IDENTIFICATION AND QUANTIFICATION OF ATOPIC DERMATITIS PATIENTS WITH INSUFFICIENT DISEASE CONTROL UNDER CONVENTIONAL SYSTEMIC TREATMENTS IN GERMANY: A FEASIBILITY STUDY

Weber V [1], Zügel F [2], Pawlowska-Phelan D [3], Ploner T [3], Mocek A [1], Herrath J [2], Kisser A [2]

[1] **IGES Institut GmbH**, Berlin, Germany – [2] Pfizer Pharma GmbH, Berlin, Germany – [3] **InGef – Institute for Applied Health Research Berlin GmbH**, Berlin, Germany

Introduction

Background

- Atopic Dermatitis (AD) is a chronic inflammatory skin disorder with significant quality-of-life impairment [1].
- Depending on patient responsiveness to first-line topical therapy, such as topical corticosteroids (TCS) and topical calcineurin inhibitors (TCI), and disease severity, for some patients, the decision is made to initiate systemic drug therapy [2].
- In recent years, in addition to conventional systemic drug therapy options such as cyclosporine, systemic corticosteroids (SCS, not recommended for long-term use), or off-label immuno-modulators (azathioprine, methotrexate and mycophenolate mofetil), targeted therapies suitable for continuous systemic therapy of AD have become available (e.g., dupilumab) [3].

Objective

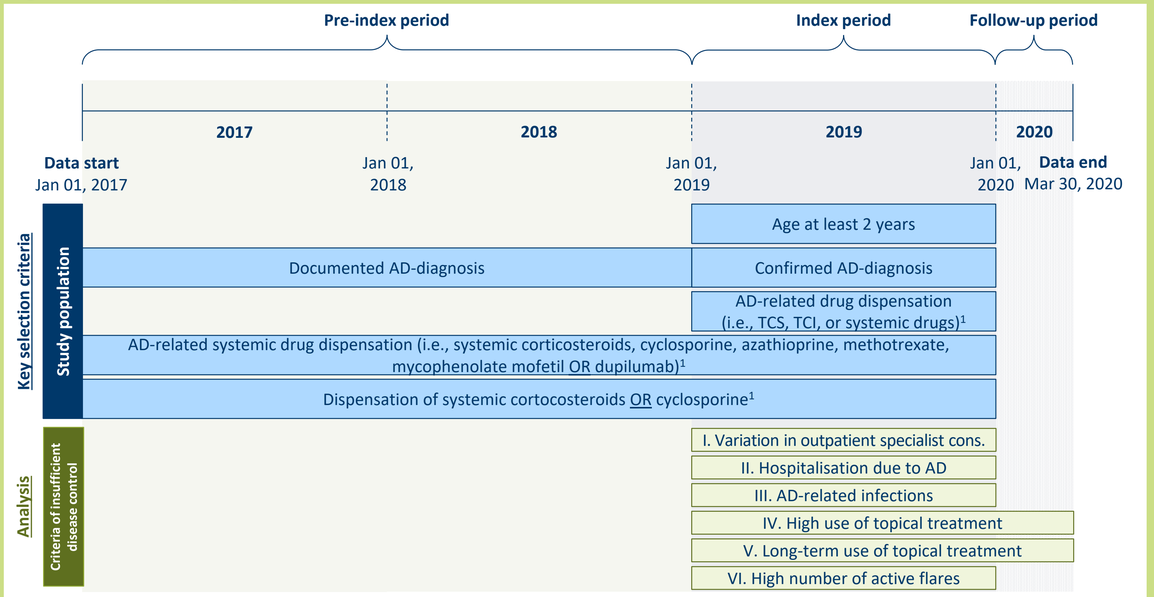
- The aim of this study was to identify and quantify patients with AD and insufficient disease control under conventional systemic treatment using a set of proxies in German health claims data.

Methods

Study design

- A retrospective cross-sectional study was conducted using anonymized German statutory health insurance (SHI) claims data from the InGef research database (Figure 1).
- A sample of approximately 4 million insured persons was used, which is considered representative of the German population regarding age and sex [4].
- An index period ranging from January 01, 2019 to December 31, 2019 and a pre-index period ranging from January 01, 2017 to December 31, 2018 were defined.
- Insufficient disease control operationalized by six predefined criteria was analyzed during the index period and a follow-up period ranging from January 01, 2020 until March 31, 2020, the latter being only applicable to the criteria IV. “High use of topical treatment” and V. “Long-term use of topical treatment” (Figure 2).

Figure 1: Study design



Study population – Patients with AD under conventional systemic therapy

- Continuously insured during the study period and age at least 2 years in the index period
- At least one documented inpatient or outpatient specialist AD diagnosis (ICD-10-GM L20.-, L20.8, L20.9) during the index period
- At least one documented inpatient or two documented outpatient AD diagnosis during the pre-index period
- At least one dispensation of AD-related medication (i.e., TCS, TCI or systemic drugs) during the index period
- At least one dispensation of AD-related systemic drugs (i.e., SCS, cyclosporine, azathioprine, methotrexate, mycophenolate mofetil, or dupilumab) during the index period or the pre-index period
- Without dispensation of dupilumab or an off-label drug (i.e., azathioprine, methotrexate, mycophenolate mofetil) during the pre-index or index period
- Note: All AD-related drug dispensations required a documented AD diagnosis in the same quarter.

Figure 2: Predefined criteria of insufficient disease control

I. Variation in outpatient specialist consultations	II. Hospitalization due to AD	III. AD-related infections	IV. High use of topical treatment*	V. Long-term use of topical treatment*	VI. High number of active flares
▪ Outpatient pediatrician or dermatologist contact with a documented AD diagnosis in the index period AND ▪ At least one outpatient contact with a documented AD diagnosis with another specialist (pediatrics/derma-tology) within the same quarter	▪ At least one inpatient AD diagnosis (main discharge diagnosis) in the index period	▪ At least one diagnosis of AD-related infections[1] in the index period OR ▪ At least one dispensation of AD-related antibiotics, antivirals, antiseptics, or antimycotics[1] in the index period	▪ Dispensation of TCS or TCI[1] in the index period AND ▪ Further dispensation of TCS or TCI[1] within a 3-month period following the first dispensation AND ▪ Calculated “run-out-period” is higher than the period between the date of the first and the second dispensation of TCS or TCI	▪ Dispensation of TCS or TCI[1] in the index period AND ▪ Further dispensation of TCS or TCI[1] within a 3-month period following the first dispensation	▪ At least two dispensations of TCS (class IV), SCS, or cyclosporine[1] in the index period

* While all TCS classes (I-IV) were considered in children/adolescents (2-17 years), only TCS from class II were considered in adult patients (≥ 18 years).
[1] In combination with a documented AD diagnosis (hospital main or secondary discharge or confirmed outpatient diagnosis) within the same quarter

References

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Acknowledgement

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Disclosure of interest

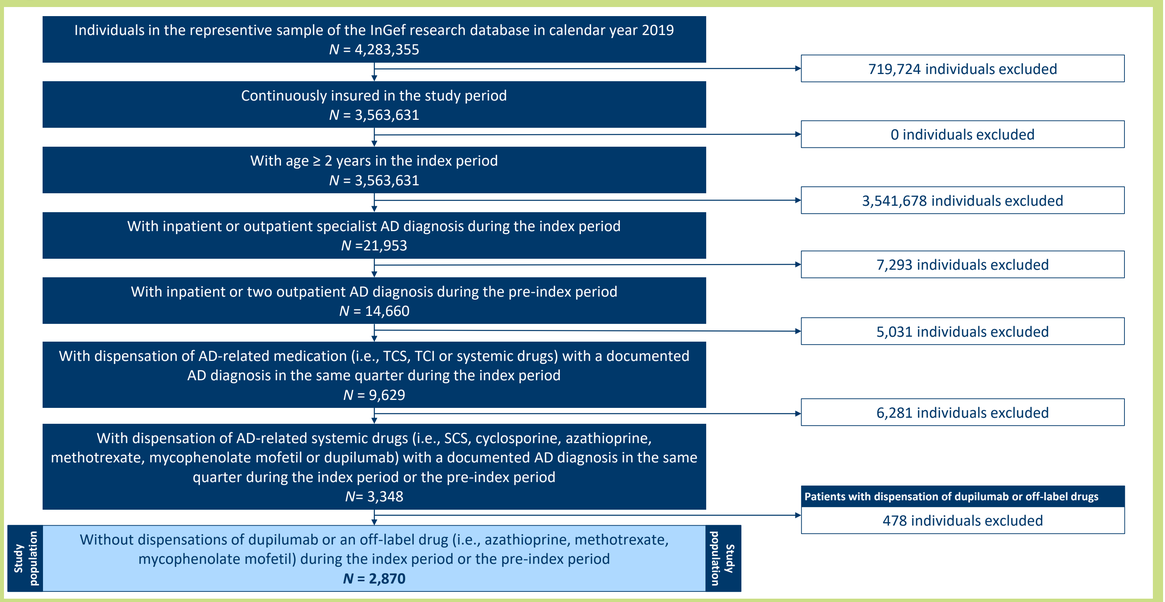
Jessica Herrath and Agnes Kisser are paid employees of Pfizer Pharma GmbH. Franziska Zügel was a paid employee of Pfizer Pharma GmbH at the time of study. Valeria Weber and Anja Mocek are employees of the vendor IGES Institut GmbH, which is a paid consultant of Pfizer Pharma GmbH for designing the study, carrying out the analyses, interpreting the results and developing the poster publication. Dorota Pawlowska-Phelan and Tina Ploner are employees of the vendor InGef - Institute for Applied Health Research Berlin GmbH, which executed the data analysis and was contracted and reimbursed by the IGES Institut GmbH.

Results

Study population

- A total of 3,348 patients had at least one dispensation of AD-related systemic drug therapy with a documented AD diagnosis within the same quarter during the index period or the pre-index period, corresponding to 76,511 patients extrapolated to the German population.
  - Of those, 478 patients (14.3%) had at least one dispensation of dupilumab or off-label drugs during the index period or the pre-index period. For 472 patients, dispensations of dupilumab or off-label drugs were linked to a documented AD diagnosis within the same quarter. Extrapolated to the German population, this resulted in 10,787 patients.
  - 2,870 patients (85.7%) had received at least one dispensation of cyclosporine or SCS during the index period or the pre-index period and were included in the study population of patients with AD under conventional systemic drug therapy.

Figure 3: Patient flow



Insufficient disease control in patients with AD under conventional systemic therapy

- From 2,870 patients with AD under conventional systemic drug therapy, 2,158 (75.2%) fulfilled at least one criterion of insufficient disease control in the patient identification period, corresponding to 49,316 patients extrapolated to the German population.
- Stratifying by quarter of first observable dispensation of systemic drugs, 17.4% and 12.4% of the patients with at least one criterion of insufficient disease control fulfilled had their first dispensations of systemic drugs in Q1 or Q2 2019 and in Q3 or Q4 2019, respectively. 71.2% of those patients received their first observable dispensation of systemic therapy before Q1 2019.
- The criteria (III.) AD-related infections (48.0%), (V.) Long-term use of topical treatment (31.7%), and (VI.) High number of active flares (26.7%) were most frequently met (Figure 4).
- 52.1% (n=1,496) had a high number of active flares (VI.) or fulfilled at least two further criteria of insufficient disease control (I.-V.). The share of patients with high number of active flares and at least one further criterion of insufficient disease control (I.-V.) fulfilled was 19.0% (n=545).
- For validation, frequency of criterion relevant events were analyzed in the index period (Table 1).

Figure 4: Distribution by criterion of insufficient disease control

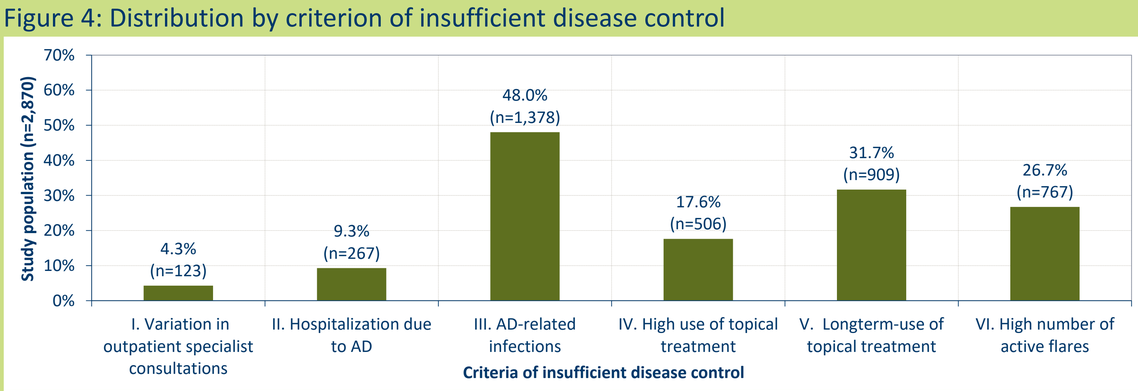


Table 1: Measures of central tendency, position and dispersion of relevant events for criteria of insufficient disease control in the study population during the index period

Criterion relevant event	n (%)	Mean	Standard Deviation	Median (Min; Max)
Outpatient specialist contacts (dermatologist/pediatrician)	2,738 (95.4%)	4.76	7.88	3 (0; 151)
Hospitalization due to AD	267 (9.3%)	0.14	0.51	0 (0; 5)
AD-related infections	1,267 (44.2%)	0.89	1.35	0 (0; 9)
Dispensations of topical treatment	2,311 (80.5%)	3.09	3.73	2 (1; 110)
Further dispensations of topical treatment still falling within the run-out period of the previous dispensation	520 (18.1%)	0.54	2.41	0 (0; 91)
Active flares	1,969 (68.1%)	1.25	1.57	1 (0; 21)

Conclusions

- For 2019, a total of 2,630 patients with AD were identified who had received targeted or off-label systemic drug therapy either in the past two years or currently, or who had signs of current insufficient disease control.
- When summing up the extrapolated patient numbers, this corresponds to 60,103 patients in Germany.

Limitations

- German health claims data do not allow to obtain information about the reason for prescriptions.
- The identification of insufficient disease control was not temporally linked to the dispensation of a specific systemic drug and patients were not followed individually longitudinally. Therefore, it cannot be completely ruled out that patients in the study population were found to have insufficient disease control during the index period, but the first dispensation of systemic drug therapy occurred afterwards. However, stratification by quarter of the first observable dispensation of systemic drugs suggests that overestimation is unlikely.