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Peak Pruritus Numeric Rating Scale response with abrocitinib in patients with moderate to severe atopic dermatitis: Results from a randomized phase 3 clinical trial

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Introduction: Pruritus imparts a significant burden to patients suffering with atopic dermatitis (AD). Abrocitinib is an oral Janus kinase 1 (JAK1) selective inhibitor under investigation for the treatment of AD. JAK1 inhibitors may have unique itch-mitigating effects in the setting of AD.

Design: Randomized, double-blind, placebo-controlled phase 3 trial (NCT03349060; JADE MONO-1).

Methods: Patients ≥12 years old with clinical diagnosis of moderate to severe AD and Peak Pruritus Numeric Rating Scale (PP-NRS) ≥4 at baseline were randomly assigned (2:2:1) to once-daily abrocitinib 200 mg, abrocitinib 100 mg, or placebo for 12 weeks. PP-NRS was assessed daily through day 15 and weekly thereafter. Proportions of patients and times to achieving PP-NRS2 or PP-NRS4 response (≥2 point or ≥4-point improvement, respectively) were analyzed, as well as percentage of change from baseline in PP-NRS.

Results: 156, 154, and 77 patients received abrocitinib 100 mg, abrocitinib 200 mg, or placebo, respectively. At week 12, significantly greater proportions achieved weekly average PP-NRS2 or PP-NRS4 response with abrocitinib 200 mg (87% and 57.2%) or 100 mg (66% and 37.7%) versus placebo (20% and 15.3%; $P < .05$ for all). Times to PP-NRS2 response were significantly shorter for abrocitinib 200 mg (median days, 4.0 [95% CI, 3.0-5.0]) or 100 mg (7.0 [6.0-9.0]) vs. placebo (19.0 [8.0-57.0]; $P = .025$ and $P < .001$, respectively). Percent reductions in PP-NRS were significantly greater for abrocitinib (both doses) versus placebo from day 2 through week 12 ($P < .05$ for all); these effects were generally observed regardless of baseline PP-NRS.

Conclusions: Abrocitinib rapidly (within 1 day) and significantly improved pruritus versus placebo regardless of baseline PP-NRS.

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Rates of herpes zoster, hepatitis C, and tuberculosis among patients with psoriasis treated with apremilast, biologics, disease-modifying antirheumatic drugs, and corticosteroids: A cohort study in the US MarketScan database

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Introduction: Patients with psoriasis are at increased risk of infections. We compared rates of herpes zoster, hepatitis C (HepC) and tuberculosis (TB) by treatment in psoriasis patients.

Methods: We conducted a cohort study of patients with treated psoriasis in MarketScan, 2014-2018. Patients were considered currently exposed from first apremilast (APR), disease-modifying antirheumatic drug (DMARD), tumor necrosis factor inhibitor (TNFi), or interleukin inhibitor (ILi) prescription date after March 21, 2014, through prescription duration + 30 days, and followed through censor (date patient became case, psoriatic arthritis diagnosis, end of record, or October 31, 2018). Study exposures were APR only or in combination, DMARD only, TNFi only, ILi only, corticosteroid (CS) only, DMARD+CS, TNFi+DMARD and/or CS, ILi+DMARD and/or CS. Cases were patients with herpes zoster, hepatitis C (HepC), or tuberculosis (TB) diagnosis with treatment within 15 days. We calculated incidence rates (IRs) and 95% confidence intervals per 1000 patient-years.

Results: The study population included 73,373 patients (median age 48.6). Among the 935 herpes zoster cases, IRs were highest for users of DMARD+CS (13.8 [9.4-15.4]), TNFi+DMARD and/or CS (12.0 [9.2-15.4]), and CS only (11.9 [8.6-16.0]), compared with DMARD only (9.6 [7.9-11.6]). IRs were lowest for users of APR only (5.4 [4.1-7.1]) and ILi only (6.4 [5.3-7.7]). IRs among the other exposures were around 9.0. IRs of HepC (n = 61) and TB (n = 34) were low and between-treatment differences did not reach statistical significance.

Discussion: Rates of herpes zoster varied by treatment and were highest among those who received polytherapy or CS only. IRs for HepC and TB were low for all exposures.

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Tumor necrosis factor alpha levels predict hidradenitis suppurativa activity

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Hidradenitis suppurativa (HS) is a chronic, recurrent skin disorder characterized by painful nodules, pustules, purulent abscesses, and sinus tracts ("tunnels") of intertriginous areas leading to progressive disability in advanced disease. Tumor necrosis factor alpha (TNF-α) is a proinflammatory cytokine implicated in the pathogenesis of HS. Previous studies have demonstrated that TNF-α inhibition diminishes disease burden. We explore the relationship between serum TNF-α levels and HS activity. This study included 36 TNF-α inhibitor naïve, ethnically-diverse patients at a dedicated HS Treatment Center. Disease activity was classified according to the HS-Physician Global Assessment (HSPGA) scale, and serum samples were obtained to quantify TNF-α levels before the initiation of therapy. Ordinal regression analysis revealed that increasing serum TNF-α levels correlate with higher HSPGA scores ($P = .04$). Specifically, for every one-unit increase in serum TNF-α, a patient was 9.74 times (CI 1.1-107.8) more likely to have severe disease (HSPGA 4 or 5) than a lesser disease state (HSPGA 1 or 2). Though various clinical scales exist to stratify HS disease activity, there is a paucity of objective measures that reliably correlate with clinical status. Our study suggests that TNF-α levels may predict the severity of HS. Though limited by sample size and single-timepoint data collection, these results invite further investigations to distill our understanding of the relationship between TNF-α levels and HS activity.

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Histaminergic angioedema: Burden of illness and impact on quality of life

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Introduction: Idiopathic histaminergic angioedema (IH-AAE) is defined as recurrent episodes of angioedema without hives, with no allergic cause, that respond to the treatment of chronic spontaneous urticaria (CSU). There are no quality of life studies in IH-AAE, except those carried out in the context of CSU associated to angioedema attacks.

Methods: We performed a multicenter prospective study including 70 patients with IH-AAE. Angioedema Quality of Life (AE-QoL) and Angioedema Activity Score for 28 consecutive days (AAS28) questionnaires were employed to analyze the quality of life and the disease activity.

Results: We included 31 men and 39 women, aged 53.5 (20.2-85.4) years. A total of 63 patients responded both questionnaires (90% response rate). The median AE-QoL score was 19 [6-40]. The most affected dimension was fear/shame (38 [0-58]), followed by fatigue/mood (15 [0-40]), nutrition (0 [0-13]), and functioning (0 [0-25]). Thirty-seven patients reported no IH-AAE episodes in the past month (AAS28 = 0). Nineteen patients had low scores and 7 patients had moderate scores on the AAS28. Patients who reported any IH-AAE episode (AAS28 > 0) had substantially impaired quality of life (Spearman $r = 0.53$, $P = .005$). There was significant association and AE-QoL in all dimensions. The dimensions of nutrition and fear/shame had the highest correlations.

Conclusions: Our study demonstrated a considerably decrease on quality of life in IH-AAE patients. The AE-QoL dimensions most affected in IH-AAE are nutrition and fear/shame, which are slightly different from those most affected in hereditary angioedema (fear/shame and fatigue/mood).

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