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ORIGINAL RESEARCH

Treatment Patterns and Treatment Satisfaction Among Adults with Alopecia Areata in the United States

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ABSTRACT

Introduction: Alopecia areata (AA), an autoimmune disease, is characterized by non-scarring hair loss involving the scalp, face, and/or body. Prior to 2022, no US Food and Drug Administration (FDA)-approved treatments for AA were available in the USA; existing treatment options had limited efficacy and durability and are often associated with side effects. This study aimed to evaluate the current AA treatment patterns and treatment satisfaction as reported by dermatologists.

Methods: Real-world data from a 2019 cross-sectional survey of US dermatologists and their adult patients with AA were analyzed. Dermatologists provided comprehensive data on their patients with AA, including AA dermatologist-assessed severity, treatments, treatment duration, treatment satisfaction, and reasons for dissatisfaction. The switching patterns among the proportion of patients on each of the treatment groups at the time of survey and, for those with prescription history, were reported.

Results: A total of 442 patients with AA, treated by 90 dermatologists, were included in this analysis. At the time of survey, 45% of patients were being prescribed a combination of corticosteroids, 21% injectable corticosteroids, 11% topical corticosteroids/topical calcineurin inhibitor, and 10% immunomodulator as monotherapy or in combination. The majority (65%) of patients had no prior reported therapy. Among patients who were reported to have a prior therapy, frequent switching was to combination corticosteroids, injectable corticosteroids, and immunomodulators. Overall treatment dissatisfaction was high (24% dissatisfied and 29% neutral) and increased with AA severity.

Conclusions: This analysis provides a snapshot of the different local and systemic treatment options currently being used in a real-world treatment setting. Unfortunately, none of these treatments provide a sustainable, safe, and relapse-free solution, which leads to high treatment dissatisfaction rates and hence indicates a significant unmet need for the new and advanced treatment options for patients with AA.

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Key Summary Points

The current therapies for alopecia areata (AA) have limited efficacy and durability, and often have restrictive side effects. Best practice standards for AA treatments are lacking as well.

At the time of survey, combination of corticosteroids was the most common treatment (45%), followed by injectable corticosteroid (21%), and topical corticosteroid/ calcineurin inhibitor (11%). Less commonly prescribed treatments included immunomodulator, either in monotherapy or in combination (10%), and oral corticosteroids (2%).

The dissatisfaction levels for AA treatments among dermatologist was high, which increased with AA severity. Only 17% treatment satisfaction was reported for patients with severe AA. The "lack of efficacy overall" and the "impact of AA on patients' quality of life" were identified as the top reasons for dissatisfaction.

There is an unmet need for safe and effective treatments to help alleviate the functional impairment experienced by patients with AA and to improve their health-related quality of life.

INTRODUCTION

Alopecia areata (AA) is an autoimmune disease that has an underlying immuno-inflammatory pathogenesis, and is characterized by non-scarring hair loss involving the scalp, face, and/or body [1]. Hair loss may occur in one or many patches or there may be complete scalp hair loss (alopecia totalis, AT) or complete loss of scalp, facial, and body hair (alopecia universalis, AU) [1]. In the USA, about 700,000 individuals suffer from AA [2].

Prior to 2022, there were no US Food and Drug Administration (FDA)-approved treatments for AA. Therapies were being used off-label with limited efficacy and durability, and often have restrictive side effects [3, 4]. As data are scarce, best practice standards for treatment are lacking. Currently, there are no AA treatment guidelines in the USA and divergent opinions exist among the experts on optimal AA treatment pathways. For instance, a recent international Delphi panel on treatment reached consensus for only a third of treatment-specific questions [5]. Two recently published USA-based national studies contain limited treatment information, without reporting on treatment switches, treatment by AA severity, or treatment satisfaction [6, 7]. The most common AA treatments reported for US data were topical and injectable corticosteroids [7].

Patients reported high levels of dissatisfaction with the ineffectiveness and side effects of currently available treatment options [8–10]. A survey conducted by the National Alopecia Areata Foundation (NAAF) among 1083 patients with AA reported that 63.0% ($n = 682$) of patients were very unsatisfied with the current medical treatments, whereas 15.1% ($n = 164$) were somewhat unsatisfied [9].

The purpose of this study was to present real-world data on utilization of AA treatments and dermatologists' satisfaction with treatments by AA severity, and treatment switching, as reported in a recent cross-sectional survey of US dermatologists for patients in their practice. Dermatologists' satisfaction with AA treatment was also examined.

METHODS

Study Design

A cross-sectional survey of the US dermatologists and their adult patients with AA was conducted in 2019 using the Adelphi AA Disease Specific Programme DSP™ [11]. DSP™ are

point-in-time surveys conducted in the real-world clinical practice gathering retrospective medical record data, physician survey data, and patient-reported outcomes related to current disease management, disease burden, and treatment preferences and satisfaction [12, 13]. Dermatologists were identified from publicly available lists and invited to participate in the DSP if they were actively involved in treating patients with AA; with a minimum monthly workload of five patients (including one patient with mild AA, and four patients with moderate/severe AA including at least one patient with severe AA, based on the assessment of AA severity by the dermatologists).

Patients 18 years of age or older, diagnosed with AA, and not a participant of any clinical trial at the time of survey were included in the DSP^{TM}. Patients were recruited consecutively from the pool of prospective AA adult patients visiting the clinic for a consultation until the severity quota described earlier had been reached. Patients with exclusively AA barbae (i.e., beard facial hair loss) disease type were excluded a priori from this analysis because of their likely different clinical manifestations and patient characteristics [14, 15].

Data Collection

Dermatologist Survey Data

Data for this study were collected using a Patient Record Form (PRF) completed by the dermatologists. The PRFs included information on patient demographics, comorbidities, percentage of scalp and body hair loss, AA diagnosis and type, disease history, current (at time of survey) and prior AA treatment, and dermatologists' satisfaction with AA control. If there was dissatisfaction expressed regarding AA control, reason for dissatisfaction was collected. In addition, AA severity at the time of survey administration as well as date of current treatment initiation was collected from dermatologists. The physician overall assessment of AA severity was a global rating based on the following question: "What is/was your overall assessment of the severity of alopecia areata symptoms in this patient based on your own definition of the terms mild, moderate & severe?"

Classification of AA Treatments and Treatment Satisfaction

Dermatologists identified all current and prior treatment options for each of their patients: (1) topical corticosteroids, (2) oral corticosteroids, (3) injected corticosteroids, (4) topical immunotherapy (including diphenylcyclopropenone, dinitrochlorobenzene, squaric acid dibutylester), (5) immunomodulator (including azathioprine, cyclosporine A, mycophenolate mofetil, methotrexate), (6) topical anthralin, (7) minoxidil, (8) finasteride, (9) dithranol, (10) Retin-a/tretinoin, (11) psoralen and ultraviolet radiation A (PUVA), (12) ultraviolet radiation A (UVA), (13) tofacitinib, (14) ruxolitinib, (15) clobetasol ointment, (16) excimer laser, (17) slow-release iron, (18) vitamin E, and (19) other (specify).

These reported options, including examination of the "other" specified treatments, were combined into the following mutually exclusive AA monotherapy and combination therapy treatment groups:

1. Not currently prescribed treatment
2. Oral corticosteroids
3. Injectable corticosteroids
4. Topical corticosteroids/topical calcineurin inhibitor (TCI) (including clobetasol ointment)
5. Topical immunotherapy (anthralin, dithranol)
6. Other (includes PUVA, UVA, panretinal photocoagulation (PRP), vitamins, minoxidil, finasteride, iron, bimatoprost, simvastatin/ezetimibe)
7. Combination with or solo immunomodulator (tofacitinib, ruxolitinib)
8. Combination corticosteroids
9. Combination with topical immunotherapy

Combination corticosteroids was defined as any combination that includes corticosteroids, including multiple types of corticosteroids (e.g., topical + oral corticosteroids, oral corticosteroids + other). Therapy combinations that met more than one treatment group definition from 7 to 9 above were classified to a unique

treatment group using the following prioritization: first priority 7 (combination with or solo immunomodulator), followed by 8 (combination corticosteroid), followed by 9 (combination with immunotherapy).

Treatment duration was determined from the initiation date to either stop date or date of survey for those with ongoing therapy. Dermatologist's treatment satisfaction was assessed with the following question: "How satisfied are *you* with the current control of this patient's alopecia areata?" with a 7-point Likert scale response scale ranging from "extremely dissatisfied" to "extremely satisfied". Reasons for dissatisfaction were asked of those responding "dissatisfied" or worse on the treatment satisfaction question. Multiple response options included (1) lack of efficacy overall, (2) slow onset of action, (3) efficacy is diminishing over time, (4) persistent symptoms (pain, burning sensation, itch, tingling sensation), (5) alopecia areata is still impacting the patient's quality of life, (6) side effects, (7) patient dislikes mode of administration/finds it too burdensome, (8) lack of compliance, (9) patient not satisfied, (10) other.

This study was conducted in accordance with ethical principles of the Declaration of Helsinki and Good Clinical Practice guidelines. All subjects provided informed consent to participate in the study. Institutional review board (IRB) exemption for the study was granted by the Western IRB. All patient data were de-identified and compliant with the Health Insurance Portability and Accountability Act of 1996.

Statistical Analysis

Data were summarized using descriptive statistics (number of subjects [*n*], mean, standard deviation [SD]) for continuous variables and frequency and percentage for categorical variables.

A Sankey diagram was used to describe the proportion of patients on each of the treatment groups at the time of survey (current therapy); and for those with prescription history, this diagram illustrates the switch from their prior therapy. Bar charts were used to show the distribution of current treatment group, satisfaction by treatment group and by severity. Given the low rate of missing values reported for these data there was no plan to impute missing values. Analyses were performed using SAS version 9.4.

RESULTS

Patient Demographics and Disease Characteristics

A total of 442 patients with AA, treated by 90 dermatologists, were included in analyses. The overall mean (SD) patient age was 39.3 (13.8) years, average time since AA diagnosis was 4.5 (7.5) years with 85% of patients first experiencing AA symptoms in adulthood (18 years or older). In total, 51% of patients were female, 75% were white, 24% had other autoimmune comorbidities, 13% had a concomitant mental health condition, 75% never smoked, and 75% were employed.

Dermatologist-rated AA severity was 20% mild, 53% moderate, and 27% severe; and AA subtypes were 16% monolocularis, 77% multilocularis/diffuse/ophiasis, and 7% totalis/universalis.

Treatment Patterns

Out of a total of 439 patients with non-missing treatment at time of survey (current treatment), 45% were prescribed a combination of corticosteroids, 21% an injectable corticosteroid, 11% a topical corticosteroid/TCI, and 10% an immunomodulator, either in monotherapy or in combination. Only 2% of patients were being prescribed oral corticosteroids (Fig. 1 and Supplemental Table 1).

Among 154 patients who switched prescription from a prior therapy, we observed a trend of switching as follows: (1) from topical corticosteroids/TCI to combination corticosteroids (40%) or injectable corticosteroids (33%), (2) from combination corticosteroids to another type of combination corticosteroids (43%),

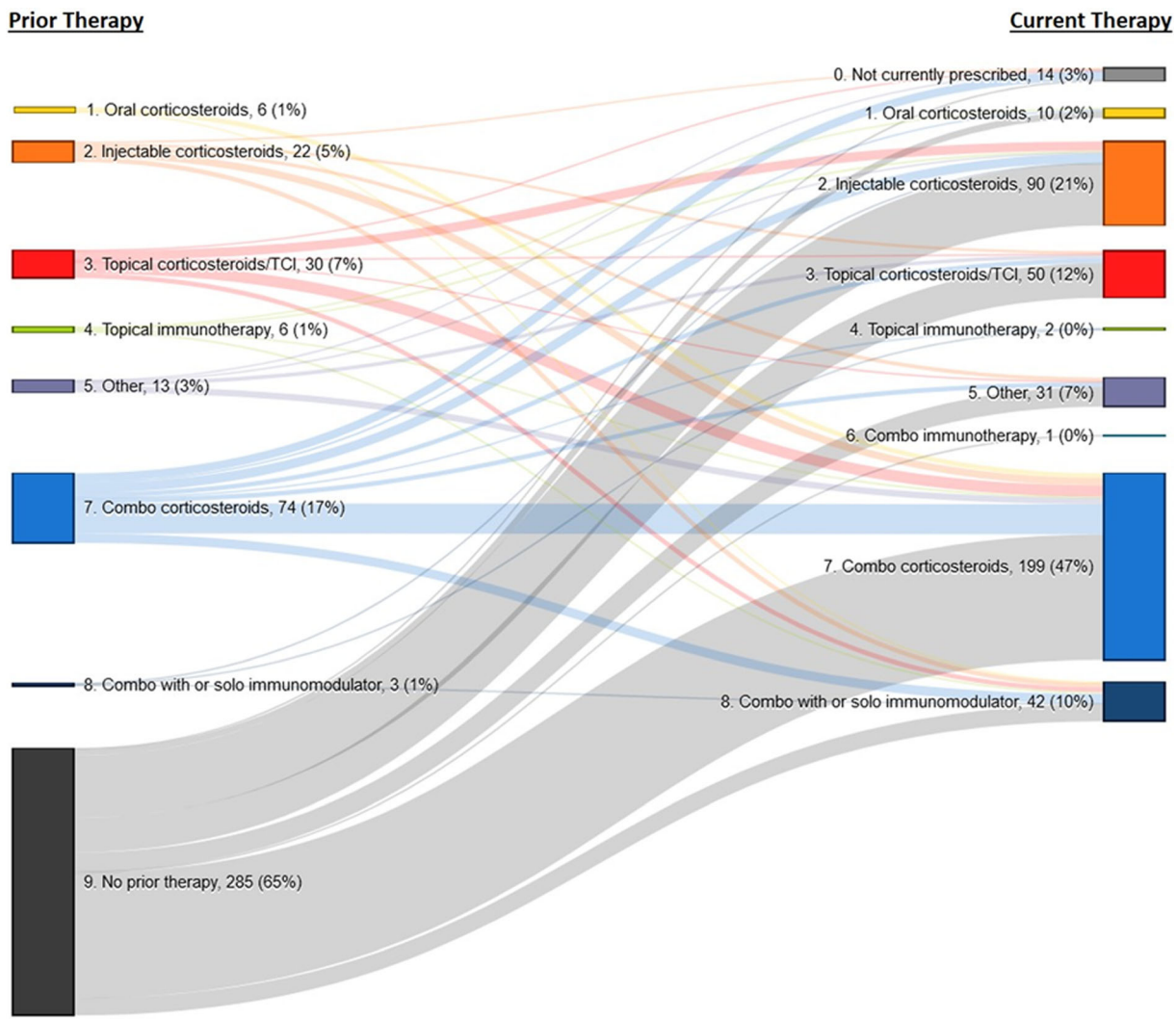

Fig. 1 Switches from prior to current therapy. Total $n = 439$, $n = 3$ missing due to no responses for treatment regimen questions. Combination (combo) corticosteroids was defined as any combination that includes corticosteroids, including multiple types of corticosteroids (e.g., topical + oral corticosteroids, oral corticosteroids + other). "Other" included treatment with psoralen and ultraviolet radiation A, ultraviolet radiation A, panretinal photocoagulation, vitamins, minoxidil, finasteride, iron, bimatoprost, or simvastatin/ezetimibe

combination with or solo immunomodulator (14%), or injectable corticosteroids (14%), and (3) from injectable corticosteroids to combination of corticosteroids (36%), combination with or solo immunomodulator (23%), or other (18%) (Supplemental Table 1).

Median times in days for current treatment duration were 146, 174, and 193 days for topical, oral, and injectable corticosteroids, respectively. Whereas, 227 days for combination of corticosteroids, 224 days for combination or solo immunomodulator, and 163 days for other therapies were reported.

More frequent use of topical corticosteroids/TCI was observed in mild patients with AA (20%) compared to moderate AA (12%) and severe AA (4%), whereas, injectable corticosteroids were more common in mild (26%) and moderate (21%) patients than severe patients (14%). Additionally, combination of

corticosteroids was most commonly used among moderate patients (54%) compared to mild and severe patients (34% and 37%, respectively). Combination with or solo immunomodulator was mostly prescribed to severe patients with AA (27%) compared to mild and moderate patients with AA (1% and 4%, respectively) (Fig. 2).

Treatment Satisfaction

Dermatologist dissatisfaction (survey response of dissatisfied or worse) was highest for oral corticosteroids (50%), followed by combination with or solo immunomodulator (39%) and combination of corticosteroids (23%). Some dermatologists were also dissatisfied with topical corticosteroids/TCI (18%) and injectable corticosteroids (14%). Additionally, dermatologists' neutral satisfaction responses (neither satisfied nor dissatisfied) for treatment groups ranged from 21% to 35% (Fig. 3). The overall dissatisfaction with treatment was prominent (24% dissatisfied and 29% neutral) and increased with AA severity (Fig. 4).

Common reasons for overall treatment dissatisfaction (for n = 103 patients) included "lack of efficacy overall" (73%), "AA impacting patient's quality of life" (50%), "slow onset of action" (37%) and "patient not satisfied" (33%). For patients on a combination of corticosteroids and combination with or solo immunomodulator, "slow onset of action" (41% and 50%, respectively) and "patient not satisfied" (39% and 25%, respectively) were also commonly reported reasons for the dissatisfaction. "Patient dislikes mode of administration" was commonly reported as a dissatisfaction reason with combination with or solo immunomodulator (38%). "Side effects" as a dissatisfaction reason was most commonly reported with oral corticosteroids (40%) and combination with or solo immunomodulator (25%) (data not shown).

DISCUSSION

This study of dermatologist-reported data on their practices sought to describe treatment patterns and treatment satisfaction among US patients with AA.

A US claims data study by Senna et al. using 2011–2018 data on treatment information over the first year after AA diagnosis reported 80.3% of patients treated with topical corticosteroids, 30.0% with oral corticosteroids, 6.2% with systemic antihistamines, 5.7% with topical nonsteroids (e.g., minoxidil, anthralin or dithranol, and topical antihistamines), 3.8% with finasteride, 3.6% with an immunomodulator, and

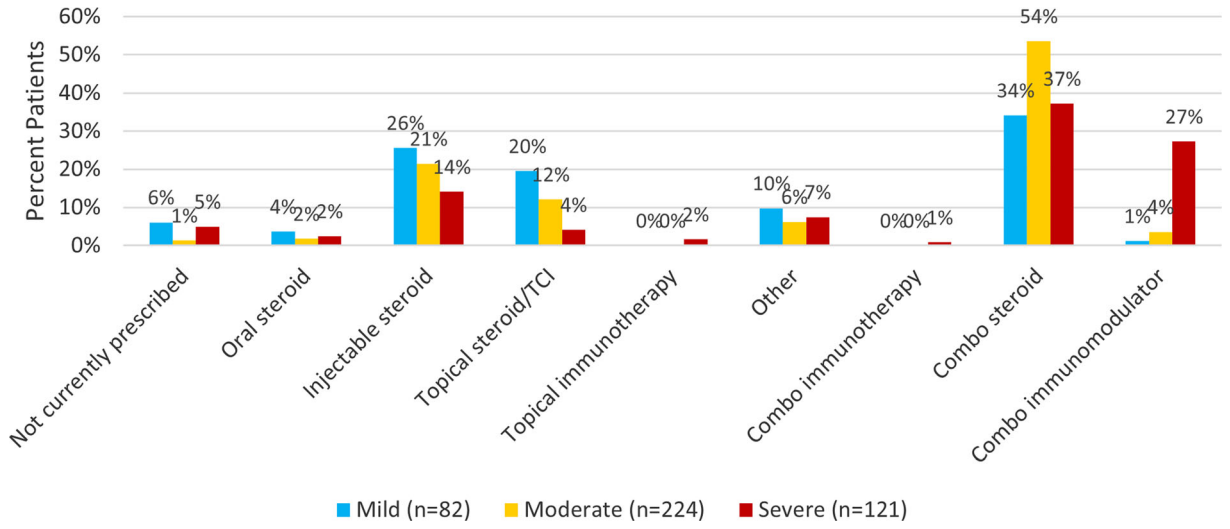

Fig. 2 Current treatment groups by severity of AA at therapy initiation. Missing n = 15 patients due to "severity at Initiation" missing or unknown

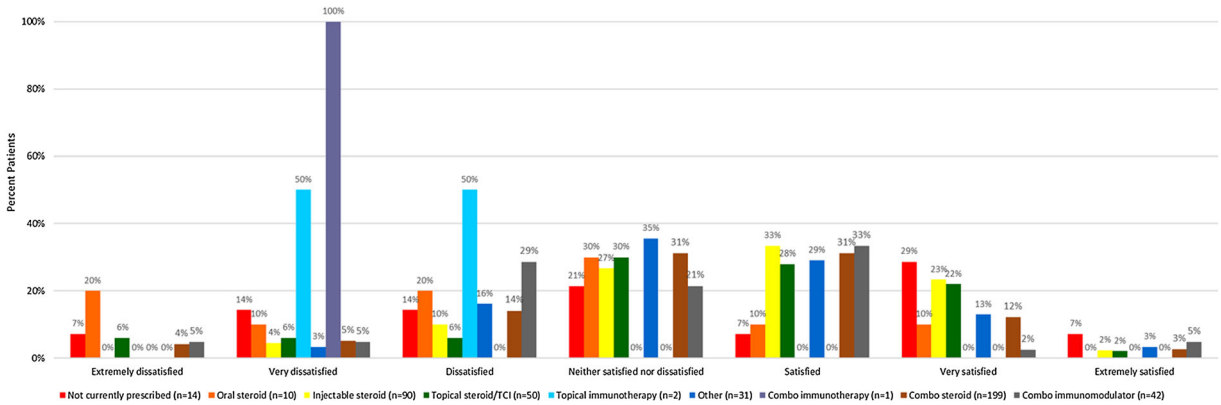

Fig. 3 Dermatologist satisfaction with current AA control by current treatment group

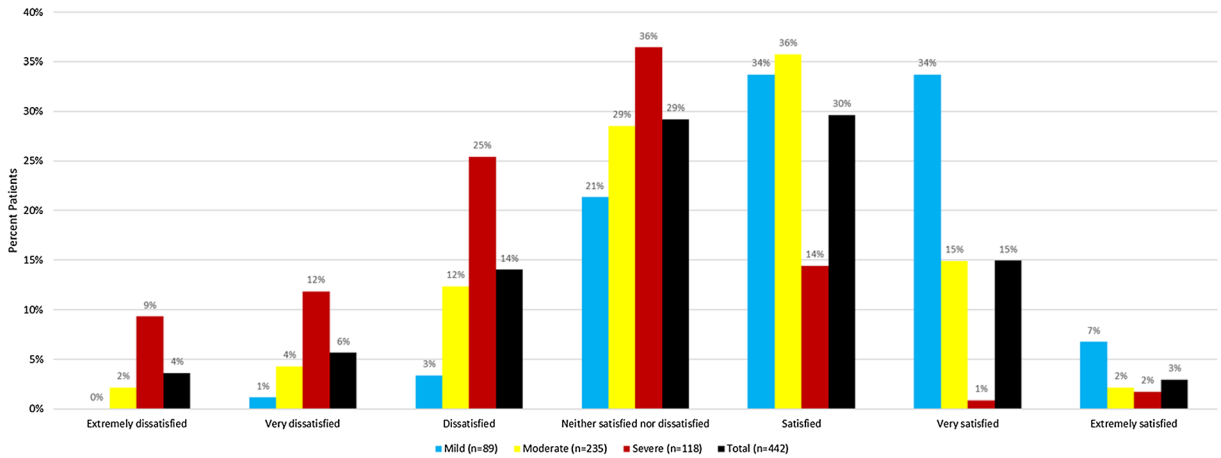

Fig. 4 Dermatologist satisfaction with current AA control by AA severity and overall

less than 2% with other treatments (e.g., acupuncture, phototherapy) [6]. A direct comparison with this claims database study was not feasible as reported treatments were not mutually exclusive as we defined mutually exclusive treatment groups considering combination therapy groups. Besides, there were some differences in classification of topical non-steroids anthralin and dithranol (we classified as topical immunotherapy), antihistamines (we classified as "other"), and finasteride (we classified as "other"). However, the claims data study reported an apparent much higher rate of topical corticosteroids use (80.3% vs our 11% topical corticosteroids/TCI and 45% combination corticosteroids use) and a lower immunomodulators use (3.6% vs 10%). Further, Senna et al. also did not report use of injectable corticosteroids [6]. Differences may be in part due to different AA severity distributions (not reported for the claims database study) and the difference in study period. Another cross-sectional US population-based analysis from 2006 to 2016 reported AA treatments from outpatient visits using the Centers for Disease Control and Prevention National Ambulatory Medical Care Survey (NAMCS) [7]. The rates reported in this study for topical corticosteroids (34%) and injectable corticosteroids (25%) were more in line with those in our study.

As expected, more frequent use of topical corticosteroids/TCI was observed in mild AA, whereas injectable corticosteroids were frequently prescribed in mild and moderate disease. Combination of corticosteroids was most common among patients with moderate AA

which is consistent with recommendations to prescribe topical corticosteroids/TCI as first-line treatment for mild cases and the ineffectiveness of topical or injectable corticosteroids alone in more severe types of AA [3, 16]. Combination with or solo immunomodulator was almost exclusive to patients with severe AA, likely due to concerns about treatment side effects [17].

The most common therapy switch patterns reported (from topical to combination or injectable corticosteroids, from combination corticosteroids or injectables to immunomodulators) were consistent with overall lack of efficacy that was stated as the most common reason for treatment dissatisfaction. Topical corticosteroids may not be beneficial in the long term and injectable corticosteroids alone will not prevent development of hair loss at other sites [3, 18]. For most patients, continued systemic corticosteroid treatment is needed to maintain hair growth but the response is often insufficient to justify the side effect profile of corticosteroids [3, 18].

The median durations of corticosteroid therapy observed in this study were 174 days for systemic and 227 days for combination. These durations are greater than the maximum duration recommendation of 6 months for systemic corticosteroid use [4, 5].

Dermatologist dissatisfaction with treatment was high and increased with AA severity, with only 17% treatment satisfaction reported for patients with severe AA. This highlights an unmet need for safe and effective treatments for patients with severe AA. Lack of efficacy overall and the impact of AA on patients' quality of life were the top dissatisfaction reasons, emphasizing the need for effective, sustainable treatments to help alleviate impairment in daily activity and function experienced by patients with AA.

At present there are no practice guidelines for the management of AA that originate from either the American Academy of Dermatology or a patient advocacy organization such as the National Alopecia Areata Foundation. Despite that, these results confirm that utilization of steroids, both topically and injectable, is foundational to the treatment of AA. These treatments appear to be used both initially and for long-term care, highlighting a similar need as seen in atopic dermatitis and psoriasis to develop safer and more effective non-steroidal alternatives.

The large sample of patients with mild, moderate, and severe AA coupled with individual patient clinical characteristics and treatment management provided by treating dermatologist are strengths of this study. However, retrospective survey data limitations apply to this study and include potential for biases and generalizability outside the studied population. Given that patients selected by dermatologists to participate in this study were only among those who had a visit to their practice, the patient sample may have lacked representation of patients in remission or of those not on prescription medication at time of survey. Future efforts need to identify changes in behavior as new drugs are approved and prescribed.

CONCLUSION

These real-world data provide a cross-sectional view of the different local and systemic treatment options being used for the treatment of AA. Combination of corticosteroids followed by injectable corticosteroid and topical corticosteroid/calcineurin inhibitor were reported as the most common treatments. Given current treatment dissatisfaction with variability in effectiveness, tolerability, and inadequacy in improving patients' quality of life, there is a need to enhance the available treatment options for patients with AA. The results highlight the unmet need for better treatments that could potentially be addressed with an approved treatment option proven to be efficacious and safe for patients with AA.

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Compliance with Ethics Guidelines. Institutional review board (IRB) exemption for the study was granted by the Western IRB. The survey was performed in accordance with relevant legislation at the time of data collection, including the US Health Insurance Portability and Accountability Act 1996 [HIPAA 2003], and Health Information Technology for Economic and Clinical Health Act legislation [HITECCH Act]. It was conducted in accordance with the ethical principles of the Declaration of Helsinki and Good Clinical Practice guidelines. All subjects provided informed consent to participate in the study.

Data Availability. All data supporting the survey is the intellectual property of Adelphi Real World and can be made available upon request. Requests may be sent to Adelphi Real World for more information on data availability and licensing (james.jackson@adelphigroup.com).

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