Effects of Localized Vibration Therapy on Bone-Remodeling Biomarkers in Postmenopausal Women

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DISCLOSURES: N. Viswanathan: 3A; TheraNova LLC. M. Jaasma: 3A; TheraNova LLC. S. Mangrum: 4; TheraNova LLC. A. Vergara: 3A; TheraNova LLC. C. Lindquist: 3A; TheraNova LLC. D. Burnett: 3A; TheraNova LLC. 4; TheraNova LLC. L. Bilek: 5; TheraNova LLC.

INTRODUCTION: Osteoporosis is a highly prevalent, debilitating condition characterized by accelerated loss of bone mineral density (BMD) and increased risk of fracture. One in two women and one in four men over age 50 will suffer an osteoporotic fracture in their lifetime, accounting for two million broken bones and $19 billion in related healthcare costs in the US annually[1]. Unfortunately, there are few early non-drug interventions available to prevent disease progression. Whole-body vibration (WBV) therapy has been identified as a potential treatment for osteoporosis. Loading of the bone matrix, as created through vibration therapy, has been shown to increase bone mineral density[2]. However, a limitation of several researched and commercially-available devices is poor energy transmission from the device, which the user stands on, to the hip and spine, the regions most vulnerable to fracture. This study sought to answer whether vibrational therapy applied locally to the hip and lower spine would result in acute changes in bone-remodeling biomarkers indicative of long-term beneficial effects on BMD.

METHODS: A crossover study was conducted at University of Nebraska Medical Center under IRB approval and with written informed consent. Eligibility criteria included: female, within six years post-menopause, ambulatory, and BMD T-score greater than -2.5 (low bone mass or normal BMD). Subjects were excluded if they had osteoporosis or high fracture risk, weighed more than 300 lbs., or had pharmacologic or lifestyle interventions affecting musculoskeletal or endocrine systems. Subjects were all assigned to receive a sham treatment, then receive the verum treatment one week later. Vibration was applied with a device worn around the waist with the vibrating element placed on the sacrum. The device provided acceleration of approximately 0.6g at 30 Hz. The sham treatment consisted of wearing the device, motor off, for 30 minutes while standing or walking, while verum was the same with the device motor on. Blood draws were performed before and 30 minutes after both the sham and verum treatments. Levels of bone-specific alkaline phosphatase (BAP, bone formation marker) and serum type-I collagen cross-linked N-telopeptide (NTX, bone resorption marker) were quantified via ELISA, and the average of triplicate readings was used for analyses. BAP and NTX were quantified as percent difference between pre- and post-treatment readings. Information about daily activities including alcohol and tobacco intake and exercise was captured. A related-samples Wilcoxon Signed Rank test was completed in SPSS to compare biomarker results.

RESULTS: A total of 18 subjects were enrolled, and 17 subjects completed both treatments. Of the 17 subjects, all identified as Caucasian, the mean age was 54.6 ± 3 years (SD), and mean BMI was 26 ± 4.6 (SD). 11 subjects consumed alcohol (less than one standard drink daily), one subject was a current smoker, and all subjects could perform routine daily activities up to walking one mile. Pre-post changes in NTX between verum and sham groups were highly statistically significant (verum: -5.4 ± 8.8% (SD); sham: 8.8 ± 7.6% (SD); $p<0.001$; Figure 1). In contrast, the changes in BAP between verum and sham conditions were not statistically significant (verum: -0.3 ± 6.1% (SD); sham: -1.1 ± 5.3% (SD); $p=0.7$). All patients responded that the treatment was comfortable and acceptable for daily use.

DISCUSSION: Despite some subject-to-subject variability, all patients exhibited a decrease (average 14%) in NTX between verum and sham, indicating that treatment produced an immediate inhibitory effect on bone resorption. It has been shown that NTX decreases acutely in response to resistance training[3], so the results point to localized vibrational therapy having an acute biochemical effect on bone resorption similar to that of resistance-exercise. In contrast to NTX, no changes were seen in BAP. However, there are conflicting reports in the literature about the temporal sequence of loading-induced increases in BAP[4], so our study may have evaluated BAP too soon after the vibration treatment. Nonetheless, the short-term inhibitory effect on bone resorption activity warrants a long-term efficacy study to confirm that the vibration therapy produces beneficial effects on bone mass and strength.

Some limitations of this study include a small, racially-homogenous study population and inability for blinding and placebo-control. During the sham treatment, participants were told that vibration may occur at low levels so as to be imperceptible. However, during the verum treatment, it would have become immediately obvious that the device was on, and was off for the previous treatment. Beyond that, the study was well-controlled in terms of inter- and intra-patient variability by having each patient serve as their own control performing a pre- and post-treatment blood draw on both days.

An important result was that all subjects indicated that the treatment would be acceptable for daily use. No adverse effects were reported. Traditional approaches to prevention of osteoporosis such as exercise have low compliance rates[5]. In a 2011 report, the Agency for Healthcare Research and Quality stated "Compliance and access to… vibration therapy must also be considered when analyzing the potential benefits for the prevention and treatment of osteoporosis."

SIGNIFICANCE/CLINICAL RELEVANCE: Low cost, ease of use, and effectiveness of localized vibration therapy make it a promising clinical solution. Vibrational therapy must be considered as a first-line therapy in long-term osteoporosis prevention plans.

REFERENCES:

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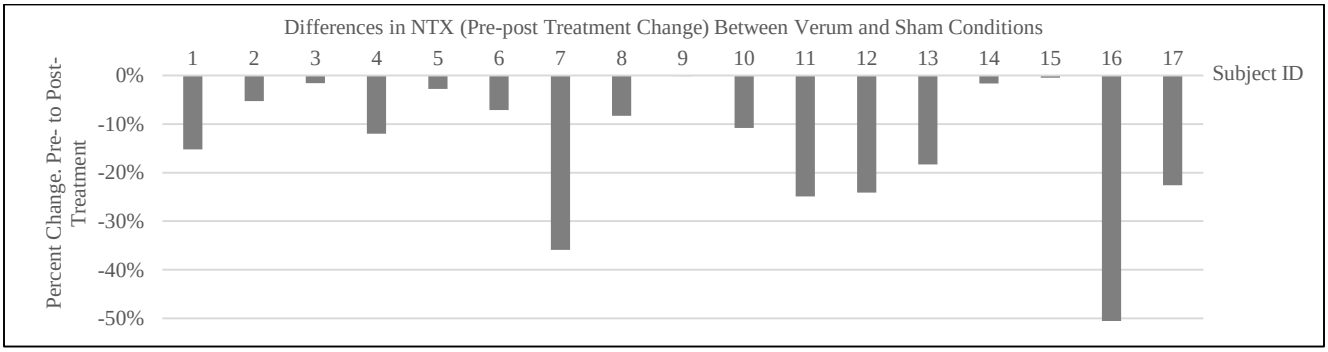

FIG. 1: Sham NTX results (as percent change, pre-post) subtracted from verum NTX results (as percent change, pre-post)