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Events Supposedly Attributed to Vaccine or Immunization of the AstraZeneca Vaccine: a Case Study

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Authors' contributions

This work was carried out in collaboration among all authors. All authors read and approved the final manuscript.

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Case Report

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ABSTRACT

A case of Events Supposedly Attributed to Vaccination or Immunization (ESAVI) due to the application of the AstraZeneca vaccine was presented on December 14th of 2021, with 14 days from beginning to resolution. It was treated with 2 administrations of Dexamethasone of 8 mg, one every 24 hours and Fexofenadine 120 mg 1 tablet every 12 hours for 7 days, stating being discharged on Tuesday 28th with vital signs within normal parameters, although wheals were slightly visible, they gradually disappeared.

Keywords: AstraZeneca; attributable; ESAVI; vaccine.

1. INTRODUCTION

Vaccines are considered as one of the most important inventions in the history of humankind, They represent the most simple and profitable intervention to protect against epidemics and pandemics. Essentially, the benefits are related with the decrease of mortality and morbidity, including, at the same time, financial benefits by avoiding hospitalization, preventing long term disability and maintaining the economy. Nevertheless, the development of new vaccines is a very complex process, given that they have to undergo extensive review and approval processes by national regulatory agencies before they can be applied to the population [1,2]. A vaccine basically trains the immune system to recognize and attack the virus when it is found, since its function is to protect both the person to whom it is applied and the community [3].

Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) appeared in a moment of maturity of the basic scientific knowledge in some fields, including genomics, structural biology, antigenic cartography and reverse vaccinology. In this manner, the global scientific investigation was able to be realized at a pandemic speed and the development of vaccines underwent a change of paradigm as well [4].

Nowadays, as a world scientific priority, there are multiple projects around the world based on the development of a vaccine against COVID-19 [5]. For example, Mexico's vaccines authorized on March 9th of 2021, which include Oxford-AstraZeneca, Pfizer-BioNtech, Sputnik V, CanSino and SinoVac [2].

In this article we are going to be specifically referring to AZD1222 vaccine from the AstraZeneca laboratory, which is a recombinant vaccine that has a non-replicating chimpanzee adenovirus as a viral vector (ChAdOx1-S), whose overall efficiency documented against primary symptomatic COVID-19 was of 66.7%. Accordingly to the World Health Organization (WHO), it can be considered the possibility of applying a booster dose between 4 and 6 months after the first dosis, paying special attention to the risk groups established in the "WHO roadmap for priority setting" [6].

In participants who received two standard doses, efficacy was higher in those with a longer interval (81.3% efficacy at ≥12 weeks) than in those with a shorter interval (55.1% efficacy at <6 weeks) [7]. The real concern has been side effects.

Regarding the security of this vaccine, there are analysis done by the Global Advisory Committee on Vaccine Safety, which consists of a group of experts who performs various an Studies and well-founded guidelines to the WHO regarding the safe use of vaccines, through the review of reports published by healthcare institutions about suspicious security events that may lead to international consequences.

Within these effects, a very rare adverse event has been reported following the administration of this vaccine, known as thrombosis with thrombocytopenia syndrome. This syndrome consists in uncommon and severe blood coagulation alterations associated to low platelet count, situation that implies a serious risk to people's health. Very rarely, cases of Guillain-Barré syndrome associated with the application of the vaccine have been reported, in which its causal association has not yet been determined [6].

Regarding the safety data in clinical studies, an interim pooled analysis was performed using trial data COV001 and COV003 (both realized in the United Kingdom), COV003 (realized in Brazil) and COV005 (realized in South Africa). The safety database included 23,745 participants. AZD1222 vaccine was well tolerated, with the majority of local and systemic side effects being

mild to moderate. On the official page of the Mexican Federal Government, the most common complications attributable to the application of this vaccine are indicated as: pain in the application area, pain in the arm, nausea, adynamia and shivers [8]. Similarly, the presence of headache, myalgia, arthralgia, fatigue, malaise, fever and heat or itching in the puncture area has been documented [9].

Since mid-March of 2021, the European Medicines Agency (EMA) has been reporting the analysis of cases of blood clots formation in the brain's veins (cerebral venous sinus thrombosis, CVST), the abdomen's veins (splanchnic vein thrombosis) and in arteries with thrombocytopenia and sometimes bleeding, which occurred after vaccination with AZD1222.

On April 7th the EMA pointed out that the Pharmacovigilance Risk Assessment Committee (PRAC) concluded that the unusual blood clots with low platelet count (thrombocytopenia) must be included as very rare adverse effects from AstraZeneca's COVID-19 vaccine [10].

The dermatology reactions published to date are rare and include acute and chronic urticaria with or without anaphylaxis, the so-called "COVID arm" (a plaque of erythema at the application site appears two to seven days after inoculation), [11] it can be severe if the reaction occurs within the first 4 hours after its application *(12,13)*. 90% of women develop it, 78% of caucasians, 21% occurred in the first dosis, 63% after the second one and 16% in both applications [12].

The case here presented had a progressive evolution with an impact on health that caused confusion as to whether it was a case of COVID, or rather, the adverse complication derived from the vaccine given that the test was positive, but this result can be emitted due to the circulation of the attenuated virus.

This kind of complication or reaction presumably attributable to the application of this vaccine has an incidence of 1 every 1000 applications [13].

In events like these, it is important to notify the suspected adverse reactions to the medicine after its authorization. This allows a continuous monitoring of the drug's risk/benefit ratio [14].

The Advisory Committee on Vaccines and Immunization Strategies (CAVEI) in 2021 recommended that facing an increased risk of serious adverse events, is important to update the decision to apply AstraZeneca based on the strategy matrix of immunization recommended facing ESAVI [15].

2. CASE PRESENTATION

This case study corresponds to an ESAVI, in this case of AstraZeneca. The case was manifested on a 61-year-old male, stating that he had received the first and second dose of Pfizer without any symptoms. He received the AstraZeneca vaccine on December 14th of 2021 at midday, within the first minutes the only manifestation was pain in the application area, an hour later he presented tremors in the fingers, most often in the thumbs, on Wednesday 15th three papular lesions were observed around the application area as well as arm pain; during the night he presented anxiety, temperature of 37.5°C, intense shivering and bright red wheals on the chest, abdomen and extremities. He took one dose of ibuprofen during the night of December 15th, the next day he took acetaminophen 500mg every 6 hours, on the 17th the wheals had covered the whole body with the exception of the genitals and the face, on this day excessive sweating was added as well as headache, dry cough, shivers, adynamia, intense pain in the lumbar region, anorexia and nausea, for this reason the patient seek medical attention with a private physician who applied 2 injections of dexamethasone of 8 mg, one every 24 hours. He then went to a medical unit where he was diagnosed with ESAVI, during the medical revision his weight was 73 kgs, his height 1.68m and his blood pressure was 120/80 mmHg treated with an unspecified drug, 7 days later it decreased to 110/70 mmHg, the patient had an adequate pulmonary ventilation without breathing difficulty, no lymph nodes were detected and the rest of the physical examination was normal. The antihistamine Fexofenadine of 120 mg was administrated for 7 days, one tablet every 12 hours. He was discharged on Tuesday 28th with normal vital signs, although the wheals were still slightly visible, they persisted until January 7th as well as the paresthesias in the fingers of the upper extremities and areas of the right leg.

3. DISCUSSION

The patient indicates that 15 days before receiving the AstraZeneca vaccine, took a droplet of coronavirus-nosodes (homeopathic preparation from the secretion of a positive Coronavirus patient). During the first days before

the vaccine the patient observed red whealing; proceeded to administer 30c Belladonna atropa 30c, 5 drops in water/3 times a day, orally during every morning, afternoon and evening; this apparently delayed more severe allergic-type or intoxication-type reactions because of the vaccine.

It has been confirmed that AstraZeneca vaccine is safe and effective against severe COVID-19 cases, which include hospitalizations and death. Nonetheless, in 2021 some countries such as Germany, France, Italy, Spain and other european countries suspended the use of Oxford-AstraZeneca Covid-19 vaccine, besides the WHO requisition to continue its application. The decision was taken due to the harm and impact on the population's health.

It is important to determine the benefit obtained against the possible risks of administering this type of biologicals that have been helpful to diminish the presence and consequences of this infection that has challenged society in general.

4. CONCLUSIONS

COVID-19 vacaciones have shown systemic reactions similar to those of a mild or moderate SARS-CoV-2 virus infection. More than 80% of the vaccinated population can experience pain in the inoculation area, regardless of the vaccine received. In most cases, this pain lasts from 24 to 72 hours, with exceptions to those complications caused due to the injection technique (hematoma, neuritis due to irritation of the circumflex nerve).

It is clear that there is yet a lot to learn and discover regarding this topic. It is true that the presence of primary prevention measures urged to stop the pandemic because of the impact on the population and Healthcare institutions. Although, the velocity and agility on the vaccine fabrication process caused that up until today, the long term effects are unknown to us; hoping that the benefits are greater than the consequences that may yet to occur with years after its application.

The importance of this matter, that we shall not forget, is considering the benefits of receiving a complete vaccination schedule (including any of the SARS-CoV-2 vaccine), compared to any impicated biological risk against getting infected by this virus.

ETHICAL APPROVAL

As per international standard or university standard written ethical approval has been collected and preserved by the author(s).

CONSENT

As per international standard or university standard, patient(s) written consent has been collected and preserved by the author(s).

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COMPETING INTERESTS

Authors have declared that no competing interests exist.

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