Medeniyet Med J. 2020;35:79-84
doi:10.5222/MMJ.2020.18828

Original Study

Validity of the Korebalance® Balance System in Patients with Postmenopausal Osteoporosis

Korebalance Denge Sisteminin Postmenopozal Osteoporotik Hastalarda Geçerliği

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Ethics Committee Approval: This study was approved by the Istanbul Medeniyet University Goztepe Training and Research Hospital, Clinical Studies Ethics Committee, 27 June 2018, 2018/0236.
Conflict of interest: The authors declare that they have no conflict of interest.
Funding: None.
Informed Consent: Informed consent was taken from the patients enrolled in this study.

Cite as: Dogruoz Karatekin B, Yasin S, Yumusakhuylu Y, Bayram F, Icagasioglu A. Validity of the Korebalance® balance system in patients with postmenopausal osteoporosis. Medeniyet Med J. 2020;35:79-84.

ABSTRACT

Objective: *Balance is impaired in postmenopausal osteoporosis. Balance can be assessed with several tests and balance assessment systems. In our study, we investigated validity of Korebalance Balance System (KBS).*
Method: *52 postmenopausal osteoporotic patient evaluated with balance tests (Berg Balance Scale (BBS) and Time Up&Go Test (TUG)) and Korebalance Balance System. KBS is a balance evaluation and exercise system. The higher the score, the greater the deterioration in the balance. Static and dynamic balance evaluation results are recorded as score values. KBS, BBS and TUG compared with demographic and clinic parameters (age, 25OHvitD, menopausal age, fall history in last year, fracture history).*
Results: *According to Pearson r correlation analysis, Korebalance Dynamic Test (KDT) and BBS had moderately negative correlation (r=-.38, p<.01), KDT and TUG had moderately positive correlation (r=-.42, p<.01). According to Spearman rho correlation analysis, Korebalance Static Test (KST) and BBS had moderately negative correlation (r=-.30, p<.05). Age and KST (r=.33, p<.05), age and KDT (r=.31, p<.05) had moderately positive correlation. No significant correlation was found with other parameters. In discriminant validity, there was no correlation between other nonfunctional demographic and clinical parameters.*
Conclusion: *Korebalance Balance System was found to be a convenient assessment tool with moderate convergent validity compared with BBS and TUG and has an excellent intraclass correlation.*

Keywords: *Balance, osteoporosis, postmenopausal osteoporosis*

ÖZ

Amaç: *Postmenopozal osteoporoz hastalarında denge bozulmuştur. Denge çeşitli test ve denge sistemleri ile değerlendirilmektedir. Çalışmamızda Korebalance Denge Sistemi© ve denge testleri ile hastalarımızı değerlendirip Korebalance Denge Sistemi'nin geçerliğini araştırdık.*
Yöntem: *52 postmenopozal osteoporoz hastası denge testleri (Berg Denge Testi (BDT) ve Zamanlı Kalk&YürüTesti (ZKY)) ve Korebalance Denge Sistemi ile değerlendirildi. Korebalance Denge Sistemi bir denge değerlendirme ve egzersiz sistemidir. Skor değeri ne kadar artarsa dengedeki bozulma da aynı oranda artmaktadır. Statik ve dinamik denge değerlendirme sonuçları skor değeri olarak kaydedilmektedir. Çalışmamızda Korebalance Denge Sistemi, BDT ve ZKY testleri ile ve demografik ve klinik diğer parametrelerle (yaş, 25OHvitD düzeyi, menopoz yaşı, son 1 yıl içinde düşme, kırık öyküsü) karşılaştırılmıştır.*
Bulgular: *52 postmenopozal osteoporotik hastanın yaş ortalaması 65,48±9,11, ortalama BKI 26,97±5,06, ortalama menopoz yaşı 46,09±5,57 ve ortalama 25OHvitD düzeyi 23,84±12,43 idi. Pearson r korelasyon analizine göre Korebalance dinamik testi BDT ile orta derecede negatif korelasyona (r=-.38, p<.01), ZKY testi ile orta derecede pozitif korelasyona (r=-.42, p<.01) sahipti. Spearman rho korelasyon analizine göre Korebalance statik denge testi BDT ile orta derecede negatif korelasyona sahipti (r=-.30, p<.05). Yaş ile korebalance statik test (r=.33, p<.05) ve dinamik test (r=.31, p<.05) orta derecede korele bulundu. Diğer parametreler ile anlamlı ilişki saptanamadı. Diskriminant geçerlilikte, bakılan diğer fonksiyonel olmayan demografik ve klinik parametrelerle korelasyon saptanmadı. Sınıf içi korelasyon analizine göre Korebalance statik test (.987) ile dinamik test (.965) mükemmel sınıf içi korelasyona sahipti.*
Sonuç: Korebalance Denge Sistemi, Berg Denge Testi ve ZKY ile kıyaslandığında orta derecede konverjan geçerlilik gösteren, iyi sınıf içi korelasyona sahip bir denge değerlendirme aracı olarak bulunmuştur.

Anahtar kelimeler: *Denge, osteoporoz, postmenopozal osteoporoz*

Received: 3 March 2020
Accepted: 18 May 2020
Online First: 30 June 2020

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INTRODUCTION

Balance is defined as the ability to maintain the center of gravity of an individual within the base of support through postural adjustments at rest and during activity. Both static and dynamic balance are impaired as a result of impaired postural control in the elderly individuals[1]. Balance disturbances have also been shown by several studies in postmenopausal osteoporosis[2,3]. Balance can be assessed using a number of tests and balance systems.

With the advances in technology, various balance evaluation systems have been introduced in addition to the current balance assessment. Examples of balance assessment systems include posturography, computerized balance trainers, Korebalance® systems and three-dimensional systems. Although these systems are referred to by different names, their working mechanisms are very similar. They all have built-in features that allow acquisition and recording of data based on body sways tested under static and dynamic conditions on a balance platform[4].

Figure 1. Korebalance Balance System

The Korebalance® System is a computerized balance and exercise system offering a high-tech way for balance assessment (Figure 1). It has a variable air pressure bladder system and a tilt sensor (solid-state accelerometer) underneath the platform to track movements 360 degrees horizontal and 20 degrees vertical. The software of the system issues a score following static and dynamic balance assessments (Figure 2 and 3). Higher scores indicate greater impairment of balance.

While the Korebalance® System has been used in clinical settings, its validity and reliability have not been yet demonstrated. In the present study, we

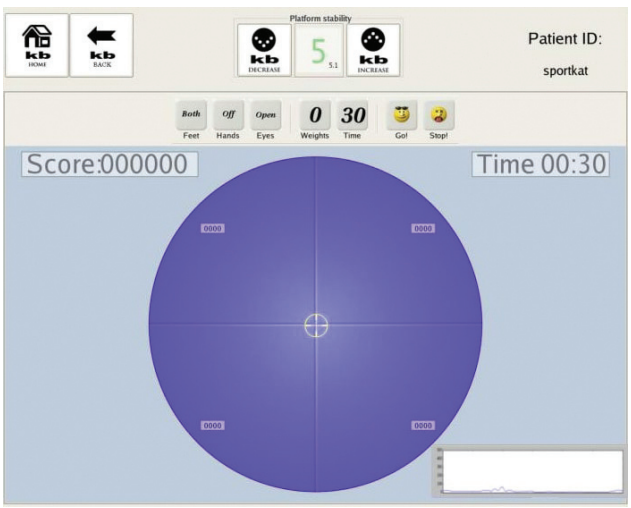

Figure 2. Korebalance Static Balance Test

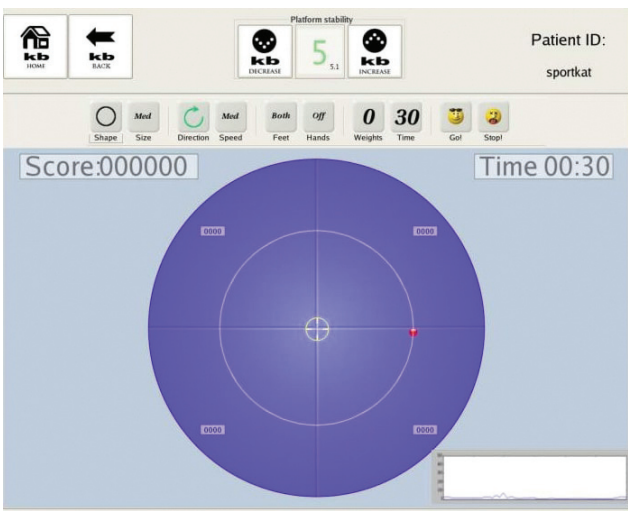

Figure 3. Korebalance Dynamic Balance Test

evaluated the patients using the Korebalance® System and other balance tests (Berg Balance Scale, Timed Up & Go Test) with the aim to investigate the validity and reliability of the Korebalance® System.

MATERIALS and METHODS

This study was approved by the Istanbul Medeniyet University Goztepe Training and Research Hospital, Clinical Studies Ethics Committee, on 27 June 2018, with a registration number of 2018/0236. All patients signed written informed consent before participating in the study.

Fifty-three patients with postmenopausal osteoporosis were evaluated using balance tests including the Berg Balance Scale (BBS), Timed Up & Go Test (TUG) and the Korebalance Premiere-19 Balance System (Figure 1). Patients with any musculoskeletal, neurological or orthopedic problem that could interfere with static or dynamic balance test, prior surgery (within the last 6 months), history of psychiatric disorder and patients with visual or hearing impairments were excluded.

Berg Balance Scale (BBS)

This is a scale designed to measure balance of older adults. Of the 14 items, standing with a decreased base of support, rising from sitting to standing position, standing with feet in tandem position and standing on one foot are used to measure the ability to maintain postural control during challenging tasks. Other items (transfer between positions, reaching forward with outstretched arm, turning to look behind and receiving object from floor) measure the ability to perform specific tasks. Each item is scored on a 5-point scale, ranging from 0 to 4 points. "0" indicates the lowest level of function and "4" is the highest level of function. The total score ranges between 0 and 56 points. Scores are interpreted as follows: 41-56=low risk for falling, 21-40=medium risk for falling, 0-20=high risk for falling. A cut-off score of 45/56 has been identified for safe and independent ambulation[5,6].

Timed Up & Go Test (TUG)

The aim of the test is to determine the risk of falling and to measure the progress of balance, from sitting to standing and walking. At the beginning, the patient is in seated position, than stands up upon the therapist's command, walks 3 meters, turns around, walks back to the chair and sits down. The chronometer is stopped as the patient sits. The patient is allowed to use an assistive device (documented if used). If an older person takes longer than 12 seconds to complete the test, he or she is classified as at high risk of falling[7].

Korebalance Static Balance Test

The Korebalance Premiere-19 device and software were used for balance assessment. The static test requires standing steady and balancing on the platform, keeping the crosshairs of the cursor in the center of the test pattern. The score indicates the deviation of the user's center of gravity from the center of the pattern (Figure 2). The higher score is associated with the worse balance.

Korebalance Dynamic Balance Test

The Korebalance Premiere-19 device and software were used for assessment of dynamic balance. The dynamic test involves a moving cursor that the user "follows". The cursor forms a circle pattern in clockwise direction (Figure 3). The higher score is associated with the worse balance.

In the present study, the Korebalance® Balance System was compared with BBS and TUG test in relation to demographic and other clinical parameters (age, body mass index [BMI], 25-hydroxyvitamin D (25OH-vitD) status, menopausal age, history of falls in the previous year, history of fracture and maternal history of fracture). Korebalance Balance System tests were repeated 10 minutes apart by 2 investigators.

Statistical Analysis

All statistical analyses were performed using

the SPSS Statistics Version 25.0 software package (IBM, Chicago, IL, USA). Descriptive statistics were presented as mean±standard deviation and minimum-maximum values for continuous variables and frequency (percentage) for categorical variables. For the analysis of differences among groups, the independent t-test was used for the data that followed a normal distribution and Mann-Whitney U test for the data with a non-normal distribution. Pearson r correlation analysis was used to test the correlation between two variables if normality assumptions were met and Spearman Rho correlation analysis, if not. Pearson r or Spearman Rho correlation analyses were conducted to explore relations among the results of Korebalance static and dynamic tests and other balance tests (Berg Balance Scale and Timed Up & Go Test). Intraclass correlation coefficient analysis was used for Korebalance static and dynamic test results of 2 investigators. For all analyses, the level of statistical significance was set at 0.05.

RESULTS

The patients with postmenopausal osteoporosis (n=53) had a mean age of 65.48±9.11 years, mean BMI of 26.97±5.06 kg/m^2, mean menopausal age of 46.09±5.57 years and mean 25OHvitD level of 23.84±12.43 (ng/mL). Of 53 patients, 22 (41.5%) had a history of fracture, 16 had a history of falls in the previous year (30.2%) and 17 (32.1%) had a maternal history of fracture. The results of all balance tests are provided in Table 1.

Pearson r correlation analysis showed that Korebalance dynamic test had a moderate negative correlation with BBS (r=-0.38, p=0.005) and a moderate positive correlation with TUG (r=-0.42, p=0.002). Based on Spearman Rho correlation analysis, Korebalance static balance had a moderate negative correlation with BBS (r=-0.30, p=0.029) (Table 2).

According to intraclass correlation analysis, Korebalance static test (.987) and dynamic test (.965) have excellent intraclass correlation coefficients (Table 3 and 4).

Relations between Korebalance balance test results and patient age, 25OH-vitD level and meno-

Table 1. Balance test results.

Balance Tests	Mean±SD	Min.-Max
Korebalance Static Test	494.91±345.55	80-1254
Korebalance Dynamic Test	3802.87±909.68	1554-5598
Berg Balance Scale	51.34±4.60	39-56
Timed Up & Go Test	9.71±2.18	4.75-16.65

Table 2. Pearson r correlation analysis.

	Korebalance Dynamic Test		Korebalance Static Test	
Balance Tests	r	p	rho	p
Berg Balance Scale	-0.38[a]	<0.01**	-0.30[b]	<0.05*
Timed Up & Go Test	0.42[a]	<0.01**		

*[a]Pearson r. [b]Spearman rho. *Significance level of the correlation is 0.05. **Significance level of the correlation is 0.01.*

Table 3. Intraclass correlation coefficient analysis for Korebalance static test.

		95% Confidence Interval	
	Intraclass Correlation[a]	Lower Bound	Upper Bound
Single Measures	.974	.955	.985
Average Measures	.987	.977	.992

Two-way mixed effects model where people effects are random and measures effects are fixed.
[a]Type C intraclass correlation coefficients using a consistency definition. The between-measure variance is excluded from the denominator variance.

Table 4. Intraclass correlation coefficient analysis for Korebalance dynamic test.

		95% Confidence Interval	
	Intraclass Correlation[a]	Lower Bound	Upper Bound
Single Measures	.932	.885	.960
Average Measures	.965	.939	.980

Two-way mixed effects model where people effects are random and measures effects are fixed.
[a]Type C intraclass correlation coefficients using a consistency definition. The between-measure variance is excluded from the denominator variance.

Table 5. Independent t-test and Mann-Whitney U test data.

		Korebalance Dynamic Test			Korebalance Dynamic Test		
	n	Mean±SD	t	p	Mean±SD	t	p
History of fracture							
Yes	22	3777.41±974.67	0.17	0.87	565.91±346.04	257.00	0.13
No	31	3820.94±876.68			444.52±341.80		
History of falls in the previous year							
Yes	16	3798.81±645.43	0.02	0.98	514.69±400.85	290.00	0.91
No	37	3804.62±1010.80			486.35±324.46		

**The difference is significant at 0.05 level.*

pausal age were investigated. Patient age was moderately correlated with Korebalance static test (r=0.33, p<0.025) and dynamic test (r=0.31, p<0.005). Any significant correlation were not found between Korebalance balance tests and other parameters (Table 5).

DISCUSSION

Falls and resulting fractures are the major cause of disability in osteoporotic patients. Balance impairment is one of the well-known causes of falls in the elderly people[8,9].

Tinetti et al.[10] reported that the frequency of falls increases with advancing age but only 44% of falls are related to environmental factors, and impaired postural balance and reduced lower extremity muscle strength account for the majority of the falls not associated with environmental factors. One study showed that the group with a history of fall had significantly lower scores on the Berg Balance Scale compared to the group without history of falls and higher quality of life scores were observed in the latter group[11]. Thus, control of postural balance decreases with age and is associated with an increased frequency of falls. In our patient sample, Korebalance static and dynamic balance tests were correlated with age. Therefore, assessment of balance in patients with postmenopausal osteoporosis is important.

Several tests are utilized for the assessment of balance. The BBS and TUG are commonly used to evaluate balance in patients with osteoporosis. With the recent advances in technology, various systems have been developed that provide both balance assessment and balance training. While these systems are commonly used in clinical settings, few studies have been conducted so far to evaluate their utility. Korebalance® Balance System is a combined balance assessment and exercise system.

The BBS and TUG are reliable and validated tests for which good correlations have been demonstrated[12,13]. In the present study, Korebalance Static and Dynamic test results were correlated with BBS and TUG results. In our study, the men time for TUG test of the patients was 9.71 seconds which was compatible with the results of other studies[14,15].

Vitamin D insufficiency is associated with reduced proximal muscle strength particularly in lower extremities and results in an increased number of falls. However, there are studies that have reported contradictory results on the relation between vitamin D and balance. In some of the studies, no association was found between vitamin D status and balance[16,17]. Consistently, there is no significant correlations between vitamin D level and balance tests in our study. Nevertheless, some studies in the literature demonstrated the presence of a significant association between vitamin D status and balance[18,19].

The rates of falls and related fractures were high in our patient group. Falls are also prevalent among community dwelling older adults. In the older

people living in the society over 65 years old, one out of every 3 people falls every year and approximately 10% of falls result in fractures[20]. In the current study, dynamic or static balance was not significantly correlated with the history of fracture and falls in the previous year. Osteoporosis itself is a major risk factor for falls and fractures[21]. Also, there are many known risk factors for falls and fractures. Falls and fractures in our patients may have occurred due to reasons other than balance impairment including arthrosis, vision problems and depression which are all common among elderly population.

We conducted a literature search and could not find any study involving Korebalance® System. According to our knowledge, this is the first study to test the validity of this system. One of the limitations of this study is ite small sample size. In addition, although inter-observer reliability of Korebalance® System was found high, temporal reliability could not be investigated since test-retest reliability analyses could not be performed. Further studies on the reliability and validity of this system involving a greater patient sample are needed to corroborate our findings.

CONCLUSION

As a balance assessment tool, Korebalance Balance System showed a moderate level of reliability and convergent validity compared with the Berg Balance Scale and Timed Up & Go Test with an excellent intraclass correlation values.

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