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Original Article

Assessment of hematological and coagulation changes following COVID-19 vaccination: Implications for thrombotic risk

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ABSTRACT

The rapid global deployment of COVID-19 vaccines has played a critical role in reducing disease severity and mortality; however, concerns regarding their potential effects on hematological and coagulation parameters persist. This study aimed to assess changes in hematological indices and coagulation profiles following administration of commonly used COVID-19 vaccines, including Pfizer-BioNTech, AstraZeneca, and Janssen. Materials and methods: An observational study design was employed, involving adult participants who received one of the aforementioned vaccines. Blood samples were collected and analyzed for complete blood count parameters, including hemoglobin, white blood cell count, and platelet count, as well as coagulation markers such as prothrombin time (PT), activated partial thromboplastin time (aPTT), and D-dimer levels. The findings demonstrated mild and transient variations in hematological parameters following vaccination, with slight fluctuations in platelet counts and white blood cell levels that remained within normal physiological ranges. Coagulation profiles showed no significant abnormalities in the majority of participants, although a small subset exhibited temporary elevations in D-dimer levels without clinical evidence of thrombotic events. No cases of severe thrombosis or vaccine-induced immune thrombotic thrombocytopenia were observed during the study period. COVID-19 vaccines appear to have minimal and transient effects on hematological and coagulation parameters in healthy individuals. The results support the overall safety of these vaccines with respect to thrombotic risk. Continued post-vaccination monitoring and larger-scale studies are recommended to evaluate rare adverse events further and ensure a comprehensive safety assessment.

Keywords: COVID-19, PT, APTT, D-dimer, Thrombosis

Introduction

The global spread of coronavirus disease 2019 (COVID-19) prompted an unprecedented effort to develop effective vaccines to reduce morbidity and mortality [1]. Several vaccines, including the adenoviral vector-based Janssen COVID-19 vaccine and AstraZeneca COVID-19 vaccine, as well as the mRNA-based Pfizer-BioNTech COVID-19 vaccine, have been widely administered worldwide. These vaccines have demonstrated high efficacy in preventing severe disease and hospitalization; however, their large-scale use has also raised important questions about their safety profiles, particularly regarding hematological and coagulation parameters [2, 3].

COVID-19 infection itself is strongly associated with coagulopathy, characterized by elevated D-dimer levels, fibrinogen abnormalities, platelet activation, and an increased

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risk of thromboembolic events. This hypercoagulable state is driven by complex interactions among inflammation, endothelial dysfunction, and coagulation cascade activation. Given that vaccination mimics certain immunological aspects of infection to induce protective immunity, it is biologically plausible that vaccines may transiently influence coagulation pathways. Consequently, evaluating the impact of different COVID-19 vaccines on coagulation parameters has become an important area of clinical and laboratory research [4].

Early post-marketing surveillance and clinical observations identified rare but serious thrombotic events associated primarily with adenoviral vector vaccines, particularly the AstraZeneca and Janssen vaccines. These events, termed thrombosis with thrombocytopenia syndrome (TTS) or vaccine-induced immune thrombotic thrombocytopenia (VITT), are characterized by unusual thrombosis (such as cerebral venous sinus thrombosis) accompanied by low platelet counts. Although extremely rare—occurring in only a few cases per million vaccinated individuals these findings prompted intensive investigations into vaccine-related coagulation changes and their underlying mechanisms [5, 6].

Subsequent studies have explored both clinical and subclinical alterations in coagulation markers following vaccination. Evidence suggests that COVID-19 vaccines, regardless of platform, may induce mild and transient changes in hemostatic parameters. For instance, increases in D-dimer, fibrinogen, and prothrombin fragment levels have been observed after vaccination, alongside modest reductions in natural anticoagulants such as activated protein C and tissue factor pathway inhibitor. Importantly, these changes generally remain within physiological ranges and are not associated with clinically significant thrombotic risk in the vast majority of individuals [7].

Comparative studies between vaccine types have further highlighted differences and similarities in their effects on coagulation. Adenoviral vector vaccines (Janssen and AstraZeneca) have been more frequently associated with rare immune-mediated thrombotic complications, possibly linked to platelet factor 4 (PF4) antibodies and abnormal platelet activation. In contrast, mRNA vaccines such as Pfizer-BioNTech are less commonly associated with such events, although mild inflammatory responses and transient coagulation activation have still been reported. These observations suggest that while the mechanisms may differ, all vaccine platforms can influence the delicate balance between coagulation and anticoagulation pathways to some extent [6, 8, 9].

In addition, several observational and case-control studies have assessed routine coagulation parameters including prothrombin time (PT), activated partial thromboplastin time (APTT), platelet count, and D-dimer levels before and after vaccination. Most findings indicate no significant or sustained abnormalities in these parameters among healthy individuals, supporting the overall safety of COVID-19 vaccines. However, subtle variations may occur depending on individual factors, such as age, comorbidities, prior SARS-CoV-2 infection, and the type of vaccine administered [10].

Despite reassuring evidence, ongoing research remains essential to elucidate the relationship between COVID-19 vaccination and coagulation fully. Understanding these effects is particularly important for high-risk populations, including individuals with pre-existing coagulation disorders, autoimmune conditions, or a history of thrombosis [11, 12]. Furthermore, distinguishing vaccine-related effects from the profound coagulopathy associated with COVID-19 infection itself is critical, as the risk of thrombotic complications is significantly higher following infection than after vaccination [13].

In this context, the present study aims to assess and compare the effects of Janssen, AstraZeneca, and Pfizer COVID-19 vaccines on coagulation parameters. By evaluating changes in key hematological and hemostatic markers, this research seeks to contribute to a deeper understanding of vaccine safety and to inform clinical decision-making regarding vaccination strategies in diverse populations.

Materials and Methods

Study design

This study was designed as an observational case study aimed at evaluating the effects of COVID-19 vaccination on selected hematological and coagulation parameters. The study was conducted at COVID-19 vaccination centers located within the Military Hospital in Omdurman, Khartoum State, Sudan. The study population comprised adult males and females aged between 20 and 80 years. A total of 75 participants were included in the study. These were equally divided into three groups: 25 individuals vaccinated with Pfizer, 25 with AstraZeneca, and 25 with Johnson & Johnson vaccines.

Inclusion criteria

The study included apparently healthy adults who had received COVID-19 vaccination.

Exclusion criteria

Individuals were excluded if they were children, adults with chronic diseases, or those currently receiving antiplatelet or anticoagulant medications.

Sample collection

Data were collected using a structured questionnaire in addition to laboratory analysis of blood samples obtained from participants. Two venous blood samples were collected from each participant under aseptic conditions from a superficial vein. The first sample (3 mL) was collected into a K3-EDTA container for complete blood count (CBC) analysis. The second sample (1.8 mL) was collected into a trisodium citrate container for coagulation studies, including prothrombin time (PT), activated partial thromboplastin time (APTT), and D-dimer assay.

Sample processing

Platelet counts were determined using a fully automated hematology analyzer (Sysmex KX-21N). Prothrombin time (PT) and activated partial thromboplastin time (APTT) were measured using a manual coagulometer. D-dimer levels were assessed using the iChroma II analyzer.

Sysmex 21N hematological analyzer

Used for CBC, usually provides 17 reportable parameters for the basic CBC and white blood cell differential, with a high level of precision and accuracy (Sysmex Corporation, Kobe, Japan).

Manual coagulometer

is an opto-mechanical coagulation analyzer that uses turbo-densitometric measurement. These instruments can be used for all standard coagulometric clotting tests, including fibrinogen, activated partial thromboplastin time, prothrombin time, and single-factor assays (Mindray Bio-Medical Electronics Co., Ltd., Shenzhen, China).

iChroma II

The test employs a sandwich immunoassay technique, in which the detector antibodies in buffer bind to the antigens in the sample to form antigen-antibody complexes, which are then transferred to the nitrocellulose matrix for capture by the other immobilized antibodies on the test strip. More antigens in the sample will result in more antigen-antibody complexes, leading the detector antibodies to produce a stronger fluorescence signal. This signal is then processed by an instrument for ichroma testing to demonstrate the concentration of D-Dimer in the sample (Boditech Med Inc., Chuncheon (Gangwon-do), South Korea).

Statistical analysis

Before the statistical analysis, the dataset was migrated to MS Excel to be thoroughly cleaned for inconsistencies. The cleaned data were then analyzed using the Statistical Package of Social Science (SPSS) version 30. Descriptive statistics were used to determine the frequencies and percentages of the socio-demographic characteristics, such as age and gender. For categorical variables, including age and coagulation parameters (Platelet count, PT, APTT, and D-dimer), means and standard deviation (SD) were calculated to summarize the data. Multiple regression analysis was used to determine the effects of vaccine types (Janssen, AstraZeneca, and Pfizer) on coagulation parameters (platelet count, PT, APTT, and D-dimer), adjusted for age and gender; results were reported with 95% CIs, and p-values less than 0.05 were considered statistically significant.

Results and Discussion

The three study groups had twenty-five (25) participants in each group. The three study groups were "Johnson", "AstraZeneca", and "Pfizer. **Table 1** shows the distribution of vaccines according to gender type.

Table 1. Gender among the Three Study Groups

	Gender	participants	Percent
Janssen	Male	17	68%
	Female	8	23%
	Total	25	100%
AstraZeneca	Male	11	44%
	Female	14	56%
	Total	25	100%
Pfizer	Male	10	40%
	Female	15	60%
	Total	25	100%

Table 2 presents the Distribution of socio-demographic characteristics of adults vaccinated with the Janssen, AstraZeneca and Pfizer COVID-19 vaccine. Concerning gender, the proportion of male participants was highest among those vaccinated with the Janssen vaccine (22.7%), followed by AstraZeneca (14.7%) and Pfizer (12.0%). In contrast, female participants were vaccinated with Pfizer (21.3%), followed by AstraZeneca (18.7%) and only 10.7% vaccinated with Janssen.
In relation to the age of participants, those aged 18-25 years constituted a similar proportion across the three types of vaccine, accounting for 13.3% in Janssen and 14.7% in both AstraZeneca and Pfizer. However, in the age group 26-44 years, the highest proportion was observed among Janssen recipients (16.0%), followed by Pfizer (13.3%) and AstraZeneca (10.7%). Participants belonging to the age group more than 45 years represent a smaller proportion across all types of vaccine.

Table 2. Distribution of socio-demographic characteristics of adults vaccinated with the Janssen, AstraZeneca and Pfizer COVID-19 vaccine (N = 75)

Variables	Categories	Vaccine types		
		Janssen (No/%)	AstraZeneca (No/%)	Pfizer (No/%)
Gender	Male	11 (22.7)	11 (14.7)	9 (12.0)
	Female	8 (10.7)	14 (18.7)	16(21.3)
Age	18-25	10 (13.3)	11 (14.7)	11 (14.7)
	26-44	12 (16.0)	8 (10.7)	10 (13.3)
	>45	3 (4.0)	6 (8.0)	4 (5.3)

Overall, the mean age was (32.1±12.5) years; for male it was (32.7±12.9) and for female (31.5±12.3) years

Table 3 illustrates a comparison of coagulation parameters before and after COVID-19 vaccination with the Janssen, AstraZeneca, and Pfizer vaccines among study participants; overall results showed relative stability in all coagulation markers across all types of vaccine. Related to the Platelet count, minimal changes were reported between pre- and post-vaccination values. In the group vaccinated with Janssen, the platelet counts slightly decreased from (268.2±69.2 to 265±68.7 x 109 /L). Similarly, a slight decrease was reported among those who were vaccinated with AstraZeneca (295.7±108.6 to295.5±83.4 x 109

/L), while a small reduction was also reported among those who were vaccinated with Pfizer (321.6±91.5 to316±81.2), all of which were not statistically significant.

With regard to the prothrombin time (PT sec), slight reduction was reported after vaccination in Janssen (16.7±5.3 to16.1±4.3 sec) and AstraZeneca (14.9±3.8 to 14.2±4.2 sec), but Pfizer showed lesser change (16.5±7.3 to 16.4±6.1 sec). These findings indicate general stability in coagulation pattern among those who were vaccinated.

Concerning the thromboplastin time (APTT, the results showed a slight decrease in the Janssen (42.1±7.6 to 41.3±1.3 sec), and in the AstraZeneca APTT values remained the same pre- and post-vaccination (38.2±6.8 to38.2±7.3). While an increase was observed in the Pfizer group, rising from 45.4±8.8 to 48.7±7.3 sec, suggesting a possible variation in coagulation pattern among the vaccinated group.

In terms of D-dimer levels, the results showed that the Janssen vaccine reported a lesser reduction (268.2±69.2 to 265.1±68.7). The AstraZeneca demonstrated a slight decrease (345.8±272.0 to356.6±32.7). Remarkably, Pfizer showed an increase in D-dimer levels from 260.4±21.6 to414.0±428.1), which was statistically significant ($p<0.05$), indicating a potential post-vaccination response.

In conclusion, the findings indicate that COVID -19 vaccination with Janssen, AstraZeneca, and Pfizer is not associated with significant changes in platelet count, PT, and APTT. While Pfizer reported a significant increase in D- dimer levels.

Table 3. Comparison of coagulation parameters before and after COVID-19 vaccination with the Janssen, AstraZeneca and Pfizer among study participants (N = 75)

Variables	Vaccine types					
	Janssen (mean±sd)		AstraZeneca (mean±sd)		Pfizer (mean±sd)	
	Before	After	Before	After	Before	After
Platelet count x 10^9 /L	268.2±69.2	265±68.7	295.7±108.6	295.5±83.4	321.6±91.5	316±81.2
PT (sec)	16.7±5.3	16.1±4.3	14.9±3.8	14.2±4.2	16.5±7.3	16.4±6.1
APTT (sec)	42.1±7.6	41.3±1.3	38.2±6.8	38.2±7.3	45.4±8.8	48.7±7.3
D-dimer	268.2±69.2	265.1±68.7	345.8±272.0	356.6±32.7	260.4±21.6*	414.0±428.1*

- P- value: * p < 0.05; ** p < 0.01; *** p < 0.001.

Table 4 shows the correlation between post-vaccination coagulation parameters and age, as well as the comparison of these parameters by gender among participants vaccinated with Janssen, AstraZeneca, and Pfizer. Generally, the correlation analysis showed weak and inconsistent associations between age and coagulation parameters across the three vaccines. Platelet count showed weak negative to positive correlations with age (r=-.06 to 0.081), indicating no obvious change pattern related to age. Likewise, PT showed a weak correlation with age (r= -0.317 – 0.052), suggesting lesser influence of age on prothrombin time. However, APTT showed a weak correlation with age in Janssen and AstraZeneca, while a slightly positive correlation was reported in Pfizer (r=0.194. Regarding D-dimer, it showed a moderate positive correlation with age in Pfizer (r=0.466), while correlations in Janssen and AstraZeneca were not significant.

Concerning gender differences, platelet counts were slightly higher in females compared with males in AstraZeneca and Pfizer, whereas the opposite trend was observed in the Janssen vaccine. PT values were relatively comparable between genders across vaccine types with small variations. For APTT, significantly higher values were reported in Pfizer ($p<0.01$) and Janssen ($p<0.001$), reflecting a statistically significant gender-associated difference in intrinsic coagulation function. D-dimer levels were higher in females in Pfizer, where a significant difference was observed ($p<0.05$), while differences in Janssen and AstraZeneca were less observed.

Together, the findings showed weak correlations between age and coagulation parameters, whereas gender related differences were more evident, specifically for APTT and D- dimer in the Pfizer vaccine.

Table 4. Correlation of coagulation parameters after vaccination with age and gender of participants (n=75).

Variables	Age			Male			Female		
	Vaccine types								
	Janssen Age (r)	AstraZeneca Age (r)	Pfizer Age (r)	Janssen (Mean±SD)	AstraZeneca (Mean±SD)	Pfizer (Mean±SD)	Janssen (Mean±SD)	AstraZeneca (Mean±SD)	Pfizer (Mean±SD)
Platelet count x 109 /L	-.061	-.236	.081	258.9 ±61.27	261.0±92.14	284.8±45.80	278.3±85.43	322.6±67.29	334.3±92.21
PT sec	-.317	.052	-.178	14.9±3.98	13.7±4.10	15.8±5.89	18.6±3.96	14.6±4.38	16.8±6.43
APTT (sec)	.031	-.280	.194	41.2±6.73	36.8±6.59	50.3±7.40***	41.8±6.32	39.4±7.80	47.8±7.35**
D-dimer	-.075	-.018	.466*	362.1±337.93	364.9±383.93	279.2±256.90	231.4±146.21	350.1±276.48	489.9±490.86

P- value: * p < 0.05; ** p < 0.01; *** p < 0.001.

This study assessed the impact of three COVID-19 vaccines (Janssen, AstraZeneca, and Pfizer) on coagulation parameters among healthy adult participants. The findings provide valuable insight into vaccine safety, particularly regarding hemostatic alterations.

The demographic distribution showed variability across vaccine groups, with males predominating in the Janssen group (68%), while females were more represented in the AstraZeneca (56%) and Pfizer (60%) groups. The mean age of participants was relatively young (32.1 ± 12.5 years), which is important because both age and sex are known to influence immune and coagulation responses. Previous studies have demonstrated that younger individuals tend to mount stronger immune responses to COVID-19 vaccines, potentially leading to transient inflammatory and coagulation changes [14]. Furthermore, sex differences in immune response are well established, with females generally exhibiting stronger humoral and cellular responses, which may also influence coagulation pathways [15].

Regarding platelet count, no significant differences were observed before and after vaccination in any of the groups. This finding aligns with major clinical trials of COVID-19 vaccines, which reported no clinically significant thrombocytopenia in the general population [16, 17]. Although rare cases of vaccine-induced immune thrombotic thrombocytopenia (VITT) have been associated with adenoviral vector vaccines such as AstraZeneca and Janssen, these events are extremely uncommon [18]. The absence of significant platelet changes in this study supports the evidence that routine vaccination does not adversely affect platelet levels in healthy individuals.

The prothrombin time (PT) results demonstrated slight, non-significant reductions following vaccination across all groups. PT reflects the function of the extrinsic coagulation pathway, and stable PT values indicate that these vaccines do not significantly disrupt coagulation factor activity. This observation is consistent with findings from other studies, which reported no meaningful alterations in PT following COVID-19 vaccination [19]. Therefore, the vaccines appear not to induce a hypercoagulable state detectable by conventional coagulation assays.

In terms of activated partial thromboplastin time (APTT), minimal changes were observed in the Janssen and AstraZeneca groups, whereas an increase was noted in the Pfizer group after vaccination. Although this increase was not consistently statistically significant, it may reflect transient activation of the intrinsic coagulation pathway. mRNA vaccines such as Pfizer are known to induce strong innate immune responses, including cytokine production, which may temporarily influence coagulation factors [20]. However, such changes are typically mild and not associated with clinical complications, suggesting that the observed APTT variation is likely of limited clinical relevance.

The most notable finding in this study relates to D-dimer levels, particularly in the Pfizer group, where a statistically significant increase was observed after vaccination. D-dimer is a sensitive marker of fibrin degradation and is commonly elevated in thrombotic and inflammatory conditions. Elevated D-dimer levels following vaccination have been reported in some studies and are thought to reflect transient activation of coagulation and fibrinolysis due to immune stimulation [21]. Importantly, mild increases in D-dimer are not uncommon in inflammatory states and do not necessarily indicate pathological thrombosis. In the absence of clinical symptoms, such elevations are generally considered benign.

The AstraZeneca group also demonstrated relatively higher baseline and post-vaccination D-dimer levels, although these changes were not statistically significant. This observation is noteworthy given the association between adenoviral vector vaccines and rare thrombotic events characterized by elevated D-dimer levels [18]. However, the lack of significant changes in this study suggests that such effects are not common among healthy individuals and may require additional risk factors or immune predispositions.

The correlation analysis revealed weak and non-significant associations between age and most coagulation parameters across vaccine groups. However, a moderate positive correlation between age and D-dimer levels was observed in the Pfizer group ($r = 0.466$, $p < 0.05$). This finding is consistent with established evidence that D-dimer levels increase with age due to changes in hemostatic balance and increased fibrin turnover [22]. Therefore, this association likely reflects physiological aging rather than a vaccine-specific effect.

Gender-based comparisons showed some statistically significant differences, particularly in APTT values in the Pfizer group, where males had higher values than females. While this finding contrasts with some literature suggesting higher coagulation activity in females, sex-specific immune responses may contribute to these differences. It has been shown that males and females exhibit distinct immune and inflammatory profiles following vaccination, which may influence coagulation pathways differently [15].

Overall, the results of this study indicate that COVID-19 vaccines do not produce clinically significant alterations in coagulation parameters in healthy adults. The observed changes in platelet count, PT, and APTT were minimal and remained within normal physiological ranges. Although a significant increase in D-dimer was observed in the Pfizer group, this is likely attributable to transient immune-mediated activation rather than pathological thrombosis.

These findings are consistent with the broader literature supporting the safety of COVID-19 vaccines. Large randomized clinical trials and real-world studies have demonstrated a low incidence of serious coagulation-related adverse events [16, 17]. While rare complications such as VITT have been reported, particularly with adenoviral vector vaccines, their occurrence is extremely low and does not outweigh the benefits of vaccination in preventing severe COVID-19 and its complications.

Limitation

However, this study has limitations that should be acknowledged. The sample size was relatively small ($n = 75$), which may limit the ability to detect rare adverse events or subtle changes. Additionally, the study population consisted of healthy

individuals, and the findings may not be generalizable to individuals with comorbidities or pre-existing coagulation disorders. Future studies with larger sample sizes and more diverse populations are recommended to validate these findings further.

Conclusion

In conclusion, this study provides additional evidence supporting the hematological safety of COVID-19 vaccines, including Janssen, AstraZeneca, and Pfizer. The minor changes observed in coagulation parameters are likely transient and not clinically significant, reinforcing the continued use of these vaccines in public health programs.

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