Open Journal of Public Health

Research Article
Published: 12 May, 2022

Factors Associated with Adverse Events Following COVID-19 Immunization in Brazzaville

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Abstract

Aim: Vaccination against COVID-19 on a global scale aims at limiting the spread and severe forms of the disease. Monitoring of Post-Immunization Adverse Events (PIAE) is an important activity of vaccination units. The objective of this study was to investigate the factors associated with PIAE in Brazzaville.

Population and Method: This was an analytical cross-sectional study conducted in all centers attached to the Expanded Program on Immunization (EPI) in Brazzaville. All persons over 18 years of age who reported a post-vaccination reaction were selected.

Results: A total of 1,010 persons reporting at least one PIAE were selected. The mean age was 46 ± 12.6 years and the predominance of males was not statistically significant; males were more affected by PIAE than females in a non-significant way (p-value =0.063). Factors associated with these PIAE were: Janssen vaccine (OR=2.7; CI = [1.4; 3.8]; p-value <0.001) for joint pain; Janssen vaccine (OR=2.03; CI = [1.3; 4.1]; p-value =0.034), the time of occurrence from 1 to 7 days after vaccination (OR=1.43; CI = [1.12; 5.01]; p-value =0.0415) and age (OR=2.01; CI = [1.91; 3.34]; p-value =0.032) for headache. Finally, for fever, the associated factors were the administration of Jansen (OR=2.4; CI = [2.01; 4.5]; p-value =0.0018) and Sputnik V (OR=1.5; CI = [1.11; 3.2]; p-value =0.041) vaccines; and the delay of occurrence from 1 to 7 days after vaccination (OR=3; CI = [2.06; 5.1]; p-value <0.001).

Conclusion: Severe forms of PIAE were very uncommon. These results plead in favor of improving vaccination coverage to better protect populations against the COVID-19 pandemic.

Keywords: Associated factors, PIAE, COVID-19, Brazzaville

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Received Date: *11 Apr 2022*
Accepted Date: *06 May 2022*
Published Date: *12 May 2022*

Citation:
Mavoungou YVY, Niama AC, Annette B, Ndziessi G, Pandzou G, Ossou-Nguiet P-M. Factors Associated with Adverse Events Following COVID-19 Immunization in Brazzaville. Open J Public Health. 2022; 4(3): 1036.

Introduction

Post-Immunization Adverse Events (PIAE) is considered any adverse event that occurs after vaccination and is not necessarily related to the use of the vaccine. It may be a syndrome complained of by the vaccinated person, an abnormal laboratory finding, a sign, or an illness. It is considered serious when it requires or prolongs hospitalization, is life-threatening, results in death, persistent disability or incapacity, or is a birth defect [1].

The protective effect of vaccines against COVID-19 is increasingly documented, as vaccines generally save millions of lives each year. Their mode of action is to train and prepare the immune system to recognize and fight the viruses and bacteria they target [2,3]. However, in the face of this mass vaccination, it seems fundamental to consider the questions of benefits/risks incurred by the population [3,4]. Thus, the FDA recommends reporting of vaccine-related errors, serious adverse events, cases of multisystemic inflammatory disease, and cases of COVID-19 resulting in hospitalization or death after administration of a COVID-19 vaccine. The CDC also encourages reporting of any other clinically significant and non-clinical adverse events, even if not clearly associated with vaccination [5,6].

For example, surveillance of the effects of some vaccines has resulted in the recording of myocarditis and thrombosis [7,8]. Post-vaccination events classified as serious have been documented in several countries, including Brazil, South Africa and the United Kingdom [9].

In Africa, as in Congo, very few data are available on post-vaccination events related to COVID-19 [10]. Because of the lack of formal and in-depth studies on this issue, this work proposed to study

the factors associated with anti-COVID-19 IPD in Brazzaville.

Population and Methods

Type and period of study

This was an analytical cross-sectional study conducted from March 25th to October 15th, 2021.

Study setting

This study was conducted at the Congo's Expanded Program on Immunization (EPI) headquarters, where all data on PIAE are centralized, as well as in the Brazzaville vaccination centers. Each center has a PIAE surveillance team within its organization. In addition to the PIAE reporting teams, a toll-free number 3434 was used to identify and register some reported cases.

Study population

This study included all persons vaccinated against COVID-19 in Brazzaville who reported one or more cases of PIAE.

Selection criteria

Inclusion criteria: Our study included all persons over 18 years of age, vaccinated against COVID-19, whose records included the declaration of one or more PIAE that occurred during the study period.

Non-inclusion criteria: Individuals whose symptoms reported as PIAE began before vaccination were not included in the study.

Sampling

This was a comprehensive sampling of all individuals who reported at least one case of PIAE

Data collection

The data collection tool was a WHO-validated standardized adverse event reporting form. A database was created by meticulously recording all reports from each center and from the 3434 messaging service.

Study variables

The variables were divided into four groups:

1. **Socio demographic variables:** Age and gender.
2. **Vaccination variables:** Type of vaccine and dose.
3. **PIAE-related variables:** The different PIAEs, time of onset of PIAE, course and severity.
4. **Antecedents:** Hypertension, diabetes, asthma, epilepsy, stroke, cancer, smoking, sinusitis.

Data entry, processing and analysis

Data entry was performed with the ODK software. The processing and statistical analysis of the data was done with the software R Studio version 4.0.3. Categorical variables were expressed in numbers and percentages. The Chi-2 test was used for the comparison of qualitative variables. Quantitative variables were expressed as mean, standard deviation, maximum and minimum. They were expressed as mean with standard deviation, maximum and minimum. The following statistical tests were performed: Student's t-test (two groups) or ANOVA (more than two groups) to compare the quantitative variables. The variable of interest was the occurrence of headache, fever, and muscle and joint pain. The other variables were explanatory variables. Logistic regression was used to identify factors associated with the occurrence of PIAE. The calculation of odds ratios and their 95% confidence intervals was used to estimate the strength of associations. The threshold of significance was 0.05.

Ethical considerations

We obtained administrative authorization from the authorities of the Faculty of Health Sciences, the Director of the EPI and the person in charge of coordinating anti-COVID-19 vaccination activities in the Republic of Congo. Confidentiality and anonymity were required throughout this study.

Results

A total of 1010 vaccinated persons reported at least one PIAE in our study period. The vaccines used in Congo since March 2020 are: Sinopharm (2 doses), Sputnik V (2 doses), Sputnik light (one dose), and Janssen (one dose) (Table 1).

Socio demographic characteristics

Age: The overall mean age of the vaccines was 46 ± 12.6 years with a range of 18 to 96 years.

The most commonly used vaccine was Sinopharm. The second booster doses of Sinopharm and Sputnik showed remarkable decreases.

Sex: The gender distribution shows a male predominance (63.27%) with a male-female sex ratio of 1.72. Men were more vaccinated than women, including with all types of vaccines (Table 2).

Medical history recorded

At least one medical history was found in 14.46% of people. Chronic diseases were found, of which hypertension, diabetes and asthma were the most frequent (Figure 1).

Description of PIAE

Twenty (20) types of PIAE were recorded during this study. Joint or muscle pain (63.07%), headache (59.70%), fever (55.84%), dizziness (35.64%), chills (35.25%), digestive disorders (31.88%),

Table 1: Type of vaccines used according to age.

Vaccines	Age (ans)			
	Mean	Ecart type	Minimum	Maximum
Sinopharm dose 1 (n=439)	45	12.7	18	96
Sinopharm dose 2 (n=162)	43	12.5	18	79
Sputnik V dose 1 (n=203)	47	12.7	18	82
Sputnik V dose 2 (n=18)	45	13.0	18	76
Sputnik light (n=63)	51	12.7	18	67
Janssen (n=125)	44	11.8	18	72
Global	**46**	**12.6**	**18**	**96**

Table 2: Type of vaccines used according to gender.

Vaccines	Male		Female		Ratio
	n	%	n	%	H/F
Sinopharm dose 1 (n=439)	269	61.27	170	38.72	1.58
Sinopharm dose 2 (n=162)	101	80.16	61	19.84	1.65
Sputnik V dose 1 (n=203)	146	71.92	57	28.08	2.56
Sputnik V dose 2 (n=18)	12	66.67	6	33.33	2.00
Sputnik light (n=63)	39	62.00	24	38.00	1.62
Janssen (n=125)	72	57.77	53	42.23	1.36
Total	639	63.27	371	36.73	1.72

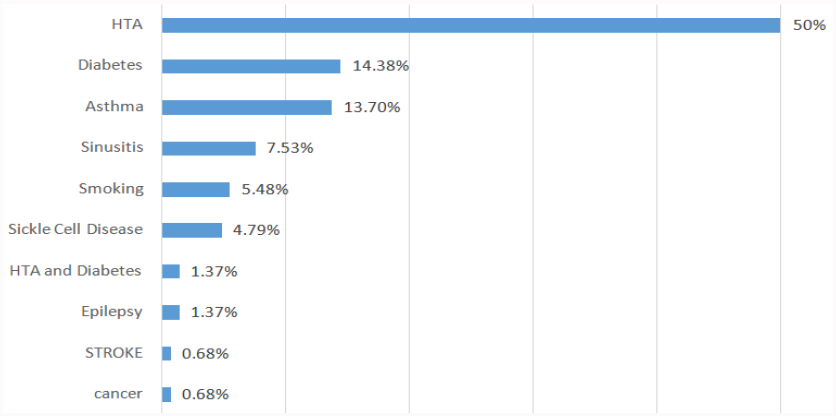

Figure 1: Reported medical history.

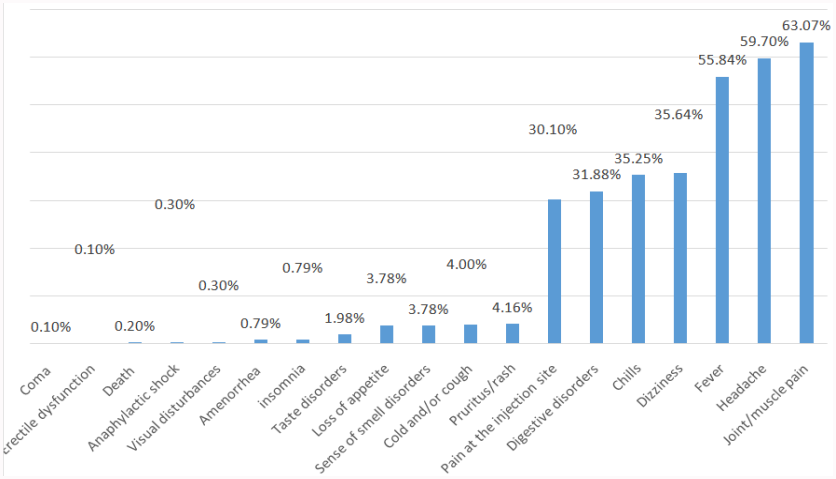

Figure 2: Reported post-immunization adverse events.

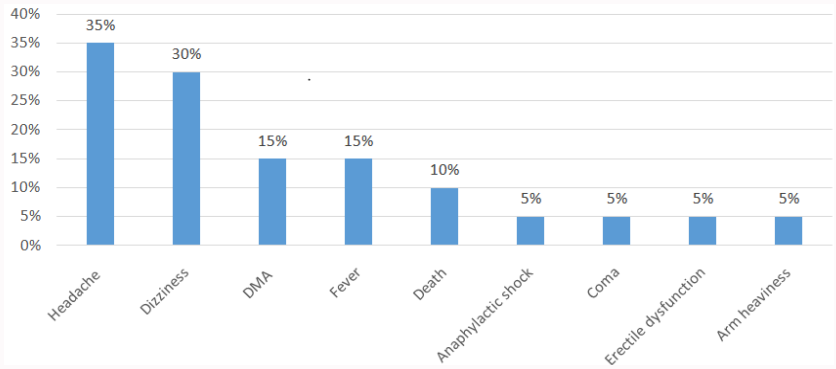

Figure 3: Adverse events following reported severe immunizations.

injection site pain (30.10%) and pruritus or rash (20.50%) were the most reported PIAE (Figure 2).

Among the reported PIAE, a total of nine (9) were severe, of which the most predominant were: Headache (35%), dizziness (30%), AMD (15%), and fever (15%).

Among the severe ABI reported, 50% of the cases had a positive thick blood drop (positive diagnosis for malaria).

Factors associated with the occurrence of PIAE

Explanatory factors for the occurrence of PIAE were analyzed according to the most reported adverse events of the COVID vaccines. The dependent variables were: joint or muscle pain, headache and fever (Figure 3).

Muscle or joint pain: Multivariate analysis identified a single factor significantly associated with PIAE in the form of muscle or joint pain in relation to the Janssen vaccine (OR=2.7; CI = [1.4; 3.8]; p-value <0.001) (Table 3).

Headache: In multivariate analysis, the variables: Janssen vaccine (OR=2.03; CI = [1.3; 4.1]; p-value =0.034), time of occurrence 1 to 7 days after vaccination (OR=1.43; CI = [1.12; 5.01]; p-value =0.0415),

Table 3: Univariate analysis of factors associated with muscle and joint pain.

Variables	MJP (Yes) (n=622)		MJP (No) (n=388)		OR	IC 95%	p-value
	n	%	n	%			
Age (mean ± SD)	45 ± 12.1 ans		46 ± 10.3				
[18-45]	198	52.10	182	47.90			
>45 year	420	66.66	210	33.34	2.4	[0.2; 3.5]	0.418
Gender							
Male	501	88.02	272	88.51			
Female	121	11.98	116	11.48	1.27	[0.57; 3.1]	0.989
Vaccines							
Sputnik light	42	6.75	21	5.41			
Sinopharm	256	41.16	345	88.9	1.1	[0.92; 1.6]	0.946
Sputnik V	200	32.15	21	5.41	2.3	[0.81; 3.9]	0.411
Janssen	124	19.94	1	0.26	2.6	[1.2; 4.1]	<0.001*
Medical History							
Smoking	9	1.41	1	0.27	1.02	[0.2; 2.5]	0.569
HTA	71	11.15	4	1.07	1.89	[1.5; 3.2]	0.047*
Diabetes	20	3.14	1	0.27	1.7	[1.3; 2.9]	0.032*
Asthma	18	2.83	2	0.54	2.2	[1.7; 3.1]	0.006*
Sickle Cell Disease	7	1.09	0	0.00	1.7	[1.1; 3.4]	0.037*
Sinusitis	8	1.26	3	0.80	1.12	[0.4; 2.1]	0.145
Associated Signs							
Headache	423	69.45	49	12.62	2.21	[1.84; 4.53]	0,029*
Fever	273	43.89	31	7.99	2.59	[1.62; 3.93]	0,042*
Pain at the injection site	90	14.47	52	13.40	1.5	[0.6; 2.3]	0,087
Severity							
Yes	3	0,48	17	4,38			
No	619	99.52	371	95.62	2.3	[1.5; 2.93]	0.0356*

and age (OR=2.01; CI = [1.91; 3.34]; p-value =0.032) were significantly associated with headache (Table 4).

Fever: In multivariate analysis; factors associated with fever after Covid-19 vaccination were: The Janssen vaccine (OR=2.4; CI = [2.01; 4.5]; p-value =0.0018), the Sputnik V vaccine (OR=1.5; CI = [1.11; 3.2]; p-value =0.041) and the time of onset of 1 to 7 days (OR=3; CI = [2.06; 5.1]; p-value <0.001).

Discussion

Methodological interest

Our study concerned vaccinated persons who showed post-vaccination effects over a period of six months after vaccination. The methodology adopted in our study allowed an exhaustive recruitment to better specify the characteristics of the PIAE and to reduce as much as possible the various selection biases.

Socio-demographic characteristics

Age: The mean age of the individuals reporting IPFs, across all vaccines, was 46 ± 12.6 years. This could be explained both by the assumption of a better knowledge of the reporting circuit of PID and of the right to free coverage of post-vaccination accidents. Our result is lower than the mean age of 29.83 ± 11.72 years found in Polish health workers who were vaccinated with Modern, Pfizer, Astra Zeneca and Janssen vaccines [11].

Gender: Our study showed that PIAE affected more men (nearly 64%). This could be explained by the fact that in Congo, men are more likely to be vaccinated than women, as shown by data from the national health information system [12]. This finding is different from the one made in France, where women are more vaccinated (52%) than men [13]. The same observation was made in Poland by Dziedzic et al. [14] who found a predominance of females in their study (79.8%) [11]. The trend towards feminization of the medical profession, could explain this difference with the Polish data where the study was done among health care workers.

Prevalence

Our study showed an overall prevalence of 60 PIAE per 10,000 vaccinated persons, including 1 severe case (0.60% with 1.98% of severe cases).

Despite the low proportions of PIAE observed worldwide, their frequency seems to be homogeneous in all countries. In France, the Agencenationale de sécurité du médicament et des produits de santé recorded 0.11% of post-vaccine events (report of October 27th, 2021), of which 21% were severe. The difference with the French data could be explained by the fact that the number of people vaccinated is much higher in France, where, in addition, the vaccines used are not the same as those administered in the Republic of Congo [15]. In Poland, Dziedzic et al. [14] reported a prevalence of 78.9% among health

Table 4: Univariate analysis of factors associated with headache.

Variables	Headache (Yes) (n=603)		Headache (No) (n=407)		OR	IC 95%	P-value
Age (age ± SD)	45 ± 11.05		46 ± 11.30				
[18-45]	200	52.63	180	47.37			
>45 year	430	68.25	200	31.75	2.60	[1.12; 3.53]	0.048*
Gender							
Male	504	83.58	275	67.57			
Female	99	16.41	132	32.43	1.02	[0.57-3.21]	0.439
Vaccines							
Sputnik light	58						
Sinopharm	267	44.28	334	82.06	1.78	[0.92; 2.96]	0.056
Sputnik V	154	25.53	67	16.46	1.12	[1.01; 5.62]	0.034*
Janssen	124	20.56	1	0.25	1.56	[1.22; 2.31]	0.023*
Medical History							
Smoking	5	0.83	3	0.74	1.5	[0.9; 1.01]	
HTA	71	11.77	2	0.49	2.01	[1.4; 2.6]	0.047*
Diabetes	17	2.82	4	0.98	1.37	[1.26; 2.33]	0.032*
Asthma	8	1.33	12	2.95	1.80	[1.67; 3.12]	0.006*
Sickle cell disease	5						
Sinusitis	6	0.99	5	1.23	0.89	[0.43; 2.35]	0.059
Associated Signs							
Muscular or joint pain	423						
Fever	312	51.74	31	7.62	2.59	[1.62; 3.93]	0.042*
Pain at the injection site	85						
Evolution							
Death	0	0.00	2	0.49			
Remission	597	99.01	317	77.88	0.56	[0.32; 2.91]	0.357
Unknown	6	0.99	88	21.62	1.21	[0.14; 3.11]	0.967
Time of Onset							
2-3 months	56	9.29	64	15.72	0.76	[0.13; 5.13]	1.451
7 à 30 days	162	26.87	141	34.64	1.21	[0.85; 2.10]	0.237
1 à 7 days	184	30.51	79	19.41	2.10	[1.15; 2.23]	0.05*
<1 hours	201	33.33	123	30.22	1.89	[1.73; 4.03]	0.0076
Severity							
Yes	7	1.16	13	3.19			
No	596	98.84	394	96.81	2.30	[1.5; 2.93]	0.03568*

professionals; this difference can be explained, among other things, by the fact that this study involved a specific population (health professionals), unlike ours, which was conducted in the general population. In addition to this aspect, three of the four vaccines used in this study are not used in Congo [11].

In the Republic of Congo, PIAE is more frequent for the Sinopharm and Sputnik V vaccines. These findings could be explained by a large number of vaccines effect for Sinopharm. On the other hand, it is possible that the second dose effect induces psychological effects that are very difficult to isolate following the administration of Sputnik V and Sinopharm.

However, both vaccines showed a higher incidence of PIAE with the first dose (9 per 1000 vaccinated persons for Sinopharm and 18 for Sputnik V) than with the second dose (4 per 1000 vaccinated persons for Sinopharm and 2 for Sputnik V). Anderson et al. [16] describe the opposite, as their work shows that post-vaccination events are more frequent with the second dose. In addition, the number of severe cases increased with the second dose of the mRNA vaccine, not yet used in the Republic of Congo.

Paradoxically, the first dose of Sputnik V, equivalent to Sputnik light [17], showed more IPM. This could confirm the hypothesis of a psychological effect linked to the second dose. The alternative of a single-dose regimen would be more reassuring to the population and would limit stress or anxiety than a two-dose regimen.

Description of the different PIAE

The most frequently recorded PIAE were muscle and joint pain (63.07%), headache (59.70%), fever (55.84%), and injection site pain (30.10%). These results corroborate those of Logunov et al.

Table 5: Univariate analysis of factors associated with fever.

Variables	Fever (Yes) (n=564)		Fever (No) (n=446)		OR	IC 95%	P-value
Age (mean ± SD)	45 ± 12.5		47 ± 1.3				
[18-45]	130	34.22	250	65.78			
>45 year	405	64.28	225	35.72	2.4	[0.2; 3.53]	0.248
Gender							
Female	129	22.87	106	23.77			
Male	435	77.13	340	76.23	1.27	[0.57; 3.21]	0.389
Vaccines							
Sputnik light	44	7.80	19	4.26			
Sinopharm	220	39.01	381	85.42	1.8	[0.92; 3.6]	0.456
Sputnik V	178	31.56	43	9.64	2.32	[1.51; 5.2]	0.021*
Janssen	122	21.63	3	0.67	3.56	[1.2; 4.1]	0.003*
Medical History							
Smoking	4	0.71	4	0.89	1	[0.7; 2.8]	0.063
HTA	69	12.23	6	1.35	3.01	[1.9; 3.6]	0.047*
Diabetes	20	3.55	1	0.22	2.7	[1.6; 4.9]	0.032*
Asthma	17	3.01	3	0.67	2.2	[1.7; 3.1]	0.006*
Sickle Cell Disease	7	1.24	0	0.00	1.4	[1.2; 2.1]	0.037*
Sinusitis	9	1.59	2	0.45	4.89	[0.4; 5.1]	0.145
Associated signs							
Muscular or Joint Pain	273	48.40	41	9.19	2.21	[1.84; 4.53]	0.029*
Headache	312	55.32	62	13.67	2.59	[1.62; 3.93]	0.042*
Pain at the injection site	75	13.29	59	13.23	1.9	[0.12; 2.13]	0.187
Evolution							
Deaths	0	0.00	2	0.45			
Remission	531	94.15	380	85.2	0.6	[0.32; 2.91]	0.307
Unknown	33	5.85	64	14.35	2.21	[-0.14; 3.11]	0.693
Time of onset							
2-3 months	21	3.72	11	2.47	0.96	[0.1; 2.2]	1.042
7 à 30 days	136	24.11	272	60.98	1.45	[0.5; 2.5]	0.637*
1 à 7 days	208	36.88	69	15.47	2.78	[1.5; 3.37]	0.019
<1 day	199	35.28	94	21.08	1.89	[1.7; 4.03]	0.716
Severity							
Yes	3	0.53	17	3.81			
No	561	99.47	429	96.19	2.3	[1.5; 2.93]	0.0356*

[18] in Russia who found the same manifestations, but in different proportions. This could be explained by the difference in the study methods used, as Logunov et al. [18] conducted an open, non-randomized phase 1/2 trial. Other studies have also reported similar PIAE, including Zhu et al. [19], who also report similar effects at higher rates. These differences are probably due to different sample sizes and methodological issues. For example, the Zhu et al. [19], study was a non-randomized, open-label trial in which participants were required to report any post-vaccination effects.

Other manifestations were found, among which: pruritus and skin rash (20.50%), cold sometimes accompanied by cough (4.16%), digestive disorders (31.88%), loss of appetite (3.76%), and taste disorder (3.76%) and smell disorder (1.98%). These events are recognized but described as infrequent in the Janssen summary of vaccine characteristics [20].

Less frequent or rare were insomnia (0.79%), amenorrhea (0.79%), hypersensitivity reaction (0.30%), visual disturbances (0.30%), death (0.20%), coma (0.10%), and erectile dysfunction (0.10%).

In France, the National Agency for the Safety of Medicines and Health Products has recorded 21% of serious post-vaccination effects, including deaths, although the vaccines involved are not the same [15].

Time to onset and evolution of PIAE

The onset of PIAE in our study was more frequent in the first month after vaccination and especially in the first week. Our results are similar to those of Zhu, who describes a greater number of effects at the one-week interval after vaccination [4].

PIAE mostly progressed to remission (90.69% of cases). Two deaths were recorded and about 8% of the persons had signs that persisted after more than one week. PIAE had a generally favorable evolution, which would reassure us about the safety of the vaccines.

Factors associated with the occurrence of PIAE

Our study revealed statistical associations highlighting PIAE in the form of muscle or joint pain, headache and fever.

Muscle or joint pain was significantly associated only with the Janssen vaccine (OR=2.7; CI = [1.4; 3.8]; p value <0.001). Headache was associated with Janssen vaccine (OR=2.03; CI = [1.3; 4.1]; p-value =0.034), time to onset of 1 to 7 days after vaccination (OR=1.43; CI = [1.12; 5.01]; p-value = 0.0415), and age (OR=2.01; CI = [1.91; 3.34]; p-value =0.032), respectively. Fever was significantly associated with administration of Jansen vaccines (OR=2.4; CI = [2.01; 4.5]; p-value =0.0018), Sputnik V vaccine (OR=1.5; CI = [1.11; 3.2]; p-value =0.041); and time to onset of 1 to 7 days (OR=3; CI = [2.06; 5.1]; p-value <0.001). It is evident that all of these PIAE show a significant association with the Janssen vaccine. This could be explained by the fact that more people wanted to receive this vaccine when they had the choice. In addition, media coverage of the Janssen vaccine may have created reluctance and induced a negative psychological effect. Our observations are not isolated in that the aforementioned PIAE is common worldwide. However, the heterogeneity of vaccines between countries makes it difficult to compare our observations with those of others.

Conclusion

This study described COVID-19-related PIAE in Brazzaville. It revealed the most reported and severe post-vaccine events, which were very infrequent. The hypothesis of the safety and security of the vaccine therefore seems credible. Hence the interest in reinforcing public health communications based on scientific evidence, in order to optimize public confidence in vaccination. This, in the interest of maximizing the effectiveness of the vaccine coverage against COVID-19.

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