The effects of high-frequency high-magnitude whole body vibration in physical actively osteoporotic women: a pilot study.

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Abstract

Purpose: Osteoporosis is nowadays affecting a large population. Recent studies, performed on animals and human been, have shown that low magnitude, high frequency mechanical stimuli produce anabolic effects on bone tissue, increasing both bone density and strength. Aim of this study is to verify the effects of whole body vibration on bone tissue of trained osteoporotic women underwent to high magnitude and high-frequency vibration exercise on a vibrating platform.

Method: Twenty-six osteoporotic women, trained with low impact exercise regimen, voluntarily participated in the study and were randomly divided in two groups: experimental (E) and control (C). All subjects aren't submitted to any pharmacological therapy. The T-score, Ultrasound Bone Profile Index (UPBI) was calculated using the Amplitude-Dependent Speed of Sound (AD-SoS) measured with QUS.

Results: Thirteen osteoporotic women following four months of ten-minute treatments, three per week, of high-level of magnitude (5,0 g) and high frequency (30Hz) mechanical vibration improved the Amplitude-Dependent Speed of Sound (AD-SoS) QUS parameter from 1.878 ± 79,45 to 1.971, 17 ± 78,69 ($p<0,002$). The T-score in the experimental group show an inversion trend passing from -3,50 ± 1,13 to -2, 18 ± 1,12 ($p<0.002$) and the Ultrasound Bone Profile Index (UPBI) improve from 0,34 ± 0,11 to 0,47 ± 0,21 ($p<0,01$). In the control group (low impact exercise) any of these parameters considered show significantly changes over the same period of time.

Conclusion: Given that these accelerations were well tolerated by the experimental cohort, that vibrations similar to these stimulated an increase in bone density and strength in animals and humans, and that skeletal loading is an inevitable product of functional load bearing, we believe this strongly anabolic, non-invasive intervention represents, associated to good physical fitness also, early evidence of an unique non-pharmacologic treatment for osteoporosis.

Introduction

Osteoporosis is currently affecting a large population. Over 40% of women in the United States over the age of 65 are currently affected, determining a cost, which exceeds $15B per year to the health care services [1]. According to the E.S.O.P.O. study (Epidemiological Study On the Prevalence of Osteoporosis) in Italy 23% of women older than 40 years and 14% of men older than 60 years are affected by osteoporosis [2].

Many different prevention and treatment regimens have been developed to resolve the increasing problem of the osteoporosis and related fractures. Reversal of bone loss is then a critical goal for science for improving the long-term well being of the aged population. Several investigations have been conducted trying to identify an effective countermeasure to osteoporosis. However, while several pharmacological interventions have been implemented for the management of this disease [3, 4, 5, 6], it seems that sometimes the risks connected to the side-effects exceed the apparent benefits [7]. Several authors showed that the mechanical stimulus, mediated by physical activity or exercises, is the only mean which can positively influence not only the bone mass and strength but increasing muscle strength too [8, 9, 10, 11]. In addition, regular physical activity enhances health and physical fitness improving overall the quality of life in elderly population by reducing the risk of deterioration of functional capacity [12, 13]. Moreover, the osteogenic adaptation of skeleton is site-specific and related to training regimens [14, 15]. Scientific evidence shows that low impact type movement, like endurance training, has not significant results in bone gain [11]. Therefore, the impact type movement, that generates a versatile stimulus on whole muscle-skeletal system can generate osteogenic adaptation on skeletal sites [14]. In fact, according the Wolff's law (Wolff, 1892) [16], the bone tissue is constantly adapting to changes in its loading environment accommodating the structures of the skeleton to mechanical demands. The loading-induced deformation in bone tissue (strain) are responsible of the adaptations in bone architecture and mass [17, 18]. The mechanical strain, for determining the effects on bone remodelling, is related to the other specific factors like magnitude, frequency and application time [19, 20]. Changes of gravitational conditions can be produced also by varying magnitude and frequency of mechanical stimulus, like mechanical vibrations applied to the whole body [21]. Recent clinical studies have suggested that the whole body vibration represents a mechanical stimulus enough to improve both the muscular performance [21, 22, 23, 24]. The interaction between muscle and bone responds to patterns of use or disuse with relative alterations in structure and strength [25, 26]. The whole body vibration has been shown to effectively counteract bone loss. The first clinical studies was conducted on animal model. Flieger in 1998 [27] showed that applying the mechanical stimulus at 50 Hz of frequency and 2 g of magnitude for 30 min per day for 12 weeks on ovariectomized rats, the bone loss was less than the other rats not exposed to vibration stimulus. Rubin et al. [28] exposed, first a mature turkey stimulated on vibrating platform, oscillating at 30Hz, 0,3 g of magnitude (g = 9,81) for 5 minutes per day for 30 days of treatment showing an increase of new bone formation in the trabecular bone of the distal tibia. Continuing on their animal studies, Rubin et al. [29] showed that applying stimulated at 30Hz for 20 minutes per day, it is obtained a 34% of increase in the density of trabecular bone in the proximal femur of adult male sheep following one year of treatment. Oxlund [30] found that an oscillating frequency of 45 Hz was enough to increase bone formation and preserving biomechanical bone strength on ovariectomized rats.

The first clinical studies on human been show a positive effects in adolescents with cerebral palsy [31] and in osteoporotic female [32]. Recently other authors show the increase as in muscle strength than in bone mass after exposition to vibration stimulus in post-menopausal women. Rubin [33] showed an improvement bone mass density (BMD) of 1,5% in the spine and 2,17% in the femur, whereas the control group lost 1,6 % in the spine and 2,13% in the femur, in postmenopausal women submitted at Whole Body Vibration (WBV) treatment at 30 Hz of frequency for 20 min (2 bouts of 10 min) per day, every days for 12 months. Improvements on BMD and on muscular strength was found also after six months of WBV treatment at 35-40 Hz of frequency and 5 g of magnitude [34]. These results seems to suggest that this intervention may have an anabolic effect on bone tissue. In contrast, the modest physical activity at low impact doesn't have any effect on BMD of postmenopausal woman [11].

Aim of this study is to verify the effects of whole body vibration associated to exercise training at low impact, on bone tissue of osteoporotic women underwent to 4 months of high-frequency vibration exercise on a vibrating platform. For ethical reasons connected not only to the experimental nature of this study but also to the short time of treatment, it was used the Quantitative Ultrasound that represent a feasible, sensitive and non-invasive method for assessing bone tissue, over others methods that use radioactive sources or ionizing radiations [35, 36, 37, 38].

Methods

To evaluate the effects of whole body vibration on bone loss condition, twenty-six osteoporotic women (T-score –3.67 ± 1.10, Age 63 ± 8.6 years, Weight 66.12 ± 10.7 kg, Height, 161.7 ± 5.9 cm) voluntarily participated in the study and were randomly divided in two groups: experimental (E) and control (C). Table 1 presents physical characteristics of the subjects of both groups. All subjects participating at this study aren't submitted to any pharmacological therapy.

The subjects of both groups participated at the same exercise training program (one hour three times per week) consisted in walking (15 min), flexibility and joint mobility exercises (15 min), free body exercises (15 min.), low impact step exercise (10 min.) cool down exercise (5 min.).

In addition, the subjects of experimental group performed the vibration treatment in the same day before the exercise training program.

The subjects of experimental group were instructed on the outcomes and the potential benefits associated with their participation in the study. Each subject was familiarised with the experimental protocol and signed an informed participation consent, approved by the Ethical Committee of the Italian Society of Sport Science. Subjects under specific traditional treatment for osteoporosis with previous history of fractures or bone injuries were excluded from the study. They underwent to the experimental treatment consisting of whole body vertical sinusoidal vibration delivered through a specially designed vibrating plate (Nemes LB, Ergotest Europe, Italy). The magnitude of vibration was 5 g (1g = 9.81 m•s^{-2}) and the frequency was 30Hz. The subjects exercised three times per week for a total period of three months. The treatment protocol has been previously described [39]. The total vibration exposure was ten minutes per session. The subjects were standing with both legs in semi-squat position (knees bent at 100°) and were allowed to hold a standing stationary metal bar to maintain equilibrium during the exposure to vibration (Figure1). To obtain a complete whole body vibration, the mechanical waves, generated by vibrating plate, were also transmitted to the hands through the metal bar connected to it. During the time-course of the experiment, none of the subjects in the experimental group reported any discomfort from the treatment and only one subject of this group, after the first week of vibration treatment, drop-out from this experiment without appreciable reason. The Compliance of each subject participant to this study, calculated as the number of days attended divided by the 48 days in for months trial (3 days per week for 16 weeks) [40] was about 88%, without statistical difference between both groups.

Quantitative Ultrasonogrammetry (QUS)

Quantitative ultrasound (QUS) measurements were performed before and after the three months treatment period in the proximal phalange of digit II and IV of the dominant arm, using a DBM Sonic 1200 (Igea, Italy) ultrasound device. Two probes are applied to the lateral surface of the fingers, one acting as generator of signal (US frequency = 1.5 MHz) and the other as receiver. The coupling of them with the skin is mediated by a water-based gel. The velocity at which the US traverses the phalanges, in a lateral-medial direction, was calculated by rate between the distance separating the probes, directly measured by the calliper, and the time elapsing from the emission of the US signal to its reception and expressed in m/s. The device measures the time when the electrical signal, generated by reaches an amplitude of 2 mV at the receiving probe, thus the QUS parameter calculated is the Amplitude-Dependent Speed of Sound (AD-SoS,) for each four fingers and its average value. The AD-SoS has been shown reflecting the mass and the elasticity of bone

[36]. The phalanges reflect the largest variations of BMD over lifetime in women [41]. The decreasing of AD-SoS is correlated with decreasing of BMD and loss of trabecular structures, typical conditions of elderly women [42, 43].

Among the other parameters analysed by the device, in the present study, in addition to the average values of AD-SoS and the Ultrasound Bone Profile Index (UBPI) also the T-score will be considered..

The UPBI is an optimum logistic multivariate model, derived from different parameters, for fracture discrimination. It expresses the probability that the subject has a vertebral fracture at the time of QUS evaluation [44].

The T-score was calculated using the AD-SoS measurements. The individual values of QUS were then converted to a T-score according to the following formula:

T-score = (measured values – average values in young adult)/SD in young adult

The device has been calibrated by manufacturer using a composite mother phantom and weekly calibrations are performed to control the ultrasound velocity in a Plexiglas phantom. All the QUS measurements were performed by the same operator. The intraoperator reproducibility was already scientifically documented [45] and the Coefficient of Variation (SD*100/Mean of measurements) of repeated examinations was 0.15% for AD-SoS parameter, calculating on repeated measurements effectuated in the same day on the second finger of a subject 30 times. In vivo short term reproducibility was also assessed by measuring 5 times 7 subjects, randomly selected from both groups, at an interval time not exceeding 7 days; the CV% was 0.75. All the measurements effectuated in this study were performed blind, because the operator didn't know the belonging of patients at the experimental or control group.

Statistical analysis

The data were analysed using the statistical software for the Social Science (SPSS Inc.). A paired Student's *t*-test was used when comparing longitudinal data within the each group of women. The p values resulting from this calculations are two sided and the minimum level of p value to be considered as significant is 0.05. The data referred to the subject's characteristics are expressed as mean $\pm$ standard deviation.

Results

As expected, the evaluation of the control group (trained subjects only) showed mainly no changes over the QUS parameters in four months time (table 4). In detail, only five subjects showed slight improvements (table 3). On the other side, the experimental group (vibrated and trained subjects) showed remarkable improvements on the AD-SoS QUS parameter ($p = 0,002$), on the UPBI ($p = 0,01$) and on the T-score ($p = 0,002$) (table 4) except only one subject (table 2).

Discussion

The magnitude of musculo-skeletal interactions is of paramount importance for the maintenance of bone integrity. Physical activity performed early in life has been shown to contribute to high peak bone mass [46]. The results of this study confirm the scientific evidence that some forms of exercise, in particular the ones producing high impact forces, seem to be able to reduce or reverse the age-related loss of bone [47], whereas low impact exercise regimen doesn't have effects on remodelling bone tissue [11]. In effect, a lack of weight bearing activity could favour the likeliness of sarcopenia [48] reducing in this way signals critical to the maintenance of bone mass [26]. Vibration represents a strong stimulus for musculoskeletal structures due to the need to quickly modulate muscle stiffness to accommodate the vibratory waves [39]. Our results suggest that vibrations transmitted to the body by means of vibrating plates may be an effective alternative countermeasure to bone loss. This hypothesis is strongly supported by the effects of such treatment on human skeletal muscles. Vibration has been in fact shown to produce remarkable enhancement in strength and power production following acute [22, 23] and chronic treatments [49]. The extent of the response observed in our experiment (increase in QUS T-score by 57%) is surprising. However, it is our opinion that high magnitude (5 g), frequency (30 Hz) and time of exposure (10 min) of vibration treatment could be it assimilated to an high impact mechanical stimulus like that experienced during contact time (~ 200 mms) (references) in ballistic movements (drop jump or high jump, high velocity run), enough to influence the bone tissue remodelling [21, 22, 23]. Moreover, also some influence from hormones could have determined such a remarkable adaptation to vibration treatment considering that the total exposure time to vibration was relatively short (~360 minutes). Vibration has been in fact shown to acutely increase testosterone and growth hormone levels in healthy individuals [23] following the same protocol used in the current experiment. Taking into consideration the results of these preliminary studies it would not seem far-fetched, then, to suggest that the combination of high-frequency mechanical stimuli and hormonal responses provided by vibration could represent an anabolic signal to musculo-skeletal tissues. The higher improvement obtained in these study, respect to the results present in scientific literature, could be due to different factors. One of these, associated to the overestimation of QUS measurement, following our opinion, could regards the effects of incommensurable vibration transmitted by metal bar to the hand directly, determining a local effect that could not completely representative of proper skeletal specific sites of the QUS measure. However, the present findings demonstrate, the effectiveness of high impact stimulus of vibration exercise on bone tissue and provide support for its use as a non-pharmacological intervention to prevent and/or reverse bone loss in humans.

These preliminary studies are promising, longer term, larger population scale studies must be performed in order to verify the effectiveness of vibration treatments and its combination with exercise regimen on the spine and the lower limbs for to prevent bone loss falls and related bone fractures.

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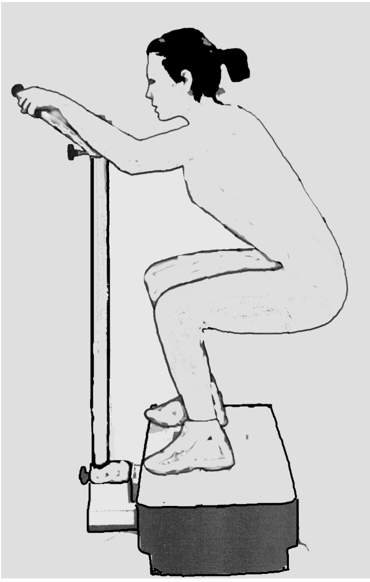

Fig.1

	Control Group		**Experimental Group**	
Variables	Mean	SD	Mean	SD
Age (years)	61.2	7.3	64.8	5.6
Height (cm)	161.6	4.4	173.1	10.6
Weight(kg)	68.6	11.2	68.0	11.9

Table 1

Exp Group	T-Score		AD-SoS		UPBI	
Subjects	**pre**	**post**	**pre**	**post**	**pre**	**post**
subject 1	-2,46	-2,39	1952	1957	0,39	0,38
subject 2	-2,49	-0,16	1950	2113	0,57	0,84
subject 3	-5,24	-2,04	1757	1981	0,18	0,34
subject 4	-3,04	-2,63	1911	1940	0,49	0,57
subject 5	-2,33	-1,37	1961	2028	0,36	0,45
subject 6	-3,86	-1,24	1854	2037	0,26	0,74
subject 7	-3,41	-3,54	1885	1876	0,29	0,26
subject 8	-4,53	-1,31	1807	2032	0,23	0,7
subject 9	-3,93	-3,31	1849	1892	0,27	0,24
subject 10	-2,77	-2,46	1930	1952	0,32	0,4
subject 11	-5,59	-4,11	1733	1836	0,25	0,22
subject 12	-2,41	-1,63	1955	2010	0,41	0,45

Table 2

Control Group	T-Score		AD-SoS		UPBI	
Subjects	**pre**	**post**	**pre**	**post**	**pre**	**post**
subject 1	-2,43	-2,74	1954	1932	0,63	0,58
subject 2	-3,63	-4,39	1870	1817	0,28	0,22
subject 3	-3,83	-3,96	1856	1847	0,21	0,22
subject 4	-3,41	-3,80	1885	1858	0,35	0,23
subject 5	-3,61	-4,11	1871	1836	0,35	0,27
subject 6	-5,23	-5,91	1758	1710	0,18	0,11
subject 7	-2,29	-2,06	1964	1980	0,38	0,39
subject 8	-4,20	-4,16	1830	1833	0,21	0,21
subject 9	-3,60	-3,51	1872	1878	0,20	0,20
subject 10	-5,64	-5,77	1729	1720	0,13	0,21
subject 11	-3,51	-3,44	1878	1883	0,26	0,31
subject 12	-3,83	-3,96	1856	1847	0,21	0,22
subject 13	-2,76	-2,20	1931	1970	0,40	0,48

Table 3

	Control Group			Experimental Group		
QUS Variables	**Pre**	**Post**	**T-test (p) =**	**Pre-treatment**	**Post-treatment**	**T-test (p) =**
T-Score	-3,69 (0,96)	-3,85 (1,15)	n.s.	-3,50 (1,13)	-2,18 (1,12)	0,002
AD-SoS (m/s)	1865,69 (67,13)	1854,69 (80,50)	n.s.	1878,67(79,45)	1971,17 (78,69)	0,002
UPBI	0,29 (0,13)	0,28 (0,13)	n.s.	0,34 (0,11)	0,47 (0,21)	0,01

Table 4

Figures and Tables

Figure 1. Position assumed by subjects of Experimental Group on vibrating plate (Nemes)

Table 1: Descriptive data (mean ± SD) of the subjects of both groups

Table 2. QUS parameters for individual subjects, at the beginning and four months after the vibration treatment.
The treatment was effective in all except one of the subjects of the Experimental Group.

Table 3. QUS parameters for individual subjects, at the beginning and four months of control group. Only five subjects showed slight benefit of exercise treatment.

Table 4: Mean values ± SD of AD-SoS and UPBI before (Pre) and after (Post) three months in Experimental Group treated with Whole Body Vibration and in Control Group. Statistical differences in either groups were analysed using Student's t-test for paired observation.