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# Effect of COVID-19 pandemic on the treatment process and adherence to treatment of the patients receiving allergen-specific immunotherapy

Effect of the SARS-CoV-2 pandemic on treatment processes of allergen-specific immunotherapy

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**Abstract**

Aim: During the COVID-19 pandemic, the number of hospital admissions has significantly decreased, due to both the risk of transmission and the restrictions imposed. The most adversely affected ones are patients who need to admit to a hospital due to their chronic diseases, such as those receiving allergen immunotherapy.

Material and Methods: Files of the patients who were administered subcutaneous immunotherapy (SCIT) regularly, were retrospectively reviewed. At first outpatient clinic visits during the period of so-called normalization process (June-July-August 2020), the patients were asked to fill a mini questionnaire and validated coronavirus anxiety questionnaire.

Results: A total of 151 patients receiving SCIT were included in the study. The most common government-related factors hindering outpatient clinic visits of the patients were travel restrictions (40.6%) and the most common patient-related factors were fear of contracting SARS-CoV-2 (39.7%). Overall adherence to treatment during the 3-month period from March to April-May 2020 was determined to be 54.3%. The duration of immunotherapy, increased allergic symptoms, the need for additional treatment and treatment switch in SCIT because of the pandemic were significantly higher in patients non-adherent to SCIT treatment compared to adherent ones (p: 0.031, p: 0.001, p: 0.001 and p: 0.001, respectively).

Discussion: Access to allergen immunotherapy, applicability, and maintenance of the immunotherapy should be a priority during the COVID-19 pandemic. Considering both patient-related and government-related factors in the administration of immunotherapy, the process of immunotherapy should be continued, minimizing the risk of SARS-CoV-2 transmission. Furthermore, patients' worry and anxiety levels may be reduced with these measures and their adherence to treatment may be promoted.

**Keywords**

COVID-19; Allergen immunotherapy; Anxiety questionnaire

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## Introduction

The 2019 Coronavirus disease (COVID-19), which emerged in the People's Republic of China in December 2019 and was declared as a pandemic by WHO (World Health Organization) on March 11, 2020 has affected the whole world, particularly in health, and in social, cultural and economic aspects [1-3]. During the pandemic, the number of hospital admissions due to reasons other than COVID-19 has significantly decreased, due to both the risk of transmission and measures taken and the restrictions imposed [4]. The most adversely affected ones, surely, are the patients who need to admit to the hospital due to their chronic diseases. Patients receiving allergen-specific immunotherapy (AIT) may also be included in this patient group [5-7]. AIT is the only disease-modifying treatment option in allergic asthma, allergic rhinitis (AR), seasonal allergic rhinitis (SAR) and venom allergy. There are two main routes of administration: Sublingual and subcutaneous immunotherapy (SCIT), which has been used for a longer period of time and with more experience. AIT is a treatment modality that continues at gradually increasing doses, for a long period of time, modifies T-cell-mediated immune responses and provides an improvement in symptoms and clinical course [8-10]. Patients receiving SCIT should be administered immunotherapy at regular intervals and the COVID-19 pandemic adversely affects access to treatment for this patient group that needs to be treatedt at 1-4-week intervals. In addition, during the pandemic, the risk of SARS-CoV-2 transmission to the patient or his/her family members and some measures taken including isolations like quarantine, international and intercity travel restrictions, additional restrictions and prohibitions for certain age groups increases fear, worry and anxiety in patients. Such a case may also adversely influence adherence to treatment in patients receiving SCIT [11-13]. Therefore, in this study, we aimed to investigate the effect of the SARS-CoV-2 pandemic on adherence to treatment of the patients receiving AIT due to allergic diseases in our clinic, to determine the reasons why patients are coming late/not coming for treatment and to reveal the effect of SARS-CoV-2 pandemic on the anxiety of this patient group.

## Material and Methods

Files of the patients who admitted to the allergy outpatient clinic between June 2015 and March 1, 2020 and were administered SCIT regularly with diagnoses of AR, SAR, asthma, and venom allergy that were established in accordance with clinical history, skin prick tests, allergen-specific IgE results and international guidelines [14, 15] were retrospectively reviewed. Adult patients over the age of 18 were included in the study. Patients who did not regularly attend SCIT treatment between June 2015 and March 1, 2020, whose treatment was terminated due to SCIT for a sufficient time, and whose files did not have sufficient data, were excluded from the study. In addition, patients who were diagnosed with allergic diseases in our center and continued their SCIT follow-up in other centers were excluded from the study. Age, gender, education level, history of comorbid diseases, presence of individual atopy, type of IT received and frequency of administration of patients included in the study were obtained from their files. At first outpatient clinic visits during the so-called period of normalization process (June, July-August 2020), the patients were asked to fill out a mini questionnaire developed by us about the March-April-May period, when the first SARS-CoV-2 case in Turkey was identified and some restrictions were imposed due to risk of transmission. Patients who had been administered AIT regularly before the pandemic but did not come for outpatient clinic visits during this period were asked to fill out a mini questionnaire by phone calls. The patients who did not come to at least one outpatient clinic visit during March-April-May 2020 were considered not adherent to treatment. This mini questionnaire asked whether they admitted to the hospital for AIT during March-April-May 2020, and, if they came late or did not come, the reasons were investigated. Government-related reasons (curfew, intercity travel restriction, failure to get an outpatient clinic appointment, disability and pregnancy status etc.) and patient-related factors (fear of contracting the virus, fear of transmitting the virus to family members, availability of direct access to drugs during this period, not feeling the need for treatment, COVID-19 infection or COVID-19 quarantine etc.) were addressed. Each patient was asked to fill the validated coronavirus anxiety questionnaire [16]. In this questionnaire, patients were asked if he/she felt dizzy and dull or was about to faint when he/she read or heard the coronavirus news. Additionally, they were asked if he/she had problems with falling asleep or sleeping because he/she thought about coronavirus, and if he/she felt like having a stroke or petrified when he/she thought about coronavirus or was subject to these issues. Also, they were asked if he/she lost my appetite when he/she thought about coronavirus or was subject to these issues and if he/she had nausea or stomach discomfort when he/she thought about coronavirus or was subject to these issues. Patients were asked to answer these questions with the appropriate one of the "Always, Usually, Sometimes, Seldom and Never" options.

Additionally, the patients were investigated about whether they experienced an increase in allergic complaints and, if present, the types of complaints, the need for additional anti-allergic medication, admission to the emergency department, additional drug supplement in addition to on-going treatments and use of food or herbal supplements.

Statistical analysis was performed with the IBM SPSS Statistics Version 22 software package (New York, United States). Normally distributed parameters were presented as mean ± standard deviation, and data that is not have a normal distribution were expressed as median (interquartile range: minimum–maximum). Descriptive data were presented as frequencies and percentages and compared using the Chi-square test. Comparisons between baseline characteristics were performed using independent Student t-test, Mann-Whitney rank-sum, Fisher's exact or Chi-square tests where appropriate.

The study was approved by the Turkish Republic Ministry of Health Scientific Research Platform. In addition, the ethics committee approval was obtained from Karatay University Ethics Committee (with a decision dated 17.07.2020 and numbered 2020/014). Informed consent was obtained from the participants of the study.

## Results

A total of 151 patients receiving SCIT in our clinic were included in the study. The median age of the patients was 31 (15-71) years and 55.6% of the patients were female. Eighty-three patients (55%) were postgraduate and above. The mean duration of allergic diseases was 5 (1-35) years and the duration of immunotherapy was 20 (3-58) months. The most common government-related factors hindering outpatient clinic visits of the patients were travel restrictions (40.6% of the patients) and curfew (40.4% of the patients). The most common patient-related factors were fear of contracting SARS-CoV-2 (39.7%) and transmitting SARS-CoV-2 to family members (30.5%). Patient's demographic data are represented in Table 1.

When adherence to treatment of the patients was evaluated, overall adherence to treatment during a 3-month period from March to April-May 2020 was determined to be 54.3%. On a monthly basis, adherence to treatment was observed to be lowest in April (in ascending order, 79.5% in March, 61.6% in April and 62.3% in May). During the pandemic, 50.3% of the patients receiving SCIT had an increase in allergic complaints. The most commonly reported allergic complaint was sneezing (%22.5). Furthermore, 45% of the patients receiving SCIT needed additional treatment for these symptoms. The most commonly used additional treatment was oral antihistamines (24.5%). The treatment switch was performed in 60 patients (39.7%) due to non-adherence to SCIT. In 28 patients (18.5%), immunotherapy was discontinued at the patient's own request and/or physician's suggestion, immunotherapy doses were reduced in 32 patients (21.2%). Three patients (2%) admitted to the emergency department with allergic complaints; 9.3% of the patients received additional treatments like herbal and vitamin supplements.

When the patients adherent and non-adherent to SCIT treatment were compared, no significant difference was determined between both groups in regard to age, gender, education level, duration of allergic diseases, type of immunotherapy administered, presence of an additional comorbid disease and admission to emergency department (p: 0.174, p: 0.234, p: 0.809, p: 0.078, p: 0.230, p: 0.118 and p: 0.664, respectively). However, the duration of immunotherapy, increased allergic symptoms, the need for an additional treatment and treatment switching in SCIT because of the pandemic were significantly higher in non-adherent to SCIT treatment patients compared to adherent ones (p: 0.031, p: 0.001, p: 0.001 and p: 0.001, respectively) (Table 2). There was a statistically significant difference between the patients adherent and non-adherent to SCIT in regard to their responses in the anxiety questionnaire (Table-3).

**Table 1.** Demographic features of the patients

| Parameters | Results |
|---|---|
| Age, year | 31 (15-70) |
| Gender, female, n (%) | 84 (55.6%) |
| Education, n (%) | |
| Illiterate | 3 (2%) |
| Primary School | 31 (20.5%) |
| High School | 34 (22.5%) |
| University | 83 (55%) |
| Diagnosis, n (%) | |
| AR | 42 (27.8%) |
| SAR | 84 (55.6%) |
| Venom allergy | 23 (15.2) |
| Asthma | 2 (1.3%) |
| Duration of the disease, year | 5 (1-35) |
| Duration of immunotherapy, month | 20 (3-58) |
| Type of IT | |
| Pollen | 84 (55.6%) |
| Mite | 40 (26.5%) |
| Bee venom | 24 (15.9%) |
| Animal dander | 3 (2.1%) |
| Adherence to therapy, n (%) | 82 (54.3) |
| March | 120 (79.5) |
| April | 93 (61.6) |
| May | 94 (62.3) |
| Government-related reasons, n (%) | |
| Curfew | 61 (40.4) |
| Travel restriction | 28 (40.6) |
| Pregnancy / disability status | 3 (2) |
| COVID-19 quarantine | 5 (3.3) |
| COVID-19 disease | 5 (3.3) |
| Individual-related reasons, n (%) | |
| Fear of SARS-CoV-2 transmission | 60 (39.7) |
| Fear of transmitting SARS-CoV-2 to family | 46 (30.5) |
| Not feeling the need for treatment | 40 (26.5) |
| Accessing drugs directly from pharmacies | 3 (2.0) |
| Terminating of treatment at own request | 30 (19.9) |
| COVID-19 disease | 4 (2.6) |
| Need for additional treatment, n (%) | 68 (45) |
| Oral antihistamine | 37 (24.5) |
| Nasal steroid | 8 (5.3) |
| Leukotriene inhibitors | 5 (3.3) |
| Nasal decongestant | 3 (2.0) |
| Inhaled steroid | 3 (2.0) |
| Admission to emergency department, n (%) | 3 (2.0) |
| Increase in symptoms, n (%) | 80 (50.3) |
| Sneezing | 34 (22.5) |
| Nasal discharge | 12 (7.9) |
| Nasal congestion | 5 (3.3) |
| Postnasal drip | 5 (3.3) |
| Treatment switch, n (%) | 60 (39.7) |
| Termination of treatment | 28 (18.5) |
| Dose tapering | 32 (21.2) |
| Those receiving alternative treatments | 14 (9.3%) |

## Discussion

In our study, the COVID-19 pandemic was determined to hinder the treatment process in patients receiving allergen immunotherapy, leading to an increase in allergic complaints and, hence, to the need for additional treatment and treatment switch in AIT. In addition, it was shown that it may lead to the impaired mental and psychological status of the patients. AIT is a treatment method, which has been used for a long period of time, providing symptomatic and clinical improvement by modifying Th2-induced immune responses against bee venom and aeroallergens [14]. It requires physician visits at long-term and regular intervals (4-6). There has been a global hindering

**Table 2.** Comparison of groups adherent and not adherent to treatment

| Parameters | Those adherent to treatment (n: 82) | Those not adherent to treatment (n: 69) | p |
|---|---|---|---|
| Age, year | 33 (15-65) | 29 (18-70) | 0.174 |
| Gender, female, n (%) | 42 (52.1) | 42 (60.9) | 0.234 |
| Education, n (%) | | | |
| Illiterate | 1 (1.2) | 2 (2.9) | 0.809 |
| Primary School | 17 (20.7) | 14 (20.3) | |
| High School | 17 (20.7) | 17 (24.6) | |
| University | 47 (57.3) | 36 (52.2) | |
| Diagnosis, n (%) | | | |
| AR | 24 (29.3) | 18 (26.1) | 0.405 |
| SAR | 46 (56.1) | 38 (55.1) | |
| Venom allergy | 10 (12.2) | 13 (18.8) | |
| Asthma | 2 (2.4) | 0 | |
| Duration of the disease, year | 5 (1-35) | 4 (1-30) | 0.078 |
| Duration of immunotherapy, month | 18 (3-58) | 23 (3-55) | 0.031 |
| Type of IT, n (%) | | | |
| Pollen | 50 (61.0) | 34 (59.3) | 0.230 |
| Mite | 22 (26.8) | 18 (26.1) | |
| Bee venom | 9 (11.0) | 15 (21.7) | |
| Additional disease, yes, n (%) | 15 (18.3) | 7 (10.1) | 0.118 |
| Need for additional treatment during pandemic, yes, n (%) | 25 (30.5) | 43 (62.3) | 0.001 |
| Admission to emergency department, n (%) | 2 (2.4) | 1 (1.4) | 0.664 |
| Increase in symptoms, n (%) | 33 (40.2) | 47 (68.1) | 0.001 |
| Those switched treatment, n (%) | 0 | 57 (62.3) | 0.001 |
| Treatment switch, n (%) | | | |
| Dose tapering | 0 | 29 (42) | 0.001 |
| Same dose | 82 (100) | 12 (17.4) | |
| Termination of treatment | 0 | 28 (40.6) | |
| Those receiving alternative treatments | 5 (6.1) | 9 (13) | 0.167 |

**Table 3.** Responses of patients to the validated coronavirus anxiety questionnaire

| Questions | Answers | Those adherent to therapy (n: 82) | Those not adherent to treatment (n: 69) | p |
|---|---|---|---|---|
| Question 1, n (%) | Always | 0 | 2 (2.9) | 0.001 |
| | Usually | 3 (3.7) | 2 (2.9) | |
| | Sometimes | 1 (1.2) | 9 (13) | |
| | Seldom | 3 (3.7) | 17 (24.6) | |
| | Never | 75 (91.5) | 39 (56.5) | |
| Question 2 n (%) | Always | 1 (1.2) | 3 (4.3) | 0.001 |
| | Usually | 3 (3.7) | 2 (2.9) | |
| | Sometimes | 3 (3.7) | 10 (14.5) | |
| | Seldom | 11 (13.4) | 24 (34.8) | |
| | Never | 64 (78) | 30 (43.5 | |
| Question 3 n (%) | Always | 0 | 2 (2.9) | 0.002 |
| | Usually | 1 (1.2) | 3 (4.3) | |
| | Sometimes | 3 (3.7) | 8 (11.6) | |
| | Seldom | 7 (8.5) | 15 (21.7) | |
| | Never | 71 (86.6) | 41 (59.4) | |
| Question 4 n (%) | Always | 0 | 2 (2.9) | 0.001 |
| | Usually | 2 (2.4) | 13 (18.8) | |
| | Sometimes | 3 (3.7) | 4 (5.8) | |
| | Seldom | 10 (12.2) | 16 (23.2) | |
| | Never | 67 (81.7) | 34 (49.3) | |
| Question 5 n (%) | Always | 0 | 2 (2.9) | 0.001 |
| | Usually | 2 (2.4) | 10 (14.5) | |
| | Sometimes | 3 (3.7) | 6 (8.7) | |
| | Seldom | 6 (7.3) | 19 (27.5) | |
| | Never | 71 (86.6) | 32 (46.4) | |

of SCIT administrations during the COVID-19 pandemic. For allergy clinics, the guidelines offer several recommendations for patient follow-up and procedures to be performed. These recommendations include suspension of the vaccines in the build-up phase of AIT and prolongation of intervals between the shots in the maintenance phase [11-13]. Other recommendations include examining patients at regular intervals in the clinic, procurement of social distancing, injecting one patient at once and ventilating the room for immunotherapy for a certain period of time after each patient [6, 11-13, 17].

In our current study, the overall adherence to treatment of patients receiving AIT was determined to be reduced by half (54.3%). During the pandemic, patients' adherence to treatment and physician-patient interaction have been significantly reduced in many clinics, with increased use of telemedicine [4, 17-20]. Ojetti et al. reported that admissions to the emergency department in February and March 2020 reduced by 37.6% compared to the same period in 2019 [20]. Although international guidelines recommend continuation to allergen immunotherapy during the COVID-19 pandemic, in a previous study from Turkey, it was reported that 21% of the allergists could not continue to SCIT as it should have been and that 31% of the allergists had to terminate immunotherapy in patients in the build-up phase [17, 21]. Some restrictions brought by the pandemic may have influenced patient's adherence to treatment, and higher COVID-19 anxiety levels of the non-adherent to AIT patients compared to those adherent to treatment may also have led to avoidance of environments at high risk for COVID-19 and reduction in their adherence to treatment.

In our current study, the duration of immunotherapy was higher in patients adherent to AIT, compared to the patients nonadherent to AIT. This may be due to the fact that some patients who are aware of the need for at least 3 years of immunotherapy may consider the received immunotherapy sufficient, leading to hindering of the treatment. In a study from Spain, 6.5% of the patients receiving venom immunotherapy terminated the treatment at their own request and refused to restart immunotherapy [22].

An increase in the number of allergic complaints and, hence, the need for additional treatment in patients nonadherent to AIT may be related to nonadherence to AIT, as well as to pollen dispersal that increases during March-April-May 2020 when the study was interested in. The idea that steroids may increase the risk of SARS-CoV-2 transmission during the pandemic has led to a reduction in the use of intranasal steroids, although there are opposite recommendations, and this reduction, in turn, may have caused an increase in complaints of rhinitis [23]. Some restrictions like curfews may have led to an increase in complaints of rhinitis by causing the patients to spend more time at home and be exposed to domestic allergens for a

longer period of time.

AIT is a treatment method that is administered at regular intervals with particular standard doses. When the treatment is suspended, the dose of AIT should be readjusted. Therefore, in our current study, it is unsurprising that patients nonadherent to AIT had a higher rate of treatment termination and switching. Martinez-Lourido et al. reported that 22.9% of the patients receiving venom immunotherapy had a delay in treatment and, thus, a dose adjustment was performed [22]. Ozturk et al. reported that 72% of allergists increased SCIT intervals in patients in the maintenance phase of SCIT, as well as terminated SCIT in approximately one-third of the patients in the build-up phase [17]. In our study, however, the rate of patients whose SCIT was terminated was 18%.

In conclusion, immunotherapy patients require treatment during the COVID-19 pandemic as well. Access to AIT, the applicability, and maintenance of the immunotherapy should be a priority during this period. Considering both patient-related and government-related factors in the administration of AIT, the process of AIT should be continued, minimizing the risk of SARS-CoV-2 transmission in accordance with the recommendations by the guidelines and science councils. Furthermore, these measures can reduce patients' worry and anxiety and their adherence to treatment may be promoted.

***Scientific Responsibility Statement***

*The authors declare that they are responsible for the article's scientific content including study design, data collection, analysis and interpretation, writing, some of the main line, or all of the preparation and scientific review of the contents and approval of the final version of the article.*

***Animal and human rights statement***

*All procedures performed in this study were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. No animal or human studies were carried out by the authors for this article.*

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