

# Adverse Events following AstraZeneca COVID-19 Vaccination: A Case Study in Abidjan, Côte d'Ivoire

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## Abstract

**Introduction:** Pharmaceutical companies have boosted vaccine production following the global COVID-19 pandemic. In Côte d'Ivoire, the first vaccination campaign with the AstraZeneca vaccine began on March 1, 2021, as part of the Covax program. Despite the positive benefit/risk balance, the adverse effects of vaccination should not be minimized. **Objective:** To identify adverse events of AstraZeneca's COVID-19 vaccination for better management. **Materials and Methods:** This is a case of a 57-year-old obese (BMI = 39 kg/m<sup>2</sup>) female health care worker who experienced adverse events in March 2021 after the second dose of AstraZeneca vaccine administered 4 weeks apart. These were subject to mandatory case reporting. **Results:** Major post-vaccination events occurred in a noisy systemic picture with parameters showing significant disturbances. Biological surveillance remains costly and makes the accountability of the vaccine complex. **Conclusion:** Vaccination remains the ultimate weapon in the fight against endemic diseases but should not overshadow the reporting of adverse events.

#### **Keywords**

Adverse Events, Post-Second Immunization, AstraZeneca Vaccine, Abidjan

# **1. Introduction**

The COVID-19 pandemic was very deadly from 2020 to 2021 [1] [2]. Prevention through strict adherence to barrier measures and successive confinements coupled with internal and border travel restrictions was not sufficient to limit the spread of the virus. The implementation of a global policy of large-scale vaccine strate-

gies in collaboration with WHO and GAVI (Global Alliance for Vaccine and Immunization) has allowed many countries, particularly in Africa, such as Côte d'Ivoire, to be among the first to benefit. Indeed, on February 26, 2021, Côte d'Ivoire is the second African country and the first French-speaking country to receive the first doses of AstraZeneca COVID-19 vaccine, from the COVAX program (COVID-19 Vaccines Global Access) deployed thanks to European Union assistance [3]. A few sporadic cases of post-immunization complications have been observed with AstraZeneca vaccine. The purpose of reporting a clinical-biological observation is to identify and follow the evolution of a case of Post-Vaccine Adverse (PVA) events to improve management.

# 2. Materials and Methods

This was a clinical and biological observation. In April 2021, a 57-year-old woman, health worker, obese (BMI =  $39 \text{ kg/m}^2$ ), with a history of phlebitis, hypercholesterolemia (2.43 g/l) and a normal coronary angiography for recurrent chest pain, reported a malaise 7 days after her second injection of the AstraZeneca vaccine (April 7, 2021, lot 4120Z027) at a four-week regulatory interval from the 1st (March 6, 2021, lot 4120Z027). A doctor goes to her bedside at home. He conducts an interrogation, looking for general signs, T°, and BP, then performs a clinical examination, state of consciousness, SaO<sub>2</sub>, cardiovascular auscultation, etc.) to assess the degree of severity. With her informed consent, a nasal swab was immediately performed for a COVID-19 PCR which came back negative. Blood and urine samples were taken for blood count, COVID-19 serology, CRP, LDH, Troponin, CCP, Rheumatoid Factor, D-dimer, and urine protein assays respectively. To look for another etiology of hyperthermia such as malaria and typhoid fever. Thick film and Vidas and Felix serology are requested. Several laboratory automatons, the GeneXpert, the Cobas C311Hitachi, the Sysmex XN 1000, the Vidas, and the Architect plus i1000sr Abbott, were used for the different explorations.

# 3. Results

The results of the clinical examination and biological tests are recorded in **Figure 1**, below in chronological order of the evolution of the symptomatology.

# 4. Comments and Discussion

The clinical symptomatology of this patient was noisy with temporary disability. The risk factors are revealed through her medical history of phlebitis, hypercholesterolemia, and recent coronary angiography 2 months ago for the indication of recurrent chest pain. The absence of a COVID-19 infection concomitant with the presence of cutaneous and subungual thrombosis, hyperthermia, hypotension, and red urine accompanied by major biological disturbances in the body fluids, indicate the possibility of major systemic Adverse Post-Vaccination Events (APEs) of the AstraZeneca vaccine administered. However, the evolution was favorable with some sequelae.

ILLUSTRATIONS	BIOLOGY	DAY	CLINICAL
		JO APR7	Minimal pain at the injection site (left arm) and a slight fleeting feeling of tightness in the chest.
		J6 APR 13	Heaviness in the right upper limb opposite the injection site; Curvature, intense headache isolated without hyperthermia
Image: Precipitate urinary at 4'CImage: Precipitate redissolved at 37'C	Covid 19 PCR negative(4 previous swabs negative) Skin thrombus Intraungual depot -CRP :60 x higher -D-dimer:6 xhigher -LDH(lactic Degydrogenase):Normal -Thrombocytopenia:80,000/mm3. -Thick Gout, Vidal and Felix negative. -Anti-CCP and RF negative. -Urine: Glucose =0,Alb 426 mg/l -Angioscanner and cororonarography without abnormality 2 months ago	J9-J13 APR 16-20	-Sawtooth hyperthermia with a noctumal peak at 40°C. -SaO2:80~90%, BP = 80/60 mm Hg. -Transient neurological disorders: logorrhea, incoherent speech, agitation, skin hyperesthesia, dental hypersensitivity. -Heavy sweating, insatiable thirst without skin folds(3 L per day ). -Red Porto urine. Nasolabial herpes .Thrombus of the right thigh
-CRP normalized,D-dimer:6 x higher-LDH increasedThrombocytopenia normalized Existence of IgGanti Covid19		J15 APR 22	Apyrexia, asthenia, disappearance of headaches, curvatures -Residual pain in right arm and lower limbs
		J19 APR 26	Residual numbness and pain in the right arm with paresthesia tingling, itching in the palm of the hand. Heaviness of the lower limbs

Figure 1. Description of clinico-biological disorders observed.

The frequency of post-vaccination systemic events according to the package insert for this vaccine is often observed. The most frequent minor adverse events, as with other vaccines, are mainly fatigue, headache, injection site reaction. In addition, flu-like symptoms (fever, chills, etc.) have been reported in most cases. They usually disappear spontaneously within a few days with or without treatment [4] [5].

These minor adverse events are most commonly reported for the first dose with AstraZeneca vaccine. Adverse events are considered serious as soon as they result in temporary inability to work, inability to leave the house, need for hospitalization, life-threatening illness, or death [5]. Over time, serious adverse events secondary to AstraZeneca vaccine have been better documented [6]-[12].

Unusual thrombosis, associated with thrombocytopenia (low blood platelet count), is listed as a risk in the European Medicines Agency's Summary of Product Characteristics. These are blood clots, in different or unusual locations (e.g. brain, intestine, liver, spleen), associated with a low level of blood platelets, in some cases accompanied by bleeding. The majority of cases were in women. Thrombocytopenia associated with increased D-dimer is a serious factor [9].

Hemodynamic disturbances in the setting of a nephrotic syndrome secondary to Minimal Glomerular Damage (MGD) nephropathy have been reported after vaccination with AstraZeneca's SARS-CoV-2 mRNA vaccines. The presentation is one of sudden onset anasarca resembling a capillary leakage pattern, occurring 3 weeks in one patient after a first dose of vaccine. Results of pharmacovigilance studies are still needed to determine whether there is a causal link between the occurrence of this nephrotic syndrome and vaccination [10].

Authors describe the development of a form of Guillain-Barré syndrome in individuals, all of whom received a first dose of AstraZeneca vaccine and reported paresthesias, tingling sensation and facial involvement [4]. Guillain-Barré syndrome is a peripheral nerve disorder characterized by muscle weakness and even progressive paralysis, most often beginning in the legs and sometimes progressing to the respiratory muscles and then to the nerves of the head and neck. It is listed as a potential risk by the European Medicines Agency [11].

Thus, we must retain from this observation, clinico-biological arguments on the adverse effects of the AstraZeneca vaccine, as for any vaccine, for which pharmacovigilance studies are still necessary to confirm whether there is a causal link. From this observation, some recommendations seem necessary:

*Recommendation 1*: Carry out a targeted interrogation in people at potential risk (elderly people, BMI > 30 kg/m<sup>2</sup>, history of thrombocytopenia, previous thromboembolic complications, tingling, facial paralysis, etc.) before administration of any type of COVID-19 vaccine dose.

Indeed, among vaccine trial participants of AstraZeneca vaccine, aged 56-65 years, 8 cases of COVID-19 were reported in those who received AstraZeneca COVID-19 Vaccine (≥15 days after the second dose) compared with 9 cases in the control group [4].

*Recommendation 2*: Recommend systematically spacing AstraZeneca vaccine injections by more than 4 weeks or even 8 to 12 weeks for people at potential risk, in strict compliance with the manufacturer's instructions.

This leaflet states that protection begins about 3 weeks after the first dose of vaccine and lasts up to 12 weeks [4].

*Recommendation 3*: Systematically indicate the dosage of certain simple biological markers (urine tests with strips) before and from the first 5 days after the vaccine injection to anticipate the occurrence of post-vaccination renal complications.

*Recommendation 4*: Encourage routine oral rehydration through regular fluid intake during the week of vaccine administration to reduce dose-dependent effects.

#### **5.** Conclusion

These post-vaccination reactions to AstraZeneca vaccine can be serious or even fatal, warranting pharmacovigilance studies to determine if there is a causal link between the occurrence of IPD and vaccination. Hence, the interest in implementing simple recommendations is necessary, especially since vaccination remains the ultimate solution for effective control to avoid fatal complications of this viral disease.

### **Conflicts of Interest**

The authors declare no conflicts of interest regarding the publication of this paper.

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