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27630 Assessing signs and symptoms of hidradenitis suppurativa from the patient perspective

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Effects of ruxolitinib cream in patients with atopic dermatitis with baseline body surface area ≥10% and Eczema Area and Severity Index score ≥16: Pooled results from two phase 3 studies

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Atopic dermatitis (AD), a highly pruritic inflammatory skin disease, is often stratified using objective (Investigator's Global Assessment [IGA], Eczema Area and Severity Index [EASI], body surface area [BSA]) and subjective (eg, itch numerical rating scale [NRS]) assessment tools. Efficacy and safety of ruxolitinib cream, a Janus kinase (JAK) 1/JAK2 inhibitor, was investigated in two phase 3 randomized studies (TRuE-AD1 [NCT03745638]; TRuE-AD2 [NCT03745651]) that enrolled patients aged ≥12 years with AD for ≥2 years, an IGA score of 2 or 3, and 3%−20% affected BSA. In total, 1249 patients (both studies combined) were enrolled; median age was 32 years. Patients were randomized (2:2:1) to 0.75% ruxolitinib, 1.5% ruxolitinib, or vehicle cream (all twice daily) for 8 weeks of double-blinded treatment. Here we report the efficacy of ruxolitinib using pooled data from these studies in a subpopulation of patients with BSA ≥10% and EASI ≥16 at baseline (n = 81). In these patients, higher response rates were observed with ruxolitinib (0.75%/1.5%) vs vehicle for IGA-treatment success ([score of 0 or 1 with ≥2-grade improvement from baseline]; 50.0%/59.4% vs 0%), ≥75% improvement in EASI from baseline (75.0%/71.9% vs 7.7%), and a ≥4-point reduction in itch NRS score (50.0%/61.1% vs 27.3%). In summary, this subset of patients with AD (eligible for both topical and systemic therapies) showed high rates of clinical response with ruxolitinib cream. In patients such as those described here, ruxolitinib cream may be efficacious, delaying or avoiding the use of systemic therapy.

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U.S. academic dermatologists' attitudes and perceptions toward chaperone use during genital examinations

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Chaperones play a central role in enhancing patient care and assure the safety of both patient and provider. Yet, chaperone use varies among physicians. We aim to explore dermatologists' viewpoint on chaperone use and determine frequency of genital examination in practice.

Methods: A 12-item questionnaire was distributed to 500 academic dermatologists using the Association of Professors of Dermatology and Medical Dermatology Society listserv. Data were collected from January to May 2020.

Results: 80 respondents completed the questionnaire (mean [SD]; age 47.8[12.7] years; 45 females [55.6%]; clinical experience 17[13.3] years; response rate 16%). 8.8% of participants 'never or very rarely' examine female genitalia, while 1.3% of participants 'never or very rarely' examine male genitalia. Dermatologists were more likely to 'always' use a chaperone when performing a genital exam on the opposite gender (female patient 41 [51.25%], 26 male, 15 female dermatologists; male patient 26 [32.5%]; 19 female, 7 male dermatologists), with male dermatologists more likely to 'always' use a chaperone ($P < .0001$) with cisgender female patients. 47.25% had an overall positive perception of chaperone use, with 31.3% of physicians 'very familiar' with their clinic/hospital chaperone policy.

Conclusion: Our findings highlight the variability of chaperone use and gender differences among dermatologists when performing genital examinations.

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Malignancy rates through 4 years of follow-up in guselkumab-treated moderate to severe psoriasis patients from the VOYAGE 1 and 2 trials and comparisons to the general United States population

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Objective: To summarize the incidence of malignancies by NMSC and malignancies other than NMSC/cervical cancer in situ, using pooled VOYAGE1&2 data through 4-years of guselkumab (GUS) treatment; results were compared with expected rates in the general USpopulation.

Methods: Rates of malignancies were evaluated cumulatively through 4-years in 3groups: GUS (GUS,PBO→GUS), adalimumab (ADA)→GUS, and Combined GUS (GUS,ADA→GUS). Cumulative rates/100PY of follow-up, and by-year of exposure through Yr1, fromYr1-Yr2, from Yr2-Yr3, and from Yr3-Yr4 were evaluated. Standardized incidence ratios (SIR; 95%CI) of malignancies other than NMSC/cervical cancer in situ reported in GUS-treated patients were compared with rates expected in the general US population derived from the SEER database (2000-2015). Postmarketing data were also evaluated.

Results: 1,721 patients were treated with GUS (medianPY of follow-up:3.6) through 4-years; 21 had NMSC and 26 had a malignancy other than NMSC. Rates/100PY (95% CI) of NMSC were: GUS 0.34 (0.19,0.57); ADA→GUS 0.50 (0.20,1.03); and Combined GUS 0.38 (0.23,0.58). Rates for other malignancies were: GUS 0.53 (0.33,0.80); ADA→GUS 0.28 (0.08,0.72); and Combined GUS 0.47 (0.31,0.69). Over time, there was year-to-year variability, but no increasing trend was evident. Rates of malignancies (other than NMSC/cervical cancer in situ) through 4-years of GUS exposure were generally consistent with those from the general US population (Combined GUS SIR [95%CI]: 0.98 [0.64,1.43]). Most commonly reported malignancies (n; SIR [95%CI]) were: breast cancer (n = 5; 1.61 [0.52,3.75]), melanoma (n = 4; 1.79 [0.49,4.59]), and prostate cancer (n = 4; 0.78 [0.21,1.99]). Reporting rates of malignancy/100PY in postmarketing surveillance (81,502 PY), since first drug approval in 2017, were 0.02 for NMSC and 0.25 for other than NMSC, without identification of new safety signals for malignancies.

Conclusions: Through 4-years of GUS treatment in VOYAGE1&2, overall incidence rates of malignancy were low and generally consistent with those expected in the general US population.

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Assessing signs and symptoms of hidradenitis suppurativa from the patient perspective

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Background: Qualitative research was conducted to develop a patient reported outcome (PRO) measure assessing symptoms/signs of hidradenitis suppurativa (HS), the HS Symptom Diary (HSSD).

Methods: Concept elicitation (CE) and combined CE/cognitive debriefing (CD) interviews were conducted with adult patients with moderate-to-severe HS from 5 dermatology practices in North America. The CE portion of the interview sought to fully understand important concepts of HS. Subjects then completed the draft HSSD, and answered questions to evaluate its content, clarity, and relevance. Revisions were made iteratively to the HSSD. The study received institutional review board approval; subjects provided written informed consent.

Results: 36 subjects were interviewed [6 = CE and 30 = CE/CD, 65% female; mean age = 39]. The most commonly reported lesion locations were armpits (81%), groin (75%), or under the breasts (31%). Subjects reported pain (100%), drainage (100%), itching (100%), swelling/ inflammation (94%), odor (86%), tenderness (81%), heat (64%), and pressure (64%) related to their lesions. The most bothersome symptoms were pain (94%), drainage (50%), swelling/inflammation (42%), and itching (33%). Pain was the most difficult symptom to manage (53%). In general, respondents were able to paraphrase each item and found the content to be clear and relevant. The final HSSD, developed as a daily diary with a 24-hour recall period, contains 8 items evaluating severity of each symptom/sign using an 11-point numeric rating scale. A 7-day version was also developed.

Conclusion: Content validity of the HSSD in patients with moderate-to-severe HS has been demonstrated. Its measurement properties will be assessed using data from upcoming clinical studies.

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