

## RESEARCH

### Post-vaccination COVID-19 side effects in the Zacatecas population

### Efectos secundarios post vacunación COVID-19 en población Zacatecana

### Efeitos colaterais da COVID-19 pós-vacinação na população Zacatecana

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### Abstract

**Introduction:** COVID-19 is a pathology that can be fatal; vaccination has been shown to be effective in reducing mortality, side effects may occur, the management and administration of vaccines by nursing personnel has been essential to reduce the presence of severe cases. **Objective:** To compare the side effects presented in the first and second doses of COVID-19 vaccines by sociodemographic characteristics in the Zacatecas population. **Methodology:** descriptive, comparative study, in 366 Zacatecas adults selected by non-probabilistic sampling, of legal age, who had two doses of anticovid-19 vaccine, those who did not have a national health card or proof of vaccination were excluded, the Technical Sheet of Adverse Effects post-vaccination COVID-19

was applied; Adverse effects were considered as an unwanted response following vaccination. The study subjects participated voluntarily, anonymously and obtained prior signature of informed consent. Data were analyzed using descriptive statistics and non-parametric tests. **Results:** The majority were women, with 2 doses of vaccine, 45.9 % were vaccinated Pfizer, 68.6 % had COVID-19 before being vaccinated, there were greater side effects in the group of 18 to 30 years, there were no statistically significant differences by education, marital status, socioeconomic level and place of residence, in the first and second doses of the AstraZeneca vaccines, Cansino and Moderna had more side effects than Pfizer. **Conclusions:** The present study coincides with research conducted where side effects were lower at the second dose. The present study reaffirms that research conducted on the side effects of COVID-19 vaccines.

**Key words:** After effect; COVID-19; Vaccines (DeCS).

### Resumen

**Introducción:** La COVID-19 es una patología que puede ser mortal, la vacunación ha demostrado ser eficaz para reducir la mortalidad, pudiesen presentarse efectos secundarios, la gestión y administración de vacunas por personal de enfermería ha sido fundamental para disminuir la presencia de casos graves. **Objetivo:** Comparar los efectos secundarios presentados en la primera y segunda dosis de vacunas COVID-19 por características sociodemográficas en población zacatecana. **Metodología:** Estudio descriptivo, comparativo, en 366 adultos zacatecanos seleccionados por muestreo no probabilístico, mayores de edad, que contaban con dos dosis de vacuna anticovid-19, se excluyeron a quienes no contaran con cartilla nacional de salud o comprobante de vacunación, se aplicó Ficha técnica de Efectos adversos post-vacunación COVID-19; los efectos adversos se consideraron como una respuesta no deseada posterior vacunación. Los sujetos de estudio participaron de manera voluntaria, anónima y se obtuvo firma previa de consentimiento informado. Los datos se analizaron mediante estadística descriptiva y pruebas no paramétricas. **Resultados:** La mayoría fueron mujeres, con 2 dosis de vacuna, 45.9 % se aplicó vacuna Pfizer, 68.6 % presentó COVID-19 antes de ser vacunado, hubo mayores efectos secundarios en el grupo de 18 a 30 años, no hubo diferencias estadísticas significativas por escolaridad, estado civil, nivel socioeconómico y lugar de residencia, en primera y segunda dosis las vacunas AstraZeneca, Cansino y Moderna presentaron mayor efecto secundario que Pfizer. **Conclusiones:** El presente estudio coincide con investigaciones realizadas donde los efectos secundarios fueron menores en la segunda dosis.

**Palabras clave:** Efecto Secundario; COVID-19; Vacunas (DeCS).

### Abstrato

**Introdução:** A COVID-19 é uma patologia que pode ser fatal; a vacinação tem se mostrado eficaz na redução da mortalidade, efeitos colaterais podem ocorrer, o manejo e administração de vacinas pela equipe de enfermagem tem sido essencial para reduzir a presença de casos graves. **Objetivo:** Comparar os efeitos colaterais apresentados na primeira e segunda doses de vacinas COVID-19 por características sociodemográficas na população Zacatecas. **Metodologia:** estudo descritivo, comparativo, em 366 adultos Zacatecanos selecionados por amostragem não probabilística, maiores de idade, que receberam duas doses da vacina anticovid-19, excluídos aqueles que não possuíam cartão nacional de saúde ou comprovante de vacinação, aplicou-se a Ficha Técnica de



Efeitos Adversos pós-vacinação COVID-19; Efeitos adversos foram considerados como uma resposta indesejada após a vacinação. Os sujeitos do estudo participaram de forma voluntária, anônima e obtiveram assinatura prévia do termo de consentimento livre e esclarecido. Os dados foram analisados por meio de estatística descritiva e testes não paramétricos. **Resultados:** A maioria eram mulheres, com 2 doses da vacina, 45,9 % foram vacinados Pfizer, 68,6 % tiveram COVID-19 antes de serem vacinados, houve maiores efeitos colaterais no grupo de 18 a 30 anos, não houve diferenças estatisticamente significativas por escolaridade, estado civil, nível socioeconômico e local de residência, na primeira e segunda doses das vacinas da AstraZeneca, Cansino e Moderna tiveram mais efeitos colaterais do que a Pfizer. **Conclusões:** O presente estudo coincide com a pesquisa conduzida onde os efeitos colaterais foram menores na segunda dose. O presente estudo reafirma que a pesquisa conduzida sobre os efeitos colaterais das vacinas COVID-19.

**Palavras-chave:** Efeito colateral; COVID-19; Vacinas (DeCS).

## Introduction

The pandemic <sup>(1)</sup> caused worldwide by COVID-19 reiterated the fundamental role carried out by the nursing and health personnel in Mexico <sup>(2)</sup> and worldwide <sup>(3)</sup>, nursing leadership was key in the development of health care processes to achieve immunization against COVID-19. All vaccines against COVID-19 must comply with rigorous efficacy and safety standards for their development, established by the World Health Organization, as well as regulatory entities of each country <sup>(4,5)</sup>. The information provided by this research may be useful to carry out an analysis of the adverse reactions reported after the application of vaccines against COVID-19 in the Zacatecas population and to expand the knowledge in conjunction with the clinical trials and reports of epidemiological pharmacovigilance reports about the adverse effects of vaccination. According to the Center for Disease Control and Prevention (CDC), antiCOVID-19 vaccines protect people from becoming infected with the disease and from developing serious symptoms if they become infected <sup>(6)</sup>. Occasionally, after vaccination, the process of generating immunity can cause symptoms, such as fever <sup>(7)</sup>. Among the nucleic acid vaccines we find: Pfizer-BioNTech, Moderna, CureVac, ARCoV, Zydus Cadila, Osaka University/Anges, Inovio Pharmaceutical, for viral vectors; Oxford-AstraZeneca, Janssen from Johnson & Johnson, Sputnik V, CanSino, Patria of AVI-MEX



Laboratory, GRAd-COV2 of ReiTher, of inactivated live viruses; CoronaVac of Sinovac, BBIBP-CorV of Sinopharm, Covaxin of Bharat BioNTech, Vero Cells, QazVac, COVIran Barekat, acellular vaccines; Novavax, Sanofi Pasteur/GSK, Soberana 2, EpiVacCorona, Abdala, Medicago, Vaxxinity, among others <sup>(8)</sup>. Some documented possible side effects consist of: pain, redness or swelling of the injection site, fever, fatigue, headache, myalgia, chills, arthralgia, nausea, vomiting, lymphadenitis and asthenia <sup>(9,10)</sup>. The deployment of above described vaccines occurred by prioritizing the population: first, health personnel who faced COVID-19 were vaccinated, second, the population aged 60 and over, and fifth the rest of the population <sup>(11)</sup>. The frequently reported systemic adverse reactions were fatigue, headache, fever and myalgia <sup>(6)</sup>, the Moderna vaccine (mRNA-1273) reported hypersensitivity 48 hours after the first dose, after receiving the second dose of the vaccine no severe adverse events were observed <sup>(12)</sup>.

Studies on side effects of COVID-19 vaccines have been reported; after the application of the first dose the reactions reported were: fever, headache, myalgia, chills, asthenia, local reaction, general malaise, nausea, lymphadenopathy, arthralgia, pain in extremity and insomnia. After applying the second dose, results were similar to those of the first dose, presenting adverse reactions reported as mild or moderate <sup>(13)</sup>, in Spain <sup>(14)</sup> 87.4 % of participants notified the presence of side effects after the 1<sup>st</sup> dose and 86.6% showed side effects after the 2<sup>nd</sup> dose, consisting of: fever, headache, myalgia, chills, asthenia, local reaction, general malaise, nausea, lymphadenopathy, arthralgia, pain in extremity and insomnia. In Ecuador, the adverse reactions notified were mild or moderate <sup>(15)</sup>, arm pain (31.9 %), headache (15.4 %) and fever (13.9 %).

In Paraguay <sup>(16)</sup>, the side effects presented were: arm pain (84.1 %) weakness/fatigue (75.9 %), headache (65.5 %), joint pain (48.8 %), chills (41.4 %), fever (39.1 %) and nausea (33.3 %), in another study in Paraguay <sup>(16)</sup> the 76.3 % described at least one side effect; pain at the puncture site (57.3 %), asthenia (28.4 %), and headache (23.7 %), after vaccination, 9.3 % of respondents



claimed to have been infected with COVID-19, 6.3 % required hospitalization. In Ecuador, the AstraZeneca vaccine reported a higher incidence of side effects: muscle pain, headache and fever, the manifestations were of mild intensity in women <sup>(17)</sup>, in Chihuahua, Mexico, 70.7 % were female, pain was reported in: puncture site, body, head, joints, fever, tiredness, dizziness, swollen glands, lack of appetite, insomnia, tiredness <sup>(12)</sup>. As described above, the purpose of the study was to compare the side effects presented in the first and second doses of COVID-19 vaccines by sociodemographic characteristics in the Zacatecas population.

### **Methodology**

Quantitative, cross-sectional, descriptive and comparative study <sup>(18)</sup>. The population consisted of people between 18 and 85 years old who attended the application of COVID-19 vaccines during the period from March to September 2022, in a first level public health institution. Sample of 366 participants, non-probabilistic sampling for convenience, those who came on the day of data collection were included, with 2 doses of vaccine applied independently of whether a vaccine from a different laboratory was administered in the 2 doses, and agreed to participate in the study, the elderly adult who was accompanied at the time of the interview by a family member or guardian to whom the interview was directed <sup>(19)</sup>, was considered a participant; including those who had 1 dose of CanSino vaccine as a complete schedule; excluded were those who did not have any dose of COVID-19 vaccine and those who presented incomplete proof of vaccination or of national health card; eliminated were those who did not accept to participate and did not respond adequately to the surveys; authorization was requested from the directors of the institution who designated the day and time for the collection of data, the participants were contacted face to face in the hallway of the institution, if they accepted to participate, they filled out the informed consent and afterwards the survey, it took them approximately 15 minutes to answer, their participation was thanked for and the telephone number of the main researcher was provided to them, in case of any doubt.



For the data collection a sociodemographic data sheet prepared by the study's authors was used, including dates of application of the last vaccine dose, number of doses received, type of vaccine, whether it had any side effects, duration time, also used was the Technical Sheed of Adverse Effects (FTEA) post-COVID-19 vaccination used in the Mexican population, <sup>(12)</sup> which includes possible adverse effects through dichotomous response options: a) fever, b) headache, c) muscle aches, d) chills, e) weakness, f) pain in the application area, g) nausea, h) general malaise, i) joint pain, j) insomnia, k) diarrhea, and l) sore throat. For the development of the research, the criteria established in articles 13, 114 and 16 of the Regulations of the General Health Research Law were considered, which state: voluntary, anonymous participation and signing of informed consent <sup>(20)</sup>, the Declaration of Helsinki of 1975 <sup>(20)</sup>, the bioethical principles: non-maleficence, beneficence, justice and autonomy, in addition, was obtained from the Research Ethics Committee with registration CEI-UAMHyCS-02-2023.

The data analysis was carried out with the statistical program Statistical Package for the Social Sciences (SPSS) version 23, the sociodemographic variables were analyzed with descriptive statistics, frequencies and proportions were obtained for the dichotomous variables and the mean and standard deviation for the continuous variables, inferential statistics were used through non-parametric Mann Whitney U and Kruskall Wallis H tests.

## **Results**

The participants were 70.8 % women, with a bachelor's education (68 %), medium socioeconomic level (77.9 %), residing in Zacatecas capital (31.4 %) or a municipality (32.8 %), the minimum age was 18 years and the maximum 85 years old. Regarding the COVID-19 vaccination data, 33.1 % had more than 6 months of application of the COVID-19 vaccine, 87.4 % had 2 doses applied, 45.9 % had the Pfizer vaccine, 37.2 % AstraZeneca, 13.1 % Cansino and 2.5 % Moderna, 68.6 %



reported having gotten sick from COVID-19 before being vaccinated, 90.3 % had some post-vaccination side effect, (Table 1).

Table 1. COVID-19 vaccine application data in the Zacatecas population 2023 (n=366).

Variable	n	%
Application date		
Less than 6 months	29	7.9
More than 6 months	121	33.1
Less than 1 year	102	27.9
More than a year	114	31.1
COVID-19 vaccine doses		
1st dose	46	12.6
2nd dose	320	87.4
Type of vaccine applied		
Pfizer	168	45.9
AstraZeneca	136	37.2
Moderna	9	2.5
Cansino	48	13.1
Other	5	1.4
Did you have COVID-19 before being vaccinated?		
Yes	115	31.4
No	251	68.6
Did you have any side effects after receiving the vaccine?		
Yes	273	74.6
No	93	25.4

Source: Self-development

The main side effects in the 1st dose were pain at the application site with 69.1% and muscle pain with 55.7%; while in the 2<sup>nd</sup> dose the main post vaccination side effects were pain at the application site with 53.3% and headache with 41.3%, (Table 2).

Table 2. Data sheet scores for adverse effects after COVID-19 vaccination, 2021, (n=366)

Variable	Response	1st dose		2nd dose	
		n	%	n	%
1. Fever	Yes	162	44.3	107	29.2
	No	204	55.7	259	70.8
2. Headache	Yes	200	54.6	151	41.3
	No	166	45.4	41.3	58.7
3. Muscle pain	Yes	204	55.7	146	40.1
	No	162	44.3	218	59.9
4. Chills	Yes	155	42.3	105	28.7
	No	210	57.4	261	71.3
5. Weakness	Yes	179	48.9	115	31.4
	No	187	51.1	251	68.6
6. Pain in the application area	Yes	253	69.1	195	53.3
	No	113	30.9	171	46.7
7. Nausea	Yes	41	11.2	27	7.4
	No	325	88.8	339	92.6
8. General malaise	Yes	111	30.3	80	21.9
	No	255	36.7	286	78.1



Continue table 2...

9. Joint pain	Yes	91	24.9	47	12.8
	No	275	75.1	319	87.2
10. Insomnia	Yes	53	14.5	27	7.4
	No	313	85	339	92.6
11. Diarrhea	Yes	25	6.9	5	1.4
	No	341	93.2	361	98.6
12. Sore throat	Yes	47	12.8	27	7.4
	No	319	87.2	339	92.6

Source: Self-development

Table 3, additionally shows that more side effects occurred in the 1<sup>st</sup> dose than in the 2<sup>nd</sup> dose ( $X^2=16.67$ ,  $p<.01$ ), participants who did not present COVID-19 before being vaccinated had more side effects in the 1<sup>st</sup> dose. ( $X^2=15.29$ ,  $p<.01$ ).

Table 3. Comparison of side effects after COVID-19 vaccination by number of doses and COVID-19 history, 2023, (n=366)

Side effects	Yes		No		$X^2$	p value
	n	%	n	%		
Number of doses						
1st dose	318	86.9	48	13.1	16.67	.001
2nd dose	235	64.2	131	35.8		
¿Did you have COVID-19 before being vaccinated?						
1st dose	231	63.1	135	36.8	15.29	.001
2nd dose	91	24.9	275	75.3		

Source: Self-development

Regarding sex, education, type of vaccine, socioeconomic level and place of residence of the participants and the presence of side effects in the Zacatecas population, significant statistical differences were observed; the AstraZeneca vaccine showed higher medians of side effects in both doses, Pfizer showed lower medians with respect to side effects in the 1<sup>st</sup> and 2<sup>nd</sup> doses, in terms of sex, women presented more side effects in the 1<sup>st</sup> dose than men ( $U= 13273.00$ ,  $p<.05$ ), participants aged 18 to 30 had greater side effects in the 1<sup>st</sup> and 2<sup>nd</sup> dose ( $H= 11.815$ ,  $p<.01$ ).

Regarding the comparison of side effects after COVID-19 vaccination according to education, marital status, socioeconomic level and place of residence, there were no significant statistical differences. It should be noted that there were no significant statistical differences in side effects





presented in the study population according to the time of having been vaccinated against COVID-19, (Table 4).

Table 4. Comparison of side effects after COVID-19 vaccination by marital status, age, education, socioeconomic level and place of residence of the participants, 2021 (n=366)

Side effects:	U	p
Sex		
1st dose	13273.00	.001
2nd dose	12111.00	.401
Side effects	H	P
Education		
1st dose	53.514	.000
2nd dose	11.815	.000
Type of vaccine		
1st dose		
Pfizer		
AstraZeneca	10.800	.004
Moderna		
Cansino		
Other		
2nd dose		
Pfizer	15.761	.000
AstraZeneca		
Moderna		
Cansino	12.752	0.74
Other	6.479	0.372
Socioeconomic level	1.364	.506
Place of residence	3.442	.328

Source: Self-development

## Discussion

In relation to the main objective of the study: to compare the side effects presented in the 1<sup>st</sup> and 2<sup>nd</sup> doses of COVID-19 vaccines in the Zacatecas population, it was possible to identify that all people had at least one dose of vaccine against COVID-19, this reflects the importance of the role played by the nurse in being part of the cold network and the immunization processes in Mexico as a pillar of public health <sup>(20)</sup>, which has made it possible to significantly reduce new cases of COVID-19, the participants had less than 1 year after the application of the last dose of anti-Covid-19 vaccination, and the vaccine that was mostly applied was Pfizer, which coincides with studies



carried out in Ecuador <sup>(17)</sup> and differs from what was reported in Paraguay <sup>(15)</sup>, where doses of AstraZeneca were mostly applied, while in Chihuahua, Mexico Sinovac was applied <sup>(12)</sup>.

There were greater side effects in the application of the 1<sup>st</sup> dose than in the 2<sup>nd</sup> dose, which were: fever, headache and muscle pain, which coincides with studies carried out in Spain <sup>(13)</sup>, Ecuador <sup>(15)</sup>, Paraguay <sup>(17)</sup>, and differs from what was reported in Chihuahua, Mexico <sup>(12)</sup> where the insomnia effect was greater, which could be due to the type of vaccine applied and the difference in climates that could influence the immune status of people since in Chihuahua it has a dry semi-arid climate which could be related to the greater presence of insomnia in the participants.

It is important to highlight that the side effects were greater in the 1<sup>st</sup> dose and in those people who had suffered from COVID-19 before vaccination, so vaccination in the population is essential to prevent the spread of emerging and re-emerging diseases, in the case COVID-19 is a disease that has become an everyday pathology, which is why vaccination campaigns against COVID-19 could continue to be reinforced in the Zacatecas population. Regarding side effects by type of vaccine, AstraZeneca, Moderna and Cansino reported greater effects in both doses than Pfizer, the above described coincides with studies carried out in Spain <sup>(13)</sup> and Chihuahua, Mexico <sup>(12)</sup>, where women showed greater side effects than men and differs from what was reported in Ecuador <sup>(17)</sup>. This could be due to the fact that the study was carried out on men; in various cultures women have always shown greater self-care for their health than men, which is why it is considered one of the reasons why those who come to request health and care services are mostly women. Regarding the age range, participants from 18 to 30 years old presented greater side effects in both doses than those from 69 to 85 years old. This result coincides with what was reported in Paraguay <sup>(15)</sup>, it could be due to the fact that it began with the application of vaccines against COVID-19 in risk groups such as elder adults, who have an immune system with a lower response and in some pathologies such as diabetes, sensory capacity decreases, it would be interesting in future research to investigate the



pathologies of the population and if there is any association whether or not a side effect occurs after vaccination. The side effects presented by the Zacatecas population in the present study, such as fever, pain at the application site and muscle pain, were similar to those reported in populations from Spain <sup>(13)</sup>, Ecuador <sup>(17)</sup>, Paraguay <sup>(15)</sup> and Peru <sup>(16)</sup>, where the presence of symptoms considered mild stands out, the campaign in Mexico against COVID-19 began in vulnerable groups such as elder adults and health professionals, later young people and finally in children, the majority of the participants in this study were young people to whom AstraZeneca was administered, which is why greater side effects could be reported in that age group, it would be interesting to carry out a study with equal samples of each vaccine and thus elucidate the research biases presented, in the present investigation no significant statistical association in marital status, education, socioeconomic level and place of residence was reported, the results described coincide with those reported by the WHO, PAHO and epidemiological surveillance systems worldwide and in our country with the data reported by the Secretary of Health of Mexico <sup>(21-25)</sup>, as described above, a surveillance and monitoring system for vaccinated patients should be developed to timely report the side effects presented after COVID-19 vaccination in the population.

The limitations of the present study were the sample size, because higher power calculations could not be carried out, so they cannot be inferred to the general population. Additionally, no validated instruments were found in the Mexican population that measured the variable of interest. A nationwide randomized trial study is recommended to improve the available evidence on the side effects of COVID-19 vaccines.

## **Conclusions**

The present study reaffirms the research carried out on the side effects of COVID-19 vaccines where it agrees that the younger the age, the greater the side effects in women and the decrease in side effects in the second dose, which coincides with the development of acquired immunity and



immunological memory obtained through vaccination, which is substantial in stopping emerging and re-emerging diseases, which is why the national COVID-19 vaccination strategy in the Mexican population has allowed us to reduce costs at an economic, social and mental level of the pandemic.

However, vaccination will continue to be a constant challenge mediated by the emergence of new diseases, technological advances and new knowledge through research and continuous updating of nursing professionals. It is suggested to carry out research with a randomized trial design in broad sectors of the Mexican population to reinforce vaccination actions against COVID-19.

### **Conflict of interests**

The authors declare that there is no conflict of interest.

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