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RESEARCH ARTICLE

THE HEMATOLOGICAL CHANGES ASSOCIATED WITH COVID-19 VACCINE AMONG PEOPLE SEEKING VACCINATION AT THIKA LEVEL 5 HOSPITAL, KIAMBU COUNTY, KENYA

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ABSTRACT: Vaccination still remains the cornerstone of protection against SARS CoV2.S to date. Data has shown that the vaccine starts working soon after the first dose and has an efficacy rate of 95% seven days after the second dose. This means that about 95% of people who get the vaccine are protected from becoming seriously ill. The objective was to determine the hematological changes associated with the COVID-19 vaccine among the general population. A blood sample was drawn from the subjects before vaccination and analyzed for coagulation profile (D-dimer) and full blood count profile. The same analysis was done just before the administration of the second dose and six months after the second dose using BC 5000 Automated Hematology Analyzer and C3510 Auto coagulation analyzer respectively. Data was entered in excel sheets and exported to SPSS version 29 of 2023 analysis software program for statistical analysis. Of the 100 samples, 56 (56%) were male and 44 (44%) females with their age being between 20-75years and a mean age group of 25-35 years. Of these only 2 (2%) had a confirmed covid-19 test previously with the rest 98 (98%) having had not been tested for covid-19. Of the total subjects 10 (10%) had blood pressure, 6(6%) had diabetes and the rest 84 (84%) had no underlying conditions. There was no statistically significant difference between the change in the, hemoglobin, white blood cells, d-dimer levels with all having a p-value <0.05. From the study we conclude that the covid-19 vaccine is safe for administration but close monitoring of the vaccinated individuals is necessary.

Keywords SARS CoV2-19, Vaccine, Immunity

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INTRODUCTION:

Vaccination still remains the most effective way to combat Covid-19. To date, [1]the FDA has given emergency use authorization to updated mRNA COVID-19 vaccines, updated version of the Novavax COVID-19 vaccine that more closely targets currently circulating variants to provide better protection against serious consequences of COVID-19, including hospitalization and death. [1]. Data has shown that the vaccines start working soon after the first dose and has an efficacy rate of 95% seven days after the second dose. This means that about 95% of people who get the vaccine are protected from becoming seriously ill with the virus. This vaccine is being given to people from the age of 16 years and above and requires two injections given 21 days apart [2]. Data available has shown that the Morderna Covid-19 vaccine has a 94.1% efficacy rate while the Jansen Ad26.CoV2.S was found to have an efficacy of 85.4% against severe disease and 93.1 % against hospitalization[3]. When administering the Morderna and Pfizer/BioNTech vaccines they should be given in two injections with a 28 days interval while the Jansen AD26.Cov2.S vaccine is a single dose [4]. Pfizer/BioNTech and Morderna vaccines use the messenger RNA [mRNA] technology and the Jansen AD26.Cov2. S vaccine uses the viral vector technology. The corona-viruses have a spike-like structure [S protein] on their surface, when someone is injected with the COVID-19 mRNA vaccines, the vaccine give cells instructions on how to make a harmless piece of an S protein [5]. On making the harmless S proteins they are displayed on the surfaces of the cells [6]. Once displayed the immune system recognizes them as not belonging the and in response to this the immune system will produce antibodies against the vaccine. In Kenya an Emergency Response Committee was established through an executive order No. 2 of 2020. During the meeting on 20th March 2020, they resolved and directed Kenyans of taking pre-cautionary measures to try and cub the spread of the virus. Following a whole year of the country ravaging with the Covid-19 pandemic, the country received its first batch of Astra Zeneca Vaccine in March 2021, this was a global initiative to make the vaccine available to both higher-income and low-income countries [4]. The vaccine was only administered to the frontline health workers in Kenya, protecting them as they treat the victims of COVID, and provide essential health services but later rolled out to the general population. There were several COVID-19 vaccines approved for use by WHO [given Emergency Use Listing] and from other stringent regulatory agencies [SRAs] with the first mass vaccination program starting in early December 2020 [5]. This has continued over years with world health organization still campaigning on the importance of having 100% vaccination.

Before the vaccine is approved and introduced to the national immunization program, it must be proven to be safe and effective across a broad population. The vaccine safety and efficacy bar is usually extremely high since the vaccines are given to people who are healthy and specifically free from the illness being vaccinated against [3]. Further monitoring takes place in an ongoing way once the vaccine is introduced,[7] through the systems put to monitor the safety and effectiveness of all vaccines. With this it enables scientists to keep track of the vaccine impact and safety even as the number of people using increases over a long-time frame. Such data is used when adjusting policies for vaccine usage thus optimizing their impact, they also allow the vaccine safe tracking throughout its use. Once in use the vaccine must be continuously monitored to make sure its safety is continually guaranteed [8].

It is important to monitor the long term benefits of a new vaccine to the local population as well as monitor and be on the lookout for any adverse effects [9]. The possible side effects of a COVID-19 vaccine may include pain, redness or swelling where the shot was given, fever, fatigue, headache, muscle pain, chills and joint pain[10]. During the first few days after vaccination, some reaction may happen and these can last for three to four days. The subjects are advised to seek medical advice if they experience any of these allergic reactions which are deemed as side effects of

the vaccine. These allergic reactions may include hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, and weakness [11]

Physiological adverse effects are harmful outcome that are usually indicated by some result such as morbidity, mortality, alteration in body weight, levels of enzymes, loss of function, or as a pathological change detected at the microscopic, macroscopic or physiological level [12]. These effects may also be indicated by related symptoms that reported by a patient. Progression of the disease is also associated with changes in hematological indices[13] this may affect the management of covid-19 positive patients. Since the early stage of the disease, not only the platelets and lymphocytes but also hemoglobin, eosinophils, and basophils present a marked decrease, associating with the disease severity and clinical outcome [14]. The tests can reflect different aspects of either liver function or the kidney function or general blood picture which are useful for management of patients.

In some patients with COVID-19 abnormal blood clots development was experienced, including in the smallest blood vessels. These clots may form in multiple places in the body, causing different complications, including organ damage, heart attack and stroke. [15]. The clotting may be triggered by the high levels of inflammation caused by the SARS-CoV-2 infection and this can affect multiple organs and resulting in severe disease. D-dimer test is an important prognostic value for the prediction of poor outcome in patients with covid-19 [16]. The adverse effects due to the covid-19 disease and those due to covid-19 vaccine are similar since the vaccine is developed to imitate the virus such that once given it raises the body alarm training the body to fight against the virus once under attack [17].

MATERIALS AND METHODS:

Study Area

The study was conducted at Thika Level 5 Hospital which is a county referral hospital located in Kiambu County, Thika West District, Thika Municipality division in Biashara sub-location along the General Kago Road.

Study design

The study was conducted using an Experimental study design where one group pretest-posttest design was used.

Study population

The study focused on people above 18 years of age coming for their first dose of Covid-19 vaccine at Thika Level 5 county hospital during the period of the study. These subjects seeking vaccination at the time of the study were recruited for the study but only those that were taken through the informed consent and agreed to take part were sampled and took part in the study.

The Inclusion Criteria

The study included all volunteers above 18 years seeking vaccination at Thika Level 5 county hospital, willing to be vaccinated and having filled and signed the consent form to take part in the study.

The Exclusion Criteria

Those with underlying conditions like cancer and those who declined to sign the consent form were excluded from the study

Sample size

Single population proportion formula was used to calculate sample size with the assumption of 5% margin of error, 95% confidence interval and 7.3 % proportion of patients with COVID-19 in Nairobi County as of December 2020[18]. The sample size for study subjects was calculated using the formula derived by Lwanga [19]:

$n = Z^2\rho\,[1-\rho]/d^2$

Where n= Minimum sample size; Z= Standard normal deviation value corresponding to 95% confidence interval [=1.96]; ρ= Estimated prevalence of the disease under study [7.3%] and d= error margin [set at 5%].

$n= [1.96]^2 0.073[1-0.073]/0.05^2$

n=100

Therefore, the sample size for the study subjects was 100 and a 5% increase was added to cater for dropouts and therefore the total target sample size was 105 study subjects. Since there were no dropouts the final sample

size was 100 study subjects.

Sampling Method

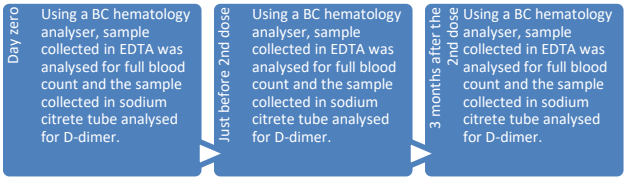
Convenient random sampling method was used in which subjects were randomly selected from the population that visited the hospital for vaccination during the study period. The subjects were introduced to the study, taken through the aim of the study and further given a consent form that they read through with the help of the investigator filled and further provided a blood sample for analysis.

Recruitment of study subjects

All the individuals recruited in the study were on voluntary basis after a brief explanation of the aims and purpose of the study. Those who accepted to participate in the study were given a form to fill in their basic demographic information. A clinician assisted in examining them to determine the inclusion criteria using medical history and clinical examination. The subjects who met the inclusion criteria and accepted to be part were included to the study and a blood sample collected before vaccination against COVID-19. The subjects who did not meet the inclusion criteria were excluded from the study. The subjects follow up was done by the principal investigator only via a phone call and or short message, those that were not reachable their next of kin were contacted for follow-up.

Blood sample collection

The specimen required was blood where through venous blood collection technique, 2 different tubes were used to collect blood. In one tube about 3-4ml in an EDTA vacutainer and another 2ml, in a sodium citrate vacutainer tube**.** The same procedure was repeated just before the second dose and 3 months after the second dose vaccination**.**



Statistical analysis

The data obtained was entered in an Excel Spreadsheet, cleaned and then exported to SPSS version 29 of 2023 analysis software program for statistical analysis. The data was then tested to determine whether it was normally distributed in order to decide the type of statistical analysis to be carried out. Normality or non-normality defined the way the results were to be expressed [mean ± SD or median and range] and the statistics to be used in the data set analysis and comparisons [t test for comparison of means for a pair of data sets, and ANOVA as the cases demanded].

RESULTS:

A total of 100 adult participants both male and female aged 18 years and above were recruited. From the 100 participants, 56 [56%] were male whereas the rest 44[44%] were female randomly selected from the vaccination centre during the time of the study. The total number of participant's distribution according to age was 18-30years 20%, 31-40years 45%, 41-60years 25% and >60years 10%. On recruitment, the participants were followed for 6months from the time of the first dose at which collection of the last sample was done. Before every run a quality control [level1 and Level2] were run to ensure quality of the results generated from the analysis.

Table 1. Summary of the means of different parameters at different time

Parameters	Mean 0	Mean 1	Mean 2
HB	14.031	13.482	13.605
Platelets	259.39	245.50	252.54
WBC	4.7685	4.3885	4.3785
Lymphocyte	41.4333	41.974	41.7397
MCH	28.840	29.424	29.425
MCHC	35.276	35.556	35.450
D-Dimer	188.95	376.26	303.20
Valid N	100		

Table 1 shows a summary of the means of different parameters before vaccination [Mean 0], one month after vaccination [Mean 1] and six months after vaccination [Mean 2]. From these values, we can see the trend of the parameters over time. Some

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parameters increased after the first month of vaccination and then their levels started dropping thereafter, resulting to a lower level after six months. The parameters that had an increase were lymphocytes, MCHC, D-Dimer. Other parameters decreased upon vaccination and then started rising towards the end of 6 months. These include: HB, platelets and MCH levels rose then appeared to have remained almost constant after 6 months. This is in agreement with a study [20] where he concluded that vaccination alters the blood count and other parameters in the body. The study also points out that the vaccine had significant manifestation on the hemopoietic system and thus the abnormalities in the hematological parameters. **Tables, 2,3 and 4** shows results for hematological changes for the subjects at day zero, just before the second dose and 3 months after the second dose.

Table 2. Results for day zero (before vaccination)

Parameters	N	Average	Mean	Std. Deviation	Variance
HB (g/dl)	100	12.5	14.031	2.0534	4.217
PLATELETS (10-3/ul)	100	460	259.39	74.173	5501.594
WBC(10-3/ul)	100	7.56	4.7685	1.42014	2.017
LYMPHOCYTE (%)	100	41.90	41.4333	8.63893	74.631
MCH(pg)	100	18.5	28.840	2.9730	8.839
MCHC(g/dl)	100	8.0	35.276	1.1200	1.254
D-DIMER(ng/ml)	100	2048	188.95	335.623	112642.856
Valid N	100				

Table 3. Results for analysis just before second dose vaccination

Parameters	N	Average	Mean	Std. Deviation	Variance
HB	100	7.7	13.482	1.8596	3.458
Platelets	100	279	245.50	64.316	4136.535
WBC	100	4.32	4.3885	1.06941	1.144
Lymphocyte	100	36.0	41.974	8.7287	76.190
MCH	100	11.9	29.424	2.9374	8.628
MCHC	100	14.0	35.556	2.3185	5.375
D-Dimer	100	2057	376.26	457.191	209023.366
Valid N	100				

Table 4. Results for analysis 3months after the second dose vaccination

Parameters	N	Average	Mean	Std. Deviation	Variance
HB	100	7.7	13.605	1.8208	3.315
Platelets	100	294	252.54	64.265	4130.049
WBC	100	4.32	4.3785	1.03830	1.078
Lymphocyte	100	36.00	41.7397	8.31994	69.221
MCH	100	12.5	29.425	2.8455	8.097
MCHC	100	14.0	35.450	1.9812	3.925
D-Dimer	100	2108	303.20	437.209	191151.394
Valid N	100				

Table 5. Pairwise comparisons for haematological and coagulation parameters

Variable	Time	Mean Differences	P-value	Significance
HB	1-2	0.549	0.034	Significant
	1-3	0.426	0.174	Not significant
	2-3	-0.123	0.75	Not significant
Platelets	1-2	13.89	0.411	Not significant
	1-3	6.85	1.000	Not significant
	2-3	-7.04	0.343	Not significant
White Blood count	1-2	0.38	0.124	Not significant
	1-3	0.39	0.112	Not significant
	2-3	0.01	1.00	Not significant
Lymphocyte	1-2	-0.541	1.00	Not significant
	1-3	-0.306	1.00	Not significant
	2-3	0.234	1.00	Not significant
MCH	1-2	-0.584	0.48	Not significant
	1-3	-0.585	0.458	Not significant
	2-3	-0.001	1.00	Not significant
MCHC	1-2	-0.28	0.817	Not significant
	1-3	-0.174	1.00	Not significant
	2-3	0.106	1.00	Not significant
D-dimer	1-2	-187.31	0.00	Significant
	1-3	-114.25	0.032	Significant
	2-3	73.06	0.008	Significant

From **Table 5** it is clear that, the mean differences for HB count between time 1 and time 2, time 1 and time 3 and time 2 and time 3. The mean differences between time 1 and time 2 [before vaccination and one month after vaccination] were found to be significant [mean differences = 0.549, p-value = 0.034<0.05]. this suggests that there was a significant change in HB count after vaccination. However, between time 1 and time 3 [six months after vaccination], there seems to be no significant change in HB count [mean difference = 0.426, p-value = 0174>0.05]. However, this appears to be more significant compared to the mean differences between time 2 and time 3 [between one and six months after vaccination] [mean difference = -0.123, p-value = 0.75>0.05]. Table 5 also shows the mean differences of platelets between time 1 and time 2, time 1 and time 3 and time 2 and time 3. None of the mean differences between the given times were found to be significant. The mean differences between time 1 and time 2 [mean differences = 13.89, p-value = 0.411>0.05] and between time 1 and time 3 [mean difference = 6.85, p-value = 1 >0.05] while between time 2 and time 3 [mean difference = -7.04,

p-value = 0.343>0.05]. The decrease in platelets count between time 1 and time 2 and the slight increase between time 2 and time 3 were not statistically significant at 5% level of significance.

The table also shows the mean differences in white blood count between time 1 and time 2, time 1 and time 3 and time 2 and time 3. None of the mean differences between the given times were found to be significant. The mean differences between time 1 and time 2 [mean differences = 0.38, p-value = 0.124>0.05] and between time 1 and time 3 [mean difference = 0.39, p-value = 0.112 >0.05] while between time 2 and time 3 [mean difference 0.01, p-value = 1.0 >0.05]. The decrease in platelets count between time 1 and time 2 and the slight decrease between time 2 and time 3 were not statistically significant at 5% level of significance. Table demonstrates the mean differences of lymphocytes between time 1 and time 2, time 1 and time 3 and time 2 and time 3. None of the mean differences between the given times were found to be significant. The mean differences between time 1 and time 2 [mean differences =-0.541, p-value = 1.0>0.05] and between time 1 and time 3 [mean difference = -0.306, p-value = 1.0 >0.05] while between time 2 and time 3 [mean difference = 0.234, p-value = 1.0>0.05]. The increase in lymphocyte count between time 1 and time 2 and the slight decrease between time 2 and time 3 were not statistically significant at 5% level of significance.

From table, we can also see the mean differences of MCH between time 1 and time 2, time 1 and time 3 and time 2 and time 3. None of the mean differences between the given times were found to be significant. The mean differences between time 1 and time 2 [mean differences =-0.584, p-value = 0.48>0.05] and between time 1 and time 3 [mean difference = -0.585, p-value = 0.458 >0.05] while between time 2 and time 3 [mean difference =-0.001, p-value = 1.0>0.05]. The increase in MCH between time 1 and time 2 and the slight increase between time 2 and time 3 were not statistically significant at 5% level of significance. The table also shows the mean differences of MCHC between time 1 and time 2, time 1 and time 3 and time 2 and time 3. None of the mean differences between the given times were found to be significant. The mean differences between time 1 and time 2 [mean differences =-0.28, p-value = 0.817 > 0.05] and between time 1 and time 3 [mean difference = -0.174, p-value = 1.00 > 0.05] while between time 2 and time 3 [mean difference =0.106, p-value = 1.0 > 0.05]. The increase in MCHC between time 1 and time 2 and the slight decrease between time 2 and time 3 were not statistically significant at 5% level of significance.

Consequently, the table shows the pairwise comparisons of the mean differences for D-dimer between time 1 and time 2, time 1 and time 3 and time 2 and time 3. The mean differences between time 1 and time 2 were found to be significant [mean = -187.31, p-value = 0.0<0.05]. This suggests that there was a significant change in D-dimer levels after vaccination. The same was true between time 1 and time 3 [mean difference = -114.25, p-value = 0.032<0.05], and between time 2 and time 3 [mean difference = 73.06, p-value = 0.008<0.05]. All the test results were statistically significant at a 5% level of significance.

DISCUSSION:

Developing a vaccine is an attempt to arm people with a tool that keeps them from contracting an illness or passing it on to others [11]. By the end of 2020, there were more than 40 distinct COVID-19 vaccines undergoing human trials and more than 150 in pre-clinical trials that were ready for distribution worldwide. The WHO often keeps an up-to-date list of vaccine candidates that are being assessed [21]. Despite the fact that the FDA in the USA and the corresponding health departments in other countries had approved some vaccines for use in emergencies, the antigenic drift necessitates periodic evaluations of the vaccines' efficacy and effectiveness.

While vaccinations are still given all over the world, it is important to note that the population that has received at least one dose of a vaccine represents approximately three-fifths of the total population. For many, the main concerns and reasons for hesitation are safety and effectiveness. Covid-19 vaccine inequity is another major issue affecting vaccination coverage; if prompt action is taken to increase supply and ensure equal access for all countries, the impact

on vaccine supply will be severe and long-lasting, negatively affecting the socioeconomic recovery of low- and lower-middle-income countries [LMIC]. Costs may have increased if LMIC vaccination rates were comparable to those of high-income countries [HIC] due to the need to expedite manufacturing scaling and supply of sufficient vaccine doses. Additionally, the cost of the COVID-19 vaccine is high per dose when compared to other vaccines [22]. The delivery costs including those associated with the health workforce surge could severely strain already precarious health systems, jeopardizing immunization programs and vital healthcare services while also resulting in concerning increases in the cases of measles, pneumonia, and diarrhea. Several studies enrolled varying numbers of participants to investigate a range of outcomes with variable endpoints, offering varying vaccination doses at variable intervals. This meta-analysis examined the efficacy and effectiveness of various COVID-19 vaccine types in lowering mortality and severity with the goal of giving decision-makers in the health policy sectors solid evidence to address the ongoing pandemic.

Virus-neutralizing antibodies are basically answerable for the protection furnished by the vaccine, these antibodies frequently inhibit the virus's binding with its cellular receptor or prevent the virus from undergoing the conformational modifications vital for fusion with the cellular membrane. Available data has shown that vaccination against COVID-19 decreased the number of cases reported per week after the second dose of vaccination [OR = 0.06 [95% CI, 0.02–0.21], I2 = 98%]. The primary determinants of vaccine efficacy and effectiveness were the kind of vaccine and the nation in which the research was carried out [23]. Meta-regression explained about 100% of this heterogeneity [vaccine type and country]. Early-pandemic trials generally demonstrated high vaccine efficacy against the original Wuhan-Hu-1 strain of SARSCoV-2.5,6. Since then, a number of vaccinations have been introduced with success and respectable safety profiles in spite of infrequent adverse events connected to the platform. There have been reports of decreased protection as a result of waning immunity and the emergence of variants more recently. Booster doses are being used to increase cross-protection against various variants and replenish neutralizing antibody levels. The need for primary vaccination in populations that have not received vaccinations and the demand for booster shots in populations with high vaccination rates have created tensions that indicate more vaccines will be required to meet the demand worldwide. Vaccines that remain stable at refrigerator temperatures or that can overcome concerns in vaccine-hesitant populations could also be useful.

The study reveals that the full blood count, D-dimer tests were within the normal ranges prior to vaccination. This was a good indication of a normal physiology in the body despite the previous exposure to the Covid-19 virus. The COVID-19 vaccine can be viewed as a type of drug therefore like any drug, COVID-19 vaccine can cause adverse drug reactions. According to the study, hemoglobin and leucocytes were to some extent affected by the vaccine this agrees with previous studies that have been done on adverse effects of covid-19 vaccine[10]. This finding were in agreement with other studies done on effects of hematological indices on covid-19 patients by[13]. In his study he concluded that there were changes in hemoglobin levels on patients with mild to moderate infection.

From the study, there was also reported leukocytopenia and this result compares to other studies done [13] and [20] on hematological changes associated with covid-19 infection. In both studies, hematological changes were not prominent in non-severe cases, with mainly lymphocytopenia [80.4%] being observed. Neutrophilia, lymphocytopenia, elevated D-dimer, prolonged PT, and reduced fibrinogen are indicators of disease progression and adverse outcome in severe, critically ill patients and those experiencing cytokine storm. This conclusion agrees with our study where we found that there was a significant change in increase of D-dimer levels after vaccination. Thus, patient monitoring on the hematological parameters is crucial in order to detect and predict any patient requiring additional care and stratify risk of severe physiological effects that may lead to development of the disease on vaccination.

CONCLUSION:

Based on the study findings, the hematological picture in our study concludes that the vaccine is safe for administration to the general public though close monitoring is required and especially those people with other comorbidities.
We recommend further studies on the T-lymphocyte and B-lymphocyte response on the administration of the vaccine. We also recommend bi annual monitoring of the vaccinated individuals on any adverse effect that may arise on the hematological indices

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Conflict of Interest: The authors of the manuscript declare that here is no conflict of interest.

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