

Cutaneous reactions following COVID-19 vaccination assessed by dermatologists: a single-institutional study in Germany

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Summary

Background and objectives: Cutaneous reactions following COVID-19 vaccination have been frequently described, whereas larger case series by dermatologists are lacking. This study assesses SARS-CoV-2 vaccination-associated skin reactions, severity, treatment, course, eliciting vaccines, allergy test results and tolerance to revaccination.

Patients and methods: Single-institutional, non-interventional study of dermatologists assessing cutaneous manifestations in 83 patients in Germany.

Results: 93 reactions were presented. Manifestations clustered into immediate (n = 51, 54.8%) and delayed hypersensitivity reactions (n = 10, 10.8%), chronic inflammatory skin diseases (n = 13, 14.0%), reactivation of latent herpes virus infection (pityriasis rosea/herpes zoster; n = 9; 9.7%) and others (n = 10, 10.8%). Vaccination was associated with new (76.3%) – mostly hypersensitivity reactions – or exacerbation of known skin diseases (23.7%), in this case predominantly chronic inflammatory skin diseases. Reactions occurred primarily within the first week (72.8%) and after first vaccination (62.0%). Treatment was required in 83.9% and hospitalization in 19.4%. In 48.8% revaccination led to recurrence of the same reactions. Disease was ongoing at last consultation in 22.6%, primarily in chronic inflammatory skin diseases. Allergy tests were performed in 15 patients (18.1%) and resulted negative.

Conclusions: It can be assumed that vaccination may trigger immune activation-related reactions especially in those patients predisposed to develop respective skin diseases.

KEYWORDS

COVID-19 vaccination, cutaneous reactions, hypersensitivity reactions, urticaria

INTRODUCTION

Coronavirus disease 2019 (COVID-19), which is caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), has resulted in a global pandemic lasting until today.¹ Infection with SARS-CoV-2 can lead to disease manifestations including skin manifestations, respiratory failure, multiorgan failure and death.^{2–5} Vaccination is effective at preventing infections and crucial to combat COVID-19. The mRNA vaccines *Comirnaty*[®] (BioNTech/Pfizer; BNT162b2), *Spikevax*[®] (Moderna; mRNA-1273), and viral vector vaccines

Vaxzevira[®] (AstraZeneca; ChAdOx1), and *COVID-19 Vaccine Janssen*[®] (Janssen-Cilag International NV; Ad26.COV2.S) have been licensed for vaccination in Germany.⁶ Well-known common reactions following COVID-19 vaccination include flu-like symptoms and local injection site reaction.^{7,8} Anaphylaxis against COVID-19 vaccines or vaccine excipients like polyethylene glycol (PEG) is feared, but appears to be exceptional.⁹ Cutaneous reactions following COVID-19 vaccination have been described in single case reports, surprisingly few small case series, registries and an abundance of reviews.¹⁰ A review published in January

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2022 summarized seven randomized controlled trials, one registry-based study, one prospective cohort study, four retrospective studies, 21 case series and 41 case reports with 48,740 reported cutaneous reactions in 125,713 patients.¹¹ As some of the included clinical trials focused predominantly on vaccine efficacy, details regarding cutaneous reactions and participant information were largely missing. Large registry analyzes fed also by non-dermatologists, nurses and physician assistants may perhaps have led to partial misclassification.^{12,13} Even self-reported questionnaire studies with questionable reliability have been published.¹⁴ Case series often centered on specific manifestations, such as the so-called “COVID-arm”.^{11,15,16} On the other hand, single-center case series with non-selected patients analyzed by dermatologists are lacking.¹⁵⁻¹⁷

To our knowledge, this is the largest single-center study performed in a department of dermatology at a university hospital, allowing a meticulous categorization of cutaneous manifestations after receiving different SARS-CoV-2 vaccinations and assessing the course of disease and allergy diagnostics when indicated.

PATIENTS AND METHODS

This monocentric, non-interventional, retrospective study at the Department of Dermatology and Allergy Biederstein, Technical University of Munich, Germany, analyzed medical charts, histological and allergological findings and photographs from March 2021 to January 2022 for cutaneous manifestations, which developed within 30 days after vaccination against SARS-CoV-2.

All 83 patients who reported cutaneous manifestations were recruited to the study. They were assessed by at least one dermatologist and a diagnosis was made; in 19 patients histopathologic analysis was added. In addition, previous skin diseases, the vaccines, number of vaccinations, days until onset, course of cutaneous manifestations and recurrences of cutaneous manifestations after further vaccinations were assessed. Two different manifestations in one patient were evaluated separately. One patient with a filler reaction could not determine the start of her symptoms as she described a gradual onset and was excluded from the analyses regarding onset and timing. Manifestations were clustered into immediate (urticaria, angioedema, flush and pruritus) or delayed hypersensitivity reactions (exanthema, local injection reaction and filler reaction), chronic inflammatory skin diseases, reactivation of latent human herpes virus infection including pityriasis rosea (human herpesvirus 6/7, HHV-6/7) and herpes zoster (varicella-zoster virus, VZV) or “other” (online supplementary Table S1). Skin diseases were categorized into “new conditions” or “renewals/flare ups”.

Immediate and delayed hypersensitivity reactions were defined purely clinically as resembling allergic reactions, but without any demonstration of an immunological mechanism. In fact, initially immediate-type allergy was excluded

in 15 patients. Skin prick (1%, 10% in saline) and intradermal tests (0.01%, 0.1% in aqua destillata) were performed with PEG 2000, PEG 4000 and PEG 6000, polysorbate (PS) 80 (Carl Roth GmbH + Co. KG), and trometamol (hospital pharmacy) and with vial remnants (undiluted and 10% in aqua destillata, respectively) of available COVID-19 vaccines (BNT162b2, mRNA-1273, ChAdOx1, Ad26.COVS) depending on the history.

Statistical analyses were performed using GraphPad Prism (Version 8.4.2, GraphPad Software Inc., San Diego, CA, USA). Statistical differences were calculated by Mann-Whitney test and paired t-tests, respectively, and expressed as *P* values: *P* ≥ 0.05 = not significant; **P* < 0.05; ***P* < 0.01; ****P* < 0.001.

The study was approved by the ethics committee of the Technical University of Munich (44/22 S-NP).

RESULTS

Patient characteristics

Overall, 83 patients attended our department because of cutaneous manifestations within 30 days after SARS-CoV-2 vaccination (Figure 1). Ten patients reported more than one skin reaction (8 female and 2 male). Most patients were female (59 females [71.1%] vs. 24 males [28.9%]) (Figure 2a). The average age of the patients was 47.3 years ± 18.3 years (Figure 2b). The majority of patients received BNT162b2 (57; 68.7%), twelve mRNA-1273 (14.5%), eleven ChAdOx1 (13.3%), two Ad26.COVS (2.4%) and one CVnCoV (CureVac, studied in Germany) (1.2%) before initial occurrence of skin alterations (Figure 2c).

Dermatological diagnoses were grouped into disease clusters. About two thirds of the reactions after vaccination were classified as hypersensitivity reactions (65.6%; therefrom 54.8% immediate hypersensitivity reactions; 10.8% delayed hypersensitivity reactions). Furthermore, patients with chronic inflammatory skin diseases (14.0%) and with reactivation of latent human herpes virus infection (9.7%) were common (Figure 1). Urticaria was seen in 39 cases, which does not only display this reaction to be predominant within the disease cluster of immediate hypersensitivity reactions, but also within the overall patient collective.

The majority of skin reactions arose anew, however, in about one quarter of the cases patients have reported that they already had suffered from this specific skin reactions in the past. Those reactions either recurred after a prolonged symptom-free time period or flared up and worsened during stable disease after vaccination (Figure 3a). These renewals or flare ups of already known conditions were most common in patients with chronic skin inflammatory diseases (53.8% renewals/flare ups vs. 46.2% new conditions), while most hypersensitivity reactions arose new (immediate hypersensitivity reactions 76.4% and delayed hypersensitivity reactions 100% new condition) (Figure 3b).

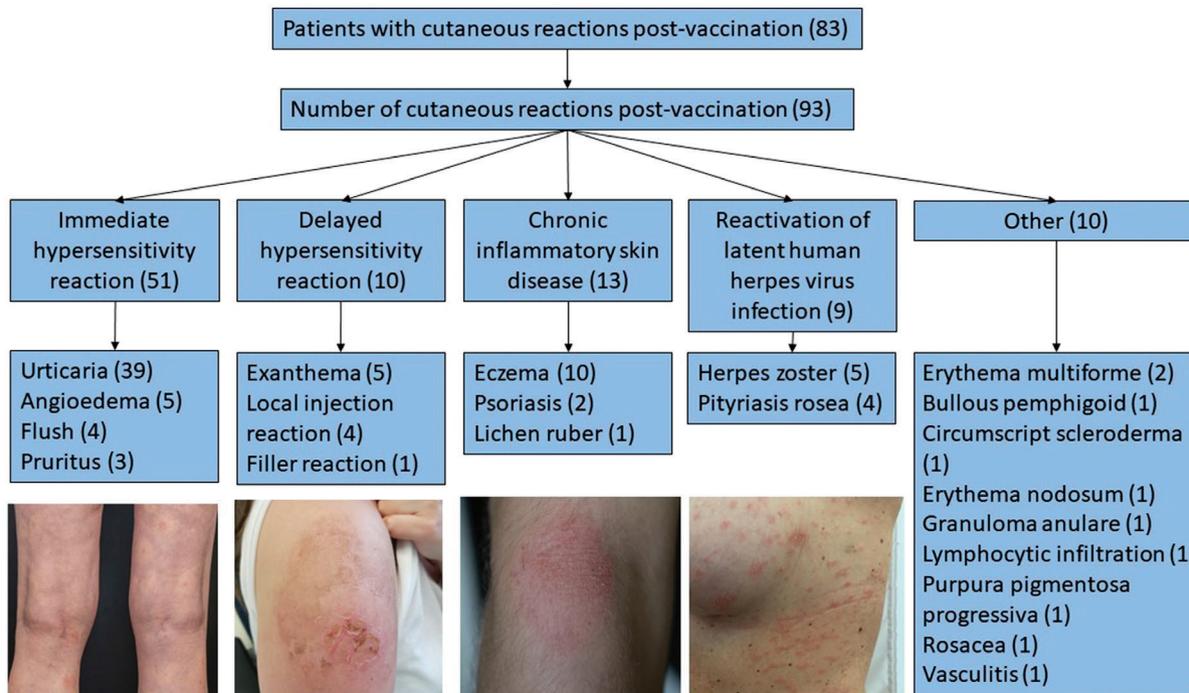
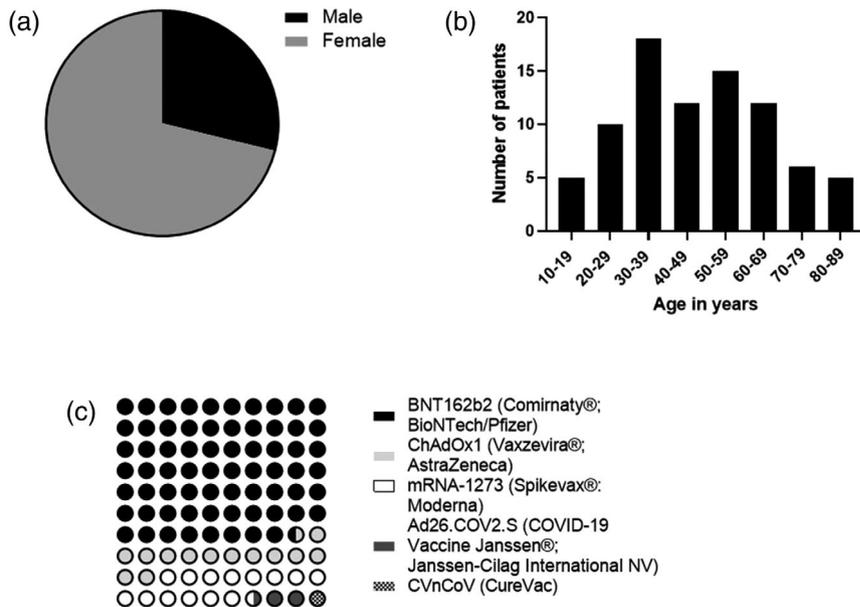


FIGURE 1 Cutaneous reactions reported after COVID-19 vaccination sorted into reaction clusters (number of patients or reactions, respectively, given in brackets). Exemplary pictures from left to right: urticaria, local injection reaction, eczema, pityriasis rosea.

FIGURE 2 Patient characteristics and vaccines administered. (a) Distribution of sex. (b) Distribution of age. (c) Distribution of vaccines administered.



Of those with renewals/flare ups, 59.1% flared up compared to 40.9%, which renewed. In chronic inflammatory skin diseases, more flare ups were detected (71.4%); in comparison, immediate hypersensitivity reactions as urticaria were more likely to be triggered and renewed after a past time period without actual disease activity (41.6%).

Timing of occurrence

While 62.0% of the initial cutaneous reactions occurred after the first vaccination, 28.3% appeared after the second vaccination for the first time and 9.8% after the third vaccination, respectively. In the latter cases, the first and/or the second vaccinations have been well tolerated.

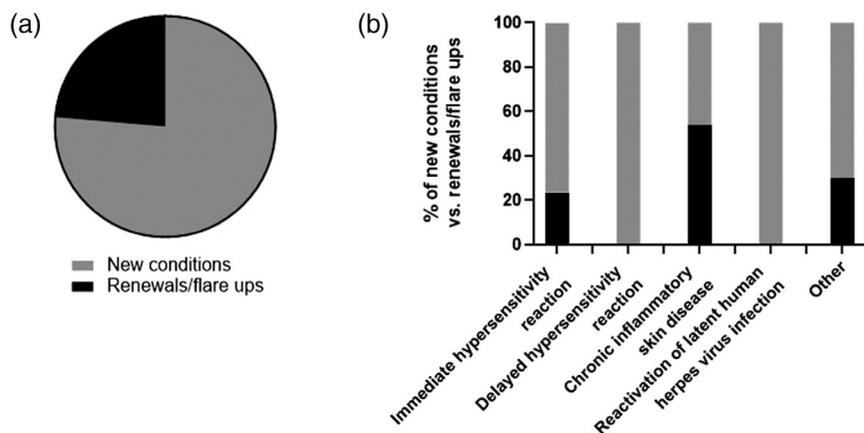


FIGURE 3 Distribution of cutaneous reactions clustered into renewals/flare ups and new conditions. (a) All patients. (b) Patients clustered into reaction clusters.

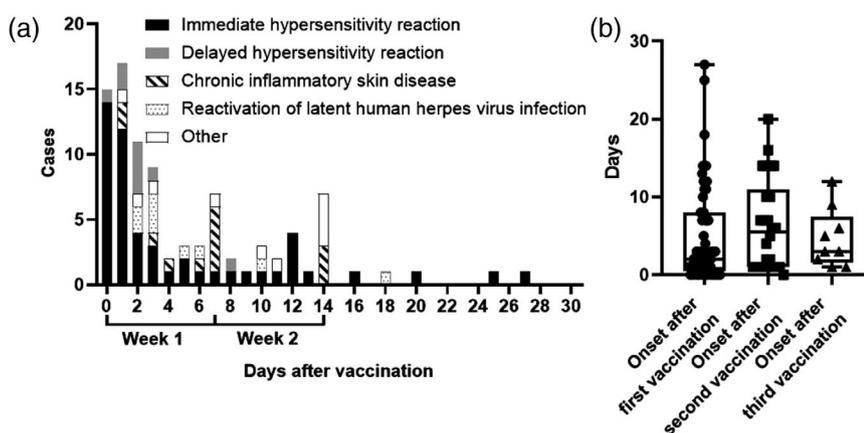


FIGURE 4 Timing of cutaneous reactions. (a) Reactions clustered into reaction clusters. Immediate hypersensitivity reactions tend to occur earlier after vaccination than other reactions such as chronic inflammatory skin diseases. (b) Reactions clustered into onset after first, second or third vaccination.

Of all reactions, 72.8% appeared within the first week after vaccination – with 16.3% appearing on the day of the vaccination – and 21.7% appeared in the second week after vaccination (Figure 4a). The median time until onset was 3 days. Interestingly, immediate hypersensitivity reactions as for urticaria particularly developed in the first week with a median time lag of 1 day, while chronic inflammatory skin diseases rather appeared later with a median time lag of 7 days ($P = 0.02$).

Cutaneous manifestations after first vaccination occurred with a median time lag of 2 days compared to 5.5 days after the second ($P = 0.19$) and 3 days after the third vaccination ($P = 0.50$) (Figure 4b).

Clinical course

In the majority of cases (83.9%), treatment was required (Figure 5a). Treatment included antihistamines (56.3%), topical (46.3%), systemic steroids (35.0%) and in 19.4% of the cases reactions were so severe that, according to German health care regulations, patients were hospitalized (Figure 5b). In 77.4% of cases, cutaneous alterations resolved and 22.6% were still ongoing during the observation time of the study (Figure 5c). An ongoing course

was most common in chronic inflammatory skin diseases (46.2%) (Figure 5d).

Tolerance of further vaccination

Revaccination was recommended in all patients. In 14 cases, there was no information about the further vaccination and therefore, possible recurrence could not be evaluated. Information on tolerance was available in 75% (43/57). The reason for the lack of information was primarily the fact that patients had not been vaccinated at the time of the last visit. After follow-up vaccination, no new skin reactions occurred in 51.2% (22/43) of cases (Figure 6a). Premedication was given in four patients: three patients took antihistamines prophylactically; one was additionally tapering out 10 mg prednisolone at the time of the second vaccination despite known negative consequences on vaccination effect. In 48.8% (21/43) previously reported cutaneous reactions recurred (Figure 6a). Also here, most of the skin findings appeared in the first week after the second vaccination with a median of 2 days and not significantly earlier compared to the initial appearance, when the skin findings appeared after a median of 3 days ($P = 0.063$) (Figure 6b). Regarding immediate hypersensitivity reactions, which comprised

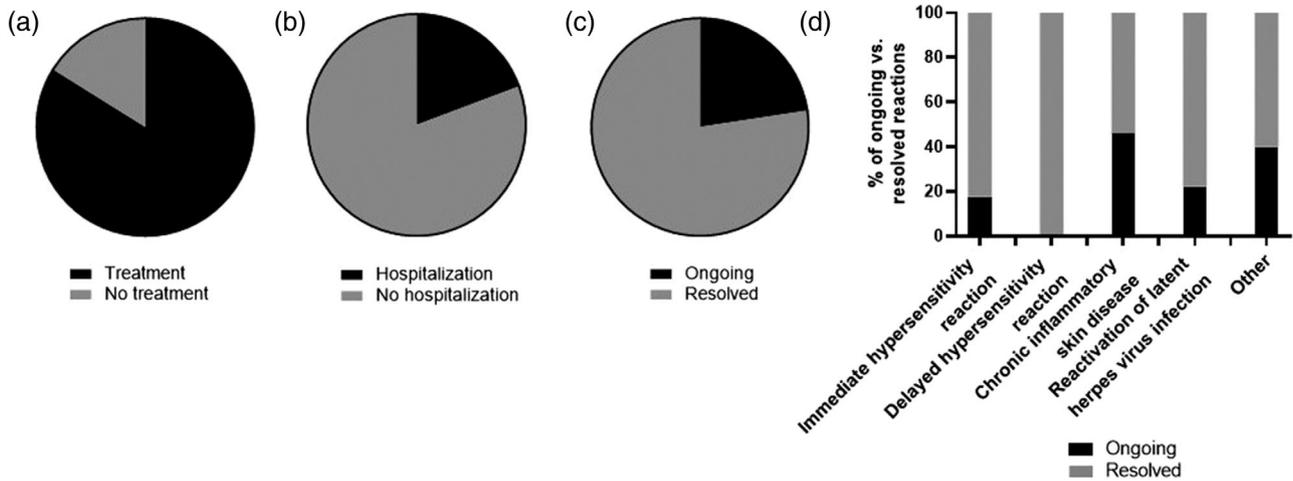


FIGURE 5 Severity and clinical course of cutaneous reactions. (a) Need of treatment. (b) Hospitalization. (c) Clinical course. (d) clinical course according to reaction cluster.

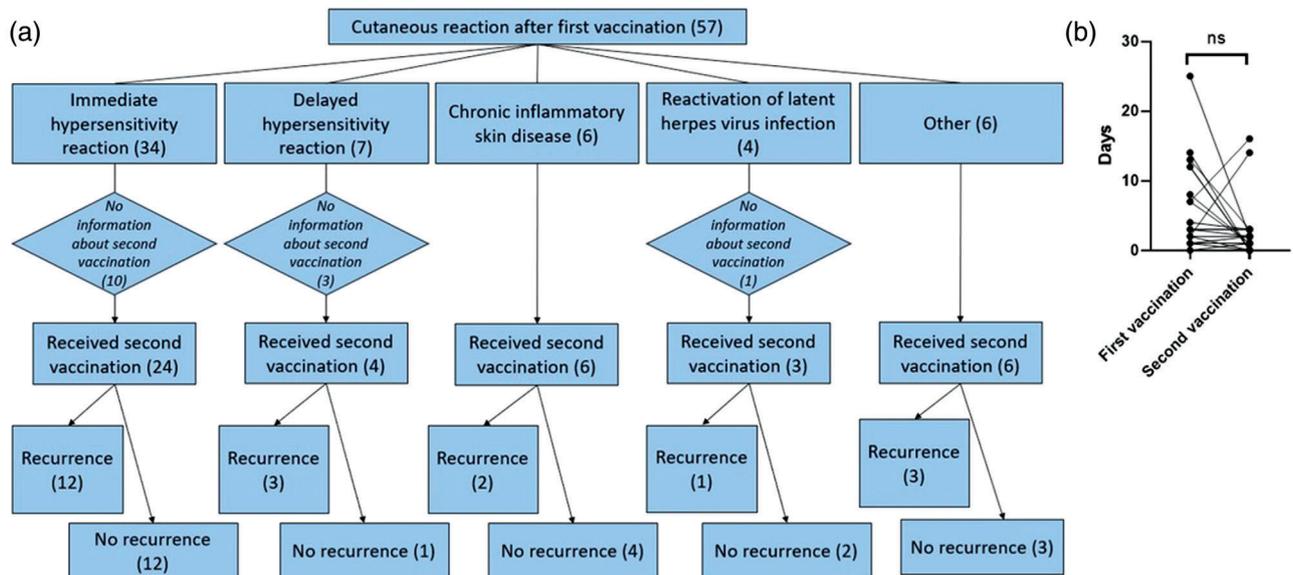


FIGURE 6 Recurrence of cutaneous reactions after the second vaccination. (a) Recurrence clustered into reaction clusters (number of reactions given in brackets). (b) Onset of cutaneous reactions in days following vaccination.

the majority of reactions in our cohort (34 reactions: 26 urticaria, 4 flush, 3 pruritus, 1 angioedema), information about further vaccination was available in 24 patients and in 50% of those (12/24), exactly the same reaction recurred.

Allergy testing

Skin allergy tests were performed in 15 patients (ten patients with urticaria, two patients with local injection reaction and urticaria, one with flush and pruritus, one with flush, one with eczema). These resulted all negative and thus, showed no evidence for an immediate-type allergy as mode of action for the reactions.

DISCUSSION

Cutaneous manifestations after SARS-COV-2 vaccination have been mostly described in case reports as well as in uncontrolled registries, where misclassification is possible.^{8,12,18} Dermatological assessment and follow-up of our large single-center patient cohort revealed that the reactions did not focus on specific vaccines, were non-allergic, clustered in disease groups commonly seen in the dermatological emergency department, included exacerbations of known skin diseases and did not occur after every vaccination in most patients indicating that vaccination may primarily trigger immunological disease in those patients who are already predisposed to the respective

diseases. Symptomatic treatment was often required, but most reactions were mild and self-limited.

Case reports and registries on dermatological manifestations following SARS-COV-2 vaccination may display severe reporting bias, which also affects reviews on the topic. Furthermore, registries also included results from non-dermatologists with the potential for misclassification. In absence of population-based studies, we initiated our large observational study to better understand the dermatological pattern of skin reactions after SARS-COV-2 vaccination.

In our study, 71.1% of patients presenting cutaneous changes were female, which confirms previously published observations.^{7,19,20} This might be related to a predominance of women in the health care sector seeking vaccination,¹⁵ stronger immune responses and higher rates of hypersensitivity reactions of women to vaccination *per se*,²¹ or a higher likelihood for doctor visits leading to reporting bias.²²

Interestingly, the reaction rates to the different vaccines BNT162b2 (68.7%), followed by mRNA-1273 (14.5%) and ChAdOx1 (13.3%), reflected the distribution of the given vaccines in Germany (77%, 17% and 7%, respectively) at that time.²³ In contrast, due to increased risk and prioritization, elderly patients did have a higher vaccination coverage in Germany,²⁴ but in our study were not affected more often by cutaneous events. This phenomenon has also been reported in phase 3 trials where adverse events accumulated in patients younger than 55–65 years.^{7,25,26} This may be related to the known alleviated immune response of elderly,²⁷ resulting in not only a higher vulnerability to infections,²⁸ and poorer response to vaccines,²⁹ but also in a reduced number of immune reactions after vaccination.

Hypersensitivity reactions including local injection reactions, urticaria, angioedema, flushing and exanthema constituted more than two third of the cutaneous manifestations reported in our patients. Local injection reactions and urticarial eruptions were frequent and also the most common conditions in patient registries.^{12,16} The lower frequency of local injection reactions in this study might reflect that patients are not sufficiently worried about a local injection reaction to present to a university clinic and that information about this reaction was commonly available. One patient reported reactions to dermal filler after vaccination, which is in agreement with previous case reports.^{30,31} Maculopapular rashes as seen in this study may occur upon vaccination.³² Ackerman et al. published one case with a maculopapular exanthema after first injection of BNT162b2, which persisted for one month and improved with corticosteroids.³² However, in our study, all exanthems were treated and resolved.

In comparison, onset of chronic inflammatory skin diseases was less frequently observed.¹² We observed several flare ups and recurrences of chronic inflammatory skin diseases such as atopic dermatitis, psoriasis or lichen planus. Although this reaction pattern is less well documented in

the literature, Krajewski et al. reported a severe flare up of psoriasis five days after the second vaccination with BNT162b2,³² which is consistent with our observation that chronic inflammatory skin disease exacerbations develop later than cutaneous hypersensitivity reactions. Flare ups of psoriasis and of atopic dermatitis have also been described after other vaccinations related to a shift of immune homeostasis induced by vaccinations.^{32–35}

Pityriasis rosea, a self-limiting exanthematous disease supposedly caused by reactivation of HHV-6/7, has been discussed to be associated with immune reactions following application of drugs and vaccinations.^{36,37} Some groups even distinguish between pityriasis rosea-like eruptions, occurring after infections or in the context of medication or vaccination as a kind of drug eruption and “classic” pityriasis rosea arising sporadically and irrespectively of the aforementioned.³⁸ Recently, pityriasis rosea after both COVID-19 infection and COVID-19 vaccination have been published.^{39,40} The exact pathologic mechanism is unknown but systemic reactivation of latent HHV-6/7 is believed to play a role.⁴¹ Vaccination or infection and the subsequent immune-mediated inflammation might distract T-cell-mediated immune control on latent viruses.⁴² The same might also be the case for reactivation of VZV in herpes zoster: Post-vaccination herpes virus reactivation has been reported not only after vaccination against influenza, hepatitis A, rabies, but also after vaccination for prevention of herpes zoster itself.^{43,44} In our study, four cases of pityriasis rosea and five cases with herpes zoster were observed; two cases of pityriasis rosea occurred after the first vaccination – with one second-dose recurrence – and two occurred after the third vaccination.

In agreement with the previously published literature, most skin reactions in our study were mild or moderate and self-limiting in the further course. However, in 83.9% of cases treatment was required and 19.4% were hospitalized for faster recovery.

Only few studies included patient follow-up regarding subsequent vaccinations. We recommended subsequent vaccinations to all patients. For patients having experienced immediate hypersensitivity reactions such as urticaria, we recommended antihistamine premedication, which included one tablet beginning one day before until one day after the planned vaccination, and for patients with a flare up or renewal of a chronic inflammatory skin disease, proactive enhanced therapy with topical corticosteroids was recommended. Our study found recurrence of the same skin reactions in 48.8% confirming registry data – with the highest shares in immediate hypersensitivity reactions as urticaria. McMahon et al. reported a second-dose recurrence rate of 43% in their registry-based study.¹² Interestingly, recurring reactions after the second dose were of same type of cutaneous manifestations as after the first vaccination. This suggests the hypothesis that even those so-called unspecific reactions follow a specific immune pattern in the individual patient. Additionally, we

also observed that cutaneous manifestations tend to recur faster after the second vaccination compared to the first appearance arguing for a priming for this type of response in at least part of the patients.¹²

After reports of anaphylaxis following SARS-COV-2 vaccination, it was initially unclear whether patients who developed allergy-like intolerance reactions, such as urticaria, flush or exanthema could be revaccinated.^{19,45,46} Park et al. reported anaphylaxis after first vaccination in a patient with cholinergic urticaria, whereas skin prick test for PEG and also the vaccine were negative and the second vaccination was well tolerated.⁴⁷ In order to exclude immediate-type allergy as the cause of skin manifestations, we tested 15 of our patients and none of them were positive for a broad range of test substances; thereafter, a non-allergic mechanism due to an unspecific immune stimulation was assumed in all further patients.

This study has some limitations. This is not a population-based study and conclusions regarding incidence cannot be made. Moreover, causality in regard to the vaccine and the reaction cannot be proven ultimately; nevertheless, recurrence of the same manifestation after the second vaccination pleads against pure coincidence in about half of the patients. Mild "COVID arms" might be under-represented in our cohort, because such mildly affected patients might not consult our specialists' dermatological outpatient department, rather those with more severe and allergy-like reactions seeking treatment. However, in contrast to registry-based studies, where reporting bias is more likely,^{12,13} this study presents a cross-section of skin presentations after vaccination confirmed by dermatologists and allergists and provides data on allergy diagnostics, therapies, outcome and individual past medical history.

In summary, this study clustered cutaneous reactions after COVID-19 vaccination, most commonly presenting as hypersensitivity reactions, but also often as renewals/flare ups of underlying, known conditions, which were also mostly temporary and did not requiring hospitalization. Type I allergy was excluded by skin tests and revaccination did not lead to allergic reactions. Nevertheless, recurrences after the second dose can occur in less than half of the cases and are most likely to be the same as the first reaction. This suggests that the reactions may be favored by individual immune deviations.

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CONFLICT OF INTEREST

None.

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