Cross-cultural validation of a short-form of the Vitiligo Impact Patient scale (VIPs)

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Background: There is a lack of short-form questionnaires evaluating the burden of vitiligo according to skin phototype.

Objective: To develop and validate a 12-item short-form of the Vitiligo Impact Patient scale (VIPs) that takes into account skin phototype.

Methods: Multicenter, prospective, cross-sectional study conducted in France (Créteil and Bordeaux) and the US (Worcester, Massachusetts, and Dallas, Texas).

Results: In total, 891 patients completed the questionnaire. Of these, 509 patients belonged to the French Development sample—313 with dark skin (DS) (phototypes IV to VI) and 196 with fair skin (FS) (phototypes I to III). The US validation sample comprised 382 patients—113 DS and 269 FS. There was a very high correlation between VIPs-FS and its 12-item short-form, VIPs-12-FS, in both the development and validation samples (respectively, rho = 0.96, $P < .0001$ and rho = 0.98, $P < .0001$). Similarly, the correlations between VIPs-DS and its short-form, VIPs-12-DS, in both the development and validation samples were very high (respectively, rho = 0.95, $P < .0001$ and rho = 0.96, $P < .0001$).

Limitations: Responsiveness of the 12-item short-forms should be confirmed.

Conclusions: These data enabled the development and validation of 12-item short-forms of the VIPs questionnaires for fair (VIPs-12-FS) and dark (VIPs-12-DS) skin. (J Am Acad Dermatol 2019;81:1107-14.)

Key words: burden; patient reported outcomes; quality of life short-form; questionnaire; vitiligo; vitiligo impact scale.

Vitiligo, a common depigmenting disorder, affects approximately 1% of the world population.[1] The disease has major effects on patients' quality of life, as many of them feel stressed and stigmatized by their condition.[2] These effects are not surprising because the skin has a central role in many aspects of life and its integrity is relevant in cultural, religious, and economic contexts. Thus, any modification in skin tone might have negative consequences on the quality of life of the individual. For example, in some countries, vitiligo is still confused with leprosy and carries a considerable

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social stigma. In some religions, change in skin color is believed to affect expectations for the destiny of the soul after death.[3] Despite this negative perception, and even though vitiligo is classified by the World Health Organization as a disease (L80), it is still often considered a benign disorder and many dermatologists do not address the psychological and social impact of the disease. Indeed, many studies have documented significant effects of vitiligo on health-related quality of life, using validated generic and dermatology-specific health-related quality of life scales.[4-6] Overall, the notion of "burden" is increasingly being reported in the medical field in evaluating the care of chronic diseases, and more specifically skin diseases. We therefore developed and validated a vitiligo-specific burden questionnaire that takes into account skin phototype—namely, the Vitiligo Impact Patient scale (VIPs).[7] This final version of the VIPs is composed of 29 items (19 items common to all patients, 3 specific to fair skin, and 7 to dark skin), but it is difficult to use efficiently in daily clinical care.

CAPSULE SUMMARY

- We validated 12-item short-forms of the Vitiligo Impact Patient scale, a Vitiligo burden score, in fair and dark skin that highly correlate with the original forms and are easy to use in daily care and clinical studies.
- Patients with genital involvement have high impact on their quality of life.

In this context, we developed a short version of this tool ("short-form") that may therefore be useful in assessing the effectiveness of therapies, whether for research or daily clinical practice. This short-form was limited to 12 items and should allow the assessment of the individual burden of vitiligo and its improvement after treatment, thus enabling better evaluation of treatment efficacy.

METHODS

Participants

We initiated an international, multicenter, prospective, cross-sectional study that lasted from June 20, 2017, to December 20, 2017. Patients were recruited from medical centers in France (Bordeaux and Créteil) and the US (Worcester, Massachusetts, and Dallas, Texas). The study was approved by the local ethics committees of the University Hospital Centres of Paris [reference number 2017-A01753-50]; the institutional review board of the Dallas vitiligo registry at the University of Texas Southwestern Medical Center [reference number STU 032013-069] and the University of Massachusetts [reference number 14848-10]. The the study was conducted according to the Declaration of Helsinki. Oral informed consents were obtained from all participants prior to their participation in the study. Participants were asked to respond to the VIPs fair skin version (VIPs-FS; skin phototypes I to III) or the VIPs dark skin version (VIPs-DS; phototypes IV to VI) according to their phototype. In addition, sociodemographic data and clinical data, such as gender, age, disease duration, Fitzpatrick skin type, and localization of lesions, were collected.

Patients recruited in France were considered in the development sample, and patients recruited in the US were considered in the validation sample. The purpose of using a US validation sample was to assess the invariance across cultures and societies of the measurement model that underlies the VIPs. Using this approach, we aimed to evaluate whether the VIP questionnaires were applicable to other societies and cultures and to judge the ability to generalize across communities.

The Vitiligo Impact Patient scale instrument

The Vitiligo Impact Patient scale consists of 29 items—19 items common to all patients, 3 specific to fair skin (phototypes I to III), and 7 to dark skin (phototypes IV to VI). The dimensionality of the items was evaluated using factor analyses, with results suggesting 3 factors in fair-skinned patients (VIPs-FS) and dark-skinned patients (VIPs-DS). These domains were "Psychological Effects on Daily Life," "Relationships and Sexuality," and "Economic Constraints, Care & Management of Disease." The final version of VIPs-FS consisted of 22 items: "Psychological Effects on Daily Life" (9 questions), "Relationships and Sexuality" (8 questions), and "Economic Constraints, Care, & Management of Disease" (5 questions). The final version of VIPs-DS consisted of 26 items: "Psychological Effects on Daily Life" (17 questions), "Economic Constraints, Care, & Management of Disease" (5 questions), and "Relationships and Sexuality" (4 questions). More details on VIPs structure are available in the article by Salzes et al.[7]

Responses to VIPs for each item were rated using a 6-point Likert scale: "never" (rated 0), "rarely" (1), "sometimes" (2), "often" (3), "very often" (4), and "constantly" (5). The score of each item is calculated as follows: a total score for the VIPs and VIPs-short-forms was calculated by summing the total of each item. Thus, the total VIPs score ranged from 0-110 for the 22 VIPs-FS items and 0-130 for the 26 VIPs-DS

Abbreviations used:

DS: dark skin
FS: fair skin
PRO: patient-reported outcome
VIPs: Vitiligo Impact Patient scale

items. In these scores, 0 represents no effect and 110 and 130 the maximal burden for fair-skinned patients and dark-skinned patients, respectively. The total score for the VIPs short-forms (VIPs-12-DS and VIPs-12-FS) ranged from 0-60 for the 12 items. Finally, to allow comparisons, the total scores of VIPs-FS, VIPs-DS, VIPs-12-FS, and VIPs-12-DS were reported as a percentage of the total possible score.

Statistical analyses

As a first step, demographic and clinical characteristics were expressed as mean (standard deviation) or n (%). Quantitative variables were reported as median (interquartile range) or mean (standard deviation). Qualitative variables were reported as the n (%) of participants.

To obtain a short-form of the VIPs, we performed an item response theory analysis with graded response model because of ordered categorical responses in order to estimate the a_i parameter or item discrimination parameter that allows determination of how well items identify patients at different levels of the latent scale.[8,9] An item with a large discrimination value has a high correlation between the latent scale and the probability of success on the item. Subsequently, we selected items with the highest a_i for the short VIPs forms, as recommended.[10] We then looked at item difficulty or item location, commonly denoted by b, in order to describe how difficult it is to achieve a 0.5 probability of a correct response for a specific item given the respondent's level of the latent variable. To accomplish this, we first rescaled the item responses to 0-100 to match the scale of the score because the unidimensionality of the VIPs total score has been previously validated.[7] We then calculated the Lin concordance correlation coefficient, which measures the agreement between 2 variables, between each item and the VIPs total score.[11] Values range from −1 (perfect negative agreement) to 1 (perfect positive agreement), with 0 denoting no agreement. Moreover, we also looked for the correlations (1) between each item and the total VIPs score and (2) between scores of the short-forms of VIPs-DS and VIPs-FS and the full VIPs form using the Spearman correlation. Finally, the Wilcoxon-test was used to look for the association between the VIPs short-forms and the clinical presentation of disease, that is, presence or absence of lesions in the different body areas (head/neck, trunk, hands and feet, upper limbs, lower limbs, and genitals). These analyses were performed in a French Development sample and duplicated in the US validation sample to ensure that the instrument and scores can be generalized across populations.

The threshold for statistical significance was set at $P < .05$. All analyses were performed using STATA 14 and R version 3.4.4. In addition, P values were 2-tailed and the alpha level was set at 0.05.

RESULTS

In total there were 509 patients in the development sample—313 DS and 196 FS. The validation sample was composed of 382 patients—113 DS and 269 FS. Descriptive characteristics of the 2 samples are presented in Table I.

We aimed to obtain a 12-item short VIPs for DS and FS and to be representative of the weight of each domain. For the short VIPs-12-DS, domain 1 was reduced from 17 items to 5 items, domain 2 from 5 items to 4 and domain 3 from 4 items to 3 in order to be representative of all domains to obtain a 12-item score that is easily usable in daily care. In the domain "Relationships and Sexuality" of the VIPs-12-DS, we found that the items "I feel that medicine has abandoned me" and "I feel a sense of abandonment where medicine (my doctor) is concerned" were redundant and decided to keep only the item with the highest a_i parameter.

For VIPs-12-FS, items were reduced in domain 1 from 9 to 5 items, domain 2 from 8 to 4 items, and domain 3 from 5 to 3.

Results of the item response theory analysis that allowed the production of the 2 scores are shown in Table II for VIPs-12-FS and Table III for VIPs-12-DS. Strikingly, the highest Lin concordance correlation coefficients and Spearman correlations coefficients were found in items with the highest a_i parameters. The final short-forms are presented in Table III. The results of the Spearman correlation between VIPs and the shorts-forms are presented in Fig 1, *A* (development sample) and Fig 1, *B* for VIPs-12-FS (validation sample) and Fig 1, *C* (development sample) and Fig 1, *D* (validation sample) for VIPs-12-DS. Briefly, there was a strong correlation between VIPs-FS and its short-form, VIPs-12-FS, in both the development and validation samples (respectively, rho = 0.96, $P < .0001$ and rho = 0.98, $P < .0001$). Similarly, the correlation between VIPs-DS and its short-form, VIPs-12-DS, in both the development and validation samples were very

Table I. Descriptive characteristics of the French Development and US validation samples

	French Development sample (n = 509)		US validation sample (n = 382)	
	Fair skin	Dark skin	Fair skin	Dark skin
Age, y, mean (SD)*	46.71 (15.5)	43.54 (17.7)	46.8 (14.7)	48.87 (15.9)
Disease duration, y, mean (SD)	15.28 (12.5)	13.38 (13.9)	15.29 (15.1)	18.67 (20.5)
Gender				
Men	103 (32.9)	55 (28.1)	41 (36.3)	76 (28.3)
Women	210 (67.1)	141 (71.9)	72 (63.7)	193 (71.7)
Head/neck				
Yes	216 (69)	162 (83.1)	65 (57.5)	152 (56.7)
No	97 (31)	33 (16.9)	48 (42.5)	116 (43.3)
Upper limbs				
Yes	182 (58.5)	119 (62.3)	46 (40.7)	100 (37.3)
No	129 (41.5)	72 (37.7)	67 (59.3)	168 (62.7)
Lower limbs				
Yes	138 (44.4)	116 (61.4)	43 (38.1)	93 (34.7)
No	173 (55.6)	73 (38.6)	70 (61.9)	175 (65.3)
Hands/feet				
Yes	256 (81.8)	123 (63.7)	90 (79.6)	223 (83.2)
No	57 (18.2)	70 (36.3)	23 (20.4)	45 (16.8)
Trunk				
Yes	117 (37.6)	106 (56.1)	39 (34.5)	75 (28)
No	194 (62.4)	83 (43.9)	74 (65.)	193 (72)
Genitals				
Yes	105 (34.2)	59 (32.4)	51 (45.1)	145 (54.1)
No	202 (65.8)	123 (67.6)	62 (54.9)	123 (45.9)

SD, Standard deviation.
*Values are n (%) unless otherwise noted.

high (Fig 1; respectively, rho = 0.95, $P < .0001$ and rho = 0.96, $P < .0001$).

When looking specifically at the association between involved areas and VIPs-12-DS and VIPs-12-FS short-forms scores, we found a significant association between hands/feet ($P = .01$), head/neck ($P = .02$), and genital involvement ($P = .004$) and higher VIPs-12-DS score in dark skin. Additionally, we found a significant association between hands/feet ($P = .01$), head/neck ($P = .03$), and upper limb involvement ($P = .02$) and the short VIPs-12-FS score in fair skin.

DISCUSSION

To date, besides the VIPs, a few vitiligo-specific quality of life instruments have been developed and are listed and compared for their properties in Table IV.[7,12-14] In the present study, we validated a 12-item short-form of the VIPs questionnaire in fair skin (Fitzpatrick phototypes I to III, VIPs-12-FS) and dark skin (Fitzpatrick phototypes IV to VI, VIPs-12-DS). Our short-form scores strongly correlate with the total score of the initial longer version of the VIPs questionnaire in both the development and the validation samples, which supports the use of the questionnaire obtained in a French population in other populations as well. In these shorter versions, we found a reduced set of 3 common items pertaining to all the "Economic Constraints, Care, & Management of Disease" domain. These findings confirm the need for weighing the burden of vitiligo according to skin phototype. One example is the item "I dread nice weather because of my vitiligo," which is mainly true in fair skin as sun exposure may accentuate the contrast between vitiligo and normal skin in fair-skinned patients, whereas the contrast is always present in dark-skinned patients. In addition, besides the well-known high burden associated with the involvement of visible areas such as hands and feet, we strikingly found that genital area involvement is also associated with a high burden.

Despite recommendations for the inclusion of patients' views when evaluating interventions,[15,16] patient-reported outcomes (PROs) have not been commonly used in trials to date,[17] and validated tools are lacking. Indeed, we expect that for most individuals, living well is as important as living long. As a result, it is of prime importance to ensure that best health requires more than just measuring mortality and morbidity.

Table II. Item response theory analysis with graded response model for fair skin

Item discrimination parameter	a_i parameter*	rS†	Lin concordance‡
"Psychological effects on daily life"			
I feel discouraged because of my vitiligo	**3.18**	**0.72**	**0.80**
My reflection in the mirror makes me anxious	**2.55**	**0.69**	**0.75**
The progression of my vitiligo worries me (makes me anxious)	**2.13**	**0.65**	**0.68**
My vitiligo has repercussions on my physical appearance	**2.05**	**0.62**	**0.67**
I dread nice weather because of my vitiligo	**1.90**	**0.64**	**0.66**
I worry that my vitiligo will spread	1.87	0.56	0.54
I often tell myself that my life would be very different without vitiligo	1.73	0.68	0.61
I experience my vitiligo as a daily handicap	1.68	0.57	0.56
Passing my vitiligo on to my children worries me, makes me anxious	1.49	0.58	0.52
"Relationships and Sexuality"			
I dread first meetings because of my vitiligo	**2.66**	**0.65**	**0.74**
Questions about my vitiligo bother me, disturb me	**2.03**	**0.56**	**0.74**
I tend to withdraw into myself because of my vitiligo	**1.95**	**0.69**	**0.71**
My vitiligo is an obstacle (a barrier) to my sexuality	**1.90**	**0.55**	**0.68**
My vitiligo has a negative impact on my libido (sexual desire)	1.85	0.58	0.66
The looks in my loved ones' eyes are difficult to bear	1.68	0.50	0.48
I am not comfortable talking about my vitiligo with those around me	1.58	0.53	0.63
I feel that medicine has abandoned me	1.06	0.63	0.55
"Economic Constraints, Care & Management of Disease"			
I dip into my savings in order to treat my vitiligo	**4.17**	**0.63**	**0.74**
I make sacrifices to afford my vitiligo treatments	**3.66**	**0.51**	**0.73**
Managing my vitiligo on a daily basis is a burden	**1.39**	**0.51**	**0.63**
Applying a treatment every day is a burden	1.34	0.32	0.62
I sometimes feel like giving up	1.03	0.44	0.58

Items shown in bold are those retained for the short-form (VIPs-12-FS) based on the highest a_i or item discrimination parameter.
*a_i parameter for item response theory analysis with graded response model (item discrimination parameter).
†rS correlation coefficient for Spearman correlation test between VIPs total score and each item.
‡Lin concordance correlation coefficient between VIPs total score and each item.

The measurement of patient-reported outcomes, including the patient's perceived symptom burden, functional status, and health related quality of life, in routine clinical care will be a part of this assessment of value.

To provide more patient-centered health care for vitiligo, a strategy to accurately document patients' perspectives of their disease and track their trajectories across treatment is a priority. Unfortunately, despite its importance, this goal often remains an unfulfilled need. Additionally, despite a long-standing call to incorporate measures of patients' reported outcomes, such as the VIPs, into routine clinical care, this has seldom been done even in randomized clinical trials.[18]

A report from the Patient-Centered Outcomes Research Institute that involved multiple health care stakeholders, including patients, advocates, and the Food and Drug Administration emphasized the importance of including PROs in electronic health records, clinical care, and drug/device approval.[19] One of the critical barriers to the routine use of the VIPs as a PRO in clinical care is the length of the instrument. In this regard, shortening PRO instruments to improve their user-friendliness was recently acknowledged as a research priority in supporting their adoption into clinical care. A second key priority has been improving the interpretability and efficiency of the measures.[16] To improve the feasibility of routinely using the VIPs, we developed a shortened version of the instrument (VIPs-12) that can more easily be completed by patients at the time of a clinic visit or before and after a treatment procedure. Accordingly, we also created a global VIPs-12 summary score that combines the 3 domains into a single summary score that may be potentially easier to interpret than sub-domain scores.

Importantly, we were able to demonstrate that the VIPs-12 generates noticeably similar scores to the original VIPs instrument. By minimizing the response burden for patients and preserving the psychometric properties of the original VIPs, we developed a shortened vitiligo-specific status instrument to support measurement of PROs in future research studies for patients with vitiligo. Although

Table III. Results of the item response theory analysis with graded response model for dark skin

Item discrimination parameter	a_i parameter*	rS†	Lin concordance‡
"Psychological effects on daily life"			
I tend to withdraw into myself because of my vitiligo	**2.87**	**0.81**	**0.76**
I am ashamed of the consequences of my vitiligo	**2.85**	**0.75**	**0.73**
I often tell myself that my life would be very different without vitiligo	**2.81**	**0.75**	**0.73**
I dread first meetings because of my vitiligo	**2.76**	**0.77**	**0.74**
I experience my vitiligo as a daily handicap	**2.71**	**0.71**	**0.72**
The progression of my vitiligo worries me (makes me anxious)	2.55	0.69	0.65
I feel discouraged because of my vitiligo	2.48	0.66	0.63
My reflection in the mirror makes me anxious	2.46	0.69	0.65
The looks I get from people because of my vitiligo are hard to bear	2.35	0.59	0.66
Questions about my vitiligo bother me, disturb me	2.16	0.70	0.70
My vitiligo has repercussions on my physical appearance	2.14	0.69	0.59
I dread nice weather because of my vitiligo	1.95	0.66	0.63
The looks in my loved ones' eyes are difficult to bear	1.90	0.63	0.63
I worry that my vitiligo will spread	1.81	0.62	0.43
The looks I get from children because of my vitiligo are hurtful	1.56	0.63	0.59
I am not comfortable talking about my vitiligo with those around me	1.44	0.50	0.55
I have learned to live with my vitiligo	0.80	−0.23	−0.18
"Economic Constraints, Care & Management of Disease"			
I dip into my savings in order to treat my vitiligo	**2.95**	**0.69**	**0.71**
I make sacrifices to afford my vitiligo treatments	**2.66**	**0.65**	**0.72**
I have had to change my vacations, leisure activities because of my vitiligo	**1.15**	**0.63**	**0.61**
Managing my vitiligo on a daily basis is a burden	**1.10**	**0.68**	**0.62**
Applying a treatment every day is a burden	1.05	0.37	0.54
"Relationships and Sexuality"			
I feel that medicine has abandoned me	**3.69**	**0.65**	**0.73**
I feel a sense of abandonment where medicine (my doctor) is concerned	3.20	0.53	0.70
In the evening, once I've applied all the creams, I feel depressed	**1.10**	**0.53**	**0.67**
My vitiligo has a negative impact on my libido (sexual desire)	**0.82**	**0.55**	**0.69**

Items shown in bold are those retained for the short score (VIPs-12-DS) based on the highest a_i or item discrimination parameter and Spearman correlation between each item and the total VIPs score.

*a_i parameter for item response theory analysis with graded response model (item discrimination parameter).

†rS correlation coefficient for Spearman correlation test between VIPs total score and each item.

‡Lin concordance correlation coefficient between VIPs total score and each item.

further responsiveness testing is needed, we think that the VIPs short-forms have the potential to improve the efficiency of clinical care by enabling patients to complete the 12-item instrument before an office visit and for clinicians to instantly compare the overall summary score with a previous score to know whether, and how much, quality of life and disease burden in vitiligo patients have changed. Such a measurement from the patient's perspective can more accurately describe PROs than one assigned by physicians.

By systematically asking the same questions in the same way over time, the VIPs-12 offers substantial advantages compared with other outcomes assessing vitiligo severity from the patient's perspective, because it uses a reproducible and sensitive standard. In fact, it is possible that the VIPs-12 may facilitate measurement of vitiligo severity in routine clinical care, prompting physicians when a significant change in a patient's perception has occurred. Whether the summary score can improve population management, shared decision-making, or individual patient's clinical outcomes needs to be formally tested in prospective studies. The use of a shorter instrument and an overall summary score, besides the use of specific clinical PROs such as the Self-Assessment Vitiligo Extent Score,[20] may also have applications in quality assessment when dealing with vitiligo e-cohorts over time.

The main limitation of our study is that we did not test the responsiveness of our instrument to treatment, which should be confirmed in e-cohorts or further clinical studies.

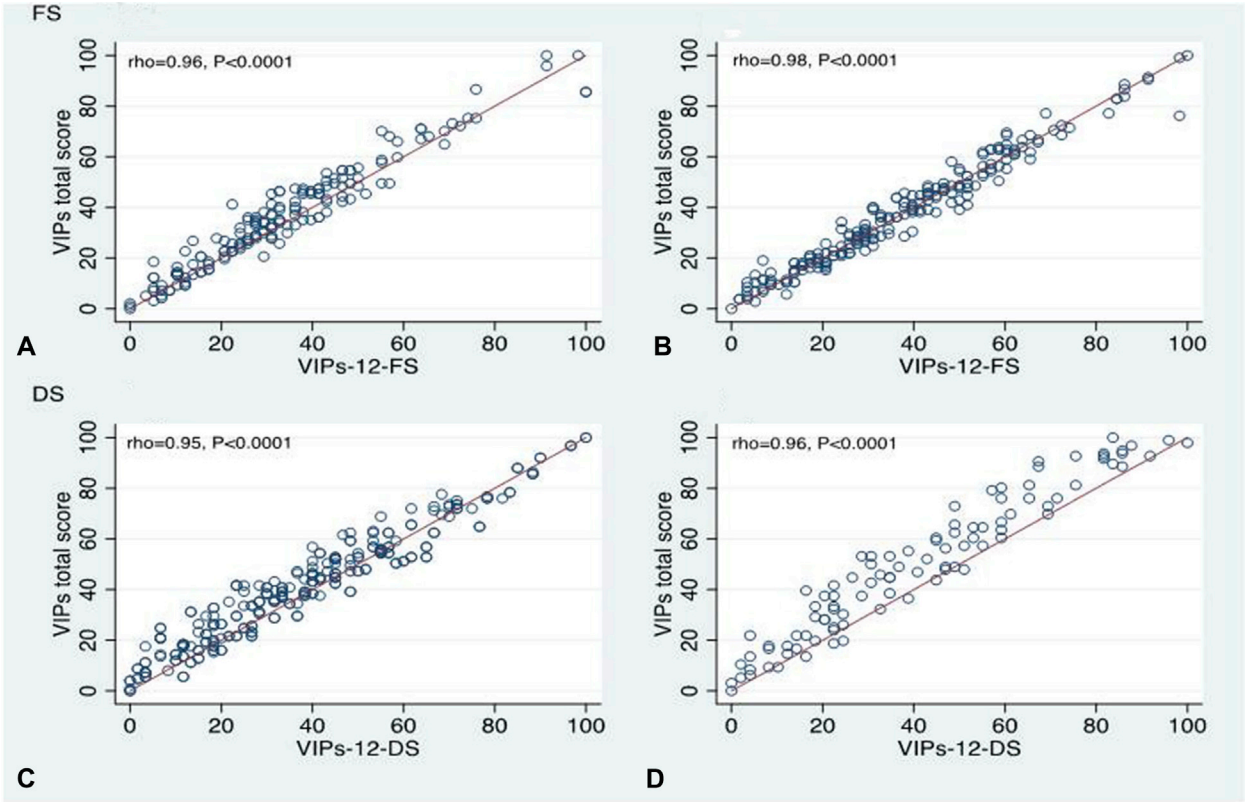

Fig 1. Spearman correlations between the 12-item short-forms and the full forms of the Vitiligo Impact Patient scale (VIPs) in fair (FS) and dark (DS) skin in the French Development and US validation samples. **A**, Spearman correlation between total VIPs-FS score and its short-form, VIPs-12-FS, in the development sample. **B**, Spearman correlation between total VIPs-FS score and its short-form, VIPs-12-FS, in the validation sample. **C**, Spearman correlation between total VIPs-DS score and its short-form, VIPs-12-DS, in the development sample. **D**, Spearman correlation between total VIPs-DS score and its short-form, VIPs-12-DS. in the validation sample.

Table IV. Comparison of the properties of the 4 available vitiligo-specific quality of life questionnaires

Instrument	Number of subjects in the development sample	Specific to phototype	Number of items	Cross-cultural comparison	Responsiveness	Validation of a global score
VIS-22	161	No	22	No	Yes	No
VitiQOL	90	No	16	No	No	No
VLQI	183	No	25	No	No	No
VIPs-SF	509	Yes	12	Yes	No	Yes

VIS, Vitiligo Impact Scale; *VitiQOL*, Vitiligo Quality of Life; *VLQI*, Vitiligo Life Quality Index; *VIPs-SF*, Vitiligo Impact Patient scale—short-form (this instrument).

CONCLUSION

Although PROs are cornerstones of clinical research, they are rarely used in routine clinical care. For PROs to be accepted and widely implemented in routine clinical practice, they will have to be concise and easy to collect and provide an interpretable score for clinical use. This is what we aim to do with the VIPs short-form: produce a short PRO that can be easily used in daily clinical practice and that will help to monitor how patients cope with their vitiligo.

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