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Validity and Reliability of the Scale Assessment and Rating of Ataxia Persian Version Questionnaire

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ABSTRACT

Introduction: The Ataxia Assessment and Rating Scale (SARA) has been validated in English and a standardized tool having translation and modification according to Iranian language and culture was needed. Therefore, we aimed to determine the validity and reliability of the SARA.

Methods: This cross-sectional study was conducted among patients with ataxia who were referred to the otolaryngology office from April 2023 to January 2024. The SARA questionnaire consists of 8 objects that have been translated into Persian. Cronbach's alpha coefficient was measured to find the internal consistency. Moreover, the intra-class correlation coefficient (ICC) was calculated to evaluate the test-retest reliability. Furthermore, the content validity ratio (CVR) and the content validity index (CVI) were calculated to assess the content validity.

Results: A total of 11 patients with ataxia (aged 48.5±18.8 years) enrolled in the current study. After examining the face validity, the experts did not mention any particular problem. In the content validity, each CVI and CVR index item was equal to one. Cronbach's alpha obtained was equal to 0.893 that indicates a high level of internal consistency of this scale in the first iteration. In the second iteration, this index was obtained as 0.892. In all the items, except the heel shin item, the value of the ICC could not be estimated because the scores in the first and second iterations were the same. ICC for the heel shin item was equal to 0.944 .

Conclusion: The Persian version of the SARA questionnaire achieved the necessary validity and reliability and can be used in patients with ataxia to detect the ataxia symptoms and its severity in the country.

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Introduction

Ataxia (balance disorder) is defined as impaired muscle control or coordination of voluntary movements including walking or picking up objects. Ataxia may affect the several behaviors and cause complications in speech, eye movements and swallowing (1-3).

Ataxia can occur by damage, change or loss of nerve cells in the cerebellum or the brain in where controls muscle coordination (4). As well, some diseases can damage to the spine and peripheral nerves that joining the cerebellum to the muscles and cause ataxia. Severe head trauma, cerebral palsy, stroke, autoimmune diseases, infection, paraneoplastic syndrome or symptoms resulting from cancer, brain abnormalities, reaction to toxic substances, vitamin E deficiency, vitamin B12 deficiency, thyroid problems (5), and covid-19 infection (6), can be one of the causes of chronic or acute ataxia (7,8).

An immediate treatment strategy can be effective in improving the ataxia patient's symptoms and thereby providing good long-term results, as well as being effective in managing treatable reasons of ataxia and save the patient's life. Therefore, the availability of a tool to measure the neurological manifestations of cerebellar ataxia (such as stance, gait and sitting and etc.) in order to improve the symptoms or measure the effect therapeutic interventions on them could be very beneficial (9).

In 2006, the Scale for the Assessment and Rating of Ataxia (SARA) was initially validated in patients with spinocerebellar ataxia (SCA) and includes 8 items of cerebellar ataxia neurological manifestations (10). The SARA's metric properties have been confirmed in further ataxia disorders including Friedreich ataxia (FRDA), (11), non-SCA ataxia (11), multiple sclerosis patients with ataxia (12), and acute ataxic stroke (13). A great number of studies have also used this tool to evaluate their patients, such as those with cervical dystonia (14), opioid-dependent individuals (15), and even in ultra-rare neurodegenerative diseases like Niemann-Pick type C, the GM2 gangliosidoses, multiple sulfatase deficiency and ataxia telangiectasia (16-19).

Considering ataxia can be the complication of different problems and SARA also has wide applications, therefore we aimed to investigate validity and reliability of the Persian form of the SARA in patients with ataxia.

Methods

Questionnaire and scale structure

This questionnaire comprises following items reflecting neurological indexes of cerebellar ataxia: 1-gait, 2-stance, 3-sitting, 4-speech, 5-finger-chase, 6-nose-finger-test, 7-fast alternating hand movements, and 8-heel-shin-slide. The ratings for each item range from 0 (normal, absence of sign) to a maximum of 8 for gait, 6 for stance and speech and 4 for the remaining items. The items of limb coordination are rated for the right and left sides separately and the average of both sides included in the SARA total score. Finally, a sum score of all eight items can be reported that ranging from 0 (no ataxia) to 40 (maximal ataxia or unable to perform), (10).

Participation

The patients were selected from patients suffering from chronic genetic or non-genetic ataxia with clinical symptoms who referred to the otolaryngology office from April 2023 to January 2024. Patients who received concurrent speech therapy and physiotherapy had to have been on a stable dose and type of treatment for at least 6 weeks prior to their first visit. Likewise, if the patients are taking medicine, they should maintain the same dose over the study period. Dissatisfaction to cooperation, failure to complete the second visit, low vision/hearing loss (which was not corrected using glasses), arthritis or other musculoskeletal disorders were the criteria for exiting and not entering the study. At the first visit, 8 tests included in this questionnaire were performed on selected patients. This study has been approved by the Ethical Committee of Mashhad University of Medical Sciences (IR.MUMS.MEDICAL.REC.1401.693).

Translation

The forward-backward translation method has been applied for translating the English version questionnaire into Persian. In this way, two English language experts independently translated this English questionnaire to Persian. Formerly, a consolidated Persian version of the above two translations presented. Subsequently, two experts, who had not got the original version of the English questionnaire, translated the Persian version into English and was matched with the original version and the primary Persian version by a research team consisting of clinical experts and English language experts.

Face validity

This questionnaire was given to the relevant experts (1 neurologist, 1 pediatric neurologist, 2 otolaryngologist and 2 occupational therapist) to measure its appropriateness, grammar, vocabulary, difficulty, and transparency as a quick overall validity of the items. The experts did not mention any specific problems and this questionnaire was prepared in the same way for psychometry.

Content validity

The content validity was evaluated by 6 experts (1 neurologist, 1 pediatric neurologist, 2 otolaryngologist and 2 occupational therapist) who were asked to the degree to which each item was relevant, simple, clear, and necessary. Content validity index (CVI) to investigated validity was calculated. This index was introduced by Waltz and Bausell (20), and for the calculation of CVI, experts were requested to determine the relevancy score of every item with the following four-part spectrum: completely relevant, relevant, relatively relevant and not relevant. This index is obtained by dividing the number of experts who have chosen completely relevant or relevant options by the total number of the experts. If the index value is <0.7, the item is rejected, if it is between 0.7 and 0.79, it need to be revised, and if it is >0.79, it is acceptable. In this research, each item got score of 1. Content validity ratio (CVR) was designed by Lawshe (21). Regarding the calculation of CVR, the experts were requested to score each item on a three-point Likert scale as follow: 1-essential, 2-useful but not essential, and 3-not necessary. Based on the number of experts who evaluated the items, the minimum acceptable CVR value was determined according to the specific table. Items for which the calculated CVR value was lower than the desired value according to the total number of experts, should be better to exclude. Based on Lawshe's table with 6 experts, the CVR value of 0.99 was acceptable value for this study. The CVR formula is as follows:

$$\frac{n_e - N/2}{N/2} \qquad (1)$$

in where N= total number of experts, and n_e = the number of experts who have chosen necessary option.
In our study, CVR value of 1 was achieved for each item.

Reliability testing

It is well known that reliability can be tested by either measuring the Cronbach's alpha for internal consistency or intra-class correlation coefficient (ICC) for test-retest reliability (reproducibility). Commonly accepted values for Cronbach's alpha were defined as excellent for α>0.9 and unacceptable for α< 0.5 (22). Test-retest reliability was tested by running a questionnaire to a patient on two separate occasions without any substantial changes in his/her symptoms. A correlation coefficient of 0 indicated no reliability, whereas a value of 1 indicated excellent reliability. To test the reliability, all subjects accepted to reoccurrence for the 2nd visit after at least 2 weeks to measure ataxia by the SARA without receiving any major treatment or changes in symptoms.

Results

In this research, 11 subjects aged 48.5±18.8 years referred to the otorhinolaryngologist's office participated. 54.5% of these patients were male. Patients were visited with diagnosis of the meniere's disease (n=4, 36.4%), brain trauma (n=1, 9.1%), labyrinthitis (n=2, 18.2%), ataxia telangiectasia (n=1, 9.1%), benign ataxia

Table1. Assessment of endpoint: mean/median SARA scores at baseline and after 2 weeks of first visit.

Patients number	SARA at baseline (mean or median)	SARA after at least 2 weeks (mean or median)
1	0.13/0	0.13/0
2	0.13/0	0.13/0
3	2/0.5	2/0.5
4	0.13/0	0.13/0
5	0.25/0	0.25/0
6	0.13/0	0.13/0
7	2.63/1.5	2.63/1.5
8	0.25/0	0.25/0
9	3.75/4	3.75/4
10	0.5/0.5	0.63/1
11	0.25/0	0.25/0

(n=2, 18.2%) and sudden sensory neural hearing loss (n=1, 9.1%).

Discussion

SARA is known as a reliable and valid measurement method to detect the ataxia severity that is simple to use at the clinic (23, 10). In current research, the translation validity, face validity, content validity and reliability of the SARA Persian version have been assessed in subjects with ataxia. In order to achieve this goal, 11 patients with chronic genetic and non-genetic ataxia referred to the ear, nose and throat clinic were examined with the SARA questionnaire. More recently, disease-specific instruments for some types of ataxia comprising the FARS for Friedreich's ataxia (24), besides the Unified System Multiple Atrophy Rating Scale (25). Numerous systems have been developed for atrophy. The Abbreviated Ataxia Rating Scale (BARS) has been developed by Schmahmann et al., according to a modified form of the International Cooperative Ataxia Rating Scale (ICARS), (26). ICARS has been extensively used as a scale to assess the severity or effectiveness of cerebellar ataxia treatment. Though, its daily use in patients with ataxia is not straight forward due to the assessment items (27). SARA was recently proposed by Schmitz-Hubsch et al. This assessment tool has fewer assessment items comparing with the ICARS and consequently has the advantage of a more convenient daily assessment (11). SARA can be used in other types of ataxia including ataxic stroke (22). There are some studies that evaluated the usefulness of SARA and its comparison with other criteria (28). One study shown that SARA can be useful in patients with ataxic stroke and reported a substantial correlation with modified Barthel index, leaf balance scale and gait status. Therefore, SARA can be a beneficial tool to predict the activity of daily living dependence, gait status and developing treatment plans (23, 29). The use of imprecise terms including "mild, moderate, and severe" is abridged in SARA instrument comparing with ICARS. This suggests that SARA can allow for a more objective assessment without the subjective judgment of the evaluator (9). Though, it is necessary to mention that these tools were developed in the West and validated in English and a standardized tool for Iranians having translation and modification according to Iranian language and culture was needed. As a result, if there is a reliable Persian version of SARA, it can be widely used for all types of ataxia patients in the country in the future.
Therefore, we translated SARA into Farsi and checked its validity.

All researchers, experts and translators stated that the Farsi version is as cool to understand as the original form. The present results more highlight the usefulness of SARA for the measureable assessment of ataxia. The results presented here are very similar to those reported in previous studies conducted in ataxic stroke patients (9). As a result, in our study, SARA was confirmed with good reliability and validity in Persian language. Persian SARA can be useful clinically for

disorder assessment or rehabilitation planning.

The CVI was calculated for the investigated validity. In this research, each item scored 1, which means that the statement is acceptable. CVR value of 0.99 was an acceptable value for current study. Also, in this study, the patients were requested to check the SARA index at the beginning, and return after two weeks without receiving any special treatment for re-examination, and the results show that the scores of the patients are the same in these two examinations. 10 of our 11 patients had the same first and second visit scores, and only one patient had a score of 0.5/0.5 in the first visit and 0.63/0 in the second visit.

Conclusion

The Persian version of the SARA questionnaire can be used clinically as a reliable and valid instrument for disorder assessment and rehabilitation planning in patients with ataxia.

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Conflict of Interest

The authors confirm no conflicts of interest.

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تاریخ ..... **نوبت/ویزیت :** ..... **نام/کد بیمار** ..... **نام/کد کاردرمانگر**.....

معیار ارزیابی و طبقه بندی آتاکسی به روش پرسشنامه SARA

1. راه رفتن

از داوطلب (1) خواسته می شود تا در مسافتی ایمن و موازی با یک دیوار یک نیم دور راه برود (به دور خود بچرخد در جهت مخالف راه رفتن) و *(2) بدون کمک پشت سر هم (حرکت گردوشکن) راه برود

0- نرمال است، بدون هیچ مشکلی در راه رفتن، چرخش و پشت سر هم راه رفتن (حداکثر یک حرکت اشتباه مجاز است)

1- مشکل کمی دارد، فقط هنگام 10گام متوالی پشت سر هم راه رفتن، قابل مشاهده است

2- به طور واضح غیر طبیعی است، راه رفتن پشت سر هم بیش از 10 قدم ممکن نیست

3- بطور قابل توجهی در چرخش مشکل دارد، اما بدون کمک

4- کمک زیاد و متناوب دیوار مورد نیاز است

5- کمک بسیار زیاد یعنی حمایت دائمی با یک عصا یا حمایت اندکی از یک بازو مورد نیاز است.

6- راه رفتن بیش از 10 متر فقط با کمک زیاد (دو عصای مخصوص یا کالسکه یا شخص همراه)

7- راه رفتن کمتر از 10 متر فقط با کمک زیاد (دو عصای مخصوص یا کالسکه یا شخص همراه)

8- قادر به راه رفتن نیست، حتی در حالتی که کمک می شود

2. ایستادن

از داوطلب خواسته می شود بایستد (1) در حالت طبیعی، (2) در حالی که پاها به موازات هم قرار گرفته اند (انگشتان شست یکدیگر را لمس می کنند) و *(3) در حالتیکه پاها پشت سر هم قرار دارند {(هر دو پا روی یک خط هستند، فاصله ای بین پاشنه و انگشت وجود ندارد، (حرکت گردوشکن)}. داوطلب نباید کفش بپوشد، و باید چشم ها باز باشند. برای هر وضعیت، سه آزمایش مجاز است. بهترین آزمایش نمره داده شود.

0- نرمال است، قادر به ایستادن در وضعیت تاندم (heels to toes) برای بیش از 10 ثانیه است

1- قادر به ایستادن با پاها کنار هم و بدون تاب خوردن است، اما نه به حالت تاندم برای بیش از 10 ثانیه

2- قادر به ایستادن در حالت پاها درکنار هم برای بیش از 10 ثانیه می باشد، اما فقط با نوسان

3-قادر به ایستادن برای بیش از 10 ثانیه بدون کمک در موقعیت طبیعی است، اما با پاهای کنار هم خیر

4- قادر به ایستادن برای بیش از 10 ثانیه در موقعیت طبیعی تنها با کمک متناوب است

5- قادر به ایستادن برای بیش از 10 ثانیه در موقعیت طبیعی تنها با کمک دایمی یک بازو است

6- حتی با کمک دایم یک بازو، قادر به ایستادن برای بیش از 10 ثانیه نیست

نمره		**نمره**	

3- نشستن

از داوطلب خواسته می شود بدون کمک پا، با چشم باز و بازوهای کشیده به جلو، روی تخت معاینه بنشیند.

0- نرمال است، بدون هیچ مشکلی در نشستن برای بیش از 10 ثانیه

1- مشکل کمی دارد، یعنی نوسان متناوب

2- نوسان مداوم دارد، اما قادر به نشستن برای بیش از 10 ثانیه بدون کمک می باشد

3- فقط با کمک متناوب قادر به نشستن برای بیش از 10 ثانیه است

4- بیش از 10 ثانیه بدون کمک مداوم نمی تواند بنشیند

4- اختلال گفتار

گفتار در هنگام مکالمه عادی، ارزیابی می شود.

0- نرمال است

1- اختلال در گفتار به ذهن خطور می کند

2- گفتار مختل شده، اما درک آن آسان است

3- درک کلمات گاها"دشوار است

4- درک بسیاری از کلمات دشوار است

5- تنها کلمات منفرد قابل درک هستند

6-گفتار نامفهوم / anarthria

نمره		**نمره**	

6- تست انگشت-بینی

دارای رتبه بندی جداگانه برای هر طرف است

داوطلب به راحتی می نشیند. در صورت لزوم، کمک پا و تنه مجاز است. از داوطلب خواسته می شود تا به طور مکرر با انگشت اشاره اش از بینی خود به سمت انگشت معاینه کننده که در مقابل داوطلب و در حدود 90٪ از دسترسی داوطلب است، اشاره کند. حرکات با سرعت متوسط انجام می شود. عملکرد متوسط حرکات باتوجه به دامنه لرزش حرکتی (کینتیک ترمور)درجه بندی شود.

0- ترمور ندارد

1- ترمور با دامنه کمتر از 2 سانتی متر

2- ترمور با دامنه کمتر از 5 سانتی متر

3- ترمور با دامنه بیشتر از 5 سانتی متر

4- قادر به انجام 5 حرکت اشاره ای نیست

نمره	نمره دست راست:	نمره دست چپ:
میانگین هر دو طرف (چپ+ راست)/2		

5- تعقیب انگشت

برای هر طرف جداگانه رتبه بندی شده است.

داوطلب به راحتی می نشیند. در صورت لزوم، کمک پا و تنه مجاز است. معاینه کننده در جلوی داوطلب نشسته و 5 حرکت اشاره ناگهانی را بصورت متوالی و سریع در جهات غیر قابل پیش بینی در سطح مقطع فرونتال، در محدوده ایکه داوطلب به 50٪ از آن دسترسی یابد انجام می دهد. دامنه حرکات 30 سانتی متر و با فرکانس 1 حرکت در هر 2 ثانیه است. از داوطلب خواسته می شود که حرکات را با انگشت اشاره خود، هرچه سریعتر و دقیق تر دنبال کند. عملکرد متوسط 3 حرکت آخر نمره داده شود.

0- عدم وجود دیسمتری

1- دیسمتری، under/ overshooting target کمتر از 5 سانتی متر

2- دیسمتری، under/ overshooting target کمتر از 15 سانتی متر

3- دیسمتری، under/ overshooting target بیشتر از 15 سانتی متر

4- انجام 5 حرکت اشاره ای امکان پذیر نیست

نمره	نمره دست راست:	نمره دست چپ:
میانگین هر دو طرف (چپ+ راست)/2		

8- لغزش پاشنه پا

دارای رتبه بندی جداگانه برای هر طرف است.

داوطلب روی تخت معاینه دراز کشیده، بدون اینکه پاهایش را ببیند. از داوطلب خواسته می شود یک پا را بلند کند، پاشنه را روی زانوی مقابل قرار دهد، در امتداد ساق پا تا مچ پا به پایین بلغزاند و پا را روی تخت معاینه قرار دهد. این کار، 3 بار انجام شود. حرکات لغزشی به پایین باید در عرض 1 ثانیه انجام گیرد. اگر داوطلب پا را در هر سه آزمایش، بدون تماس با ساق پا به سمت پایین کشید، نمره 4 می گیرد.

0- نرمال است

1- کمی غیر طبیعی است، تماس با ساق پا حفظ شده است

2- به طور واضح غیر طبیعی است، تماس با ساق در طی 3 سیکل، تا 3 بار از بین می رود

3- بشدت غیر طبیعی است در طی 3 سیکل، 4 بار یا بیشتر تماس با ساق از بین می رود

4- انجام این کار، امکان پذیر نیست

نمره	نمره پای راست:	نمره پای چپ:
میانگین هر دو طرف (چپ+ راست)/2		

7- حرکات دست متناوب سریع

دارای رتبه بندی جداگانه برای هر طرف است.

داوطلب به راحتی می نشیند. در صورت لزوم ، کمک پا و تنه مجاز است.. از داوطلب خواسته می شود که 10 دوره پشت سرهم پروناسیون وسوپینیشن را درحد ممکن تکرار کند (به طور متناوب دستش را به حالت پرو نیشن وسپس سوپینیشن بچرخاند و این حرکت را ده بار پشت سر هم تکرار کند). حرکت توسط معاینه کننده با سرعت تقریبی10 چرخه در 7 ثانیه نشان داده می شود. زمان دقیق اجرای حرکات باید مورد نظر قرار گیرد.

0- نرمال است، بدون بی نظمی (کمتر از 10 ثانیه انجام می شود)

1- کمی نامنظم (کمتر از 10 ثانیه انجام می شود)

2-بطور مشخص نامنظم است، یعنی تشخیص حرکات منفرد و وقفه های مربوطه دشوار است اما در کمتر از 10 ثانیه انجام می شود

3- حرکات بسیار نامنظم است، تشخیص حرکات منفرد و وقفه های مربوطه دشوار است و در بیشتر از 10 ثانیه انجام می شود

4- انجام 10 سیکل امکان پذیر نیست

نمره	نمره دست راست:	نمره دست چپ:
میانگین هر دو طرف (چپ+ راست)/2		

نمره کل:

نمره کل، حاصل مجموع خانه های خاکستری رنگ است. *heels to toes