

Validation and Cross-Cultural Adaptation of Arabic Version of the Rhinosinusitis Disability Index (ar-RSDI)

Original Article

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ABSTRACT

Objective: Arabic is ranked fourth in the most spoken languages after Chinese, English, and Spanish. Our goal was to assess the validity of Arabic version of the Rhinosinusitis Disability index (ar-RSDI) which is rhinosinusitis-specific instrument to assess quality of life (QoL) of affected patients.

Patients and Methods: Our study included 302 chronic rhinosinusitis (CRS) patients and 150 healthy controls. The RSDI English version was translated to Arabic and pretest trial was performed. We assessed the internal consistency using Cronbach's alpha test. Correlation between item scores and total score of the ar-RSDI, and test-retest validity were evaluated using Spearman's ranks correlation coefficient. The ar-RSDI ability to discriminate between patients and controls, and sensitivity to changes after management of CRS were assessed by Mann-Whitney, and Wilcoxon signed ranks tests, respectively.

Results: The ar-RSDI showed high internal consistency. Strong correlation between each item and subscale scores with the total ar-RSDI scores was detected. The test-retest validity of the ar-RSDI revealed a significant association between the total ar-RSDI and its subscale scores on the first and second readings. The ar-RSDI was able to distinguish between patients and controls where the differences between their mean values were all significant. There were significant differences in the ar-RSDI total and subscale scores for the patients' group before and after the intervention, which reflect the ar-RSDI ability to detect the sensitivity to changes.

Conclusion: The ar-RSDI is a simple and reliable tool with good internal consistency, reproducibility, and validity for the QoL assessment in Arabic-speaking CRS patients in clinical practice.

Key Words: Quality of life, questionnaire, rhinosinusitis disability index, sinusitis, validation.

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INTRODUCTION

Rhinosinusitis is a global health problem that represents an increasingly common cause of patient visits either to primary care or specialized rhinology services. Chronic rhinosinusitis has a daily influence on a patient's emotional and social well-being that often outweighs the disease's physical "local" effect. With such a compromise of the major quality of life (QoL) aspects, the condition can mount up to "a disability" of different degrees that should be considered either with the initial evaluation or during the assessment of the effectiveness of the treatment offered to patients.^[1-3]

Nasal endoscopy and computed tomography of the nose and paranasal sinuses have been routinely used for the evaluation of patients with nose and sinus diseases before and after the intervention. However, it has been

reported that physician-based assessment data are not always consistent with the severity of symptoms, or the degree of improvement perceived by patients after treatment. As patient satisfaction remains the ultimate goal of the health service, a treatment that would result in improvement according to physician-reported findings without equivalent patient-perceived satisfaction can't be considered a success.

Patient-based assessment of the management of nose and sinus diseases has been adopted by the development and validation of patient-reported outcomes instruments in the form of questionnaires to be completed by the patient before and after treatment. For nose and sinus diseases, questionnaires focusing on specific "local" symptoms have been criticized for omitting the well-established effect of the condition on the general health, emotional and mental aspects of the QoL.^[4] Also, global QoL instruments were

found limited by the lack of sensitivity to subtle changes in the health status induced by the relevant condition, being confounded by other comorbidities, and failure to specify the most disturbing symptoms of the condition.^[5,6]

Disease-specific QoL instruments were proposed as tools designed to measure the patient's perception of both disease-specific symptoms and the associated QoL changes. In pursuit of a simple, reliable, and rhinosinusitis-specific QOL measurement tool, many instruments were developed and implemented in multiple studies.

Rhinosinusitis Disability Index (RSDI) is a rhinosinusitis-specific, self-reported outcomes measurement tool developed and validated by Benninger and Senior in 1997.^[7] Since its publication, RSDI has been utilized by many authors to measure the patient-perceived effect of different treatment modalities for rhinosinusitis. The final version of RSDI is composed of 30 questions designed to cover three main domains of the QOL that may be influenced by CRS, the emotional, functional, and physical subscales. Every question is related to a specific symptom of CRS and a patient is asked to answer whether such a symptom is experienced on a scale from 0 to 4 where 0 means (never) and 4 means (always).

To be appropriate for the Egyptian population, RSDI should be Arabic-translated and cross-culturally adapted to a form that demonstrates a good performance during a validation process comparable to the generic questionnaire. The objective of this study is to test an Arabic form of RSDI (ar-RSDI) for validity criteria in comparison to the original RSDI before being widely applicable to Arabic-speaking populations.

PATIENTS AND METHODS:

This is a comparative cross-sectional study for validation of the Arabic-translated version of RSDI (ar-RSDI) that was performed following the principles described for this purpose when dealing with patient-related outcome measures.^[8]

This study was conducted in the Department of Otolaryngology, Tanta University, Egypt, between August 2018 to February 2022. The study protocol was designed in alignment with the Declaration of Helsinki and approved by the institutional ethical committee of Tanta University. We received informed consent from all the participants in our study.

2.1 Sample Size:

The sample size and power analysis were calculated using Epi-Info software statistical package created by the World Health Organization and Center for Disease Control and Prevention, Atlanta, Georgia, USA version 2002.

At a 95% confidence level, with an expected accuracy of diagnosis at 75% and a margin of error of 5 %, a sample of size 288 was needed. However, we opted to recruit 320 patients to compensate for missed information, and to improve the quality of data of the study data.

2.2 Participants:

The participants were recruited from the rhinology clinic and fulfilled the diagnostic criteria of chronic rhinosinusitis according to EPOS 2020.^[1] Patients included were 18 years or older and can independently complete the questionnaire. Exclusion criteria were illiteracy, pregnancy, sinonasal tumors, history of radiotherapy to the head and neck region, craniofacial abnormalities, nasal valve collapse, external nasal traumatic deformities, and history of chronic diseases. We included 150 controls that were volunteer medical staff, medical students, and visitors to the department who agreed to participate in our study and had no history or records of sinonasal diseases, sinonasal surgeries, upper respiratory tract infections, or allergic reactions three weeks before completing the questionnaire.

2.3 Generation of ar-RSDI:

The English Version of RSDI was translated into Arabic by a professional translator who is not medical personnel. The authors whose Arabic is the mother language reviewed the translated version. The authors executed minor modifications to ensure that the translation is palatable to Arabic-speaking regular individuals and composed of simple terms used daily in conversations with patients with sinus conditions with no vague or ambiguous terms that are difficult to comprehend or may be perceived improperly by patients in the literal translation. The translated version was then translated back to English by an independent bilingual English/Arabic speaker who was not aware of the original RSDI or involved in the initial translation. The Authors reviewed the back-translated version for any discrepancies in comparison to the original RSDI. Minor refinements of the translated version were proposed by the authors to maintain the desired conceptual content of the Arabic version. After these modifications, the back-translation was performed again by another professional translator to ensure re-test alignment with the original RSDI. The final Arabic version was pre-tested (pilot study) as ten patients in the outpatients' clinic were offered a printed copy and were allowed to fill out the questionnaire form independently in the presence of one of the senior authors who made sure that each patient got the right meaning of the words specific for the disease symptoms in the questionnaire and whether there was a more expressive alternative for words that may be peculiar or difficult to understand by a regular individual. The Arabic version of RSDI is demonstrated in (Figure 1).

مؤشر القصور الخاص بالأنف والجيوب الأنفية
هذه الجمل تعبر عما تشعر به أو تواجهه من مصاعب بسبب مرض الجيوب الأنفية لديك.
ضع علامة (X) الموضع الذي يعبر عن حالتك بدقة

تكرار الحدث					التصريح
دائما	معظم الوقت	أحيانا	نادرا	أبدا	
					1. أشعر بالتوتر في العلاقات مع الأصدقاء والعائلة بسبب مشكلتي.
					2. أشعر بالارتباك بسبب مشكلتي.
					3. أجد صعوبة في الانتباه بسبب مشكلتي.
					4. أتجنب التواجد حول الناس بسبب مشكلتي.
					5. أشعر بالغضب بشكل متكرر بسبب مشكلتي.
					6. لا أحب الاختلاط بسبب مشكلتي.
					7. كثيرا ما أشعر بالتوتر بسبب مشكلتي.
					8. كثيرا ما أشعر بالضيق ويسهل إثارة غضبي بسبب مشكلتي.
					9. أنا مكتئب بسبب مشكلتي.
					10. تضع مشكلتي ضغوطا على علاقاتي بأفراد عائلتي أو أصدقائي.
					11. أشعر بأنني معاق بسبب مشكلتي.
					12. أشعر أنني مقيد في أداء أنشطتي اليومية الروتينية بسبب مشكلتي.
					13. أقوم بتقييد أنشطتي الترفيهية بسبب مشكلتي.
					14. أشعر بالإحباط بسبب مشكلتي.
					15. أشعر بالإرهاق بسبب مشكلتي.
					16. أتجنب السفر بسبب مشكلتي.
					17. أفقد العمل أو الأنشطة الاجتماعية بسبب مشكلتي.
					18. تتأثر رويتي للعالم الخارجي بمشكلتي.
					19. أجد صعوبة في تركيز انتباهي بعيدا عن مشكلتي وعلى أشياء أخرى بسبب مشكلتي.
					20. ألم الضغط في وجهي يجعل من الصعب على التركيز.
					21. الألم في عيني يجعل من الصعب على القراءة.
					22. أجد صعوبة في الانحناء لرفع الأشياء بسبب ضغط الوجه.
					23. بسبب مشكلتي أجد صعوبة في العمل الشاق في الفناء والأعمال المنزلية.
					24. الإجهاد يزيد أو يفاقم مشكلتي.
					25. أنا منزعج من سيلان أنفي المزمّن.
					26. لا طعم جيد للطعام بسبب تغير الرائحة.
					27. الاستنشاق المتكرر يزعج أصدقائي وعائلتي.
					28. بسبب مشكلتي لا أنام جيدا.
					29. أجد صعوبة في بذل مجهود بسبب انسداد أنفي.
					30. يتأثر نشاطي الجنسي بمشكلتي.

Fig. 1: The Arabic version of the Rhino-sinusitis Disability Index "ar-RSDI"

2.4 Validation of ar-RSDI:

Patients who agreed were asked to complete the ar-RSDI questionnaire again two days after the first visit with no change in the treatment or health status in between for test re-test reliability that evaluated the reproducibility of the ar-RSDI questionnaire.

Patients and controls were asked to independently complete the ar-RSDI questionnaire. The ar-RSDI questionnaire and its subscale scores of the CRS patients were compared to those of the control group to determine the construct validity of the questionnaire.

Patients who went through endoscopic sinus surgery or continued medical treatment determined by clinicians

according to EPOS 2020^[1] were invited to re-take the ar-RSDI questionnaire before the intervention and at least three months after to evaluate the responsiveness of the questionnaire.

2.5 Statistical analysis

The collected data were organized, tabulated, and statistically analyzed using SPSS version 19 (Statistical Package for Social Studies) created by IBM, Illinois, Chicago, USA. We calculated the range mean and standard deviations for numerical values. We tested the internal consistency of the ar-RSDI questionnaire by using Cronbach's alpha test. Spearman's ranks correlation coefficient (rho) was used for testing the correlation between the item scores and the total score of the ar-RSDI.

The validity of ar-RSDI as a measurement tool for CRS was tested by calculating the differences between the mean values of ar-RSDI scores and its subscale scores of the patients and controls using the Mann-Whitney test. The ar-RSDI sensitivity to change was evaluated by testing the differences between the mean values of the total ar RSDI score and its subscale scores before and after intervention by the Wilcoxon signed ranks test.

RESULTS:

Three hundred and twenty CRS patients were initially enrolled in our study, we excluded patients who did not fill out the ar-RSDI after the management of CRS. Eighteen patients were lost during the follow up-period and they failed to complete the questionnaire after the planned intervention. Eventually, 302 patients completed our study, 144 males, and 158 females with ages ranging from 18 to 76 years (44.95 ± 17.16). The control group included 150 individuals (92 males, and 58 females) with an age range of 22 to 63 years (44.08 ± 17.10). No statistically significant difference as regards age and sex between the patient and control groups was identified.

Within the CRS patients' group, the test of internal consistency showed high reliability of the ar-RSDI questionnaire where Cronbach's alpha was 0.978. We found a strong correlation between each item's scores and the total ar-RSDI scores and between each subscale's scores and total ar-RSDI scores. The Spearman's rank correlation coefficient range was 0.708-0.964 with a highly significant association ($p < 0.001$), as shown in (Table 1).

Of the patient group, 165 patients retook the ar-RSDI for reproducibility testing. The test re-test validity of ar-RSDI showed a significantly high association ($p < 0.001$) between the first and second reading of the total ar-RSDI and its subscale scores, as demonstrated in (Table 2).

The ar-RSDI was found to successfully discriminate between patients and controls as the mean values for the patients were higher than controls both for the total scores and each subscale scores, the total ar-RSDI score of the control group ranged from 0 to 96 (14.03 ± 21.21) while for the patient group, the range was from 4 to 102 (51.31 ± 21.89). The differences between patients' and controls' mean values were all highly significant ($p < 0.001$), as demonstrated in (Table 3).

One hundred and fifteen patients had endoscopic sinus surgery according to the type and degree of the pathology of the CRS, while 187 patients received systemic and local medications that were adjusted to each patient's pathology. All our patients were assessed using the ar-RSDI questionnaire before, and at least three months after surgery or medical treatment. Regarding sensitivity to change, the ar-RSDI scores demonstrated a statistically

significant difference when comparing its total and different subscale scores for the patients' group before and after the intervention ($p < 0.001$), as shown in (Table 4).

Table 1: Correlation between the item and subscale scores with the total score of the Arabic version of the Rhino-sinusitis Disability Index (ar-RSDI)

ar-RSDI items	Total score	
	rho	p-value
Item 1	0.823	<0.001
Item 2	0.788	<0.001
Item 3	0.862	<0.001
Item 4	0.838	<0.001
Item 5	0.777	<0.001
Item 6	0.828	<0.001
Item 7	0.841	<0.001
Item 8	0.794	<0.001
Item 9	0.802	<0.001
Item 10	0.787	<0.001
Item 11	0.814	<0.001
Item 12	0.849	<0.001
Item 13	0.827	<0.001
Item 14	0.824	<0.001
Item 15	0.820	<0.001
Item 16	0.790	<0.001
Item 17	0.807	<0.001
Item 18	0.764	<0.001
Item 19	0.813	<0.001
Item 20	0.746	<0.001
Item 21	0.733	<0.001
Item 22	0.697	<0.001
Item 23	0.791	<0.001
Item 24	0.749	<0.001
Item 25	0.616	<0.001
Item 26	0.721	<0.001
Item 27	0.708	<0.001
Item 28	0.776	<0.001
Item 29	0.790	<0.001
Item 30	0.742	<0.001
Emotional subscale	0.937	<0.001
Functional subscale	0.964	<0.001
Physical subscale	0.927	<0.001

Table 2: Test-retest reliability of the Arabic version of the Rhino-sinusitis Disability Index (ar-RSDI)

ar-RSDI subscales	rho	<i>p</i> -value
Emotional subscale	0.808	<0.001
Functional subscale	0.770	<0.001
Physical subscale	0.727	<0.001
Total score	0.862	<0.001

Table 3: Comparison of the mean total score of the Arabic version of the Rhino-sinusitis Disability Index (ar-RSDI) and its subscales scores between the patient and control groups

Ar-RSDI subscales	Control group (n=150)		Patient group (n=302)		Z	<i>p</i> -value
	Range	Mean±SD	Range	Mean±SD		
Emotional subscale	0-32	4.15±7.09	0-38	15.67±9.00	13.137	<0.001
Functional subscale	0-35	5.20±7.59	0-38	18.11±8.71	14.620	<0.001
Physical subscale	0-38	5.21±7.88	2-40	19.46±7.43	14.860	<0.001
Total score	0-96	14.03±21.21	4-102	51.31±21.89	14.916	<0.001

Table 4: Comparison of the mean total score of the Arabic version of the Rhino-sinusitis Disability Index (ar-RSDI) and its subscales scores before and after management of CRS in patient group

ar-RSDI subscales	Before management of CRS		After management of CRS		Z	<i>p</i> -value
	Range	Mean±SD	Range	Mean±SD		
Emotional subscale	0-38	15.67±9.00	0-24	7.69±5.33	14.480	<0.001
Functional subscale	0-38	18.11±8.71	0-23	8.02±4.56	14.907	<0.001
Physical subscale	2-40	19.46±7.43	0-23	8.17±4.44	15.044	<0.001
Total score	4-102	51.31±21.89	0-59	23.03±11.82	15.061	<0.001

DISCUSSION

There is a growing interest in using patient-based assessment tools for the measurement of the degree of the disability inflicted by a disease. These tools are utilized to determine both the need for intervention and its effectiveness.^[7, 9] This is even more valued in diseases with a high degree of subjectivity of manifestations like nose and sinus diseases.

The Rhino-sinusitis Disability Index (RSDI) is a unique patient-based assessment tool that has been developed through a robust process of validation and has been deployed in many studies as a measurement tool of the patient-perceived impact of nose and sinus conditions on the QoL.^[10-13] The RSDI is a 30 items questionnaire that covers the three main domains (emotional, physical, and functional) of the QoL pertinently related to nose and sinus disease. This treats the shortcomings of global QoL tools and others with disease-specific assessments with no QoL evaluation. While some tools focus on particular symptoms like those of allergic rhinitis^[14] or CRS^[15], RSDI addresses a wide range of nose and sinus symptoms.

Quintanilla-Dieck *et al.*^[16] also conducted a systematic review of the CRS-specific QoL questionnaires and found that the SNOT-20 and its

derivatives, RSDI, and chronic sinusitis survey were the most utilized CRS-specific QoL instrument.

Most of the health status questionnaires were developed in English-speaking countries.^[17] To be reliably used for a non-English speaking population, a questionnaire in the English language has to, not only be merely translated into the required language to be readable by the target population but also be culturally adapted to maintain the intellectual content of each item and to establish conceptual equivalence between an original and translated version of the questionnaire.^[18] Also, the translated version should be tested for internal consistency, validity, test retest reliability, and sensitivity to changes in the condition.^[19] We noticed that the RSDI has been adapted and validated for use with Nigerian populations.^[20]

Cross-cultural adaption of a validated measurement instrument is less expensive and less time-consuming than developing a new QoL assessment tool. Furthermore, it enables the comparison of data from research investigating CRS burden and treatment across cultures using similar tools, as well as the conduct of multi-center and multi-national investigations.^[21]

Arabic is ranked fourth in the most spoken languages after Chinese, English, and Spanish, with

385 million speakers around the world, and is one of the six official languages of the United Nations.^[22] The objective of this study was to translate, and culturally adapt RSDI into Arabic and to test the Arabic version of RSDI (ar-RSDI) through a validation methodological process. Arabic version of RSDI is intended to enhance Egyptian patients' knowledge about the impact of their conditions on the QOL, help clinicians with disease assessment and decision-making, and allow multinational, multicultural outcomes research using the same questionnaire. Translation and cross-cultural adaptation of RSDI were conducted in a step-wise standardized process.^[23]

The way the items are related to each other inside the same questionnaire is referred to as internal consistency^[24] which is a precise method for verifying the questionnaire's reliability. The Cronbach's alpha test in our study was high, which reflects a very good internal consistency of the ar-RSDI. Our result was similar to that reported by the original^[7] and the Nigerian^[20] versions of the RSDI, where the Cronbach's alpha test for the total score was 0.95 and 0.936 respectively. The Spearman's rank correlation coefficient detected a statistically significant correlation between each item's scores and the total ar-RSDI scores and between each subscale's scores and total ar-RSDI scores.

The test-retest reliability measures the questionnaire's consistency over time, it refers to the degree that the questionnaire yields consistent results over time.^[25] In this study, Spearman's rank correlation showed a significantly high association between the first and second reading of the total ar-RSDI as well as its subscale scores. Benninger and Senior^[7], utilizing Spearman's rank correlation, detected a high test-retest correlation in the original RSDI, where 26 questions had a correlation of ≥ 0.69 and the other questions correlated ≥ 0.52 .

The capacity of the questionnaire to distinguish between the patients and healthy people is known as discriminatory validity.^[26] The Mann-Whitney test showed a statistically significant difference in the total and each item mean scores of the ar-RSDI questionnaire between the CRS patients and the control groups, declaring the ability of the ar-RSDI questionnaire to discriminate between the CRS patients and healthy people.

Sensitivity to change is the ability of the questionnaire to detect clinical changes over time.^[26] In our study, the non-parametric Wilcoxon signed ranks test demonstrated a statistically significant difference in the total and each item's mean scores of the ar-RSDI questionnaire before and after the management of CRS.

In a study by Aldrees T *et al.*^[27] that included 75 patients with chronic rhinosinusitis and 49 healthy control subjects, both the Rhinosinusitis Disability Index (RSDI) and the Chronic Sinusitis Survey (CSS) questionnaires had been adapted and validated for use in Saudi Arabian populations, while our study was focused only on the Arabic validation of the RSDI questionnaire. They have translated the English version of the RSDI to the formal Arabic language, while our translation has been more refined for Egyptian dialect-speaking patients. Both Aldrees T. *et al.*^[27] study and our study have concluded high reliability and validity of the different Arabic translations of the RSDI, this reflects its high level of reproducibility in two different Arabic dialects, paving the way for its widespread use in other Arabic populations in clinical practice. We have also increased the sample size to include 302 patients with chronic rhinosinusitis and 150 healthy controls to boost the study's power and ensure the validity of the results.

Our study supports the reliability and validity of the ar-RSDI questionnaire for evaluating the quality of life in Arabic adult patients with CRS. The application of the ar-RSDI in everyday clinical practice and epidemiological and outcome research is then suggested, making it easier to compare the results of different investigations.

CONCLUSION

The Arabic version of the RSDI questionnaire is an accessible and reliable instrument, with proper internal consistency, reproducibility, and validity to be used in clinical practice to evaluate the quality of life in Arabic-speaking CRS patients.

CONFLICT OF INTEREST

There are no conflicts of interest.

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