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Is Whole Body Vibration (WBV) a Safe and Effective Adjunctive Therapy for Reducing Fall Risk in the Elderly?

Harry J. Guarino
Philadelphia College of Osteopathic Medicine, harrygu@pcom.edu

Is Whole Body Vibration (WBV) a Safe and Effective Adjunctive Therapy For Reducing Fall Risk In The Elderly?

Harry J. Guarino, PA-S

A SELECTIVE EVIDENCE BASED MEDICINE REVIEW

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ABSTRACT

OBJECTIVE: The objective of this selective EBM review is to determine whether or not whole body vibration (WBV) is a safe and effective adjunctive therapy for reducing fall risk in the elderly.

STUDY DESIGN: A review of English language randomized controlled blinded trials published within peer-reviewed journals from 2005-2010 evaluating the effectiveness of WBV in reducing fall and fall risk. The studies included elderly participants age 60 and older.

DATA SOURCES: Randomized controlled blinded trials were found using PubMed, Medline and OVID databases.

OUTCOMES MEASURED: Outcomes measured were reduction in fall number and reduction in fall risk. Fall number was assessed using a prospective self-reported count on number of falls via calendar system. Fall risk was assessed via three measures: a multifactorial fall risk parameter (the Physiological Profile Assessment), the Timed Up & Go (TUG) test which evaluates functional mobility and the Tinetti test which measures balance and identifies gait abnormalities.

RESULTS: One RCT found that WBV added onto an 18 month multifunctional exercise program significantly reduced the fall rate compared to the control group who did not receive WBV. The other two RCT's that evaluated fall risk reduction displayed mixed results – one showed a significant positive change in both the Tinetti and TUG tests in the experimental group receiving WBV; the other RCT's outcome measurement of the Physiological Profile Assessment displayed a positive change after WBV that did not reach significance when compared to control while the TUG test improved significantly in the experimental group receiving WBV.

CONCLUSION: The results of the three RCT's presented evidence that WBV can significantly and safely reduce falls and certain parameters that confer for a reduction in fall risk. While the Physiological Profile Assessment did not reach a significant change entirely, when the fall risk parameter was examined on the level of stratified subgroups, a significant change was displayed in fall risk when comparing the most high-risk group to control groups. However, the duration and length of therapy and vibration parameters need to be more accurately determined through future comparative trials.

KEY WORDS: Whole body vibration, fall

INTRODUCTION:

Falls represent a significant public health concern and conundrum, as they affect health-related quality of life and are one of the leading causes of disability, injury and death among older adults.[1,2] This paper evaluates three blinded, randomized controlled studies comparing the efficacy of whole body vibration as an adjunct to traditional methods in order to reduce fall risk in the elderly.

At least 30% of people over the age of 65 years fall each year (~ 1in 3 adults) and this percentage increases to over 40% after age 75.[2,4,5] Of those who fall, 20-30% suffer injuries severe enough to impair mobility and independent living that increase their risk for early death.[6] Elder adults are also hospitalized for fall-related injuries five times more often than they are for injuries from any other causes.[6] While falls remain ubiquitous in our society, the cost and burden on our health care system is likewise immense. The Centers for Disease Control and Prevention (CDC) stated that in the year 2000, falls among older adults cost the U.S. health care system over $19 billion, which calculates to $30 billion in 2010 dollars.[7] As our population shifts towards an older age, this number is likely to increase and is estimated to reach over $50 billion in 2020. This number fails however to incorporate the indirect costs of disability, cost of lost time from work and the cost associated with reduced quality of life. Additionally, in 2009, emergency departments alone across the U.S. treated 2.4 million nonfatal fall injuries among older adults – more than 662,00 of which required a hospitalization – a hospitalization that costs on average $17,500.[7]

The cause of falls in the elderly is often multifactorial but age-related decreases in postural control and muscle strength combined with changes to vision, perception and proprioception/balance are major risk factors for falls.[1] Falls in this population cause significant morbidity and mortality due to: coexisting changes in bone mineral density (osteopenia/osteoporosis) resulting in fractures and significant trauma; reduced reserve and capacity for healing intrinsic to the aging process; and complications that may arise in other pre-diagnosed conditions/comorbidities during treatment for the fall. In 2000, 78% of fall deaths were due to traumatic brain injuries and injuries to the lower extremities, while injuries to internal organs represented an additional 20%.[7]

Falls and fall-related injuries are conventionally prevented by employing daily physical exercise (e.g. Tai Chi, physical therapy, aerobic conditioning) and ensuring adequate intake of calcium and vitamin D to support good bone and muscle health. If patients display an unsteady gait they may be prescribed a cane or other ambulatory assistive device. Increasing ambient lighting, placing handrails on stairs and getting rid of area rugs are other strategies that may be utilized to decrease the risk of falling.

While resistance training and physical exercise are uniformly considered the best training methods to decrease fall probability, its risk in the elderly may outweigh the benefit as it may cause injury due to excessive strain and stress.[1,2,3] Furthermore, the difficulty of these exercises in the elderly can lead to a low compliance rate. Whole body vibration (WBV) provides itself as an attractive, cost-effective alternative to vigorous exercise in this population as exercises performed on the platform stimulates muscle spindle fibers via vibration. This stimulation induces reflexive muscle contractions, providing a safe, low intensity surrogate to exercise and bone loading while achieving similar results.[1,2,3]

OBJECTIVE:

The objective of this selective EBM review is to determine whether or not whole body vibration is a safe and effective adjunctive therapy for reducing fall risk in the elderly.

METHODS:

All three studies selected for this systematic review included randomized controlled trials with ambulatory elderly patients age 60 years and greater who possessed no contraindications to WBV therapy (see Table 1 below). Each study included an intervention of whole body vibration added onto some form of physical exercise/physical therapy while the control was a group receiving identical exercises with the exception of WBV and/or a control that did not change or alter their daily physical activity level. Outcomes measured in the studies were reduction in number of falls and reduction in fall risk.

Slight variations in each of the three studies did exist. The trial by von Stengel et al. ensured adequate daily calcium and vitamin D intake (1500 mg & 400 IU, respectively) for all subjects, assessed using a 4-day nutrition protocol, while the study conducted by Bogaerts et al. added an extra intervention of high (1600 IU) and conventional doses (880 IU) of vitamin D to WBV therapy. Neither the exercise regimen nor the duration of therapy in the interventional groups was the same between the three studies. Furthermore, the frequency and amplitude of vibration was different between studies and the trials performed by Bruyere et al. and Bogaerts et al. conducted therapy sessions three times per week while the von Stengel et al. trial conducted sessions four times per week. Control groups were similar except in the study conducted by Bogaerts et al. where the control did not participate in a structured training program and were not asked to change their lifestyle. Additional inter-study variations are mentioned elsewhere.

Articles selected for this review were found using the search engines PubMed, Medline and OVID databases. The key words “whole body vibration” and “falls” were used with filters active for papers published in peer-reviewed journals in the English language within the past 10 years. Articles were chosen based on their relevance to the proposed question and if they included outcomes that matter to patients (Patient-Oriented Evidence that Matters/POEMS). Included studies were randomized, controlled and blinded with elderly patients and contained POEMS. The studies excluded contained patient population under age 60 (non-elderly patients), studies not published within the past 10 years and studies that did not contain either fall number or fall risk reduction as a main outcome. Statistics used in the three trials included chi-square test, P-values, CI, RRR, ARR and NNT.

Table 1 – Demographics and characteristics of included studies

Study	Type	# Pts	Age (yrs)	Inclusion Criteria	Exclusion Criteria	W/D	Interventions
Bogaerts[1] (2010)	Double blind RCT	113	> 70 (mean = 79.6)	Institutionalized women over 70 years of age	Systematic engagement in endurance and/or strength training in the two years preceding the study, participation in low-intensity exercise programs for more than 2 hours a week at moment of recruitment and intake of medication influencing bone mineral density	10	Randomized to either a WBV training group or a control group receiving conventional dose (880 IU) or high dose (1600 IU) of vitamin D3
Bruyere[2] (2005)	Blinded RCT	42	63-98 (mean = 81.9 ± 6.9)	Ambulatory residents that had no major cognitive disorders that would affect their ability to complete a questionnaire	Those with a high risk of thromboembolism or a history of hip or knee joint replacement	6	Randomized to receive WBV plus a standard PT regimen or a standard PT regimen alone
von Stengel[3] (2010)	Double blind RCT	151	> 65 (mean = 68.5 ± 3.1)	Postmenopausal women aged 65 years and older living independently	Diseases or medications affecting bone metabolism, diseases or medications affecting neuromuscular performance and falls, implants of lower extremity or of the spine, eye diseases affecting the retina and low physical capacity	16	Randomized to either a training group including WBV, a training group not receiving WBV or a wellness control group

OUTCOMES MEASURED:

The outcomes that were measured were a reduction in fall number and fall risk. Reduction in fall frequency was assessed by von Stengel et al. using a prospective self-reported count on number of falls via calendar method. Reduction in fall risk was assessed in the studies conducted by Bruyere et al. and Bogaerts et al. via: 1) multifactorial fall risk parameter – the Physiological Profile Assessment – a validated assessment used to differentiate between people with different degrees of risk for falls; 2) Timed Up & Go (TUG) test – which assesses functional mobility by asking the patient to rise from a chair, walk 3m away, turn, walk back and sit down again; 3) Tinetti test – assesses balance and identifies gait abnormalities by grading functions such as gait speed, stride, symmetry and balance while standing, turning and nudging.

RESULTS:

This selective EBM systematic review was performed on three randomized controlled trials; two of which compared WBV added onto physical exercise to a control group receiving identical exercises and one compared WBV with physical exercise to a control group not asked to alter their daily physical activity levels. All three studies examined the elderly population above age 60 years and applied interventions for differing lengths of time.

In the 2010 study by von Stengel et al., an 18-month whole body vibration intervention was compared to two control groups – a training group that received identical exercises without WBV and a control group that conducted light physical exercises and relaxation programs. The trial found a significant between-group difference for the total number of falls ($p=0.003$). A significant higher fall rate ($p=0.004$; 95% CI=0.272/0.783) was observed in the control group (1.50 +/- 1.98) compared to the WBV interventional group (0.70 +/- 0.83). Thus fall frequency was significantly lower in the group receiving WBV therapy (0.7 falls/person) compared with control group (1.5 falls/person). No significant difference (p=0.07) was displayed between the training group not receiving WBV (0.96 +/- 1.10) and the control group.

Table 2: Whole Body Vibration group (WBV) vs. Control Group on the reduction of falls (von Stengel et al., 2010)[3]

Control Event Rate (CER)	Experimental Event Rate (EER)	Relative Risk Reduction (RRR)	Absolute Risk Reduction (ARR)	Number Needed to Treat (NNT)
		$\frac{EER-CER}{CER}$	EER - CER	1/ARR
1.50	0.70	-0.53	-0.8	-1.00

Table 2 displays the treatment effects of the study completed by von Stengel et al. The CER was calculated as the fall rate of the control group while the EER was calculated as the fall rate of the WBV intervention group. These two statistical parameters were then used to calculate the ARR, which shows the decrease in amount of falls of the WBV intervention group compared to the control. Then the RRR was calculated to determine the effectiveness of WBV therapy and also the relative likelihood of experiencing a subsequent fall despite WBV therapy. NNT was finally calculated to determine the number of patients that need to be introduced to WBV therapy to prevent a bad outcome (a fall) to occur – i.e. with WBV therapy, 1 patient needs to be treated for 18 months to prevent 1 person from falling.

Table 3 – Whole Body Vibration group (WBV) vs. Control (CON) on the reduction of fall risk in the elderly (Bogaerts et al., 2010)[1]

	WBV		CON	
	Change from baseline (6 mos)	P-value	Change from baseline (6 mos)	P-value
Physiological Profile Assessment	-9.69%	0.114	+7.09%	0.490
TUG test, preferred speed	-13.16%	< 0.001	-5.21%	< 0.001
TUG test, maximal speed	-7.73%	< 0.001	+2.57%	0.993

Table 3 displays results for the 2010 trial conducted by Bogaerts et al., which compared a six month whole body vibration therapy with exercises conducted three times weekly to a control group who were asked not to change their lifestyle during the course of the study. Overall fall risk, as assessed by the Physiological Profile Assessment, did not change significantly between the two groups. The net reduction in fall risk for the WBV group was 18% but again was a non-significant change. When data was examined once stratifying subgroups, a significant decrease in fall risk was noted for the group at highest risk for falling – the WBV group decreased from 35.2% to 27.8% while the control group increased risk from 29.1% to 36.3% ($\chi^2 > 3.841$ for both). The time needed to perform the TUG test at preferred speed decreased significantly in the WBG group and in control group – but the improvement was significantly larger for the WBV group (p=0.002). TUG time at maximal speed also decreased significantly in the WBV group while it remained unchanged in the control group. The improvement in the TUG at maximal speed was significantly larger in the WBV group than in the control group ($p < 0.001$). In summary, WBV improved TUG performance with 13% at preferred speed and 8% at maximal speed, both of which were significant changes.

Table 4 – Whole Body Vibration group (WBV) vs. Physical Therapy group (PT) on reduction of fall risk in the elderly (Bruyere et al., 2005)[2]

	WBV		PT	
	Mean change from baseline (6 weeks)	P-value	Mean change from baseline (6 weeks)	P-value
Tinetti, gait quality	+2.4 +/- 2.3	< 0.001	0	< 0.001
Tinetti, balance	+3.5 +/- 2.1	< 0.001	-0.3 +/- 1.2	< 0.001
Global Tinetti	+5.6 +/- 3.7	< 0.001	-0.3 +/- 1.3	< 0.001
TUG test	-11.0 +/- 8.6 sec	< 0.001	+2.6 +/- 8.8 sec	< 0.001

Table 4 presents results for the 2005 study by Bruyere et al. who compared a WBV intervention group that conducted training sessions three times per week for six weeks to a physical therapy group, who conducted identical exercises without the WBV intervention. Data was expressed as mean change from baseline. The Tinetti test run for gait quality improved significantly ($p < 0.001$) in the WBV group compared to no change in the control group. The Tinetti test for balance also displayed a significant improvement ($p < 0.001$) in the WBV group compared with a decline in performance in the control group. The global Tinetti score combines results from the individual tests for balance and gait and displayed significant performance improvement in the WBV when compared with PT control. Additionally, changes in the TUG test improved significantly ($p < 0.001$) for the WBV group compared to the control group.

Two of the trials in this systematic review made note on intervention compliance. Bogaerts et al. reported that training compliance was greater than 90% in most of the subjects and that only five of their subjects reported a lower compliance rate due to personal problems or health problems. von Stengel et al. commented that no significant group differences in training attendance existed as the WBV intervention group and training group had 80% and 75% compliance respectively. Similarly home training compliance reached no significant difference (45% for WBV and 43% for the training group).

Only the RCT by Bruyere et al. reported an unfavorable adverse event related to WBV therapy. Two patients dropped out of the study because of “transient minor tingling of the lower limbs.”[2] No serious adverse events were observed. Bogaerts et al. stated that no adverse side effects of vibration training were reported while von Stengel et al. reported that adverse events did not exist for either the training program or whole body vibration stimulus.

DISCUSSION:

While the trial by Bogaerts et al. did not show a significant change in overall fall risk, a post-hoc analysis using the McNemar test was able to stratify the WBV group and control group into a low, intermediate and high risk for falling. When evaluating fall risk in these subgroups, the percentage of subjects deemed at high risk decreased significantly in the WBV group compared to controls – thus suggesting a positive effect of WBV on fall behavior.[1] Researchers in the Bogaerts 2010 trial also speculated that the overall fall risk might have not reached significance due to the large variability of the subject population before testing.

The other outlier that remains in this systematic review is that the study conducted by von Stengel et al. looks at a reduction in fall frequency and not necessarily fall risk. It was a novel study at time of publication and the author of this review feels it remains an indicator of fall risk. If the main endpoint of reducing fall risk is to prevent a fall from occurring then a study that reduces fall number implies a decrease in fall risk.

As previously mentioned, there was variability between the three studies reviewed. No similarity existed on vibration parameters between studies and it remains possible that certain parameters used (amplitude & frequency of vibration, duration of WBV) could have affected performance results. Additionally, the exercise regimens that the WBV groups and control groups performed differed between studies and could have potentiated results seen in vibration therapy.

The accessibility of WBV as a therapy to reduce falls in the elderly should also be a topic of discussion. Two of the studies (Bruyere 2005 and Bogaerts 2010) conducted research on subjects that were either institutionalized or living in a nursing home and a case can be made that WBV therapy would be most effective as a community based rehabilitation technique. The vibrating machines are expensive (available online; prices range from $1500 - $5000+)[8] and one would need to have specially trained physical therapists available who are knowledgeable about both vibration therapy and exercise in order to guide and directly observe treatment. Currently, no organization provides accreditation or training for vibration therapy to be used in the professional setting.[9] The FDA has not approved whole body vibration platforms for medical purposes yet, so no standards exist that regulate their manufacturing.[9] The out-of-pocket costs to the consumer for WBV therapy is unknown and there have been no published articles regarding utilization of WBV therapy among Medicare beneficiaries or other health insurance plans.[9]

WBV is to be used as an adjunct therapy. It cannot address all health risks associated with later life, especially in the cardiovascular system, and should be combined with physical therapy/exercise and aerobic conditioning when possible. WBV as a means for fall reduction is also limited to the elderly population and may not show the same effectiveness in a younger population whose risk of vigorous exercise is less.

Contraindications to WBV were stated only in the trial conducted by Bogaerts et al. and they consisted of diabetes, neuromuscular diseases, stroke, serious heart sicknesses, implants in lower extremities, bypass and stenting.[1] While a minor adverse event (transient tingling) was reported in only one of the studies, potential harms do exist. Vibration is often recognized as an occupational hazard and has been associated with low back pain, cardiovascular disorders, neurovestibular disorders Raynaud's syndrome and trauma.[9] These effects, while rare, are seen with high frequency exposures for long durations which should not be experienced by a patient receiving WBV therapy to prevent falls.

Multiple limitations exist in the trials included within this review and will be the next point of discussion. All three studies applied stringent criteria for participation in the vibration program that excluded many elderly individuals with conditions/diseases that are common to that population and thus may provide a study sample that is not representative of the elderly as a whole. Additionally, due to the older age of the population, the intensity and duration of vibration was lower compared to younger subjects (previously studied) and potentially could have been suboptimal in reducing falls. For the two studies that compared WBV intervention group to a physical therapy group receiving identical exercises, an underestimation of the vibration effects may have occurred when compared to a fully sedentary control group, which may be more representative of the population in interest. Another limitation is the generalizability (or lack thereof) of the results due to the smaller sample sizes of the individual studies. Finally, all three trials contained different controls, different vibration parameters, different durations of WBV therapy and different exercises so the most effective method at reducing fall risk with whole body vibration therapy can not be elucidated at this time.

CONCLUSION:

Whole body vibration, when used in the elderly population without aforementioned contraindications, provides itself as an effective and safe adjunctive therapy to reduce fall risk in the elderly.

Since these three studies were some of the first to evaluate the effectiveness of WBV on fall reduction, additional RCT's need to be performed with a larger sample size and longer follow up to see the treatment effects observed here replicated and to determine the long term effects of WBV on fall behavior. Further research is warranted to identify the most effective vibration protocols with respect to vibration mode, frequency, amplitude, duration of vibration stimulus and the exercise regimen to be performed on the vibrating plates in order to diminish fall risk. Investigation is needed to determine the most appropriate length of WBV treatment to reduce falls in the elderly. More research must be conducted on an elderly population that is representative of the geriatric population as a whole. Lastly, since little is known about the threshold above which vibration becomes harmful and can lead to overload and adverse effects, more study is needed to determine the maximal tolerable dose of vibration stimulus.

REFERENCES:

1. Bogaerts A, Delecluse C, Boonen S, Claessens AL, Milisen K, Verschueren SM. Changes in balance, functional performance and fall risk following whole body vibration training and vitamin D supplementation in institutionalized elderly women. A 6 month randomized controlled trial. *Gait Posture*. 2011;33(3):466-472. doi: 10.1016/j.gaitpost.2010.12.027.

2. Bruyere O, Wuidart MA, Di Palma E, et al. Controlled whole body vibration to decrease fall risk and improve health-related quality of life of nursing home residents. *Arch Phys Med Rehabil*. 2005;86(2):303-307. doi: 10.1016/j.apmr.2004.05.019.

3. von Stengel S, Kemmler W, Engelke K, Kalender WA. Effects of whole body vibration on bone mineral density and falls: Results of the randomized controlled ELVIS study with postmenopausal women. *Osteoporos Int*. 2011;22(1):317-325. doi: 10.1007/s00198-010-1215-4.

4. Tinetti ME, Speechley M, Ginter SF. Risk factors for falls among elderly persons living in the community. N Engl J Med 1988;319:1701-7.

5. Nevitt MC, Cummings SR, Kidd S, Black D. Risk factor for recurrent nonsyncopal falls; a prospective study. JAMA 1989;261:2663-8.

6. Alexander BH, Rivara FP, Wolf ME. The cost and frequency of hospitalization for fall-related injuries in older adults. American Journal of Public Health 1992;82(7):1020–3.

7. Centers for Disease Control and Prevention. Cost of Falls Among Older Adults. Available at: http://www.cdc.gov/HomeandRecreationalSafety/Falls/fallcost.html. Accessibility verified on 27 September 2012.

8. VibraFit Body. Products. Available at: http:// http://www.vibrafitbody.com/products-page/. Accessibility verified on 15 November 2012.

9. Wysocki A, Butler M, Shamliyan T, et al. Whole-Body Vibration Therapy for Osteoporosis [Internet]. Rockville (MD): Agency for Healthcare Research and Quality (US); 2011 Nov. (Comparative Effectiveness Technical Briefs, No. 10.) Available from: http://www.ncbi.nlm.nih.gov/books/NBK83043/. Accessibility verified on 20 November 2012.