A Retrospective Cohort Study of Real-World Experience With Apremilast in Patients With Plaque Psoriasis

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INTRODUCTION

- Psoriasis is a chronic, systemic inflammatory disease affecting 1% to 4% of the world's population.[1-3]
- Apremilast (APR), an oral, small-molecule phosphodiesterase 4 inhibitor, has been studied in phase 2 and phase 3 clinical trials in >2,000 adult patients with moderate to severe plaque psoriasis.
- Clinical trial data, however, do not fully provide insight into the effectiveness of APR at the patient level from populations that are reflective of the demographically and clinically diverse patients treated at dermatology practices.
- This study examined APR from the patient perspective in the dermatology practice setting, including prescribing patterns, clinical effectiveness, and patient-perceived overall treatment effectiveness (POTE) using Modernizing Medicine's electronic medical record (EMR) database of >550,000 psoriasis patients.

METHODS

Study Design

- This was a multicenter, longitudinal, retrospective observational cohort study in adults with psoriasis in real-world dermatology practices across the United States. The study period was from October 1, 2014, through January 31, 2016.
- Structured data, de-identified in accordance with HIPAA, were collected from Modernizing Medicine's EMR platform.

Patient Inclusion Criteria

- Adults ≥18 years of age with a dermatologist-given psoriasis-specific diagnosis who at study initiation or at any time during the study period received APR, either alone or in combination.

Assessments and Analysis

- Patient demographic and clinical characteristics at the most recent clinic visit were recorded; frequencies of psoriasis-related comorbidities were also determined.
- Efficacy outcomes were evaluated among the subset of patients who received APR monotherapy and who had ≥2 efficacy outcome data points during the study period: the first at the time of initial APR prescription and ≥1 other within 6 months.
- For efficacy analyses of APR monotherapy, patients were stratified according to whether they had received any prior conventional or biologic systemic treatment (naive/experienced).
- Efficacy outcomes were examined using a linear mixed-effect model, adjusted for demographic characteristics and psoriasis-related comorbidities.
- POTE was examined among patients receiving APR monotherapy for ≥90 days; POTE was scored on a 5-point Likert scale, where 1=strongly agree and 5=strongly disagree in response to the following statement: "I believe this treatment is effective in clearing my skin of psoriasis." The frequency of each response category was determined.

RESULTS

Patients

- A total of 7,517 patients were on APR at study initiation or during the study period; demographic and baseline clinical characteristics are summarized in **Table 1**.
- More than half of the patients (52.4%) had a psoriasis-related comorbidity (**Table 1**).

RESULTS (cont'd)

Table 1. Baseline Characteristics of Patients Prescribed APR

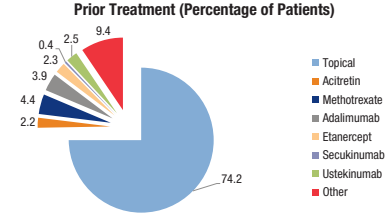
Characteristic	APR Patients N=7,517
Age, mean (SD), years	52.3 (14.8)
Male, n (%)	3,611 (48.0)
Race/ethnicity, n (%)	
White	4,795 (63.8)
African American	191 (2.5)
Asian	155 (2.1)
Hispanic	439 (5.8)
Other	422 (5.6)
Unknown	1,515 (20.2)
Comorbidity, n (%)	
Arthritis	1,781 (23.7)
Cardiovascular disease	2,487 (33.1)
Depression	762 (10.1)
Diabetes	991 (13.2)
Hepatitis	152 (2.0)
Lymphoma	23 (0.3)

Note: Some patients were recorded as having multiple comorbidities, and therefore are counted more than once.

Pattern of Switching From Other Therapies to APR Treatment

- Among the patients who changed from non-APR treatments to APR monotherapy during the study period, almost three-quarters (74.2%) changed from topical treatment alone to APR monotherapy (**Figure 1**).
- The majority of patients (>75%) who started on phototherapy, methotrexate, adalimumab, or ustekinumab and who received APR did so as add-on therapy to their ongoing treatment.

Figure 1. Prior Treatments in Patients Who Switched to APR Monotherapy



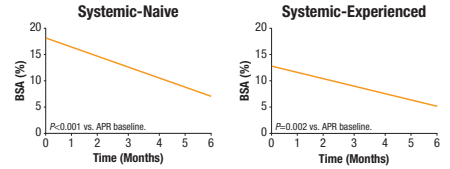
Data are based on the subset of patients who switched from non-APR treatment to APR monotherapy during the study period.

Effect of APR Monotherapy on Psoriasis-Affected BSA

- A total of 196 systemic-naive and 177 systemic-experienced patients on APR monotherapy met inclusion criteria for analysis of psoriasis-affected body surface area (BSA) scores (i.e., BSA values recorded at ≥2 visits during the study period).
- In this patient subgroup, adjusted BSA scores significantly decreased in both the systemic-naive patients (–11.12%; $P<0.001$) (a decrease from baseline of approximately 62.0%) and the systemic-experienced patients (–7.70%; $P=0.002$) (a decrease from baseline of approximately 60.0%) within 6 months of initiating APR monotherapy (**Figure 2**).

RESULTS (cont'd)

Figure 2. Adjusted Psoriasis-Affected BSA During APR Monotherapy

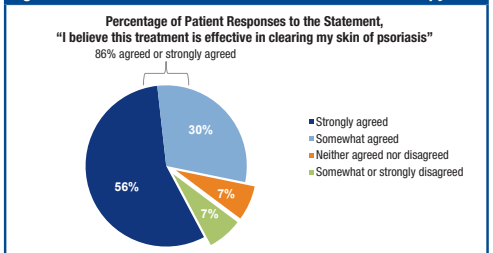


BSA scores were adjusted for demographic characteristics and psoriasis-related comorbidities.

Patient-Perceived Overall Treatment Effectiveness of APR Monotherapy

- Among patients who received APR monotherapy for ≥90 days and had ≥1 POTE assessment (n=160), the majority (n=138; 86%) somewhat agreed or strongly agreed that APR treatment was effective in clearing their skin of psoriasis (**Figure 3**).

Figure 3. Patient-Perceived Effectiveness of APR Monotherapy



Responses were captured by providers asking patients to indicate level of agreement.

CONCLUSIONS

- In this analysis of the US psoriasis population from dermatology clinical practices, APR significantly reduced BSA within 6 months after treatment initiation, regardless of whether patients were systemic-naive or systemic-experienced.
- Most patients who switched to APR monotherapy had previously received only topical therapy.
- The majority of patients included in the POTE analysis perceived APR to be effective in clearing their psoriasis.

REFERENCES

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DISCLOSURES

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