Adverse drug reactions from two COVID-19 vaccines reported in Saudi Arabia	
Authors	Amjad Alfaleh , Abdullah Alkattan , Nashwa Radwan , Mona Elzohri , Abrar Alzaher , Mona Ibrahim , Eman Alsalameen , Amani Alsultan , Dina Alhabib , Alanood Alshelwah , Nagla Mahmoud , Khlood Sagor , Khaled Alabdulkareem
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Abstract:

Background: Several reports have been published about the impact of coronavirus disease 2019 (COVID-19) vaccines on human health, and each vaccine has a different safety and efficacy profile. The aim of this study was to reveal the nature and classification of reported adverse drug reactions (ADRs) of the two COVID-19 vaccines (tozinameran and ChAdOx1) among citizens and residents living in Saudi Arabia, and show possible differences between the two vaccines and the differences between each batch on the health of populations.

Methods: A cross-sectional study was conducted in Saudi Arabia between December 2020 and March 2021. Saudi citizens and residents aged ≥ 16 years who had at least one dose of any batch of either of the two approved COVID-19 vaccines (tozinameran and ChAdOx1) and who reported at least one ADR from the vaccines were included. The study excluded people who reported ADRs after receiving tozinameran or ChAdOx1 vaccines but no information was provided about the vaccine's batch number.

Results: During the study period, 12,868 vaccinated people, including a high-risk group (i.e., those with chronic illness or pregnant women), reported COVID-19 vaccine ADRs that had been documented in the General Directorate of Medical Consultations, Saudi Ministry of Health. The study reported several ADRs associated with COVID-19 vaccines, with the most common (> 25%) being fever/chills, general pain/weakness, headache, and injection site reactions. Among healthy and high-risk people, the median onset of all reported ADRs for tozinameran and ChAdOx1 vaccine batches were 1.96 and 1.64 days, respectively ($p < 0.01$). Furthermore, significant differences ($p < 0.05$) were recorded between the two studied vaccines in regard to fever/chills, gastrointestinal symptoms, headache, general pain/weakness, and neurological symptoms, with higher incidence rates of these ADRs observed with the ChAdOx1 vaccine than the tozinameran vaccine. However, the tozinameran vaccine was found to cause significantly ($p < 0.05$) more palpitation, blood pressure variations, upper respiratory tract symptoms, lymph node swelling, and other unspecified ADRs than the ChAdOx1

vaccine. Among patients vaccinated with seven different batches of the tozinameran vaccine, people vaccinated with the T4 and T5 batches reported the most ADRs.

Conclusion: There were significant differences regarding most of the reported ADRs and their onset among tozinameran and ChAdOx1 vaccines on both healthy people and high-risk individuals living in Saudi Arabia. Moreover, the study found that the frequencies of most listed ADRs were statistically different when seven batches of tozinameran vaccine were compared