

Baseline characteristics and allergic comorbidities in infants with moderate to severe atopic dermatitis: First results from the German TREATkids registry

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Kind B¹, Siegels D¹, Abraham S², Ott H³, Heinrich L¹, Nemat K⁴, Weidinger S⁵, Werfel T⁶, Schmitt J¹

¹Center for Evidence-Based Healthcare, University Hospital and Faculty of Medicine Carl Gustav Carus, TU Dresden, Germany, ²Department of Dermatology, University Allergy Center, Medical Faculty Carl Gustav Carus, TU Dresden, Germany; ³Department of Pediatric Allergology, Children's Hospital Auf der Bult, Academic Hospital, Hannover, Germany; ⁴Pediatric Pneumology und Allergology, Children's Center Dresden Friedrichstadt (kid) Dresden, Germany; ⁵Center for Inflammatory Skin Diseases, Department of Dermatology and Allergy, University Hospital Schleswig-Holstein, Campus Kiel; ⁶Department of Dermatology and Allergy, Hannover Medical School, Hannover, Germany

Conflict of interest: SA has received lecture and/or consultancy fees from Novartis, LEO Pharma, Amgen, Lilly, Sanofi, Beiersdorf, Janssen, UCB and AbbVie. SW has received institutional research grants from LEO, Pfizer and Sanofi; and has performed consulting work and lectures for AbbVie, Almirall, Eli Lilly, Galderma, Kymab, LEO Pharma, Pfizer, Sanofi, and Regeneron. JS has received institutional grants from Novartis and Pfizer for scientifically initiated research; and has received honoraria for consulting from Sanofi, Lilly, Novartis and ALK. TW has received honoraria for lectures or scientific advice on atopic dermatitis from AbbVie, Almirall, Galderma, Janssen/JNJ, LEO Pharma, Leti, Lilly, Novartis, Pfizer and Regeneron/Sanofi. All of the other authors declare they have no conflicts of interest.

Introduction: Since 2020, the TREATkids registry, a new branch of the German Atopic Dermatitis (AD) registry TREATgermany, collects data on infants and adolescents with moderate to severe AD. In addition to demographic characteristics, non-allergic and allergic comorbidities, disease progression, patient-reported outcomes and therapies are documented using validated instruments.

Methods: TREATkids collects routine data as a non-interventional, prospective cohort study. The inclusion criteria of the registry are: infants and adolescents aged 0 to 17 years with moderate to severe AD according to the UK Working Party diagnostic criteria, an objective SCORing of Atopic Dermatitis (oSCORAD) >20 despite guideline-compliant topical therapy and/or anti-inflammatory systemic therapy for AD within the past 24 months prior to inclusion in the registry.

References:

- ¹ Statistisches Bundesamt (Destatis), Mikrozensus, 2023-08-25
 - ² World Bank (worldbank.org; 2000 – 2022)
 - ³ Zentralverband Zoologischer Fachbetriebe Deutschlands e.V.(2020 – 2022)
 - ⁴ S3-Leitlinie „Atopische Dermatitis“ (AWMF-Registernr. 013-027)
- * Discrepancies in total numbers are due to missing values.



Results - Demographic characteristics of the TREATkids cohort in May 2023

Number of patients in TREATkids stratified by age and sex

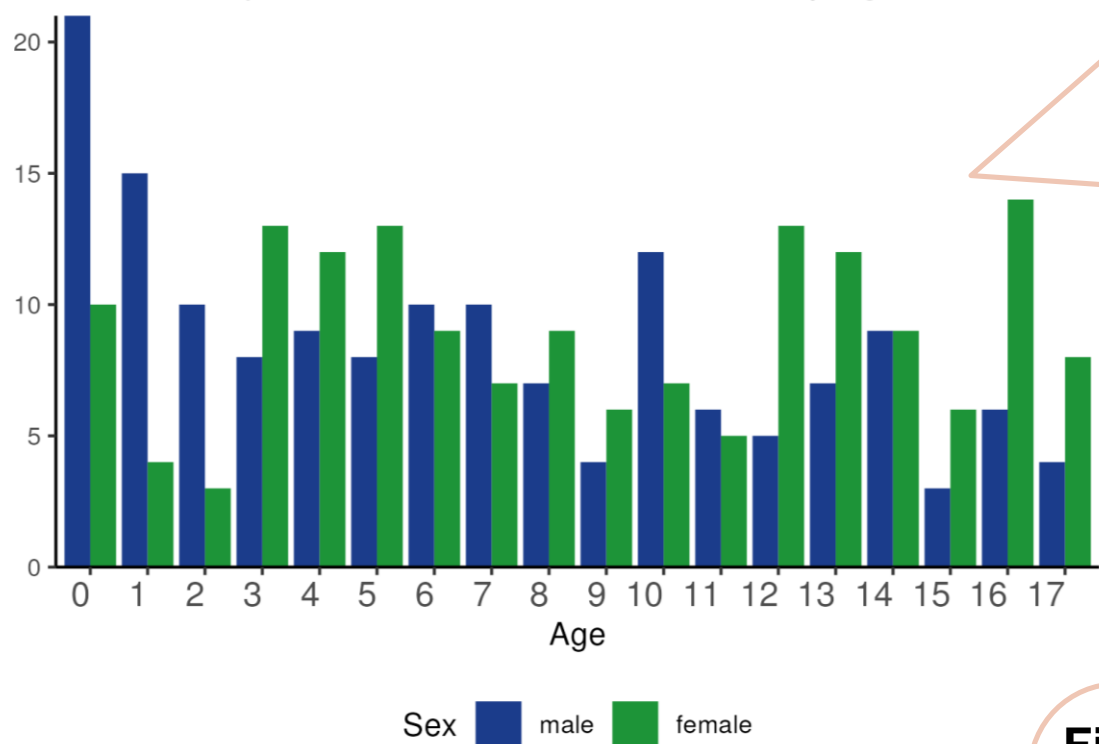


Figure 1: Age and sex of the TREATkids population. 314 children are present in the TREATkids registry so far. All age group are represented. Between 0 and 3 years of age, boys are overrepresented. From 12 years on more girls are enrolled in the registry. 51.0% of all children are female. In 2022 only 46.2% of all German inhabitants below the age of 18 were female¹.

Pets

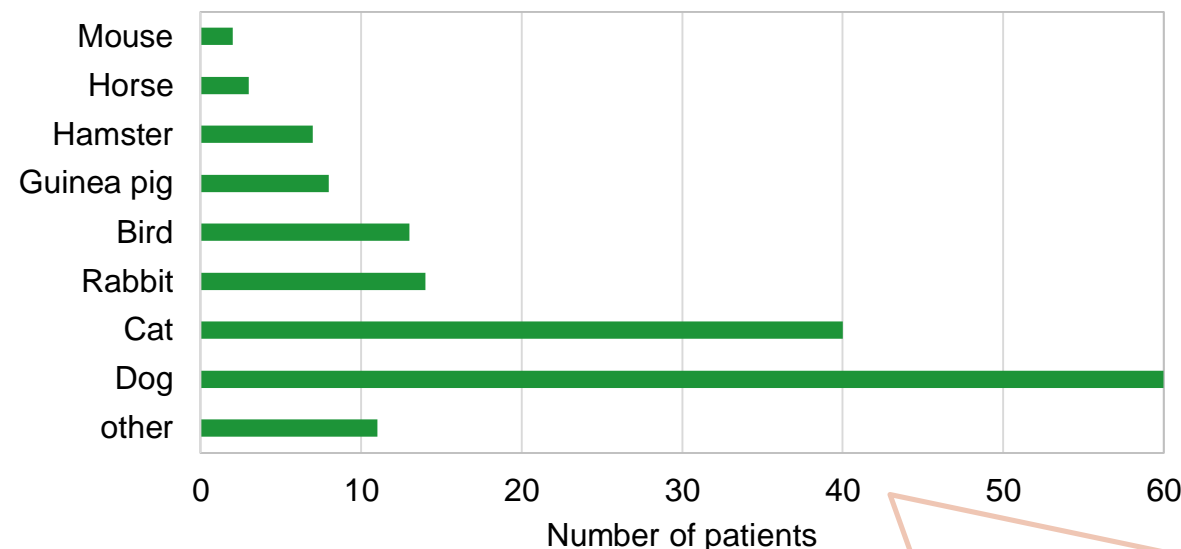


Figure 3: Pets of the children enrolled in TREATkids. 38.9% of all children in the registry do have pets (n=312*). Favorite pets are dogs, cats and rabbits. This in contrast to the overall German society, where cats were the most favorite pets in 2022, followed by dogs³.

Main residence

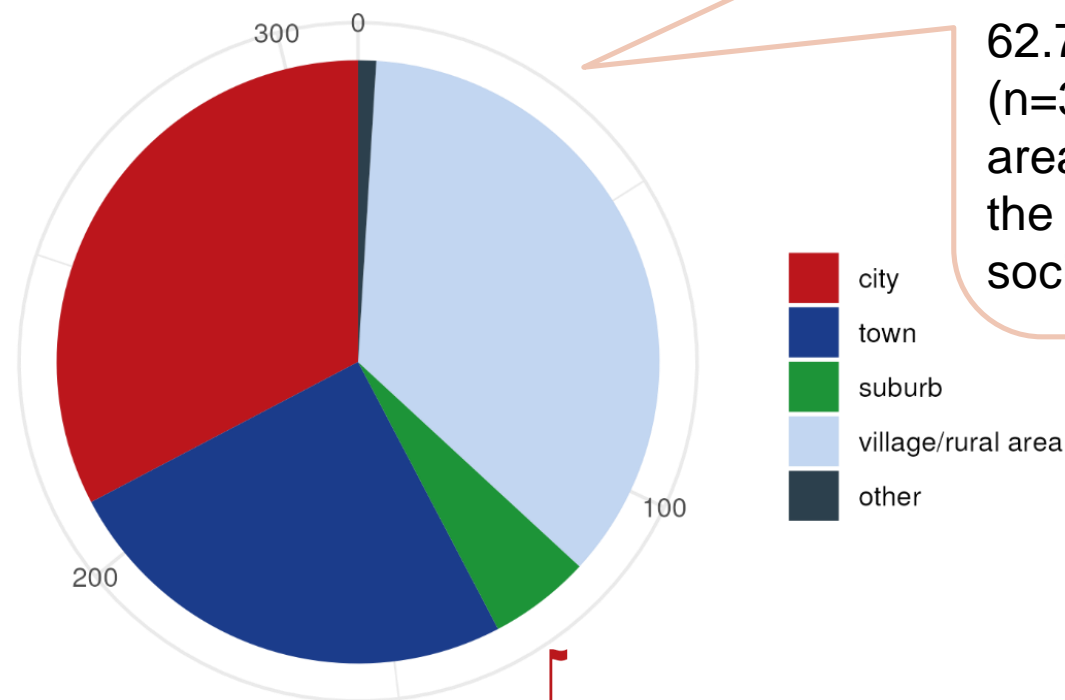


Figure 2: Main residence of the TREATkids patients. 62.7% of all children (n=312*) live in urban areas, this is less than the overall Germany society (77.7% in 2022)².

Smoking status of the family

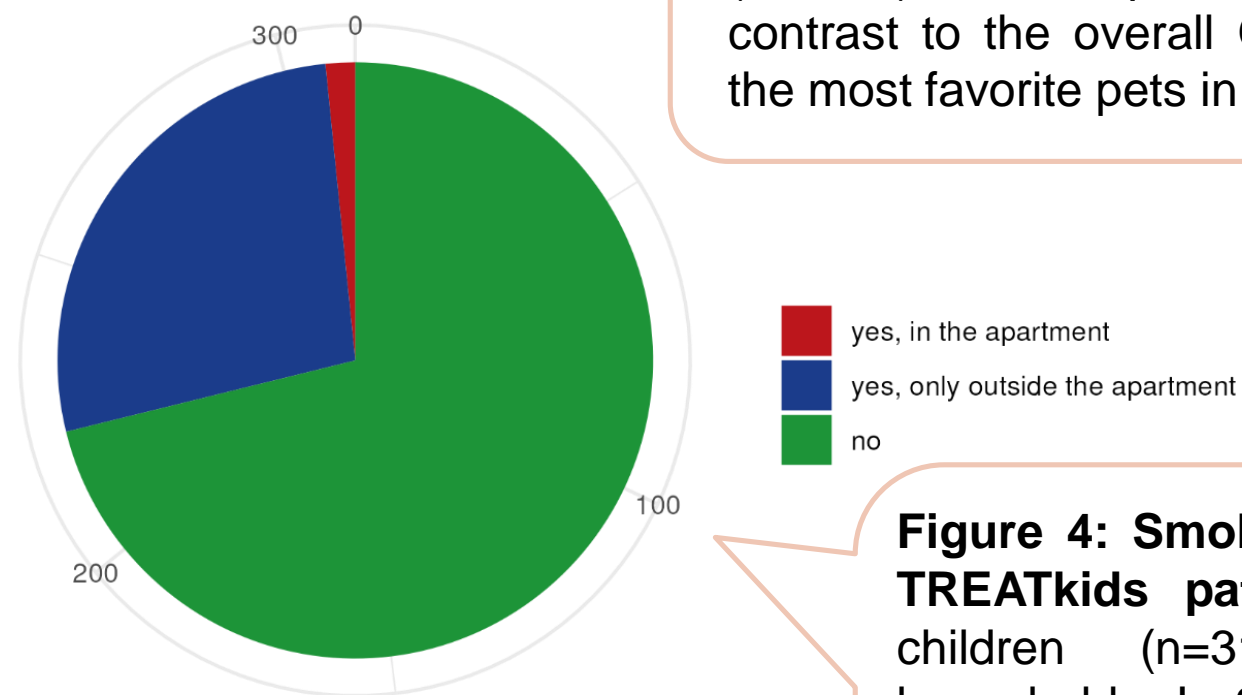
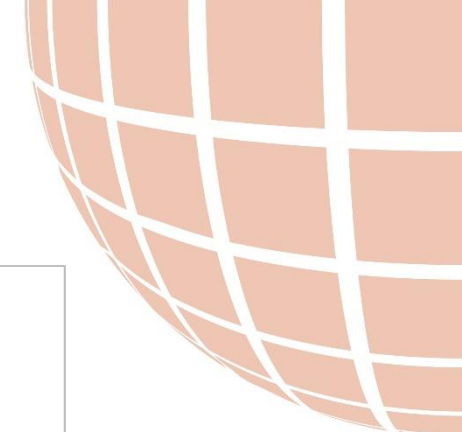


Figure 4: Smoking status of the families of TREATkids patients. 70.7% of the enrolled children (n=312*) live in smoking-free households. In 27.1% of all families smoking is done outside the apartments and only in 1.6% of all cases smoking is performed inside. In 2021, 18.9% of all Germans above the age of 15 did smoke¹.



Results – AD characteristics, comorbidities and systemic therapies in the TREATkids cohort in May 2023

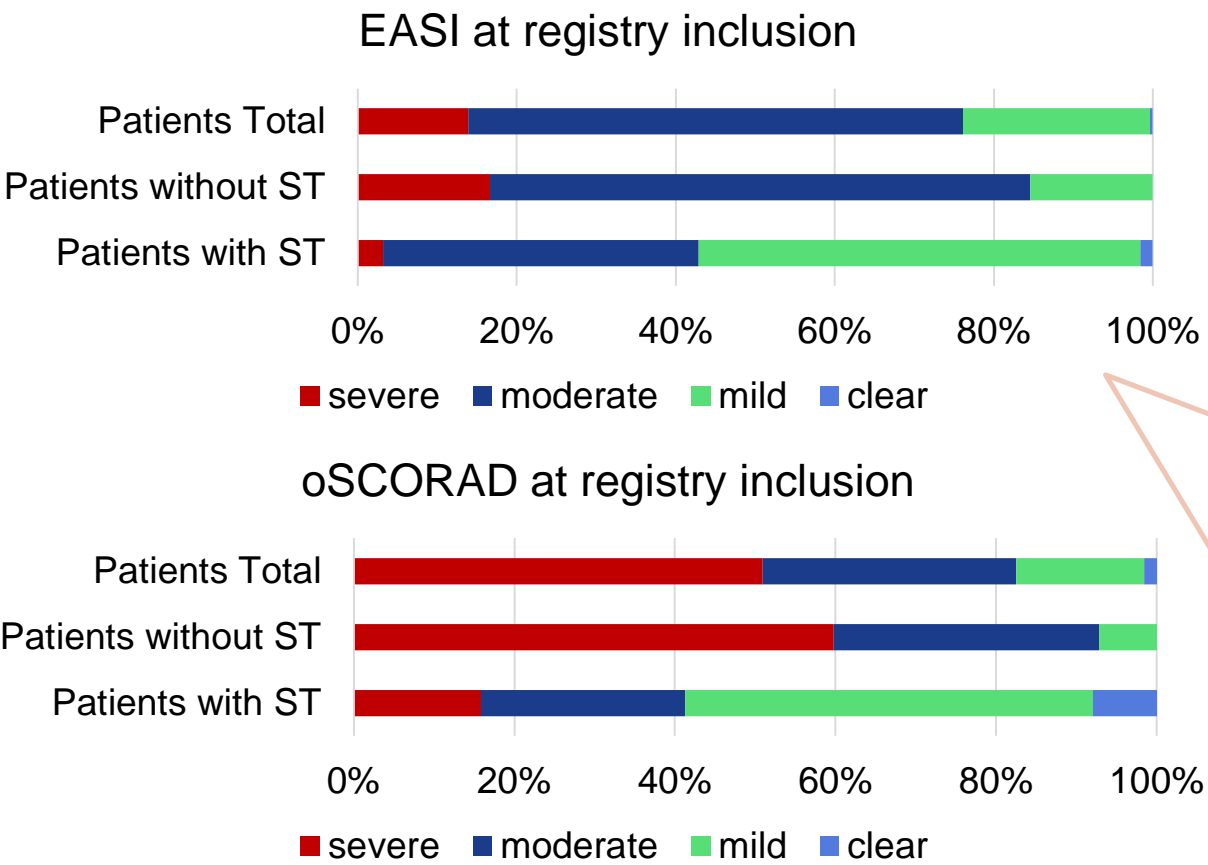
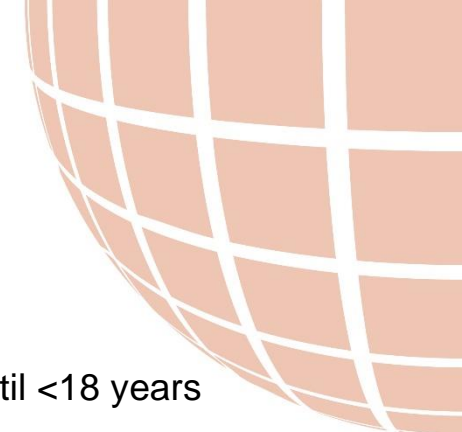


Figure 5: Main clinical scores of the TREATkids patients. The overall Eczema Area and Severity Index (EASI) in the TREATkids cohort is 13.4 ± 9.9 at inclusion that indicates a moderate to severe AD. Without systemic therapies, the EASI is 15.1 ± 9.9 and decreases to 6.5 ± 6.3 in patients with systemic therapy at registry inclusion. The overall oSCORAD of the TREATkids cohort at registry inclusion is 38.1 ± 14.4 indicating a severe AD. Without systemic treatment, the oSCORAD is 41.5 ± 12.6 and in the group of patients that receive systemic therapies at registry inclusion the oSCORAD is 24.4 ± 13.1 indicating a moderate to severe AD.

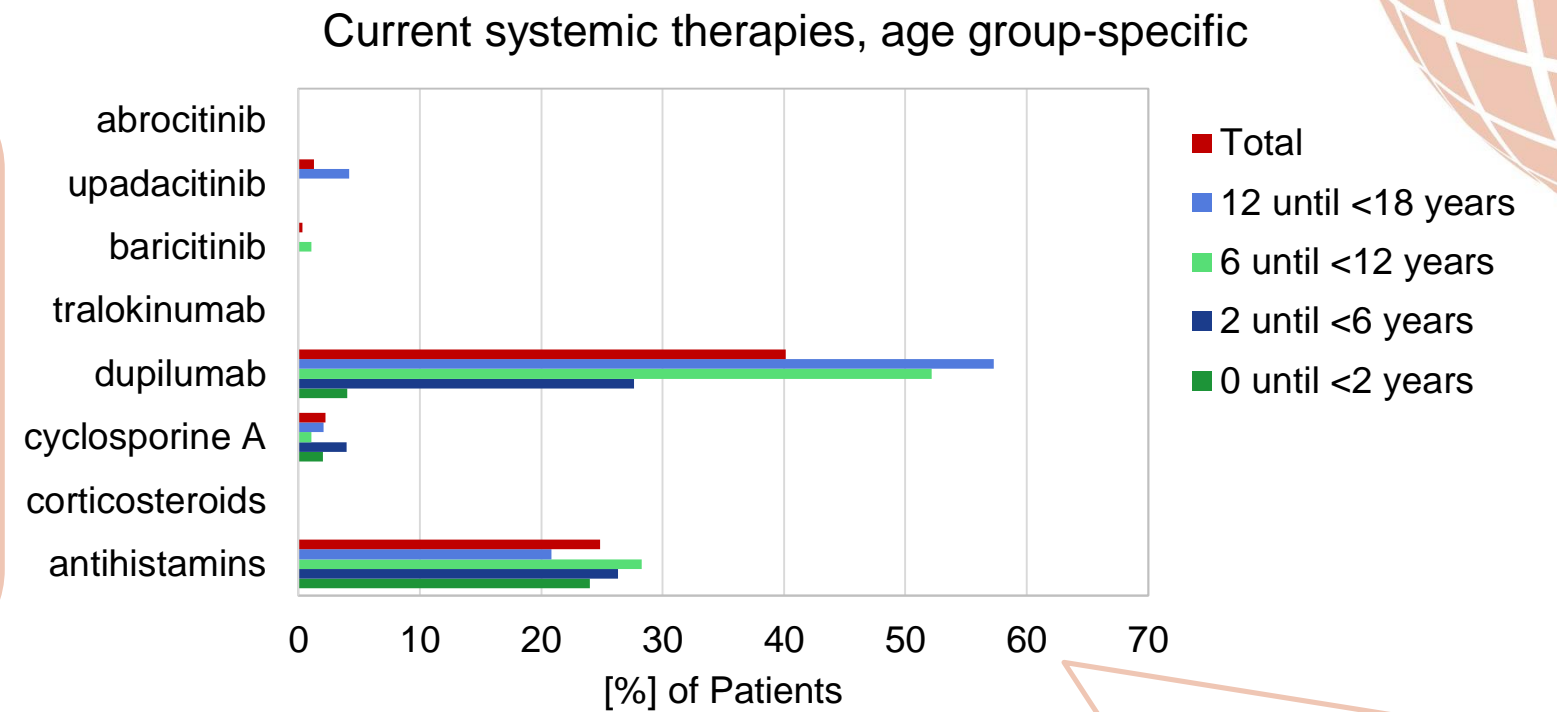
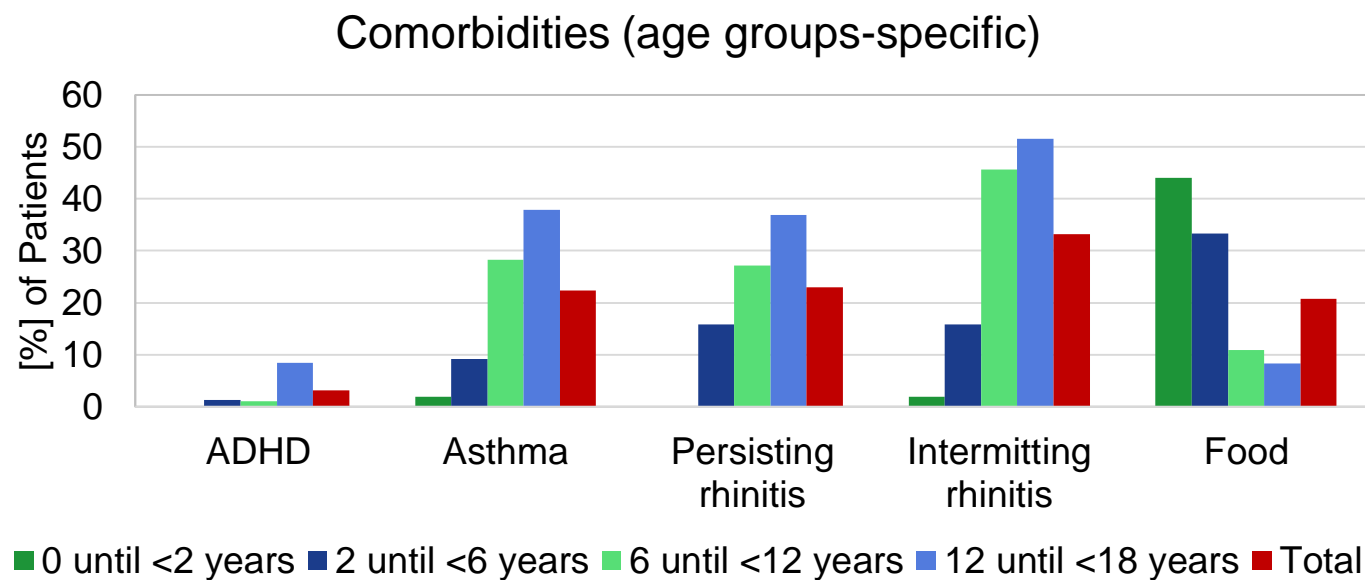


Figure 7: Current systemic therapies in TREATkids. For children, only the biological dupilumab is approved from the age of 6 months on. It is in use in an increased trend in all age groups (4.0%, 27.6%, 52.2%, 57.2%). Overall, 40.1% of all children enrolled in TREATkids are treated with dupilumab. The biological tralokinumab and the JAK-inhibitor upadacitinib are approved from 12 years on. Tralokinumab is not in use in TREATkids so far. 4.2% of the patients between 12 and 18 years are treated with upadacitinib. Cyclosporine A is approved from 16 years on, but is in off-label use to a small percentage (2.2%) in all age groups in TREATkids. The JAK-inhibitors baricitinib and abrocitinib are only approved for adults. Baricitinib is in off-label use in 1.1% of the patients between 6 and 12 years. Corticosteroids and antihistamins should only be used as short-term therapy ("rescue therapy"). Corticosteroids are not in use in the TREATkids cohort. Antihistamins are also only recommended to interrupt acute relapses. Approximately 1/4 (24.8%) of all patients of all age groups receive antihistamins in TREATkids.⁴

Figure 6: Comorbidities present in the TREATkids cohort (n=313*). Between the age of 2 and 12 years only approx. 1.2% of all children are diagnosed for ADHD (Attention Deficit Hyperactivity Disorder). This percentage increases to 8.5% in the age group of 12 to 18 years. Asthma increases with age (2.0%, 9.2%, 28.3%, 37.9%). The same is the case for persisting rhinitis (0%, 15.8%, 27.2%, 36.8%) and for intermittent rhinitis (2.0%, 15.8%, 45.7%, 51.6%). The proportion of patients with isolated food allergies decreases with age (44.0%, 33.3%, 10.9%, 8.3%).



Conclusion: Here, we report on the first German registry for infants with moderate to severe AD. With the expansion of the existing clinical registries in Europe for moderate to severe AD to children and adolescents, the routine care of this sensitive patient group will be documented. Now, scientific questions on the frequency of allergic comorbidities, disease severity, care and treatment can be answered from an evidence-based and patient-centered perspective.

