Recategorization of psoriasis severity: Delphi consensus from the International Psoriasis Council

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Background: Psoriasis severity categories have been important tools for clinicians to use in treatment decisions as well as to determine eligibility criteria for clinical studies. However, owing to the heterogeneity of severity classifications and their lack of consideration for the impact of psoriasis involvement of special areas or past treatment history, patients may be miscategorized, which can lead to undertreatment of psoriasis.

Objective: To develop a consensus statement on the classification of psoriasis severity.

Methods: A modified Delphi approach was developed by the International Psoriasis Council to define psoriasis severity.

Results: After completion of the exercise, 7 severity definitions were preferentially ranked. This most preferred statement rejects the mild, moderate, and severe categories in favor of a dichotomous definition: Psoriasis patients should be classified as either candidates for topical therapy or candidates for systemic...
therapy; the latter are patients who meet at least one of the following criteria: (1) body surface area >10%, (2) disease involving special areas, and (3) failure of topical therapy.

**Limitations:** This effort might have suffered from a lack of representation by all relevant stakeholders, including patients.

**Conclusion:** The consensus statement describes 2 categories of psoriasis severity, while accounting for special circumstances where patients may require systemic therapy. (J Am Acad Dermatol 2020;82:117-22.)

**Key words:** BSA; psoriasis; severity; systemics; topicals.

In both clinical practice and clinical trials, psoriasis severity is often categorized as mild, moderate, and severe, which is guided by measurements such as body surface area (BSA), Physician’s Global Assessment (PGA), and the Psoriasis Area and Severity Index (PASI). These objective measures may underestimate disease severity, however, if lower degrees of skin involvement (eg, BSA <10%) are recorded while ignoring disease involvement of “special areas” (eg, face, palms, soles, genitalia, scalp), prior treatment history, the impact of psoriasis on quality of life, or a combination of these. Therefore, it is often emphasized that dermatologists should consider the location of lesions and quality of life (eg, using the Dermatology Life Quality Index [DLQI]) to more fully and accurately assess psoriasis severity.

Many different guidelines and consensus definitions of psoriasis severity exist and include a combination of assessor- and patient-reported measures for disease classification. For example, the rule of tens describes “current severe psoriasis” if BSA involved >10% or PASI >10 or DLQI >10. Other proposed systems similarly use combined ranges of PASI and DLQI to compartmentalize patients into severity categories.

Patient-reported severity is commonly misaligned with physician-reported severity. Severity measures used in routine practice often underclassify psoriasis severity, resulting in undertreatment. Furthermore, there is no consensus regarding the definition for patients affected by lower levels of BSA involvement who, nonetheless, have disease characteristics that may severely impact quality of life and disability. Typically, only patients with a minimum of 10% BSA are permitted entry to clinical trials of newer targeted agents, so evidence is lacking about the efficacy of these agents in patients with lower BSA involvement or disease involving special sites. This also impacts the approval of agents for patients with lower degrees of skin involvement, with some national health systems and third-party payers declining reimbursements for patients who do not have at least 10% BSA involvement.

To define psoriasis disease severity in a practical manner that is useful in both clinical and research settings, the International Psoriasis Council (IPC) used the collective experience of global psoriasis experts in a Delphi exercise.

**METHODS**

**Study management**

The study was designed and led by the Steering Committee (A.B., C.R., P. v.d.K., and J. v.d.W.) under the leadership of Dr Bruce Strober, the Project Chair. The database was managed through Question Mark Media, LLC, which provided web development services to configure and maintain the hosting environment (IPCDelphi.com). The web-based interface was used for the anonymous collection and rating of content submitted by participants.

**Participants**

The IPC is a dermatology-led, voluntary, nonprofit organization that represents psoriasis experts from 32 countries. Participants have established expertise in psoriasis clinical practice, basic psoriasis research, or psoriasis clinical trials. The Delphi process consisted of a brainstorming stage, 2 rounds of voting, and a consensus meeting. See Fig 1 and the Supplemental Tables (available at https://data.mendeley.com/datasets/4svjdh4yrd/1) for details. All IPC Board members and councilors were invited to participate in all steps of the Delphi exercise. In

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**CAPSULE SUMMARY**

- Psoriasis severity classifications are often defined by objective measures; however, there is no international consensus.
- An international Delphi exercise was used to categorize psoriasis severity. The consensus statement should prove useful for guiding therapeutic decisions in clinical practice and changing enrollment criteria in psoriasis clinical research.
addition, one representative from each IPC corporate sponsor was invited to participate in only the brainstorming stage.

RESULTS

In total, 78 anonymous statements were collected (68 from IPC Board and Councilors and 10 from corporate sponsors). The statements from IPC participants reflected views on psoriasis severity across geographic regions, including Europe (Denmark, France, Germany, Ireland, Italy, the Netherlands, Portugal, Spain, and United Kingdom; 24 statements), North America (Canada and United States; 25 statements), and other regions (Argentina, Australia, Brazil, Chile, China, Colombia, Egypt, Iran, Israel, Japan, Kuwait, Malaysia, and Singapore; 19 statements) (Supplemental Table I).

A total of 74 voters participated (62% of the IPC Board and Councilor membership) in round 1. Mean scores were calculated for each statement. Subsequently, results were displayed for a discussion session whereby participants anonymously could comment online on the ranking of round 1 statements. A total of 39 comments were submitted.

Seventy-two voters participated in round 2 voting. The mean scores of rounds 1 and 2 were recorded, and differences in mean scores were calculated (Supplemental Table II).

From the 30 statements, 7 statements receiving the highest scores after round 2 were chosen for voting in round 3 at the in-person consensus meeting. After all 7 statements were presented and discussed, the participants voted anonymously via smartphone or tablet to arrive at a final ranking of the statements. Table I lists the final ranking derived from the round 3 voting.

Statement ID 6 achieved the highest score; however, the group decided that the statement could be optimized for wording and clarity. Therefore, 2 amended versions of the statement were written and then uploaded for online voting to the entire group of participants (all IPC board and councilors and IPC corporate sponsor representatives).

The final consensus statement is as follows: Psoriasis patients should be classified as candidates
### Table I. Psoriasis severity classification statements ranking from round 3

<table>
<thead>
<tr>
<th>Rank</th>
<th>Statement ID</th>
<th>Statement text</th>
<th>Round 3, mean (SD)</th>
<th>Round 2, mean (SD)</th>
<th>Difference</th>
<th>Round 3 votes</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>6</td>
<td>There are “candidates for topical therapy,” and then there are “candidates for systemic therapy” who are patients who meet at least 1 of the following criteria: 1. BSA &gt;10% 2. Disease involving special areas 3. Failure of topical therapy</td>
<td>4.2778 (1.193)</td>
<td>3.6667 (1.093)</td>
<td>0.6111</td>
<td>18</td>
</tr>
<tr>
<td>2</td>
<td>7</td>
<td>Two degrees of severity: 1. That which can be adequately controlled with topical therapy alone (mild or mild to moderate). 2. That which requires phototherapy or systemic therapy (including biologics) (moderate to severe or severe, respectively). Adequate control may be determined by both objective (eg, PASI, BSA, PGA) and subjective (eg, DLQI, PDI, PSS, SF-36, EQ-5D) means/measurements/instruments.</td>
<td>2.8889 (0.994)</td>
<td>3.5634 (−1.11)</td>
<td>−0.6745</td>
<td>18</td>
</tr>
<tr>
<td>3</td>
<td>2</td>
<td>Moderate to severe: the dermatologist perceives the need of a systemic treatment after a careful consideration of several factors (eg, PASI, QoL impairment, comorbidities, and others). Mild: the dermatologist perceives that only topical treatment needs to be prescribed.</td>
<td>2.6111 (−1.112)</td>
<td>3.9718 (−1.048)</td>
<td>−1.3607</td>
<td>18</td>
</tr>
<tr>
<td>4</td>
<td>15</td>
<td>Mild: BSA 0%-5% with special areas not affected and with DLQI &lt;5. Moderate: BSA 5%-10% or special areas affected; or BSA 1%-5% and DLQI 5-10. Severe: &gt;10% BSA or special areas affected; or BSA 5%-10% and DLQI &gt;10.</td>
<td>2.5 (1.258)</td>
<td>2.875 (1.117)</td>
<td>−0.375</td>
<td>18</td>
</tr>
<tr>
<td>5</td>
<td>29</td>
<td>Mild: &lt;3% BSA and not affecting special areas. Moderate: BSA 3%-10% or &lt;3% BSA and involvement of special areas that cannot be managed with topical therapy alone. Severe: BSA &gt;10% or &lt;10% BSA and involvement of 2 special areas that cannot be managed with topical therapy alone.</td>
<td>2.3889 (1.061)</td>
<td>2.7746 (1.064)</td>
<td>−0.3857</td>
<td>18</td>
</tr>
<tr>
<td>6</td>
<td>24</td>
<td>Mild: managed by topical treatment alone. Moderate to severe: requires systemic treatment or phototherapy.</td>
<td>2.1111 (0.875)</td>
<td>2.9306 (0.962)</td>
<td>−0.8195</td>
<td>18</td>
</tr>
<tr>
<td>7</td>
<td>3</td>
<td>Mild: does not interfere with the patient’s daily life and requires no treatment or only infrequent topical treatment. Moderate: sometimes interferes with the patient’s life due to social or occupational challenges or psoriasis-related pain. Requires regular treatment with topical medications, phototherapy, oral medications, or biologic therapy. Severe: psoriasis or psoriatic arthritis interferes daily or frequently with the patient’s life and prevents them from achieving their social or occupational goals.</td>
<td>1.7778 (0.916)</td>
<td>2.9722 (1.013)</td>
<td>−1.1944</td>
<td>18</td>
</tr>
</tbody>
</table>

BSA, Body surface area; DLQI, Dermatology Life Quality Index; EQ-5D, EuroQol 5D; PASI, Psoriasis Area and Severity Index; PDI, Psoriasis Disability Index; PGA, Physician’s Global Assessment; PSS, Psoriasis Symptom Scale; QoL, quality of life; SF-36, 36-Item Short-Form Health Survey.
for topical therapy or candidates for systemic therapy. The latter are patients who meet at least 1 of the following criteria:

1. BSA >10%
2. Disease involving special areas
3. Failure of topical therapy

Systemic therapies for psoriasis were understood to include both biologic and nonbiologic treatments such as phototherapy and older systemic agents. For clarity and brevity, the term “special areas” was used in the severity statement to refer to psoriasis affecting more impactful sites such as the face, palms, soles, genitalia, scalp, or nails.

DISCUSSION

The iterative, interactive, and anonymous approach of the Delphi method was selected as the best method to collect and prioritize statements that reflect global expert opinion on the classification of psoriasis severity. This method allowed the identification of a most-favored final consensus statement.

The multistep process of this exercise encouraged ample interspersed discussion. The merits and weaknesses of many statements were debated after the first round of voting and during the in-person consensus meeting. The participants highlighted a concern regarding high variability across countries and regions on use of different severity measures. The PASI, for example, is a complex measure that is frequently used by dermatologists in Europe to assess severity and monitor disease response to treatment and is often needed for reimbursement decisions.15 However, PASI is infrequently used in the United States in routine clinical practice where the BSA is the preferred measure for therapeutic decision making and reimbursement.2,16

Importantly, neither severity scoring tool can measure patient symptoms or quality of life, and neither tool considers how psoriasis can affect special areas or past failure of topical therapy. Therefore, participants agreed that any system of severity classification must go beyond strict assessor-driven cutoffs, which in many instances incorrectly downgrade disease severity and thus restrict access to therapies appropriate for more severely affected patients.

The group ultimately agreed that severity definitions in part require objective numeric thresholds. However, such parameters need to be coupled with other measures and concepts that are relevant to the patient’s experience. In this vein, in addition to the extent and intensity (erythema, scaling, and induration) of skin involvement, the participants highlighted the importance of lesion locations (ie, special areas) that impact quality of life and function.

Because objective measures do not account for psychologic burden or indirect costs and consequences to the patient, the classification of severity, in part, should be patient-centered. Although the group agreed that the patient-reported outcome metrics are relevant, they are often disregarded by payers and might explain why the top vote winner in this exercise omits the use of a patient-reported outcome.

The IPC consensus statement determined here is similar to the severity definition proposed in 2007 by the National Psoriasis Foundation where 2 tiers of severity stratified by the response to topical therapy were endorsed.6 In addition, the Spanish Psoriasis Group and the European Consensus Group also recognize that response to topical treatment is an important consideration of psoriasis severity.5,9

The European Consensus Group recognized that the presence of clinical manifestations (involvement of scalp, genitals, palms, soles, or nails; involvement of visible areas; recalcitrant plaques) may warrant systemic treatment in a patient diagnosed as mild based on symptom severity and BSA.5 The British Association of Dermatologists guidelines also include areas of involvement and functional or psychosocial impact as criteria for severity classification and treatment decisions.17 The Canadian guidelines also define severity categories of psoriasis based in part on lack of control of symptoms with topical therapy and the impact on the patient’s quality of life.18

The top vote-receiving statement includes BSA >10% as severity criterion, because it is easily performed and a well-established standard of psoriasis severity. Importantly, the statement also includes involvement of special areas and failure of topical therapy as criteria for more severe disease. Thus, this definition is more complex than “BSA >10%” alone, accounting for important exceptions to this standard that are practical and patient centered.

The results of Delphi exercises are limited by those who choose to participate. Although this effort was large and international, it may have suffered from a lack of representation by all relevant stakeholders, particularly community dermatologists who are not involved in academic research, and importantly, psoriasis patients.

CONCLUSION

This Delphi exercise resulted in an international consensus for the classification of psoriasis severity. The statement that received the highest score endorses a simple, practical approach to classifying
psoriasis disease severity. The terms mild, moderate, and severe were rejected in favor of considerations of (1) a basic standard objective criteria (BSA); (2) involvement of special areas of the body; and (3) the patient’s response to topical therapy. Hopefully, this new consensus statement will extend to the realm of clinical research and allow expanded access of psoriasis patients into clinical trials.

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REFERENCES