Psoriasis Outcome Measures: A Report from the GRAPPA 2012 Annual Meeting

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ABSTRACT. Psoriasis is a multisystem disease. The cutaneous and musculoskeletal manifestations (psoriatic arthritis) are well recognized. However, the other manifestations of psoriatic disease including metabolic syndrome, atherosclerotic cardiovascular disease, depression, poor self-esteem, and self-destructive habits including obesity, smoking and excess alcohol consumption are underappreciated. At the 2012 annual meeting of the Group for Research and Assessment of Psoriasis and Psoriatic Arthritis (GRAPPA), members addressed the need to develop uniform, validated, standardized outcome measures for psoriatic disease, measures that are useful to all stakeholders including patients, physicians, regulators, and payers. (J Rheumatol 2013;40:1428–33; doi:10.3899/jrheum.130456)

Key Indexing Terms:
PSORIATIC DISEASE PSORIASIS OMERACT
NATIONAL PSORIASIS FOUNDATION COMORBIDITIES

Over the years, several differing models of psoriasis care have emerged: (1) Primary care physicians manage all aspects of psoriatic disease; (2) single specialists manage all aspects of psoriatic disease; (3) multiple specialists work independently on different aspects of psoriatic disease [patient sees a dermatologist for psoriasis and a rheumatologist for psoriatic arthritis (PsA)];(4) multidisciplinary clinics where specialists from different fields work together to care for the patient; and (5) patients drop out of the system, receive no psoriasis care from established medical facilities, or seek over-the-counter and/or alternative care.

While the optimal model would be multiple specialists contributing to care of patients with psoriasis, the reality is that many patients receive no care, or care only from primary care physicians.

We need better psoriasis outcome measures that are useful in the clinic setting and that satisfy the needs of physicians, regulators, payers, and patients, because access is the major obstacle to optimal psoriasis care (Tables 1, 2, 3). In the United States, patients have limited ability to see doctors offering the full repertoire of treatments. Only 25% of US dermatologists use methotrexate, which has been approved for use in psoriasis for decades[1]. In a National Psoriasis Foundation (NPF) survey, about 50% of patients with severe psoriasis are treated only with topical therapies[2].

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Supported in part by a grant from the Advancing Innovation in Dermatology Foundation.

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Many dermatologists do not inquire about signs and symptoms of PsA, nor the other manifestations of psoriatic disease, primarily because of economic disincentives[3,4]. Treating moderate to severe psoriasis patients who require systemic treatment increases office overhead and decreases revenue, especially when compared to treating patients in need of surgical or cosmetic interventions. Payers often stratify physicians based on their cost efficiency (physician tiering), which could appear less cost effective if they offer a full spectrum of therapies for patients with psoriasis. Primary care physicians (PCP) may not refer their patients to specialists who offer a full range of treatments because PCP are financially rewarded for not referring to specialists (e.g., capitation, accountable care organizations). Additionally, patients may be levied high copays or coinsurances to obtain expensive drugs or see physicians offering expensive treatments. Many primary care physicians receive limited training during residency and therefore have inadequate knowledge about the serious aspects of dermatologic diseases. Many patients are not aware of the natural history of their psoriatic diseases or the range of treatment options, and they may not have appropriate expectations regarding the benefits and risks of these treatments. Importantly, patients may not be aware that physicians differ widely in their expertise with regard to psoriasis care. If patients lack access to a comprehensive psoriasis care center or specialists experienced in treating psoriasis, their likelihood of achieving significant improvement in psoriasis severity and their quality of life (QOL) is lower than those with such access. Most patients with moderate to severe psoriasis do not know that they bear an increased risk of dying prematurely due to their psoriasis.

Current psoriasis outcome measures lack aspects of truth, discrimination, and feasibility. They do not measure key

Table 1. Physician-reported disease severity measures in psoriasis.

Scale	Clinical Signs			Disease		Functional	Psychosocial	Treatment
	Erythema	Induration	Scaling	Extent	Pruritus	Limitation	Impact	History
Psoriasis Area and Severity Index[5,7,8]	x	x	x	x				
Physician's Global Static Assessment[5,7,9]	x	x	x					
Variation of Physician's Static Global Assessment[5,7,9]	x	x	x					
Physician's Dynamic Global Assessment[5,7,9]	x	x	x	x				
Body Surface Area[10,25]				x				
NPF Psoriasis Score[14,23]	x	x	x	x	x			
Lattice System Physician's Global Assessment[7]	x	x	x	x				
Overall Lesion Assessment[14]	x	x	x					
Overall Lesion Severity Scale[15,16]	x	x	x					
Psoriasis Severity Index[17]	x	x	x					
Psoriasis Assessment Severity Score[18,19]	x	x	x	x				
Simplified PASI[20]	x	x	x	x				
Psoriasis Log-Based Area and Severity Index[19,21]	x	x	x	x				
Psoriasis Exact Area and Severity Index[19,21]	x	x	x	x				
Copenhagen Psoriasis Severity Index[22]	x	x	x					
Dermatology Index of Disease Severity*[26]				x		x		
Salford Psoriasis Index[24]	x	x	x	x			x	x
Nail Psoriasis Severity Index[13]				Nail involvement				

* A general disease severity measure located in a psoriasis outcomes review[25].

Table 2. Patient-reported disease severity measures in psoriasis.

Scale	Skin Signs		Skin Symptoms		Other Signs	Body	Global Frequency	Global Severity	Assessment of
	Erythema	Induration	Scaling	Pain	Pruritus	or Symptoms	Surface Area	of Psoriasis Signs and Symptoms	of Psoriasis Signs and Symptoms	Treatment Response
Psoriasis Symptom Inventory[28]	x		x	x	x	x				
Self-administered PASI[29,32]	x	x	x				x			
Psoriasis Symptom Assessment[16,33]								x*	x*	
National Psoriasis Foundation Itch Scale[16]					x					
Visual analog scale for pain and pruritus[16,34]				x	x					
Patient's global assessment (examples of generic scales)[35-40]									x	
Patient's overall assessment of treatment response[41]										x
Subject's Assessment of Treatment (SAT)†[42]	Could not find further information on this scale.									

* Signs and symptoms included pain, burning or stinging, itching, bothered by water, irritation, sensitivity, bleeding, and scaling. Frequency and severity of each symptom were measured over the preceding 2 weeks[38]. † Could not find information on this scale. PASI: Psoriasis Area and Severity Index.

aspects of psoriatic disease and are not useful in clinical practice. Further, psoriasis-specific outcomes are not currently captured in routine clinical databases. When payers make decisions on psoriasis treatment algorithms and which physicians to favor for their quality and cost effectiveness, the decision makers do not have available data outside of clinical trials. Psoriasis outcome measures may partially address the needs of clinical researchers and regulators but often do not address the needs of patients or payers, and may not be practical to use in the clinic setting (Tables 1, 2, 3). Many aspects of psoriatic disease are not addressed at all, e.g., QOL, PsA, nail disease, metabolic syndrome, cardiovascular morbidity and mortality, and cost efficacy. Too often, psoriasis is viewed by payers and regulators as largely a cosmetic problem, i.e., not as serious as the rheumatologic disorders.

Table 1 shows the physician-based disease severity outcome measures used currently for regulatory approval

Table 3. Patient-reported quality-of-life measures in psoriasis.

Scale	Functioning						Emotions			Skin Signs					Skin Symptoms						
	Physical		Social																		
	Basic Functions	Activities	Interpersonal	Activities	Daily Activities	Sexual Health	Depression	Anxiety	Embarrassment	Bleeding	Redness	Flaking	Scarring	Change in Skin Color	Itch	Pain	Sting/burn	Soreness	Treatment	General Health	Other Comorbidities
Dermatology Life Quality Index[11]		x	x	x																	
Children's Dermatology Life Quality Index[43]		x	x	x	x		x		x						x	x		x	x		
Skindex-29[33-35]			x	x	x	x	x		x	x					x	x	x				
Short Form Health Survey[46]	x	x		x	x		x	x								x				x	
Short Form Health Survey[47,48]		x		x	x		x	x								x				x	
Psoriasis Disability Index[49,50]		x	x	x	x	x													x		x
Dermatology Quality of Life Scales[51]	x	x		x	x	x	x	x	x	x	x	x	x	x	x	x	x	x			
Freiburg Life Quality Assessment for Chronic Dermatoses[52]	x	x	x	x	x		x	x	x	x		x			x	x	x	x	x	x	
Sickness Impact Profile[49,53,54]	x			x	x	x	x														
Hospital Anxiety and Depression Scale (HADS)[55,56]						x	x														
Beck Depression Inventory[57-59]							x	x													
Work Productivity and Activity Impairment Questionnaire for Psoriasis[60]		x			x																
Work Limitations Questionnaire[61,62]					x																
Psoriasis Quality of Life Questionnaire[63]	x	x	x		x	x	x		x						x	x		x			

and their limitations. The Psoriasis Area and Severity Index (PASI) has been validated in multiple phase 2 and 3 clinical trials[5,6,7,8]. It has acceptable intraobserver variability but falls short with respect to interobserver variability. It lacks sensitivity, especially in patients with milder disease. It is impractical to use in the clinic setting. It does not measure patient symptoms, e.g., itch, and measures only severity of skin disease. It measures none of the other aspects of psoriatic disease listed above.

The Physician Global Assessment (PGA)[5,7,9], although relatively easy to use, with acceptable intra- and interobserver variability, and practical for use in the clinic, fails on multiple levels. It is not standardized (it has both 5-point and 6-point scales), which make the results difficult to compare. PGA measures only lesion morphology and not body surface area (BSA) (Table 1). Investigators are often confused or inconsistent about assessing current lesions or describing them. Partially cleared lesions are difficult to assess. PGA assumes all lesions clear identically at the same rate; in reality this often does not happen. Like PASI, it does not address patient symptoms, QOL, nail disease, or the multisystem expression of psoriatic disease.

While BSA is practical to use in the clinic setting[10], it too fails in multiple ways. There is a large degree of interobserver variability. It does not measure the quality or morphology (scaling, erythema, thickness) of lesions. Like PASI and PGA, it does not measure nail changes, QOL, patient symptoms, or other aspects of psoriatic disease. Recently the product of BSA plus PGA has been suggested as a better alternative to the use of BSA and PGA separately[7]. PASI, BSA, and PGA have been the 3 most common efficacy measures used in phase 2 and 3 clinical trials.

Dermatology Life Quality Index (DLQI) is the most common QOL instrument used in phase 2 and 3 clinical trials of psoriasis (Table 3)[11,12]. However, DLQI is a generic dermatology QOL measure that is not specific to psoriasis and does not adequately identify the unique QOL of psoriatic disease.

Nail disease has been measured most often in clinical trials by the Nail Psoriasis Severity Index (NAPSI)[13]. Advantages include being simple to calculate, sensitive to change, and reproducible in clinical trials. However, practicing dermatologists will not be likely to include it in their health records.

Other, less commonly used skin symptom measurement tools include Overall Lesion Assessment[14], Overall Lesion Severity Scale[15,16], Psoriasis Severity Index[17], Psoriasis Assessment Severity Score[18,19], Simplified PASI[20], Psoriasis Log-based Area and Severity Index[19,21], Psoriasis Exact Area and Severity Index[19,21], Copenhagen Psoriasis Severity Index[22], National Psoriasis Score[14,23], Lattice System Physician's Global Assessment[7], Salford Psoriasis Index[24], and Dermatology Index of Disease Severity[25,26,27] (Table 1). Other patient-assessed disease severity measures are summarized in Table 2[16,28,29,30,31,32,33,34,35,36,37,38,39,40,41,42,43,44,45]. Use of QOL measures is described in Table 3[11,33,34,35,43,46,47,48,49,50,51,52,53,54,55,56,57,58,59,60,61,62,63].

Dermatologists need to develop uniform, validated, standardized outcome measures for psoriatic disease that are useful to all stakeholders including patients, physicians, regulators, and payers. These measures need to be applicable not only to clinical researchers but also to practicing dermatologists. They have been discussed at an international meeting in January 2013 where attendees determined whether an OMERACT (Outcome Measures in Rheumatoid Arthritis)-like approach will improve the culture of assessment in dermatology. Participants included representatives from OMERACT, GRAPPA, the NPF, patient leaders, payers, regulators, clinical researchers, and epidemiologists/statisticians. Pharmaceutical industry sponsors were invited to attend as observers. A review was conducted of how OMERACT identified which domains to measure for fibromyalgia and PsA and how they designed and validated specific outcome measurement tools for those diseases. Representatives from all attending groups discussed the benefits and shortfalls of current psoriasis outcome measurement instruments and provided their perspectives on what these tools should measure.

The group used techniques similar to those used by OMERACT to identify which disease domains to study[64]. The group discussed whether to focus solely on the cutaneous manifestations, or if outcome tools should include other aspects of psoriatic disease (e.g., patient-related symptoms, QOL, nail disease, PsA, metabolic syndrome, cardiovascular morbidity and mortality, cost efficacy, and comparative efficacy). Additionally, the group discussed creation and maintenance of an outcomes website for posting key articles and providing a forum for online debate. A Delphi process is being conducted over the following 6 months in order to pick domains to assess with outcome measurement tools. A second psoriasis outcomes meeting is planned to coincide with the GRAPPA annual meeting in Toronto, Canada, in July 2013. Proceedings of all meetings will be submitted for publication.

In conclusion, in order to improve the access of patients to optimal care we need new psoriasis outcome measures that meet the needs of all stakeholders and are feasible to use in clinical practice. It is hoped that improved outcome measures will lead to improved access for patients. The finish line is not at regulatory approval or when an article is published in the *New England Journal of Medicine* or *The Lancet*. It is when patients lead their daily lives free from psoriasis, psoriatic arthritis, and their associated comorbidities.

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