ORIGINAL ARTICLE

Validation of the dermatology-specific proxy instrument the Infants and Toddlers Dermatology Quality of Life

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Abstract

Background The first dermatology-specific proxy health-related quality of life (HRQoL) instrument for children 0–4 years old with skin diseases, the Infants and Toddlers Dermatology Quality of Life (InToDermQoL), was recently developed. In order to avoid the problem of cross-cultural inequivalence focus groups work and pilot tests were organized simultaneously in all national centres of the project. The InToDermQoL showed good comprehensibility, clarity and acceptance.

Objective To validate the InToDermQoL questionnaire during international field tests.

Methods Internal consistency, test–retest reliability, convergent and discriminant validity of the InToDermQoL questionnaire were checked during international field tests.

Results Parents of 473 children with skin diseases filled in the national language versions of the InToDermQoL questionnaire. All three age-specific versions of the InToDermQoL questionnaire with 10, 12 and 15 items, respectively, showed high internal consistency (Cronbach's α 0.90–0.93), good test–retest reliability (correlation coefficients > 0.9), significant correlations with the most widely used atopic dermatitis-specific proxy instrument, the Infants Dermatitis Quality of Life Index (correlation coefficients 0.68–0.79). The InToDermQoL versions for children <3 years old well correlated with the atopic dermatis severity measure Scoring of Atopic Dermatitis (correlation coefficients 0.66 and 0.86 for 10 and 12 items versions, respectively). The InToDermQoL questionnaire discriminated well among different diagnoses and disease severity levels.

Conclusion Our field tests confirmed internal consistency, test–retest reliability, convergent and discriminant validity of the InToDermQoL questionnaire. Development and validation of the InToDermQoL questionnaire make it possible to assess dermatology-specific aspects of HRQoL in youngest children with skin diseases. There are many reasons to assess HRQoL in dermatologic clinical practice, and we hope that our new instrument will be used internationally in paediatric dermatology for research and practical needs.

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Conflicts of interest
None declared.

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Introduction
The first dermatology-specific proxy health-related quality of life (HRQoL) instrument for children 0–4 years old with skin diseases, the Infants and Toddlers Dermatology Quality of Life (InToDermQoL), was recently developed.[1] The need of dermatology-specific proxy HRQoL questionnaire for use in very young children with skin conditions was underlined in reviews and recommendations of the European Academy of Dermatology and Venereology (EADV) Task Force on QoL.[2,3]

In order to avoid the problem of cross-cultural inequivalence, focus groups work and pilot tests of the InToDermQoL were performed simultaneously in different national centres of the project as in the case of the European KIDSCREEN/DISABKIDS project.[4] Three age-specific versions of the InToDermQoL questionnaire with 10, 12 and 15 items, respectively, have shown good comprehensibility, clarity and acceptance and were approved for field tests.[1] The EADV Task Force on QoL recommendations stated that only validated HRQoL instruments with appropriate content are recommended for use in children. All such measures should be validated on the same principles as those for use in adults.[3] The aim of the present study was to validate the InToDermQoL questionnaire during the international field tests.

Methods
National centres of the InToDermQoL project that took part in the pilot test (Croatia, Germany, Greece, Malta, Poland, Romania, Ukraine, France, Denmark and Spain) were invited to participate in the field tests of the questionnaire.

Participants
Parents or other adult relatives of children with skin diseases from birth to 4 years old were asked on a voluntary base to fill in the questionnaires in participating centres of the project. Diagnosis of skin diseases was confirmed by dermatologists in all cases. Children that had manifestations of two or more different skin diseases or those who had also manifest non-skin diseases were excluded from the study. To formally confirm dermatologic specificity of the InToDermQoL questionnaire, parents of healthy children of the same age and parents of children with non-dermatologic diseases were also asked on a voluntary base to fill in the InToDermQoL questionnaire. Their scores were compared with the InToDermQoL scores obtained from parents of children with skin diseases. For the test–retest reliability, parents of children with skin diseases completed the InToDermQoL questionnaire a second time. Test–retest reliability was assessed by measuring the level of agreement between the baseline and follow-up scores. Internal consistency was measured using the Cronbach's α. Discriminant validity was assessed by the ability to discriminate among different severity grades. Convergent validity was measured through the correlation of the InToDermQoL scores with scores of Infants Dermatitis Quality of Life Index (IDQoL)[5] and Scoring of Atopic Dermatitis (SCORAD).[6] The study was approved by an ethics committee (in accordance with the Declaration of Helsinki). The new word 'quimp', meaning 'QoL impairment', was recently proposed.[7] The EADV TF on QoL and patient-oriented outcomes recommends the word 'quimp' for routine clinical and research use,[8] and we used it in our present study.

Measures
The InToDermQoL consists of three versions: 10 items for children <1 year of age, 12 items for children from 1 to 2 years of age and 15 items for children of 3–4 years of age. Responses of the InToDermQoL questionnaire are on a 4-point scale, from 0 to 3. The total score is calculated by summing the score of each question. Maximum total score for children <1 year of age is 30. Maximum total score for children from 1 to 2 years of age is 36. Maximum total score for children of 3–4 years of age is 45. There are 10 national language versions of the InToDermQoL.[1] The epidermolysis bullosa-specific module of the InToDermQoL questionnaire was recently developed.[9]

The Infants Dermatitis Quality of Life Index (IDQoL) is an AD-specific proxy HRQoL instrument designed for use in infants below the age of 4 years. It consists of 10 questions scored on a range of 0–3 for a maximum score of 30. It also contains a single initial item asking for a parental assessment of global clinical severity, which is scored separately on a range of 0–4 (from none to extremely severe).[5] The IDQoL has been translated into many languages. Test–retest reliability, internal consistency, construct validity, responsiveness to change and interpretability of the IDQoL have been reported.[10] Greek, Polish, Romanian and Ukrainian[11] national versions of the IDQoL were used.

Scoring of atopic dermatitis (SCORAD) index was used for the assessment of disease severity in children with AD. The intensity part of the SCORAD consists of six items: erythema, oedema/papulation, excoriations, lichenification, oozing/crusts

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and dryness. Each item can be graded on a scale from 0 to 3. The subjective items include daily pruritus and sleeplessness. The SCORAD Index formula is: 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 maximal score of the SCORAD index is 103. SCORAD is the best validated scoring system in atopic dermatitis.[6,12] AD with a SCORAD higher than 50 was regarded as severe, whereas AD with a SCORAD below 25 was regarded as mild.[13]

Statistical methods

Data were presented as mean ± standard deviation of the mean. Unpaired t-test with Welch correction (two-tailed *P*-value) was used to compare continuous variables, and Pearson's correlation coefficient was used to measure correlation between scores. The results were considered significant if $P < 0.05$.

Results

Parents of 473 children from Croatia, Romania, Greece, Poland and Ukraine with skin diseases filled in the national language versions of the InToDermQoL questionnaire. Detailed information on diagnosis of children with skin diseases is presented in Table 1. Information on who filled in the questionnaires, children's mean age and gender are presented in Table 2. All parents well understood the questions.

The InToDermQoL version for children under 1 year of age was filled in by 172 parents or relatives of children with skin diseases. According to dermatologists' assessment, 42.2% of children had mild, 48.9% moderate and 8.9% severe grade of severity. Mean total InToDermQoL score was 7.00 ± 6.56. Results of separate InToDermQoL items scores are presented in Table 3. Cronbach's α for the InToDermQoL version for children <1 years old was 0.906. Cronbach's α for different patients groups is presented in Table 4. The InToDermQoL version for children above 1 year and under 3 years of age was filled in by 175 parents or relatives of children with skin diseases. According to dermatologists' assessment, 54.6% of children had mild, 36.1% moderate and 9.2% severe grade of severity. Mean total InToDermQoL score was 5.69 ± 6.46. Cronbach's α for the InToDermQoL version for children above 1 year and <3 years of age was 0.913. InToDermQoL version for children above 3 years of age was filled in by 126 parents or relatives of children with skin diseases. According to dermatologists' assessment, 55.3% of children had mild, 35.1% moderate and 9.6% severe grade of severity. Mean total InToDermQoL score was 5.98 ± 7.54. Cronbach's α for the InToDermQoL version for children above 3 years of age was 0.927.

Parents of 30 healthy children and 38 parents of children with non-dermatology diseases were asked on a voluntary base to fill in the InToDermQoL questionnaire versions according to the age of their children. Thirty two parents filled in the version for children <1 year of age, 12 parents filled in the version for children from 1 to 3 years and 24 parents filled in the version for children above 3 years of age. Two children had total score one (item on itching or scratching and item on restrictions and limitations), and two other had total score two (item on problems with treatment in both cases). All other healthy children and children with non-skin diseases had zero total score of the InToDermQoL questionnaire. The InToDermQoL scores of the healthy children and children with non-skin diseases were significantly different ($P < 0.001$). To check test–retest reliability of the InToDermQoL questionnaire 18 parents of children with skin diseases <1 year of age, 21 parents of children above 1 year and under 3 years of age and 21 parents of children above 3 years who were not on active treatment filled in the questionnaire twice with the time interval of about 2 weeks. Good test–retest reliability of all three InToDermQoL versions was confirmed (Table 5). The questionnaires discriminate well among different diagnoses and severity levels. In children younger than 1 year, mean total InToDermQoL score was 9.0 ± 5.34 for allergic dermatitis, 8.89 ± 6.81 for AD, 8.10 ± 5.58 for seborrhoeic dermatitis, 4.50 ± 5.93 for diaper dermatitis, 1.75 ± 1.71 for pityriasis alba and zero for haemangiomas. In children older than 1 year but younger than 3 years mean total InToDermQoL score was 25.33 ± 10.02 for epidermolysis bullosa, 7.54 ± 6.77 for AD, 7.17 ± 5.19 for allergic dermatitis, 4.2 ± 1.64 for diaper dermatitis, 1.75 ± 2.06 for urticaria, 0.75 ± 0.96 for molluscum contagiosum and zero for pigmented nevi. In children older than 3 years, mean total InToDermQoL score was 22.36 ± 10.59 for epidermolysis bullosa, 6.02 ± 5.87 for AD, 6.0 ± 2.65 for urticaria, 2.62 ± 3.30 for molluscum contagiosum and 1.0 ± 1.10 for alopecia. Mean total InTodermQoL scores for different severity grades are presented in Table 6. The scores increased with increasing severity. Correlations of the InToDermQoL versions with the IDQoL and SCORAD in children with AD are presented in the Table 7.

Discussion

This study presents the results of the validation of the InToDermQoL questionnaire. Parents or other relatives of children with different skin diseases had no problems with filling in the InToDermQoL questionnaire. Mothers filled in the questionnaire in almost 90% of cases. It was previously shown that the gender of parent completing AD-specific proxy HRQoL questionnaire did not significantly influence the results of the studies[14,15] but may be different on individual level; inside couples spouses could have alternative view, which is not associated with gender.[15] There were more boys in the youngest age group and more girls in two other age groups of our patients, but both genders were well represented. It was also previously shown that parents of small children with AD assessed girls' HRQoL as more impaired than boys.[16] Thus, representation of patients of both genders is important.

Only 23.8%, 14.3% and 12.7% of children from each age group had problems during physical activity, and 9.5% of

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Table 1 Diagnosis of children with skin diseases whose parents filled in the Infants and Toddlers Dermatology Quality of Life (InToDerm-QoL) questionnaire

Diagnosis	From birth to 1 year (*n* = 172)	From 1 to 3 years (*n* = 175)	From 3 to 4 years (*n* = 126)	Diagnosis	From birth to 1 year (*n* = 172)	From 1 to 3 years (*n* = 175)	From 3 to 4 years (*n* = 126)
Atopic dermatitis	75	84	52	Granuloma annulare	–	1	–
Pityriasis alba	5	–	3	Balanitis	–	1	–
Miliaria	3	2	–	Epidermal cyst	–	1	–
Intertrigo	3	2	–	Insect bites	–	1	–
Seborrhoeic dermatitis	42	3	1	Candidiasis	–	1	–
Nevi	1	3	3	Pityriasis versicolor	–	1	–
Pseudoxanthoma	1	–	–	Paronychia	–	1	–
Diaper dermatitis	6	5	1	Pyogenic granuloma	–	1	–
Neonatal pustulosis	1	–	–	Warts	–	1	3
Acne neonatorum	1	–	–	Folliculitis	–	1	–
Perioral dermatitis	2	2	2	Molluscum contagiosum	–	4	8
Contact dermatitis	2	6	3	Pityriasis rosea	–	2	–
Impetigo	4	3	3	Vascular malformation	–	1	–
Urticaria	3	5	5	Psoriasis	–	3	2
Haemangiomas	4	–	–	Epithelioma	1	1	–
Multiple cafe au lait spots	1	–	–	Keratosis pilaris	–	1	2
Ichthyosis	2	5	2	Histiocytosis	–	1	–
Giant melanocytic naevus	1	–	–	Morbilliform exanthema	–	1	–
Prurigo	2	4	4	Scabies	–	1	–
Sebaceous naevus	1	–	–	Alopecia	–	1	6
Ichthyosiform erythroderma	1	–	–	Lichenoid dermatitis	–	–	1
Lichen striatus	1	–	–	Exfoliative dermatitis	–	–	1
Eczema	1	8	1	Koilonychias	–	–	1
EB	1	3	11	Angular cheilitis	–	–	1
Allergic dermatitis	5	7	1	Temporal comedone	–	–	1
Acrodermatitis	1	1	–	Acanthosis nigricans	–	–	1
Nummular eczema	1	–	–	Vitiligo	–	–	1
Mycosis	–	3	–	Tinea capitis	–	–	2
Hand eczema	–	1	–	Pityriasis lichenoides et varioliformis acuta	–	–	1
Herpes	–	1	–	Onychomadesis	–	–	2
Solar erythema	–	1	–	Aplasia cutis	–	–	1

Table 2 Information on who filled in the questionnaires, children's mean age and gender

InToDermQoL version	Who filled the questionnaires			Children's gender		Children's mean age in months ± SD
	Mother	Father	Another person	Male	Female	
<1 year	153 (89.5%)	14 (8.2%)	4 (2.3%)	109 (63.4%)	63 (36.6%)	6.06 ± 2.83
>1 <3 years	157 (89.7%)	12 (6.9%)	6 (3.4%)	77 (45.8%)	91 (54.2%)	21.81 ± 6.19
3–4 years	103 (81.7%)	21 (16.7%)	2 (1.6%)	52 (44.1%)	66 (55.9%)	42.01 ± 5.79

oldest children had problems because of rejection by others. Some other items had an impact on <20% of children. However, <10% of our patients had severe grades of clinical severity and the time frame of the InToDermQoL is limited with 1 week period. It was possible to artificially balance the number of included patients with different severity grade and probably increase mean total and separate items scores by this, but we decided not to change the real picture during the field test. Itching, mood changes and sleeping problems were the highest scored items of the InToDerm-QoL versions for children <1 year of age and from 1 to 3 years of age. Itching was also the highest scored item followed by the problems with treatment in 3–4 years old children.

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Table 3 Results of separate Infants and Toddlers Dermatology Quality of Life items scores. (a) Version for children <1 year of age. (b) Version for children from 1 to 2 years of age. (c) Version for 3–4 years old children

(a)	Items	0		1		2		3	
		Abs.	%	Abs.	%	Abs.	%	Abs.	%
1	Itching	40	23.3	61	35.5	45	26.2	26	15.1
2	Bleeding	116	67.4	40	23.3	13	7.6	3	1.7
3	Pain	105	61.0	38	22.1	17	9.9	12	7.0
4	Sleep problems	73	42.4	53	30.8	27	15.7	19	11.0
5	Mood changes	68	39.5	58	33.7	31	18.0	15	8.7
6	Problems with bathing	111	64.5	36	20.9	11	6.4	14	8.1
7	Problems with dressing	102	59.3	43	25.0	17	9.9	10	5.8
8	Problems with feeding	125	72.7	25	14.5	16	9.3	6	3.5
9	Problems during physical activity	131	76.2	27	15.7	9	5.2	5	2.9
10	Treatment	95	55.2	44	25.6	22	12.8	11	6.4

(b)	Items	0		1		2		3		Missing	
		Abs.	%	Abs.	%	Abs.	%	Abs.	%		
1	Itching	38	21.7	74	42.3	46	26.3	17	9.7		
2	Bleeding	122	69.7	42	24.0	9	5.1	2	1.1		
3	Pain	122	69.7	33	18.9	17	9.7	2	1.1	1	0.6
4	Sleep problems	113	64.6	43	24.6	7	4.0	12	6.9		
5	Mood changes	99	56.6	50	28.6	16	9.1	10	5.7		
6	Problems with bathing	118	67.4	42	24.0	11	6.3	3	1.7	1	0.6
7	Problems with dressing	122	69.7	35	20.0	15	8.6	3	1.7		
8	Problems with feeding	140	80.0	20	11.4	12	6.9	3	1.7		
9	Problems during physical activity	150	85.7	15	8.6	7	4.0	3	1.7		
10	Treatment	119	68.0	35	20.0	15	8.6	6	3.4		
11	Tiredness	140	80.0	24	13.7	6	3.4	5	2.9		
12	Restrictions	138	78.9	20	11.4	7	4.0	10	5.7		

(c)	Items	0		1		2		3		Missing	
		Abs.	%	Abs.	%	Abs.	%	Abs.	%		
1	Itching	31	24.6	48	38.1	39	31.0	8	6.3		
2	Bleeding	81	64.3	37	29.4	6	4.8	2	1.6		
3	Pain	88	69.8	24	19.0	12	9.5	2	1.6		
4	Sleep problems	88	69.8	26	20.6	8	6.3	4	3.2		
5	Mood changes	82	65.1	25	19.8	15	11.9	4	3.2		
6	Problems with bathing	91	72.2	25	19.8	6	4.8	4	3.2		
7	Problems with dressing	102	81.0	15	11.9	6	4.8	3	2.4		
8	Problems with feeding	109	86.5	8	6.3	2	1.6	6	4.8	1	0.8
9	Problems during physical activity	104	82.5	11	8.7	6	4.8	5	4.0		
10	Treatment	81	64.3	30	23.8	8	6.3	7	5.6		
11	Tiredness	108	85.7	11	8.7	5	4.0	2	1.6		
12	Restrictions	100	79.4	9	7.1	9	7.1	7	5.6	1	0.8
13	Questions of others	102	81.0	17	13.5	5	4.0	2	1.6		
14	Asked why he is different	104	82.5	15	11.9	4	3.2	3	2.4		
15	Rejection by others	114	90.5	10	7.9	0	0	2	1.6		

All questions of the InToDermQoL are related to skin diseases and therefore not surprisingly the scores of all three versions of the questionnaire showed the difference with very high level of significance from scores of healthy children and children with non-skin diseases. One mother of healthy child may have really noticed mild scratching in her 11 months boy and, probably, ignored the information about skin disease in the text of the questionnaire. Three other mothers also by mistake assessed items related to treatment problems and restrictions caused by non-skin diseases in their children. The InToDermQoL questionnaire also discriminated well among severity grades (mild, moderate and severe) and different skin diseases. The highest

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Table 4 Internal consistency (Cronbach's α) of the Infants and Toddlers Dermatology Quality of Life (InToDermQoL) questionnaire in patients with different severity grades and gender

InToDermQoL version	Cronbach's α in different patients' groups				
	Mild	Moderate	Severe	Male	Female
<1 year	0.740	0.767	0.905	0.881	0.924
>1 <3 years	0.829	0.792	0.906	0.872	0.941
3–4 years	0.867	0.932	0.938	0.916	0.802

Table 5 Test–retest reliability results of the Infants and Toddlers Dermatology Quality of Life (InToDermQoL) questionnaire. Pearson's correlation coefficient was used to measure correlation between scores

InToDermQoL version	Total score 1	Total score 2	Correlation coefficient
<1 year (n = 18)	5.28 ± 5.73	5.06 ± 5.74	0.976
>1 <3 years (n = 21)	6.24 ± 5.66	6.19 ± 5.61	0.982
3–4 years (n = 21)	16.81 ± 10.82	16.72 ± 10.67	0.997

Table 6 Mean total Infants and Toddlers Dermatology Quality of Life (InTodermQoL) scores for different severity grades

InToDermQoL version	Mean total InToDermQoL scores		
	Mild	Moderate	Severe
<1 year	3.23 ± 2.99	7.98 ± 4.81	16.92 ± 8.06
>1 <3 years	3.57 ± 3.92	6.33 ± 4.56	14.27 ± 8.93
3–4 years	3.54 ± 4.55	10.58 ± 9.51	12.67 ± 11.26

Table 7 Correlations (Pearson's correlation coefficient) of the Infants and Toddlers Dermatology Quality of Life (InToDermQoL) versions with the Infants Dermatitis Quality of Life Index (IDQoL) (n = 132) and Scoring of Atopic Dermatitis (SCORAD) (n = 96)

InToDermQoL version	SCORAD	IDQoL
<1 year	0.86	0.68
>1 <3 years	0.66	0.79
3–4 years	0.35	0.71

scores were in patients with epidermolysis bullosa, moderate scores in AD, allergic dermatitis, seborrhoeic dermatitis, and low scores in molluscum contagiosum, haemangiomas and alopecia. Similar results were obtained from older children during self-assessment by the Children Dermatology Life Quality Index (CDLQI)[17,18] and in small children with haemangiomas using haemangioma-specific proxy instrument.[19]

All three versions of the InToDermQoL questionnaire showed good internal consistency. The Cronbach's α was higher than 0.7 for all three versions, for boys and girls, and for each severity grade of all three versions. If Cronbach's α is too high, it may suggest that some items may be redundant as they are testing the same question but in a different guise. Some experts recommend a maximum Cronbach's α value of 0.90.[20] Meanwhile, others consider that Cronbach's α >0.95 may reflect the risk of redundancy.[21] All three versions of the InToDermQoL showed high levels of test–retest reliability and well correlated with AD-specific proxy instrument the IDQoL. In children with AD, the InToDermQoL versions for children <1 year of age and under 3 years of age also well correlated with the AD severity measure SCORAD. Lower level of correlation of the InToDermQoL version for 3–4 years old children was reported. It is clear that HRQoL is generally more impaired in patients who have a more severe clinical course of AD.[22] Significant correlation of the quimp with SCORAD was reported in the number of studies where HRQoL was measured by validated measures.[23–25] However, in other studies on the same age groups such correlation was not found.[26–28] In some patients, even small skin lesions may cause severe impact and vice versa.

Further studies are needed to check the responsiveness of the InToDermQoL to successful treatment, estimate minimal clinically important differences and validate it in separate skin diseases.

The dermatology-specific Family Dermatology Life Quality Index (FDLQI) was created to measure the impact in family members of patients with skin diseases[29] and may be as effectively used by parents of youngest children as it can be used by family members of adult dermatology patients.[30] In contrast, HRQoL of children with skin diseases should be measured by the instruments especially created and validated for this age group. Proxy HRQoL instruments should be used in youngest children.[2,3] There are many dermatology-specific HRQoL instruments for adults and the Children's Dermatology Life Quality Index (CDLQI) for self-assessment of HRQoL in children from 4 to 16 years old.[31] Now, we have validated dermatology-specific InToDermQoL questionnaire for children from birth to 4 years of age. The InToDermQoL was created solely on the actual experience of the patients reported by proxy as recommended.[32] It was created and validated simultaneously in different national centres of the project as in the case of the European KIDSCREEN/DISABKIDS project[4] to avoid the problem of cross-cultural inequivalence, and there are 10 national language versions available. Meanwhile, the highest scored items of the AD-specific proxy questionnaire the IDQoL were rather similar in international studies on young AD children from different countries.[33,34]

Our field tests confirmed internal consistency, test–retest reliability, convergent and discriminant validity of the InToDermQoL questionnaire. Development and validation of the InToDermQoL questionnaire make it possible to assess dermatology-specific aspects of HRQoL in youngest children with skin diseases. There are many reasons to assess HRQoL in dermatologic clinical practice,[35] and we hope that our new instrument

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will be used internationally in paediatric dermatology for research and practical needs.

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