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Original Research Article

Assessment of Fibrinogen Level and Platelets Parameters among Vaccinated Healthy Individuals with COVID-19 Vaccine at Shendi Town

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Abstract: ***Background:*** Covid-19 vaccine is an immunization method used to reduce coronavirus incidence but lately caused life-threatening events such as thrombosis with thrombocytopenia syndrome. ***Methods***: This is a case-control study conducted at Shendi town to evaluate platelet parameters and fibrinogen levels in vaccinated healthy individuals With Covid-19 vaccines between Augusts to November 2021. A total of (100) vaccinated healthy individual With the Covid-19 vaccine was enrolled in the study as test groups, compared with (50) healthy volunteers as a control group. Venous blood samples were transferred into Trisodium citrate and EDTA anticoagulant. Data was collected using a questionnaire and the (SPSS) version (22) program was used for data analysis. ***Results:*** The study revealed that the vaccinated healthy individuals were; (50%) male and (50%) female. The platelets parameter and fibrinogen indicated the mean values of platelets count, mean platelets volume, platelets distribution width, platelet crit, and fibrinogen, in Janssen vaccine groups, were (251.14 109\L), (8.39 fl), (15.6), (0.203%), and (158 mg\dl) respectively. The results study revealed the mean of PLT, MPV, PDW, PCT, and Fibrinogen, in Astrazeneca vaccine groups, were (272.08 109\L), (8.13fl), (15.56), (0.2211%), (159 mg/dl) respectively. Also explained the mean of PLT, MPV, PDW, PCT and Fibrinogen, in Astrazeneca vaccine groups were (272.08 109\L), (8.13fl), (15.56), (0.2211%), (159 mg\dl) respectively and in Janssen vaccine groups the mean values of PLT, MPV, PDW, PCT, Fibrinogen were (251.14 109\L), (8.39fl), (15.63), (0.2034%), (158 mg\dl) respectively. ***Conclusions:*** Covid-19 vaccines are responsible for significant changes in fibrinogen level in both AstraZeneca and Janssen vaccine groups.

Keywords: Covid-19, vaccines, Fibrinogen, Platelets, AstraZeneca, Janssen, Healthy Individuals, Shendi, Sudan.

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. However, the dynamics of COVID-19 keep on evolving with the emergence 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 inside the human body and infects the lungs as a primary and predominant organ [5].The entry is mediated 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, serving 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 found to be expressed 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]. The SARS-COV-2 associated extra-pulmonary manifestations are encephalitis, rashes on the skin, meningitis, conjunctivitis, and acute hepatic, and renal injury. Surprisingly, autopsies of COVID-19 patients have revealed clots in the small vessels of the lungs, heart, liver, and kidney which are responsible for strokes and heart attacks [10]. More than 33% of critical COVID-19 patients' are reported with critically high levels of blood clotting [10]. Fibrinogen and platelet play major role in the body's ability to Formation of blood clotting [10].

MATERIALS AND METHODS

Study design

This is a case-control analytic study conducted in Shendi town during the period August to November 2021 and aimed to evaluate fibrinogen level and platelet parameters among vaccinated healthy individuals With Covid-19 vaccines.

Study area

This study was conducted at Shendi town which is located in River Nil state.

Study population

A total of one hundred healthy individuals vaccinated With the Covid-19 vaccine were enrolled in this study as a test group, while fifty healthy individuals without covid 19 vaccine as a control group.

Sample processing

5.0 ml of venous blood was taken from each patient and transferred into Trisodium citrate and EDTA anticoagulant. The sample was then sent as early as possible for analysis. Fibrinogen level was done by the semi-automated method; platelet parameter was done by the automated method.

Methods

Platelets parameter is done by using MindrayHaematology Analyzer. (Mindray bc-3000). Blood cells are diluted in a buffered electrolyte solution. A measured volume of the sample passes through an aperture tube (e.g. 100-micrometer meter in diameter) between two electrodes. Pulse is proportioned to the volume of the cell which caused it. A threshold circuit ensures only those pulses that exceed the pre-set threshold level are counted. The cell count is determined from the total number of pulses obtained from a measured volume of blood. Platelets counts and indices were measured by using an automatic blood cell counter (Mindray-3000 analyzers). The assay was performed according to the instructions provided by the manufacturer. The analyzer was controlled by normal control, abnormally high, and abnormal low. The EDTA blood samples were aspirated into the analyzer through a sample probe, and the counting was started automatically the results were displayed on the screen within (20) seconds.

Data collection tools

The primary data was collected by using a questionnaire involving different information about the study participants.

Data analysis and presentation

Data collected in this study were analyzed using SPSS version 22. Kai squire test that used to assess the enter group significance .other variable and outlier values were calculated and presented in form of 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 result in high privacy and confidentiality.

RESULTS

This case-control analytical study was conducted in Shendi town and aimed to evaluate platelet parameters and fibrinogen levels in apparently healthy individuals vaccinated with the covid-19 vaccine. A total of (100) blood samples were collected from vaccinated healthy individuals with COVID 19 vaccines as a test group and (50) samples as control from healthy individuals of both sexes with different ages. Regarding demographic data, the results of this study revealed that about (50%) of individuals enrolled in this study were males, while the remaining (50%) were female as

demonstrated (Table1). Furthermore, the majority of the frequency of age group was 20-30years (40%) while the remaining was <20years (9%), 30-40 years was (26%), 40-50 years was (18%) and >60 years (7%). As explained (Table2). The laboratory results of this study showed that the mean platelet count, mean platelet volume, platelet distribution width, platelet crit, and fibrinogen level in the test group vaccinated with the Janssen vaccine were (251.14 109\L), (8.39 fl), (15.6), (0.2034 %), and (158 mg\dl) respectively, while in the control group were (266.24 109\l),(8.17 fl),(15.6),(0.216 %), and (165 mg\dl) respectively as noted (Table 3). Also the results revealed that the mean of PLT, MPV, PDW, PCT, Fibrinogen in test group vaccinated with Astrazeneca vaccine were (272.08 109\L), (8.13 fl), (15.56), (0.2211 %), (159 mg\dl) respectively, while in control groups were (266.24 109\L), (8.17 fl), (15.60), (0.2165 %), (165 mg\dl) respectively as referred (Table 4). The comparison between both vaccines revealed that the mean of PLT, MPV, PDW, PCT, and Fibrinogen, in the group vaccinated with the Astrazeneca vaccine were (272.08 109\L), (8.13 fl), (15.56), (0.2211 %), (159 mg\dl) respectively, while in those vaccinated with Janssen vaccine were (251.14 109\L), (8.39 fl), (15.63), (0.2034 %), (158 mg\dl) respectively as demonstrated (Table 5).

Table-1: Distribution of study population according to sex.

Characteristic		**Percent%**
Study groups	Case	100%
	Control	50%
Sex	Male	50%
	Female	50%

Table-2: Distribution of study population according to age.

Characteristic		**Frequency**	**Percent %**
Age/yrs	*Less than* 20yrs	9	9%
	20-30yrs	40	40%
	30-40yrs	26	26%
	40-50yrs	18	18%
	More than 60yrs	7	7%

Table-3: Comparison between Janssen vaccine and control in PLT, MPV, PDW, PCT, and Fibrinogen level.

Groups		**No**	**Mean**	**SD**	**P. value**
PLT\L	Case	50	251.14	59..422	0.298
	Control	50	266.24	65.113	
MPV fl	Case	50	8.39	0.806	0.119
	Control	50	8.17	0.665	
PDW	Case	50	15.6	0.286	0.504
	Control	50	15.6	0.293	
Pct%	Case	50	0.203	0.0542	0.276
	Control	50	0.216	0.0523	
Fibrinogen Mg\dl	Case	50	158	10.898	0.000
	Control	50	165	7.696	

Table-4: Comparison between AstraZeneca vaccine and control groups in PLT, MPV, PDW, PCT, and fibrinogen level.

Groups		**No**	**Mean**	**SD**	**P. value**
PLT\L	Case	50	272.08	58.587	0.648
	Control	50	266.24	65.113	
MPV fl	Case	50	8.13	0.7317	0.770
	Control	50	8.17	0.6655	
PDW	Case	50	15.56	0.5499	0.638
	Control	50	15.60	0.2931	
PCT%	Case	50	0.2211	0.0481	0.648
	Control	50	0.2165	0.0523	
Fibrinogen Mg\dl	Case	50	159	13.602	0.020
	Control	50	165	7.696	

Table-5: Comparison between AstraZeneca vaccine and Janssen vaccine group in PLT, MPV, PDW, PCT, and fib rinogen level.

Groups		No	Mean	SD	P. value
PLT\L	AstraZeneca	50	272.08	58.587	0.094
	Janssen	50	251.14	59.422	
MPV fl	AstraZeneca	50	8.13	0.8063	0.086
	Janssen	50	8.39	0.7317	
PDW	AstraZeneca	50	15.56	0.5499	0.435
	Janssen	50	15.63	0.2869	
PCT %	AstraZeneca	50	0.2211	0.0481	0.097
	Janssen	50	0.2034	0.0542	
Fibrinogen Mg\dl	AstraZeneca	50	159	13.60	0.648
	Janssen	50	158	10.89	

DISCUSSION

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]. Many studies were established and others are in going to solve the problems and understand the pathophysiology of the covid-19 disease. Statistical analysis of the results of this study demonstrates significant variation in fibrinogen levels in those individuals vaccinated with the Janssen vaccine compared to the control group with a (*P-value* 0.000). This Result was similar to the results of a study done by an expert hematology panel (UK) and the American society of hematology. Also, the study demonstrates a decrease in the mean platelet count and PCT and an increase in MPV in Janssen vaccine groups. Value (>0.05). This result was not similar to the result of a study that was done by an expert hematology panel (UK) and the American society of hematology. Also, the Statistical analysis of this study explained significant variation in fibrinogen levels in individuals vaccinated with the AstraZeneca vaccine compared to control groups with a *(P-value* of <0.05). This result was agreed with to result of a study conducted by the Australian government, health.gov.au\covid19-vaccine.the results of this study confirmed an increase in the mean platelet count and decrease in MPV in the AstraZeneca vaccine (*P-value*>0.05), this result was disagreed with two result done by the Australian government health.gov.au\covid19-vaccine. Finally, the comparison of two types of vaccine (AstraZeneca and Janssen vaccine) showed that there is no relationship between them.

CONCLUSION

Fibrinogen was lower in the Janssen vaccine when compared to healthy individuals in the control group. Fibrino gen was lower in the AstraZeneca vaccine when compared to healthy individuals in the control group. This study demons trates a decrease in the mean platelet count and PCT and an increase in MPV in Janssen vaccine groups. Also, increase in the mean platelet count and a decrease in MPV in AstraZeneca vaccine groups.

RECOMMENDATION

1) Further studies should be carried out on this topic by increasing the sample size and extending the study area to obtai n new data with accurate results.
2) Platelet parameters and fibrinogen levels should be checked regularly in vaccinated healthy individuals to avoid the r isk of thrombosis.
3) Health education and urgent medical evaluation for TTS if any of the following symptoms develop 4 to 30 days after vaccination: severe headache, visual changes, leg pain and swelling, abdominal pain, petechiae, or easy bruising.
4) More investigations should be done for vaccinated healthy individuals With Covid-19 vaccines, to determine which r isk factors and thrombotic markers are important predictors of thrombotic risk among vaccinated healthy individuals With Covid-19 vaccines.
5) Increasing monitoring after taking of vaccine if the people have any history of blood clots or people have received an ticoagulant therapy.

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