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Does balance training improve quality of life in adults with osteoporosis?

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A SELECTIVE EVIDENCE BASED MEDICINE REVIEW

In Partial Fulfillment of the Requirements For

The Degree of Master of Science

In

Health Sciences – Physician Assistant

Department of Physician Assistant Studies
Philadelphia College of Osteopathic Medicine
Philadelphia, Pennsylvania

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Abstract

Objective: The objective of this selective EBM review is to determine whether or not balance training improves quality of life in adults with osteoporosis.

Study Design: Review of two randomized controlled trials and one case series.

Data Sources: All three studies were found using Pubmed. They were originally published in peer-reviewed journals between 2010 and 2017.

Outcomes Measured: The outcome measured was quality of life. The randomized controlled trials measured quality of life using frequency of falling, and the case series measured it using the Activities-specific Balance Confidence scale (ABC-6).

Results: Mikó et al. was a RCT that showed balance training could reduce falls in a statistically significant number of people ($p < 0.05$). The other RCT, Madureira et al., also found that balance training reduced frequency of falling in a statistically significant percentage of people ($p = 0.025$). Konak et al. was a case series which revealed that balance training increased balance self-confidence when performing the daily activities measured via the ABC-6 scale by a statistically significant amount ($p < 0.001$).

Conclusions: All three of the studies examined in this EBM review suggest that adults with osteoporosis who undergo a balance training program can improve their quality of life, as balance training can prevent or reduce falls in addition to increasing self-confidence in performing daily activities. Future studies should include more men and younger patients at risk for fragility fractures so that the results can be more generalizable. Additionally, future studies should investigate the optimal length of time that a balance training regimen needs to last in order to have the most benefit, as well as how long the benefit from the training lasts after the program stops.

Key Words: Osteoporosis, Balance Training, Quality of Life

Introduction

Osteoporosis is a silent disease where one loses bone strength due to increased osteoclast and decreased osteoblast activity; this imbalance ultimately weakens the bone.¹ Risk factors for this condition include, but are not limited to, advanced age, estrogen deficiency, long term corticosteroid use, smoking, and poor nutrition.¹ Having more fragile bones means that it takes less force to fracture a bone, so osteoporotic individuals are more likely to sustain fragility fractures.^{1,2} These people are at increased risk of fracture, and therefore need to avoid falling. However, in addition to being more fracture prone, the osteoporotic elderly in particular are also more likely to fall due to development of postural disorders, muscle weakness, and more significantly, balance impairment.^{2,3}

Osteoporosis related fractures are already a large public health burden, with osteoporosis causing over 1.5 million fractures annually in the US.¹ One out of five falls results in a broken bone or a head injury, which means every year, 800,000 people are hospitalized for a fall injury.⁴ Of the people hospitalized, 300,000 of those are for hip fractures, which are fractures notorious for their high mortality and causing decreased independence.^{1,4} Total medical cost for all these fall injuries in the US exceeded \$50 billion in 2015, with 75% of that cost covered by Medicare and Medicaid.⁴ Osteoporosis is already a common issue, especially among the elderly, affecting 1 in 4 women and 1 in 20 men over 65 years old; it will only become more relevant in the future as the US population ages.⁵ As more people enter this demographic, more people will be at risk for falling and osteoporosis related fractures.^{4,5}

Fear is another possible negative factor that affects the lives of adults who receive an osteoporosis diagnosis. When the elderly fall at least once a year, their fear of falling and sustaining an osteoporosis related fragility fracture increases.⁶ This fear can cause them to lose autonomy if they become reluctant to perform activities of daily living without assistance.⁶

Common methods used to reduce osteoporosis related fragility fractures currently include home safety, calcium and vitamin D supplementation, bisphosphonates, smoking/corticosteroid cessation, denosumab, and PTH analogs.¹ These ways of managing osteoporosis and reducing fracture risk mainly focus on strengthening the bone. But, another way to approach the problem of osteoporosis related fragility fractures is to prevent the actual falls through balance training. Since impaired balance seems to be a major contributor to falls in this population, improving balance deficits may reduce incidence of falls, and consequently, incidence of fragility fractures.^{3,6,7} If adults with osteoporosis do not fall as much, their quality of life may improve, as they will not have to be hospitalized for as many fragility fractures. This will allow them to maintain independence and a sense of security, in addition to reducing fall and fracture related mortality.⁷

Objective

The objective of this selective EBM review is to determine whether or not balance training improves quality of life in adults with osteoporosis.

Method

Two randomized controlled trials and one case series will be examined to assess whether correcting balance deficits using some form of balance training improves quality of life in osteoporotic adults facing increased falling and fracture risk as they age. The studies selected for this EBM review were found using Pubmed and searching with the keywords: “osteoporosis” and “balance training.” From the search results, articles were chosen if they fit within the parameters set by my inclusion criteria, in addition to whether or not they had outcomes that could be perceived by patients. As well as including studies containing adults diagnosed with osteoporosis undergoing balance training, my inclusion criteria encompassed studies published between 2010-2020, human studies, and studies published in English. Studies that were excluded

consisted of disease-oriented evidence (DOE) only studies, secondary literature, or studies that included different types of exercise training (e.g., aerobic training) as separate interventions.

Outcome of interest in all studies was quality of life.

All three studies were published in peer reviewed journals; the Mikó et al. study was published by *Clinical Rehabilitation* in 2017, Madureira et al. by *Maturitas* in 2010, and Konak et al. by *Osteoporosis International* in 2016. The first two studies are randomized controlled trials, with both studies containing control groups who received osteoporosis treatment like calcium/vitamin D supplementation and instructions to prevent falls without the actual balance training intervention.^{6,7} The NNT and p-value for the Mikó et al. and Madureira et al. studies are analyzed in this review. Konak et al. was treated as a case series, and as such, did not have a comparison group. The statistics analyzed from Konak et al. are p-value, mean change from baseline, and standard deviation. The specific characteristics of each study are broken down in Table 1.

Outcomes

Improved quality of life is the outcome from these studies being focused on in this review. In the Mikó et al. and Madureira et al. studies, improvement in quality of life via balance training was measured by whether or not the intervention affected frequency of falling over the course of each respective yearlong study.^{6,7} The Mikó et al. study had its participants keep a fall diary to write down every fall and the circumstances surrounding the fall only during the study year. Frequency of falling was defined by counting the number of people in each group who experienced a fall at some point during the study year.⁷ In the Madureira et al. study, they determined the number of falls from the year before the study via patient history.⁶ Then, all participants got a calendar to record every fall that occurred during the course of the study; the number of falls in the study year were then subtracted from baseline to see if there was any

reduction in falls between the intervention and control group.⁶ Alternatively, the Konak et al. study measured quality of life using the patient's level of self-confidence when performing daily activities; specifically, self-confidence was assessed using the Activities-specific Balance Confidence scale (ABC-6).² This scale had individuals self-report their balance confidence on a scale of 0 (no confidence) to 100 (total confidence) when doing six different activities.² The mean of these six numbers was calculated, meaning the higher the ABC-6 score, the more confident the individual felt in their balance ability.²

Table 1. Characteristics of Included Studies

Study	Type	# of Pts	Age	Inclusion Criteria	Exclusion Criteria	WD	Interventions
Mikó et al. ⁷ (2017)	RCT	100	≥65	Hx of at least 1 osteoporotic fx + an osteoporosis dx according to the 2004 WHO criteria for postmenopausal women (T-score < -2.5)	Sensory/vestibular deficiency, use of assistive walking devices, inability to walk independently for >10m, locomotor/neuro/unstable cardiovascular disease, recent participation in an exercise program	3	12-month balance training program consisting of twice a week sessions in an outpatient setting led by a physiotherapist + 60 min sessions a day individually the rest of the week
Madureira et al. ⁶ (2010)	RCT	66	≥65	Osteoporosis dx according to the 1994 WHO criteria and the 2007 International Society for Clinical Densitometry criteria	2° osteoporosis, sensory/vestibular/articular/coordination deficiency, need of assistive walking devices, inability to walk independently for >10m, cardiovascular conditions that CI exercise	6	12-month balance training program consisting of a single 1h session a week led by a physiotherapist + individual home sessions 3x a week for 30 min
Konak et al. ² (2016)	Case Series	22	45-88	Osteoporosis dx according to the 1994 WHO criteria	Scoring <24 on Folstein MMSE, scoring >52 on Berg Balance scale, severe ortho/eye/ear pathology, vitamin B12/folate deficiency, use of balance altering drugs, DM, neuro/rheum/heart/lung disease, uncontrolled HTN or hypotension	2	4-week single task balance training program consisting of 45 min training sessions 3x a week

Results

Mikó et al. performed a randomized controlled trial where numbered prefilled envelopes randomized the 100 eligible ≥ 65 -year-old women into either the intervention group (underwent balance training for a year) or the control group (who received “osteoporosis treatment and had no intervention” for a year).⁷ More detailed criteria for eligibility and exclusion can be found in Table 1. The balance training program in this study was created by physiotherapists, who guided the participants through exercises twice a week in an outpatient setting; participants were also supposed to perform the exercises on their own for 60 minutes a day at home using a booklet.⁷ The exercises focused first on stabilization; after this static phase, participants moved on to dynamic balance with arm/leg exercises.⁷ The final functional stage brought the first two stages together to help the participants develop stabilization skills when changing positions during certain activities.⁷ Participant compliance to the training program is not reported in the study.

Throughout the course of this study year, the participants recorded the number and circumstances of every fall in a fall diary.⁷ Of the people in the intervention group, one person lost interest in the study and discontinued the balance training; in the control group, one person also lost interest and another person withdrew without explanation, which means 49 people in the balance training group and 48 people in the control group finished the study.⁷

As seen in Table 2, there were both fewer total falls and fewer people who fell in the balance training group than in the control group.⁷ In this study, frequency of falling was determined as the “number of patients who fell in the study year,” so the number of people who experienced a fall was compared between the balance training and control group.⁷ Since the desired result was no falls, the study reported the relative risk of falling (i.e. the EER and CER) based on the number of patients who fell during the study, not the total number of falls. The balance training group had a lower relative risk of falling at 0.12, and the control group had a

higher risk at 0.29.⁷ There was a statistically significant difference between the intervention and control groups since the p-value was <0.05, meaning the estimated treatment effect can be indicated as precise.⁷

Further preventative outcomes were extrapolated from the study's reported data, as shown in Table 3. The NNT of -10 asserts that for every ten people who underwent this balance training program, one fewer person had a fall than if they did not receive the training. So, based on this study's results, this intervention has a large efficacy that can positively impact quality of life in adults with osteoporosis.

Table 2. Frequency of Falling and Relative Risk of Falling in Mikó et al.⁷

	Number of total falls	Number of patients who fell	Relative risk of falling
Balance training group	7	6	0.120*
Control group	16	11	0.229*

*p<0.05

Table 3. Calculations of Prevention Outcomes from Mikó et al.⁷

EER	CER	ARR	RRR	NNT
0.12	0.22	-0.10	-0.45	-10

Madureira et al. completed a randomized controlled study involving 66 women aged 65 or older.⁶ Refer to Table 1 for further inclusion and exclusion criteria. These 66 participants were randomized into two groups via the lottery method; all participants received calcium carbonate and vitamin D supplementation, but the control group only got instructions to prevent falls, while the intervention group underwent the balance training program.⁶ This program consisted of 40 classes (each class was one hour a week) lead by a physiotherapist.⁶ Every class was divided into 30 minutes of warm-up/stretching, and then 30 minutes of balancing in dynamic and static positions.⁶ Like the Mikó et al. balance training program, the Madureira et al. program also had a home portion; participants were supposed to do the same exercises from the class at home at

least three times a week for 30 minutes.⁶ The study recorded compliance for both attending the classes and completing the home exercises: 60% of participants went to all 40 of the classes, and 77% of participants performed the home exercises at least once a week.⁶ 40% of participants reported completing the home exercises every day.⁶

At the beginning of the study, participants told the study makers how many falls they experienced in the last year.⁶ Throughout the course of the study year, all participants wrote down when they had a fall in a calendar.⁶ The balance training group started with 34 participants, but one person dropped out because of foot pain, another because of physical limitations, and two for personal reasons.⁶ This means the other 32 eligible participants were randomized into the control group; this group also had one person drop out because of physical limitations and one for personal reasons.⁶ As a result of these dropouts, 30 people completed the entire year-long study in each group.

In the Madureira et al. study, the goal of balance training effect on frequency of falling was reduction in falls.⁶ An “initial – final” calculation was used to measure this treatment effect, with the “final” number representing falls sustained during the study year, and the “initial” number representing falls sustained in the preceding year (obtained by patient history and therefore subject to recall bias).⁶ Table 4 shows that the average reported number of falls per patient from the year before the study was not statistically significant between the two groups ($p=0.745$), so both the balance training and control groups started out with similar baselines in initial number of falls.⁶ Table 4 also shows that after the study was completed, the balance training group had a higher percentage of people with decreased falls; this difference was statistically significant ($p=0.025$).⁶ 50% of the balance training participants (15 people out of 30) experienced a reduction in falls, while only 26.6% of patients in the control group (8 people out

of 30) had decreased falls (Table 4).⁶ Additionally, there was a statistically significant difference in the mean number of falls per patient ($p=0.018$).⁶ An average of 0.77 (± 1.76) falls were reduced per person in the intervention group; this was higher than the -0.03 (± 0.98) falls that were reduced per person in the control group, meaning the balance training was more successful at decreasing falls per person than the control (Table 4).⁶

To determine the efficacy of these results, treatment outcomes were calculated based on the number of people who experienced the desired outcome of reduced falls, which can be seen in Table 5. The NNT of 5 suggests that for every five people treated with balance training, one more person had reduced falls than if they did not get balance training. This large treatment effect further supports the efficacy of balance training, as decreasing the number of falls an osteoporotic adult sustains improves quality of life.

Table 4. Initial Number of Falls, Percentage of Patients with Reduced Falls, and Reduction in Number of Falls from Madureira et al.⁶

	Number of falls per patient in the year before the study (mean \pm SD)	Percentage of patients with reduced falls (%)	Reduction in the number of falls per patient (mean \pm SD)
Balance training group	1.20 \pm 1.88*	50.0 \dagger	0.77 \pm 1.76 \ddagger
Control group	0.87 \pm 0.86*	26.6 \dagger	-0.03 \pm 0.98 \ddagger

* $p = 0.745$

$\dagger p = 0.025$

$\ddagger p = 0.018$

Table 5. Calculations of Treatment Effects from Madureira et al.⁶

EER	CER	ABI	RBI	NNT
0.5	0.27	0.23	0.85	5

Konak et al. was a case series assessing the effect that single task balance training had on patient confidence level when performing activities.² ABC-6 scores were collected at baseline, and then for the next four weeks, 22 participants did single task balance exercises recommended by the American College of Sports Medicine.² This balance training program included dynamic

movements (e.g., tandem walks, circle turns), postural muscle training (e.g., heel/toe stands, tandem stand, 1-legged stand), and reduced sensory input (e.g., standing with closed eyes).² Over the course of this four week study, participants went to individualized training sessions three times a week, with each session lasting 45 minutes.² Of the 22 people eligible for this study (see Table 1 for inclusion/exclusion criteria), one person withdrew participation because of medical reasons and another person moved away, so 20 people completed the training.² This study did not include a home training aspect and compliance with attending the training sessions is not reported.

On average, the ABC-6 scores improved by 9.85 (± 5.88), as seen in Table 6.² With a p-value of < 0.001 , this change from baseline suggests that the participant's balance confidence when doing daily activities increased by a statistically significant amount.² The ABC-6 score measures participant self-reported confidence in doing activities on a scale of 0 to 100, so even with the standard deviation of 5.88 taken into account, the mean increase in ABC-6 score of 9.85 after just four weeks is a large improvement in confidence. The wide confidence interval of 95% also indicates the treatment effect to be precise; there is a 95% likelihood that the true mean improvement in ABC-6 score lies between 3.97 and 15.73.² Therefore, these results suggest that that one month of single task balance training is effective at improving quality of life in this patient population.

Table 6. Konak et al. ABC-6 Scores at Baseline, Week 4, and Mean Change²

	Baseline (mean \pm SD)	Week 4 (mean \pm SD)	Change (mean \pm SD)
ABC-6 score of single task balance training group	69.52 \pm 17.09	79.11 \pm 12.31	9.58 \pm 5.88*

*p < 0.001

Discussion

Osteoporosis is a condition of weak bones, and people with this condition are at increased risk of fracture.¹ Since osteoporosis usually affects older adults, the physiologic changes that come with age mean the typical osteoporosis patient is at both increased risk of fracture and falls.² The goal of this EBM review was to determine the efficacy of balance training in improving quality of life by preventing falls or increasing confidence. One of the limitations in all the studies is that the participant populations were overwhelmingly women. While white postmenopausal women are at the highest risk of sustaining an osteoporosis related fracture, men do not escape this condition – hypogonadal men or men with prostate cancer who undergo anti-androgen treatment are especially at risk for osteoporosis.¹ Even though none of the studies explicitly listed men in their exclusion criteria, the guidelines used in the inclusion criteria were mostly aimed at menopausal osteoporosis; as such, Madureira et al. and Mikó et al. had no men in their respective patient populations, and Konak et al. only studied one man.^{2,6,7} This limitation in sampling means the results are only generalizable to postmenopausal women, and not men or younger adults with osteoporosis.

Another limitation of Madureira et al. and Mikó et al. was that the nature of the intervention meant it was impossible to blind patients to whether or not they were receiving the treatment of interest. While both studies used blinded raters to measure separate DOE outcomes of interest not looked at in this EBM review, only the Madureira et al. study reports using a blinded rater to process the fall calendars filled out by participants.⁶ Ultimately though, while patients were randomized into intervention and control groups, those in the balance training groups knew they were receiving the intervention and not a placebo. This knowledge in and of itself may have subconsciously affected their performance and confidence throughout these studies.

Finally, none of the studies reported adverse events or injuries that occurred because of the balance training, but the Madureira et al. study reported one participant who dropped out due to “physical limitations.”⁶ This suggests balance training requires a certain level of physical fitness in order to be completed, and as such, may not be tolerable for everyone.

Conclusion

The results from the three studies examined in this review – the NNT of -10 in preventing falls, the NNT of 5 in reducing falls, and the large 9.85 (± 5.88) increase in confidence – suggest balance training has clinical significance in improving quality of life for adults with osteoporosis.^{2,6,7} However, before routine ubiquitous use can be recommended, future studies whose participant demographics include more men and younger patients also at risk for fragility fractures need to be conducted. This will reveal if balance training is generalizable to osteoporotic populations outside of postmenopausal women.

The difference in study length between the RCTs (12 months long) and the case series (1 month long) is also worth noting.^{2,6,7} Balance training needs time to become effective, but an 11 month difference in study lengths raises questions about the optimal length of time a patient needs to participate in a balance training program in order to receive maximum benefits from it. Future studies about optimum balance training length should also include follow up years after the study to see if the impact of balance training on quality of life remains significant years down the road, or if the effect of balance training wears off in the patients who receive it.

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