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FOOD ADDITIVE PATCH TESTING IN CHILDREN WITH ALLERGIC SKIN SYMPTOMS

ALERJİK CİLT SEMPTOMLARI OLAN ÇOCUKLARDA BESİN KATKI MADDELERİ İLE YAMA TESTİ

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Abstract

Objective: Food additives may cause various allergic symptoms in children; however, there are limited studies investigating sensitivity to food additives. The aim of this study was to evaluate the diagnostic value of food additive patch testing (FAPT) in patients who have detected allergen sensitivity with FAPT and have been recommended a diet.

Material and Methods: Data of patients aged 2-18 years who presented between January 2017 and January 2023, reported allergic symptoms associated with the consumption of prepared and packaged foods and underwent FAPT were retrospectively recorded.

Results: A total of 342 patients who underwent FAPT in our study were evaluated. The positivity rate for at least one allergen among the 342 patients was 28.7%. Amaranth was detected as a suspected allergen in 48 (14.0%) out of 342 patients who underwent FAPT. Among the 98 patients who tested positive for the FAPT, acute/intermittent urticaria was found in 56 (57.1%) of them. Additionally, confectionery and chocolates were identified as suspicious foods that could cause symptoms in 58 (59.2%) of the 98 patients who tested positive for the FAPT. It was observed that 56.1% of the patients followed a diet after detecting the food additive product, and 46.9% of 98 patients who tested positive for the FAPT benefited from the diet. During the 4-month follow-up, 45 patients (45.9%) who did not fully adhere to their diet experienced a recurrence of symptoms upon consuming the allergen to which they were sensitive.

Conclusion: Performing a FAPT in patients describing symptoms after consuming processed foods may be beneficial; however, further studies are needed to support this issue.

Öz

Amaç: Besin katkı maddeleri, çocuklarda çeşitli alerjik semptomlara neden olabilir, ancak besin katkı maddelerine duyarlılığı araştıran çalışmalar sınırlıdır. Bu çalışmanın amacı, besin katkı yama testi (BKYT) ile alerjen duyarlılığı tespit edilen ve diyet önerilen hastalarda BKYT'nin tanısal değerini değerlendirmektir.

Gereç ve Yöntemler: Ocak 2017 ile Ocak 2023 tarihleri arasında başvuran, hazır ve paketlenmiş gıdaların tüketimi ile ilişkili alerjik semptomlar bildiren ve BKYT uygulanan 2-18 yaş arası hastaların verileri retrospektif olarak kaydedildi.

Bulgular: Çalışmamızda BKYT uygulanan toplam 342 hasta değerlendirildi. Bu 342 hastanın %28,7'sinde en az bir alerjene pozitiflik tespit edildi. BKYT uygulanan 342 hastanın 48'inde (%14,0) amarant şüpheli alerjen olarak tespit edildi. BKYT'de pozitiflik saptanan 98 hastanın 56'sında (%57,1) akut/aralıklı ürtiker en sık klinik başvuru sebebiydi. Ayrıca, BKYT pozitif olan 98 hastanın 58'inde (%59,2) semptomlara neden olabilecek şüpheli besin olarak şekerlemeler ve çikolata olarak belirlendi. BKYT pozitif olan hastaların %56,1'inin diyet uyguladığı ve %46,9'unun diyetten fayda gördüğü belirlendi. Ayrıca, 4-aylık takipte, diyete tam olarak bağlı kalmayan 45 hastada (%45,9) hassasiyet gösterdikleri allerjenin tüketiminde semptomların tekrar ortaya çıktığı tespit edildi.

Sonuç: İşlenmiş gıdaları tükettikten sonra semptom tarifleyen hastalarda BKYT uygulanmasının faydalı olabileceği düşünülmektedir, ancak bu konuyu destekleyecek daha fazla çalışmaya ihtiyaç vardır.

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Anahtar Kelimeler Alerji · amarant · çocuklar · besin katkı maddeleri · yama testi

INTRODUCTION

Food additives are compounds added to products to fulfil specific functions, such as colouring, flavouring, or preservation, and they are widely used in food ingredients. The Food and Drug Administration has reported that there are more than 3000 registered food additives in use today (1).

Food additives can lead to various allergic reactions, including IgE-mediated, non-IgE-mediated, and mixed-type (IgE/non-IgE) reactions, such as exacerbation of symptoms such as chronic urticaria (CU), atopic dermatitis (AD), anaphylaxis, angioedema, asthma, or allergic rhinitis (AR) (2, 3).

Among the food additives commonly used to improve the flavour, appearance and shelf life, antioxidants such as butylated hydroxyanisole and butylated hydroxytoluene prevent the oxidation of fats, while food colourings such as tartrazine, carmine, annatto and amaranth give the products the desired colour but can rarely cause urticaria and anaphylaxis. Emulsifiers and stabilisers such as guar gum and propylene glycol are used to improve the texture and consistency of foods, while artificial sweeteners such as aspartame offer a low-calorie sweetness and can sometimes be associated with urticaria. Preservatives such as benzoates, nitrites and sulphites can inhibit microbial growth, but can also cause skin reactions in sensitive individuals and aggravate asthma symptoms (2, 3).

In a study conducted in Denmark, the prevalence of hypersensitivity to food additives was found to be approximately 1-2%, in a population-based study in Britain, the prevalence was found to be 0.026%, and in an adult study in the Netherlands, the prevalence was found to be 0.2% (4-6).

Despite numerous studies on atopy patch tests (APT) used to identify delayed-type hypersensitivity reactions to foods, there are limited studies on the use of APT for diagnosing reactions caused by food additives (7-9).

In a study Anıl and colleagues, evaluating children with AD and healthy children, 62% of children with AD and 20% of healthy controls reported a positive APT reaction to at least one food additive allergen (10).

Similar to food allergies, double-blind oral challenge tests are considered the gold standard for confirming hypersensitivity to food additives (11).

However, due to the lack of a standardised protocol for food additives in the literature and difficulties in sourcing these substances, its application is not always feasible.

Therefore, conducting APT to determine the cause of allergic symptoms in patients consuming food additive products and subsequently eliminating the identified suspicious allergen substance from the diet may be an option (12).

In our study, the most frequently reported food additives in the literature were selected, and patch tests were conducted for *amaranth, aspartame, azorubine, benzoic acid, butylated hydroxyanisole, butylated hydroxytoluene, carmine, cochineal red, sodium diphosphate, sodium nitrite*, and *tartrazine*.

The aim of this study was to assess the diagnostic accuracy of the food additive patch test (FAPT) by determining whether any suspicious substances were identified in the FAPT and evaluating the clinical benefit of patients' diets against responsible food additives.

MATERIAL AND METHODS

Patient Group

Our study was designed as a retrospective study. The results of patients aged 2-18 who presented to our Paediatric Allergy Clinic between 2017 and 2023, reported allergic symptoms (urticaria, angioedema, itching, eczema, erythema) associated with the consumption of prepared foods and/or packaged foods containing food additives and underwent FAPT for suspected food consumption and symptom relationship were recorded retrospectively. Symptoms were primarily based on caregiver (parental) reports obtained during outpatient visits and were subsequently documented by physicians in the medical records. In cases of overlapping symptoms, each symptom reported by the caregivers was documented as a separate entry, regardless of their co-occurrence in the clinical presentation. Patient data, including age, gender, presenting symptoms (urticaria, angioedema, itching, eczema, erythema), family history of atopy, suspected food consumed in the last 10 days (confectionery, chocolate, carbonated beverages, processed meat, chips, ready jam, other (spices)), accompanying history of allergic diseases (asthma, AR, AD), serum total IgE level, eosinophil count and percentage, and allergy skin prick test (SPT) results (food and/or aeroallergens) were recorded. Patients who tested positive for sensitivity in the FAPT were provided with label information and were given a restricted diet containing the allergen to which they were sensitive. Diet responses were recorded during the 2nd and 4th month outpatient clinic evaluation.

Patients who did not experience symptoms (urticaria, AD, itching, angioedema, and erythema) during the period when they did not consume the suspected food were considered

to have benefited from the diet. Conversely, patients who continued to experience symptoms despite adhering to the diet were considered not to have benefited from it. The restricted diet is given in Table 1. Patients with chronic comorbidities and those without a history of prepared and/or packaged food consumption were not included in the study.

Table 1. Recommended food additive-free diet

Jam, jelly, ice cream
Coloured drinks
Chewing gums, candies, biscuits and wafers
Ready-made cakes
Coloured milk and yogurt
Ready-made sauces
Snack foods
Sausages

Atopy patch test for food additives

All patients participating in this study underwent patch testing on the upper back using 11 allergens from the food additives series (*amaranth, aspartame, azorubine, benzoic acid, butylated hydroxyanisole, butylated hydroxytoluene, carmine, cochineal red, sodium diphosphate, sodium nitrite, tartrazine*) (AllergeEAZE company). Petrolatum and an empty Finn chamber were used as control tests. Before applying the patch test, families were instructed not to use antihistamine and corticosteroid-containing cream/ointment on their children for 10 days. Patients who discontinued systemic corticosteroid treatment at least one month prior were included in our study. Results were evaluated by the same paediatric allergist 72 h after applying the patch test. In case of any suspected reaction, patients were advised to return on the fifth day. The evaluation was interpreted according to the American Academy of Dermatology guidelines. Reactions of +1, +2, and +3 were considered positive (13).

Patients with positive FAPT results were recommended a diet without food additives, and their dietary responses were evaluated at the outpatient clinic visits at the 2nd and 4th months.

Skin Prick Test

The skin prick test aeroallergen panel used in our study included house dust mites (*Dermatophagoides pteronyssinus* and *Dermatophagoides farinae*), pollen allergens (*weed, tree, and grass pollens)*, mould fungi (*Alternaria*), and animal epithelia (*cat fur epithelium, dog epithelium, and cockroach*). In addition, all patients underwent SPT for common food allergens, including cocoa, egg white, egg yolk, milk, peanut, and wheat.

Ethics

Our study was conducted following the principles of the Helsinki Declaration and Good Clinical Practices. Informed voluntary consent forms were obtained from the patients. This study was approved by the Clinical Research Ethics Committee of Sağlık Bilimleri University, Prof. Dr. Cemil Taşcıoğlu City Hospital (Date: 14.04.2025, No: 134).

Statistics

The SPSS 15.0 for Windows programme (SPSS Inc., Chicago, IL, USA) was used for statistical analysis. Descriptive analyses of the groups were given as mean, standard deviation, median, minimum, and maximum for the numerical variables and as number and percentage for the categorical variables. Rates between groups were compared using the chi-square test. Since the normal distribution condition was not met for the comparison of numerical variables in the two independent groups, the Mann–Whitney U test was used. Correlation matrices were generated using the Python programming language. The statistical alpha significance level was set as $p<0.05$.

RESULTS

A total of 342 patients who underwent FAPT were evaluated in our study. Of the patients, 42.1% were female and 57.9% were male. The mean age of the patients was determined to be 7.1 years (2-17.5). The positivity rate for at least one allergen among the 342 patients was 28.7%. Amaranth was detected as a suspected allergen in 48 (14.0%) out of 342 patients with all FAPT (Table 2). Among a total of 28 patients, only amaranth positivity was observed, while in the remaining 20 patients, amaranth positivity was observed alongside other substances *(azorubine, cochineal red, butylated hydroxyanisole, butylated hydroxytoluene, tartrazine, and carmine)*. The correlation matrix of food additives in patch test-positive patients is presented in Figure 1. The heatmap illustrates the relationships between different food additives, with correlation values ranging from −0.26 to 1.00.

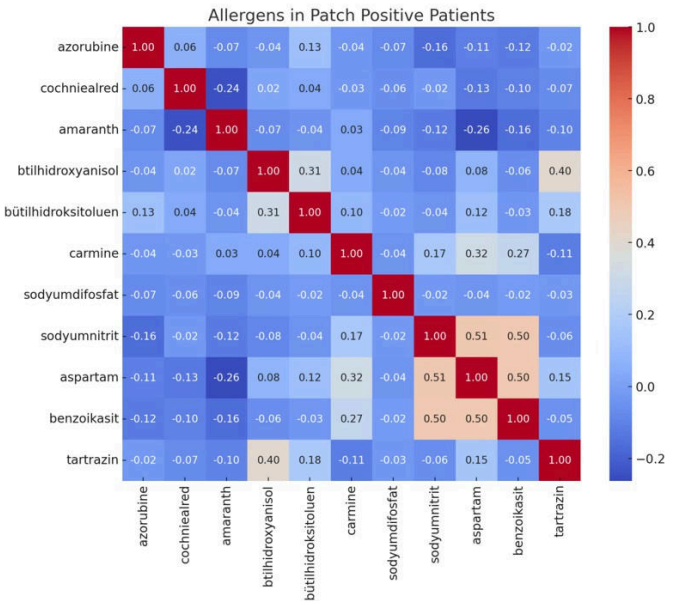

Figure 1. Correlation matrix of food additives in patch test-positive patients

No strong allergen correlations were identified. However, some moderate correlations are notable in the table. The highest correlations were observed between sodium nitrite and aspartame (r=0.51, p<0.001), and between sodium nitrite and benzoic acid (r=0.50, p<0.001). Additionally, moderate correlations were found between aspartame and benzoic acid (r=0.50, p<0.001), and between butylated hydroxyanisole (BHA) and tartrazine (r=0.40, p<0.001). These findings suggest that sensitivities to certain food additives may co-occur.

Table 2. Characteristics of all patients who underwent nutritional supplement patch testing

		Total n=342
		n (%)
Gender	Female	144 (42.1)
	Male	198 (57.9)
Age (years) Mean±SD Min-Max (Median)		7.1±3.8
		2-17.5 (6)
Complaint at admission	Acute/ intermittent urticaria	200 (58.5)
	Itching	133 (38.9)
	Angioedema	106 (31.0)
	Eczema	48 (14.0)
	Erythema	5 (1.5)
Family history of atopy	None	277 (81.0)
	Present	65 (19.0)
Suspected food	Sweets, chocolate	181 (53.1)
	Chips	74 (21.7)
	Acidic drink	47 (13.8)
	Processed meat	22 (6.5)
	Spices	18 (5.3)
	Ready-made jam	12 (3.5)
Other allergic diseases	None	231 (67.5)
	Asthma	35 (10.2)
	Allergic rhinitis	34 (9.9)
	Atopic dermatitis	30 (8.8)
	Other	12 (3.5)
IgE Mean±SD Min-Max (Median)		262.2±549.0
		1-7485 (114)
		3,40±3.54
Eosinophil % Mean±SD Min-Max (Median)		0-45 (2.6)
Allergy skin test positivity	Negative	232 (74.1)
	Aeroallergen	61 (19.5)
	Food	14 (4.5)
	Aeroallergens and food	6 (1.9)
	Unknown	29 (8.5)
Food additive patch test result	*Amaranth*	48 (14.0)
	Azorubine	34 (9.9)
	Cochineal red	25 (7.3)
	Carmine	14 (4.1)
	Butylated hydroxyanisole	11 (3.2)
	Aspartame	11 (3.2)
	Tartrazine	8 (2.3)
	Sodium Nitrite	5 (1.5)
	Benzoic acid	4 (1.2)
	Butylated hydroxytoluene	3 (0.9)
	Sodium diphosphate	1 (0.3)

The percentage of male patients was significantly higher among those with positive FAPT results compared to those with negative results (p=0.003), and the mean age was significantly lower (p=0.023) (Table 3).

Among the 98 patients who tested positive for the FAPT, acute or intermittent urticaria was found in 56 (57.1%) of them. No significant difference was found in the clinical symptoms between patients with positive and negative FAPT results (p>0.01) (Table 3).

The correlation between different symptoms in patients with positive patch test results is presented in Figure 2. Correlation analysis revealed a significant and moderate positive relationship between urticaria and angioedema (r=0.500, p<0.001).

Table 3. Comparison of patients with positive and negative food additive patch test results

		Food additive patch test		
		Negative n=244 (71.3%)	**Positive n=98 (28.7%)**	
		n (%)	**n (%)**	**p**
Gender	Female	115 (47.1)	29 (29.6)	0.003
	Male	129 (52.9)	69 (70.4)	
Age (years) Mean±SD Min-Max (Median)		7.4±3.8	6.3±3.4	0.023
		2-17.5 (7)	2-17 (5.25)	
Complaint at admission	Acute or intermittent urticaria	144 (59.0)	56 (57.1)	0.751
	Itching	87 (35.7)	46 (46.9)	0.053
	Angioedema	75 (30.7)	31 (31.6)	0.871
	Eczema	34 (13.9)	14 (14.3)	0.933
	Erythema	5 (2.0)	0 (0.0)	0.327
Family history of atopy	None	210 (86.1)	67 (68.4)	<0.001
	Present	34 (13.9)	31 (31.6)	
Suspected food	Sweets, chocolate	123 (50.6)	58 (59.2)	0.151
	Chips	53 (21.8)	21 (21.4)	0.938
	Acidic drink	38 (15.6)	9 (9.2)	0.118
	Processed meat	14 (5.8)	8 (8.2)	0.414
	Spices	14 (5.8)	4 (4.1)	0.530
	Ready-made jam	9 (3.7)	3 (3.1)	1.000
Other allergic diseases	None	165 (67.6)	66 (67.3)	0.994
	Asthma	25 (10.2)	10 (10.2)	
	Allergic rhinitis	25 (10.2)	9 (9.2)	
	Atopic dermatitis	21 (8.6)	9 (9.2)	
	Other	8 (3.3)	4 (4.1)	
IgE Mean±SD Min-Max (Median)		249.7±566.4	293.0±505.7	0.55
		1-7485 (99)	2.4-2873 (125)	
Eosinophil % Mean±SD Min-Max (Median)		3.45±5.12	3.45±5.12	0.289
		0-16.6 (2.80)	0-45 (2.35)	
Allergy skin test positivity	Negative	170 (75.9)	62 (69.7)	0.354
	Aeroallergen	38 (17)	23 (23.7)	
	Food	11 (4.9)	3 (3.4)	
	Aeroallergens and food	5 (2.2)	1 (1.1)	

A strong negative correlation was observed between urticaria and itching (r=-0.590, p<0.001), while a moderate negative correlation was found between angioedema and itching (r=-0.464, p<0.001).

Additionally, a moderate negative correlation was identified between eczema and urticaria (r=0.412, p<0.001).

Among the patients who presented with urticaria and had a positive FAPT, 12 were positive for respiratory allergens and two were positive for the food prick test. However, no reactions to foods were observed in these two patients during the food challenge test. Additionally, confectionery and chocolates were identified as suspicious foods that could cause symptoms in 58 (59.2%) of the 98 patients who tested positive for the FAPT (Table 3).

When comparing the group with positive FAPT test results to the negative group, the rate of atopy in the family was significantly higher in the positive group (p<0.001) (Table 3).

Table 4 summarises the distribution of hypersensitivity symptoms, including acute/intermittent urticaria, angioedema, itching, and eczema, among FAPT-positive patients based on specific food additives.

Out of the 98 patients with positive FAPT results, 68 attended the outpatient clinic follow-up at the 2nd and 4th months, and their dietary compliance was questioned. It was observed that

Table 4. Distribution of hypersensitivity symptoms among FAPT-positive patients based on specific food additives

Food additives	Total				
	N (%)	Acute/or intermittent urticaria N (%)	Angioedema N (%)	Itching N (%)	Eczema N (%)
Amaranth	48 (14.0)	27 (56.3)	14 (29.2)	25 (52.1)	8 (16.7)
Aspartame	11 (3.2)	6 (54.5)	3 (27.3)	5 (45.5)	1 (9.1)
Azorubine	34 (9.9)	25 (73.5)	9 (26.5)	9 (26.5)	4 (11.8)
Benzoic acid	4 (1.2)	2 (50.0)	1 (25.0)	2 (50.0)	1 (25.0)
Butylated hydroxyanisole	11 (3.2)	7 (63.6)	3 (27.3)	4 (36.4)	2 (18.2)
Butylated hydroxytoluene	3 (0.9)	1 (33.3)	0 (0.0)	2 (66.7)	0 (0.0)
Carmine	14 (4.1)	8 (57.1)	5 (35.7)	8 (57.1)	1 (7.1)
Cochineal red	25 (7.3)	17 (68.0)	10 (40.0)	13 (52.0)	3 (12.0)
Sodium diphosphate	1 (0.3)	1 (100)	1 (100)	0 (0.0)	0 (0.0)
Sodium nitrite	5 (1.5)	3 (60.0)	1 (20.0)	3 (60.0)	0 (0.0)
Tartrazine	8 (2.3)	4 (50.0)	2 (25.0)	4 (50.0)	1 (12.5)

Table 5. Diet results of patients with a positive patch test

		n	%
Non-adherent follow-up (2nd month)		30	30.6%
Diet (2nd month)	Patients who are not on the diet	13	13.2
	On diet	55	56.1
Benefit from diet (2nd month)	No	9	9.1
	Yes	46	46.9
Still on diet (4th month)*	No	34	34.6
	Yes	34	34.6
Recurrence when diet is discontinued (4th month)**	No	11	11.2
	Yes	45	45.9

*: The equal number of patients in the "Still on Diet (4th month)" category is due to some patients who were not on the diet in the 2nd month starting the diet by the 4th month,

**: During the 4-month follow-up, patients who generally adhered to the diet but briefly deviated once or twice experienced symptom recurrence before resuming their diet.

56.1% of the patients adhered to a diet after identifying the food additive product, and 46.9% of those with positive FAPT results showed improvement from the diet.

During the 4-month follow-up, it was found that 45 patients (45.9%) did not fully comply with their diet and experienced symptoms reoccurring when they consumed the allergen to which they were sensitive (Table 5).

Figure 3 summarize the follow-up process and dietary adherence of FAPT-positive patients, highlighting the outcomes in terms of symptom recurrence during the 4-month follow-up period.

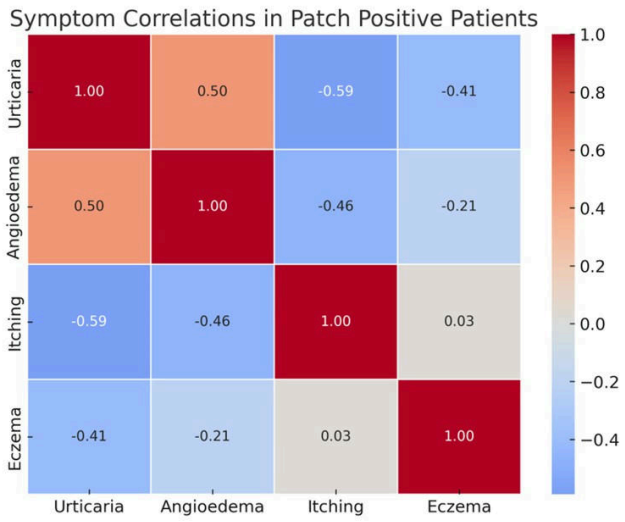

Figure 2. A symptom correlation matrix was created for patients who tested positive in the patch test.

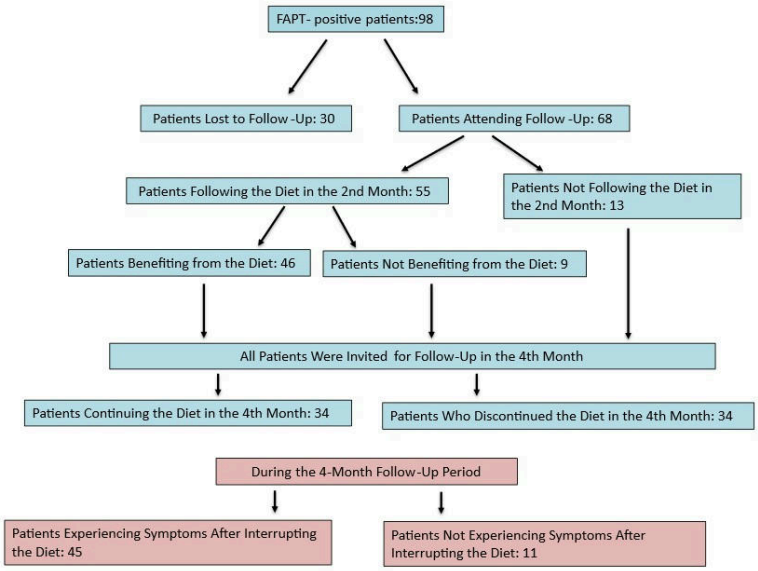

Figure 3. Flowchart of the diet results in FAPT-positive patients
FAPT: Food Additive Patch Test

DISCUSSION

The widespread use of food additives has been associated with various hypersensitivity reactions (14-16). In one study, 41.2% of children in the atopic eczema group had positive atopy patch test results to food additives (17). In a study using SPT, APT and specific IgE, sensitivity to food additives was found in 8% of CU patients (18).

In our study, the rate of sensitivity to at least one allergen in the food additive group reporting complaints was 28.7%. Our study yielded results similar to those reported in the literature; we attribute these differences to the subjective nature of symptoms and the evaluation of different tests and allergens in the diagnostic process. The gold standard test for both type 1 and type 4 hypersensitivity reactions due to food additives in children is the double-blind, placebo-controlled food challenge with food additives.

However, its applicability in children is limited due to the lack of pediatrically adapted doses for purified food additive extracts used in oral provocation. Additionally, it is not routinely preferred due to being time-consuming, costly, and difficult to implement in the clinic, as well as its actantial to cause anaphylactic reactions (19).

Therefore, numerous studies have been conducted to find suitable alternatives to the oral food challenge. For the diagnosis of allergy to food additives, SPT and specific IgE tests are recommended to detect IgE-mediated reactions, while APT is recommended for non-IgE-mediated reactions (20).

In our study, we identified *amaranth* sensitivity most frequently (14%) through the patch test. Some studies in children have associated *amaranth* with the exacerbation of urticaria and AD (11).

Amaranth is a food dye, also known as E123 in the European Union. *Amaranth* is a reddish-purple colour, powder, and water-soluble dye. It is used in various commercially prepared foods such as confectionery, ice cream, cakes, fillings, and jellies as a red colouring. *Amaranth* sensitivity is mostly associated with many IgE-mediated hypersensitivity reactions defined in adults, but there is limited research in children (12).

Different sensitivities have been reported in studies conducted in different allergic disease groups. In a study conducted in patients with AD, carmine was reported to be the most common sensitivity, while *azorubin* and *cochineal red* were reported as the most common in patients with CU (17). Similarly, in the study by Fuglsang et al., synthetic colourants such as *tartrazine, quinoline yellow, sunset yellow, Ponceau 4R, azorubin*, and *benzoic acid* were tested, and positive reactions were generally observed against synthetic colourants. Young et al. also reported that the most common reaction was to *Annatto*, a natural colourant, leading to symptoms such as headache and abdominal pain. Furthermore, Jansen et al. identified positive reactions most frequently against *tartrazine, benzoic acid*, and *monosodium glutamate*, with skin rashes and urticaria being the predominant symptoms (4-6).

Carmine was reported to be the cause of AD flares in children in one case report using APT (21).

In another study, *carmine* has been identified as a actantial allergen, especially in patients with chronic inducible urticaria accompanied by systemic symptoms, and SPT have been shown to be helpful methods for diagnosing *carmine* hypersensitivity (18).

Another food additive dye, *annatto*, causes adverse reactions leading to both urticaria and angioedema in children (22).

In a study by Özçeker and colleagues, a FAPT was performed on 120 CU patients and 61 healthy persons in the control group (23). At least one positive result against an allergen was obtained in 14% of children diagnosed with CU in the APT, while no positivity was detected with any food additive in the control group (p=0.001). *Azorubin and cochineal red* were identified as food additives with the highest sensitivity rates. *Tartrazine*, a synthetic azo dye, has been shown in many studies to be a rare cause of CU and to increase the symptoms in asthmatic patients (23, 24).

Furthermore, *tartrazine, benzoates, and parabens* have been reported to occasionally intensify CU. This finding aligns

with Jansen et al., where *tartrazine and benzoic acid* were frequently associated with positive reactions and urticaria (6).

In our study, urticaria was found to be the most common reason for referral (58.5%). In a study, *carmine*, a food additive, was reported as a actantial allergen, especially in patients with chronic inducible urticaria accompanied by systemic symptoms (18).

However, Rajan and colleagues showed in a study evaluating 11 food additive allergens in patients with CU that only two out of 100 patients had sensitivity (25).

Our study also evaluated aeroallergen sensitisation among FAPT-positive individuals. However, no statistically significant difference was observed between the FAPT-positive and FAPT-negative patients regarding aeroallergen or food allergen sensitisation. This finding suggests that food additive sensitivity does not necessarily coexist with aeroallergen or food allergen sensitisation.

Studies on this topic are still insufficient and need support from double-blind, placebo-controlled tests. However, due to concerns about obtaining the responsible allergen in a pure form and the actantial risks of anaphylaxis, our study aimed to confirm the diagnosis through treatment. In our study, it was reported that 56.1% of patients who underwent FAPT had a diet against the detected food additive, and 46.9% of 98 patients who tested positive for the FAPT benefited from the diet, while 45.9% did not implement the diet, resulting in the recurrence of symptoms. Although some FAPT-positive patients reported significant symptom improvement following the elimination diet, several factors limit the reliability of these findings. Variability in patient adherence to the diet (with a non-compliance rate of 45.9%) has made it difficult to evaluate the clinical response consistently. Moreover, the lack of objective measures to monitor treatment response has limited the ability to accurately assess the extent of the benefit derived from the diet.

Although our study design considered both convenience and packaged foods as actantial sources of exposure to food additives, because we did not have patients who consumed convenience foods, dietary recommendations and subsequent analyses focused predominantly on the elimination of packaged foods containing additives.

Based on our results and the existing literature, dietary elimination of food additives identified via FAPT may support symptom control in selected patients, although further confirmatory testing is needed (3, 7).

In our study, considering that patients who followed an elimination diet for food additives experienced clinical improvement, while symptoms recurred in those who did not adhere to the diet, FAPT may assist in the clinical evaluation and management of food additive sensitivity. The limitations of our study include its retrospective design, the absence of a control group, and the lack of double-blind, placebo-controlled food challenge tests, which are considered the gold standard for diagnosing food additive hypersensitivity. Relying on caregiver-reported outcomes and available clinical records may have introduced recall or reporting bias. Moreover, in the absence of standardized provocation protocols and objective outcome measures, the generalizability and diagnostic accuracy of our findings are limited. Future prospective and controlled studies are needed to validate these results.

Nevertheless, our study adds to the limited number of publications examining FAPT in children and provides initial observations that may support its actantial use in clinical evaluation and dietary guidance.

CONCLUSION

We believe that conducting FAPT in patients describing symptoms after consuming processed foods may be beneficial. In our study, 46.9% of the 98 patients who tested positive for the FAPT benefited from the diet. Limited diets containing these allergens can be given to appropriate patients. However, further studies with double-blind placebo-controlled food challenge tests are needed to address this issue.

Ethics Committee Approval: Our study was conducted following the principles of the Helsinki Declaration and Good Clinical Practices. Informed voluntary consent forms were obtained from the patients. This study was approved by the Clinical Research Ethics Committee of Sağlık Bilimleri University, Prof. Dr. Cemil Taşcıoğlu City Hospital (Date: 14.04.2025, No: 134).

Informed Consent: Consent was obtained from all patients who participated in the study.

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