ORIGINAL REPORT

Epidemiology and Comorbidity of Vitiligo in Germany: A Claims Data Analysis

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Vitiligo is a chronic skin disease resulting in destruction of melanocytes and loss of pigmentation. Little is known about epidemiology and comorbidity in Germany. This retrospective cohort analysis used nationwide statutory health insurance data (2016 to 2020). Disease rates were calculated using varying case definitions. Comorbidity was assessed against 3 control groups: persons without vitiligo, with atopic dermatitis, and with psoriasis (1:3 propensity score matching). In 2020, 4,631 persons were diagnosed with vitiligo in DAK-Gesundheit (DAK-G, mean age 56.93 years, ~148,437) and 5,820 persons in the German Analysis Database for Evaluation and Health Services Research (~144,855). Prevalence ranged from 0.12% (confidence interval [CI] 0.12–0.12) to 0.20% (CI 0.19–0.20), and incidence from 0.04% (CI 0.03–0.04) to 0.06% (CI 0.06–0.06). Rates increased with age. Women (mean age 58.60 years) were more frequently affected. Vitiligo was associated with alopecia areata (relative risk 7.14, CI 4.63–11.00) and systemic sclerosis (relative risk 3.20, CI 1.58–6.47). Several mental illnesses (depression: relative risk = 1.23, CI 1.15–1.32, anxiety: relative risk = 1.32, CI 1.19–1.47), were linked to skin diseases like vitiligo, atopic dermatitis, or psoriasis. Vitiligo affects a notable proportion of the population, with detected comorbidities supporting prior findings. To ensure reliable results, claims data should be validated through primary data linkage or sensitivity testing.

Key words: prevalence; incidence; skin diseases/epidemiology; insurance claim reporting.

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SIGNIFICANCE

Vitiligo is more than just a cosmetic problem. Our study, based on 2 large data sets, sensitive case definitions, and matched comparison groups provides reliable epidemiological case numbers for vitiligo and associated comorbidities for the first time. We show that vitiligo affects many people and is often associated with other health problems such as hair loss, certain autoimmune diseases, and diabetes, but also with psychological distress such as depression or anxiety. These new findings help to better understand the full extent of the disease and underscore the need for more comprehensive, holistic care for those affected in our society.

Vitiligo is a chronic skin disease leading to progressive destruction of melanocytes and thus loss of pigmentation (1). The global prevalence of vitiligo is estimated to be between 0.2% and 2% (2–4). A systematic review based on secondary data reports a prevalence of around 0.4% (95% confidence interval (CI) 0.37–0.44), while an earlier review of studies on children, adolescents, and adults describes a similar range of 0.1–2% (2, 3). In Germany, analyses based on statutory health insurance data (SHI-Data) show a prevalence ranging from approximately 0.17% to 0.77%. Reliable population-based incidence estimates for Germany specifically are not yet available (5). The range of prevalence may be due to study design and study populations, such as hospital populations, cases of chemical and toxic depigmentation, working adults or employees. To identify insured persons with diseases using SHI data, the validity of the case definitions and wash-out times must be analysed and compared with other data sources (6). Although previously published studies have provided valuable and well-documented stratified prevalence estimates for vitiligo, given the use of SHI data there is still a need for internal and external validation to account for potential unmeasured confounders and to ensure the robustness and generalizability of the results (5).

International studies report associations between vitiligo and dermatological and autoimmune comorbidities (5, 7, 8). Vitiligo is also associated with stigmatization, impaired quality of life and psychosocial comorbidities (especially depression and anxiety) (9–13). To our knowledge, there is currently no comprehensive, population-based data on comorbidities of vitiligo in Germany – with the exception of a few studies that are limited to dermatological comorbidities (5).

The paucity of literature and inconsistent results highlight the need for a more comprehensive understanding of the epidemiology and comorbidity of vitiligo in Germany in order to determine the socioeconomic burden

of the disease. Hence, this study aimed to obtain valid and reliable estimates of the prevalence, incidence,, and comorbidity of vitiligo in the general population using routine data from the German SHI system. Different case definitions were used to get more robust and valid results.

METHODS

Study design and population

This retrospective, cross-sectional health services research study was based on anonymized routine data from 2 German health insurance companies: first, from the DAK-Gesundheit (DAK-G) (n=5.9 million members respectively in 2019) with a random 40% sample of all persons who were insured for at least 1 day between 2016 and 2020 (n=2.9 million) and second: from the German Analysis Database for Evaluation and Health Services Research (DADB) (n=3.2 million). The analyses were conducted based on the availability of data and access windows. This covered the period from 2016 to 2020 for the DADB and DAK-G data.

Case definition

The study population had to be continuously insured in the respective calendar and observation years (and preceding year for incidence assessment). Persons who died during the observation period were not excluded from the analyses. All epidemiological measures were estimated according to the German Institute for Medical Documentation and Information ICD-10-GM.

The identification of insured persons with vitiligo (ICD-10-GM L80) in Germany was based on at least 1 relevant and confirmed diagnosis during outpatient and inpatient care (case definition 1) in 2016 to 2020. Outpatient diagnoses and inpatient secondary diagnoses were also determined in 2 quarters of 1 year (case definition 2) and over a 3-year period (case definition 3, only with DAK-G data). For inpatient primary diagnoses, 1 diagnosis was sufficient for all case definitions.

The annual incidence corresponded to the number of insured persons without a diagnosis (wash-out time) from 1 year to 4 years before the year of observation, to reduce misclassification of prevalent cases and assess robustness under different lookback assumptions. Incidence cases were counted as such as soon as a diagnosis was available in the year of observation. In the DAK-G data case, the incidence rates were also calculated on a quarterly basis (8, 12, or 16 quarters before the respective incidence quarter).

Comorbidities of vitiligo

A team of 4 healthcare professionals, consisting of nurses and physicians, defined 115 relevant comorbidities of vitiligo based on a literature review and clinical expertise (Table SI). Prevalences of these comorbidities were calculated for 2020 and based on DAK-G data. Comparison cohort 1 comprised individuals without a vitiligo diagnosis. Cohorts 2 and 3 were individuals with atopic dermatitis (ICD-10-GM L20) and psoriasis (ICD-10-GM L40) respectively and were defined in the same way as the vitiligo cohort. In cohorts 2 and 3, we excluded persons with vitiligo. To ensure comparability between the cohorts, all comorbidities were determined uniformly according to case definition scheme 1.

Statistics

Annual prevalence and incidence rates were expressed as percentages with corresponding 95% Wilson CI for the years of observation, which were determined taking age and gender into account (14). The numerator of the estimator was the number of insured persons in the exposed cohort. The denominator consisted of all continuously insured persons in the sample. In addition, the rates were standardized by age and sex for persons in the SHI in Germany (KM6 statistics) on 31 December of the respective year (direct standardization). The standardized prevalence was extrapolated by multiplying it by the KM6 population size (95% uncertainty intervals were derived from the 95% CI of the prevalence). Basic characteristics (age, sex, and comorbidities) were analysed and presented descriptively, as percentages for categorical variables and as medians and ranges for continuous variables. The comparison cohorts were exact-matched by age and sex using the 1:3 nearest neighbour method without caliper on the logit of the propensity score (propensity score matching [PSM], with replacement). Logistic regression was used to generate the required propensity score (PS). Relative risk (RR) and 95% CI represented differences between the comparison cohorts. All analyses were performed with SAS v. 9.4 (SAS Institute, Cary, NC, USA).

RESULTS

Prevalence of vitiligo

In 2020, the standardized prevalence rate of vitiligo for case definition 1 was 0.19% (CI 0.19–0.20) in the DAK-G data and 0.20% (CI 0.19–0.20) in the DADB data. It remained stable throughout the observation period. Case definition 2 showed a decreased standardized prevalence rate of 0.12% (DAK-G: CI 0.12–0.12; DADB: CI 0.12–0.13). Case definition 3 showed a standardized prevalence rate of 0.15% (CI 0.15–0.16) in the DAK-G data (**Table I**). This prevalence range corresponds to ~88,473 and ~148,855 insured persons in the German population.

In DAK-G, prevalence increased with age and decreased slightly after the age of 80 years (**Fig. 1**). The highest prevalence rate of vitiligo (case definition 3) occurred in the 75 to <80 age group (total: 0.44%, 2016–2020). Overall, the cohort included 63% women,

Table I. Standardized prevalence rate of persons with vitiligo by case definition over the observation years 2016 to 2020

	Case definition 1 (≥ 1 diagnosis in 1 quarter per year)				Case definition 2 (≥ 1 diagnosis in 2 quarters per year)				Case definition 3 (≥ 1 diagnosis in 2 quarters within 3 years)	
	DAK-G[1]		DADB[2]		DAK-G[1]		DADB[2]		DAK-G[1]	
Year	Rate (%)	CI	Rate (%)	CI	Rate (%)	CI	Rate (%)	CI	Rate (%)	CI
2016	0.19	0.18–0.19	0.19	0.19–0.20	0.11	0.11–0.12	0.11	0.11–0.12	–	–
2017	0.19	0.19–0.20	0.20	0.19–0.20	0.12	0.11–0.12	0.12	0.11–0.12	–	–
2018	0.20	0.20–0.21	0.21	0.21–0.22	0.12	0.12–0.12	0.12	0.12–0.13	0.15	0.15–0.16
2019	0.20	0.20–0.21	0.21	0.20–0.21	0.12	0.12–0.12	0.12	0.12–0.13	0.16	0.15–0.16
2020	0.19	0.19–0.20	0.20	0.19–0.20	0.12	0.12–0.12	0.12	0.12–0.13	0.15	0.15–0.16

[1]Deutsche Angestellten-Krankenkasse Gesundheit. [2]German Analysis Database for Evaluation and Health Service Research.
CI: confidence interval, mean age in 2020 56.93 (SD 20.77, DAK-G); DAK-G: population 2016 *n* = 2,334,946; 2017 *n* = 2,311,115; 2018 *n* = 2,292,468; 2019 *n* = 2,273,022; 2020 *n* = 2,258,836, Persons with vitiligo (case definition 1): 2016 *n* = 4,662; 2017 *n* = 4,705; 2018 *n* = 4,932; 2019 *n* = 4,866; 2020 *n* = 4,631.
DADB: population 2016 *n* = 2,847,480; 2017 *n* = 2,907,334; 2018 *n* = 2,982,573; 2019 *n* = 3,009,703; 2020 *n* = 2,981,155, Persons with vitiligo (case definition 1): 2016 *n* = 5,422; 2017 *n* = 5,669; 2018 *n* = 6,208; 2019 *n* = 6,148; 2020 *n* = 5,820.

who had the significantly highest standardized prevalence rates between the ages of 45 and 80 (case definition 3: women 0.17% CI 0.16–0.17 vs men 0.14% CI 0.13–0.14 in 2020). Case definition 1 and case definition 2 showed similar distributions of prevalence by age and gender.

Incidence of vitiligo

The standardized incidence rates were 0.06% (CI 0.06–0.06; DAK-G) and 0.06% (CI 0.06–0.07; DADB) for the wash-out time of 1 year in 2020, with a slight decrease from 2016. For the wash-out time of 3 years, the incidence changed only marginally to 0.04% (CI 0.04–0.04) in the DAK-G data and 0.05% (CI 0.04–0.05) in the DADB data. In terms of the wash-out times of 2 and 4 years, however, no difference was found in the incidence estimate (**Table II**). Extrapolated to the German SHI population, this corresponds to ~26,100 to ~46,670 incident cases.

The sensitivity analyses at quarterly level (in DAK-G) showed an overall higher standardized incidence rate compared with the annual level (2020: wash-out time of 1 year [0.08% (CI 0.08–0.08)], wash-out time of 2 years [0.05% (CI 0.05–0.05)]). No change was observed for the other wash-out times.

The incidence of vitiligo stratified by age and sex for wash-out time of 2 years in 2020 (Table II) showed a similar distribution pattern to the prevalence rate (**Fig. 2**). Persons aged between 75 and < 80 years had the highest incidence rate of 0.09% (CI 0.09–0.09). In contrast, the lowest incidence rate was observed in the age group 25 to <30 years, with rates of 0.03% (CI

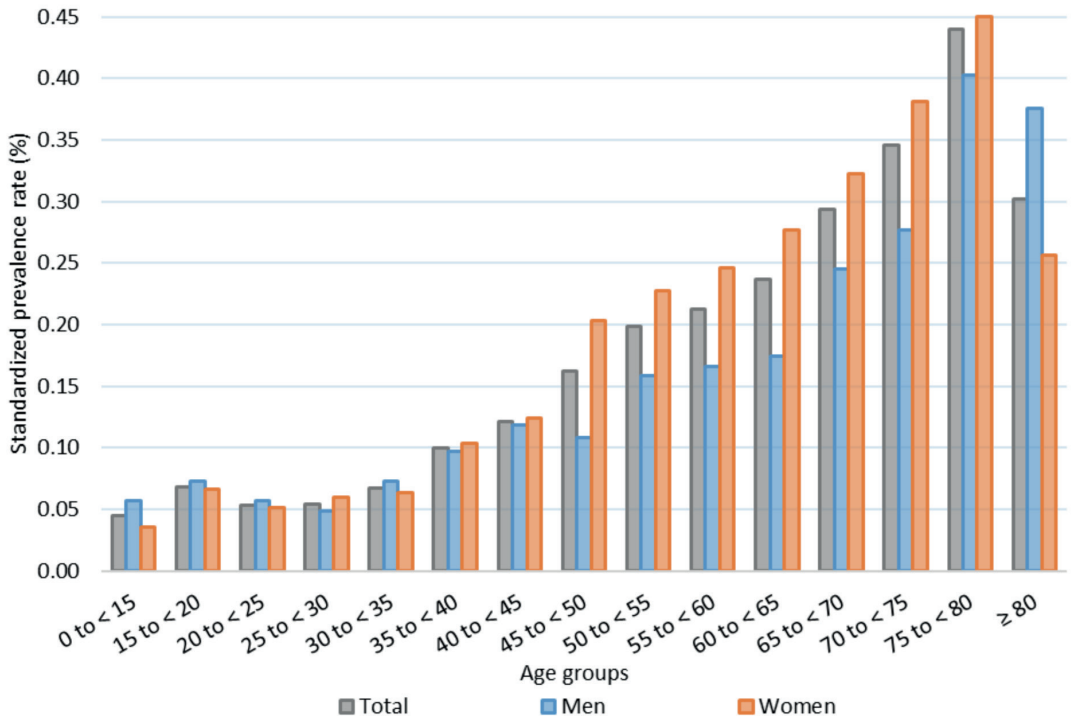

Fig. 1. Standardized prevalence rates of vitiligo stratified by age and sex in 2020. DAK-G data, case definition 3, rate total: 0.15% (CI 0.14–0.16), men: 0.14% (CI 0.12–0.14), women: 0.17% (CI 0.16–0.17).

Table II. Standardized incidence of persons with vitiligo by case definition over the observation years 2016 to 2020

	Case definition 4 (no diagnosis in the last year)				Case definition 5 (no diagnosis in the last 2 years)				Case definition 6 (no diagnosis in the last 3 years)				Case definition 7 (no diagnosis in the last 4 years)			
	DAK-G[1]		DADB[2]		DAK-G[1]		DADB[2]		DAK-G[1]		DADB[2]		DAK-G[1]		DADB[2]	
Year	Rate (%)	CI	Rate (%)	CI	Rate (%)	CI	Rate (%)	CI	Rate (%)	CI	Rate (%)	CI	Rate (%)	CI	Rate (%)	CI
2017	0.07	0.06–0.07	0.07	0.07–0.08	–	–	0.06	0.06–0.06	–	–	0.05	0.05–0.06	–	–	0.05	0.05–0.05
2018	0.07	0.07–0.08	0.08	0.08–0.08	0.06	0.05–0.06	0.07	0.06–0.07	–	–	0.06	0.06–0.06	–	–	0.06	0.05–0.06
2019	0.07	0.06–0.07	0.07	0.07–0.07	0.05	0.05–0.05	0.06	0.05–0.06	0.04	0.04–0.05	0.05	0.05–0.05	–	–	0.05	0.04–0.05
2020	0.06	0.06–0.06	0.06	0.06–0.07	0.05	0.04–0.05	0.05	0.05–0.05	0.04	0.04–0.04	0.05	0.04–0.05	0.04	0.03–0.04	0.04	0.04–0.05

[1]Deutsche Angestellten-Krankenkasse Gesundheit. [2]German Analysis Database for Evaluation and Health Service Research.
CI: confidence interval, mean age in 2020 50.12 (SD 22.37, DAK-G). DAK-G: population $n = 2{,}334{,}946$; 2017 $n = 2{,}311{,}115$; 2018 $n = 2{,}292{,}468$; 2019 $n = 2{,}273{,}022$; 2020 $n = 2{,}258{,}836$, Persons with vitiligo (case definition 1): 2017 $n = 2{,}017$; 2018 $n = 2{,}114$; 2019 $n = 1{,}991$; 2020 $n = 1{,}822$.
DADB: population 2016 $n = 2{,}847{,}480$; 2017 $n = 2{,}907{,}334$; 2018 $n = 2{,}982{,}573$; 2019 $n = 3{,}009{,}703$; 2020 $n = 2{,}981{,}155$, Persons with vitiligo (case definition 1): 2017 $n = 1{,}484$; 2018 $n = 1{,}591$; 2019 $n = 1{,}347$; 2020 $n = 1{,}166$.

0.03–0.03). Incidence was higher in men up to age 45 years and higher in women thereafter. The incidence rates between the broader wash-out times (1 year) and the more sensitive wash-out times (2 to 4 years) did not differ in their trends.

Comorbidity

Among skin diseases and compared with persons without vitiligo (control group 1), alopecia areata turned out to have the highest rate of comorbidity at RR = 7.14 (CI 4.63–11.00), followed by pityriasis versicolor at RR = 5.81 (CI 3.80–8.89) and impetigo at 3.41 (CI 2.08–5.62, Fig. S1). Among all other comorbidities, systemic sclerosis (in the group of autoimmune diseases) showed the highest RR of 3.20 (CI 1.58–6.47), followed by metabolic disorders like diabetes mellitus type 1 (RR = 3.03; CI 2.49–3.69) and mental and neurological disorders like profound developmental disorders (RR = 2.09; CI 1.10–3.95). Furthermore, persons with vitiligo had higher ratios for mental health disorders such as anxiety disorders (RR = 1.32; CI 1.19–1.47), insomnia (RR = 1.26; CI 1.14–1.40), and depression (RR = 1.23; CI 1.15–1.32) compared with persons without vitiligo. Significant effects ≤ 1 were estimated for fever (RR = 0.70; CI 0.51–0.96), stroke (RR = 0.72; CI 0.53–0.96), dementia (RR = 0.78; CI 0.64–0.95), and schizophrenia (RR = 0.57; CI 0.36–0.90, **Fig. 3,** Table SII).

Compared with control group 2 the only skin comorbidities with RR > 1 were pityriasis versicolor (RR = 2.66; CI 1.89–3.73) and alopecia areata (RR = 1.83; CI 1.36–2.47). However, food allergies (RR = 0.28; CI 0.12–0.64) and allergic contact dermatitis (RR = 0.40; CI 0.33–0.48) showed the lowest significant RRs (Fig. S2). Further-

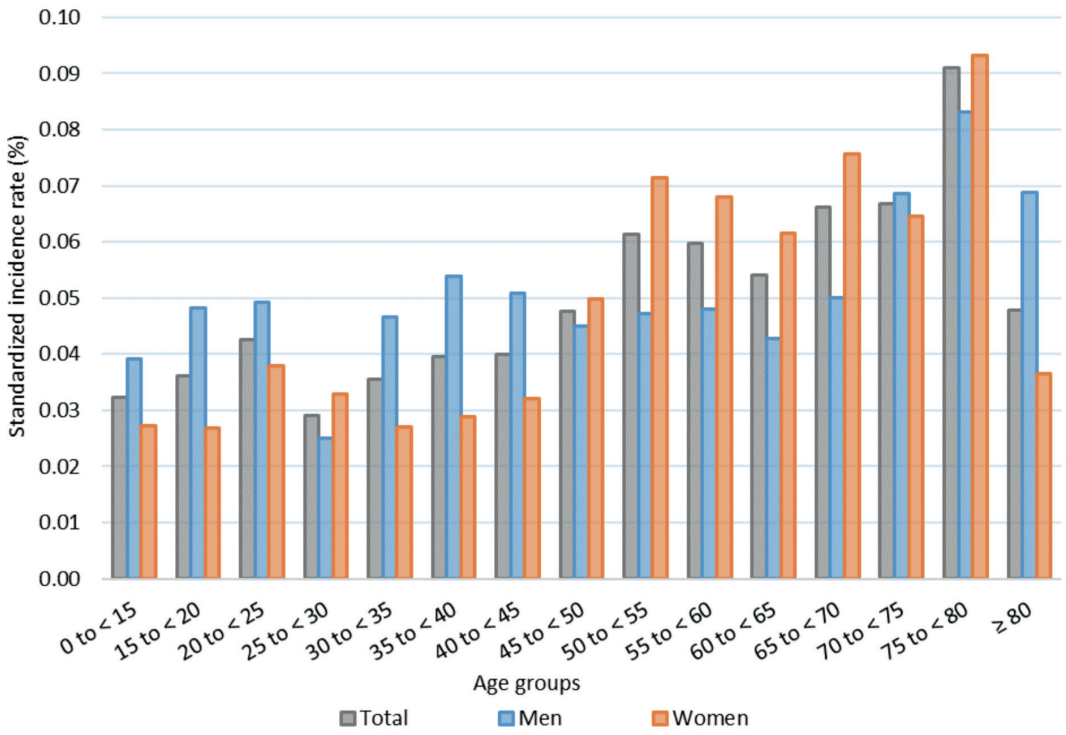

Fig. 2. Standardized incidence rates of vitiligo stratified by age and sex in 2020. DAK-G data, wash-out time of 2 years; after a wash-out time of 2 years, rate total: 0.05% (CI 0.05–0.05), men: 0.05% (CI 0.04–0.05), women: 0.05% (CI 0.04–0.05).

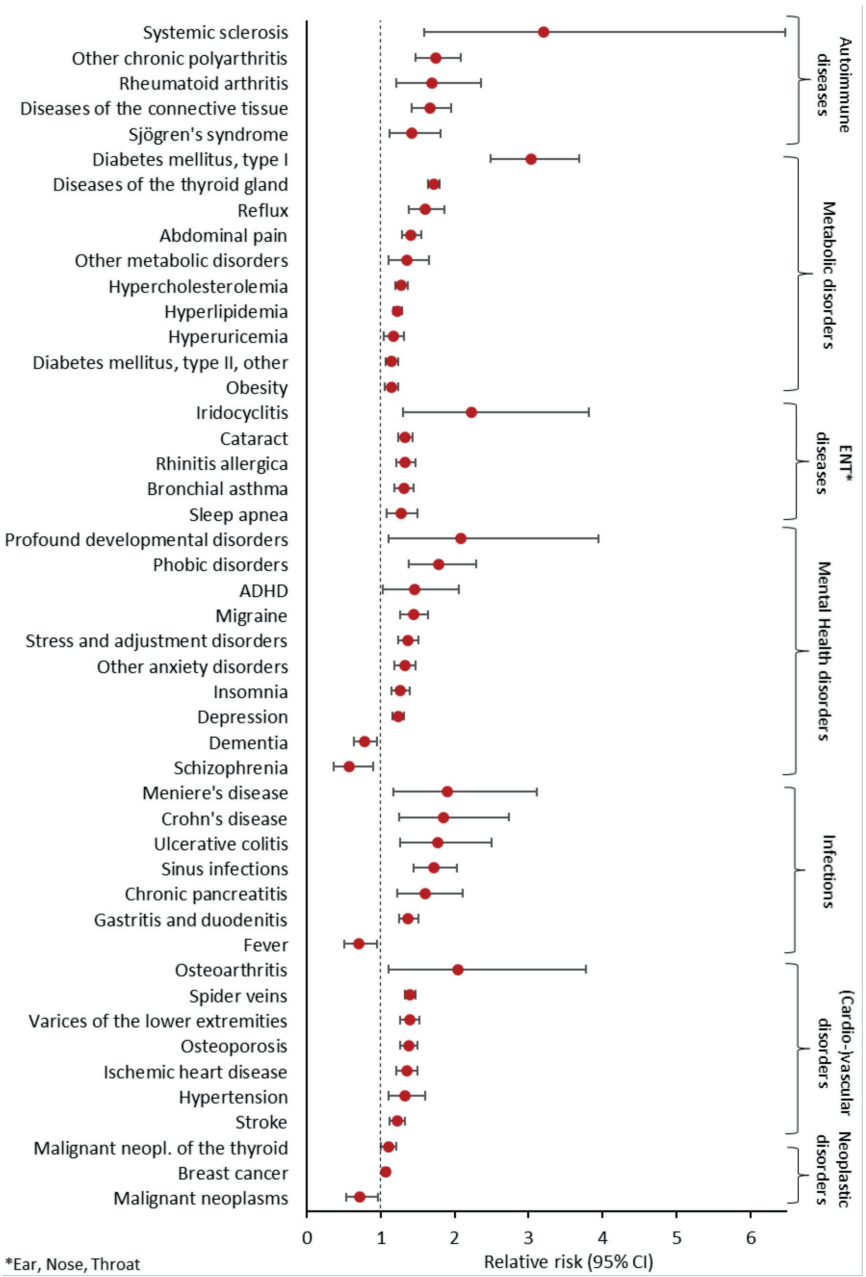

Fig. 3. Relative risk (RR) of predefined comorbidities (skin comorbidities excluded) in persons with vitiligo compared to persons without vitiligo. Comparison group 1; 1:3 propensity score matching, for numerical values of prevalences see Table SII.

more, systemic sclerosis (RR = 3.00; CI 1.50–5.99), diabetes mellitus type 1 (RR = 2.50; CI 2.08–3.02), and diseases of the thyroid gland (RR = 1.44; CI 1.38–1.50) showed the highest RRs. Bronchial asthma (RR = 0.54; CI 0.50–0.59) and allergic rhinitis (RR = 0.51; CI 0.47–0.56) showed lower observed prevalence RR (**Fig. 4,** Table SIII). Comparison group 3 had similar comorbidities to comparison group 2 (Table SIV).

DISCUSSION

This retrospective, longitudinal health services research study presents an internal validation concept for the estimation of prevalence, incidence, and comorbidities of vitiligo based on SHI data. In 2020, vitiligo had an estimated prevalence of 0.12% to 0.20% and an incidence of 0.04% to 0.06% depending on the case definition and wash-out time. Disease frequency remained largely stable over the 5-year observation period. Looking at the prevalence, a similar study based on SHI data reported a rate of 0.17% among adults in 2010 (5). Using a comparable case definition, but without age restrictions, our estimate was slightly higher, between 0.19% and 0.20% in 2020. Although studies on a secondary data basis concerning the prevalence of vitiligo exist, their comparability is limited by differences in study populations, skin phototy-

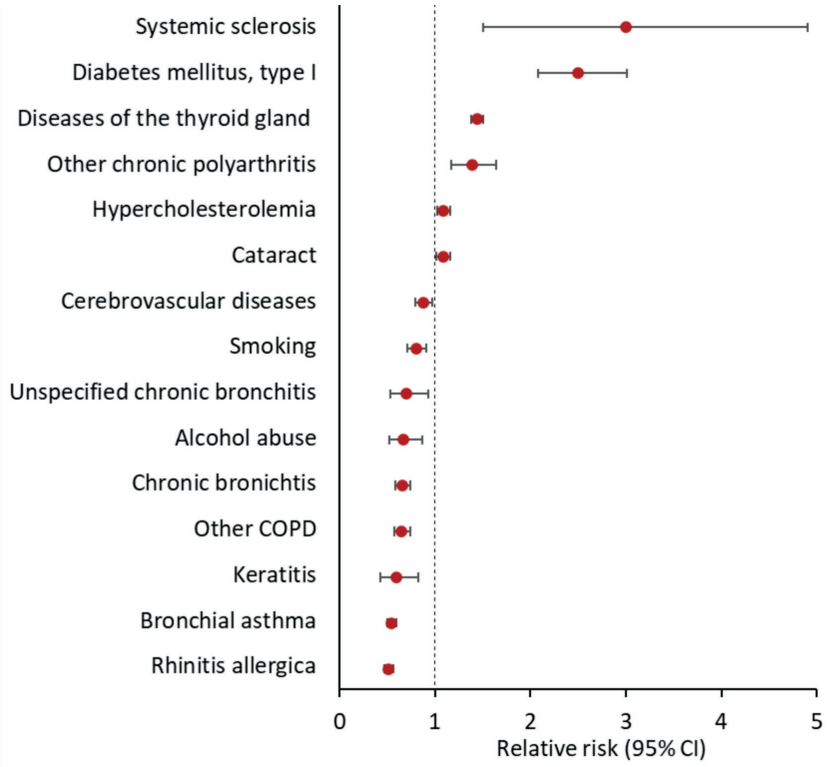

Fig. 4. Relative risk (RR) of predefined comorbidities (skin comorbidities excluded) in persons with vitiligo compared to persons with atopic dermatitis. Comparison group 2; 1:3 propensity score matching, for numerical values of prevalences see Table SIII.

pes, access to healthcare, and methodology (3–5). These selection effects are even more pronounced in primary studies, e.g., by including only dermatological care (15), and for self-reported data, which may overestimate diagnosed prevalence (16). The relatively low prevalence and incidence observed in our study could therefore be partly attributable to underreporting of vitiligo in claims data. Furthermore, limited treatment options and dissatisfaction with available therapies may have reduced the utilization of medical services and contributed to underestimation (17, 18).

Given the chronic nature of vitiligo, repeated diagnosis codes over a defined period are generally recommended when using SHI data (19). In our analyses, case definition 1 slightly overestimated whereas case definition 2 tended to slightly underestimate vitiligo prevalence. Extending the wash-out period to 2 years resulted in more stable incidence estimates over time, suggesting that a longer lookback period may improve accuracy. However, an excessively long lookback period may introduce selection effects and bias (20). Treatments such as medications were not included because they are not disease-specific and are also used for other skin diseases. Beyond these methodological considerations, women aged ≥ 45 years were more likely to have vitiligo than men, which may partly reflect greater healthcare-seeking behaviour among older women (21, 22). This could lead to under-ascertainment of vitiligo among men in SHI data. In addition, the 75–80 age group (DAK-G data) had the highest prevalence and incidence, which is consistent with the literature in Germany (5).

In group comparisons, pityriasis versicolor consistently ranked among the 3 most common comorbidities. This may be due to misdiagnosis resulting from similar clinical presentations (23). Nevertheless, it must be considered a relevant comorbidity, given that the autoimmune nature of vitiligo could be associated with an increased susceptibility to this opportunistic skin infection. The ratio between vitiligo and systemic sclerosis has been reported in the past and may be due to shared genetic factors. Previous studies have identified genes that play a role in both diseases, as well as a genetic susceptibility to abnormal immune regulation (24). For respiratory diseases, the vitiligo cohort showed hazard ratios of less than 1, particularly when compared with skin diseases. This may be due to differences in the characteristics of the comparator group, such as a higher prevalence of COPD and smoking among persons with psoriasis, rather than indicating a protective effect (25). Furthermore, our data showed that people with vitiligo had a higher risk of developing depression, insomnia, anxiety, stress, and adjustment disorders. As these effects were predominantly found in comparison with persons without vitiligo, this suggests that skin diseases are generally associated with psychological distress. A recent German statutory health insurance claims analysis examined mental illness in more detail and supports this finding: people with vitiligo showed a high internally validated prevalence of affective and stress-related disorders and, compared with people without vitiligo, an increased risk of anxiety disorders and social phobia in particular (26). A systematic review also reported depression, anxiety,

and sleep disorders as relevant comorbidities in vitiligo and significant differences compared with individuals without vitiligo, which is further supported by recent studies of hospitalized individuals in GKV analyses (13, 27). However, the "protective" effects (RR ≤ 1) for dementia and schizophrenia should be interpreted with caution: the aforementioned SHI analysis also found evidence of lower observed risks, which could be explained by misclassification (26).

The estimation of "causal effects" is particularly difficult in SHI data, as systematic bias due to specific selection processes cannot be excluded (28). Although PSM has been described in the literature as a reliable method for adjusting for confounding (29), sensitivity analysis using alternative methods such as bootstrapping or subsampling may also provide valid results and should be considered in future studies (30, 31).

Strengths and limitations

The fundamental strength of this analysis lies in the use of extensive SHI routine data, which enable a population-based description of our cohort as well as robust estimates of epidemiological measures. Data and methodological limitations should be considered, as populations differ across health insurance funds (32), so prevalence and incidence rates were adjusted for age and sex. SHI data, which are collected for billing purposes, include only reimbursed services and not privately paid services, and potentially relevant information on weight, lifestyle, and education is missing (33). Misclassification due to poor differential diagnosis or physician coding behaviour can also bias results in both the vitiligo and the comparison cohorts (34). In addition, given the exploratory nature of our analyses and the large number of endpoints examined, findings should be interpreted as hypothesis-generating, as multiple comparisons may increase the risk of false-positive results. Despite these limitations, the prevalence rates between DAK-G and DADB differ only slightly, which supports the validity of the results. Furthermore, extrapolation of the age- and gender-standardized estimates to the SHI population allows the potential number of cases to be classified (35).

Conclusion

Our results underline the importance of vitiligo as a common disease with a number of comorbidities. Further tests of external validity are needed. For such an assessment, a future linkage of routine SHI data and primary data (e.g., registers) is necessary. This would also enable demonstration of the reliability and validity of the results obtained. Otherwise, we recommend that sensitivity tests be carried out for prevalence and incidence estimates based on claims data, which should consider other inclusion criteria (e.g., therapies) in order to avoid misclassification of the ICD-10-GM code. The study also showed a general increased risk of mental illness in people with chronic skin disease like vitiligo, but also atopic dermatitis and psoriasis. Future studies should focus on this issue to identify possible criteria for a valid representation of the psychosocial effects of vitiligo in SHI data and to determine corresponding frequency estimates. Efforts should also be made to address the particular challenges faced by persons with vitiligo and to ensure their holistic care.

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Data availability statement: SHI billing data is subject to legal and contractual access restrictions and cannot be shared freely. Access is only possible with the consent of the data owner. Aggregated results and analysis code can be provided by the corresponding author upon reasonable request.

Ethical approval: The study was conducted according to national guidelines for the use of administrative databases (36, 37). According to those guidelines, no approval by an ethical committee is required.

Conflict of interest statement: MA has served as a consultant, lecturer, researcher, and/or has received research grants from companies researching on or manufacturing drugs for vitiligo, including AbbVie, Almirall, Incyte, and Pfizer. SB is an employee and shareholder of Incyte Biosciences. JR is an employee of Gesundheitsforen Leipzig GmbH, which was commissioned and funded by Incyte to conduct the study. CG was also employed at the Gesundheitsforen Leipzig GmbH at the time of conducting the analysis. AK is an employee and shareholder of Incyte Biosciences. MB has served as a consultant, researcher, and lecturer for companies researching on or manufacturing drugs for vitiligo including AbbVie, Pfizer, Incyte, and Clinuvel. KH and TK declare no conflicts of interest.

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