Patient-Reported Outcome Measures as Complementary Information to Clinician-Reported Outcome Measures in Patients With Psoriasis

Psoriasis has been associated with major changes in patients’ psychosocial, emotional, and physical functioning. Thus, clinician-reported outcomes (CROs) for disease severity may not adequately capture patients’ lived experience of the disease, which is supported by the fact that CROs do not correlate highly with patient-reported outcome measures (PROMs). Patient-reported outcome measures may provide complementary information, allowing clinicians to better understand the patient’s unique experience of living with psoriasis, which could facilitate individualized treatment. The purpose of this study was to evaluate the potential complementary value of PROMs and CROs among patients being treated for psoriasis in routine clinical practice.

Methods | This cross-sectional study was conducted using data from the Dermatology Clinical Effectiveness Research Network, a multicenter partnership formed to perform clinical research on dermatologic disorders, which has previously been described in detail. Data for the present study were collected from February 2010 through June 2011 and were analyzed in May 2021. The University of Pennsylvania Institutional Review Board deemed this study exempt from review and waived the requirement for patient informed consent because only deidentified data were used.

The Dermatology Life Quality Index (DLQI) is a 10-item questionnaire (PROM) that evaluates patients’ views of their dermatology-specific health-related quality of life; scores range from 0 to 30, with 0 to 5 indicating mild, 6 to 10 indicating moderate, and 11 to 30 indicating severe disease. The Psoriasis Area Severity Index (PASI) is a CRO measure that assesses the skin area coverage and plaque appearance (score range, 0-72, with higher scores indicating severe disease). Body surface area (BSA) can be classified as less than 3% for mild disease, 3% to 10% for moderate disease, and 11% or greater for severe disease.

To examine whether the PROMs (DLQI) provide clinicians with potential complementary information to the CROs (PASI and BSA), we compared the percentage of patients with psoriasis who met the guideline criteria established by the British Association of Dermatologists and other European organizations for initiating systemic therapy (DLQI score >10, BSA >10%, or a PASI score ≥10). We also compared the number and percentage of patients who met treatment goal criteria defined as a DLQI score lower than 5 or a PASI score lower than 3. In addition, correct classification rates (a measure of agreement) for initiation of systemic therapy were calculated by adding the number of patients who would meet criteria via both PROMs and CROs and dividing by the sample of patients included to compare the percentage of patients who met the criteria according to the CRO measures (PASI and BSA) and the PROM (DLQI). Stata, version 15 (StataCorp, LLC) was used to analyze the data. The threshold for statistical significance was P < .05.

Results | Among 1733 patients with psoriasis (48.6 [16.0] years; 879 [50.7%] female patients), 1201 (69.3%) had mild, 293 (16.9%) had moderate, and 239 (13.8%) had severe disease as assessed by the DLQI. A total of 725 patients (41.8%) had a 1-level difference in disease severity compared with PASI and 615 (35.5%) had a 1-level difference compared with BSA. A 2-level difference in disease severity was observed in 158 patients (9.1%) compared with PASI and 199 (11.5%) compared with BSA (Table 1).

Among patients with psoriasis who met the criteria for systemic therapy initiation based on PASI scores of 10 or higher or BSA greater than 10%, 72.4% (249 of 344; 95% CI, 67.3%-77.0%) did not have a DLQI score higher than 10. Among patients who did not meet the criteria for systemic therapy based on PASI scores or BSA, 10.4% (144 of 1389 patients; 95% CI, 8.8%-12.1%) had a DLQI score higher than 10. Among patients with psoriasis who met the criteria for achieving the treatment goal based on PASI scores of 10 or higher or BSA greater than 10%, 50.5% (505 of 1000 patients; 95% CI, 47.4%-53.6%) had a DLQI score lower than 5. Among patients who did not meet the criteria for achieving the treatment goal based on PASI scores, 50.5% (505 of 1000 patients; 95% CI, 47.4%-53.6%) had a DLQI score lower than 5. The correct classification rate for modification of therapy (treatment goal) was 62.3% (95% CI, 59.9%-64.6%).

Table 1. Comparison of Patient- and Clinician-Reported Outcome Measures Assessing Disease Severity Among Patients With Psoriasis

<table>
<thead>
<tr>
<th>DLQI score for disease severity</th>
<th>No. of patients (%) (N = 1733)</th>
<th>BSA for disease severity</th>
<th>No. of patients (%) (N = 1733)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mild (&lt;3) Moderate (3-9) Severe (≥10)</td>
<td>Mild (&lt;3) Moderate (3%-10%) Severe (&gt;11%)</td>
<td></td>
</tr>
<tr>
<td>Mild (&lt;6) (n = 1201)</td>
<td>621 (35.8) 461 (26.6) 119 (6.9)</td>
<td>700 (40.4) 353 (20.4) 148 (8.5)</td>
<td></td>
</tr>
<tr>
<td>Moderate (6-10) (n = 293)</td>
<td>73 (4.2) 149 (8.6) 71 (4.1)</td>
<td>79 (4.6) 135 (7.8) 79 (4.6)</td>
<td></td>
</tr>
<tr>
<td>Severe (&gt;10) (n = 239)</td>
<td>39 (2.3) 120 (6.9) 80 (4.6)</td>
<td>51 (2.9) 104 (6.0) 84 (4.9)</td>
<td></td>
</tr>
</tbody>
</table>

Abbreviations: BSA, body surface area; DLQI, Dermatology Life Quality Index; PASI, Psoriasis Area Severity Index.
Discussion | In this comparison of DLQI (PROM) and PASI and BSA (CRO) scores, there were differences with respect to disease severity assessment and whether patients met the criteria for systemic therapy initiation. These findings highlight that evaluating patients with CROs or PROMs alone could lead to an incomplete understanding of disease severity, which may lead to undertreatment or overtreatment.

Because psoriasis and other chronic inflammatory skin diseases can affect patients differently depending on their personal circumstances, PROMs could be viewed as a vital sign to be captured at each visit to obtain complementary information to the history and physical examination. In oncology, routine collection of PROMs has been shown to improve symptom management, patient satisfaction, and clinical outcomes, such as quality of life and survival. Routinely capturing both CROs and PROMs could facilitate more effective shared decision-making discussions, particularly when there are differences in severity assessments among CROs and PROMs. This study is limited by the observational nature of the design. Although additional research is needed to understand the implications of collection of PROMs for clinical efficiency, quality of care, and patient outcomes in dermatology, increasing the use of PROMs in routine clinical care may ensure that clinicians are appropriately individualizing care to patients’ needs.

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Author Contributions: Dr Barbieri had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

Concept and design: Barbieri.

Acquisition, analysis, or interpretation of data: All authors.

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Table 2. Comparison of Patient- and Clinician-Reported Outcome Criteria for Systemic Therapy Initiation

<table>
<thead>
<tr>
<th>Met DLQI criteria?</th>
<th>Met PASI criteria?</th>
<th>Met BSA criteria?</th>
<th>Met PASI or BSA criteria?</th>
</tr>
</thead>
<tbody>
<tr>
<td>No (≤ 10) (n = 1494)</td>
<td>No (score &lt;10)</td>
<td>Yes (score ≥10)</td>
<td>No (≥10%)</td>
</tr>
<tr>
<td>1321 (76.2)</td>
<td>173 (10.0)</td>
<td>1267 (73.1)</td>
<td>227 (13.1)</td>
</tr>
<tr>
<td>Yes (&gt; 10) (n = 239)</td>
<td>165 (9.5)</td>
<td>74 (4.3)</td>
<td>155 (8.9)</td>
</tr>
</tbody>
</table>

Abbreviations: BSA, body surface area; DLQI, Dermatology Life Quality Index; PASI, Psoriasis Area Severity Index.

Postmarketing Cases of Enfortumab Vedotin–Associated Skin Reactions Reported as Stevens-Johnson Syndrome or Toxic Epidermal Necrosis

During routine surveillance, the US Food and Drug Administration (FDA) Division of Pharmacovigilance identified postmarketing cases of Stevens-Johnson Syndrome (SJS) and toxic epidermal necrosis (TEN) associated with enfortumab vedotin (EV) from the FDA Adverse Event Reporting System (FAERS). To investigate a potential association between EV and SJS/TEN, we evaluated all sources for postmarketing cases of SJS/TEN and report our findings.

Methods | We reviewed FAERS, PubMed, and Embase from December 18, 2019, the FDA approval date for EV, through October 7, 2020, to identify cases of SJS/TEN with EV. The analysis was completed manually over the course of several months in 2020. Cases of SJS/TEN diagnosed by a dermatologist or reporting confirmatory biopsy results were considered confirmed cases. Cases were excluded if there was insufficient information to confirm the diagnosis of SJS/TEN or temporal association with EV, or if an alternative etiology was considered.