

Validity and Reliability of the Turkish Version of The International Restless Legs Syndrome Study Group Rating Scale

Uluslararası Huzursuz Bacaklar Sendromu Çalışma Grubu Değerlendirme Ölçeğinin Türkçe Versiyonunun Geçerlilik ve Güvenilirliği

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ABSTRACT

Aim: The purpose of this study is to prepare the Turkish version of the International Restless Legs Syndrome (RLS) Study Group Rating Scale and to investigate its validity and reliability.

Materials and Methods: A total of 89 individuals with RLS were included. These subjects were divided into two groups: A pilot study group (n=20) and a study group (n=69). The scale was translated into and adjusted for Turkish and was applied to the groups.

Results: In the analysis conducted to test the factor structure of the scale, it was clearly seen that the items were collected under two factors and that the two factors in total accounted for 68.19% of the variance. The Kaiser-Meyer-Olkin (Kaiser-Meyer-Olkin) coefficient for validity of the scale was 0.84 and Bartlett Sphericity index was significant with $p < 0.005$. The Cronbach's Alpha coefficient, which determined the reliability of the scale, was 0.0896.

Conclusions: This study demonstrated that the Turkish version of this scale that is frequently used for scientific and clinical trials is valid.

Keywords: Restless Legs Syndrome; validity; reliability

ÖZ

Amaç: Bu çalışmanın amacı, Uluslararası Huzursuz Bacaklar Sendromu (HBS) Çalışma Grubu Şiddet Ölçeği'nin Türkçe versiyonunu hazırlayarak geçerlilik ve güvenilirliğini araştırmaktır.

Materyal ve Metod: Çalışmaya toplamda 89 HBS'li birey alındı. Hastalar iki gruba ayrıldı: pilot çalışma grubu (n=20), çalışma grubu (n=69). Türkçe çeviri ve düzenlemeleri yapılan ölçek gruplara uygulandı.

Sonuç: Ölçeğin faktör yapısını test etmek için yapılan analizde maddelerin iki faktör altında toplandığı ve iki faktörün toplamda varyansın %68,19'unu açıkladığı görülmektedir. Ölçeğin geçerliliği için saptanan KMO (Kaiser-Meyer-Olkin) katsayısı 0,84, Bartlett Küresellik indeksi $p < 0.005$ olarak anlamlı bulundu. Ölçeğin güvenilirliğini belirlemek amacıyla elde edilen Cronbach's Alpha katsayısı 0.896'dır.

Tartışma: Bu çalışmada bilimsel ve klinik çalışmalarda sık kullanılan bu ölçeğin Türkçe versiyonu gösterilmiştir.

Anahtar kelimeler: Huzursuz Bacaklar Sendromu, geçerlilik; güvenilirlik

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INTRODUCTION

Diagnostic criteria for Restless Legs Syndrome (RLS) were established by the International RLS Study Group in 1995 and revised by the same group in 2003 and 2014. Accordingly, the criteria are as follows: 1-unpleasant and disturbing feelings in the legs that cause the need to constantly move them; 2-symptom onset or deterioration at rest (sitting, lying); 3-diminishing or partial loss of symptoms with movement; 4-increase and deterioration of symptoms at night; 5-exclusion of situations such as myalgia, venous stasis, leg edema and leg cramps. Patients that meet all five criteria are diagnosed with RLS [1,2].

Restless Legs Syndrome is common, with a prevalence of 3-15% in the world [3] and 3.2-9.7% in Turkey [4,5]. Most of the epidemiological studies have shown that the disease is more frequent in women and the elderly [6]. The severity of the disease is evaluated by International RLS Study Group Rating Scale (IRLSSGRS) [7](App 1). The scale has been translated into Portuguese in 2008 [8] Japanese in 2013 [9], and Arabic in 2015 [10].

The objective of this study was to determine the reliability and validity of the Turkish version of the scale and to lead the way to clinical studies on RLS.

MATERIALS AND METHODS

This study included a total of 89 subjects of whom 43 were male and 46 female diagnosed with RLS in our neurology department between January and September 2017. The patients with uncontrolled high blood glucose and also the patients who were diagnosed with polyneuropathy, myopathy, dementia, stroke, Parkinson's Disease were excluded. All the patients were examined by a neurologist specialized in movement disorders (N.H.Y). After receiving consent by explaining the content and purpose of the study, pre-application group (n=20) and application group (n=69) were selected.

IRLSSGRS is a scale composed of 10 questions that evaluates the severity of RLS. Question 1 is for evaluating the overall severity of the disease; Question 2 is for the severity of the urge to move around; Question 3 is for the relief of the complaints after moving around; Question 4 is for the

quality of sleep; Question 5 is for the effect of RLS during the day; Question 6 determines the patient's opinion for the severity; Question 7 shows the frequency of RLS; Question 8 is for the duration of the symptoms; Question 9 evaluates the daily activities of RLS patients and Question 10 measures the effect of RLS on mood. (The Turkish form is at the end of the article).

Initially, researchers who developed scales were contacted via e-mail and their consent was obtained. The original scale was translated to Turkish by three certified translators. The translated scale was presented to five expert opinions, and each item was analyzed for content integrity in Turkish and conceptual equivalence.

Pre-application was done with 20 individuals with RLS who had the same criteria as the study group. The translated scale was applied to patients and the data were recorded. At the end of the application, unclear points were questioned and the scale was reestablished. Final adjustments were made on the scale based on a pilot study involving 20 patients with RLS. The scale adapted to Turkish was applied to the study group consisting of 69 individuals. Two weeks after the first application, the same scale was applied again (test/re-test).

Statistical Analysis

Data were analyzed by Statistical Package for the Social Sciences (SPSS) 22 software and p value was <0.05 with 95% confidence level. Kaiser-Meyer-Olkin (KMO) coefficient was obtained in order to determine whether the data set from the samples are suitable for factor analysis and significance value for Bartlett sphericity test was checked. The Bartlett sphericity test significance level lower than 0.05 ($p < 0.05$) met the required conditions and a KMO coefficient close to 1 showed whether the data set was totally suitable for factor analysis.

Cronbach's Alpha coefficient obtained from the application to determine internal consistency shows reliability. According to evaluation criteria in which Cronbach's Alpha coefficient varies between 0-1; 0.00 - < 0.40 was considered as unreliable, 0.40 - < 0.60 as of low reliability, 0.60 - < 0.80 as of high reliability, and 0.80 - < 1.00 as highly reliable.

App 1: TURKISH VERSION OF THE INTERNATIONAL RESTLESS LEGS SYNDROME STUDY GROUP RATING SCALE

Geçen hafta;	(0)	Yok
1. Bacaklar ve kollardaki huzursuzluğunuz ne orandıydı?	6.	Genel olarak Huzursuz Bacaklar Sendromunuzun şiddeti sizce ne kadar?
(4) Çok ciddi	(4)	Çok ciddi
(3) Ciddi	(2)	Ciddi
(2) Orta	(3)	Orta
(1) Hafif	(1)	Hafif
(0) Yok	(0)	Yok
2. Huzursuz Bacaklar Sendromu belirtileri nedeniyle etrafta dolaşma isteğiniz ne orandıydı?	7.	Huzursuz Bacaklar Sendromu belirtileri hangi sıklıkla ortaya çıkıyor?
(4) Çok ciddi	(4)	Çok sık (Haftada 6-7 gün)
(2) Ciddi	(2)	Sık (Haftada 4-5 gün)
(3) Orta	(3)	Bazen (Haftada 2-3 gün)
(1) Hafif	(1)	Nadiren (Haftada 1 gün)
(0) Yok	(0)	Hiçbir zaman
3. Etrafta dolaşmayla kollar veya bacaklardaki huzursuzluğunuzda ne kadar rahatlama oldu?	8.	Huzursuz Bacaklar Sendromu belirtileri olduğunda ortalama olarak sizce ne şiddettedir?
(4) Rahatlama yok	(4)	Çok ciddi (24 saat içinde 8 saat veya daha uzun süre)
(2) Hafif derecede rahatlama	(2)	Ciddi (3-8 saat)
(3) Orta derecede rahatlama	(3)	Orta (1-3 saat)
(1) Tam veya tama yakın rahatlama	(1)	Hafif (24 saatte 1 saatten az süre)
(0) Huzursuz Bacaklar Sendromu belirtileri yok	(0)	Yok
4. Huzursuz Bacaklar Sendromu belirtilerine bağlı olarak uyku kalitesinin etkilenmesi ne düzeydeydi?	9.	Huzursuz Bacaklar Sendromu belirtilerinin günlük aktiviteleriniz (aile, ev, sosyal, okul veya iş hayatı) üzerinde etkisi sizce ne orandıydı?
(4) Çok ciddi	(4)	Çok ciddi
(2) Ciddi	(2)	Ciddi
(3) Orta	(3)	Orta
(1) Hafif	(1)	Hafif
(0) Yok	(0)	Yok
5. Huzursuz Bacaklar Sendromu belirtilerine bağlı olarak gün içindeki yorgunluk ve uykusuzluğunuz ne orandıydı?	10.	Huzursuz Bacaklar Sendromu belirtileri duygu durumunuzu ne oranda etkiliyor (sinirli, mutsuz, üzgün veya tedirgin)?
(4) Çok ciddi	(4)	Çok ciddi
(2) Ciddi	(2)	Ciddi
(3) Orta	(3)	Orta
(1) Hafif	(1)	Hafif
	(0)	Yok

RESULTS

We first determined whether the data was suitable for factor analysis. Factor analyses were performed for pre-application and application. Results were summarized in table 1.

Table 1: Bartlett sphericity test pre-application and application

		pre-application	application
KMO		0.672	0.84
Bartlett sphericity test	ki square	84.701	431.59
	sd	45.00	45.00
	p	0.00	0.00

p<0.05=abnormal distribution; p>0.05=normal distribution

KMO: Kaiser-Meyer-Olkin; sd: standard deviation

Based on the measurements for pre-application group, the significance level for Bartlett sphericity test is lower than 0.05 despite the KMO coefficient is not close to 1. The Bartlett sphericity test significance level lower than 0.05 (p<0.05) indicates that it meets the required condition and a KMO coefficient close to 1 shows that the data set is totally suitable for factor analysis. The KMO coefficient close to 1 and Bartlett sphericity test index with p<0.05 indicates that the data set is suitable for factor analysis. Table 1 shows that data of the study group was suitable for factor analysis.

Items 4 and 8 of the IRLSSGRS show close weights under both factors and therefore should be

excluded from the study. However, the measurements included all 10 items considering that both items had no significant negative impact on the results and the data set in the investigation was limited. Ten items may be considered to be weighted under 2 factors since there are 2 factors with specific value greater than 1 in the total variance table. The first and second factors alone account for 54.12% and 14.07%, respectively, of the total variance while two factors together account for 68.19% of the total variance. These results are presented in table 2.

Findings from statistical measurements demonstrate that the scale showed a two-factor structure similar to the original scale. Based on the original scale, the first 5 questions indicated the severity of the syndrome while the remaining 5 was used to measure the daily activities and quality of life of the patients. The 68.19% of the total variance in the scale created two factors for explanation

Table 2: The factor structure of IRLSSGRS and the power of the factor items

The factor structure of IRLSSGRS	Factor 1	Factor 2
Question 5	0.866	
Question 2	0.828	
Question 7	0.773	
Question 6	0.736	
Question 1	0.735	
Question 3	0.699	
Question 4	0.622	0.617
Question 8	0.545	0.462
Question 9		0.837
Question 10		0.691
The power of the factor items		
Question 1	0.721	
Question 2	0.821	
Question 3	0.612	
Question 4		0.735
Question 5		0.701
Question 6		0.706
Question 7		0.707
Question 8		0.816
Question 9		0.871
Question 10		0.858

IRLSSGRS: International Restless Legs Syndrome Study Group Rating Scale

power and the first 3 questions were gathered under the first factor. The resulting first factor alone

accounted for 54.12% of the variance. The other items of the scale were gathered under the second factor which alone had the power to account for 14.07% of the variance (table 3).

Table 3: Factor and variance components of IRLSSGRS

Component	Initial Eigenvalues			Squares Sum Return		
	Sum	Variance%	Cumulative %	Sum	Variance%	Cumulative %
1	5.41	5.12	54.12	4.42	44.20	44.20
2	1.41	14.07	68.19	2.40	23.99	68.19
3	0.95	9.45	77.64			
4	0.59	5.87	83.51			
5	0.43	4.31	87.82			
6	0.38	3.77	91.60			
7	0.27	2.68	94.28			
8	0.25	2.53	96.81			
9	0.18	1.84	98.66			
10	0.13	1.34	100.00			

IRLSSGRS: International Restless Legs Syndrome Study Group Rating Scale

In the application with 69 patients, internal consistency of the scale applied with 2-week intervals defined reliability. This value was determined by Cronbach's Alpha coefficient.

Reliability coefficient of factor 1 sub-dimension was 0.913. Accordingly, the reliability level was very high for the dimension. Reliability coefficient of factor 2 sub-dimension was 0.657. Accordingly, the reliability level was very high for the dimension. The reliability coefficient for IRLSSGRS was 0.896. Accordingly, the reliability level was very high for the scale. Consistency of the repeated measures in the context of reliability analysis was determined for each question individually by in-class correlation values. These values are between 0.925 and 0.776. This indicated that the consistency between raters was high. These results are presented in table 4.

Table 4: Reliability analysis of the sub-dimension of factor 1, factor 2 and IRLSSGRS

	Cronbach's Alpha	Number of items
Factor 1	0.913	7
Factor 2	0.657	3
IRLSSGRS	0.896	10

IRLSSGRS: International Restless Legs Syndrome Study Group Rating Scale

DISCUSSION

This study investigated the validity and reliability of the Turkish version of IRLSSGRS. In the literature, we found the validity and reliability studies of IRLSSGRS in different languages. Cronbach's Alpha coefficient was found to be 0.82 in a validity study in Arabic conducted by Shalash and colleagues in 2015 in Egypt on 46 patients with RLS [10]. In a validity and reliability study conducted by Inoue et al. in 2013 in Japan on 59 patients with RLS, Cronbach's Alpha coefficient was 0.95 [9]. In the study by Masuko et al. in 2008 in Brazil, the scale was applied to 30 patients with RLS and the validity and reliability in Portuguese were examined. The reliability coefficient of the scale was found to be 0.83 [8]. In our study, Cronbach's Alpha coefficient was 0.896 indicating comparable reliability with similar studies. The sample size of this study was superior to the likes regarding the number of samples. The validity and reliability studies in other languages utilized 'comparison with a known group' for validity analysis. In our study, validity was assessed under three main topics as linguistic validity, structural validity, and factor analyses.

The scale generated by Walters et al. in 2003 consisted of two factors in which the first 5 questions indicated the severity of the syndrome and the latter 5 were used to measure the daily activities and the quality of life of the patients [7]. Our factor analyses resulted in two factors that account for 68.19% of the total variance in the scale where the first 3 questions were gathered under the first factor and the others were included into the second factor.

Although no validity and reliability studies for this scale was carried out in Turkish before, the study by Aksu et al. is of note [11]. This study investigated the correlation with polysomnography, an objective method to determine the severity, by using the Turkish version of IRLSSGRS. The scale was found to be reliable. Another scale to measure severity of RLS is John Hopkins RLS severity scale (JHRLSSS) [12]. This scale involved 4 items that question the hours of symptom onset. It can be concluded that 4 items in JHRLSSS correspond to a single item in IRLSSGRS indicating that IRLSSGRS provides a more extensive query to measure severity, when the two scales are extensively examined. The same patients were

applied John Hopkins Severity Scale with 'comparison with known group' method that is used in validity analyses in similar studies and the consistency between the two scales were examined. However, this scale was considered as one step lower to IRLSSGRS and therefore not approved for such an evaluation since it contains four questions and only covers symptom duration. These two scales were compared in another study which suggested that IRLSSGRS demonstrates clinical features more clearly compared to JHRLSSS and better determines disease severity. When the validity and reliability of these two scales were compared, Cronbach's Alpha coefficient in JHRLSSS and IRLSSGRS were found to be 0.975 and 0.896, respectively.

Severe RLS causes a humanistic and economic burden [13]. The quality of life is decreased markedly in RLS patients and about 11% of the patients cannot go to work [14]. IRLSSGRS is an objective scale that evaluates the severity of the disease and helps the neurologists for the suitable time to initiate therapy. Dopamine agonists are effective drugs for RLS [15]. This scale is also used to follow up the patient after the therapy starts. Translation and validation of a questionnaire is mandatory for follow up and for especially researches.

Our results are close to similar studies in terms of validity and reliability. It can be concluded that the present scale can be safely used to measure the severity of RLS while the Turkish version is not satisfactory in terms of validity.

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