

National Psoriasis Foundation Clinical Consensus on Disease Severity

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Objectives: A task force of the National Psoriasis Foundation Medical Board was convened to evaluate the current severity criteria of mild, moderate, and severe psoriasis and to make recommendations concerning a 2-tiered categorization of severity based on current clinical practice and related to intent to treat.

Participants: This volunteer task force, led by David M. Pariser, MD, included Jerry Bagel, MD, Joel M. Gelfand, MD, MSCE, Neil J. Korman, MD, PhD, Christopher T. Ritchlin, MD, Bruce E. Strober, MD, PhD, Abby S. Van Voorhees, MD, and Melodie Young, MSN, RN, ANP. Meetings were held by teleconference and were coordinated and funded by the National Psoriasis Foundation.

Evidence: This task force reviewed psoriasis severity criteria and other published psoriasis consensus statements. Current standards of care and expert opinion were used to inform the process.

Consensus Process: Based on meetings of the task force and under the guidance of David M. Pariser, MD, a statement was drafted by Elizabeth J. Horn, PhD, presented to the task force, and reviewed and approved by the task force. This statement was then reviewed and approved by Robert E. Kalb, MD, Gerald G. Krueger, MD, and Alan Menter, MD. The National Psoriasis Foundation Medical Board reviewed and endorsed this statement by a majority vote on March 2, 2006, at the medical board meeting.

Conclusions: This clinical consensus statement proposes a 2-tiered system for plaque psoriasis therapy that reflects more accurately than the current system how patients are treated in clinical practice. This statement, focused on plaque psoriasis, is intended to assist medical professionals and insurance payers in understanding these 2 categories of patients with psoriasis and choosing appropriate therapies for these patients.

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PSORIASIS IS A COMMON, chronic, systemic, inflammatory disease that manifests in the joints (as psoriatic arthritis) as well as the skin. Psoriasis affects approximately 2% to 3% of the world's population of both sexes across all ages and ethnicities.¹ Psoriasis often appears between ages 15 and 25 years.¹ On the skin, it is characterized by raised, sensitive, painful, disfiguring, and erythematous lesions appearing on any part of the body. Approximately 50% of patients with psoriasis have pruritus, which can be severe. Psoriasis is a heterogeneous disease that waxes and wanes over the patient's lifetime. Patients experience a broad range of symptoms and disease severity with episodic flares and few spontaneous remissions. Plaque psoriasis is the most common form, affecting approximately 80% to 90% of patients. Other less common forms of psoriasis are classified as inverse (intertriginous), erythrodermic, pustular, and

guttate. Psoriasis is a complex genetic disease and is frequently passed from one generation to the next, although the mechanism of inheritance is unknown.

Psoriatic arthritis is an inflammatory joint disease found in 6% to 42% of patients with psoriasis, depending on the

*See also pages 223,
233, and 270*

population studied.² Psoriatic arthritis is characterized by stiffness, pain, swelling, and tenderness of the joints and surrounding ligaments and tendons (dactylitis and enthesitis). Enthesitis, dactylitis, and nail disease are frequently seen in psoriatic arthritis. Symptoms range from mild to very severe. Many patients, possibly as many as 67%, seen in psoriatic arthritis clinics have erosive or deforming arthritis.² In the vast majority of patients, joint symptoms are preceded by skin symptoms by ap-

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proximately 10 years, although joint symptoms can arise concurrently or even prior to skin symptoms.²

The exact causes of psoriasis and psoriatic arthritis are unknown, although genetic, environmental, and immunologic factors all influence disease susceptibility. Psoriasis and psoriatic arthritis are serious, life-long, and life-altering conditions, and there is no cure. While the natural history of psoriasis is not yet fully elucidated, some patients are successfully treated intermittently, while most require chronic therapy. A significant challenge in caring for patients with psoriasis is the lack of objective and validated outcome measures and instruments that are commonly used and accepted in clinical practice to provide ongoing assessment of skin disease.

PSORIASIS SEVERITY

In clinical practice, the physician assesses the severity of a patient's psoriasis by combining the objective assessment of body surface area (BSA) of involvement, disease location, thickness, and symptoms with the subjective assessment of the physical, financial, and emotional impact of the disease on the patient's life. This subjective assessment is combined with the physician's global assessment of psoriasis to determine psoriasis severity and appropriate therapy. Classification systems that are used in clinical trials are more rigorous and less subjective but are often not practical for use in clinical situations. These clinical classification systems are not part of the current standard of care, and a thorough discussion of these systems is beyond the scope of this statement.

Affected BSA has been frequently used to assess disease severity. One percent of BSA is approximately equal to the patient's open hand (from wrist to tips of fingers) with fingers tucked together and the thumb tucked to the side, as stated in the Koo-Menter Psoriasis Instrument.³ In clinical trials, severe disease often is commonly defined as more than 10% affected BSA, and the Food and Drug Administration has used 20% BSA to indicate severe disease.⁴ The National Psoriasis Foundation Medical Board has described criteria to assist medical professionals in distinguishing between mild, moderate, and severe disease based on BSA and impact on quality of life.⁵

In 2002, the American Academy of Dermatology published a consensus statement on psoriasis therapies that also used the mild, moderate, and severe criteria to guide treatment plans.⁶ In this system, patients with mild disease have limited BSA involvement and may be treated with topical therapies. Although moderate and severe disease categories may overlap, patients with moderate to severe disease generally have greater than 5% affected BSA, and appropriate therapies include phototherapy or systemic therapy. This viewpoint was reiterated by Feldman et al³ and is reflected in clinical practice, where there is little distinction between therapies for moderate and severe psoriasis.

THE EFFECT OF PSORIASIS ON PATIENT WELL-BEING

Psoriasis is a serious disease. Patients with psoriasis will experience physical and mental disability comparable to that associated with other chronic diseases.⁷ Psoriasis

negatively affects patient functioning through physical, emotional, social, sexual, and financial aspects of well-being.⁸⁻¹¹ Patients with psoriasis report having difficulties performing daily activities including sleeping, using their hands, walking, sitting or standing for long periods, and losing time from work owing to both the direct effects of their disease and the indirect effects of seeking necessary treatment for their disease.

Patients also report feeling that the public and even their own physicians fail to appreciate the impact psoriasis has on their well-being. The chronic and uncontrolled inflammation experienced by patients with psoriasis is often accompanied by comorbidities such as obesity, hypertension, diabetes, cardiovascular disease, and myocardial infarction.¹² Patients with both skin and joint disease often experience marked impairment in overall physical and emotional functioning. We recommend that physicians give equal consideration to both the physical and the emotional functioning of their patients in determining treatment plans for psoriasis. Based on our collective clinical experience, we recommend a 2-tiered system that categorizes patients based on treatment plans as candidates for localized therapy or for systemic therapy and/or phototherapy.

CANDIDATES FOR LOCALIZED THERAPY

Patients who are candidates for localized therapy have localized plaque psoriasis typically affecting less than 5% of the BSA. Appropriate therapies include, but are not restricted to, topical corticosteroids, topical cholecalciferol analogs, combinations of these 2, topical retinoids, tar preparations, anthralin, keratolytics, and excimer (UV-B) laser treatments. Topical pimecrolimus and tacrolimus, although off-label, may be helpful for facial, flexural, and genital psoriasis. These therapies may also be used in combination with other localized therapies, systemic therapies, or phototherapy or in sequence with them.

CANDIDATES FOR SYSTEMIC AND/OR PHOTOTHERAPY

Patients who are candidates for systemic and/or phototherapy have significant disease, typically affecting 5% or more of the BSA. Some of these candidates may also have less than 5% BSA affected but have psoriasis in vulnerable areas such as the face, genitals, hands or feet (palmar-plantar), nails, scalp, or intertriginous areas. Other forms of psoriasis regardless of BSA (erythrodermic, pustular, or guttate) usually require systemic therapy and/or phototherapy. Patients with psoriatic arthritis regardless of skin involvement may require systemic therapy such as methotrexate or tumor necrosis factor–blocking biologics. In addition, patients with limited psoriasis-affected BSA but whose disease is inadequately controlled by localized therapy and causes significant disability or impairment in physical or mental functioning should be considered candidates for systemic therapy and/or phototherapy.

A variety of agents are available, including phototherapy (UV-B broadband and narrowband) and photochemotherapy (psoralen UV-A), traditional systemic

agents (acitretin, cyclosporine, and methotrexate), and biologics (alefacept, efalizumab, and the tumor necrosis factor–blocking agents adalimumab, etanercept, and infliximab). All biologics listed are approved by the Food and Drug Administration for treatment of psoriasis and/or psoriatic arthritis, and these agents are part of the current standard of care for treatment of psoriasis.

These therapies may be used alone, in combination with localized therapies, or in combination with each other. Not all combinations of systemic therapy and/or phototherapy are appropriate. The treating physician must take into account a variety of factors in choosing an appropriate combination for a particular patient, including treatment efficacy, treatment safety, patient comorbidities, and patient preference. Treatment choice may also be influenced by patient age, childbearing potential, skin type, and financial issues.

While systemic therapy and/or phototherapy may be appropriate for a patient, there currently are no prognostic (pharmacogenomic or pharmacogenetic) factors that allow us to ascertain which therapies will be most efficacious and least toxic. If the chosen therapy is not efficacious or produces adverse effects, then the patient should be treated with another agent. Some therapies appear to be more likely to induce remission of psoriasis for a period of months in some patients, but the mechanisms are not well understood, and the patients who will experience a remission cannot be predicted. These therapies include UV-B, psoralen UV-A, and alefacept. Other highly effective therapies, including cyclosporine, acitretin, efalizumab, and the tumor necrosis factor–blocking biologics, have little remittent effect. In fact, optimal control of psoriasis usually requires continued therapy for long periods. Discontinuing therapy will likely lead to worsening of psoriasis in these patients.

CONTINUED NEEDS

These guidelines for psoriasis treatment are based on expert opinion. Studies should be designed using this 2-tiered system so that future treatment guidelines can be evidence based.¹³⁻¹⁵ This will assist clinicians in determining the most appropriate therapy for individual patients. The development or endorsement of validated quality-of-life measures that can be used to inform treatment decisions in the clinic is also recommended because there are currently limited uniformly reproducible and accepted measures for the purpose of informing clinical decisions for treating patients with psoriasis.

In conclusion, we believe that the current system using the criteria of mild, moderate, and severe disease categories is suboptimal in determining psoriasis severity for the purpose of selecting therapeutic options. Clinicians have historically treated patients with moderate psoriasis with the same therapies used for those with severe psoriasis. In endorsing a 2-tiered system of candidates for localized therapy and candidates for systemic therapy and/or phototherapy, we have moved beyond mild, moderate, and severe into a therapy-based intent-to-treat approach reflective of current clinical practice.

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REFERENCES

1. Nickoloff BJ, Nestle FO. Recent insights into the immunopathogenesis of psoriasis provide new therapeutic opportunities. *J Clin Invest*. 2004;113:1664-1675.
2. Gladman DD, Antoni C, Mease P, Clegg DO, Nash P. Psoriatic arthritis: epidemiology, clinical features, course, and outcome. *Ann Rheum Dis*. 2005;64(suppl 2):ii14-ii17.
3. Feldman SR, Koo JY, Menter A, Bagel J. Decision points for the initiation of systemic treatment for psoriasis. *J Am Acad Dermatol*. 2005;53:101-107.
4. Winterfield LS, Menter A, Gordon K, Gottlieb A. Psoriasis treatment: current and emerging directed therapies. *Ann Rheum Dis*. 2005;64(suppl 2):ii87-ii92.
5. Krueger GG, Feldman SR, Camisa C, et al. Two considerations for patients with psoriasis and their clinicians: what defines mild, moderate, and severe psoriasis? what constitutes a clinically significant improvement when treating psoriasis? *J Am Acad Dermatol*. 2000;43:281-285.
6. Callen JP, Krueger GG, Lebwohl M, et al. AAD consensus statement on psoriasis therapies. *J Am Acad Dermatol*. 2003;49:897-899.
7. Rapp SR, Feldman SR, Exum ML, Fleischer AB Jr, Reboussin DM. Psoriasis causes as much disability as other major medical diseases. *J Am Acad Dermatol*. 1999;41:401-407.
8. Choi J, Koo JY. Quality of life issues in psoriasis. *J Am Acad Dermatol*. 2003;49:S57-S61.
9. Krueger G, Koo J, Lebwohl M, Menter A, Stern RS, Rolstad T. The impact of psoriasis on quality of life: results of a 1998 National Psoriasis Foundation patient-membership survey. *Arch Dermatol*. 2001;137:280-284.
10. Stern RS, Nijsten T, Feldman SR, Margolis DJ, Rolstad T. Psoriasis is common, carries a substantial burden even when not extensive, and is associated with widespread treatment dissatisfaction. *J Invest Dermatol Symp Proc*. 2004;9:136-139.
11. Gelfand JM, Feldman SR, Stern RS, Thomas J, Rolstad T, Margolis DJ. Determinants of quality of life in patients with psoriasis: a study from the US population. *J Am Acad Dermatol*. 2004;51:704-708.
12. Gelfand JM, Neimann AL, Shin DB, Wang X, Margolis DJ, Troxel AB. Risk of myocardial infarction in patients with psoriasis. *JAMA*. 2006;296:1735-1741.
13. Lebwohl M. A clinician's paradigm in the treatment of psoriasis. *J Am Acad Dermatol*. 2005;53:S59-S69.
14. Kyle S, Chandler D, Griffiths CE, et al. Guideline for anti-TNF-alpha therapy in psoriatic arthritis. *Rheumatology (Oxford)*. 2005;44:390-397.
15. Smith CH, Anstey AV, Barker JN, et al. British Association of Dermatologists guidelines for use of biological interventions in psoriasis 2005. *Br J Dermatol*. 2005;153:486-497.