

The Static Physician's Global Assessment of Genitalia: A Clinical Outcome Measure for the Severity of Genital Psoriasis

Joseph F. Merola MD MMSc,[a] Alison Potts Bleakman PhD,[b] Alice B. Gottlieb MD PhD,[c] Alan Menter MD,[d] April N. Naegeli PhD,[b] Robert Bissonnette MD MS FAAD FRCPC,[e] Lyn Guenther MD FRCPC,[f] John Sullivan MBBS MS,[g] Kim Meeuwis MD PhD,[h] Kyoungah See PhD,[b] and Kristina Callis Duffin MD MS[i]

[a]Department of Dermatology and Medicine, Division of Rheumatology, Harvard Medical School, Brigham and Women's Hospital, Boston, MA, USA
[b]Eli Lilly and Company, Indianapolis, IN, USA
[c]Department of Dermatology, New York Medical College at Metropolitan Hospital, New York, NY, USA
[d]Department of Dermatology, Baylor University Medical Center, Dallas, TX, USA
[e]Innovaderm Research, Montreal, QC, Canada
[f]The Guenther Dermatology Research Centre, London, ON, Canada
[g]Department of Medicine, UNSW, Sydney, New South Wales, Australia
[h]Department of Dermatology, Radboud University Medical Center, Nijmegen, The Netherlands
[i]Department of Dermatology, University of Utah, Salt Lake City, UT, USA

ABSTRACT

Introduction: Genital psoriasis is a common but frequently overlooked manifestation of psoriasis with a considerable impact on patients' quality of life. Currently no validated clinical trial outcome measures exist to assess genital psoriasis severity that meet regulatory agency requirements.

Methods: This study describes the development of the static Physician's Global Assessment of Genitalia (sPGA-G) scale, a clinical outcome measure for the assessment of genital psoriasis severity that accounts for the erythematous clinical presentation of genital psoriasis. The reliability of the sPGA-G was evaluated using scores collected from clinician assessments of photographs of genital psoriasis cases. Scores were collected from 10 academic and clinical experts in genital psoriasis and 95 clinician assessors who participated in either in-person (n=28) or online (n=67) sPGA-G training modules.

Results: The sPGA-G had a high inter-rater reliability (IRR, measured by Kendall's W) for expert raters (W=0.856, $P<0.0001$), in-person assessors (W=0.822, $P<0.0001$), and online assessors (W=0.678, $P<0.0001$). IRR was also high for all clinical assessors combined, (W=0.714, $P<0.0001$).

Discussion: This study demonstrates that the sPGA-G is an intuitive and reliable clinical outcome measure that specifically measures the severity of genital psoriasis.

J Drugs Dermatol. 2017;16(8):793-799.

INTRODUCTION

Psoriasis is a chronic immune-mediated skin disorder affecting approxmiately 2% to 3% of adults in the United States and 0.5% to 8.5% globally.[1] Questionnaire-based studies estimate that 28.6% to 45.5% of patients with psoriasis are affected by genital psoriasis.[2-4] Recent studies involving a physical examination of patients with psoriasis indicate that 38% have current genital involvement and 63% develop genital psoriasis at least once over the course of their disease.[5,6] Because of friction, moisture, and maceration in the genital region, genital psoriasis is characterized by thin, symmetrical, and bright red plaques with well-defined edges, generally lacking the characteristic scale and thickness observed on other body areas.[3,7] Genital psoriasis also has a considerable impact on patient quality of life by affecting daily activities, social interactions, and sexual health.[5,8] Guidelines for the treatment of psoriasis suggest that cases of mild psoriasis with genital involvement may justify classification as moderate or severe disease and may warrant systemic treatment, especially if topical treatments are ineffective.[9-12]

Because genital psoriasis is a high burden[5,8] subset of disease that is often overlooked or misdiagnosed,[3,7,9,13,14] there is a scientific need for validated outcome measures that meet the requirements of the Food and Drug Administration (FDA) and other regulatory agencies for use in assessing genital psoriasis severity in clinical trials. Few clinical outcome measures exist for the assessment of genital psoriasis, and none are well established or appropriately validated. The Static Physician's Global Assessment of Genitalia (sPGA-G) scale is a well-defined clinician reported outcome measure developed to evaluate the severity of genital psoriasis. The objective of this study is to describe the sPGA-G scale, the methodology used

in its development, and to determine its reliability by analyzing assessment scores from clinicians involved in evaluating photographs of patients with genital psoriasis.

MATERIALS AND METHODS

sPGA-G Development and Assessment Instructions

An advisory group of five global experts on genital psoriasis was formed in collaboration with Eli Lilly and Company to develop the sPGA-G for the assessment of genital psoriasis in clinical trials. Advisor input was incorporated into the design of the scale, the assessment instructions, and the associated training and clinical certification materials based on their clinical experience in treating patients with genital psoriasis.

The sPGA-G is a 6-point numerical scale ranging from 0 (clear) to 5 (very severe) to assess genital psoriasis severity at a given time point (Table 1). In order to ensure consistency between assessments in clinical trials, the sPGA-G assessment area was precisely defined using guidance from the advisors and in consideration of the areas defined in the modified Genital Psoriasis Area and Severity Index (mGPASI).[5,15] The assessment area includes the vulvar region from the clitoral prepuce to the perineum, including the labia majora, labia minora, and perineum for females, and the penis, scrotum, and perineum for males. The sPGA-G assessment does not include the pubis, inguinal folds, peri-anal region, or the gluteal cleft.

Consistent with other sPGA scales used in clinical trials for the assessment of plaque psoriasis, the sPGA-G evaluates three clinical features of genital psoriatic lesions: erythema, plaque elevation, and scale. Not all three individual features are always present on evaluation, especially the latter two. Thus, while the overall score represents a combination of all three features, it should primarily be determined by the degree of erythema, as erythema is the dominant feature in the majority of cases of genital psoriasis.[3,7,13]

Erythema descriptions distinguish each severity level. A score of 0 (clear) represents the absence of erythema with or without residual post-inflammatory hyper- or hypo-pigmentation. The descriptions and associated scores for erythema are: (1) light pink (minimal), (2) pink to light red (mild), (3) definite red (moderate), (4) bright red (severe), and (5) extreme, deep red (very severe).

The severity of elevation is determined by plaque thickness relative to the surrounding skin (eg, indistinct, slight, or marked elevation) together with the sharpness of plaque edges (eg, indistinct, sloped, or hard and sharp edges). Scaling severity is determined by the extensiveness of scale (eg, scale absent or present on some, most, or all plaques) plus scale roughness and adherence (eg, fine, coarse and non-adherent, or coarse and adherent scale).

The sPGA-G was reviewed and approved by the advisory group and additional experts on genital psoriasis and clinical outcome measures. Additional review was conducted by Eli Lilly and Company employees specializing in developing clinical outcomes measures for use in evaluating treatment benefit in clinical trials in accordance with FDA guidelines.

Patient Photographs

Photographs of suspected cases of genital psoriasis were obtained from dermnetnz.org, VisualDx, ScienceSource, and a dermatologist experienced with genital psoriasis diagnosis. All patients provided written informed consent and all photographs were de-identified. Photographs were reviewed and selected by an academic dermatologist (JFM) with extensive

TABLE 1.

The Static Physician Global Assessment of Genitalia

Score[1]	Category	Category Description[2]
0	Clear	Erythema: residual or no erythema Plaque elevation: no elevation Scaling: no scale
1	Minimal	Erythema: faint, light pink erythema Plaque elevation: elevation is very slight and difficult to confirm Scaling: some fine, white surface dryness
2	Mild	Erythema: mild, pink erythema Plaque elevation: slight elevation with sloped edges Scaling: fine scale on some or most lesions
3	Moderate	Erythema: moderate, red erythema Plaque elevation: moderate elevation with definite edges that are either sloped or rough Scaling: coarse scale on most lesions
4	Severe	Erythema: severe, bright red erythema Plaque elevation: substantial elevation, hard or sharp edges Scaling: coarse, non-adherent scale on most to all lesions
5	Very Severe	Erythema: very severe, deep red erythema Plaque elevation: very significant elevation with hard and sharp edges Scaling: very coarse, thick, and adherent scale completely or nearly completely covering most or all lesions.

Copyright of the Static Physician Global Assessment of Genitalia is reserved by Eli Lilly and Company. For permission to reproduce or use the sPGA of genitalia, please contact copyright@lilly.com.

[1]The final sPGA-G score is on a 0-5 scale. Each score is associated with a severity category.

[2]Severity is determined by a combination of 3 plaque characteristics (erythema, elevation, and scale) based on descriptions of each characteristic. Erythema is the primary characteristic that should influence the rating, with plaque elevation and scaling considered secondarily. Assessment does not require all three characteristics to be present.

clinical experience with genital psoriasis. Photographs were selected if the reviewer confirmed that the image was a case of genital psoriasis, if the image quality was high (eg, in-focus, well lit, and lacking obstructions of the affected area), and no comorbid conditions (eg, candidiasis) were present that could interfere with sPGA-G assessment. Fifty photographs were selected to represent a full spectrum of severity levels (including "clear") in both female and male patients.

Ten experts in genital psoriasis rated photographs using the sPGA-G. The expert raters were from multiple global regions, including the United States, the European Union, Canada, and Australia. Expert rater specialties and clinical expertise included dermatology, psoriasis, psoriatic arthritis, venereology, and genital dermatology. Seven of ten expert raters had previous experience in clinical outcome measure development. The expert raters had ≥7 years of experience in clinical trials (mean, 20.4 years) and ≥9 years of experience in assessing and diagnosing both psoriasis (mean, 22.6 years) and genital psoriasis (mean,17.9 years).

Nineteen photographs (11 male and 8 female) were selected by the expert raters for use in the sPGA-G training and certification materials. Photographs were selected if they (1) satisfied the initial photograph selection criteria (utilizing feedback from the larger group of experts), (2) provided sufficient detail to make an accurate assessment using the sPGA-G, and (3) if the majority (>50%) of expert raters had assigned the same score using the sPGA-G. Final photographs were selected to represent both male and female genital psoriasis across a broad range of severities. Photograph licensing for inclusion in the training materials was completed as required.

sPGA-G Training Modules

The sPGA-G training module included an overview of the sPGA-G scale and guidelines for its use (with a particular emphasis on the importance of erythema), examples of its application in assessing the full range of severity levels for both males and females (as illustrated by patient photographs), and a training examination consisting of 9 photographs (5 male, 4 female).

Assessors completed the training examination by providing their best assessment of each photograph using the sPGA-G scale. Assessor scores were compared to the score range assigned by expert raters for the corresponding photograph. If an assessor's score was within the range assigned by expert raters, it was marked correct. In order to pass training and to become certified to use the sPGA-G in clinical trials, assessors had to assign correct scores for 7 of 9 photographs. Training modules were provided both in-person and online. The in-person training module was delivered as a formal presentation of the training materials followed by the examination. Either a response sheet or an electronic voting response system was used to collect answers. The online training was a narrated computer-based module, identical in content to the in-person training.

Statistical Analysis

Scores from expert raters during photograph selection and from the training examination were analyzed for inter-rater reliability (IRR) using Kendall's coefficient of concordance (Kendall's W). Analysis groups included scores from expert raters, in-person assessors, online assessors, and a combined group of the in-person and online assessors. Comparisons between groups were applied using chi-square and Kolmogorov-Smirnov tests comparing the proportion of correct responses and score distribution, respectively. All other values are summarized using descriptive statistics.

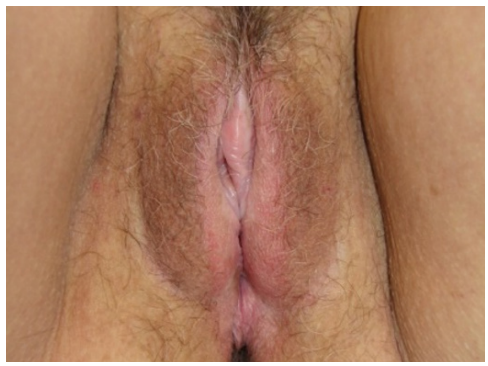
RESULTS

Assessment of Genital Psoriasis Using the sPGA-G

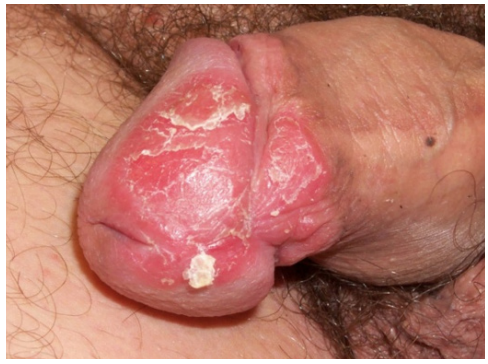
Representative examples of female and male genital psoriasis and their associated sPGA-G scores are provided in Figure 1. Figure 1A shows a case of genital psoriasis in a female patient

FIGURE 1. sPGA-G assessment of genital psoriasis. Photographic examples of genital psoriasis in female (A) and male (B) patients. Based on majority scores from 10 experts in genital psoriasis, the sPGA-G score best representing the severity of genital psoriasis in panel (A) is 1 (minimal) and in panel (B) is 4 (severe).
Photos published with permission from DermnetNZ. For permission to reproduce or reuse, please contact www.dermnetnz.org.

(A)



(B)



with faintly visible erythema and no obvious signs of plaque elevation or scale. This photograph best corresponds to a sPGA-G assessment of 1 (minimal). Figure 1B shows a case of male genital psoriasis characterized by bright red erythema, coarse and adherent scaling, and mild-to-moderate elevation. Overall, this case best corresponds to a sPGA-G score of 4 (severe).

Evaluation of sPGA-G Reliability

Results from expert rater assessments of 19 photographs included in the sPGA-G assessor training module are provided in Table 2. A total of 95 clinician assessors participated in either an in-person (n=28) or online (n=67) standardized training module for the sPGA-G scale. For the in-person training, all assessors (28, 100%) passed the training module on their first attempt: 19 (67.9%) passed with 9/9 (100%) correct, 8 (28.6%) passed with 8/9 (88.9%) correct, and 1 (3.6%) passed with 7/9 (78%) correct.

TABLE 2.

Results from Expert Rater Assessment of 19 Photographs Used in the sPGA-G Training Materials

Photograph	Sex	Majority Score[1]	Rater Scores Score (# of raters)[2]	Used for Examination[3]
1	F	0	0 (8), 1 (2)	No
2	F	1	1 (6), 2 (4)	Yes
3	F	2	2 (9), 3 (1)	Yes
4	F	2	1 (3), 2 (7)	Yes
5	F	3	2 (3), 3 (7)	No
6	F	3	2 (4), 3 (6)	No
7	F	4	4 (6), 5 (4)	No
8	F	4	4 (7), 5 (3)	Yes
9[4]	M	0	0 (8), 1 (2)	No
10	M	1	1 (10)	No
11	M	2	1 (2), 2 (7), 3 (1)	Yes
12	M	2	2 (9), 3 (1)	Yes
13	M	3	2 (2), 3 (8)	Yes
14	M	3	3 (9), 4 (1)	No
15	M	3	2 (2), 3 (6), 4 (2)	Yes
16	M	4	4 (8), 5 (2)	Yes
17	M	4	3 (1), 4 (7), 5 (2)	No
18	M	5	4 (3), 5 (7)	No
19	M	5	4 (3), 5 (7)	No

[1]Majority score is the most frequent score assigned by raters.
[2]For each photograph, rater scores are listed with the number of raters who assigned the corresponding score.
[3]Nine photographs assessed by expert raters were used for the training examination (see Table 3). The remaining 10 photographs were used as examples in the training materials.
[4]Photograph 9 was digitally modified from photograph 10 to reduce apparent disease severity, with permission from the photograph provider.

In the online training module, 66 (98.5%) completed the examination. Of those who completed the training examination 64 (97.0%) passed on the first attempt: 31 (47.0%) passed with 9/9 correct, 27 (40.9%) passed with 8/9 correct, and 6 (9.1%) passed with 7/9 correct. Two (3.0%) assessors did not pass the training module on the first attempt (Scores: 5/9 and 6/9 correct). After reviewing the training module a second time, both passed on a second attempt with 9/9 correct. One assessor passed the training module on the first attempt with 7/9 correct but did not provide an answer for one of the two questions marked incorrect.

Overall, IRR was high within each analysis group as determined by Kendall's coefficient of concordance (Kendall's W). For the expert raters, the Kendall's W was 0.856 ($P<0.0001$). For in-person and online assessors, Kendall's W was 0.822 ($P<0.0001$) and 0.678 ($P<0.0001$), respectively. For the combined group of all assessors (online and in-person), Kendall's W was 0.714 ($P<0.0001$). Variability was low when comparing the proportion of correct responses (Chi Square) and the distribution of scores (Kolmogorov-Smirnov) between assessor groups (Table 3).

DISCUSSION

Genital psoriasis is a common feature of patients with plaque psoriasis associated with a significant reduction in quality of life, self-esteem, and sexual health compared to psoriasis patients without genital involvement.[5,8,16] Despite its prevalence and burden, genital psoriasis is frequently misdiagnosed or left untreated because of either insufficient communication between health care providers (HCPs) and patients or a lack of routine examination of genital psoriasis by HCPs.[7,9,13] The erythematous presentation of genital psoriasis can also contribute to its misidentification as atopic dermatitis, candidiasis, tinea, or sexually transmitted diseases.[3,14]

Clinical outcome measures, such as the Psoriasis Area and Severity Index (PASI) and the Static Physician's Global Assessment (sPGA) assess overall psoriasis severity and are routinely used as primary or secondary endpoints in clinical trials.[17-19] However, there have been no large scale clinical trials for genital psoriasis, with tools to measure its severity being limited. Those tools that do exist[20-22] have not been widely used or appropriately validated.

Currently, the most well established clinical outcome measure for genital psoriasis is the modified genital PASI (mGPASI), derived from the overall PASI scale.[5,15] However, the mGPASI requires assessors to determine the percentage of involvement of the genital area, which may be challenging given the small body surface involved (approximately 1% of the overall body surface).[23] In addition, the mGPASI does not account for the predominantly erythematous presentation of genital psoriatic lesions. Moreover, regulatory agencies including the FDA and the European

TABLE 3.

Comparison Between Assessor Groups in sPGA-G Assessments

Question	Photograph[1]	Expert vs In-person		Expert vs Online		In-person vs Online	
		Chi Square (*P*-value)	Kolmogorov-Smirnov (*P*-value)	Chi Square (*P*-value)	Kolmogorov-Smirnov (*P*-value)	Chi Square (*P*-value)	Kolmogorov-Smirnov (*P*-value)
1	13	N/A[2]	0.91 (0.38)	1.36 (0.24)	1.31 (0.06)	3.71 (0.05)	0.49 (0.97)
2	2	0.75 (0.39)	0.27 (1.00)	1.17 (0.28)	0.50 (0.96)	0.27 (0.60)	0.31 (1.00)
3	12	1.60 (0.21)	1.09 (0.19)	1.36 (0.24)	1.05 (0.23)	0.08 (0.77)	0.20 (1.00)
4	3	0.75 (0.39)	0.50 (0.96)	1.17 (0.28)	0.73 (0.66)	0.27 (0.60)	0.28 (1.00)
5	16	N/A[2]	0.04 (1.00)	0.81 (0.37)	0.22 (1.00)	2.24 (0.13)	0.34 (1.00)
6	11	0.37 (0.55)	0.16 (0.14)	0.47 (0.49)	0.75 (0.63)	0.05 (0.83)	0.86 (0.45)
7	8	N/A[2]	0.45 (0.99)	0.31 (0.58)	0.14 (1.00)	0.87 (0.35)	0.51 (0.95)
8	15	N/A[2]	0.54 (0.93)	0.31 (0.58)	0.48 (0.97)	0.87 (0.35)	1.45 (0.03)
9	4	0.37 (0.55)	0.45 (0.99)	0.64 (0.42)	0.37 (1.00)	0.24 (0.62)	0.18 (1.00)

[1]Photograph number matches Table 1.
[2]N/A indicates that the Chi Square result could not be calculated due to all participants getting a correct answer for this question.

Medicines Agency recommend including a Physician's Global Assessment as an efficacy endpoint for psoriasis clinical trials.[24-27]

The sPGA-G was developed as a collaborative effort between academic and clinical dermatologists and Eli Lilly and Company as an efficacy outcome measure for clinical trials in patients with genital psoriasis. The sPGA-G emphasizes erythema during assessment given the erythematous clinical presentation of genital psoriasis and because erythema is considered the most significant physical characteristic by patients with genital psoriasis.[13] Because the sPGA-G was designed to evaluate psoriasis affecting the genitalia, it does not assess adjacent body regions such as the perianal area. It also does not assess secondary features of genital psoriasis such as erosion, fissures, and secondary candidiasis.[7] In clinical practice, HCPs should still consider the impact of these additional features and body sites when treating patients with genital psoriasis.

In this study, there was a high degree of concordance between raters and assessors using the sPGA-G. However, there are limitations to these analyses. For example, the number of experts in the area of genital psoriasis is currently small. In addition, the availability of high quality photographs of genital psoriasis that have the required patient consent for use in training materials is limited. Moreover, photographs may limit the ability of raters to fully assess physical characteristics as compared to a physical examination.

In summary, genital psoriasis is a common and often overlooked manifestation of psoriasis yet to be studied in a large-scale clinical trial. It is essential that reliable outcome measures for genital psoriasis are available for use as clinical trial endpoints. The sPGA-G scale was developed as a collaboration between clinical, academic, and industry experts to address this unmet need. The results presented here indicate that the sPGA-G should be considered a well-defined outcome measure in the clinical assessment of the severity of genital psoriasis, present in up to 60% of psoriasis patients.[5]

DISCLOSURES

J. F. Merola is a consultant/advisor for Biogen IDEC, AbbVie, Amgen, Eli Lilly and Company, Novartis, Pfizer, Janssen, UCB, Kiniksa, and Momenta and Mallinckrodt; is on the advisory board for Biogen IDEC, AbbVie, Amgen, Eli Lilly and Company, Novartis, Pfizer, Janssen, UCB, Kiniksa, and Momenta and Mallinckrodt; is a speaker for AbbVie, is an investigator for Biogen IDEC, Amgen, Pfizer, and Boehringer Ingelheim; has received grant support from Biogen IDEC; and has a licensed outcome measure for AbbVie.

A.B. Gottlieb is a consultant/advisory board member for Amgen, Astellas, Akros, Centocor (Janssen), Celgene, Bristol Myers Squibb, Beiersdorf, Abbot Labs (Abbvie), TEVA, Actelion, UCB, Novo Nordisk, Novartis, Dermipsor, Incyte, Pfizer, Canfite, Eli Lilly and Company, Coronado, Vertex, Karyopharm, CSL Behring Biotherapies for Life, Glaxo Smith Kline, Xenoport, Catabasis, Meiji Seika Pharma, Takeda, Mitsubishi, Tanabe Pharma Development America, Genentech, Baxalta, Kineta One, KPI Therapeutics, Crescendo Bioscience, Aclaris, Amicus, Reddy labs, Valeant, Dermira, and Allergan. Dr Gottlieb also received research/educational grants from Centocor (Janssen), Amgen, Abbott (Abbvie), Novartis, Celgene, Pfizer, Eli Lilly and Company, Levia, Merck, Xenoport, Dermira, and Baxalta.

A. Menter is an advisory board member for AbbVie, Allergan, Amgen, Boehringer Ingelheim, Eli Lilly and Company, Janssen

Biotech, and LEO Pharma; is a consultant for AbbVie, Allergan, Amgen, Eli Lilly and Company, Janssen Biotech, and LEO Pharma; is an investigator for AbbVie, Amgen, Boehringer Ingelheim, Celgene, Dermira, Eli Lilly and Company, Janssen Biotech, LEO Pharma, Merck, Neothetics, Novartis, Pfizer, Regeneron, and Syntrix; and is a speaker for AbbVie, Amgen, Janssen Biotech, and LEO Pharma. He has received grant support from AbbVie, Amgen, Boehringer Ingelheim, Cellgene, Dermira, Janssen Biotech, LEO Pharma, Merck, Neothetics, Novartis, Pfizer, Regeneron, and Syntrix; and has received honoraria from AbbVie, Allergan, Amgen, Boehringer Ingelheim, Eli Lilly and Company, Galderma, Janssen Biotech, LEO Pharma, Novartis, and Pfizer.

R. Bissonnette is an advisory board member and has received honoraria from AbbVie, Amgen, BMS, Janssen, and Merck; is a consultant for and receives honoraria from AbbVie, Amgen, Celgene, Eli Lilly and Company, Galderma, Incyte, Janssen, Leo Pharma, Merck, and Novartis; is a speaker for and receives honoraria from AbbVie, Amgen, Galderma, Janssen, Leo Pharma and Merck; is an investigator for, and his institution receives grant support from, AbbVie, Amgen, Boehringer Ingelheim, Celgene, Eli Lilly and Company, Galderma, GSK Steifel, Merck, Novartis, Pfizer, Kineta, Incyte, Janssen, and Leo Pharma.

L. Guenther has received research grants from, and has been a speaker and consultant for, Abbvie, Amgen, Celgene, Eli Lilly, Galderma, Glaxo Smith Kline, Janssen, Leo pharma, Merck Frosst, Novartis, Pfizer, Roche and Valeant. Dr. Guenther also received research grants from Boehringer Ingelheim, and has been a speaker for, and consultant to, Tribute.

J. Sullivan is a consultant and advisory board member for Abbvie, Celgene, Eli Lilly and Company, Leo Pharma, and Novartis.

K. Meeuwis is a consultant and received honoraria from Eli Lilly and Company, and Eucerin and has been an advisory board member and received honoraria from Eucerin, Netherlands.

K. Callis Duffin is a consultant and advisory board member for Amgen, Eli Lilly and Company, Janssen, Stiefel, AbbVie, Bristol-Myers Squibb, Celgene, Pfizer, Novartis, and Boehringer Ingelheim. She has received grant/research support from Amgen, Eli Lilly and Company, Janssen, Stiefel, AbbVie, Bristol-Myers Squibb, Celgene, Novartis, Regeneron, and Boehringer Ingelheim.

A. Potts Bleakman, A. N. Naegeli, and K. See own stock and are employees of Eli Lilly and Company.

ACKNOWLEDGMENTS

The authors thank Caitriona Ryan MD, Scott Fretzin MD, Lotus Mallbris MD PhD, and Abrar Qureshi MD MPH for valuable scientific feedback on the development of the sPGA of Genitalia scale. The authors thank Amanda Oakley MBChB FRACP PGDipHealInf FNZDS (DermNet NZ) for her assistance in acquiring patient photographs. The authors thank Missy McKean-Matthews, MS, a statistician at inVentiv Health Clinical for providing statistical support. The authors also thank Clinton C. Bertram PhD, a medical writer and employee of Eli Lilly and Company, for writing support.

REFERENCES

1. Rachakonda TD, Schupp CW , Armstrong AW. Psoriasis prevalence among adults in the United States. *J Am Acad Dermatol* 2014;70:512-6.
2. Fouere S, Adjadj L , Pawin H. How patients experience psoriasis: results from a European survey. J Eur *Acad Dermatol Venereol* 2005;19 Suppl 3:2-6.
3. Meeuwis KA, de Hullu JA, Massuger LF et al. Genital psoriasis: A systematic literature review on this hidden skin disease. *Acta Derm Venereol* 2011;91:5-11.
4. Meeuwis KA, de Hullu JA, de Jager ME et al. Genital psoriasis: a questionnaire-based survey on a concealed skin disease in the Netherlands. *J Eur Acad Dermatol Venereol* 2010;24:1425-30.
5. Ryan C, Sadlier M, De Vol E et al. Genital psoriasis is associated with significant impairment in quality of life and sexual functioning. *J Am Acad Dermatol* 2015;72:978-83.
6. Ji S, Zang Z, Ma H et al. Erectile dysfunction in patients with plaque psoriasis: the relation of depression and cardiovascular factors. *Int J Impot Res* 2016;28:96-100.
7. Meeuwis KA, de Hullu JA, IntHout J et al. Genital psoriasis awareness program: physical and psychological care for patients with genital psoriasis. *Acta Derm Venereol* 2015;95:211-6.
8. Meeuwis KA, de Hullu JA, van de Nieuwenhof HP et al. Quality of life and sexual health in patients with genital psoriasis. *Br J Dermatol* 2011;164:1247-55.
9. American Academy of Dermatology Work Group, Menter A, Korman NJ et al. Guidelines of care for the management of psoriasis and psoriatic arthritis: section 6. Guidelines of care for the treatment of psoriasis and psoriatic arthritis: case-based presentations and evidence-based conclusions. J *Am Acad Dermatol* 2011;65:137-74.
10. Canadian Dermatology Association. Canadian Guidelines for the Management of Plaque Psoriasis. Available at: http://www.dermatology.ca/wp-content/uploads/2012/01/cdnpsoriasisguidelines.pdf. Accessed September 13, 2016.
11. Mrowietz U, Kragballe K, Reich K et al. Definition of treatment goals for moderate to severe psoriasis: a European consensus. *Arch Dermatol Res* 2011;303:1-10.
12. Canadian Psoriasis Guidelines Addendum C. 2016 Addendum to the Canadian Guidelines for the Management of Plaque Psoriasis 2009. *J Cutan Med Surg* 2016;20:375-431.
13. Meeuwis KA, van de Kerkhof PC, Massuger LF et al. Patients' experience of psoriasis in the genital area. Dermatology 2012;224:271-6.
14. Welsh BM, Berzins KN, Cook KA et al. Management of common vulval conditions. *Med J Aust* 2003;178:391-5.
15. Bissonnette R, Nigen S , Bolduc C. Efficacy and tolerability of topical tacrolimus ointment for the treatment of male genital psoriasis. *J Cutan Med Surg* 2008;12:230-4.
16. Schmid-Ott G, Kuensebeck HW, Jaeger B et al. Validity study for the stigmatization experience in atopic dermatitis and psoriatic patients. *Acta Derm Venereol* 1999;79:443-7.
17. Langley RG, Elewski BE, Lebwohl M et al. Secukinumab in plaque psoriasis--results of two phase 3 trials. *N Engl J Med* 2014;371:326-38.
18. Gordon KB, Colombel JF , Hardin DS. Phase 3 Trials of Ixekizumab in Moderate-to-Severe Plaque Psoriasis. *N Engl J Med* 2016;375:2102.
19. Gordon KB, Langley RG, Leonardi C et al. Clinical response to adalimumab treatment in patients with moderate to severe psoriasis: double-blind, randomized controlled trial and open-label extension study. *J Am Acad Dermatol* 2006;55:598-606.
20. Martin Ezquerra G, Sanchez Regana M, Herrera Acosta E et al. Topical tacrolimus for the treatment of psoriasis on the face, genitalia, intertriginous areas and corporal plaques. *J Drugs Dermatol* 2006;5:334-6.
21. Jemec GB , Baadsgaard O. Effect of cyclosporine on genital psoriasis and lichen planus. *J Am Acad Dermatol* 1993;29:1048-9.

22. Liao YH, Chiu HC, Tseng YS et al. Comparison of cutaneous tolerance and efficacy of calcitriol 3 microg g(-1) ointment and tacrolimus 0.3 mg g(-1) ointment in chronic plaque psoriasis involving facial or genitofemoral areas: a double-blind, randomized controlled trial. *Br J Dermatol* 2007;157:1005-12.
23. de Rie MA, Goedkoop AY , Bos JD. Overview of psoriasis. *Dermatol Ther* 2004;17:341-9.
24. Merola JF, Armstrong AW, Saraiya A et al. International Dermatology Outcome Measures Initiative as Applied to Psoriatic Disease Outcomes: An Update. J *Rheumatol* 2016;43:959-60.
25. Paul C, Bushmakin AG, Cappelleri JC et al. Do Patients and Physicians Agree in Their Assessment of the Severity of Psoriasis? Insights from Tofacitinib Phase 3 Clinical Trials. *J Dermatolog Clin Res* 2015;3:1048.
26. Feldman SR , Krueger GG. Psoriasis assessment tools in clinical trials. *Ann Rheum Dis* 2005;64 Suppl 2:ii65-8; discussion ii9-73.
27. European Medicines Agency. Committee for Medicinal Products for Human Use (CHMP). Guideline on Clinical Investigation of Medicinal Products Indicated for the Treatment of Psoriasis. Available at: http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2009/09/WC500003329.pdf. Accessed March 20, 2017.

AUTHOR CORRESPONDENCE

Joseph F. Merola MD MMSc
E-mail:..... jfmerola@bwh.harvard.edu