ISSN 0973-2063 (online) 0973-8894 (print)

Bioinformation 20(5): 430-433 (2024)

BIOINFORMATION
Discovery at the interface of physical and biological sciences

BIOMEDICAL INFORMATICS

www.bioinformation.net

Volume 20(5)

Research Article

Received May 1, 2024; Revised May 31, 2024; Accepted May 31, 2024, Published May 31, 2024

DOI: 10.6026/973206300200430

BIOINFORMATION Impact Factor (2023 release) is 1.9 with 2,198 citations from 2020 to 2022 across continents taken for IF calculations.

Edited by Vini Mehta
Citation: Sunita *et al*. Bioinformation 20(5): 430-433 (2024)

Risk assessment for arrhythmia among Indians after CoViD-19 vaccination

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ISSN 0973-2063 (online) 0973-8894 (print)
Bioinformation 20(5): 430-433 (2024)

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Abstract:
The Oxford/AstraZeneca CoViD-19 vaccine delivers viral proteins directly to the host body. This triggers an adaptive immune response, giving the body viral immunity. Post-vaccination myocarditis is usually moderate and transient, recovering quickly with conservative treatment. Occasionally, myocardial fibrosis or scarring might disrupt the conduction route, causing irregular cardiac rhythms and ECGs. We looked for ECG abnormalities in a small cohort of participants after 52 weeks after receiving the Oxford/AstraZeneca CoViD-19 vaccination.

Keywords: ECG, Covieshield vaccine, myocarditis, arrhythmia.

Background:
The global CoViD-19 epidemic has caused over 660 million illnesses and over 6.7 million deaths as of January 2023 **[1]**. The main weapon in the fight to stop this epidemic is vaccination. The CoViD-19 pandemic's full impacts were felt in India. The Oxford–Astra Zeneca vaccine, manufactured under licence by Serum Institute of India and sold as Covishield, was the first vaccination to receive emergency use authorization in India for the prevention of Covid-19 infection **[1]**. The effectiveness and safety of CoViD-19 immunisations in preventing major CoViD-19 episodes have been shown by randomised controlled trials. During these trials, headaches, nausea, vomiting, diarrhoea, and myalgia (muscle pain) were among the most frequent adverse effects reported by participants **[2, 3]**. There have been cases of suspected myocarditis following immunisation, even though myocarditis was not noted as a side effect in clinical trials **[4,5]**. Myocarditis can present with a wide variety of symptoms, from modest trouble breathing or chest pain that goes away on its own to more serious effects including cardiogenic shock or sudden death **[6]**. This could have led to undetected cases of myocarditis following immunisation. Defects in the studies could be the reason why the CoViD-19 immunisation clinical trials were unable to identify uncommon side effects **[4]**. It is well recognised that myocarditis can result in extensive or localised heart muscle scarring or fibrosis. This can disrupt the heart's regular electrical activity and create an abnormal conduction pathway. The circumstances for re-entry events and subsequent arrhythmias are produced by this altered path **[7]**. Therefore, it is of interest to assess abnormalities in the electrocardiogram (ECG) patterns of individuals who were given a precautionary dosage (which was administered 52 weeks following the Oxford/AstraZeneca CoVid-19 vaccination).

Materials and Method:
This study used a cross-sectional observational approach and context. Analysing ECG interval, duration, and amplitude variations 52 weeks after vaccination was the goal. Beginning on March 16 and running until March 30, 2022, was the study. For the study, seventy adults over the age of sixty were enlisted. 52 weeks following the first treatment, these individuals went to the IGIMS, Patna Community Medicine OPD to receive a prophylactic dose. Following a review of their medical histories, 14 were disqualified due to a history of SARS-CoV-2 infection, hypertension, diabetes, thyroid issues, cardio-respiratory disease, or use of medications that might affect sinus rhythm. Signal aberrations in ECG recordings led to the exclusion of data from six individuals from the analysis. Data from 50 patients were used for the final study (of whom 27 were female and 23 were male). Anthropometry: The study subjects' weight and height were measured, and the information was used to calculate their body mass index (BMI). Just one researcher who had experience with anthropometry performed the measurements. To help and get female participants ready for the height and weight measurements, a female attendant was on hand. A 1 mm accurate portable stadiometer (Precision Model, Prime Surgical, and New Delhi, India) was used to measure height, and kilogrammes were used to measure weight.

Recording of the electrocardiogram: Initial measurements were taken of the diastolic blood pressure (DBP), systolic blood pressure (SBP), and resting heart rate (RHR). We also measured the amplitudes of P, Q, R, S, and T waves, as well as RR, PR, QRS, QT, QTc, JT intervals, and T peak-T end intervals. A 4-channel Power Lab15 T (Model ML 818) was used for the data collecting, and LAB Chart Pro software, version 8.1.13 (AD Instrument Ltd. Australia), was used for the analysis. Analogue ECG impulses were successfully recognised and uninterruptedly converted into digital data using the Power Lab data acquisition apparatus. Furthermore, the LAB Chart Pro software's ECG Analysis Module made it possible to identify Lead II ECG waveforms and automatically determine heart rhythm, amplitude, and the start of P, Q, R, S, and T waves.

Results:
The data from a total of 23 males and 27 females were analysed, with results expressed as mean (standard errors). **Table 1** displays the anthropometric parameters of the participants. **Table 2** presents the hemodynamic parameters and ECG

intervals. Additionally, ECG wave amplitudes were measured and found to be within normal limits for both males and females. (**Table 3**) **[8]**

Table 1: Anthropometric parameters of participants

Parameters	Male (mean ± SD)	Female(mean ± SD)
Age (years)	66.75±3.025	63.12±2.054
Body weight (kg)	70.25±2.375	54.036±2.885
Height (meter)	1.702±0.228	1.560±0.028
BMI (kg/m²)	24.236±1.480	21.418±1.577

Mean ± SD, SD, standard deviation; BMI, body mass index.

Table 2: Haemodynamic parameters and ECG intervals of the participants

Parameter	Male (mean ± SD)	Female (mean ± SD)
Heart Rates(Beats/minutes)	80.325 ± 8.096	84.906 ± 10.225
SBP (mm Hg)	134.1 ± 2.7	128.88 ± 2.764
DBP (mmHg)	85.55 ± 1.995	77.92 ± 6.176
RR(Second)	0.763 ± 0.077	0.721 ± 0.085
PR interval(Seconds)	0.159 ± 0.018	0.153 ± 0.024
P duration(Second)	0.96 ± 0.011	0.090 ± 0.024
QRS interval(Seconds)	0.075 ± 0.011	0.063 ± 0.010
QT interval(Seconds)	0.318 ± 0.014	0.317 ± 0.025
QTc (Seconds)	0.366 ± 0.021	0.375 ± 0.025
JT interval (Seconds)	0.242 ± 0.014	0.254 ± 0.022
T-peak T-end interval(Seconds)	0.052 ± 0.006	0.055 ± 0.008

Mean ± SD, SD, standard deviation; SBP, systolic blood pressure; DBP, diastolic blood pressure; HR, heart rate.

Table: 3 ECG wave amplitudes of the participants

Parameter	Male (mean ± SD)	Female (mean ± SD)
P (mV)	0.129 ± 0.027	0.121 ± 0.032
Q (mV)	-0.081 ± 0.046	-0.073 ± 0.042
R (mV)	0.918 ± 0.228	1.035 ± 0.418
S (mV)	-0.144 ± 0.117	-0.126 ± 0.084
T (mV)	0.219 ± 0.118	0.181 ± 0.076

Mean ± SD, SD, standard deviation

Statistical analysis:

Data obtained was analysed using Excel software and SPSS version 22 to find the mean and standard deviation of parameters in all subjects.

Discussion:

Instances of post-vaccination myocarditis have been documented in the United States, United Kingdom, and Israel, and a small number of cases have also been reported in India **[9,10,11,12].** Diagnosing acute myocarditis is difficult due to the absence of a specific clinical presentation and the potential for confusion with several other non-inflammatory cardiac illnesses, such as acute coronary syndrome (ACS) **[6].** Moreover, myocarditis can result in serious outcomes, including undetected heart problems that may only become apparent several months after a person has recuperated from COVID-19, potentially leading to heart failure **[13].** If fibrosis or scarring occurs in the myocardium, it can impede the conduction route and result in abnormal ECG patterns and re-entrant arrhythmias in cases of myocarditis. The presence of fibrosis or scarring in the myocardium can lead to specific alterations in the electrocardiogram (ECG). These changes include lengthening of the QRS complex, deep Q waves, T wave inversions, and fragmentation of the QRS complex. These ECG findings are all diagnostic of the presence of myocardial fibrosis **[14].**

In India, there is a shortage of studies examining the possible enduring electrocardiogram (ECG) alterations in patients aged 60 and above after receiving the Oxford/AstraZeneca CoVID-19 vaccine. To fill this need, our research sought to investigate the possibility of ECG analysis as a non-invasive technique for the early identification of fibrotic cardiomyopathy **[15]**. This could potentially assist in the prevention of arrhythmias. The study utilized 4 channels of Power Lab for data collecting and the analysis was performed using the LAB Chart Pro software version. Analysed ECG data from a combined group of 23 males and 27 females were examined 52 weeks following vaccination **[16]**. The study noted that RR, PR, QRS, QT, QTc, JT, and T peak T end intervals did not show any signs of prolongation. In addition, the amplitudes of P, Q, R, S, and T were measured and determined to be within the normal range **[17]**. Significantly, there were no reported instances of QRS extension, deep Q waves, T wave inversions, or QRS fragmentation. Furthermore, the current study did not identify any cases of clinical myocarditis **[18]**.

In our study no abnormalities in the electrocardiogram (ECG) after 52 weeks after the initial dose was detected. This reduces the possibility of life-threatening irregular heart rhythms in the population vaccinated with the Oxford/AstraZeneca CoVID-19 vaccine. These findings have important implications for the general population, clinicians, and policymakers. They provide reassurance regarding the vaccine's safety about cardiac health. Multiple studies have emphasized the heightened likelihood of myocarditis after receiving mRNA-based CoViD-19 vaccinations, especially among individuals of different age groups and genders. Significantly, the likelihood of risk is most pronounced among teenage males and young adult males after receiving the second dose of the vaccine **[9].** Patone *et al.* conducted population-based research that identified links between rare cardiac effects and both the three CoViD-19 vaccinations and the SARS-CoV-2 infection. Their research uncovered those adults who received vaccinations against SARS-CoV-2 faced a heightened likelihood of developing myocarditis within one week of getting the initial dosage of both adenovirus and mRNA vaccines, as well as after receiving the second dose of mRNA vaccines **[4].** These observations highlight the crucial importance of on-going monitoring and evaluation of possible negative consequences associated with CoViD-19 immunization. Monitoring is crucial for upholding public health and guaranteeing the safety of immunization programs. Data shows no evidence of an increased risk of myocarditis or cardiac arrhythmias after 52 weeks of Covishield vaccination. These findings offer crucial information on the safety of the vaccine regarding these particular cardiac events.

Conclusion:

Post-vaccination myocarditis is usually moderate and transient, recovering quickly with conservative treatment. Occasionally, myocardial fibrosis or scarring might disrupt the conduction route, causing irregular cardiac rhythms and ECGs. Our investigation indicates that the Oxford/AstraZeneca CoVid-19

vaccine is improbable to result in any alterations in electrocardiogram (ECG) readings after 52 weeks from the initial dosage, and hence, it is improbable to induce life-threatening irregular heart rhythms in the general population.

Limitation of study:
The limitation of our study is the small sample size, which reduces its applicability to a larger population. Large prospective population studies with longitudinal follow-up are needed to understand the long-term effects of the Covishield vaccine for various age and sex subsets. Secondly, we were only able to examine Lead II ECG due to the limitation of our Power Lab data collection equipment. All twelve leads of the ECG should be taken into consideration.

Acknowledgements:
The authors would like to appreciate patients who agree to participate in the study protocol patiently.

Financial support and Sponsorships: Nil.

Conflicts of Interest:
There are no conflicts of interest.

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