SECTION – FUNDAMENTAL AND APPLIED KINESIOLOGY

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EFFECT OF VIBRATION THERAPY ON FASTING GLUCOSE, INSULIN LEVEL AND HOMA2 SCORE IN WOMEN WITH PRE-DIABETES HISTORY

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Authors' contribution:

A. Study design/planning
B. Data collection/entry
C. Data analysis/statistics
D. Data interpretation
E. Preparation of manuscript
F. Literature analysis/search
G. Funds collection

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Abstract:

Introduction. Low-frequency vibrations affect the whole body. They can activate a large number of muscles, and can be an effective tool for improving glycemia by increasing body temperature and decreasing body fat. The condition of vibrotherapy effectiveness is the application of a stimulus characterized by appropriate parameters (frequency, amplitude, time) and propagation into precisely defined places.

Aim of the study. The aim of the study was to evaluate the effect of a series of 21 cycloidal vibration treatments for women aged over 60 with a history of fasting hyperglycemia on carbohydrate metabolism index levels.

Material and methods. The study included 50 women (age: 67.0±5.9) randomly assigned to two groups. The study group was subjected to 21 vibration therapy treatments. The placebo group received similar treatment with a placebo device. Before beginning of treatment and on the 10^{th} and 21^{st} day, blood glucose and insulin levels were measured, after that $HOMA2_{IR}$, HOMA%B and HOMA%S were calculated.

Results. After 21 days of vibrotherapy procedures, a significant decrease in the concentration of insulin in the experimental group was indicated (from 21.9±11.2 μIU/ml to 12.8±2.7 μIU/ml). These changes were also confirmed by changes in $HOMA2_{IR}$.

Conclusions. The applied stimulus in the form of 21 vibration treatments seems to be a promising form of improving glycemic control. The favourable results of our pilot study indicate that it is necessary to perform further analyses with the use of a modified protocol of stimulus propagation, especially with additional nutrition control.

Introduction

Physical activity plays a significant role in preventing and controlling type 2 diabetes mellitus (T2DM) [1]. Both aerobic and resistance training improve the effects of insulin and can support controlling glycaemia, lipidemia, blood pressure, this influencing mortality and the quality of life of patients. However, regularity of training is key [1,2]. Morreto's research indicates that most people with T2DM are physically inactive, and the basic problem is the result of the lack of appropriate habits and the presence of numerous motivational barriers (lack of interest, lack of time, depression) [3]. Increased kinesiophobia is indicated in this group of patients [4]. Physical therapists have the appropriate knowledge and skills, and they can help in planning individualised physical exercise programmes, the purpose of which is a balanced level of glucose in the blood and achieving optimum body mass [5]. Physical therapists can also intervene by means of physical techniques (manual or manipulation procedures), electrophysical and mechanical means [5,6]. An alternative is to introduce procedures with the application of low-intensity vibrations in order to prepare a patient for increased physical activity. It is known that vibration training can have application in restoring homoeostasis, being the basis of success in the treatment process, provided that the applied stimulus has specific parameters, such as: frequency, amplitude, time and its propagation in specific locations.

The broadest scientific documentation concerns whole body vibration procedures (WBV). The beneficial influence of WBV was shown both in healthy persons and in patients with various health problems [7]. It is assumed that vibrations activate muscle spindles and cause muscle contractions produced by neurophysiological medullary and supra-medullary mechanisms known as tonic vibration reflex. It allows to activate muscles even in static positions [8]. Vibrotherapy can be an interesting alternative for patients with neurological diseases, such as Parkinson's disease, multiple sclerosis, or after stroke [9]. The effects of vibration included decreased intensity of pain and physical function improvement in persons with degenerative knee joint disease [10], improvement in the ability to perform exercises and in the quality of life parameters among patients with chronic obstructive pulmonary disease [11].

There are few studies dealing with the effects of procedures with the application of vibration in patients with T2DM [12-15]. Several randomised studies on subjects with type 2 diabetes mellitus were reported [16, 17]. However, the effects in the patient population with subclinical lesions are still unknown, and the role and need to introduce early pharmacological or non-pharmacological interventions in this group of patients is widely emphasised [18].

Study Objective

The objective of the study was to evaluate the influence of a series of 21 vibrotherapy procedures applied in females above the age of 60 with hyperglycaemia in fasting conditions indicated in medical history on the level of carbohydrate indices. The number of days with procedures was adjusted to the length of rehabilitation and health resort programmes (21 days), which was aimed at evaluating the effectiveness and the ability of using vibrotherapy in such conditions.

Material and Methods

The project was approved by the Bioethics Commission (approval No. 155/KBL/OIL/2016). The study included a group of females above the age of 60 with episodes of hyperglycaemia in their medical history, students of the University of the Third Age in Nowy Sącz, who were willing to participate in the research project. The volunteers were randomly assigned to the following groups: experimental (n=25) and control (n=25). Before the beginning of the experiment, the subjects were informed about the objective and method of study, the potential side effects and the possibility to resign at any moment without giving reason, and they also signed written consent to participate in the studies. The volunteers kept diet diaries for 5 days (including one holiday), which were then analysed with the use of Dieta 5 software (National Food and Nutrition Institute in Warsaw).

The project exclusion criteria included: using stimulants (in the period at least two weeks before the beginning of the study), previous vibrotherapy procedures, diagnosed diabetes mellitus and taking drugs and/or dietary supplements with hypoglycaeminating effects.

Medical qualification, based on medical history was conducted in order to exclude contraindications for vibrotherapy, to evaluate general health conditions (measuring blood pressure, heart rate and laboratory blood tests: peripheral blood count). The level of physical activity was evaluated by means of the international physical activity questionnaire (IPAQ) – short version [19,20]. Females with moderate and low levels of physical activity were qualified for the tests. Persons qualified to the group with moderate physical activity had to meet the following criteria: 3 or more days of vigorous activity at least 20 minutes per day; or 5 or more days of activity with moderate intensity or walking at least 30 minutes per day; or 5 or more days of any combination of activities, which allowed to reach at least 600 MET min/week. Persons with a low level of physical activity did not meet the aforementioned criteria. Exceeding the 1,600 MET value was a study exclusion criterion.

Based on the diet diary kept for 5 days and the Dieta 5 software, the nutritional value of the consumed meals was established. The subjects were asked not to change dietary habits during the project.

Vibration Procedure

50 females were subjected to vibrotherapy in prone position with the Vitberg+ Rehabilitation Massage Device (RAM Vitberg+ Basic module + Metabolism module). Low-frequency vibrations influence of the whole human body, and mainly, the muscles and fascia, causing an increase in microcirculation, while the flow of liquids in soft tissues are responsible for biological activity. The Vitberg+ Rehabilitation Massage Device (class IIa medical device) uses cycloidal vibrations (CV) as therapeutic stimulus, directed in three perpendicular directions (3D) with a small amplitude and low and medium frequency, and a variable pulse sequence. The experimental factor was full body vibrotherapy (f=20-52 Hz, A=0.1-0.5 mm, a=6.9-13.5 m/s^2) – intermittent vibrations at different frequency, amplitude and acceleration during the 30-minute procedure. The control group received identical procedures with the use of specially prepared placebo modules (Vitberg, Nowy Sącz). The procedures were performed twice a day for 30 minutes, from Monday to Friday, before noon.

Body Composition Tests

Somatic measurements of body height (BH), body mass (BM), waist circumference, hip circumference, skin-fat fold thickness were performed before starting the series of procedures and one day after applying the last vibration procedure. For precise evaluation of body composition, DEXA – dual-energy X-ray absorptiometry, – was used and performed with the GE Healthcare Lunar Prodigy (USA) densitometer. The measurement method uses the phenomenon of a weakened radiation beam going through the body tissues. The tests included i.e. body mass (BM), percentage (PF) and mass of adipose tissue (TBF), lean body mass (LBM) and bone mineral density (BMD), maintaining all standards ensuring plausibility of the results [21].

Biochemical Tests

Before starting the series of procedures and after the 10th and the 21st day of the project, venous blood samples were collected from the vein in cubital fossa in the amount of approximately 6 ml, using BD Vacutainer closed vacuum system, in accordance with the current standards. Biochemical assays were performed in accordance with the methodology of the manufacturer, in full blood (CBC), plasma (glucose) or serum (insulin). In all subjects, glucose and insulin levels were assayed in fasting conditions, and peripheral blood count was performed. The HOMA2$_{IR}$, HOMA%B and HOMA%S factors were calculated for every volunteer with the HOMA calculator (University of Oxford) [22]. The HOMA (Homeostasis Model Assessment) model (HOMA2) accounts glucose resistance, estimating steady state beta cell function (%B) and insulin sensitivity (%S) as percentages of a normal reference population.

Statistical Methods

STATISTICA 13.1 (StatSoft, Poland) statistical software was used for statistical analysis. The results were presented as arithmetic mean ± standard deviation. The normality of distribution was tested with the Shapiro-Wilk test, and variance homogeneity was tested with the Levene test. To compare the significance of difference between the means in the analysed groups, meeting the assumptions of parametric tests, the Student's *t* test was used for independent trials while ANOVA two-factor variance analysis was used for systems with repeated measures, along with the Tukey post-hoc test. If the assumptions of normality of distribution were not fulfilled, logarithmic conversion was used. A 0.05 significance level (α) was assumed.

Results

The mean age of the studied females was 67.0 ± 5.9 years and was not significantly different in the experimental and control groups. The general characteristics of the studied volunteers qualified for the study at the beginning of procedure series and after its end are presented in Table 1. The results of the performed analysis of diet diaries are presented in Table 2 and Table 3.

The results of glycaemia and insulinaemia assays in fasting conditions at three time points is presented in Figure 1. Preliminary tests showed that the subjects in both groups had glycaemia levels with mean values: 5.73±0.41 mmol/l (the experimental group) and 5.64±0.51 mmol/l (the control group), and insulinaemia levels with mean values 21.9±11.2 μIU/ml (the experimental group) and 20.5±9.1 μIU/ml (the control group), which was not a statistically significant difference. On the 10th day of the experiment, these values remained at similar levels for the he experimental and control groups, respectively: 5.78±0.48 and 5.61±0.46 mmol/l for glucose, and for insulin: 18.4±8.9 and 20.2±14.4 μIU/ml, however, on the 21st day of the project, a statistically significant decrease in the level of insulin in fasting state was recorded for the experimental group. These changes of HOMA2 indices are shown in Table 4.

Table 1. General characteristics of the studied groups

	Control group		Experimental group		p*
	Before	After	Before	After	
Body height [m]	1.59 ± 0.07		1.59 ± 0.07		-
Body mass [kg]	73.1 ± 9.4	72.8 ± 9.0	75.1 ± 10.4	74.9 ± 10.6	0.865
%FAT [%]	43.6 ± 4.0	43.5 ± 4.3	43.8 ± 4.6	44.0 ± 4.6	0.471
FAT [kg]	31.1 ± 6.4	31.0 ± 6.4	32.3 ± 7.5	32.3 ± 7.3	0.651
LBM [kg]	39.9 ± 4.0	39.7 ± 3.6	40.7 ± 3.9	40.5 ± 4.4	0.722
BMC [kg]	2.1 ± 0.2	2.1 ± 0.2	2.2 ± 0.3	2.2 ± 0.3	0.817
BMI [kg ·m-2]	28.8 ± 3.0	28.7 ± 2.9	29.4 ± 3.5	29.5 ± 3.8	0.533

The results are presented as mean values along with standard deviation. % FAT – percentage of adipose tissue; FAT – mass of adipose tissue; LBM – lean body mass; BMC – bone mass; BMI – body mass index. * two-way ANOVA with repeated measures.

Table 2. Average energy and basic nutrient content in the diet of the studied groups

	Control group		Experimental group		p*
Energy [kcal]	1496 ± 454	(45% < EER)	1616 ± 493	(37% < EER)	0.427
Protein [g]	66 ± 23	(45% < RDA)	71 ± 27	(27% < RDA)	0.438
Protein %E [%]	18 ± 3	(9% < R)	18 ± 3	(10% < R)	-
Carbohydrates [g]	216 ± 73	(5% < RDA)	242 ± 91	(3% < RDA)	0.368
Carbohydrates %E [%]	53 ± 8	(7% < R)	55 ± 8	(10% < R)	-
Dietary fibre [g]	21 ± 8	(41% < AI)	22 ± 9	(37% < AI)	0.498
Fats [g]	49 ± 18	(18% < RDA)	47 ± 15	(47% < RDA)	0.895
Fats %E [%]	29 ± 7	(29% < R)	27 ± 7	(23% < R)	-
SFA [g]	19 ± 6	-	18 ± 6	-	0.605
MUFA [g]	18 ± 8	-	18 ± 6	-	0.856
PUFA [g]	6.3 ± 4.5	-	7 ± 4	-	0.328
Cholesterol [mg]	226 ± 81	-	291 ± 116	-	0.073
Water [ml]	2086 ± 840	(64% < AI)	1783 ±892	(57% < AI)	0.165

SFA – saturated fatty acids; MUFA – monounsaturated fatty acids; PUFA – polyunsaturated fatty acids; EER – group energy demand; RDA – recommended dietary allowance; AI – adequate intake; R – recommendation. The results are presented as mean values with standard deviations and % of people with a sub-standard intake or recommendation for PAL = 1.4 according to the 2017 IŻŻ (Polish National Food and Nutrition Institute) recommendations * Student's *t* test for independent samples.

Table 3. Average content of selected vitamins and mineral salts in the diet applied in the studied groups

	Control group		Experimental group		p*
Vit. A [μg]	1069 ± 631	(27% < RDA)	1339 ± 1263	(13% < RDA)	0.437
Vit. D [μg]	2.9 ± 3.4	(54% < AI)	4.1 ± 6.9	(87% < AI)	0.378
Vit. E [mg]	7.0 ± 3.5	(45% < AI)	7.1 ± 3.7	(47% < AI)	0.960
Vit. C [mg]	93 ± 40	(23% < RDA)	94 ± 52	(27% < RDA)	0.936
Vit B1 [mg]	1.1 ± 0.2	(36% < RDA)	1.0 ± 0.4	(40% < RDA)	0.561
Vit. B2 [mg]	1.4 ± 0.4	(9% < RDA)	1.5 ± 0.6	(13% < RDA)	0.393
Vit. B6 [mg]	1.9 ± 0.8	(27% < RDA)	1.8 ± 0.9	(23% < RDA)	0.914
Sodium [mg]	3170 ± 836	(0% < AI)	3291 ± 1350	(0% < AI)	0.876

Table 3. (continued)

	Control group		Experimental group		*p**
Potassium [mg]	3315 ± 1144	(59% < AI)	3504 ± 1540	(40% < AI)	0.760
Calcium [mg]	536 ± 218	(64% < RDA)	600 ± 299	(70% < RDA)	0.543
Phosphor [mg]	1112 ± 399	(0% < RDA)	1205 ± 422	(0% < RDA)	0.445
Magnesium [mg]	294 ± 95	(41% < RDA)	291 ± 135	(50% < RDA)	0.773
Iron [mg]	10 ± 3	(36% < RDA)	12 ± 5	(30% < RDA)	0.936

RDA – recommended dietary allowance,; AI – adequate intake. The results are presented as mean values with standard deviations and % of people with a sub-standard intake according to the 2017 IŻŻ (Polish National Food and Nutrition Institute) recommendations
* Student's *t* test for independent trials.

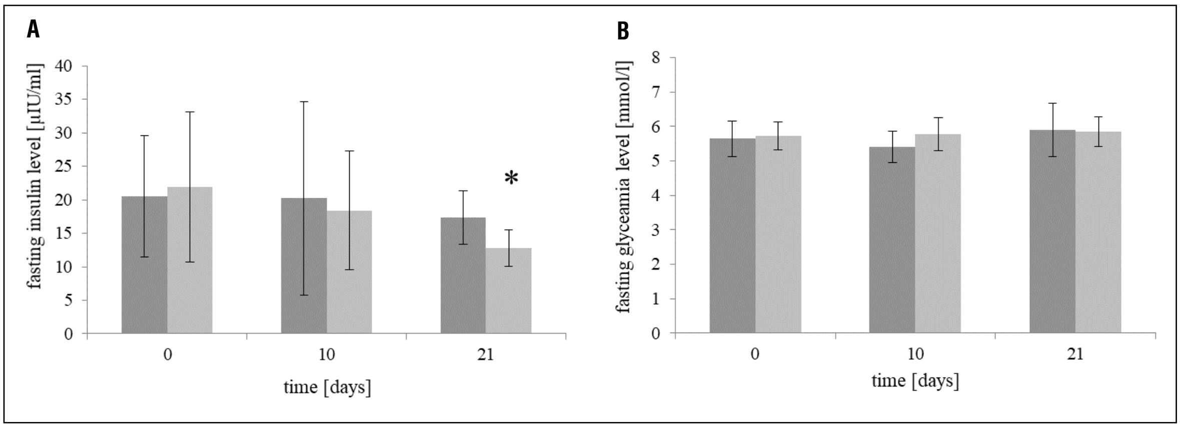

Figure 1. Average fasting insulin (A) and glucose (B) levels in the blood among studied groups on days 0, 10 and 21. The results are presented as mean values with standard deviations. * $p < 0.05$ two-way ANOVA with repeated measures + Tukey post-hoc test for unequal groups sizes.

Table 4. Average HOMA2IR, HOMA2%B and HOMA2%S levels in studied groups on days 0, 10 and 21

	0	10	21	*p***
HOMA2IR				
Experimental group	2.69±1.41	2.26±1,13	1.93±0.65	p <0.05
Control group	2.60±1,21	2.52±1,35	2.09±0.62	
*p**	p >0.05	p >0.05	p >0.05	
HOMA2%B				
Experimental group	143.69±60.57	136.55±61.38	125.80±52.28	p >0.05
Control group	156.91±68.89	150.06±74.57	119.82±52.96	
*p**	p >0.05	p >0.05	p >0.05	
HOMA2%S				
Experimental group	48.82±28.57	57.89±45.38	56.33±20.44	p >0.05
Control group	44.39±29.54	50.54±25.39	61.23±28.12	
*p**	p >0.05	p >0.05	p >0.05	

The results are presented as mean values with standard deviations. * $p < 0.05$ two-way ANOVA with repeated measures + Tukey post-hoc test for unequal groups sizes.

Discussion

Analysis of the results showed that the proposed vibrotherapy did not influence changes in body composition of the study participants. Both in the experimental and control groups, the somatic indicators, such as: body mass, adipose tissue in kg and as a percentage of total body mass, hydration, or BMI, did not undergo statistically significant changes. However, the biochemical tests allowed for detection of differences between the groups. The project included females with episodes of hyperglycaemia in their medical history, but glucose concentrations did not point to fully symptomatic diabetes (it is diagnosed when the random glycaemia result $\geq$11.1 mmol/l is reached at least twice, or glycaemia in fasting conditions is $\geq$7.0 mmol/l). On the 21st day of the project, for the experimental group, a statistically significant decrease in the level of fasting state insulin was recorded. This change took place only after 21 days, which confirms the earlier reports on the necessity of repeated and regular application of vibration procedures to generate changes regarding the biochemical indicators in the blood [23]. The change of the aforementioned parameters was not observed at the level of statistical significance in the control group.

The influence of the vibration stimulus was also revealed on the basis of the analysed $HOMA2_{IR}$ values, allowing to estimate the insulin sensitivity in stationary conditions. These observations are important, especially in light of the report by Bonor et al., in which it was postulated that $HOMA2_{IR}$ can be considered a significant predictor of cardiovascular diseases in patients with glycaemia disorders [24].

Low frequency vibrations applied systemically generate increased muscle congestion and metabolism [23, 25], thus, increasing the demand for glucose in this tissue. In the body, of the majority of glucose and fatty acids are collected and stored by skeletal muscles. Glucose enters the skeletal muscles mainly with the help of the GLUT4 transporter, over 90% of molecules of this protein are inactive under normal conditions [26]. However, several factors can influence the quantity of glucose transporters visible on the surface of a cell. Physical training is the strongest stimulus increasing the expression of skeletal muscle GLUT4, and this effect can contribute to the improvement of insulin and glucose metabolism activity [27]. Studies in animal models indicate that vibrations can also lead to increased expression of GLUT4 on myocytes and to improved control of glycaemia [28, 29]. If there is a similar phenomenon taking place in human body – is still unknown.

Insulin binds with its receptors on skeletal muscle fibres and influences increased exposure of the GLUT4 transporter to the cell membrane, which allows for the transport of glucose molecules inside the cell and decreases its concentration in the blood, however, chronic hyperinsulinaemia has an opposite effect, leading to insulin resistance, which is the basis for the development of type 2 diabetes [30]. In light of this information, the decrease of insulinaemia in fasting conditions observed in our research, resulting from regular vibration training, can be used as a form of antidiabetic prophylaxis or a method extending the time until the manifestation of fully symptomatic type 2 diabetes in predisposed patients.

In this study, we were unable to observe decreased glycaemia in fasting state, but it should be taken into consideration that this index is highly dependent on the changes related to dietary habits and rapid fluctuations influenced by dietary errors. No changes in this parameter, despite other positive biochemical modulations, were observed in patients with type 2 diabetes subjected to vibrotherapy [31]. Analysis of the diet diaries kept by the participants of our project indicated many deviations from dietary recommendations in the self-designed diets. 45% of the volunteers from the experimental group and 37% from the control group did not consume enough protein, and a very similar percentage in both groups revealed too low fibre content in the diet. The observation related to the reported amount of water is highly disturbing. In the experimental group, as much as 64% and 57% of volunteers from the control group drank too little water. The negative water balance can lead to dehydration resulting from a too low supply with constant demand (depending on various external and internal factors) [32]. Low water supply can be alarming, especially with increased diuresis induced by vibrotherapy, as reported by the participants, however, the methodology of the conducted study does not allow for objective confirmation of the increased production of urine due to the applied therapy. Further studies are required to fully confirm this thesis. In subsequent projects, it is necessary to take the control of hydration of the body into account, for example by determining BUN (blood urea nitrogen)/creatinine ratio.

Diet analysis showed the highly insufficient nature of the diets and decidedly too low levels of nutrient supply. Both groups of females showed an insufficient amount of vitamins (A, D, E, C, B1, and B6) and microelements (K, Ca, Mg, Fe) supplied in the diets self-composed by the participants. Data in the literature related to this issue includes contradictory information and indicates dietary insufficiencies in persons above the age of 60 concerning vitamins D and E, potassium, calcium and magnesium, excess of vitamins A and C, and phosphorus [33], or insufficiency of calcium, and to a lesser degree, also of iron, magnesium, zinc and copper [34]. The common denominator is the too high supply of sodium, also observed in our research.

Discussion of the results is very difficult due to the small number of available trials performed in a similar model, and the differences in the effects of vibrotherapy applied in standing position (WBV) and lying position, as in this study. This paper is the first report analysing the possibility of using vibrotherapy among patients in prediabetic condition in a lying position – much safer and producing less injuries than the standing position. The results of this project, however, need to be interpreted very carefully due to inaccurate results of diet analysis. The low general calorific value declared by our subjects, which most probably resulted from concealing snacks, is the basic limitation of this paper and unquestionably indicates the necessity of repeating the trials in a model taking strict diet control into account (e.g. studies during a rehabilitation programme with collective meals, including a diet designed by a dietician). Controlled conditions can ensure better visualisation of the influence of vibration stimulus on body composition, which has been already indicated by Bellia et al. for WBV [31].

The adverse effects, such as hypoglycaemia, discomfort and musculoskeletal system injuries are rare complications for vibration procedures, and they are more frequently related to the methods including stimulus propagation in standing position [35].Vibrotherapy is a great supplement or form allowing for milder introduction of the proper habits related to physical activity and a regular form of performing procedures and exercises allowing for activating muscular utilisation of glucose.

Conclusions

This paper is the first report analysing the possibility of using vibrotherapy applied to patients in prediabetic condition in a lying position. The stimulus applied in the form of 21 days of vibration procedures with the Vitberg+ Rehabilitation Massage Device (RAM Vitberg+) seems to be a promising form of augmentation of other procedures aimed at improvement in glycaemia control. In the experimental group, a decrease of insulinaemia in fasting state was observed, which also resulted in the improvement of the $HOMA2_{IR}$. The promising results of our pilot study indicate that it is necessary to perform further analyses with the use of a modified protocol of stimulus propagation, especially with additional nutrition control.

Conflicts of Interest:

The authors of this manuscript declare no conflict of interest.

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