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Tildrakizumab efficacy by metabolic syndrome status in psoriasis: Post hoc analysis of 3-year data from the phase 3 reSURFACE 1 study

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Introduction: Metabolic syndrome (MetS) may reduce response to treatment for psoriasis. Tildrakizumab (TIL), a high-affinity, humanized, immunoglobulin G1κ, anti−interleukin-23p19 monoclonal antibody, is approved for treatment of moderate to severe plaque psoriasis. We present TIL efficacy in patients with psoriasis with vs without MetS with up to 3 years of follow-up.

Methods: This post hoc analysis of a phase 3, double-blind, randomized controlled study (reSURFACE 1 [NCT01722331]) included adult patients with moderate to severe chronic plaque psoriasis who continuously received the same TIL dose (TIL 100 or 200 mg) administered at week 0, wk 4, and every 12 weeks thereafter. We evaluated proportion of patients with ≥75% Psoriasis Area and Severity Index score improvement from baseline (PASI 75) and PASI change from baseline up to wk 148 stratified by MetS status.

Results: Of patients continuously receiving TIL 100/200 mg (n = 124/147), 26/34 (21%/23%), respectively, had MetS at baseline. Baseline demographic and disease characteristics were similar except for higher baseline weight, body mass index, and prevalence of cardiovascular disease and diabetes mellitus in patients with vs without MetS. Proportions of patients receiving TIL 100/200 mg who achieved PASI 75 were comparable between those with vs without MetS at wk 52 (85%/76% vs 86%/76%), wk 100 (65%/68% vs 76%/81%), and wk 148 (69%/71% vs 71%/74%). At wk 148, overall PASI scores decreased from baseline 89%/88% vs 92%/91% in patients with vs without MetS receiving TIL 100/200 mg, respectively.

Conclusions: TIL efficacy was maintained over 148 weeks and comparable in patients with vs without Mets.

Commercial disclosure: The studies were funded by Merck Sharp & Dohme Corp, a subsidiary of Merck & Co, Kenilworth, New Jersey. Analyses were funded by Sun Pharmaceutical Industries, Princeton, New Jersey.

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Topical 5% imiquimod for cutaneous primary and metastatic melanoma: A systematic review

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Surgical excision is the criterion-standard treatment for primary cutaneous melanoma and isolated metastatic melanoma lesions. However, surgery may not be suitable given patient comorbidities, lesion size or location, and anticipated functional impairment. Thus, the use of non-surgical treatment options for cutaneous melanoma and metastatic disease has expanded rapidly. Imiquimod is one topical immunotherapy notable for its controversial off-label use for locally advanced melanoma. The aim of this systematic literature review is a critical analysis of the efficacy of imiquimod as adjuvant or monotherapy for invasive primary or metastatic melanoma. The review was based on a search inclusive of imiquimod and melanoma in PubMed, Embase, and Web of Science. Inclusion criteria comprised any use of imiquimod in the treatment of invasive melanoma. Eligible studies were evaluated by two researchers independently and in 2 phases: the title/abstract phase and the full text phase. Of 1114 results, 62 studies met inclusion criteria. These studies were reviewed for methodological quality and strength, and then synthesized using a narrative approach. Results were compiled into a table and used to inform recommendations for future research. Most studies were case reports or case series and a majority described cutaneous or in-transit melanoma metastases. While most showed successful treatment outcomes, the treatment regimens and end point definitions varied widely between studies. The results of this study indicate the promise of imiquimod for the treatment of melanoma, however, future work including more rigorous prospective trials is required to further validate its efficacy and standardize treatment regimens.

Commercial disclosure: None identified.

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Safety of tildrakizumab in patients with preexisting metabolic syndrome: Long-term data from the post hoc analysis of two phase 3 clinical studies (reSURFACE 1 and reSURFACE 2)

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Introduction: We present long-term safety data for tildrakizumab (TIL), a high-affinity, humanized, immunoglobulin G1κ, anti−interleukin-23p19 monoclonal antibody approved for treatment of moderate to severe plaque psoriasis, in patients with versus without metabolic syndrome (MetS).

Methods: In the phase 3, double-blind, randomized, controlled, 64/52 week reSURFACE 1/2 base studies (NCT01722331/NCT01729754) and their long-term extensions, adults with moderate to severe chronic plaque psoriasis received TIL 100 or 200 mg. This post hoc analysis of pooled safety data evaluated treatment-emergent adverse events (TEAEs), stratified by MetS status, through up to 5 years of exposure.

Results: Of patients who continuously received TIL 100/200 mg (n = 369/330) in the base studies, 79/67 (21.4%/20.3%), respectively, met MetS criteria at baseline. Base period TEAE incidence rates were generally comparable between patients with and without MetS; the most frequent TEAE was infections (TIL 100 mg, 50.6% vs 53.1%, n = 40 vs 154; TIL 200 mg, 62.7% vs 52.9%, n = 42 vs 139). Of 335/305 patients who continuously received tildrakizumab 100/200 mg throughout base and extension periods (total 1401.5/1362.3 patient years [PY]), 70/64 (20.9%/21%), respectively, had MetS. Overall exposure-adjusted rates (number of patients with events/100 PY) of tier 1 TEAEs were comparable between patients with vs without MetS (TIL 100 mg, 2.4 vs 2.7 per 100 PY; 200 mg, 1.5 vs 2.6 per 100 PY). No reports of diabetes worsening by MetS status were noted, and only 1 myocardial infarction event was reported.

Conclusions: Tildrakizumab safety did not vary by MetS status over up to 5 years of treatment.

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Dermoscopy of early and advanced folliculotropic mycosis fungoides: A correlation of dermoscopic and trichoscopic criteria with clinical features

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There are limited data concerning dermoscopic/trichoscopic presentation of folliculotropic mycosis fungoides (FMF).The aim of this study was to analyze dermoscopic/trichoscopic features in FMF patients in relation to lesion morphology and location. The study group included patients diagnosed/treated owing to FMF at the Department of Dermatology, Venereology, and Allergology or the Dermatology Outpatient Clinic (from May 2016 to May 2019). In all patients (n = 6) the diagnosis was made based on clinical and histopathologic criteria. Yellow dots of different size were present in all analyzed cases of FMF. The presence of white peripheral circle (white halo) was more prevalent within the facial and auricular lesions, compared with other anatomic locations. Scalp lesions also revealed yellow dots associated with various anomalies of hair shafts. Yellow dots were most evident in comedogenic lesions, less visible in plaques and tumours, and discrete within the papular/erythematous lesions. In long standing scalp lesions yellow dots became replaced by hairless white/pinkish structureless areas with white dots and/or lines (representing scarring). The vascular pattern (polymorphic vessels/ branched vessels of large diameter) was more evident in plaques and tumours, and more discrete in papules. The present study supports the role of dermoscopy in the diagnosis of FMF. This diagnosis should be taken into consideration in the presence of yellow dots (with or without white peripheral ring) and polymorphic vascular pattern. The details and distribution of these features may differ depending on the lesion location and morphology. Later in the course of disease yellow dots may become replaced with structureless areas and white dots/lines.

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