



Outcome Measures of Psoriasis in Clinical Trials: An Overview

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ABSTRACT

Psoriasis is a common chronic inflammatory dermatological disorder resulting from interactions between genetic pre-disposition and triggering environmental factors. It affects approximately 1-3% of the population and poses a lifelong burden on those, affected. Psoriasis typically follows a relapsing and remitting course. It can occur at any age, although is uncommon in children (0.71%) but the majority of cases occur before 35 years. Psoriasis is associated with arthritis in a significant proportion of patients (reported in one study at 13.8%). Usually the psoriasis is not life threatening but it can be life ruining due to its visibility. In clinical trials, several outcome measures have been used to assess the severity of psoriasis. The common outcome measures include PASI (psoriasis area and severity index) score, Psoriasis Life Stress Inventory (PLSI), Psoriasis disability index (PDI), The National Psoriasis Foundation Psoriasis Score (NPF-PS), Physician Global Assessment (PGA), Self-Administered PASI (SAPASI), Simplified PASI (SPASI), Psoriasis Assessment Severity Score (PASS), Psoriasis Log-Based Area and Severity Index (PLASI), Psoriasis Exact Area and Severity Index (PEASI) and Beer Sheva Psoriasis Severity Score (BPSS). Among these, the PASI score is most popular and commonly used in clinical trials. To assess the quality of life in the patients of psoriasis the DLQI (dermatologic life quality index) is most commonly used in clinical trials.

Several such instruments have been developed and continue to be developed to provide an assessment of the severity of the skin lesions. Since the skin lesions of psoriasis have an impact on quality of life of patients, there has been growing recognition of the need to measure the impact of the disease on quality of life along with the severity of the lesions.

KEYWORDS: *Psoriasis, outcome measures, PASI, DLQI, Quality of life.*

INTRODUCTION

Psoriasis is a systemic chronic, relapsing inflammatory skin disorder with worldwide distribution, affecting 1–3% of the world population. Prevalence varies according to race,

geographic location and environmental factors^[1].

The disease has wide clinical spectra that range from epidermal (scaly) and vascular (thickened, erythematous) involvements of the skin to the

malignant form known as generalized erythrodermia.

Several epidemiological and clinical studies have confirmed that psoriasis is associated with many co-morbid conditions which include, arthritis, cardio-metabolic disorders including myocardial infarction, stroke, diabetes, obesity, dyslipidemia and non-alcoholic fatty liver disease. These co-morbidities confer a higher mortality rate. The presence of any co-morbid diseases worsens the psoriasis and also associated with an increase in concomitant medication ^[2]. Psoriasis can have profound effects on patients' daily living and functioning ^[3,4].

During measurements of clinical severity, separately using tools such as the Psoriasis Area and Severity Index (PASI) ^[5] are not sufficient and may not reflect patients' own perceptions of the impairment due to psoriasis, it is important to assess the impact of psoriasis on patients' physical condition, self-perception, and social life ^[6,7]. Health Related Quality of Life (HRQOL), covering almost all these parameters, is therefore increasingly part of the clinical research and practice. HRQOL assessment can provide valuable information that helps to make clinical decision and to select suitable health care programmes ^[8]. There has been a wide variety of generic, dermatological and psoriasis-specific instruments used for the assessment of HRQOL of psoriasis patients ^[9-11]. However, the reliability and validity of these instruments are not fully known ^[12-13]. The reliability and validity are the major evaluations of instrument's performance for reflecting concepts or ideas such as quality of life (QOL) in a study population ^[14]. Evaluating the characteristics of instruments used to measure patient's perceptions is important in clinical health care and decision making.

For most people, psoriasis is managed in primary care, with specialist referral being needed at some point for up to 60% of people. Supra-specialist (level 4) tertiary care is required in the very small minority with especially complex, treatment

resistant and/or rare manifestations of psoriasis ^[15].

Good communication between healthcare professionals and patients is essential. It should be supported by evidence-based written information tailored to the patient's needs. Treatment and care and the information given by patient about it, should be culturally appropriate. It should also be accessible to people with additional needs such as physical, sensory or learning disabilities, and to people who do not speak or read English.

Adult and pediatric healthcare teams should work jointly to provide assessment and services to young people with psoriasis. Diagnosis and management should be reviewed throughout the transition process, and there should be clarity about who is the lead clinician to ensure continuity of care.

OUTCOME MEASURES

Several instruments have been described to assess psoriasis severity in recent years, such as PASI (psoriasis area and severity index) score, Dermatology Life Quality Index, Physician's Global Assessment, Psoriasis Disability Index, Psoriasis Life Stress Inventory, and the Salford Psoriasis Index, etc. ^[16-21].

A clinician should have to assess the impact of disease on physical, psychological and social wellbeing, psoriatic arthritis and other co-morbidities. In non-specialist clinical setting the patient should be refer to dermatologist if there is uncertainty of diagnosis, severe or extensive psoriasis (for example more than 10% of the body surface area is affected), topical therapy fails to control the psoriasis, nail disease has a major functional or cosmetic impact and Psoriasis is having a major impact on a person's physical, psychological or social wellbeing ^[22].

When assessing the disease severity in any healthcare setting, there should be proper recording of the body surface area affected, any involvement of nails, high-impact and difficult-to-treat sites (for example, the face, scalp, palms, soles, flexures and genitals), systemic upset such

as fever and malaise, etc. and in specialist settings, use a validated tool to assess severity of psoriasis, for example the Psoriasis Area and Severity Index (PASI) [23].

In specialist settings, use a validated tool to assess the impact of any types of psoriasis on physical, psychological and social wellbeing, for example the, Dermatology Life Quality Index (DLQI) for adults or Children's Dermatology Life Quality Index (CDLQI) for children and young people. When using an assessment tool for a person with any type of psoriasis take account of their age, any disabilities (such as physical, visual or cognitive impairment), and any language or other communication difficulties, and provide help and support if needed. Ensure that the chosen assessment tool continues to be a sufficiently accurate measure. In children, young people and adults with psoriasis new tools can be developed and/or existing ones further refined and validated to Assess disease severity and impact in both non-specialist and specialist healthcare settings to facilitate assessment, appropriate referral, treatment planning and measurement of outcomes.

Importance of Assessment

Assessment of disease severity and impact is fundamental to delivering high-quality health care and measuring outcomes. The evidence review indicates that the existing tools have important limitations, and have not been validated in relevant healthcare settings or in children or young people. Future research should ensure that such type of tools will be developed that capture information on site of involvement as well as extent and the impact of previous treatments. Tools should capture all aspects of impact on life including physical, psychological and social wellbeing and factors that may influence this impact, such as distress and beliefs about psoriasis. Tools that can be used by patients as well as by healthcare professionals to assess disease severity and that encompass new technologies should be evaluated to facilitate

(when appropriate) modern healthcare delivery models like remote monitoring of disease activity. In addition, understanding the true burden and effect of disease activity, severity and impact for both psoriasis and psoriatic arthritis has not previously been comprehensively studied. Capturing this information and distilling out significant factors for focused investigation will lead to better understanding of the needs of this particular group of people and the impact of treatments that benefit both disease compartments i.e. skin and joints.

PASI (Psoriasis Area and Severity Index)

PASI was developed to assess the effects of retinoids in psoriasis by Fredriksson T and Pettersson U in 1978^[24]. Clinical assessment of psoriasis severity was done at base line and at the end of the treatment period using PASI^[25].

Four affected anatomical sites, the head (h), upper limb (u), trunk (t) and lower limbs (l), are separately scored by using three parameters, erythema, induration and desquamation/scaling, each of which is graded on a severity scale of 0 to 4, where 0 = nil, 1 = mild, 2 = moderate, 3 = severe and 4 = very severe. The area-wise percentage involvement of the involved sites is calculated as: 1 = less than 10% area; 2 = 10-29%; 3 = 30-49%; 4 = 50-69%; 5 = 70-89%; and 6 = 90- 100%. The head, the trunk, the upper extremities, and the lower extremities correspond to 10%, 20%, 30%, and 40% of the total body area, respectively^[26].

Calculation of PASI

The PASI score is calculated by following formula

$$\text{PASI} = 0.1 (E_h + S_h + I_h) A_h + 0.2 (E_u + S_u + I_u) A_u + 0.3 (E_t + S_t + I_t) A_t + 0.4 (E_l + S_l + I_l) A_l$$

The affected area and lesion characteristics are entered in a formula that results in a score from 0 to 72. The PASI is most often used in clinical trials. The maximum score of PASI is 72. PASI 75 is a 75% reduction of baseline PASI score. It is commonly considered as a denominator for

satisfactory results of any treatment modality for psoriasis^[27].

The Psoriasis Area and Severity Index has widely used and serves as a surrogate for a gold standard for the assessment of psoriasis severity. However, the PASI has several drawbacks that prevent it from becoming a practical clinical instrument for routine clinical use. It does not consider involvement of the face, palms and soles, or the genital area. Even mild involvement in these locations may greatly affect the patient's suffering but is under estimated in the total PASI score. Moreover, PASI does not include quality of life parameters^[28-31]. The PASI score is too long to perform and therefore impractical for routine clinical use. The need for a new instrument to assess psoriasis severity for both research and routine clinical use is widely recognized in the dermatological world^[32-33].

PASI and Clinical Trials

Improvement in this score in clinical trials is presented as a percent improvement over the baseline score. Patients who experience a 75% improvement in their PASI scores after treatment (e.g from a score of 20 to 5) are said to have achieved PASI 75.

For most clinical trials, the number of patients on the study drug achieving PASI 75 is the primary efficacy measure. In terms of clinical improvement, a PASI 75 improvement correlates well with a physician global assessment (PGA) of clear to almost clear.

There is also an excellent correlation with statistically significant improvement in the patient's quality of life.

Limitations of PASI

- In everyday practice, the ultimate goal regarding psoriasis treatment outcome is patient quality of life not Psoriasis Area Severity Index (PASI) improvement. What one patient perceives as success another patient may consider an unacceptable amount of improvement.

- Clinical trials use PASI 75 and PASI 50 as bench marks for improvement. Some drugs have PASI 90 data, which is even more impressive. But, if you consider the myriad of different presentations psoriasis may have in any given patient or in the population as a whole, initial PASI scores cannot adequately capture the severity of the disease in all patients. For example, patients with palmo-plantar psoriasis, which affects approximately 4% body surface area (BSA), will have a low PASI score since PASI scores are weighted by the extent of area of involved as well as the severity of the erythema, induration and scaling in that area. Despite these low PASI scores, patients suffering from palmo-plantar psoriasis typically have very low quality of life (QOL).
- The low PASI scores do not correctly correspond to quality of life for these patients. These patients may not be able to walk, conduct business, or function in society due to the visible nature of their disease.

Moreover, PASI is the most widely used measure of severity in the researches as well as in the clinical setting. This makes it an important tool in gauging the impact of the disease on QOL, though other instruments to measure QOL are encouraged. Since PASI or SAPASI do not measure the impact of psoriasis on patient's QOL directly, use of other QOL scales is recommended^[34].

DLQI (Dermatology Life Quality Index)

DLQI, developed by Finlay and Khan in 1994, was the first tool of QOL evaluation related to dermatology^[35]. It developed according to the principles of classical test theory as a skin disease specific instrument to assess HRQOL. It consists often items, which estimate disease influence regarding: symptoms and feelings, daily activities, leisure, work, school, personal relationships and treatment. Due to its easy application and the

increasing importance of HRQOL in the evaluation of clinical studies, the DLQI became the most commonly used HRQOL measure in dermatology [36-37]. The aim of this questionnaire

is to measure how much your skin problem has affected your life over the last week.

Table.1. Tabular presentation of questionnaire and outcome score to assess the DLQI. Modified from [38].

Questionnaire	Outcome score
1. Over the last week, how itchy, sore, painful or stinging has your skin been?	Not at all = 0
	A little = 1
	A lot = 2
	Very much = 3
2. Over the last week, how embarrassed or self-conscious have you been because of your skin?	Not at all = 0
	A little = 1
	A lot = 2
	Very much = 3
3. Over the last week, how much has your skin interfered with you when going shopping or looking after your home or garden?	Not at all / Not relevant = 0
	A little = 1
	A lot = 2
	Very much = 3
4. Over the last week, how much has your skin influenced the clothes you wear?	Not at all / Not relevant = 0
	A little = 1
	A lot = 2
	Very much = 3
5. Over the last week, how much has your skin affected any social or leisure activities?	Not at all / Not relevant = 0
	A little = 1
	A lot = 2
	Very much = 3
6. Over the last week, how much has your skin made it difficult for you to do any sport?	Not at all / Not relevant = 0
	A little = 1
	A lot = 2
	Very much = 3
7. Over the last week, has your skin prevented you from working or studying?	Yes = 3
	No
If "No", over the last week how much has your skin been a problem at work or studying?	Not at all / Not relevant = 0
	A little = 1
	A lot = 2
	Very much = 3
8. Over the last week, how much has your skin created problems with your partner or any of your close friends or relatives?	Not at all / Not relevant = 0
	A little = 1
	A lot = 2
	Very much = 3
9. Over the last week, how much has your skin caused any sexual difficulties?	Not at all / Not relevant = 0
	A little = 1
	A lot = 2
	Very much = 3
10. Over the last week, how much of a problem has the treatment for your skin been, for example by making your home messy, or by taking up time?	Not at all / Not relevant = 0
	A little = 1
	A lot = 2
	Very much = 3

Calculation and Interpretation of DLQI

The DLQI is calculated by summing the score of each question resulting in a maximum of 30 and a minimum of 0. The higher the score, the more quality of life is impaired. The DLQI is interpreted as follows^[39].

DLQI Score	Effect on patient's life
0 – 1	no effect at all
2 – 5	small effect
6 – 10	moderate effect
11 – 20	very large effect
21 – 30	extremely large effect

Methods of quality of life assessment

There are several approaches to design the questionnaires used for QOL measurement^[40]. In the design and creation of these questionnaires a series of validation steps need to be undertaken. These include the requirement that the information on which the questions are based, comes from patient sources and that the questions are understandable by patients. The questionnaires need to be validated to check that they are answered consistently by patients and that the scores are sensitive to change if the clinical condition changes. There needs to be cross validity with other measures and the internal consistency of the questions needs to be established^[41].

Psoriasis Life Stress Inventory (PLSI)

The psychosocial impact of psoriasis can lead to significant daily stress to the patients which largely arises as a result of cosmetic disfigurement and social stigma^[42]. The psoriasis related daily stress represents chronic, recurrent low grade stress or hassles that occurs largely as a result of having to live with chronic, relapsing and disfiguring disease. The studies on stress and psoriasis have focused mainly on the role of major stressful life events such as death of loved one, in the onset and exacerbation of disease^[43]. There is a large body of literature that supports the role of

stressful life events in the onset and or exacerbation of psoriasis^[44].

The PLSI is a 15-item questionnaire that provides a measure of the daily hassles of psychosocial stress associated with having to cope with everyday events in living with psoriasis. Scores on this scale range from 0 to 45. It is developed by Finlay et al to measure the psychosocial disability associated with psoriasis^[45]. The PLSI was developed with the view of obtaining an index of the stress associated with various psoriasis related events. PLSI is scored on a four point scale ranging from zero (not at all) to three (a great deal) as a measure of various psoriasis related events experienced by the patients in the last 4 weeks. The PLSI also permits patients to be classified as a function of their distribution of scores into two groups, which is as follows^[46].

- Those patients who react significantly to the stress associated with having psoriasis (score of > 10) and
- Those patients who are not significantly affected with having psoriasis-related stress (score of < 10).

In PLSI we measure the 15 items associated with various psoriasis related events and scored on a four point scale, ranging from 0 to 3, which is tabulated below.

Table.2 Tabular presentation of PLSI ^[47]

S. No.	Items of PLSI	Outcome score			
		Not at all = 0	Slight degree = 1	Moderate degree = 2	Great deal = 3
1	Inconvenienced by shedding of your skin				
2	Feeling self-conscious among strangers				
3	Feeling that you have to set aside a large part of your time to take care of your psoriasis				
4	Not going to public place (like swimming pool, health club, restaurant, etc) when you would have liked to.				
5	Wearing unattractive or uncomfortable cloths in order to cover the certain regions of the body.				
6	Having to avoid sunbathing in the company of others.				
7	Fear of having serious side effects from medical treatment				
8	People treating you as if your skin condition is contagious				
9	Avoid social situations				
10	Strangers (children or adults) making rude or insensitive remarks about your appearance				
11	Not enough money to pay medical bills				
12	Feeling like an ‘outcast’ or ‘social misfit’ a great deal of time.				
13	People making a conscious effort not to touch you.				
14	Hairdresser or barber appearing reluctant to cut your hair				
15	People implying that your skin condition may be due to AIDS, leprosy or a venereal disease.				

Psoriasis disability index (PDI)

The PDI, developed by Finlay and Coles, concerns the functional life style disabilities caused by psoriasis ^[48]. It contains 15 items with 5 subscales: daily activities, work, personal relations, leisure, and treatment. All items are rated on a 4-point scale, with responses of “not at all”, “a little”, “a lot”, and “very much” scored 0, 1, 2, and 3, respectively. Item scores are summed to yield a total score (range: 0–45) with higher score indicating greater limitations experienced because of psoriasis. Particularly, the PDI has a possible 5 work items, out of which only 3 items need to be responded. Respondents who are working (either full- or part-time) respond to item 6a, 7a, and 8, whereas respondents who are not working respond to items 6b, 7b, and 8. When one item of the PDI was not responded, it was scored “0”. When two or more items of the PDI were not responded, the questionnaire was excluded from the analysis. ^[49].

Table.3. Tabular presentation of parameters assessed by PDI. Modified from ^[49]

Scale	Items
Daily activities	1. House/garden work
	2. Different clothes
	3. Change/wash clothes
	4. Hair dresser problem
	5. More baths
Work	6a. Time off work
	7a. Inhibit work
	6b. Less activity
	7b. Different activity
Personal relations	8. Career affected
	9. Sexual difficulties
Leisure	10. Social relations
	11. Social activities
	12. Sport difficulties
Treatment	13. Communal changing
	14. More smoke/drink
	15. Home messy/untidy

Beer Sheva Psoriasis Severity Score (BPSS)

The BPSS is a novel tool for the ambulatory assessment of patients with psoriasis. It has

several advantages over the traditional PASI, namely, it is simple and includes items of disease distribution that are lacking in PASI (face, palms and soles, genital area, nails), as well as items of quality of life assessment, global severity indices (assessed by both patients and physicians), and assessment of pruritus. BPSS includes eight items that are recorded by the physician (total severity

of the disease, and seven items relating to the physical distribution of the disease) and eight items recorded by the patient (total severity, physical and psychological severity, pruritus, and assessment of involvement in the face, nails, palms and soles, and genital regions). Tabular presentation of different parameters of BPSS are as follows. Modified from ^[50].

Table 4. Beer Sheva Psoriasis Severity Score (BPSS)
Physician Assessment (Assess the severity of the psoriasis during the last month)

	0	1	2	3	4	5	6	7	8	9	10
	No disease	Very mild									Very severe
Total severity											

	0	1	2	3
	No Involvement	Mild involvement	Moderate involvement	Severe involvement
AREA				
Scalp involvement				
Face and neck involvement				
Upper limbs involvement				
Palms involvement				
Trunk involvement				
Lower limbs involvement				
Soles involvement				

Patient Assessment (Assess the severity of your psoriasis during the last month)

	0	1	2	3	4	5	6	7	8	9	10
	No disease	Very mild									Very severe
Total severity											

	0	1	2	3	4	5	6	7	8	9	10
	No disease	Very mild									Very severe
Assess the physical severity of your disease											
Assess the psychological severity of your disease											
Assess the severity of pruritus											
Assess the severity of involvement of the face											
Assess the severity of involvement of nails											
Assess the severity of involvement of the palms and soles											
Assess the severity of involvement of the genitals											

Calculation and interpretation of BPSS

All variables in BPSS are assessed using linear 4–10 point visual analogue scales. All scores are summed directly, except for the seven items of disease distribution assessed by the physician (which have four-point scales, and are multiplied by 2.5). BPSS ranges from 0 to 160, with the high scores representing severe disease^[51].

The National Psoriasis Foundation Psoriasis Score (NPF-PS)

It is a composite assessment of investigator and patient characteristics developed to answer the US Food and Drug Administration's criticisms of the PASI and to include skin involvement of Psoriasis in a system that uses ACR and PsA response criteria assessment of joint disease^[52]. The instrument is based on characteristics felt to be most sensitive [thickness of 2 target lesions and change in body surface area (BSA), from baseline] in assessing Ps, and was also created to provide better cross-study comparisons versus the current instruments.

The NPF-PS includes both objective and subjective assessment. It has 6 endpoints. Two representative target lesions are selected, and the thickness of each is assessed relative to set thickness (induration; 0–1.25 mm) on an embossed card. The third element is change in BSA from baseline. There is a PGA and a PtGA as well as an itch assessment. The different parameters of NPF-PS includes^[53].

- Induration of representative target lesion A (0 to ≥ 1.25 mm)
- Induration of representative target lesion B (0 to ≥ 1.25 mm)
- Body surface area relative to baseline as a percentage (score is 20% intervals)
- Physician's global assessment (static and defined)
- Patient's global assessment (relative to worst the disease has been ever)
- patient's assessment of itch (defined score = average over 24 h)

These above six parameters assessed on the 6 point scale ranging from 0 to 5. Therefore, total outcome score ranges from 0 to 30.

A brief overview on other outcome measures

Physician Global Assessment (PGA)

In clinical trials, the PGA is recommended by the FDA as an efficacy end point, with its summary score used to measure overall disease severity. The PGA requires physicians to evaluate the severity of plaques for three clinical signs (erythema, induration, and scaling) across the whole body. Although the PGA does not take into account other aspects of psoriasis, such as amount of body surface area affected, pain or pruritus. It is routinely used in clinical trials since it provides a relatively simple assessment of overall disease severity^[54].

Typically, the PGA is a 5, 6 or 7-point ordinal rating ranging from “clear” to “very severe psoriasis”. The PGA can be used to show improvement by a comparison with baseline disease severity (dynamic PGA) or it can be an assessment made at one moment in time (static PGA)^[55].

Self-Administered PASI (SAPASI)

The SAPASI is a structured PASI-like instrument designed for self-assessment of severity by patients^[56].

Patients shade in affected areas on a silhouette of a body to estimate body surface area and complete visual analogue scales for the extent of erythema, induration and scaling of their “average” lesion. The investigator uses these data and combines them into a complex score, ranging from 0–72. Psoriasis is defined as^[57].

- In remission when SAPASI = 0
- Mild when SAPASI = 0-3
- Moderate when SAPASI = 0- 15 and
- Severe when SAPASI = more than 15

Simplified PASI (SPASI)

The SPASI is mathematically derived from the PASI and is developed to measure disease severity

in simplified way. The SPASI equals the sum of the average erythema, induration and scaling of all the psoriasis lesions and multiplied by an estimate of total percentage body surface areas involved^[58].

Psoriasis Assessment Severity Score (PASS)

The PASS was developed to measure the severity of disease in simpler and faster way than the PASI. The evaluation is divided in two stages, in the first the BSA is determined in percentage and then the general erythema, scaling and induration are assessed on a three-point scale. Finally, the sign scores together with the total percentage BSA are combined in a complex formula, which results into an overall score between 0 and 140^[59].

Psoriasis Log-Based Area and Severity Index (PLASI) and Psoriasis Exact Area and Severity Index (PEASI)

The PLASI and PEASI are derived from PASI. These are intended to provide more accurate assessment of improvement. The PLASI uses six BSA groupings (100–46, 46–21, 21–10, 10–5, 5–2 and 2–0%) with finer partitioning for smaller extents of BSA affected. This is supposed to reduce the error resulting from inaccurate estimation of BSA in patients with less extensive disease and also to increase sensitivity among patients with mild-to-moderate disease in detecting changes in psoriasis severity^[60].

The PEASI uses actual BSA percentages instead of an area score for each body area. The PEASI and PLASI have not been validated and are not tested for reliability. Considering responsiveness, the observed percentage change was greater for both the PLASI and the PEASI than with the PASI^[61].

CONCLUSION

Good clinical psoriasis measures are necessary to measure disease severity and effectiveness of therapies. A large number of clinical outcome measures of psoriasis are used in clinical trials and daily practice. The present review article is aimed

to introduce different outcome measures of psoriasis severity and to discuss their importance. Assessing the severity of disease over time is important for optimizing patient care, since it allows for the critical evaluation of individual response to treatment. In addition to assess disease severity, it is often a key aspect of quality care and quality guidelines, which are increasingly important to improve the level of care in the community. It can be concluded that the PASI score is most important and successfully used outcome measure to assess the disease severity and DLQI is most commonly used outcome measure to assess the quality of life in the patients of psoriasis. Overall, none of the instrument was identified as being the best and different situations and clinical states may call for different measures based on the specificity of the clinical condition.

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