Vibration Therapy as a Rehabilitation Intervention for Postural Training and Fall Prevention after Distal Radius Fracture in Elderly Patients: A Randomized Controlled Trial

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Executive Summary:

The occurrence of distal radius fractures is well known to be a sentinel event as these fractures are associated with 2 to 4 times increased risk of subsequent hip fractures in elderly patients. Studies have shown a significantly increased degree of postural sway in these patients, which is strongly associated with recurrent falls. The latest Cochrane systematic review also shows a lack of evidence on the effectiveness of current rehabilitation interventions.

Low-magnitude high-frequency vibration (LMHFV) is a biophysical intervention that provides non-invasive, systemic mechanical stimulation and has been shown to improve muscle strength and balancing abilities in healthy, independent and active elderly women in our previous study. Our animal studies have also shown LMHFV promoting myogenic proliferation and hypertrophy, muscle contractibility, and increased fast-fiber switching to muscle fiber type IIA.

Previous rehabilitation studies have used clinical functional performance tests, which lack sensitivity and specificity in predicting impaired postural control. The Biodex Balance System SD consists of a dynamic balance platform interfaced with computer software, which offers objective and reliable tests for postural stability and fall risk.

This study is a single-blinded, prospective randomized controlled trial to investigate the effect of 6 months of LMHFV after a distal radius fracture in elderly patients. 100 patients will be recruited and randomized to control or LMHFV group (n=50 per group) by envelope drawing of computer-generated random numbers. The intervention group will undergo LMHFV at 35Hz, 0.3g (peak to peak magnitude), displacement of <0.1mm, 20 min/day, at least 3 days/week for 6 months in community centres. Control group will remain in their habitual life style and no vibration used. Outcome assessments will be performed at baseline 0 days, 6 weeks, 3 months and 6 months. Outcome assessor and statistician will be blinded to group allocation.

The primary outcome is the effect of LMHFV on postural stability. The Biodex Balance System SD is used to measure the static and dynamic ability of the subjects to maintain the center of balance. Secondary outcomes are the occurrence of fall for the patients in both groups, the health-related quality of life (SF-36), and Timed Up and Go test for

basic mobility skills.

Background

Distal Radius Fractures and Medico-socioeconomic Impact

Fractures of the distal radius account for approximately 380,000 fractures in the United States each year and occur in 15% of women older than 50 years of age (1). These fractures are a particular health concern amongst the elderly, who are at risk of fragility fractures, and are associated with long-term functional impairment, pain and a variety of complications. Over the past 10 years, there has been increased popularity of surgical interventions for the treatment of distal radius fractures, especially with the introduction of volar locking plates in 2000 (2, 3). Current medical costs for distal radius fractures are estimated to exceed USD 535 million each year and projected to rise as the incidence and use of internal fixation increases (1, 4).

The Concept of Impaired Postural Stability and Prevention of Fall

The occurrence of distal radius fractures is well known to be a sentinel event as these fractures are associated with 2 to 4 times increased risk of subsequent hip fractures in elderly patients (5, 6). This is an important concept as it is well established that these patients have an increased risk of falling (7). Fall prevention is therefore crucial to decrease further morbidity and mortality. Studies have shown a significantly increased degree of postural sway in patients with distal radius fractures, in both anteroposterior and lateral directions, which is strongly characterized in older subjects for recurrent falls (8). A recent study has also revealed that older adults have significantly impaired postural stability by using objective measurements from computerized instruments (5). Despite on-going studies on distal radius fractures, the latest Cochrane systematic review shows a lack of evidence on the effectiveness of current rehabilitation interventions (9). The American Academy of Orthopaedic Surgeons (AAOS) position statement also recommends patients with fragility fractures to undergo evaluation of osteoporosis and treatment to prevent future fractures (5). Notably, there are no recommendations on the role of balance training or physical conditioning. Consequently, the evaluation and treatment of fall risks have been largely overlooked (10). Further research that target rehabilitation and treat postural instability after distal radius fracture to reduce fall rates are therefore warranted.

Low-magnitude High-Frequency Vibration as a Rehabilitation Intervention to

Improve Postural Instability and Prevent Fall

Low-magnitude high-frequency vibration (LMHFV) is a biophysical intervention that provides non-invasive, systemic mechanical stimulation and has been shown to improve muscle strength and balancing abilities in healthy, independent and active elderly women in our previous institute's study (11, 12). Furthermore, our animal studies have also shown the ability of LMHFV to promote myogenic proliferation and hypertrophy, muscle contractibility, and increase fast-fiber switching to muscle fiber type IIA compared with control (13, 14). Numerous other studies have reported whole body vibration to have positive effects on blood circulation in lower extremities and enhanced muscle performance including muscle strength in the elderly (15, 16). Previous rehabilitation studies have mainly used clinical functional performance tests, which lack sensitivity and specificity in predicting impaired postural control in osteoporotic patients (17). Therefore, the use of more objective measures to assess instability and fall risk derived from computerized instruments have been recommended (17, 18). The Biodex Balance System SD (Biodex Medical Systems Inc, Shirley, NY) consists of a dynamic balance platform interfaced with computer software that provides up to 20° tilt from horizontal in a 360° range of motion. The system offers objective and reliable tests for postural stability and fall risk, which have been shown in multiple studies and in elderly patients (19, 20).
In order to provide effective rehabilitation regimens for our patients, the validation of our interventions using objective outcomes is essential. To our knowledge, this is the first study to use an objective device to assess and validate our rehabilitation tool to prevent falls in patients after a distal radius fracture.

Specific Aims and Hypotheses

Aims:
1. Investigate the effect of LMHFV on postural stability in elderly patients post distal radius fracture treatment
2. To investigate the effect of LMHFV on recurrent falls in elderly patients post distal radius fracture treatment

Hypotheses:
1. LMHFV enhances postural stability in elderly patients post distal radius fracture treatment
2. LMHFV decreases recurrent falls in elderly patients post distal radius fracture treatment

Pilot and/or previous data

Our previous randomized controlled trial with 710 healthy, active and independent postmenopausal women over 60 years old has shown LMHFV, as an intervention for 18 months, to have significant improvements in reaction time, movement velocity, and maximum excursion of balancing ability assessment and also quadriceps muscle strength ($p<0.001$). In addition to these findings, the LMHFV intervention group had significantly lower fall or fracture incidences with 18.6% of 334 vibration group subjects compared with 28.7% of 327 control group subjects (adjusted HR=0.56, $p=0.001$). The conclusion is that LMHFV was effective in fall prevention with improved muscle strength and balancing ability in the elderly (11). Our recent case-control study showed that at 1 year post-intervention of LMHFV for the subjects, the muscle strength, balancing ability and quality of life relative to 18 months did not show significant differences. Therefore, the benefits of LMHFV were retained 1 year after cessation of LMHFV. Our animal studies have also supported the data with significant improvement in the LMHFV group to promote myogenic proliferation and hypertrophy, muscle contractibility, and fast-fiber switching to fiber type IIA compared with the control group (13, 14).

Research design: patients, materials and methods

This study will be a single-blinded, prospective randomized controlled trial to investigate the effect of 6 months of LMHFV on postural stability and fall rates after a distal radius fracture. 100 patients will be recruited consecutively for the study with consent.

Inclusion criteria: 1) aged 60 or above 2) fracture distal radius after 6 weeks to 3 months 3) injury was due to unintentional fall. Exclusion criteria: 1) medical condition causing balance disturbance 2) participated in supervised regular exercise or physiotherapy for twice a week or more 3) Activities of Daily Living (ADL) dependent 4) malignancy 5) medications or condition that affect metabolism of the musculoskeletal system e.g. bisphosphonates

Randomization: Randomization to either control or LMHFV group (n=50 per group) will be performed by envelope drawing of computer-generated random numbers.

LMHFV: Each patient in the intervention group will undergo vibration in community centers. The patient will stand upright without knee bending on a specially designed vibration platform that provides vertical synchronous vibration at 35Hz, 0.3g (peak to

peak magnitude), displacement of <0.1mm, 20 min/day, at least 3 days/week for 6 months. The research staff will instruct the safety issues and operative procedures.

Control group: Each patient in the control group will remain in their habitual life style and no vibration machine is used.

Outcome assessments for both groups will be performed at baseline 0 months, 6 weeks, 3 months and 6 months time-points. The change will be assessed. Outcome assessors and the statistician will be blinded to group allocation.

Blinding: Group allocation of the patients will be performed by an independent research staff by envelope drawing of computer-generated random numbers. The outcome assessor and statistician will be blinded to the group allocation. A central technical staff in our Orthopaedics and Traumatology Department will perform all measurements. The participants will be reminded not to tell the assessor of their allocation. Blinding the subjects is not feasible because the vibration signal from the platform is easily felt and placebo is rare in vibration clinical trials (11).

The primary outcomes are the effect of LMHFV on postural stability. To assess the postural stability, the Biodex Balance System SD is used to measure the static and dynamic ability of the subjects to maintain the center of balance. The score generated by the machine assesses the deviation from the center via an Overall Stability Index (OSI), Anterior/Posterior Stability Index (APSI) and Medial/Lateral Stability Index (MLSI), measuring in degrees, the tilt about each axis. The Limits of Stability (LOS) will be assessed, which measures the Directional Control in % and Test Duration in seconds, this test is a good indicator of dynamic control. The Biodex Balance System SD has been shown to be a reliable tool for objective assessment of postural stability in several studies for elderly patients (20).

Secondary outcome is the occurrence of fall for the patients in both groups. To assess the occurrence of fall, subjects are required to self-report these events via a fall calendar, which has to be returned at every follow-up visit. Calendar reporting has been well proven to be reliable for fall studies (11). Additionally, the health-related quality of life with a validated Chinese Version of the 36-Item Short-Form Health Survey (SF-36) will be assessed. The physical component, mental component and total score will be analysed. All scores range from 0 to 100 with a higher score indicating better quality of life. In addition the Timed Up and Go (TUG) test will be used to test the basic mobility skills.

Sample size calculation

Postural stability is used as the primary outcome in this study. As this is the first clinical study to evaluate the effects of LMHFV on postural control of distal radius fracture patients, we can only use our institute's previous clinical data of LMHFV on balancing ability in elderly (11) for reference. In our study, we detected 7.89 mean difference in endpoint excursion (key parameter of balancing ability) between two groups after treatment. A sample size of 43 in each group will have 80% power to detect a significant difference using two-sided independent t-test with a 0.05 significance level (PASS 11.0, NCSS, LLC, Utah, USA). Our previous clinical trial also showed a satisfactory compliance rate of LMHFV (averaged 66%) with a ~15% dropout (11). Taking account of the dropout, we further increase the sample size to n=50 for each arm (total n=100).

Data Analysis/Statistical analysis

Data in this study will be analysed according to the intention-to-treat principle. All results will be expressed in mean±SD (parametric data). Normality test will be performed to determine the normal distribution of data. Independent t-test and equivalent non-parametric tests (for non-parametric data) will be performed to compare the above parameters between groups. The statistical analysis will be performed using SPSS 20.0 (IBM, NY, USA). Significant level is set at $p \leq 0.05$ (2-tailed).

Clinical relevance for Orthopaedic Trauma Patients

With our aging population and increase in fragility fractures, this study will have a large impact for distal radius fractures in the elderly by providing an effective rehabilitation intervention to improve postural stability and prevent future falls.

Relevant publications of members of project group

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