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BioNTech COVID-19 (BNT162b2) Vaccination and Varicella Zoster Reactivation: A Comprehensive Cross-sectional Study

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Herpes zoster (HZ) results from reactivation of latent varicella-zoster virus. Recent observations have suggested that HZ is associated with vaccination against COVID-19. To investigate the association between the vaccine and HZ severity, a single-centre, cross-sectional study of all patients diagnosed with HZ and 2 control diagnoses (cellulitis and bone fractures), between 2017 and 2021, was performed. Hospital visits and hospitalization rates were compared. All medical records of patients diagnosed with HZ in the first year after the COVID-19 vaccination campaign began were reviewed, in order to generate a retrospective cohort comparing vaccinated and unvaccinated patients with HZ. All participants had received the Pfizer–BioNTech COVID-19 (BNT162b2) vaccine. During the study period, 2,413 patients were diagnosed with HZ, and when normalized to control diagnoses the number of cases remained stable. The retrospective cohort included 365 patients. A multivariate analysis controlling for sex, age, autoimmune diseases, malignancies, and immunosuppressive therapy showed higher admission rates in vaccinated compared with unvaccinated individuals (odds ratio (OR) 2.75, 95% CI 1.27–5.96, $p = 0.01$). However, matching techniques and stratification by age, used to better control for confounders, invalidated these findings. No differences were observed in other variables indicative of disease severity (hospital stay length and complications). In conclusion, COVID-19 vaccination was not found to be associated with an increased risk of HZ-related admission and complications.

Key words: herpes zoster; COVID-19; Pfizer–BioNTech COVID-19 (BNT162b2) vaccine.

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SIGNIFICANCE

Previous studies have shown that the BNT162b2 COVID-19 vaccine may increase the risk of varicella-zoster reactivation, resulting in herpes zoster. To investigate this, this study compared HZ-related cases and hospitalization rates between 2017 and 2021. The study also reviewed hospital records of all patients with herpes zoster during the first year after the COVID-19 vaccination campaign began, comparing vaccinated and unvaccinated patients. This study found no evidence that the COVID-19 vaccine increases the severity of herpes zoster cases, or the number of hospitalizations caused by herpes zoster.

Herpes zoster (HZ) is caused by the reactivation of latent varicella-zoster virus (VZV) in the sensory or autonomic ganglia. Reactivation is usually attributed to impaired cell-mediated immunity associated with advanced age, comorbidities and iatrogenic causes (1). Other factors associated with VZV reactivation are various infections, including severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) (2–5), as well as some vaccines (6).

SARS-CoV-2 caused a worldwide pandemic, COVID-19, beginning December 2019. In December 2020, the US Food and Drug Administration (FDA) authorized the Pfizer-BioNTech COVID-19 (BNT162b2) vaccine under Emergency Use Authorizations. The Israeli COVID-19 vaccination campaign began soon after, on 20 December 2020. At first, all residents 60 years of age and older and high-risk individuals (such as severely immunocompromised patients and front-line healthcare workers) were eligible for vaccination, and by 4 February 2021, all persons over the age of 16 years became eligible (7). By March 2021, more than half of Israel's population had received 2 doses of the BNT162b2 vaccine (https://ourworldindata.org/coronavirus). This created a unique situation, as most Israeli residents received the same vaccine in a relatively short period of time. Moreover, since Israel's healthcare system provides medical insurance to all citizens, and medical files are shared between health organizations, vaccines' effectiveness and adverse reactions could be assessed in real-world settings (8, 9).

There are conflicting data regarding the association between BNT162b2 COVID-19 vaccine and VZV reactivation. While accumulating evidence supports increased incidence, and even severity, of HZ following vaccination (9–16), other studies refute it, including a large historic cohort from Israel (17, 18). A recent meta-analysis on this subject concluded that there is an increased risk of HZ within 7–10 days of vaccination (19). Therefore, the goal of this study was to evaluate the association between BNT162b2 vaccine and HZ severity and hospitalization rates.

MATERIALS AND METHODS

Two modalities were used to test the hypothesis. First, a cross-sectional study was conducted of all patients diagnosed with any manifestation of acute HZ and HZ-related complications between January 2017 and 31 December 2021 at Tel-Aviv Sourasky Medical Center, a university-affiliated tertiary medical centre. This hospital has 1,500 beds, and hosts approximately 400,000 inpatients and 1.8 million outpatient visits each year.

Data were initially collected from the hospital's database using MDClone (MDClone Ltd, Beer Sheva, Israel, version 6.1), a platform for big data extraction. All emergency department and outpatient clinic visits were screened. Characteristics of patients with HZ were compared over the years.

As emergency department visits and admission rates decreased globally during the pandemic (20), to control for these changes, HZ visits and admission rates were compared with those of other acute conditions that require immediate medical attention, but were not previously associated with COVID-19 vaccinations: cellulitis (of any anatomical site other than the upper limbs) and bone fracture (of any anatomical site). Based on the time of diagnosis, the study population was divided into 3 groups: "period 1", before the COVID-19 pandemic in Israel (January 2017 to February 2020); "period 2", during the COVID-19 pandemic and before the vaccination programme began (March 2020 to 19 December 2020); and "period 3", after the vaccination programme began (20 December 2020 to December 2021). Sex, age, comorbidities (haematological and solid malignancy, and autoimmune diseases), use of immunosuppressive therapy (immunosuppressive agents, biologics, chemotherapy) were extracted, as well as data regarding current illness (acute diagnosis, hospital admission, length of hospital stay and laboratory tests).

Although rare events of recurrent HZ may occur, to avoid potential confounders, in cases of multiple HZ events reported in a patient's medical record, only the first event was included in the analysis.

For patients diagnosed with HZ between 20 December 2020 and 31 December 2021, the first year after initiation of the COVID-19 vaccine campaign, an additional retrospective cohort study was performed, using a manual survey of all electronic medical records for validation. COVID-19 infection and vaccination status were extracted through the national digital vaccination database, including number of vaccines given and their dates. The last COVID-19 vaccine dose given prior to HZ diagnosis was considered.

As SARS-CoV-2 infection was previously reported to be associated with HZ reactivation, cases of confirmed infection prior to diagnosis of HZ were excluded from the analysis (total 18 cases, 7 of which were vaccinated).

The study protocol was approved by our institutional review board in adherence with the principles of the Declaration of Helsinki.

Statistical analysis

Comparison of categorical characteristics between the 3 periods and between vaccinated and unvaccinated patients was done using χ^2 test, while Mann–Whitney test was applied to compare continuous data. Hospital visits and admissions in the 3 periods were compared between the different diagnoses using χ^2 test and logistic regression. Multivariable logistic regression was used to study the association between vaccination and admission, while controlling for confounders: age, sex, autoimmune disease, and malignancy. To better control for potential confounders, vaccinated and unvaccinated patients were matched based on sex, age at diagnosis (±2 years), and presence of a previous diagnosis of solid malignancy, haematological malignancy, and autoimmune disease. Hospital admissions were compared between the matched pairs using McNemar's test.

All statistical tests were 2-sided and statistical significance was defined as p-value <0.05. Statistical analysis was performed using IBM SPSS Statistics for Windows, version 27 (IBM Corp., Armonk, NY, USA, 2020).

RESULTS

Demographic characteristics of the study participants

A total of 2,413 patients were diagnosed with HZ during the study period (1,589 cases in period 1, 336 cases in period 2, and 488 cases in period 3) (**Table I**). The median age at HZ diagnosis did not change significantly between the different study periods ($p=0.88$), and other demographics collected were also similar between the groups including sex ($p=0.3$), previous diagnosis of solid malignancy ($p=0.14$) and haematological malignancy ($p=0.58$). Previous diagnosis of an autoimmune disease was slightly higher in patients with HZ diagnosed in period 2 compared with period 1, but returned to baseline in period 3, after the vaccine ($p=0.03$, see Table I).

Out of 488 patients diagnosed with HZ between 20 December 2020 and 31 December 2021, only 365 patients had a definite diagnosis of HZ. A definite diagnosis was defined as typical clinical symptoms, and/or a confirmation by a positive PCR test for VZV. A positive PCR test for VZV was available for 86.9% of the patients. Of the 365 patients, 18 had previously recovered from COVID-19, and were therefore removed from the analysis. Of the remaining 347 subjects, 299 had been previously vaccinated at least once, and 48 had never previously been vaccinated (**Table II**). Of note, the total vaccination rate among all patients with VZV was 86.2%.

Herpes zoster related visits and hospitalization rates over the years

The number of HZ-related visits decreased significantly during the pandemic, from a mean of 41.3 cases per month before the pandemic, to 34.3 and 38.8 in periods 2 and 3, respectively. To control for this change, the proportion of HZ-related hospital visits was assessed compared with the total number of visits due to the control diagnoses, which were not previously associated with COVID-19 vaccine (cellulitis and bone fractures),

Table I. Characteristics of patients with HZ over the study period

	Period 1[a]	Period 2[b]	Period 3[c]	p-value
Number of patients	1,589	336	488	
Male sex, %	45.1%	41.4%	47.7%	0.3
Age, years, median, IQR	63.11 (42.83–76.68)	63.24 (43.81–75.06)	63.23 (42.7–74.34)	0.88
Autoimmune disease	5.7%	9.5%	5.7%	**0.03**
Solid malignancy	10.7%	11.9%	13.9%	0.14
Haematological malignancy	5.8%	7.1%	5.5%	0.58
Admission percentage	52.4%	38.7%	39.5%	**<0.01**

[a]January 2017 to February 2020. [b]March 2020 to 19 December 2020. [c]20 December 2020 to December 2021.
HZ: herpes zoster: IQR: interquartile range. Bold values denote statistically significant results ($p<0.05$).

Table II. Comparison between clinical characteristics and disease severity between vaccinated and unvaccinated patients with herpes zoster diagnosed after 20 December 2020

	Unvaccinated	Vaccinated	*p*-value
Number of patients	48	299	
Male sex, %	54.2%	45.5%	0.279
Age (years), median (IQR)	54.9 (33.5–68.4)	65.8 (43.4–75.3)	**0.011**
Autoimmune disease	8.3%	13%	0.481
Solid malignancy	12.5%	12.7%	0.97
Haematological malignancy	8.3%	7.7%	1
Immunosuppressive therapy	6.3%	9.4%	0.596
Biological therapy	4.2%	4.7%	1
Chemotherapy	12.5%	2.7%	**0.007**
Admission percentage	27.1%	48.2%	**0.008**
Length of hospitalization, days, median (IQR)	6.1 (3.04–7.5)	8.4 (4.45–12)	0.08
Associated neurological symptoms*	10.4%	9.4%	1
Associated complications**	6.3%	3.3%	0.401
White blood count			
Normal, 4–11*10³/μL	82.5	85.4%	0.72
Leukopaenia	7.5%	8.3%	
Leukocytosis	10%	6.3%	
Lymphocytes			
Normal, 1.2–3*10³/μL	62.5%	63.8%	0.122
Lymphopaenia	22.5%	29.9%	
Lymphocytosis	15%	6.3%	
C-reactive protein, normal range 0.03–5 mg/L	9.22	12.49	0.185

*Refers to severe headache, vomiting, nuchal rigidity, neurological deficiencies, altered mental state, etc. **Refers to herpes zoster ophthalmicus, acute retinal necrosis, Ramsay Hunt syndrome, and neurological complications.
IQR: interquartile range. Bold values denote statistically significant results ($p<0.05$)

over the 3 study periods. Out of all cases, the number of HZ-related visits remained similar (5.3%, 5.6% and 5.5% for periods 1, 2, 3 respectively, $p=0.137$). Admission rates for HZ decreased significantly during the pandemic, both in period 2 and 3 compared with period 1, the pre-COVID era (52.4%, 38.7%, 39.5%, $p<0.001$). Both control diagnoses showed a decrease in admission rates during the pandemic; however, to a lesser extent than HZ. After adjustment for age and sex, hospitalization rates were higher in both period 2 and period 3 for cellulitis (period 2: odds ratio (OR) 1.45, 95% confidence interval (95% CI) 1.11–1.9, $p<0.001$, period 3: OR 1.07, 95% CI 0.85–1.35 $p<0.001$) and bone fractures (period 2: OR 1.4, 95% CI 1.08–1.82, $p=0.01$, period 3: OR 1.32, 95% CI 1.06–1.54, $p=0.01$), compared with HZ.

Comparison between vaccinated and unvaccinated patients with herpes zoster

Demographics and patients' characteristics were compared between vaccinated and unvaccinated patients with HZ (Table II). Among the vaccinated group, 8.4% of patients had HZ following the first dose, 57.2% following the second dose, and 34.4% following the third dose. Of note, the intervals between the 3 vaccines were not constant per vaccination protocol, with 3 weeks between the first and the second vaccine, and 12–49 weeks between the second and third vaccine in the study cohort.

Reactivation occurred within 30, 30–90 and over 90 days following vaccination in 23.4%, 35.5% and 41.1% of patients, respectively, with a mean of 82.84 days and a median of 70 days (IQR 35–125).

The vaccinated patient population was significantly older than the unvaccinated (mean 65.84 (IQR 43.41–75.33) vs 54.89 (IQR 33.48–68.42) years of age, $p=0.011$ (Table II)). Although both groups had similar rates of solid and haematological malignancy (12.5% vs 12.7% for solid malignancy, $p=1$, and 8.3% vs 7.7% $p=1$, in unvaccinated and vaccinated, respectively), higher rates of current chemotherapy were observed among unvaccinated patients compared with vaccinated (12.5% vs 2.7%, $p=0.007$); however, the number of patients in each group was low (6 and 8 patients, respectively) (Table II). This could be easily attributed to avoidance of vaccination during profound immunosuppression states.

No significant differences were observed between the groups in terms of sex, autoimmune comorbidities, and other immunosuppressive therapy (Table II).

Herpes zoster severity

Admission rates were significantly higher in the vaccinated compared with the unvaccinated group (48.2% vs 27.1%, respectively, $p=0.008$ (Table II)). Variations in variables indicating infection severity, such as abnormal lymphocytes and leukocytes counts, and elevated C-reactive protein (CRP) rates, were not statistically significant (Table II). Of note, higher rates of elevated CRP, leukocyte and lymphocytes abnormalities were seen in hospitalized patients, regardless of their vaccination status (61.8% vs 42.8, $p<0.001$, 21% vs 8%, $p=0.007$, 45.2% vs 26.3%, $p<0.001$).

To control for confounders, multivariable logistic regression was used. Variables included in the analysis were sex, age, presence of an autoimmune disease, solid organ or haematological malignancy and immunosuppressive therapy (including biologic treatment, chemotherapy, and disease-modifying antirheumatic drugs (DMARDs)). The OR for hospitalization among vaccinated patients was 2.75 (95% CI 1.27–5.96, $p=0.01$). Other significant variables in our analysis were age (OR 1.02, 95% CI 1.01–1.03, $p=0.006$), presence of a haematological malignancy (OR 3.84, 95% CI 1.33–11.06, $p=0.01$), and usage of DMARDs (OR 3.08, 95% CI 1.06–8.93, $p=0.04$). However, sample size for the latter 2 was rather small (a total of 27 and 31 patients, respectively).

To better control these confounders, vaccinated and unvaccinated patients were matched based on sex, age at diagnosis (±2 years), presence of a previous diagnosis of an immunosuppressive condition and current immunosuppressive therapy, as mentioned above. Of the 48 unvaccinated patients in the study cohort, 39 were successfully matched. Hospitalization rates became similar among vaccinated patients compared with unvaccinated patients after matching (46.2% vs 23.1%, $p=0.078$) (**Table III**).

Table III. Comparison between clinical characteristics and disease severity between 39 matched pairs of vaccinated and unvaccinated patients with herpes zoster

	Unvaccinated	Vaccinated	*p*-value
Age, years, median, IQR	56.81 (31.58–65.67	57.53 (31.45–66.99)	
Sex (male), %	56.4	56.4	
Autoimmune disease, %	2.6	2.6	
Solid malignancy, %	10.3	10.3	
Haematological malignancy, %	2.6	2.6	
Admission percentage, %	23.1	46.2	0.78

IQR: interquartile range.

Similarly, no difference was observed in hospitalization rates between vaccinated and unvaccinated patients when stratified by age group (under 30, over 90 years of age, and in 10 years interval in between; data not shown).

A sub-analysis of the vaccinated group, according to number of days between the last vaccine (within 30, 30–90, over 90 days), showed no difference in hospitalization rates (hospitalization rates were 48.6%, 49.1% and 47.2%, respectively, $p=0.96$), further arguing against an association between HZ and the vaccine.

To further investigate the possibility that COVID-19 vaccines influence HZ severity, the study used several parameters that may be indicative of a more severe infection, none of which yielded significance. Among hospitalized patients, the length of hospital stay was similar between the 2 groups, with a median of 6.1 days in vaccinated (IQR 3.04–7.5) and 8.4 in unvaccinated individuals (IQR 4.45–12), $p=0.08$ (Table II). HZ complications (HZ ophthalmicus, acute retinal necrosis, Ramsay Hunt syndrome, and neurological complications) were seen in a total of 13 patients, 3.3% of the vaccinated population and 6.3% of unvaccinated patients; however, this difference was not significant ($p=0.36$). Vaccination status was also not associated with the number of dermatomes clinically involved. In the current study cohort, 62.2% of vaccinated patients and 72.9% of unvaccinated patients had an involvement of 1 dermatome, 27.1% vs 20.8% of 2 dermatomes, and 4.3% vs 6.3% of 3 dermatomes, respectively. Of note, disseminated HZ was seen only in the vaccinated group, in 19 patients (6.4%); however, as mentioned above, significance was not reached ($p=0.13$).

DISCUSSION

This study sought to investigate possible associations between exposure to the BNT162b2 vaccine and HZ reactivation. Overall, the results do not point to a significant impact of BNT162b2 vaccination on HZ severity and hospitalization rates. The results do not agree with those of some previously mentioned studies (9–16, 19). This may be, at least in part, due to publication bias (21).

In this research project we used a unique methodology. We performed a retrospective cohort study on all patients diagnosed with HZ, regardless of their vaccination status, during the first year after vaccination campaign began. We did not see a rise in the number of cases of HZ during 2021 compared with other diagnoses, despite the fact that more than 50% of the Israeli population was vaccinated during that year, nor was a change seen in HZ patients' characteristics over the previous 5 years.

Several variables were used to compare complication rates and disease severity between vaccinated and unvaccinated patients. Hospitalization rates were compared, and although results of a multivariate analysis initially indicated higher admission rates in vaccinated patients, a comprehensive review of possible confounders and the use of stratification and matching techniques eventually ruled out this association. It seems that the higher admission rates among vaccinated patients in the multivariate analysis is attributed to a violation in 1 or more of the logistic regression assumptions. Furthermore, among vaccinated patients, hospitalization rates were similar regardless of the length of time from the last vaccine, contradicting previous reports, including 1 report suggesting that increased risk of HZ hospitalizations occurred 2–4 weeks after COVID-19 vaccination (22).

Previous studies have demonstrated lymphopaenia and elevated CRP following COVID-19 vaccine, that were considered as pharmacodynamic markers of mRNA vaccines (23). The duration of these changes is not yet known. Decreased lymphocyte count may impair immune response against VZV infection and predispose reactivation. On the other hand, these laboratory abnormalities may be a consequence of increased severity of HZ infection, rather than its cause. The current study did not find significant laboratory abnormalities in vaccinated patients. However, hospitalized patients had higher rates of laboratory abnormalities, suggesting the latter explanation for findings of previous studies.

The strength of the current study arises from its methodology, using 2 different data extraction modalities, as mentioned above, a gross, cross-sectional study using big data modalities, and subsequent revalidation by an individual inspection of all patients' medical records, creating a retrospective cohort. Of note, the differences seen between the retrospective cohort group and its time equivalent in the cross-sectional study (488 vs 365 patients) are attributed to lower quality of data that is often seen in big data studies, and points to some disadvantages of this type of study. As the data were used only to demonstrate trends in HZ incidence, we assume similar distributions of intervening factors along the years and between study and control groups.

The high quality of the study cohort data are also reflected by the high rates of positive VZV PCR tests (86.9% of patients), confirming clinical HZ diagnosis.

Limitations

This study's limitations arise from its design, as a single-centre study. Although serving a relatively large

heterogeneous population, it does not reflect the entire population of Israel. This can also be seen in the high vaccination rate in the study cohort (86.2% vs approximately 72% of Israel's population during the study period).

This study does not adress the association between HZ and other COVID-19 vaccines, as during the study period, none of the patients in our cohort received any COVID-19 vaccine other than BNT162b2.

A possible confounder of the association between vaccine and hospitalization rate may be mediated by attitude toward medical care, with unvaccinated patients less inclined to accept medical care in a hospital setting. This was indirectly controlled for by using matching techniques. Also, for these reasones, incidence of HZ could not be assesed in this study.

An additional limitation may be the impact of SARS-CoV-2 itself, and not the vaccine on HZ rates. Even though we attempted to monitor for this by excluding patients previously infected with COVID-19, some infections were asymptomatic, and the sensitivity of COVID-19 tests is limited.

Conclusion

The results of this study do not indicate an association between BNT162b2 COVID-19 vaccine and HZ reactivation, nor does the vaccine affect the severity of HZ disease. These findings emphasize the importance of publishing non-significant results. Further studies are needed to confirm these observations.

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This study protocol was reviewed and approved by the Tel-Aviv Medical Center institutional review board in adherence with the principles of the Declaration of Helsinki (approval number TLV-0382-21). Written informed consent was not required.

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