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BRIEF REPORT

Characteristics and Management of Patients with Alopecia Areata and Selected Comorbid Conditions: Results from a Survey in Five European Countries

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ABSTRACT

Introduction: Alopecia areata (AA) is an autoimmune condition that causes non-scarring hair loss and can impose a high psychosocial burden on patients. The presence of comorbid conditions may impact the management of AA in clinical practice. This analysis aims to describe disease characteristics and management of AA in patients with concomitant atopic, autoimmune, and psychiatric comorbid conditions.

Methods: Data were collected from the Adelphi Disease Specific Programme™, a cross-sectional survey of physicians and their adult patients with AA conducted in France, Germany, Italy, Spain, and the UK between October 2021 and June 2022. Patients' disease severity was based on physician's definition. Physician-reported data on demographics, AA clinical characteristics, comorbid conditions, and information related to AA therapies were analyzed. Analyses were descriptive.

Results: Overall, 239 dermatologists provided data for 2083 patients, of which 558 patients (27%) had at least one atopic, autoimmune, or psychiatric comorbid conditions. The most common comorbid conditions were atopic dermatitis, autoimmune thyroid disease, and anxiety. The mean (standard deviation) patient age

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for the three comorbidity groups was 37.6 years (12.1) and 56% of the patients were women (n = 313). In the three comorbidity groups, 51%, 50%, and 55% of patients with atopic, autoimmune, and psychiatric comorbidities had severe AA with disease progression reported as worsening in 30%, 28%, and 30%, respectively, whereas in the group with no comorbidities, 37% were described as having severe AA and 21% getting worse. Scalp hair loss was the primary sign reported across the three groups of comorbid conditions (atopic, 91%; autoimmune, 91%; psychiatric, 88%). Patients with preselected comorbidities presented more frequently AA-related signs and symptoms beyond scalp hair loss than patients without comorbid conditions. These patients were also more likely to receive topical calcineurin inhibitors, topical immunotherapy, conventional systemic immunosuppressants, and oral Janus kinase inhibitors for the treatment of their AA. ***Conclusion***: This analysis provided insights into the burden and management of AA in patients presenting with atopic, autoimmune, and psychiatric comorbid conditions in five European countries.

Keywords: Alopecia areata; Comorbid conditions; Disease management

Key Summary Points
Alopecia areata (AA) is an autoimmune disorder characterized by non-scarring hair loss and unpredictable disease course.
AA has broader impacts beyond hair loss, as it can negatively affect a patient's quality of life.
The presence of comorbid conditions can impact the management of patients with AA and the choice of treatment available in clinical practice.
This study aimed to describe disease characteristics and the management of AA in adults with selected comorbid conditions, using dermatologist-reported data collected in five European countries.

INTRODUCTION

Alopecia areata (AA) is an autoimmune condition characterized by non-scarring hair loss, which can vary from small, well-defined patches to extensive, or even total, hair loss on the scalp, face, and/or body [1]. The lifetime incidence of AA is reported to be around 2% globally, with the onset of hair loss usually occurring before the age of 40 years [2]. AA disease evolution is unpredictable, often with alternating cycles of hair loss and regrowth [1]. Beyond hair loss, AA can result in a profound impact on patient's quality of life (QoL). A scoping review found that extremely severe QoL impairment is reported by up to one-third of patients with AA, with highest impact reported on emotional and social functioning [3]. Patients with AA can experience significant psychosocial distress, which can be worsened by the fact these feelings are not being supported or recognized [3].

Several therapies have been traditionally used off-label for the management of AA, including corticosteroids, topical immunotherapy, and traditional immunosuppressants such as azathioprine, cyclosporin A, and methotrexate [4–7]. Recently, newer therapies have been approved by the European Medicines Agency and the US Food and Drug Administration for the treatment of adults with severe AA [8–10]. Treatment algorithms for AA in adults are generally based on the extent and duration of hair loss [4–6]. However, other factors may impact the management of patients with AA and the choice of treatment in clinical practice, such as the presence of comorbid conditions.

Multiple studies have been conducted to better understand the burden of AA comorbid conditions. Two recent systematic reviews and meta-analyses provided detailed information on the risk of comorbid conditions in patients with AA [11, 12]. When compared with controls without AA, these studies have shown that AA is associated with an increased prevalence of various comorbid conditions, especially atopic, autoimmune, and psychiatric disorders. A recent analysis of a national administrative claims database in the USA also observed higher

rates for several autoimmune, inflammatory, and mental health conditions in patients with AA compared to a matched cohort of subjects without AA [13]. Similar findings were reported in two large studies conducted in Denmark and the UK [14–16].

While the prevalence of comorbid conditions in patients with AA has been extensively studied, there is still limited evidence available regarding AA characteristics and therapeutic management in adults who present with concomitant comorbid conditions. One study conducted in the USA suggested an association between severity of AA hair loss and the presence of atopic, autoimmune, or psychiatric disorders [13]. Two other studies using data from claims databases in the USA and in Japan found that comorbid conditions were more commonly reported in patients with more severe forms of AA [17, 18].

Our study aimed to describe disease characteristics and the management of AA in adults with atopic, autoimmune, or psychiatric comorbid conditions, from five European countries.

METHODS

Study Design and Participants

Data were drawn from the Adelphi Real World AA Disease Specific Programme (DSP)™ [19], a large, cross-sectional survey with retrospective data collection of physicians and their patients with AA conducted in France, Germany, Italy, Spain, and the UK between October 2021 and June 2022. Dermatologists identified from public lists of healthcare professionals were invited to participate if they were treating a minimum of seven patients with AA each month. Physicians were requested to recruit at least seven patients with mild (n = 1), moderate (n = 3), and severe (n = 3) AA consecutively, until the severity quota had been reached. The patients were adults (aged ≥ 18 years) who had a physician-diagnosed AA and were not enrolled in a clinical trial at the time of the study. Physicians completed a patient record form for each patient with information on patient demographics, clinical characteristics, and treatments for AA. Disease severity was determined by dermatologists according to their own definition of the terms "mild," "moderate," and "severe," thus reflecting how AA severity is assessed in clinical practice.

Study Variables and Analysis

The analysis focused on patients with at least one physician-reported concomitant condition from the three following groups: atopic comorbid conditions (i.e., atopic dermatitis, atopy, asthma, allergic rhinitis, urticaria, angioedema, allergic contact dermatitis, atopic keratoconjunctivitis, other allergic conditions, and/or nasal polyps), autoimmune comorbid conditions (i.e., rheumatoid arthritis, Crohn's disease, ulcerative colitis, lupus, psoriasis, thyroid disease, vitiligo, celiac disease, type 1 diabetes, connective tissue disease, psoriatic arthritis, ankylosing spondylitis, and/or non-radiographic axial spondylitis), and psychiatric comorbid conditions (i.e., depression, anxiety, insomnia, bipolar disorder, and/or attention deficit disorder). The control group consisted of the patients enrolled in the AA DSP who did not present any of the preselected atopic, autoimmune, or psychiatric concomitant conditions. Patient demographics, AA clinical characteristics, as well as information related to AA therapies were presented for the groups with and without preselected comorbid conditions. Continuous variables were described using mean and standard deviation (SD). Categorical variables were summarized as the frequency and percentage within each category. No imputation of missing data was conducted. Analyses were performed using IBM SPSS Data Collection Survey Reporter Version 7 (Armonk, NY, US).

Compliance with Ethics Guidelines

Data collection was undertaken in line with the European Pharmaceutical Marketing Research Association guidelines [20] and, as such, it did not require institutional review board (IRB)/independent ethics committee approval [21]. The DSP was performed in full accordance with

relevant legislation at the time of data collection, including the US Health Insurance Portability and Accountability Act 1996. However, the AA DSP was submitted to the Western IRB for methodological review in 2019 and was granted an exemption. The DSP was conducted in compliance with the International Council for Harmonization 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. Physicians were compensated for their participation according to fair market research rates.

RESULTS

Study Population

In this study, 239 dermatologists provided data for 2083 patients with AA. The prevalence of atopic, autoimmune, and psychiatric comorbid conditions in the overall study population is presented in Table 1. The most common comorbid conditions in each of these three groups were atopic dermatitis (5%), autoimmune thyroid disease (4%), and anxiety (8%), respectively.

Patient Demographics and AA Clinical Characteristics

The mean (SD) age was 39.9 (12.1) and 39.2 (12.5) years in the autoimmune and psychiatric groups, respectively, compared to 35.8 (12.1) years in the atopic group, and 35.0 (11.3) years in the group without preselected comorbid conditions (Table 2). Women represented respectively 63%, 61%, and 51% of the patients in the groups with autoimmune, psychiatric, and atopic comorbid conditions, and 45% in the group without preselected comorbid conditions. Disease progression was judged uncontrolled (i.e., stable or worsening) for 74%, 72%, and 70% of the patients with autoimmune, psychiatric, and atopic comorbid conditions, respectively, compared to 64% of those without preselected comorbid conditions. Within the three groups of comorbid conditions, 50–55% of patients had severe AA and 7–8% of patients had a mild form of AA; in the group without preselected comorbid conditions, severe AA was reported for 37% of patients and mild AA for 17% (Table 2). Scalp hair loss was the primary sign reported across the four groups (no comorbid conditions: 85%, autoimmune: 91%, atopic: 91%, psychiatric: 88%; Fig. 1). Eyebrow and eyelash hair loss were the most frequent signs reported beyond scalp hair loss across the four groups (Fig. 1).

Treatment Patterns

At the time of data collection, 21 (8%), 16 (8%), and 9 (4%) patients were not receiving any treatment in the groups with atopic, autoimmune, and psychiatric comorbid conditions, respectively. A similar result was observed in the population of patients without preselected comorbid conditions (84 [6%]). A combination therapy was used in 60% and 68% of patients in the groups with autoimmune and psychiatric comorbid conditions, respectively. In the groups with atopic and no preselected comorbid conditions, the use of combination therapy was reported in 51% and 49% of patients, respectively. The treatments currently used at the time of the survey are reported in Fig. 2. The use of corticosteroids was similar across the groups. Conversely, the use of topical immunotherapy, topical calcineurin inhibitors, conventional systemic immunosuppressants, and oral Janus kinase (JAK) inhibitors was reported respectively in 13%, 15%, and 17% of patients with atopic, autoimmune, and psychiatric comorbid conditions. These treatments were only used in 8% of patients in the group without preselected comorbid conditions.

DISCUSSION

This study investigated the clinical characteristics and management of AA in adults with atopic, autoimmune, or psychiatric comorbid conditions, using dermatologist-reported data collected in five European countries.

Table 1 Prevalence of preselected comorbidities

Diagnosed concomitant conditions*, *n* (%)	Overall population (*n* = 2083)
Atopic comorbidities	
Atopic dermatitis	101 (5%)
Atopy	75 (4%)
Allergic rhinitis	49 (2%)
Asthma	48 (2%)
Allergic contact dermatitis	15 (1%)
Urticaria	11 (1%)
Nasal polyps	11 (1%)
Other allergic condition(s)	9 (< 1%)
Atopic keratoconjunctivitis	5 (< 1%)
Angioedema	1 (< 1%)
Autoimmune comorbidities	
Autoimmune thyroid disease	88 (4%)
Vitiligo	31 (1%)
Celiac disease	23 (1%)
Lupus	16 (1%)
Psoriasis	15 (1%)
Diabetes (type 1)	12 (1%)
Rheumatoid arthritis	12 (1%)
Crohn's disease	7 (< 1%)
Connective tissue disease	6 (< 1%)
Ulcerative colitis	5 (< 1%)
Psoriatic arthritis	3 (< 1%)
Psychiatric comorbidities	
Anxiety	158 (8%)
Depression	97 (5%)
Insomnia	36 (2%)
Bipolar disorder	4 (< 1%)
Attention deficit disorder	1 (< 1%)
Number of patients with preselected comorbidities	
≥ 1 of any of the three groups of comorbidities	558 (27%)
≥ 1 atopic and ≥ 1 autoimmune comorbidity	36 (2%)
≥ 1 atopic and ≥ 1 psychiatric comorbidity	54 (3%)
≥ 1 autoimmune and ≥ 1 psychiatric comorbidity	28 (1%)
≥ 1 atopic and ≥ 1 autoimmune and ≥ 1 psychiatric comorbidity	5 (< 1%)

Physicians were asked to list any diagnosed concomitant conditions for each patient

*Comorbidities with at least one patient

The most common preselected comorbid conditions (i.e., reported in 2% of patients or more) were atopic dermatitis, atopy, allergic rhinitis, asthma, autoimmune thyroid disease, anxiety, depression, and insomnia. This is consistent with the findings from two recent systematic reviews and meta-analyses, and several large studies conducted in the USA, Europe, and Japan [11, 18, 22]. In the most recent systematic review and meta-analysis that included 102 studies, patients with AA had higher odds of having atopic dermatitis, allergic rhinitis, asthma, and unspecified atopic conditions [13]. In the same study, AA was positively associated with the risk of presenting several thyroid diseases and notably those with an autoimmune origin. The risk for psychiatric diseases was only assessed in a meta-analysis of 87 studies that confirmed a greater risk of developing anxiety and depression [13]. Sleep disorders were not significantly associated with AA, but these results were only based on a single study.

Dermatologists more commonly rated AA in the three comorbidity groups as severe and with an uncontrolled progression (i.e., stable or worsening) when compared to the group without preselected comorbid conditions. Several studies have reported similar findings, although with a varying definition of severity. In our study, disease severity was determined by dermatologists according to their own definition of

Table 2 Demographics and AA clinical characteristics for patients with and without preselected comorbidities

	No preselected comorbidities (n = 1525)	Atopic comorbidities (n = 255)	Autoimmune comorbidities (n = 195)	Psychiatric comorbidities (n = 221)
Patient demographics				
Mean (SD) age, years[a]	35.0 (11.3)	35.8 (12.1)	39.9 (12.1)	39.2 (12.5)
Female, n (%)	684 (45)	129 (51)	122 (63)	134 (61)
BMI, kg/m^2	24.4 (3.1)	24.3 (3.3)	24.0 (3.5)	24.2 (3.8)
White/Caucasian, n (%)	1396 (92)	215 (84)	175 (90)	193 (87)
Clinical characteristics				
Mean (SD) time since AA diagnosis, years[b]	2.5 (4.3)	3.1 (4.3)	5.0 (7.6)	5.3 (7.7)
Mean (SD) age at onset of AA, years	31.5 (10.8)	32.0 (11.3)	33.8 (12.2)	34.3 (13.5)
Current AA Disease Severity, n (%)[c]				
Mild	256 (17)	19 (7)	15 (8)	15 (7)
Moderate	703 (46)	107 (42)	83 (43)	85 (38)
Severe	566 (37)	129 (51)	97 (50)	121 (55)
Disease progression, n (%)[d]				
Improving	552 (36)	76 (30)	56 (29)	57 (26)
Stable	658 (43)	103 (40)	85 (44)	97 (44)
Worsening (rapidly and slowly)	314 (21)	76 (30)	54 (28)	67 (30)
Uncontrolled (stable/worsening)	972 (64)	179 (70)	139 (72)	164 (74)

AA alopecia areata, *BMI* body mass index, *SD* standard deviation
[a]Patients < 90 years only. n = 2 (< 1%) patients ≥ 90 years old
[b]Excludes patients for whom their physician does not know
[c]Physicians were asked to rate AA severity as "mild", "moderate", or "severe" according to their own judgment
[d]"How would you describe this patient's disease?"

the terms "mild," "moderate," and "severe," thus reflecting how AA severity is assessed in clinical practice. In the analysis of a claims database in Japan, the prevalence of comorbid conditions was higher in patients with severe AA (diagnosis code of alopecia totalis, universalis, ophiasis, or widespread alopecia), when compared with all the patients with a diagnosis code of AA [18]. Furthermore, two recent US claims cohort studies using a similar approach to assess disease severity reported that patients with severe AA were more frequently diagnosed with autoimmune and inflammatory diseases as well as mental health disorders than patients with a less severe form of AA [13, 17].

Although the exact cause of AA is unknown, current research findings support the conclusion that AA is an autoimmune disease directed against the hair follicle that happens in genetically predisposed individuals and can be triggered by environmental factors [23, 24]. Therefore, a shared genetic background and

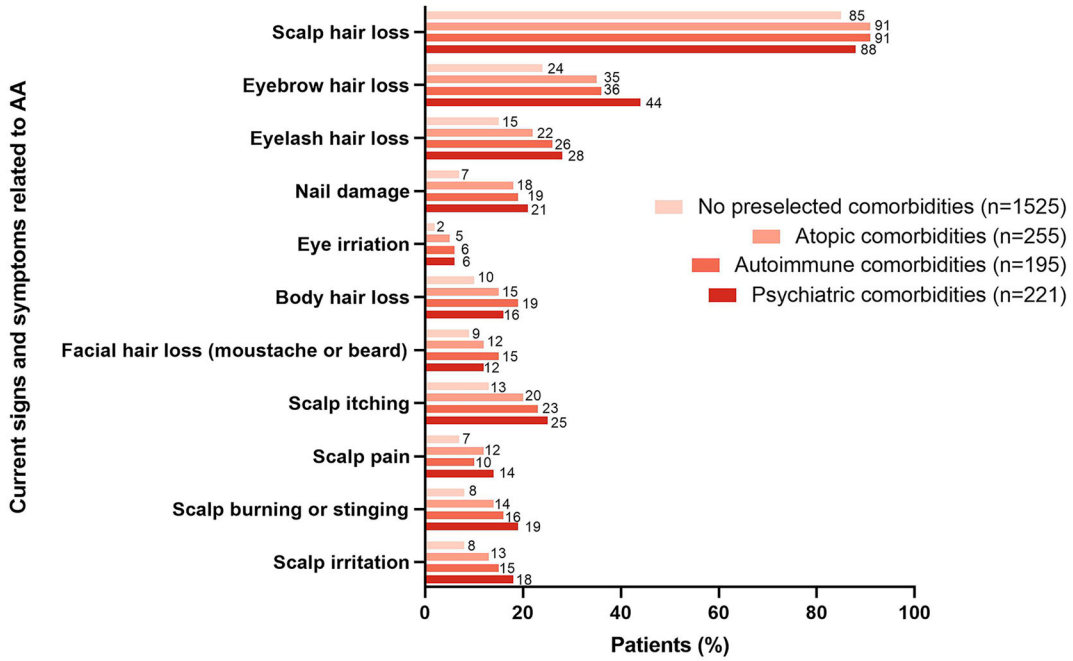

Fig. 1 Current signs and symptoms related to AA in patients with and without preselected comorbidities. *AA* alopecia areata

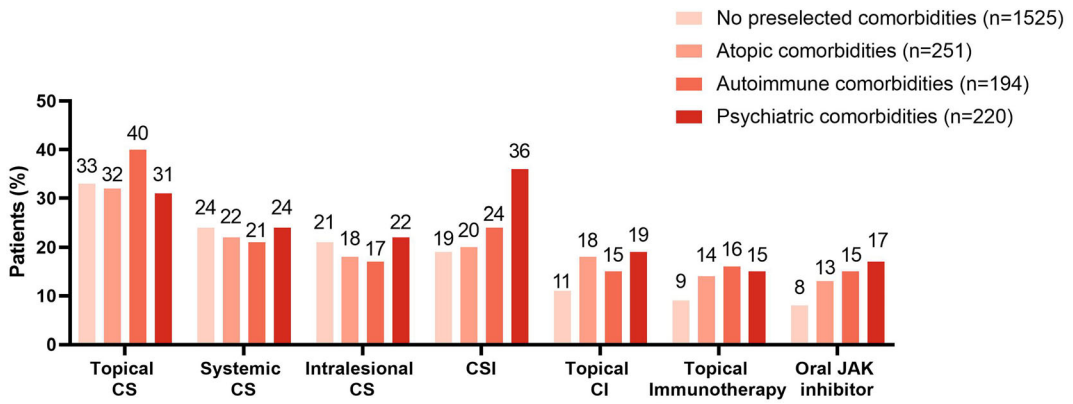

Fig. 2 Current treatments for AA in patients with and without preselected comorbidities. *AA* alopecia areata, *CI* calcineurin inhibitors, *CS* corticosteroid, *CSI* conventional systemic immunosuppressant, *IMT* immunotherapy, *JAK* Janus kinase, *JAKi* Janus kinase inhibitor. Systemic CS included oral and intravenous CS. Conventional systemic immunosuppressants included azathioprine, cyclosporine, or methotrexate. Topical CI included topical pimecrolimus and tacrolimus. Topical immunotherapy included diphencyprone, squaric acid dibutylester, dinitrochlorobenzene, and others. Oral JAKi included baricitinib, ruxolitinib, tofacitinib, and other JAKis. Physicians could list more than one treatment

overlapping mechanisms of disease may contribute to the association between AA and atopic, autoimmune, or psychiatric disorders [3, 25]. The presence of atopic and autoimmune diseases has been associated with poor prognosis in patients with AA [26]. On the other hand, the distortion of appearance resulting from AA hair loss and the unpredictable disease course can have a profound impact on patients [27, 28].

While the use of corticosteroids was similar across the groups, we observed that the use of topical immunotherapy, topical calcineurin inhibitors, conventional systemic immunosuppressants, and oral JAK inhibitors was numerically higher in the three groups of comorbid conditions than in the group of patients without any of the preselected comorbid conditions. Furthermore, patients in the three groups of comorbid conditions were more commonly receiving a combination therapy for AA. These elements are consistent with the longer disease duration and the higher severity reported for patients with AA in the three groups of comorbid conditions. Corticosteroids are considered an appropriate first-line option for the treatment of AA, irrespective of disease severity [4–6]. Despite limited evidence, topical calcineurin inhibitors are often proposed on the eyebrows to reduce the use of topical corticosteroids on the face [1]. The use of topical immunotherapy for AA is mostly recommended in extensive and chronic scalp hair loss [4–6]. Conventional immunosuppressants are generally proposed after failure of corticosteroids or as steroid-sparing agents [5, 29]. Before the approval of baricitinib, the use of oral JAK inhibitors was reported in patients with severe AA and often after failure of systemic therapy [30].

There are some limitations to this study. Firstly, analyses were conducted on three groups of comorbid conditions and findings may not be generalizable to individual comorbid conditions within each group. As information on the clinical characteristics and management of comorbid conditions was not collected, the potential impact of AA severity on atopic and autoimmune comorbid conditions was not evaluated. The description of AA therapies was also limited to several mutually exclusive groups of treatments. This choice was made to focus on interventions generally recommended for adults with AA [6, 7]. Dermatologists participating in this study were asked to describe the treatments received by enrolled patients for the management of AA. However, the selection of these treatments may have been influenced in some cases by the presence of comorbid conditions, such as atopic and autoimmune diseases. The cross-sectional design, the absence of a comparator population without AA, the descriptive nature of the analyses, and the potential for sampling selection do not allow us to conclude on causality and limit the interpretation of some of the results. Recall bias, a common limitation of surveys, might also have affected physicians' responses. However, physicians did have the ability to refer to patients' medical records while completing the form, thus minimizing the possibility of recall bias. Finally, the definition of AA severity was determined using clinical judgment, which may vary among physicians. As AA disease severity has no unique definition, this approach should reflect the way physicians assess severity in clinical practice.

CONCLUSION

This large study conducted in five European countries provided insights into the burden and management of adults with AA in the presence of comorbid atopic, autoimmune, and psychiatric conditions. In comparison to patients without selected comorbid conditions, we observed that more patients with concomitant atopic, autoimmune, and psychiatric disorders had severe AA according to their dermatologist's judgment, with a higher prevalence of AA-related signs and symptoms beyond scalp hair loss. These patients were also more frequently receiving topical calcineurin inhibitors, topical immunotherapy, conventional systemic immunosuppressants, and oral JAK inhibitors for the treatment of their AA. Our study indicates that, for patients with AA, disease severity may be associated with greater prevalence of mental health conditions and immune-mediated diseases, and that patients with more severe AA disease are more likely to require systemic and other immunotherapies. Additional research is needed to increase understanding of the relationship between AA and its comorbid conditions.

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Data Availability Lilly provides access to all individual participant data collected during the trial, after anonymization, with the exception of pharmacokinetic or genetic data. Data are available upon request 6 months after the indication studied has been approved in the USA and EU and after primary publication acceptance, whichever is later. No expiration date of data requests is currently set once data are made available. Access is provided after a proposal has been approved by an independent review committee identified for this purpose and after receipt of a signed data sharing agreement. Data and documents, including the study protocol, statistical analysis plan, clinical study report, blank or annotated case report forms, will be provided in a secure data sharing environment. For details on submitting a request, see the instructions provided at https://vivli.org/.

Declarations

Conflict of Interest. Sergio Vañó-Galván reports consulting fees and payment/honoraria from Pfizer and Lilly. Alexander Egeberg reports grants from Abbvie, Danish Nathional Psoriasis Foundation, Eli Lilly, Janssen, Kgl. Hofbundtmager Aage Bangs Foundation, Novartis, Pfizer, Boehringer Ingelheim, Bristol-Myers Squibb, Almirall and Simon Spies Foundation in relation to research funding. Consulting fees from AbbVie, Almirall, Boehringer Ingelheim, Bristol-Myers Squibb, Dermavant, Eli Lilly, Galderma, Galapagos NV, Janssen, LEO Pharma, Mylan, Novartis, Pfizer, Samsung Bioepis Co., Ltd., UCB, Union Therapeutics and Horizon Therapeutics. Payment/honoraria from AbbVie, Almirall, Amgen, Boehringer Ingelheim, Bristol-Myers Squibb, Boehringer Ingelheim, Bristol-Myers Squibb, Dermavant, Eli Lilly, Galderma, Janssen, LEO Pharma, Mylan, Novartis, Pfizer, Samsung Bioepis Co., Ltd. and UCB. Support for attending congresses from Abbvie, Eli Lilly, Bristol-Myers Squibb and Janssen. Participation on a Data Safety Monitoring Board or Advisory Board from Samsung Bioepis and Horizon Therapeutics. Bianca Maria Piraccini received payment/honoraria from Pierre fabre-Ducray, ISDIN, Legacy Healthcare, Pfizer, Almirall, Eli Lilly, Difa Cooper and Dercos-L'Oreal. Simran Marwaha is an employee of Adelphi Real World. Anthony Bewley reports royalties from Wiley. Ad hoc consultancy with Abbvie, Almirall, Lilly, UCB, Pfizer, Sanofi, Leo Pharma, Galderma, Janssen, Novartis and BMS. Travel support to attend congresses from Almirall, Lilly, Janssen. Catherine Reed, Erin Johansson and Frederick Durandare employees and minor shareholders of Eli Lilly and Company.

Ethical Approval. Data collection was undertaken in line with European Pharmaceutical Marketing Research Association guidelines (EphMRA) and as such it did not require institutional review board (IRB)/independent ethics committee approval. The DSP was performed in full accordance with relevant legislation at the

time of data collection, including the US Health Insurance Portability and Accountability Act 1996. However, the AA DSP was submitted to the Western IRB for methodological review in 2019 and was granted an exemption. The DSP was conducted in compliance with the International Council for Harmonization 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. Physicians were compensated for their participation according to fair market research rates.

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