Post-immunization adverse events of COVID-19 vaccines in people vaccinated from June 2021 to March 2022 in Ouagadougou

ABSTRACT

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Aims: To study post-immunization adverse events of Covid-19 vaccines in people vaccinated from June 14, 2021 to March 13, 2022 at the vaccination center of University Hospital Yalgado Ouedraogo.
Study design: Our study was a descriptive and analytical cross-sectional study.
Place and Duration of Study: Department of Medicine, from June 14, 2021 to March 13, 2022 at CHU-YO.
Methodology: To identify the factors associated with the occurrence of post-immunization adverse events, we used univariate binary logistic regression and a threshold of $p < 0.2$ was used for inclusion in the multivariate analysis. The significance threshold was then 0.05. We have obtained authorization to use the data from the ethics committee.
Results:A total of 646 people were included. The mean age was 49.84 years [18 - 78 years]. The sex ratio (M/F) was 1.73. Health workers accounted for 32.2% of those vaccinated. Hypertension, allergy and diabetes were the most frequently reported medical conditions in 15.2%, 10.4% and 6.7% of those vaccinated respectively. Four hundred and forty-eight 448 (69.3%) presented at least one post-immunization adverse events, of which 446 (99.6%) were minor and 2 (0.4%) major. Pain at the injection site, headache and fever accounted for 87.4%, 82.6% and 67.8% of cases respectively. The two major post-immunization adverse events were anaphylactic shock and hemiparesis. In the majority of cases, post-immunization adverse events occurred within 48 h of COVID-19 vaccination. Healthcare workers and history of allergy were statistically associated with the occurrence of post-immunization adverse events.
Conclusion: We need to study the post-immunization adverse events associated with COVID-19 vaccines, in order to increase the population's adherence to the vaccine and better combat this Coronavirus pandemic.

Keywords: Vaccines, Covid-19, post-immunization adverse events, Burkina Faso.

1. INTRODUCTION

The development of vaccines against SARS-COV-2 began as soon as the viral genome sequence was published. This development progressed at an unprecedented pace, with the first clinical trial carried out in March 2020 [1]. A year later, a dozen vaccines based on different concepts, some of which had only been tested in clinical trials, were approved under emergency procedures [1]. After a year of development, several vaccines were shown to be effective against COVID-19 disease, and received conditional marketing authorization [1]. As of April 6, 2021, WHO counted over 200 vaccines in preclinical development, 86 in clinical development, including 23 in phase II/III or III, and 12 approved worldwide for population vaccination [2]. The rapid development of these vaccines contributed to the emergence of numerous rumors and concerns, which persisted into the post-vaccination period [3]. Rumors that COVID-19 vaccines are linked to various post-vaccination adverse events continue to circulate and be debated on various social media sites [3;4].

In Burkina Faso, various vaccines have been used in national vaccination campaigns against Coronavirus disease. It is therefore necessary to evaluate the adverse events reported in people who have received the COVID-19 vaccines, in order to help combat vaccine reluctance and rumors. The aim of the present study is therefore to investigate the post-immunization adverse events (PIAE) identified in people who received the COVID-19 vaccines used in Burkina Faso at the vaccination center of the University Hospital Yalgado Ouedraogo..

Provide a factual background, clearly defined problem, proposed solution, a brief literature survey and the scope and justification of the work done.]

2. MATERIAL AND METHODS

The study took place at the University Hospital Yalgado Ouédraogo (HUYO), one of the largest referral hospitals in Burkina Faso. With the devolution of the management of COVID-19, this university hospital takes charge of cases. The vaccination center was set up for COVID-19 vaccination at the start of the vaccination campaigns, and dispensed two types of vaccine according to the country's guidelines: Astra-Zeneca (2 doses at 8-week intervals) and Johnson and Johnson (single dose). This center served as our study setting. It consists of 4 rooms, with an average 15-minute circuit for a given candidate, including, in order, a waiting room, a registration room, a vaccination room and a monitoring room.

This was a descriptive and analytical cross-sectional study that took place from June 2021 to March 2022 at the HUYO vaccination center.

The study involved all people who had received the anti-COVID-19 vaccination at CHUYO. All subjects of any age and sex who had received the anti-COVID-19 vaccination between June 2021 and March 2022, and who had agreed to receive the google forms link on their phone to complete the questionnaire (self-completion), were included. The questionnaire was collected from all people who received the anti-COVID-19 vaccination and who agreed to report any post-vaccination adverse events that occurred in the hours or days following vaccination. An interview and history were taken beforehand. Subsequently, a google forms link containing the study questionnaire was sent to each

vaccinated person who had a functional telephone number via simple messaging (SMS) or WhatsApp. After sending the questionnaire, we retrieved the data on an Excel file for processing and analysis. The data collected in our study included the socio-demographic, clinical and evolutionary variables of the study subjects.

Data processing and statistical analysis were carried out using Stata 14 software. Results were expressed as percentages for qualitative variables and as mean ± standard deviation for quantitative variables. To identify the factors associated with the occurrence of post-immunization adverse events, we used univariate binary logistic regression and a threshold of $p < 0.2$ was used for inclusion in the multivariate analysis. The significance threshold was then 0.05. We have obtained authorization to use the data from the ethics committee (number 2022 000150/MSHP/MESR/CERS).

3. RESULTS

During the study period, 841 people were vaccinated at the CHU YO vaccination center. A total of 670 people completed the data collection form, giving a response rate of 79.7%. A total of 646 people were included. The sex ratio (M/F) was 1.73 and the mean age 42.1 ± 1.1 years. Health workers accounted for 32.2% of those vaccinated. Arterial hypertension (15.2%), allergy (10.4%) and diabetes (6.7%) were the histories most frequently reported by those vaccinated. Four hundred and forty-eight (69.3%) vaccinees had at least one PIAE, including 446 (99.6%) minor cases and 2 (0.4%) major cases. (Table 1).

Table 1: Characteristics of people vaccinated from June 2021 to March 2022 at the University Hospital Yalgado Ouedraogo.

Socio-demographic characteristics	Workforce	Percentage
Age (years) (n=646)		
< 30	140	21,7
[30-50[	160	24,8
[50-60[	159	24,6

≥ 60 years	98	15,2
Gender (n=646)		
Male	410	63,5
Female	236	36,5
Marital status (n=646)		
Married	383	61,6
Single	210	33,7
Widowed	21	3,4
Divorced	8	1,3
Occupation (n=646)		
Other civil servant	314	48,6
Health agents	226	35,0
Pupil/Student	45	7,0
Unemployed	23	3,6
Informal sector	14	2,2
Retailer	13	2,0
Housewife	11	1,7
Medical history (n=232)		
HTA	98	42,2
Allergy	69	29,7
Diabetes	43	18,5
Asthma	18	7,8
Sickle cell disease	17	7,3
Covid-19	15	6,5
Renal insufficiency	5	2,2
Pregnancy	3	1,3
Chronic sinusitis	3	1,3
Type of vaccine		
Astra-Zeneca	241	37,4
Johnson and Johnson	405	62,6

Pain at the injection site (87.39%), headache (82.61%) and fever (67.83%) were the most frequent (figure 1).

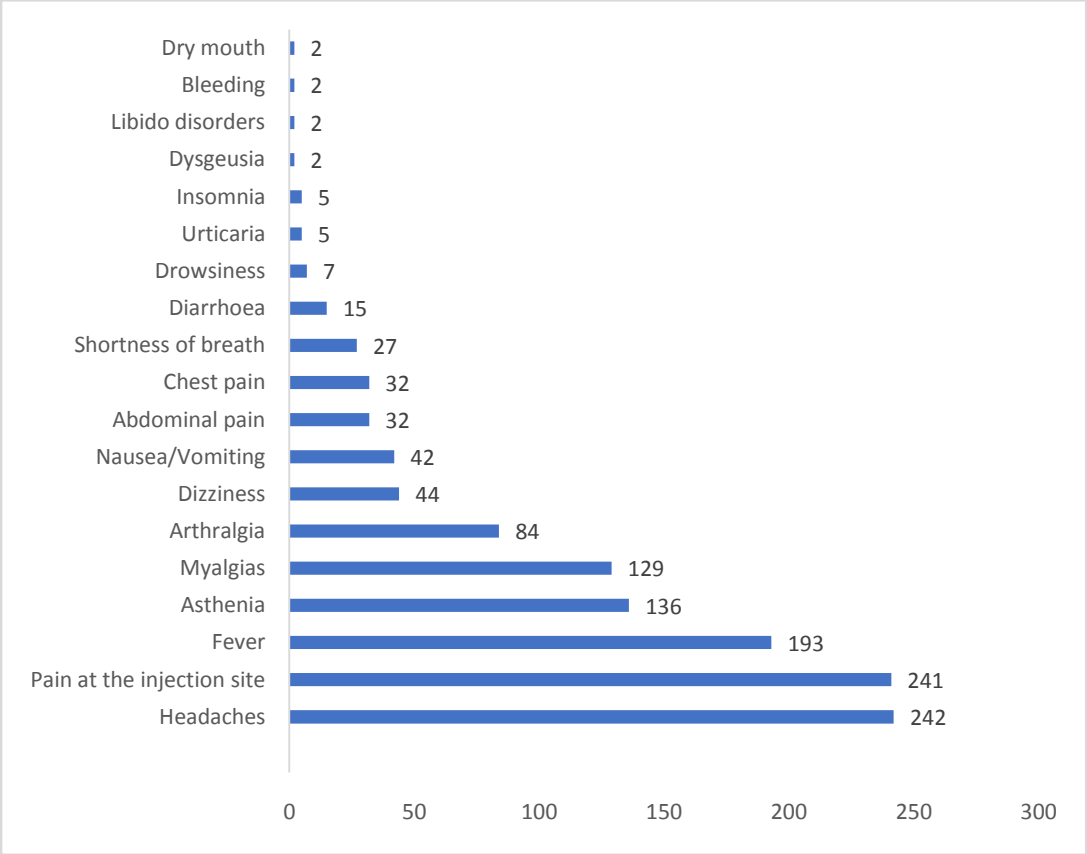

Figure 1 : Minor post-immunization adverse events in people vaccinated from June 2021 to March 2022 at the University Hospital Yalgado Ouedraogo.

The two major PIAE were anaphylactic shock and hemiparesis. In 77% of cases, post-immunization adverse events occurred less than 48 h after COVID-19 vaccination. Being a health worker and having a history of allergy were statistically associated with the occurrence of PIAE (Tables 2 and 3).

Table 2: Factors associated with post-immunization adverse events of COVID-19 vaccines in people vaccinated from June 2021 to March 2022.

	MAPI		**Univariate**	
	Yes	**No**	**OR [95% CI]**	***p-value***
Features				
Socio-demographic (n=646)				
Age				

≤ 45	102	28		
> 45	343	173	0,54[0,34]	**.009**
Gender				
M	270	140		
F	175	61	0,67[0,47-0,96]	**.029**
Health agent				
Yes	212	35		
No	233	166	4,31[2,86-6,50]	**<.001**
Marital status				
Life alone	53	19		
In couple	128	33	1,39[0,72-2,66]	.319
Medical history (n=646)				
HTA				
Yes	64	34		
No	381	167	0,82[0,52-1,29]	.406
Allergy				
Yes	59	10		
No	386	191	2,92[1,46-5,83]	**.002**
Renal insufficiency				
Yes	1	4		
No	444	197	0,11[0,01-0,99]	.05
Diabetes				
Yes	27	16		
No	418	185	0,74[0,39-1,42]	.373
Asthma				
Yes	15	3		
No	430	198	2,3[0,65-8,04]	.191
Sickle cell disease				
Yes	12	433		
No	5	196	1,08[0,37-3,12]	.878

Type of vaccine (n=646)				
Astra-Zeneca	57	144		
Johnson	184	57	1,78[1,24-2,55]	**.002**

Table 3: Factors associated with post-immunization adverse events of COVID-19 vaccines in people vaccinated from June 2021 to March 2022.

	MAPI		**Multivariate**	
	Yes	**No**	**OR [95% CI]**	***p-value***
Features				
Age				
≤ 45	102	28		
> 45	343	173	0,55[0,29-1,03]	.066
Gender				
M	270	140		
F	175	61	0,82[0,48-1,37]	.495
Health agent				
Yes	212	35		
No	233	166	4,28[2,75-6,64]	**<.001**
Allergy				
Yes	59	386		
No	10	191	2,61[1,24-5,47]	**.011**
kidney failure				
Yes	1	4		
No	444	197	0,16[0,17-1,56]	.117
Asthma				
Yes	15	3		
No	430	198	1,69[0,57-1,29]	.431
Type of vaccine				

Astra-Zeneca	57	144		
Johnson	184	57	0,86[0,57-1,29]	.474

4. DISCUSSION

In our study of PIAE in people vaccinated against COVID-19, we found a prevalence of 69.3% of people having presented with at least one PIAE, of which 446 (69%) were minor and 2 (0.3%) major, which were anaphylactic shock and hemiparesis following administration of the Astra-Zeneca vaccine. The pathophysiology of anaphylactic shock during anti-covid19 vaccination has been described, and is thought to be due to a hypersensitivity reaction [5]. As for paresis, cases of facial paralysis have been described following the administration of several vaccines. However, this type of adverse event has not been reported with Astra-Zeneca vaccines. On the other hand, acute facial paralysis has been described as a probable non-specific consequence of the post-vaccination inflammatory response to the specific vaccine, and not a direct consequence of it [6]. Also, two factors were significantly associated with the occurrence of minor PIAE: health-care profession and history of allergy.

Like all vaccines, those against COVID-19 may cause adverse reactions. Most are mild to moderate in intensity and disappear on their own within a few days. It is normal to experience some side effects after a dose of vaccine. This is because the immune system reacts differently depending on the body of the person vaccinated.

During vaccinations, awareness-raising is needed to explain to those vaccinated the possible post-immunization manifestations that can be expected. This could increase the number of post-vaccination notifications.

According to the WHO, injection-site pain, fever, headache, shivering and fatigue are typical adverse events associated with COVID-19 vaccines [7]. Injection-site pain was one of the most frequent signs after vaccination in most studies [8,9]. Pain is related to muscle breakthrough and diffusion of the vaccine into the muscle. Headache is one of the side effects reported with the Astra-Zeneca and Janssen vaccines used in our study [10,11]. Fever is one of the most consistent and frequent reactions to vaccination. It is a reaction to an aggression, whatever it may be, and is the consequence

of an activation of the cells of our immune system. Whatever the vaccine used, myalgia and asthenia have been classified as PIAE in several studies [12, 13, 14].

As the vaccination center is located at the CHUYO, it is more frequented by health workers. What's more, their familiarity and knowledge of adverse events following immunization means that they are more likely to fill in the notification form correctly, and their numbers make them more representative. Vaccination is necessary, especially for people at risk, so widespread communication on PIAE and post-vaccination surveillance, combined with free and effective treatment, would help to reassure the population and encourage greater adherence.

5. CONCLUSION

People vaccinated with anti-covid-19 vaccines developed PIAE, which in the majority of cases was minor. The study of PIAE associated with anti-COVID-19 vaccines, including all vaccination centers and the advanced strategy, is necessary in order to reinforce the vaccination adherence of the Burkinabe population for a better fight against this Coronavirus pandemic.

CONSENT (WHERE EVER APPLICABLE)

Verbal consent was required to take part in the study.

ETHICAL APPROVAL (WHERE EVER APPLICABLE)

Ethical clearance for this study was obtained from the National Ethics Committee of Burkina Faso (No2022/000150/MSHP/MESRI/CERS). All methods were performed in accordance with the relevant guidelines and regulations and the principles of the Declaration of Helsinki.

REFERENCES

1. Feraoun Y, Maisonnase P, Grand RI, Beignon AS. COVID-19, vaccines at lightning speed. Med Sci (Paris). 1 aout 2021 ;37(8-9) :759-72.
2. Zimmer C, Corum J, Wee SL, Times NY. Coronavirus Vaccine Tracker. 2021.
3. Sallam M et al. High rates of COVID-19 Vaccine Hesitancy and its association with conspiracy beliefs: a study in Jordan and Kuwait among other Arab countries. Vccines (Base1). 12 Jan 2021,9(1) :42.
4. Ball P. The lightning-fast quest for COVID vaccine- and what it means for other diseases. Nature. January 2021 ;589(7840) :18_8.
5. Castells M, Demoly P, Tanno LK. Anaphylaxis and COVID-19 vaccines. Rev Fr Allergol. Dec 2021;61(8):8S30-5.

6. Volk GF, Kuttenreich AM, Geitner M, Guntinas-Lichius O. [Acute facial paresis as a possible complication of vaccination against SARS-CoV-2]. Laryngorhinootologie. July 2021;100(7):526-8.
7. World Health Organization. Adverse reactions to COVID-19 vaccines. Dashbord 2021.
8. Babamahmoodi et al. Side effects and Immunogenicity following administration of the Sputnik V COVID-19 vaccine in the health care workers in Iran. Sci Rep. 2 Nov 2021 ;11(1) :21464.
9. Massip E et al. Cutaneous reactions to COVID-19 vaccines: a regional prospective descriptive cohort. Annales de Dermatologie et de Vénéréologie. Dec 1, 2021;1(8, Supplement 1):A93-4.
10. National Agency for the Safety of Medicines and Health Products. Adverse reactions to astrazeneca vaccine, what you need to know. 20210413-covid-19-vaccins-fiche-ei-astrazeneca-ps.pdf [Internet]. [cited March 30, 2023]. Available from: https://ansm.sante.fr/uploads/2021/04/13/20210413-covid-19-vaccins-fiche-ei-astrazeneca-ps.pdf
11. National Agency for the Safety of Medicines and Health Products. Adverse reactions to janssen vaccine, what you need to know. 20210429-fiche-ei-janssen-ps.pdf [Internet]. [cited March 30, 2023]. Available from: https://ansm.sante.fr/uploads/2021/04/29/20210429-fiche-ei-janssen-ps.pdf
12. Aitnasser K, Serhane H, Moubachir H. Side effects of COVID 19 vaccines in the population of southern Morocco. Revue des Maladies Respiratoires Actualités. 2022 ;14(1):67-8.
13. Cloarec E, Gloaguen A, Saidani N, Khatchatourian L. "What if we vaccinated directly in the wards?" Evaluation of Astra-Zeneca vaccine tolerance in caregivers during the first week of the vaccination campaign. Infectious Diseases Now August 1, 2021;51(5, Supplement):S146-7.
14. Im JH et al. Adverse Events with the Pfizer-BioNTech COVID-19 Vaccine among Korean Healthcare Workers. Yonsei Med J. Dec 2021 ;62(12):1162-8