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ORIGINAL PAPER/*PRACA ORYGINALNA*

Evaluation of quality of life of patients with pollen allergy before and after sublingual immunotherapy course

Ocena jakości życia pacjentów z alergią na pyłki przed zastosowaniem i po zastosowaniu immunoterapii podjęzykowej

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ABSTRACT

Introduction: The presence of clinical symptoms significantly deteriorates quality of life (QOL) of patients with pollen allergy and requires proper allergy immunotherapy.

Aim: To analyze QOL of patients with allergy to weed pollen before and after sublingual immunotherapy (SLIT) based on a MiniRQLQ questionnaire.

Material and methods: Totally, 485 individuals, 24 ±4.5 years old were examined. Clinical diagnosis of AR was made according to ARIA criteria (2014). SPT to standard inhaled allergens (Diater Laboratorios, Spain), total serum and specific immunoglobulins IgE, IFA, type-specific components of allergens, immunofluorescent method ImmunoCAP ("Phadia AB", Swiss) were determined. Analysis of quality of life was performed based on a MiniRQLQ questionnaire.

Results: Among patients of the Lviv region with pollen allergy, the most commonly detected positive SPTs were to Artemisia – in 62.3%, less to Ambrosia – 13.9% of individuals, combined sensitization – 23.8% of patients. Among them, genuine allergy to Artemisia was confirmed in 88.1%, to Ambrosia – 88.2% of individuals, co-sensitization – in 21 patients. According to the results of molecular investigations, SLIT was performed for 69.6% of patients (1st group), and 30.4% of individuals were treated symptomatically (2nd group). Based on the MiniRQLQ questionnaire, it was revealed that QOL indices in patients with pollen allergy, who underwent SLIT, were reliably lower after the first and the second years of treatment compared to the indices before SLIT. Reliable changes were not detected in patients of the second group.

Conclusions: Improvement of QOL indices after a course of SLIT indicated the efficacy of this treatment method in patients with pollen allergy.

KEY WORDS

quality of life, allergic rhinitis, pollen allergy, sublingual allergy immunotherapy.

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INTRODUCTION

Allergy to weed pollen is quite common worldwide including Ukraine. It is known that over 1.5 thousand types of weed plants grow on the territory of Ukraine, which may provoke the development of allergic reactions. The most common clinically significant weed allergens worldwide are present in the pollen of Artemisia, Ambrosia, orach, plaintain, and saltwort [1].

The main clinical manifestations of allergy to weed pollen are allergic rhinitis/rhinosinusitis (AR), conjunctivitis and bronchial asthma (BA). Thus, symptoms vary in patients, and in most cases, there are rhinorrhea, sneezing, itching, conjunctivitis, cough, breathlessness, etc. [2]. This condition is considerably deteriorated due to a person's quality of life (QOL) and often results in temporary disability.

The basic method of treatment of sensitized patients with clinical manifestations of allergy to weed pollen is allergy immunotherapy (AIT). Currently, there are many evidence investigations concerning AIT efficacy in patients with pollen allergy. However, the majority of them focus only on the analysis of AIT influence on reduction of clinical manifestations or comparison of efficacy of different AIT methods (sublingual, subcutaneous, etc.) [3].

Nowadays there is a need to pay more attention to investigations concerning estimation of QOL of patients with allergic pathology, especially after treatment. Undoubtedly, implementation of the notion "QOL" into somatic medicine practice can be considered a significant progress compared with the traditional tendency to focus solely on the disease and its symptoms. Besides, medical aspects of QOL define not only patients' health condition, but also the condition of social, material, intellectual and mental well-being etc. [4].

AIM

The aim of our research was to analyze QOL of patients with allergy to weed pollen before and after sublingual immunotherapy (SLIT) based on a specialized questionnaire – MiniRQLQ.

MATERIAL AND METHODS

STUDY DESIGN

This cohort prospective investigation was performed at the department of clinical immunology and allergology and in the regional medical center of clinical immunology and allergology, Ukraine. The research had been lasting for three years starting from March 2014.

In the given period, 485 individuals aged from 3 to 67 years were examined (mean age: 24 ±4.5), including 291 (60.0%) males and 194 (40.0%) females. The criteria for inclusion were age from 18 years, clinical diagnosis of AR made according to ARIA criteria (2014), and sensitization at least to one weed extract (Ambrosia and/or Artemisia (according to the data of skin prick tests (SPT)). The criteria for exclusion were combination of AR and BA, age under 18, adults who had received AIT previously, the presence of mental, lingual and cognitive disorders. Thus, 122 individuals with mean age 29.3 ±2.95 years (from 18 years to 53 years) were selected for further investigation.

At the time of selection, patients' allergy symptoms were evaluated and analysis of case history was done. Total laboratory, instrumental and specific immunological investigations were performed, in particular, SPTs to standard inhaled allergens (Diater Laboratorios, Spain): Der. pteronyssinus, Der. farina, a mixture of spring trees, a mixture of grass, Artemisia, Ambrosia, Alternaria alternata, cats and dogs [5]. Determination of total serum and specific immunoglobulins IgE (sIgE) class was performed with enzyme immunoassay using test-systems Euroimmun. For detection of the levels of specific IgE class antibodies, ImmunoCAP was used (Thermo Scientific, Uppsala, Swiss). Three marker allergens of genuine sensitization to pollen of Artemisia (nArt v 1, rArt v 3) and Ambrosia (rAmb a 1) were determined. Levels of sIgE > 0.35 KU/l were considered positive.

SPECIFIC IMMUNOTHERAPY

Totally, 71 individuals with AR received a two-year course of immunotherapy using sublingual allergens Artemisia and Ambrosia (Diater Laboratorios, Spain). Immunotherapy was started after the end of the flowering season of these plants (end of autumn-winter), when clinical symptoms were absent – during the period of remission. Special preparation for desensitization was not carried out. However, if necessary, antihistamines of the 2nd generation, inhaled beta-agonists, ICS and antileukotriene drugs were prescribed to control respiratory symptoms. Patients of the second group received symptomatic treatment in the form of non-sedative antihistamines (tablets, eye drops, nasal sprays etc.). Monitoring of QOL was con-

ducted before therapy (SLIT or symptomatic) and after the first and the second years of treatment, during visits for consultations. More data are given in Table 1. The study was conducted in accordance with the seventh revision of the principles of the Declaration of Helsinki on Human Rights (2013), the Council of Europe Convention on Human Rights and Biomedicine, and relevant laws of Ukraine. The Ethical Committee or Institutional Animal Care and Use Committee Approval: Danylo Halytsky Lviv National Medical University 20/12/2014 No. 10.

ANALYSIS QOL

Analysis of quality of life was conducted based on validated questionnaire – MiniRQLQ (Table 2). The MiniRQLQ has 14 items in five domains (activity limitation (n = 3), practical problems (n = 2), nose symptoms (n = 3), eye symptoms (n = 3) and other symptoms (n = 3)). The questionnaire is in a self-administered format and is completed by patients without an interviewer's assistance. Patients are asked to consider how they have been and to respond to each question on a seven-point scale (0 = not troubled, 1 = hardly troubled at all, 2 = somewhat troubled, 3 = moderately troubled, 4 = quite a bit troubled, 5 = very troubled, 6 = extremely troubled).

STATISTICAL ANALYSIS

The data that met normal distribution criteria, such as age and disease duration, were analyzed using Student's t-test for independent variables. Other non-parametric data were compared with the χ^2 test. The summary odds ratio, 95% confidence intervals and standard errors using random-effects models were also computed.

Statistical processing of the obtained results was made using the standard statistical package Statistics for Windows 7.0.

For the statistical significance of the results, we used a value of $\alpha = 0.05$. The p value of the statistical test is used for accepting or rejecting the hypothesis ($p \geq \alpha$: hypothesis is accepted; $p < \alpha$: hypothesis is rejected). All results are elaborated, documented and presented in absolute and relative numbers and with statistical results using statistical markers.

RESULTS AND DISCUSSION

Among 472 patients with pollen allergy, positive SPTs to weeds were detected in 122 (25.8%) individuals (Figure 1). Among them, monosensitization to Artemisia was in 7 (5.7%) persons, monosensitization to Ambrosia – in 3 (2.5%) individuals. As predicted, polysensitization was observed in 112 (91.8%) patients. Among polysensitized individuals, positive SPTs to Artemisia were detected in 69 (61.6%), to Ambrosia – in 14 (12.5%) patients, combined sensitization to two types of weeds was found in 29 (25.9%) patients. Thus, sensitization to Artemisia was observed in 76 (62.3%) individuals, to Ambrosia – in 17 (13.9%), co-sensitization – in 29 (23.8%) persons.

TABLE 1. Characteristics of the investigated group of patients

Indicator	Results
Number of patients, *n*	122
Sex, *n* (%):	
Male	74 (60.7)
Female	48 (39.3)
Age (M ± m) [year]	29.3 ±2.95
Clinical symptoms, *n* (%)*:	
Rhinitis	118 (96.7)
Rhinoconjunctivitis	63 (51.6)
Allergic asthma	9 (7.4)
Wheezing	8 (6.6)
Upper palate itching	13 (10.7)
Cough	70 (57.4)
Sneezing	100 (81.9)
The results of SPT (mean diameter of papule) [mm]:	
Artemisia	4.7 ±2.7
Ambrosia	11.2 ±3.4
Number of patients with polyvalent sensitization, *n* (%) – according to the data of SPT	112 (91.8)
Monosensitized, *n* (%):	10 (8.2)
Ambrosia	3 (2.5)
Artemisia	7 (5.7)

Therefore, to detect genuine sensitization to Artemisia and Ambrosia for selection of correct treatment tactics, we offered mono- and polysensitization to patients to perform allergen-component analysis. Among 76 patients with positive SPTs to Artemisia, the presence of genuine allergy was confirmed in 67 (88.1%) individuals. Among them, two major molecules of Artemisia – Art v 1 and Art v 3 were detected in three patients. Out of 17 patients with positive SPTs to Ambrosia, genuine allergy was confirmed in 15 (88.2%) individuals. Meanwhile, co-sensitization to Ambrosia and Artemisia was observed in 21 persons. According to the results of molecular investigation, immunotherapy is recommended for 102 patients with detected major allergens of these weeds. However, SLIT was performed for only 71 (69.6%) patients who constituted the first group of investigation.

TABLE 2. MiniRQLQ for patients with allergic rhinitis/rhinosinusitis

Variable	Not troubled	Hardly troubled at all	Somewhat Troubled	Moderately troubled	Quite a bit troubled	Very troubled	Extremely troubled
Activities:							
1. Regular activities at home and at work (your occupation or tasks that you have to do regularly around your home and/or garden)	0	1	2	3	4	5	6
2. Recreational activities (indoor and outdoor activities with friends and family, sports, social activities, hobbies)	0	1	2	3	4	5	6
3. Sleep (difficulties getting a good night's sleep and/or getting to sleep at night)	0	1	2	3	4	5	6
Practical problems:							
4. Need to rub nose/eyes	0	1	2	3	4	5	6
5. Need to blow nose repeatedly	0	1	2	3	4	5	6
Nose symptoms:							
6. Sneezing	0	1	2	3	4	5	6
7. Stuffy blocked nose	0	1	2	3	4	5	6
8. Runny nose	0	1	2	3	4	5	6
Eye symptoms:							
9. Itchy eyes	0	1	2	3	4	5	6
10. Sore eyes	0	1	2	3	4	5	6
11. Watery eyes	0	1	2	3	4	5	6
Other symptoms:							
12. Tiredness and/or fatigue	0	1	2	3	4	5	6
13. Thirst	0	1	2	3	4	5	6
14. Feeling irritable	0	1	2	3	4	5	6

A control group of investigation involved 31 (30.4%) individuals, who, for different reasons, and, first of all, due to financial problems, refused SLIT and were treated only symptomatically.

Using validated mini-questionnaire MiniRQLQ for patients in both groups, QOL estimation was performed before treatment and after the first and the second years of SLIT (1st group) and symptomatic treatment (2nd group). Data of analysis are given in Table 3.

As it is seen in the table, a reliable decrease in all indices was detected in patients of the first group following SLIT after the second year of treatment ($p < 0.05$). Such indices as «Practical problems», «Nose, Eye and Other symptoms» improved already after the first year of SLIT ($p < 0.05$). Concerning patients of the second group, improvement of indices was not observed after the first year of symptomatic therapy, and a reliable reduction of indices «Other symptoms» was observed after the second year compared with those before treatment ($p < 0.05$).

In our examination of patients with allergy to weed pollen based on MiniRQLQ questionnaire, we observed positive changes of QOL indices, indicating the efficacy of SLIT compared with symptomatic therapy. A reliable reduction of indices was observed in patients of the first

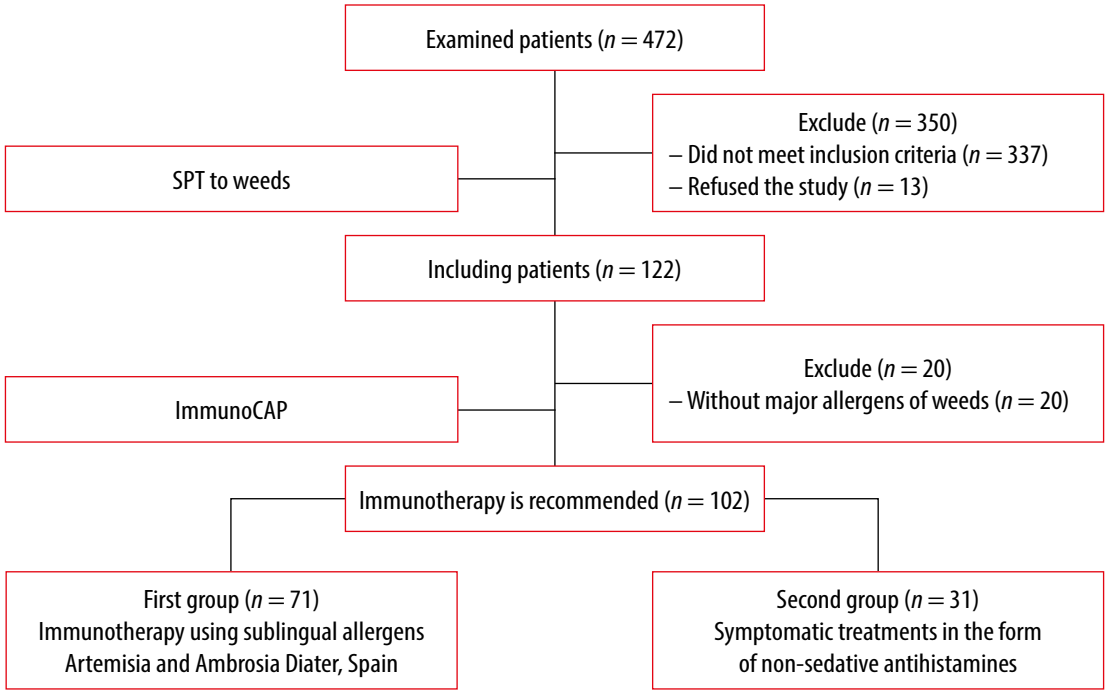

FIGURE 1. Design of the study

TABLE 3. Estimation results of patients' quality of life on the background of SLIT and symptomatic therapy (1st and 2nd years), M ± m

Domains	1st group (n = 71)			2nd group (n = 31)		
	Before SLIT	In 1 year	In 2 years	Before SLIT	In 1 year	In 2 years
Overall	3.29 ±1.12	2.09 ±0.89	1.46 ±0.13*	3.27 ±0.74	2.62 ±0.40	3.12 ±0.31
Activities	3.16 ±0.86	2.01 ±0.67	1.53 ±0.23*	3.11 ±0.49	2.85 ±0.42	2.95 ±0.23
Practical problems	4.07 ±0.71	2.64 ±0.4°	1.69 ±0.17*	3.97 ±0.34	3.20 ±0.50	2.29 ±0.45
Nose symptoms	3.63 ±0.62	2.31 ±0.3°	1.56 ±0.21*	3.64 ±0.43	3.57 ±0.21	3.54 ±0.17
Eye symptoms	3.02 ±0.42	1.89 ±0.2°	1.38 ±0.14*^	3.08 ±0.37	2.03 ±0.49	2.79 ±0.16
Other symptoms	2.61 ±0.19	1.62 ±0.1°	1.13 ±0.14*^	2.56 ±0.11	1.88 ±0.35	1.65 ±0.18*

*$p < 0.05$ in 2 years of SLIT/symptomatic therapy compared with the indices before treatment; °$p < 0.05$ in 1 year of SLIT compared with the indices before treatment; ^$p < 0.05$ in 2 years of SLIT compared with the indices in 1 year of treatment.

group both after the first and the second year of SLIT ($p < 0.05$). The majority of patients in this group noted a significant alleviation of physical and mental condition, since reduction of clinical symptoms in the pollination season allowed them to drive a car for a long time, join sport groups, actively carry out everyday duties etc. There was only a tendency for improvement of seasonal clinical symptoms in 4 persons of the first group among polysensitized individuals. This fact is due to exacerbation of symptoms caused by the influence of other allergens. Besides, several patients in the SLIT period had frequent respiratory viral diseases, and thus, decreased immune activity and temporary cessations of SLIT. Further, 68 patients agreed to continue SLIT, and three patients refused to proceed with the treatment due to personal causes.

CONCLUSIONS

Among patients of the Lviv region with pollen allergy, the most common is sensitization to Artemisia (62.3%) and less to Ambrosia (13.9%). Component investigations enable us to diagnose the presence of genuine allergy to weed pollen and thus to administer effective AIT. In our research, genuine allergy is confirmed in 88.1% (Artemisia) and 88.2% (Ambrosia) of patients. Improvement of QOL indices after SLIT treatment indicated the efficacy of this therapy method in patients with pollen allergy.

CONFLICT OF INTEREST

The authors declare no conflict of interest.

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