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A Possible Cluster of AEFI (Adverse Event Following Vaccination) Following AZD1222 (Covishield) Vaccination in India?

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Abstract

In order to mitigate the spread of the COVID-19 infection in India, the Indian government granted approval for the emergency use of Oxford-AstraZeneca's COVID-19 (coronavirus disease 2019) vaccine AZD1222 (Covishield). The biggest large-scale COVID-19 vaccination drive in the world is being carried out continuously till date in India. In this research article, a possible cluster of AEFI (Adverse Event Following Vaccination) following AZD1222 (Covishield) vaccination in India has been briefly presented.

Keywords: AZD1222 (Covishield); Covishield vaccine; COVID-19 vaccination; AEFI (Adverse Event Following Vaccination); Acute myocardial infraction Pulmonary fibrosis; Selenium nanoparticles; Bleomycin; Antioxidant enzymes; Interleukin- 6

Abbreviation: AEFI: Adverse Event Following Vaccination; COVID-19: Coronavirus Disease 2019; WHO: World Health Organization; AEFI: Adverse Events Following Immunization; GBS: Guillain-Barre Syndrome

Introduction

In an effort to curb the present escalating number of active COVID-19 cases in India, in January 2021, the Indian government granted approval for the emergency use of Oxford-AstraZeneca's COVID-19 (coronavirus disease 2019) vaccine AZD1222 (Covishield). The first phase of the largest COVID-19 vaccination program in the world was launched on 16th January 2021. The first phase carried out the vaccination of frontline healthcare workers as well as essential service personnel. At present, the second phase of the vaccination program commenced on 2nd March 2021. This phase is targeting people over the age of 60 and those in the 45- 59 years with comorbidities [1]. Since 2021 until date, the rate of vaccination in the Indian population has been continuously good and at present, keeping in mind the predicted possible fourth wave due to the spread on the new XE Omicron variant, many in every eligible age bracket have already taken booster doses.

Discussion

The percentage of severe AEFIs following vaccination with Covishield has been very few (as low as 0.003% of the total vaccinated population) as compared with the large number of people who only suffered mild symptoms of AEFIs such as fatigue, myalgia, mild fever, headaches, injection site pain, pain in the body, nausea and stomach problems [2]. The range of reported or severe AEFIs amongst the 69-71 deaths following vaccination with Covishield includes diagnosis of Guillain-Barre Syndrome (GBS) causing significant disability (in 2 severe AEFI cases), hospitalization due to life-threatening breathing difficulties and death [3-7].

The fatalities following vaccination using Covishield have been recorded in the states of Delhi, Uttar Pradesh, Gujarat, Karnataka, Telengana, Andhra Pradesh, Odisha and Haryana. The six men and three women who died were between 27 and 56 years old. The deaths occurred between 1-6 days after vaccination with Covishield. After the release of the first Serious Adverse Events Following Immunization (AEFI) on 4th June 2021, there have been 18 documented cases that were said to show inconsistent causal association to vaccination (the causality assessments have not been made public) [8-10]. What is of utmost importance is that in the majority of the recorded fatalities following vaccination with Covishield, there has been a commonly recurring cause of death namely cardiovascular problems or "brain stroke."

In every reported case, the central and state authorities have announced that the deaths cannot be attributed to the vaccination using Covishield but up till date, no causality assessment and the associated results have been made public. This has been stated repeatedly by the authorities despite the fact that in a few of the recorded AEFI deaths, the patients were not found to have any pre-existing morbidities [4-7]. However, the reported cause of death in many of fatality cases (where autopsies have been said reported as done) cited the cause of death as being "changes to the heart" and myocardial infarction [5-9]. The WHO (The World Health Organization) defines "a cluster of AEFIs as two or more cases of the same adverse event related in time, place or vaccine administered" [8,9].

I outline the potential importance of the above described severe AEFIs and deaths (due to acute myocardial infarction/ acute coronary syndrome) in more than 21 vaccine recipients after vaccination with Covishield till date. The findings suggest a possible cluster of AEFIs in this case since the confirmed cause of death in at least 21 cases has been heart changes or myocardial infarction (this is supported by reported results of the performed autopsy which is evidence). Following this first AEFI report released in June 2021, several more Covid-19 vaccination associated AEFI reports have been released by the concerned government department.

Conclusion

I concur that even though the rate of recorded severe AEFIs and deaths following vaccination using Covishield in India remains very low (0.003%), there is still the need to carry out further large-scale investigations on the possibility of a presented cluster of AEFIs after Covishield vaccination with stringent causality assessments (based on the documented AEFI cases of cardiac complications of the first released government report). As India continues to move forward in the largest, worldwide vaccination program against COVID-19, there is an urgent need for very strict and transparent monitoring of all possible clusters of AEFIs.

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