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Evaluating the severity of dermatologic disorders

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ABSTRACT: Assessment of a patient's disease severity is an essential component of formulating therapeutic strategies. However, disorders of the skin are often not amenable to strict classification criteria, and the dermatologist relies upon personal thresholds of severity when assessing the patient's overall condition. A number of grading systems have arisen, primarily from the need for standardized end points in clinical trials; in some circumstances, these severity assessments may assist the clinician in the evaluation and treatment of dermatologic disease. In this review, we will summarize the results of available severity scores of frequently encountered dermatologic disorders and discuss their utility in the management of disease in a clinician's office.

KEYWORDS: disease severity, quality of life, skin disease

Introduction

The severity of a patient's disease is a major factor in guiding choice of therapy. Numerous clinical trials have aimed at standardizing judgments of severity and have attempted to establish and evaluate grading systems for objective classification of disease intensity. For example, hypertension is separated into well-defined categories that are determined by the measured value of systolic and diastolic blood pressure. Into which of these classes the patient falls dictates the recommended program of treatment. However, judgments of severity of skin disorders, such as acne and psoriasis, cannot be performed as simply as the measurement of blood pressure. Objective measures of relevant criteria for skin disease may be difficult to determine in a rapid and reproducible fashion (1).

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Thus, dermatologic diseases are less amenable to strict classifications of severity because the nature of physical examination may be less reproducible, and lack of standard and routine laboratory tests makes it difficult to rank objectively and monitor the extent and magnitude of symptom severity (2). Approaches to treatment are often based on gestalt and shaped over years of practice; even during the period of training, the young dermatologist develops strategies for guiding treatments that evolve into paradigms that drive patient care.

Objective measures of dermatologic disease severity do exist and are critical in regulatory approvals for therapies. Clinical trials have used grading scales for various dermatologic disorders, primarily in the context of mapping the efficacy of treatment (3). Although such grading scales are often complex, their implementation could be helpful in guiding the course of treatment for individual patients, and thus have the potential to improve quality of care.

Objective measures that are specific to evaluating response to treatment frequently have arisen from government-run drug approval procedures. Static forms of scoring disease severity entail

evaluating a patient at one point in time, without regard for the patient's prior status, and are required in drug efficacy trials. Dynamic scoring systems (such as evaluating improvement from before therapy) rely heavily on the physician's memory of the patient's prior disease status, and thus are susceptible to recall bias; as a result, such evaluations are rarely permitted in drug regulation. Understanding scoring systems is important in evaluating the efficacy of a particular treatment. In this review we will summarize severity scores of several common dermatologic disorders and discuss their utility in the management of disease in a clinician's office.

Psoriasis

Physicians generally base their treatment decisions for patients with psoriasis on intuitive impressions of the severity of the patient's disease, as well as their sense of the impact of symptoms on the patient's overall well-being. However, symptom severity is not always effectively communicated among patients and their physicians: a study of 17,000 patients with psoriasis revealed that 32% of patients did not believe their physician was aggressive enough with their therapy (4).

Recently, the threshold for patients with moderate psoriasis has been suggested to be greater than 5% body surface area (BSA), and patients with greater than 10% BSA are said to have severe involvement (5). Patients who would otherwise have mild or moderate disease may be graded higher if the impact of their psoriasis on their quality of life is greater than expected (5).

The Psoriasis Area and Severity Index (PASI) is the most commonly used method for grading psoriasis in clinical trials (6). The PASI combines the average redness, thickness, and scaliness of lesions, each on a 0–4 point scale, and the extent of involvement across four body areas (Table 1) (7). Scores range from 0.0 to 72.0 (8). In most clinical trials, the percentage of patients who achieve a 75% or greater reduction from pretherapy PASI scores (PASI-75) is reported (6). However, there is no universally agreed benchmark for effective therapies. Some therapies in clinical trials have induced 80% or more of patients to achieve a reduction in PASI of 75% or more. In clinical research jargon, this is an 80% PASI-75. Yet, for a therapy to be considered effective, achieving PASI-75 is considered too stringent by some; PASI-50 also indicates clinical improvement (9).

Known limitations of the PASI include poor correlation with quality of life, and poor sensitivity to change in the score among patients with small areas of involvement. Although this scale is widely used in clinical trials for the assessment of benefits of treatment, there are different versions in use, and it is not routinely used by clinicians and therefore is poorly understood by both physicians and patients (6). This makes it difficult to translate the results of clinical trials using the PASI into treatment strategies for patients with psoriasis.

Whereas the PASI assigns a numerical score based on an assessment of psoriasis signs, other scoring systems have incorporated the physician's overall impression. The Physician Global Assessment (PGA) has been commonly used in clinical trials, in part because both the US Food and Drug Administration (FDA) and the European Medicines Agency have moved toward global scores as primary end points (6,8,10). In the most common version of this system, psoriasis is evaluated by

Table 1. Method for calculating the Psoriasis Area and Severity Index (PASI)

	Score
Surface involved (in each body region)	
<10%	1
10–29%	2
30–49%	3
50–69%	4
70–89%	5
90–100%	6
Plaque qualities: degree of severity (in each body region)	
No symptoms	0
Slight	1
Moderate	2
Marked	3
Very marked	4

The PASI requires assessment over four body regions (head (h), trunk (t), upper (u), and lower (l) extremities), which represent approximately 10, 30, 20, and 40% of body surface area, respectively. In each of the body regions, a score for the degree of psoriasis is determined according the plaque qualities of erythema (E), infiltration (I), and desquamation (D), and body surface area involvement (A).

The final PASI score from 0 to 72 is calculated by the formula:

$$\text{PASI} = 0.1(E_h + I_h + D_h)A_h + 0.2(E_u + I_u + D_u)A_u + 0.3(E_t + I_t + D_t)A_t + 0.4(E_l + I_l + D_l)A_l$$

Other methods of determining the PASI score induce variations as a result of renaming the plaque qualities (e.g., induration or thickness instead of infiltration); providing descriptions or photographs of the degrees of severity for the plaque qualities; or defining the parts of the body that compose the body regions (e.g., whether the buttocks are part of the lower extremities or the trunk).

Table 2. One example of a Physician's Global Assessment (PGA) for psoriasis

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 scaling plaque elevation, scaling, and/or erythema
Almost clear	Intermediate between mild and clear
Clear	No signs of psoriasis (postinflammatory hyperpigmentation may be present)

Other PGAs with different definitions have been used in various studies. The amount of body surface involved is not included in most PGAs.

the physician using a 0–7 point scale from clear to severe (Table 2).

PGAs exist in two primary forms: a static form measuring the physician's impression at a single point, and a dynamic form measuring the overall improvement from baseline (8). However, the latter is rarely used because of the necessity to remember a patient's condition at a prior time. Limitations of the PGA include poor definitions of severity levels difficulty in identifying subtle changes in disease (6). In addition, varieties of the PGA are in use, making the comparison of results of different clinical trials tricky. Benefits of the PGA include its simplicity and ease, which make it more accessible for daily use in the clinic, and lack of consideration of BSA that may overweight resistant plaques (6).

The Lattice System Physician's Global Assessment (LS-PGA) (11) provides an eight-step rating of psoriasis severity from "clear" to "very severe." Assessment of plaque character (erythema, scaliness, and elevation) is performed on a four-level scale (from "none" to "marked" with each category clearly defined) and integrated with ranges of percent BSA involved. In the final severity rating, more weight is given to plaque elevation (the hallmark of psoriasis) than to scale or erythema. With minimal training, the LS-PGA is easy to use and, importantly, correlates well with PASI and PGA scores (11,12).

It is clear that the PASI alone will no longer be a sufficient means of evaluating a patient's response to treatment in clinical trials; the European Medicines Agency now requires that a global score (citing the LS-PGA as an example) be used in addition to the PASI (10). The FDA has also required a global score as the primary study variable in recent psoriasis trials.

The NPF Psoriasis Score (NPF-PS) was developed by the National Psoriasis Foundation (NPF) (6). It involves six subdomains: induration at two target sites, current and baseline BSA, physician global assessment, patient global assessment, and patient assessment of itch (6). A key feature of the NPF-PS is a reference card embossed with elevations that increase at 0.25-mm intervals (6). Advantages of the NPF-PS include well-defined elements, the use of patient input, positive correlation with quality of life, good discrimination when BSA is low, and use of plaque elevation as a predominate component. Limitations include the fact that it has not been widely tested and has not been accepted by approving agencies or clinicians (6).

The Copenhagen Psoriasis Severity Index (CoPSI) (8) requires assessment of three characteristics: plaque thickness, erythema, and scaling. Each characteristic is graded on a four-point scale, ranging from "none" to "severe," and evaluated in 10 locations: face, scalp, upper limbs, hands and wrists, chest and abdomen, back, buttocks and sacral area, genitalia, lower limbs, feet, and ankles (8). The CoPSI provided reproducible assessments of psoriasis (8). It is unique from the PASI in that it does not require an estimation of percent skin involved and has increased sensitivity when assessing milder cases (8).

In summary, a number of diverse and extensive scoring systems for assessing severity of psoriasis have been devised. In a review of 171 randomized clinical trials for the treatment of psoriasis, more than 40 different systems for evaluating disease severity were used (13). Although many of these methods are well suited for the evaluation of new treatment modalities in clinical trials, most are cumbersome and impractical for use in daily practice. However, the development of scales with appropriate grading criteria has the potential to standardize evaluations of treatments and, in the long run, to improve care for patients with psoriasis.

Atopic dermatitis

There are many systems for scoring the severity of atopic dermatitis. However, as with psoriasis, many of these scoring systems are complex and difficult to use in the clinician's office. An additional issue stems from the fact that many of the scales were devised with either adults or children in mind, and are not applicable to the other demographic.

The SCORing Atopic Dermatitis (SCORAD) index was developed in 1993 as a result of a report from the European Task Force on Atopic Dermatitis (14). There are three components to the SCORAD: item A includes extent of the disease by using the Rule of Nines, and accounts for 20% of the overall score; item B involves intensity of disease and consists of six items (erythema, edema/papulation, oozing/crust, excoriation, lichenification, dryness) graded on a 0–3 point scale, and accounts for 60% of the total score; item C takes into account subjective symptoms, consisting of pruritus and sleep loss, and this imparts the final 20% of the score (15). The patient or parent is asked to rate pruritus and sleep loss on a 10-point scale as an average over the previous three nights. Because the SCORAD was created for use in children, it is difficult to apply to adults. In addition, the SCORAD is time-consuming and complicated – the most experienced physicians typically require 7 minutes to complete this scale, whereas inexperienced physicians may take up to 10 minutes (16).

The SCORAD is different from other severity scales in that it takes into account both subjective and objective opinions. Based on the argument that the end result is too heavily weighted by widely varying ratings by patients, parents, or caregivers, the "objective SCORAD" was developed as a result of a European consensus to reduce variability created by the subjective portion (16). In the objective SCORAD, 10 bonus points are added for disfiguring lesions or lesions that limit the patient's function (16). It has been proposed that using only the objective SCORAD in clinical comparative trials would eliminate confusion that arises when comparing studies that have used either the SCORAD alone or the objective SCORAD alone, given that the final scores may differ by up to 10 points (16).

The Three-Item Severity score (TIS) is a much simpler severity scale for atopic dermatitis. The most representative lesion is scored on three of the intensity items used in the SCORAD index (intensity of erythema, edema, and excoriation each on a scale of 0–3, for a total score of 9) (16). Studies comparing the SCORAD with the TIS have shown a positive correlation between the two scales. The benefit of the TIS lies in its simplicity, as it can be completed within 1 minute, making it a more practical choice for use in the physician's office (16).

The Six Area, Six Sign Atopic Dermatitis (SASSAD) severity score looks at six defined body sites and grades each area using six clinical features: erythema, excoriation, exudation, cracking, dryness, and lichenification. It grades each feature on a 0–3 point scale, with a maximum score of 108 (14). The SASSAD has proved to reflect disease severity accurately, both by observer assessment and by patient assessment. It does not require a calculation of total BSA involved and is simply and quickly performed without training.

The Eczema Area and Severity Index (EASI) uses a complicated formula based on scoring four defined cutaneous areas (17); thus it has similarities to PASI. The regions are scored on a scale of 0 to 6, defining overall extent of disease, and each area is also scored based on four criteria (erythema, induration/papulation, excoriation, and lichenification) on a 0–3 point scale (14). A major weakness of the EASI is that it does not consider pruritus. To address this, a modified EASI (mEASI) was created, with the inclusion of a scale for pruritus, similar to the one used in the SCORAD (15). The EASI is limited in that it does not apply to children younger than 2 years, thereby excluding a large portion of patients with atopic dermatitis (15). Overall, the EASI is a time-consuming method that requires training for use, making it less suitable for use in the clinician's office.

Although a number of other scoring systems for atopic dermatitis exist, many have not been adequately tested for reliability or validity. These include the Rajka and Langeland Scoring System, the Atopic Dermatitis Area and Severity Index, Costa's Simple Scoring System, the Basic Clinical Scoring System, the Atopic Dermatitis Severity Index, the Skin Intensity Score, and the Assessment Measure for Atopic Dermatitis (14). The large number of scales can confuse scientific communication and make it difficult for clinicians to interpret studies for use in their own daily practice. Furthermore, many of these scales are too cumbersome and difficult to use in daily practice (17). Unfortunately, none of the atopic dermatitis severity scales has been tested for simplicity and ease of use in physician's office.

Acne

As with dermatologic disorders in general, severity of acne is judged by the physician's overall impression of lesion type and extent, and treatment decisions are based on the physician's developed gestalt. Because patients' self-esteem can be severely affected, quality of life is important when dealing with acne. One study estimated that 7% of patients with acne develop suicidal ideation (18), indicating the need for appropriately intensive treatment. Therefore, physicians must assess, in

a quick and consistent manner, the severity of acne (including its effect on the patient) and the response to treatment.

More than 25 acne severity scales have been used in various studies, and there does not seem to be one preferred method for evaluating acne. Current acne trials typically incorporate analysis of final lesion counts and Investigator Global Evaluation to evaluate treatment efficacy (19).

The Leeds acne-grading technique is a scoring system that incorporates both the look and feel of the patient's skin, as well as acne scarring. Inflamed and noninflamed lesions are evaluated, and acne is graded on a 1–10 point scale (20). The simplicity and breadth of this scale make it an attractive choice for use in the clinic.

A recent study set out to establish another clinically useful grading system for acne (21) based on lesion counts of inflammatory eruptions on half the face: mild is considered 0–5 lesions, moderate 6–20, severe 21–50, and very severe more than 50. This grading system is based on the finding that most dermatologists graded acne similarly and that their overall assessment correlated with the counts of inflammatory eruptions and not with numbers of comedones. This method would not work for all patients, however, as patients with an overwhelming number of comedones or significantly asymmetric facial involvement would be incorrectly scored.

Grading scales have also been created specifically to score the severity of acne scars. The Echelle d'Evaluation Clinique des Cicatrices d'Acne (ECCA) grading scale is a complex system that consists of six categories of scars (22). Each category is given a score of 0–3 that is entered into a weighted formula to generate a final score that ranges from 0 to 540. Although perhaps useful in clinical trials, the ECCA's utility in a busy clinical setting is doubtful; however, if undertaken to monitor success in conjunction with a series of corrective procedures, the ECCA may be helpful and worth the time taken to obtain it.

Alopecia areata

There are few drugs for the treatment of alopecia areata. Although a wealth of small-scale studies have examined various treatment modalities for alopecia areata, large, controlled clinical trials assessing treatment efficacy have yet to be undertaken. The Severity of Alopecia Tool (SALT) (23) is a global assessment score that takes into account duration of current instance of hair loss, percentage of total hair loss, type of hair remaining on the scalp, pattern of hair loss, body hair loss, and nail involvement; it combines the percent of hair loss with the percent surface area of the scalp affected, and adds four major regions together. In addition, the SALT can be categorized into a 0–5 class (23). Although the SALT score is valuable in clinical trials, it should be used in conjunction with standard photographs of the four major scalp regions and a quality of life questionnaire (23).

Table 3. The Hyperhidrosis Disease Severity Scale (25)

Score	How would you rate the severity of your hyperhidrosis?
1	My sweating is never noticeable and never interferes with my daily activities
2	My sweating is tolerable but sometimes interferes with my daily activities
3	My sweating is barely tolerable and frequently interferes with my daily activities
4	My sweating is intolerable and always interferes with my daily activities

Hyperhidrosis

Hyperhidrosis is a condition characterized by sweating in excess of what is needed for normal thermoregulation (24). Unlike other dermatologic conditions, hyperhidrosis cannot be measured based on its appearance at any single office visit. Therefore, the evaluation of treatment efficacy must be guided primarily by the effect the disease is having on the patient's life.

The Hyperhidrosis Disease Severity Scale (HHDS) is a one-question instrument that allows the physician to assess the severity of the patient's hyperhidrosis. The question "How would you rate the severity of your hyperhidrosis?" is posed, followed by four options (Table 3). A score of 1 or 2 corresponds to mild or moderate hyperhidrosis, whereas a score of 3 or 4 corresponds to severe hyperhidrosis. A 50% improvement in sweat production was associated with a 1-point reduction in the scale, whereas an 80% reduction in sweat production was found to represent a 2-point overall reduction. The reliability and validity of the HHDS has been tested, and the HHDS has closely correlated with general and specific measures of quality of life (25). Of the many severity scales for various disorders, the HHDS appears to be the simplest and easiest to implement in clinical practice, while still providing a clear connection with the overall efficacy of treatment.

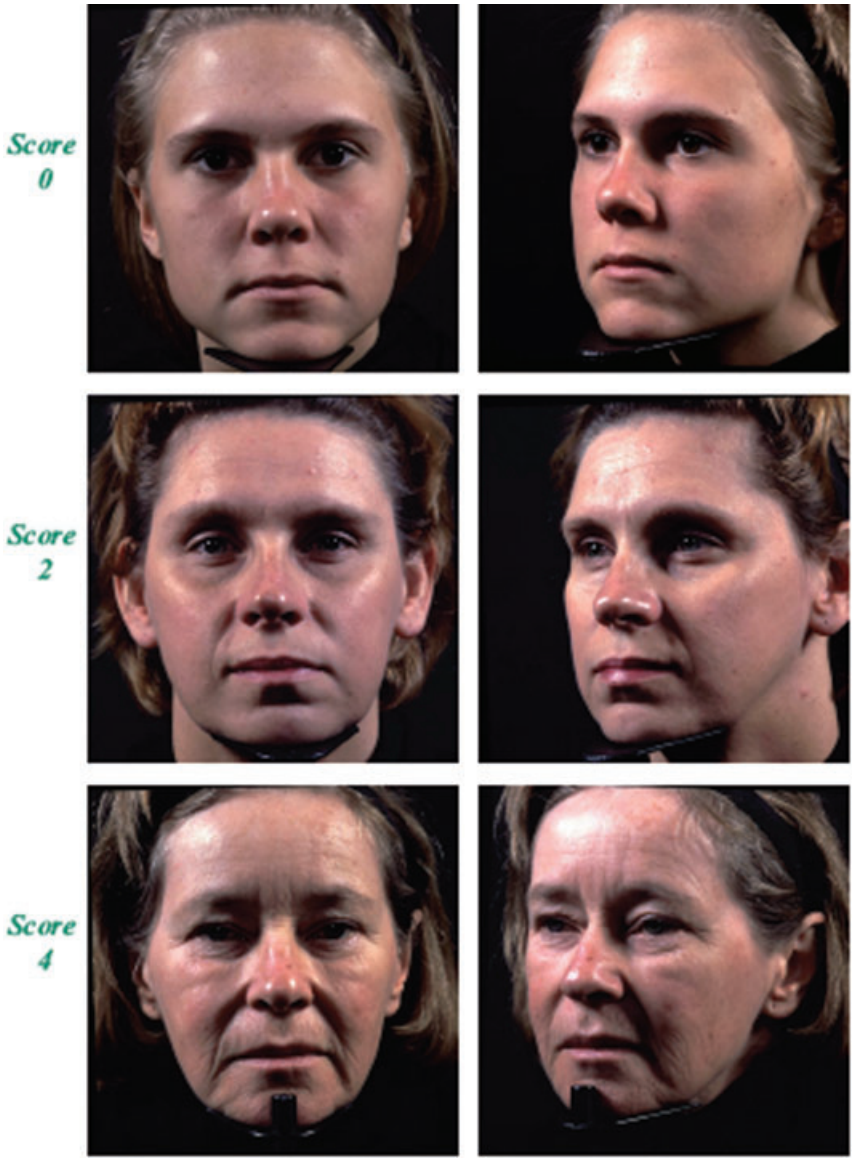

FIG. 1. Photonumeric Scale for the assessment of photodamage. Each score corresponds to two photographs (*en face* and 45° oblique). Although the Photonumeric Scale ranges from 0 to 8, only pictures of 0 to 4 are shown here. To use the method, the patient is placed under even lighting and the physician selects the picture most representative of the patient's photodamage; integer scores between the reference pictures may be used. (© The Regents of the University of Michigan. All rights reserved; may not be used without the permission of the University of Michigan Department of Dermatology.)

Photodamage

With the increasing number of tools at our disposal for the treatment and prevention of photoaging, it is becoming more important to assess accurately the severity of a patient's photodamage. The Photonumeric Scale uses reference photographs to judge the degree of photodamage (26). This scale scores patients from 0 to 8, with a higher score indicating increasing severity (FIG. 1). Scores of 0, 2, 4, 6, and 8 each correspond to a set of two photographs. A direct comparison is made between the photographs and the subject. If a precise match is not apparent, the physician may use the intervening numbers (i.e., 1, 3, 5, or 7) (26). Patients should be placed under appropriate lighting and all makeup must be removed. The Photonumeric Scale has better interobserver reliability than a written, descriptive scoring method (26). Because the appearance of photodamage varies with race, this method is best used in Caucasians. Although the Photonumeric Scale was designed for use in clinical trials, its ease of use, given its pictorial basis, makes it appropriate for use in the clinician's office.

Conclusion

By definition, objective measures, regardless of specificity, are performed by a physician; subjective measures are reported by the patient. Whereas the majority of the scoring systems described utilize objective means of measuring severity of disease, e.g., lesion count, thickness and size, and degree of erythema, the subjective component – the patient's own evaluation of disease magnitude – largely drives patient satisfaction in treatment outcomes (27). Indeed, with many dermatologic diseases, objective measures alone are not sufficient for a comprehensive assessment of severity, and subjective measures play an important role (28). For example, patients' reports of pruritus, insomnia, self-esteem issues, embarrassment in public, relationship trouble, and inability to perform daily activities are often more important than objective measures such as lesion counts, biopsy results, BSA affected, and degrees of lesion qualities such as erythema and scale.

Patient-reported outcome measures may be used to support FDA approval for marketing of treatments for various indications (29), although there are scant examples in dermatology. The FDA has provided a draft Guidance for Industry that provides a thoughtful and concise summary of the issues of patient-reported outcome measures (29).

Cumulatively, the subjective experience of the patient amounts to quality of life. Interestingly, many of the objective scoring systems show poor correlation with quality of life measures (14). An important study by Salek et al. (28) addressed this issue and showed that routine use of quality of life measurements are needed, because quality of life and objective disease severity are not always directly related. This study utilized the Dermatology Life Quality Index (DLQI), a self-administered 10-question instrument based on the patient's experience over the previous 7 days. The DLQI is scored from 0 to 30 and requires an average time of 2 minutes to complete. The DLQI is simple to use and has been validated. Results of the study demonstrated clear differences in patient- and physician-rated scores of numerous aspects of disease. This suggests that improvements in physician–patient communication could facilitate physicians' sense of the overall impact of disease on their patients, which might influence the selection of treatment regimens (4).

Clinical trials have evaluated the ability of objective scores of disease severity to reflect patients' quality of life assessments. Kirby et al. (27) found that many of the physical scores of psoriasis used in clinical trials, e.g., PASI, SAPASI (self-administered PASI), and the "signs" portion of the Salford Psoriasis Index, only revealed a small portion of the overall psychosocial disability being caused by psoriasis, and in many patients the physical scores did not reflect psychosocial disability at all. Therefore, discussions of disease severity in dermatology must include impact of the disease on the patient's quality of life. But as with the various objective severity assessment methods, one must be wary in choosing from the large number of quality of life scales that are available.

In recent clinic trials, it has become commonplace to assess both objective measures of improvement and quality of life ratings. We have yet to discover a dermatologic trial in which the objective measures improved statistically but the mean quality of life did not. However, these data exist only for groups of patients; for an individual in the trial, change in quality of life (often assessed over the prior week) may not relate to the change in objective measures of disease over the course of treatment.

Quality of life for an individual patient at a specific office visit may reflect aspects of disease beyond therapeutic success or failure, or may reflect recent life events that affect the patient's perspective on current quality of life. Although formal assessments may be more reliable than informal questioning (29), it may not be practical for physicians to use formal quality of life assessment in their daily practice. It may be easier for physicians to find their own ways of assessing these factors, perhaps with a simple but often-used query (see Table 3 for an example), to help guide their treatments.

In summary, most scoring systems that are invaluable in assessing treatment outcomes in clinical trials are not practical for clinical use. Yet patients participating in clinical trials are often selected on the basis of severity measures, and they may not be representative of those seen in the clinician's office. In addition, the results in clinical trials do not always predict equivalent results in office use. For these reasons, navigating patient treatment based solely on scoring systems and results of clinical trials is not easy. The challenge for the physician is to blend the results of clinical trials with his or her own time-tested strategies.

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