Sensitivity to treatment and score bands of the Infants and Toddlers Dermatology Quality of Life questionnaire

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Background: The Infants and Toddlers Dermatology Quality of Life (InToDermQoL) questionnaire is the first dermatology-specific proxy health related QoL instrument for children from birth to 4 years. Score meaning bands and the sensitivity to successful therapeutic intervention are important to interpret the clinical meaning of an instrument.

Objective: The aim of the present study was to check the sensitivity to successful therapeutic intervention and establish score bands of the InToDermQoL questionnaire.

Methods: Parents or grandparents of 424 children with skin diseases from Spain, Malta, Croatia, Romania, Greece, and Ukraine filled in national language versions of the InToDermQoL questionnaire. Disease severity of children with atopic dermatitis was assessed by SCORAD (Scoring atopic dermatitis). Cohen's d was used to assess the responsiveness of the instrument.

Results: The mean total InToDermQoL scores significantly decreased after treatment. Severity grading of the SCORAD scores gave stratification of the InToDermQoL severity grades based on 95% confidence intervals. Scores below a calculated minimal important difference of 2 corresponded to no effect on patient's health related QoL.

Limitations: Score banding may be slightly different across patient population and study context.

Conclusion: All 3 age-specific versions of the InToDermQoL questionnaire showed sensitivity to treatment. Score bands for the InToDermQoL questionnaire have been established. (JAAD Int 2023;10:61-7.)

Key words: patient-reported outcome measures; pediatric dermatology; quality of life; treatment; severity banding.

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INTRODUCTION

The Infants and Toddlers Dermatology Quality of Life (InToDermQoL) questionnaire is the dermatology-specific proxy health related quality of life (HRQoL) instrument for children from birth to 4 years.[1] In order to avoid the problem of cross-cultural inequivalence, development and validation of the InToDermQoL were performed simultaneously in different national centers of the project.[1,2] Results of the international field tests confirmed internal consistency, test-retest reliability and, convergent and discriminant validity of the InToDermQoL questionnaire.[2] The InToDermQoL was used to study QoL in children with seborrheic, allergic contact, and atopic dermatitis (AD) before and during COVID-19 pandemic.[3] An epidermolysis bullosa-specific module of the InToDermQoL was developed and underwent initial validation separately.[4-6]

CAPSULE SUMMARY

- This article provides important steps for validation of the dermatology-specific proxy health related quality of life instrument for young children, the Infants and Toddlers Dermatology Quality of Life.
- Sensitivity to treatment and score banding system of the Infants and Toddlers Dermatology Quality of Life questionnaire may help to interpret severity of the quality of life impairment by clinicians and researchers.

Score meaning bands are important to interpret the clinical meaning of a change in score by clinicians and researchers.[7] The dermatology-specific HRQoL instrument for adults Dermatology Life Quality Index score descriptor banding system[8] has been used in clinical trials on different skin diseases and some national and international guidelines contain detailed recommendations on treatment goals and changes of treatment approaches based on the Dermatology Life Quality Index score banding.[9] Scores banding system of the dermatology-specific HRQoL instrument for children from the age of 4 years to 16 years (Children's Dermatology Life Quality Index) was presented.[10]

The aim of the present study was to check the sensitivity to successful therapeutic intervention and establish score bands for the InToDermQoL questionnaire.

MATERIALS AND METHODS

National centers of the InToDermQoL project were invited to participate in the study. Parents or other adult relatives of children with skin diseases from birth to 4 years old were asked to fill in the InToDermQoL questionnaire, (Table I) from December 2019 to January 2022. Diagnosis of skin diseases were confirmed by dermatologists in all cases. Ethical approval was obtained from the local ethical research committees were it is required. Informed consent from patients' parents or guardians was obtained in all cases.

Scoring of atopic dermatitis (SCORAD) index was used for the assessment of disease severity in children with AD because this is the best validated scoring system amongst this group of patients.[11,12] The intensity part of the SCORAD consists of the following 6 items: erythema, edema/papulation, excoriations, lichenification, oozing/crusts, and dryness. Each item can be graded on a scale of 0 to 3. The subjective items include daily pruritus and sleeplessness. The SCORAD Index formula is as follows: A/5 + 7B/2 + C. In this formula A is defined as the extent (0-100), B is defined as the intensity (0-18), and C is defined as the subjective symptoms (0-20). The maximum score of the SCORAD index is 103. Two different severity grades of the SCORAD have been proposed. In one a SCORAD higher than 50 was regarded as severe, whereas AD with a SCORAD below 25 was regarded as mild.[13] Meanwhile, in another one a SCORAD higher than 40 was regarded as severe, whereas AD with a SCORAD below 20 was regarded as mild.[14]

Data were presented as mean ± standard deviation (SD) of the mean. Wilcoxon matched pairs test (two-tailed) was used to compare variables before and after the treatment. Pearson's correlation coefficient was used to measure correlation between scores. The results were considered significant if $P < .05$. Cohen's d was used to assess the responsiveness of the instrument (0.2 represents a small effect size, 0.5 a medium effect size, and 0.8 a large effect size).[15] Cohen's d determined by calculating the mean difference between scores before and after the treatment dividing the results by the pooled SD (Cohen's d= [M1-M2]/SD pooled). The SD of the baseline scores was multiplied by the small effect size to calculate minimally important difference (MID).[16] The InToDermQoL total scores' 95% confidence intervals (CIs) corresponding to severity grades of the SCORAD were used to propose score bands.

RESULTS

Parents or grandparents of 424 children with skin diseases from Spain, Malta, Croatia, Romania, Greece, and Ukraine filled in national language

Abbreviations used:

COVID-19:	coronavirus disease of 2019
DLQI:	Dermatology Life Quality Index
HRQoL:	health related quality of life
InToDermQoL:	Infants and Toddlers Dermatology Quality of Life
M:	mean
MID:	minimally important difference
SCORAD:	scoring of atopic dermatitis
SD:	standard deviation

versions of the InToDermQoL questionnaire. Information on diagnoses of children with skin diseases is presented in Table II. The vast majority of questionnaires were filled in by mothers (Table III). After the treatment, total InToDermQoL scores significantly decreased. Large Cohen's thresholds were reported for 1 to 2 and 3 to 4 years InToDermQoL age versions. Medium Cohen's threshold was reported for 0 to 11 months InToDermQoL age version. Calculated MID was above 1 and below 2 for all 3 versions of the InToDermQoL. Therefore the MID of 2 for all 3 age-specific versions of the InToDermQoL was established. The mean InToDermQoL scores before and after the treatment, Cohen's d, and MID for all 3 age-specific versions of the InToDermQoL questionnaire are presented in Table IV. The InTodermQoL scores significantly correlated with SCORAD in children with AD before and after treatment except for the age version of 3 to 4 years before treatment (Table V). The InTodermQoL scores of children with AD before and after treatment were matched with disease severity grading of the SCORAD. The InToDermQoL total scores' 95% CIs corresponding to severity grades of the SCORAD were used to propose score bands. Severity grading where SCORAD higher than 50 was regarded as severe, whereas AD with a SCORAD below 25 was regarded as mild[13] leading to several overlaps of the InToDermQoL 95% CIs among different severity grades (data not shown). Another variant of severity grading where a SCORAD higher than 40 was regarded as severe, whereas AD with a SCORAD below 20 was regarded as mild[14] gave almost ideal stratification of the InToDermQoL severity grades based on 95% CIs (Table VI). Based on these results and the hypothesis that total scores below MID correspond to no effect on patient's HRQoL, score

Table I. The Infants and Toddlers Dermatology Quality of Life questionnaire

Infants and Toddlers Dermatology Quality of Life

The aim of this questionnaire is to measure how much your child's skin problem has affected him/her over the last week.

Child's name: *Child's age:* *Child's gender:* *Date:*
Diagnosis: *Disease severity:* *Filled by: mother/father/another person*

1.	Your child's itching or scratching is because of his/her skin disease	Very much Quite a lot Only a little Not at all	☐
2.	Your child's bleeding (from injured skin and/or mucosa) is because of his/her skin disease	Very much Quite a lot Only a little Not at all	☐
3.	Your child's pain is because of his/her skin disease	Very much Quite a lot Only a little Not at all	☐
4.	Your child's sleep problems are because of his/her skin disease	Very much Quite a lot Only a little Not at all	☐
5.	Your child's mood changes are because of his/her skin disease	Very much Quite a lot Only a little Not at all	☐
6.	Your child's bathing problems are because of his/her skin disease	Very much Quite a lot Only a little Not at all	☐
7.	Your child's problems with dressing/undressing (irritation of lesions, and pain) are because of his/her skin disease	Very much Quite a lot Only a little Not at all	☐
8.	Your child's feeding problems because of his/her skin disease	Very much Quite a lot Only a little Not at all	☐

Continued

Table I. Cont'd

9.	Your child's problems during physical activity (infant's movements or walking, running, crawling, etc. in older children) are because of his/her skin disease	Very much Quite a lot Only a little Not at all	☐
10.	Your child's problems with treatment (eg, home treatment, bandaging, skin care, etc.) are because of his/her skin disease	Very much Quite a lot Only a little Not at all	☐
If your child is over 1 year of age:			
11.	Your child's tiredness is because of his/her skin disease	Very much Quite a lot Only a little Not at all	☐
12.	Restrictions and limitations (social, nutritional, physical activity and sports, pets, etc.) your child had are because of his/her skin disease	Very much Quite a lot Only a little Not at all	☐
If your child is over 3 years of age:			
13.	Do other peoples' questions about your child's skin disease affect your child	Very much Quite a lot Only a little Not at all	☐
14.	Your child's feeling of being different from peers because of his/her skin disease	Very much Quite a lot Only a little Not at all	☐
15.	Rejection by other children because of his/her skin disease	Very much Quite a lot Only a little Not at all	☐

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InToDermQoL, Infants and Toddlers Dermatology Quality of Life.

Table II. Diagnoses of children with skin diseases whose parents filled in the InToDermQoL questionnaire

Diagnosis	0-11 months (n = 132)	1-2 years (n = 133)	3-4 years (n = 159)
Atopic dermatitis	80	90	86
Seborrheic dermatitis	18	3	2
Pityriasis alba	-	1	-
Miliaria	1	1	1
Intertrigo	1	-	-
Pyoderma	2	3	6
Nevi	-	-	2
Mastocytoma	1	-	-
Diaper dermatitis	6	4	-
Acne neonatorum	2	-	-
Perioral dermatitis	4	1	3
Contact dermatitis	3	-	2
Impetigo	2	2	5
Urticaria	2	10	3
Hemangiomas	2	-	2
Xeroderma	-	4	4
Pediculosis	-	-	3
Ichtyosis	-	-	1
Prurigo	1	4	4
Eczema	4	1	3
Allergic dermatitis		1	2
Fungal infection	1	2	7
Hand eczema	-	-	3
Hand, foot, and mouth disease	-	1	-
Furunculosis	-	-	2
Insect bites	-	-	1
Warts	-	1	1
Folliculitis	-	-	2
Molluscum contagiosum	1	-	1
Psoriasis	-	1	9
Keratosis pilaris	1	1	1
Scabies	-	1	2
Lichenoid dermatitis	-	1	-
Vitiligo	-	-	1

InToDermQoL, Infants and Toddlers Dermatology Quality of Life.

Table III. Who filled in the InToDermQoL questionnaire (absolute numbers and percentage)

Who filled in the InToDermQoL questionnaire	0-11 months (n = 132)	1-2 years (n = 133)	3-4 years (n = 159)
Mother	109 (82.57%)	107 (80.45%)	125 (78.62%)
Father	13 (9.85%)	15 (11.28%)	24 (15.09%)
Another person	10 (7.58%)	11 (8.27%)	10 (6.29%)

InToDermQoL, Infants and Toddlers Dermatology Quality of Life.

Table IV. InToDermQoL scores before and after the treatment (mean ± standard deviation), Cohen's d and minimally important difference

InToDermQoL age version	Before treatment	After treatment	Cohen's d	MID
For 0-11 mo (n = 126)	7.69 ± 6.95	3.56 ± 6.14*	0.63	1.39
For 1-2 y (n = 128)	10.97 ± 7.66	5.03 ± 7.18*	>0.80	1.53
For 3-4 y (n = 157)	12.80 ± 9.53	4.52 ± 6.70*	1.01	1.91

InToDermQoL, Infants and Toddlers Dermatology Quality of Life; *MID*, minimally important difference.
*$P < .001$ (Wilcoxon matched pairs test).

Table V. Correlation of the InToDermQoL scores with SCORAD

InToDermQoL age version	Correlation coefficient (Pearson's)	
0-11 mo	Before treatment (n = 56) .76†	After treatment (n = 52) .72†
1-2 y	Before treatment (n = 72) .49†	After treatment (n = 76) .51†
3-4 y	Before treatment (n = 76) .21*	After treatment (n = 77) .42†

InToDermQoL, Infants and Toddlers Dermatology Quality of Life; *SCORAD*, scoring atopic dermatitis.
*$P = .06$.
†$P < .001$.

bands for the InToDermQoL questionnaire are being proposed (Table VII).

DISCUSSION

In this study, the mean total InToDermQoL significantly decreased after treatment.

Furthermore, the use of score bands based on the InToDermQoL total score 95% CIs corresponding to severity grades of the SCORAD[14] gave almost perfect

Table VI. The InToDermQoL total scores' 95% confidence intervals corresponding to severity grades of the SCORAD

SCORAD	Corresponding InToDermQoL mean total score	95% confidence intervals	
		Minimum	Maximum
0-11 mo			
Mild (n = 38)	2.50 ± 3.73	1.28	3.73
Moderate (n = 51)	6.98 ± 6.80	5.07	8.89
Severe (n = 19)	21.05 ± 9.52	17.81	24.30
1-2 y			
Mild (n = 34)	4.06 ± 6.38	1.83	6.29
Moderate (n = 78)	10.60 ± 8.15	8.76	12.44
Severe (n = 36)	17.11 ± 8.24	14.32	19.90
3-4 y			
Mild (n = 42)	6.21 ± 4.90	4.69	7.74
Moderate (n = 60)	11.29 ± 9.09	8.90	13.69
Severe (n = 51)	18.08 ± 11.65	14.80	21.36

InToDermQoL, Infants and Toddlers Dermatology Quality of Life; *SCORAD*, scoring atopic dermatitis.

Table VII. Score bands of the InToDermQoL questionnaire (total score ranges)

InToDermQoL age version	InToDermQoL severity banding			
	No effect	Mild effect	Moderate effect	Severe effect
For 0-11 mo	0-1	2-4	5-11	12-30
For 1-2 y	0-1	2-7	8-13	14-36
For 3-4 y	0-1	2-8	9-14	15-45

InToDermQoL, Infants and Toddlers Dermatology Quality of Life.

stratification of the InToDermQoL severity grades except for an uncertain border between moderate and severe effects in the InToDermQoL version for 0 to 11 months. Scores below the MID were considered as no effect on patients' HRQoL. According to the proposed InToDermQoL severity banding, mean total scores improved from moderate to mild disease severity. Difference of HRQoL instrument scores among the sexes should be studied in children matched by other factors.[17] Disease-specific HRQoL instruments may theoretically be more sensitive than general dermatology-specific instruments. However, the dermatology-specific InToDermQoL and the Family Dermatology Life Quality Index showed good correlation with disease specific instruments in previously published studies.[2,18] There is severity banding available for dermatology-specific HRQoL instruments for adults and older children.[8,10] Attention to treatment of younger children with chronic skin disease is also growing, and a validated HRQoL measure with established score

banding may help with interpretation of quimp (the European Academy of Dermatology and Venereology Task Force on Quality of Life and Patient Oriented Outcomes recommends using the word "quimp"[19][quality of life impairment] in routine clinical work and research[20]) in these patients.

This study has some limitations. Because responsiveness and MID depend on population and contextual characteristics, there is not necessarily a single MID value for an instrument across all applications and patient samples. There is often a range in MID estimates that varies across patient population and clinical study context.[21] Similarly, score banding may also be slightly different across patient population and study context. HRQoL assessment in different countries may be similar but not identical.[22] Finally, external factors as in case of the COVID-19 pandemic may have multidirectional effects on patient's HRQoL.[3,23] Similar to our study the person who fills-in the proxy- ratings in most cases is the mother.[24] However, no significant difference between mothers' and fathers' assessment of AD-specific proxy questionnaire was previously reported.[25] Anchor-based methods are also important and we are planning to organize a special study for this. Eventually we intend to have MID and score banding obtained by means of different methods. There are no other dermatology-specific HRQoL proxy instruments for the selected age group and it is well known that generic proxy HRQoL instruments may not adequately reflect the impact caused by skin diseases. Furthermore there is no established score banding system for the available disease-specific instruments used in dermatology validated for the selected age group.[1,24] Subjective assessment of severity grades of skin disease or HRQoL by proxies or alternatively by the doctor may be used to determine InToDermQoL score banding, and we are planning to use this approach in our future study. SCORAD is a popular measure of AD disease severity with at least 2 widely recognized different score banding methods.[13,14] Significant correlation of the InToDermQoL with SCORAD scores allowed us to use SCORAD banding as descriptors for the InToDermQoL in the presented manuscript. Results of our future study may confirm the proposed banding system or may lead to some modifications. We feel that availability of the dermatology-specific instrument for the youngest age group with a reasonable score banding system represents important progress in the field and may be used for practical reasons and research. The fact that, based on SCORAD severity grades, the InToDermQoL scores showed no overlapping in our study confirmed that the presented system well differentiates severity of the impact on patients' HRQoL.

Sensitivity to treatment and interpretation system of the InToDermQoL scores should lead to more active use of this instrument in research, clinical practice, and inclusion to core outcome sets.[26] Reasons why QoL measurement is important in dermatology clinical practice are presented in the position statement of the European Academy of Dermatology and Venereology Task Force on Quality of Life and Patient Oriented Outcomes.[27] Assessment of responsiveness and clinical validation of the InToDermQoL severity banding in children with different skin diseases will be aims of our future studies.

CONCLUSIONS

In this study all 3 age-specific versions of the InToDermQoL questionnaire showed sensitivity to treatment. Score bands of the InToDermQoL questionnaire have been established.

Conflicts of interest

None disclosed.

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