

SHORT COMMUNICATION

Association study between herpes zoster reporting and mRNA COVID-19 vaccines (BNT162b2 and mRNA-1273)

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Several cases of herpes zoster (HZ) following mRNA COVID-19 vaccination (BNT162b2 and mRNA-1273) have been reported, and the first epidemiological evidence suggests an increased risk. We used the worldwide pharmacovigilance database VigiBase to describe HZ cases following mRNA COVID-19 vaccination. We performed disproportionality analyses (case/non-case statistical approach) to assess the relative risk of HZ reporting in mRNA COVID-19 vaccine recipients compared to influenza vaccine recipients and according to patient age. To 30 June 2021, of 716 928 reports with mRNA COVID-19 vaccines, we found 7728 HZ cases. When compared to influenza vaccines, mRNA COVID-19 vaccines were associated with a significantly higher reporting of HZ (reporting odds ratio 1.9, 95% CI 1.8–2.1). Furthermore, we found a reduced risk of reporting HZ among under 40-year-old persons compared to older persons (reporting odds ratio 0.39, 95% CI 0.36–0.41). Mild and infrequent HZ reactions may occur shortly after mRNA COVID-19 vaccination, at higher frequency than reported with influenza vaccination, especially in patients over 40 years old. Further analyses are needed to confirm this risk.

KEYWORDS

COVID-19, disproportionality, herpes zoster, mRNA vaccines, pharmacovigilance

1 | INTRODUCTION

Vaccination is the cornerstone of coronavirus disease-19 (COVID-19) prevention. To date, two mRNA vaccines, BNT162b2 (Pfizer-BioNTech) and mRNA-1273 (Moderna), have been approved.^{1,2} Although these vaccines have a very good safety profile, post-marketing monitoring is key, especially during mass immunizations.³ Several cases of herpes zoster (HZ) following mRNA COVID-19 vaccination have been reported.^{4–6} A safety signal was raised by the French National Medicine Agency (ANSM) in March 2021 (<https://ansm.sante.fr/actualites/point-de-situation-sur-la-surveillance-des-vaccins-contre-la-covid-19-9>). An increased risk of HZ infection has been observed in BNT162b2 mRNA vaccine recipients, while infection characteristics are not known so far.⁷ The aim of this analysis was

to describe HZ cases following mRNA COVID-19 vaccination at a global level, and to appraise this risk.

2 | METHODS

We used VigiBase (<https://www.who-umc.org/vigibase/vigibase/>), the WHO global individual case safety report database, which contains about 27 million spontaneous reports of suspected adverse drug reactions collected by national drug authorities in more than 130 countries. This unique database provides a powerful tool to assess relative risk of adverse drug reaction using disproportionality analyses.⁸ This pharmacovigilance statistical approach, also called case/non-case study, is similar to a case-control study nested in a large cohort and estimates the differential proportion of a specific adverse drug reaction reported in a specific group (e.g., according to

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drug exposure or patient age) with the proportion of the same adverse drug reaction for a control group. The association is expressed using the reporting odds ratio (ROR) and its 95% confidence interval (CI), which is similar in concept to the odds ratio in case-control studies.

Cases are reports registered in VigiBase up to 30 June 2021 containing a HZ reaction with BNT162b2 or mRNA-1273, identified using ad-hoc terms from the Medical Dictionary for Regulatory Activities (Table S1 in the Supporting Information), whereas non-cases are reports including all other adverse reactions with these vaccines. Cases were categorized by clinical presentation, such as skin rash, herpes zoster ophthalmicus and oticus, and central nervous system (CNS) injuries. First, disproportionality analysis was used to assess the risk of HZ reporting compared to influenza vaccine (J07BB using the Anatomical Therapeutic Chemical Classification System) recipients, given the similarity of the vaccine recipients, especially in the first months of the campaign in early 2021. Second, disproportionality analysis was used to assess a possible different risk of HZ reporting according to patient age among mRNA COVID-19 vaccine recipients. We further performed sensitivity analyses, by restricting our disproportionality analysis to serious cases only and to cases reported by healthcare professionals.

3 | RESULTS

Of 26 246 383 reports, 716 928 reports concerned mRNA COVID-19 vaccines, among which we observed 5931 HZ cases with BNT162b2 and 1797 with mRNA-1273 (Table 1). Of these 7728 cases, 5135 (66.4%) concerned female patients. Median (interquartile range [IQR]) age was 60 (46–72) years. An mRNA COVID-19 vaccine was the only suspected drug in all except 62 (0.8%) cases. Most cases (7494, 97.0%) were skin rash, with a median time to onset of 7²⁻¹⁵ days and requiring hospitalization in 173/7494 cases (2.3%). Herpes zoster ophthalmicus and oticus involved respectively 197 (2.5%) and 60 (0.8%) cases. Central nervous system involvement, such as meningitis, meningoencephalitis or meningoradiculitis accounted for 0.3% of cases for each mRNA vaccine. The time to onset was 17.5 (12.5–29) days following vaccination in this setting, with 14 (56%) vaccine recipients requiring hospitalization. No HZ-related death was reported. Irrespective of the type of injury, reactions were more frequently reported after the first dose of vaccine than after the second dose (14.4% and 8.5%, respectively).

When compared with influenza vaccines, mRNA COVID-19 vaccines were associated with an increased HZ reporting for BNT162b2 (ROR 2.0, 95% CI 1.8–2.2), mRNA-1273 (ROR 1.5, 95% CI 1.2–1.8) and overall (ROR 1.9, 95% CI 1.8–2.1) (Table 2, Table S2 in the Supporting Information). Furthermore, among mRNA COVID-19 recipients, we found a reduced risk of reporting HZ among under 40-year-old persons compared to older persons (ROR 0.39, 95% CI 0.36–0.41) (Table 2). These results were consistent with further sensitivity analyses restricted to serious reports and to reports originating from a healthcare provider (Tables S3 and S4 in the Supporting Information). Finally, we also found a slight increase in HZ reporting

What is already known about this subject

- Several cases of herpes zoster (HZ) following mRNA COVID-19 vaccination have been reported.
- First epidemiological evidence suggests an increased risk of HZ after mRNA COVID-19 vaccination.
- HZ infection characteristics are not known so far and this risk has not yet been assessed at a global level.

What this study adds

- HZ may occur shortly after mRNA COVID-19 vaccination, at higher frequency than reported with influenza vaccination.
- This risk of HZ reporting was reduced among under 40-year-old persons compared to older age groups.
- HZ reactions following mRNA COVID-19 vaccination usually remain mild and infrequent as reflected by the billions of doses administered so far.

for BNT162b2 compared to mRNA-1273, but this was not confirmed by our sensitivity analyses (Table S5 in the Supporting Information).

4 | DISCUSSION

Our study first describes the occurrence of HZ after mRNA COVID-19 vaccination at a global level and shows an increased relative risk of HZ reporting in mRNA COVID-19 vaccine recipients as compared to influenza vaccine recipients. HZ reactions were mostly skin rash, and occurred among all age groups, although the risk of reporting was reduced in patients under 40 years old, which was as expected given the classical epidemiology of HZ reactions. Time to HZ onset following mRNA COVID-19 vaccination was about 1 week after injection, which seems similar to that observed following COVID-19 infection.⁹ Some cases of CNS injuries were also reported with a later onset and it is noteworthy that no fatal outcomes were reported. A significantly different risk for HZ reporting between BNT162b2 and mRNA-1273 appears unlikely, although it cannot be ruled out.

HZ may occur in patients previously infected with varicella-zoster virus, especially in patients with cellular immune defects or older people.¹⁰ It mainly presents as shingles, cranial nerve palsy, meningitis, myelitis, retinitis or hepatitis. Recently, Barda et al. found an excess of HZ infection of 15.8 (from 8.2 to 24.2) events per 100 000 persons during the 21 days following BNT162b2 vaccination compared to non-vaccinated people.⁷ This national study did not present a detailed description of HZ cases. Our study shows that patients were younger

TABLE 1 Characteristics of herpes zoster cases reported with mRNA COVID-19 vaccines in the WHO global safety database

Reporting characteristics	BNT162b2 (n = 5931)	mRNA-1273 (n = 1797)	Overall (n = 7728)
Continent of reporting			
Africa	13 (0.2%)	–	13 (0.2%)
Asia-Oceania	112 (1.9%)	1 (0.1%)	113 (1.5%)
Europe	3616 (61.0%)	358 (19.9%)	3974 (51.4%)
North America	2173 (36.6%)	1438 (80.0%)	3611 (46.7%)
South America	17 (0.3%)	–	17 (0.2%)
Type of reporter			
Pharmacist	162 (2.7%)	19 (1.1%)	181 (2.3%)
Physician	1431 (24.1%)	192 (10.7%)	1623 (21.0%)
Other health professional	252 (4.2%)	5 (0.3%)	257 (3.3%)
Consumer	1869 (32.5%)	144 (8.0%)	2013 (26.0%)
Unknown	2217 (37.4%)	1437 (80.0%)	3654 (47.3%)
Vaccine dose number			
Dose 1	1057 (17.8%)	57 (3.2%)	1114 (14.4%)
Dose 2	606 (10.2%)	50 (2.8%)	656 (8.5%)
Unknown	4268 (72.0%)	1690 (94.0%)	5958 (77.1%)
Cases with another suspected reported drug	45 (0.8%)	17 (0.9%)	62 (0.8%)
Sex—Female	3903 (65.8%)	1232 (68.6%)	5135 (66.4%)
Age—Years	61 (46–73)	58 (44–70)	60 (46–72)
Age—Ranges			
< 12 years	10 (0.2%)	–	10 (0.1%)
12–17 years	13 (0.2%)	1 (0.1%)	14 (0.2%)
18–39 years	831 (14.0%)	312 (17.4%)	1143 (14.8%)
40–64 years	2230 (37.6%)	780 (43.4%)	3010 (38.9%)
65–74 years	1188 (20.0%)	374 (20.8%)	1562 (20.2%)
≥ 75 years	1200 (20.2%)	288 (16.0%)	1488 (19.3%)
Unknown	459 (7.7%)	42 (2.3%)	501 (6.5%)
Type of injury: Skin rash^a			
Age—Years	61 (46–73)	57 (44–70)	60 (45–72)
Time to reaction onset—Days	7 (2–14)	7 (2–16)	7 (2–15)
Requiring hospitalization	131 (2.3%)	42 (2.4%)	173 (2.3%)
Vaccine dose number			
Dose 1	1048 (18.3%)	57 (3.2%)	1105 (14.7%)
Dose 2	639 (11.2%)	51 (2.9%)	690 (9.2%)
Unknown	4046 (70.5%)	1653 (93.9%)	5699 (76.1%)
Type of injury: Ophthalmicus			
Age—Years	68 (56–78)	69 (57–76)	68 (56–78)
Time to reaction onset—Days	8 (2.8–15)	4 (2–13.8)	7 (2–14.8)
Requiring hospitalization	21 (12.7%)	2 (6.0%)	23 (11.7%)
Vaccine dose number			
Dose 1	29 (17.6%)	4 (12.5%)	33 (16.8%)
Dose 2	11 (6.7%)	5 (15.6%)	16 (8.1%)
Unknown	125 (75.7%)	23 (71.9%)	148 (75.1%)
Type of injury: Oticus			
Age—Years	57 (45–67)	47 (40–59)	57 (42–66)
Time to reaction onset—Days	5 (2–12)	3 (1–11)	4 (1.75–11.75)

(Continues)

TABLE 1 (Continued)

Reporting characteristics	BNT162b2 (n = 5931)	mRNA-1273 (n = 1797)	Overall (n = 7728)
Requiring hospitalization	6 (12.8%)	–	6 (10%)
Vaccine dose number			
Dose 1	8 (17%)	–	8 (13.3%)
Dose 2	7 (14.9%)	–	7 (11.7%)
Unknown	32 (68.1%)	13 (100%)	45 (75%)
Type of injury: Central nervous system	19 (0.3%)	6 (0.3%)	25 (0.3%)
Meningitis	9 (47.4%)	3 (50%)	12 (48%)
Meningoencephalitis	5 (26.3%)	2 (33.3%)	7 (28%)
Meningoradiculitis	2 (10.5%)	–	2 (8%)
Unspecified neurological infection	3 (15.8%)	1 (16.7%)	4 (16%)
Age—Years	65 (55–78)	47.5 (33–73)	65 (47–77)
Time to reaction onset—Days	18 (2.5–30)	17 (13–21)	17.5 (12.5–29)
Requiring hospitalization	11 (57.9%)	3 (50%)	14 (56%)
Vaccine dose number			
Dose 1	5 (26.3%)	1 (16.7%)	6 (24%)
Dose 2	2 (10.5%)	–	2 (8%)
Unknown	12 (63.2%)	5 (83.3%)	17 (68%)
Month of reporting			
December	5 (0.1%)	0	5 (0.1%)
January	151 (2.5%)	5 (0.3%)	156 (2.0%)
February	370 (6.2%)	24 (1.3%)	394 (5.1%)
March	542 (9.1%)	86 (4.8%)	628 (8.1%)
April	728 (12.3%)	129 (7.2%)	857 (11.1%)
May	1680 (28.3%)	660 (36.7%)	2340 (30.3%)
June	2455 (41.4%)	893 (46.7%)	3348 (43.3%)

Data are presented as n (%) or median (IQR).

As patients could develop more than one type of lesion, the number of types of injury exceed the number of cases.

^aIncluding seven genital injuries for BNT162b2 and none for mRNA-1273.

in vaccine-associated HZ as compared to HZ in the general population, suggesting a specific pathophysiology, although we did not find an increased risk in people under 40 years old. Our results seem consistent with a systematic review of the literature¹¹ on 54 patients (36 patients over 50 years old) as well as with a review¹² of 35 cases (median age: 46 years old) of HZ reactivation following COVID-19 vaccination registered in an international dermatology registry. The median time to onset observed was 7 days for these two studies. For the second study, a relatively similar number of cases was found between BNT162b2 and mRNA-1273. Finally, in these two studies, HZ occurred mainly after the first dose of vaccine, as our study also suggests.

Mechanisms involved in post-vaccination HZ are not fully understood but might imply toll-like receptors (TLRs) 3 and 7 stimulation by mRNA vaccines^{13,14} as discussed by others.⁴ Noteworthy, other neurological disorders have been reported following COVID-19 vaccination such as facial-nerve palsy.¹⁵ The hypothesis of a mechanism involving Type I interferons has been discussed with a possible role of HZ infection as the potential trigger for facial palsy.^{7,16}

Several limitations must be acknowledged. First, VigiBase is based on spontaneous reports, which will likely feature under-reporting of total real-world cases and variable data quality, all of which are inherent to any pharmacovigilance system. However, VigiBase, which covers more than 90% of the world population, provides a unique opportunity to analyse rare adverse events at a global scale. Furthermore, disproportionality analysis on VigiBase has proven its value in detecting increased risk of events. Some evidence suggests that estimates of disproportionality analysis correlate most of the time with adverse drug reaction risks.⁸ Second, disproportionality studies are subject to notoriety bias and to residual confounders. To address these issues, we restricted the study period to a time frame that limited these biases, and selected an active comparator based on influenza vaccine recipients.¹⁷ Last, the available data did not allow us to investigate patient comorbidities associated with HZ reaction, nor the risk of HZ recurrence in the case of a second shot of vaccine after a first episode of HZ.

Overall, our study shows that HZ may occur shortly after mRNA COVID-19 vaccination, at higher frequency than reported with

TABLE 2 Herpes zoster reporting and reporting odds ratios for mRNA COVID-19 vaccines within the WHO global safety database

	Cases	Non-cases	ROR [95% CI]
First analysis—compare to influenza vaccines			
Both mRNA COVID-19 vaccine recipients	1449	228 489	1.9 [1.8–2.1]
BNT162b2 recipients	1292	196 365	2.0 [1.8–2.2]
mRNA-1273 recipients	157	32 124	1.5 [1.2–1.8]
Influenza vaccine recipients	665	201 452	Ref
Second analysis—according to age			
≤ 40 years mRNA COVID-19 vaccine recipients	1262	233 937	0.39 [0.36–0.41]
> 40 years mRNA COVID-19 vaccine recipients	5964	431 063	Ref

Cases are reports containing a herpes zoster reaction (Table S1), whereas non-cases are reports including all other adverse reactions with these vaccines.

ROR [95% CI] are calculated as $ROR = \frac{ad}{bc} \left[e^{\pm 1.96 \sqrt{\left(\frac{1}{a} + \frac{1}{b} + \frac{1}{c} + \frac{1}{d} \right)}} \right]$, where a is the number of herpes zoster cases in a group of interest, b is the number of other reaction cases in a group of interest, c is the number of herpes zoster cases in a comparator group and d is the number of other reaction cases in a comparator group.

First analysis: the group of interest was mRNA COVID-19 vaccine recipients and the comparator group was any influenza vaccine recipients. Reports that involved any influenza vaccine or varicella-zoster virus vaccine in addition to mRNA COVID-19 vaccine were excluded. To avoid notoriety bias, a longstanding known bias in disproportionality studies, which is related to an inflation reporting following a scientific communication, this analysis was restricted to reports recorded in VigiBase before 12 April 2021 (corresponding to the date of first publication of herpes zoster following mRNA vaccination case series).⁴ For influenza vaccine, analysis included reports registered after 1 January 2011 (coinciding with the H1N1 mass immunization).

Second analysis: the group of interest was mRNA COVID-19 vaccine recipients being under the age of 40 and the comparator group was mRNA COVID-19 vaccine recipients being over the age of 40. Of note, patient age is not recorded in some reports, so these were not considered in this analysis. ROR, reporting odds ratio; 95% CI, 95% confidence interval.

influenza vaccination. HZ reactions following mRNA COVID-19 vaccination usually remain mild, without reported case-related mortality, and appeared infrequent as reflected by the billions of doses administered so far. Further clinical data are needed to confirm this signal, which should not hamper the use of mRNA COVID-19 vaccines, whose benefits dramatically outweigh this risk.

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COMPETING INTERESTS

The authors report that there are no conflicts of interest to declare.

CONTRIBUTORS

L.-H.P., A.C. and L.C. conceived and designed the study. L.-H.P., A.C. and L.C. were responsible for data acquisition, analysis and interpretation. L.-H.P. and A.C. drafted the manuscript, which was critically reviewed by all the authors. L.C. supervised the study.

DATA AVAILABILITY STATEMENT

Vigibase is a fully anonymized database of spontaneous reports from WHO, access is granted for national or regional pharmacovigilance centers, as our team. The information within VigiBase, the WHO global pharmacovigilance database, comes from a variety of sources, and the probability that the suspected adverse effect is drug-related is not the same in all cases. The present analysis does not represent the opinion of the UMC or the World Health Organization and only reflects the authors opinion.

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SUPPORTING INFORMATION

Additional supporting information may be found in the online version of the article at the publisher's website.

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