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Adverse cutaneous reactions reported post COVID-19 vaccination in Al Buraimi governorate, Sultanate of Oman

Amal Al Salmi[1] | Maryam Al Khamisani[1] | Abdullah Al Shibli[2] | Shahira Al Maqbali[3]

[1]Dermatology department, Al Buraimi Hospital, Al Buraimi, Oman

[2]General Foundation Program, Oman Medical Specialty Board

[3]Directorate of Primary Health Care, Al Buraimi Polyclinic, Al Buraimi, Oman

Correspondence
Amal Al Salmi, Dermatology Department, Al Buraimi Hospital, Al Buraimi, Oman.
Email: a.hope1200@gmail.com

Abstract

On March 11, 2020, the World Health Organization (WHO) declared the novel coronavirus (COVID-19) a global pandemic. This has led to the rapid development and emergency approval of vaccines to overcome the alarming spread of the virus. Data on the cutaneous side effects related to the COVID-19 vaccine remains limited. In this prospective observational study, which was conducted from June 20 to September 20, 2021, we evaluated the incidence and various patterns of cutaneous side effects reported post COVID-19 vaccination in Al Buraimi Governorate in Oman. All vaccinated individuals aged 12 years and older, who had a skin reaction within 4 weeks following any dose of the COVID-19 vaccine, were enrolled in the study. The demographic data, medical history, vaccine-related information of all the patients were documented and the analysis was performed using the SPSS version 23 software. In total, 67 cutaneous reactions were reported by 55 patients accounting for 0.11% of all vaccinated individuals. The mean age of the patients was 33.3 years, 80.6% were females, 61.2% of the reactions were reported after the first vaccine dose, and 38.8% were reported after the second dose. We observed a wide range of cutaneous reactions and categorized them into three major patterns: local injection site reaction (2%), new onset rash (81.6%), and flare up of pre-existing dermatological conditions (16.4%). Notably, urticaria was the most common reaction overall, followed by generalized pruritus and maculopapular rash. In general, we reported a diversity of cutaneous side effects that healthcare workers should be aware of as some reactions may be overlooked and not linked to the COVID-19 vaccination.

KEYWORDS
COVID-19, cutaneous reactions, side effects, vaccination, vaccine

1 | INTRODUCTION

Since the emergence of the strain of COVID-19 severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in the city of Wuhan and its global spread, the rapid development of novel vaccines to combat this pandemic became mandatory.[1] More knowledge and safety profiles of these new vaccines can be obtained after implementing them in a population at a proportion much larger than the clinical trials.

A preliminary literature review showed that there are many reports regarding cutaneous reactions post COVID-19 vaccines, such as local injection site reactions, delayed large local reactions, pityriasis rosea, vasculitis, urticaria, morbilliform, pernio, chilblains, erythema multiforme, and many other skin reactions.[2–7] In May 2021, Bogdanov et al. published an article about the cutaneous adverse effects of the available COVID-19 vaccines which showed that the injection-site reaction is the most frequent side effect.[8] Serious adverse events,

such as anaphylaxis, have also been described. The cutaneous symptoms can be the first presentation and the key to a timely and potentially lifesaving diagnosis and treatment.[8]

One of the initial and largest studies examining cutaneous reactions was a registry-based study of 414 cases, conducted in the USA between December 2020 and February 2021, which reported on cutaneous reactions experienced after a Moderna or Pfizer COVID-19 vaccination.[9] In this study, cutaneous adverse reactions were characterized based on their different morphologies and onset post vaccination, however, the incidence was not investigated since the cases were collected from a data-based registry. Another report came from Northeast Italy in January 2021, which studied cutaneous reactions to the Comirnaty@-BioNTech/Pfizer vaccine.[10]

With the start of the massive COVID-19 vaccination campaigns in Al Buraimi Governorate in Oman, we started seeing patients with different cutaneous side effects. Hence, we conducted this observational study to estimate the incidence of cutaneous adverse effects post vaccination with the four available vaccines: Pfizer (PF), AstraZeneca (AZ), Sinovac (SI), and Sputnik (SP). In addition, we aim to describe the different patterns of these cutaneous side effects, their time of onset, and correlate them to the type of vaccine used, number of doses received, patient's medical history, and age group.

2 | MATERIALS AND METHODS

Tarassud+ is the Sultanate of Oman's official Covid-19 application (app), developed and maintained by the Ministry of Health (MOH) as a standardized electronic vaccination registry system for the country. Healthcare workers use this app for the surveillance and reporting of adverse events following a COVID-19 vaccination.

This observational prospective study was conducted over a three-month period (June 20 to September 20, 2021). We included residents of Al Buraimi Governorate of any nationality aged 12 years and older who had been registered for a COVID-19 vaccine in the Tarassud+ MOH web application and who had a skin reaction within 4 weeks of receiving any dose of MOH approved vaccines. Exclusion criteria were as follows: individuals with explainable cutaneous reactions other than COVID-19 vaccination, individuals who were vaccinated outside the Al Buraimi Governorate, or residents of other areas of Oman. Also, patients with localized pain/tenderness at the injection site were excluded as this reaction was considered very common. The actual recruitment period of this study was 4 months because we had to wait 4 weeks after September 20, 2021 to include cutaneous reactions, which may have developed in participants who had the vaccine on this date. The 4-week period was deemed appropriate as most local injection reactions occur within 7 days and other systemic rashes may present within 26 days post vaccination, according to the adverse events following vaccinations-COVID-19 vaccines manual which is developed by the MOH.[11]

All health institutes, including both governmental (a total of eight primary care facilities and Al Buraimi Hospital) and private health sectors (a total of seven private clinics) in Al Buraimi Governorate, were formally informed about the study. We designed a data collection sheet for the health institutes providing information regarding the possible cutaneous reactions that should not be overlooked. The data sheet included general instructions concerning the information that should be obtained from the participants, such as their demographic data (sex, age, nationality, national ID, hospital ID, Phone Number), past medical history, vaccine type, vaccine dose (first /second), morphology of the cutaneous reactions (diagnosis), onset, and treatment received. All cases included in the study were evaluated by dermatologists or other physicians. Physicians were instructed to refer any case with an unclear or doubtful diagnosis to the dermatology department at Al Buraimi hospital for further evaluation. The health institutes were contacted periodically to obtain the complete data collection sheets, which were also reported in the electronic notification system on the Tarassud+ app.

The data were submitted regularly to the principal investigator (PI) and co-principal investigator (Co-PI), who are both dermatologists. The validity of the data was double-checked through the Tarassud+ app by the PI and Co-PI using the national ID number of each patient before entering the data into the record file. Any error or missing information in the data collection sheet was returned to the local investigator inputting the data for revision before final entry.

The Regional Ethical Committee (MoH/CSR/21/24858) authorized this study. Verbal consent was obtained from all participants and photographs of rare/ unique cutaneous adverse reactions were taken after written informed consent was given.

The initial sample size was not calculated because it was difficult to determine how many individuals would be vaccinated during the recruitment period. The data entry was done using Microsoft Excel. Descriptive data were expressed in numbers (*n*), percentages (%), or means ± standard deviation (SD). All analyses and tables were performed using SPSS (version 23, IBM, USA).

3 | RESULTS

From June 20, 2021, to September 20, 2021, a total of 51,063 residents of Al Buraimi Governorate were vaccinated: 18018 received their first dose, 9404 received their second dose, and 23,641 completed two doses. Table 1 summarizes the distribution of doses according to the vaccine types. There was no equal distribution between the four available vaccines (Table 1).

Out of these vaccinated individuals, 102 (0.2%) developed post vaccination adverse events which were reported on the Tarassud+ app. Adverse cutaneous reactions were present in 56 individuals, accounting for 54.9% of all reported adverse events, and 0.11% of all vaccinated individuals.

All patients presenting with cutaneous reactions were evaluated after face-to-face interviews with doctors working in the governorate. The majority were examined by dermatologist [n = 40 (71.4%)] and remaining by general practitioners [*n* = 16 (28.6%)]. Some of these patients had one or more cutaneous reactions, therefore a total of 68 cutaneous reactions were evaluated in 56 patients. One patient

TABLE 1 Distribution of COVID-19 doses according to the types of the vaccine

Vaccine Type	Doses			Total
	First dose	Second dose	Both doses	
Pfizer (PF)	9359	9200	18,413	36,972
AstraZeneca (AZ)	8658	91	5201	13,950
Sinovac (SI)	0	0	12	12
Sputnik (SP)	1	113	15	129
Total	18,018	9404	23,641	51,063

TABLE 2 Baseline characteristics of patients with cutaneous reactions

Characteristics	Total
No. of Patients	55
Mean (SD) age in years	33.31 (11.07)
Age range	13–62
No. of reported cutaneous reactions	67
Sex[a]	
Male	13 (19.4%)
Female	54 (80.6%)
Nationality[a]	
Omani	60 (89.5%)
Non-Omani	7 (10.4%)
Age groups in years[a]	
12–18	5 (9.1%)
19–44	43 (78.2%)
45 and above	7 (12.7%)
Medical history[a]	
Atopy[b]	6 (8.9%)
Urticaria	3 (4.5%)
History of allergy to drugs/vaccines	2 (3.0%)

Abbreviation: SD, standard deviation.
[a]These data are based on the number of total cutaneous reactions.
[b]Atopy includes all patients with atopic dermatitis, asthma, allergic Rhinitis, and allergic conjunctivitis.

was excluded as an alternative cause other than vaccination was found to explain his reaction. Therefore, the final sample size of cutaneous reactions was 67 from 55 patients after vaccination with: PF [$n = 60$ (89.5%)], AZ [$n = 6$ (9.0%)], and SP [$n = 1$(1.5%)]. No reactions were reported in individuals who received the SI vaccine; therefore, it was removed from the final analysis.

The baseline characteristics of the patients are shown in Table 2. The majority of the patients were Omanis (89.5%), with a mean age of 33.3 years, and 80.6% were females.

Regarding the cutaneous reactions, 41 (61.2%) were reported after the first vaccination dose and 26 (38.8%) after the second dose. Three patients reported reactions after both vaccine doses, two of them were after the PF vaccine and one patient after the AZ vaccine. Of these three patients, two had reported eczematous dermatitis after the first dose and one had reported urticarial rash within 24 h of receiving the first dose. However, all three patients reported generalized pruritus after their second dose with onset between 10 h and 3 days.

Two reactions (3.0%) were reported at the injection site and the remaining 65 reactions (97.0%) occurred beyond the injection site. We divided all these cutaneous reactions into three major categories: (1) local injection site reactions, (2) new onset rash beyond the injection site, (3) flare up of pre-existing dermatological conditions. The different cutaneous reactions with their mean time of onset are shown in Table 3.

In the local injection site reactions category, only two [$n = 2$ (3%)] reactions were reported in our study with a mean time of onset of 1 day post vaccination in the form of tender erythematous plaques. In one individual, blisters formed on top of the lesion (Figure 1A).

In the category of new rashes, we found that the most common cutaneous reactions in order of frequency were: urticaria with/without angioedema [$n = 11$(16.4%)] of which 45.4% of cases reported within 24 h but none of them were immediate or occurred in less than 4 h (Figure 1B), generalized pruritus [$n = 10$ (14.9%)], morbilliform eruptions [$n = 7$ (10.4%)] in the form of maculopapular rash involving the upper parts of the body (Figure 1C), generalized, nonspecific itchy erythematous swelling of the upper body [$n = 4$ (6%)], eczematous dermatitis [$n = 4$ (6.0%)] which was generalized in three patients and localized in the upper back of one patient(Figure 1D), herpes zoster [$n = 3$ (4.5%)] (Figure 1E), pityriasis rosea like eruption [$n = 2$ (3%)] (Figure 1F), papulopustular rash [$n = 2$ (3%)] (Figure 1G), nonspecific tender axillary swelling [$n = 2$ (3%)], and purpura/ecchymosis [$n = 2$ (3%)] where one case required hospital admission because of a very low platelet count which was later diagnosed as immune thrombocytopenic purpura (ITP).

Less common reactions were also reported: excessive hair shedding, cherry angioma like eruptions, erythromelalgia with skin peeling involving hands and feet (Figure 1H), keratolysis exfoliativa (hands), aphthous ulcers, dry lips with angular cheilitis, and nonspecific scaly erythematous plaques (face).

In the category of flare up of pre-existing dermatological conditions, we reported 11 (16.4%) reactions, of which the flare up of acne and psoriasis were the most common, accounting for 6% and 4.5% of total cutaneous reactions, respectively. The flare up of herpes simplex, lichen planus, pemphigus foliaceus, and pompholyx were also reported.

TABLE 3 Cutaneous reactions reported after the different types of vaccines with their mean time of onset

Cutaneous reactions	Mean onset (SD)[a] (in days)	Pfizer ($n = 60$)	AstraZeneca ($n = 6$)	Sputnik ($n = 1$)	Total ($n = 67$)
Local site injection reaction	1.0 (0.0)	2 (3.0%)	0 (0.0%)	0 (0.0%)	2 (3.0%)
New onset rash					
Urticaria with/without angioedema					11(16.4%)
<24 h	> 4 h	4 (6.0%)	1 (1.5.0%)	0 (0.0%)	
>24 h	7.5 (7.8)	6 (8.9%)	0 (0.0%)	0 (0.0%)	
Generalized pruritus	4.2 (5.1)	9 (13.4%)	1 (1.5%)	0 (0.0%)	10 (14.9%)
Maculopapular	7.9 (8.7)	4 (6.0%)	2 (3.0%)	1 (1.5%)	7 (10.4%)
Eczematous dermatitis	13.3 (10.3)	2 (50.0%)	2 (50.0%)	0 (0.0%)	4 (6.0%)
Non-specific erythematous swelling of upper body	2.3 (1.5)	4 (6.0%)	0 (0.0%)	0 (0.0%)	4 (6.0%)
Herpes zoster	11.3 (9.6)	3 (4.5%)	0 (0.0%)	0 (0.0%)	3 (4.5%)
Pityriasis rosea like eruption	12.0 (1.4)	2 (3.0%)	0 (0.0%)	0 (0.0%)	2 (3.0%)
Papulopustular rash	6.5 (6.4)	2 (3.0%)	0 (0.0%)	0 (0.0%)	2 (3.0%)
Nonspecific tender axillary swelling	2.5 (2.1)	2 (3.0%)	0 (0.0%)	0 (0.0%)	2 (3.0%)
Purpura/ecchymosis	4.5 (3.5)	2 (3.0%)	0 (0.0%)	0 (0.0%)	2 (3.0%)
Excessive hair shedding	21.0 (–)	1 (1.5%)	0 (0.0%)	0 (0.0%)	1 (1.5%)
Cherry angioma like eruption	4.0 (–)	1 (1.5%)	0 (0.0%)	0 (0.0%)	1 (1.5%)
Erythromelalgia	2.0 (–)	1 (1.5%)	0 (0.0%)	0 (0.0%)	1 (1.5%)
Keratolysis exfoliativa	2.0 (–)	1 (1.5%)	0 (0.0%)	0 (0.0%)	1 (1.5%)
Aphthous ulcers	2.0 (–)	1 (1.5%)	0 (0.0%)	0 (0.0%)	1 (1.5%)
Angular cheilitis	1.0 (–)	1 (1.5%)	0 (0.0%)	0 (0.0%)	1 (1.5%)
Non-specific scaly erythematous plaques	14.0 (–)	1 (1.5%)	0 (0.0%)	0 (0.0%)	1 (1.5%)
Flare up of pre-existing dermatological condition					
Acne vulgaris	9.8 (5.1)	4 (6.0%)	0 (0.0%)	0 (0.0%)	4 (6.0%)
Psoriasis	17.7 (6.4)	3 (4.5%)	0 (0.0%)	0 (0.0%)	3 (4.5%)
Herpes simplex	12.0 (–)	1 (1.5%)	0 (0.0%)	0 (0.0%)	1 (1.5%)
Lichen planus	10.0 (–)	1 (1.5%)	0 (0.0%)	0 (0.0%)	1 (1.5%)
Pemphigus foliaceus	2.0 (–)	1 (1.5%)	0 (0.0%)	0 (0.0%)	1 (1.5%)
Pompholyx	7.0 (–)	1 (1.5%)	0 (0.0%)	0 (0.0%)	1 (1.5%)

Abbreviation: SD, standard deviation.
[a]Mean onset is measured in days unless otherwise specified.

4 | DISCUSSION

In this study, we described the incidence and various presentations of cutaneous adverse reactions reported post vaccination with three COVID-19 vaccines (two viral vector vaccines and one mRNA vaccine). We divided these reactions into three major categories: local site injection reactions, new onset rash, and flare up of pre-existing dermatological conditions. To the best of our knowledge, this is the first study that describes cutaneous adverse reactions reported post COVID-19 vaccines in Oman and one of the few studies conducted in the Middle East.

In contrast to the initial studies and articles that were published on the COVID-19 vaccine side effects, which were based on registries or self-reported surveys,[9,10,12,13] all cases of cutaneous reactions in this study were evaluated prospectively by physicians; 71.4% of the cutaneous reactions were diagnosed by dermatologists to avoid misdiagnosis. Also, a more representative sample of the general population was included compared to initial researches that focused mainly on healthcare workers and older individuals.

We found that the incidence of reporting these adverse cutaneous reactions among the general population was only 0.11%, indicating that these reactions are not common. This finding is consistent with other publications.[10] However; a higher incidence reaching 1.9% after the first dose of mRNA COVID-19 vaccine was reported by another study conducted mainly on healthcare workers using self-reported surveys.[12]

Similar to the study by McMahon et al.[9] and Catala et al.,[14] we found that the reporting of cutaneous side effects post COVID-19 vaccination was higher in females (82.8%), supporting the fact that the response to vaccines differs between sexes and that women

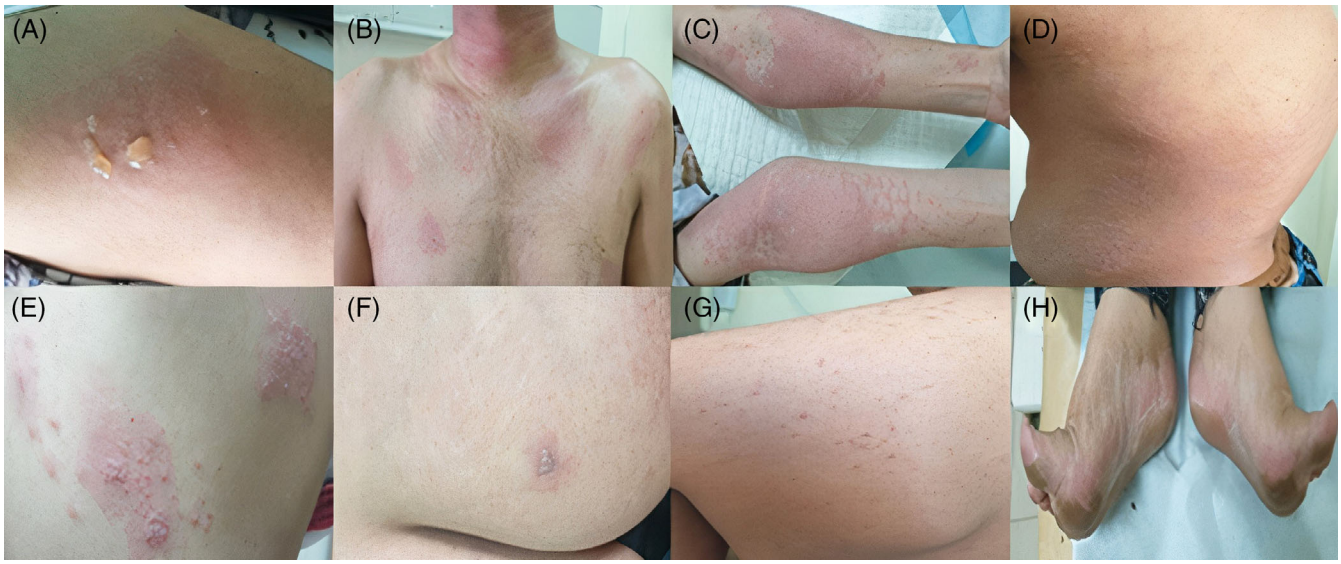

FIGURE 1 Photographs of some of the reported cutaneous side effects. (A) local injection site reaction with tender erythematic plaque and blisters, (B) urticarial wheals, (C) morbilliform rash coalescing together involving mainly upper limbs, (D) generalized eczematous dermatitis, (E) herpes zoster, (F) pityriasis rosea like eruption, (G) papulopustular eruption upper back, and (H) erythromelalgia with exfoliative dermatitis

exhibit a stronger immune response to vaccines leading to more frequent side effects.[15,16] Another study conducted in Oman by Al Ghafri et al. showed that reporting at least one adverse effect post-COVID-19 vaccination was also higher in females.[17]

In our study, we noticed that most reactions were reported in Omanis compared to non-Omanis. This can be explained by the fact that government health care services are free for Omani nationalities compared to non-Omanis who may not seek medical advice for mild to moderate complaints because of financial issues.

Reactions were more frequent (78.2%) in the 19- to 44-year-old age group. This may be attributed to a reporting bias or actual difference, as 67.7% of vaccinated individuals at the time of the study were in this age group, and studies have shown that reactogenicity to COVID-19 vaccine was higher in younger individuals since their immunity boosts a faster and stronger immune response to vaccines compared to older individuals.[18]

Most of the reactions observed in our study occurred after the first vaccine dose (61.2%) compared to the second dose (38.8%). Interestingly, all three patients who reported reactions after both doses developed generalized pruritus after their second dose that was managed symptomatically. This observation could be reassuring to patients who reacted to their first dose of the vaccine regarding their subsequent doses, as there were no reports of anaphylaxis or other serious adverse effects.[9]

Although the literature review revealed that local injection site reactions are the most common cutaneous adverse reactions to all COVID-19 vaccines, we reported a lower incidence of local site injection reactions (3%) compared to similar studies.[9,14,19] Hence, we assume there is under reporting of local injection side effects in our study population as most patients may not seek medical advice for these reactions which appear harmless and can be managed by simple analgesia and cold compress. In addition, we excluded the localized pain and tenderness at injection site from the beginning of the study, which also led to this lower incidence compared to other published reports.

The most common reaction in our study was urticaria with/without angioedema [$n = 11(16.4\%)$], of which five cases were reported within 24 h, and the remaining six cases were reported after 24 h, with a mean time of onset of 7.5 days. Generalized pruritus [$n = 10$ (14.9%)] and maculopapular rash [$n = 7$ (10.4%)] were also frequent in the new rash category with a mean time of onset of 4.2 and 7.9 days after vaccination. Interestingly, we had one female patient who reported itchy cherry angioma like eruptions on day 4 post vaccination, which is rarely reported. Mohta et al.[20] reported five cases of healthcare workers who developed similar eruptive pseudoangiomatosis after the Covishield™ vaccination. The most probable explanation is that this reaction was mediated by the immunological response to the viral component of the vaccine itself as it has been reported after SARS-CoV-2 (COVID-19) infection as well.[21] Another rare case observed in our study was that of a middle-aged female patient who developed immune mediated thrombocytopenia (ITP) 1 week after her second dose of the Pfizer vaccine; her platelet count reached 14×10^9/L. Similar cases of ITP were also described within 2 weeks of vaccination with the Pfizer and Moderna vaccine, which may suggest a causal link between ITP and COVID-19 vaccines.[22]

In a recent study from Kuwait by Al Mutairi et al.,[23] an increase in the number of herpes zoster cases was noted following COVID-19 infection and vaccination. This increased vulnerability to herpes zoster virus was speculated to be caused by a decrease in the absolute lymphocyte count and the immune dysregulation that occurs following COVID-19 infection and vaccination. Similarly, we reported 4.5% of new herpes zoster cases after Pfizer vaccinations in our study population. Furthermore, this vaccine-mediated immunomodulation has been shown to activate other viruses like human herpesvirus 6 and 7, and

Epstein–Barr virus, which may explain the pityriasis rosea like eruptions reported.[5,9]

New onset rashes that were less common in our patients consisted of: nonspecific itchy erythematous swelling of the upper body, eczematous dermatitis, papulopustular rash, nonspecific tender axillary swelling, excessive hair shedding, erythromelalgia, keratolysis exfoliativa (hands), aphthous ulcers, dry lips with angular cheilitis, and nonspecific scaly erythematous plaques (face).

We did not report any cases of anaphylactic reactions or immediate hypersensitivity reactions, such as urticaria, angioedema, flushing, and pruritus, occurring within the first 4 h post vaccination; as defined by the Centers of Disease Control and Prevention (CDC).[24] Past medical history of atopy, urticarial, and allergy to drugs or vaccine were present in 8.9%, 4.5%, and 3% of our study population respectively, however, these conditions are not considered contraindications for the vaccine as per the CDC guidelines.

We also observed the worsening or flare up of different pre-existing skin conditions including acne, psoriasis, herpes simplex, pemphigus foliaceus, and pompholyx. Similar findings were also described in the literature.[9,14,19]

Notably, none of our patients required hospitalization for management of their side effects except for the one who was diagnosed with ITP.

One of the major limitations of this study is that some individuals may not seek medical advice for minor complaints, especially local site reactions, and others may seek medical advice outside the Al Buraimi Governorate. This may lead to an underestimation of the actual incidence of cutaneous adverse reactions reported. In addition, a comparison between the different available vaccines and the reported cutaneous reactions was not possible as there was no equal distribution of the four available vaccines. Therefore, it was anticipated that the Pfizer group would experience more side effects since it was the most widely used vaccine at the time of the study.

5 | CONCLUSION

Generally, we reported a wide spectrum of cutaneous reactions post COVID-19 vaccination, however, their incidence is regarded as low and most of them resolve with symptomatic management. Notably, most cutaneous reactions occurred after the first dose, but none were considered contraindications for subsequent doses. Nonetheless, healthcare workers should be aware of the miscellaneous presentations of these side effects, which will help in their early detection and proper management. In addition, we encourage the documentation of these vaccine- related side effects, which can aid in the overall safety data collection of the current COVID-19 vaccines available in the world.

AUTHOR CONTRIBUTIONS

The authors confirm contribution to the study as follows: *study conception and design*: Amal Al Salmi, Maryam Al Khamisani, Abdullah Al Shibli; *data collection*: Amal Al Salmi, Maryam Al Khamisani, Abdullah Al Shibli, Shahira Al Maqbali; *data management and analysis*: Amal Al Salmi, Maryam Al Khamisani, Abdullah Al Shibli; *interpretation of results*: Amal Al Salmi; *draft manuscript preparation and writing*: Amal Al Salmi; *critical reviewing with intellectual input*: Amal Al Salmi, Shahira Al Maqbali. All authors have read and approved the final version of the manuscript.

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CONFLICT OF INTERESTS

The authors have no conflict of interest to declare.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available on request from the corresponding author. The data are not publicly available due to privacy or ethical restrictions.

ORCID

Amal Al Salmi https://orcid.org/0000-0001-5913-5282
Maryam Al Khamisani https://orcid.org/0000-0002-3534-1994
Abdullah Al Shibli https://orcid.org/0000-0003-3706-0974
Shahira Al Maqbali https://orcid.org/0000-0002-8971-5242

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