▪ Headache Medicine 2024, 15(1): 7-12 ▪ p-ISSN 2178-7468, e-ISSN 2763-6178

Headache Medicine

▪ DOI: 10.48208/HeadacheMed.2024.3

Original

Headache as the most prevalent post-vaccination adverse event after Covid-19 vaccination

Francisco Ricardo Nascimento Freitas[1], Edmar José Fortes Júnior[2], Débora Joyce Nascimento Freitas[3], Samara Menali Pereira Caproni[4], Daniela França de Barros[1], Raimundo Pereira da Silva Neto[1]

[1]Universidade Federal do Delta do Parnaíba, Parnaíba, Piauí, Brazil
[2]Instituto de Educação Superior do Vale do Parnaíba, Parnaíba, Piauí, Brazil
[3]Universidade Federal do Ceará, Fortaleza, Ceará, Brazil
[4]Universidade José do Rosário Vellano, Alfenas, Minas Gerais, Brazil[5]

Francisco Ricardo Nascimento Freitas
ricardofreitasac@gmail.com

Edited by:
Marcelo Moraes Valença

Background
In 2020, the first vaccines were approved, according to the WHO. However, speculations arose regarding their efficacy and post-vaccination adverse events (AEFV).

Objective
To evaluate the prevalence of headache as AEFI from the SARSCoV-2 vaccine in Piauí, Brazil.

Methods
This is a quantitative, observational, cross-sectional, and prevalence study. Data were provided by the Post-Vaccination Adverse Event Information System (SI-AEFV), from reported cases from January to September 2021. Data were analyzed, and the research was approved by the UFPI Research Ethics Committee.

Results
A total of 2,008 cases were analyzed. Headache was reported in 752 cases (27.99%) as an AEFV after vaccination against SARS-CoV-2. In most cases, patients were from Teresina (67.62%), of brown race/ethnicity (52.67%), female (79.00%), and the majority were not healthcare professionals (54.27%). The most common age of patients, with the original data, was 33 years. After data correction, the most common age was 28 years. The majority of these cases were not severe (96.44%), and the majority of cases were associated with the first dose of the Covid-19-Covishield-Oxford/AstraZeneca vaccine (43.18%).

Conclusion
Thus, it is concluded from the partial analysis of the results that headache is the most common adverse event after vaccination against SARS-CoV-2. The profile of patients with the most notifications was brown women aged 30 to 40 years who received the first dose of the Covid-19-Covishield-Oxford/AstraZeneca vaccine. Regarding the severity of events, the vast majority were considered non-severe, and no deaths were mentioned, demonstrating the safety of immunobiologicals.

Keywords:
Adverse Events
Headache
COVID-19 Vaccines

Submitted: December 20, 2023
Accepted: January 15, 2024
Published online: January 30, 2024

Introduction

COVID-19 is a disease caused by SARS-CoV-2, a virus from the family of betacoronaviruses. It emerged in December 2019, from an outbreak of pneumonia of unknown origin in Wuhan, Hubei province, China. The infection by the new virus was declared a pandemic by the World Health Organization (WHO) on March 12, 2020, characterized by the global spread of a disease. The disease, when advancing to an advanced state, is marked by severe pneumonia, causing thousands of deaths in the years 2020 and 2021(1).

In late December 2020, the first vaccines against SARS-CoV-2 were approved on an emergency basis by almost all countries in the world. As a prerequisite by the WHO, vaccines should have pre-established efficacy levels with a minimum threshold of 50%. All reported research involving vaccines approved for use against SARS-CoV-2 achieved an adequate level of efficacy and did not report serious adverse events in the participants involved in the analysis(2).

Immunization is one of the most effective areas of public health against preventable immunological diseases, responsible for saving millions of lives. Vaccines are one of the main tools in this area, classified as safe and effective products, although, like any other medication, they are not exempt from adverse events(3). Based on this, since the approval of the first vaccines against SARS-CoV-2, there has been a significant amount of speculation about vaccination, especially regarding its efficacy and AEFV.(4)

AEFVs are unintended or unwanted clinical occurrences that happen after vaccination but may not necessarily have a causal relationship with the use of the vaccine or other immunobiological. They can be classified as serious when there is a risk of death, requires hospitalization, causes significant dysfunction and/or permanent disability, results in congenital anomaly, or leads to death, and non-serious when events do not meet any of the serious criteria(5, 6).

Such events can be a symptom, a new disease, or even an abnormal laboratory finding. In addition to the composition of the vaccine itself, they may be related to the technique used in its administration, inappropriate prescriptions and/or administration, to the vaccinated individuals themselves, either due to individual genetic predisposition, considered one of the main factors, or coinciding with other aggravations(5, 6).

The objective of this research was to identify the prevalence of headache as a AEFV and the associated aspects of reported cases in the public health services of Piauí after vaccination against SARS-CoV-2.

Methods

This is a quantitative project of a cross-sectional, observational, descriptive, and epidemiological nature. In this type of research design, deductive reasoning is employed, which is based on the process where the researcher starts with an established theory or framework and then collects data to assess or test if the theory is confirmed. Additionally, this type of study utilizes the tool of generalization, which uses evidence collected from a sample to extend it to a larger population (7).

This research will be conducted with data from cities in the state of Piauí. According to the Brazilian Institute of Geography and Statistics (IBGE), Piauí has a territorial area of 251,755,481 km^2 and an estimated population of 3,289,290 people, characterizing a demographic density of 12.40 inhabitants/km^2. The cities with the largest population in the state are Teresina, Parnaíba, Picos, Piripiri, and Floriano. The Human Development Index (HDI) of Piauí is 0.646, representing medium development, and it has a budgetary revenue (2017) of R$12,124,215.62 ($\times$1000)[8](11).

The study population will consist of 2078 cases of AEFV, reported in the Post-Vaccination Adverse Event Information System (SI-AEFV) of the Piauí State Health Department, from January 2021 (the start date of COVID-19 vaccination in Brazil) to September 2021, which corresponds to the data collection period's conclusion. Cases of AEFV from the vaccine against SARS-CoV-2 reported in the state of Piauí during the study period will be included. Cases with incomplete notification forms or duplicates in the system will be excluded.

This research will be conducted with access to data from the Piauí State Health Department. The research will use only secondary data, and data collection will take place in September 2021 based on the data from the Post-Vaccination Adverse Event Surveillance Information System - SV-AEFV/SESAPI and will cover the period from January 2021 (the start date of COVID-19 vaccination in Brazil) to September 2021, which is the period when data collection will conclude. Vaccine data from DATASUS (a public domain database) will also be used for vaccine coverage analysis. An instrument adapted from the Ministry of Health/ National Immunization Program Notification and Investigation Form for Post-Vaccination Adverse Events will be used.

The dependent variable is the presence of systemic manifestation with outcome, and the independent variables include: notification municipality, age, sex, race/ethnicity, priority group, vaccination scheme used, and severity of AEFV. Data were tabulated using Microsoft Excel

software for data analysis. The main information about the analyzed variables was extracted for formatting the results table through absolute number (n) and percentage (%) attribution.

In conducting this study, all legal ethical principles based on the National Health Council (CNS) Resolution No. 466/12 will be respected, ensuring confidentiality, privacy, and the non-use of information to the detriment of participants. The research project was submitted to the UFPI Research Ethics Committee and approved through opinion 4,305,494 (CAAE 35364419.0.0000.5214). Participants will be presented with the informed consent form, guaranteeing confidentiality, privacy, image protection, and non-stigmatization.

Results

The number of cases of AEFV after vaccination against SARS-CoV-2 collected through SV-AEFV/SESAPI from January 2021 to December 29, 2021, was 2,008 patients. In a general analysis of all cases involved in the final sample of this study, 53.78% (n=1,080) were of brown race/ethnicity, 72.21% (n=1,450) were female, and 56.87% (n=1,142) were not healthcare professionals (although a significant quantity was classified in this occupational category, n=884, 44.02%). Furthermore, regarding the age of patients on the respective dates of AEFV notifications, 40.89% (n=821) of this data was unknown. However, considering the final analysis date (12/29/2021) for all patients to accommodate the cases with unknown ages, the average age was 44.22 years. Table 1 details this information.

Table 1. User identification information attended for an AEFV of the vaccine against SARS-CoV-2 reported in the State of Piauí

	(n)	(%)
Years – corrected	**1 PPTF (n = 78)**	**2 PPTF (n = 56)**
32	55	2.74%
37	60	2.99%
39	60	2.99%
33	61	3.04%
36	61	3.04%
30	62	3.09%
35	67	3.34%
40	67	3.34%
31	68	3.39%
34	76	3.78%
Race/Color		
Yellow	47	2.34%
White	349	17.38%
Ignored	27	21.26%
Brown	80	53.78%
Black	123	6.13%
Sex		
Woman	1,450	72.21%
Man	576	28.69%
Healthcare professional		
No	1,142	56.87%
Yes	884	44.02%

The doses of immunobiologicals against SARS-CoV-2 administered that led to adverse events, the regimen that generated the highest number of cases overall was the first dose with the Covid-19-Covishield-Oxford/AstraZeneca vaccine (n=952, 47.41%). As for the severity of the reported events, 1,777 (88.50%) did not present any severe events. Table 2 provides more detailed descriptions of the main reported categories, with numbering related to the regimen used and the sequence of doses respectively according to each immunobiological.

Table 2. Top 10 categories of SARS-CoV-2 vaccination regimens that most frequently reported adverse events in the state of Piauí and their severity

	(n)	(%)
Vaccination schedule		
1: Covid-19 Pfizer - comirnaty 2: Covid-19 Pfizer - comirnaty	20	1.00%
1: Covid-19-RNAm, Pfizer (Comirnaty)	25	1.25%
1: Covid-19 - Covishield | 2: Covid-19 - Covishield	26	1.29%
1: Covid-19-inativada, Sinovac/Butantan (Coronavac)	27	1.34%
1: Covid-19-recombinante, AstraZeneca/Fiocruz (Covishield)	30	1.49%
1: Covid-19 - BNT162b2-BioNTech/Fosun Pharma/Pfizer	38	1.89%
1: Covid-19 - Covishield	40	1.99%
1: Covid-19-Covishield-Oxford/Fiocruz	255	12.70%
1: Covid-19-Coronavac-Sinovac/Butantan	324	16.14%
1: Covid-19-Covishield-Oxford/AstraZeneca	952	47.41%
Gravity		
Serious	102	5.08%
No Serious	1,777	88.50%
Ignored	129	6.42%

The adverse events described in the final analyzed sample, these were numbered sequentially according to the patient's complaint, with the possibility of the same individual reporting more than one AEFV in the notification. Thus, complaints of signs and symptoms were grouped into categories, with "Incorrect vaccine administration," "Fever," and "Headache" being the ones described most frequently, respectively, 144 (7.17%), 123 (6.13%), and 69 (3.44%). Table 3 provides more detailed descriptions of the main reported categories.

Table 3. Top 10 categories of complaints of signs and symptoms considered adverse events after vaccination against SARS-CoV-2 in the state of Piauí

	(n)	(%)
1: Incorrect vaccine administration	144	7.17%
1: Vaccine administration for inappropriate age	44	2.19%
1: Headache	69	3.44%
1: Abdominal pain.	16	0.80%
1: Pain at the injection site	54	2.69%
1: Muscle pain	23	1.15%
1: Fever	123	6.13%
1: Fever | 2: Headache	13	0.65%
1: Fever | 2: Myalgia	13	0.65%
1: Myalgia	67	3.34%
1: Use of expired vaccine	40	1.99%

The cases in which only headache was reported as a AEFV after vaccination against SARS-CoV-2, there were 69 cases (4.38%, relative to the total sample). However, when considering all categories in which headache was present as one of the patient's complaints, the condition was the most prevalent AEFV after vaccination against SARS-CoV-2 with 752 cases (37.45%), surpassing fever (n=730, 36.35%), and myalgia (n=622, 30.98%). Regarding the patients' profile, 52.67% (n=296) were of brown race/ethnicity, 79.00% (n=444) were female, the most prevalent age was 28 years (n=34, 4.98%), and 54.27% (n=305) were not healthcare professionals. Table 4 provides detailed information on these data.

Table 4. User identification information attended for headache as one of the AEFV reported in the state of Piauí for the SARS-CoV-2 vaccine.

	(n)	(%)
Years – corrected		
43	18	3.20%
46	18	3.20%
27	19	3.38%
39	20	3.56%
30	21	3.74%
31	21	3.74%
33	21	3.74%
35	21	3.74%
40	22	3.91%
36	24	4.27%
34	28	4.98%
Race/Color		
Yellow	16	2.85%
White	89	15.84%
Ignored	124	22.06%
Brown	296	52.67%
Black	37	6.58%
Sex		
Woman	444	79.00%
Man	118	21.00%
Healthcare professional		
No	305	54.27%
Yes	257	45.73%

The doses of immunobiologicals against SARS-CoV-2 administered that led to adverse events, the regimen that generated the highest number of cases overall was the first dose with the Covid-19-Covishield-Oxford/ AstraZeneca vaccine (n=347, 61.74%). As for the severity of the reported events, 20 (3.56%) presented headache considered severe, and 542 (96.44%) did not present severe headache. Table 5 provides more detailed descriptions of the main reported categories.

Table 5. Top 10 categories of SARS-CoV-2 vaccination regimens that most frequently reported headache as one of the adverse events in the state of Piauí and the severity of these events.

	(n)	(%)
Vaccination schedule		
1: Covid-19-Covishield-Oxford/ AstraZeneca	347	61.74%
1: Covid-19-Coronavac-Sinovac/ Butantan	71	12.63%
1: Covid-19-Covishield-Oxford/Fiocruz	46	8.19%
1: Covid-19 Pfizer-comirnaty 2: Covid-19 Pfizer-comirnaty	13	2.31%
1: Covid-19 – Covishield	12	2.14%
1: Covid-19 - BNT162b2-BioNTech/ Fosun Pharma/Pfizer	11	1.96%
1: Covid-19-recombinante, AstraZeneca/ Fiocruz (Covishield)	9	1.60%
1: Covid-19-RNAm, Pfizer (Comirnaty)	9	1.60%
1: Covid-19 - Covishield 2: Covid-19 – Covishield	5	0.89%
Gravity		
Serious	20	3.56%
No Serious	542	96.44%

Discussion

According to the World Health Organization, the most common AEFV include myalgia, chills, diarrhea, headache, fever, and injection site pain, which can vary depending on the type of vaccine (WHO). Headache, commonly known as a pain in the head, is a prevalent and disabling condition that often does not receive proper diagnosis and treatment(12). This condition was the most frequent AEFV in the investigated population of this study, present in 752 patients (37.45%), followed by fever and myalgia.

In another study conducted in the United Kingdom analyzing AEFVs from two vaccines, Pfizer-BioNTech (BNT162b2) and Oxford-AstraZeneca (ChAdOx1 nCoV-19), through the COVID Symptom Study app, headache was also identified as the main systemic side effect post-vaccination. The manifestation was present in 7.8% (n= 21,910) of patients who received the first dose of BNT162b2, 13.2% (n= 3,731) in the second dose of the same vaccine, and in 22.8% (n= 78,734) in the first dose of ChAdOx1 nCoV-19(8).

Several other studies have also identified headache as the most prevalent AEFV in this context. In a Brazilian study conducted with workers from the Hospital de Clínicas de Porto Alegre, among 548 records, headache was present in 16% of cases, being the most reported systemic manifestation by the authors(13).

Headache as an AEFV after Covid-19 vaccination primarily affected brown-skinned women aged 30 to 40, although these conditions also had the highest number of cases compared to all reported events. One hypothesis raised was the greater demand for healthcare services by this audience. In line with this idea, an analysis conducted by the National Health Data Network (RNDS) revealed that the highest number of adherents to the Covid-19 vaccine in Brazil were females (53.4%)(14).

Regarding the biologic with the highest number of reported AEFVs, the first dose of the Covid-19-Covishield-Oxford/AstraZeneca vaccine was the most reported category, both when analyzing all categories of AEFVs and when specifically analyzing headache. The highest prevalence related to the biologic was also noted in the study by Gabriela Sbors and Peder,(9) whose biologic was the major contributor to AEFVs, reported in 38%.

In Brazil, vaccination against COVID-19 began in early 2021 using the CoronaVac and Oxford/AstraZeneca vaccines through emergency use, initially for healthcare professionals and the elderly. The Oxford/AstraZeneca vaccine uses a different technology, based on a genetically modified attenuated virus, which acts differently, stimulating the immune system to create defenses against possible coronavirus infections, possibly contributing to the higher prevalence of AEFVs(15). However, as in this study, even when analyzing the outcome of systemic manifestations, almost all AEFVs were reported as non-serious, with no cases of death, including cases of headache.

However, despite the certification of safety and the absence of significant data on serious AEFVs and deaths related to COVID-19 vaccines, vaccine hesitancy remains a significant issue. One of the reasons raised for this is the significant influence that social media debates have on individuals. In Recuero, Volcan & Jorge(10) study, the authors described the intimate correspondence between participants' opinions and vaccine hesitancy content on Twitter, with the categories with the greatest reach being 'individuality' and 'fear of adverse events/distrust.

This entire scenario becomes concerning when adopting these ideals for other vaccines as well. In 2020, vaccination rates in Brazil were below 80% for all vaccines, and less than 50% of Brazilian municipalities achieved the National Immunization Program's goal, considered insufficient for eradicating many diseases(16). Brazil is an international reference in vaccines and was the pioneer in eradicating smallpox, almost a decade before the World Health Organization (WHO) recognized the global eradication of the disease. Therefore, it is imperative to mobilize campaigns to debunk the prejudices related to vaccination that have emerged after the COVID-19 pandemic(17,18).

Conclusion

Thus, it is concluded from the partial analysis of the results that headache was one of the most common adverse events after vaccination against SARS-CoV-2. Firstly, by analyzing the data related to all complaints mentioned in the data collection, the profile of patients with the most notifications were brown women aged 30 to 40 years who were not pregnant, breastfeeding, or healthcare professionals, although the latter criterion presented relevant contradictions for discussion. The primary vaccination scheme against SARS-CoV-2 correlated with adverse events was the first dose of the Covid-19-Covishield-Oxford/AstraZeneca vaccine. Regarding the severity of events, the vast majority was considered non-severe, and no deaths were mentioned, demonstrating the safety of immunobiologicals. When analyzing the aspect of headache as a Post-Vaccination Adverse Event against SARS-CoV-2, the profile of affected patients was homogeneous in relation to cases overall, with the scheme and severity also classified the same. One aspect that changed in relation to all events was the higher incidence of headache as the sole adverse event in healthcare professionals. Finally, it is worth noting that the study is still ongoing, and statistical analyses will still be conducted to establish significant differences between the variables analyzed.

Authors contributions:

FRNF, Methodology, Project administration; Software, Supervision, Validation, Visualization, Writing – original draft, Writing – review & editing; EJFJúnior, Formal Analysis, Funding acquisition, Data curation, Project administration, Resources; DJNF, Formal Analysis, Funding acquisition, Data curation, Project administration, Resources; SMPC, Formal Analysis, Funding acquisition, Data curation, Project administration, Resources; DFB, Supervision, Validation, Visualization; RPSNeto; Methodology; Supervision, Validation, Visualization, Writing – original draft, Writing – review & editing.

Conflict of interest: The authors and the research have no conflict of interest.

Francisco Ricardo Nascimento Freitas
https://orcid.org/0000-0003-2655-619X
Edmar José Fortes Júnior
https://orcid.org/0000-0002-0114-9937
Débora Joyce Nascimento Freitas
https://orcid.org/0000-0002-9052-1365
Samara Menali Pereira Caproni
https://orcid.org/0009-0003-8755-2237
Daniela França de Barros
https://orcid.org/0000-0002-3667-7510
Raimundo Pereira da Silva Neto
https://orcid.org/0000-0002-2343-9679

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