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Identifying barriers and disparities in the healthcare of patients with alopecia areata: a mixed-methods analysis using claims data and qualitative interview data

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ABSTRACT

Objectives Alopecia areata (AA) is a chronic immune-related disease with non-scarring hair loss. Treatment may reduce disease activity but cannot cure. Even though AA can be very burdensome to patients, the German social act has categorised AA as a 'lifestyle disease' and treatment is not covered by statutory health insurances (SHI). We aimed to characterise the healthcare situation of patients with AA in Germany, including potential inequalities, and to derive recommendations for action.

Design This mixed-methods study combined: (1) semistructured qualitative interviews with patients and dermatologists, analysed through qualitative content analysis and (2) claims data analyses of a large nationwide German SHI from 2016 to 2020. Both types of data were collected and analysed in parallel to enable integrated analysis. Consecutively, an expert panel derived recommendations for action.

Setting Interviews were conducted online or via telephone.

Participants Patients were recruited conveniently via a dermatological outpatient clinic, patient organisations and social media. Dermatologists were recruited from a nationwide network and the dermatological societies.

Primary and secondary outcome measures Exploration of the healthcare situation of adult persons with AA in Germany, investigating potential barriers to adequate care and identifying potential inequalities of access to care.

Results We interviewed 20 patients (mean age 40.7 years; 75.0% female) and 14 dermatologists (mean age 48.4 years, 50.0% female). SHI data included 4692 persons with AA in 2020 (prevalence 0.23%; mean age 55.8 years; 76.2% female). The lack of reimbursement was criticised by both patients and dermatologists. Though 57.5% of patients received at least one drug prescription, mostly topical therapies, access to approved systemic drugs was very low. Drugs were prescribed mostly by general practitioners (41.1%) and dermatologists (32.8%). Some patients were sceptical regarding the side effects of treatment and criticised exclusively symptomatic treatment. Patients reported an urge for information and exchange with others, as well as different ways of handling their disease, such as acceptance, and frustration or desperation. Patients living in urban areas received topical therapies more often than patients in rural areas. Furthermore, women were more likely to receive treatment than men. Recommendations for action include reimbursement of AA medication and developing a platform providing information on AA to physicians and patients.

Conclusions The disease burden and frustration of patients with AA is high, mostly caused by limited treatment options and lack of reimbursement, limiting access to approved drugs such as Janus kinase inhibitors. Through the mixed-methods design, we were able to combine patient experiences and quantitative data reflecting the reality of healthcare in Germany.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ In the interviews, only German-speaking patients could participate, and due to the nature of qualitative data, no quantitative assumptions can be made.
⇒ Claims data analyses cover only services that are reimbursed by the statutory health insurance, and data might be overestimated or underestimated due to insufficient or inadequate differential diagnoses, misclassifications or coding behaviour of the practitioner.
⇒ The major strength of this study is the mixed-methods design, in which the different methods compensated for their limitations.
⇒ The mixed-methods approach allowed us to generate and investigate additional research questions and enabled a comprehensive interpretation of the results.

INTRODUCTION

Alopecia areata (AA) is an inflammatory, immune-mediated disease leading to non-scarring hair loss. It is associated with other chronic inflammatory skin and autoimmune diseases.[1 2] Furthermore, AA can be triggered by numerous factors.[2] In patients with milder forms, around two-thirds experience

spontaneous remission.[1] However, an increased risk of recurrences remains. AA is characterised by a mostly high psychosocial burden. Since mostly visible body areas are affected, most patients experience or perceive stigmatisation, interpersonal strain and increased levels of psychosocial stress.[3 4]

Disease-halting drugs used for AA traditionally include topical glucocorticosteroids (TGCs) and calcineurin inhibitors (TCI), systemic glucocorticosteroids (SGCs) and immunosuppressants such as methotrexate and Janus kinase inhibitors (JAKi). With the JAKi baricitinib (since 2022) and ritlecitinib (since 2023), the first systemic drugs have been approved in Europe. Psychosocial support is indicated in many patients.[5 6] The first German therapy guideline for AA is expected to be available in 2026.[7]

The prevalence of AA is about 1.6% worldwide[8] and 0.2% in Germany.[9] Few studies have been conducted on the care of AA patients. The statutory health insurance (SHI) data from the USA show that 44.2% of patients remained untreated after diagnosis[10] and that male gender patients were predicted to have fewer medical visits.[11] In the UK, access to care was influenced by gender, socioeconomic status, ethnicity and urban residence.[12] Patients reported high out-of-pocket costs.[13]

In Germany, the German Social Act V includes a 'lifestyle paragraph' excluding drugs from reimbursement by the SHI when they serve for improving hair growth. From the perspective of the Federal Joint Committee regulating details of healthcare in the SHI system, this applies to all forms of hair loss, including AA,[14] resulting in drugs for AA generally not being covered by the SHI. Hence, approved and evidence-based therapies such as JAK inhibitors are rarely used in patients with SHI status (constituting 89% of the German population)[15] but in markedly more patients who have private health insurance.

Thus, the quality of care for AA in Germany is suboptimal, and there seems to be an unmet need for adequate and equal treatment in this burdensome disease. This study, being part of the project 'Inequalities in access to medication for atopic dermatitis (AD) and AA in Germany: mixed-methods study (AMEDA)' (online supplemental file 1), aimed to analyse the healthcare situation of adult persons with AA in Germany by: (a) investigating potential barriers to adequate care and (b) identifying potential inequalities of access to care. Recommendations for action were to be derived from the results and addressed to the stakeholders in the German health system.

DESIGN

The mixed-methods study design combined qualitative interviews and claims data from a large nationwide German SHI.

Qualitative analyses

Online or telephone interviews were conducted between June 2022 and April 2023. We used a semistructured, pilot-tested interview guideline (online supplemental files S2 and S3) based on the research questions and the literature. If necessary, the guideline was adapted throughout the study to allow for integrating new aspects found in previous interviews and in the claims data analysis. The interviews were conducted by two female researcher associates (health scientists, M.Sc; BH, TMJ) experienced in conducting qualitative interviews through their university education and previous qualitative studies. We took a neopositivist philosophical position with a realist approach, meaning that we sought to approach objective reality.[16] Data collection and analysis were not theory-based.

Patients were recruited conveniently via a dermatological outpatient clinic, patient organisations and social media. Dermatologists were recruited from a nationwide network and the dermatological societies, representing >95% of professionally working German dermatologists. All participants gave written informed consent. Participants had the right to withdraw their consent at any time until pseudonymised data were anonymised. Only members of the study team had access to interview data and information on the participants. For patients, it was stated explicitly that non-participation had no influence on their treatment. The interviewers had no personal, professional or therapeutic relation with the interviewees, except for one dermatologist working at the same institute. Interviews introduced themselves, their background and the aim of the study prior to the interview. Recruitment stopped as soon as further interviews added no additional content, meaning that thematic saturation was reached. For this, we documented which categories were newly developed per interview. We defined thematic saturation to be reached once no new categories emerged on the two highest levels of the category system.

All interviews were audiorecorded and transcribed verbatim, in the process of which the interviews were pseudonymised. Data were analysed with MAXQDA V.24 (VERBI GmbH, Berlin, Berlin, Germany) using qualitative content analysis according to Kuckartz[17]: two researchers (BH, TMJ) formulated research questions and derived main categories from these. Afterwards, both researchers familiarised themselves with the interview transcripts and case summaries and categorised the first transcript jointly. Based on this, they revised the main categories. One researcher categorised three subsequent transcripts, and the categorisation was checked by the other. In the further categorisation, additional (levels of) subcategories were developed, if necessary. The category system was frequently discussed by the study team (BH, CB, TMJ).

Claims data analyses

The analysis was based on an anonymised 40% sample (n=2 513 860; 58.0% women, average age 55.1 years in 2020) of all persons (aged at least 18 years) who were insured for at least 1 day with the DAK-Gesundheit (DAK-G) between 01 January 2016 and 31 December 2020. Based on the guidelines and recommendations for ensuring good secondary data (good practice statements (GPS))

and good epidemiological practice (GEP), these data from the SHI system do not require an ethical vote or the consent of the insured persons.[18 19] This is because these data sets are based on existing data originally collected for other purposes. In addition, the data are anonymised, which prevents the identification of individuals and thus minimises the associated risks. The use of the project's database is well protected by legal and institutional regulations, such as the GPS and the GEP. These regulations ensure ethical and responsible use of the data.

Prevalent insured persons were considered to have AA (ICD-10 GM L63) if they had at least one confirmed outpatient or inpatient main or secondary diagnosis. Incident cases had to have a 3-year diagnosis-free period in 2020.[9]

The utilisation of outpatient care for prevalent AA was determined based on all physician contacts.[20] AA-related drug prescriptions (coded by the Anatomical Therapeutic Chemical definition system) and defined daily doses (DDD) or treatments (ambulatory doctors fee schedule (German: einheitlicher Bewertungsmaßstab, EBM)) were only recorded if an AA (online supplemental file S4, table S1) diagnosis was made in the same quarter.

In the sensitivity test, systemic antibiotics and their proportion of prescriptions in the total population were analysed to determine the population effect. The treatment history of AA patients was followed over four quarters using drug prescriptions. The proportion of outpatient psychotherapy (at least one prescription; online supplemental file S4, table S2) was compared between prevalent AA patients and other skin diseases (ICD-10 'L' diagnosis excluding L63). Hospitalisation rates for full and partial inpatient stays with a principal diagnosis of AA were also recorded.

The administrative estimates of period prevalence and incidence (annual) were expressed as percentages with 95% CIs and were standardised according to the German federal statistics institute DESTATIS as of 31 December for the observation year. Descriptive statistics and multivariate analysis methods were used according to the data level of variables. For comparative analyses, the data were adjusted for age, sex and federal state using 1:3 nearest neighbour propensity score matching (PSM). Logistic regression was used to compute propensity scores. Relative risks (RR) and 95% CI were calculated to assess differences between the comparison cohorts. The analyses were performed with SAS V.9.4 German (SAS Institute, Cary, North Carolina, USA).

Mixed-methods approach

Both types of data were collected and analysed in parallel to enable integrated analysis: The study team met on a monthly basis to discuss interim results of all parts of the study. Hence, patterns found in one study part were presented and possibilities discussed to investigate from these originating hypotheses in the other study part. As an example, we detected a high use of antibiotics in the claims data analysis. Accordingly, we asked dermatologists in interviews if they prescribe antibiotics for patients with AA and, if so, in which cases, and we probed this topic in interviews with patients.

The data were synthesised into an overall conclusion and from this, recommendations for action were derived.

Development of recommendations for action

Based on the results of all study parts, an expert meeting was held with two dermatologists, two patient representatives and four scientists (researchers responsible for analyses of qualitative and claims data). Within the meeting, recommendations for action to reduce inequalities in the care of patients with AA were developed.

Patient and public involvement

In the expert panel, members of a patient organisation participated to discuss results and develop recommendations. At the end of the project, all participants received a lay summary of the results.

RESULTS

Sample description and baseline characteristics

In the qualitative interviews (table 1), 20 patients and 14 dermatologists participated (duration 20–85 min).

For each patient and dermatologist, distinct category systems were established through qualitative content analysis. The category system was considered final when the last two participant interviews and the three last dermatologist interviews had revealed no new categories on the two highest levels of the category system. Main categories in patient data were 'healthcare' and 'life with AA'. Main categories derived from dermatologist interview were: 'healthcare stations', 'treatment' and 'reasons for visits at dermatologist'. For the full category system, see online supplemental file S5, tables S3 and S4.

According to claims data, the standardised prevalence of AA in 2020 was 0.23% (n=4692; mean age 55.8 years (SD 19.0, median 57); 76.2% women) and incidence was 0.09% (n=1565; 2019), corresponding to about 150 000 prevalent and 53 000 incident persons across Germany. The prevalence and incidence increased with age.

Treatments for AA

Following the claims data, 57.5% of the persons with AA received at least one drug prescription in 2020. Topical and systemic non-biological drugs were prescribed to 36.8% and 35.1%, respectively; among the topical drugs, 95.3% were TGCs (mostly class III and IV) and 11.1% received SGCs (table 2). Less than 0.02% (n=9) used JAKi inhibitors, namely tofacitinib and baricitinib (each 0.06%), ruxolitinib (0.04%) and upadacitinib (0.02%). Ultraviolet light (UV) therapy received 0.53% of the insured persons with AA in 2020 (0.78% in 2016), with selective phototherapy being the most common form of treatment. With 32.0% of insurees with AA receiving psychotherapeutic treatment, they were 19% (RR 1.19, CI

Table 1 Characteristics of patients and dermatologists participating in the interviews

	Mean (range)/n (%)	
	Patients (n=20)	Dermatologists (n=14)
Age (years)	40.7 (25–61)	48.4 (31–69)
Gender		
Female	15 (75.0)	7 (50.0)
Male	5 (25.0)	7 (50.0)
Education		
(Vocational) A-levels (12–13 years of education)	15 (75.0)	n.a.
10 years of education	3 (15.0)	n.a.
9 years of education	2 (10.0)	n.a.
Living/practicing*		
Baden-Wuerttemberg	3 (15.0)	1 (7.1)
Bavaria	4 (20.0)	1 (7.1)
Berlin	1 (5.0)	0 (0)
Hamburg	1 (5.0)	1 (7.1)
Lower Saxony	4 (20.0)	2 (14.3)
North Rhine-Westphalia	3 (15.0)	4 (28.6)
Rhineland-Palatine	1 (5.0)	4 (28.6)
Saxony	1 (5.0)	0 (0)
Saxony-Anhalt	0 (0.0)	1 (7.1)
Schleswig-Holstein	2 (10.0)	1 (7.1)
Insurance		
Statutory	19 (95.0)	n.a.
Private	1 (5.0)	n.a.
Duration of AA symptoms (years)	16.3 (0.25–51)	n.a.
Missing hair		
Scalp	54% (0.0–100%)	n.a.
Face/body	62% (0.0–100%)	n.a.
Employment situation*		
Practice	n.a.	10 (71.4)
Clinic	n.a.	5 (35.7)
Experience as dermatologist (years)	n.a.	19.7 (7–37)

*multiple answers possible.
AA, alopecia areata.

1.13 to 1.25) more likely to receive psychotherapy than persons with another skin disease (according to PSM).

The total prescription volume decreased continuously. The number of DDD dispensed fell from around 288 398 in 2016 to 2 33 264 in 2020. Only systemic biologics (ie, dupilumab) showed a slight increase from 1206 DDDs in 2018 to 2580 DDDs in 2020 (figure 1).

41.1% of the AA-related drugs were prescribed by general practitioners (GPs), 32.8% by dermatologists and 4.2% by internists. GPs prescribed antibiotics (65.6%), TGCs class I (63.4%), systemic antihistamines (53.4%), azathioprine (66.7%) and SGCs (50.4%) more often than dermatologists (figure 2). Dermatologists prescribed the majority of biologics (ie, dupilumab; 75.0%). A total of 27.3% of insured persons with AA received a systemic antibiotic, compared with 21.7% of the general population (all insured persons without AA).

In the qualitative data, patients reported the use of different *therapeutic options* including *local, systemic* and *further therapies* or products. Some patients *decided against therapy* (table 3, Q1.1), mostly due to experienced lack of improvement. Some reported the therapy was too time-consuming or was not likely to be successful (Q1.2). Female patients also reported ending treatment due to pregnancy.

Patients who received *topical therapies* reported different therapeutic success: in some patients, hair started growing again, while others did not see improvement.

Table 2 Alopecia areata (AA) related prescriptions in prevalent insured persons with AA and at least one drug prescription in 2020

Drug group	Drug therapy	Patients with AA diagnosis (N)	≥1 Rx (n)	≥1 Rx (%)	Total DDD	Mean Rx per patient	Mean DDD per patient
Total	Any therapy	4692	2701	57.57	233 305.49	2.67	86.38
Topicals	Total	4692	1726	36.79	121 928.74	1.85	70.64
	Antibiotics	1726	124	7.18	1117.01	1.18	9.01
	Antihistamines	1726	2	0.12	30.00	1.00	15.00
	Corticosteroids, dermatological preparations	1726	1644	95.25	117 745.80	1.78	71.62
	Group I	1726	41	2.38	1589.17	1.20	38.76
	Group II	1726	153	8.86	6312.73	1.35	41.26
	Group III	1726	1064	61.65	75 501.70	1.57	70.96
	Group IV	1726	454	26.30	26 499.54	1.50	58.37
	Corticosteroids, combinations with antiseptics	1726	28	1.62	592.00	1.18	21.14
	Corticosteroids, combinations with antibiotics	1726	117	6.78	1947.33	1.28	16.64
	Corticosteroids, other combinations	1726	97	5.62	5303.32	1.40	54.67
	Pimecrolimus	1726	51	2.95	1602.50	1.39	31.42
	Tacrolimus	1726	42	2.43	860.00	1.31	20.48
	Tars	1726	4	0.23	573.44	1.00	143.36
Systemics	Total	4692	1649	35.14	111 376.749	2.44	67.54
Biologics	Total - Dupilumab	4692	8	0.17	2579.56	4.50	322.45
Non-biologics	Total	4692	1644	35.04	108 797.189	2.42	66.18
	Methotrexate	1640	41	2.49	8829.95	3.41	215.36
	Mycophenolic acid	1640	7	0.43	1437.50	3.43	205.36
	Alitretinoin	1640	2	0.12	465.00	4.50	232.50
	Systemic antibiotics	1640	1283	78.04	21 484.73	1.74	16.75
	Systemic antihistamines	1640	142	8.64	15 380.99	1.89	108.32
	Azathioprine	1640	18	1.09	3249.99	4.83	180.55
	Cyclosporine	1640	4	0.24	530.00	8.50	132.50
JAKi	Janus kinase inhibitors (JAKi)*	4692	9	0.19	42.00	4.67	4.67
	Tofacitinib	9	3	33.33	1163.40	6.67	387.80
	Upadacitinib	9	1	11.11	120.00	2.00	120.00
	Baricitinib	9	3	33.33	735.00	3.00	245.00
	Ruxolitinib	9	2	22.22	317.34	5.50	158.67
GCS	Glucocorticosteroids (GCS)*	4692	520	11.08	57 377.03	2.21	110.34
	Prednisolone depot	520	6	1.15	92.50	1.17	15.42
	Triamcinolone depot	520	52	10.00	3705.96	1.13	71.27

Multiple counting was possible.
*Sub-type of non-biological treatment.
DDD, defined daily dose; Rx, prescription.

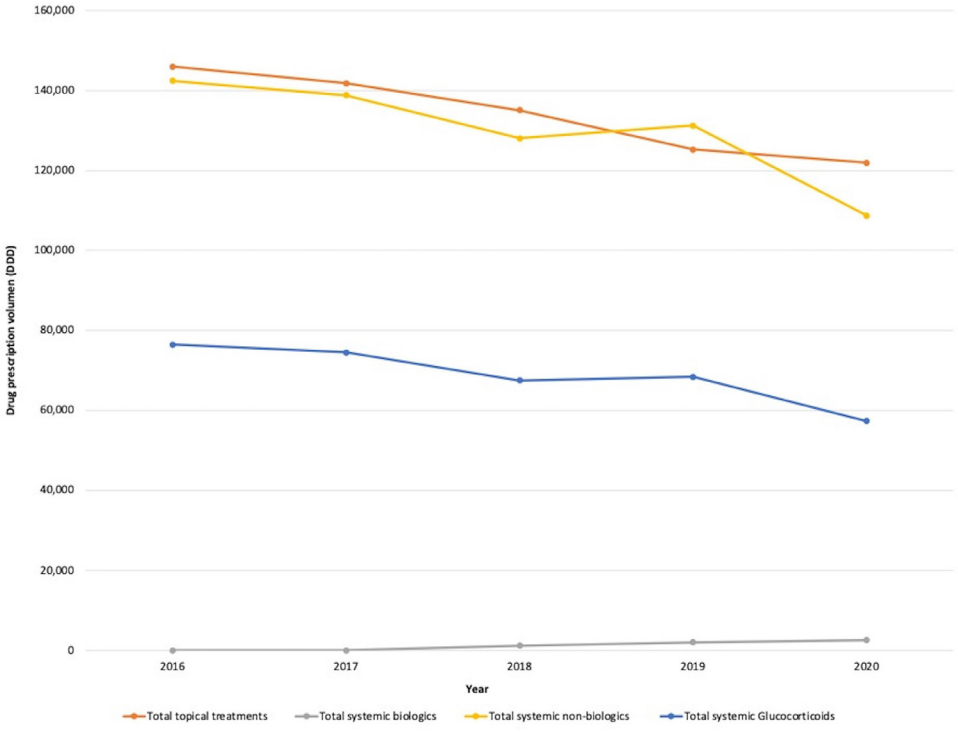

Figure 1 AA-related drug prescription volume (defined daily doses (DDD)) in prevalent adult persons with AA and at least one prescription from 2016 to 2020 by drug group (2016 n=3337; 2017 n=3294; 2018 n=3321; 2019 n=3045; 2020 n=2699).

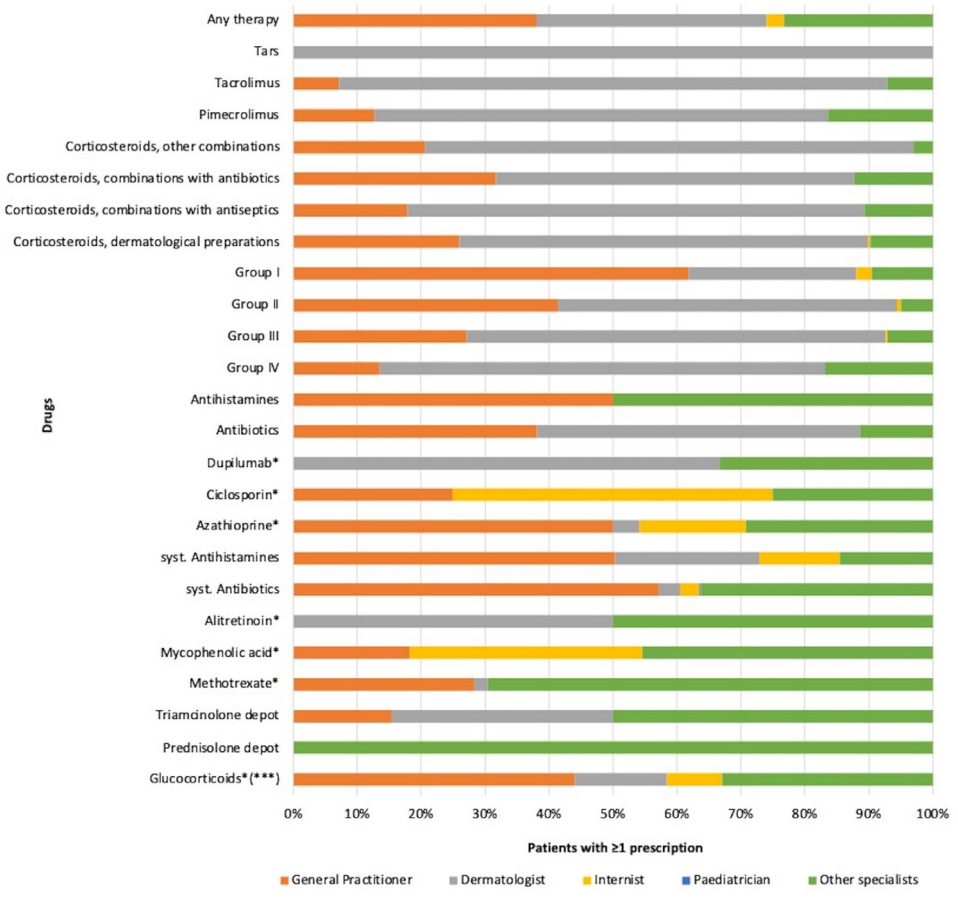

Figure 2 AA-related topical prescriptions in prevalent adult persons with AA with at least one drug prescription by prescriber in 2020 (n=1726); possible multiple counting; *Anti-inflammatory. *** Sub-type of non-biological treatment

Table 3 Quotes by patients and dermatologists referring to therapy options

Quote number	Quote	Participant
Q1.1	"No, except for taking zinc supplements, I don't do anything anymore. I let it [the hair] come and go."	Patient, female, 30–39 years
Q1.2	"I would have had to go to (city 8), I think every week or so (…)and that, um, I would not have managed in terms of time, to be honest. I then also heard, as soon as the treatment is finished, the hair will fall out again."	Patient, female, 50–59 years
Q1.3	"The wig I got quite early, without the wig I would feel very stigmatised, because I have neither the strength nor the self-confidence to walk around without hair on my head."	Patient, female, 30–39 years
Q1.4	"That worked well. I was symptom-free for a relatively long time. My hair stopped falling out.(…)Then it abruptly stopped working."	Patient, female, 20–29 years
Q1.5	"So it was always said [by the dermatologist]: change of medication. Let's look for something new. I didn't have much say in the matter."	Patient, female, 20–29 years
Q1.6	"I would have liked to have the possibilities, treatment options in more detail, in an overview,(…) but instead we get something different [different information] from every dermatologist"	Patient, male, 40–49 years
Q1.7	"If the patient has a high level of suffering, I would send him to the university hospital, with the idea of getting into a study, because there is currently a lot happening. In our practice, we don't do too much, I have to say."	Dermatologist, female, 30–39 years
Q1.8	"And with baricitinib, regarding the experience so far, you really have a great therapy option, but with the restriction that it is not reimbursed."	Dermatologist, male, 50–59 years
Q1.9	"Sometimes the wig is so well made that you don't even see it. (…) And they [the patients] are really happy. With the wig, you have to say, a new phase begins for them."	Dermatologist, female, 40–49 years
Q1.10	"But these are patients who have been to other places [physicians] and who are simply hoping that you will prescribe them a systemic therapy that you may not be able to get from other doctors. (…) I used to put a lot of work into asking the health insurance companies to cover it. (…) The answer is always: Yes, you can prescribe it, but it is a lifestyle medication"	Dermatologist, female, 40–49 years
Q1.11	"But for the patient, I think it's an agony. It [the DCP therapy] is very tedious and almost always leads to a relapse when they stop taking it."	Dermatologist, male, 60–69 years
Q1.12	"Of course, we have a number of patients where there is a spontaneous remission, who do not come back into the practice."	Dermatologist, female, 30–39 years
Q1.13	"What is important, patients must be educated well that this disease runs in relapses." This means that once we have brought on a 'cure', we cannot guarantee that a relapse will not occur at some point (…)"	Dermatologist, male, 40–49 years
Q1.14	"But they are actually/do what we recommend. (…) I always explain to them that theoretically you can also just wait. (…) But they are very willing to undergo therapy"	Dermatologist, female, 40–49 years

Many reported wearing headgear (Q1.3), having permanent make-up or using specific shampoos. Furthermore, patients reported lifestyle changes to improve hair growth.

For *systemic therapies*, patients reported the use of immunosuppressants (Q1.4), oral or intralesional systemic corticosteroids and (in few patients) JAKis and biologics through participation in a clinical study or as an off-label therapy. The patient with JAKi reported improvement of symptoms.

Most patients reported *having tested various therapies and products*, including prescribed therapies and over-the-counter products or home remedies. They also mentioned *critical aspects regarding therapy*: most patients were frustrated because of few therapeutic options. When receiving treatment, many felt a lack of shared decision-making (Q1.5). Many reported scepticism towards medication and side effects. This scepticism includes a general scepticism not only against conventional medicine but also towards JAKi. Some patients criticised the exclusively symptomatic treatment and that no long-term improvement was achieved. Some wanted their practitioner to provide more information about the disease and therapy options (Q1.6). The most discussed aspects regarding therapy options were *costs and external conditions*. Patients reported major differences in cost reimbursement between different SHIs and criticised that their insurance did not pay for the necessary equipment (eg, wigs).

The dermatologists reported that they usually start treatment with *local therapies*, mostly TGCs. Most dermatologists

also mentioned therapies with diphenylcyclopropenone or platelet-rich plasma as treatment options; however, only a few reported using these in practice. Also, both therapies could only be offered as privately paid treatments. Other local therapies were TCI and UV therapy.

Dermatologists also reported offering *new therapies* to patients, namely JAKi or immunomodulating therapies as off-label therapies. Study inclusion was reported as another possibility to offer persons with AA access to modern treatments (Q1.7). Regarding *systemic therapies*, SGCs were described as a short-term, acute treatment. Dermatologists described JAKi as a very effective treatment (Q1.8), but as only a theoretical therapeutic option in Germany. As a treatment to '*simply stop this acute phase of the disease*' (dermatologist, male, 60–69 years), immunosuppressants such as cyclosporine and methotrexate, as well as minoxidil, were reported. Finally, dermatologists described that patients were often content with using *wigs and other supportive devices* (Q1.9), and some patients did not require or want any additional treatment.

Dermatologists also reported *issues regarding the therapy*, notably the overall limited therapy options, especially for those working in office-based practice. The second major aspect was the lack of reimbursement by the health insurances (Q1.10). Further issues were recurrence after treatment end (Q1.11) and non-respondence to therapies.

Almost all dermatologists reported *spontaneous remission* in many patients with mild AA. They encouraged these patients to wait and document the symptoms (Q1.12).

An important aspect of AA treatment was *patient involvement*, which could be achieved through *patient education* (Q1.13) or by considering *patient preferences*. Dermatologists reported overall high levels of *adherence* (Q1.14).

Life with AA

Patients reported their *symptoms* describing different severity of hair loss ranging from a few bald spots to total hair loss; most had severe AA, including some with a long disease history. Few patients had experienced a *spontaneous remission*. Some reported *co-morbidities*, including allergies, bronchial asthma and other autoimmune diseases or a *family history of AA*.

Few patients reported *no obvious trigger*; most patients assumed their AA to be triggered by different factors such as *stress*, for example through work (table 4, Q2.1), private life or relationships. Few patients had experienced their

Table 4 Quotes by patients referring to life with alopecia areata (Q2) and quotes by patients and dermatologists referring to patient pathways and healthcare disparities (Q3)

Quote number	Quote	Participant
Q2.1	"It started in 2015, a circular spot at the back of the head (…), I wanted to quit my job at the time and was afraid to tell my boss and I think that was the stress."	Patient, female, 30–39 years
Q2.2	"With approaching winter (…) I already notice that the head hair is also thinner and not as good. (…) And in summer it grows again."	Patient, female, 40–49 years
Q2.3	"I'm feeling fine with it so far, in the sense that I have accepted it."	Patient, male, 40–49 years
Q2.4	"For me in my everyday life, this disease plays no role in this sense, (…) I am fine."	Patient, female, 20–29 years
Q2.5	"What interests me now is whether I can influence it (…) by my actions, by my way of life, because although I have accepted it (…), I would like to understand it."	Patient, male, 40–49 years
Q3.1	"I would say if I didn't need the prescription [for the wig], I wouldn't go there at all."	Patient, female, 50–59 years
Q3.2	"I would say that pharmacists are not really educated about AA. I don't think they would suggest anything to you on their own."	Patient, female, 20–29 years
Q3.3	"I started the therapy and that simply helps to focus on this stress management and partly also these fears that go along with it, to learn strategies."	Patient, female, 30–39 years
Q3.4	"(…) to see the psychosocial side of this disease, that is not just your hair falling out, but what it does to the people and that would, I would just wish that (…) that is also addressed and is also dealt with sensitively with those affected, that they feel taken seriously."	Patient, female, 20–29 years
Q3.5	"He was very empathetic. He explained well that you really can't do much."	Patient, female, 20–29 years
Q3.6	"The dermatologists were very overwhelmed here in the area."	Patient, female, 20–29 years
Q3.7	"If this attempt has brought no success over weeks, months, then the dermatologist in private practice usually stops the treatment. (…) And that is actually when the normal topical steroid has failed, that the patient is then referred to us [a university]. hospital."	Dermatologist, male, 40–49 years

first symptoms after an *infection*. Several female patients reported changes in their symptoms (both increased and reduced) in relation to *physical or hormonal changes* such as pregnancy, miscarriage or breast feeding. Some patients experienced a *seasonal influence* on symptoms (Q2.2). Of these, all but one reported hair growth in spring/summer and hair loss in autumn/winter.

Information and exchange with other patients were very important for the participants, making use of social media, patient support groups or other ways of connecting with other patients. Some reported searching for new research results online. Few patients said they did not want or need exchange with other patients.

Patients have found different ways of *handling their disease*. Some patients reported having *accepted the disease* (Q2.3, Q2.4). Others talked about the *mental burden*, ranging from "*of course, mentally you're not doing so great*" (female patient) to severe depression and suicidal thoughts. The *visibility* of the disease was a severe burden for many patients. They described *resignation/frustration*, *feeling uncomfortable* and *desperate* or *repressing* thoughts about their AA.

Some patients described wanting to *understand the causes* of their disease and how to influence its progression (Q2.5); some *hoped for a spontaneous remission*.

Patient pathways

In the qualitative interviews, for the initial examination of the AA, generally including blood tests, some patients visited a dermatologist while others first saw a GP. After this, the GP was mostly no longer a relevant provider for AA treatment. Visits at the dermatologist mostly happened as needed (table 4, Q3.1), while some patients saw their dermatologist regularly for the monitoring of the disease/therapy progression. Some patients visited specific dermatological consultations for hair loss. Pharmacies were only used by patients to pick up prescribed therapies (Q3.2). Most patients had made use of alternative options, including visits to homoeopaths or acupuncture therapy. Most of these patients reported no improvement in their symptoms, and some mentioned the high costs of alternative providers; however, some appreciated that, "*you are perceived quite differently. Of course, they have a completely different time register for you*" (female patient). Some patients attained psychological care, mostly looking for help in handling their disease (Q3.3) but also hoping to reduce stress and improve the symptoms.

Most patients criticised a lack of empathy or felt like they were not taken seriously by the physician (Q3.4). However, some reported being taken seriously and appreciating the dermatologists' empathy and honesty (Q3.5). Some patients experienced a lack of competencies or expert knowledge (Q3.6) and therefore saw multiple different dermatologists. Patients mostly reported long waiting times until their appointment and difficulties finding good physicians.

Dermatologists reported that patients usually first visit GPs or dermatologists. GPs would usually do routine blood tests to exclude other diagnoses and then refer the patient to dermatologists. Patients with a long or complicated disease history are often referred to university clinics or specialised outpatient clinics (Q3.7). Inpatient clinic visits were reported to play a minor role. Furthermore, dermatologists reported that some patients used over-the-counter products from the pharmacy, for example, shampoos against hair loss. Few mentioned suggesting the option of psychological support to patients.

Alternative medical options were mentioned by some dermatologists but reported that patients with AA generally make less use of these compared with other patient groups. Dermatologists also reported that information and exchange with other patients was important for many patients.

In 2019, 53.3% of the 1565 patients with AA initially received prescriptions for AA. In the first quarter, 70.5% were treated by dermatologists and 31.5% by GPs, with 47.7% receiving prescriptions, falling to 39.6% in the third quarter. In the fourth quarter, the proportion of patients treated by GPs rose to 53.5%, while the proportion treated by dermatologists fell to 27.0% (figure 3).

The proportion of persons with AA having received systemic non-biologic drugs increased by age (table 5). The user rate of topical treatment was significantly higher in women (26.2%; p<0.001) and those from urban areas (26.5%; p =0.002). Dermatologists prescribed topical and biological drugs more frequently (63.7%; 75.0%; each p <0.001), whereas GPs prescribed systemic non-biologics, especially GCs more frequently (60.3%; 48.1%; p <0.001).

Recommendations for action

In the expert meeting, recommendations for action to reduce barriers of access and/or inequalities in the healthcare of patients with AA were developed. The English translation on the recommendations for action can be found in online supplemental file S6. In the following, a summary is provided.

1. Evidence of poorer healthcare for patients with SHI: to ensure that patients with SHI receive the same level of care as those with private health insurance, we recommend that the German legislation body (Bundestag) recognises AA as a relevant autoimmune disease instead of classifying it as a lifestyle disease.
2. Evidence of regional differences in the quality of care: the data show that dermatologists need more information on AA to provide adequate care. We recommend the development of a platform on AA that presents data on current scientific results; this platform could also be helpful for patients and might empower them by being well-informed about their disease.

DISCUSSION

This mixed-methods study analysed the healthcare situation of adult persons with AA in Germany and investigated potential inequality, in particular regarding medication;

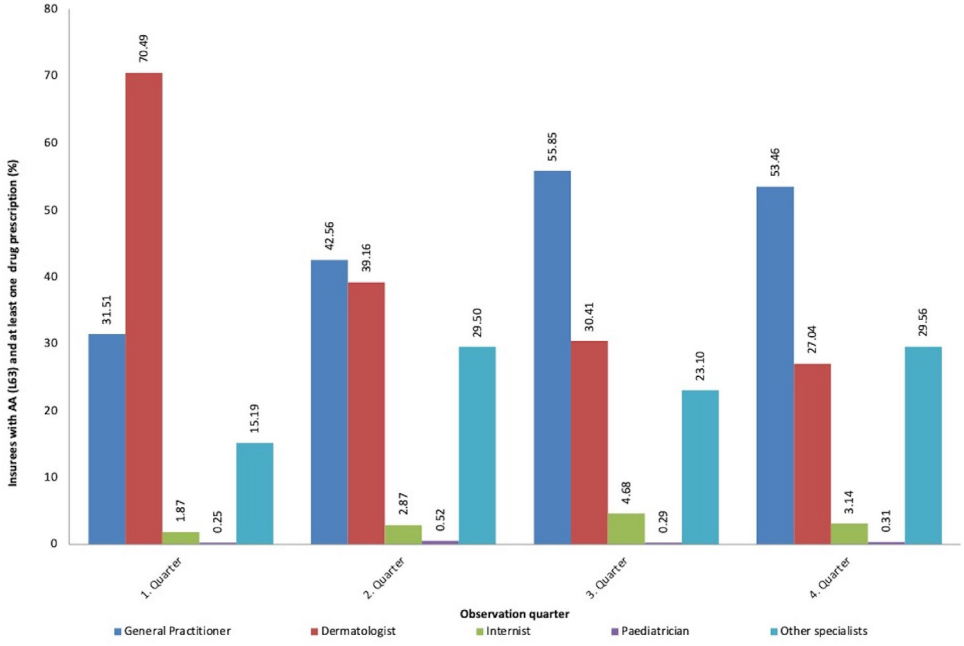

Figure 3 Distribution of specialties treating incident adult persons with AA in 2019. Persons with at least one AA-related drug prescription were included (quarter 1 n=803; quarter 2 n=383; quarter 3 n=342; quarter 4 n=318). Washout for incidence assessment: 3 years. Note: the first observation quarter corresponded to the quarter in which the medication was prescribed.

from the study results, recommendations for action were derived.

Both the SHI data and the qualitative data reveal a large gap in healthcare for persons with AA in Germany. Concordantly, they show that there is much less use of advanced therapies for AA as recommended. Baricitinib and ritlecitinib show efficacy in treatment[1] but have only been approved in 2022 and 2023 and, hence, after the time period represented by the claims data analysed for this study. At this time, these and other JAKis might have

Table 5 Subgroup analyses of prescribed treatment groups in prevalent adult persons with alopecia areata in 2020 (n=4692)

Treatment	Topicals	Systemic biologics	Systemic non-biologics	Systemic GCS*
Age (years), p value	**<0.001**	0.158	**<0.001**	**<0.001**
Up to 30, n(%)	**393 (7.9)**	2 (0.0)	**250 (5.0)**	**44 (0.9)**
> 30–45, n(%)	**377 (7.6)**	1 (0.0)	**285 (5.7)**	**64 (1.3)**
> 45–65, n(%)	**590 (11.9)**	5 (0.1)	**576 (11.6)**	**207 (4.2)**
> 65, n(%)	**499 (10.0)**	0 (0.0)	**611 (12.3)**	**215 (4.3)**
Gender, p value	**<0.001**	0.471	**<0.001**	**<0.001**
Male, n(%)	**559 (11.2)**	4 (0.1)	**370 (7.4)**	**82 (1.6)**
Female, n(%)	**1300 (26.2)**	4 (0.1)	**1352 (27.2)**	**448 (9.0)**
Insurance district types, p value	**0.002**	0.272	0.723	0.588
Urban, n(%)	**1315 (26.5)**	4 (0.1)	1176 (23.7)	365 (7.3)
Rural, n(%)	**543 (10.9)**	4 (0.1)	543 (10.9)	163 (3.3)
Specialist, p value	**<0.001**	**<0.001**	**<0.001**	**<0.001**
None of both, n(%)	**131 (7.0)**	**2 (25.0)**	**523 (30.4)**	**187 (35.3)**
General practitioner, n(%)	**367 (19.7)**	**0 (0.0)**	**1038 (60.3)**	**255 (48.1)**
Dermatologist, n(%)	**1184 (63.7)**	**6 (75.0)**	**116 (6.7)**	**80 (15.1)**
Both n(%)	**177 (9.5)**	**0 (0.0)**	**45 (2.6)**	**8 (1.5)**

Bold values display significant differences.
*Subtype of non-biologics.
GCS, glucocorticosteroid.

been only prescribed as off-label treatment. Our qualitative results confirm that prescribing advanced therapies still remains challenging due to the lack of reimbursement through the SHIs, which originates from the exclusion of drug treatments for AA by the Germans Social Act, which is based on a false interpretation of the terms alopecia (hair loss) and 'drugs improving hair growth' by the legislators. The intention was to exclude reimbursement of treatments for simple hair loss as caused by androgenetic alopecia, a common and harmless disease. The legal process by the German parliament failed to consider that AA is a distinct severe immune disease with a different pathogenesis, disease course, phenotype and disease burden. Being associated with a multitude of other immune-mediated diseases and autoimmune conditions, it needs stringent diagnostics and consequent treatment. The exclusion of such treatments thus violates the imperative of the German Social Act to provide support for persons with severe health conditions. Another reason for low prescribing rates might be the discussion about long-term safety of these new drugs. JAKis were approved in the years before baricitinib received a black box warning[21] and Alert warning[22] ('Rote Hand Brief'; BfARM Germany) which derived from data for the pan-JAKi tofacitinib in high treatment doses for patients with rheumatoid arthritis or colitis. These analyses were used for generalised warnings about increased risk of blood clots, serious heart-related events or cancer for several JAKis,[23] although their mode of action and targeted enzymes are different, for example, baricitinib selectively and reversibly binds to JAKi1 and JAKi2, whereas its effect on JAKi3 or Tyrosin kinase 2 (TYK2) is low.[24 25] This will be under investigation and a closer look for all further safety analyses, but it created an alerted atmosphere for prescribers.

While expensive innovative drugs are not reimbursed, health insurances tend to pay for cheaper, often topical treatments. As in other dermatological diseases,[26] lower potency TGCs were mostly prescribed by GPs and higher potency TGCs by dermatologists. Additionally, in persons with AA, GPs might be hesitant to prescribe higher dosed medication due to limited research and experiences. While in the interviews, GPs were often mentioned as the first contact person but considered as not relevant in the treatment process, claims data showed that the number of patients contacting GPs increased over time. Throughout the observation period following the initial AA diagnosis, there was a notable decline in the prescription volume, from 48% in the first quarter to 40% in the third quarter. The results are in accordance with the findings from the USA, which indicated that 44% of individuals with AA were not prescribed treatment in the year following diagnosis.[10] This corresponds to reports about resignation and ending treatment in case of lacking improvement. The participants emphasised their frustration with the lack of treatment options and sometimes inadequate knowledge by their healthcare provider. This may result from AA being a predominantly visual diagnosis. While patients expect to undergo more detailed examinations in the hope of finding triggers, once diagnosis has been confirmed, the patient is often left with regular monitoring, which might cause frustration.

Similar to previous findings,[27 28] patients reported high mental burden. A study on younger adolescents identified feeling isolated and being self-conscious as psychological strain for patients. AA was regarded as more than just hair loss, and unpredictability regarding whether hair would grow was seen as a difficult experience. [29]Also, claims data show a higher probability of using psychotherapy compared with other skin diseases. Therefore, the mental health of people with AA should be considered, and physicians should be made aware of this issue. Psychological interventions might not only help patients to cope with their disease but also improve AA through reduced stress levels of patients.[30]

Patients in the qualitative study part often reported lacking empathy and understanding by healthcare providers. This is in line with a previous study, which identified the need for more information and addressing the emotional impact in young patients.[29]

We found higher prevalence and higher therapy prescription in women. A possible reason is that women might be more sensitive to hair loss than men due to cultural factors. Furthermore, treatment prescription grows with age. Patients in urban areas receive more topical medication. This might confirm considerations in the qualitative interviews that dermatologists in rural areas often lack knowledge about AA treatment or are worried about reimbursement. Additionally, long travel distances might reduce the acceptance of therapies requiring regular physician visits. Surprisingly, a marked proportion of patients received prescription drugs attributable to AA, though they are legally excluded from reimbursement. Two reasons may contribute to this: low-cost drugs may not be queried by the payers and thus are tolerated in spite of the ban. Second, further diagnoses may have been used to hide the use of drugs for an indication not covered by the SHI. For example, patients with comorbid rheumatism might receive JAKis more often, as in these indications, advanced therapies are more likely to be remunerated. This might also explain why JAKis were not prescribed by dermatologists in our claims data set.

As part of this study, recommendations for action to reduce health disparities were developed. First, the expert panel recommended recognising AA as an autoimmune disease instead of classifying it as a lifestyle disease. Through this recognition, all patients will be able to receive adequately reimbursed care. This would reduce the patient burden and improve the healthcare situation significantly. Second, the expert panel outlined the differences between urban and rural areas. Physicians should be better informed about AA, its treatment options and options for reimbursement and study inclusion; this should be done through an independent platform that informs about scientific results. The current development of treatment guidelines for AA will also help inform

physicians better to enable providing adequate care for patients.

The major strength of our study is the mixed-methods design, which allowed us to generate additional research questions. Furthermore, the combination of the different results enabled a more comprehensive interpretation. Due to the nature of qualitative data, no quantitative assumptions can be made and results are not generalisable to the wider public. In the interviews, only German-speaking participants could participate, which excludes the experience of non-German speaking patients in the German healthcare system. Additionally, even though we recruited participants in different settings (dermatology clinics, patient organisation, social media), patients with higher severity, better online access and more engaged patients are most likely to participate, whereas patients with only light symptoms are likely to be underrepresented in the qualitative data. Claims data cover all patients who have received healthcare covered by the respective SHI, and they allow for an objective quantification of the healthcare received. Even if claims from private insurance are not included, the SHI covers about 90% of the population in Germany and thus provides an extremely robust and representative data base.[31] Its breadth and depth allow reliable statements to be made about the realities of healthcare in Germany, even though privately insured persons are not included. For example, there are differences between the groups of people insured by the various health insurance funds.[32] To minimise these differences, the prevalence rates have been adjusted for age and sex. However, only services that are reimbursed by the SHIs are recorded. Therefore, data on privately paid services are not collected. In addition, the proportion of patients with AA could be overestimated or underestimated, for example, due to insufficient or inadequate differential diagnoses, misclassifications or coding behaviour of the practitioner. To account for this, we used validity criteria such as confirmed outpatient diagnoses.

Overall, this study provides important new data on the healthcare of persons with AA. By including interviews with patients and dermatologists and linking these with quantitative data, we draw a wide picture on the current healthcare of patients with AA. We were also able to show that the treatment conditions need to be improved through the health insurance to provide adequate care to all patients. Finally, the recommendations for action that we developed based on our study results aim to reduce disparities in healthcare.

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Patient and public involvement Patients and/or the public were not involved in the design, conduct, reporting or dissemination plans of this research.

Patient consent for publication Not applicable.

Ethics approval This study involves human participants and the study has been approved by the Local Ethics Committee at the University Medical Center Hamburg-Eppendorf (LPEK-0427). Participants gave informed consent to participate in the study before taking part.

Provenance and peer review Not commissioned; externally peer reviewed.

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