Allergologia et immunopathologia
Sociedad Española de Inmunología Clínica, Alergología y Asma Pediátrica
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ORIGINAL ARTICLE

OPEN ACCESS

Quality of life of Turkish children and families of Caucasian origin with atopic dermatitis

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Received 04 April 2020; Accepted 29 July 2020
Available online 2 January 2021

KEYWORDS
atopic dermatitis;
Caucasian;
children; family;
quality of life

Abstract
Introduction and objectives: To determine the quality of life (QoL) in Caucasian children with atopic dermatitis (AD) and their families and possible factors that might impact their QoL.
Materials and methods: In this cross-sectional study, 83 children aged 2-7 with AD and their families were enrolled as the study group, and 83 age-matched healthy children were included as controls. All patients in the AD and control groups were sorted into two age-based groups: (1) 2-4 and (2) 5-7 years of age. The parents of all children completed the Turkish version of the Pediatric Quality of Life Inventory (PedsQL).

The Family Impact Scale for Dermatological Diseases (FIS-DD) was administered to the study group. Disease severity was evaluated with the Patient-Oriented Scoring Atopic Dermatitis (PO-SCORAD) scale.
Results: In both age groups, a negative correlation between the PedsQL and the FIS-DD scores ($p < 0.001$) was found. A positive correlation was found between the PO-SCORAD and FIS- DD scores among the second age group ($p = 0.011$). In the first age group, AD patients with comorbid allergic diseases had higher FIS-DD scores than those without any other allergic problems ($p = 0.007$).
Conclusions: We suggest that considering family QoL may positively contribute to the treatment of pre-school age AD children.

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https://doi.org/10.15586/aei.v49i1.13

Introduction

Atopic dermatitis (AD) is a chronic inflammatory skin disease that is characterized by relapse and remission. Lifetime AD prevalence in children is estimated to be 15–30% and 2–10% in adults. In industrialized nations, AD has increased two to three times over the previous prevalence rates of the disease in the last three decades.[1]

This disease most frequently manifests itself during the 3- to the 6-month-old infancy period.[2,3] The primary symptom of AD is itchiness, which leads to insomnia, fatigue, and irritability and may negatively influence the quality of life (QoL) of patients because of problems ranging from social isolation to psychological disorders. Additionally, the families of AD patients might also be socially, emotionally, and financially affected by this condition.[4–6]

Even though the relationship between AD and QoL is known and the factors that influence the QoL of individuals with AD have been determined, these findings show considerable variation across cultures.[7–10] To date, QoL studies of AD in different populations have evaluated data, such as the Scoring Atopic Dermatitis (SCORAD) index, ages, and genders, which are factors that are suspected to be associated with AD.

We aimed to concurrently evaluate the QoL of Turkish (Caucasian) families and children with AD ranging in age from two to seven who underwent AD treatment. We also aimed to investigate the impact of individual and family variables and disease-related factors (disease severity, comorbid allergic diseases, atopy, age and sex, parental education levels, and income levels of families) on the QoL of the patients and families.

Compliance with ethical standards

Ethics approval

Approval was obtained from the Keçiören Research and Training Hospital's ethics committee. The procedures used in this study adhere to the tenets of the Declaration of Helsinki.

Consent to participate

Informed consent was obtained from all individual participants included in the study.

Materials and methods

Children with ages ranging from 2 to 7 years old with AD (n = 83) who were admitted to Dr. Sami Ulus Hospital's Children's Allergy and Immunology Clinic between July 28, 2016 and June 30, 2017 and their families were recruited for this cross-sectional survey study nested with a randomized trial.

The control group (n = 83) was formed of randomly selected age-matched healthy children without taking their gender into account. For randomization, two healthy children with registration numbers 1 and 2 at the social pediatrics outpatient clinic applied for routine child follow-up were invited to the study daily if they had no chronic diseases. The age-appropriate study questionnaire was administered to the control group who agreed to participate in the study. All patients in the AD and the control groups were sorted into two age-based groups: (1) 2–4 and (2) 5–7 years of age (first and second age groups, respectively) in order to administer the appropriate questionnaire forms.

The AD diagnosis was made based on the Hanifin–Rajka criteria.[11] Patients who were diagnosed with and/or those who previously received treatment for AD in another clinic before were excluded from the AD patient group in order to avoid any bias due to possible differences in AD diagnosis and treatment. Children diagnosed with AD but in remission were not enrolled in the study. Only the children showing acute symptoms of AD and treatment-naive were included in the study. Moreover, individuals with any other chronic diseases other than AD and children with prior surgery or hospitalization histories were excluded from the study.

Approval for this study was obtained from Keçiören Research and Training Hospital's Ethics Committee on July 27, 2016 with protocol number 2012-KAEK-15/1185. Informed consent forms were received from all patient families and healthy controls who participated in the study. A query form was prepared and filled out for children with AD that included information such as age and sex of the patients, disease duration, presence of atopy and other comorbid allergic diseases, and a family history of the presence of allergic diseases. On the skin allergy test, >3 mm endurance compared to the negative control and/or high serum-specific IgE (>0.35 ×103) value for at least one allergen (aero-allergen, mold, animal, and food panels) was accepted as atopy.

The disease severity of patients was measured using the electronic version of the Patient-Oriented (PO)-SCORAD[12] under the supervision of the same physician. The PO-SCORAD scores were classified as mild (≤15), medium (>15 to ≤40), and age group of the patients (first and second age groups), the appropriate version of the adapted and validated Turkish version of the *Pediatric Quality of Life Inventory* (PedsQL)[14] was used as the questionnaire for the parents of children in the AD and control groups. In the PedsQL inventory, respondents were requested to answer each one of the questions by selecting one of the five choices ranging from 0 to 5 corresponding to never, rarely, sometimes, often, or almost always. Answers were then quantified by assigning 100 points to "never," 75 points to "rarely," 50 points to "sometimes," 25 points to "often," and 0 points to "almost always." The average score was calculated by summing all scores and then dividing by the number of items in the inventory. No cut-off thresholds were implemented in scoring; lower scores indicated a bad QoL. PedsQL scores were calculated for each of the physical, emotional, social, and school subcategories in addition to the total score for the entire inventory

To evaluate the QoL of the families of the patients with AD, we implemented the *Family Impact Scale for Dermatological Diseases* (FIS-DD).[15] The FIS-DD includes items concerning psychological problems, health expenditures, physical well-being, burden of caring, and social life. The scoring in FIS-DD is based on Likert-type answers

ranging from 0 to 4, corresponding to never, rarely, sometimes, often, or always. Higher scores on the FIS-DD indicated poor QoL. All necessary permission was obtained from the authors who conducted the validity and reliability studies of the Turkish adaptation of the scales used in this study.

Statistical analyses

For the QoL scale, the mean score for the universe was 71.6. The mean approved score specific to our study was 70.0 ± 10.0. When these scores were taken into consideration, it was found that the sample of 83 children was sufficient for the study to reach a significant difference of 1.6 points when the univariate t-test was applied at 80% power and 0.05 significance level. All statistical analyses were performed with IBM SPSS Statistics for Windows (Version 23.0; IBM Corp., Armonk, NY, USA). Descriptive statistics for quantitative variables were summarized with mean, standard deviation (mean ± SD), and median with range (min–max). Categorical variables were summarized with frequencies and percentages. Parametric/non parametric tests used in the statistical analyses were selected according to data distribution. Relationships between categorical variables were tested with the chi-squared test. The normality of the quantitative variables was examined with the Shapiro–Wilk test. Mean differences between the two groups were investigated using the independent Student's t-test, provided that the parametric assumptions were met. When these assumptions were violated, we used the Mann–Whitney U-test. When the numbers of groups were more than two, a comparison of means was examined using the Kruskal–Wallis test. The relationship between two continuous variables was tested using Spearman's correlation coefficient. Multivariable linear regression was used to determine the relationship between variables and QoL scores. The comparison among groups was performed with the Least Significant Difference test. The significance level for all analyses was accepted as $p \leq 0.05$.

Results

No statistically significant differences between study and control groups (n = 83 in each group) in terms of age and sex were noted (Table 1).

Among all participants, the survey questions were answered by mothers in 79.3 and 79.7% of cases in the first and second age groups, respectively. Parents who answered the questions in both groups were similar with respect to education levels ($p = 0.882$ and 0.190 for the first and second age groups, respectively). The monthly income of the study and control groups of the first age group were similar, whereas the second age group study children's families had significantly higher-income than the controls ($p = 0.001$).

When we evaluated the PO-SCORAD scores, the mean score of the patients with AD in the first age group was 25.6 ± 16, whereas, in the second age group, it was 23.5 ± 14.7. Based on the PO-SCORAD scores, 15 of the 47 patients in the first age group were diagnosed with mild, 24 were diagnosed with medium, and eight were diagnosed with heavy dermatitis. Twelve of the 36 patients in the second age group were diagnosed with mild, 18 with medium, and six with heavy dermatitis. We found atopy in 27.7% of the AD patients. Based on the allergy tests, we detected egg (n=11) as the most frequent allergen. In 37.3% of the AD group (n=31), at least one additional allergic disease along with AD was detected (Table 2).

Pediatric quality of life inventory

When the PedsQL and its sub-category scores of the AD and the control groups were compared with consideration of age groups, no statistically significant mean differences ($p > 0.05$) within the first age group were detected. However, in the second age study group, physical, social, and total scores were significantly different from the control group ($p = 0.020$, 0.011, and 0.018, respectively). These scores were positively correlated with the income levels of the families of the second age group ($r = 0.569$, $p \leq 0.001$; $r = 0.456$, $p = 0.005$; $r = 0.724$, $p \leq 0.001$, respectively). A negative correlation was also found between the age of the participants and the total scores of PedsQL ($r = -0.219$, $p = 0.005$).

In both the first and second age groups, there were weak negative correlations between PedsQL and PO-SCORAD scores of the AD group; however, these relationships were not statistically significant ($r = -0.155$, $p = 0.300$ and $r = -0.241$, $p = 0.156$, respectively). In the second group, we found a weak negative correlation between the PO-SCORAD index and PedsQL physical subgroup scores ($r = -0.380$, $p = 0.022$).

Table 1 Comparison of the Demographic variables for the atopic dermatitis and control groups of children.

Demographic Variables			AD Group n= 83 (%)	Control group n= 83	p
Age	2–4 age group		33.1 ± 7.7	36.7 ± 7.4	0.116
(Mean ± SD, month)	5–7 age group		64.8 ± 8.9	68.7 ± 10.1	0.540
Sex (n, %)	2–4 age group	Female	18 (38.2%)	15 (37.5%)	
		Male	29 (61.8%)	25 (62.5%)	1.000
	5–7 age group	Female	17 (47.2%)	26 (60.5%)	
		Male	19 (52.8%)	17 (39.5%)	0.342

SD: standard deviation, n: number; AD: atopic dermatitis

Table 2 Baseline characteristics of patients with atopic dermatitis.

Basal Characteristic Features		First age group of children (2-4 Ages) (n=47) (%)	Second age group of children (5-7 Ages) (n=36) (%)	Total (n=83) (%)
Atopy (n, %)	Exists	14 (29.7)	9 (25)	23 (27.7)
Triggering food (n, %)	Exists	15 (31.9)	11 (30.5)	26 (31.3)
Comorbid Allergic	Asthma	1 (2.1)	12 (33.3)	13 (15.6)
Disease (n, %)	Allergic rhinitis	3 (6.3)	5 (13.8)	8 (9.6)
	Food allergy	5 (10.6)	2 (5.5)	7 (8.4)
	Drug allergy	2 (4.2)	1 (2.7)	3 (3.6)
	Total	11 (23.2)	20 (55.3)	31 (37.2)
PO-SCORAD Score	Mean ± SD	25.6 ± 16	23.5 ± 14.7	
	Median	22.2	18.7	
	Range (Min-Max)	3.2-68.4	5.4-55.9	
Duration of the Disease	Mean ±SD	20.3±12.5	38.6±25.3	28.2±21.1
(Atopic Dermatitis,	Median	24	46.5	24
month)	Range (Min-Max)	1-39	2-84	1-84

SD: standard deviation, n: number; PO-SCORAD: Patient-Oriented Scoring Atopic Dermatitis; AD: atopic dermatitis

In the second age group, we recorded a statistically significant difference between the girls and boys in emotional life quality (p = 0.028). Boys' emotional scores (mean: 79.2 ± 20.7; median: 100; range: 35–100) were higher than those of the girls (mean: 64.4 ± 19.4; median: 65; range: 20–100).

When we checked the relationship between the duration of AD and QoL, we realized that no statistically significant relationships either in the first age group (r = –0.282; p = 0.055) or in the second age group (r = –0.199; p = 0.244) were detected.

No statistically significant correlation was found between the education levels of the parents of patients with AD (p = 0.736 and 0.992 for the first and second age groups, respectively).

Family impact scale for dermatological diseases

The QoL of families of patients with AD was measured with the FIS-DD (Table 3). We did not find a correlation between the age and sex of AD patients with the FIS-DD scores (p-value for age was 0.384, and the p-values for sex of the first and second age groups were 0.303 and 0.318, respectively).

Investigation of the relationship between the PO-SCORAD scores of the patients with AD and the QoL scores of their families revealed that while no statistically significant correlation between these two existed in the first age group (r = 0.253, p = 0.087), there was a weak positive correlation between them in the second age group (r = 0.424, p = 0.11).

We tested whether the FIS-DD scores of the AD groups (both age groups) varied across different education levels and gender of their parents, but no statistically significant relationship for the first and second age groups was noted (p = 0.303; 0.954 for the first age group, and p = 0.318; 0.470 for the second age group, respectively).

After examining the relationship between AD duration and FIS-DD, we found that even though the QoL of the parents had deteriorated as the duration of the disease increased, the relationship was not statistically significant (r = 0.203, p = 0.170 for the first age group and r = 0.218, p = 0.208 for the second age group).

There was a relatively strong and statistically significant negative correlation between the PedsQL and FIS-DD scores of the patients with AD in both age groups (r = −0.607, p < 0.001 for the first age group and r = −0.571, p < 0.001 for the second age group).

In the study group for both age groups, we evaluated and compared the effects of the presence of atopy and/or any additional allergic diseases on PedsQL and FIS-DD scores, as shown in Table 4. In the first age group, AD patients with comorbid allergic diseases had higher FIS-DD scores than those without any other allergic problems (p = 0.007). Additionally, a statistically significant difference was found in the second age group among patients with and without atopy when the FIS-DD score of families of AD patients was compared according to these parameters (p = 0.034).

Table 3 Family impact scale for dermatological diseases for the two age groups of children with atopic dermatitis

Age group	Mean ± SD	Median	Range (Min-Max)
2-4 Years n=47	23.5 ± 13.1	23	0-50
5-7 Years n=36	19.1 ± 12.4	15	1-53
Total n=83	21.6 ± 12.9	20	0-53

SD: standard deviation, n: number

Multiple linear regression of variables associated with QoL measures

In the first age group, comorbid allergic diseases (β = −0.353, p = 0.017), and in the second age group, the

Table 4 The relationship between the pediatric quality of life inventory and family impact scores for dermatological diseases scores with the presence of atopy and/or comorbid allergic diseases in AD patients.

Age Group	Atopy	PedsQL Total Score	p	FIS-DD Score	p
2-4 Years	Exists n=14	74	0.055	29.7	0.056
	Not exists n=33	82.6	20.9		
5-7 Years	Exists n=9	71.6	0.086	29.8	0.034
	Not exists n=27	85	15.9		
	Comorbid Allergic Disease	PedsQL Total Score	p	FIS-DD Score	p
2-4 Years	Exists n=11	70.8	0.061	32.6	0.007
	Not exists n=36	82.8	20.7		
5-7 Years	Exists n=17	77.4	0.190	21.5	0.441
	Not exists n=19	85.4	17		

n: number, PedsQL: Pediatric Quality of Life Inventory, FIS-DD: Family Impact Scale for Dermatological Diseases

Table 5 Multiple linear regression of variables associated with QoL measures.

Age group	Domain	Predictor variable	P-value	β	R^2
2-4 Years	PedsQL	Comorbid allergic diseases	0,017	−0,353	0,125
	FIS-DD	Comorbid allergic diseases PO-SCORAD	0,001	0,475	0,319
			0,019	0,309	0,322
5-7 Years	PedsQL	Atopy	0,030	−0,361	0,131
	FIS-DD	Atopy	0,003	0,461	0,369
		Level of income of families / month	0,011	−0,378	0,375

β: Beta coefficient, R^2: coefficient of determination

presence of atopy (β = −0.361, p =0 .030) significantly contributed to the variance in PedsQL. Considering FIS-DD scores as the domain, in the first age group comorbid allergic diseases (β = 0.475, p = 0.001) and PO-SCORAD scores (β = 0.309, p = 0.019), and in the second age group atopy and monthly income levels of families significantly contributed to the variance (β = 0.461, p = 0.003 and β = −0.378, p = 0.011, respectively) (Table 5).

Discussion

In this prospective cross-sectional study addressing children with AD in the first age group, we highlight three primary outcomes: (1) it was shown that the QoL of children with AD and their families were significantly associated with each other; (2) as the PO-SCORAD index increased, the QoL of patients and their families deteriorated. Although there was a significant correlation between the PO-SCORAD index increase and FIS-DD scores only in the second age group; multiple linear regression analyses revealed a significant relationship between FIS-DD and the PO-SCORAD index in the first age group; (3) family QoL was found to be adversely affected by atopy in the second age group, and any accompanying comorbid allergic disease(s) had an adverse effect on QoL in the first age group.

As is widely known, PedsQL is a reliable survey instrument for measuring the QoL of children[14] from ages 2 to 18 years. Even though PedsQL is not a disease-specific instrument, PedsQL provides valuable research advantages, such as the capability of separately evaluating different factors that influence the QoL, the capacity to uncover information specific to different age groups, and easy administration. In the first age group, no statistically significant mean differences in QoL between the AD and control groups in terms of the total score and subcategories of PedsQL were noted. However, in the second age group, patients with AD had higher QoL scores than those in the control group in both the total score and physical and social QoL subcategories of PedsQL. In a study by Daud et al.,[16] it was found that children with heavy AD demonstrated significant behavioral problems compared to those in the control group. This finding contrasted with ours and might be the result of the high-income status of the second age study group of families admitted to our hospital, as we demonstrated by correlation analysis. Another reason might be the fact that PedsQL was not specifically developed for patients with dermatological diseases.

Because AD is a chronic disease characterized by relapse and remission, caring for children with AD is a complicated process for their families that restricts their lives and finances and has the great potential to cause hopelessness, exhaustion, and even depression for parents. Therefore as expected, the QoL of the families with children who have AD is found to be lower than those who have healthy children.[17] In our study, we used the FIS-DD[15] to measure family QoL. This scale has high validity and reliability and consists of 15 uncategorized items for evaluating

the different life dimensions. When we ran a bivariate correlation test between the PedsQL and FIS-DD for children with AD in either group, we found a negative correlation in which an increase in FIS-DD was matched with a decrease in the PedsQL scores. However, the FIS-DD questionnaire form was not categorized into subgroups; thus, we were not able to determine the specific areas of families that were most affected.[16–18] Therefore, in the management of children with AD, families' well-being must also be taken into consideration.

The PO-SCORAD was used as a self-assessment tool to monitor the status of patients with AD as its reliability and applicability have already been proven.[19] Although the QoL of the patients decreased as the PO-SCORAD scores increased, this relationship was not statistically significant. Only in the second age group did we find a statistically significant relationship between PO-SCORAD and physical QoL, a subcategory of PedsQL. Use of PedsQL allows for evaluation of daily activities, such as walking and running in the physical QoL subcategory along with "pain-ache" and "low energy," from which children with AD are expected to be negatively affected. These findings demonstrate the importance of disease-specific instruments in the evaluation of the relationship between disease severity and QoL.

When the relationship between AD severity and QoL of the families was compared with the correlation method, it was seen that the QoL of families declined only in the second age group. However, multiple linear regression analyses also revealed a significant relationship between FIS-DD and the PO-SCORAD index in the first age group. Similar to our results, Monti et al.[20] reported a statistically significant correlation between the SCORAD index and DFI separately for the 1–4 and 5–7-year-old age groups. We did not find a relationship between disease duration and QoL of the patients and their families similar to the study by Chernyshov et al.[9] However, in contrast to our study, the age of children was negatively correlated with DFI scores. The authors did not view significant differences after considering either the age range of a child as a variable or AD severity × child's age. A study by Marciniak et al.[21] on a group of 50 families with AD children revealed that when both parents were considered separately, the QoL of the mothers was more negatively affected compared to that of fathers. In our study, we administered the survey to only one of the parents, among whom mothers were in the majority. As shown in several studies, these families need more than just relief of physical AD-related symptoms and can benefit from a multidisciplinary approach.[22]

In our study, we did not find any statistically significant difference between male and female patients in the first age group with respect to the PedsQL total and subcategory scores. Nevertheless, in the second age group, male emotional scores were higher than females, indicating the male quality of emotional life was better. Since their basic needs and social expectations are similar in younger children, it can be predicted that there would be no relationship between the age and gender of the patients and their QoL. Research by Chernyshov[23] concerning children with AD < 4 years old showed that parents of female patients report a significant amount of negative influence due to AD on the emotional condition of their daughters. In our study, as age increased, the quality of emotional life was negatively affected. This negative effect could be attributed to the importance of the aesthetic concerns of girls and the importance of girls' appearances assigned to them by their families. In both age groups, we could not find a statistically significant difference between girls and boys and their families' FIS-DD scores. In the literature, several studies have reported that in children with AD in any period ranging from 1 month to 16 years of age, the QoL of families of female patients was much worse than in the families of male patients although another study did not describe this type of finding.[23–25]

In the patient and control groups, there was no statistically significant correlation between the education levels of the parents of the participants who completed the questionnaire and the PedsQL total and FIS-DD scores in each age group. Balkrishnan et al.[26] found no statistically significant correlation between parents of children aged 6–12 years with AD from the USA who had an education level of at least high school with the scores. To date, there is no study evaluating the effect of parental education levels on the QoL of children with AD. Monti et al.[20] did not find a relationship between the socioeconomic status of families and the QoL of children and families. Contrary to them, we found a significant relationship between FIS-DD and income levels in the second age group with multiple linear regression analysis.

We report that in the dermatological allergy tests, the highest sensitivity was against milk and egg in 18 out of 23 cases. However, while the existence of atopy did not affect the QoL of children with AD in both study groups, we found that this food allergy only caused a decline in QoL of families of the second age group. In our study, the existence of atopy did not have any effect on the QoL of first age group families. We detected house dust mites and pollen sensitivity as the most frequent allergens among the second age group. AD patients with aeroallergen sensitivity might experience exacerbation throughout the year, and difficulties in avoiding these allergens could lead to deterioration in QoL for the patients' families.

Of the 31 AD cases in our study, the patients had at least one comorbid allergy (asthma was the most prevalent) in addition to AD. Although the existence of additional comorbid allergic diseases did not have any negative influence on second age study group children in our study, AD patients and their families in the first age group who had other allergies had worse QoL scores than families of patients without any other allergies. When we searched the literature for information about the relationship between comorbid allergic diseases and QoL, it was reported that children with food allergies in addition to AD had lower QoL scores than children who only had AD.[7] Similarly, in our study, it was found that a food allergy was the most common comorbid allergy in the first AD group. However, due to the limited number of patients, we could not conduct any further analyses to investigate the effect of different comorbid allergic diseases on QoL.

Among the limitations of our study, we used the PedsQL because there is no readily available validated specific Turkish QoL questionnaire form for children with AD. Second, we could not cover the infant period in which AD is most commonly seen, and patients are evaluated at a single visit; therefore, we could not assess whether there was an

improvement in QoL after treatment. Although the assessment of disease severity via PO-SCORAD might be biased due to subjective patient reporting, the supervision of the same physician during these evaluations might be considered as an advantage. On the other hand, this is the first study that evaluated the relationship between QoL of children with AD under 7 years of age and their families in Turkey.

Consequently, as a chronic disease, AD should be managed not only with patient treatment but also through the social-psychological support of the children and their parents. We may assume that the QoL improvements for AD patient's family members, such as the ease of accessing healthcare services, relieving their financial concerns, and raising awareness of the health status of their children may all be useful in contributing positively to the treatment of these children. Therefore, we suggest that the improvement in the QoL of families of children with AD may positively contribute to this chronic condition and may improve our treatment in preschool-age children.

Acknowledgments

We thank Prof. Ilknur Bostanci, MD, who guided us with her experience at every stage of our research.

Funding

No sources of funding were used to assist in the preparation of this study.

Conflicts of interest

Dr. Ekin, Dr. Nazlı, and Professor Serap confirmed that they have no conflicts of interest or financial ties to disclose.

Consent for publication

Authorship statement confirming that listed authors meet the authorship criteria and that the authors are in agreement with the consent of the manuscript. This manuscript has not been published or submitted elsewhere for publication except "Allergologia et Immunopathologia."

Authors' contributions

I confirm that Dr. E.O and Dr. N.E. listed as authors equally contributed to the study under the supervision of Prof S.Ö. All people listed as authors of the manuscript have read and approved the final submitted version of this manuscript to "Allergologia et Immunopathologia."

Prof S.Ö., as the leader of the group, contributed to the design of the study, and Dr. N.E. and Dr. E.O. substantially and equally contributed to the study planning, data collection, interpretation of the results, and wrote the manuscript and critically revised where necessary. All authors of the original manuscript have read, approved, and in full agreement with the submitted manuscript.

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