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ORIGINAL RESEARCH

Real-World Effectiveness of Newly Initiated Systemic Therapy for Atopic Dermatitis in the United States: A Claims Database Analysis

Jashin J. Wu · Marie-Hélène Lafeuille · Bruno Emond · Iman Fakih · Mei Sheng Duh · Joseph C. Cappelleri · Natalie Yin · Claire Feeney · Daniela E. Myers · Marco DiBonaventura

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ABSTRACT

Introduction: Atopic dermatitis (AD) is associated with significant quality-of-life and economic burdens. Real-world evidence is needed to identify optimal treatment pathways for AD. Here we evaluate real-world effectiveness of systemic therapies for moderate-to-severe AD in the USA.

Methods: Data (September 2016 to December 2019) were from the IQVIA Health Plan Claims data set (IQVIA, Danbury, CT) from patients aged 12 years or older with AD (ICD-9/10-CM, 691.8/L20.x) initiating a systemic immunosuppressive (SIS) agent (methotrexate, cyclosporine, mycophenolate, or azathioprine) or dupilumab and continuously enrolled for at least 6 months before and after the index date. Indicators of non-response (i.e., adding on/switching systemic therapy, AD-related inpatient/emergency room visits, or incident staphylococcal/streptococcal skin infection) and predictors of non-response were evaluated. Descriptive statistics and Kaplan–Meier rates and times were obtained; Cox regression models were used.

Results: In 3249 patients, 45.4% exhibited at least one indicator of non-response, with median time to non-response being longer for dupilumab than for any SIS therapy (27.0 vs 4.0–7.7 months, respectively). Key non-response predictors were age, geographic region, and baseline number of annual AD-related medical visits.

Conclusion: Non-response was common in patients with AD who required systemic treatment, and non-response indicators occurred significantly more frequently with SIS treatment than with dupilumab treatment.

Keywords: Atopic dermatitis; Dupilumab; Non-response; Real-world study; Systemic immunosuppressive agents

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J. J. Wu
Dermatology Research and Education Foundation, Irvine, CA, USA

M.-H. Lafeuille · B. Emond · I. Fakih
Analysis Group, Montreal, QC, Canada

M. S. Duh
Analysis Group, Boston, MA, USA

J. C. Cappelleri
Pfizer Inc., Groton, CT, USA

N. Yin · M. DiBonaventura (✉)
Pfizer Inc., New York, NY, USA
e-mail: marco.dibonaventura@pfizer.com

C. Feeney
Pfizer Ltd., Surrey, UK

D. E. Myers
Pfizer Inc., Collegeville, PA, USA

Key Summary Points

Why carry out this study?

Moderate-to-severe atopic dermatitis, a chronic inflammatory skin disease, affects 6.6 million adults in the USA.

Systemic therapies such as conventional immunosuppressive agents and the biologic agent dupilumab are recommended treatment options in adult patients with moderate-to-severe atopic dermatitis who do not respond to topical treatments or phototherapy.

This study evaluated the real-world treatment effectiveness of current systemic therapies for atopic dermatitis based on specific indicators of non-response in US patients with moderate-to-severe disease who initiated these therapies.

What was learned from the study?

Indicators of non-response occurred significantly more frequently with conventional systemic immunosuppressive therapy than with dupilumab treatment; key predictors of non-response were age, geographic region, and baseline number of annual atopic dermatitis-related medical visits.

Factors that predict non-response should be considered before initiation of systemic therapy in patients with moderate-to-severe atopic dermatitis.

INTRODUCTION

Atopic dermatitis (AD), a common chronic inflammatory skin disease characterized by intense pruritus and eczematous lesions [1], is associated with significant impairment in health-related quality of life in patients and caregivers [2–4]. Worldwide, AD affects up to 23% of the pediatric population and 17% of the adult population each year [5], and its burden on patients, payers, and society is significant [2, 6, 7]. In 2017, it was estimated that moderate-to-severe AD would affect up to 6.6 million adults in the USA alone [8].

For adults with moderate-to-severe AD who do not respond adequately to topical treatments or phototherapy or following treatment with short courses of systemic corticosteroids (SCSs) as bridging therapy [9], the alternative treatment options are conventional systemic immunosuppressive (SIS) agents (methotrexate, cyclosporine, mycophenolate, azathioprine [10]) and the biologic agent dupilumab [11]. Although conventional SIS agents are not approved by the US Food and Drug Administration (FDA) [10], they are clinically recommended for a subset of patients with refractory or severe AD [9]. However, guidelines do not recommend long-term use of these agents because of the possibility of cumulative toxicity [10].

Because systemic therapies for AD are rapidly evolving, it is necessary to understand treatment effectiveness based on evidence that reflects real-world practice. This study was conducted to evaluate the real-world effectiveness of current systemic AD therapies, based on indicators of non-response among patients in the USA with moderate-to-severe AD who were newly initiating these therapies.

METHODS

Study Design

We conducted a retrospective cohort analysis based on data from the IQVIA Health Plan Claims data set (IQVIA, Danbury, CT), which is composed of data from over 100 different health plans in the USA. Data were used from patients newly initiating systemic AD therapies from September 28, 2016 (6 months before FDA approval of dupilumab [12]) to December 31, 2019. The systemic AD treatments considered were based on American Academy of Dermatology clinical guidelines and reviews of treatments for moderate-to-severe AD [10, 13].

Three patient cohorts were examined: a SIS cohort, which included patients newly initiating (i.e., no claims in the baseline period) a SIS therapy (methotrexate, cyclosporine, mycophenolate, or azathioprine); a dupilumab cohort, which included patients newly initiating dupilumab therapy; and an overall cohort, which included all patients newly initiating either a SIS or dupilumab therapy. The index date was defined as the initiation date (i.e., date of the first claim) of systemic treatment (Fig. 1). The baseline period was defined as the 6-month period before the index date. The follow-up period was at least 6 months and spanned from the index date to the end of insurance eligibility or data availability, whichever occurred first.

Participants: Patient Inclusion and Exclusion Criteria

Patients were required to be aged at least 12 years and to have at least two claims for the same index systemic AD treatment (methotrexate, cyclosporine, mycophenolate, azathioprine, or dupilumab) by March 28, 2017, or later to coincide with the availability of dupilumab [12]. Patients were also required to have been continuously enrolled for at least 6 months before and after the index date and have been given two or more AD diagnoses (ICD-9/10-CM, 691.8/L20.x) during their enrollment, including one during the baseline period. Patients were excluded if they had any claims for any SIS or dupilumab during the baseline period. Data are de-identified and compliant with the Health Insurance Portability and Accountability Act (HIPAA). This study was an analysis of secondary data and was exempt from institutional review board approval.

Outcomes

Demographics and clinical characteristics were evaluated in the baseline period and/or on the index date. Indicators of non-response of patients to their index treatment in the follow-up period (excluding the index date) were also evaluated. In lieu of data on clinical response (e.g., at least 50% improvement in Eczema Area and Severity Index score), which are not available in a claims database, we considered non-response to be indicated by adding on or switching to a different moderate-to-severe AD treatment (i.e., dupilumab, SIS, SCS, and/or phototherapy), having an AD-related inpatient or emergency room (ER) visit, or having staphylococcal or group A streptococcal skin infection.

We also evaluated the annual frequency of medical visits and healthcare costs. Medical

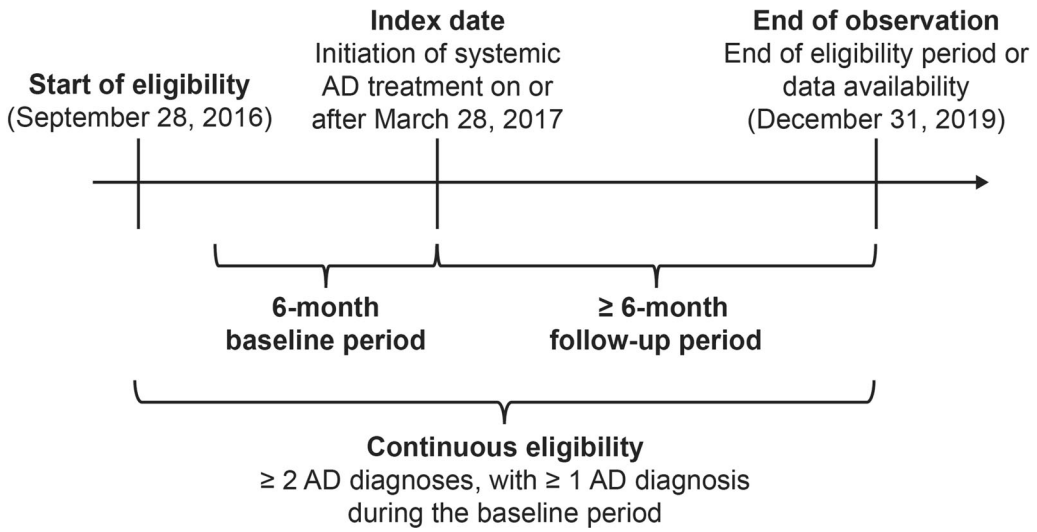


Fig. 1 Study design. *AD* atopic dermatitis

visits included inpatient admission; ER visits; outpatient visits and other visits that occurred during the follow-up period (excluding the index date) and that were calculated for all causes; and visits for AD-related, infection-related, and staphylococcal-related or group A streptococcal-related causes.

Analyses

Patient demographics and clinical characteristics were described using mean, standard deviation (SD), and median for continuous variables; frequencies and proportions were reported for categorical variables (overall and by index treatment) and compared between SIS index treatment and dupilumab cohorts using χ^2 tests [14]. For each cohort, mean annual frequency of medical visits and mean annual costs were estimated by dividing the total number of visits as well as total costs in the follow-up period by the total number of follow-up years per patient, and then calculating the mean value across the cohort.

The proportion of patients with an indicator of non-response was reported for the overall group and by index treatment. Kaplan–Meier rates [with 95% confidence intervals (CIs)] provided estimates of the time to the earliest indicator of non-response across index treatments and were compared using log-rank tests [14, 15].

To identify predictors of non-response in patients new to systemic therapy, we explored the univariate associations between baseline factors and the indicators. Univariate Cox regression models were fitted, with the time to a non-response indicator defined as the dependent variable and baseline characteristics as independent variables. We then fitted three different multivariate Cox regression models for the overall sample and for the subgroup of patients initiating dupilumab [14, 15].

The multivariate models were model 1, which included clinically important variables; model 2, which included variables having $p < 0.25$ in univariate analyses; and model 3, which included variables having $p < 0.05$ in univariate analyses. Patient demographics and other baseline characteristics were included as covariates in all multivariate models (models 1–3). All variables in each model are listed in detail in Supplementary Table S1 (overall sample) and Supplementary Table S2 (dupilumab subgroup). Hazard ratios, 95% CIs, and p values are reported for each baseline covariate. We confirmed that the proportionality assumption was held through a visual assessment using Schoenfeld residuals and using an interaction term between time and the variables of interest [14, 15].

RESULTS

Patient Demographics and Clinical Characteristics

In the overall cohort ($n = 3249$ patients), the mean age (SD) was 40.6 (± 16.1) years, and 54.2% of patients were female. The most prevalent comorbidities (Table 1 and Supplementary Table S3) were atopic conditions [35.5%; including allergic rhinitis (26.6%) and asthma (20.7%)] followed by psychological conditions (27.8%), uncomplicated hypertension (18.5%), infections (17.9%), and AD-related conditions (16.1%). Most patients initiated systemic AD treatment with dupilumab ($n = 2455$; 75.6%), and patients in this cohort were on average younger than those in the SIS cohort (39.8 years ± 15.5 vs 43.4 years ± 17.4; $p < 0.001$). Chronic inflammatory conditions were more prevalent in the SIS cohort than in the dupilumab cohort (24.7% vs 6.5%; $p < 0.001$) and were highest in the azathioprine (36.5%) and methotrexate (32.1%) cohorts (data not shown).

Baseline Treatments

Compared with patients in the dupilumab cohort, patients in the SIS cohort were more likely to have used SCSs (57.9% vs 48.3%; $p < 0.001$) or high-potency topical corticosteroids at baseline (49.2% vs 44.5%; $p = 0.019$) (Table 1).

Table 1 Baseline demographics and clinical characteristics among patients new to systemic atopic dermatitis treatment

Patient characteristics	Overall N = 3249	Index treatment	
		Dupilumab n = 2455	SIS n = 794
Age on index, years, mean ± SD*	40.6 ± 16.1	39.8 ± 15.5	43.4 ± 17.4
Female, *n* (%)	1761 (54.2)	1321 (53.8)	440 (55.4)
Region, *n* (%)			
South	1510 (46.5)	1169 (47.6)	341 (42.9)
Northeast	688 (21.2)	521 (21.2)	167 (21.0)
Midwest	700 (21.5)	544 (22.2)	156 (19.6)
West	351 (10.8)	221 (9.0)	130 (16.4)
Payer type, *n* (%)			
Commercial: fully insured	1811 (55.7)	1333 (54.3)	478 (60.2)
Commercial: self-insured	1417 (43.6)	1104 (45.0)	313 (39.4)
Medicaid	14 (0.4)	13 (0.5)	1 (0.1)
Medicare	5 (0.2)	3 (0.1)	2 (0.3)
Unknown	2 (0.1)	2 (0.1)	0 (0.0)
Comorbidities, *n* (%)			
Atopic march conditions	1155 (35.5)	917 (37.4)	238 (30.0)
Psychological conditions	902 (27.8)	653 (26.6)	249 (31.4)
Infections	583 (17.9)	396 (16.1)	187 (23.6)
AD-related conditions	523 (16.1)	335 (13.6)	188 (23.7)
Chronic inflammatory conditions*	355 (10.9)	159 (6.5)	196 (24.7)
Treatment used at baseline, *n* (%)			
SCS*	1646 (50.7)	1186 (48.3)	460 (57.9)
Phototherapy	200 (6.2)	150 (6.1)	50 (6.3)
Topical corticosteroids	2474 (76.1)	1850 (75.4)	624 (78.6)
Tacrolimus ointment*	557 (17.1)	482 (19.6)	75 (9.4)
Crisaborole*	349 (10.7)	289 (11.8)	60 (7.6)
Pimecrolimus cream*	329 (10.1)	288 (11.7)	41 (5.2)
No pharmacological treatment	340 (10.5)	265 (10.8)	75 (9.4)

AD atopic dermatitis, *SCS* systemic corticosteroid, *SIS* systemic immunosuppressant
*$p < 0.001$

Follow-Up Medical Visits and Healthcare Costs

During the follow-up period [median, 433 days; interquartile range (IQR) 287–632 for the overall population), outpatient visits were the most common type of medical visit (mean per year ± SD, 18.3 ± 20.8); most patients (99.5%) had at least one outpatient visit during the period (Supplementary Table S1). Mean per year all-cause healthcare costs were $34,483 ± 32,484 in the follow-up period (Supplementary Table S2).

Patients who initiated systemic therapy with any SIS (median follow-up, 477 days; IQR, 316–691) had a higher mean number of annual all-cause outpatient visits (21.6 ± 21.0 vs 17.3 ± 20.7) and ER visits (0.6 ± 2.9 vs 0.5 ± 1.1) (Supplementary Table S1) than patients in the dupilumab cohort (median follow-up, 412 days; IQR, 279–611), which translated into higher mean annual all-cause medical costs ($11,640 ± 32,293 vs $6038 ± 18,233, respectively). However, the dupilumab cohort had substantially higher mean annual AD-related total healthcare costs ($29,946 ± 12,048 vs $8633 ± 16,848), mostly composed of higher mean pharmacy costs ($29,392 ± 11,629 vs $6689 ± 10,539), than the SIS cohort (Supplementary Table S2).

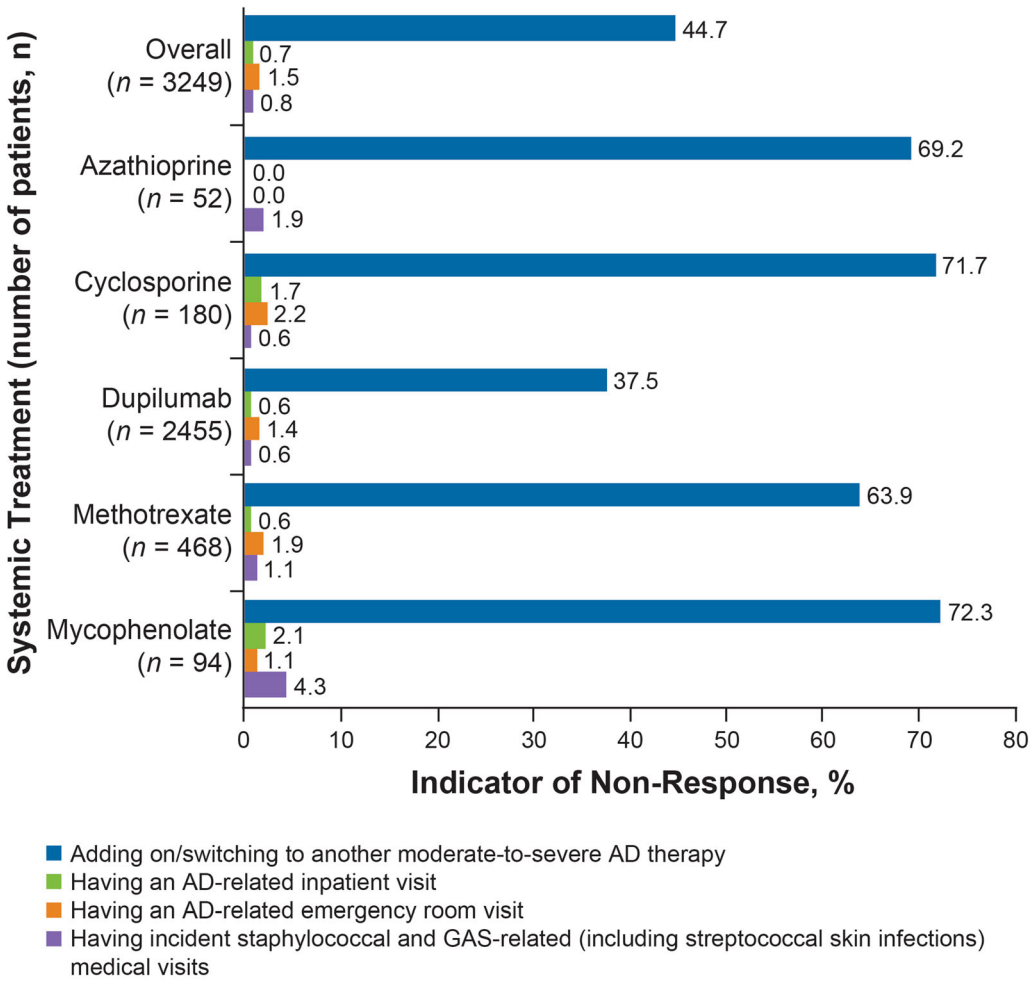


Fig. 2 Non-response outcomes for patients new to systemic treatments for AD. *AD* atopic dermatitis, *GAS* group A streptococci

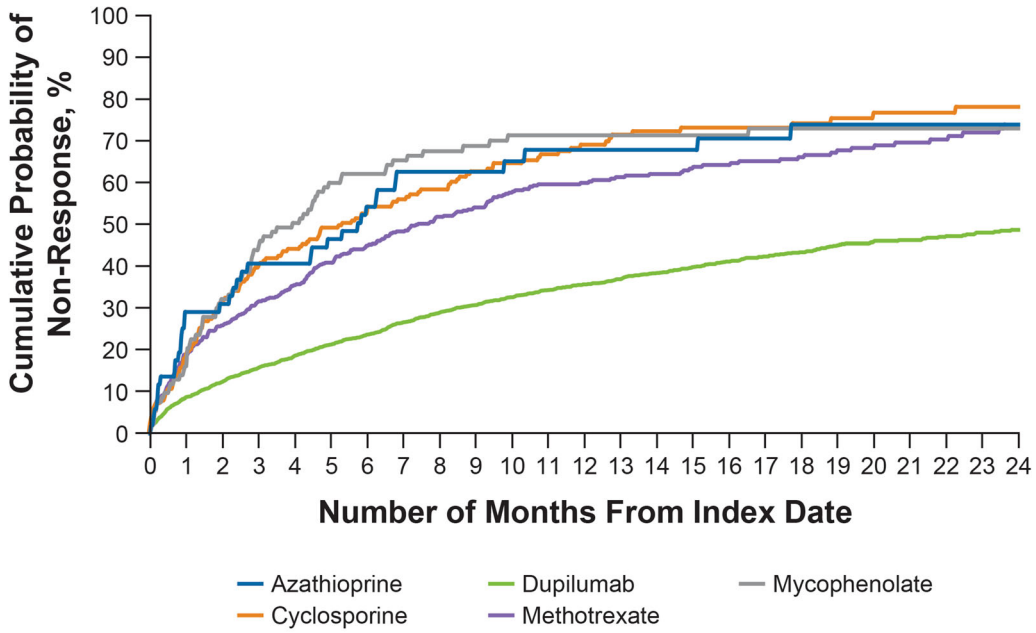


Fig. 3 Kaplan–Meier curve of indicators of non-response to index treatment

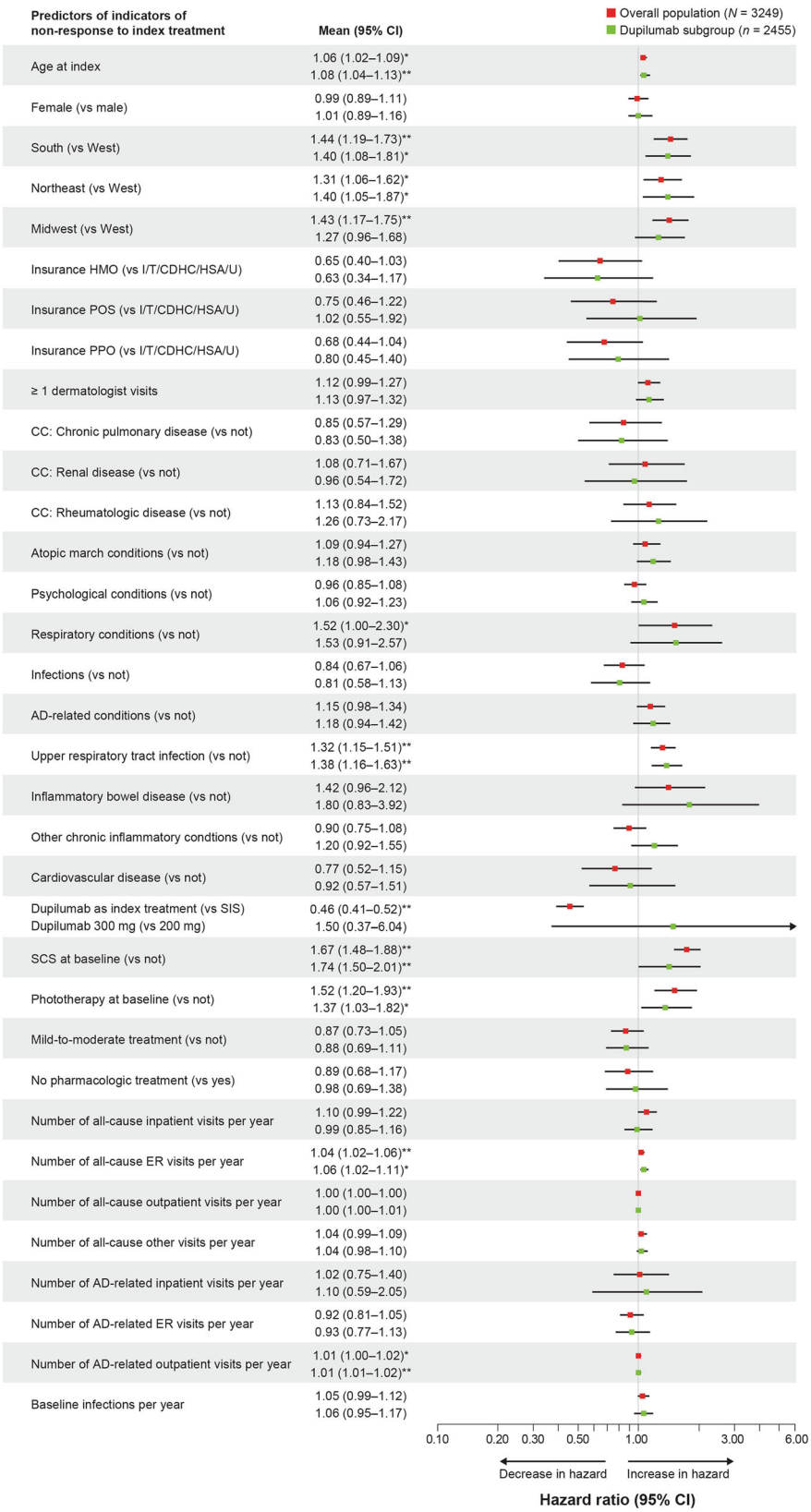
Indicators of Treatment Non-Response

During follow-up, 45.4% of the overall cohort exhibited at least one indicator of non-response. Adding on/switching to another moderate-to-severe AD therapy (44.7%) was the most common indicator across all index treatments; the rate was highest for patients treated with mycophenolate mofetil (72.3%) and lowest for those treated with dupilumab (37.5%) (Fig. 2). Dupilumab had the lowest Kaplan–Meier rate of non-response at month 12 (35.4%) and the longest median time to non-response (27.0 months) compared with methotrexate (59.6%; median time to non-response, 7.7 months), cyclosporine (68.7%; median time to non-response, 5.6 months), mycophenolate (70.9%; median time to non-response, 4.0 months), and azathioprine (67.4%; median time to non-response, 5.8 months). Comparisons of non-response indicator rates for all other index treatments versus dupilumab were statistically significant at $p < 0.001$ (Fig. 3).

Predictors of Non-Response to Index Treatment

Results of the multivariate analysis that included only clinically important baseline characteristics (model 1) in the overall cohort are shown in Fig. 4 and Supplementary Table S4. The variables significantly ($p < 0.05$) associated with increased hazard ratios (95% CI) of non-response were age at index date [1.06 (1.02–1.09)]; residing in the South [1.44 (1.19–1.73)], the Northeast [1.31 (1.06–1.62)], or the Midwest [1.43 (1.17–1.75)] of the USA relative to the West; having respiratory conditions [1.52 (1.00–2.30)]; having an upper respiratory tract infection [1.32 (1.15–1.51)]; having received SCSs in the baseline period [1.67 (1.48–1.88)]; having received phototherapy in the baseline period [1.52 (1.20–1.93)]; number of all-cause ER visits per year [1.04 (1.02–1.06)]; and number of AD-related outpatient visits per year [1.01 (1.00–1.02)]. The only statistically significant factor associated with a lower hazard ratio of non-response was dupilumab versus a SIS agent as index treatment [0.46 (0.41–0.52)].

Results of the multivariate analysis for the dupilumab cohort that included only clinically


Predictors of indicators of non-response to index treatment
Mean (95% CI)
Overall population (N = 3249)
Dupilumab subgroup (n = 2455)
Age at index
1.06 (1.02–1.09)*
1.08 (1.04–1.13)**
Female (vs male)
0.99 (0.89–1.11)
1.01 (0.89–1.16)
South (vs West)
1.44 (1.19–1.73)**
1.40 (1.08–1.81)*
Northeast (vs West)
1.31 (1.06–1.62)*
1.40 (1.05–1.87)*
Midwest (vs West)
1.43 (1.17–1.75)**
1.27 (0.96–1.68)
Insurance HMO (vs I/T/CDHC/HSA/U)
0.65 (0.40–1.03)
0.63 (0.34–1.17)
Insurance POS (vs I/T/CDHC/HSA/U)
0.75 (0.46–1.22)
1.02 (0.55–1.92)
Insurance PPO (vs I/T/CDHC/HSA/U)
0.68 (0.44–1.04)
0.80 (0.45–1.40)
≥ 1 dermatologist visits
1.12 (0.99–1.27)
1.13 (0.97–1.32)
CC: Chronic pulmonary disease (vs not)
0.85 (0.57–1.29)
0.83 (0.50–1.38)
CC: Renal disease (vs not)
1.08 (0.71–1.67)
0.96 (0.54–1.72)
CC: Rheumatologic disease (vs not)
1.13 (0.84–1.52)
1.26 (0.73–2.17)
Atopic march conditions (vs not)
1.09 (0.94–1.27)
1.18 (0.98–1.43)
Psychological conditions (vs not)
0.96 (0.85–1.08)
1.06 (0.92–1.23)
Respiratory conditions (vs not)
1.52 (1.00–2.30)*
1.53 (0.91–2.57)
Infections (vs not)
0.84 (0.67–1.06)
0.81 (0.58–1.13)
AD-related conditions (vs not)
1.15 (0.98–1.34)
1.18 (0.94–1.42)
Upper respiratory tract infection (vs not)
1.32 (1.15–1.51)**
1.38 (1.16–1.63)**
Inflammatory bowel disease (vs not)
1.42 (0.96–2.12)
1.80 (0.83–3.92)
Other chronic inflammatory condtions (vs not)
0.90 (0.75–1.08)
1.20 (0.92–1.55)
Cardiovascular disease (vs not)
0.77 (0.52–1.15)
0.92 (0.57–1.51)
Dupilumab as index treatment (vs SIS)
0.46 (0.41–0.52)**
Dupilumab 300 mg (vs 200 mg)
1.50 (0.37–6.04)
SCS at baseline (vs not)
1.67 (1.48–1.88)**
1.74 (1.50–2.01)**
Phototherapy at baseline (vs not)
1.52 (1.20–1.93)**
1.37 (1.03–1.82)*
Mild-to-moderate treatment (vs not)
0.87 (0.73–1.05)
0.88 (0.69–1.11)
No pharmacologic treatment (vs yes)
0.89 (0.68–1.17)
0.98 (0.69–1.38)
Number of all-cause inpatient visits per year
1.10 (0.99–1.22)
0.99 (0.85–1.16)
Number of all-cause ER visits per year
1.04 (1.02–1.06)**
1.06 (1.02–1.11)*
Number of all-cause outpatient visits per year
1.00 (1.00–1.00)
1.00 (1.00–1.01)
Number of all-cause other visits per year
1.04 (0.99–1.09)
1.04 (0.98–1.10)
Number of AD-related inpatient visits per year
1.02 (0.75–1.40)
1.10 (0.59–2.05)
Number of AD-related ER visits per year
0.92 (0.81–1.05)
0.93 (0.77–1.13)
Number of AD-related outpatient visits per year
1.01 (1.00–1.02)*
1.01 (1.01–1.02)**
Baseline infections per year
1.05 (0.99–1.12)
1.06 (0.95–1.17)
0.10
0.20
0.30
0.50
1.00
3.00
6.00
Decrease in hazard
Increase in hazard
Hazard ratio (95% CI)

◀**Fig. 4** Forest plot of hazard ratios (95% CI) for predictors of indicators of non-response to index treatment (overall population and dupilumab subgroup). *AD* atopic dermatitis, *CI* confidence interval, *ER* emergency room, *HMO* health maintenance organization, *I/T/CDHC/HAS/U* Indemnity/Traditional/Consumer Directed Healthcare/Health Savings Account/Unknown, *POS* point of service, *PPO* preferred provider organization, *SCS* systemic corticosteroid, *SIS* systemic immunosuppressant. $^{*}p < 0.05$, $^{**}p < 0.001$

important baseline characteristics are shown in Fig. 4 and Supplementary Table S5. As in the overall population, the variables significantly ($p < 0.05$) associated with an increased hazard ratio (95% CI) of non-response were age at index date [1.08 (1.04–1.13)], residing in the South [1.40 (1.08–1.81)] or the Northeast [1.40 (1.05–1.87)] of the USA relative to the West, having an upper respiratory tract infection [1.38 (1.16–1.63)], having received SCS agents in the baseline period [1.74 (1.50–2.01)], having received phototherapy in the baseline period [1.37 (1.03–1.82)], number of all-cause ER visits per year [1.06 (1.02–1.11)], and number of AD-related outpatient visits per year [1.01 (1.01–1.02)]. Results of the multivariate models 2 and 3 for the full cohort and the dupilumab cohort, based on variables that showed statistical significance in the univariate regressions, are listed in Supplementary Tables S4 and S5.

DISCUSSION

This retrospective cohort study highlights the challenges of treating patients with AD who require systemic therapy. Some of these challenges include the high cost associated with treatment and the frequency of concomitant corticosteroid use. Additionally, almost half the patients in the overall cohort who newly initiated systemic AD therapies had an indicator of treatment non-response during follow-up; this proportion was larger among patients initiated on any SIS treatment than among patients initiated on dupilumab therapy. The median time to non-response for each of the SIS index treatment cohorts was also substantially shorter than that for the dupilumab cohort (4.0–-7.7 months vs 27.0 months), with significantly higher rates of non-response indicators at all time points across the 24-month period.

As for baseline patient characteristics, the relatively larger proportions of patients with chronic inflammatory conditions in the SIS cohort must be interpreted with caution because the reason for prescribing a SIS therapy may not have been for the treatment of AD but for the treatment of other inflammatory conditions. However, it is likely that including patients with chronic inflammatory conditions did not impact the results of the current study because similar results were observed after a sensitivity analysis that excluded patients with baseline evidence of chronic inflammatory conditions (i.e., excluding patients for whom the index prescription may have been for chronic inflammatory conditions instead of AD).

We defined non-response as adding/switching AD treatment, having an AD-related medical visit, or having a skin infection. Lack of adherence or discontinuation was not considered a lack of response because of the intermittent nature of the use of these AD treatments in actual clinical practice.

We also identified key predictors of non-response. We observed that, across the overall and dupilumab cohorts, patients with respiratory conditions, with infections, or receiving SCSs or phototherapy at baseline had 32–74% higher hazard of an indicator of non-response. To the extent that the use of additional treatments at baseline represents more severe disease, these outcomes highlight the significance of AD severity as an indicator of non-response to systemic AD treatment. In addition, we found that regional differences were notable indicators of non-response. These differences may be explained through different population characteristics and climate conditions across regions. Analogously, in the overall cohort, dupilumab as index treatment was associated with a greater than 50% reduced hazard of non-response. Separately, univariate analysis indicated that dupilumab was associated with a

lower mean number of annual medical visits than were SISs.

The factors of non-response identified herein may provide information to enhance the clinical treatment of patients with AD before initiating systemic therapy. AD treatment response rates have improved since the availability of dupilumab; the results of our study show that the rate of non-response was reduced by nearly 50% with dupilumab therapy compared with SIS agents, and patients remained on dupilumab treatment for a median of 27 months. Nevertheless, approximately 35% of patients who initiated dupilumab showed a non-response after 12 months. Variables associated with a significantly higher hazard of non-response and related to baseline treatment appear to be driven by a lack of efficacy, with add-ons or switches largely driving the difference in treatment non-response between index treatment cohorts. Time-on-therapy differences between index treatment cohorts, in addition to the lack of efficacy, could partly be explained by differences in safety.

Limitations

Our findings must be considered in light of the study limitations. We applied claims-based indicators as proxy variables to determine indicators of non-response; however, given the nature of the data, the reliability of these indicators could not be medically confirmed. The reasons for switching treatment are not always known and may be unrelated to response in many cases. For example, a patient may have had a flare that was resolved by brief treatment with cyclosporine, and then subsequently for other reasons used a different treatment for another flare; this would not be an indication of treatment failure with cyclosporine. Poor adherence to SIS therapies (or even to dupilumab or concomitant topical therapies) could have resulted in suboptimal disease control and thus impacted measures of non-response; however, we did not assess adherence in this study. Because SIS therapies are associated with a substantial risk of side effects, considerable patient monitoring is required [10]. A previous retrospective real-world study showed that fewer than one-third of patients with AD receiving SIS therapy persisted with treatment [16]. Additionally, the duration of follow-up achieved in this study (median, approximately 430 days) was constrained by time intervals imposed on the database query to obtain comparable follow-up between the SIS and dupilumab cohorts. Therefore, it is possible that rates and predictors of non-response could have been different with longer follow-up.

Another limitation is that AD is not always correctly identified using ICD codes. We have mitigated this limitation by incorporating both ICD codes and use of treatment (SIS therapy or dupilumab) [17], although the possibility of misclassification remains.

Some medications are not recorded in the claims database, such as over-the-counter medication or medication received during an inpatient stay. Hence, AD-related costs may have been underestimated. The current study was conducted to additionally assess only direct healthcare costs. Indirect costs, such as work productivity and health-related quality of life, were not included in the evaluation.

Finally, the generalizability of the current findings is limited to the populations represented within the database (i.e., insured US patients, with Medicaid and Medicare patients and those residing in the West representing only a small proportion) and to patients meeting the inclusion and exclusion criteria.

CONCLUSIONS

By evaluating baseline characteristics and applying indicators of non-response to a retrospective cohort of patients with moderate-to-severe AD, the current study showed the challenges of treating AD with available systemic treatments. Indicators of treatment non-response are frequent outcomes among patients new to systemic AD therapy. To enhance the treatment of patients with AD, the factors used to predict non-response identified in the current study may be considered before initiation of systemic therapy.

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Compliance with Ethics Guidelines. Data are de-identified and compliant with the Health Insurance Portability and Accountability Act (HIPAA). This study was an analysis of secondary data and was exempt from institutional review board approval. Permission to publish analysis of the data was provided by IQVIA, the company owning the database.

Data Availability. Upon request, and subject to review, Pfizer will provide the data that support the findings of this study. Subject to certain criteria, conditions and exceptions, Pfizer may also provide access to the related individual de-identified participant data. See https://www.pfizer.com/science/clinical-trials/trial-data-and-results for more information.

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