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ORIGINAL RESEARCH

Satisfaction with Control of Mild to Moderate Atopic Dermatitis with Ruxolitinib Cream: US Physician and Patient Perspectives

Lawrence F. Eichenfield · Jinan Liu · Simran Marwaha · James Piercy · Daniel Sturm · Peter Anderson

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ABSTRACT

Introduction: The 2021 US approval of ruxolitinib cream for treatment of atopic dermatitis (AD) in patients aged ≥ 12 years was based on the results of two pivotal phase 3 studies. Currently, real-world data to describe effectiveness of ruxolitinib cream and physician satisfaction with treatment remain limited. Our objective is to describe disease control among adults with mild to moderate AD prescribed ruxolitinib cream and physician satisfaction with treatment.

Methods: Data were from the Adelphi AD Disease Specific Programme™, a US real-world, cross-sectional survey of physician-reported data, undertaken between August 2022 and March 2023. For patients aged ≥ 18 years, physicians reported patient demographics, clinical characteristics, treatment patterns, and physician satisfaction with disease control. Descriptive analysis of data for patients with mild to moderate AD prior to the initiation of ruxolitinib cream and treated with ruxolitinib cream for ≥ 1 month was undertaken.

Results: Among physician-reported data from 1360 patients with AD, 149 patients had received ruxolitinib cream (in combination or as monotherapy) for ≥ 1 month, including 59 patients receiving monotherapy. Prior to treatment with ruxolitinib cream, 84.6% of patients had moderate AD (Investigator's Global Assessment, IGA of 3), whereas after treatment (median duration, 26 weeks), only 21.5% had an IGA of 3, with 48.3% of patients having clear or almost clear skin (IGA of 0/1). For these patients, 81.2% were not currently experiencing a flare, and physicians were satisfied with disease control for 87.3%. Results were similar in patients receiving monotherapy. The most frequent physician-reported reasons for prescribing ruxolitinib cream included relieving itch, improving lesion redness/thickness, achieving disease control, and reducing/controlling flares.

Conclusions: These real-world findings demonstrate effective disease control and physician

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satisfaction with ruxolitinib cream for the treatment of AD in adults in a clinical practice setting. Outcomes were similar whether ruxolitinib cream was prescribed as monotherapy or in combination regimens, suggesting a role for ruxolitinib cream across the spectrum of disease.

PLAIN LANGUAGE SUMMARY

Atopic dermatitis (AD) is a disease in which skin can be itchy, inflamed, and cracked. Traditional therapies for mild to moderate AD can be limited by side effects and long-term safety issues. After US approval of ruxolitinib cream for the treatment of mild to moderate AD in 2021, the goal of this study was to describe disease control and doctor satisfaction with ruxolitinib cream in a real-world setting. The Adelphi AD Disease Specific Programme™ surveyed 159 doctors who treated people with AD between August 2022 and March 2023. Doctors reported records from 1360 patients with mild to moderate AD. In these patients, ruxolitinib cream was used for at least 1 month in 149 patients and was used alone in 59 patients. Before the use of ruxolitinib cream, nearly 85% of the 149 patients had moderate AD. After the use of ruxolitinib cream, about 20% had moderate AD, with half having clear or almost clear skin. About 80% were not currently experiencing flares. Doctors were satisfied with disease control in more than 85% of patients. Patients applying ruxolitinib cream alone had similar results. Doctors most often prescribed ruxolitinib cream for itch relief, disease control, and to reduce or control flares. In summary, when ruxolitinib cream was used by patients, it provided good disease control, and doctors were satisfied with results. Outcomes were similar in patients who applied ruxolitinib cream alone or with another treatment. This suggests that ruxolitinib cream may be useful for patients with AD of differing levels of severity.

Keywords: Atopic dermatitis; Patient-reported outcomes; Real-world data; Treatment patterns

Key Summary Points

Why carry out this study?

Clinical benefit of traditional topical therapies for atopic dermatitis (AD) may be limited by local adverse events or long-term safety and tolerability.

Ruxolitinib cream, a nonsteroidal topical therapy, was approved for the treatment of AD, but real-world data on effectiveness and physician satisfaction are limited.

The objective of this cross-sectional survey of physician-reported data was to describe real-world disease control and physician satisfaction with ruxolitinib cream treatment in patients with mild to moderate AD.

What was learned from the study?

Ruxolitinib cream treatment demonstrated effective disease control and physician satisfaction in real-world clinical practice.

Outcomes were similar for monotherapy and combination therapy, suggesting that ruxolitinib cream could be used across the spectrum of AD.

INTRODUCTION

Atopic dermatitis (AD) is a chronic, relapsing, inflammatory skin disease characterized by itchy, scaly, painful skin that frequently results in sleep disturbances and can greatly impact patients' work productivity and quality of life [1–8]. The prevalence of AD in the USA has been estimated at between 5% and 10% in adults [4, 9, 10].

For patients with mild or moderate AD, traditional topical therapies have included corticosteroids (various potencies), topical calcineurin inhibitors (TCIs; tacrolimus and pimecrolimus), and more recently,

phosphodiesterase 4 (PDE-4) inhibitors (e.g., crisaborole) [11–15]. However, clinical benefit for the patient may be limited by anatomic use restrictions and local adverse events, including skin atrophy, striae, and/or application site reactions. Long-term application may not be appropriate due to safety and tolerability concerns [11, 16, 17]. More severe disease typically requires intensive treatment regimens, including oral treatments [15].

In a previous study, physicians reported uncontrolled disease in approximately one-quarter of adult and adolescent patients with AD receiving traditional topical therapy [i.e., topical corticosteroids (TCS), TCIs, and PDE-4 inhibitors] [18]. Patients reported worse quality of life, higher symptom burden, and more work impairment versus those with controlled disease. There remains an unmet need for a nonsteroidal topical therapy that is highly effective, well tolerated, and provides rapid and durable resolution of inflammatory lesions and pruritus.

Ruxolitinib cream, a topical formulation of ruxolitinib, a potent, selective inhibitor of Janus kinase (JAK) 1 and JAK2, was first approved in the USA in 2021 for the treatment of patients ≥ 12 years old with mild to moderate AD [19]. US approval was based on results from the two pivotal phase 3 studies, which found monotherapy with ruxolitinib cream demonstrated significant and rapid reductions in signs and symptoms of AD [20, 21]; long-term disease control was observed in the majority of patients with as-needed use [22]. Similar results were observed in a subset of patients with moderate and/or extensive disease at baseline [23]. However, real-world data to describe efficacy and physician satisfaction in clinical practice are limited [24].

Ruxolitinib cream may address an important treatment gap in the AD topical treatment paradigm as a safe and effective nonsteroidal therapy used twice daily to reduce signs and symptoms and as needed longer term to maintain disease control. The objective of our real-world analysis was to describe disease control and physician satisfaction among patients with mild to moderate AD who have been prescribed ruxolitinib cream.

METHODS

Study Design

Data were drawn from the Adelphi Adult Atopic Dermatitis Disease Specific Programme (DSP)™, a real-world, cross-sectional survey with elements of retrospective data collection of physicians and their patients with AD in the USA between August 2022 and March 2023. The DSP methodology has been previously published and validated [25–28].

A geographically representative sample of physicians was recruited to participate in the DSP by local fieldwork agents. Physician participation was financially incentivized, with reimbursement upon survey completion according to fair market rates.

Primary care physicians/internists and specialists (dermatologists and allergists/immunologists) from the USA were eligible to participate if they were actively involved in AD management and had a minimum monthly workload of five adult patients (≥ 18 years old) with a history of moderate to severe AD (≥ 1 moderate and ≥ 1 severe; Fig. 1). Each physician was asked to complete an initial attitudinal survey and a patient record form for their next five consecutively consulting patients with AD regardless of what treatment(s) they were receiving. Each physician was then asked to provide data for up to five additional patients whose current treatment regimen included at least one of the following therapies: abrocitinib, baricitinib, ruxolitinib cream, tralokinumab, or upadacitinib. Here we report results for patients prescribed ruxolitinib cream.

Physician-Reported Data

Physicians reported data on clinical and demographic characteristics including Investigator's Global Assessment (IGA) scale and percentage of body surface area (BSA) affected at the time of initiating the current treatment regimen and at the time of form completion; current and previous treatment(s); reason for choice of current treatment(s); duration of current treatment regimen and of AD condition; whether the

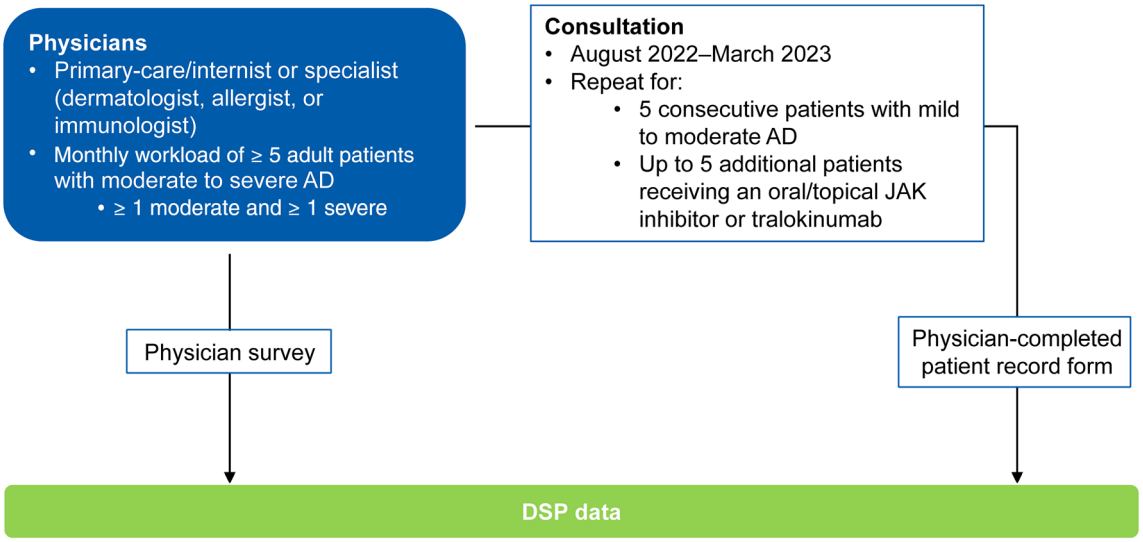

Fig. 1 Study design. *AD* atopic dermatitis, *DSP* Disease Specific Programme, *JAK* Janus kinase

patient was currently experiencing an acute episode (flare); and whether the physician was satisfied with the current control of AD achieved for that patient.

Completion of the patient record forms was performed through consultation of existing patient clinical records, as well as the judgment and diagnostic skills of the respondent physician.

Patients were eligible for inclusion if they were adults (≥ 18 years old), currently experiencing mild or moderate AD, and had been receiving ruxolitinib cream treatment for at least 1 month prior to data collection. AD severity was based on subjective rating by the treating physician.

Ethical Considerations

Data collection was undertaken in line with European Pharmaceutical Marketing Research Association guidelines. Each survey was performed in full accordance with relevant legislation at the time of data collection, including the US Health Insurance Portability and Accountability Act of 1996 [29] and Health Information Technology for Economic and Clinical Health Act legislation [30]. This research was submitted to the Pearl Institutional Review Board, study protocol number (reference AG9174). The DSP was conducted in compliance with the International Council for Harmonisation Declaration of Helsinki. Physicians and patients provided informed consent before participation, and no personally identifiable information, as defined by the Health Insurance Portability and Accountability Act, was collected. Physician and patient data were pseudo-anonymized. A code was assigned when data were collected. Upon receipt by Adelphi Real World, data were pseudo-anonymized again to mitigate against tracing them back to the individual. Data were aggregated before being shared with the subscriber and/or for publication.

Data Analysis

Analyses were descriptive. Mean and standard deviation (SD) or median and interquartile range (IQR) were calculated for continuous variables, and frequency counts and percentages for categorical variables.

All analyses were conducted in Stata v17.0 [31]/UNICOM Intelligence Reporter version 7.5.1 [32]. Missing data were not imputed; therefore, the base of patients for analysis could vary from variable to variable and was reported separately for each analysis.

Table 1 Demographics and clinical characteristics

	All patients receiving ruxolitinib cream (n = 149)	Ruxolitinib cream monotherapy (n = 59)
Age, years, mean (SD)	36.9 (14.8)	36.6 (14.4)
Sex, female, n (%)	99 (66.4)	37 (62.7)
Ethnicity, n (%)		
White	100 (67.1)	37 (62.7)
Black or African American	21 (14.1)	7 (11.9)
Asian	20 (13.4)	9 (15.3)
Other[a]	8 (5.4)	6 (10.2)
Baseline IGA score, n (%)		
Clear (0)	0	0
Almost clear (1)	3 (2.0)	2 (3.4)
Mild (2)	20 (13.4)	10 (17.0)
Moderate (3)	126 (84.6)	47 (79.7)
Severe (4)	0	0
% BSA at initiation, mean (SD)	17.0 (13.8)	13.5 (9.9)
AD disease duration	n = 60[b]	n = 59[b]
Years, mean (SD)	7.9 (13.5)	4.6 (12.8)
Ruxolitinib cream treatment duration	n = 131[b]	n = 54[b]
Days, median (IQR)	179 (94.0, 280.0)	189.5 (131.0, 260.0)

In instances when base sizes change, the n number has been provided above

AD atopic dermatitis, *BSA* body surface area, *IGA* Investigator's Global Assessment, *IQR* interquartile range

[a]'Other' includes any other ethnicity as specified in free text

[b]Number of patients with data available

RESULTS

A total of 159 physicians (70 dermatologists, 22 allergists, and 67 primary care physicians) reported data for 1360 adult patients with AD. Of these, 149 patients who had been receiving ruxolitinib cream for at least 1 month were included in analyses. Among these 149 patients, mean (SD) age was 36.9 (14.8) years, 66.4% of patients were female, and 67.1% were white. Mean (SD) AD duration was 7.9 (13.5) years, and median (IQR) duration of treatment with ruxolitinib cream was 179 (94.0, 280.0) days (26 weeks; Table 1). Among the 59 patients receiving ruxolitinib cream as monotherapy, mean (SD) age was 36.6 (14.4) years, 62.7% were female, 62.7% were white, and mean (SD) AD duration was 4.6 (12.8) years.

Of the 110 patients for whom first-line treatment data are available, 22 patients (20.0%) were receiving ruxolitinib cream as part of a combination regimen or as monotherapy. Of all of those receiving ruxolitinib cream for whom the immediate previous therapy was known (n = 100; patients could have received more than one prior treatment), 41.0% had been treated with a moderate-potency TCS, 37.0% a potent TCS, 31.0% a TCI, 14.0% a very potent TCS, 14.0% a PDE-4 inhibitor, and 10.0% dupilumab in their previous regimen (Fig. 2). Of the 36 patients receiving ruxolitinib cream monotherapy whose previous therapy was known, 41.7% were on a moderate-potency TCS, 22.2% a high-potency TCS, 30.6% a TCI, 13.9% a very-high-potency TCS, and 13.9% dupilumab in their previous regimen.

Of the 149 total patients, ruxolitinib cream was used in combination with other topical agents in 41.6% of patients, in combination with advanced therapies in 18.8%, and as a monotherapy in 39.6% of patients (Fig. 3). Most patients receiving ruxolitinib cream in combination with an advanced AD treatment were also receiving dupilumab (67.9%).

Prior to ruxolitinib cream treatment, as assessed by IGA, 2.0% of patients receiving ruxolitinib cream had almost clear skin, 13.4% had mild AD, and 84.6% had moderate AD. After treatment with ruxolitinib cream, 20.1%

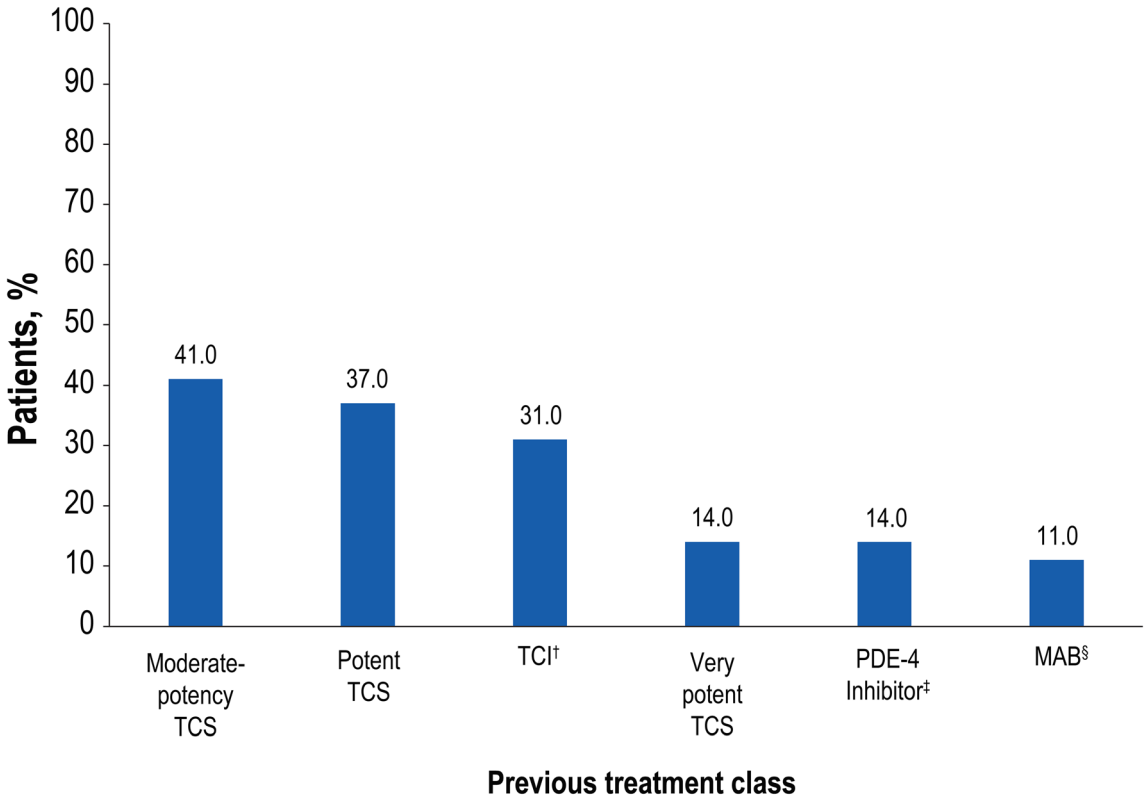

Fig. 2 Treatment history before ruxolitinib cream initiation (n = 100)*. *Patients may have received ≥ 1 previous treatment. †TCI includes pimecrolimus or tacrolimus. ‡PDE-4 inhibitor includes crisaborole. §MAB includes dupilumab. *MAB* monoclonal antibody, *PDE-4* phosphodiesterase 4, *TCI* topical calcineurin inhibitor, *TCS* topical corticosteroid

had clear skin, 28.2% almost clear skin, 29.5% mild AD, 21.5% moderate AD, and only one had severe AD (Fig. 4a). Similar disease control was observed in patients treated with ruxolitinib cream monotherapy (20.3% clear; 22.0% almost clear; Fig. 4b).

Among all patients receiving ruxolitinib cream, 81.2% were not currently experiencing a flare, and among patients who received ruxolitinib cream monotherapy, this percentage was 89.8%. Physicians were satisfied with disease control for 87.3% of all patients using ruxolitinib cream and for 91.5% among those who received ruxolitinib cream monotherapy.

The most common reasons for physicians to choose ruxolitinib cream included relieving itch (for 56.9% of patients), improving lesion redness/thickness (46.7%), achieving clear/almost clear skin (46.0%) and long-term disease control (44.5%), and reducing/controlling flares (40.9%, Fig. 5). The most common physician-reported reasons for starting ruxolitinib cream as a monotherapy included loss of response/efficacy over time (for 33.3% of patients), lack of long-term disease control (30.6%), patients' requests (27.8%), and inadequate resolution of symptoms (22.2%).

DISCUSSION

Our study looked at disease control and physician satisfaction with ruxolitinib cream in a real-world setting (i.e., routine clinical practice). We found that for a median duration of 26 weeks, almost half of patients (48.3%) applying ruxolitinib cream had clear skin or almost clear skin (i.e., IGA of 0 or 1), whereas before treatment the majority (84.6%) had

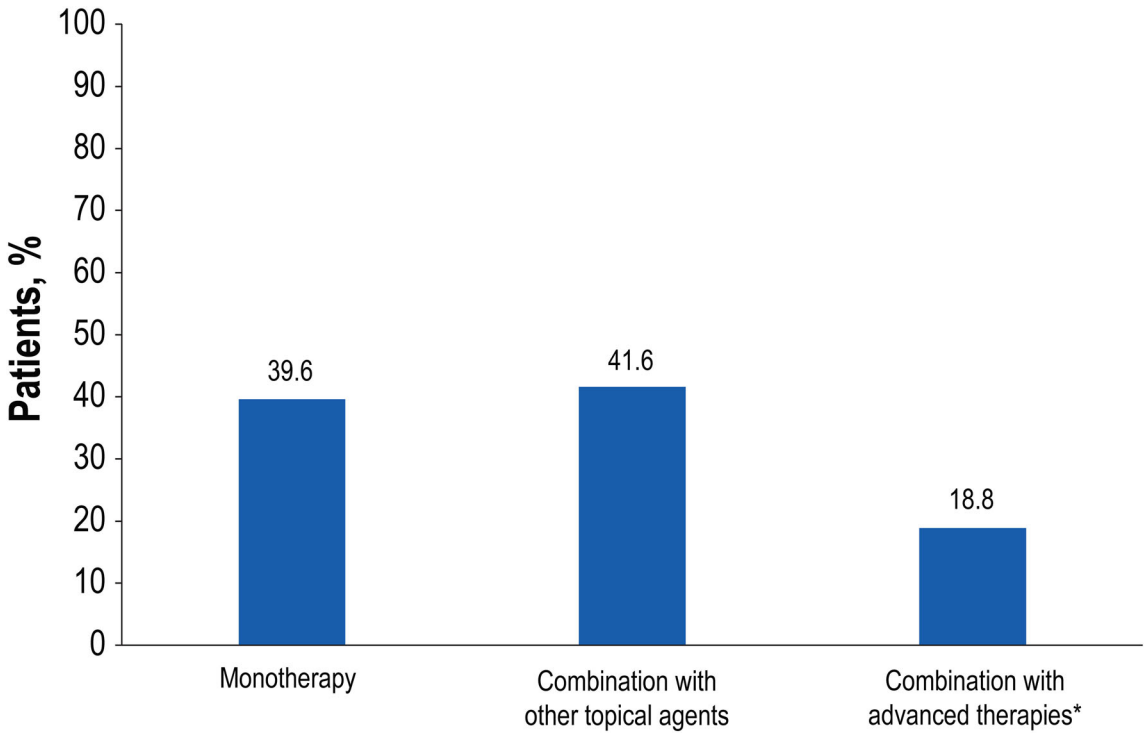

Fig. 3 Use of ruxolitinib cream as monotherapy or in combination with other therapies (n = 149). *Advanced therapies include biologics, oral JAK inhibitors, and phototherapy. *JAK* Janus kinase

moderate AD (i.e., IGA of 3). This improvement was observed regardless of whether ruxolitinib cream was received in combination or as monotherapy. In addition to these clinical benefits, we observed that among all patients on ruxolitinib cream, the majority of patients (81.2%) were not currently experiencing a flare, with even more of those on ruxolitinib cream monotherapy (89.8%) not currently experiencing a flare. Furthermore, physicians were satisfied with disease control for the majority of all patients (87.3%) using ruxolitinib cream, even among those on ruxolitinib cream monotherapy (91.5%).

These real-world findings are therefore consistent with the evidence of improvement described in clinical trials despite the baseline characteristics of patients initiated on ruxolitinib cream in our study including a higher percentage of patients with moderate disease as measured by IGA [33, 34]. Topical therapy with twice-daily ruxolitinib cream 1.5% for 8 weeks improved disease severity and pruritus measures in patients aged ≥ 12 years with mild to moderate AD [20, 21]. Specifically, ruxolitinib cream significantly reduced signs of AD and rapidly decreased itch compared with vehicle cream within 12 h of application [21]; in an open-label phase 2 study, ruxolitinib cream 1.5% reduced itch within 15 min of initial application [35]. These results are consistent with the JAK pathway being an intracellular mediator of multiple inflammatory cytokines [interleukin (IL)-4, IL-13, and IL-22] and pruritogenic cytokines (IL-31 and thymic stromal lymphopoietin) and a critical mediator of chronic itch in sensory neurons, making it a crucial target [36, 37]. Ruxolitinib cream has also been demonstrated to provide long-term disease control at 52 weeks with more than 75% of patients having clear or almost clear skin [22, 38]. Finally, in patients with AD, ruxolitinib cream was well tolerated and was not associated with any clinically significant safety concerns through 52 weeks of treatment; further, the incidence of application site reactions was low [22, 39]. Compared with oral JAK inhibitors, mean plasma concentrations of ruxolitinib in

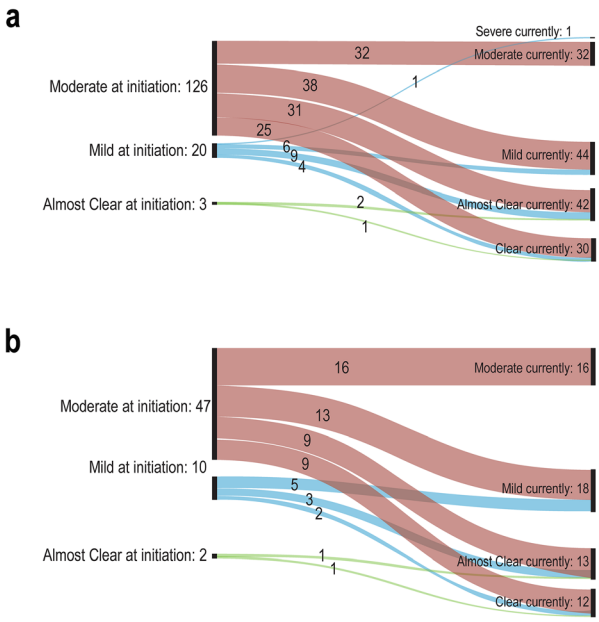

Fig. 4 Change in IGA between initiation of ruxolitinib cream and at time of analysis for **a** all patients receiving ruxolitinib cream (n = 149) and **b** patients receiving ruxolitinib cream monotherapy (n = 59). **In response to the questions: What is your global assessment of this patient's AD at the initiation of current treatment? And currently? *AD* atopic dermatitis, *IGA* Investigator's Global Assessment

patients applying ruxolitinib cream remain well below levels associated with systemic JAK inhibition and were not associated with clinically relevant changes in hematologic parameters, even in the group of patients with affected BSA $\geq$ 40% at baseline [40, 41]. These data support possible addition of ruxolitinib cream to the range of treatments available for the management of AD [33].

The evidence from our study has shown that in both monotherapy and combination therapy regimens, ruxolitinib cream provides effective disease control, reduces current flaring, and is associated with physician satisfaction in patients with similar baseline disease severity. This suggests that ruxolitinib cream can be used as monotherapy, thus potentially reducing the need for traditional steroid and non-steroidal therapies, given the inherent limitations of duration of use and tolerability concerns [11, 16, 17]. Thus, as demonstrated in clinical trials [38], real-world evidence supports the call for the use of ruxolitinib cream as an effective nonsteroidal topical option for the treatment of patients with mild to moderate AD.

Because the JAK pathway is a master regulator of immune function, it can be targeted in other inflammatory and autoimmune dermatologic conditions [42]. Targeting the JAK pathway with ruxolitinib cream in vitiligo, an autoimmune disease in which melanocyte destruction results in patches of depigmented skin, resulted in significantly greater repigmentation of lesions after 24 weeks of treatment versus vehicle cream, with continuing improvement through 52 weeks of treatment [43]. On the basis of this pivotal study, ruxolitinib cream became the first approved treatment for repigmentation of vitiligo in the USA, European Union, and United Kingdom [19, 44, 45]. Development of ruxolitinib cream is also ongoing in chronic hand eczema [46], prurigo nodularis [47], and lichen planus [48].

Strengths and Limitations

One of the values of real-world data sources such as the DSP is that all adult patients with AD were eligible for inclusion; in contrast, randomized controlled trials (RCTs) have strict eligibility criteria limiting patient enrollment (e.g., age restrictions, medical history, absence of concomitant conditions). Through the collection of routine clinical practice data, the DSP also includes patients who may be less likely to be adherent to medication than those included in RCTs. A unique element of the DSP is the consistent methodology and data capture from participants within and between countries, resulting in the ability to compare treatment patterns and outcomes across multiple regions.

Limitations of the DSP methodology must also be recognized. Participation by physicians is voluntary, and the DSP criteria do not require patient samples to be representative of the population in terms of race, income, social class, or age. Participating patients may not reflect the general population with AD because the DSP only includes patients who consult with their physician and have access to healthcare. Patients who cannot access

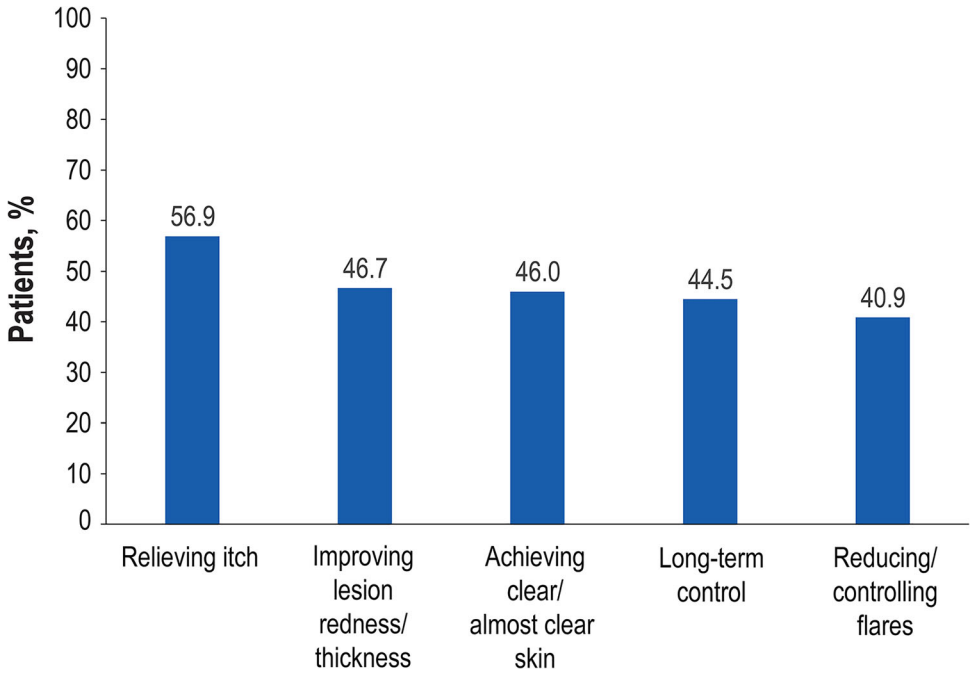

Fig. 5 Physician-reported rationale for choosing ruxolitinib cream (n = 137). ** In response to the question: What are the key reasons that influenced your choice and/or recommendation of ruxolitinib cream for this patient?

healthcare are not represented, and those who consult more frequently might have a higher likelihood of being included. Although DSPs collect retrospective data from physicians regarding treatment patterns and clinical severity, it must be noted that this is in the context of its cross-sectional methodology approach, and although the retrospective elements of data collection such as disease severity at different timepoints are collected, the fact that data are not captured longitudinally means establishing causality is not straightforward. Finally, it should be noted that in our study, the median duration of treatment was 26 weeks for all patients on ruxolitinib cream and 27 weeks for those on ruxolitinib cream monotherapy. Further research would be needed to see if the disease control and other benefits were sustained over time.

CONCLUSIONS

These findings are among the first to demonstrate the effective AD disease control and physician satisfaction with ruxolitinib cream in a clinical practice setting. Furthermore, results were similar regardless of ruxolitinib cream use as monotherapy or in combination with other treatments, suggesting a role for ruxolitinib cream across the spectrum of disease.

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Data Availability. Access to individual participant-level data is not publicly available for this study.

Declarations

Conflicts of Interest. Lawrence F. Eichenfield has served as an investigator, consultant, speaker, or data safety monitoring board member for AbbVie, Amgen, Arcutis, Aslan, Bristol Myers Squibb, Castle, Dermavant, Eli Lilly, Forte Biosciences, Galderma, Incyte, Janssen, LEO Pharma, Novartis, Ortho Dermatologics, Otsuka, Pfizer, Regeneron, Sanofi Genzyme, Trialspark, and UCB. Jinan Liu and Daniel Sturm are employees and shareholders of Incyte Corporation. Simran Marwaha, James Piercy, and Peter Anderson are employees of Adelphi Real World.

Ethical Approval. The Disease Specific Programme (DSP) fulfills the definition of a market research survey under the EphRMA Code of Conduct and is therefore conducted to market research, rather than clinical, guidelines. Market research surveys are exempt from requiring institutional review board (IRB) approval; however, the Pearl IRB conducted a methodologic review of the atopic dermatitis DSP and provided an exemption (reference AG9174). Each survey was performed in full accordance with relevant legislation at the time of data collection, including the US Health Insurance Portability and Accountability Act of 1996 and Health Information Technology for Economic and Clinical Health Act legislation. In addition, the DSP was conducted in compliance with the International Council for Harmonisation Declaration of Helsinki. Freely given, specific, and informed consent was obtained from each respondent to take part in the DSP and for the processing of their personal data. All data provided by physicians and patients were anonymized.

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