Original Article

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Translation and Evaluation of the Content Validity and Reliability of the Persian Version of the Modified-Restless Legs Syndrome Diagnostic Questionnaire

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Abstract

Background: Restless Legs Syndrome (RLS) is a common disease with an estimated overall prevalence of 3% based on findings from a recent meta-analysis. Due to the lack of a reliable Persian questionnaire for the diagnosis of RLS, this study aimed to translate and evaluate the content validity and reliability of the Persian version of the modified-Restless Legs Syndrome Diagnostic Questionnaire (m-RLS-DQ).

Methods: The m-RLS-DQ, a reliable and accurate tool for diagnosing RLS was selected. Three bilingual physicians translated it into Persian, then unified by the fourth expert. Eight specialists evaluated the content validity using a Likert scale for relevance. Reliability was tested by administering the final version to 10 RLS the patients.

Results: The reliability index (*i.e.*, Cronbach's alpha coefficient) was also obtained as 0.78. The content validity was determined with the help of Microsoft Excel software, showing a Content Validity Index (CVI) of 0.98.

Conclusion: In this study, the appropriate validity and reliability of the Persian version of m-RLS-DQ was confirmed.

Keywords: Prevalence, Reproducibility of results, Restless legs syndrome, Surveys and questionnaires

Introduction

Restless Legs Syndrome (RLS) is a common disease with an overall prevalence of 3%, according to a recent meta-analysis study and also another study reported that 34.5% of the participants aged over 40 years old were afflicted with this disorder (1). However, the prevalence of this condition is relatively higher in some population groups, including women (2). Restless leg syndrome is associated with numerous diseases, and there is evidence supporting the association of this condition with iron deficiency and renal dysfunction (3). This syndrome has also been observed in association with neurological disorders, for example, its prevalence has been reported as 27.8% in Multiple Sclerosis (MS) patients, 14% in those suffering from Parkinson's disease (4,5), and 8% among all individuals referring to neurology clinics (6). Citing a well-designed cross-sectional study, the prevalence of RLS was reported to be 6% in Iran (7); however, a systematic review declared a prevalence of 30% in Iran (8). Restless leg syndrome refers to a condition in which the patient is urged to move or rub the foot in response to an unpleasant or painful sensation in the extremities. The symptoms are exaggerated in the evening or during rest but subside after walking or by moving the legs (9). This condition may become so severe that can trigger suicidal thoughts and behaviors in affected people (10). The correct diagnosis of RLS can be problematic due to ambiguous and non-specific symptoms, and unfortunately, many patients are misdiagnosed (11). Therefore, new diagnostic criteria emphasize ruling out other differential diagnoses such as postural pain, myalgia, *etc*. (9).

Various questionnaires have been developed to diagnose RLS, most of which are unable to rule out various differential diagnoses of this syndrome (12). Recently, a promising questionnaire has been developed with the ability to not only assess multiple differential diagnoses of RLS but also to identify the comorbidities associated with this syndrome (13). Compared to the conventional tools, the recent questionnaire has offered higher average sensitivity and specificity (14). As far as it is known, none of the mentioned recommended tools for RLS screening have been translated into Persian (12). Most studies conducted in Iran have used the IRLSS questionnaire (6,15), a tool that has not been modified for up-to-date diagnostic criteria and cannot rule out differential diagnoses (16). Thus, regarding the lack of a valid Persian language questionnaire for RLS diagnosis, this study aimed to translate it into Persian and validate the modified-Restless Legs Syndrome Diagnostic Questionnaire (m-RLS-DQ).

Materials and Methods

This study took place in Iran in 2024. The most recent questionnaire (*i.e*., m-RLS-DQ) was selected for the diagnosis of RLS. The m-RLS-DQ is a diagnostic tool (not for severity) with item-based scoring and strong sensitivity (94.9%) and specificity (94.1%). It was redesigned to include RLS mimics, tested in English and Hindi, and validated for clinical use. It shows excellent psychometric properties and allows comorbid mimic identification. The English version of this questionnaire was independently translated into Persian by three physicians who mastered both Farsi and English. In the next step, these three translated versions were matched together and unified by the fourth person to finally compile a Persian version of the tool. To assess the content validity, the final Persian version of the questionnaire was provided to 8 medical specialists who were proficient in the diagnosis and treatment of RLS (movement disorder neurologist, psychiatrist, sleep specialist and physical medicine and rehabilitation specialists), and their comments on the questions in terms of appropriateness and relevance to the objective (*i.e*., the diagnosis of RLS) were received on a Likert scale. The experts assigned a score between 1 and 4 to each question based on the level of its relevance or need for modifications. The reliability of the final Persian version of the tool was assessed by providing it to 10 patients suffering from RLS. The inclusion criteria were having symptoms compatible to RLS including feeling restlessness or discomfort in the legs along with the urge to move them.

Validity

A valid study is one that can measure the intended objective without any errors in the study design. The American Psychological Association (APA) defines the following categories for the type of validity: Construct Validity, Content Validity, Concurrent

Validity and Predictive Validity.

This research focuses on the second category. Reviewing the content of scale to determine content validity is one of the most important parts of evaluating the validity of a questionnaire. The goal of this evaluation is to determine whether the content of the questionnaire is capable of measuring the defined objective. Experts should consider three key steps when evaluating content validity:

1. Defining the domain that the tool's content aims to measure.
2. Identifying the specific content area that each item aims to measure.
3. Comparing the tool's content with the content of study.

Two qualitative and quantitative methods are used to determine content validity. Experts are asked to review the tool based on criteria such as grammar, wording, item allocation, and scaling for qualitative content analysis, and provided feedback for necessary revisions. Two indices are used for quantitative content analysis: CVR and CVI. Experts are asked to review each item on a three-point scale (essential, useful but not essential, and not essential) to calculate CVR.

The obtained CVR is compared to a corresponding table value for decision-making. If this value exceeds the table threshold, the item's content validity is confirmed. For CVI assessment, simplicity, relevance, and clarity are rated on a four-point Likert scale by 8 experts for each item (*e.g.*, 1: irrelevant, 2: somewhat relevant, 3: relevant, and 4: highly relevant). CVI is calculated by aggregating the ratings of the items which have values of 3 or 4 and divided by the total number of experts. Items with a CVI score above 0.79 are accepted.

Internal consistency

The goal of internal consistency is to evaluate the correlation between items within a scale. This study used Cronbach's alpha for evaluation of internal consistency. After receiving the experts' opinions, required statistical methods were performed in Microsoft Excel software to calculate CVI. After gathering the answers from the patients, the reliability index (*i.e.*, Cronbach's alpha coefficient) was calculated using STATA 11.5 software (Stata Corp., College Station, TX, USA). Due to the low frequency of the disorder, the number of 10 was confirmed by the methodologist of the study for the initial reliability testing. The patients were chosen among all the psychiatry outpatients who were visited in Fajr clinic in Ilam in 3 months by a psychiatrist.

Results

The validity of the Persian Modified-Restless Legs Syndrome Diagnostic Questionnaire (m-RLS-DQ) was carefully evaluated by eight medical experts, who reviewed each item using a four-point Likert scale. CVR was calculated as shown in table 1; most items received a perfect CVR score of 1.0, indicating that all the experts agreed on their necessity. Only two items (Q21 and Q25) had a slightly lower score of 0.75, which still met the minimum required threshold, confirming their importance in the questionnaire.

CVI was also calculated to measure how relevant, clear, and simple the items were. The CVI of the questionnaire was 0.98, which is above the recommended 0.79 cutoff, indicating strong expert consensus on its effectiveness for diagnosing RLS.

Additionally, Cronbach's alpha coefficient was calculated to assess the internal consistency of the questionnaire, yielding a value of 0.78. This result confirms that the items work well together and consistently measure what they are intended to assess.

Discussion

The diagnosis of RLS is not always straightforward, and patients are misdiagnosed in many cases. The prevalence of this condition has been reported to be about 3% in most recent studies (2,11). A practical way to boost diagnostic accuracy for this condition is to use a validated and appropriate questionnaire with high sensitivity and specificity. Fortunately, numerous suitable questionnaires have been developed for this purpose so far (12); however, none of these possess Persian versions yet, a problem that was addressed in the present study.

Other valid questionnaires are available for diagnosis of RLS, with acceptable psychometric properties. The validity and reliability RLS-Self-care Behaviour questionnaire (RLS-ScBq) were assessed in a study by Odzakovic *et al* which demonstrated that the eight-item RLS-ScBq can be used by healthcare professionals to assess the use and effectiveness of self-care activities in patients with RLS (17). The

Table 1. Content validity measures for the persian m-RLS-DQ

Question	Specialist								CVR	Number of experts rating essential
	1	2	3	4	5	6	7	8		
Feeling restlessness	4	4	3	3	4	4	4	4	1	8
Urge to move	4	4	4	4	4	4	4	4	1	8
Relief on moving	4	4	4	4	3	4	3	4	1	8
Recurring by immobility	4	4	4	4	3	4	4	4	1	8
Circadian pattern q^1	4	4	4	4	4	4	4	4	1	8
Circadian pattern q^2	4	4	4	4	4	4	4	4	1	8
Circadian pattern q^3	4	4	4	4	4	4	4	4	1	8
Restlessness after walking	4	4	4	4	4	4	3	4	1	8
Relief by immobility	4	4	4	4	4	4	4	4	1	8
Relievers	4	4	4	4	4	4	4	4	1	8
Anxiety	4	4	4	3	3	4	3	4	1	8
Leg edema	4	4	4	3	4	4	3	4	1	8
Knot in muscles	4	4	4	3	4	4	3	4	1	8
Positional discomfort	4	4	4	4	4	4	3	4	1	8
Habitual foot tapping	4	4	4	3	3	4	3	4	1	8
Pain in joints	4	4	4	4	4	4	4	4	1	8
Exertional myalgia	4	4	4	4	4	4	4	4	1	8
Tingling	4	4	4	4	4	4	4	4	1	8
Burning	4	4	4	4	4	4	4	4	1	8
Venous engorgement	4	4	4	4	4	4	4	4	1	8
Venous engorgement q^2	4	4	4	3	4	4	4	4	0.75	7
First emergence of symptoms	4	4	4	4	4	4	4	4	1	8
Symptom frequency	4	4	4	4	4	4	4	4	1	8
Symptom duration	4	4	4	4	4	4	4	4	1	8
Intermittent symptoms	4	4	4	4	4	4	3	4	0.75	7

Note: CVR was calculated for each item in the Persian m-RLS-DQ, along with the number of experts who rated each item as essential. CVR: Content Validity Ratio.

Cambridge-Hopkins diagnostic questionnaire for RLS (CH-RLSq) was another widely studied tool. In one study, the sensitivity and specificity of that were 87.2 and 94.4%, respectively, indicating that it provides a reasonable level of sensitivity and specificity for identifying RLS in population-based studies (18). While a sensitivity of 94.9% and a specificity of 94.1% for m-RLS-DQ was prepared and validated by Kumar *et al* in 2023 and offers a sensitivity of 94.9% and a specificity of 94.1% (13), representing particularly higher values compared to previous tools. In a systematic review and meta-analysis of 52 studies on RLS diagnostic tools by Fulda *et al*, the means of sensitivity and specificity

were obtained as 88% and 90%, respectively (14).

The m-RLS-DQ questionnaire not only has appropriate psychometric properties but is also able to discern conditions mimicking RLS. Moreover, this tool is capable of detecting concomitant comorbidities associated with RLS in individuals. In a study by Kwatra *et al,* the differential diagnoses of RLS were reviewed, denoting conditions such as night-time leg cramps, postural pain, vascular disorders, vascular lameness, Akathisia, restlessness leg movement, neuropathies, and radiculopathy (11). Notably, the m-RLS-DQ contains queries related to most of the above-mentioned conditions. Considering the prevalence of RLS, it is important to pay attention to the Positive Predictive Value (PPV) of any given screening tool. In this study, the PPV of this questionnaire at a prevalence of 5% was obtained as 45.9% (95%CI=30.6, 60.8%). In the meta-analysis conducted by Fulda *et al*, the average value of PPV was obtained as 31% (14). These studies show that the m-RLS-DQ delivers a higher PPV compared to its previous counterparts.

In a 2016 systematic review, the prevalence of RLS was reported as 30% in Iran, which was significantly higher compared to the rate of 6% reported by a population-based study in the country conducted on 19,176 participants (7).

In the recent systematic review, the authors acknowledged that they included all the relevant studies regardless of their quality, which may be a possible explanation for this considerable gap. This discrepancy further confirms that no reliable and appropriate diagnostic tool for RLS is available in Iran, leading to the inclusion of possible differential diagnoses and the overestimation of the prevalence of this condition.

Limitations

While m-RLS-DQ demonstrated strong content validity and reliability, it was validated using a small sample size. The study assessed content validity with eight medical specialists and tested reliability on ten patients, which may not fully represent the broader population. Additionally, as the questionnaire relies on self-reported symptoms, there is a risk of bias. Therefore, large-scale studies are necessary to confirm its generalizability, as well as its widespread applicability and reliability.

Conclusion

The result of the present study verified the applicability of the Persian version of the m-RLS-DQ questionnaire as a screening tool for RLS, and it can be used as a suitable instrument in epidemiological studies in Iran. The authors will be happy to provide this tool to Iranian researchers working on RLS.

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Conflict of Interest

There was no conflict of interest in this manuscript.

References

1. Khazaie H, Jalali A, Khazaie A, Mohammadi R, Jalali R, Moheb SB, et al. The prevalence of sleep disorders in Iranian adults – an epidemiological study. BMC Public Health 2024;24(1):3141.

2. Broström A, Alimoradi Z, Lind J, Ulander M, Lundin F, Pakpour A. Worldwide estimation of restless legs syndrome: a systematic review and meta-analysis of prevalence in the general adult population. J Sleep Res 2023;32(3):e13783.

3. Trenkwalder C, Allen R, Högl B, Paulus W, Winkelmann J. Restless legs syndrome associated with major diseases:

a systematic review and new concept. Neurology 2016;86(14):1336-43.

4. Miri S, Rohani M, Sahraian MA, Zamani B, Shahidi GA, Sabet A, et al. Restless legs syndrome in Iranian patients with multiple sclerosis. Neurol Sci 2013;34(7):1105-8.

5. Yang X, Liu B, Shen H, Li S, Zhao Q, An R, et al. Prevalence of restless legs syndrome in Parkinson's disease: a systematic review and meta-analysis of observational studies. Sleep Med 2018;43:40-6.

6. Najafi MR, Saadatnia M, Saffarifard A, Keyhanian K, Davoudi V. Epidemiology of restless legs syndrome in the Iranian population. Sleep Biol Rhythms 2011;9(1):56-9.

7. Fereshtehnejad SM, Rahmani A, Shafieesabet M, Soori M, Delbari A, Motamed MR, et al. Prevalence and associated comorbidities of restless legs syndrome (RLS): data from a large population-based door-to-door survey on 19,176 adults in Tehran, Iran. PLoS One 2017;12(2):e0172593.

8. Ghanei-Gheshlagh R, Parizad N, Zahednezhad H, Sarokhani M, Sayehmiri K, Baghi V. Prevalence of restless legs syndrome in Iran: a systematic review and meta-analysis. J Sleep Sci 2016;1(3):131-8.

9. Allen RP, Picchietti DL, Garcia-Borreguero D, Ondo WG, Walters AS, Winkelman JW, et al. Restless legs syndrome/Willis-Ekbom disease diagnostic criteria: updated International Restless Legs Syndrome Study Group (IRLSSG) consensus criteria—history, rationale, description, and significance. Sleep Med 2014;15(8):860-73.

10. Para KS, Chow CA, Nalamada K, Kakade VM, Chilakamarri P, Louis ED, et al. Suicidal thought and behavior in individuals with restless legs syndrome. Sleep Med 2019;54:1-7.

11. Kwatra V, Khan MA, Quadri SA, Cook TS. Differential diagnosis and treatment of restless legs syndrome: a literature review. Cureus 2018;10(9):e3297.

12. Walters AS, Frauscher B, Allen R, Benes H, Chaudhuri KR, Garcia-Borreguero D, et al. Review of diagnostic instruments for the restless legs syndrome/Willis-Ekbom disease (RLS/WED): critique and recommendations. J Clin Sleep Med 2014;10(12):1343-9.

13. Kumar R, Krishnan V, Das A, Kumar N, Gupta R. Modification and validation of a diagnostic questionnaire for restless legs syndrome: Modified-RLS Diagnostic Questionnaire (m-RLS-DQ). Ann Indian Acad Neurol 2023;26(4):475-83.

14. Fulda S, Allen RP, Earley CJ, Högl B, Garcia-Borreguero D, Inoue Y, et al. We need to do better: a systematic review and meta-analysis of diagnostic test accuracy of restless legs syndrome screening instruments. Sleep Med Rev 2021;58:101461.

15. Mousavi Z, Ghaemmaghami M, Alipour R, Rahimpour S. The relationship between chronic kidney disease and restless legs syndrome and its effective factors: a case-control study. Med J Tabriz Univ Med Sci 2021;43(3):—.

16. Walters AS, LeBrocq C, Dhar A, Hening W, Rosen R, Allen RP, et al. Validation of the International Restless Legs Syndrome Study Group rating scale for restless legs syndrome. Sleep Med 2003;4(2):121-32.

17. Odzakovic E, Sandlund C, Hellström A, Ulander M, Blom K, Jernelöv S, et al. Self-care behaviours in patients with restless legs syndrome (RLS): development and psychometric testing of the RLS–Self-care Behaviour questionnaire. J Sleep Res 2024;33:e14390.

18. Allen RP, Burchell BJ, MacDonald B, Hening WA, Earley CJ. Validation of the self-completed Cambridge-Hopkins questionnaire (CH-RLSq) for ascertainment of restless legs syndrome (RLS) in a population survey. Sleep Med 2009;10(10):1097-1100.