EASI Data Visualization: A New Interactive Tool to Evaluate the Efficacy of Drugs by EASI Clinical Sign and Body Region Using Example Data From a Phase 2b Study of Lebrikizumab in Atopic Dermatitis

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BACKGROUND

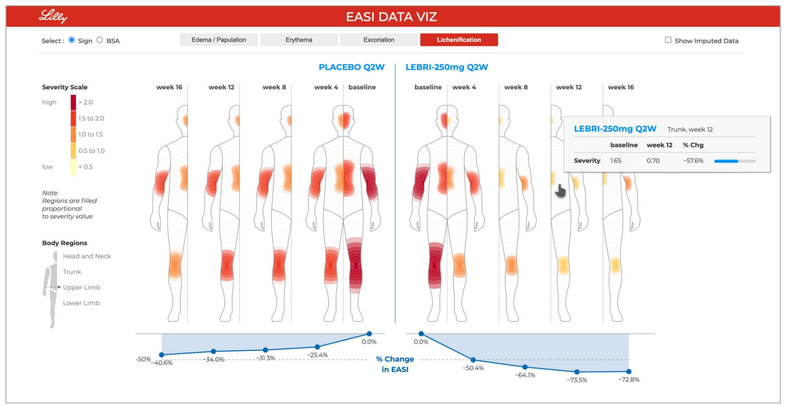
- The Eczema Area and Severity Index (EASI) is an important measure of atopic dermatitis (AD) signs and is the preferred outcome measure for clinical signs of AD in clinical trials by the HOME Group[1]
- The EASI total score is a composite based on the evaluation of signs (redness, swelling, scratching, and lichenification), area, and severity in each of the 4 body regions and is reported as a single number
  - The total score alone gives no indication of the weight of the driving forces behind it
- The EASI Data Visualization tool is a custom-designed, dynamic, and interactive tool
  - The tool facilitates rapid dermatological evaluation of the intensity and extent of lesion involvement in patients with AD participating in clinical trials

OBJECTIVE

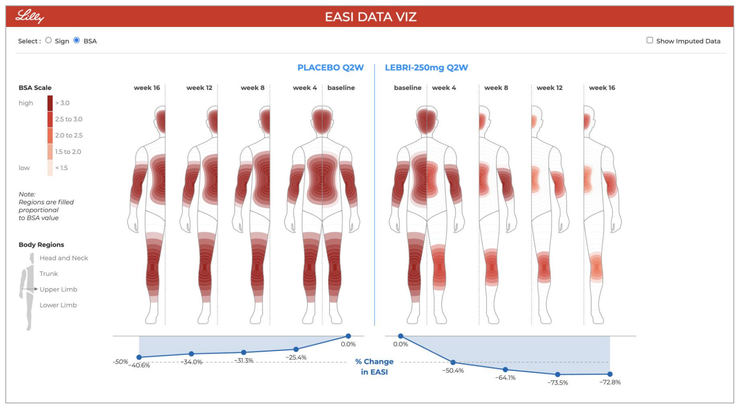
- To demonstrate the EASI Data Visualization tool functionality for visualizing the EASI components, including each skin sign and body surface area by body region, using lebrikizumab Phase 2b data

KEY RESULTS

EASI Data Visualization: Lichenification



EASI Data Visualization: BSA



- Pop-out “tooltip” box displays data selected by the user

CONCLUSIONS

- EASI Data Visualization offers a visual representation of disease severity and allows for rapid and comprehensive interpretation of each component of the EASI total score
- The accessibility of the application allows clinicians to better understand the data collected in clinical trials at their convenience

REFERENCE

1. Chalmers JR, et al. *BR J Dermatol Venereol*. 2014;171:1318-25.

ABBREVIATIONS

BSA=body surface area; Chg=change; EASI=Eczema Area and Severity Index; LD=loading dose; LEBRI=lebrikizumab; Q2W=every 2 weeks; Q4W=every 4 weeks; W=Week

METHODS

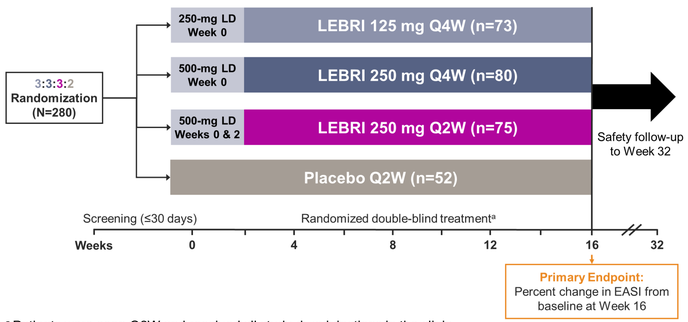
Tool Development

- EASI Data Visualization was developed with feedback from dermatologists and clinical trial investigators
- The tool illustrates changes in the EASI total score components by body region over time
- EASI Data Visualization is intended to communicate data entered by the clinical trial sponsor, using visual elements for enhanced accessibility
- The web-based application features a responsive design that renders well on various devices, including phones

Materials and Methods

- Data from a randomized, placebo (PBO)-controlled, double-blind, Phase 2b study (NCT03443024) were used to demonstrate tool functionality
- Analysis included data from 2 treatment arms:
  - Patients receiving lebrikizumab 250 mg every 2 weeks (Q2W) following a loading dose of 500 mg at baseline and Week 2
  - Patients receiving PBO Q2W for 16 weeks
- Full EASI data, including for each component, are available through EASI Data Visualization
  - EASI lichenification of the trunk is used to demonstrate how the tool can be used to visualize data
- Post-rescue or treatment discontinuation observed data were excluded
- Last observation carried forward was used for imputation

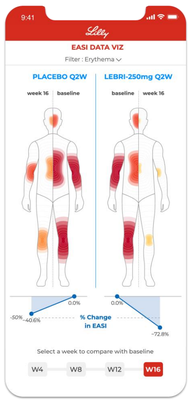
Study Design



[a] Patients were seen Q2W and received all study drug injections in the clinic

RESULTS

EASI Data Visualization: Erythema



DISCLOSURES

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