



# Determinants and Factors of Satisfaction with Sublingual Immunotherapy in Patients with Allergic Rhinitis

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## Abstract

**Introduction:** Allergen specific immunotherapy provides effective treatment of allergic rhinitis. Despite its efficacy, it can be significantly compromised by a possible treatment dissatisfaction of patients.

**Aim:** To explore determinants and factors of satisfaction with sublingual immunotherapy in patients with allergic rhinitis.

**Materials and methods:** A total number of 191 patients with allergic rhinitis who completed a three-year course of sublingual immunotherapy were included in the study. Of these, 76 had house dust mite (HDM) allergy - 42 men (55.26%) and 115 had grass pollen allergy - 63 men (54.78%) (mean age 27.3 years, SD: 6.14). The patients assessed their satisfaction using a visual analog scale. Health-Related Quality of Life was assessed by Rhinoconjunctivitis Quality of Life questionnaire. A visual analog scale was used to determine severity of the allergic rhinitis.

**Results:** The mean overall satisfaction, compared with that in previous therapy, increased significantly from 4.80 (SD 2.16) to 7.47 (SD 2.05) in the grass pollen allergy group and from 3.42 (SD 2.31) to 7.61 (SD 2.38) in the patients with HDM SLIT ( $p < 0.001$ ). No relation between satisfaction and sex, type of immunotherapy extracts and duration of the disease was established. A strong correlation was found between satisfaction with treatment and quality of life ( $R=0.62$ ) and severity of allergic rhinitis ( $R=0.69$ ) after a three-year course.

**Conclusion:** The results of this real-life study demonstrated that most patients with allergic rhinitis appeared to be satisfied with a three-year course of sublingual immunotherapy. The study provided evidence that reduction in severity of symptoms and improvement in quality of life could determine satisfaction with treatment.

## Keywords

allergic rhinitis, determinants, factors, sublingual immunotherapy, satisfaction, quality of life, severity

## INTRODUCTION

Allergic rhinitis (AR) is a symptomatic disorder of the nose induced after allergen exposure by an IgE-mediated inflammation. It is the most frequent allergic disease with increasing prevalence worldwide.<sup>1</sup> It is often associated with bothersome symptoms, which can impair quality of life,

productivity at work and school, quality of sleep.<sup>2</sup> The relation between AR and other comorbidities including asthma is well established.<sup>3</sup> The most common allergens that cause AR are house dust mite (HDM) and grass pollen.<sup>4</sup> Management of the disease includes allergen avoidance, if possible, pharmacotherapy and allergen specific immunotherapy.<sup>5</sup>

Allergen specific immunotherapy (subcutaneous or

sublingual) provides effective treatment for allergic rhinitis with clinical improvement following an adequate course of therapy persisting in most patients for years after treatment has been discontinued.<sup>6,7</sup> Immunotherapy in patients with AR may decrease the risk of developing asthma.<sup>8</sup> In recent years, many trials have demonstrated that sublingual immunotherapy (SLIT) is effective in reducing symptoms of AR, medication reliance and have a well-tolerated safety profile.<sup>9,10</sup> This comparatively new form of allergen specific immunotherapy is recommended by Allergic Rhinitis and its Impact on Asthma (ARIA) guidelines for adults with moderate to severe AR, sensitized to HDM and grass pollen.<sup>11</sup> Despite its efficacy, this self-administered treatment, which requires prolonged courses of therapy for three years, can be significantly compromised by dissatisfaction of the patients from the treatment. Satisfaction with prescribed treatment is a crucial issue that may significantly affect treatment compliance and success.<sup>1</sup> It is one of the Patient-Reported Outcomes (PROs) which is gaining increasing awareness because of its relevance to the overall treatment assessment.<sup>12,13</sup> In this regard, there is a paucity of data concerning satisfaction with allergen immunotherapy. No publications on determinants and factors of satisfaction at the end of the recommended three-year course of SLIT are available.

## AIM

The aim of the present study was to explore determinants and factors of satisfaction with sublingual immunotherapy in patients with allergic rhinitis.

## MATERIALS AND METHODS

### Study design

This real-life study was conducted in the Allergy Unit of the Internal Consulting Department of St. George University Hospital, Plovdiv, Bulgaria. All patients were referred either by their general practitioners or were self-referred. It was designed to include patients who completed a three-year course of HDM SLIT and grass pollen SLIT as a routine management of their AR according to ARIA recommendations. It was approved by the review board of the University Hospital and performed in full compliance with the declaration of Helsinki. Informed consent was obtained from all participants. The patients were evaluated before initiation of immunotherapy and on the third year of SLIT. Follow up was performed in the course of treatment. Each patient was evaluated by the same physician. Assessment was performed throughout the year in one and the same month for treated with HDM SLIT and in May and June for grass

pollen SLIT— months with the highest grass pollen concentration.

## Patients

A total number of 449 patients with AR and clinically relevant sensitization to HDM or grass pollen and symptoms inadequately controlled with pharmacotherapy were evaluated. Diagnosis of AR was made on the basis of detailed clinical history, a complete physical examination and positive skin prick test in conformity with the validated criteria. AR was classified according to ARIA guidelines classification.<sup>14</sup> Duration of symptoms before SLIT initiation was evaluated.

SLIT was conducted with standard extract of HDM (1:1 mixture of *D. pteronyssinus* and *D. farinae*) or a mixture of pollen extracts of five grasses and four cereals [Staloral® 300 IR (Stallergens, France)] as sublingual drops, following the schedules recommended by the manufacturer. The treatment was administered perennially in patients with HDM allergy and pre- and co-seasonally in allergic to grass pollen. The study was a part of overall assessment of effectiveness of SLIT on some clinical outcomes according to EAACI recommendations.<sup>13</sup>

## Assessment of satisfaction and other patient-reported outcomes

Satisfaction with treatment was assessed by a 10-cm visual analogue scale (VAS). Patients were asked to assess “Your overall satisfaction with the treatment” before SLIT initiation while taking pharmacotherapy and on the third year of SLIT. Patients graded their satisfaction from 0: “no satisfied at all” to 10: “completely satisfied”. Some other PROs were explored as well. Health-Related Quality of Life was assessed by interviewer-administered version of Rhinoconjunctivitis Quality of Life questionnaire (RQLQ).<sup>14</sup> The questionnaire is designed for adults and consists of 28 items, distributed in 7 domains: activities – three items; sleep – three items; general problems – seven items; practical problems – three items; nasal symptoms – four items; eye symptoms – four items; emotions – four items. Patients are scored on a 7-point scale, from 0 to 6. Lower scores indicate better QOL. Bulgarian version of the questionnaire was used with the permission of the author.

VAS was used to assess AR severity. Patients graded their discomfort by putting a vertical line on a 10-cm line representing severity from 0: “no symptom” to 10: “highest level of symptom”.<sup>15</sup>

## Statistical analysis

Continuous variables were described as mean standard deviation (SD) and categorical variables were described as frequencies. The distribution of continuous samples was assessed by One-Sample Kolmogorov-Smirnov Test. For

the comparison independent and paired samples t-test was used for quantitative data and Fisher's exact test for qualitative data. P-value < 0.05 was regarded as statistically significant. Pearson's correlation coefficient was used as appropriate to analyze the relationship between variables. Statistical significance was ascertained using the One-way Analysis of Variance (ANOVA). Data were analyzed using IBM SPSS STATISTICS v. 20 (Chicago, IL, USA).

## RESULTS

A total number of 191 patients [105 (54.97%) men; mean age 27.3 years (SD 6.14)] were prospectively evaluated in the course of the management of AR. HDM SLIT was performed in 76 (39.8%) patients and grass pollen SLIT – in 115 (60.2%). Age, sex, and severity of AR, in relation to type of sensitization and duration of symptoms before initiation of SLIT are presented in **Table 1**. No significant difference in age and sex between two treatment groups was established. All patients were with moderate to severe AR and those with persistent AR predominated.

**Table 1.** Patients' characteristics

Characteristics	Type of sensitization	
	HDM (n=76)	Grass pollen (n=115)
<b>Age (years)</b>		
mean (SD)	26.10 (5.85)	25.73 (6.43)
range	18 – 48	18 – 46
<b>Gender</b>		
Male	42 (55.26%)	63 (54.78%)
Female	34 (44.74%)	52 (45.22%)
<b>Type of AR</b>		
moderate/severe intermittent	0	31 (26.96%)
moderate/severe persistent	76 (100%)	84 (73.04%)
<b>Disease duration (years)</b>		
≤ 4	18 (23.68%)	37 (32.17%)
5-8	33 (43.42%)	38 (33.04%)
> 8	25 (32.89%)	40 (34.78%)

n: number of patients; HDM: house dust mite; AR: allergic rhinitis.

The mean overall satisfaction with previous pharmacotherapy assessed by VAS was 3.42 (SD 2.31) in sensitized to HDM and 3.42 (SD 2.31) in grass pollen group. When assessed on the third year it increased significantly: 7.61 (SD 2.38) and 7.47 (SD 2.05), respectively ( $p < 0.001$ ) (**Table 2**). No significant difference in satisfaction of patients between both types of SLIT was established ( $t=1.03$ ;  $p=0.72$ ).

**Table 2.** Overall satisfaction before and after sublingual immunotherapy (self-assessed by Visual Analogue Scale, cm)

	Satisfaction	Mean	SD	SEM	t	p
Pollen SLIT	before SLIT	4.80	2.16	0.23	8.83	< 0.001
	after SLIT	7.47	2.05	0.22		
HDM SLIT	before SLIT	3.42	2.31	0.33	9.28	< 0.001
	after SLIT	7.61	2.39	0.34		

SLIT: sublingual immunotherapy; HDM: house dust mite.

In order to explore some factors of satisfaction, its relation with sex was evaluated. No significant difference in satisfaction between sexes was found ( $t=1.19$ ;  $p=0.71$ ) (**Table 3**).

The relation between satisfaction and disease duration was evaluated as well. On the base of duration of symptoms before initiation of SLIT patients were divided in three groups: symptoms up to four years, from five to eight years, and more than eight years. Data were analyzed. It was found that there was no relation between satisfaction and disease duration ( $p=0.81$ ) (**Table 4**).

**Table 3.** Satisfaction of patients with sublingual immunotherapy in relation with gender (self-assessed by Visual Analogue Scale, cm)

Gender	n	Mean	SD	SEM	t	p
Male	105	7.50	2.37	0.43	1.19	0.71
Female	86	7.58	2.14	0.34		

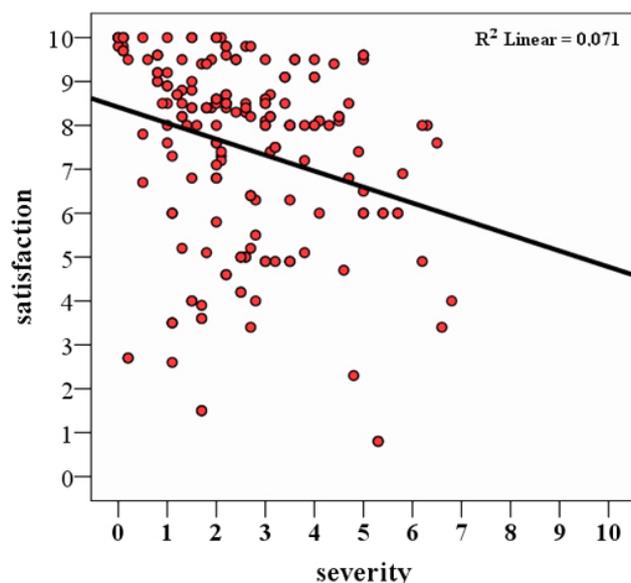
n: number of patients.

**Table 4.** Satisfaction of patients with sublingual immunotherapy in relation with disease duration

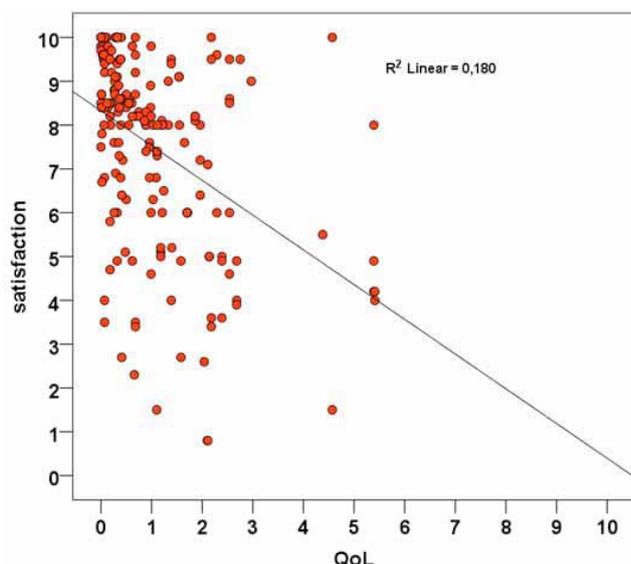
Disease duration (years)	n	Mean	SD	SEM	t	p
≤ 4	55	7.49	1.65	0.38	0.21	0.81
5 – 8	71	7.65	2.15	0.42		
> 8	65	7.51	2.73	0.55		

n: number of patients

A significant increase in mean QOL scores assessed by RQLQ ( $p < 0.0001$ ) had been found and published previously.<sup>16</sup> Reduction in severity of AR assessed by VAS was established as well ( $p < 0.0001$ ) (data are not published here). In order to determine dependence of satisfaction on PROs a possible correlation with QOL and VAS was explored. The results are presented in **Figs 1, 2**. A strong correlation was found between satisfaction with SLIT and improvement in quality of life ( $R=0.62$ ) and decreased severity of AR ( $R=0.69$ ) after a three-year course.



**Figure 1.** Correlation between satisfaction and severity of AR after a three-year course of SLIT [results of assessment by VAS, presented in cm].



**Figure 2.** Correlation between satisfaction and quality of life after a three-year course of SLIT [results from RQLQ scores and assessment of satisfaction by VAS in cm].

## DISCUSSION

The presented study aimed to explore, for the first time, factors and determinants of satisfaction on the third year of SLIT.

SLIT is a valuable causal treatment for respiratory allergy, which is comparatively new with accumulating data on its efficacy. However, it is a long treatment and patients' attitude can influence the final results. Satisfaction, as a cognitive product of the comparison between the ideal life and reality, can predict adherence to treatment. SLIT is suggest-

ed by ARIA in adults with persistent and with moderate to severe AR due to pollens or house dust mites.<sup>14</sup> All patients included in the study had such forms of AR and such sensitizations.

In an attempt to measure patient satisfaction, a questionnaire, the Satisfaction Scale for Patients Receiving Allergen Immunotherapy (ESPIA), has been specially designed for this purpose.<sup>17</sup> A shortcoming of this questionnaire is that it has yet no multilingual version available. In our study, we decided to use VAS to measure overall satisfaction with treatment. As a psychometric measuring instrument it can be used to monitor the course of treatment of a chronic disease such as AR.<sup>18</sup> Moreover, a strong correlation between ESPIA scores and VAS satisfaction has been found.<sup>17</sup> We assessed satisfaction with pharmacotherapy before initiation of SLIT to compare it with satisfaction on the third year of immunotherapy. In a real-life study Ciprandi et al. demonstrated that most of the allergic patients suffering from AR were dissatisfied with prescribed pharmacotherapy.<sup>20</sup> Comparatively low satisfaction with previous pharmacotherapy was established in our study as well with mean value of 4.11 cm (SD 2.24) for both types of sensitizations ( $p < 0.0001$ ). SLIT on the third year was related to a significant increase in satisfaction - 7.54 (SD 2.22). This observation confirmed and expanded our previously published data.<sup>21</sup> These findings are in agreement with the results of Baiardini et al. who assessed satisfaction with specific immunotherapy (subcutaneous and sublingual) by VAS in patients with AR and reported the mean global satisfaction degree for the treatment 7.77 cm (SD 2.13).<sup>22</sup> Established satisfaction is an important PRO which can contribute to the assessment of clinical effectiveness of SLIT according to published recommendations.<sup>13</sup>

Independently of the types of allergen extracts for SLIT patients indicated similar satisfaction with no significant difference. It was interesting to investigate this correlation because there was a difference in the schedule of HDM SLIT and grass pollen SLIT: all the year round and six months, respectively. Despite its longer duration, HDM SLIT was adopted equally as grass pollen SLIT.

Our analysis demonstrated that sex was not a factor related to satisfaction with SLIT. Regarding sex there are publications that female patients had lower satisfaction with treatment of some diseases than men, including pharmacotherapy of AR.<sup>20,23</sup> Our study provided evidence that there was no significant difference in satisfaction between sexes on the third year of SLIT. There have been no other publications on immunotherapy to compare these results.

The next factor that was investigated in the study was the disease duration. It is known that AR is often underdiagnosed and undertreated and many patients seek medical help when symptoms become very troublesome or comorbidities such as asthma occur.<sup>24</sup> The results from the presented study confirmed that many patients tolerated their symptoms and some of them had symptoms for more than 8 years. It was established, for the first time, that disease duration was not a factor which determined satisfaction

with SLIT. It was an important observation from a clinical point of view. In suitable patients it makes sense to initiate SLIT regardless of the duration of the disease. Moreover, this treatment can prevent development of asthma in patients with AR.

Regarding PROs, the data from the study found a strong correlation between the impact of SLIT on symptom severity and satisfaction. The results were consistent with those reported by Ciprandi et al. who found that the dissatisfaction level depends on symptoms severity.<sup>25</sup> The results from the presented study demonstrated that there is a strong correlation between severity of AR and patients' satisfaction.

Another outcome assessed in relation with satisfaction was quality of life. The positive effect of SLIT on the quality of life and its strong correlation with satisfaction were important observations in the study.

Having no data to compare the results with, it was found that patients' PROs had more influence on satisfaction with SLIT than other factors. It could be speculated that patients who would achieve improvement in severity and quality of life would be those that are satisfied with SLIT.

The main strength of the study is that data collection was performed in real life and obtained from a large number of patients who completed three-year course of SLIT according to the recommendation for this treatment. It is the first study in Bulgaria which has assessed satisfaction with SLIT in great detail. The limitations of the study are the use of self-report tools and that there was no control group. Moreover, our results refer to a specific product and thus cannot be generalized. However, the outcomes which were assessed were in accordance with the recent recommendations for standardized clinical outcomes used in allergen immunotherapy trials for AR. We believe this reinforces the value of our findings.

## CONCLUSION

Although patient satisfaction with SLIT presents an important issue and is included in the most recent guidelines, it is still poorly researched. The results of this real-life study demonstrated that most patients with allergic rhinitis appeared to be satisfied with SLIT on the third year of treatment. No factors like duration of symptoms, sex and type of SLIT seemed to influence satisfaction which is important from a practical point of view. The study provided evidence that reduction in severity of symptoms and improvement in quality of life could determine satisfaction of patients.

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# Детерминанты и факторы удовлетворённости сублингвальной иммунотерапией у пациентов с аллергическим ринитом

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## Резюме

**Введение:** Аллерген-специфическая иммунотерапия обеспечивает эффективное лечение аллергического ринита. Несмотря на свою эффективность, она может быть значительно скомпрометирована возможной неудовлетворённостью пациента.

**Цель:** Изучить детерминанты и факторы удовлетворённости сублингвальной иммунотерапией (СЛИТ) у пациентов с аллергическим ринитом.

**Материалы и методы:** В исследование были включены 191 пациента с аллергическим ринитом, прошедшими трёхлетний курс сублингвальной иммунотерапии. Из них 76 имели аллергию на клещей домашней пыли (house dust mite (HDM), 42 мужчины (55,26%) и 115 – на пыльцу травы – 63 мужчины (54,78%) (средний возраст 27,3 года, SD: 6,14). Пациенты оценивали удовлетворённость с помощью визуальной аналоговой шкалы. Качество жизни, связанное со здоровьем, оценивали с помощью анкеты качества жизни при риноконъюнктивите. Для определения степени аллергического ринита использовали визуальную аналоговую шкалу.

**Результаты:** Средняя общая удовлетворённость по сравнению с предыдущей терапией значительно увеличилась с 4,80 (SD 2,16) до 7,47 (SD 2,05) в группе пациентов с аллергией на пыльцу травы и с 3,42 (SD 2,31) до 7,61 (SD 2,38) у пациентов с HDM SLIT ( $p < 0,001$ ). Не было обнаружено связи между удовлетворённостью и полом, типом иммунотерапии и продолжительностью заболевания. Была обнаружена сильная корреляция между удовлетворённостью лечением и качеством жизни ( $R = 0,62$ ) и тяжестью аллергического ринита ( $R = 0,69$ ) после трёхлетнего курса лечения.

**Выводы:** Результаты исследования в режиме реального времени показали, что большинство пациентов с аллергическим ринитом удовлетворены трёхлетним курсом сублингвальной иммунотерапии. Исследование предоставило доказательства того, что уменьшение выраженности симптомов и улучшение качества жизни приведёт к удовлетворённости лечением.

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## Ключевые слова

аллергический ринит, детерминанты, факторы, сублингвальная иммунотерапия, удовлетворённость, качество жизни, тяжесть

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