Product of the Physician Global Assessment and body surface area: A simple static measure of psoriasis severity in a longitudinal cohort

Jessica A. Walsh, MD,[a] Molly McFadden, MS,[b] Jamie Woodcock, MD,[c] Daniel O. Clegg, MD,[a] Philip Helliwell, MD,[d] Erica Dommasch, MD,[e] Joel M. Gelfand, MD, MSCE,[f,g,h] Gerald G. Krueger, MD,[c] and Kristina Callis Duffin, MD[c]

Salt Lake City, Utah; Leeds, England; Boston, Massachusetts; and Philadelphia, Pennsylvania

Background: The Psoriasis Area and Severity Index (PASI) is considered the gold standard assessment tool for psoriasis severity, but PASI is limited by its complexity and insensitivity in people with mild psoriasis.

Objective: We sought to evaluate the product of a Physician Global Assessment (PGA) and Body Surface Area (BSA) (PGAxBSA) as an alternative to PASI.

Methods: Psoriasis severity was evaluated at 6-month intervals in participants of the Utah Psoriasis Initiative registry. Correlation coefficients were used to compare PGAxBSA with PASI and the Simplified PASI (SPASI).

Results: Between August 2008 and November 2010, 435 assessments were completed in 226 participants. The median PASI score was 3.2 (interquartile range 1.8-5.4) and the median BSA was 3.0% (interquartile range 1.0%-5.0%). PGAxBSA had higher correlations with PASI than SPASI (0.87 vs 0.76, $P < .001$). PGAxBSA also had higher correlations with a Global Patient Assessment of psoriasis severity (0.65) than both PASI (0.59, $P < .001$) and SPASI (0.51, $P < .001$).

Limitations: The use of PGAxBSA for measuring severe psoriasis and response to therapy is unclear, because most participants had mild to moderate psoriasis and data were not collected at predefined intervals in relation to therapy initiation. Interrater reliability was not assessed.

Conclusions: PGAxBSA is a simple and sensitive instrument for measuring psoriasis severity. (J Am Acad Dermatol 2013;69:931-7.)

Key words: disease activity instrument; Physician Global Assessment; product of Physician Global Assessment and Body Surface Area; psoriasis; Psoriasis Area and Severity Index; severity measurement.

Quantifying the severity of psoriasis in a consistent and clinically meaningful way is important when conducting clinical research. Several psoriasis severity tools have been used over the last several decades, but no instrument meets all validity criteria.[1,2] The most commonly

From the Divisions of Rheumatology[a] and Epidemiology,[b] and Department of Dermatology,[c] University of Utah; Section of Musculoskeletal Disease, University of Leeds[d]; Department of Dermatology, Boston University[e]; and Department of Dermatology,[f] Department of Biostatistics and Epidemiology,[g] and Center for Clinical Epidemiology and Biostatistics,[h] University of Pennsylvania.

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Reprint requests: Jessica A. Walsh, MD, Division of Rheumatology, University of Utah, Room 4B200, School of Medicine, 30 N 1900 E, Salt Lake City, UT 84132. E-mail: jessica.walsh@hsc.utah.edu.

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used instrument, the Psoriasis Area and Severity Index (PASI), was introduced in an etretinate trial for psoriasis in 1978.[3] PASI is widely considered the gold standard measure of disease severity and is frequently used as a primary efficacy end point in clinical trials of moderate to severe psoriasis.[3,4]

PASI has several limitations. Common criticisms are that PASI is cumbersome to use and difficult to interpret. To perform PASI, an evaluator must assign erythema, induration, desquamation, and area scores to each of 4 body sections (head/neck, trunk, upper extremities, and lower extremities) and then mathematically calculate a score that ranges from 0 to 72. This process of performing a PASI assessment is time-consuming, and the final score is not meaningful to most clinicians.

CAPSULE SUMMARY

- Numerous limitations restrict the use of commonly used psoriasis severity measurement instruments, including the Psoriasis Area and Severity Index and Physician Global Assessments.
- The product of a Physician Global Assessment and Body Surface Area is a simple and effective alternative for measuring psoriasis severity.
- The product of a Physician Global Assessment and body surface area is a promising instrument that is well suited for use in a wide range of settings including patient care, registries, and clinical trials.

In recent years, the US Food and Drug Administration has not accepted PASI as a stand-alone efficacy end point and has required a static Physician Global Assessment (PGA) for most late-phase clinical trials of psoriasis therapies.[5,6] The most commonly used versions of PGA assess only plaque qualities, as they measure degrees of erythema, induration, and desquamation averaged over the entire body. Most PGA instruments do not provide an overall measure of psoriasis severity because they do not account for Body Surface Area (BSA) involvement. For example, a patient with extensive surface involvement (ie, 30%) could have the same PGA score as a patient with limited area involvement (ie, 1% BSA), if the degrees of lesion erythema, induration, and desquamation are the same.

To address the limitations of both PASI and PGA, alternative instruments have been developed. The Simplified PASI (SPASI) multiplies the sum of the global erythema, induration, and desquamation scores by a total body area score.[7] Like PASI, SPASI is limited by insensitivity in patients with mild to moderate disease, because area scores are based on ranges and areas between 1% and 9% are assigned the same area score of 1.[8]

Given the need for a simple and sensitive instrument, we hypothesized that the product of PGA and BSA would perform well as a measure of global psoriasis severity. The primary objective of this study was to evaluate the validity of the product of a static PGA and BSA (PGAxBSA) by comparing PGAxBSA with PASI and SPASI in a longitudinal registry of patients with psoriasis.

METHODS

This cohort study was designed to assess the validity of PGAxBSA relative to PASI and SPASI. Data from the Utah Psoriasis Initiative were used. The Utah Psoriasis Initiative is a registry of over 1200 consecutively enrolled patients with psoriasis. Participants were evaluated at 6-month intervals between August 2008 and November 2010 by 3 dermatology investigators. Each investigator was trained by a psoriasis expert with extensive experience in educating investigators on psoriasis severity measurements (K. C. D.). Interrater reliability was not assessed. At each visit, investigators recorded both physician- and patient-assessed psoriasis severity end points. Utah Psoriasis Initiative participants were eligible for this study if they were exposed to or were candidates for phototherapy or systemic therapy. Participant evaluations were excluded if participants were clear of psoriasis at the time of their evaluations. These exclusions were made to avoid misleading elevations in correlation coefficients that would result from perfect correlations with instrument scores of 0. All enrollees provided written consent for participation and approval was granted by the Institutional Review Board at the University of Utah.

Variables used in this investigation included scores for PASI, BSA, PGA, and Global Patient Assessment (GPA) of disease severity. The PASI score consisted of the sum of the erythema, induration, and desquamation for each body region, multiplied by weighted area scores (Table I). BSA was defined as the percent of body surface involvement, where 1% was approximately the area of the patient's handprint. The National Psoriasis Foundation Psoriasis Score version of a static PGA was calculated by averaging the total body erythema, induration, and desquamation scores.[9] Erythema, induration, and desquamation were scored on a 6-point scale, ranging from 0 (clear) to 5 (severe).

Abbreviations used:

BSA:	body surface area
GPA:	Global Patient Assessment
PASI:	Psoriasis Area and Severity Index
PGA:	Physician Global Assessment
PGAxBSA:	product of Physician Global Assessment and body surface area
SPASI:	Simplified Psoriasis Area and Severity Index

For GPA, participants rated their disease severity over the past week on a scale from 0 to 5, with 0 being no psoriasis and 5 being the worst their psoriasis had ever been. The PGAxBSA instrument was calculated by multiplying the BSA by the PGA score, PGAxBSA = [(E + I + D)/3] × BSA, where E is erythema, I is induration, and D is desquamation. SPASI was calculated by multiplying the PASI area score by the sum of the total body erythema, induration, and desquamation SPASI = $A_{PASI} \times (E + I + D)$.

Statistical analysis

The correlations among all physician-derived measures (PASI, SPASI, PGAxBSA) were evaluated by Spearman correlation coefficients. Scores from physician-derived measures were also correlated to GPA scores. Correlation coefficient values of 0.20, 0.40, 0.70, and 0.90 were considered low, moderate, high, and very high, respectively.[10] Subgroup analyses were performed in patients with low (0.1%-2.9%), moderate (3.0%-9.9%), and high ($\geq$10%) BSA. Responsiveness to change was evaluated by: (1) correlating changes in PGAxBSA and SPASI to changes in PASI; and (2) correlating changes in PGAxBSA, PASI, and SPASI to changes in GPA scores.

Within each category of BSA involvement (all BSAs, low BSA, moderate BSA, and high BSA), the correlations of instruments to PASI and GPA were compared. The Steiger Z test was used to determine if 2 correlation coefficients were statistically different.[11] The instrument with the highest correlation to PASI or GPA in each category was used as the referent standard for each Steiger Z comparison. Instruments with the highest correlations in each category were considered statistically superior to the other instruments if the *P* value for the Steiger Z test was less than .05.

The floor effect range was used to compare the instruments' abilities to capture differences in psoriasis severity in the 10% of participants with the lowest instrument scores. Similarly, the ceiling effect analysis was used to compare the instruments' abilities to differentiate between disease states in the 10% of participants with the highest instrument scores. Floor and ceiling effect ranges of greater than 0 indicated that the instruments were able to detect differences in psoriasis severity within the subgroups with the lowest and highest psoriasis severity.

RESULTS

Patient demographics

The analyses were performed on 435 patient evaluations from 226 participants. The static disease assessments were performed with 435 evaluations and the responsiveness to change analyses were performed with 240 evaluations. The average age of participants at entry to the study was 50 ± 15 years, and 113 (50%) were male (Table II). Caucasian race was reported in 206 (91%) participants. The average disease duration, at entry, was 23 ± 15 years. The median PASI score was 3.2 (interquartile range 1.8-5.4) and the median BSA involvement was 3.0% (interquartile range 1.0%-5.0%). The BSA was low in 211 (49%), moderate in 157 (36%), and high in 67 (15%) participant evaluations. Participants were using systemic therapies at the time of evaluation in 178 (41%) evaluations.

Correlation analyses

The correlation between PGAxBSA and PASI was higher than the correlation between SPASI and PASI. This difference was significant in all participants (0.87 vs 0.76, $P < .001$) and in the subset with a high BSA (0.89 vs 0.78, $P < .001$) (Table III). In all participants, PGAxBSA had higher correlations with GPA (0.65) than PASI (0.59, $P < .001$) and SPASI (0.51, $P < .001$). In all BSA subgroups, the correlations between GPA and all instruments were low to moderate (0.19-0.41) and significantly different only in the subgroup with low BSA (PGAxBSA 0.35, PASI 0.26, SPASI 0.19).

In the responsiveness to change analyses, changes in PGAxBSA (ΔPGAxBSA) and SPASI (ΔSPASI) had moderate to high correlations with changes in PASI (ΔPASI) (0.53-0.89) (Table IV). The differences were statistically significant only in the subgroup with moderate BSA (ΔPGAxBSA 0.75 vs ΔSPASI 0.63, $P = .03$). When correlated to change in GPA (ΔGPA), changes in each provider instrument score (ΔPASI, ΔPGAxBSA, ΔSPASI) were low to moderate in participants with low to moderate BSA (0.30-0.52) and high in participants with high BSA (0.74-0.78). The correlations between changes in provider instrument score and ΔGPA were not statistically different.

Ceiling and floor effects

The ceiling effect analysis demonstrated that PASI, PGAxBSA, and SPASI were able to differentiate between variations in psoriasis severity in the 10% of participants with the highest instrument scores,

Table I. Instrument formulas

Instrument	Lesion severity	Body surface estimate	Formula	Score range
PASI	Sum of E, I, and D for each body region	Area score ranging from 0-6 with smaller partitions for lowest and highest area categories	$PASI = 0.1A_H (E_H + I_H + D_H) + 0.2A_{UL} (E_{UL} + I_{UL} + D_{UL}) + 0.3A_T (E_T + I_T + D_T) + 0.4A_{LL} (E_{LL} + I_{LL} + D_{LL})$	0-72
PGA	Average of E, I, and D	None	$PGA = (E + I + D)/3$	0-5
PGAxBSA	Average of E, I, and D	Percent of BSA	$PGAxBSA = BSA \times (E + I + D)/3$	0-500
SPASI	Sum of E, I, and D	Area score identical to PASI area score	$SPASI = A \times (E + I + D)$	0-90

A, Area score (body surface area): 0 for no involvement, 1 for up to 10%, 2 for 10%-29%, 3 for 30%-49%, 4 for 50%-69%, 5 for 70%-89%, and 6 for ≥90%; *BSA*, body surface area; *D*, desquamation; *E*, erythema; *H*, head; *I*, induration; *LL*, lower limb; *PASI*, Psoriasis Area and Severity Index; *PGA*, Physician Global Assessment; *PGAxBSA*, product of Physician Global Assessment and body surface area; *SPASI*, Simplified Psoriasis Area and Severity Index; *T*, trunk; *UL*, upper limb.

Table II. Characteristics of 226 participants with 435 evaluations

		Sample size, n
Age at entry, ±SD	50 ± 15 y	226
Male, no. (%)	113 (50)	226
Caucasian, no. (%)	206 (91)	226
Psoriasis duration at entry, ±SD	23 ± 15 y	226
Systemic therapy at evaluation, no. (%)	178 (41)	435
Median PASI at evaluation (IQR)	3.2 (1.8-5.4)	435
Median % BSA at evaluation (IQR)	3.0 (1.0-5.0)	435
BSA, no. (%)		
0.1%-2.9%	211 (49)	435
3.0%-9.9%	157 (36)	435
≥10%	67 (15)	435

BSA, Body surface area; *IQR*, interquartile range; *PASI*, Psoriasis Area and Severity Index.

with ranges greater than 0 (Table V). In contrast, only PASI and PGAxBSA differentiated between variations in psoriasis severity in the 10% of participants with the lowest instrument scores, with ranges greater than 0. For SPASI, the floor effect range of 0 demonstrated that SPASI was unable to differentiate between disease states in the 10% of participants with the lowest SPASI scores.

DISCUSSION

We explored the validity of PGAxBSA by comparing it with PASI, SPASI, and a patient-derived instrument (GPA) in the setting of a psoriasis registry. PGAxBSA correlated well with PASI and GPA and was sensitive in patients with mild disease. In addition, our data demonstrated that the PGAxBSA may function well as a measure of disease change.

Other instruments have previously been evaluated as alternatives to PASI. The Lattice Systemic PGA,[12] the Psoriasis Exact Area and Severity Index,[8] and the Extended 10-Area Linear PASI[13] may be more accurate than PASI, but they are often perceived as cumbersome. PGA instruments are simpler than PASI but they are not consistently meaningful as standalone instruments, because most PGA instruments do not account for BSA involvement. SPASI was chosen as a comparator instrument in this study because of its overall ease and its high correlation with PASI in a computer-simulated model.[6] However, the sensitivity of SPASI in mild disease was limited by its use of the PASI area score. PGAxBSA has the advantages of being a simple measure of psoriasis severity that is consistently sensitive to differences in disease states.

Compared with PASI, the clinical use of PGAxBSA may be most evident in people with BSA involvement of less than 10%. For example, consider a patient with 9% BSA, erythema 3, induration 3, and desquamation 3 for each body region, and another patient with 1% BSA and identical lesion severity scores. Using PASI, both patients would have the same scores of 9. In contrast, the patient with 9% BSA would have a PGAxBSA score of 27, and the patient with 1% BSA would have a PGAxBSA score of 3.

PASI and other physician-assessed severity instruments have been criticized for failing to adequately mirror patient assessments of psoriasis severity.[14] In an exploratory analysis, the correlation comparisons of each instrument to GPA demonstrated that PGAxBSA may better reflect psoriasis severity, as perceived by patients, than PASI. Because the GPA has not been psychometrically tested in a rigorous manner, comparisons of PGAxBSA and PASI with other patient assessment instruments will be required to confirm these findings.

In addition to measuring static disease severity, an optimal psoriasis assessment instrument should capture responsiveness to change, including response to

Table III. Correlations of instruments with Psoriasis Area and Severity Index and Patient Global Assessment

	All participants (n = 435)				Low BSA (0.1%-2.9%) (n = 211)				Moderate BSA (3.0%-9.9%) (n = 157)				High BSA (≥ 10%) (n = 67)			
		*R**	Z†	*P*		*R**	Z†	*P*		*R**	Z†	*P*		*R**	Z†	*P*
PASI	PGAxBSA	0.87	Ref	NA	PGAxBSA	0.61	Ref	NA	PGAxBSA	0.69	Ref	NA	PGAxBSA	0.89	Ref	NA
	SPASI	0.76	6.9	<.001	SPASI	0.53	1.5	.13	SPASI	0.64	1.4	.16	SPASI	0.78	3.3	<.001
GPA	PGAxBSA	0.65	Ref	NA	PGAxBSA	0.35	Ref	NA	PGAxBSA	0.41	Ref	NA	SPASI	0.40	Ref	NA
	PASI	0.59	3.6	<.001	PASI	0.26	1.7	.01	SPASI	0.35	1.2	.22	PGAxBSA	0.34	0.9	.37
	SPASI	0.51	5.5	<.001	SPASI	0.19	2.7	.01	PASI	0.30	1.9	.06	PASI	0.28	1.5	.14

Change in each instrument score was correlated to change in scores for both PASI and GPA. Steiger Z test was used to determine if correlation coefficients were statistically different. The instrument with highest correlation coefficient in each category was used as referent standard.

BSA, Body surface area; *GPA*, Global Patient Assessment; *NA*, not applicable; *PASI*, Psoriasis Area and Severity Index; *PGAxBSA*, product of GPA and body surface area; *Ref*, referent standard; *SPASI*, Simplified Psoriasis Area and Severity Index.

*Spearman correlation coefficient.

†Z = Steiger Z coefficient.

Table IV. Correlations between changes in instrument scores and ΔPatient Global Assessment

	All participants (n = 240)				Low BSA (0.1%-2.9%) (n = 119)				Moderate BSA (3.0%-9.9%) (n = 87)				High BSA (≥ 10%) (n = 34)			
		*R**	Z†	*P*		*R**	Z†	*P*		*R**	Z†	*P*		*R**	Z†	*P*
ΔPASI	ΔPGAxBSA	0.54	Ref	NA	ΔPGAxBSA	0.77	Ref	NA	ΔPGAxBSA	0.75	Ref	NA	ΔSPASI	0.89	Ref	NA
	ΔSPASI	0.53	0.4	.66	ΔSPASI	0.74	0.7	.48	ΔSPASI	0.63	2.2	.03	ΔPGAxBSA	0.84	1.3	.21
ΔGPA	ΔPGAxBSA	0.54	Ref	NA	ΔPGAxBSA	0.52	Ref	NA	ΔPGAxBSA	0.40	Ref	NA	ΔPASI	0.78	Ref	NA
	ΔPASI	0.53	0.4	.66	ΔPASI	0.46	1.1	.26	ΔPASI	0.36	0.5	.62	ΔSPASI	0.75	0.5	.62
	ΔSPASI	0.47	1.8	.08	ΔSPASI	0.45	1.1	.27	ΔSPASI	0.30	1.3	.19	ΔPGAxBSA	0.74	0.7	.48

Change in each instrument score was correlated to change in scores for both PASI and GPA. Steiger Z test was used to determine if correlation coefficients were statistically different. Instrument with highest correlation coefficient in each category was used as referent standard.

BSA, Body Surface Area; Δ, change; *GPA*, Global Patient Assessment; *NA*, not applicable; *PASI*, Psoriasis Area and Severity Index; *PGAxBSA*, product of Physician Global Assessment and Body Surface Area; *Ref*, referent standard; *SPASI*, Simplified Psoriasis Area and Severity Index.

*Spearman correlation coefficient.

†Z = Steiger Z coefficient.

Table V. Ceiling and floor effects

	PASI	PGAxBSA	SPASI
Ceiling			
n	43	45	48
Minimum score	9.1	30	14
Maximum score	30.7	240	45
Range	21.6	210	31
Floor			
n	43	42	45
Minimum score	0.3	0.1	3
Maximum score	0.8	0.3	3
Range	0.5	0.2	0

Ranges >0 indicate that instruments were able to detect differences in psoriasis severity within subgroups with highest (ceiling) and lowest (floor) psoriasis severity.
PASI, Psoriasis Area and Severity Index; *PGAxBSA*, product of Physician Global Assessment and body surface area; *SPASI*, Simplified Psoriasis Area and Severity Index.

therapy. The responsiveness to change analyses in this study suggested that PASI and PGAxBSA had similar abilities to capture change, when GPA scores were used as the reference standard. A limitation of this study is that we were unable to specifically assess response to therapy, because participants were on many different therapies and were not evaluated at predefined time intervals in relation to therapy changes.

Another limitation of this study is that interrater reliability was not assessed. There are multiple reports of good interrater reliability with PASI and PGA among trained assessors,[15-17] and each assessor in this investigation was extensively trained by an expert in the education of psoriasis assessments (K. C. D.). Additional studies with PGAxBSA will provide opportunities to evaluate interrater reliability.

Although the low median PASI and BSA scores in this population were optimal for studying PGAxBSA in well-controlled psoriasis, the generalizability of the study findings is limited by the relatively low proportion of participants with severe or uncontrolled psoriasis. The subgroup analyses of participants with BSA 10% or greater demonstrated that PGAxBSA performed well in the subset of participants with severe disease; however additional research is necessary to better characterize the use of PGAxBSA in patients with severe psoriasis.

A potential barrier to the consistent application of the PGAxBSA instrument is the lack of standardization for measuring PGA. Several versions of the PGA have been developed with different scale ranges. Furthermore, lesional PGA instruments take into account only plaque qualities, whereas global PGA versions may also incorporate other severity factors such as area involvement. The 6-point lesional static PGA developed by the National Psoriasis Foundation is well suited for the PGAxBSA instrument because it is widely used in studies of psoriasis therapies. The standardization of PGA measurements for the PGAxBSA will enable consistent and accurate interpretations of PGAxBSA scores.

In conclusion, our data demonstrated that PGAxBSA and PASI similarly measure psoriasis severity. A comparison of PGAxBSA and PASI in clinical drug trials will characterize the ability of PGAxBSA to measure response to therapy and will provide opportunities to measure interobserver and intraobserver concordance with PGAxBSA. PGAxBSA is a promising instrument because of its simplicity and sensitivity to differences in disease states, particularly in mild disease. With these advantages, PGAxBSA has the potential to be successfully used in a wide variety of settings, including patient care, registries, and clinical trials.

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