

Coronavirus Pandemic

Side effects of the Pfizer BioNTech vaccine in health workers of a hospital in the southeast of Mexico

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Abstract

Introduction: The goal of this study was to evaluate the side effects of application of the Pfizer BioNTech vaccine on the workers at a Mexican hospital.

Methodology: A cross-sectional study was carried out, in which 1351 workers from a tertiary care center in the Mexican southeast were included. Sociodemographic data, comorbidities, and side effects after the Pfizer BioNTech vaccine were obtained through an online survey. The variables were analyzed through descriptive statistics. The presence or absence of side effects was analyzed through the Chi-square test or t-test, as appropriate. The result was considered statistically significant at $p < 0.05$.

Results: A total of 1351 health workers participated in the online survey. The mean age was 37.8 ± 10.9 years and 56.4% were women. Among them, 8.2% suffered from high blood pressure. In addition, 76.7% manifested pain in the application area. The presence of side effects was associated with the female gender ($p < 0.01$). Side effects were more prevalent in younger age (37.2 ± 10.7) than older age (41.5 ± 10.8) ($p < 0.01$). There was no association with the presence of comorbidities ($p > 0.05$).

Conclusions: The data suggest that pain in the application area is the most frequent side effect among workers in a Mexican hospital who received the Pfizer BioNTech vaccine against COVID-19. In addition, we observed sialorrhea as a side effect in the studied population and this had not previously been reported. The highest number of adverse events occurred between 24 to 72 hours after application.

Key words: BNT162; vaccine; pain; COVID-19; hospital; workers.

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Introduction

The coronavirus disease 2019 (COVID-19) is caused by Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) and was declared a pandemic by the World Health Organization (WHO) on 11 March 2020. COVID-19 is a heterogeneous infection that has contributed to more than 2.5 million deaths around the world [1]. The deaths are primarily associated with the poor prognosis associated with advanced age [2], high blood pressure, diabetes, obesity [3] and employment in the health sector [4].

Given the need to minimize the unwanted immune response caused by SARS-CoV-2 and contain the pandemic [5], the accelerated production of approximately 140 vaccines was initiated. These vaccines consisted mainly of mRNA, DNA, and adenovirus vectors [6]. Based on data from clinical trials, the BNT162b2 vaccine (produced by Pfizer &

BioNTech) received authorization for use on 26 November 2020 [7].

The Dr. Juan Graham Casasús tertiary care center was officially designated as a COVID Center in Tabasco, Mexico. Large scale efforts were needed to contain the pandemic because the cases were increasing rapidly, and the hospital converted to a COVID-19 care center in April 2020. This change included increasing the number of hospital beds to 125, which included 75 Intensive Care Unit (ICU) beds. Nearly 900 new health care workers were hired for this COVID-19 care center.

The Pfizer BioNTech COVID-19 vaccine was administered to the health care workers in the first line of care as an emergency strategy to prevent collapse of the health system and reduce mortality [8]. Efficacy of this vaccine is under constant evaluation [9]; however, there are a few scientific reports of related adverse events among Mexicans. Therefore, the main objective

of this study was to evaluate, in a simplified way, the side effects of the application of the Pfizer BioNTech COVID-19 vaccine.

Methodology

A quantitative investigation with a retrospective cross-sectional design was carried out between February and March 2021. We recruited 1351 workers from the Dr. Juan Graham Casasús hospital, Tabasco México.

This study included all the subjects assigned to the hospital, who belonged to any of the work categories, who received the first dose of the Pfizer BioNTech vaccine against COVID-19 in February 2021, who responded to the online survey, and who agreed to participate by signing an informed consent document.

Data collection

We designed a data collection form with three parts. The first part collected sociodemographic information and antecedents, such as age, sex, and comorbidities, the second and third parts explored the side effects that occurred immediately after injection and the appearance of reactions through 24, 48, and 72 hours after administering the vaccine.

Systematization and statistical analysis

The data collection form was distributed through the online tool Google Forms. Subsequently, the variables were systematized and analyzed in the statistical program SPSS (Statistical Package for Social Sciences) v21. All the variables were summarized through appropriate descriptive statistics. The

Table 1. Frequency of comorbidities in health workers of a hospital in southeast of Mexico.

	Yes, N (%)	No, N (%)
Hypertension	111 (8.2)	1240 (91.8)
DM2	78 (5.8)	1273 (94.2)
Asthma	35 (2.6)	1316 (97.4)
Hypothyroidism	11 (0.8)	1340 (99.2)
Cardiovascular disease	7 (0.5)	1344 (99.5)
Fibromyalgia	4 (0.3)	1347 (99.7)
Rheumatoid arthritis	5 (0.1)	1346 (99.9)
Multiple sclerosis	1 (0.1)	1350 (99.9)
Lupus Erythematosus	1 (0.1)	1350 (99.9)
Osteoporosis	1 (0.1)	1320 (99.9)

DM2: type 2 diabetes; N: frequency, %: percentage.

quantitative variables were described through mean and standard deviation; the qualitative variables described through frequency and percentage. We used a t-test for age for the comparisons between the groups. Sex and comorbidities were dichotomized, and we used the Chi Square test. A *p* value of < 0.05 was considered statistically significant.

Results

Sociodemographic characteristics

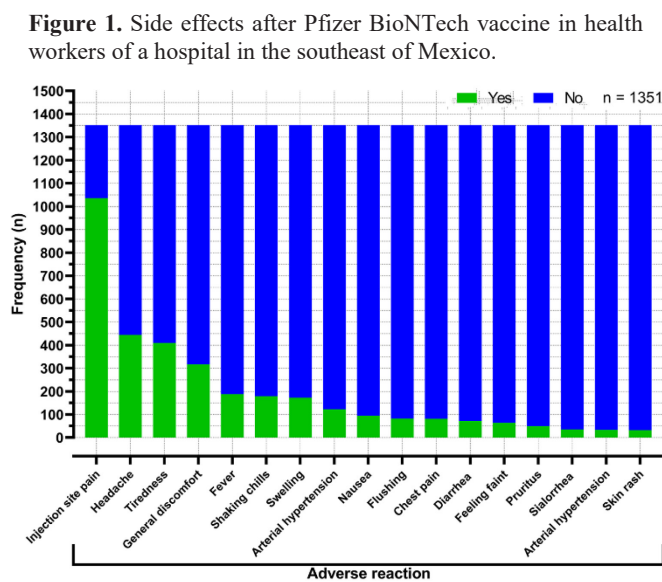
We included a total of 1351 subjects. Based on the sociodemographic characteristics, the mean age was 37.8 ± 10.9 years with a minimum of 19 and a maximum of 70 years, 56.4% (n = 762) were women and 43.6% (n = 589) were men, and 84.1% (n = 1136) had no comorbidities. However, the mean of number of comorbidities was 0.18 ± 0.45, with a maximum of 3 comorbidities. In addition, 8.2% of the population suffered from arterial hypertension and 5.8% had type 2 diabetes mellitus (Table 1).

Analysis of reactions after the application of the Pfizer BioNTech vaccine

There was a mean of 2.5 ± 2.3 side effects resulting from the vaccine. Among these side effects, the most frequent was a pain in the application area in 76.7% (n = 1036) of the subjects, 32.9% (n = 444) presented headache, and 30.3% (n = 409) reported fatigue (Figure 1).

Pain in the injection area, headache, and general discomfort appeared immediately after application with a tendency to increase 24 hours after application until disappearing at 72 hours (Figure 2). Interestingly, our data showed that sialorrhoea was a side effect among the Mexican health workers.

There were significantly higher side effects among the younger (37.2 ± 10.7 yrs) than older (41.5 ± 10.8 yrs) workers (*p* < 0.000). Side effects were significantly higher in females than males (*p* < 0.000). However,



The bars represent the frequency by the event.

there was a lack of association of side effects with the presence of comorbidities ($p > 0.05$) (Table 2).

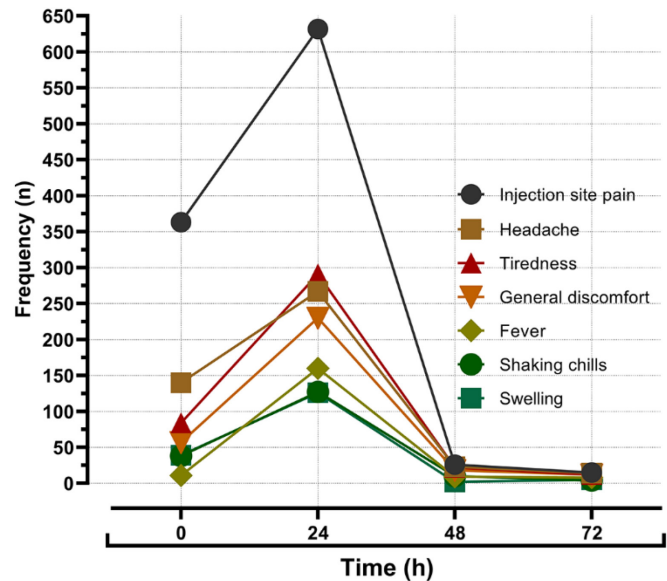
Discussion

This study represents the first investigation on the side effects reported by healthcare workers after receiving the first dose of the Pfizer BioNTech vaccine against COVID-19 in a Mexican hospital. The most frequent side effect in the overall cohort was pain at the injection site, followed by headache, tiredness, and general discomfort. Comparable results were reported previously for the injection site pain. Fatigue, headache, myalgia, fever, dizziness, chills, and nausea were the most common reactions in a group that received the vaccine against the COVID-19 [10,11] However, it should be noted here that Gee *et al.* reported that an American cohort had 6,994 reports of side effects after vaccination, and 113 reports of death without any association with COVID-19 vaccination [10]. Similarly, there were no reports of death among our study population.

Interestingly, in this study, we determined that 3% of the total population developed sialorrhea as a symptom following the administration of the Pfizer BioNTech vaccine. Based on the above considerations, it is necessary to integrate previous reports that confirm the presence of morbilliform rash [12] increased heart rate (tachycardia) [13], and acute onset supraclavicular lymphadenopathy [14] after receiving the COVID-19 vaccine. Interestingly, sialorrhea is not described in the vaccine's technical data sheet and has not been reported in previous studies.

Overall, the side effects increased after 24 hours and remained for up to 72 hours after vaccine administration. However, a previous report suggested that 1% of the US population had a non-severe side effect after the injection of the first dose of the Pfizer BioNTech COVID-19 vaccine in the form of increased pain at the site of application, which was present for up to 7 days after vaccination [10]. This discrepancy with the presence of side effects can be attributed to the variability of the population and the environment. A

Figure 2. Temporal course of most frequent side effects in health workers of a hospital in southeast of Mexico.



The values were expressed as frequency through the time

limitation of this study is that we examined only the adverse reactions over three days.

Surprisingly, the data indicated that side effects were more frequent in women and in the younger subjects (< 38 years), while there was no correlation with presence of comorbidities. These results are consistent with those reported by the Centers for Disease Control and Prevention (CDC), where it has been suggested that adverse reactions are more frequent in females, although these findings were attributed to the fact that women constituted the largest proportion of the study group [15].

Conclusions

Finally, the data suggest that in a heterogeneous group of healthcare workers in a Mexican hospital, pain in the area the application is the most frequent side effect after the application of the Pfizer BioNTech vaccine against COVID-19.

Table 2. Side effects in health workers of a hospital in southeast of Mexico.

Characteristics	Side effects		P
	Yes	No	
Age	37.2 ± 10.7	41.5 ± 10.8	0.000*
Gender			
Male	81.3% (479)	18.7% (110)	0.000*
Female	88.2% (672)	11.8% (90)	
Comorbidities			
Yes	87.0% (187)	13.0% (28)	0.465
No	84.9% (964)	15.1% (200)	

N: frequency, %: percentage, * $p < 0.05$ Chi-square test or t-Test.

The current study provided evidence of the presence of sialorrhoea as a side effect present in the studied population and it had not been reported previously. The most significant number of side effects were observed from 24 to 72 hours after application.

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