

# Measuring Patient-Reported Dermatologic Side Effects of Cancer Treatment: Psychometric Evaluation of the SKINDEXTM-16 in Non-Small Cell Lung Cancer

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### Key Takeaway

Results from this study support the validity and aid the interpretation of the SKINDEXTM-16 for the assessment of dermatologic side effects of cancer treatment.

### Conclusions

- This study is the first to examine psychometric properties of the SKINDEXTM-16 in the context of side effects of cancer treatment.
- Results provide evidence of high reliability and validity in this context of use.
  - High values of internal consistency and test-retest reliability
  - Correlations with other PROs conformed to expectations (e.g., worse skin problems most highly correlated with pain, fatigue, insomnia, and functioning)
  - Worse patient-reported skin problems associated with greater severity of skin-related adverse events
- Results suggest that the 10-point meaningful change threshold previously established for skin diseases<sup>1</sup> may also apply when evaluating skin-related treatment side effects.
  - Estimated thresholds for meaningful change ranged from 9-13 points

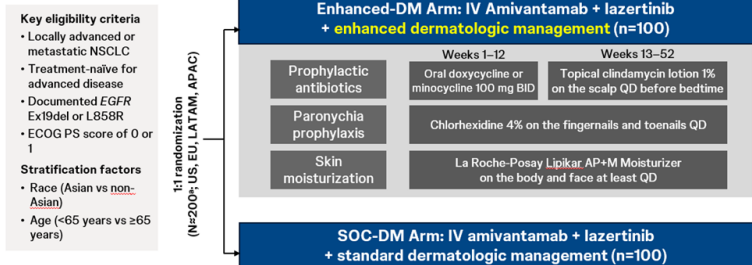
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**Disclosures**  
The authors are employees of and may hold stock in Johnson & Johnson.

## Introduction

- Reliable, valid measures of patient-reported treatment tolerability are important to complement adverse event data in clinical trials.
- EGFR inhibitors used to treat certain types of cancers are associated with skin-related symptoms.
- The SKINDEXTM-16<sup>1</sup> was developed to measure the effect of skin disease on quality of life.
- Objective:** Evaluate psychometric properties of the SKINDEXTM-16 in non-small cell lung cancer (NSCLC) treated with amivantamab.

## Methods



Patient-Reported Outcome (PRO) instruments were completed at study baseline and every 2 weeks for the first 12 weeks

- SKINDEXTM-16
- EORTC-QLQ-C30
- PGI-S (global impression of skin symptom severity)

| Analysis   | Methods   |
|--|---|
| Internal consistency                             | Cronbach's alpha based on baseline assessment   |
| Test-retest reliability                          | Correlation in scores among a stable subset (same PGI-S response at 4 and 8 weeks post-baseline)  |
| Convergent / discriminant validity               | Correlations between SKINDEXTM and EORTC scores at 8 weeks post-baseline  |
| Known groups validity & Responsiveness to change | Clinically meaningful subgroups defined by presence and severity of skin-related adverse events at 12 weeks post-baseline   |
| Meaningful change thresholds                     | <ul style="list-style-type: none"> <li>½ standard deviation (SD) at each timepoint</li> <li>Mean score changes for patients with 1-point change in PGI-S</li> </ul> |

## Results

### Participants

- 199 adults with EGFR-mutated NSCLC treated with amivantamab and lazertinib
- Median age = 63 years

### Reliability

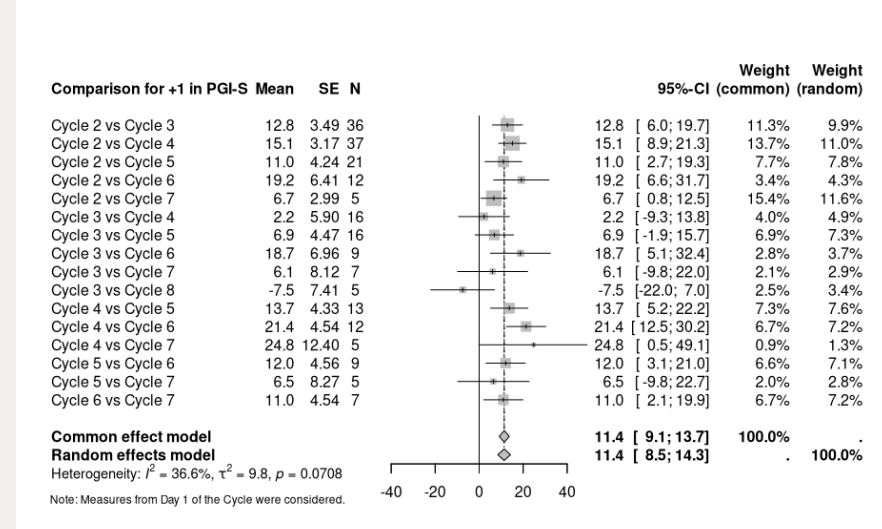
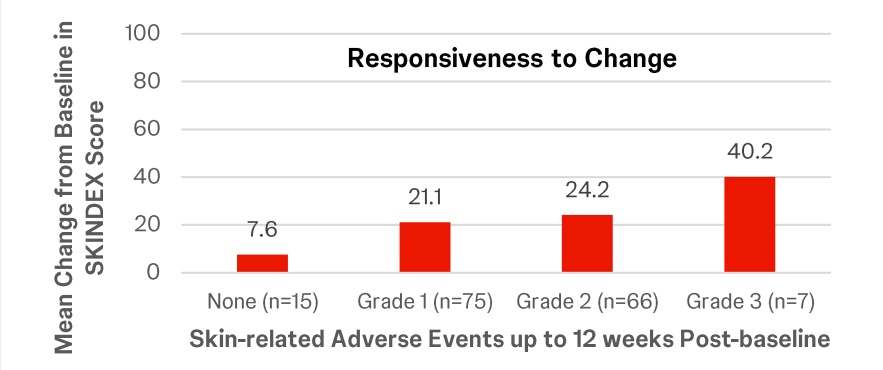
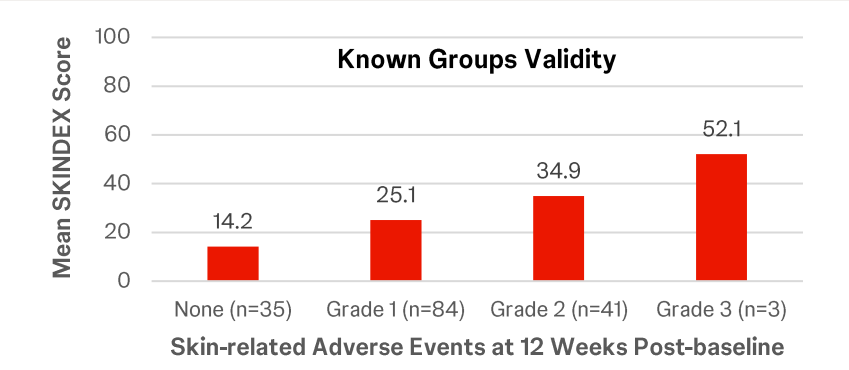
- Internal consistency: alpha = 0.95
- Test-retest reliability: r = 0.83

| EORTC Symptom Scale    | Pearson r |
|------------------------|-----------|
| Pain                   | 0.53      |
| Fatigue                | 0.49      |
| Insomnia               | 0.41      |
| Constipation           | 0.35      |
| Financial Difficulties | 0.34      |
| Nausea and Vomiting    | 0.31      |
| Appetite Loss          | 0.27      |
| Dyspnea                | 0.23      |
| Diarrhea               | 0.20      |

## Convergent and Discriminant Validity

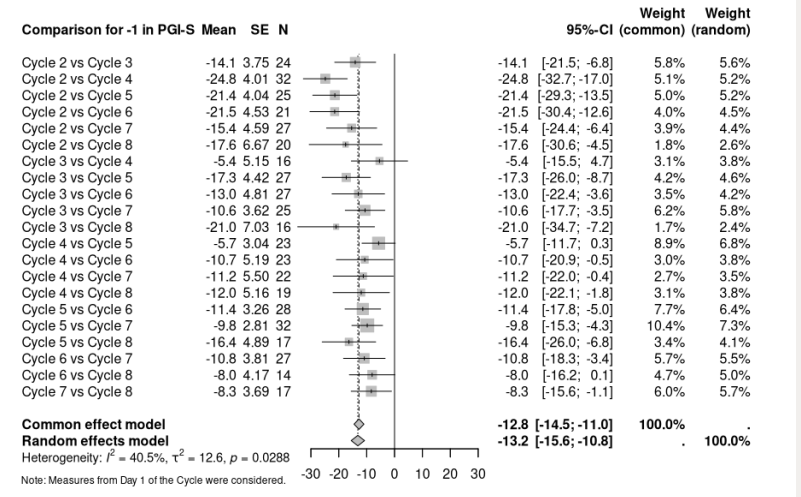
- Correlations with other PROs conformed to expectations
- Positive correlations with SKINDEXTM scores = greater symptoms associated with worse skin problems
- Negative correlations with SKINDEXTM scores = worse functioning associated with worse skin problems

| EORTC Function Scale | Pearson r |
|----------------------|-----------|
| Emotional Function   | -0.63     |
| Social Function      | -0.57     |
| Role Function        | -0.49     |
| Physical Function    | -0.43     |
| Cognitive Function   | -0.39     |
| Global Health Status | -0.38     |



## Meaningful Change Thresholds

- Distribution-based (interquartile range of ½ SD): 9-12 points
- Anchor-based (worsening): 11 points
- Anchor-based (improvement): 13 points



**References**  
<sup>1</sup>Mapi Research Trust. 2023. SKINDEXTM-16 Version 1.0 - Scaling and Scoring.  
<sup>2</sup>Cho, B. C., Li, W., Spira, A. I., Sauder, M., Feldman, J., Bozorgmehr, F., ... & Girard, N. (2025). Enhanced versus standard dermatologic management with amivantamab-lazertinib in EGFR-mutated advanced NSCLC: The COCOON global randomized controlled trial. *Journal of Thoracic Oncology*, 20(10), 1517-1530.