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Gender differences in moderate to severe psoriasis: Analysis of the PSOLAR registry

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Background: There are little data regarding differences in clinical characteristics between men and women with psoriasis. This study analyses patient disease characteristics at enrollment by gender in the Psoriasis Longitudinal Assessment and Registry (PSOLAR).

Methods: Using data from the August 2017 data cut, a cross-sectional study of PSOLAR patients was conducted to determine whether gender is an independent predictor of disease characteristics. Differences between genders were assessed among patients who were biologic therapy naïve (n = 3329) and systemic therapy naïve (n = 1290). Statistical comparisons were made using an independent *t* test for continuous variables and chi-square testing for categoric variables, with significance determined as $P < .05$ (not adjusted for multiplicity).

Results: In the biologic-naïve cohort, differences between men and women were found in baseline body surface area (BSA) (19.9% vs16.6%, $P < .001$), baseline Physician's Global Assessment (PGA) score (2.6 vs 2.4, $P < .001$), peak historical, BSA (27.0% vs 23.8%, $P = .003$), and baseline Dermatology Life Quality Index (DLQI) score (9.2 vs 9.8, $P = .008$); no difference in peak historical PGA score was observed (3.0 vs 2.9, $P = .084$). In the systemic therapy-naïve cohort, gender was an independent predictor of baseline, BSA (20.0% vs 16.0%, $P < .001$), peak historical, BSA (24.1% vs 19.6%, $P = .006$), baseline PGA score (2.7 vs 2.5, $P = .018$), and peak historical PGA score (2.9 vs 2.7, $P = .007$); there was no difference in baseline DLQI score (10.9 vs 11. 5, $P = .173$). There were no differences in disease duration for either cohort.

Conclusions: Some differences in disease characteristics were noted between men and women enrolled in PSOLAR, laying the groundwork for future investigations into gender differences in treatment outcomes.

Commercial disclosure: This study was sponsored by Janssen Research & Development.

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Evaluation of a ceramide-containing lotion on skin hydration and cellular morphology assessed by reflectance confocal microscopy

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Background: Ceramides are important components of intercellular lipids, necessary to link corneocytes into a waterproof barrier and enhance skin hydration. Skin hydration has impact on cell morphology at the surface and deeper layers of epidermis. Objective: Evaluate the morphology of dry skin before and after treatment with a ceramide-containing moisturizer using in vivo reflectance confocal microscopy (RCM).

Methods: Thirty female patients from 18 to 45 years old, presenting dry skin (corneometry value ≤40 au), were instructed to apply a ceramide-containing lotion twice daily to one forearm whereas the other was kept untreated for comparison. Subjects submitted to corneometer and RCM evaluations at baseline, day 7, and day 28. RCM features analyzed were: corneal and epidermal thickness, irregularity of stratum corneum, size and morphology of epidermal folds, and morphology of keratinocytes in granular layer.

Results: A statistically significant increase in hydration for the treated compared with the untreated arm at day 28 was accompanied by a significiant reduction in the size of epidermal folds, which also displayed more linear morphology. The treated site showed a reduction in thickness of stratum corneum and improvement in regularity of skin surface. At the granular level, the treated site displayed a significantly more homgeneous keratinocyte morphology and an increase in reflectance of keratinocytic contour.

Conclusions: RCM is a useful imaging tool for analyzing the effect of topical formulations on cellular morphology. The improvement in morphological features when using a ceramide-containing lotion reflects an increase in hydration at the deepest layers of stratum corneum.

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Efficacy and safety of mirikizumab in patients with moderate to severe plaque psoriasis: 104-week results from a randomized phase 2 study

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Background: Mirikizumab, a p19-directed interleukin-23 antibody, demonstrated statistically significant Psoriasis Area and Severity Index (PASI) 90 response versus placebo at week 16 in patients with moderate to severe plaque psoriasis. This analysis reports long-term efficacy and safety results with mirikizumab at 2 years.

Methods: Adult patients randomized 1:1:1:1 in a phase 2 trial (AMAF; NCT02899988) received subcutaneous placebo (n = 52), mirikizumab 30 mg (n = 51), 100 mg (n = 51), or 300 mg (n = 51) at wk 0 and wk 8. At wk 16, mirikizumab-treated patients with <PASI90 response and placebo subjects received mirikizumab 300 mg every 8 weeks (q8w), and mirikizumab-treated patients with ≥PASI90 response were treated as needed (PRN) with initial dosing when <PASI90 until ≥PASI90 response was regained up to wk 104. PASI90/100 response rates and safety at wk 104 were summarized. Missing data were imputed as nonresponder.

Results: At wk 104, among patients with <PASI90 at wk 16 treated with placebo/300 mg (n = 50), 30/300 mg (n = 34), 100/300 mg (n = 21), or 300/300 mg (n = 15) mirikizumab: 38 (76%), 26 (76%), 15 (71%), 9 (60%) achieved PASI90; 28 (56%), 17 (50%), 12 (57%), 6 (40%) achieved PASI100. Among patients with ≥PASI90 at wk 16 treated PRN with 30 mg (n = 15), 100 mg (n = 30), or 300 mg (n = 34) mirikizumab: 8 (53%), 10 (33%), 21 (62%) had PASI90 response at wk 104. The most common treatment-emergent adverse event (≥1%) overall was nasopharyngitis.

Conclusions: PASI90/100 responses at 2 years were achieved by 40%-76% of wk 16 PASI90 nonresponders treated with mirikizumab 300 mg q8w. PASI90 response at 2 years was achieved by 33%-62% of wk 16 PASI90 responders with PRN treatment. Safety was consistent with previously disclosed mirikizumab safety data.

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Real-world utility of a noninvasive gene expression test to rule out primary cutaneous melanoma: A large US registry study

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The Pigmented Lesion Assay (PLA) analyzes gene expression to objectively rule out melanoma. The test uses a noninvasive adhesive patch-based sample collection platform that enables guidance on biopsy decisions and elevates pigmented lesion management beyond what can be visually ascertained. The test's negative predictive value of 99%, and rapid, painless application make it an attractive pre-biopsy solution. It reduces biopsies by 90% while improving care and reducing cost. This registry study (53 US dermatology offices, 90 providers, median patient age 48 years, 60.80% female patients) assesses real-world utility to determine if the PLA changes clinical practice. The PLA assessed 3418 concerning pigmented skin lesions. Three hundred twenty-four lesions (9.48%) were PLA(+) and 3094 (90.52%) were negative. A PLA test result is positive if LINC, PRAME, or both target genes are detected. These molecular pathology findings are known to correspond with histopathology findings of in situ or invasive primary melanoma in 7%, 50%, and 93%, respectively. The 9.48% PLA(+) cases consisted of 5.15% LINC-only, 1.93% PRAME-only, and 2.40% LINC and PRAME double positive cases. Notably, PLA(+) lesions were almost universally surgically biopsied (97.53%), while PLA(−) cases were nearly always monitored and not biopsied (99.94%). These studies demonstrate that the PLA has true clinical value in community-based practices where providers make important decisions based on the test's results. Pigmented lesions with PLA(+) test results are subjected to surgical biopsies, whereas PLA(−) lesions are followed clinically and not biopsied.

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