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Integrating data from an electrical impedance spectroscopy device improves pigmented lesion diagnostic accuracy among dermatology mid-level providers

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Background: Electrical impedance spectroscopy (EIS) is a noninvasive FDA-approved technology to aid clinicians in selecting appropriate pigmented skin lesions for biopsy. Concerns have been raised regarding patient care with dermatology providers that may have less experience and diagnostic acumen. Technology that can augment diagnostic skills could help to enhance diagnostic accuracy.

Methods: A group of 160 dermatology mid-level providers (PAs and NPs) were surveyed on their clinical decisions of whether or not to biopsy pigmented lesions. Clinical images of 43 lesions (16 melanomas and 27 benign) were presented. Each participant was asked to determine whether biopsy was indicated based on clinical morphology alone and then on the same images with EIS data added. Overall improvement in diagnostic accuracy with the addition of EIS data was assessed. Results were grouped into 4 quartiles of years of experience with overall percentage improvement being derived.

Results: Management accuracy improved by 10.2% with the integration of EIS data. Mid-levels with less experience had a significantly greater percentage improvement than those with more experience (least experienced quartile = 11.8%, Q2 = 12.1%, Q3 = 8.2%, most experienced quartile = 8.5%; $P = .01$).

Conclusions: Integrating EIS data into the biopsy decision significantly improved diagnostic accuracy among mid-level providers. Management accuracy among less experienced PAs and NPs improved significantly more than those of their more experienced counterparts. These results suggest that EIS technology can aid in the management of pigmented lesions and may be particularly useful to clinicians with lesser diagnostic skills by enhancing the accuracy of their biopsy decisions.

Commercial disclosure: This study was sponsored in part by a grant from Scibase.

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Development of a lip health assessment scale for clinical use

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Background: A photonumeric scale for evaluating lip health does not currently exist. Lip health includes 3 important characteristics not assessed in other lip photonumeric scales: texture, shine, and vermilion border definition. This study was conducted to develop a photonumeric scale evaluating these lip health characteristics.

Methods: Healthy female or male subjects ≥18 years of age with Fitzpatrick skin types I-III (n = 103) underwent visible light VISIA-CR 4.3 lip photography. All subjects were instructed to not use skin care products or topical medications on the face or lips on imaging day. The images were organized for distribution to a 4-member expert panel that used the proposed lip health scale. Prior to rating the images, raters completed a training session conducted by the lead investigator to arrive at consensus regarding image evaluation. The raters then received the images in random order and rated each based on the proposed rating scale. Images were graded for texture, shine, and vermilion border using an ordinal scale: 0 = none, 1 = minimal, 2 = mild, 3 = moderate, 4 = severe. Specific characteristics were provided for each parameter. The images were chosen for the final scale based on rating agreement between 3 of the 4 raters.

Results: One image was selected for each of the 5 ordinals representing the 3 lip health characteristics, resulting in a total of 15 images comprising the photonumeric scale.

Conclusions: This photonumeric scale may effectively assess lip health and, after further validation, potentially serve as an outcome measure in trials evaluating the effectiveness of products that promote lip health.

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BMS-986165, an oral selective TYK2 inhibitor, in the treatment of moderate to severe psoriasis as assessed by the static Physicians Global Assessment/body surface area composite tool, a clinically useful alternative to the Psoriasis Area and Severity Index score

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Background: In a phase 2 trial of the oral, selective tyrosine kinase 2 (TYK2) inhibitor BMS-986165, in 267 patients with moderate to severe plaque psoriasis (NCT02931838), 67%-75% achieved PASI75 at wk 12 (primary end point) at doses ≥3 mg twice daily (bid) versus 7% with placebo ($P < .001$). The product of the static Physicians Global Assessment and body surface area (sPGA×BSA) accounts for extent and severity of psoriasis and may be a simple, clinically useful alternative to PASI.

Methods: This post hoc analysis of the phase 2 trial evaluated sPGA×BSA for assessing response to BMS-986165. Patients were randomized (n = 44-45/group) to 1 of 5 oral BMS-986165 doses (3 mg every other day, 3 mg once daily [QD], 3 mg bid, 6 mg bid, 12 mgQD) or placebo. Assessments included: PASI, sPGA, BSA, DLQI. Spearman correlation coefficients (corr) for all treatment groups evaluated sPGA×BSA and PASI score relationship at baseline and wk 12. Agreement was based on concordance rates.

Results: All randomized patients were assessed. Percentage change from baseline to wk 12 was similar for sPGA×BSA and PASI in BMS-986165 treatment groups and placebo group. At wk 12, sPGA×BSA correlated strongly with PASI (corr = 0.94) and moderately with DLQI (corr = 0.58) across all treatment groups. 75% reduction in sPGA×BSA and PASI scores was achieved by similar proportions of patients receiving the most effective BMS-986165 doses (≥3 mg bid) (sPGA×BSA75: 78.4%; PASI75: 70.1%) and placebo (sPGA×BSA75: 13.3%; PASI75: 6.7%).

Conclusions: In patients with moderate to severe psoriasis, PASI strongly correlated with sPGA×BSA at wk 12 in all BMS-986165 treatment groups and placebo, further supporting sPGA×BSA as a simple, accurate, convenient alternative to PASI.

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Long-term safety of tildrakizumab in patients 65 years of age or older with moderate to severe psoriasis: Pooled analysis through 3 years (148 weeks) from reSURFACE 1 and reSURFACE 2 phase 3 trials

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Background: Tildrakizumab (TIL) is a high-affinity anti−IL-23p19 monoclonal antibody approved for the treatment of plaque psoriasis.

Objective: To report 148-week pooled safety data in patients ≥65 years of age from 2 phase 3 trials: reSURFACE 1/2 (NCT01722331/NCT01729754).

Methods: Post hoc pooled analysis of patients ≥65 years of age with moderate to severe plaque psoriasis from reSURFACE 1 (64 wk) and reSURFACE 2 (52 wk) trials. This safety analysis includes pooled data from both trials (all-subjects-as-treated population). Extended major adverse cardiovascular events (MACEs) included non-fatal myocardial infarction, non-fatal stroke, unstable angina, coronary revascularisation, resuscitated cardiac arrest, and cardiovascular deaths that were confirmed as "cardiovascular" or "sudden." Exposure-adjusted incidence rates (EAIRs) are reported (ie events per 100 patient-years of exposure).

Results: A total of 161 patients ≥65 years of age were exposed to TIL up to wk 148 (159.5 patient-years of exposure to TIL 100 mg, 170.8 patient-years of exposure to TIL 200 mg). The EAIRs of drug-related serious adverse events (SAEs) were 2.51/1.76/6.83 in the TIL100 mg/TIL200 mg/etanercept (ETN) groups respectively. The EAIRs of severe infections were 3.76/2.34/6.83 events per 100 patient-years of exposure [TIL100 mg/TIL200 mg/ETN]. The EAIRs of malignancies (excluding nonmelanoma skin cancer [NMSC]) were 1.88/1.76/6.83 [TIL100 mg/TIL200 mg/ETN]. The EAIRs of NMSC were 3.76/2.93/6.83 [TIL100 mg/TIL200 mg/ETN]. The EAIRs of confirmed extended MACE were 0.63/1.17/6.83 [TIL100 mg/TIL200 mg/ETN]. The EAIRs of injection site reactions were 0.63/2.34/20.48 [TIL100 mg/TIL200 mg/ETN].

Conclusions: Up to wk 148, TIL was well tolerated in patients ≥65 years of age, with low drug-related SAEs and adverse events of special interest. No dose-related increase in the rate of adverse events was observed.

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