Profile of Patients With Moderate-to-Severe Atopic Dermatitis and Chronic Urticaria Undergoing Biological Treatment in Hospital Allergy Units in Spain: First Report of the Alergodata Registry

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Cutaneous immune-mediated diseases have become a significant global health concern, generating high health care costs worldwide. Their prevalence has increased steadily during the last decade [1,2]. Fortunately for current and future patients, recent advances in our understanding of the pathophysiological mechanisms of these diseases, especially those involving type 2 inflammation [3], have led to the development of new therapeutic alternatives, mainly biological treatments [3-6].

Created on the initiative of the Spanish Society of Allergology and Clinical Immunology, Alergodata is the first registry designed to obtain data on the use of biologic drugs for the treatment of severe diseases evaluated in hospital allergy units throughout Spain. The conditions studied in this registry can be divided into 2 groups, namely, respiratory diseases and skin diseases. We present the first-year results for the skin diseases group (collected from November 19, 2021 to December 1, 2022) and propose a profile for recruited patients with chronic spontaneous urticaria (CSU) and with moderate-to-severe atopic dermatitis (AD). As the registry is still young, we present only initial data, which were recorded at the inclusion visit.

The study resulting from the registry is an observational, prospective, multicenter, and national study conducted under conditions of routine clinical practice. The methodology was published previously [7].

Before inclusion in the Alergodata Registry, patients were informed by means of the patient information sheet and signed an informed consent form. Patients also had to have been treated in a hospital allergy unit during the above-mentioned period and have a diagnosis of CSU or moderate-to-severe AD with an indication for biologic treatment according to the summary of product characteristics (SmPC) approved in Spain. The minimum age for inclusion was therefore determined according to the SmPC. The information was recorded by investigators on an electronic case report form designed specifically for the study.

A total of 200 patients with CSU were recruited from 38 centers; of these, 173 were evaluable. In the case of moderate-to-severe AD, data were from 63 eligible patients evaluated at 58 centers. Missing data were not imputed, resulting in data loss.

Patient profiles of the 2 pathologies of interest were established using sociodemographic variables (view online only supplementary table). In the case of moderate-to-severe AD, there was a slight predominance of men (51.7%), who were mostly Caucasian (86.8%), with a mean (SD) age of 39.6 (13.9) years. These data do not agree with previous findings for patients with moderate-to-severe AD regarding sex and ethnicity [8,9]. Moreover, a female preponderance has been widely observed in adults [6,10,11], and a higher prevalence in Black and Hispanic individuals than in White individuals [11]. Nevertheless, data on ethnicity should be interpreted with caution, as they are highly area-dependent, thus indicating potential selection bias.

Regarding CSU, there was a clear predominance of women (68.6% women vs 31.4% men) and 2 predominant ethnic groups (80.1% White and 18.7% Hispanic), confirming the results of previous studies [5,12]. Mean age was 47.9 years, slightly higher than generally observed for patients with this condition [5,12,13]. As for data on ethnicity, previous studies have shown that, as in the case of CSU, these vary depending on the area, and potential selection bias should be taken into account.

No relationship was established between disease and place of residence or educational level for either of the 2 diseases.

Disease activity and patients' quality of life were measured using various scales and tools (Online supplementary table); the results were consistent with the diagnosis in both cases.

Among patients with CSU, 32.2% had associated angioedema (1-3 episodes) and 32.9% inducible urticaria (dermographism, 70.2%; cholinergic, 28.9%; pressure, 19.6%). The other most frequently reported comorbidities were nonatopic diseases (42.4%) and rhinitis (20.3%). Regarding the AD registry, the most common comorbidities were rhinitis (77.2%), conjunctivitis (61.4%), and mild-to-moderate asthma (57.1%). Total IgE levels were elevated in both diseases with respect to normal levels (≤100 IU/mL [14]), in line with previous data. However, in the case of CSU, only 24.9% of patients presented clinically significant allergic sensitization, compared with 76.7% of patients with AD. Antihistamine treatment was administered to 94.8% of patients with CSU and 97.9% of patients with moderate-to-severe AD.

The only biological treatment prescribed to patients with CSU during the inclusion visit was omalizumab, which is, in fact, the only monoclonal antibody (mAb) with an indication for CSU. Two cases of adverse effects were reported (arthralgia in the lower limbs and erythema/pruritus at the injection site) and led to withdrawal of treatment. As for patients with AD, the vast majority were prescribed dupilumab (91.7%), and the rest received tralokinumab (5%), omalizumab (2%), and benralizumab (2%). Benralizumab was prescribed for comorbid asthma in the hope of a double therapeutic benefit. Only 2 mild-to-moderate adverse events were recorded (1 case of conjunctivitis and 1 of labial herpes); these were both attributed to dupilumab.

The other treatments prescribed before the initial visit were topical corticosteroids in 87.2% of AD patients and systemic immunosuppressants in 46.9%. Among the patients enrolled with CSU, only 15% reported prior treatment with systemic corticosteroids. While rather low, this figure can probably be explained by early up-dosing of antihistamine treatment.

Although we report valuable data, our study is subject to limitations. Despite the rather good quality of CSU data series, relatively few data on AD are available, probably because most AD patients consult dermatologists or primary care centers rather than allergy specialists. Alergodata is a potent registry but still too young to yield significant data. Since the registry will remain open for 5 years, it will be interesting to compare intermediate and final results with those presented here, including safety and efficacy data on biologics collected from follow-up visits.

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Conflicts of Interest

In the last 3 years, Ignacio Jáuregui Presa has received the following: fees as an advisor from Sanofi, Novartis, and Faes Farma; congress support from Sanofi and Faes Farma; and speaker's honoraria from Sanofi, AbbVie, MSD, LETI Pharma, Novartis, Gebro Pharma, Organon, GSK, and Faes Farma.

In the last 3 years, Anna Sala-Cunill has received the following: payment for lectures, including service on speaker's bureaus from Takeda, Behring, Allergy Therapeutics, Chiesi, Leti Pharma, Novartis, AbbVie, Sanofi, Organon, Faes Farma, MSD, and Chiesi; and consultancy fees from Takeda, AbbVie, Novartis, Sanofi, and Pfizer.

In the last 3 years, Paula Ribó González has received speakers' honoraria and personal fees for advisory boards from Sanofi, Novartis, and MartiTor Alergia.

In the last 3 years, Santiago Quirce, has been on advisory boards for and has received speaker's honoraria from ALK, Allergy Therapeutics, AstraZeneca, Chiesi, GSK, Leti, Mundipharma, Novartis, Sanofi-Genzyme, and Teva.

In the last 3 years, María Cesárea Sánchez Hernández has received speakers' honoraria and personal fees for advisory boards from Sanofi, Novartis, Faes Farma, and Lilly.

In the last 3 years, Alejandro Joral Badas has received payment for lectures and speaker's honoraria from Takeda, GSK, Allergy Therapeutics, and Leti.

In the last 3 years, Carmen Vidal Pan has received personal fees for advisory boards from Stallergenes Freer and Leti and speakers' honoraria from Mundipharma, GSK, Leti, Chiesi, and ALK-Abelló.

In the last 3 years, Darío Antolín-Amérigo has received the following: payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing, and educational events from Astra Zeneca, GSK, Novartis, and Sanofi; and payment for expert testimony by Astra Zeneca, GSK, and Sanofi.

In the last 3 years, Beatriz Veleiro Pérez took part in an advisory board for Novartis. She has received speaker's honoraria from Novartis and acted as a teacher-trainer supported by Novartis, Sanofi, AstraZeneca, and Cipla.

In the last 3 years, Milagros Lázaro Sastre has received fees for advisory boards from AbbVie and speaker's honoraria from Sanofi, AbbVie, Novartis, Chiesi, Faes Farma, Organón, and LETI Pharma.

The remaining authors declare that they have no conflicts of interest.

References

1. Torres T, Ferreira EO, Gonçalo M, Mendes-Bastos P, Selores M, Filipe P. Update on Atopic Dermatitis. Acta Med Port. 2019;32(9):606-13.
2. Gonçalo M, Gimenéz-Arnau A, Al-Ahmad M, Ben-Shoshan M, Bernstein JA, Ensina LF, et al. The global burden of chronic urticaria for the patient and society. Br J Dermatol. 2021;184(2):226-36.
3. Muñoz-Bellido FJ, Moreno E, Dávila I. Dupilumab: A Review of Present Indications and Off-Label Uses. J Investig Allergol Clin Immunol. 2022;32(2):97-115.
4. Zuberbier T, Abdul Latiff AH, Abuzakouk M, Aquilina S, Asero R, Baker D, et al. The international EAACI/GA²LEN/EuroGuiDerm/APAAACI guideline for the definition, classification, diagnosis, and management of urticaria. Allergy. 2022;77(3):734-66.

5. Hon KL, Leung AKC, Ng WGG, Loo SK. Chronic Urticaria: An Overview of Treatment and Recent Patents. Recent Pat Inflamm Allergy Drug Discov. 2019;13(1):27-37.
6. Sicras-Mainar A, Navarro-Artieda R, Armario-Hita JC. Severe Atopic Dermatitis In Spain: A Real-Life Observational Study. Ther Clin Risk Manag. 2019;15:1393-401.
7. Antolín Amérigo D, Colás C, Dávila I, Del Cuvillo A, Delgado Romero J, Domínguez-Ortega J, et al. ALERGODATA: Sentinel registry of health outcomes in allergic patients treated with biological therapies from specialized allergology clinics in Spain. J Investig Allergol Clin Immunol. 2023;33(6):479-82.
8. Katoh N, Saeki H, Kataoka Y, Etoh T, Teramukai S, Takagi H, et al. Atopic dermatitis disease registry in Japanese adult patients with moderate to severe atopic dermatitis (ADDRESS-J): Baseline characteristics, treatment history and disease burden. J Dermatol. 2019;46(4):290-300.
9. Kleyn CE, Barbarot S, Reed C, Losi S, von Arx LB, Robert C, et al. Burden of Moderate to Severe Atopic Dermatitis in Adults from France, Italy, and the UK: Patient-Reported Outcomes and Treatment Patterns. Dermatol Ther (Heidelb). 2022;12(8):1947-65.
10. Ojeda P, Sastre J, Olaguibel JM, Chivato T. Alergológica 2015: A National Survey on Allergic Diseases in the Adult Spanish Population. J Investig Allergol Clin Immunol. 2018;28(3):151-64.
11. Sacotte R, Silverberg JI. Epidemiology of adult atopic dermatitis. Clin Dermatol. 2018;36(5):595-605.
12. Maurer M, Houghton K, Costa C, Dabove F, Ensina LF, Giménez-Arnau A, et al. Differences in chronic spontaneous urticaria between Europe and Central/South America: results of the multi-center real world AWARE study. World Allergy Organ J. 2018;11(1):32.
13. Curto-Barredo L, Pujol RM, Roura-Vives G, Gimenez-Arnau AM. Chronic urticaria phenotypes: clinical differences regarding triggers, activity, prognosis and therapeutic response. Eur J Dermatol. 2019;29(6):627-35.
14. Altrichter S, Fok JS, Jiao Q, Kolkhir P, Pyatilova P, Romero SM, et al. Total IgE as a Marker for Chronic Spontaneous Urticaria. Allergy Asthma Immunol Res. 2021;13(2):206-18.

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