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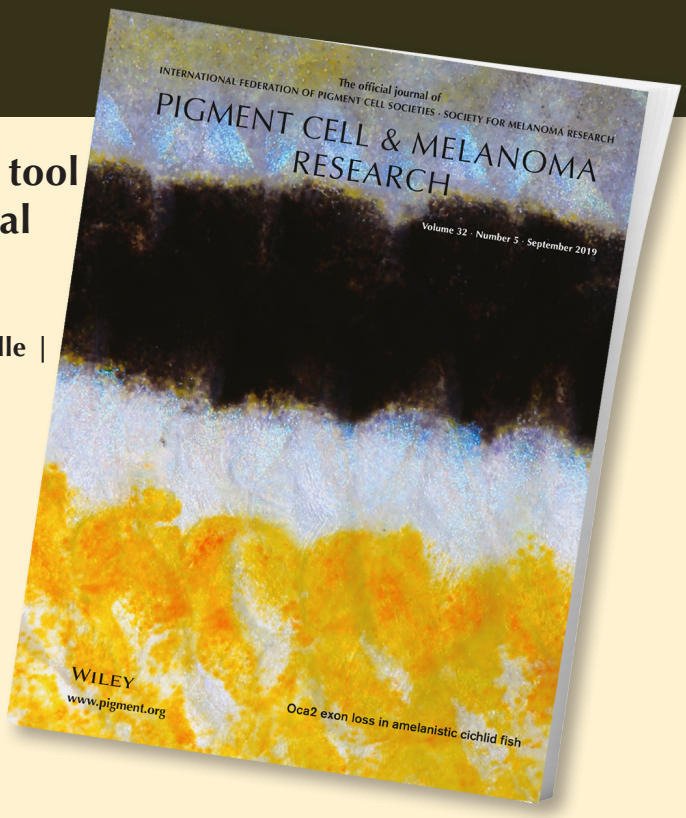

Validation of a physician global assessment tool for vitiligo extent: Results of an international vitiligo expert meeting

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DOI: 10.1111/pcmr.12784

Volume 32, Issue 5, Pages 728–733

Received: 13 December 2018 | Revised: 10 March 2019 | Accepted: 27 March 2019

DOI: 10.1111/pcmr.12784

SHORT COMMUNICATION

WILEY

Validation of a physician global assessment tool for vitiligo extent: Results of an international vitiligo expert meeting

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Abstract

Currently, vitiligo lacks a validated Physician Global Assessment (PGA) for disease extent. This PGA can be used to stratify and interpret the numeric scores obtained by the Vitiligo Extent Score (VES). We investigated the interrater reliability of a 5-point PGA scale during an international vitiligo workshop. Vitiligo experts from five

*See Appendix 1 for Participants of the VGICC to the workshop.

Prior presentations of this work: Vitiligo Global Issues Consensus Conference (VGICC) IPCC 2017, Denver, USA, 25 August 2017, and Vitiligo International Symposium, Detroit, USA, 10 November 2018.

We would like to dedicate this work to our very dear friend and wonderful colleague Tag Anbar. He will stay in our hearts forever.

Funding information
Scientific Research Foundation-Flanders (FWO Senior Clinical Investigator), Grant/Award Number: 1831512N; Leo Foundation grant, Grant/Award Number: LF16092; EADV grant (EADV Project proposal), Grant/Award Number: 2015-030

different continents rated photographs of non-segmental vitiligo patients with varying degrees of extent with the PGA score. Good interrater agreements (intraclass correlation coefficient >0.6) were observed between the raters overall and within each continent. All hypotheses to evaluate construct validity were confirmed. Median VES values per category were for limited 1.10 [IQR: 0.21–1.67], moderate 3.17 [IQR: 1.75–6.21], extensive 9.58 [IQR: 6.21–13.03] and very extensive 42.67 [IQR: 21.20–42.67]. Defined categories for vitiligo extent can be valuable for inclusion criteria and may impact future reimbursement criteria.

KEYWORDS
body surface area, extent, global assessment, outcome measure, severity, vitiligo

Defining disease severity is a useful means to stratify patients and to guide treatment decisions in disease management. In dermatology, three well-known tools to define disease severity are found in the fields of psoriasis and eczema. The Psoriasis Area and Severity Index (PASI) is a scoring instrument to measure the severity of psoriasis, while the Scoring Atopic Dermatitis (SCORAD) and Eczema Area and Severity Index (EASI) are instruments for measuring the severity of atopic dermatitis. More importantly, in addition to a numeric score, patients can be stratified into different categories of severity. For instance, a PASI score of more than 10 has been considered to be moderate–severe psoriasis, although this stratification is still debated (Llamas-Velasco et al., 2017; Schmitt & Wozel, 2005). For the EASI, a score of 23 or more was recently suggested to be the cut-off for moderate–severe eczema (Chopra et al., 2017). The determination of the affected body surface area (BSA) is an important part in the assessment of vitiligo severity. For this purpose, we recently validated the Vitiligo Extent Score (VES) to measure the affected BSA from the physician's point of view (van Geel et al., 2016). The International Initiative for Outcomes (INFO) for vitiligo recommended the use of the VES for clinical trials (Eleftheriadou et al., 2018). The VES instrument yields a numeric score, for which the interpretability (stratification) is a significant aspect in the development of novel instruments. The relevance of interpretability was highlighted by Schmitt et al. in the Harmonizing Outcome Measures for Eczema (HOME) roadmap for the development and implementation of core outcome sets (COS), currently recognized as a standardized methodology to develop COSs in dermatology (Schmitt et al., 2015). Furthermore, this is also acknowledged in the quality criteria proposed by the COnsensus-based Standards for the selection of health Measurement INstruments (). Interpretation and stratification of scores obtained by physician-reported outcome measures are usually based on an "anchor question." The latter is dependent on the domain of interest and is generally based on Physician Global Assessment (PGA) scores, including a 5-point scale that is preferably validated in advance. For vitiligo, such validated PGA is lacking so far. A PGA score may also be useful for standardizing definitions of inclusion criteria for clinical trials, epidemiological profiling of populations or define global disease evolution over time.

Significance

In this study, we validated a Physician Global Assessment (PGA) for extent in vitiligo based on an international workshop including worldwide vitiligo experts. This PGA can be used to stratify and interpret the numeric scores obtained by other instruments (e.g., Vitiligo Extent Score). The stratification of patients according to extent scores is crucial to define inclusion criteria and may impact future reimbursement criteria.

The first aim of this study was to assess the interrater reliability and validity of a PGA score for disease extent in an international panel of vitiligo experts. The second aim was to determine the median BSA values per category for limited, moderate, extensive and very extensive vitiligo.

This study was based on a workshop conducted at the San Gallicano Institute in Rome during the Vitiligo Global Issues Consensus Conference Workshop "Outcome measurement instruments," organized from 30 November to 1 December 2016. The meeting including the workshop was announced at the local ethics committees in Rome (M Picardo) as well as in Ghent (reference number Ghent: B670201421409). Written informed consent was obtained from all patients for the use of their pictures during the workshop. Patients were selected randomly (Research Randomizer) from a pool of consecutively included patients (prior divided in different degrees of extent) recruited at the Ghent University Hospital (Ghent, Belgium).

The workshop was based on questions and a series of 219 photographs [mainly with UV pictures (97.2%)] of 20 patients with non-segmental vitiligo including different degrees of extent. Skin phototypes were II (2/20), III (13/20), IV (1/20) and V (1/20). As segmental vitiligo is known to present in a different distribution pattern, this subtype was excluded for selection.

All participating physicians were considered vitiligo experts. Photographs were presented during the workshop in a randomized

order, and the physicians were asked to score the grade of extent on the 5-point global assessment scale for each patient. This 5-point scale was defined in advance by several investigators (NvG, AW, MB, RS) and a methodologist (CP). The PGA was given to the participants with a small introduction in advance. To gather more information regarding median values per category for vitiligo extent, the total affected BSA of each patient was assessed by one expert (NvG) based on the pictures through VES.

The COSMIN checklist was used as a guidance for designing and reporting our study (Mokkink et al., 2010b, 2010a). The reliability of the PGA was evaluated by assessing the interrater agreement among all participants. The interrater agreement was calculated and interpreted from the following definitions: below 0.4 was considered poor, 0.4–0.59 was considered fair, 0.6–0.74 was considered good, and higher than 0.74 was defined as excellent (Cicchetti, 1994). The assessment of validity was based on testing hypotheses (construct validity) (Terwee et al., 2007). We tested against four hypotheses (Appendix S1), formulated by two investigators (AW and MB) and checked by a methodologist (CP). If 75% of the hypotheses were in accordance with the results, it was assumed that there is evidence for accepting the construct validity of the PGA (Terwee et al., 2007). Three comparison assessment instruments were included in the hypotheses: (a) VES (assessed by 1 vitiligo expert), (b) SA-VES (assessed by the patient for their individual situation), (c) BSA 1% rule (assessed by 1 vitiligo expert). The fourth hypothesis included an expected difference between limited and extensive vitiligo (Appendix S1).

To gather more information regarding possible categories for extent (BSA based on expert VES), the PGA scores of all raters per patient were used as anchor question.

Statistical analyses were performed using SPSS 25.0 (SPSS Science). The interrater agreement was calculated by intraclass correlation coefficient (ICC) and reported as single measures. To evaluate the construct validity, four hypotheses were formulated including correlations to other extent measures. To test the hypotheses, Pearson's correlation coefficients were calculated between PGA scores and VES, SA-VES and BSA 1% rule. Missing values were excluded from the final analysis. Outliers were investigated; 1 rater was excluded based on a negative correlation in scoring answers compared to the remaining raters ($r = -0.38$). In all cases, significance level was set at $p < 0.05$.

A total of 29 vitiligo experts from five continents participated in the workshop. Table 1 lists the number of participating physicians per continent: twenty-eight scoring sheets were suitable for analyses. A good interrater agreement (> 0.6) was observed within each separate continent that did not differ significantly (Table 1). The highest agreement was achieved for raters from North and South America (0.817; 95% CI: 0.694–0.911 and 0.720; 95% CI: 0.424–0.878, respectively). The overall agreement among all raters was 0.671 (95% CI: 0.530–0.816), which is deemed acceptable. All hypotheses formulated for validity testing were confirmed, and a high correlation was found with VES (Pearson $r = 0.932$, $p < 0.001$), SA-VES ($r = 0.877$, $p < 0.001$) and BSA 1% rule ($r = 0.932$, $p < 0.001$).

Table 2 shows the median and range of VESs per extent category. Median VES values per category were for limited 1.10 [IQR: 0.21–1.67], moderate 3.17 [IQR: 1.75–6.21], extensive 9.58 [IQR: 6.21–13.03] and very extensive 42.67 [IQR: 21.20–42.67]. Figure 1 includes a box plot representing four categories of extent.

Based on the low sample size, exact cut-off points per category could not be defined in this study.

In this study, we validated a PGA for extent assessment in vitiligo using a simple scoring system based on a single question ranging from no involvement to very extensive. The PGA is an intuitive and simple measure that is often used in clinical trials, also known as the Investigator Global Assessment (IGA). The stratification of patients according to extent scores is crucial to perform research on homogenous study populations but can also be a useful tool in future reimbursement criteria. Psoriasis is categorized into mild, moderate and extensive, and this categorization is widely used both as a selection criterion for clinical trials and reimbursement of expensive drugs such as biologicals. Importantly, severity in vitiligo is more than disease extent only. Yet, a PGA of disease extent would be a simple and objective tool to categorize vitiligo patients facilitating the interpretation of clinical trials. The availability of such an important instrument to better define severity is pragmatic. However, this instrument often lacks validity studies (Schmitt, Langan, Williams, & Network, 2007). In this pilot project, it was evident that the tool was easy to use and required no or minimal training in an international setting. Here, we confirm the acceptable interrater reliability based on international vitiligo experts from five continents. Satisfactory interrater agreements were observed, especially in North America. Furthermore, the

TABLE 1 Geographic origins of vitiligo experts present and intraclass correlation coefficients

Continent	Vitiligo experts (*n*)	ICC; 95% CI
Europe	7	0.647; 0.451–0.816
Asia	9	0.630; 0.464–0.796
Africa	4	0.658; 0.462–0.824
North America	6	0.817; 0.694–0.911
South America	2	0.720; 0.424–0.878
Overall	28	0.671; 0.530–0.816

TABLE 2 PGA categories based on median VESs

PGA categories[a]	Median VES (%)	IQR	95% CI for the median
Limited extent	1.10	0.21–1.67	1.07–1.10
Moderate extent	3.17	1.75–6.21	2.69–3.55
Extensive	9.58	6.21–13.03	7.72–11.44
Very extensive	42.67	21.20–42.67	30.02–42.67

Notes: CI, confidence interval; IQR, interquartile range; PGA, Physician Global Assessment; VES, Vitiligo Extent Score.
[a]Assessed by all raters.

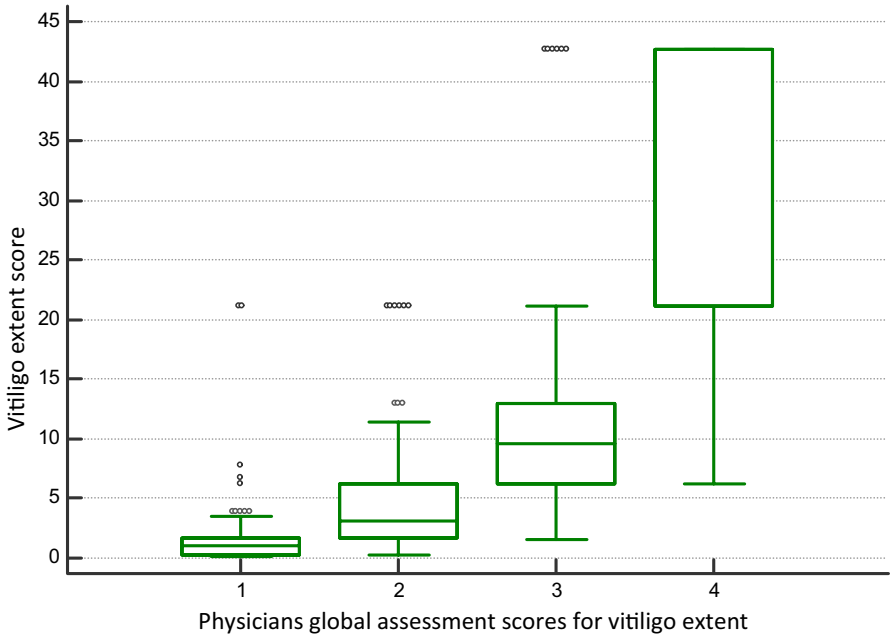

FIGURE 1 Box plot representing four categories of extent. Cases were rated based on photographs by the raters using a Physician Global Assessment score for extent (x-axis 1: limited; 2: moderate; 3: extensive; and 4: very extensive). The VES of all cases was assessed by a vitiligo expert. Bars represent median ± lower and upper limit. Number of raters' PGA scores per category: limited 197; moderate 212; extensive 112; and very extensive 33

PGA significantly and positively correlated with the VES. Using a PGA-anchor question, the median values of the VES per category could be assessed. In comparison, a BSA score of more than 10% is considered as moderate psoriasis—here, a median VES of 3.17 was already considered as moderate extent. Unfortunately, exact cut-off VESs for each extent category could not be assessed in this study due to the low sample size. Moreover, based on practical limitations, a second scoring round to assess the intra-rater agreement was not performed. For these aspects, further research will be required. Similarly, an additional study, assessing more patients of skin types V and VI will be of interest. However, as the focus of this study was *extent* (surface area affected) and not *severity* (taken into account possible additional aspects to vitiligo extent as for instance skin type, location of lesions and disease activity), and UV pictures were used in most of the cases, we believe any possible bias due to skin phototype is mainly applicable for a PGA based on *severity*. One important critical note related to this study is that all participating physicians were experienced vitiligo experts from different continents, which can be considered as a possible advantage for the stratification into categories, but consequently may have contributed to the relatively high reliability reported in this study. Therefore, it could be valuable to repeat this evaluation within a group including dermatologists considered as non-expert in vitiligo. Another point of attention in this study was that the number of vitiligo experts of South America was low (n = 2); however, as the ICC was within the range of all the other continents, this was considered to be useable. Furthermore, only extent was assessed here, whereas assessment of severity may contribute to a greater interrater variability. However, severity assessment requires the dimension of the patient's point of view as well. Insight into patients' experiences is crucial to properly define severity in a way that is both useful to the physician and reflective of the patient's status. For instance, location of lesions or disease activity is often not included in a PGA as a separate aspect but may significantly impact the patient's experience—especially for a skin disease like vitiligo. This brings up a limitation of a tool only focusing on extent. Therefore, a thorough investigation within the (international) vitiligo patient population may offer additional criteria to better define vitiligo severity. Also, the lack of validation in a clinical trial intervention is an item that will have to be addressed in the future.

In conclusion, this study demonstrated the possible categorization of extent in vitiligo, with good corresponding results among physicians worldwide. We also provide a first guide for the interpretation of the numerical output of the VES based on a physician global assessment. The relatively low median BSA value for moderate extent indicates that clinical decisions will be already impacted in the initial categories of body area involvement. Future studies are necessary to confirm our findings.

ACKNOWLEDGEMENT

We thank all participants of the VGICC workshop, with a very special word of gratitude to our dear friend Tag Anbar (in memoriam). We would like to express our gratitude to the volunteering patients for the use of their pictures during the workshop. We acknowledge the Vitiligo International Symposium (VIS) and the Vitiligo Global Issues Consensus Conference (VIGCC) groups as a supporting organizing source of the workshop. Funding sources related to the workshop and/or analyses afterwards: EADV grant (EADV Project proposal reference number 2015-030) and LEO Foundation grant (Leo Foundation project reference number LF16092). The research activities of N. van Geel are supported by the Scientific Research Foundation-Flanders (FWO Senior Clinical Investigator: 1831512N).

We would like to thank I. Sperduti for local (Italy) statistical support and T. Mostien for assistance in processing of data.

CONFLICT OF INTEREST

Nanja van Geel : consultant and/or investigator in Pfizer, Laboratoire Génévrier, Incyte. Drs van Geel, Speeckaert, Wolkerstorfer, Bekkenk, Lommerts and Prinsen were involved to a certain extent in the preparative stage of the PGA score used. Albert Wolkerstorfer was consultant in Incyte, is investigator in Novartis, and received a research grant from AvitaMedical. Iltefat Hamzavi was a consultant in Incyte and received fees; an investigator in Bayer (grant paid to institution); an investigator in Johnson and Johnson (provided equipment to institution); an investigator in Incyte, Estee Lauder, Unigen Inc, Allergan and Ferndale Laboratories (grant paid to institution); a consultant in Pfizer and received fees; and co-chair in Global Vitiligo Foundation and played a non-compensated role. Amit G. Pandya was a consultant in Sun pharmaceuticals and TWi pharmaceuticals; an investigator for Aclaris pharmaceuticals, Incyte pharmaceuticals and Pfizer pharmaceuticals; and was the board of directors and owned stock options with Clarify Medical.

ETHICS

The meeting including the workshop was announced at the local ethics committees San Gallicano Institute, Rome (M Picardo), as well as approved in Ghent (reference number Ghent: B670201421409).

DATA AVAILABILITY STATEMENT

The study design, material and methods (including the PGA score) and methodology that support the findings of this study are available on request from the corresponding author. The database is not available due to privacy and ethical restrictions.

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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section at the end of the article.

How to cite this article: van Geel N, Wolkerstorfer A, Ezzedine K, et al; On behalf of all the participants of the Rome International VGICC /VIS Workshop. Validation of a physician global assessment tool for vitiligo extent: Results of an international vitiligo expert meeting. *Pigment Cell Melanoma Res*. 2019;32:728–733. https://doi.org/10.1111/pcmr.12784

APPENDIX 1

Participants of the VGICC to the workshop

Tag Anbar (Egypt)†, Mohamed Anbar (Egypt), Laïla Benzekri (Morocco), Marcel Bekkenk (Netherlands), Markus Böhm (Germany), Caïo Castro (Brasil), Tania Cestari (Brasil), Samia Esmat (Egypt), Viktoria Eleftheriadou (United Kingdom), Khaled Ezzedine (France), Yvon Gauthier (France), Maria Gnarra (Italy), Iltefat Hamzavi (USA), John E. Harris (USA), Jorge Hinojosa (USA), Min Bae Jung (S Korea), Hee Young Kang (S Korea), Ichiro Katayama (Japan), Ki-Ho Kim (S Korea), Prasad Kumarasinghe (Australia), Cheng-Che Eric Lan (Taiwan), Seung-Chung Lee (S Korea), Caroline Le Poole (USA), Henry Lim (USA), Silvia Moretti (Italy), Amit Pandya (USA), Mauro Picardo (Italy), Davinder Parsad (India), Noufal Raboobee (South Africa), Julien Seneschal (France), Reinhart Speeckaert (Belgium), Richard Spritz (USA), Tamio Suzuki (Japan), Alain Taieb (France), Nanja van Geel (Belgium), Albert Wolkerstorfer (Netherlands) and Flora Xiang (Rep China).