Comparison of a 24-Hour and 7-Day Version of a Patient-Reported Outcome Measure for Psoriasis Symptom Severity

Donald M. Bushnell,1 Mona L. Martin,1 Kelly P. McCarrier,1 Chiun-Fang Chiou,2 Brian Ortmeier3

1Health Research Associates, Inc., Seattle, WA, USA; 2Janssen Global Services, LLC, Raritan, NJ, USA (at Amgen during work on this project); 3Global Health Economics, Amgen, Inc., Thousand Oaks, CA, USA

BACKGROUND
• Psoriasis severity is often assessed by dermatologists using clinical measures such as the Psoriasis Area and Severity Index (PASI), psoriasis-affected body surface area (BSA), and the patient’s Global Assessment (GA).
• The patient’s perspective of his or her health status is important1,2 but often correlates poorly with clinical measures.3
• We developed the Psoriasis Symptom Inventory (PSI) to provide a patient-reported measure of psoriasis symptoms.

OBJECTIVE
• The primary objective of the study was to evaluate differences between a 24-hour and 7-day recall of the PSI.

METHODS
Study Design
• The cross-sectional, randomized, study was conducted over a period of 14 days in 138 patients with moderate to severe plaque psoriasis.
• Two study arms were employed (Arm 1 = 75%; Arm 2 = 25%).
• In Arm 1, patients completed the 24-hour recall PSI on days 1-14, and completed the 7-day retrospective PSI on days 1, 7, and 14.
• In Arm 2, patients completed the 7-day retrospective PSI on days 1, 7, and 14, but completed the 24-hour recall PSI only on days 8-14 to allow for analysis of the potential effect of daily symptom assessment on the symptom reporting associated with the 7-day retrospective PSI.
• Clinical measures (PASI, BSA) were assessed at baseline.

Study Population
• Eligible patients had moderate to severe psoriasis (BSA > 15% PASI score > 15).
• Patients continued on standard of care; no intervention was initiated as part of the study.

Figure 1. Diagram of Study Data Collection

RESULTS
Table 1. Comparison of the 24-Hour and 7-Day Versions of the PSI: By Item

<table>
<thead>
<tr>
<th>Item Group</th>
<th>Arm 1</th>
<th>Mean (SD)</th>
<th>7-Day PSI</th>
<th>24-Hour PSI</th>
<th>Difference (7-Day – 24-Hour)</th>
<th>P-Value</th>
<th>Limits of Agreement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pain from lesions</td>
<td>Arm 1</td>
<td>1.89</td>
<td>1.29</td>
<td>0.98</td>
<td>0.00</td>
<td>0.98</td>
<td>-0.5 to 1.5</td>
</tr>
<tr>
<td>Scaling of skin lesions</td>
<td>Arm 1</td>
<td>2.95</td>
<td>2.51</td>
<td>0.98</td>
<td>0.17</td>
<td>0.98</td>
<td>-0.5 to 1.5</td>
</tr>
<tr>
<td>Itch, scaling, and flaking</td>
<td>Arm 1</td>
<td>2.79</td>
<td>2.47</td>
<td>0.98</td>
<td>0.00</td>
<td>0.98</td>
<td>-0.5 to 1.5</td>
</tr>
</tbody>
</table>

CONCLUSION
• Our overall findings showed that the two PSI versions yield equivalent results.
• Both the 24-hour PSI and 7-day PSI would provide comprehensive capture of symptoms in psoriasis studies and clinical trials.

REFERENCES