H.2 Tools for assessing disease severity and impact

H.2.1 Comparative data

<table>
<tr><th>Reference</th><th>Study type</th><th>Number of patients</th><th>Patient characteristics</th><th>Intervention</th><th>Comparison</th><th>Length of follow-up</th><th>Outcome measures</th><th>Source of funding</th></tr>
<tr>
<td>B. Kirby, H. Richards, P. Woo, E. Hindle, C. J. Main, and C. Griffiths. Physical and psychologic measures are necessary to assess overall psoriasis severity. J.Am.Acad.Dermatol. 45 (1):72-76, 2001.

Ref ID: KIRBY2001</td>
<td>Observational: cross sectional study

Patients recruited from inpatient ward, psoriasis clinic and dermatology clinic at Hope Hospital, UK</td>
<td>N = 101</td>
<td>Stage of disease journey: unclear

Inclusion criteria: Age ≥ 18 years

Exclusion criteria: Suffering mental health problems

<table>
<tr><th>Parameter</th><th>All (n=101)</th></tr>
<tr><td>Mean age – years</td><td>46 ± 1.7</td></tr>
<tr><td>Gender M/F (%)</td><td>56/44</td></tr>
<tr><td>Inpatients (n)</td><td>67</td></tr>
<tr><td>Outpatients (n)</td><td>34</td></tr>
<tr><td>Mean PASI score</td><td>14.7 ± 1.1</td></tr>
</table>
</td>
<td>SPI, PDI, PASI, SAPASI, HADS, IPQ

PASI assessed by one of three experienced clinicians

SAPASI and self-report psychological questionnaires completed by the patients

Unclear how</td>
<td>SPI, PDI, PASI, SAPASI, HADS, IPQ</td>
<td>N/A</td>
<td>Construct validity</td>
<td>None stated</td>
</tr>
</table>

				SPI score was obtained				

Effect size

Construct validity

Score 1	**Score 2**	**Correlation (Spearman's r)**	**p-value**	**Construct validity**	
				Convergent	**Divergent**
Signs score of SPI (derived from PASI)	Psychosocial disability score of SPI	0.46	<0.01		Adequate – measure different constructs
	PDI	0.51	<0.01		Adequate
	PASI	0.99	<0.01	Adequate	
	SAPASI	0.67	<0.01	Adequate	
PASI	**SAPASI**	**0.65**	**<0.01**	**Acceptable**	
Psychosocial disability score of SPI	PDI	0.69	<0.01	Acceptable	
	PASI	0.46	<0.01		Adequate

Interventions score of SPI (historical disease severity)	Any assessment of clinical severity or psychological impact		NS		
PDI	**Physical scores of psoriasis severity**	**0.50-0.52**	**<0.01**	**Poor**	
SAPASI	**PDI**	**0.52**	**<0.01**		**Adequate**
	Psychosocial disability score of SPI	0.49	<0.01		Adequate

In-patient vs out-patient groups

- There was no significant difference between the groups in terms of age
- Mean PASI, SAPASI and 'signs' score of SPI were significantly higher in the in-patients than out-patients ($p<0.001$)
- In-patients also had significantly higher score on PDI ($p<0.001$) and depression scale of HADS ($p<0.02$)

Summary/author's conclusion

- There is considerable discordance between the amount of physical disease and the degree of psychological disability; therefore, it is necessary to assess the patient holistically
- SPI provides information on clinical extent, psychosocial disability and historical severity

<table>
<tr><th>Reference</th><th>Study type</th><th>Number of patients</th><th>Patient characteristics</th><th>Intervention</th><th>Comparison</th><th>Length of follow-up</th><th>Outcome measures</th><th>Source of funding</th></tr>
<tr>
<td>F. Sampogna, F. Sera, E. Mazzotti, P. Pasquini, A. Picardi, D. Abeni, and IDI Multipurpose Psoriasis Research on Vital Experiences (IMPROVE) Study Group. Performance of the self-administered psoriasis area and severity index in evaluating clinical and sociodemographic subgroups of patients with psoriasis.[Erratum appears in Arch Dermatol. 2003 Jul;139(7):950]. Arch.Dermatol. 139 (3):353-358, 2003. Ref ID:</td>
<td>Observational: cross sectional study

Part of the IDI Multipurpose Psoriasis Research on Vital Experiences study, Feb-Aug 2000

In-patient wards of hospital in Italy</td>
<td>N = 351 (of 376 eligible and willing to participate)</td>
<td>Stage of disease journey: unclear

Inclusion criteria: Specialist-confirmed diagnosis of psoriasis; age ≥ 18 years; absence of severe mental or physical illness; at least 5 years of education, ability to read Italian; and first hospitalisation for psoriasis since the data of the study beginning

Exclusion criteria: Not stated

<table>
<tr><th>Parameter</th><th>All (n=351)</th></tr>
<tr><td>Age (years), n (%)</td><td></td></tr>
<tr><td>18-31</td><td>92 (26.2)</td></tr>
<tr><td>32-45</td><td>89 (25.4)</td></tr>
<tr><td>46-60</td><td>90 (25.6)</td></tr>
<tr><td>≥61</td><td>80 (22.8)</td></tr>
<tr><td>Gender M/F (%)</td><td>63/37</td></tr>
<tr><td>Duration (years), n (%)</td><td></td></tr>
<tr><td>0-3</td><td>99 (28.2)</td></tr>
</table>
</td>
<td>PASI

Measurement taken soon after admission before any medication was taken

Note: It is unclear whether the assessments were given in Italian</td>
<td>SAPASI

Given to patients after the visit and scored by an assessor who had not seen the patients and was blind to PASI scores</td>
<td>N/A</td>
<td>Construct validity</td>
<td>None stated</td>
</tr>
</table>

SAMPOGNA2003			4-9: 85 (24.2) 10-18: 83 (23.7) ≥19: 84 (23.9) **Clinical type** Palmoplantar: 21 (6.2) Pustular, localised: 10 (2.9) Guttate: 52 (15.2) Plaque, localised: 73 (21.4) Plaque, generalised: 149 (43.7) Psoriatic arthritis: 22 (6.5) Other: 14 (4.1)					

Effect size

Construct validity (Pearson correlation coefficient)

- Overall correlation coefficient between lnPASI and lnSAPASI (log values used because frequency distributions were skewed) was 0.69 (acceptable construct validity)
- There was substantial variation in the agreement between PASI and SAPASI among different patient variables and among the subcomponents of the two tools (different body sites)

Variable	Difference between PASI and SAPASI	Correlation coefficient between lnPASI and lnSAPASI	Convergent construct validity

Overall	-6.26 ± 8.81	0.69	Acceptable	
Head		0.55	Poor	
Upper extremities		0.40	Poor	
Trunk		0.68	Acceptable	
Lower extremities		0.49	Poor	
Sex				
Male	-5.74±8.56	0.68	Acceptable	
Female	-6.99±9.24	0.70	Adequate	
Clinical type				
Palmoplantar	-2.06±3.51	0.31	Poor	
Pustular, localised	-1.97±2.49	0.50	Poor	
Guttate	-11.16±9.92	0.60	Acceptable	
Plaque, localised	-2.87±4.08	0.58	Poor	
Plaque, generalised	-6.83±8.88	0.58	Poor	
Psoriatic arthritis	-6.25±9.94	0.76	Adequate	
Other	-9.16±16.69	0.91	Adequate	
Physician rated severity score				
1	-3.14±4.27	0.45	Poor	
2	-4.28±5.59	0.64	Acceptable	
3	-7.36±8.22	0.56	Poor	

4	-9.15±12.76	0.60	Acceptable
Duration (years)			
0-3	-6.04±8.07	0.64	Acceptable
4-9	-7.00±8.06	0.70	Adequate
10-18	-6.02±9.64	0.70	Adequate
≥19	-5.98±9.59	0.68	Acceptable

Summary/author's conclusion

- There was a high correlation between PASI and SAPASI scores
- SAPASI scores were higher and had wider scattering than the PASI values
- SAPASI could be used as a severity measure for psoriasis
- Caution is needed when using SAPASI to strictly estimate PASI measurements, especially for guttate psoriasis

<table>
<tr><th>Reference</th><th>Study type</th><th>Number of patients</th><th>Patient characteristics</th><th>Intervention</th><th>Comparison</th><th>Length of follow-up</th><th>Outcome measures</th><th>Source of funding</th></tr>
<tr>
<td>F. Sampogna, F. Sera, D. Abeni, and IDI Multipurpose Psoriasis Research on Vital Experiences (IMPROVE) Investigators. Measures of clinical severity, quality of life, and psychological distress in patients with psoriasis: a cluster analysis. J.Invest.Dermatol. 122 (3):602-607, 2004.

Ref ID: SAMPOGNA2004</td>
<td>Observational: cross sectional study

Part of the IDI Multipurpose Psoriasis Research on Vital Experiences study, Feb 2000-July 2001

In-patient wards of hospital in Italy</td>
<td>N = 786

This relates to a participation rate of 88.5%</td>
<td>Stage of disease journey: a wide range of clinical presentations (including mild-to-moderate cases)

Inclusion criteria: Specialist-confirmed diagnosis of psoriasis; age ≥ 18 years; absence of severe mental or physical illness; at least 5 years of education, ability to read Italian; and first hospitalisation for psoriasis since the date of the study beginning

Exclusion criteria: Not stated

<table>
<tr><th>Parameter</th><th>All (n=786)</th></tr>
<tr><td>Mean age (years</td><td>45.5</td></tr>
<tr><td>Gender M/F (%)</td><td>59.2/41.8</td></tr>
<tr><td>Mean PASI score</td><td>8.6</td></tr>
<tr><td>Mean age at onset (years)</td><td>33.6</td></tr>
<tr><td>Global severity as assessed by</td><td></td></tr>
</table>
</td>
<td>Clinical status: PASI and SAPASI

QoL: Skindex-29, DLQI, PDI, Impact of Psoriasis Questionnaire (IPSO)

Psychological distress index: Psoriasis Life Stress Inventory (PLSI)

PASI measurement taken soon after admission before any medication was taken</td>
<td>All comparisons

Note: It is unclear whether the assessments were given in Italian</td>
<td>N/A</td>
<td>Convergent and divergent construct validity</td>
<td>Italian Ministry of Health</td>
</tr>
</table>

			dermatologists (%) Severe or very severe Moderate Mild	 24.7 29.0 46.3	Self-administered questionnaires completed before hospital discharge			
			Clinical type (%)					
			Palmoplantar	7.3				
			Pustular, localised	2.0				
			Guttate	12.8				
			Plaque, localised	16.8				
			Plaque, generalised	47.1				
			Psoriatic arthritis	7.9				

Effect size

Note that log values were used for PASI and SAPASI because frequency distributions were skewed

Construct validity (Pearson's correlation coefficient)

- Correlation matrix:

	PLSI	**PDI**	**DLQI**	**IPSO**	**Skindex**	**SAPASI**

					Social functioning	**Emotions**	**Symptoms**	
PASI	0.258	0.198	0.190	0.175	0.122	0.116	0.175	0.647
SAPASI	0.354	0.269	0.261	0.286	0.175	0.189	0.223	
Skindex								
Social functioning	0.663	0.710	0.723	0.781	0.598	0.815		
Emotions	0.635	0.600	0.633	0.728	0.588			
Symptoms	0.433	0.489	0.542	0.512				
IPSO	0.738	0.798	0.758					
DLQI	0.627	0.805						
PDI	0.664							

- Cluster analysis revealed 2 main clusters: PASI and SAPASI in one and all of the QoL and psychological scales in another
- Correlations between QoL measures and SAPASI were slightly higher than those with PASI

Summary/author's conclusion

- The dissimilarity between clinical severity assessment and patient-centered measures stresses the need for a more comprehensive assessment of psoriasis severity

<table>
<tr><th>Reference</th><th>Study type</th><th>Number of patients</th><th>Patient characteristics</th><th>Intervention</th><th>Comparison</th><th>Length of follow-up</th><th>Outcome measures</th><th>Source of funding</th></tr>
<tr>
<td>M. B. Nichol, J. E. Margolies, E. Lippa, M. Rowe, and J. Quell. The application of multiple quality-of-life instruments in individuals with mild-to-moderate psoriasis. Pharmacoeconomics 10 (6):644-653, 1996.

Ref ID: NICHOL1996</td>
<td>Observational: cross sectional study

Clinical trial (US multicentre)</td>
<td>N = 644</td>
<td>Stage of disease journey: unclear, but 65% were on medication

Inclusion criteria: Adults who met entry criteria for 2 multicentre trials for a new psoriasis medication; stable plaque psoriasis on trunk, legs or arms (≤20% BSA); 2 target lesions ≥2 cm in diameter (1 on elbow or knee and 1 on trunk arms or leg);

Exclusion criteria: Not stated

<table>
<tr><th>Parameter</th><th>All (n=644)</th></tr>
<tr><td>Mean age (years), ±SD</td><td>48.2±15.1</td></tr>
<tr><td>Mean gender M/F (%)</td><td>60.9/39.1</td></tr>
<tr><td>Mean age at onset of psoriasis (years), ±SD</td><td>30.42±15.44</td></tr>
<tr><td>Mean duration of psoriasis (years), ±SD</td><td>17.74±12.23</td></tr>
</table>
</td>
<td>DLQI – 10-item questionnaire rated on a 0-3 scale considering the previous 7 days

Self-administered at baseline

Expressed as a % of maximum possible disability to improve comparability

In the case of missing values the maximum</td>
<td>PDI – 15 questions rated on a 7-point linear scale (transformed to 0-6 in this study) considering the past 4 weeks

Self-administered at baseline

Expressed as a % of maximum possible disability to improve comparability

Population</td>
<td>N/A</td>
<td>Construct validity</td>
<td>Allergan Ltd.</td>
</tr>
</table>

			Mean body involvement (%)±SD: 7.19±5.02 **Mean prescriptions (n)** Total population (n=644): 1.46 Patients on medication (n=362): 2.60	possible disability was based on the number of questions answered	mean substituted for missing values			

Effect size

Construct validity

- PDI and DLQI were strongly and positively correlated with each other: adequate construct validity (r = 0.82; Pearson coefficient; p<0.001)
- PDI and DLQI both also correlated with 6 measured psoriasis characteristics. The PDI was most sensitive to % body involvement, while the DLQI was most influenced by pruritus and pain:

QoL scale	**Psoriasis characteristics**					
	Body involvement (% - estimated using palm = 1%)	Lesional severity (clinician rating)	Pain (self-rated)	Pruritus (self-rated)	Age at onset	Duration
PDI score (%)	**0.27**	0.08	0.20	0.21	-0.15	-0.08
DLQI score (%)	0.26	0.11	**0.30**	**0.32**	-0.14	-0.12

Summary/author's conclusion

- Patients averaged 16.5% of maximum possible disability as measured by the PDI and 23.4% as measured by DLQI
- Impairment in life quality in mild-to-moderate psoriasis has a strong psychosocial component

<table>
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<tr>
<td>R. Shikiar, M. K. Willian, M. M. Okun, C. Thompson, and D. A. Revicki. The validity and responsiveness of three quality of life measures in the assessment of psoriasis patients: results of a phase II study. Health & Quality of Life Outcomes 4:71, 2006.

Ref ID: SHIKIAR2006</td>
<td>Within group comparison of data from an RCT (but focus on psychometric properties of tools and not on drug efficacy)

Phase II, randomised, double-blind, parallel group, placebo controlled, multicentre clinical trial</td>
<td>N = 147</td>
<td>Stage of disease journey: unclear

Inclusion criteria: Moderate-to-severe plaque psoriasis; BSA≥5% for at least 1 year; age ≥18 years; ability to self-inject medication/nurse or designee who can inject randomised assignment

Exclusion criteria: Not stated

<table>
<tr><th>Parameter</th><th>All (n=147)</th></tr>
<tr><td>Mean age (years), ±SD</td><td>44.2±12.7</td></tr>
<tr><td>Mean gender M/F (%)</td><td>67.3/32.7</td></tr>
<tr><td>Mean age at onset of psoriasis (years), ±SD</td><td>30.42±15.44</td></tr>
</table>
</td>
<td>DLQI</td>
<td>PASI

PGA:

• Severe: very marked plaque elevation, scaling, and/or erythema

• Moderate to Severe: marked plaque elevation, scaling, and/or erythema

• Moderate: moderate plaque elevation, scaling, and/or erythema

• Mild to moderate: intermediate between moderate and mild

• Mild: slight plaque elevation, scaling, and/or erythema</td>
<td>12 weeks (30-day follow-up visit for patients not completing 12 weeks active treatment)</td>
<td>Sensitivity to change; construct validity; internal consistency</td>
<td>Abbot Laboratories</td>
</tr>
</table>

<table>
<tr>
<td></td>
<td>(adalimumab vs placebo); North America

7 patients lost to follow-up</td>
<td></td>
<td>
<table>
<tr><td colspan="2">Race (%)</td></tr>
<tr><td>White</td><td>90.5</td></tr>
<tr><td>Black</td><td>2.7</td></tr>
<tr><td>Asian</td><td>3.4</td></tr>
<tr><td>Other</td><td>3.4</td></tr>
</table>
</td>
<td></td>
<td>• Almost clear: intermediate between mild and clear
• Clear: no signs of psoriasis (post-inflammatory hypopigmentation or hyperpigmentation could be present).</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td colspan="9">Effect size

Sensitivity to change (in a group including pooled placebo and active treatment groups)

DLQI vs PASI or PGA
• DLQI demonstrated acceptable sensitivity to clinically meaningful change (r = 0.69 vs PASI and 0.71 vs PGA)
• There was also a significant difference in improvement on DLQI between responders (PASI75) and non-responders (<PASI50); difference = -10.39 (p<0.0001)
• DLQI was able to demonstrate statistically significant differences between responders (PASI improvements ≥75%) and partial responders (PASI improvements 50-74%)

PASI vs PGA
• Acceptable sensitivity to clinically meaningful change (r = 0.75)
• Note: PASI showed a mean score reduction of 56.5% (from 15.69 to 6.84); while PGA showed a mean score reduction of 39.1% (from 5.48 to 3.36)

Construct validity (correlation coefficient not stated)</td>
</tr>
</table>

PASI vs PGA

- Adequate construct validity (r = 0.83) at trial end point, but poor construct validity (r = 0.59) at baseline

Internal consistency

- Adequate for DLQI: α = 0.89 at baseline and 0.92 at week 12

Summary/author's conclusion

- DLQI was the most responsive patient-reported outcome measure (compared with EQ-5D and SF-36) and was equally responsive to both PASI and PGA
- DLQI was correlated to clinical endpoints both at baseline and week 12

<table>
<tr><th>Reference</th><th>Study type</th><th>Number of patients</th><th>Patient characteristics</th><th>Intervention</th><th>Comparison</th><th>Length of follow-up</th><th>Outcome measures</th><th>Source of funding</th></tr>
<tr>
<td>L. Kotrulja, M. Tadinac, N. A. Joki-Begi, and R. Gregurek. A multivariate analysis of clinical severity, psychological distress and psychopathological traits in psoriatic patients. Acta Derm.Venereol. 90 (3):251-256, 2010.

Ref ID: KOTRULJA2010</td>
<td>Case-control study

Convenience sample

Department of Dermatology and Venerology, University Hospital and School of Medicine, Croatia</td>
<td>N = 140

70 with psoriasis 70 with other (non-psychosomatic) dermatoses</td>
<td>Stage of disease journey: unclear

Inclusion criteria: note stated

Exclusion criteria: Age <18 years, severe mental or physical illness

<table>
<tr><th>Parameter</th><th>Cases (n=70)</th><th>Controls (n=70)</th></tr>
<tr><td>Mean age (years)</td><td>Males: 48.7
Females: 51.4</td><td>Males: 53.7
Females : 47.2</td></tr>
<tr><td>Mean gender M/F (%)</td><td>57.1/42.9</td><td>38.6/62.4</td></tr>
<tr><td>Mean age of onset (years±SD)
-Early onset
-Late onset</td><td>

25.8±7.2
52.0±8.93</td><td></td></tr>
<tr><td>Disease</td><td></td><td></td></tr>
</table>
</td>
<td>PASI</td>
<td>Psoriasis Life Stress Inventory (PLSI) – 15-item version

(also used General Health Questionnaire, Beck Depression Index, State-Trait Anxiety Inventory, Minnesota Multiphasic Personality Inventory and Inventory of Stress Life Events)</td>
<td>N/A</td>
<td>Construct validity</td>
<td>None stated</td>
</tr>
</table>

			duration (years±SD) -Early onset -Late onset	 16.2±9.42 11.0±8.74						
			PLSI ≥10 (significant impact of disease-associated stress)	82.4%						

Effect size

Construct validity (divergent)

PASI vs PLSI – calculated in psoriatic patients

- Adequate divergent construct validity (Pearson's r = 0.30) – PASI and PLSI are not measuring the same construct (although the correlation was statistically significant; $p<0.05$)

Summary/author's conclusion

- PLSI showed a significant correlation with clinical extent of psoriasis, as measured by PASI; however, this was only moderate correlation and demonstrated that they are likely to be measuring different constructs

<table>
<tr><th>Reference</th><th>Study type</th><th>Number of patients</th><th>Patient characteristics</th><th>Intervention</th><th>Comparison</th><th>Length of follow-up</th><th>Outcome measures</th><th>Source of funding</th></tr>
<tr>
<td>S. P. McKenna. Development of the PSORIQoL, a psoriasis-specific measure of quality of life designed for use in clinical practice and trials. Br.J.Dermatol. 149 (2):323-331, 2003.

Ref ID: MCKENNA2003</td>
<td>Observational: within-group comparison

Development of the measure in 62 patients recruited through dermatology clinics (UK, Italy and the Netherlands)

Validation in a new sample of 148 UK patients recruited by postal survey of individuals randomly selected from a hospital database</td>
<td>N = 148

(of 445 mailed packages)

Second package sent to 119 of respondents and 88 (74%) were returned and adequately completed</td>
<td>Stage of disease journey: unclear; 78% on treatment; 80% experiencing a flare

Inclusion criteria: note stated

Exclusion criteria: not stated

<table>
<tr><th>Parameter</th><th>Postal sample (n=148)</th><th>Retest sample (n=88)</th></tr>
<tr><td>Mean age (years±SD)</td><td>45.1±14.9</td><td>46.2±15.5</td></tr>
<tr><td>Mean gender M/F (%)</td><td>50/50</td><td>44/56</td></tr>
<tr><td>Disease duration (years±SD)</td><td>20.9±13.5</td><td>21.6±13.6</td></tr>
<tr><td>On current treatment (%)</td><td>78</td><td>72</td></tr>
</table>
</td>
<td>PSORIQoL – 25-item version</td>
<td>DLQI (and General Well-Being Index)</td>
<td>2 weeks</td>
<td>Construct validity; internal consistency; test-retest reliability</td>
<td>None stated</td>
</tr>
</table>

	(Dermatology Clinic, Hope Hospital, Manchester)		Current flare (%)	80	45				
			Parts of body affected (%)						
			Face	27	29				
			Hands	36	31				
			Other	51	51				
			None	1	1				

Effect size

Test-retest reliability

- **PSORIQoL:** acceptable (ICC = 0.89)

Internal consistency

- **PSORIQoL:** Adequate (α=0.94)
- **DLQI:** Adequate (α=0.88)

Convergent construct validity: PSORIQoL vs DLQI

- Adequate overall construct validity (Spearman's r = 0.70)
- Individual subscales of the DLQI showed lower correlation with PSORIQoL score
  - Symptoms and feelings: 0.55
  - Daily activities: 0.66
  - Leisure: 0.53
  - Work and school: 0.32
  - Personal relationships: 0.45
  - Treatment: 0.47

Site-specific involvement

- PSORIQoL scores were related to whether or not patients had lesions on their face and/or hands

Area affected	Median PSORIQoL score	n	p-value
Not face or hands	9.0	67	<0.01
Face or hands	14.0	61	

Practicability

- 21 interviewees found the initial 45-item version easy to complete and relevant to their situation

Summary/author's conclusion

- PSORIQoL appears to be a practical, reliable and valid instrument for measuring the impact of psoriasis on QoL
- It is still necessary to test the instrument's responsiveness to change in QoL associated with treatment

<table>
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<tr>
<td>S. P. McKenna. Development of the US PSORIQoL: A psoriasis-specific measure of quality of life. Int.J.Dermatol. 44 (6):462-469, 2005.

Ref ID: MCKENNA2005</td>
<td>Observational: within-group comparison

Validation by postal survey of a convenience sample of individuals from Mount Sinai School of Medicine</td>
<td>N = 72</td>
<td>Stage of disease journey: unclear (but 80% were receiving treatment)

Inclusion criteria: note stated

Exclusion criteria: not stated

<table>
<tr><th>Parameter</th><th>Postal sample (n=72)</th></tr>
<tr><td>Mean age (years±SD)</td><td>47.3±13.9</td></tr>
<tr><td>Mean gender M/F (%)</td><td>55.6/44.4</td></tr>
<tr><td>Mean duration of psoriasis (years±SD)</td><td>17.2±11.1</td></tr>
<tr><td>Currently receiving treatment (%)</td><td>80</td></tr>
<tr><td>Current flare (%)</td><td>62</td></tr>
</table>
</td>
<td>PSORIQoL – 25-item US version</td>
<td>DLQI</td>
<td>2 weeks</td>
<td>Construct validity; internal consistency; test-retest reliability</td>
<td>None stated</td>
</tr>
</table>

			Face and/or hands affected: 53.5					

Effect size

Test-retest reliability

- **PSORIQoL:** adequate (Spearman's r = 0.90)
- **DLQI:** acceptable (Spearman's r = 0.80)

Internal consistency

- **PSORIQoL:** Adequate ($\alpha \geq 0.88$)
- **DLQI:** Adequate ($\alpha \geq 0.88$)

Construct validity: PSORIQoL vs DLQI

- Adequate overall construct validity (Spearman's r = 0.81 at time 1 and r = 0.82 at time 2)

Summary/author's conclusion

- The US PSORIQoL appears to be a reliable and valid instrument for measuring the impact of psoriasis on QoL
- It is still necessary to test the instrument's responsiveness to change in QoL associated with treatment

<table>
<tr><th>Reference</th><th>Study type</th><th>Number of patients</th><th>Patient characteristics</th><th>Intervention</th><th>Comparison</th><th>Length of follow-up</th><th>Outcome measures</th><th>Source of funding</th></tr>
<tr>
<td>E. D. Dommasch, D. B. Shin, A. B. Troxel, D. Margolis, and J. Gelfand. Reliability, validity and responsiveness to change of the Patient Report of Extent of Psoriasis Involvement (PREPI) for measuring body surface area affected by psoriasis. Br.J.Dermatol. 162 (4):835-842, 2010.

Ref ID: DOMMASCH2010</td>
<td>Observational: Cross sectional study and prospective case series

Patients presenting to University of Pennsylvania Department of Dermatology enrolled Oct 2004-Oct 2008</td>
<td>N = 140 (N=76 for follow-up study assessing responsiveness to change at second out-patient visit)

Sample size calculation based on number needed to measure criterion validity with CIs of ±5%</td>
<td>Stage of disease journey: both new patients and patients in active follow-up for psoriasis in out-patient setting

Inclusion criteria: Diagnosis of plaque psoriasis; ≥18 years old

Exclusion criteria: unable to provide informed consent

<table>
<tr><th>Parameter</th><th>All (n=140)</th></tr>
<tr><td>Median age, years (IQR)</td><td>45.5 (33.5-57.0)</td></tr>
<tr><td>Mean gender M/F (%)</td><td>55/45</td></tr>
<tr><td colspan="2">Baseline skin involvement (median palms; IQR)</td></tr>
<tr><td>Patient estimated</td><td>4 (1-10)</td></tr>
<tr><td>Physician-estimated</td><td>3.5 (1-10.5)</td></tr>
</table>
</td>
<td>Body surface area (BSA) – patient report of extent of psoriasis involvement (PREPI) method

This involves asking the patient to estimate how many palm areas it would take to cover up all the patches of psoriasis (the first 15 patients were asked to select from categorised scores (little or no visible psoriasis [<1 palm]; only a few patches [1-2 palms]; scattered patches [3-10 palms]; extensive psoriasis covering large areas of the</td>
<td>Skindex -29

BSA assessed by dermatologist blinded to patients assessment</td>
<td>Median 2 days between test and re-test

Median duration between visit 1 and 2 for sensitivity to change was 98 days</td>
<td>Test-retest reliability; construct validity; responsiveness to change; practicability</td>
<td>Grant from NIH and National Institute of Arthritis, Musculoskeletal and Skin Diseases</td>
</tr>
</table>

			Race (%)		body [>10 palms]) Subsequent patients were allowed to classify their psoriasis as a continuous variable, which was categorised by the investigators			
			White	80				
			Black	7.9				
			Asian	6.4				
			Hispanic	3.6				
			Other	2.1				

Effect size

Test-retest reliability (comparing the patients' two self assessments administered over the telephone and during visit 1)

- Patient-reported number of palms (n=22): adequate test-retest reliability (ICC = 0.99; 95% CI 0.97-0.99)
- Categorized score (n=37): adequate test-retest reliability (ICC = 0.98; 95% CI 0.96-0.99)

Inter-rater reliability

- Self-estimated vs physician estimated PREPI:
  - Visit 1 (n=140): number of palms ICC = 0.82 (95%CI 0.75-0.87)
    : categorized score ICC = 0.80 (95%CI 0.73-0.85)
  - Visit 2 (n=76): number of palms ICC = 0.68 (95%CI 0.54-0.74)
    : categorized score ICC = 0.71 (95%CI 0.58-0.80)

Sensitivity to change (measured by area under the ROC curve [AUC], which describes how well changes in PREPI discriminate between patients who have changed and those who have not based on patient judgements in response to the Global Rating of Change Questionnaire. Improvement on GRC = global rating ≥2; worsening = global rating ≥-2)

- Both physician and patient-reported assessments discriminated well between those who did and did not improve and those who did or did not worsen

Measure	AUC (95% CI)	
	Patients assessment (n=62)	Physician's assessment (n=72)
Delta number of palms - improvement	0.7(0.58-0.81)	0.78 (0.67-0.90)
Percentage change - improvement	0.7 (0.57-0.81)	0.76 (0.63-0.88)
Delta number of palms - worsening	0.7 (0.56-0.80)	0.76 (0.64-0.87)
Percentage change - worsening	0.73 (0.59-0.83)	0.81 (0.70-0.90)

Construct validity: BSA vs Skindex (does PREPI capture information on health-related quality of life)

- Number of palms: adequate divergent construct validity (**Patient** estimated: Spearman's r = 0.59; 95%CI: 0.45-0.69; p<0.0001; **Physician** estimated: r = 0.48; 95%CI: 0.34-0.60)
- Categorised score: adequate divergent construct validity (**Patient** estimated: Spearman's r = 0.50; 95%CI: 0.53-0.62; p<0.0001; **Physician** estimated: r = 0.48; 95%CI: 0.33-0.60)

Practicability

- PREPI instrument required 2-3 mins to administer

Summary/author's conclusion

- PREPI appears to be a responsive, reliable and valid instrument for measuring body surface area affected by psoriasis

Reference	Study type	Number of patients	Patient characteristics	Intervention	Comparison	Length of follow-up	Outcome measures	Source of funding
H. Iyatomi, H. Oka, M. Hagiwara, A. Miyake, M. Kimoto, K. Ogawa, and M. Tanaka. Computerized quantification of psoriasis lesions with colour calibration: preliminary results. *Clin.Exp.Dermatol.* 34 (7):830-833, 2009. Ref ID: IYATOMI2009	**Observational:** Prospective within-group comparison Patients volunteered	N = 5	**Stage of disease journey:** 3 on oral ciclosporine 2 on UVB phototherapy **Inclusion criteria:** mild psoriasis **Exclusion criteria:** none stated **No baseline data available**	Digital photograph (with colour reference marker – Casmatch® – assessed using Computer assisted Area and Severity Index (CASI; evaluates severity from size and redness of lesions)	PASI	28 days	Construct validity	Grant from Ministry of Education, Science, Sports and Culture (Japan)

Effect size

Construct validity: Photograph vs PASI

- Adequate construct validity (r = 0.922)

Summary/author's conclusion

- Although only erythema was evaluated, this method appears to be capable of quantifying psoriasis lesions

<table>
<tr><th>Reference</th><th>Study type</th><th>Number of patients</th><th>Patient characteristics</th><th>Intervention</th><th>Comparison</th><th>Length of follow-up</th><th>Outcome measures</th><th>Source of funding</th></tr>
<tr>
<td>D. Farhi, B. Falissard, and A. Dupuy. Global assessment of psoriasis severity and change from photographs: a valid and consistent method. J.Invest.Dermatol. 128 (9):2198-2203, 2008.

Ref ID: FARHI2008</td>
<td>Observational: Prospective within-group comparison

Consecutive patients between December 200 and February 2006 approached in out-patient and phototherapy clinics

All photographic assessments were blinded to clinical data</td>
<td>N = 30</td>
<td>Stage of disease journey: varied (see table below)

Inclusion criteria: clinical diagnosis of psoriasis; agreement to be photographed at 2 visits 1 month apart

Exclusion criteria: none stated

<table>
<tr><th>Parameter</th><th>All N=30</th></tr>
<tr><td>Gender M/F (%)</td><td>60/40</td></tr>
<tr><td>Median age (range)</td><td>42(19-74)</td></tr>
<tr><td colspan="2">Past treatments, n (%)</td></tr>
<tr><td>Hospitalisation</td><td>7 (23)</td></tr>
<tr><td>Retinoid, MTX, ciclosporine</td><td>17 (57)</td></tr>
</table>
</td>
<td>Dynamic and static physician global assessment (PGA) from photographs

Dynamic PGA: global assessment of change between 2 photographs taken 1 month apart

(+5) Very large improvement/cleared (+90 to 100%)

(+4) Large improvement (+70 to 89%)

(+3) Moderate to large improvement (+50 to 69%)

(+2) Moderate improvement (+30 to +49%)

(+1) Mild improvement (+10 to +29%)</td>
<td>In-person clinical PGA rating

Assessment made by a single clinician</td>
<td>1 month</td>
<td>Inter-rater reliability; test-retest reliability; construct validity; practicability</td>
<td>Wyeth France provided funding for the camera used</td>
</tr>
</table>

	Sample size calculation for number of patient sand assessors was performed		<table><tr><td>Biologics</td><td>8 (27)</td></tr><tr><td colspan="2">Present treatments, n (%)</td></tr><tr><td>Retinoid, MTX, ciclosporine</td><td>6 (20)</td></tr><tr><td>Biologics</td><td>15 (50)</td></tr><tr><td>Topicals</td><td>8 (27)</td></tr></table>	(0) No or minimal change (–10 to +10%) (–1) Mild deterioration (–2) Moderate deterioration (–3) Moderate to large deterioration (–4) Large deterioration (–5) Very large deterioration **Static PGA:** (6) Severe psoriasis (5) Moderate to severe psoriasis (4) Moderate psoriasis (3) Mild to moderate psoriasis (2) Mild psoriasis (1) Psoriasis almost cleared (0) Clear (no lesion) Photographs were standardised and taken				

				under artificial neon light 9 standardised poses were adopted Assessments made by a panel of experts				

Effect size

Practicability

- Time to take a full set of photographs was approximately 5 minutes

Construct validity:

ICC calculated from percentage of total variance that results from patient effect using static scores (photographic vs clinical assessment)

- Change in static photographic PGA from baseline vs change in static clinical PGA from baseline: acceptable construct validity (ICC = 0.64 [95% CI 0.51-0.79])
- Mean panel photographic static PGA vs clinical static PGA: adequate construct validity (ICC = 0.87 [95% CI 0.75-0.93])

Reliability

- **Photographic dynamic PGA (n=5)**
  – acceptable intra-rater (test-retest) reliability (ICC = 0.85; 95% CI: 0.74-0.92); note that this was over a period of 1 month but using the same set of photographs

– acceptable inter-rater reliability (ICC = 0.73; 95% CI: 0.56-0.87)

- **Photographic static PGA (n=5)**
  – acceptable intra-rater (test-retest) reliability (ICC = 0.84; 95% CI: 0.78-0.90); note that this was over a period of 1 month same set of photographs
  – acceptable inter-rater reliability (ICC = 0.80; 95% CI: 0.68-0.89)

Summary/author's conclusion

- Global assessment of psoriasis severity and change from photographs by a panel of experts was accurate and consistent

<table>
<tr><th>Reference</th><th>Study type</th><th>Number of patients</th><th>Patient characteristics</th><th>Intervention</th><th>Comparison</th><th>Length of follow-up</th><th>Outcome measures</th><th>Source of funding</th></tr>
<tr>
<td>J. Berth-Jones, J. Thompson, K. Papp, and Copenhagen Psoriasis Working Group. A study examining inter-rater and intrarater reliability of a novel instrument for assessment of psoriasis: the Copenhagen Psoriasis Severity Index. Br.J.Dermatol. 159 (2):407-412, 2008.

Ref ID: BERTHJONES2008</td>
<td>Observational: cross sectional study

Volunteers with very mild to very severe chronic plaque psoriasis

To minimise memory or recall bias (due to similar assessment of plaque quality in PASI and CoPSI a 2-sequence design was adopted:

PGA, CoPSI, PASI or PGA, PASI, CoPSI – raters were</td>
<td>N = 16</td>
<td>Stage of disease journey: unclear

Inclusion criteria: not stated

Exclusion criteria: pustular, erythrodermic or acute guttate psoriasis

<table>
<tr><th>Parameter</th><th>All N=16 (224 ratings)</th></tr>
<tr><td>Gender M/F (%)</td><td>75/25</td></tr>
<tr><td>Mean age (range)</td><td>55(42-75)</td></tr>
<tr><td>Mean CoPSI ± SD</td><td>32.6±14.3</td></tr>
<tr><td>Mean PASI± SD</td><td>10.8±9.0</td></tr>
<tr><td>Mean PGA±SD</td><td>3.7±1.3</td></tr>
</table>
</td>
<td>Copenhagen Psoriasis Severity Index (CoPSI)

Note that the genitalia were not scored in this study so the score range was restricted to 0-81

Assessed by 14 senior dermatologists in the morning and the afternoon.

Dermatologists had a 2.5-h education session on the use of all 3</td>
<td>PGA, PASI

Note the PGA score was based on the average intensity of the most prominent sign (thickness, erythema or scaling) and the proportion of skin involved was not considered. It was rated on a 7-point scale:
• Clear
• Almost clear
• Mild
• Mild-to-moderate</td>
<td>N/A</td>
<td>Inter-rater reliability; test-retest reliability; construct validity</td>
<td>Leo Pharma</td>
</tr>
</table>

	randomly assigned to follow one sequence in the morning and the other in the afternoon			scales before the study Lighting and temperature were maintained at a consistent level Subjects remained in one examination room and raters moved between rooms in a pre-defined order	• Moderate • Moderate-to-severe • Severe			

Effect size

Responsiveness

- Half of the theoretical range of PASI (0-72) appears to be redundant, while the results obtained with CoPSI occupy a much larger part of the total range (0-81)
- PASI fails to separate out the subjects at the lower end of the severity spectrum but CoPSI separates these subjects out more effectively

Construct validity: using the mean of the two scores for each individual

- **CoPSI:** Adequate construct validity (r = 0.89 vs PASI and r = 0.75 vs PGA)

- **PASI vs PGA:** Adequate construct validity (r = 0.75)
- **For pairs of individual readings:**

Comparison	Correlation (Spearman's r)	
	Morning ratings	Afternoon ratings
PGA vs PASI	0.67	0.75
PGA vs CoPSI	0.68	0.73
PASI vs CoPSI	0.86	0.89

- Note: for all of the above correlations p<0.0001

Reliability

Score	Intra-rater reliability, ICC (95% CI)	Inter-rater reliability, ICC (95% CI)
CoPSI	0.95 (0.92-0.98)	0.83 (0.71-0.95)
PASI	0.96 (0.93-0.99)	0.91 (0.84-0.97)
PGA	0.81 (0.71-0.90)	0.61 (0.43-0.79)

Summary/author's conclusion

- The CoPSI and the PASI both provided reproducible psoriasis severity assessments, and they were both superior to PGA in terms of inter- and intra-rater reliability
- The CoPSI may overcome several of the problems of the PASI, including the ability to separate milder cases and avoiding the need to estimate the percentage skin involvement.
- The CoPSI also incorporates more meaningful weighting of different anatomical areas

<table>
<tr><th>Reference</th><th>Study type</th><th>Number of patients</th><th>Patient characteristics</th><th>Intervention</th><th>Comparison</th><th>Length of follow-up</th><th>Outcome measures</th><th>Source of funding</th></tr>
<tr>
<td>J. C. S. Szepietowski. Clinical evaluation of the self-administered psoriasis area and severity index (SAPASI). Acta Dermatovenerologica Alpina, Panonica et Adriatica 10 (3):79-83, 2001.

Ref ID: SZEPIETOWSKI2001</td>
<td>Observational: cross sectional study

Poland</td>
<td>N = 51</td>
<td>Stage of disease journey: unclear

Inclusion criteria: not stated

Exclusion criteria: not stated

<table>
<tr><th>Parameter</th><th>All N=51</th></tr>
<tr><td>Gender M/F (%)</td><td>64.7/35.3</td></tr>
<tr><td>Mean age, years</td><td>46.6±17.3</td></tr>
<tr><td>Disease duration</td><td>17.8±11.9</td></tr>
<tr><td>Psoriasis vulgaris (n)</td><td>40</td></tr>
<tr><td>Psoriatic arthritis (n)</td><td>11</td></tr>
<tr><td>Mean PASI score</td><td>16.1±11.9</td></tr>
</table>
</td>
<td>SAPASI</td>
<td>PASI; extent score from SPI</td>
<td>N/A</td>
<td>Construct validity</td>
<td>Wroclaw University of Medicine</td>
</tr>
<tr><td colspan="9">Effect size

Construct validity:</td></tr>
</table>

- SAPASI vs PASI: Acceptable construct validity (Spearman's r = 0.62; p<0.00001)
- SAPASI vs extent score from SPI: Acceptable construct validity (Spearman's r = 0.62; p<0.00001)
- There was no significant difference in the evaluation of skin lesions between those with and without PsA

Summary/author's conclusion

- There is a strong relationship between PASI and SAPASI assessments

<table>
<tr><th>Reference</th><th>Study type</th><th>Number of patients</th><th>Patient characteristics</th><th>Intervention</th><th>Comparison</th><th>Length of follow-up</th><th>Outcome measures</th><th>Source of funding</th></tr>
<tr>
<td>S. R. Feldman, A. B. Fleischer, D. M. Reboussin, S. R. Rapp, M. Exum, A. R. Clark, and L. Nurre. The self-administered psoriasis area and severity index is valid and reliable. J.Invest.Dermatol. 106 (1):183-186, 1996.

Ref ID: FELDMAN1996</td>
<td>Observational: within-group comparison

Wake Forest University Psoriasis and Skin Treatment Centre</td>
<td>N = 80</td>
<td>Stage of disease journey: new patients, patients returning for follow-up visits and patients returning for treatments

Inclusion criteria: not stated

Exclusion criteria: not stated

<table>
<tr><th>Parameter</th><th>All N=80</th></tr>
<tr><td>Gender M/F (%)</td><td>47.5/52.2</td></tr>
</table>
</td>
<td>SAPASI

Patients received no training in the use of the instrument</td>
<td>PASI

Assessed on the same day as the SAPASI by one of 3 clinicians blind to the SAPASI rating</td>
<td>2 days (for repeat observations)</td>
<td>Construct validity; sensitivity to change; test-retest reliability; inter-rater reliability</td>
<td>National Institute of Mental Health</td>
</tr>
<tr>
<td colspan="9">Effect size

Construct validity (Pearson’s correlation coefficient):</td>
</tr>
</table>

- SAPASI vs PASI on first day: r = 0.58
- SAPASI vs PASI on second day: r = 0.70

- **SAPASI vs PASI for BSA determinations:**
  - Head: r = 0.62 (acceptable)
  - Upper extremities r = 0.75 (adequate)
  - Trunk: r = 0.73 (adequate)
  - Lower extremities: r = 0.69 (acceptable)

- **SAPASI vs PASI for erythema, induration and scale scores:**
  - Erythema: r = 0.39 (poor)
  - Induration: r = 0.24 (poor)
  - Scale: r = 0.38 (poor)

Test-retest reliability (n=19):

- **SAPASI:** Adequate test-retest reliability (Pearson's r = 0.82; p = 0.0001)
- **PASI:** Adequate test-retest reliability (r = 0.91; p = 0.0001)

Inter-rater reliability for BSA measurements (5 raters; 40 body silhouettes):

- Adequate inter-rater reliability (ICC = 0.953)
  - Head: ICC = 0.962
  - Upper extremity: ICC = 0.944
  - Trunk: ICC = 0.939
  - Lower extremities: ICC = 0.84

Sensitivity to change (n=38 with repeated paired observations)

- Acceptable sensitivity to change (over ≥2 days): change in SAPASI vs change in PASI score (r = 0.63)
- No significant difference in mean difference between SAPASI and PASI scores at two time points:
- First test: -3.47 ± 6.46; second test: -2.50 ± 8.5 (p =0.22)

Summary/author's conclusion

- Patients can accurately assess their psoriasis in a valid and reproducible fashion using the SAPASI, and it is responsive to changes over time

<table>
<tr><th>Reference</th><th>Study type</th><th>Number of patients</th><th>Patient characteristics</th><th>Intervention</th><th>Comparison</th><th>Length of follow-up</th><th>Outcome measures</th><th>Source of funding</th></tr>
<tr><td>A. B. Fleischer, S. R. Feldman, and C. L. Dekle. The SAPASI is valid and responsive to psoriasis disease severity changes in a multi-centre clinical trial. J.Dermatol. 26 (4):210-215, 1999.

Ref ID: FLEISCHER1999</td><td>Observational: within group comparison

Population drawn from multicentre, double blind clinical trial of tazarotene</td><td>N = 182</td><td>Stage of disease journey: unclear

Inclusion criteria: not stated

Exclusion criteria: not all SAPASI items completed; not available at 12-week follow up; missing data

<table><tr><th>Parameter</th><th>All N=182</th></tr><tr><td>Gender M/F (%)</td><td>64.7/35.3</td></tr><tr><td>Mean age, years</td><td>48±14</td></tr></table></td><td>SAPASI</td><td>PASI-equivalent: (erythema + induration + scale)*BSA%</td><td>12 weeks</td><td>Construct validity</td><td>Not stated</td></tr>
<tr><td colspan="9">Effect size

Note that the population is a pooled group including those treated with tazarotene 0.1% gel alone or in combination with placebo cream, or low-, mid- or high-potency corticosteroid cream</td></tr>
</table>

Construct validity:

- SAPASI vs PASI-equivalent: Poor construct validity (Pearson's r = 0.54 at baseline; r = 0.33 at endpoint; p=0.0001)

Sensitivity to change:

- SAPASI has poor sensitivity to change (Pearson's r = 0.16; p-0.04)
- SAPASI: 39% decrease in severity
- PASI: 62% decrease in severity

Summary/author's conclusion

- This study demonstrates the general validity of the SAPASI and demonstrate that it can detect changes in disease severity in a clinical trial

<table>
<tr><th>Reference</th><th>Study type</th><th>Number of patients</th><th>Patient characteristics</th><th>Intervention</th><th>Comparison</th><th>Length of follow-up</th><th>Outcome measures</th><th>Source of funding</th></tr>
<tr><td>A. B. Fleischer, S. R. Rapp, D. M. Reboussin, J. C. Vanarthos, and S. R. Feldman. Patient measurement of psoriasis disease severity with a structured instrument. J.Invest.Dermatol. 102 (6):967-969, 1994.

Ref ID: FLEISCHER1994</td><td>Observational: within group comparison

Wake Forest University Psoriasis and Skin Treatment Centre

Development and assessment of a new scoring system</td><td>N = 43 (15 assessed for sensitivity to change)</td><td>Stage of disease journey: unclear

Inclusion criteria: diagnosis of psoriasis vulgaris

Exclusion criteria: not all SAPASI items completed; not available at 12-week follow up; missing data

<table><tr><th>Parameter</th><th>All N=43</th></tr><tr><td>Gender M/F (%)</td><td>46.5/53.5</td></tr><tr><td>Mean age, years</td><td>44.7±13.4</td></tr><tr><td>Mean PASI</td><td>8.1± 6.6</td></tr><tr><td>Mean SAPASI</td><td>1.1±10.7</td></tr></table></td><td>SAPASI</td><td>PASI

Completed on the same day as the SAPASI by one of 2 clinicians blinded to the SAPASI rating</td><td>Mean: 18.4±9.1 days</td><td>Sensitivity to change</td><td>Glaxo Dermatology Research Fellowship</td></tr>
<tr><td colspan="9">Effect size

Sensitivity to change:</td></tr>
</table>

- Mean decrease in score: PASI = 7.3±5.7; SAPASI = 5.9±4.7
- Both showed significant improvements: PASI $p<0.0003$; SAPASI $p<0.05$

Summary/author's conclusion

- Although the SAPASI may not allow for accurate prediction of clinical disease severity in an individual , the SAPASI facilitates prediction of disease severity in a population

Reference	Study type	Number of patients	Patient characteristics	Intervention	Comparison	Length of follow-up	Outcome measures	Source of funding
B. Kirby. The Salford Psoriasis Index: An holistic measure of psoriasis severity. *Br.J.Dermatol.* 142 (4):728-732, 2000. Ref ID: KIRBY2000	**Observational:** 3 separate cross sectional studies Consecutive patients seen in the Psoriasis Speciality Clinic, Hope Hospital, UK	N = 150 for SPI inter-observer reliability N= 100 for construct validity N=20 for PASI assessment	**Stage of disease journey:** unclear **Inclusion criteria:** diagnosis of psoriasis **Exclusion criteria:** not stated No baseline data available	Salford Psoriasis Index (SPI)	Psoriasis disability index (PDI), PASI, SAPASI	6 weeks	Inter-rater reliability; intra-rater reliability; construct validity; sensitivity to change	Novartis Pharmaceuticals Ltd.

Effect size

Inter-rater reliability (n=20; 6 trained clinical observers):

- PASI: Acceptable (Spearman's r= 0.71; 95% CI [0.51-0.86])
- SPI: Adequate for the historical disease severity score (r=0.86 [95% CI: 0.76-0.94) and acceptable for the extent score (r=0.70 [95% CI: 0.56-0.89)

Intra-rater reliability

- SPI: Adequate for the psychological impact score (r = 0.997[95% CI: 0.994-0.999])

Divergent construct validity (Spearman's correlation coefficient)

- PASI vs PDI: r = 0.45; p<0.001
- SPI (psychological impact score) vs PASI: r = 0.28; p<0.05
- SPI (psychological impact score) vs SAPASI: r=0.19; p = 0.1

- PDI vs SAPASI: r = 0.27; p<0.05

Convergent construct validity (Spearman's correlation coefficient)**:**

- SAPASI vs PASI: poor (r = 0.54)
- SPI (psychological impact score) vs PDI (n=100): r=0.59; p<0.001 (poor validity)

Sensitivity to change (n=20 treated with a number of different modalities)

- Statistically significant decrease for extent and psychological impact scores (p<0.0001), but not for the historical disease severity score, which wouldn't be expected to change

Summary/author's conclusion

- The SPI will be a more relevant real life categorization of psoriasis severity because it takes a holistic approach based not only on physician assessment but also psychological disability and treatment resistance

<table>
<tr><th>Reference</th><th>Study type</th><th>Number of patients</th><th>Patient characteristics</th><th>Intervention</th><th>Comparison</th><th>Length of follow-up</th><th>Outcome measures</th><th>Source of funding</th></tr>
<tr>
<td>A. Y. Finlay, G. K. Khan, D. K. Luscombe, and M. S. Salek. Validation of Sickness Impact Profile and Psoriasis Disability Index in Psoriasis. Br.J.Dermatol. 123 (6):751-756, 1990.

Ref ID: FINDLAY1990</td>
<td>Observational: Cross sectional study

Sequentially recruited at the University Hospital of Wales</td>
<td>N = 32</td>
<td>Stage of disease journey: 72% in-patients

Inclusion criteria: diagnosis of psoriasis

Exclusion criteria: not stated

<table>
<tr><th>Parameter</th><th>All N=32</th></tr>
<tr><td>Gender M/F (%)</td><td>46.9/53.1</td></tr>
<tr><td>Median age (range), years</td><td>35 (14-73)</td></tr>
<tr><td>Inpatients</td><td>72%</td></tr>
<tr><td>Median PASI (range)</td><td>5.5 (2-24)</td></tr>
<tr><td>Median PDI (range)</td><td>38 (7-88)</td></tr>
</table>
</td>
<td>Sickness Impact Profile (SIP)</td>
<td>PASI

Psoriasis disability index (PDI)

PDI: 15 questions answered on a 1-7 linear analogue scales

The questions were grouped under 5 headings: daily activities (5 items); work/school (3 items); personal relationships (2 items); leaisure (4 items); and treatment (1 item)</td>
<td>N/A</td>
<td>Discriminant construct validity</td>
<td>Not stated</td>
</tr>
<tr><td colspan="9">Effect size</td></tr>
</table>

Divergent construct validity:

- Adequate: Spearman's r = 0.40; p<0.05; therefore, PASI and PDI are not measuring the same construct

Summary/author's conclusion

- The PDI is an appropriate method to give a rapid overall measure of psoriasis disability

<table>
<tr><th>Reference</th><th>Study type</th><th>Number of patients</th><th>Patient characteristics</th><th>Intervention</th><th>Comparison</th><th>Length of follow-up</th><th>Outcome measures</th><th>Source of funding</th></tr>
<tr>
<td>J. Berth-Jones, K. Grotzinger, C. Rainville, B. Pham, J. Huang, S. Daly, M. Herdman, P. Firth, and K. Hotchkiss. A study examining inter- and intrarater reliability of three scales for measuring severity of psoriasis: Psoriasis Area and Severity Index, Physician's Global Assessment and Lattice</td>
<td>Observational: cross sectional study

Volunteers with very mild to very severe chronic plaque psoriasis

Sample size selected to ensure coefficients were calculated with a standard error of 10%, given a false positive rate of 5%</td>
<td>N = 16</td>
<td>Stage of disease journey: unclear

Inclusion criteria: diagnosis of psoriasis

Exclusion criteria: pustular, erythrodermic or acute guttate psoriasis

<table>
<tr><th>Parameter</th><th>All N=16</th></tr>
<tr><td>Gender M/F (%)</td><td>56.3/43.7</td></tr>
<tr><td>Mean age, years (range)</td><td>50 (35-71)</td></tr>
</table>
</td>
<td>PASI, Physician’s Global Assessment (PGA), Lattice-System (LS)-PGA

Assessed by 14 raters with a range of experience

To minimise memory or recall bias (due to similar assessment of BSA in PASI and LS-PGA a 2-sequence design was adopted:

PGA, LS-PGA, PASI or PGA, PASI, LS-PGA – raters were randomly</td>
<td>PASI, Physician’s Global Assessment (PGA), Lattice-System (LS)-PGA

PGA was rated on a 7-point scale:
• Clear
• Almost clear
• Mild
• Mild-to-moderate
• Moderate
• Moderate-to-severe

Severe</td>
<td>N/A</td>
<td>Construct validity; inter- and intra-rater reliability</td>
<td>Glaxo SmithKline</td>
</tr>
</table>

System Physician's Global Assessment. *Br.J.Dermatol.* 155 (4):707-713, 2006. Ref ID: BERTHJONES2006				assigned to follow one sequence in the morning and the other in the afternoon Lighting and temperature were maintained at a consistent level Subjects remained in one examination room and raters moved between rooms in a pre-defined order				

Effect size

Construct validity

Adequate construct validity for all comparisons (Spearman's rank correlation coefficient)

- LS-PGA vs PASI: r = 0.92 (p<0.001)
- LS-PGA vs PGA; r = 0.73 (p<0.001)
- PGA vs PASI; r = 0.79 (p<0.001)

Agreement for dichotomised scores

Outcome 1	Outcome 2	Agreement
PASI vs PGA		
PASI ≤4	PGA clear or nearly clear	K = 0.64 (0.53-0.74)
PASI ≥18	PGA very severe or severe	K = 0.18 (0.09-0.27)
PASI vs LS-PGA		
PASI ≤4	LS-PGA clear or nearly clear	K = 0.61 (0.50-0.73)
PASI ≥18	LS-PGA very severe or severe	K = 0.62 (0.55-0.69)
LS-PGA vs PGA		
LS-PGA clear or nearly clear	PGA clear or nearly clear	K = 0.67 (0.54-0.80)
LS-PGA very severe or severe	PGA very severe or severe	K = 0.08 (0.03-0.14)

Reliability

Score	Intra-rater reliability, ICC (95% CI)	Inter-rater reliability, ICC (95% CI)
PASI	0.94 (0.86-1.00) Adequate	0.90 (0.83-0.97) Adequate
LS-PGA	0.91 (0.77-1.00) Adequate	0.84 (0.73-0.95) Adequate
PGA	0.88 (0.69-1.00) Acceptable	0.75 (0.61-0.88) Acceptable

Note: 99% of assessment scores on PASI were <40, whereas the PGA and LS-PGA scores spanned the majority of their scales (1-6 and 2-8, respectively)

Summary/author's conclusion

- The reliability of PGA and PASI are demonstrated
- LS-PGA shows similar reliability and good levels of correlation with PASI
- In terms of inter-rater reliability the scales can be ranked in order as: PASI, LS-PGA, PGA

<table>
<tr><th>Reference</th><th>Study type</th><th>Number of patients</th><th>Patient characteristics</th><th>Intervention</th><th>Comparison</th><th>Length of follow-up</th><th>Outcome measures</th><th>Source of funding</th></tr>
<tr>
<td>T. Henseler and K. Schmitt-Rau. A comparison between BSA, PASI, PLASI and SAPASI as measures of disease severity and improvement by therapy in patients with psoriasis. Int.J.Dermatol. 47 (10):1019-1023, 2008.

Ref ID: HENSLER2008</td>
<td>Observational: within group comparison

Patients with moderate-to-severe chronic plaque psoriasis at 18 dermatologic out-patient centres treated with 1 mg/kg/wk efalizumab (subcutaneous)</td>
<td>N = 33</td>
<td>Stage of disease journey: >60% had previously been treated with at least 4 different systemic treatments

Inclusion criteria: not stated

Exclusion criteria not stated

<table>
<tr><th>Parameter</th><th>All N=33</th></tr>
<tr><td>Gender M/F (%)</td><td>63.6/36.4</td></tr>
<tr><td>Mean age, years ±SD</td><td>48.7 ±13.7</td></tr>
<tr><td>Median age of disease onset (years)</td><td>21.0</td></tr>
<tr><td>Median PASI score</td><td>20.8</td></tr>
<tr><td>History of ≥4 systemic treatments (most commonly PUVA, fumeric</td><td>>60%</td></tr>
</table>
</td>
<td>BSA, PASI, SAPASI

BSA: mean of affected skin surface assuming that head = 10%; upper extremities = 20%; trunk = 30% and lower extremities = 40% of total body surface</td>
<td>BSA, PASI, SAPASI</td>
<td>12 weeks</td>
<td>Construct validity; sensitivity to change</td>
<td>Serono</td>
</tr>
</table>

			acid esters, MTX, retinoids and ciclosporine A)						

Effect size

Construct validity

Adequate construct validity for all comparisons (correlation coefficient)

- SAPASI vs PASI: r = 0.91 (p<0.0001)
- SAPASI vs BSA; r = 0.73 (p<0.0001)
- PASI vs BSA; r = 0.81 (p<0.0001)

Note: correlation between SAPASI and PASI significantly stronger than any correlation involving BSA

Sensitivity to change

- Relative change between baseline and follow-up: SAPASI = 70.6%; PASI = 67.3%; BSA = 48.6%

Summary/author's conclusion

- There is a high correlation between all measures
- The high correlation between SAPASI and PASI suggests that both measures, one administered by the patient and one by a dermatologist, are of equivalent value

<table>
<tr><th>Reference</th><th>Study type</th><th>Number of patients</th><th>Patient characteristics</th><th>Intervention</th><th>Comparison</th><th>Length of follow-up</th><th>Outcome measures</th><th>Source of funding</th></tr>
<tr>
<td>R. Shikiar, B. W. Bresnahan, S. P. Stone, C. Thompson, J. Koo, and D. A. Revicki. Validity and reliability of patient reported outcomes used in psoriasis: results from two randomized clinical trials. Health & Quality of Life Outcomes 1:53, 2003.

Ref ID: SHIKIAR2003</td>
<td>Observational: Within group comparison

Data from 2 RCTs – blinded examination of psychometric properties of patient-reported instruments in these studies (not treatment effects)

Phase III, randomised, double-blind, parallel group, placebo controlled, multicentre clinical trial (efalizumab vs placebo); North America</td>
<td>N = 1095

Study A: n = 498

Study B: n = 597</td>
<td>Stage of disease journey: unclear

Inclusion criteria: At least moderate psoriasis (BSA≥10%; PASI≥12) for at least 6 months; age 18-70 years

Exclusion criteria: Concomitant diseases or allergies to medications used; pregnant or lactating females

<table>
<tr><th>Parameter</th><th>Study A (n=498)</th><th>Study B (n=597)</th></tr>
<tr><td>Mean age (years), ±SD</td><td>44.1±12.0</td><td>45.6±12.7</td></tr>
<tr><td>Meangender M/F (%)</td><td>72.3/27.7</td><td>64.8/35.2</td></tr>
<tr><td>Baseline PASI±SD</td><td>18.84±7.05</td><td>20.01±8.35</td></tr>
</table>
</td>
<td>DLQI</td>
<td>PASI, PGA

PGA: Physician’s global assessment of change compared to baseline condition (using photographs from baseline to aid in making the assessment)

‘Cleared’ = 100% improvement; ‘excellent’ = 75-99% improvement; ‘good’ = 50-74% improvement; ‘fair’ = 25-49% improvement;</td>
<td>12 weeks</td>
<td>Sensitivity to change; construct validity; internal consistency</td>
<td>Genentech Inc</td>
</tr>
</table>

	Analyses were performed on blinded data (separately for study A and study B)				'slight = 1-24% improvement; 'unchanged'; 'worse'			

Effect size

Sensitivity to change

Correlation between change scores for DLQI and physician reported values

- Study A – Poor (r = 0.47 compared with PASI; 0.46 compared with PGA)
- Study A – Poor (r = 0.54 compared with PASI; 0.53 compared with PGA)

Classification into PASI-defined categories (ANOVA)

- Significant difference in improvement on DLQI between responders (PASI75 or PASI50) and non-responders (<PASI50)

	Study A				**Study B**			
	Mean change score				**Mean change score**			
	<50%	**≥50% and <75%**	**≥75%**	**p-value**	**<50%**	**≥50% and <75%**	**≥75%**	**p-value**
DLQI	2.48	5.33	9.57	<0.0001	2.49	6.83	10.03	<0.0001

Divergent construct validity (DLQI vs PASI; Pearson's product moment correlation coefficient**)**

Correlations were significantly stronger at the end of the study than at baseline

- Study A – Adequate (r = 0.20 at baseline; 0.51 at end point)
- Study B – Adequate (r = 0.25 at baseline; 0.59 at end point)

Internal consistency of DLQI

- Study A – Adequate: α = 0.871 at baseline and 0.921 at week 12
- Study B – Adequate: α = 0.869 at baseline and 0.919 at week 12

Summary/author's conclusion

- The DLQI is useful for the measurement of dermatological-related limitations of functional ability and the frequency, severity and impact of psoriasis symptoms on patients' lives and psoriasis-related QoL; it provides information about the change in the subjects symptoms that supplement the physicians clinical assessments

<table>
<tr><th>Reference</th><th>Study type</th><th>Number of patients</th><th>Patient characteristics</th><th>Intervention</th><th>Comparison</th><th>Length of follow-up</th><th>Outcome measures</th><th>Source of funding</th></tr>
<tr>
<td>R. G. Langley and C. N. Ellis. Evaluating psoriasis with Psoriasis Area and Severity Index, Psoriasis Global Assessment, and Lattice System Physician's Global Assessment. J.Am.Acad.Dermatol. 51 (4):563-569, 2004.

Ref ID: LANGLEY2004</td>
<td>Observational: cross sectional study

Recruited from out-patient departments, phototherapy unit and day treatment centre of the University of Michigan Department of Dermatology, USA (aiming to recruit a range of severities)

Recall bias was minimised: patients randomly assigned to different rooms in the morning and afternoon; identical</td>
<td>N = 35

Note: “patients were compensated for their time”</td>
<td>Stage of disease journey: unclear (but no medications were used during the study)

Inclusion criteria: not stated

Exclusion criteria: not stated

<table>
<tr><th>Parameter</th><th>All (n=35)</th></tr>
<tr><td>Median age, years (range)</td><td>42 (22-62)</td></tr>
<tr><td>Mean gender M/F (%)</td><td>66/34</td></tr>
<tr><td colspan="2">Ethnicity, n (%)</td></tr>
<tr><td>White</td><td>31 (89%)</td></tr>
</table>
</td>
<td>PASI, PGA, LS-PGA

PGA:

• Severe: very marked plaque elevation, scaling, and/or erythema

• Moderate to Severe: marked plaque elevation, scaling, and/or erythema

• Moderate: moderate plaque elevation, scaling, and/or erythema

• Mild to moderate: intermediate between moderate and mild

• Mild: slight plaque elevation, scaling, and/or erythema</td>
<td>All comparisons

Each subject was evaluated twice by each of 17 physicians (who received 30 mins training on the day)

53% of physicians were experienced (previous involvement in 4 or more similar clinical trials); but none of them had previous experience with the LS-PGA</td>
<td>N/A</td>
<td>Construct validity; inter and intra-rater reliability; internal consistency</td>
<td>Biogen Inc</td>
</tr>
</table>

	assessment rooms and patient gowns; no interaction between patient and physician		Black: 2 (6%) Asian American: 1 (3%) Hispanic: 1 (3%)	• Almost clear: intermediate between mild and clear • Clear: no signs of psoriasis (post-inflammatory hypopigmentation or hyperpigmentation could be present).				

Effect size

Construct validity (Spearman correlation coefficient)

	LS-PGA	**PGA**
PASI	0.86	0.87
PGA	0.83	

Internal consistency

- Adequate internal consistency (α=0.9 for each)

Reliability (all raters; n=17)

Assessed by ANOVA; lower σ values denote lower variation

	Intrarater variation (σ by	**Intrarater variation** (σ by	**Corrected intrarater**

	ANOVA)	ANOVA)	**variation** (relative σ by ANOVA)
PASI	2.5	8.8	2.7
PGA	0.2	1.2	2.3
LS-PGA	0.4	1.6	2.2

Summary/author's conclusion

- All three measures were highly correlated and had high internal consistency
- PGA and LS-PGA had lower intra-rater variation than PASI
- Experience was beneficial in reducing variation in PASI scores, but was not required with PGA or LS-PGA
- The LS-PGA does not require experience and is a reliable measure of the therapeutic effect in psoriasis, and would allow comparisons across different trials

<table>
<tr><th>Reference</th><th>Study type</th><th>Number of patients</th><th>Patient characteristics</th><th>Intervention</th><th>Comparison</th><th>Length of follow-up</th><th>Outcome measures</th><th>Source of funding</th></tr>
<tr>
<td>S. Krenzer, M. Radtke, K. Schmitt-Rau, and M. Augustin. Characterization of patient-reported outcomes in moderate to severe psoriasis. Dermatology 223 (1):80-86, 2011.

Ref ID: KRENZER2011</td>
<td>Observational: case series

Recruited from out-patient departments and dermatological practices in Germany (all receiving efalizumab in routine care)</td>
<td>N = 1787</td>
<td>Stage of disease journey: moderate to severe plaque psoriasis receiving efalizumab

Inclusion criteria: not stated

Exclusion criteria: not stated

<table>
<tr><th>Parameter</th><th>All (n=1787)</th></tr>
<tr><td>Median age, years (range)</td><td>46 (16-93)</td></tr>
<tr><td>Mean gender M/F (%)</td><td>63.8/36.2</td></tr>
<tr><td>Mean height (cm)</td><td>174.3</td></tr>
<tr><td>Mean weight (kg)</td><td>84.1</td></tr>
</table>
</td>
<td>PASI, BSA, DLQI (German version)

BSA:

• Total BSA calculated by adding percentages of affected areas of head, trunk, upper and lower extremities

PASI:

• Measures extent and severity on a range of 0-72</td>
<td>PASI vs BSA (at baseline, 3 months and 12 months)

Change in PASI vs change in BSA (at 3 and 12 months)</td>
<td>1 year</td>
<td>Construct validity</td>
<td>Merck Serono</td>
</tr>
</table>

			Previous psoriasis phenotypes					
			Erythrodermic	39.4%				
			Pustular	28.4%				
			Palmoplantar	56.7%				

Effect size

Construct validity (Pearson correlation coefficient)

	Baseline (n=469)	**3 months (n=298)**	**6 months (n=109)**
PASI vs BSA	0.450	0.694	0.832

Sensitivity to change (Pearson correlation coefficient for change from baseline)

Change scores	**3 months (n=265)**	**6 months (n=94)**
PASI vs BSA	0.771	0.792

Summary/author's conclusion

- PASI and BSA, and change in these scores, were correlated

Reference	Study type	Number of patients	Patient characteristics	Intervention	Comparison	Length of follow-up	Outcome measures	Source of funding
V. Shankar, S. Ghosh, K. Ghosh, and U. Chaudhuri. PASI and PQOL-12 score in psoriasis: is there any correlation? Indian J.Dermatol. 56 (3):287-289, 2011. Ref ID: SHANKAR2011	**Observational**: Cross sectional study Department of Dermatology, MGM Medical College and LSK Hospital, Kishanganj, Bihar, India, from November 2008 to August 2009	N = 34	**Stage of disease journey:** unclear **Inclusion criteria:** all morphological variants of psoriasis with or without joint involvement, pre-treated or untreated. **Exclusion criteria:** psoriasiform dermatoses due to other etiologies; psoriatic arthropathy without skin involvement; nail psoriasis without skin involvement; generalized pustular psoriasis de novo without any associated or previous history of psoriatic plaque; and sebo-psoriasis, palmo-plantar pustulosis or inverse psoriasis presenting alone morphologically without any other classical clinical presentation of psoriasis elsewhere in the skin **Baseline characteristics** 47% male	**PQOL-12:** 12-item self-administered, disease-specific psychometric instrument **PASI:** Measures extent and severity on a range of 0-72	PASI vs PQOL-12	NA	Construct validity	None

			Age range: 8 to 55 years (median: 33.5 years) Duration of disease: 1 month to 20 years. PASI range: 0.8 to 32.8 PQOL-12 range: 4 to 120					

Effect size

Construct validity (correlation coefficient): PASI vs PQOL12

r = 0.422

Summary/author's conclusion

Disease severity has minimal correlation with quality of life in people with psoriasis.

Even psoriasis of limited objective severity, especially located on visible parts of the body, may induce great psychological trauma to the patients

H.2.2 Non-comparative data

<table>
<tr><th>Reference</th><th>Study type</th><th>Number of patients</th><th>Patient characteristics</th><th>Intervention</th><th>Length of follow-up</th><th>Outcome measures</th><th>Source of funding</th></tr>
<tr>
<td>A. B. Fleischer, S. R. Feldman, S. R. Rapp, D. M. Reboussin, M. Exum, A. R. Clark, and V. Rajashekhar. Disease severity measures in a population of psoriasis patients: the symptoms of psoriasis correlate with self-administered psoriasis area severity index scores. J.Invest.Dermatol. 107 (1):26-29, 1996.

Ref ID:</td>
<td>Observational: Case series

Patients identified from electronic billing records from Wake Forest University, USA; had received clinical diagnosis of psoriasis between May 1992 and December 1993

Participants invited to complete a survey on demographics, therapeutics, co-existing conditions, psychological functioning, and quality of life</td>
<td>N = 578 (but only a random sample of 30 assessed for inter-rater reliability)</td>
<td>Stage of disease journey: 23% on intense treatment; 61% moderate treatment; 16% over-the-counter treatment

Inclusion criteria: Age ≥ 18 years

Exclusion criteria: not diagnosed with psoriasis; children

<table>
<tr><th>Parameter</th><th>All (n=101)</th></tr>
<tr><td>Mean age – years</td><td>48.8 ± 14.6</td></tr>
<tr><td>Caucasian</td><td>91%</td></tr>
<tr><td>African American</td><td>6%</td></tr>
<tr><td>Native American</td><td>1%</td></tr>
<tr><td>Gender M/F (%)</td><td>43/57</td></tr>
<tr><td>Time since psoriasis diagnosis (years)</td><td>14.4 ± 12.8</td></tr>
</table>
</td>
<td>SAPASI – disease severity tool completed by the patients themselves</td>
<td>N/A</td>
<td>Inter-rater reliability

Correlation of psoriasis symptoms with SAPASI score</td>
<td>NIMH grant number MH51552</td>
</tr>
</table>

FLEISCHER1996			Mean age at psoriasis onset (years)	34.5 ± 17.1				
			Joint pain, n (%)	219 (69)				
			Psoriatic arthritis, n (%)	64 (20)				
			Comorbidities, n (%)					
			Hypertension	81 (25.5)				
			GI diseases	53 (16.7)				
			Arthritis	163 (51)				
			Heart disease	35 (11)				
			Thyroid disease	30 (9.4)				
			Urinary tract disease	26 (8.2)				
			Mental health conditions	18 (5.7)				
			Disease severity, n (%)					
			Remission (SAPASI = 0)	7 (2)				
			Mild (SAPASI >0 to 3	124 (39)				
			Moderate (SAPASI >3 to 15)	158 (50)				

			Severe (SAPASI >15) 29 (9)				

Effect size

Inter-rater reliability (scoring of self-administered form by 2 assessors)

- Adequate inter-rater reliability of SAPASI (97% agreement between 2 investigators)
- Body site specific inter-rater reliability ranged from 96-100% agreement

Correlation with patient-reported symptoms

- SAPASI predicted the severity of pruritus (p=0.004), burning (p=0.04) and skin soreness (p=0.0001) on regression analysis
- SAPASI correlated modestly with joint pain (r = 0.3; p = 0.0001) and psoriatic arthritis (r = 0.3; p = 0.0003) – this is not adequate for the criterion of convergent construct validity

Summary/author's conclusion

- The SAPASI is significantly associated with the severity of pruritus, burning, joint pain and psoriatic arthritis (as reported by patients)

<table>
<tr><th>Reference</th><th>Study type</th><th>Number of patients</th><th>Patient characteristics</th><th>Intervention</th><th>Length of follow-up</th><th>Outcome measures</th><th>Source of funding</th></tr>
<tr>
<td>M. Morgan, R. McCreedy, J. Simpson, and R. J. Hay. Dermatology quality of life scales--a measure of the impact of skin diseases. Br.J.Dermatol. 136 (2):202-206, 1997.

Ref ID: MORGAN1997</td>
<td>Observational: Prospective case series

Questionnaire developed based on items derived from the responses of 50 dermatology out-patients attending St John’s Institute of Dermatology, UK, and factor analysis performed based on responses of 118 further patients, 41 of these (who had psoriasis and were attending for phototherapy) completed the form on a second occasion</td>
<td>N = 41</td>
<td>Stage of disease journey: Phototherapy

Inclusion criteria: Psoriasis out patients

Exclusion criteria: not stated

<table>
<tr><th>Parameter</th><th>All (n=101)</th><th>Psoriasis returning patients (n=41)</th></tr>
<tr><td>Mean age – years</td><td>38 (13-84)</td><td>Median: 38 (18-83)</td></tr>
<tr><td>Gender M/F (%)</td><td>54/46</td><td>59/41</td></tr>
</table>
</td>
<td>Dermatology quality of life scales (DQOLS)

Completed unaided by clinic attendees</td>
<td>7-10 days between tests</td>
<td>Internal consistency (for mixed population);

test-retest reliability</td>
<td>None stated</td>
</tr>
<tr><td colspan="8">Effect size

Test-retest reliability</td></tr>
</table>

- Consider that at the time of the second test the patients would have had an additional phototherapy session, which may have impacted their experience of the psoriasis; therefore, the difference may be due to improvement following the out-patient phototherapy session

Score	Intra-class correlation coefficient	Reliability
Psychosocial score	**0.84**	**Acceptable**
Embarrassment	0.85	Acceptable
Despair	0.77	Poor
Irritableness	0.76	Poor
Distress	0.79	Poor
Activity score	**0.84**	**Acceptable**
Everyday	0.80	Acceptable
Summer	0.66	Poor
Social	0.68	Poor
Sexual	0.86	Acceptable

Summary/author's conclusion

- There was good overall test-retest reliability for the psychosocial and activity scores (with variable reliability for the subscales)

<table>
<tr><th>Reference</th><th>Study type</th><th>Number of patients</th><th>Patient characteristics</th><th>Intervention</th><th>Comaprison</th><th>Length of follow-up</th><th>Outcome measures</th><th>Source of funding</th></tr>
<tr>
<td>N. E. Kacar. The comparison of Nail Psoriasis Severity Index with a less time-consuming qualitative system. J.Eur.Acad.Dermatol.Venereol. 22 (2):219-222, 2008.

Ref ID: KACAR2008</td>
<td>Observational:
Cross sectional study

Dermatology out-patient clinic, Turkey

NAPSI and Cannavo’s system carried out at time one by one investigator and NAPSI re-tested at time two by a second investigator</td>
<td>N = 45</td>
<td>Stage of disease journey:
unclear

Inclusion criteria: Nail psoriasis

Exclusion criteria: Onychomycosis

<table>
<tr><th>Parameter</th><th>All (n=45)</th></tr>
<tr><td>Mean age – years

Men

Women</td><td>

42.76 (11-65)

45.15 (11-66)</td></tr>
<tr><td>Gender M/F (%)</td><td>62.5/38.5</td></tr>
</table>
</td>
<td>NAPSI – involved nail quadrants evaluated for presence of nail matrix or nail bed disease (score 0-4 depending on number of quadrants involved)

Re-evaluated by second investigator on same day and under the same conditions</td>
<td>Cannavo’s qualitative system

Severity of pitting, oncholysis, nail plate crumbling, nail bed hyperkeratosis and oil drop discolouration scored from 0 (absent) to 3 (severe). The average score of all involved nails was considered as the severity of nail involvement</td>
<td>N/A</td>
<td>Inter-rater reliability</td>
<td>None stated</td>
</tr>
</table>

Effect size

Inter-rater reliability of NAPSI

- Pearson's r=0.768 (p<0.001); acceptable

Summary/author's conclusion

- There was good correlation between the NAPSI score of the 2 dermatologists, although the system was time consuming

<table>
<tr><th>Reference</th><th>Study type</th><th>Number of patients</th><th>Patient characteristics</th><th>Intervention</th><th>Length of follow-up</th><th>Outcome measures</th><th>Source of funding</th></tr>
<tr>
<td>S. Aktan, T. Ilknur, C. Akin, and S. Ozkan. Interobserver reliability of the Nail Psoriasis Severity Index. Clin.Exp.Dermatol. 32 (2):141-144, 2007.

Ref ID: ATKAN2007</td>
<td>Observational: Cross sectional study

Consecutive patients attending dermatology out-patient clinic, Turkey</td>
<td>N = 25</td>
<td>Stage of disease journey: None of the patients were receiving systemic therapy or topical therapy for their psoriatic nails at the time of assessment

Inclusion criteria: Nail psoriasis

Exclusion criteria: Onychomycosis, psoriatic arthritis and pustular psoriasis of the nails

<table>
<tr><th>Parameter</th><th>All (n=25)</th></tr>
<tr><td>Mean age – years</td><td>50.8 (range: 28-75)</td></tr>
<tr><td>Gender M/F (%)</td><td>64/36</td></tr>
<tr><td>PASI score (mean±SD)</td><td>15.4±9.1</td></tr>
<tr><td>Duration of</td><td>18.9±9.4</td></tr>
</table>
</td>
<td>NAPSI –nail quadrants evaluated for presence of nail matrix or nail bed disease (score 0-4 depending on number of quadrants involved)

Total NAPSI score: total nail score (matrix+bed) for all quadrants of 20 nails (0-160)

Nail score: sum of all matrix+bed scores for each nail (0-32)

Evaluated by 3 dermatologists on the same day, under the same conditions, in a well-illuminated room under direct vision using a standard NAPSI sheet</td>
<td>N/A</td>
<td>Inter-rater reliability</td>
<td>None stated</td>
</tr>
</table>

			psoriasis (mean±SD)		All finger- and toe-nails were scored and each observer was blinded to the scoring of the others		
			Disease phenotype				
			Chronic plaque	21 (84%)			
			Erythrodermic	3 (12%)			
			Palmoplantar	1 (4%)			

Effect size

Inter-rater reliability of NAPSI (intra-class correlation coefficients)

Total NAPSI

Score	ICC	95% CI	Reliability
Nail matrix	0.584	0.359-0.769	Poor
Nail bed	0.869	0.765-0.935	Adequate
Total NAPSI	0.781	0.625-0.888	Acceptable

Nail score

Score	All nails (n=500)			Fingernails (n=250)			Toenails (n=250)		
	ICC	95% CI	Reliability	ICC	95% CI	Reliability	ICC	95% CI	Reliability

Nail matrix	0.603	0.558-0.646	Acceptable	0.552	0.483-0.618	Poor	0.303	0.224-0.384	Poor
Nail bed	0.705	0.667-0.739	Acceptable	0.686	0.630-0.737	Acceptable	0.690	0.635-0.741	Acceptable
Nail	0.649	0.607-0.688	Acceptable	0.659	0.601-0.714	Acceptable	0.637	0.575-0.694	Acceptable

Summary/author's conclusion

- The inter-observer reliability appeared to be better for nail-bed scores than for nail matrix scores
- Moderate-to-good agreement of scoring with the NAPSI was found among the 3 observers

<table>
<tr><th>Reference</th><th>Study type</th><th>Number of patients</th><th>Patient characteristics</th><th>Intervention</th><th>Length of follow-up</th><th>Outcome measures</th><th>Source of funding</th></tr>
<tr>
<td>T. Nijsten, D. Whalley, J. Gelfand, D. Margolis, S. P. McKenna, and R. S. Stern. The psychometric properties of the psoriasis disability index in United States patients. J.Invest.Dermatol. 125 (4):665-672, 2005.

Ref ID: NIJSTEN2005</td>
<td>Observational: Cross sectional study

Survey of US patients</td>
<td>N = 1196</td>
<td>Stage of disease journey: representative sample of all patients

Inclusion criteria: Cutaneous psoriasis; age ≥18 years

Exclusion criteria: Psoriatic arthritis

<table>
<tr><th>Characteristics</th><th>N=1196</th></tr>
<tr><td>Gender M/F (%)</td><td>40.5/59.5</td></tr>
<tr><td>Mean age, years, mean (SD)</td><td>47.4 (16.1)</td></tr>
<tr><td>Race</td><td></td></tr>
<tr><td>White</td><td>1050 (87.8%)</td></tr>
<tr><td>Other</td><td>146 (12.2%)</td></tr>
<tr><td>Extent of disease (no. of palms)</td><td></td></tr>
<tr><td>None or little</td><td>232 (19.4%)</td></tr>
<tr><td><3 palms</td><td>372 (31.1%)</td></tr>
</table>
</td>
<td>PDI</td>
<td>N/A</td>
<td>Sensitivity to change, internal consistency</td>
<td>None stated</td>
</tr>
</table>

			3-10 palms: 430 (36.0%) >10 palms: 156 (13.0%) Duration of disease, years, mean (SD): 17.1 (14.4)				

Effect size

Sensitivity to change of PDI

- All subscales had small ceiling effects (≤5%) but substantial floor effects (≥49%)

Internal consistency

- Adequate internal consistency for subscales (Cronbach's α 0.77-0.81)

PDI and it's scales	Number of items (range of score)	% floor	% ceiling	Item-rest correlation (correlation of item with other items in subscale)	Cronbach's α
PDI	15 (0-45)	14.7	0.0	-	-
Daily activities	5 (0-15)	20.5	0.2	0.35-0.59	0.78
Work	3 (0-9)	63.8	0.3	0.45-0.56	0.81
Personal	2 (0-6)	67.6	1.0	0.52-0.53	0.80

Leisure	4 (0-12)	49.3	0.2	0.33-0.56	0.77
Treatment	1 (0-3)	52.9	4.5	-	-

Summary/author's conclusion

- The PDI lacks sensitivity for mild disease (shown by substantial floor effects)
- The PDI has good internal consistency
- Note that in a Rasch analysis the PDI and its subscales appeared to measure multiple constructs, which may compromise its validity to create an overall score
- Also note that there was differential item functioning for age and gender, suggesting that people with the same disease-related disability but of a different age or gender may score differently, implying that the PDI is not intrinsically generalisable in heterogeneous populations

<table>
<tr><th>Reference</th><th>Study type</th><th>Number of patients</th><th>Patient characteristics</th><th>Intervention</th><th>Length of follow-up</th><th>Outcome measures</th><th>Source of funding</th></tr>
<tr><td>B. Ramsay and C. M. Lawrence. Measurement of involved surface area in patients with psoriasis. Br.J.Dermatol. 124 (6):565-570, 1991.

Ref ID: RAMSAY1991</td><td>Observational: Case series

In-patients selected over a 9 month period</td><td>N = 10</td><td>Stage of disease journey: unclear

Inclusion criteria: In-patients, chronic plaque psoriasis

Exclusion criteria: none stated

<table><tr><th>Characteristics</th><th>N=10</th></tr><tr><td>Gender M/F (%)</td><td>50/50</td></tr></table></td><td>BSA
Rule of nines – 4 experienced observers rated the extent of psoriasis on 2 consecutive days (order of assessment of arms, legs and trunks randomized to minimise memory recall bias)
Plaque tracings – only calculated once by a single observer
Photographs – only calculated once by a single observer</td><td>1 day</td><td>Test-retest and inter-rater reliability</td><td>None stated</td></tr>
<tr><td colspan="8">Effect size (calculated using two-way within-subject analysis of variance)

Intra-rater reliability
Acceptable intra-rater reliability between days 1 and 2 (differences of 1-2%; p>0.05 ANOVA)
Inter-rater reliability
Poor inter-rater reliability among the 4 observers (significantly different mean percentage involvement estimations; range 14-33%; p<0.001 ANOVA)</td></tr>
</table>

Note that all observers using the rule of nines over-estimated the area involved compared with the plaque traced areas (and this was more than twice the plaque traced area on 62% of observations); there was a greater degree of error when assessing patients with less surface area involvement

Compared with plaque tracings analysis of clinical photographs underestimated the area of involvement by a mean of -2%.

Summary/author's conclusion

- Untrained observers using the rule of nines will over-estimate the extent of psoriasis
- Image analysis of whole body photographs is comparable to that of traced outlines

Reference	Study type	Number of patients	Patient characteristics	Intervention	Length of follow-up	Outcome measures	Source of funding
Y. M. Yune, S. Y. Park, H. S. Oh, D. J. Kim, D. S. Yoo, I. H. Kim, J. S. Moon, M. K. Kim, and C. H. Oh. Objective assessment of involved surface area in patients with psoriasis. Skin Research & Technology 9 (4):339-342, 2003.	**Observational**: cross sectional study Department of dermatology, Korea University Hospital	N = 30	**Stage of disease journey:** unclear **Inclusion criteria:** not stated **Exclusion criteria:** not stated **Characteristics** / **N=30** Gender M/F (%) / 56.7/43.3	BSA • visual grading (% area covered as assessed by 5 dermatologists) • digital image analysis (total % BSA affected) Seven photographs were taken of each patient (head, anterior trunk, posterior trunk, both anterior upper arms, both posterior upper	N/A	Inter-rater reliability	None stated

Ref ID: YUNE2003			Mean age, years, mean (SD): 42.5 (13.6)	arms, both anterior lower legs and both posterior lower legs) by one dermatologist using the same camera, lighting and posture for each patient			

Effect size

Inter-rater reliability

- Poor inter-rater reliability (statistically significantly different: $p<0.05$, Kruskal-Wallis test)

Note that the overall difference in estimations between the visual grading method and image analysis was statistically significant, with visual grading resulting in a higher percentage involvement being reported ($p < 0.05$, Wilcoxon signed rank sum test); although for the head and neck area there was no significant difference

Summary/author's conclusion

- Measuring the involved are of psoriasis using image analysis may overcome the inevitable differences between observers using the visual grading method.

Reference	Study type	Number of patients	Patient characteristics	Intervention	Length of follow-up	Outcome measures	Source of funding

<table>
<tr>
<td>T. Nijsten. Refinement and reduction of the Impact of Psoriasis Questionnaire: Classical Test Theory vs. Rasch analysis. Br.J.Dermatol. 154 (4):692-700, 2006.

Ref ID: NIJSTEN2006</td>
<td>Observational: Prospective case series

Created 2 shortened versions of the instrument

Subjects taken from the PUVA follow-up study; 16 university centres in the USA</td>
<td>N = 792</td>
<td>Stage of disease journey: receiving PUVA and most had received systemic therapies

Inclusion criteria: not stated

Exclusion criteria: missing items on questionnaire

<table>
<tr><th>Parameter</th><th>N=792</th></tr>
<tr><td>Gender M/F (%)</td><td>62/48</td></tr>
<tr><td>Mean age (range)</td><td>56 (22-92)</td></tr>
</table>
</td>
<td>Impact of Psoriasis Questionnaire (IPSO): original version, classical test theory version (3 subscales – mental functioning, mental well-being and stigmatisation) and Rasch reduced version (unidimensional 11-item questionnaire)</td>
<td>N/A</td>
<td>Internal consistency</td>
<td>None stated</td>
</tr>
<tr>
<td colspan="7">Effect size

Internal consistency (α)
• Original version: Adequate internal consistency for physical and psychological scales (0.85 and 0.73); acceptable for social scale (0.63)
• CTT version: Adequate internal consistency for mental functioning and stigmatisation scales (0.85 and 0.75); poor for social scale (0.52)
• Rasch version: Adequate internal consistency overall (0.83)

Note that 7/16 items demonstrated differential item functioning for age and gender, particularly in the psychological and social subscales (e.g., older people were less likely to report high scores for feelings of being unattractive and/or sexually undesirable and sleeping problems)</td>
</tr>
</table>

Summary/author's conclusion

- The IPSO can be improved and shortened, and the Rasch reduced version is likely to assess the psychosocial impact of moderate-to-severe psoriasis on patients' lives best because it is short, reliable and unidimensional.

<table>
<tr><th>Reference</th><th>Study type</th><th>Number of patients</th><th>Patient characteristics</th><th>Intervention</th><th>Length of follow-up</th><th>Outcome measures</th><th>Source of funding</th></tr>
<tr>
<td>M. A. Gupta and A. K. Gupta. The Psoriasis Life Stress Inventory: a preliminary index of psoriasis-related stress. Acta Derm.Venereol. 75 (3):240-243, 1995.

Ref ID: GUPTA1995</td>
<td>Observational: case series

In- and out-patients from Department of Dermatology, University of Michigan Hospitals, USA

Original development of the PLSI</td>
<td>N = 217</td>
<td>Stage of disease journey: in- and out-patients included to obtain patients with a wide range of psoriasis severity

Inclusion criteria: for out-patients: ≤30% total body surface area affected

Exclusion criteria: other concomitant dermatologic or medical disorders

<table>
<tr><th>Parameter</th><th>In-patients N=139</th><th>Out-patients N=78</th></tr>
<tr><td>Gender M/F (%)</td><td>51.8/48.2</td><td>52.9/47.7</td></tr>
<tr><td>Mean age (years) ± SE</td><td>47.2±1.4</td><td>49.4±1.8</td></tr>
<tr><td>Total body surface area affected (%)</td><td>52±2</td><td>≤30</td></tr>
</table>
</td>
<td>Psoriasis Life Stress Inventory (PLSI)

Global self-ratings of psoriasis severity on a 10-point scale also obtained (items: redness, scaling/shedding, plaque thickness, itching and overall severity). Therefore, the total stress score could be 0-45

For the in-patients the dermatologic assessments and psychological ratings were obtained within the first week of admission at the onset of treatment

Out-patients were</td>
<td>N/A</td>
<td>Internal consistency</td>
<td>None stated</td>
</tr>
</table>

				recruited from a database			

Effect size

Internal consistency

- High degree of internal consistency within all 15 items: α= 0.90

Correlations between PLSI score and patient self-ratings:

Measure	Correlation (Pearson's r)	p-value
Redness	0.15	0.04
Scaling/shedding	0.20	0.008
Plaque thickness	0.17	0.02
Itching	0.24	0.001
Overall severity	0.19	0.01

Site-specific involvement

- There was a significant correlation between PLSI scores and self-reported psoriasis severity for the following body sites (which tended to be associated with greater cosmetic disfigurement):
  - Scalp (r=0.23; p=0.003)
  - Face (r=0.20; p=0.02)
  - Neck (r=0.23; p=0.006)
  - Chest (r=0.28; p=0.0002)
  - Right arm (r=0.26; p=0.0009)
  - Right forearm (r=0.31; p=0.0001)
  - Right hand (r=0.18; p=0.02)
  - Left arm (r=0.23; p=0.003)
  - Left forearm (r=0.29; p=0.0002)
  - Left hand (r=0.17; p=0.04)
  - Back (r=0.28; p=0.0003)
  - Abdomen (r=0.25; p=0.001)

- Psoriasis severity affecting the shoulder, hips, groin, thigh, legs and feet did not correlate significantly with PLSI scores

Note that none of the above correlations demonstrate acceptable construct validity

Summary/author's conclusion

- The PLSI represents an index of the psychosocial morbidity associate with psoriasis
- This preliminary questionnaire needs to be tested in patient samples from different samples and in prospective studies

Reference	Study type	Number of patients	Patient characteristics	Intervention	Length of follow-up	Outcome measures	Source of funding
Joana Ribeiro Costa de Faria, Aline Rezende Aarao, Luiz Miguel Zabaleta Jimenez, Oscar Hernandez Silva, and Joao Carlos Regazzi Avelleira. Inter-rater concordance study of the PASI (Psoriasis Area and Severity Index). Anais Brasileiros de Dermatologia 85 (5):625-629, 2010. Ref ID: FARIA2010	**Observational**: cross-sectional study Patients attending a psoriasis ambulatory clinic (august-October 2007) 20 patients were randomly selected	N = 20	**Stage of disease journey:** attending a psoriasis ambulatory with a wide range of psoriasis severity **Inclusion criteria:** aged 15-70 years; mild, moderate or severe disease **Exclusion criteria:** none stated Baseline characteristics not available	PASI Assessed by 3 post-graduate students of dermatology with similar experience and knowledge	N/A	Inter-rater reliability	None stated

Effect size

Inter-rater reliability

Comparison	n	ICC (95% CI)	p-value
Observer 1 vs 2	20	0.729 (0.440-0.882)	0.00007
Observer 1 vs 3	20	0.753 (0.481-0.894)	0.00003

Observer 2 vs 3	20	0.817 (0.601-0.923)	<0.00001

- The raters showed greater differences (lower reliability) for more severe patients

Summary/author's conclusion

- PASI is a reliable indicator of psoriasis severity because it shows significant concordance when independent evaluations are performed

Systematic review

Reference	Study type	Number of patients	Patient characteristics	Intervention	Comparison	Length of follow-up	Outcome measures	Source of funding
Robinson A, Kardos M, Kimball AB. Physician Global Assessment (PGA) and Psoriasis Area and Severity Index (PASI): Why do both? A systematic	**Systematic review of RCTs** 30 studies of biologic agents in moderate to severe psoriasis (2001-2010)	Unclear – 30 RCTs	**Stage of disease journey:** biologic treatment **Inclusion criteria:** RCTs of biologics, phototherapy, ciclosporin or methotrexate that record both PASI75 and PGA 0 or 1 (only biologic trials were found) No baseline	PASI75	PGA 0 or 1 PGA was rated on a 6 or 7-point scale: • Clear • *Almost clear* • Mild • Mild-to-moderate	Reported for 8-16, 17-24 and >24 weeks	Correlation – construct validity	National Psoriasis Foundation

analysis of randomized controlled trials of biologic agents for moderate to severe plaque psoriasis. *J. Am. Acad. Dermatol.* 66(3):369-75, 2012. Ref ID: ROBINSON2012A			characteristics for participants		• Moderate • Moderate-to-severe • Severe			

Effect size

Construct validity – correlation of PASI75 and PGA 0 or 1

Adequate construct validity (Pearson's correlation coefficient)

- 8-16 weeks: r = 0.9157 ($p<0.01$)
- 17-24 weeks; r = 0.892 ($p<0.01$)
- >24 weeks; r = 0.9559 ($p<0.01$)

Note: the tools correlate more tightly with more efficacious therapy during the early treatment period. For the 8-16 weeks period the correlation was 0.9201 for studies with ≥25% achieving PASI75 but 0.0612 for studies where <25% achieved this response. For 17-24 weeks the correlations were 0.9017 and 0.9925, respectively

Summary/author's conclusion

The two assessment tools are substantially redundant and either alone is a sufficient tool for assessing psoriasis severity in patients with moderate to severe disease. Because the PASI is better validated and more detailed, it remains the score of choice for clinical trials, but the simpler PGA may be well suited for community-based outcomes projects