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Vaccinovigilance: Description of adverse events of covid-19 vaccines in a frontline population.

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Abstract.

Introduction: The perception of vaccine risks can threaten the success of immunization programs. The goal of this study is to describe adverse events after the first and second doses of vaccine in frontline workers vaccinated against covid-19.

Material and method : This is a descriptive cross-sectional study based on the exploitation of post-vaccine adverse event report forms, in frontline workers from January 29 to March 14, 2021, filled in by physicians in charge of dedicated vaccination centers. The following data were collected: personal characteristics, adverse events following vaccination, the time of their occurrence, their severity, their medical management and their evolution. Statistical analysis was performed using SPSS 13.0 software.

Results : It concerns 250 frontline workers, who have been notified as having an adverse event following vaccination, with an average age of 37-/+11.57 years and a male predominance (79.2%). For medical history: 16(6.4%) had already had covid-19, 9(3.6%) were hypertensive, 6(2.4%) diabetic and 5(2%) asthmatic. The median time to occurrence of adverse events was 12 hours with a minimum of 5 minutes and a maximum of 20 days. About the adverse events: 96(38.4%) had fever, 34(13.6%) vagal discomfort, 21(8.4%) skin reaction, 70(28%) headache, 72(28.2%) asthenia. Of the total, one case (0.4%) was considered serious, 10 (4%) required hospitalization, but the evolution of all cases was favorable.

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I. INTRODUCTION

The pandemic situation triggered by the spread of COVID-19 has caused great damage worldwide. Globally, as 7 December 2021, there have been 265.713.467 confirmed cases of COVID-19, including 5.260.888 deaths, reported to WHO. As of 6 December 2021, a total of 7.952.750,402 vaccine doses have been administered. [1]. In response to this pandemic, several actors have invested in research and the implementation of treatment and prevention methods, in particular vaccines [1,2,3]. However, the major problem that threatens the success of immunization programs remains the perception of vaccine-related risks, which is accompanied by rumors that are sometimes difficult to reduce, despite the availability of credible scientific data. Vaccinovigilance which is defined by the WHO as: "the science and activities related to the detection, evaluation, understanding, prevention, and communication of post-vaccine adverse events and other immunization-related problems" [4] is responsible for the continuous evaluation of the benefit/risk ratio of vaccines and provides a reliable basis for taking appropriate measures to protect individuals and the population. The aim of this study is to describe the epidemiological profile of covid-19 vaccinees who experienced adverse events after the first and second doses of the vaccine and who were reported by the physicians in charge of the vaccination centers or their attending physicians in order to contribute to a real understanding of these events.

II. MATERIAL AND METHOD

This is a cross-sectional study based on the evaluation of post-vaccination adverse event report forms, in frontline workers between January 29 and March 14, 2021, filled in by physicians in charge of dedicated vaccination centers or by attending physicians.

For the doctors in charge of the vaccination centers, the notification forms were filled out in the 30 minutes following the vaccination act, during which time all vaccinated persons were put under surveillance. For the treating physicians the notification was made after the above mentioned period.
A sensitization, for the benefit of the two categories of declaring physicians, on the interest of vaccinovigilance and the method of filling in the notification forms as well as the information circuit was organized before the beginning of the vaccination campaign.
The following were collected::

- Data regarding personal characteristics: age, gender, medical history ;
- Adverse events following vaccination;
- The time of their appearance, their severity,
- The medical care and the evolution.

The data collection was done on paper and then transformed into electronic format on an Excel fileNotification forms with inconsistent or missing information were completed with the reporting physicians.
Statistical analysis was performed using SPSS software 13.0. Categorical variables were expressed as numbers and percentages and quantitative variables as mean and standard deviation or median and quartiles according to their distribution.

III. RÉSULTATS:

During the period of our study 285 000 frontline workers were vaccinated of which 282 000 had received both doses (98.59%). The vaccines used were Astrazeneca in 280 000 people (98.24%) and Sinopharm in 5 000 people (1.76%). We have exploited all the notification forms, i.e. 250 forms, which we have completed with reporting physicians when necessary. Of the 250 adverse events reported, which constitutes 0.87 per thousand, 249 were related to Astrazeneca (99.6%) and 1 to Sinopharm vaccination. The average age was 37-/+11.57 years with a male dominance (79.2%). For medical history: 16 (6.4%) had already had the covid-19, 9 (3.6%) were hypertensive, 6 (2.4%) diabetic and 5 (2%) asthmatic (Table 1).

Table 1. Medical history

Medical history	**n (%)**
History of covid-19	16 (6.4)
high blood pressure	9 (3.6)
Diabetes	6 (2.4)
Asthma	5 (2.0)
Cardiac disease	3 (1.2)
Neurological disease	2 (0.8)

The median time to occurrence of adverse events was 12 hours with a minimum of 5 minutes and a maximum of 20 days. About the adverse events: 96 (38.4%) had fever, 72 (28.2%) asthenia, 70 (28%) headache, 34 (13.6%) vagal discomfort, 24 (9.6%) arthralgia, 21 (8.4%) skin reaction, 12 (4.8%) dizziness and 5 (2%) motor diarrhea, Table 2. Of the total, one case (0.4%) was considered serious and it was a young adult aged 27 with no notable medical history who presented with Guillain-Barré syndrome 20 days after the first dose of vaccine by Astrazeneca. Of those who required hospitalization, 10 (4%) were hospitalized. The median duration of hospitalization was 48 hours. Of the 10 people hospitalized, 9 were admitted for medical surveillance because they had other diseases that could become complicated. The evolution for all was favorable without complication or death, 249 under symptomatic treatment and one person under treatment adapted to the Guillain-Barré syndrome.

Table 2. Distribution of adverse events.

adverse event	**n (%)**
Pain at injection site	105 (42.0)
Fever	96 (38.4)
Asthenia	72(28.2)
Headache	70 (28.0)

Vagal discomfort	34 (13.6)
Arthralgia and myalgia	24 (9,6)
Skin reaction - General - Localized	21 (8.4) 3(1.2) 18(7.4)
Vertiges	12 (4,8)
Diarrhée motrice	5 (2.0)
Guillain-Barré	1 (0,4)

IV. DISCUSSION

Our study is part of a research project whose main objective is to provide the national and international scientific community with unbiased data on post-vaccination adverse events (PVAE) associated with Covid-19 vaccines. Through it, we have targeted a particular Moroccan population, which is the frontline workers. Therefore, among 285 000 people vaccinated, we received 250 notification forms for PVAE, (0.87 per thousand) which is lower than the national average declared by the National Poison and Pharmacovigilance Centre, which is 1.3 notifications for every 1,000 vaccinations. This difference is probably due to the fact that, in our study, we relied solely on the declaration made by medical personnel, doctors in charge of dedicated vaccination centers or attending physicians, whereas the statistics reported by the National Poison and Pharmacovigilance Centre were based, in addition, on the "Yakada Liqah" application developed by the Moroccan Ministry of Health, where it is the vaccinated person who declares the PVAE through a questionnaire where the symptoms likely to occur after vaccination against Covid-19 are indicated, the doctor at the vaccination center analyzes the alerts and responds with advice, a prescription for medication, an invitation to an on-site consultation or referral to the most appropriate hospital. This percentage, when compared to the percentage recorded in international studies, was very low, due to the fact that these studies were experimental studies phase 3 that evaluated the efficacy and safety of the vaccine, where the follow-up of the groups studied was more meticulous. Thus, for the studies involving Astrazeneca, 0.7% of PVAE were reported, and 5 to 20% for Sinopharm [5,6,7]. The young average age (37-/+11.57 years) with the male dominance (79.2%) of the persons in whom we notified the PVAE are related to the nature of our population which, in order to perform its functions requiring a particular profile that can tolerate particular working conditions, and would not constitute, therefore, risk factors. In our study we found that the majority of adverse events were reported following vaccination with Astrazenaca (96%) and this could be explained by the fact that 98.24% of the study population was immunized with this vaccine. In terms of the nature of local PVAE, pain at the injection site was the most frequent in our study (42%), which was also reported in other studies, but with percentages varying between 8% and 64% [8,9,10]. For systemic adverse events the most common in our series was fever, it was not a fever reported only by the vaccinated but it was verified by the reporting physicians. Then we find, in ascending order, asthenia, headache, malaise, arthralgia and myalgiaThese are also PPVTs that have been reported by other studies in an approximate order but with quite different frequencies [8-12]. Whether local or systemic, almost all reported reactions were mild to moderate and resolved within 2 to 3 days with symptomatic treatment. We reported a single case of Guillain-Barré syndrome (GBS) 20 days after the first dose of AstraZeneca vaccine. We think that there was no causal link between GBS and the vaccine in our patient, especially considering that he reported a history of respiratory and gastrointestinal infections in the period before the onset of this syndrome in him and that this type of history has been identified in up to two-thirds of patients with GBS [13]. This adverse events has been reported by other authors with other types of vaccines (Johnson & Johnson and Pfizer-BioNTech) but without being able to demonstrate a cause-effect relationship between the vaccines and GBS [14,15].

V. CONCLUSION

In the face of the Covid-19 pandemic and the extent of its impact on the world's population, vaccination is the most effective tool for individual and collective protection against this disease. But like every pharmaceutical product, the vaccine has adverse events that vary from simple to serious. In order to detect these adverse events in time and make appropriate decisions to protect the population and ensure their adherence to immunization programs, vaccinovigilance is the best solution.

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