SFDA SAFETY SIGNAL

"A signal is defined by the SFDA as reported information on a possible causal relationship between an adverse event and a drug, the relationship being unknown or incompletely documented previously. Usually more than a single report is required to generate a signal, depending upon the seriousness of the event and the quality of the information. A signal is a hypothesis together with data and arguments and it is important to note that a signal is not only uncertain but also preliminary in nature"

03-09-2023

Saudi Food and Drug Authority (SFDA) – Safety Signal of COVID-19 Vaccine NRVV AD (CHADOX1 NCOV-19) and the Risk of Myocardial infarction

*The Saudi Food and Drug Authority (SFDA) recommends all health care professionals to be aware of the safety signal of **Myocardial infarction** associated with the use of **ChAdOx1-S/nCoV-19 Vaccine**. The signal has been originated as a result of routine pharmacovigilance monitoring activities.*

Introduction

The AstraZeneca ChAdOx1-S/nCoV-19 [recombinant] vaccine is a replication-deficient adenoviral vector vaccine against coronavirus disease 2019 (COVID-19). The vaccine expresses the SARS-CoV-2 spike protein gene, which instructs the host cells to produce the protein of the S-antigen unique to SARS-CoV-2, allowing the body to generate an immune response and to retain that information in memory immune cells. [1] Myocardial infarction (MI) is also called heart attack that take place in sudden blockage or very low blood flow to the heart's coronary arteries. The most common cause of the blockage to the coronary artery is blood clot that it get narrowed by atherosclerosis which helps its formation. In the other hand, slow blood flow in a coronary artery occurs when the heart is tachycardia or hypotensive which can be explained in the increased oxygen demand greater than the supply. [2] The aim of this review is to evaluate the risk of MI associated with the use of the vaccine and to suggest regulatory recommendations if required.

Methodology

Signal Detection team at SFDA performed a signal review using National Pharmacovigilance Center (NPC) database, and World Health Organization (WHO) database, VigiBase, with literature screening to retrieve all related information to assess the causality between Myocardial infarction and ChAdOx1-S/nCoV-19 vaccine use. The search conducted on July 2023.

Results

Case Review: Signal detection team at SFDA have searched Saudi national database and WHO database to find individual case safety reports (ICSRs) of MI associated with ChAdOx1-S/nCoV-19 vaccine. In Saudi Vigilance database, there was one reported case with possible association. Globally, the search in the WHO database resulted in 1265 global case-reports. The authors used signal detection tool (Vigilyze) to retrieve all reported cases. [3] Authors also applied WHO-UMC causality assessment

criteria on top 30 ICSRs with completeness score of (1.0). [4] Among them, 29 cases of MI were possibly linked to the vaccine.

Datamining: The disproportionality of the observed and the expected reporting rate for drug/adverse drug reaction pair is estimated using information component (IC), a tool developed by WHO-UMC to measure the reporting ratio. Positive IC reflects higher statistical association while negative values indicates less statistical association, considering the null value equal to zero. The results of (IC= -1.9) revealed a negative statistical association for the vaccine/ADR combination. [3]

Literature: On July 2023, the author searched for eligible publication using terms "ChAdOx1-S/nCoV-19 vaccine" and "Myocardial Infarction".

A case report of 62-year-old woman. She complained from central chest pain that started approximately 1.5 hours after receiving her first dose of the COVID vaccine (AZD1222 – Oxford University and AstraZeneca). She was diagnosed with ST elevation myocardial infarction (STEMI). [5] Another case report of a healthy 63-year-old man was found. He complained from chest pain for last 6 hours. He had history of taking first dose of AZD1222vaccine 2 days back. The examination showed ST elevated inferior wall myocardial infarction (STEIWMI). [6]

Conclusion

The weighted cumulative evidence identified from assessed cases and literature are sufficient to suggest causal association between ChAdOx1-S/nCoV-19 vaccine and MI. Health care professionals and health regulators must be aware of the potential risk in vaccine recipients.

Report Adverse Drug Events (ADRs) to the SFDA

The SFDA urges both healthcare professionals and patients to continue reporting adverse drug reactions (ADRs) resulted from using any medications to the SFDA either online, by regular mail or by fax, using the following contact information:

National Pharmacovigilance Center (NPC)
Saudi Food and Drug Authority-Drug sector
4904 northern ring branch rd
Hittin District
Riyadh 13513 – 7148
Kingdom of Saudi Arabia
Toll free number: 19999
Email: NPC.Drug@sfda.gov.sa

References:

1- World Health Organization (WHO), 2021. AstraZeneca ChAdOx1-S/nCoV-19 [recombinant], COVID-19 vaccine. [online] Available at: < https://www.who.int/publications/m/item/chadox1-s-recombinant-covid-19-vaccine > [Accessed 19/7/2023].]
2- Harvard Health Publishing. (2019). Heart Attack (Myocardial Infarction). Available at: https://www.health.harvard.edu/a_to_z/heart-attack-myocardial-infarction-a-to-z [Accessed on: 7/19/2023].
3- Vigilyze.who-umc.org. 2023. [online] Available at: https://vigilyze.who-umc.org/ [Accessed 17/9/2023].
4- World Health Organization WHO (2013). WHO-UMC system for standardised case causality assessment. Available at https://www.who.int/publications/m/item/WHO-causality-assessment [Accessed 17/9/2023].
5- Maadarani, O. et al. (2021) 'Myocardial infarction post covid-19 vaccine – coincidence, KOUNIS syndrome or other explanation – time will tell', JRSM Open, 12(8), p. 205427042110252. doi:10.1177/20542704211025259.
6- Chatterjee, S. et al. (2021) 'Myocardial infarction after COVID-19 vaccination-casual or causal?', Diabetes & Metabolic Syndrome: Clinical Research & Reviews, 15(3), pp. 1055–1056. doi:10.1016/j.dsx.2021.04.006.