Novel Evaluation of Psoriasis Area and Severity Index (PASI) Data: Distribution of PASI Improvements in a Trial of Etanercept for Moderate to Severe Plaque Psoriasis

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Disclosures


**M. Trivedi, D.H. Collier, and G. Kricorian** are employees and shareholders of Amgen Inc.

- Medical writing support was provided by Julia R. Gage (Gage Medical Writing, LLC, on behalf of Amgen Inc.) and Dikran Toroser (Amgen Inc.)

- Graphics support was provided by Robert Dawson (Cactus Communications, on behalf of Amgen Inc.)
Novel Evaluation of Psoriasis Area and Severity Index (PASI) Data: Distribution of PASI Improvements in a Trial of Etanercept for Moderate to Severe Plaque Psoriasis

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BACKGROUND
- PASI Area and Severity Index (PASI) assessments are used in clinical trials to evaluate the efficacy of treatment for psoriasis.
- PASI assessments are usually reported as dichotomous variables based on a predefined degree of improvement, e.g., 75% or greater (PASI 75) response.
- An analysis of the distribution of PASI responses rather than a dichotomous response may provide a more comprehensive method to evaluate response to treatment.

OBJECTIVE
- To examine the distribution of PASI responses from a pivotal trial of etanercept in patients with moderate to severe plaque psoriasis.

METHODS

Study Design
- Data for this analysis were obtained from a pivotal, phase III, randomized, controlled trial of etanercept for the treatment of moderate to severe plaque psoriasis.
- Patients were randomized to placebo, etanercept 25 mg twice weekly (BW), or etanercept 50 mg BW for 12 weeks, followed by open-label etanercept 25 mg BW for 12 weeks.
- Patients on placebo or etanercept were included in the analysis.

Patient Characteristics
- Adult ≥ 18 years of age.
- Active, clinically stable plaque psoriasis.
- Psoriasis-affected body surface area (BSA) ≥ 10%.
- PASI score ≥ 10.
- Had received or was a candidate to receive systemic psoriasis therapy or phototherapy.

Primary Endpoint
- The primary endpoint of the original study was the percentage of patients with PASI 75 response at week 12.

Statistical Considerations
- All randomized patients were included in the analysis regardless of whether or not they received study drug.
- Patients were categorized in % improvements by percentage improvement in PASI score at week 12.
- Patients with integer responses (i.e., 0.0% PASI improvement) were counted in the lowest data range (e.g., the 75.1% to 80.0% category).
- Nonresponse option was used for missing data.

RESULTS
- Data from 457 patients were analyzed, including:
  - 204 patients on placebo.
  - 203 patients on etanercept 50 mg BW.
- All-week 12:
  - 15% on placebo and 10% on etanercept achieved a PASI 90.
  - 7% on placebo and 12% on etanercept achieved a PASI 75.

CONCLUSIONS
- When evaluating clinical responses to therapy in patients with psoriasis, traditional dichotomous analyses provide a limited picture of the distribution of responses.
- Histogram analyses can provide a broader, more informative view of response that is relevant to clinicians making treatment decisions.
- With this visual representation of data, the etanercept 50 mg BW cohort demonstrated a clear shift in the distribution, showing a majority of patients with a distribution of responses throughout the PASI 50–100 range.

REFERENCES

DISCLOSURES
- Medical writing support was provided by Julia R. Regel (Sage Medical Writing, LLC, on behalf of Amgen Inc.) and Dilek Tamer (Amgen Inc.).
- Graphis support was provided by Robert Davidson (Calcite Communications, on behalf of Amgen Inc.)
Background

- Psoriasis Area and Severity Index (PASI) assessments are used in clinical trials to evaluate the efficacy of treatment for psoriasis.
- PASI assessments are usually reported as dichotomous variables based on a predefined degree of improvement, e.g., 75% or greater (PASI 75) response.
- An analysis of the distribution of PASI responses rather than a dichotomous response may provide a more comprehensive method to evaluate response to treatment.
Objective

- To examine the distribution of PASI results from a pivotal trial of etanercept in patients with moderate to severe plaque psoriasis.
Methods

Study Design

• Data for this analysis were obtained from a pivotal, phase 3, randomized, controlled trial of etanercept for the treatment of moderate to severe plaque psoriasis

• Patients were randomized to placebo, etanercept 25 mg twice weekly (BIW), or etanercept 50 mg BIW for 12 weeks, followed by open-label etanercept 25 mg BIW for 12 weeks

• Patients on placebo or etanercept 50 mg BIW were included in this analysis
Methods (Cont.)

Patients

• Adults ≥ 18 years of age
• Active, clinically stable plaque psoriasis
• Psoriasis-affected body surface area (BSA) ≥ 10%
• PASI score ≥ 10
• Had received or was a candidate to receive systemic psoriasis therapy or phototherapy
Methods (Cont.)

*Primary Endpoint*

- The primary endpoint of the original study was the percentage of patients with PASI 75 response at week 12
Methods (Cont.)

Statistical Considerations

• All randomized patients were included in the analysis regardless of whether or not they received study drug.

• Patients were categorized in 5% increments by percentage improvement in PASI score at week 12:
  • Patients with integer responses (eg, 80.0% PASI improvement) were counted in the lower data set range (eg, the 75.1% to 80.0% category).

• Nonresponder imputation was used for missing data.
Results

• Data from 407 patients were analyzed, including:
  – 204 patients on placebo
  – 203 patients on etanercept 50 mg BIW

• At week 12:
  – < 1% on placebo and 19% on etanercept achieved a PASI 90
  – 3% on placebo and 46% on etanercept achieved a PASI 75
  – 9% on placebo and 72% on etanercept achieved a PASI 50
Results (Cont.)

Percentage Change in PASI Score at Week 12 in 5% Increments

**Etanercept 50 mg BIW**

**Placebo**

*11 patients on placebo and 9 patients on etanercept were not dosed and were imputed as 0% PASI improvement (represented as −5% to 0%)*
Conclusions

• When evaluating clinical responses to therapy in patients with psoriasis, traditional dichotomous analyses provide a limited picture of the distribution of responses.

• Histogram analyses can provide a broader, more informative view of response that is relevant to clinicians making treatment decisions.

• With this visual representation of data, the etanercept 50 mg BIW cohort demonstrated a clear shift in the distribution, showing a majority of patients with a distribution of responses throughout the PASI 50–100 range.