuries; 7) and with low physical activity level.

Patients were excluded if they had 1) inhalation injury; 2) leg amputation; 3) any limitation in LL range of motion; 4) auditory or visual problems; 5) congenital musculoskeletal deformities, especially in the foot; 6) psychiatric disorders; 7) paralysis; or 8) cardiac abnormalities or cardiac pacemakers.

Ethical Considerations

After a full explanation of the aim and the protocol of the study, each patient signed an informed consent before participating in the study. All research procedures were in accordance with the Declaration of Helsinki. The study was approved by the Institutional Review Board at the

Faculty of Physical Therapy, Cairo University, Egypt, with a reference number (No.P.T. REC/012/002909) and was registered with the ClinicalTrials.gov Registry (Registry ID: NCT04587102).

Sample-Size Determination and Randomization

The ample size was computed based on the overall stability index (OSI) which is considered as the primary outcome. A sample size of 16 in each group was considered and to account for drop out; the sample was 19 in each group with a power of 0.80 and alpha level of 0.5 and the effect size was 1.0. For sample size Calculation; G*Power 3.1 software (Institut für Experimentelle Psychologie: Heinrich-Heine-Universität niversitätsstraße, Düsseldorf, Germany) was used.

Eligible patients (38) were randomly assigned by a blind, independent research assistant using computer-generated randomization cards saved in opaque sealed envelopes, into two equal groups: the whole body vibration group (vibration group) and the control group. Following randomization, there was no dropping out of subjects from the study.

Assessment Procedures

Measurements were done by a blind assessor at two occasions: at randomization (baseline assessment: pre), and at the end of the study after 8 weeks (post) Figure 1.

Demographic Data Assessment

Patients' demographic data and clinical characteristics including age, gender, weight, height, depth of burn, TBSA%, cause, length of hospital stay, the period after burn injury and the hemoglobin A1c were recorded at randomization (pre), while other measurements, dynamic balance, balance confidence and functional mobility, were done at randomization (pre) and repeated at the 8th week of treatment (post).

Dynamic Balance Assessment

The primary outcome measure was the dynamic balance score that was measured by the Biodex Balance System (Biodex Medical System, Shirley, NY, USA). Biodex Balance System is a valid and reliable method to assess the dynamic balance. The system has a movable circular platform that permits about 20◦ tilt in 360◦ range so it is free to move about the anterior-posterior and medial-lateral directions simultaneously and it is interfaced with a computer software for objective balance assessment. Biodex Balance System provides a numerical stability index (SI) that reveals the postural sway variation around the center of gravity of the body. The SI reveals the ability of the patient to control the platform's tilting angle and indicates the amount of the platform motion. A lower SI score indicates a higher level of stability and a better balance, while a high SI score indicates a lot of movement, less stability and a great deviation.[29,30] The system offers eight levels of stability, level one represents the least stability level by allowing the highest degree of tilting, while level eight represents the highest level of stability by allowing the least degree of tilting. The measured balance indices include the antero-posterior stability index (APSI) (evaluating the balance control in anterior-posterior directions in the sagittal plane), the medio-lateral stability index (MLSI) (evaluating the balance control in medial-lateral directions in the frontal plane) and the overall stability index (OSI) (evaluating the balance control in all directions).[31,32] An explanatory session was given to each patient before balance assessment regarding the evaluation procedure, according to the protocols set in the Biodex system operation manuals. All patients were tested on stability level 8 for 30 seconds. Each patient was instructed to stand barefoot on the locked platform's center and try to achieve a centered position on the platform (once the platform moves) by shifting his feet to a position that helps him to keep the cursor on the visual feedback screen at the center of the screen grid. Once centered position was achieved, the patient was instructed to maintain his feet position till stabilizing the platform. This was followed by recording feet angles (by finding a parallel line on the platform to the center line of the foot) and heels coordinate (measured from the center of the back of the heel) from the platform. After introducing these angles into the Biodex Balance System, the test started. As the platform advanced into an unstable state, the patient was instructed to focus on the screen to maintain the cursor centered. Then, the computer analyzes the patient's sway movements and records the patient's ability to control the platform variation from the balanced position. A printout report, including information about the OSI, APSI and MLSI, was obtained at the end of each test trial. Three trials were obtained for each patient with one minute of rest in-between and the average of these trials was used for statistical analysis.[33]

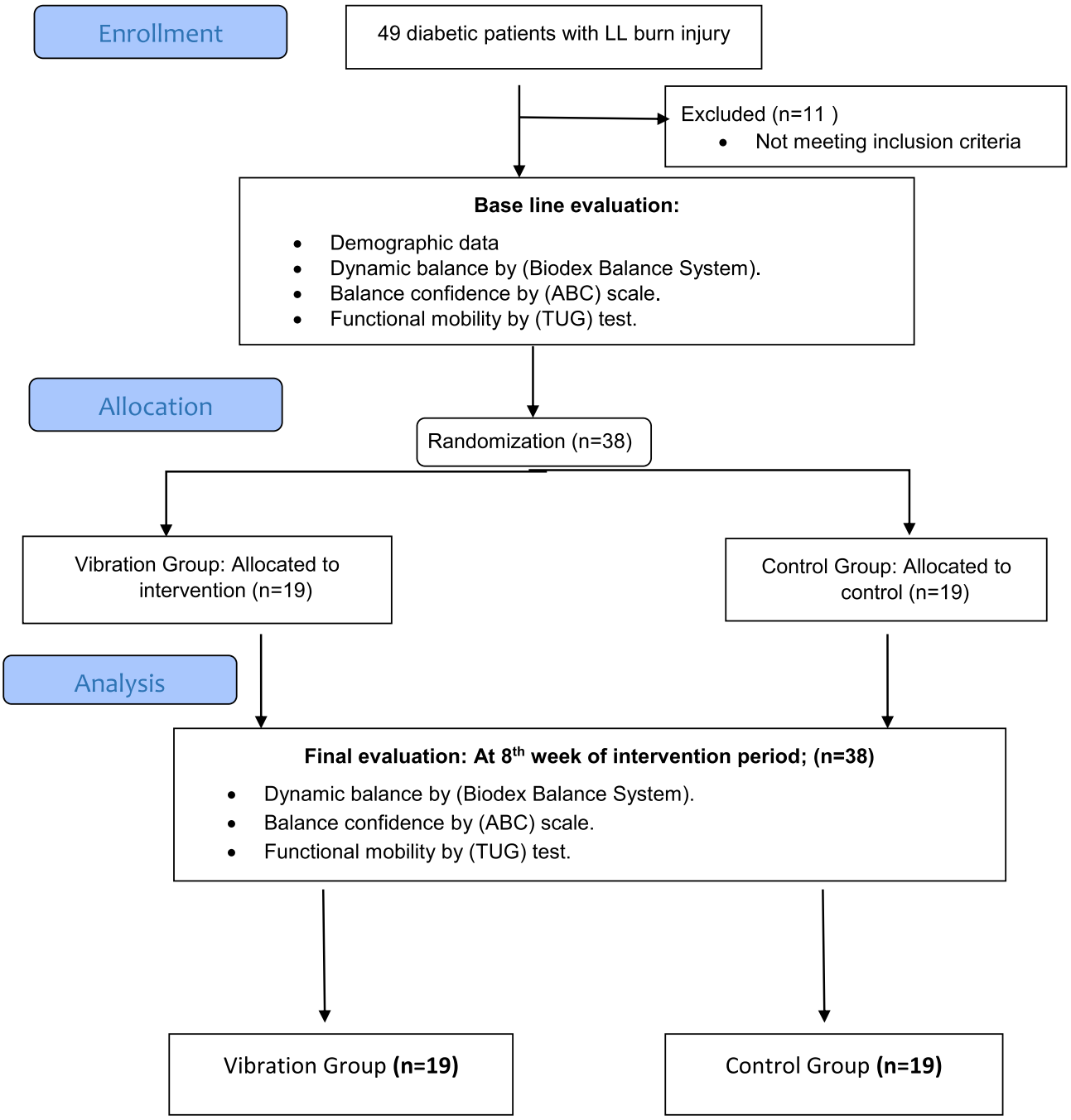

Figure 1 CONSORT flow diagram.

Balance Confidence Assessment

The Activities-specific Balance (ABC) scale is a popular and subjective questionnaire to assess balance confidence and the risk of fall in people with balance problems.[34] The ABC scale consisted of 16 items with a total score between 0% (not confident) to 100% (completely confident), where higher scores equate to higher balance confidence and vice versa. The Arabic version of the ABC scale is reliable and valid in the assessment of balance confidence. An Arabic version of the short, six-question version of the ABC scale was used (ABC-6), as it takes less time than the original 16-items ABC scale, it includes

only six items out of the original 16-item scale which are the most balance-challenging tasks (1-standing on tiptoes reaching for something above your head, 2-standing on a chair reaching for something, 3-bumped into by people as you walk through the mall, 4-walking onto or off an escalator while holding onto a railing, 5-walking onto or off an escalator while holding onto parcels such that you cannot hold onto the railing, and 6-walking outside on an icy sidewalk) with less time-consuming to administer.[35,36] Patients were instructed to record their response for each item of the (ABC-6) scale. Higher scores of ABC indicating better balance confidence, and a score of <67% indicating a risk for falls.

Functional Mobility

The timed up and go (TUG) test is a basic mobility assessment tool that records the time taken (in seconds) to get up from a chair, walk 3-meter distance, come back and sit down again on the chair. The test was performed with standardized instructions, asking patients to walk as fast as possible during the test. The used chair has a height of approximately 46 cm without arms and with a back support. The lower values indicate better mobility.[37]

Treatment Procedures

All patients in both groups received selected exercise program (balance exercises and resisted exercises), 3 sessions a week, for 8 weeks. Only patients in the vibration group received a20- 30-minute WBV with a frequency of 25–30 Hz and an amplitude of 3–5mm three times/week for 8 weeks in addition to the selected exercise program.[23,28]

Selected Exercise Program

Patients in both groups received balance exercises 3 sessions a week for 8 weeks in the form of balance exercises and resisted exercises.

Balance Exercises

Each session of balance exercises is composed of three phases, including warm-up, balance training and cool down. The warm-up phase involved gentle stretching for calf, hamstring, quadriceps, iliopsoas muscles, as well as anterior, posterior and lateral step-ups for 5–10 minutes. The active phase was performed on a balance training mat of high-elasticity for 20 minutes. It included heel and toe raises, one-legged stance for each extremity, shifting weight anteriorly, posteriorly, laterally and diagonally, turning head to the right and then to the left with maintaining the feet together, walking in slow motion, step-ups, narrow walking, backward walking, sideward walking, stepping over obstacles, passing balls arranged on the training mat in a circle, and throwing and catching a ball on the training mat. The program ended with 5–10 minutes of cool down. During the cool-down phase, patients performed deep breathing exercises and static exercises for back extensor in a recumbent position.[27,38]

Resisted Exercises

Resisted exercises were given according to the standardized Oxford technique of progressive resistance exercises for hip flexors and extensor, knee extensors and flexors, and ankle dorsiflexors. The exercises' intensity was progressed as the following; week one: 50–60% of three repetition maximum (3RM), from 2nd −6th weeks: 70–75% of 3RM and for 7th −8th weeks: 80–85% 3RM for 4–10 repetitions.[39]

Vibrational Training

Each patient in the vibration group received vibrational training in the form of WBV for 20–30 minutes per session, 3 sessions per week for 8 weeks. The vibration training was performed on a WBV platform (model OMA-701A, China).[40] Participants were asked to stand barefoot while maintaining back erect and looking straightforward. The training program comprised four positions, including standing in an erect position (knees straight) facing the screen, light squatting (knees slightly flexed), one-legged stance facing the handrail (one knee slightly flexed and the other knee was straight as much possible) and erect standing facing handrail. The duration of each position was 2 minutes in the first two weeks and increased gradually to be 3 minutes in the next two weeks then finally increased to be 4 minutes in the last four weeks. Rest periods between each position were 2 minutes in the first four weeks, while they were 1 minute in the last four weeks.[41]

The amplitude of the vibration was 3–5 mm, the frequency was 25–30 Hz and the duration of vibration was equal to the duration of rest in seconds. The rocking platform reciprocally thrusts the right and left LL upward and downward. Such kind of training causes reflex rapid muscle stimulation and contractions without serious adverse effects.[28]

Table 1 Baseline Characteristics of Both Groups

Characteristics	Vibration Group (n = 19)	Control Group (n = 19)	P value
Age (years): M±SD	46 ± 4.1	47.7 ± 4.9	0.343
BMI (Kg/m^2): M±SD	26.6± 3.2	25.2± 3.2	0.246
Sex M/F [n (%)]	11/8 (57.9/42.1%)	7/12 (35.3/61.7%)	0.103
TBSA%: M±SD	22.5± 5.1	24.1 ± 5.2	0.284
Cause of burn (flame/scold) n (%)	11/8 (57.9%/42.1%)	12/7 (63.2%/36.8%)	0.740
Depth of burn (2nd/3rd degree) n (%)	10/9 (52.6/47.4%)	8/11(42.1/57.9%)	0.516
Length of Hospital stay (days): M±SD	40.4±6.4	42.1±5.5	0.353
Post burn duration (months): M±SD	9.4±1.8	8.9±1.7	0.461
Hemoglobin A1c (HbA1c) %): M±SD	7.1±0.5	7.5±0.71	0.71

Abbreviations: M, mean; SD, standard deviation; P value, significance level; %, percentage; n, number; TBSA, total body surface area; M, male, F, female; BMI, body mass index.

Statistical Analysis

Data were described and analyzed for all available patients. Data were tested for normality using the Shapiro–Wilk test, drawing histogram and box plot, calculating the mean, median values. Outcome parameters that were measured showed a parametric distribution. Two-way mixed model MANOVA was used to compare between the measured parameters in both groups and across different time periods. For demographic data of the participants, the independent *t*-test was used for the numerical data, and chi-square was used for the nominal data. Numerical data were presented as mean and standard deviation and nominal data as number and percentage. The significance level was set at $P < 0.05$. Statistical analysis was performed with IBM SPSS version 20.

Results

Figure 1, presents the flow chart for patients during the study as recommended by the CONSORT (Consolidated Standards of Reporting Trials) statement.[42] Forty-nine patients were evaluated for eligibility, and only 38 patients met the inclusion criteria and were initially randomized into two equal groups. The data for 38 patients: the vibration group (n=19), and the control group (n=19) were available for the final analysis. Mixed model MANOVA test revealed a significant interaction for the measured outcomes (P<0.001).

Demographic and Clinical Characteristics of the Participants

A total of 38 patients with LL burn participated in this study; they were randomly divided into two groups. Comparison of both groups at the time of randomization (pre) revealed that there was no statistically significant difference between both groups' demographic data (age, BMI, and sex) and baseline clinical characteristics of the participants (TBSA %, cause of burn, depth of burn, length of hospital stay, post-burn duration, HbA1C) as p values were p>0.05 as shown in Table 1.

Dynamic Balance Score

The results showed a statistically significant difference between pre and post values in both groups in OSI, APSI and MLSI ($p < 0.05$). There was no statistically significant difference between both groups at the time of randomization (pre) as p >value 0.05. While at the 8th week (post) of treatment, there was a significant difference between groups in OSI, APSI and MLSI (p=0.001, 0.016 and 0.003, respectively,) favoring the vibration group. The patients who received vibration exercises experienced greater improvement in OSI, APSI and MLSI more than the control group. The percentage of improvement (%) in balance indices in the vibration group was more than the control group at the end of treatment (24.36±6.4, 19.3±8.7, and 21.46±1.4 versus 5.47±6.3, 11.9±3.9, and 13.2±4.4), respectively, as shown in Table 2.

ABC Scale

There was a statistically significant difference between pre- and post-values of the ABC scale in both groups ($p< 0.05$). Regarding between groups comparison, results showed no statistically significant difference between groups at the time of randomization (pre) ($p > 0.05$). However, there

Table 2 Comparison of the Outcome Measures Within and Between the Two Groups (Vibrational and Control)

	Vibration Group (n = 19)	Control Group (n=19)	P value
	(M±SD)	(M±SD)	
Overall stability index (OSI)			
Baseline	4.76± 0.74	4.6±0.66	0.555
Post vibration	3.58±0.53	4.3±0.6	0.001
MD (95% CI)	1.17(0.98,1.37)	0.27(0.07,0.46)	
P value*	<0.001	0.009	
OSI Percentage of change	24.36±6.4	5.47±6.3	
Anteroposterior stability index (APSI) (M±SD)			
Baseline	4.2±0.55	4.5±0.65	0.133
Post exercise	3.4±0.61	4±0.60	0.016
MD (95% CI)	0.79(0.655,0.93)	0.53(0.39,0.67)	
P value*	<0.001	<0.001	
APSI percentage of Change	19.3±8.7	11.9±3.9	
Mediolateral stability index (MLSI) (M±SD)			
Baseline	3±0.61	3.24±0.4	0.271
Post exercise	2.32±0.4	2.80±0.38	0.003
MD (95% CI)	0.69(0.46,0.92)	0.43(0.2,0.66)	
P value*	<0.001	<0.001	
MLSI percentage of change	21.46±1.4	13.2±4.4	
ABC (%) (M±SD)			
Baseline	60.1±9.1	61.68±5.85	0.677
Post exercise	72.5±8.4	65.94±6.1	0.016
MD (95% CI)	12.4(11, 13.78)	4.27(2.89, 5.65)	
P value*	<0.001	<0.001	
ABC percentage of change	21.45±8.46	6.96±3.32	
TUG (S) (M±SD)			
Baseline	11.43±1.4	12.1±1.4	0.142
Post exercise	7.25±1.25	9.8±1.10	<0.001
MD (95% CI)	4.19(3.39,4.98)	2.2(1.41,2.99)	
P value*	<0.001	<0.001	
TUG percentage of change	35.8±13.28	18.19±8.76	

Note: P value*, within group significance level.

Abbreviations: WBV, whole body vibration; ABC, the Activities-specific Balance, TUG, timed-up and go; P value, significance level; CI, confidence level; MD, mean difference; M, mean; SD, standard deviation.

was a significant difference between groups at the 8th week (post) of treatment; the vibration group shows a more improvement in the balance confidence more than the control ($p = 0.016$). The percentage of improvement (%) in the values of ABC score in the vibration group was more than the control group at the end of treatment (21.45±8.46 versus 6.96±3.32) as shown in Table 2.

TUG Test

Regarding TUG test, there was a statistically significant difference between pre- and post-values of the TUG test in both groups ($p< 0.05$). While between groups comparison revealed that there was no statistically significant difference between groups at the time of randomization (pre) ($p> 0.05$), however, by the end of the treatment, there was a statistically significant difference between groups favoring vibration group ($p<0.001$) as the patients who received vibration training experienced a greater decrease in the TUG test mean value, which indicates improvement in the functional mobility. The percentage of improvement in TUG mean value in the vibration group was more than the control group at the end of treatment (35.8±13.28 versus 18.19±8.76%) as shown in Table 2.

Discussion

Diabetes mellitus and burn injury are serious complications that may contribute to joint mobility limitation, muscle strength changes, foot deformities, biomechanical changes, balance impairment, and postural deviations.[2,21,43,44] Polyneuropathy and the deterioration of visual acuity in diabetic patients, increase the risk of burn trauma as diabetic patients may not distinguish or

avoid the burn source, so they are more susceptible to dangerous burn injuries with several complications that necessitate distinctive rehabilitation programs. Therefore, the current study was conducted to evaluate the impact of vibration training as an additional intervention on postural balance, balance confidence and functional mobility in T2DM patients with LL burn injury.

According to the results of the current study, there are statistically significant improvements in all dynamic balance indices: OSI, APSI and MLSI; balance confidence; and functional mobility between pre- and post-treatment in both the vibration and the control groups, with significant improvements in the vibration group when compared with the control group. These results reflected the valuable effects of balance exercises and vibration training in T2DM patients with LL burn injury, are agreeing with previous studies that evaluated the impact of either balance exercises or vibration training on either diabetic[23,25–27,33] or burned patients.[28]

The results of this study are consistent with that of Lee et al[26] who reported a significant improvement in the dynamic balance indices following six weeks of WBV training, in addition to balancing exercises in elderly people with diabetic neuropathy. In addition, Jamal et al[23] and Kordi Yoosefinejad et al[25] investigated the efficacy of six weeks of WBV training in improving balance in diabetic peripheral neuropathy. Moreover, Del Pozo-Cruz et al[27] revealed that WBV training significantly improved balance in T2DM after 12 weeks of training.

The positive effect of WBV on dynamic balance could be related to its effect on stimulating the neuromuscular system, as well as activating the postural and leg muscles via tonic vibration reflex phenomenon; the vibration stimulus stimulates the primary nerve endings of the muscle spindles, leading to tonic muscle contractions.[45–48] Additionally, the vibratory oscillations excite the central nervous system, resulting in increased motor unit synchronization, synergist muscle co-contraction, antagonist muscle inhibition, agonist-antagonist coordination and amplification of motor unit firing rates.[45,46,48] Such neural adaptations in the lower extremities contribute to body balance and mobility.[49]

Moreover, previous studies reported the advantageous effect of vibration training on muscular strength by improving knee extensor strength, vertical jump, chair-rising time and hip bone mineral density, which may explain the improvement in functional mobility in response to WBV training.[28,50]

Our study has several strengths; first, to the best of our knowledge, this is the first study to evaluate the effect of whole body vibration in diabetic patients with LL burn injury. Second, the objective assessment for balance by the Biodex Balance System. Last, there is no drop out from the study. However, the current study has some limitations, such as the sample size, lack of short and long follow-up assessments after stopping the training and finally, being only a single-blinded randomized clinical trial.

Conclusion

Based on the results of the current study, it could be concluded that adding whole body vibration training for an 8-weeks duration to balancing exercises may improve postural balance, balance confidence, as well as improving functional mobility in T2DM patients with LL burn injury. A recommendation to incorporate the vibrational training in the rehabilitation program for T2DM patients with LL burn. Further clinical trials with larger sample sizes, considering other outcome measures (eg, muscle strength, quality of life), with longer treatment period, and follow-up assessment are recommended.

Data Sharing Statement

The data supporting the present study are not publicly available, except with reasonable request from Zizi M. Ibrahim and Olfat Ibrahim Ali; zizikahla@yahoo.com; olfat_ib@yahoo.com

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Author Contributions

All authors made a significant contribution to the work reported, whether that is in the conception, study design, execution, acquisition of data, analysis and interpretation, or in all these areas; took part in drafting, revising or critically reviewing the article; gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work.".

Disclosure

The authors reported no conflicts of interest for this work.

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