








ORIGINAL ARTICLE

Real-world clinical, psychosocial and economic burden of atopic dermatitis: Results from a multicountry study

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Abstract

Background: Atopic dermatitis (AD), a relapsing, inflammatory skin disease, is associated with pruritus that can negatively affect patients' quality of life. Understanding the burden of AD is critical for informing and tailoring treatment and disease management to improve patient outcomes. This study characterized global treatment patterns and the clinical, psychosocial and economic burden of moderate-to-severe AD.

Methods: MEASURE-AD was a cross-sectional 28-country study in patients with physician-confirmed moderate-to-severe AD who were either receiving or eligible for systemic therapy for AD. Patients ≥12 years were enrolled between December 2019 and December 2020 while attending routine office or clinic visit. Primary outcomes included Worst Pruritus Numeric Rating Scale (WP-NRS; range: 0–10) and Dermatology Life Quality Index (DLQI; range: 0–30) and Children's DLQI (CDLQI; range: 0–30). Secondary outcomes included physician- and patient-reported clinical, psychosocial and economic burden.

Results: Of the 1591 patients enrolled, 1558 (1434 adults and 124 adolescents) fulfilled all patient selection criteria and were included in this analysis. Almost all patients (98.4%) in the total population were using AD medications and more than half (56%) were receiving systemic medication (15% systemic monotherapy). The most used systemic therapies were dupilumab (56.3%), systemic glucocorticoids (18.1%) and methotrexate (16.2%). Mean WP-NRS was 5.3 in the total population, and most patients (≥55%) reported moderate-to-severe pruritus (WP-NRS ≥4). Mean DLQI was 10.8 and mean CDLQI was 9.6. Secondary endpoints demonstrated substantial clinical, psychosocial, and economic burden of disease. Subgroup analysis demonstrated that patients receiving systemic therapy had lower disease burden than those not taking systemic medications.

Conclusions: While systemic therapy lowers overall disease burden, patients with moderate-to-severe AD continue to have substantial multidimensional disease burden and uncontrolled disease. Overall, there is a need for effective disease management, including effective treatments that improve patients' psychosocial outcomes and reduce the economic burden of AD.

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INTRODUCTION

Atopic dermatitis (AD) is a chronic, systemic, inflammatory disease that has multidimensional impacts on patients' lives, often resulting in a considerable physical, psychological and socioeconomic burden.¹ The burden of AD varies based on treatments, which can be influenced by accessibility, guideline recommendations and differences in healthcare resources across countries.^{2–5} Although several studies have investigated the burden of AD and treatment patterns in specific geographic regions, such as Europe, North America and Japan,^{6–11} substantial gaps remain in our understanding of the global impact of AD.

To address these gaps, the objective of this global cross-sectional study was to assess the multidimensional burden of disease, treatment patterns and healthcare resource utilisation (HCRU) in adolescent and adult patients with moderate-to-severe AD using a uniform approach across multiple geographic areas.

METHODS

Study design and participants

MEASURE-AD was a cross-sectional, observational cohort study conducted in 28 countries across Western Europe/Canada, Asia/Australasia, Eastern Europe/Middle East and Latin America. The study enrolled adults and adolescents (aged ≥ 12 years) with AD attending a routine visit at dermatology clinics and practice offices that had experience in the diagnosis and management of moderate to severe AD, had the potential to treat patients with AD with systemic therapies, and were capable of participating and conducting clinical studies according to Good Clinical Practice.

Included patients had a physician confirmed diagnosis of AD, moderate-to-severe disease and were current candidates for systemic therapy for AD according to the healthcare professional (HCP) or currently receiving systemic therapy for AD. Additional requirements included medication history available for the last 6 months, able to understand the questionnaires (with parental support as required) and willing to provide a patient authorisation form and disclose personal health information (or informed consent); for adolescents, authorisation and/or consent was provided by a parent or legal guardian, where applicable. Patients were excluded if they were currently participating in an interventional clinical trial; participation in another non-interventional study or registry did not exclude a patient from this study. Data were collected during a single visit. In addition, retrospective data (disease history and previous/current AD therapy) previously collected from HCPs were reported.

Endpoints

Endpoints were assessed at the time of the single office visit. The primary endpoints were patient-reported outcomes (PROs): Worst Pruritus Numeric Rating Scale (WP-NRS) and Dermatology Life Quality Index (DLQI; assessed in patients aged ≥ 16 years) or Children's DLQI (CDLQI; assessed in patients aged 12–15 years). WP-NRS assesses the worst itch within the past 24 h (score range: 0–10) and the DLQI/CDLQI (score range: 0–30) assesses how skin disease affects a patient's life, with higher scores indicating lower quality of life (QoL; [Table S1](#)).

Other physician assessed endpoints included Eczema Area and Severity Index (EASI), SCORing Atopic Dermatitis (SCORAD), Validated Investigator Global Assessment for Atopic Dermatitis (vIGA-AD) and body surface area (BSA). Physicians also asked patients to evaluate their sleep (hours of sleep per night in the past week, minutes until falling asleep over the past week and sleep interfering with daily function over the past week).

Other AD-related PROs ([Table S1](#)) included 5-D Pruritus score, Patient Oriented Eczema Measurement (POEM), Atopic Dermatitis Impact Scale (ADerm-IS), Atopic Dermatitis Symptom Scale (ADerm-SS), AD flare questionnaire (assesses frequency and duration of disease flares within the last 6 months) and inadequately controlled AD questionnaire (based on the question, 'I feel my current treatments are effective in controlling my atopic dermatitis', on a 5-point scale ranging from 'completely disagree' to 'completely agree').

Patient-reported psychosocial and economic outcomes included: Hospital Anxiety and Depression Scale (HADS), including HADS anxiety (HADS-A) and HADS depression (HADS-D) subscales, Short Form-12 Health Survey (SF-12) for adults and Short Form-10 Health Survey (SF-10) for adolescents (higher scores indicate a better health state), Work Productivity and Activity Impairment due to AD (WPAI-AD), HCRU, which assesses number of healthcare visits and the number of acute care visits in the last 6 months due to AD, and out of pocket expenses for specified healthcare aspects for AD ([Table S1](#)).

Statistical analyses

Approximately 1500 enrolled patients were planned. Adult patients treated with systemic agents was the smallest subpopulation of interest and estimated to be 100 patients. With 100 patients, the 95% CI for the mean DLQI assuming a standard deviation of 7.0 would have a width of 2.74 (a precision of ± 1.37) and for the mean WP-NRS assuming a standard deviation of 2.2, would have a width of 0.86 (a precision of ± 0.43).¹² These precisions are considered to be adequate as they allow detection of minimum clinically important differences between subpopulations.

The full-analysis set (FAS) consisted of enrolled patients who fulfilled the patient selection criteria. All analyses were based on observed data. Continuous data were descriptively characterized using mean, standard deviation (SD). Categorical data were descriptively characterized using frequency distributions (i.e. number and percentage of the patients). Two-sided 95% confidence intervals were calculated for the mean where appropriate.

Subgroup analyses by age group (adults vs. adolescents), EASI disease severity levels (clear: 0, mild: 0.1–5.9, moderate: 6.0–22.9 and severe: 23.0–72.0),¹³ systemic therapy (yes/no), and geographic regions were conducted. Subgroup analysis for adult patients by geographic region was conducted using 12 geographic clusters: (1) Canada, (2) Germany, (3) Italy, (4) Spain, (5) Australia and New Zealand, (6) China and Taiwan, (7) Brazil, Argentina and Mexico, (8) Netherlands, Belgium

and Ireland, (9) Switzerland and Austria, (10) Greece, Israel, Turkey and Portugal, (11) Hungary, Romania, the Czech Republic, Poland and Slovakia and (12) Saudi Arabia, Kuwait and United Arab Emirates.

Differences among subgroups were statistically compared; for continuous variables, Kruskal–Wallis tests were used; for categorical variables, chi-squared tests were used. All statistical analyses were carried out by means of the SAS® package (version 9.4).

RESULTS

Patients attended visits from 14 December 2019 to 8 December 2020. In total, 1591 patients were enrolled in the study; of these, 1558 (1434 adults and 124 adolescents) fulfilled all

TABLE 1 Baseline patient demographics and characteristics.

	Total population (<i>n</i> = 1558)	Adults (<i>n</i> = 1434)	Adolescents (<i>n</i> = 124)
Age, years, mean (SD)	37.2 (16.9)	39.1 (16.3)	14.8 (1.7)
Male, <i>n</i> (%)	808 (51.9)	748 (52.2)	60 (48.4)
BMI, kg/m ² , mean (SD)	25.3 (5.0)	25.6 (4.9)	22.0 (4.6)
Employed, <i>n</i> (%)	879 (56.4)	868 (60.5)	11 (8.9)
Duration of AD, years, mean (SD)	22.8 (15.3)	23.7 (15.6)	11.8 (4.7)
Time from AD diagnosis to first therapy, years mean (SD)	15.8 (15.0)	16.4 (15.3)	6.6 (4.2)
Time from AD diagnosis to first systemic therapy, years, mean (SD)	17.4 (15.0)	18.0 (15.2)	8.2 (5.0)
Continuous systemic therapy over previous 12 months, <i>n</i> (%)	317 (20.3)	297 (20.7)	20 (16.1)
Current therapy, <i>n</i> (%)	1533 (98.4)	1411 (98.4)	122 (98.4)
Systemic monotherapy or in combination	871 (55.9)	813 (56.7)	58 (46.8)
Dupilumab	490 (56.3)	468 (57.6)	22 (37.9)
Systemic corticosteroids	158 (18.1)	146 (18.0)	12 (20.7)
Methotrexate	141 (16.2)	124 (15.3)	17 (29.3)
Cyclosporine	129 (14.8)	122 (15.0)	7 (12.1)
Azathioprine	14 (1.6)	13 (1.6)	1 (1.7)
Mycophenolate	5 (0.6)	5 (0.6)	0 (0.0)
Systemic monotherapy	236 (15.1)	227 (15.8)	9 (7.3)
Topical monotherapy or in combination	1224 (78.6)	1118 (78.0)	106 (85.5)
Topical monotherapy	300 (19.3)	275 (19.2)	25 (20.2)
TCS or TCI monotherapy	220 (14.1)	207 (14.4)	13 (10.5)
Previous systemic therapy, <i>n</i> (%)			
Systemic monotherapy or in combination	835 (53.6)	797 (55.6)	38 (30.6)
Systemic monotherapy	126 (8.1)	116 (8.1)	10 (8.1)
Dupilumab, monotherapy or in combination	32 (2.1)	30 (2.1)	2 (1.6)
Dupilumab monotherapy	2 (0.1)	2 (0.1)	0
Treatment prior to study enrolment, <i>n</i> (%)			
Topical monotherapy	1248 (80.1)	1150 (80.2)	98 (79.0)
Suboptimal response to topical monotherapy ^a	1179 (75.7)	1084 (75.6)	95 (76.6)

Abbreviations: AD, atopic dermatitis; BMI, body mass index; TCI, topical calcineurin inhibitor; TCS, topical corticosteroid.

^aDefined by each investigator and collected by the question, 'Prior to enrolling in this study, has the patient had a suboptimal response to topical therapy (TCS/TCI) as monotherapy for AD?' Response options were: Yes, no, or patient has not received topical therapy as monotherapy for AD.

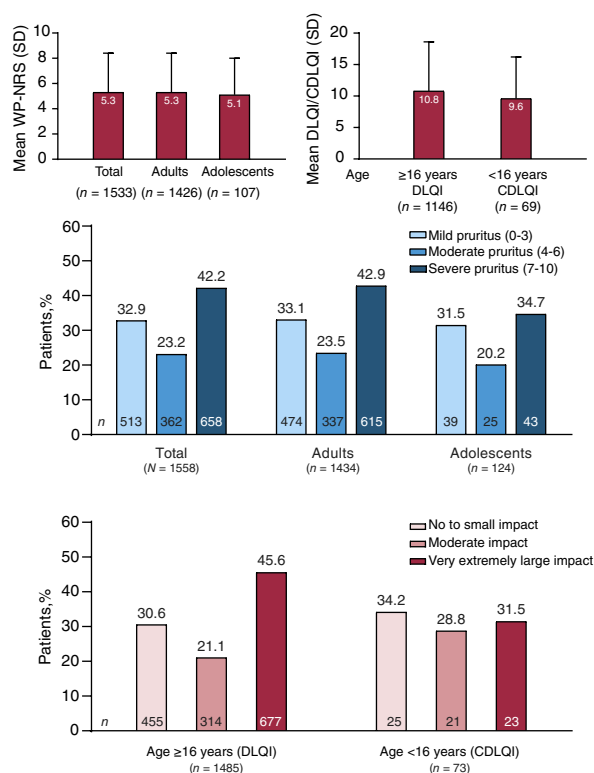


FIGURE 1 Primary endpoints mean WP-NRS and mean DLQI/CDLQI and proportion of patients in WP-NRS and DLQI/CDLQI categories. CDLQI, children's Dermatology Life Quality Index; DLQI, Dermatology Life Quality Index; WP-NRS, Worst Pruritus Numeric Rating Scale. For CDLQI/DLQI, no statistical tests regarding adult (Yes/No) were applied because the scores for adults and adolescents cannot be combined. DLQI categories: no to small impact, 0–5; moderate impact, 6–10; very large to extremely large impacts, 11–30. CDLQI categories: no to small impact, 0–6; moderate impact, 7–12; very large to extremely large impact, 13–30.

patient selection criteria and were included (FAS). The mean (SD) age of study participants was 37.2 (16.9) years; 39.1 (16.3) years (range, 18–92 years) for adults and 14.8 (1.7) years (range, 12–17 years) for adolescents (Table 1). Patients were from Germany ($n=217$ [13.9%], 210 adults and 7 adolescents), Canada ($n=212$ [13.6%], 200 adults and 12 adolescents), Italy ($n=121$ [7.8%], 118 adults and 3 adolescents), Spain ($n=95$ [6.1%], 91 adults and 4 adolescents), Greece ($n=80$ [5.1%], 69 adults and 11 adolescents), Australia ($n=72$ [4.6%], 64 adults and 8 adolescents), Mexico ($n=72$ [4.6%], 64 adults and 8 adolescents), Portugal ($n=59$ [3.8%], 52 adults and 7 adolescents), Switzerland ($n=57$ [3.7%], 55 adults and 2 adolescents), Brazil ($n=56$ [3.6%], 41 adults and 15 adolescents), Argentina ($n=52$ [3.3%], all adults), Turkey ($n=48$ [3.1%], 43 adults and 5 adolescents), China ($n=44$ [2.8%], 39 adults and 5 adolescents), Austria ($n=41$ [2.6%], 39 adults and 2 adolescents), New Zealand ($n=40$ [2.6%], 39 adults and 1 adolescent), Israel ($n=38$ [2.4%], 33 adults and 5 adolescents), Ireland ($n=37$ [2.4%], 25 adults and 12 adolescents), Saudi Arabia ($n=32$ [2.1%], 28 adults and 4 adolescents), Czechia/Czech Republic ($n=30$ [1.9%], 29 adults and 1 adolescent), Taiwan ($n=25$ [1.6%], 21 adults and 4 adolescents), Poland ($n=24$ [1.5%], 23 adults and 1 adolescent),

Romania ($n=23$ [1.5%], 19 adults and 4 adolescents), Belgium ($n=20$ [1.3%], all adults), Hungary ($n=20$ [1.3%], 19 adults and 1 adolescent), Netherlands ($n=14$ [0.9%], all adults), Slovakia ($n=13$ [0.8%], all adults), United Arab Emirates ($n=9$ [0.6%], 7 adults and 2 adolescents) and Kuwait ($n=7$ [0.4%], all adults).

At the time of the study visit, most patients already had a long AD disease history with an average disease duration of more than two decades (adults) or one decade (adolescents). The mean (SD) time between AD diagnosis until first administration of systemic treatment was particularly long (17.4 [15.0] years in the total population; 18.0 [15.2] years in adults and 8.2 [5.0] years in adolescents).

Prior to study enrolment, most patients (80%) received topical therapy as monotherapy, and most of these (76%) had a suboptimal response, defined at the investigator's discretion, to topical monotherapy (Table 1). When analysed for current therapy, almost all patients (98.4%) in the total population ($n=1558$) were using prescribed AD medications. Although all patients were eligible for systemic treatment, only 56% were receiving systemic medication (15% systemic therapy as monotherapy) and 14% were receiving topical glucocorticoids or calcineurin inhibitor monotherapy (Table 1). The most commonly used systemic therapies were dupilumab (56.3%), systemic glucocorticoids (18.1%) and methotrexate (16.2%) and 20% of patients had received continuous systemic therapy over the last 12 months in the total population (Table 1). Cyclosporine was used by 14.8% of patients. In general, current therapy trends were similar among adults and adolescents.

Primary endpoints: Itch and QoL

Mean (SD) WP-NRS was 5.3 (3.1) in the total population, 5.3 (3.1) in adults and 5.1 (2.9) in adolescents (Figure 1). The majority of patients ($\geq 55\%$) reported moderate-to-severe pruritus (WP-NRS ≥ 4) across both age groups, with severe pruritus (WP-NRS ≥ 7) reported in 42% in total population (43% of adults and 35% of adolescents). Mean (SD) DLQI was 10.8 (7.8) and mean CDLQI was 9.6 (6.6; Figure 1) and a very large or extremely large effect on patient's life was reported by 45.6% of patients ≥ 16 years of age and 31.5% of patients younger than 16 (Figure 1).

EASI, SCORAD, and vIGA-AD

The mean (SD) EASI score was 15.0 (12.9); 14.9 (12.9) for adults and 16.9 (13.3) for adolescents (Table 2). According to a categorisation by Chopra et al,¹³ 5.5% of the total population had clear skin (EASI=0), whereas 25.5% had severe AD (EASI 23–72). The mean SCORAD score was 43.7 in the total population (43.6 among adults and 45.2 among adolescents; Table 2). A categorisation according to Wollenberg et al,¹⁴ showed that 22% of the patients suffered from mild (SCORAD <25), 35% from moderate (SCORAD 25–50) and 41% from severe AD (SCORAD >50).

TABLE 2 Physician-reported and patient-reported clinical outcomes.

	Total population (<i>n</i> = 1558)	Adults (<i>n</i> = 1434)	Adolescents (<i>n</i> = 124)
<i>Physician-reported outcomes</i>			
EASI, mean (SD)	15.0 (12.9) <i>n</i> = 1552	14.9 (12.9) <i>n</i> = 1428	16.9 (13.3)
EASI categories, <i>n</i> (%)			
Clear (0)	86 (5.5)	81 (5.6)	5 (4.0)
Mild (0.1–5.9)	390 (25.0)	364 (25.4)	26 (21.0)
Moderate (6.0–22.9)	679 (43.6)	621 (43.3)	58 (46.8)
Severe (23.0–72.0)	397 (25.5)	362 (25.2)	35 (28.2)
SCORAD, mean (SD)	43.7 (21.7) <i>n</i> = 1533	43.6 (21.8) <i>n</i> = 1411	45.2 (20.3) <i>n</i> = 122
SCORAD categories, <i>n</i> (%)			
Mild (<25.0)	343 (22.0)	320 (22.3)	23 (18.5)
Moderate (25.0–50.0)	548 (35.2)	505 (35.2)	43 (34.7)
Severe (>50.0)	642 (41.2)	586 (40.9)	56 (45.2)
vIGA-AD, mean (SD)	2.6 (1.1) <i>n</i> = 1556	2.5 (1.1) <i>n</i> = 1433	2.7 (1.1) <i>n</i> = 123
Clear (0)	95 (6.1)	91 (6.3)	4 (3.2)
Almost clear (1)	200 (12.8)	184 (12.8)	16 (12.9)
Mild (2)	321 (20.6)	304 (21.2)	17 (13.7)
Moderate (3)	625 (40.1)	566 (39.5)	59 (47.6)
Severe (4)	315 (20.2)	288 (20.1)	27 (21.8)
BSA, % affected, mean (SD)	25.0 (22.7) <i>n</i> = 1550	24.9 (22.8) <i>n</i> = 1427	26.1 (22.7) <i>n</i> = 123
Average hours of sleep per night in the past week, mean (SD)	6.5 (1.7) <i>n</i> = 1539	6.4 (1.7) <i>n</i> = 1416	7.2 (1.7) <i>n</i> = 123
Average minutes needed to fall asleep per night in the past week, mean (SD)	36.4 (41.1) <i>n</i> = 1543	36.5 (41.4) <i>n</i> = 1419	35.3 (37.0)
Sleep problems interfered with daily function over the past week, <i>n</i> (%)			
I do not have sleep problems	88 (5.6)	81 (5.6)	7 (5.6)
Not at all	453 (29.1)	406 (28.3)	47 (37.9)
A little	335 (21.5)	311 (21.7)	24 (19.4)
Somewhat	313 (20.1)	291 (20.3)	22 (17.7)
Much	197 (12.6)	181 (12.6)	16 (12.9)
Very much	159 (10.2)	152 (10.6)	7 (5.6)
<i>Patient-reported outcomes</i>			
5D-Pruritus score, mean (SD)	15.2 (4.5) <i>n</i> = 1471	15.3 (4.5) <i>n</i> = 1365	14.2 (4.5) <i>n</i> = 106
POEM, mean (SD)	14.9 (8.0) <i>n</i> = 1519	15.0 (8.0) <i>n</i> = 1412	13.5 (8.0) <i>n</i> = 107
Total ADerm-IS, mean (SD)	38.4 (28.9) <i>n</i> = 1510	38.8 (29.0) <i>n</i> = 1410	32.3 (27.7) <i>n</i> = 100
ADerm-IS Sleep domain, mean (SD)	11.9 (9.9) <i>n</i> = 1531	12.1 (9.9) <i>n</i> = 1425	10.1 (9.8) <i>n</i> = 106
ADerm-SS TSS-7, mean (SD)	31.3 (20.1) <i>n</i> = 1520	31.6 (20.1) <i>n</i> = 1414	27.1 (31.0) <i>n</i> = 106
ADerm-SS TSS-11, mean (SD)	45.2 (30.4) <i>n</i> = 1507	45.6 (30.3) <i>n</i> = 1401	39.7 (31.1) <i>n</i> = 106
ADerm-SS Skin pain, mean (SD)	4.0 (3.4) <i>n</i> = 1530	4.0 (3.4) <i>n</i> = 1423	3.7 (3.3) <i>n</i> = 107

TABLE 2 (Continued)

	Total population (<i>n</i> = 1558)	Adults (<i>n</i> = 1434)	Adolescents (<i>n</i> = 124)
Number of flares in last 6 months, <i>n</i> (%)			
0	212 (13.6)	199 (13.9)	13 (10.5)
1–2	406 (26.1)	378 (26.4)	28 (22.6)
3–4	354 (22.7)	331 (23.1)	23 (18.5)
5–6	177 (11.4)	165 (11.5)	12 (9.7)
>6	305 (19.6)	280 (19.5)	25 (20.2)
Number of flares in the last 6 months, mean (SD) [range]	5.9 (11.9) [0–200]	5.9 (12.2) [0–200]	6.0 (7.4) [0–30]
Average duration of flares in last 6 months, <i>n</i> (%)			
≤2 days	299 (19.2)	282 (19.7)	17 (13.7)
3–7 days	512 (32.9)	461 (32.1)	51 (41.1)
8–14 days	268 (17.2)	250 (17.4)	18 (14.5)
≥15 days	350 (22.5)	333 (23.2)	17 (13.7)
Inadequately controlled AD, <i>n</i> (%)	412 (26.4)	396 (27.6)	16 (12.9)
SF-12 PCS, mean (SD)	NA	50.0 (8.4) <i>n</i> = 1398	NA
SF-10 PHS, mean (SD)	NA	NA	38.5 (14.9) <i>n</i> = 105

Abbreviations: ADerm-IS, Atopic Dermatitis Impact Scale; ADerm-SS, Atopic Dermatitis Symptom Scale; BSA, Body Surface Area; EASI, Eczema Area and Severity Index; NA, not applicable; POEM, Patient Oriented Eczema Measurement; SCORAD, SCORing Atopic Dermatitis; SF-12 PCS, Short Form-12 Health Survey physical component summary (adults); SF-10 PHS, Short Form-10 Health Survey physical component summary (adolescents); vIGA-AD, Validated Investigator Global Assessment for Atopic Dermatitis.

AD symptoms and sleep disturbance

A mean (SD) of 6.5 (1.7) hours slept per night was reported in the total population (Table 2). Overall, 44% of adult and 36% of adolescent patients reported ‘somewhat to very much’ sleep problems that interfered with daily function over the past week. ADerm-IS sleep domain correlated with these findings (mean [SD; range]: 11.9 [9.9; 0–30]), indicating moderate disease (Table 2).

For the total population, the mean (SD) POEM score was 14.9 (8.0; adults: 15.0 [8.0] and adolescents 13.5 [8.0]) and the mean (SD; range) ADerm-SS Skin Pain was 4.0 (3.4; 0–10), indicating moderate disease (Table 2). ADerm-SS TSS-7 (mean [SD; range]: 31.3 [20.1; 0–70]) and TSS-11 (mean [SD; range]: 45.2 [30.4; 0–110]) showed similarly moderate symptom burden (Table 2).

Overall, 1454 (93%) patients reported their flare frequency (mean [SD] of 5.9 [11.9] AD flares in the previous 6 months; Table 2). On average, flares lasted 15.3 days (adults 15.5 days and adolescents 12.6 days). Approximately 25% of patients in the total and adult populations and 13% of the adolescent population reported that they had inadequately controlled disease (Table 2).

Psychosocial and economic burden

HADS-A ≥ 8 was reported by 42.7% and HADS-D ≥ 8 by 28.2% of patients in the total population (Table 3). For adults, mean (SD) SF-12 mental component summary was

43.8 (11.3); for the adolescents, mean SF-10 psychosocial component summary was 46.7 (11.2; Table 3). A mean (SD) work productivity loss of 34.2% (29.6%) was observed in employed adults (Table 3). Similar impacts of AD were noted in ADerm-IS Emotional State (mean [SD; range]: 12.9 [10.3; 0–0]) and ADerm-IS Daily Activities (mean [SD; range]: 13.7 [11.8; 0–30]), indicating moderate disease (Table 3).

In the total population, 71.7% of the patients (adults: 72.7% and adolescents: 60.5%) had previously sought healthcare for AD in the past 6 months. Mean (SD) number of healthcare or acute care visits during the previous 6 months was similar between adults (5.8 [6.9]) and adolescents (6.4 [6.8]; Table 3).

Mean (SD) monthly healthcare-related expenses and costs of everyday necessities related to AD (converted to 2021 USD) were 157.7 (251.2) USD (range: 0.0 to 3312.0 USD) in the total population; mean (SD) monthly healthcare-related expenses were 155.5 (249.5) USD for adults and 185.5 (271.2) USD for adolescents.

Subgroup analyses

In a subgroup analysis by EASI severity, a significantly worsening pattern in clinical, psychosocial and economic outcomes was observed with increasing disease severity (Table 4). Similar results were noted in subgroup analyses by additional EASI disease severity levels, WP-NRS levels and EASI + WP-NRS levels (Figures S1–S6).

In a subgroup analysis by current systemic therapy use, significant differences in clinical, psychosocial and

TABLE 3 Psychosocial-economic burden of AD.

	Total population (n = 1558)	Adults (n = 1434)	Adolescents (n = 124)
HADS-A, mean (SD)	7.1 (4.5) n = 1521	7.1 (4.5) n = 1418	7.1 (4.1) n = 103
HADS-A ≥ 8, n (%)	666 (42.7)	616 (43.0)	50 (40.3)
HADS-D, mean (SD)	5.3 (4.2) n = 1520	5.4 (4.3) n = 1417	4.6 (3.5) n = 103
HADS-D ≥ 8, n (%)	439 (28.2)	416 (29.0)	23 (18.5)
SF-12 MCS, mean (SD)	NA	43.8 (11.3) n = 1399	NA
SF-10 PSS, mean (SD)	NA	NA	46.7 (11.2) n = 105
ADerm-IS Daily Activities, mean (SD)	13.7 (11.8) n = 1516	13.8 (11.9) n = 1415	11.5 (10.9) n = 101
ADerm-IS Emotional State, mean (SD)	12.9 (10.3) n = 1533	13.0 (10.3) n = 1426	11.5 (10.2) n = 107
WPAI-AD, Employed, n (%)	879 (56.4)	868 (60.5)	11 (8.9)
Absenteeism, %, mean (SD)	10.2 (22.0) n = 749	10.0 (21.6) n = 740	32.2 (41.3) n = 9
Presenteeism, %, mean (SD)	30.0 (27.7) n = 796	29.9 (27.6) n = 789	44.3 (42.0) n = 7
Overall work productivity impairment, %, mean (SD)	34.3 (29.7) n = 727	34.2 (29.6) n = 720	50.6 (39.3) n = 7
Activity impairment, %, mean (SD)	36.5 (30.9) n = 1500	36.5 (31.0) n = 1402	36.3 (29.8) n = 98
Hours missed from work, mean (SD)	4.3 (13.6) n = 806	4.2 (13.6) n = 795	4.8 (10.7) n = 11
HCRU			
Number of healthcare or acute care visits in previous 6 months, mean (SD)	5.9 (6.9) n = 819	5.8 (6.9) n = 766	6.4 (6.8) n = 53
Out of pocket expenses			
Total monthly healthcare-related expenses and costs of everyday necessities related to AD, USD, mean (SD)	157.7 (251.2) n = 1369	155.5 (249.5) n = 1269	185.5 (271.2) n = 100

AD, atopic dermatitis; ADerm-IS, Atopic Dermatitis Impact Scale; HADS, Hospital Anxiety and Depression Scale; HADS-A, HADS anxiety subscale; HADS-D, HADS depression subscale; HCRU, health-care research utilisation; NA, not applicable; SF-12 MCS, Short Form-12 Health Survey Mental Component Summary (adults); SF-10 PSS, Short Form-10 Health Survey Psychosocial Component Summary (adolescents); USD, United States dollars (2021); WPAI-AD, Work Productivity and Activity Impairment Atopic Dermatitis.

economic outcomes were observed (Table 4). Among patients who received systemic therapy, 41.5% and 32.6% had mild levels of signs/symptoms based on EASI (<6.0) and SCORAD (<25) scores, respectively, versus 17.4% and 8.9% of those who did not receive systemic therapy (Table 4). Despite systemic therapy, disease burden was still substantial based on mean (SD) WP-NRS (4.6 [3.1]), mean DLQI (9.1 [7.6]), mean EASI (12.6 [12.9]), mean SCORAD (38.3 [23.3]) and a mean of 5.2 (12.0) flares in the last 6 months (Table 4).

Significant differences in treatment patterns were observed between geographic clusters (Figure 2). Mean (SD) total exposure to topical treatment was highest in Cluster 5 (Australia and New Zealand), Cluster 8 (Netherlands, Belgium, and Ireland) and Cluster 11 (Hungary, Romania, the Czech Republic, Poland, and Slovakia) with 3428

(3286), 2916 (4063) and 2892 (3642) days (9.4 [9.0], 8.0 [11.1] and 7.9 [10.0] years), respectively, and lowest in Cluster 4 (Spain) with 708 (1050) days (1.9 [2.9] years). Mean total exposure to systemic treatment was highest in Clusters 4 and 8 with 1007 (1578) and 948 (1640) days (2.8 [4.3] and 2.6 [4.5] years), respectively, and lowest in Cluster 6 (China and Taiwan) and 9 (Switzerland and Austria) with 115 (334) and 289 (565) days (0.3 [0.9] and 0.8 [1.5] years; Figure S7). Use of topical therapy was mostly consistent across regions with >75% of patients currently treated with topical therapy, except in Clusters 3 (Italy) and 4. The proportion of patients with current use of systemic therapy was highest in Clusters 3 and 4, which had the lowest use of topical therapy. Highest use of dupilumab was in Clusters 12 (Saudi Arabia, Kuwait, and United Arab Emirates) and 3 (Figure 2); the highest total exposure to dupilumab was in Clusters 1 (Canada)

TABLE 4 Clinical, psychosocial and economic burden of AD by EASI disease severity level and use of systemic therapy in adults.

	EASI severity levels				<i>p</i> value	Current use of systemic therapy		
	Clear (<i>n</i> = 81)	Mild (<i>n</i> = 364)	Moderate (<i>n</i> = 621)	Severe (<i>n</i> = 362)		Yes (<i>n</i> = 813)	No (<i>n</i> = 620)	<i>p</i> value
Primary endpoints								
WP-NRS, mean (SD)	1.1 (1.9)	3.3 (2.6)	6.0 (2.7)	7.0 (2.4)	<0.0001	4.6 (3.1)	6.2 (2.7)	<0.0001
DLQI, mean (SD)	1.5 (2.7)	6.3 (6.1)	11.8 (7.0)	15.5 (7.4)	<0.0001	9.1 (7.6)	13.0 (7.5)	<0.0001
Clinical outcomes								
EASI, mean (SD)	0.0 (0.0)	2.6 (1.7)	13.4 (4.8)	33.0 (8.8)	<0.0001	12.6 (12.9)	17.8 (12.3)	<0.0001
EASI categories, <i>n</i> (%)								<0.0001
Clear (0)	NA	NA	NA	NA		74 (9.1)	7 (1.1)	
Mild (0.1–5.9)	NA	NA	NA	NA		263 (32.3)	101 (16.3)	
Moderate (6.0–22.9)	NA	NA	NA	NA		305 (37.5)	315 (50.8)	
Severe (23.0–72.0)	NA	NA	NA	NA		168 (20.7)	194 (31.3)	
SCORAD, mean (SD)	1.8 (3.6)	24.1 (11.6)	47.3 (12.6)	66.1 (12.5)	<0.0001	38.3 (23.3)	50.4 (17.5)	<0.0001
SCORAD categories, <i>n</i> (%)					<0.0001			<0.0001
Mild (<25.0)	81 (100.0)	220 (60.4)	19 (3.1)	0		265 (32.6)	55 (8.9)	
Moderate (25.0–50.0)	0	128 (35.2)	338 (54.4)	37 (10.2)		276 (33.9)	229 (36.9)	
Severe (>50.0)	0	10 (2.7)	256 (41.2)	317 (87.6)		257 (31.6)	328 (52.9)	
vIGA-AD, mean (SD)	0.0 (0.2)	1.6 (0.7)	2.8 (0.7)	3.5 (0.5)	<0.0001	2.3 (1.2)	2.9 (0.9)	<0.0001
5D-Pruritus score, mean (SD)	8.8 (3.0)	12.2 (3.9)	15.8 (3.8)	18.2 (3.7)	<0.0001	14.3 (4.7)	16.5 (4.0)	<0.0001
POEM, mean (SD)	2.5 (3.7)	10.4 (7.0)	16.5 (6.7)	19.8 (6.6)	<0.0001	13.1 (8.3)	17.5 (7.0)	<0.0001
Number of flares in the last 6 months, mean (SD)	2.3 (6.9)	4.7 (10.0)	6.2 (12.0)	7.6 (14.9)	<0.0001	5.2 (12.0)	6.8 (12.3)	<0.0001
Inadequately controlled AD, <i>n</i> (%)	3 (3.7)	31 (8.5)	188 (30.3)	171 (47.2)	<0.0001	173 (21.3)	223 (36.0)	<0.0001
Current systemic therapy, <i>n</i> (%)	74 (91.4)	263 (72.3)	305 (49.1)	168 (46.4)	<0.0001	NA	NA	
Average hours of sleep per night in the past week, mean (SD)	7.0 (1.6)	6.9 (1.5)	6.4 (1.6)	5.9 (1.7)	<0.0001	6.6 (1.7)	6.3 (1.6)	0.0006
Average minutes needed to fall asleep per night in the past week, mean (SD)	21.1 (20.5)	25.4 (28.6)	38.1 (41.0)	48.3 (51.7)	<0.0001	34.1 (42.2)	39.6 (40.3)	<0.0001
Nights out of previous 7 with sleep disturbance, mean (SD)	0.9 (1.9)	2.0 (2.5)	3.2 (2.6)	4.6 (2.5)	<0.0001	2.7 (2.7)	3.7(2.6)	<0.0001
Psychosocial outcomes								
HADS-A, mean (SD)	4.4 (4.5)	5.9 (4.2)	7.4 (4.3)	8.4 (4.6)	<0.0001	6.6 (4.4)	7.8 (4.5)	<0.0001
≥8, <i>n</i> (%)	19 (23.5)	107 (29.4)	291 (46.9)	196 (54.1)	<0.0001	308 (37.9)	307 (49.5)	<0.0001
HADS-D, mean (SD)	2.8 (3.6)	4.1 (3.7)	5.6 (4.1)	7.0 (4.7)	<0.0001	5.0 (4.2)	5.9 (4.3)	<0.0001
≥8, <i>n</i> (%)	8 (9.9)	68 (18.7)	186 (30.0)	153 (42.3)	<0.0001	210 (25.8)	205 (33.1)	0.0025
SF-12 MCS, mean (SD)	52.6 (9.6)	47.0 (10.6)	43.4 (10.8)	39.1 (11.2)	<0.0001	44.8 (11.3)	42.4 (11.2)	<0.0001
WPAI-AD								
Absenteeism, %, mean (SD)	6.5 (20.4)	4.3 (14.1)	10.2 (20.0)	15.6 (27.7)	<0.0001	7.7 (19.1)	12.7 (24.1)	0.0008
Presenteeism, %, mean (SD)	7.8 (17.0)	19.8 (25.4)	33.1 (26.4)	40.6 (27.6)	<0.0001	24.5 (27.1)	36.8 (26.7)	<0.0001
Overall work productivity impairment, %, mean (SD)	9.7 (20.3)	22.5 (27.0)	38.0 (28.1)	44.9 (29.6)	<0.0001	28.3 (29.1)	41.4 (28.5)	<0.0001
Activity impairment, %, mean (SD)	4.9 (14.7)	21.4 (26.2)	39.3 (28.8)	53.7 (29.5)	<0.0001	30.9 (31.0)	43.8 (29.5)	<0.0001

TABLE 4 (Continued)

	EASI severity levels				<i>p</i> value	Current use of systemic therapy		
	Clear (<i>n</i> = 81)	Mild (<i>n</i> = 364)	Moderate (<i>n</i> = 621)	Severe (<i>n</i> = 362)		Yes (<i>n</i> = 813)	No (<i>n</i> = 620)	<i>p</i> value
Hours missed from work, mean (SD)	2.4 (8.6)	1.5 (5.5)	5.0 (17.6)	6.1 (12.1)	<0.0001	3.0 (11.1)	5.9 (16.2)	<0.0001
HCRU								
Number of healthcare or acute care visits in the previous 6 months, mean (SD)	3.7 (2.9)	5.1 (6.4)	5.5 (7.2)	6.6 (7.0)	<0.0001	5.8 (6.5)	5.9 (7.3)	0.7709
Monthly healthcare-related expenses and costs of everyday necessities related to AD, USD, mean (SD)	89.4 (215.0)	144.1 (282.5)	144.5 (175.9)	201.0 (316.9)	<0.0001	156.4 (281.0)	154.5 (203.0)	0.0073

Note: EASI severity levels are based on score ranges per Chopra et al, 2017: clear, 0; mild, 0.1–5.9; moderate, 6.0–22.9; severe, 23.0–72.0. *p* values are based on Kruskal–Wallis tests or chi-square tests.

Abbreviations: AD, atopic dermatitis; DLQI, Dermatology Life Quality Index; EASI, Eczema Area and Severity Index; HADS, Hospital Anxiety and Depression Scale; HADS-A, HADS-Anxiety; HADS-D, HADS-Depression; HCRU, healthcare resource utilisation; NA, not applicable; SCORAD, SCORing Atopic Dermatitis; SF-12 MCS, 12-Item Short Form Health Survey Mental Component Summary; USD, US dollars (2021); WPAI-AD, Work Productivity and Activity Impairment Atopic Dermatitis; WP-NRS, Worst Pruritus Numeric Rating Scale.

and 12 (Figure S7). Although dupilumab use was recorded in all 12 clusters (ranging from 5% to 62% of patients), the approval and reimbursement status of dupilumab varied across individual countries/regions.

Similarly, significant differences in disease burden were observed between clusters and this correlated with systemic therapy use (Figure 3). Clusters 5, 6, 7 (Brazil, Argentina and Mexico), and 11 had the highest disease burden and some of the lowest systemic therapy and dupilumab use, especially Clusters 5 and 6. The relationship between the proportion of patients using systemic treatment and mean EASI showed a trend of lower EASI with higher systemic use (Figure 4).

Non-atopic comorbidities that were collected were highest in Clusters 7 (55.4%), 1 (53.5%) and 5 (52.4); the most common comorbidities were anxiety disorder, hypertension and depression (Table S2).

The primary and secondary endpoints showed variation across individual countries (Tables S3–S30; Figures S8–S35).

DISCUSSION

This analysis of more than 1500 adults and adolescents demonstrated that a considerable clinical, psychosocial and economic burden exists among patients with AD in multiple geographic areas. In the total population, 76% and 69% of patients had moderate-to-severe disease based on SCORAD and EASI, respectively, indicating their disease signs and symptoms were not sufficiently managed. Similar proportions of adult and adolescent patients suffered from severe itch (43% and 35%) and reported a very large or extremely large effect on QoL (DLQI ≥11, 46% and 41%).

The time from AD diagnosis to first systemic treatment was long, highlighting the need for better disease management in this patient population. As expected, disease burden was significantly lower for patients who received systemic therapy. More than twice as many patients who received systemic therapy had mild levels of signs and symptoms based on EASI and SCORAD scores versus those who did not receive systemic therapy. Similar patterns were observed for other PRO and economic outcomes, suggesting that patients with moderate-to-severe AD who were treated with systemic therapies had better disease management than those who did not receive systemic therapy. However, a considerable disease burden still existed among patients receiving systemic therapies as demonstrated by high mean (SD) WP-NRS (4.6 [3.1]), DLQI (9.1 [7.6]), EASI (12.6 [12.9]) and SCORAD (38.3 [23.3]) scores among this group, suggesting that at the time of this study, not all patients receiving systemic therapies had their disease signs and symptoms sufficiently managed.

These results are consistent with previous studies that demonstrated high disease burden and inadequately controlled treated disease among patients with moderate-to-severe AD in Europe, North America and Japan.^{6–10} Furthermore, patients with greater disease severity reported the highest burden of disease, as also demonstrated in previous studies.^{8,11} The observational EUROSTAD study demonstrated high disease burden among patients treated with systemic therapies, including dupilumab (mean [SD] peak pruritus: 5.5 [2.5], mean DLQI: 11.8 [6.9] and mean EASI: 16.2 [10.9]; Table S31).⁹

Similarly, high disease burden was demonstrated in other real-world studies among patients with moderate-to-severe AD receiving non-dupilumab therapies (mean EASI range between studies: 9.5–22.7; mean SCORAD range between

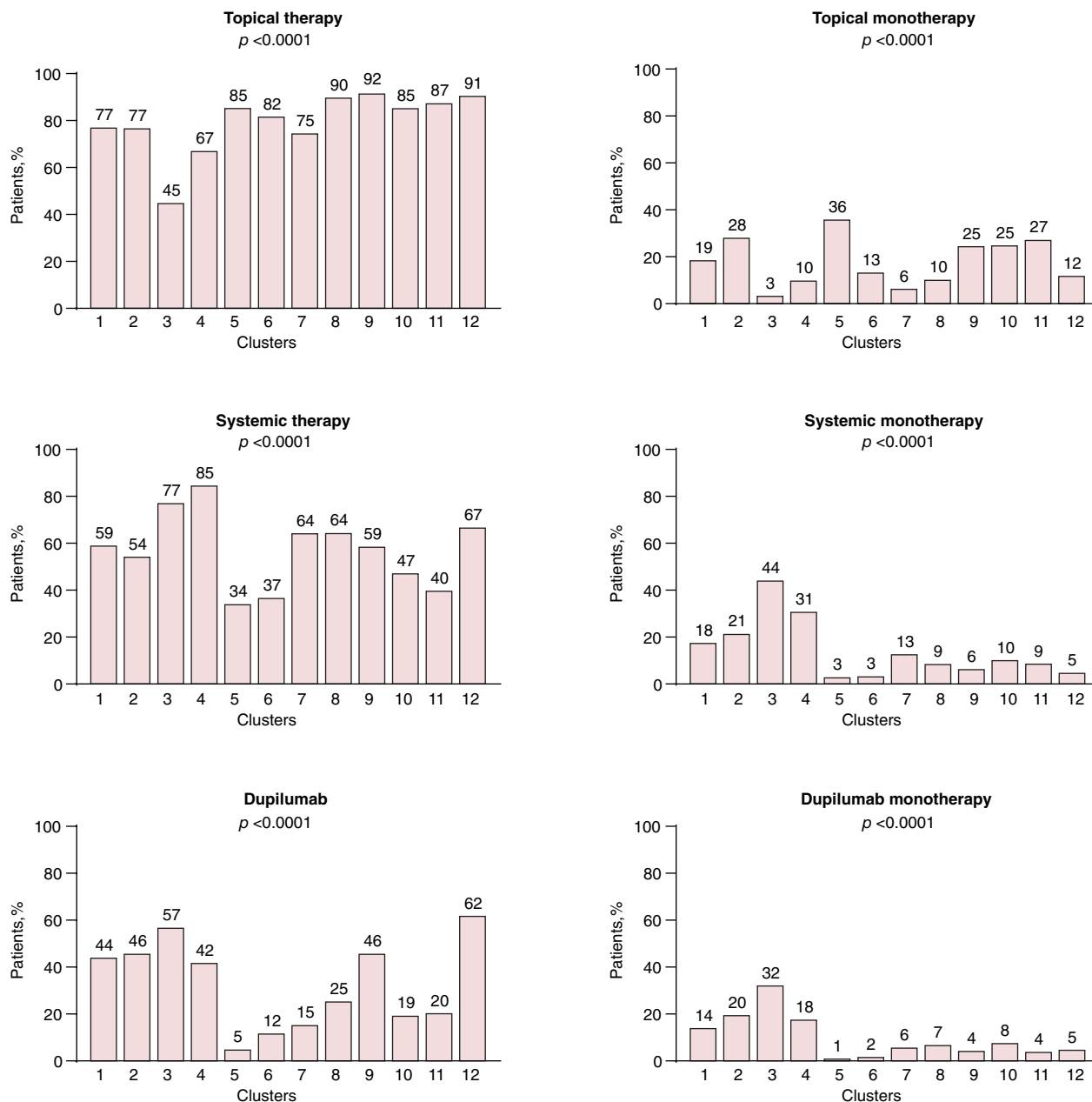


FIGURE 2 Treatment trends in adults by geographic clusters. The analysed clusters were (1) Canada ($n = 200$), (2) Germany ($n = 210$), (3) Italy ($n = 118$), (4) Spain ($n = 91$), (5) Australia and New Zealand ($n = 103$), (6) China and Taiwan ($n = 60$), (7) Brazil, Argentina and Mexico ($n = 157$), (8) Netherlands, Belgium and Ireland ($n = 59$), (9) Switzerland and Austria ($n = 94$), (10) Greece, Israel, Turkey and Portugal ($n = 197$), (11) Hungary, Romania, the Czech Republic, Poland and Slovakia ($n = 103$) and (12) Saudi Arabia, Kuwait and United Arab Emirates ($n = 42$).

studies: 49.2–68.4; mean DLQI range between studies: 9.2–16.2; mean pruritus NRS range between studies: 5.3–7.1; Table S31).^{7,8,10}

Our findings showed variability in disease burden that correlated with current treatment patterns across geographic regions. The highest disease burden was reported in geographic clusters with some of the lowest use of systemic therapies and dupilumab, that is, Cluster 5 (Australia, New Zealand), Cluster 6 (China and Taiwan), Cluster 7 (Brazil, Argentina and Mexico) and Cluster 11 (Hungary, Romania, the Czech Republic, Poland and Slovakia). In contrast,

highest use of systemic therapy was in Clusters 3 (Italy) and 4 (Spain), which had the lowest disease activity and PRO scores. Some of these differences may be related to regional or cultural differences in the perception of AD severity and eligibility for systemic therapy. At the time of this study, dupilumab was the only advanced therapy approved for AD. However, although it was used in each geographic cluster, its reimbursement (e.g. it was not reimbursed in Ireland at the time of this study) and approval status as well as the overall treatment recommendations and access to different AD therapies varied across countries.¹⁵ Since then, the number

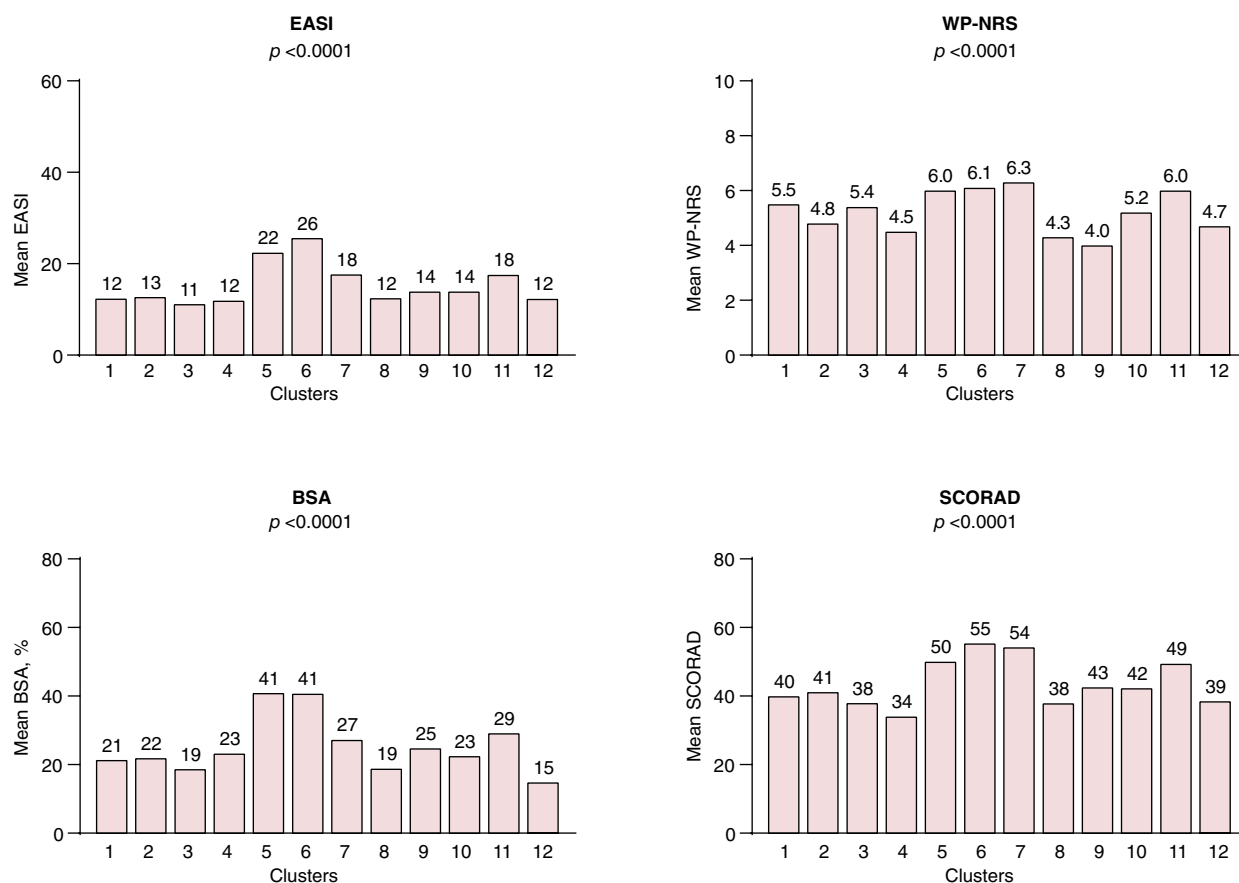


FIGURE 3 Disease burden in adults by geographic clusters. The analysed clusters were (1) Canada ($n=200$), (2) Germany ($n=210$), (3) Italy ($n=118$), (4) Spain ($n=91$), (5) Australia and New Zealand ($n=103$), (6) China and Taiwan ($n=60$), (7) Brazil, Argentina and Mexico ($n=157$), (8) Netherlands, Belgium and Ireland ($n=59$), (9) Switzerland and Austria ($n=94$), (10) Greece, Israel, Turkey and Portugal ($n=197$), (11) Hungary, Romania, the Czech Republic, Poland and Slovakia ($n=103$) and (12) Saudi Arabia, Kuwait and United Arab Emirates ($n=42$). BSA, body surface area affected; EASI, Eczema Area and Severity Index; SCORAD, SCORing Atopic Dermatitis; WP-NRS, Worst Pruritus Numeric Rating Scale.

of treatment options for AD has increased with the approval of agents such as Janus kinase (JAK) inhibitors, including baricitinib, upadacitinib and abrocitinib, and biologics, such as tralokinumab. Taken together, patients receiving systemic therapies demonstrated lower disease burden, indicating that patients with uncontrolled disease should be offered systemic therapies more frequently. Although the situation is different across geographic regions, new advanced treatment options are emerging, and disease burden observed in this study is expected to diminish with these new options.

Study limitations included inclusion criteria that selected only patients who were receiving or candidates for systemic treatment, limiting the population and excluding patients who were well treated by topical therapies. The study was also conducted at the time when only one biologic therapy (dupilumab) and no JAK inhibitors were approved for AD; the approval/reimbursement status of dupilumab also varied across geographic regions. Of note, healthcare-related expenses also varied per geographic region due to differences across countries' healthcare

systems; results will be published later in country-specific reports. MEASURE-AD was not a population-based sample and results may not be generalisable to all cohorts and across different countries. Patients without routine visits were not enrolled, and only patients treated by the investigators of this study were included. As this study recruited participants from dermatology centres with experience in good clinical practice and usually also clinical trials, a bias towards the view of expert-centre-based care cannot be excluded. Also, there may have been a recruitment channelling bias for sites where patients receiving certain therapies, for example, systemic therapies, were preferentially enrolled. These results may not reflect the experience at sites not using the full spectrum of treatment options. Because of this, we may be underestimating the burden of AD. This limitation does not change the overall conclusion of the study as the above-mentioned bias may contribute to an optimistic view for use of systemic therapy versus no systemic therapy. Furthermore, this was a cross-sectional study and patients with a wide variety of treatment statuses were included (e.g. the beginning of

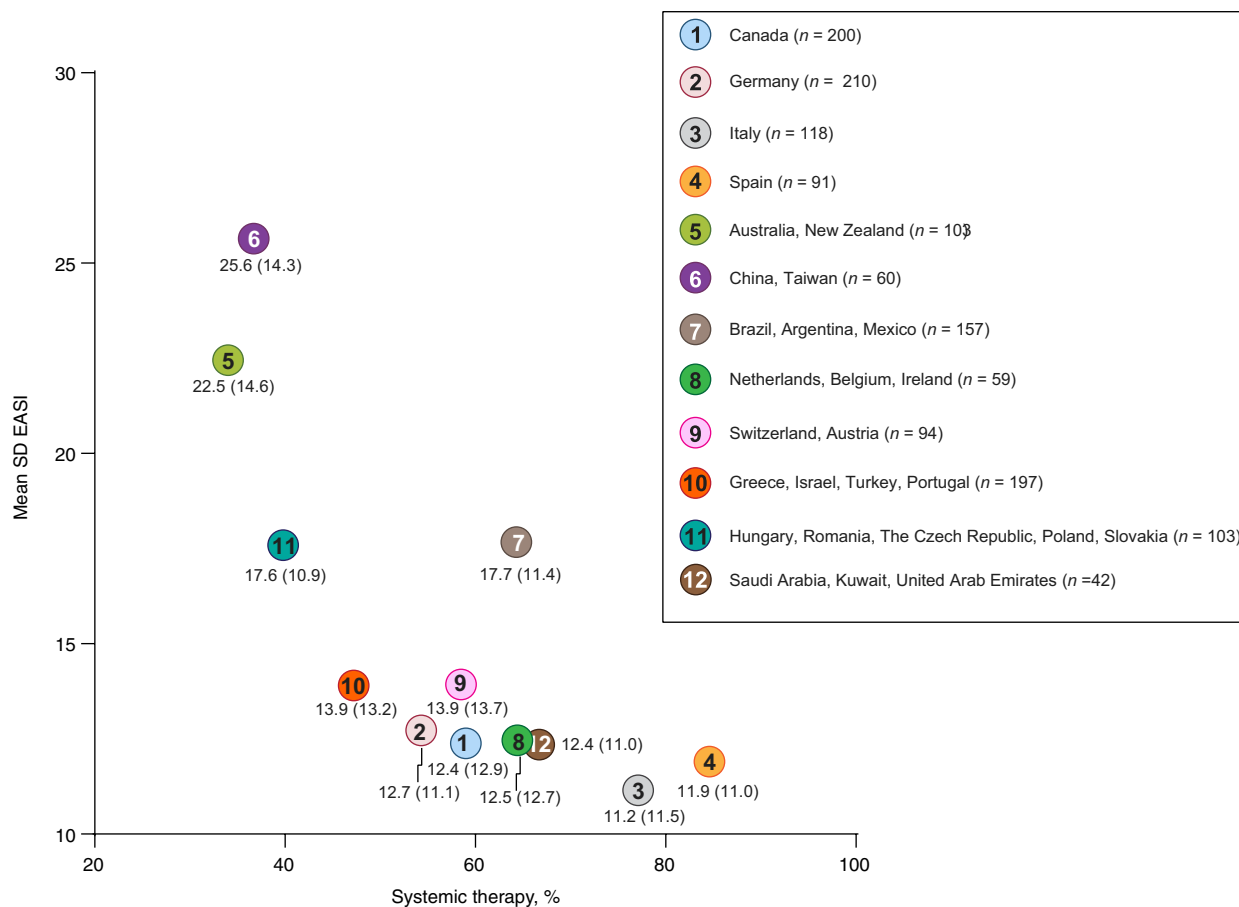


FIGURE 4 Relationship between proportion of adults using systemic treatment and mean (SD) EASI between geographic clusters. N's represent total patient number in each cluster and does not exclude missing data.

treatment and ≥ 1 year of treatment). Finally, patients with very severe disease represented a small population for some subgroup assessments (e.g. WPAI) and struggled to answer questions about flare frequency (i.e. always on one continuous flare), potentially leading to lower numbers of flares than expected for this group. Self-reported duration of sleep might also not be reliable assessment.

CONCLUSION

Patients with moderate-to-severe AD continue to have substantial multidimensional disease burden and not adequately controlled disease. Although burden is lower among those receiving systemic therapies, there is still a residual need for more effective therapies. Our results also demonstrated that outcomes, treatment patterns and access to therapies varied between countries at the time of this study. As new advanced treatment options for AD are emerging, the disease burden observed in this study is expected to diminish. Overall, these results suggest that a significant unmet need remains for optimal disease management including, but not limited

to, effective treatments to improve patients' psychosocial and clinical outcomes and reduce the economic burden of AD.

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DATA AVAILABILITY STATEMENT

AbbVie is committed to responsible data sharing regarding the clinical trials we sponsor. This includes access to anonymized, individual and trial-level data (analysis data sets), as well as other information (e.g. protocols and Clinical Study Reports), as long as the trials are not part of an ongoing or planned regulatory submission. This includes requests for clinical trial data for unlicensed products and indications.

This clinical trial data can be requested by any qualified researchers who engage in rigorous, independent scientific research, and will be provided following review and approval of a research proposal and Statistical Analysis Plan (SAP) and execution of a Data Sharing Agreement (DSA). Data requests can be submitted at any time and the data will be accessible for 12 months, with possible extensions considered. For more information on the process, or to submit a request, visit the following link: <https://www.abbvie.com/our-science/clinical-trials/clinical-trials-data-and-information-sharing/data-and-information-sharing-with-qualified-researchers.html>

DISCLOSURES

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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