Cultural adaptation of the Arabic version of the Infants' Dermatitis Quality of Life Index

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ABSTRACT

الأهداف : إنشاء والتحقق من صحة النسخة العربية من مؤشر جودة الحياة في الحساسية الجلدية (الإكزيما) لدى الأطفال وتقييم موثوقيتها ومدى صحتها لدى الأطفال السعوديين المصابين بحساسية الجلد التأتبية بمختلف درجاته من الشدة .

الطريقة: اشتملت هذه الدراسة على تقييم النسخة العربية المطورة حديثاً من مؤشر جودة الحياة في الحساسية الجلدية في الأطفال . وقد أجريت هذه الدراسة في عيادات الأمراض الجلدية والمستشفيات التابعة لجامعة القصيم، بريدة، المملكة العربية السعودية خلال الفترة من يونيو 2011م ويونيو 2012م . وقد تم تصميم هذة الدراسة لإنشاء نسخة عربية عامة من مؤشر جودة الحياة في الحساسية الجلدية لدى الأطفال باستخدام نظام الترجمة والترجمة العكسية بواسطة علماء خبراء في اللغة العربية و الإنجليزية واتبعت بالتحليل التقييمي للتحقق و الموثوقية . وهذه النسخة المطورة تحتوي علي استبيان مكون من 10 عناصرلتقييم أثر حساسية الجلد علي مختلف جوانب الحياة وقد تم تطبيقه علي 370 أسرة لديهم أطفال مصابين بحساسية الجلد و120 أسرة مراقبة لديهم أطفال سليمين . تم تقييم شدة المرض بواسطة مؤشر سكوراد .

النتائج: كانت نقاط مؤشر جودة الحياة في الحساسية الجلدية لدى الأطفال ذات مغزى معنوي عند الاطفال المصابين بحساسية الجلد التأتبية مقارنة مع المجموعة المقارنة (p=0.00) . كما كان مجموع مؤشر جودة الحياة في الحساسية الجلدية لدى الأطفال في حساسية الجلد التأتبية الشديدة مقارنة مع الخفيفة أو متوسطة الشدة وايضاً كانت نقاط ذات مؤشر أعلى (p=0.00) . كان معامل الموثوقية (كرونباخ ألفا) يساوي 0.87 . وهو معدل عال نسبياً وكانت مدي علاقة (ارتباط البنود بعضها بالبعض وارتباطها بالمجموع الكلي للنقاط مع شدة المرض) من متوسطة إلى عالية (≥0.6) وكانت ذات دلالة إحصائية (p=0.00) .

خاتمة: أثبت النسخة العربية من مؤشر جودة الحياة في الحساسية الجلدية لدى الأطفال أنها أداة ممتازة لقياس تأثير المرض على العائلات العربية اللذين لديهم أطفال يعانون من حساسية الجلد التأتبية .

Objectives: To create and validate an Arabic version of the Infants' Dermatitis Quality of Life Index (IDQoL), and to evaluate its reliability and validity in Saudi infants with atopic dermatitis (AD) of various grades of severity.

Methods: This is a study involving a validation of a newly developed Arabic version of the IDQol. The research was conducted at the dermatology clinics and hospitals affiliated to Qassim University, Buraidah, Kingdom of Saudi Arabia between June 2011 and June 2012. This Arabic generic version of the IDQoL was developed using a translation/back-translation system by 2 bilingual Arabic and English scholars followed by validation and reliability assessment analysis. The developed IDQoL contains a 10-item questionnaire that assesses the impact of AD on different aspects of life. The IDQoL was applied to 370 families with infants with AD, and to 120 control families with infants without AD. The severity of AD was evaluated by the SCORAD Index.

Results: This newly developed IDQoL scale showed higher scores among AD infants compared with their respective controls (p=0.00), and the scores were also higher in the severe AD compared to moderate or mild AD groups (p=0.00). The Cronbach's alpha was found to be 0.87. The item-item, item-total score, or item-severity correlations ranged from moderate to high (≥0.6), and were statistically significant (p=0.00).

Conclusion: This novel Arabic version of the IDQoL proved to be an excellent tool to measure the disease impact in Arabic families with infants with AD.

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Atopic dermatitis (AD) is also known as atopic eczema is the most common chronic inflammatory skin disease in children worldwide including Saudi Arabia, causing psychological, social, and functional disability in patients and their families.[1-4] The frequency of this disease is reported to be increasing gradually.[5-7] It occurs during childhood, affecting 10-20% of children in Europe, and 17% of children in the United States.[8] Atopic dermatitis pathogenesis seems to be complex, involving genetic, environmental, and psychological, in addition to immunologic factors.[9,10] The diagnosis of AD is based on clinical findings,[11] and disease' severity may be evaluated by different established scores such as: Rajka-Langeland; SCORing Atopic Dermatitis (SCORAD); and Eczema Area Severity Index (EASI).[12-15] Three clinical phases of AD have been described: infantile (0-2 years); childhood (2-12 years); and adolescence or adult.[16] Physicians working with children affected by AD are well aware of the misery it causes to children and their parents. Especially when severe, AD can be extremely disabling, causing major psychological problems, and in the case of a young child, can be overwhelming for the entire family.[17,18] People with AD tend to report lower health-related quality of life (HRQoL) and greater psychological distress than the general population, and those with some other medical conditions.[2,19] Pruritus can affect both sleep and mood with significant morbidity in affected patients. Children with AD often have behavioral problems, such as increased dependency, fearfulness, and sleep difficulties.[2] The Dermatitis Family Impact (DFI) questionnaire, the Infants' Dermatitis Quality of Life Index (IDQoL), and the Parents' Index of Quality of Life in Atopic Dermatitis (PIQoL-AD) are questionnaires, for which reliability and validity have been examined.[3,19-21] The 10-item DFI and IDQoL, which have been useful in clinical research, measure primarily symptoms and functioning, and assess emotional effects of AD with a few items. The IDQoL was developed in 2001,[22] as a disease-specific measure. It is a one-page questionnaire, which measures the impact of AD on the infant's quality of life. The aim of this study was to create and validate an Arabic version of IDQoL, and to evaluate its reliability and validity in Saudi children with AD of various grades of severity.

Methods. This is a study involving a validation of a newly developed Arabic version of IDQol. This study was conducted at the dermatology clinics and hospitals affiliated to Qassim University, Buraidah, Kingdom of Saudi Arabia between June 2011 and June 2012. The study was carried out in accordance with the Code of Ethics of the World Medical Association (Declaration of Helsinki), and was approved by the ethical review committee of the College of Medicine. Informed consent was obtained from the parents of all participants. Permission was also obtained from the University Of Wales College Of Medicine, Cardiff, United Kingdom for developing the Arabic version of IDQoL. The Arabic generic version of the IDQoL was developed first by the translation phase following the international guidelines provided by the original developer of the IDQol for the translation/back-translation process. In brief, 2 trained bilingual Arabic scholars independently translated the original English IDQoL into Arabic. Then, the 2 translators agreed together on one final Arabic translation. The final translation was translated back to English (back translation) by 2 independent bilingual English translators. The 2 "back translated" questionnaires were sent to the original author for approval. After some modifications, the final approval of the Arabic translation was received. For further testing of the construct validity of the Arabic version of the scale, it was applied on 50 random families as a pilot study in settings attended by the author to assure full comprehensibility of the scale items to the general Saudi population.

Patients and data collection. The newly developed Arabic version of IDQoL was tested for validity on 370 families having infants with AD compared to 120 control families having infants - free from any dermatologic diseases including AD. Inclusion criteria of the patients were based on the clinical diagnosis of AD by consultant dermatologists to focus on infants affected only by AD, and exclude those with other medical problems. The IDQoL was administered to all participating families as part of their routine clinical review prior to consultation. The diagnosis of AD was carried out using the UK Working Party's modification of Hannifin and Rajka criteria.[23] The socioeconomic standard was assessed arbitrarily by the interviewer utilizing relevant data including the family income, housing and premises (rented or owned privately, or with other family members), parental jobs and education, in addition to the general wealth of the family. The questionnaire consisted of 10 questions regarding the child's itching-scratching, mood, time of sleep, playtime and family activities, meal times, treatments, dressing, and bathing of the child over the last week. Each question has 4 responses: not at all = 0; a little = 1; a lot = 2; and very much = 3, except for the second item that is coded from 0-4. The overall summary score aggregates the score of each item that sums up to ranges between 0 (the best score) and 31 (the worst score). This

implies that the higher the score, the poorer the QoL for the child with AD.[20]

Assessment of disease severity. The severity of AD was evaluated using the SCORAD Index, a clinical tool that assessed the extent and intensity of AD. The SCORAD index consists of: (i) the interpretation of the extent of the disorder according to the rule of 9's (20% of the score); (ii) the measurement of disease intensity by 6 items including erythema, edema/papules, effect of scratching, oozing/crust formation, lichenification, and dryness, each graded on a scale of 0-3 (60% of the score); and (iii) assessment of subjective symptoms, for example, itching or sleeplessness (20% of the score). The most representative lesion was used for scoring purposes rather than the most severe or the mildest lesion.[24] In another question, severity is partially assessed, along with the physical findings through parents' evaluation of their children's disease as being of no severity (0); mild (1); moderate (2); severe (3); and extremely severe (4).

Statistical analysis. Data were analyzed using Statistical Package for Social Sciences software program version 16 (SPSS Inc, Chicago, IL, USA). Scale analysis was used to test reliability and internal consistency through calculation of Cronbach's alpha coefficient for the whole sample, and for each severity group. In addition, testing for aberrant items was performed through a correlation matrix for the item-item, item-total score in addition to item-severity parameters. The validity was assessed using independent Student's t-test comparing the mean scores for each item and mean total scores in different severity groups with their respective controls. Results were expressed as mean ± standard deviation (SD) unless stated otherwise.

Results. The study comprised of 167 (45.1%) male and 203 (54.9%) female infants affected with AD. Their mean ± SD age was 8.8 ± 9.9 months, with median age of 5 months. Approximately 42.7% of the surveyed parents received a university education, and 39.2% were from a moderate socio-economic stratum of society. According to the categories of the SCORAD index, 53.5% (198) of children showed mild AD (SCORAD <20), moderate AD was noticed in 31.6% (117) of infants (SCORAD 20-40), while 14.9% (55) of studied infants showed severe AD (SCORAD >40). The control group of infants with no complaints of any dermatologic disorders comprised 58 (48.3%) males and 62 (51.7%) females with a mean ± SD age of 9.0 ± 8.0 months, and a median age of 5.5 months. A large portion of the control group parents (50.8%) were university educated, and 58.3% of them belonged to a moderate socioeconomic stratum of society. A positive family history of AD was obtained from approximately 16.2% of parents of affected cases, and from 10% of control parents. Other allergic diseases like bronchial asthma and allergic rhinitis were higher among families with affected children. Cases showed no statistical significant differences compared to controls regarding their mean age, male/female ratio and other parameters related to parental education and positive family history of allergic disorders (p>0.05). However, cases showed significantly higher frequency of a lower socioeconomic class (19.5% versus 2.5%, p=0.00), and lower frequency of positive parental consanguinity compared to controls (26.5% versus 48.3%, p=0.00) (**Table 1**). The item-item, item-total, and item severity correlations were statistically significant (p=0.00) with a moderate level mostly approximately 0.60. In addition, the calculated Cronbach's alpha coefficient based on standardized items was 0.87; this might confirm the good reliability and internal consistency of the scale (**Table 2**). The mean ± SD (14.0 ± 2.91) of the total score of cases showed a highly significant difference compared to controls (3.2 ± 1.5) (p<0.005). Moreover, a statistically significant rise in IDQoL scale scores was

Table 1 - Demographic characteristics of the population included in a study conducted at the dermatology clinics and hospitals affiliated to Qassim University, Buraidah, Kingdom of Saudi Arabia.

Variables	Cases (n=370)		Controls (n=120)		*P*-values
Age, months					0.84
Mean ± SD	8.8 ± 9.9		9.0 ± 8.0		
Median	5.0		5.5		
Gender	n (%)				0.61
Male	167	(45.1)	58	(48.3)	
Female	203	(54.9)	62	(51.7)	
Parents education					0.11
Primary	56	(15.1)	10	(8.3)	
High school	156	(42.2)	49	(40.8)	
University	158	(42.7)	61	(50.8)	
Socioeconomic standards					0.000*
Low	72	(19.5)	3	(2.5)	
Moderate	145	(39.2)	70	(58.3)	
High	153	(41.3)	47	(39.2)	
Consanguinity					0.000*
Yes	98	(26.5)	58	(48.3)	
No	272	(73.5)	62	(51.7)	
Family history					0.0003*
AD and other atopies†	106	(62.0)	18	(31.0)	
AD only	65	(38.0)	40	(69.0)	
Other atopies only	98	(49.2)	25	(40.3)	
Negative	101	(50.8)	37	(59.7)	

SD - standard deviation, AD - atopic dermatitis, *significant, †other atopies include allergic rhinitis and bronchial asthma

Table 2 - Reliability statistics of the study population in terms of Infants' Dermatitis Quality of Life Index questionnaire items.

Variables	Inter-item correlation matrix	Corrected item-total correlation	Item severity correlation	Cronbach's alpha if item is deleted
Itching and scratching*	0.66-0.33	0.7	0.7	0.857
Child mood*	0.72-0.31	0.71	0.73	0.866
Time to get to sleep*	0.58-0.29	0.72	0.75	0.858
Sleep disturbances*	0.63-0.36	0.62	0.7	0.857
Disturbed playing or swimming*	0.55-0.28	0.55	0.64	0.862
Disturbed family activities*	0.52-0.27	0.61	0.65	0.854
Problems during mealtimes*	0.53-0.31	0.6	0.66	0.853
Problems from treatment*	0.22-0.49	0.51	0.45	0.865
Dressing problems*	0.58-0.26	0.62	0.47	0.857
Problems at bath time*	0.30-0.51	0.58	0.45	0.860

*p-value for each item is significant, Cronbach's alpha based on standardized items = 0.87

Table 3 - The mean Infants' Dermatitis Quality of Life Index score (standard deviation [SD]) in the total number of cases as well as in individual severity groups compared to controls.

Variables	Control (n=120)	Total (n=370)	Mild (n=198)	Moderate (n=117)	Severe (n=55)	*P*	*P*1	*P*2	*P*3
Itch suffering	0.41 ± 0.64	1.73 ± 0.40	1.27 ± 0.62	1.94 ± 0.88	2.47 ± 0.62	0.000*	0.000*	0.000*	0.000*
Child mood	0.18 ± 0.29	1.67 ± 0.21	1.18 ± 0.45	1.80 ± 0.67	2.33 ± 0.63	0.000*	0.000*	0.000*	0.000*
Time enter sleep	0.30 ± 0.64	1.51 ± 0.31	1.13 ± 0.61	1.76 ± 0.59	2.24 ± 0.57	0.000*	0.000*	0.000*	0.000*
Sleep interruption	0.50 ± 0.20	1.39 ± 0.22	1.07 ± 0.71	1.72 ± 0.58	2.16 ± 0.79	0.000*	0.000*	0.000*	0.000*
Play/swim interruption	0.10 ± 0.31	1.30 ± 0.20	0.82 ± 0.45	1.56 ± 0.63	2.13 ± 0.56	0.000*	0.000*	0.000*	0.000*
Interruption of family activities	0.21 ± 0.31	1.2 ± 0.31	0.78 ± 0.39	1.3 ± 0.47	2.12 ± 0.82	0.000*	0.000*	0.000*	0.000*
Time-meal problems	0.20 ± 0.20	1.10 ± 0.35	0.59 ± 0.78	1.25 ± 0.72	1.69 ± 0.49	0.000*	0.000*	0.000*	0.000*
Treatment problems	0.23 ± 0.33	1.28 ± 0.32	0.99 ± 0.44	1.55 ± 0.55	1.88 ± 0.68	0.000*	0.000*	0.000*	0.000*
Dressing/undressing	0.42 ± 0.49	1.67 ± 0.40	0.71 ± 0.66	1.11 ± 0.71	1.99 ± 0.71	0.000*	0.000*	0.000*	0.000*
Bath-time	0.65 ± 0.70	1.15 ± 0.19	0.61 ± 0.58	1.51 ± 0.79	1.88 ± 0.53	0.000*	0.000*	0.000*	0.000*
Total	**3.2 ± 1.3**	**14.0 ± 2.91**	**9.15 ± 2.8**	**15.5 ± 2.6**	**20.89 ± 2.2**	**0.000***	**0.000***	**0.000***	**0.000***

*significant *P*-value. *P* - cases versus controls, *P*1 - mild versus moderate, *P*2 - mild versus severe, *P*3 - moderate versus severe

observed with increasing severity of AD (p<0.001). The IDQoL scale scores were: 3.2 ± 1.3 for controls; 9.15 ± 2.8 for the mild; 15.5 ± 2.6 for the moderate; and 20.89 ± 2.2 for the severe group of cases. This confirms the effective construct validity of the scale (**Table 3**).

Discussion. There are many clinical scoring systems and indices for the assessment of disease severity in AD patients. The SCORAD index is a clinical score most widely used by physician's for assessment of AD severity.[13] It consists of objective assessment of the signs combined with subjective details of short-term symptoms over the preceding one week. The SCORAD index can measure only the short-term severity of the disease. It does not provide any information on the long-term disease severity. The Nottingham Eczema Severity Score (NESS), on the other hand, measures the disease severity over a 12-month period.[25] Some authors recommend that acute and long-term disease severity is better evaluated by using a combination of the objective SCORAD and NESS scales.[26]

In this regard, the benefits of using HRQoL measures to monitor disease severity include their ability to be administered by nurses or nonclinical personnel, need for a short time to complete, and the option of completing the questionnaire prior to a consultation, thus saving valuable time. Because the administration of IDQoL does not require undressing the child, it could be useful in epidemiologic studies, where examination may be difficult or impossible. Moreover, the proven correlation between this scale and the DFI scale gives it a more impressive applicability of being relatively simple, not dependent on clinicians' views, and handy even to paramedic personnel and parents after minimal

training.[27,28] Many studies have also confirmed the usefulness of IDQoL in follow-up sessions to monitor the patient's response to treatment. These authors found that the IDQoL improved between first and second visits.[20,29,30] This suggests that the IDQoL questionnaire could be used as an extra tool to measure the outcome in every day clinical practice, as well as in research studies.

In an original article pertaining to its development, the scale was validated with repeatability and sensitivity to changes confirmed and has been used in over 15 studies.[20,28] Clinical severity assessed by a physician has been shown to correlate with HRQoL measured by the IDQoL. Many studies confirmed that IDQoL is sensitive to changes in disease severity.[27,29,31,32] That is, poorer QoL was strictly associated to a more severe AD condition.[30] This finding conforms with findings reported by other studies, which also have shown that the severity of the child's AD is related to the degree of disturbance in the child's QoL.[20,29,30]

This work evaluates the validity and reliability of a newly developed Arabic version of IDQoL scale in measuring quality of life among Saudi infants with AD. During the translation process, abiding to careful and accurate rules of translation/back translation, testing semantic and linguistic equivalence, and field-testing were the essential steps taken for obtaining maximum validity and reliability of the Arabic version of the IDQoL scale. The results of this study confirmed that this newly developed translated Arabic version of the IDQoL is an efficient tool in terms of its reliability and validity for the measurement of the disease impact. It can also be considered a sensitive tool for assessment of disease severity, and for measuring response to treatment in follow-up settings. The present study also confirms the sensitivity of the IDQoL score to judge disease burden on the patient's family members. Thus, all of these validations confirmed the ability of the newly developed Arabic version of IDQoL scale for measuring the disease severity. The IDQoL scale showed significantly higher scores among cases compared to controls. In addition, the results also showed significantly higher scores in the severe AD group, compared to the moderate or mild AD groups. Furthermore, the Arabic version of IDQoL is related to the severity of the infant's AD, and this supports its construct validity. The overall reliability of the Arabic version IDQoL was confirmed by the high value of Cronbach alpha coefficient (0.87) and the significantly positive inter-item and item-total correlation coefficients.

For future research, this index can be utilized to test for the association of various factors impacting the quality of life of families having infants affected with AD whether being environmental, demographic, or clinical. However, this study has some limitations being used mainly for lesions giving evident symptoms rather than milder lesions that probably could be missed.

In conclusion, this novel Arabic version of the IDQoL index is a good tool to measure disease impact in Arabic families having infants with AD.

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