RBFHSS
Revista Brasileira de Farmácia Hospitalar e Serviços de Saúde

Original Paper

Open Access

Self-report of post-vaccination adverse events against COVID-19 by health workers at a university hospital

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Submitted: 25-01-2023 Resubmitted: 25-07-2023 Accepted: 02-08-2023

Double blind peer review

Abstract

Objective: To describe the adverse event profile of vaccines against Covid-19 administered to workers at a university hospital. **Methods:** An observational, longitudinal monitoring study of adverse events following immunization identified and reported through a self-report form was carried out. An adverse event following immunization self-report form was prepared in the Microsoft Office and made available via a link for access and completion from the beginning of the vaccination campaign in Brazil. The disclosure of the self-report form was carried out at the beginning of the campaigns for the first, second and third dose of vaccines against COVID-19, through the institutional email, publication of posters with access to the form via QR code on the intranet and sharing through the WhatsApp application in the groups of the Institution. At first, stimulated passive surveillance of adverse events related to the COVID-19 vaccine was performed. From February 2021, when the administration of the 2nd dose was started, in addition to stimulated passive surveillance, an active search for adverse events following immunization was carried out. Descriptive statistics were used for data analysis by calculating the absolute and relative frequencies for categorical variables and measures of central tendency to calculate continuous variables. **Results:** 225 adverse events following immunization records involving the Oxford/Covishield (Fiocruz e Astrazeneca), Coronavac (Butantan), Comirnaty (Pfizer/Wyeth) vaccines were included in this study. Local adverse events were more frequent in the third dose and systemic in the first dose. Pain, induration and swelling were the most common local symptoms. Systemic included fatigue, headache, muscle pain and fever. **Conclusion:** The use of the vaccination strategy against Covid-19 in our population proved to be a safe strategy to face the pandemic.

Key words: Vaccines; Pharmacovigilance; COVID-19; Observational Study

Autorrelato de eventos adversos pós-vacinação contra COVID-19 por trabalhadores em saúde de um hospital universitário

Resumo

Objetivo: Descrever o perfil de eventos adversos das vacinas contra Covid-19 administradas nos trabalhadores de um hospital universitário. **Método:** Foi realizado um estudo observacional descritivo dos eventos adversos pós-vacinação identificados e notificados através de autorrelato por trabalhadores em saúde de um hospital universitário. Um formulário para autorrelato de eventos adversos pós-vacinação foi elaborado no *Microsoft Office* e disponibilizado via *link* para acesso e preenchimento a partir do início da campanha de vacinação no Brasil. A divulgação do formulário de autorrelato foi realizada no início das campanhas da primeira, segunda e terceira dose das vacinas contra COVID-19, através do *e-mail* institucional, da publicação de cartazes com acesso ao formulário via *QR code* na intranet e do compartilhamento pelo aplicativo *WhatsApp* nos grupos da Instituição. No primeiro momento, foi realizada vigilância passiva estimulada dos eventos adversos relacionados à vacina contra COVID-19. A partir de fevereiro de 2021, momento em que foi iniciada a administração da 2ª dose, adicionalmente à vigilância passiva, foi realizada busca ativa de eventos adversos pós-vacinação. Para análise dos dados foi utilizada estatística descritiva através do cálculo das frequências absoluta e relativa para as variáveis categóricas e medidas de tendência central, para o cálculo das variáveis contínuas. **Resultados:** Foram incluídos nesse estudo 225 registros de eventos adversos pós-vacinação envolvendo as vacinas Oxford/Covishield (Fiocruz e Astrazeneca), Coronavac (Butantan), Comirnaty (Pfizer/Wyeth). Os eventos adversos locais foram mais frequentes na terceira dose e os sistêmicos na primeira dose. Dor, endurecimento e inchaço foram os sintomas locais mais presentes. Os sistêmicos incluíram fadiga, cefaleia, dor muscular e febre. Não foram notificados eventos graves **Conclusão:** Os achados desse estudo sugerem que as vacinas utilizadas contra Covid-19 na população investigada apresentaram bom perfil de segurança.

Palavras chave: Vacinas contra COVID-19; Farmacovigilância; Pandemia por COVID-19 Estudo Observacional.

Introduction

Infectious diseases that affect the respiratory tract are common around the world and affect the entire population, regardless of age and gender. The pathogens associated with these conditions are primarily comprised of viruses and bacteria, with the most significant concern being the infections caused by the Respiratory Syncytial Virus (RSV), Influenza A and B, and the coronavirus[1], due to their high transmissibility and potential severity.

The coronavirus belongs to a group of viruses known to cause infection in humans since the 1960s. The course of these infections varies from mild manifestations to fatal outcomes. In December 2019, the first cases of atypical community pneumonia were recorded in the province of Wuhan, China, with a type of coronavirus later attributed as the etiological agent (SARS-CoV-2-COVID-19)[2]. Three months after the initial diagnosis of the disease and due to the rapid spread of the infection throughout the global population and the escalating rate of hospitalizations and deaths, the World Health Organization (WHO) declared COVID-19 a pandemic[3] in March 2020. Consequently, researchers from various parts of the globe devoted their efforts towards the creation of vaccines by employing diverse platforms aimed at inhibiting the S (Spike) protein, thereby increasing the likelihood of achieving a sufficient immunological response, as per previous studies.

SARS-CoV-2 is a Ribonucleic Acid (RNA) virus, whose genetic material is represented by a single positive RNA molecule. Its entire genome contains less than 30,000 nucleotides. Among the viral proteins that have been identified, the most significant ones are the Spike Glycoprotein or S protein, which is responsible for entry of the virus into the host cell through binding to the cellular receptor and membrane fusion, and the N protein, a viral nucleocapsid that regulates the viral replication process[4].

The process of developing a new vaccine takes around 10 years or more. In the case of the COVID-19 vaccines, the short time for their development can be attributed to the knowledge acquired through the use of diverse platforms during the outbreaks of SARS-CoV in 2002 and MERS-CoV in 2012, enhanced by coordinated efforts and substantial funding. Added to that, the new technological platforms of the vaccines offer the advantage of expediting the development process and easing production escalation, as they are not dependent on cultivation of the virus. However, as with any new product, its use poses challenges and requires monitoring after registration due to the absence of safety data[5].

Adverse Events Following Vaccination (AEFVs) include any unwanted medical occurrences following administration of a vaccine, which may or may not have been caused by it and are referred to as such when they have a time relationship of up to 30 days after vaccination[6]. It is known that several aspects can influence the occurrence of AEFVs and must be considered in the research process, namely: factors related to the person vaccinated; type of vaccine administered; and technology involved in the process, among others[6]. Immediate notification of AEFVs is fundamental, especially in the context of new immunization agents, given the need to minimize the negative impact on the country's National Immunization Program (*Programa Nacional de Imunização*, PNI)[7].

The COVID-19 vaccination process for health professionals and workers began in Brazil on January 17th, 2021, after due authorization from the National Health Surveillance Agency (*Agência Nacional de Vigilância Sanitária*, ANVISA). Since the start of the vaccination campaign in Brazil, approximately 200 vaccines have been subjected to pre-clinical or clinical trials[8] and, as of February 2021, there were four vaccines approved in the country, namely: Oxford/Covishield (Fiocruz and Astrazeneca) and Coronavac (Butantan) for emergency use; and Comirnaty (Pfizer/Wyeth), with definitive registration. In April 2023, the bivalent Cominarty (Pfizer) and Janssen (Janssen-Cilag) vaccines were approved in Brazil.

Given the clinical data limitations and the vaccination campaign initially targeted at health professionals as a priority group, recognizing the occurrence of AEFVs is of great relevance and contribution to the PNI. Therefore, the objective of this study was to describe the adverse events profile of the COVID-19 vaccines administered to workers at a university hospital.

Methods

A descriptive and observational study was carried out, collecting prospective data on AEFVs identified and reported through self-report by health workers at a university hospital complex in Salvador, Bahia. The institution is a large-size public hospital and outpatient teaching unit, a reference in medium- and high-complexity in the state and part of the Unified Health System (*Sistema Único de Saúde*, SUS).

An AEFV self-report form was created in Microsoft Office by the team at the Pharmacovigilance Center (*Centro de Farmacovigilância*, CFV) of a university hospital complex from Salvador, and made available via a link for access and completion from January 27th, 2021. The epidemiological vaccine surveillance manuals[5,6] published by the Brazilian Ministry of Health were used as a reference to prepare the form. The initial section of the document prepared was formulated to provide an overview of its objective and indicate that completion was voluntary. Additionally, it elucidated the consent to participate in filling-out the form. The form contained objective questions such as the following: professional data; professional category; institutional affiliation; vaccine dose; vaccine administered; signs or symptoms at the vaccine site; systemic signs or symptoms; and previous COVID-19 diagnosis; as well as subjective questions such as presence of symptoms prior to the vaccine, and event reporting such as event duration, intensity, need for medical care or medication use, allergy history, chronic diseases diagnosed, and medication use during the vaccination period.

The form was disseminated via the institutional email address, publication of posters with access to the form via a QR code on the intranet and sharing via *WhatsApp* in the Institution's groups. The form was released on January 27th, 2021, a period that included the campaign for the first COVID-19 vaccines dose, with increased dissemination during the second campaigns(from February 27th, 2021,and in April 2021) and the third dose (October 2021).

The purpose of the self-reporting form was to ease communication of the events to the Pharmacovigilance Center (CFV). Filling out the form was voluntary, and access to the answers was restricted to the Pharmacovigilance Center team. In addition to that, the identification data were transformed into codes to prevent identification of the health worker that made the notification. Data collection took place in three phases, corresponding to the periods of the first, second and third COVID-19 vaccination doses. For the periods of the first and third dose vaccination campaigns,

passive surveillance of adverse events related to the COVID-19 vaccines was conducted through the self-reporting form. Contact was made with the notifier to gather complementary and essential information to assist in the investigation and causality analysis process, as well as to monitor progression of the symptoms until the event was completely solved. When necessary, health workers were advised to seek consultation with specialists from the Reference Center of Special Immunobiologicals (*Centro de Referência de Imunobiológicos Especiais*, CRIE).

For the second COVID-19 vaccine dose, in addition to stimulated passive surveillance, an active searching for AEFVs was also conducted. The active search sought to identify the occurrence of events related to the second vaccine dose in health workers who had experienced AEFVs after the first dose, as it involved the same vaccine. It was carried out through telephone contacts with the notifiers who had filled out the AEFV self-reporting form after the first dose and had not reported AEFIVs after the second dose. The active search was only conducted for the second vaccine dose from March to June 2021.

The events self-reported by health workers, as well as those identified through the active search, were promptly notified to the health authority through the e-SUS NOTIFICA system. An Excel spreadsheet was created to organize all the information collected, as well as to record the notification number generated in the e-SUS NOTIFICA system to ease information traceability.

To determine severity, the events were classified as either severe or non-severe. Serious adverse events (SAEs) were considered when they required hospitalization, when risk of death or the need for immediate clinical intervention were identified, in case of significant dysfunction and/or permanent disability, when they resulted in a congenital anomaly, or when they caused death. The other events that did not meet these criteria were classified as Non-Severe Adverse Events (NSAEs)[6].

The study inclusion criterion corresponded to being an active worker at the institution, regardless of their professional category. Incomplete forms and cases where the health worker tested positive for COVID-19 immediately after vaccination were excluded from the analysis.

Descriptive statistics were used for data analysis, including calculation of absolute and relative frequencies for the categorical variables and of central tendency measures for the continuous ones.

The study was part of a larger project submitted to and approved by the Research Ethics Committee of the Professor Edgard Santos University Hospital, with approval number 4,465,789.

Results

From January 27th, 2021, to January 27th, 2022, a total of 231 AEFIVs were recorded, with 209 coming from self-reporting form submissions and 22 identified through the active search. Six (06) self-reports were excluded due to incomplete form submissions (02), for testing positive for COVID-19 (02), and for being duplicate entries (02). Thus, this study included 225 AEFV records, with 107 (47.6%) related to the 1st vaccine dose, 65 (28.9%) related to the 2nd, and 53 (23.6%) related to the 3rd. Regarding the vaccine administered, 109 (48.4%) notifications involved Coronavac (Butantan), 60 (26.7%) Oxford/Covishield (Fiocruz and AstraZeneca), and 56 (24.9%) Comirnaty (Pfizer/Wyeth).

Table 1 describes the characteristics of the individuals who experienced AEFVs in the hospital under study. The mean age was 39 years old. Of the workers who self-reported, 176 (78.2%) were health professionals, including medical residents and multi-professionals, and 44 (19.6%) worked in administrative roles. University faculty and students accounted for 2.2% (5) of the records. Among the health professionals, nursing technicians (18.6%), nurses (14.7%), physicians (11.5%) and pharmacists (11.5%) were the categories that submitted the most AEFV notifications.

Table 1. Characteristics of the professionals working at the hospital who self-reported adverse events following vaccination from January 2021 to January 2022 (Salvador, Bahia)

Gender	**n/N (%)**
Female	187/225 (82.4%)
Male	38/225 (16.7%)
Age group (years old)	
20-59	217/225 (96.4%)
Equal to or greater than 60	8/225 (3.5%)
Chronic disease	
Yes	88/225 (39.1%)
No	137/225 (60.9%)
Previous history of adverse events to medications/vaccines/food products	
Yes	82/225 (36.4%)
No	143/225 (63.6%)
Continuous medication use	
Yes	95/225 (42.2%)
No	130/225 (57.8%)
Lactating	
Yes	9/188 (4.8%)
No	179/188 (95.2%)

Local events were more frequently reported in the third dose, whereas systemic events were more commonly reported in the first one. Table 2 describes the AEFV profile by type in relation to systemic or local signs and symptoms and dose number.

Table 2. Characterization of the adverse events following vaccination by type and dose at a university hospital from January 2021 to January 2022 (Salvador, Bahia)

Number of AEFVs notified	
Local signs and symptoms	293 (29.8%)
Systemic signs and symptoms	690 (70.2%)
Number of local manifestations by vaccine dose	
1ª Dose	114 (38.9%)
2ª Dose	59 (20.1%)
3ª Dose	120 (41.0%)
Number of systemic manifestations by vaccine dose	
1ª Dose	299 (43.3%)
2ª Dose	176 (25.5%)
3ª Dose	215 (31.2%)

The most frequently reported local symptom was pain, accounting for 55.6% (163/293) of the records, followed by induration (18.1%; 53/293), swelling/edema (9.5%; 28/293) and heat (9.2%; 27/293). There were also reports of hematoma (2.4%; 7/293), arm heaviness (1.0%; 3/293) and decreased sensitivity (0.3%; 1/293).

Among the systemic symptoms, the most frequently reported manifestations were as follows: headache (16.9%; 117/702), fatigue (13.5%; 94/702), myalgia/muscle pain (12%; 83/702), drowsiness (8.7%; 62/702), chills (6.8%; 47/702), fever (5.5%; 38/702), nausea (5.1%; 36/702) and asthenia (4.9%; 34/702). Duration of the symptoms varied from 1 hour to 15 days, with a mean of 3 days, both for local and systemic symptoms. No Severe Adverse Events (SAEs) were reported.

Discussion

In this study, women were the main AEFV notifiers, which can be explained by the professional profile of the health workers who self-reported, mainly consisting of nursing technicians and nurses. The notifiers were between 20 and 59 years old, reflecting that a significant percentage of health workers currently in the institution consists of young adults recruited through public contests held in the last 10 years. Another relevant aspect is technology ease of access and use in this age group. According to a published study, demographic factors such as age can be decisive, acting as a barrier or a facilitator to digital inclusion resulting from the perception about the social value of technology[9].

In 82 (36.4%) self-reports there was a record of previous allergy to medications, food products, insect venoms or inhalant allergens and there was only one case of an allergic reaction to the vaccine. Hypersensitivity reactions are frequently attributed to the vaccines' inactive components or excipients, including egg protein, gelatin, formaldehyde, thimerosal or neomycin[10]. Therefore, an allergy history generally does not contraindicate vaccination, unless hypersensitivity is due to some component of the vaccine[11]. In the case of the allergy notified in this study, the individual had no previous history.

The events reported were classified as non-serious and did not vary according to the type of vaccine administered. It is important to highlight that one of the main reasons for people's hesitation in getting vaccinated is related to concerns about the safety profile. In relation to adverse events, there was a similarity between the data from the current study and previous clinical trials involving the Coronavac, Pfizer and Oxford vaccines. In relation to the type, the main local symptoms were pain, edema and erythema. In turn, the systemic ones were as follows: fatigue, headache; and muscle pain, in addition to fever for the Oxford vaccine[7,12,13]. Adverse reactions to vaccines are commonly reported and largely occur through a non-immune-mediated mechanism, related to the pharmacological action of the vaccine, as observed in this study[14]. In relation to duration of the AEFV symptoms, reports were found of symptoms lasting up to seven days after vaccination with Pfizer and a mean duration of symptoms of 48 hours with Coronavac[7,12].

An epidemiological and descriptive study carried out in Brazil with data from e-SUS Notifica in the state of Minas Gerais from January 20 to March 5th, 2021, analyzed all suspected AEFV cases due to COVID-19 vaccines in the state of Minas Gerais. The occurrence of AEFVs was frequent, although only 3% were classified as severe[15]. The time between vaccination and onset of the symptoms had a median of six days[15].

Most of the self-reports were carried out by care professionals when compared to administrative workers. It is believed that this fact is explained by technical knowledge, better identification of events and greater sensitivity for reporting adverse events. Self-reporting of suspected AEFVs from health workers has the advantage of the greater expertise of some of these professionals in identifying and correlating clinical findings after vaccination with vaccine administration. It was also observed that 39.1% of the professionals who reported AEFVs had comorbidities; however, no association was made between this fact and the event presented.

Using new technology on a large scale brings with it the need for intensive surveillance. It is important to highlight that success of the vaccination policies is directly related to the use of immunobiologicals with assured quality, and health surveillance plays a fundamental role in this process. Therefore, early detection and providing an adequate and rapid response to adverse events following vaccination comprise one of the pharmacovigilance objectives and aims at minimizing negative effects on the health of the population, in addition to reducing the impact on immunization programs[5].

The current research has limitations for being a descriptive study and, therefore, the findings reflect the population included, precluding data extrapolation. The strategy for capturing the events was through stimulated passive surveillance and, in this way, it depended on health workers' awareness to record the event on the form. There is a need for new studies to determine causality with the vaccines, as it was not the object of the current research.

Conclusion

The AEFVs reported were more frequent in adult women, according to the workers' profile at the study locus. There was predominance of systemic manifestations recorded after the first and third vaccine doses. No severe events were reported in the study population.

Funding sources

The research did not receive funding for its conduction.

Collaborators

- GQA- Conception and design or data analysis and interpretation; Writing of the article; Final approval of the version to be published; Responsible for all aspects of the paper in ensuring accuracy and integrity of any of its parts.

- GNCS - Data analysis and interpretation; Writing of the article; Final approval of the version to be published; Responsible for all aspects of the paper in ensuring accuracy and integrity of any of its parts.

- ICS - Conception and design or data analysis and interpretation; Writing of the article; Final approval of the version to be published; Responsible for all aspects of the paper in ensuring accuracy and integrity of any of its parts.

- LAKT- Conception and design or data analysis and interpretation; Writing of the article; Final approval of the version to be published; Responsible for all aspects of the paper in ensuring accuracy and integrity of any of its parts.

- ACBN- Data analysis and interpretation; Relevant critical review of

intellectual content; Final approval of the version to be published; Responsible for all aspects of the paper in ensuring accuracy and integrity of any of its parts.

- LACBN - Data analysis and interpretation; Relevant critical review of intellectual content; Final approval of the version to be published; Responsible for all aspects of the paper in ensuring accuracy and integrity of any of its parts.

Declaration of conflict of interests

The authors declare that there are no conflicts of interests in relation to this article.

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