

## RESEARCH ARTICLE

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# Evaluation of Anxiety Levels and the Effect of Video Information on the Anxiety Levels of Parents Whose Children Undergo Oral Food Challenge

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## **ABSTRACT**

**Objective:** The Oral Food Challenge Test (OFC) is the gold standard for diagnosing or excluding food allergies. OFC in children may cause anxiety in the parents. The study aims to evaluate parental anxiety during children's OFC, examining the impact of informational videos with instructions, comparing anxiety levels between tested children's parents and healthy controls, and correlating parental anxiety with psychological symptoms.

Materials and Methods: The study included parents of children over 18 months of age undergoing OFC. All parents received verbal/written test information and some got informational videos. State-Trait Anxiety Inventory (STAI) and Symptom Checklist-90-Revised (SCL-90-R) were used as questionnaires.

Results: The median age of the 44 patients included in the study was 25.3 (IQR:20.2-41.6) months, and the median age of the 23 healthy children in the control group was 30 (IQR:23.85-43.96) months (p=0.125). Among the parents of the patients undergoing OFC, 29 (65.9%) were informed verbally/with text, and 15 (34.1%) were additionally provided information through video. Fourteen (31.82%) of the patients had an anaphylactic reaction in their history, and 36 (81.82%) patients were tested to evaluate the development of tolerance. No significant differences were detected in the STAI-T and STAI-S scores between parents of the control group and those of the group undergoing OFC. No statistically significant difference was observed in the assessment of the pre-OFC STAI-S scores of the patients' parents between those who received verbal/written information and those additionally informed via video. Among the parents' of patients without reactions during OFC, a decrease was noted in the post-test STAI-S scores compared to pre-test scores. STAI-T scores of the parents of patients undergoing OFC exhibited positive correlations with the general symptom index, anxiety, obsession, depression, interpersonal sensitivity, psychosis, paranoid, anger, and phobia parameters, as determined by the psychological symptom screening scale.

**Conclusion:** As evidenced by our study, the absence of reactions during OFC resulted in a reduction of parental anxiety. The effect of additional video information with verbal and written instructions on anxiety remains unclear in this study. Limited sample size may be a factor; further research with larger cohorts is needed before making generalized conclusions.

Keywords: Oral food challenge, anxiety, child

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#### INTRODUCTION

The Oral Food Challenge Test (OFC) is considered the gold standard for diagnosing or excluding IgE- and non-IgE-mediated food allergies (1). Comprehensive patient evaluation, including a detailed clinical history, assessment of food-specific IgE, and skin prick tests (SPTs), plays a crucial role in identifying the specific food allergens to be tested through provocation. The existing literature suggests that the predictive value of clinical history, with or without SPTs or food-specific IgE, varies between 50% and 100% (2-4). Moreover, self-reported food allergy has been found to have a prevalence that is approximately six times higher than challenge-proven food allergy (1). Consequently, oral food challenges are significant in confirming the diagnosis of food allergy, elucidating oral tolerance, and monitoring the dynamic nature of food allergies (1).

Anxiety manifests as an emotional state characterized by apprehension regarding future or potential threats, distinguished by symptoms of autonomic arousal and the perception of impending danger, including fear, hyperarousal/irritability, and anxious misery (5). Notably, children and adolescents with atopic diseases exhibit a higher prevalence of anxiety and depression symptoms compared to the general population (6). Marklund et al. identified fear and anxiety as recurring issues within families with children affected by food allergies (7). According to a survey study, nearly half of the parents of children with food allergies reported experiencing elevated stress levels attributed to their child's condition (8). In consideration of this data, the challenge test, a crucial for the diagnosis, may cause anxiety in the parents of pediatric patients due to the potential risk of reaction recurrence.

In the literature, Strinnholm et al. have delineated parents' encounters with introducing food to their children subsequent to the Double-Blind, Placebo-Controlled Food Challenge (DBPCFC). Their findings revealed parental apprehensions concerning the potential loss of control over their children and their symptoms, juxtaposed with a concurrent confidence in the medical staff and the methodology employed (9). Giving pre-test information to parents may also modulate their anxiety levels. This study aims to assess the anxiety levels of parents whose children undergo OFC, exploring the impact of providing informational videos in addition to verbal and written instructions on anxiety. Furthermore, it seeks to discern differences in the anxiety levels between parents of tested children and

those of a healthy control cohort, as well as investigate the correlation between parental anxiety levels and their psychological symptoms.

## **MATERIAL and METHODS**

The study enrolled parents of children aged over 18 months who underwent an Oral Food Challenge (OFC) at our clinic between March 1, 2019, and January 31, 2020. Approval for the study design and protocols was obtained from the local ethics committee. Due to potential fluctuations in parental anxiety levels amid the pandemic, patient recruitment for the study was halted (No: 2019-037).

All parents received verbal and written information regarding the test, and some additionally provided with informational videos. Parents seeking follow-up care for healthy children who consented to participate were included as the control group. Children whose caregivers provided informed consent for an open OFC with the implicated food underwent the challenges under the supervision of an allergist in accordance with EAACI guidelines (1,10).

# **Oral Food Challenge**

The food challenge tests were performed to evaluate the patients' reaction or tolerance and conducted using an open OFC approach. Prior to the challenge, all children underwent a thorough examination. Oral food challenge tests were not administered to patients with active infections or those who had taken antihistamines within the preceding 7 days. During the open OFC, the suspected food was orally administered in stepwise, escalating doses at 15-minute intervals. Patients with negative results were observed for a minimum of 2 hours following the challenge to monitor for any allergic reactions and were advised to continue consuming the suspected food. The OFC was discontinued and deemed positive upon documentation of any objective signs and symptoms. Parameters such as reaction type, onset time of reaction, and threshold dose of food protein eliciting the reaction were meticulously recorded.

# **Evaluation of Parental Anxiety**

To evaluate parental anxiety levels, the State-Trait Anxiety Inventory (STAI) was utilized to measure both state and trait anxiety levels among the parents of the patients. The test-retest reliability coefficients during the initial development study ranged from 0.31 to 0.86 across intervals spanning between 1 hour and 104 days (11). The validity and reliability study of the Turkish version of the STAI was conducted by Oner and Le Compte (12).

Parents who consented to participate in the study completed the state anxiety subscale (STAI-S) both before and after the OFC. The STAI-S comprises 20 items that assess subjective feelings of tension, nervousness, anxiety, and activation/arousal experienced "right now," with response options including "not at all," "somewhat," "moderately so," and "very much so." Prior to the DPT, parents completed the Trait Anxiety subscale (STAI-T), which includes 20 items probing anxiety tendencies independent of the current situation. Items in this subscale evaluate the general frequency of emotions, with response options ranging from "almost never" to "almost always" (11,12).

## **Evaluation of Parental Psychological Distress**

Parental psychological distress was evaluated using the Symptom Checklist-90-Revised (SCL-90-R). The SCL-90-R comprises 90 items and has been linguistically adapted into Turkish. Respondents indicate the extent to which each symptom has affected them over the past week, selecting from options ranging from 'not at all' to 'extremely'. Subscale scores are computed for anxiety, depression, interpersonal sensitivity, phobic anxiety, obsessive-compulsive behaviors, hostility, paranoid ideation, psychoticism, and somatization. Additionally, a general severity index (GSI) can be derived as a composite score. GSI values exceeding 1 are indicative of psychological distress (13,14).

Parents who consented to participate in the control group completed the STAI-S and STAI-T during the routine follow-up examination of healthy children.

## **Statistical Methods**

The statistical analyses were conducted using the SPSS v.22 statistical software package (IBM, Chicago, IL, USA) for Windows. Discrete variables were presented as numbers and percentages, while continuous variables were described as mean and standard deviation for normally distributed data and as median and interquartile range (IQR) for non-normally distributed data. The chi-square ( $\chi$ 2) test was applied to compare nonparametric data, the Mann–Whitney U test was utilized for comparisons involving non-normally distributed continuous data, and the independent-samples t-test was employed for nor-

mally distributed continuous data. Spearman or Pearson correlation analyses were employed to assess the relationships between parameters. Statistical significance was determined at a threshold of p-values less than 0.05.

## **RESULTS**

Forty-four parents of patients and twenty-three parents of the control group were included in the study. No significant differences were observed between the patient and control groups regarding the patients' ages, gender characteristics, as well as the ages and educational levels of their parents. The demographic characteristics of the patients and their parents are presented in Table I.

Oral food challenges were performed with egg in 13 patients, baked egg in 7 patients, yogurt in 9 patients, baked milk in 5 patients, milk in 9 patients.and peanuts in 1 patient. Among the parents of patients undergoing oral food challenges, 29 (65.9%) were informed with verbal or written instructions, while 15 (34.1%) were additionally provided information through video. Some patients had multiple reaction histories upon their initial presentation. Among them, 31 patients presented with atopic dermatitis, 14 with anaphylaxis, 7 with urticaria, 3 with proctocolitis, 3 with maculopapular rash, 1 with vomiting, 1 with angioedema, and 1 with complaints of wheezing associated with food ingestion. Thirty-six patients (81.82%) underwent oral food challenge (OFC) to evaluate tolerance development, while 8 patients underwent it for diagnostic purposes. Adverse reactions were observed in 8 patients (18.18%) during the OFC.

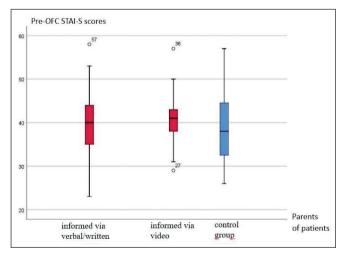
In the assessments conducted using the STAI-T and STAI-S questionnaires to evaluate state and trait anxiety levels, no significant differences were detected in the pretest scores between the parents of the control group and those of the group undergoing the OFC (Table II).

No statistically significant difference was observed in the assessment of the pre-OFC STAI-S scores of the patients' parents between those who received verbal/written information (median: 40 (IQR: 35-44.5)) and those additionally informed via video (median: 41 (IQR: 38-43)) (p=0.385) (Figure 1).

In the parents of patients experiencing reactions during the OFC, no reduction was observed in post-test STAI-S scores (median: 41 (IQR: 34.25-56) compared to pre-test scores (median: 43 (IQR: 30-52.25) (p=0.866). However, among the parents of patients without reactions during

Table I: Comparison of the clinical characteristics of the patients and their parents with those of the control group and their parents.

	Patient group	Control group	p value
Gender (patient)			
Male, n (%)	25 (56.8)	12 (52.2)	0.717
Age of the patient, median (IQR), month	25.3 (20.2-41.6)	30 (23.85-43.96)	0.125
Age of the parents, mean ± SDS, years	32.18±7.49	31.96±6.13	0.902
Initial symptoms of the patients, n (%)			
Atopic dermatitis	31 (70.5)	-	
Anaphylaxis	14 (31.82)	-	
Urticaria	7 (15.9)	-	
Proctocolitis	3 (6.8)	-	
Maculopapular exanthema	3 (6.8)	-	
Vomiting	1 (2.27)	-	
Angioedema	1 (2.27)	-	
Wheezing	1 (2.27)	-	
Education of the parents, n (%)			
Primary school	8 (18.18)	3 (13.04)	0.847
High school	19 (43.18)	10 (43.48)	
University	17 (38.64)	10 (43.48)	



**Figure 1:** Comparison of pre-OFC STAI-S scores between parents of the patient group after verbal/written information and video-based information, and the control group.

the OFC, a decrease was noted in post-test STAI-S scores (35.39  $\pm$  7.846) compared to pre-test scores (39.61  $\pm$  6.707) (p=0.001).

The mean pre-OFC STAI-S score of parents of patients with a history of anaphylactic reaction (43.43  $\pm$  6.903) was higher compared to other parents (38.50  $\pm$  7.556) (p=0.045).

Table II: Comparison of the pre-OFC STAI-T and STAI-S scores between the parents of the patients and the control group.

	Patient group	Control group	p
STAI-S scores, mean±SDS	40.07±7.635	38.96±8.911	0.595
STAI-T scores, mean±SDS	6 40.70±7.602	42.30±8.401	0.433

The Trait Anxiety Subscale (STAI-T) scores of the parents of patients undergoing OFC exhibited positive correlations with the general symptom index (r=0.534, p=0.000), anxiety (r=0.425, p=0.004), obsession (r=0.370, p=0.014), depression (r=0.609, p=0.000), interpersonal sensitivity (r=0.657, p=0.000), psychosis (r=0.330, p=0.029), paranoid (r=0.552, p=0.000), anger (r=0.547, p=0.000), and phobia (r=0.374, p=0.012) parameters, as determined by the psychological symptom screening scale (Table III).

## **DISCUSSION**

This study included 44 parents of patients and 23 parents of the control group. Among the patients undergoing OFC, 65.9% received verbal/written information, while 34.12% were additionally informed via video. No statistically significant difference was observed between the pre-test STAI-S scores of the parents of the control

Table III: Demonstration of the correlations between STAI-T scores of parents of patients undergoing OFC and sub-parameters of the SCL-90-R psychological symptom screening scale.

SCL-90-R subscales	STAI-T scores (r;p)
General Severity Index	0.534; 0.000
Anxiety	0.425; 0.004
Obsessive-compulsive	0.370; 0.014
Depression	0.609; 0.000
Interpersonal sensitivity	0.657; 0.000
Psychoticism	0.330; 0.029
Paranoid ideation	0.552; 0.000
Hostility	0.547; 0.000
Phobic anxiety	0.374; 0.012
Additional Items	0.282; 0.064

group and those of the parents of the group undergoing OFC (p=0.595). Furthermore, there was no statistically significant difference found in the STAI-T scores between the parents of the control group and those of the patients undergoing OFC (p=0.433). There was no significant difference observed in the pre-OFC STAI-S scores among the parents of the patients, whether they received verbal/written information or additional video information (p=0.385). Among the parents of patients experiencing reactions during OFC, no reduction was observed in post-test STAI-S scores, whereas among parents of patients without reactions during OFC, a decrease in posttest STAI-S scores compared to pre-test scores was noted (p=0.001). Additionally, positive correlations were found between the STAI-T scores of the parents of patients undergoing OFC and the general symptom index, anxiety, obsession, depression, interpersonal sensitivity, psychosis, paranoid, anger, and phobia parameters of the psychological symptom screening scale.

The Oral food challenge (OFC) stands as the gold standard procedure for diagnosing food allergies. The administration of OFCs can evoke parental anxiety due to the potential risk of severe allergic reactions in children (15), and those conducting OFCs must be prepared to manage heightened parental anxiety during the procedure. Entering a clinical setting and awaiting test results alone can induce anxiety. Moreover, since OFCs are designed to provoke allergic reactions, parents are informed about the potential for severe reactions. The fact that the mean pre-OFC STAI-S score of parents of patients was higher

in patients with a history anaphylaxis in our study can be interpreted as a result related to this. Also in our study, we sought to ascertain whether informing parents via video in addition to verbal/written information conferred any superiority or impact on anxiety. However, no significant difference was found between both forms of information delivery and pre-test STAI-S scores. Perhaps future research could focus on larger patient cohorts to optimize human resources and explore the efficacy of video-only information dissemination.

In a study conducted by Zijlstra et al., no significant difference was found between pre-test STAI-S scores among parents of patients undergoing OFC due to peanut and hazelnut allergies. Parental anxiety regarding a foodallergic reaction in their child (state anxiety) exhibited a significant decrease following both negative and positive outcomes of a food challenge (15). Knibb RC et al. reported disappointment among parents following an OFC resulting in a reaction due to the continuation of allergic conditions in their child, but most also commented on the advantage of having greater clarity (16). In our study, no reduction was observed in post-test STAI-S scores among parents of patients experiencing reactions during OFC, whereas parents of patients without reactions during OFC exhibited a decrease in post-test STAI-S scores compared to pre-test scores (p=0.001). In the same study, Knibb RC et al. noted that most mothers expressed feeling more at ease since they could reintroduce the food into their child's diet (16). The study by Zijlstra et al. suggests that lower levels of situational anxiety in parents after DBPCFC may imply the success of OFC not only as the gold standard for diagnosing food allergies but also in reducing parental anxiety related to food allergy reactions (15).

It was determined that a positive correlation existed between the STAI-T scores of parents whose children underwent Oral Food Challenge (OFC) and various parameters including the general symptom index, anxiety, obsession, depression, interpersonal sensitivity, psychosis, paranoid, anger, and phobia derived from the psychological symptom screening scale. The association between anxiety levels and the overall anxiety experienced by parents dealing with diverse psychiatric challenges underscores the importance of adopting a more comprehensive, supportive, and attentive approach in providing information and assistance to parents facing psychiatric difficulties prior to interventions.

As evidenced by our study, the absence of reactions during Oral Food Challenge resulted in a reduction of parental anxiety. For children experiencing reactions, future investigations should assess the necessity for modifying the format of explanatory information provided to parents regarding the reactions. The impact of supplementary video information alongside verbal and written instructions on anxiety remained indeterminate in this study. It is plausible that this circumstance could be attributed to the limited sample size; thus, further research with larger cohorts is warranted before drawing generalized conclusions.

#### Conflict of Interest

Authors indicate no such interest.

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## **Authorship Contributions**

Concept: Ozge Yilmaz Topal, Irem Turgay Yagmur, Ozden Sukran Uneri, Aysun Kara Uzun, Emine Dibek Misirlioglu, Design: Ozge Yilmaz Topal, Irem Turgay Yagmur, Ozden Sukran Uneri, Data collection or processing: Ozge Yilmaz Topal, Irem Turgay Yagmur, Ozden Sukran Uneri, Analysis or Interpretation: Ozge Yilmaz Topal, Aysun Kara Uzun, Esra Cop, Emine Dibek Misirlioglu, Literature search: Ozge Yilmaz Topal, Irem Turgay Yagmur, Muge Toyran, Writing: Ozge Yilmaz Topal, Irem Turgay Yagmur, Ozden Sukran Uneri, Aysun Kara Uzun, Muge Toyran, Esra Cop, Emine Dibek Misirlioglu, Approval: Ozge Yilmaz Topal, Irem Turgay Yagmur, Ozden Sukran Uneri, Aysun Kara Uzun, Muge Toyran, Esra Cop, Emine Dibek Misirlioglu.

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