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Assignment of Protein C Level among Vaccinated Apparently Healthy Individuals with Covid-19 vaccine AstraZeneca

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Abstract

Background: SARS COV-2 pandemic is still representing the biggest health challenge facing communities worldwide, since the winter of 2019. Covid-19 vaccine can Cause a very rare type of thrombosis. The study aimed to know the effect of COVID-19 vaccine AstraZeneca on protein C level among apparently healthy individuals.

Methods: This is a case-control study conducted at Elmak-nimir university hospital which is located in Shendi town in Sudan to evaluate protein C in a vaccinated individual with Covid-19 vaccine AstraZeneca in the period between May to September 2021. The study included (30) person who was vaccinated with the Covid-19 vaccine and the study groups were compared with (8) unvaccinated as a control group. 30 venous blood samples as case and 8 as control transferred into Tri sodium citrate anticoagulant, protein C was done by the semi-automated method (spectrophotometer) using the endpoint method. Data was collected using a questionnaire and the (SPSS) version (22) program was used for data analysis.

Results: The study revealed that of the vaccinated individual with the Covid-19 vaccine; (63%) were male and (37%) female. The mean values of Protein C in vaccinated (103.6%) and mean values of protein C in unvaccinated (54.4%).

Conclusions: Covid-19 vaccine AstraZeneca can cause significant change by increasing protein C level.

Keywords: Covid-19, Vaccinated, Protein C, Healthy Individuals, SARS-CoV2, Shendi, Sudan

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Introduction

Coronavirus Disease (COVID-19), since its emergence in Wuhan province, China in December 2019, now spreading to 213 countries worldwide, forcing the World health organization to declare this outbreak a global pandemic on 11 March 2020 [1]. COVID-19 is caused by highly infectious, severe acute respiratory syndrome coronavirus (SARS-CoV-2), infecting more than 36 million individuals, with 1,060,563 reported deaths as of 8 October 2020 [2]. The understanding of this novel virus and disease evolves sequentially over the past seven months. Initially, thought to transmit by droplets or aerosols causing fever as classical clinical symptoms, mainly in old age or immune-compromised individuals. Though, the dynamics of COVID-19 continue developing with the coming out of different SARS-CoV-2 strains. Evidence of airborne mode of SARS-CoV-2 transmission [3]. Asymptomatic clinical presentations along with extra-pulmonary manifestations are the real concern [4].

SARS-CoV-2 is a single-stranded, positive-sense RNA virus having an envelope, glycoprotein, and spike protein. Being a respiratory virus, SARS-CoV-2 enters within the human body and infects the lungs as a key and predominant organ [5]. The entrance is arbitrated by the binding of the receptor-binding domain (RBD) of the S1 subunit of the viral spike protein with the host angiotensin-converting enzyme 2 (ACE2) receptor primarily expressed in the type II pneumocytes, serve as a viral reservoir [6,7]. Usually, COVID-19 presented with fever, sore throat, dry cough, and shortness of breath as common clinical manifestations [8]. However asymptomatic cases are also being reported which are more critical to diagnose. (ACE2) is also establish to be presented in the oral, nasal mucosa, epithelial cells of lungs, kidney, and heart, enterocytes of the small intestine, and the endothelial cells of blood vessels [9].

There are several mechanisms by which (SARS-CoV-2) infection may result in microvascular and macrovascular thrombosis, including cytokine storm with activation of leukocytes, endothelium, and platelets resulting in up-regulation of tissue factor, activation of coagulation thrombin generation and

fibrin formation [10]. Activated protein C (APC) is a strong inhibitor of the coagulation system, especially in microcirculation. (APC) also reduces inflammation, and apoptosis and stabilizes endothelial and epithelial barriers. [11, 12]. Thus, (APC) is involved in many of the pathologic changes that occur in (COVID-19). In a recent study, protein C and (APC) have short half-lives and situations with increased activation of the coagulation pathway thus resulting in an acquired deficiency of protein C and the development of a thrombogenic state [13].

COVID-19 Vaccine AstraZeneca is a vaccine that can protect people from becoming ill from COVID-19. COVID-19 Vaccine AstraZeneca does not hold any life (SARS-CoV-2) virus, and it cannot give you COVID-19. It holds the genetic code for a significant ingredient of the (SARS-CoV-2) virus named the spike protein. The spike protein has been putted in into a harmless common cold 'carrier' virus (an adenovirus). The adenovirus carrier carries the spike protein into the cells so that they can read it and make copies of the spike protein. Then the immune system will learn to know and fight against the (SARS-CoV-2) virus. The adenovirus has been altered so that it cannot reproduce once it is inside cells. This means it cannot extend to other cells and cause infection [14].

Materials and Methods

Study design

This is a cross-sectional descriptive study that aimed to evaluate Haematological parameters and D-Dimer in patients with Covid-19 Infection. A case-control study was conducted in the period between June to September 2021.

Study area

Shendi town is located 172km north of the capital Khartoum, the southern part of River Nile state, and converting an area of about 30km.

Study population

30 venous blood samples were obtained from

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Vaccinated personnel with Covid 19 vaccine AstraZeneca, and 8 venous blood samples were obtained from unvaccinated people as a control group.

Sample processing

2.5 ml of venous blood will take from the patient and transferred into a Tri sodium citrate. The sample was then sent as early as possible for analysis. protein C was done by the semi-automated method.

Material and instrument

Cotton, Syringe, Centrifuge, Automatic pipettes, Spectrophotometer, Tri sodium citrate, Distilled water, 20% acetic acid, Substrate PCa-2, Protac, Protein c buffer, 3 Standard PC (1,2,3).

Principle of protein c estimation

Protein c (protac) → protein ca Pad-pro-Arg-PNA AcOH (protein ca) → pad-pro Arg-OH AcOH + P-nitroaniline.

The procedure of protein c estimation

Endpoint method Dilute the substrate PCa-2 1:5 with PC buffer (1 part substrate +4 parts buffer). Blank: 0.20 ml from acetic acid 20% mix and add 0.60ml pc buffer+37c mix and add 0.05 from the sample. Sample: 0.05ml from the sample and add 0.10 ml from protac mix and incubate for exactly 5 minutes +37c, and add 0.50 ml from substrate buffer mix (1+4) 37c mix and incubate for exactly 3-5 minutes at 37c, and add 0.20 ml from acetic acid 20%. Read the absorbance of blank against filter 405nm.

Data collection tools

The primary data was collected by using a questionnaire.

Data analysis and presentation

Data collected in this study will be analyzed using the SBSS21 Kai squire test will be used to assess the enter group significance. Other variables and outlier values will be calculated and will be presented in form of

figures and tables.

Ethical considerations

The procedure of venous blood sampling was explained to patients undergoing the test. All participants were informed about the research objectives and procedures during the interview period. Written valid consent was obtained from all participants. All results will be with high privacy and confidentiality.

Results

This study was conducted to know the level of protein C in vaccinated personnel with the Covid 19 vaccine. In this study, the mean of the test group was 103.6%. while the control was 54.4% and there was a significant variation between the test group and the control (*P-value* 0.002) (Table 1). When looking for the effect of age group on protein C level in the under-study group, the all-age group have insignificant statistical variations with high means of protein c in age group (31-40) (Table 2). For the association of the other disease with protein C levels in the participants with a history of another disease; asthma and diabetes mellitus which both consist of (3.3%), have a significant variation when compared with the mean of control group (54.4%) (Table 3). Finally, there was no effect of gender on protein C level in the understudy group, so the data show insignificant statistical variation with a *P-value* (0.803) (Table 4).

| | Group | No. | Mean | STD | P-Value |
|-----------|---------|-----|-------|------|---------|
| Protein C | Case | 30 | 103.6 | 41.4 | 0.002 |
| | Control | 8 | 54.4 | 17.4 | |

Table 1: Show Mean of protein C in case and control group.

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| Age | No | Mean | P-value |
|----------|----|-------|---------|
| (20 -30) | 13 | 111.3 | 0.396 |
| (31 -40) | 13 | 123.5 | 0.35 |
| (41-50) | 4 | 107.5 | 0.34 |
| Total | 30 | 114.1 | 0.3 |

Table 2: Show comparison between age group and protein C-level.

| Disease | No | Mean | P-value |
|-------------------|----|------|---------|
| Asthma | 1 | 35.5 | 0.031 |
| Diabetic mellitus | 1 | 40 | 0.039 |
| Non | 28 | 48.1 | 0.125 |

Table 3: show relation of other disease with protein C level.

| Gender | No | Mean | P-value |
|--------|----|-------|---------|
| Male | 19 | 115 | 0.803 |
| Female | 11 | 116.1 | |

Table 4: show comparison between gender and protein C level.

Discussion

After statistical analysis, the data of the understudy group show an elevated level of protein C in the cases when compared with the control group which may indicate increased production of this protein under the effect of AstraZeneca, while the published data discuss the elevated level of protein C in many pathological cases like in nephrotic syndrome [15]. Also, there is evidence of an association between the high level of protein c in healthy vaccinated personnel with the Covid 19 vaccine and the history of other diseases (asthma and diabetes mellitus) which agrees with the data published in nephron 2008 [15]. In addition, statistical analysis of the results of this study revealed that in the test group with age from (31-40) years there was an insignificant statistical variation with high means of protein C. Finally, no effect of gender on protein C levels in the understudy group.

Conclusion

On the bases of the finding in the study, we conclude the following: Increase protein C levels in vaccinated people when compared to an unvaccinated individual in the

control group. A vaccinated individual with other diseases is a more affected and higher level of protein C than others.

Recommendation

- The intensive study should be conducted with increased sample size and another type of vaccine.
- More investigation should be done for a vaccinated individual like: (protein S, Antithrombin III) to know the causes of thrombophilia among vaccinated people with Covid 19 vaccine.
- Health education program for risk factors of Covid 19 vaccine.

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