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The Impact of Vaccination with SARS-CoV-2 Vaccines on the Course of Chronic Spontaneous Urticaria

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ABSTRACT

Objective: Although the factors that trigger and exacerbate chronic spontaneous urticaria (CSU) are well known, there is still a lack of information about the effects of COVID-19 vaccines on CSU. This study aimed to investigate exacerbations/relapses triggered by COVID-19 vaccines in patients with CSU who are well controlled with treatment or in remission.

Materials and Methods: The study included 350 CSU patients. Demographic and clinical characteristics were collected from patients' medical records. The seven-day urticaria activity score (UAS7) and urticaria control test (UCT) were evaluated separately during the onset of the disease, pre-vaccination, and post-vaccination periods.

Results: The mean age was 39.89±13.30 years and 74.6% of the patients were female. A total of 227 patients were vaccinated with the Pfizer/BioNTech mRNA vaccine, 67 with the Sinovac/CoronaVac inactivated vaccine, and 54 with both vaccines. Urticaria exacerbations/relapses were observed in a total of 76 patients, and most CSU exacerbations/relapses occurred after the first dose (n=46). Median UAS7 scores increased significantly in the post-vaccination period in patients who experienced urticaria exacerbation ($p<0.0001$). Median UCT scores were significantly decreased due to urticaria exacerbation with vaccination ($p<0.0001$).

Conclusion: Both mRNA and inactivated COVID-19 vaccine may lead to exacerbations or relapses in patients with CSU. Even so, exacerbations/relapses associated with COVID-19 vaccines can be easily controlled with treatments and do not preclude subsequent doses.

Keywords: Chronic spontaneous urticaria, SARS-CoV-2 vaccination, urticaria activity score, urticaria control test

INTRODUCTION

Chronic spontaneous urticaria (CSU) is a skin disorder characterized by the occurrence of itchy wheals (hives), angioedema, or both, for 6 weeks or longer in the absence of an identifiable trigger (1). CSU is a common condition that affects 15-25% of the population during their lifetime and is more common in adults and women (2). The pathogenesis of CSU is still elusive, but both cutaneous mast cell and basophil activation and degranulation continue to exist central to the condition (1-3). Histamine and other mediators and/or cytokine release from cutaneous mast cells are predominantly associated with the development of this condition (1, 3). Recently, several biological mechanisms (i.e., inflammation, autoimmunity, auto-allergy, intracellular signaling defects, complement cascade, or coagulation) have been implicated in the onset of clinical manifestations of CSU (4). Many extrinsic factors are relevant to CSU exacerbation or causing CSU. Viral, parasitic, bacterial, fungal infections, emotional stress, foods and/or food additives, and drugs (e.g., angiotensin-converting

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enzyme inhibitors, nonsteroidal anti-inflammatory drugs) are some of these factors (5). Although CSU did not affect the course of coronavirus disease-19 (COVID-19), the majority of COVID-19 patients experienced an exacerbation of urticaria (6).

Immunization was seen as an important strategy to halt the COVID-19 pandemic. In our country, vaccine administration started quickly and two COVID-19 vaccines, Pfizer-BioNTech, and Sinovac-CoronaVac, are used. In a previous study, a relationship between vaccination and CSU has been reported (7). There are few studies where the development of new-onset CSU and relapse of urticaria with mRNA vaccines in patients with well-controlled CSU have been reported (8, 9). Although the factors that trigger and exacerbate CSU are well known, the development of new-onset CSU after vaccination against severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2), exacerbation of controlled CSU, or relapse in CSU after long-term remission is still unclear. We therefore aimed to determine the impact of vaccination with COVID-19 vaccines in patients whose diseases were well controlled with treatment or whose diseases were in remission for more than 3 months in this study.

MATERIALS and METHODS

Patient Recruitment

This study was performed in a tertiary outpatient adult allergy clinic. The study population consisted of 350 CSU patients diagnosed based on the recent guideline (1). CSU patients aged 18 years and older were included in the study. Patients with known vaccine allergy or hypersensitivity to any vaccine component, malignancy, pregnancy, and patients with chronic inducible urticaria only (CINDU) were excluded.

All patients included in the study were vaccinated with at least one dose of inactivated or mRNA SARS-CoV-2 vaccine. The two-week period after vaccination was questioned in these patients to exclude other possible triggers such as viral, parasitic, bacterial or fungal infections, emotional stress, foods and/or food additives and medications (e.g., nonsteroidal anti-inflammatory drugs). In the study, disease activity, and disease control of the patients were evaluated separately at the onset of the disease, before the vaccination, and in the first two weeks after each vaccination. Patients whose evaluation could not be completed in all periods were excluded from the study. This study was conducted in accordance with the World Medical Association Declaration of Helsinki. Ethical approval was obtained from the Local Ethics Committee (E2-21-1151) and written informed consents were collected from all study participants. The Turkish Ministry of Health also approved the study (2021-12-09T11_14_40).

Demographic and Clinical Assessment

The demographical and clinical features including the presence of comorbidities, disease duration, and treatment details were collected from the patient medical records. The clinical assessments were performed in outpatient clinics during the study period. CSU disease activity was evaluated with the urticaria activity score summed over 7 days (UAS7), which is a validated simple scoring system that assesses wheals and pruritus (1). Accordingly, UAS7 scores of ≤6 are considered as well-controlled, 7-15 as mild, 16-27 as moderate, and 28-42 as severe disease. Disease control of the patients was evaluated with the urticaria control test (UCT), which is a validated tool in Turkish (10). There are four questions in the urticaria control test and each question answer is scored from 0 to 4. The lowest score is 0; a score ≥12 indicates a well-controlled disease; a score of ≤11 indicates that uncontrolled disease. Patients with UAS7=0 and UCT≥12 without any treatment for urticaria for three months or longer were considered to be in remission for CSU. In addition, patients whose disease was well-controlled (UAS7≤7 and UCT≥12) with a regular antihistamine and/or omalizumab treatment, or who did not need medication but had an asymptomatic disease duration of less than 3 months were considered as a well-controlled disease.

Statistical Analysis

All analyses were performed using the SPSS 25.0 package program, (SPSS Inc., Armonk, NY, USA). Data are presented as mean ± standard deviation, median (interquartile range (IQR)), or frequency (%). The chi-square test and Mann-Whitney U test were used to compare categorical and continuous variables, respectively. Wilcoxon matched-pairs signed-rank test was used to compare variables of the pre-vaccination period and post-vaccination period. The factors showing relationships between the vaccination and urticaria exacerbation in univariate analyses were further analyzed by regression analyses. A *p*-value smaller than 0.05 was considered statistically significant. The GraphPad Prism software (San Diego, CA, USA) was used for graphical analysis.

RESULTS

Characteristics of the Patients

The demographic and clinical characteristics of the 350 CSU patients are presented in Table I. The mean age of the patients was 39.89±13.30 years, and 261 (74.6%) patients were female. The median duration of urticaria was 23 (IQR: 8-60) months. When the disease activity was evaluated in the pre-vaccination period, it was observed that 62 (17.7%) patients were in remission and 288 (82.3%) patients had a well-controlled disease. The median (IQR) remission duration of the patients was 4 (3-6) months.

Of the 288 CSU patients with well-controlled disease, 54 (18.7%) did not receive any treatment, 203 (70.5%) were treated with non-sedating antihistamines, and 31 (10.8%) were treated with omalizumab in addition to antihistamines. Angioedema with urticaria was present in 209 (59.7%) patients. The most common accompanying types of physical urticaria were symptomatic dermographism (n=47) and late pressure urticaria (n=24). 157 (44.9%) patients had at least one comorbidity including asthma (n=16), allergic rhinitis (n=8), coronary artery disease (n=15), diabetes mellitus (n=23), hyperlipidemia (n=3), hypertension (n=43), iron deficiency anemia (n=8), psychiatric disorders (n=17), rheumatologic diseases (n=11), dyspeptic symptoms (n=9) and thyroid diseases (n=41). 147 patients (42%) were using additional drugs required for the treatment of comorbid diseases, and the most commonly used drugs were levothyroxine (n=40), metformin (n=18), calcium channel blockers (n=17), and angiotensin receptor blockers (n=). 14). While 205 (58.6%) patients declared stress as a trigger of their urticaria, 49 patients reported exacerbation of urticaria with NSAIDs, 38 with food, and 31 with infections.

Table I: Demographic and clinical characteristics of the patients

Demographic and clinical features		
Age (year), Mean±SD		39.89±13.30
Urticaria duration (months), Median (IQR)		23 (8-60)
Gender, n (%)	Female	261 (74.6%)
	Male	89 (25.4%)
Angioedema accompanying urticaria		209 (59.7%)
Presence of comorbidities		157 (44.9%)
Additional drug usage		147 (42%)
Smoking status		111 (31.7%)
Alcohol consumption		23 (6.6%)
Employment	Housewife	129 (36.9%)
	Teacher	13 (3.7%)
	Engineer	12 (3.4%)
	Lawyer	2 (0.6%)
	Healthcare worker	16 (4.6%)
	Retired	26 (7.4%)
	Freelancer	152 (43.4%)
Types of physical urticaria accompanying CSU	Cold	6 (1.7%)
	Solar	2 (0.6%)
	Cholinergic	6 (1.75)
	Delayed pressure	24 (6.9%)
	Symptomatic dermographism	47 (13.4%)
	Contact	2 (0.6%)

IQR: Interquartile range, **SD:** Standard deviation, **CSU:** Chronic spontaneous urticaria

A total of 227 patients were vaccinated with the Pfizer BioNTech mRNA vaccine, 67 patients were vaccinated with the Sinovac CoronaVac inactivated vaccine, and 54 patients were vaccinated with two doses of both vaccines. In 67 (23.3%) of the patients with well-controlled disease (n=288), an increase in disease activity was observed with vaccine administration. In addition, relapses of urticaria were observed in nine (14.5%) of these 62 patients, who were in remission, during the post-vaccination period. Among these 76 patients, 46 had post-vaccination exacerbation of urticaria after the first dose, 33 after the second dose, eight after the third dose, three after the fourth dose, and one after the fifth dose. Although CSU patients experienced an exacerbation of urticaria with the first dose of the vaccine (n=46), they were willing to administer subsequent doses. While 15 of those 46 patients, who experienced exacerbation/relapse at the first dose, developed urticaria exacerbation/relapse after the second dose, the remaining patients did not have any problems after vaccination. In addition, urticaria exacerbation was reported in five of the CSU patients receiving omalizumab. The average time for the urticarial lesion reactivation was 6.3 days. The exacerbation lasted a mean duration of 4.1 days and was managed by initiation/addition of an anti-histamine and/or systemic steroids. No early vaccine-related adverse events occurred in any of the 350 CSU patients vaccinated with COVID-19 vaccines.

Results of the Urticaria Activity and Urticaria Control Test Scores

The UAS7 and UCT of all patients were evaluated separately during the onset of the disease, and pre-vaccination, and post-vaccination periods. The median (IQR) UAS7 scores of all patients at the onset of the disease, and pre-, and post-vaccination periods were 25 (IQR:28-42), 6 (0-7), and 7 (0-14), respectively. The median of the UAS7 scores was significantly decreased in the pre-vaccine period compared to the period at disease onset (p<0.0001). However, exacerbation of urticaria was observed in 76 patients after vaccination and the median UAS7 scores were significantly increased (p<0.0001). The median (IQR) UAS7 scores of patients who did not experience urticaria exacerbation with vaccination (n=274) were 35 (35-42), 6 (0-7), and 6 (0-7), respectively, at the onset of disease, and pre- and post-vaccination periods (Figure 1). Moreover, the median (IQR) UAS7 scores of patients (n=76) who experienced urticaria exacerbation with vaccination were 35 (28-35), 2.5 (0-7), and 35 (28-42), respectively, at the onset of disease, and pre- and post-vaccination periods (Figure 1).

Similarly, UCT scores of all patients were evaluated and the median (IQR) UCT scores at the onset of the disease, pre-, and post-vaccination periods were 2 (1-4), 16 (13-16), and 15 (13-16), respectively. The median of UCT scores increased significantly in the pre-vaccine period compared to the onset of the disease (p<0.0001). However, the median UCT scores were significantly decreased due to urticaria exacerbation with vaccination (p<0.0001). The median (IQR) UCT scores of the patients who did not experience urticaria exacerbation with vaccination, at the onset of disease, and pre-, and post-vaccination periods were 2 (1-4), 16 (13-16), and 16 (13-16), respectively (Figure 2). In addition, the median (IQR) UCT scores of

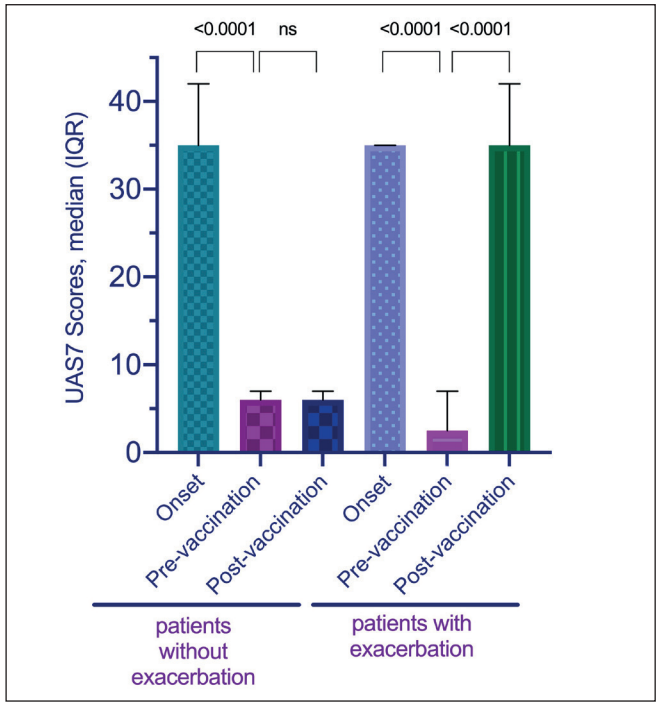

Figure 1. 7-day urticaria activity scores (UAS7) of patients with and without urticaria exacerbation/relapse with the COVID-19 vaccine. The median (IQR) UAS7 scores of the patients (n=274), who did not experience urticaria exacerbation/relapse with vaccination, at the onset of disease, pre-vaccination, and vaccination periods were 35 (35-42), 6 (0-7), and 6 (0-7), respectively. Urticaria exacerbation/relapse was observed in 76 patients with vaccination. The median (IQR) UAS7 scores of those patients at the onset of the disease, and the pre- and post-vaccination periods were 35 (28-35), 2.5 (0-7), and 35 (28-42), respectively, and the median UAS7 scores increased significantly in the post-vaccination period (p<0.0001).

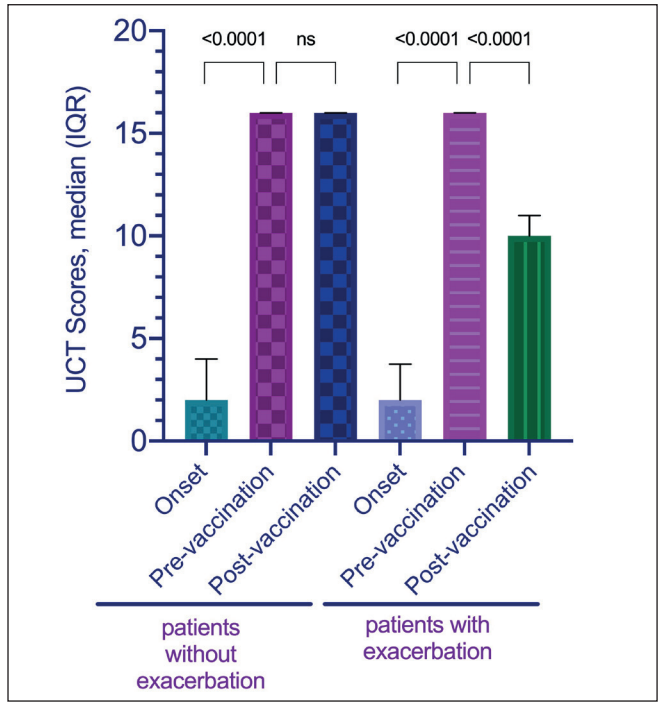

Figure 2. Urticaria control test (UCT) scores of patients with and without urticaria exacerbation/relapse with the COVID-19 vaccine. The median (IQR) UCT scores of the patients who did not experience urticaria exacerbation/relapse with vaccination, at the onset of disease, and the pre-, and post-vaccination periods were 2 (1-4), 16 (13-16), and 16 (13-16), respectively. The median (IQR) UCT scores of the patients who experienced urticaria exacerbation with vaccination (n=76) were 2 (2-3), 16 (13-16), and 10 (9-11), respectively, at the onset of disease, and the pre-, and post-vaccination periods. The median UCT scores decreased significantly in the post-vaccination period (p<0.0001).

the patients who experienced urticaria exacerbation with vaccination (n=76) were 2 (2-3), 16 (13-16), and 10 (9-11), respectively, at the onset of disease, and pre-, and post-vaccination periods (Figure 2).

While the UCT scores of females were similar to those of males in all periods, UAS7 scores were significantly higher in females than males in the post-vaccine period (p=0.02). In addition, patients in whom stress was a trigger for urticaria had a lower UCT score in the post-vaccination period compared to patients in whom stress was not a trigger. Although age was associated with vaccine-related exacerbation of urticaria in univariate analyzes (p=0.01, OR:1.50), regression analyzes showed that vaccine type (mRNA or inactivated), age, sex, duration of CSU, presence of concomitant allergic diseases, or presence of angioedema were not associated with exacerbation of CSU after COVID-19 vaccination.

DISCUSSION

To our knowledge, this is the first study with the largest series of CSU patients evaluating urticaria exacerbation following COVID-19 vaccination. In our study, symptoms such as wheal, itching, redness, and swelling in 76 CSU patients were exacerbated within two weeks of vaccination, suggesting a potential causal relationship between vaccine exposure and clinical outcome.

Not every medical condition that occurs following immunization is necessarily causally related to the vaccine. Accordingly, exacerbation/relapse of urticaria and angioedema in patients with CSU following a vaccine may be incidental. Moreover, since the incidence of exacerbation/relapse with different vaccines in CSU patients is also not clearly known, it is not possible to determine whether the prevalence is higher during the COVID-19 vaccination period. However, the short-term relationship between the vaccine and the symptoms in our CSU patients and the exacerbations/relapse after the second or subsequent vaccine doses increase the possibility that the vaccines may have an effect on this condition. Some external factors such as viral, parasitic, bacterial, or fungal infections; various foods and food additives; some drugs, and emotional stress have been accused of causing CSU or exacerbations of urticaria (5, 11, 12). However, no other factors that could be associated with exacerbation of urticaria were observed in our patients in this short-term period.

In addition, nonsteroidal anti-inflammatory drugs, antibiotics, and vaccines are reported as the most common causes of drug-related urticaria (13). It is hypothesized that vaccines cause acute or chronic spontaneous urticaria in some individuals by stimulating mast cells, immune complexes, and/or autoantibodies (13, 14). In our study, none of the patients with CSU had a type I IgE-mediated hypersensitivity reaction after administration of the COVID-19 vaccines. The average time for the exacerbation/relapse of urticaria in our patients was 6.3 days. Therefore, the pathophysiology of CSU exacerbation or relapse after COVID-19 vaccination cannot be explained by a type I hypersensitivity reaction. Although the reason has not been clearly explained yet, CSU development after vaccination with different virus vaccines has been reported previously, and CSU associated with COVID-19 vaccines, especially with the mRNA-type, has also been reported during this pandemic period (7, 8, 15-19). Similar to these studies, the vast majority of our patients with urticaria exacerbation by vaccine consisted of people vaccinated with the mRNA type (Pfizer/BioNTech) COVID-19 vaccine (n=51). In addition, in contrast to previous studies, we observed exacerbation of urticaria in 16 patients after the inactivated vaccine and in nine patients after both vaccines. Although the fact that mRNA vaccines express spike protein antigen similar to human proteins suggests that it may trigger an autoimmune response after these vaccines, further studies are needed on this issue (20).

Similar to a previous study (69.23%), it was observed in the current study that CSU exacerbation occurred after the first dose in the vast majority of patients (60.52%) (19). Although there are various recommendations regarding the management of subsequent doses in patients who develop cutaneous adverse events after vaccine administration (21, 22), there are no reported recommendations for patients who experience an exacerbation of CSU. Moreover, urticaria exacerbation/relapse in our study was easily managed with routine urticaria treatments and did not constitute an obstacle for subsequent doses of the vaccine. Therefore, a special approach is needed for CSU patients during immunization programs, including those for COVID-19, as the exacerbating/relapsing symptoms that can be expected in these patients can be misinterpreted as a vaccine allergy (23).

Similar to previous studies, most of the patients with CSU who did and did not experience exacerbations/relapses consisted of middle-aged female patients (8). On the other hand, we found that the vaccine type (mRNA or inactivated), age, gender, duration of CSU, co-existing allergic diseases, or presence of angioedema were not associated with the likelihood of CSU exacerbation after COVID-19 vaccination.

The study has some limitations. The most important of these is the retrospective design of the study. In addition, our study design cannot contribute to determining the mechanism of urticaria exacerbation. Due to the nature of the study design, we cannot reach the detailed information of patients such as mental health evaluation or living environment. Additionally, we did not perform any laboratory measurements.

Although this study has some limitations, it also has some strengths. The first of these is the inclusion of well-characterized CSU patients who experienced an exacerbation/relapse after mRNA, inactivated, and combined vaccine administration of both vaccines. In addition, patients were followed regularly in our study, and UAS7 and UCT were evaluated separately for each period. Although our study has the largest patient series and the largest number of patients with exacerbation/relapse in this field, the effects of COVID-19 vaccines on these patients need to be evaluated prospectively.

CONCLUSION

Although patients with CSU experienced increased urticaria activity and impaired urticaria control following both mRNA and inactive COVID-19 vaccination, COVID-19 vaccines can be considered safe and are recommended for CSU patients. The exacerbation/relapse of the urticaria can easily be controlled with treatments and did not preclude subsequent doses.

Conflict of Interest

The authors declare that they have no conflict of interest.

Authorship Contributions

Concept: **Şengül Beyaz,** Design: **Şengül Beyaz,** Data collection or processing: **Şengül Beyaz, Neyran Şerbetçi, Zeynep Türkan Fendoğlu, Esra Nur Bülbül, Zeynep Hancıoğlu, Dilek Öksüzer Çimşir, Özge Öztürk Aktaş, Zeynep Çelebi Sözener, Şadan Soyyiğit,** Analysis or Interpretation: **Şengül Beyaz, Neyran Şerbetçi, Zeynep Türkan Fendoğlu, Esra Nur Bülbül, Zeynep Hancıoğlu, Dilek Öksüzer Çimşir, Özge Öztürk Aktaş, Zeynep Çelebi Sözener, Şadan Soyyiğit,** Literature search: **Şengül Beyaz,** Writing: **Şengül Beyaz,** Approval: **Şengül Beyaz, Neyran Şerbetçi, Zeynep Türkan Fendoğlu, Esra Nur Bülbül, Zeynep Hancıoğlu, Dilek Öksüzer Çimşir, Özge Öztürk Aktaş, Zeynep Çelebi Sözener, Şadan Soyyiğit.**

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Statement of Ethics

This study was conducted in accordance with the World Medical Association Declaration of Helsinki. Ethical approval was obtained from the Local Ethics Committee (E2-21-1151) and written informed consent was collected from all study participants. The Turkish Ministry of Health also approved the study (2021-12-09T11_14_40).

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