Evaluation of the PGAxBSA Composite Tool in Patients With Moderate vs. Moderate to Severe Plaque Psoriasis

Kristina Callis Duffin, MD1; J. Mark Jackson, MD2; Joana Goncalves, MD2; Eugenia Levi, PharmD2; Jerry Bagel, MD3

1University of Utah, Salt Lake City, UT; 2University of Louisville, Forefront Dermatology, Louisville, KY; 3Celgene Corporation, Summit, NJ; 4Psoriasis Treatment Center of Central New Jersey, East Windsor, NJ

INTRODUCTION

The Physician Global Assessment and Body Surface Area (PGAxBSA) composite tool is simple to use for the assessment of both severity and extent of psoriasis and correlates with the product of the more complex Psoriasis Area and Severity Index (PASI) tool.1

METHODS

• Data were collected from patients with moderate plaque psoriasis who were randomly assigned to receive apremilast (APR) at baseline in the ESTEEM 1 trial (n=552) and the UNVEIL trial (n=148).

• ESTEEM 1 was a 12-wk, multicenter, randomized, double-blind, PBO-controlled study (registry NCT01194219) and involved 1001 patients with moderate plaque psoriasis (BSA=5% to 10%).

• UNVEIL was a 12-wk, randomized, double-blind, PBO-controlled study (registry NCT01232284).

• In the current analysis, the PGAxBSA was continuously monitored from baseline through Week 16.

RESULTS

• Patients in UNVEIL who received APR had a significantly greater improvement (reduction) in mean percentage change from baseline in PGAxBSA vs. the PBO group at Week 16 (P<0.0001) (Figure 3). In addition, 35.4% of APR patients in UNVEIL achieved a ≥75% reduction from baseline in PGAxBSA score (PGAxBSA-75) vs. 12.3% of PBO patients (P<0.0001) (Figure 3).

• In these 2 studies, psoriasis severity was defined as follows:

  • ESTEEM 1: PASI ≥12, BSA ≥10, static Physician Global Assessment (PGA) ≥3

  • UNVEIL: BSA=5% to 10%, sPGA=3.

• Agreement between PGAxBSA and PASI at baseline and Week 16 was evaluated using Spearman correlation (r).

• Mean percentage changes from baseline in PGAxBSA and PASI scores over the course of the 16-wk PBO-controlled period are shown in Figure 4. Improvement from baseline was greater with PGAxBSA vs. PASI at each time point.

CONCLUSIONS

• Correlation between PASI and PGAxBSA at baseline was lower in UNVEIL (baseline r=0.395, Week 16 r=0.685) than it was in ESTEEM 1 (baseline r=0.753, Week 16 r=0.807).

• The larger effect size for PGAxBSA compared with PASI in UNVEIL suggests that PASI may be less sensitive to change in patients with more moderate disease.

• PGAxBSA is a simple alternative to PASI, and may be more sensitive for assessing the response to treatment in patients with moderate (BSA=5% to 10%) plaque psoriasis.

TABLE 1. Spearman Correlations, ICC, and Effect Sizes: PASI and PGAxBSA at Baseline

<table>
<thead>
<tr>
<th>Time Point</th>
<th>PASI Mean (SD)</th>
<th>PGAxBSA Mean (SD)</th>
<th>Spearman Correlation</th>
<th>ICC (95% CI)</th>
<th>PASI vs. PGAxBSA Effect Size</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td>12.7 (7.6)</td>
<td>71.8 (40.8)</td>
<td>0.725*</td>
<td>0.86 (0.80, 0.89)</td>
<td>0.685*</td>
</tr>
<tr>
<td>UNVEIL</td>
<td>12.7 (7.6)</td>
<td>71.8 (40.8)</td>
<td>0.725*</td>
<td>0.86 (0.80, 0.89)</td>
<td>0.685*</td>
</tr>
</tbody>
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Figure 3. Mean Percentage Change in PGAxBSA at Week 16 In UNVEIL

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DISCLOSURES

MD: AbbVie, Amgen, Bauschinger Ingelheim, Bristol-Myers Squibb, Celgene Corporation, Contraflow, Janssen, Eli Lilly, Novartis, Pfizer, Regeneron, Shire, and UCB; consultant, steering committee member, advisory board member, has received grants, and/or has received honoraria, from AbbVie, Amgen, Celgene, Dermira, Gedeon, Gilead, Genentech, Janus, Lilly, Medrocs, Merck, Novartis, Pfizer, Promus, and Topdix – research, honorary, consulting and/or other support. JG: AbbVie, Amgen, Bauschinger Ingelheim, Janssen, Lilly, Medrocs, Merck, Novartis, Pfizer, and Valeant – speaker board member, consultant, and/or research support.

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