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Impact of IgE-mediated Food Allergy on Parental Quality of Life in Iranian Patients

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ABSTRACT

Food allergy is a common disorder especially in the first years of life. Strict avoidance of the responsible food is the most effective therapeutic measure so far. But this continuous vigilance could be stressful for the patient and family and decreases their quality of life (QOL). This survey was designed to evaluate the impact of IgE-mediated food allergy on parental QOL in Iranian patients and to develop a valid Persian version of "Food Allergy Quality Of Life- Parental Burden (FAQL-PB) questionnaire".

90 patients (28 females, 62 males) and their parents who were referred to the clinic of Allergy in Children's Medical Center, Tehran University of Medical Sciences, Tehran, Iran were enrolled. The questionnaire was translated with scientific method and its reliability was approved in a pilot study (ICC=0.75, cronbach- α =0.90).

Among all patients the most common allergens were wheat (60%) and cow's milk (42%). The patient's age ($p=0.02$), parent's gender ($p=0.004$), mother's age ($p=0.02$), duration of the disease ($p=0.048$), and allergen multiplicity ($p=0.004$) were found to have the most significant correlation with family and social activity (FSA) domain. The most meaningful associations were achieved between parent's gender ($p<0.001$) and emotional issues (EM); as well as meal preparation (MP) with patient's age ($p=0.02$), parent's gender ($p<0.0001$) and also allergen multiplicity ($p=0.003$); likewise nutrition and health concern (NH) domain with parent's gender ($p<0.001$). Anaphylaxis's history did not place any burden on each domain.

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It was concluded that presence of food allergic patients in families could considerably affect all domains of QOL.

Keywords: Food allergy; Food hypersensitivity; Iran; Quality of life; Questionnaire

INTRODUCTION

Food allergy is an abnormal reaction to food allergens. It has a prevalence of 4-8% among different populations.¹ There has been an increase in both prevalence and incidence of food allergy during recent years.² This condition has an effect on patient's health and social performance, and compromises the patient and parents' quality of life. Despite recent improvements in our knowledge about pathogenesis of allergies, strict avoidance of the responsible food is the most effective therapeutic measure so far.¹ It is strongly recommended to observe precise avoidance everywhere and every time. This constant nutritional care requires incessant concentration on food intake, being careful about specific nuts or spices usage in regular meals, avoiding or restricting food consumption while the patient is out especially attending a ceremony, and paying attention to ingredient's label of the prepared food provided at stores. After reassurance about the food safety, ingestion is still permitted by caution.² Doubtlessly, this kind of continuous vigilance could be stressful for the patient and family.¹ Furthermore, to the best of our knowledge, food allergy is the most common revealed cause of anaphylactic shock.³ Positive history of an undefined shock and awareness about the probability of anaphylactic shock (even without previous experience) can put a great emotional stress on the patient and family.^{1,4} Patients with atopy can present manifestations of allergic rhinitis, asthma and eczema accompanying food allergy, which may also affect patients' and parents' quality of life (QOL).⁴⁻⁷

Regardless of parents' direct control, school-age children have to learn about their responsible food allergens and observe their nutritional habits. This age is the most vulnerable period for anaphylactic reactions.³

According to previous reports, behavioral and mood disorders like internalization, anxiety and depression have a significant prevalence within food allergic patients and their families comparing to normal

population.⁸

The "quality of life" is the most appropriate parameter among the clinical and para-clinical approaches for the evaluation of the disease impacts and also the efficacy of the available therapeutic interventions. Previous studies have shown that the presence of a child with food allergy in a family, can remarkably affect the parents' QOL. The food allergy impact on QOL has been found to be more compromising than some other chronic disorders such as juvenile rheumatoid arthritis (JRA), and even more than diabetes mellitus (DM) and inflammatory bowel disease (IBS).^{9,10}

Like other countries, food allergy is prevalent in Iran,¹¹ and gives undeniable impression on patients' and families' QOL. Food Allergy Quality Of Life-Parental Burden (FAQOL-PB) was developed and introduced in 2004 by Cohen et al.¹² as a specific questionnaire to measure the burden of food-allergic patients on caregivers and was utilized in several further studies.¹³⁻¹⁵ The aim of this study was to assess the parental QOL in Iranian food- allergic patients and to develop the valid Persian version of FAQOL-PB for future clinical and research purposes.

MATERIALS AND MEHTODS

Study Design

A cross-sectional study was designed. Children with a definite diagnosis of IgE-mediated food allergy and their parents were investigated at the clinic of Allergy and Clinical immunology of Children's Medical Center affiliated to Tehran University of Medical Sciences, Tehran, Iran during 2011-2012. IgE-mediated food allergy diagnosis was confirmed by a thorough clinical history along with a positive skin prick test or serum food specific IgE (RIDA method [R-Biopharm, Darmstadt, Germany]). A total number of 90 patients (28 females and 62 males) and their parents were enrolled in the current study. Patients aged between 6 months to 12 years were classified in 3 age groups. Demographic data and personal characteristics of each

patient and parent were recorded. Only one parent (mother or father) for each patient was asked to fill and return the FAQL-PB questionnaire during their child routine follow-up visit at the hospital. Written informed consent was obtained from all participants.

Questionnaire Development

This study was designed to validate the Persian version of FAQL-PB as a valuable standard questionnaire for assessment of the QOL in subsequent studies. This questionnaire contains 17 questions. It scales quality of life using the 7-point Likert rule, which ranges from 1 (untroubled) to 7 (extremely troubled). Questions are planned to make assessment of 4 main domains of QOL issue including family and social activity (FSA), emotional issues (EM), nutrition and health concern (NH) and meal preparation (MP).

The original version of the questionnaire was used under license of main designers for Persian translation and study approach.¹²

Statistical Analysis

After data collection, statistical analysis was performed by SPSS software (version 19, SPSS, Inc, Chicago, IL, USA). Personal and demographic characteristics were obtained using descriptive variables. If *p* value was lower than 0.05, it was considered as statistically significant. Bivariate analysis and regression models were used to determine the correlation between variables and QOL in four defined domains. Numbers of avoided foods in each patient's feeding regimen were determined by "Multiplicity" variable.

RESULTS

Patients' Characteristics

Demographic and clinical data of patients and their parents are showed in Table 1.

Seventy two patients (80%) suffered from other accompanying allergic diseases such as asthma and allergic rhinitis (Table 1).

Table 1. Demographic features of food-allergic patients and their parents.

Patients' variable		Number (%)	
Gender	Female	28 (31.2%)	
	Male	62 (68.8%)	
Age (months)	24>	27 (30%)	
	24-60	34 (37.8%)	
	60<	29 (32.3%)	
Family income	170\$ >	10 (11.1%)	
	170 \$ -350\$	37 (41.1%)	
	350\$ <	43 (47.8%)	
Disease period (months)	24>	38 (42.2%)	
	24<	52 (57.8%)	
Presence of other allergic diseases in patient	yes	72 (80%)	
	no	18 (20%)	
Parents variable		Mother side (%)	Father side (%)
Number of children	1	49 (55.5 %)	49 (55.5 %)
	2	36 (40 %)	36 (40 %)
	3	5 (5.5%)	5 (5.5%)
Occupation	Employed	11 (12.2%)	90 (100%)
Participation in study	Participant	51(56.7%)	39 (43.3%)
Age (years)	35>	77 (85.6%)	43 (47.8%)
	35<	13 (14.4%)	57 (52.2%)
Graduation state	Elementary	8 (8.9%)	8 (8.9%)
	Secondary/high school	44 (48.9%)	53 (58.9%)
	Bachelor of sciences	34 (37.8%)	25 (27.8%)
	Higher	4 (4.4%)	4 (4.4%)

Quality of Life Investigations

After forward-backward translation of the questionnaire with scientific method for linguistic validation, 10 patients' parent and 10 control parents filled the questionnaire in 2 steps with a 3 weeks interval.

Data analysis of this test-retest, showed that the questionnaire achieved excellent intrinsic reliability (ICC index=0.75). In addition, cronbach- α (another index for reliability) was 0.9 nearly similar to the original questionnaire reliability.

The burden of food allergy on each aspect of parents' QOL in every question was matched to answers divided to 7 scales of severity with ascending

sequence (7-point Likert scale) and severity of impact was ranged from 0 (not limited) to 6 (extremely limited). According to previous studies employing this questionnaire, severity of impact for each question was classed in terms of minimally troubled (for answers 0, 1), moderately troubled (for answers 2, 3) and extremely troubled (for answers 4, 5, 6). Regarding this classification, the distribution of parents' answers is shown in Table 5.

Evaluation of the variables' correlation with 4 main domains of QOL (FSA, EM, NH and MP) was done separately in bivariate analysis (Table 6). The patient's age ($p=0.02$), parent's gender ($p=0.004$), patient mother's age ($p=0.02$), duration of disease

Table 2. Distribution of food-allergic patients based on the number of restricted food materials according to skin prick test and specific IgE. (No.=90)

Number of allergens	Prevalence %
1	45(50%)
2	19(21.1%)
3	14(15.6%)
4	9(10%)
5	1(1.1%)
6	2(2.2%)

Table 3. Number and percent of food-allergic patients by the type of food allergen

Type of Allergen	Number of patients (%)
Chicken	2(2.2)
Peanuts	8(8.9)
Fish	14(15.6)
Soy	16(17.8)
Almond	18(20)
Egg	31(34.4)
Cow's milk	38(42.2)
Wheat	54(60)

Table 4. Prevalence of accompanied allergic disorders in food allergy patients, at the beginning and the current time

Variable	At the beginning of the disease	At the current time
Rhinitis	48(53.3%)	40(44%)
Eczema	39(43.3%)	37(41.1%)
Asthma	30(33.3%)	30(33.3%)
Anaphylaxis	28(31.1%)	26(28.9%)
Gastroesophageal reflux	18(20%)	5(5.6%)
Urticaria	16(17.8%)	3(3.3%)
Rectorrhagia	12(13.3%)	2(2.2%)
Diarrhea	11(12.2%)	0(0%)
Colic	6(6.7%)	0(0%)

persistence ($p=0.048$), and allergen multiplicity ($p=0.004$) were found to have the most significant correlation with FSA domain.

The most meaningful associations were achieved between parent's gender ($p<0.001$) and EM, MP with

patient's age ($p=0.02$), with parent's gender ($p<0.001$), and with allergen multiplicity ($p=0.003$). Likewise parent's gender had significant association with NH domain ($p<0.001$).

Table 5. Limitations imposed by food-allergic patients on parents

No	Subjects and questions	Extremely troubled (%)	Moderately troubled (%)	Minimally troubled (%)
1	How much would your choice of Vacation be limited by your child's food allergy?	23(25.5)	22(24.5)	45(50)
2	In the past week, How much your choice of a restaurant would be limited by your child's food allergy?	52 (57.8)	18 (20)	20 (22.2)
3	In the past week, How limited your ability to participate in social activities that involves food is because of your child's food allergy?	16 (17.8)	31 (34.5)	43 (47.8)
4	In the past week, How troubled have you been by your need to spend extra time preparing meals due to your child's food allergy?	50 (55.6)	35 (38.9)	5 (5.5)
5	In the past week, How troubled have you been about your need to take special precautions before going out of the home with your child because of food allergy?	31 (34.5)	30 (33.3)	29 (32.2)
6	In the past week, How troubled have you been by anxiety related to your child's food allergy?	56 (62.2)	33 (36.7)	1 (1.1)
7	In the past week, How troubled have you been that your child may not overcome food allergy?	51 (56.6)	34 (37.8)	5 (5.6)
8	In the past week, How troubled have you been by the possibility of, or leaving your child in the care of others because of food allergy?	54 (58.9)	23 (25.7)	13 (14.4)
9	In the past week, How troubled have you been by frustration over other's lack of appreciation for the seriousness of food allergy?	36 (40)	31 (34.4)	23 (25.6)
10	In the past week, How troubled have you been by sadness regarding the burden your child carries because of food allergy?	47 (52.2)	29 (32.2)	14 (15.6)
11	In the past week, How troubled have you been about your child's attending school, camp, and other group activity because of food allergy?	64 (71.2)	13 (14.4)	13 (14.4)
12	In the past week, How troubled have you been by your concerns for your child's health because of food allergy?	49 (54.5)	28 (31.1)	13 (14.4)
13	In the past week, How troubled with the worry that you will not be able to help your child if they have an allergic reaction to food?	32 (35.6)	36 (40)	22 (24.4)
14	In the past week, How troubled have you been with the worry that your child will not have a normal upbringing because of food allergy?	22 (24.4)	37 (41.1)	31 (34.4)
15	MalnutritionIn the past week, How troubled have you been about concerns for your child's nutrition because of food allergy?	45 (50)	26 (28.9)	19 (21.1)
16	In the past week, How troubled have you been with issues concerning your child being near others while eating because of food allergy?	45 (50)	33 (36%)	12 (13.3)
17	In the past week, How troubled have you been with being frightened by the thought that your child will have a food allergic reaction?	42 (46.7)	38 (42.2)	10 (11. %)

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Table 6. Bivariate analysis of the independent variables in correlation with 4 domains of quality of life in food allergy patients' parents (No.=90).

Independent variable (categories)	Type of test	EM	NH	MP	FSA
Patient's age (months)	Anova	0.95	0.8	0.02	0.02
<24					
24-60					
60<					
Patient's gender	T-test	0.05	0.53	0.328	0.355
Female					
Male					
Parent's gender	T-test	<0.0001	<0.0001	<0.0001	0.004
Female					
Male					
Mother's occupation status	T-test	0.75	0.9	0/63	0.433
Working					
Non-working					
Father's age (years)	T-test	0.12	0.097	0.46	0.48
<35					
35<					
Mother's age (years)	T-test	0.58	0.16	0.41	0.02
<35					
35<					
Time from diagnosis to study enrolment(months)	T-test	0.89	0.18	0.11	0.048
<24					
24<					
Family income (USD)	ANOVA	0.32	0.31	0.55	0.419
<170					
170-350					
350 <					
Number of children in family	Regression	0.75	0.55	0.141	0.58
Father's education status	ANOVA	0.65	0.65	0.27	0.88
Elementary					
Secondary/high school					
Bachelor of sciences					
Higher					
Mother's education status Elementary	ANOVA	0.82	0.38	0.45	0.80
Secondary/high school					
Bachelor of sciences					
Higher					
History of anaphylactic reactions in patient	T-test	0.34	0.57	0.14	0.712
Yes					
No					
Other accompanying allergic diseases in patient	T-test	0.88	0.83	0.07	0.212
Yes					
No					
Allergens multiplicity	Regression	0.42	0.093	0.003	0.004

FSA: family and social activity; EM: emotional issues; NH: nutrition and health concern; MP:meal preparation; USD:United States dollar

DISCUSSION

To the best of our knowledge, this is the first study to investigate the level of QOL in Iranian families with a food allergic child. In a pilot study on 10 families, validity and reliability for our Persian FAQL-PB questionnaire was approved with an acceptable high internal reliability comparable to original questionnaire.

Using the Persian FAQL-PB, we confirmed the effect of having a child with food allergy on parents' QOL, it was also shown that the multiplicity of responsible food allergens have more potent impact (especially in FSA and MP aspects). This is comparable to previous studies. In a study by Bollinger et al. in US, they utilized their self-planned questionnaire (Food allergy impact) to assess the impacts of food allergy on daily activities of 101 parents and patients. About half of included parents expressed the impacts of their child's food allergy, raising stress on their activities such as preparing food and attending parties and ceremonies.¹

Regarding our study results, the most prevalent responsible food allergens were wheat and cow's milk, respectively. However, documented reports express cow's milk as the most prevalent worldwide food allergen.¹¹ This difference could be explained by the special field of patient selection. Our study was done in a referral allergy center and not among the whole community population. On the other hand, inclusion criteria for our study population were the positive serum IgE level and skin prick test, while most allergic reactions to cow's milk are non-IgE mediated. Higher prevalence of wheat allergy in our study may also emerge from the long period of tolerance development in wheat allergy in comparison to this period for milk.¹⁷

A history of anaphylaxis existed in 33.3% of subjects while majority of parents were unaware of its critical importance. An interesting finding was that from patients with anaphylaxis experience, only 14 (46.7%) of parents had managed to provide epinephrine auto-injector, but none of them used it. This can be due to lack of comprehensive instructions about the indications and method of administration, as seen in a report by Mandle et al.¹⁸ Additionally, facilities might not be provided for parents to easily gain access to epinephrine auto-injector as rescue therapy.

In agreement with the study of King et al. mothers' QOL was imposed by their child's food allergy more significantly than fathers in all aspects excluding

family and social aspects.⁸

Our results showed that patient's age has a significant correlation with meal preparation (MP) and nutrition and health concern (NH). Food allergy prevalence falls down from 6% in infancy to 3.9% in childhood.¹⁹ As the patient grows old, the impact of food allergy on QOL attenuates, which can be caused by parent's adaptation to the disease and related problems. Variable of "Parent's age" showed meaningful correlation only with FSA for mothers not fathers. Increased level of parents' awareness about their children's disease by age, along with socioeconomic condition improvement can contribute to this point.

Variable of Multiplicity of food allergens" had shown strong correlation with QOL in many preceding studies.^{4,12,15,20} In our study, the burden of disease increased and family QOL dropped in level especially in FSA and MP domains by the multiplicity of food allergens and diversity of the restricted foods.

"History of anaphylactic reactions" had no significant correlation with any QOL domains, similar to the study by Cumming et al.¹³ The impact of "being supplied with EpiPen" on QOL was separately calculated in our study and no association with family QOL was found. It seems that despite epinephrine auto-injector can decrease anaphylaxis related mortality rate, it intensifies family stress and not only has no effect on QOL improvement, but also can reduce it.¹³

Presence of other accompanying diseases (asthma, eczema and rhinitis) with food allergy is documented to be about 80% in children¹ and 65% in adolescents.²¹ Our study showed that there is no positive correlation between these presentations and family's QOL, as the same results of Marklund's study in Sweden.²² However, in Leung's study in China, food allergy accompanying atopic dermatitis presentations was related with more burden on QOL.¹⁵ Allergic rhinitis was the most common accompanying variable in several other studies, with considerable impact on patients' QOL.²³⁻²⁶ These allergic presentations in concomitant with food allergy, could substantially affect the patient's general (not food-allergy related) QOL.

We concluded that having a food-allergic child carries a heavy burden on parents' QOL and this burden is markedly greater on mothers than fathers.

Regarding the importance of QOL for management of food allergic patients, we suggest that for all new

diagnosed food-allergic patients, parents' QOL to be determined in order to assess burden of the disease and to evaluate outcomes of food allergy treatment and its shortages, which will be, in turn, very helpful in policy making. Persian version of FAQL-PB is a valid and reliable tool for this purpose and it could be applied in future for clinical and research goals. Regarding the vitality of emergent use of epinephrine auto-injector, it is necessary to provide facilities to supply parents and patients with epinephrine auto-injector and educate its usage indication and instruction.

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