Evaluation of the Immunological Efficiency for Some of COVID-19 Vaccines (Pfizer, AstraZeneca and Sinopharm) among Vaccinated People of Wasit Province in Iraq

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Abstract

Background: Coronaviruses (SARS-CoV-2) cause Severe Acute Respiratory Syndrome COVID-19 pandemic in March, 2020. After Chinese scientists published the genome of the virus vaccine manufacturer produced several COVID-19 vaccines that aimed to induce a humoral and cellular immune response to prevent the fatality and harm caused by COVID-19. Existing study aimed to evaluate the immunological activity of some approved vaccines in terms of serological tests for antibodies (IgG and IgM) for the study groups in Wasit Governorate.

Methods: The current study sample included (55) individuals who were vaccinated with two doses of one of the three vaccines and did not suffer from chronic health problems, (35) unvaccinated individuals of both genders. Their age ranges from 18-45 years, they were divided into two age ranges (18-31 and 32-45 years) and their vaccination history was confirmed according to a special form. The blood samples were collected from vaccinated individuals 2-4 weeks after the second dose of COVID-19 vaccine for the purpose of conducting immunological assays for immunoglobulins (IgG, IgM) and C-reactive protein (CRP) using ELISA kits.

Results: The results of serological immunoassay tests for (IgM) for the vaccinated participants, both age groups and both genders with the three Pfizer, AstraZeneca and Sinopharm vaccines were documented a positive percentage of (47 %), (64 %) and (42 %) and negative (53 %), (36%) and (58%) respectively. Whereas, the (IgG) among vaccinators with the same three vaccines was recorded a positive percentage (100%) and negative (0%) in terms of a significant rise (P≤0.05) in serum antibody levels (IgG) in all the three vaccines (Pfizer, AstraZeneca and Sinopharm) in both age ranges and for both genders compared to the control group (unvaccinated individuals).

Conclusions: the findings of the present study, that all three vaccines (Pfizer, AstraZeneca and Sinopharm) have shown a high efficacy and safely against coronavirus disease (COVID-19) in terms of the immune responses of the vaccinators. Current study data indicated a non-significant difference among age ranges (18-31 and 32-45 year) and gender is not associated with IgG levels.

Keywords: COVID-19 vaccine, vaccine efficiency, IgG, IgM. Immunoglobulins.

INTRODUCTION

Corona virus or Severe Acute Respiratory Syndrome Corona Virus (SARS-CoV-2), is the cause of the new world pandemic that appeared into the world 2019 named Coronavirus disease 2019 (COVID-19)(Li et al., 2020). The virus originated in bats (Singhal, 2020). The first cases of COVID-19 were related to an animal market in Wuhan, China and early investigations suggested that the origin of SARSCoV-2 may be bats (Zhou et al., 2020). On January 30, 2020 the World Health Organization (WHO) declared the outbreak of COVID-19 as a Public Health Emergency (WHO, 2020). The COVID-19 was quickly spreading internationally (Atiroglu et al., 2021). Immediate precautionary measures, such as worldwide curfew, shutting of borders and quarantining of individuals suspected to be infected have been instituted with instant effect (Al Qahtani, 2020). As soon as Chinese scientists published the genome of the virus (Wang et al., 2020) vaccine manufacturers took the initiative to stand up to this deadly virus and started with bold and unprecedented steps to produce safe vaccines in a limited period of time, (Calina et al., 2020). Pfizer was one of the vaccines that was approved by FDA (Food and Drug Administration) (FDA, 2020) BNT162b1 is a codon-optimized mRNA vaccine (Mulligan et al., 2020). There were also The AZD1222 (ChAdOx1) vaccine, which was developed by the Oxford University, United Kingdom AstraZeneca, it is one of the group of vaccines Viral vector-dependent (WHO, 2021) and there was Sinopharm COVID-19 vaccine is an inactivated vaccine by inserting dead copy of SARS-CoV-2 into the body (Xia et al., 2021). Most vaccines manufactured against COVID-19 have targeted the spike protein...
(Spike protein), which many studies have proven to be directly related to virus penetration into the host cell by binding to the angiotensin-converting enzyme 2 (ACE-2) receptor (Thanh et al., 2020). Antigen-specific antibody responses are monitored as measures of protective immunity following anti-SARS-CoV-2 vaccination (Fraussen, 2022). Immunoglobulins (Ig) are the effectors of the humoral responses toward infectious pathogens (and vaccines as well), they contribute to the control of the proliferation of pathogens by killing them through various mechanisms. A fraction of Ig can neutralize various pathogens and their toxins (Puissant et al., 2015). IgM antibodies provide an early stage responses during viral infections earlier to the maturation of the class switched, high affinity IgG response for long-term immunity and immunological memory. Only those whom developed SARS-CoV-2 specific IgM along together with SARS-CoV-2 specific IgG exhibited the best response and undoubtedly higher levels of protection following vaccination. These findings are innovative, significantly and timely improve current knowledge by signifying a crucial role of IgM in the development of anti-SARS-CoV-2 humoral response, following vaccination (Ruggiero et al., 2022). The evaluation of anti-spike protein receptor-binding domain antibodies IgG represents a useful tool to estimate the individual protection against SARS-CoV-2 infection (Lo Sasso et al., 2021). CRP is a protein produced as part of the inflammatory process. It is a routine test for heart failure; high levels of CRP may predict a bad outcome. CRP is a plasma protein, an acute phase protein produced by the liver and by adipocytes, C-reactive protein test post vaccination is used to detect possible inflammation or myocarditis (Nagasawa, 2009).

MATERIAL AND METHODS

Study Group

Total study participants were 90 volunteers with age range (18-45) year, 55 were vaccinated and 35 were unvaccinated (control group) for both genders. The vaccinated participants divided into three groups according to vaccine type (Pfizer, AstraZeneca and Sinopharm). The sera of all participants for this study were collected from vaccinated people against COVID-19, 2-4 week after second dose of COVID-19 vaccine at vaccine centers, schools, offices and vaccinated participants residents in Wasit Province, Iraq, during the period from December 1, 2021 to March, 15, 2022. They were divided as well into two groups according to their age ranges; the first age range (18-31) years and the second age range (32-45) years. Healthy people were chosen to be our study field; people with comorbidities, smokers, and autoimmune diseases patients were excluded from our study. Any participant of the study with chronic disease such as (hypertension, diabetes mellitus, heart disease, liver cirrhosis, and other diseases) was excluded from this study. Pregnant or breastfeeding women were also excluded. Detailed history of the cases was taken such as (age, gender, residence, job, and date of second dose of vaccine, date of previous possible infection with COVID-19, type of vaccine, date of second dose and date of obtaining samples for both samples groups.

Assay

Samples Collecting

Five milliliters of venous blood was drawn from control subjects and vaccinated people, after getting verbal agreement, by using disposable syringe of 5 ml any time at fasting control group and at least two weeks to five weeks after gaining second dose of COVID-19 vaccine in vaccinated groups, milliliters were put in disposable gel tubes, left at room temperature for (30) minutes for clot formation and then centrifuged for (10) minutes at (3000) run per minute the serum was distributed in to eppendrof tubes and frozen at (-20 °C) for laboratory assay.

Methodology

IgM assay was achieved by Indirect ELISA SARS-CoV-2 Spike Protein IgM ELISA Kit from Elabscience, USA and IgG assay was achieved as well by Indirect-ELISA SARS-CoV-2 Spike Protein IgG ELISA Kit. CRP was achieved using COBAS C 111.

Statistical Analysis

The results of current study were done by using statistical software package (SPSS 25) and analyzed by using ANOVA (one way analysis). Microsoft Excel 2013. The data were expressed as mean ± standard error of the mean (M ± S.E.M.) and Least significant difference (LSD) was considered to be less significant difference for study parameters at significant level (P≤0.05)
RESULTS

In present study IgM and IgG positive and negative cut-offs were determined per the manufacturers’ recommendations. Results less than cut-off were considered to be negative, whereas results greater or equal to cut-off were considered to be positive. The serum IgM results of Pfizer vaccinated indicates (47%) positive cases and (53%) negative cases, IgM positive results in AstraZeneca individuals were (64%) and negative outcomes were (36%), as for Sinopharm vaccine IgM positive percent was (42%) and (58%) was negative (figure 3-3). As well as data of IgM control individuals showed (8%) positive and (92%) negative (figure 1) The IgM (AU/ml) current outcomes, were represented in table (1), indicated that there were non-significant (P>0.05) in IgM levels for the three vaccine groups and control group in both genders for the two age ranges (18-31 year and 32-45 year). Although data indicates significant increase of IgM levels in females of AstraZeneca of first age range (18-31 year) comparing to control group (P≤0.05). Whereas, no significant difference has been documented for the rest two vaccines (Pfizer and Sinopharm) in both age ranges and both genders comparing to control group. On the other hand current study outcomes of IgG in vaccinated and control individuals Antibodies (IgG-S1) of COVID-19 The findings of serum IgG positivity percentages showed in figure (2) the results exhibited (100%) positive IgG for vaccinated individuals after vaccination for all three vaccines in this study. While the control group indicated (60%) negative IgG and (40%) positive outcomes among unvaccinated participants. The study refers that IgG levels in serum showed significant increase (P≤0.05) in IgG levels in all Pfizer, AstraZeneca and Sinopharm for vaccine individuals for both age ranges and genders comparing to control group.

Figure (1): The percentage of anti-spike IgM positivity (%) in all study individuals.

Figure (2): Percentage of anti-spike IgG (AU/mL) positivity (%) in all study individuals.
Table (1): The mean value of serum IgM (AU/ml) of control and vaccinated individuals according to age range for both genders.

<table>
<thead>
<tr>
<th>Age range (year)</th>
<th>Vaccine Type</th>
<th>(18-31) Males</th>
<th>(18-31) Females</th>
<th>(32-45) Males</th>
<th>(32-45) Females</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Control</td>
<td>0.43 ± 0.02</td>
<td>0.51 ± 0.06</td>
<td>0.44 ± 0.01</td>
<td>0.45 ± 0.01</td>
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<tr>
<td></td>
<td>Pfizer</td>
<td>0.60 ± 0.07</td>
<td>0.57 ± 0.04</td>
<td>0.64 ± 0.10</td>
<td>0.75 ± 0.30</td>
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<td>AstraZeneca</td>
<td>0.41 ± 0.01</td>
<td>0.83 ± 0.28</td>
<td>0.50 ± 0.03</td>
<td>0.74 ± 0.00</td>
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<tr>
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<td>Sinopharm</td>
<td>0.55 ± 0.07</td>
<td>0.57 ± 0.02</td>
<td>0.58 ± 0.09</td>
<td>0.40 ± 0.01</td>
</tr>
<tr>
<td></td>
<td>LSD</td>
<td></td>
<td></td>
<td>0.19</td>
<td></td>
</tr>
</tbody>
</table>

Data = Mean ± S. E. M.
Different capital letters denote to significant differences between groups (P≤0.05).
Different small letters denote to significant differences within groups (P≤0.05).
Similar capital and small letters denote to non-significant differences (P>0.05).
LSD = Least significant difference.

Table (2): The mean value of IgG (AU/mL) of control and vaccinated individuals according to age range for both genders.

<table>
<thead>
<tr>
<th>Age range (Year)</th>
<th>Vaccine type</th>
<th>(18-31) Males</th>
<th>(18-31) Females</th>
<th>(32-45) Males</th>
<th>(32-45) Females</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Control</td>
<td>0.45 ± 0.04</td>
<td>0.46 ± 0.08</td>
<td>0.36 ± 0.08</td>
<td>0.86 ± 0.08</td>
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<td></td>
<td>Pfizer</td>
<td>2.09 ± 0.22</td>
<td>2.22 ± 0.17</td>
<td>2.06 ± 0.22</td>
<td>2.45 ± 0.16</td>
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<tr>
<td></td>
<td>AstraZeneca</td>
<td>2.66 ± 0.001</td>
<td>1.93 ± 0.41</td>
<td>2.33 ± 0.29</td>
<td>2.44 ± 0.19</td>
</tr>
<tr>
<td></td>
<td>Sinopharm</td>
<td>2.56 ± 0.06</td>
<td>2.74 ± 0.08</td>
<td>2.52 ± 0.12</td>
<td>2.61 ± 0.03</td>
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<tr>
<td></td>
<td>LSD</td>
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<td></td>
<td>0.9</td>
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</table>

Data = Mean ± S. E. M.
Different capital letters denote to significant differences between groups (P≤0.05).
Different small letters denote to significant differences within groups (P≤0.05).
Similar capital and small letters denote to non-significant differences (P>0.05).
LSD = Least significant difference.
DISCUSSION

Immunoglobulins are the effectors of the humoral responses toward vaccines, they contribute to the control of the proliferation of pathogens by killing them through various mechanisms (Puissant et al., 2015). Antigen-specific antibody responses (IgM) are monitored as measures of protective immunity following anti-SARS-CoV-2 vaccination, Fraussen, reported in a study that if there was no IgM response or IgM appearing after IgG after second dose of COVID-19 vaccines, results in significantly lower anti-S IgG levels comparing to those with a coordinated (IgM then IgG) humoral response to the vaccine (Fraussen, 2022).

Negative results of IgM in some of vaccine recipient (vaccinated individuals) might refers to that blood drawing was more than four weeks post vaccination in these individuals so the IgM levels drop, or they may not developed IgM after the second dose of vaccine. A study achieved by Nabeer et al., (2021) agreed with the results of this study, they reported that about (50%) of individuals with no previous COVID-19 infection did not develop IgM after BNT162b2 vaccine. Current results were also resemble to a study done by Banga-Ndzouboukou et al., (2021), their study reported that they observed a low percentage of members whom received the second dose of vaccine developing an IgM antibody response. In the same concept, Chaudhury, (2021), explains the absence of anti-S IgM following vaccination could point towards pre-existing immunity to cross-reactive human coronaviruses.

Additionally, the positive IgG and IgM results that appeared in present study control group (unvaccinated participants) might possibly be due to prior infection, this agreed with Liu et al., (2021) whom reported that one of the participants exhibits positive for anti-SARS-CoV-2 IgM and IgG before vaccination, suggestive of potential prior infections. A study conducted same results of this study, the presence of positive IgM in unvaccinated individuals, a study indicated (64.5%) recorded positive IgM-S before vaccination, while some participants evolved IgM-S after the first and second vaccine dose (Ruggiero et al., 2022).

Current study data indicated a non-significant difference among age ranges (18-31 and 32-45 year). In this context it agreed with current study Wang et al., (2022) was achieved on 980 healthy vaccinated individuals in China, 3 weeks after getting their second vaccine dose, they reported that IgM response was not significantly different among age groups.

On the other hand current study reveals non-significant differences between males and females of Pfizer and Sinopharm vaccinated individuals comparing to control means that sex was not important in developing IgM response, agreed with the aforementioned study by Banga-Ndzouboukou et al., (2021) they found that gender was not related with anti-IgM levels after having the second dose of Sinopharm vaccine.

In addition, the current results exhibited that AstraZeneca females of first age group (18-31) year showed statistically increased in IgM levels in serum comparing to males of both AstraZeneca and control, agreed with this results Chen et al., (2022) reported that there was a significant difference between male and female groups for levels of IgM.

Serum positive outcomes of IgG in vaccinated individuals refers to post-vaccination protection and its duration. Collective data from clinical trials and followed infection study show a strong association between mean neutralization levels and reported protection (Khoury et al., 2021). It is known that serum IgG levels are critical in confirming protection against viral illnesses (Murin et al., 2019). Similar to current study results, Liu et al., (2021) had concluded100% positivity of IgG in study individuals two weeks after COVID-19 vaccination.

This present finding indicated that gender is not associated with IgG levels. Banga-Ndzouboukou et al., (2021) reported that among all vaccinated volunteers, they found that gender was not related with anti-IgG and anti-IgM levels after having the second dose vaccination. There was a study that disagree with this results achieved by Lo Sasso et al., (2021) clearing that IgG levels were higher in females than males in their results.

The negative test results of CRP for all participants in the study clearly proved that all vaccinated and control individuals had no diseases or infection at the time of blood drawn.
CONCLUSIONS

Current results indicate the highest positive IgM (AU/ml) value was among AstraZeneca volunteers followed by Pfizer and Sinopharm respectively. Also, concluded from current study that result exhibits poor IgM outcomes (positive IgM results was only 64% in AstraZeneca, 47% in Pfizer, and 42% in Sinopharm) and comparing to (100%) IgG positive outcomes in the three vaccine groups (Pfizer, AstraZeneca and Sinopharm). The CRP normal levels post vaccination indicated that there were no sign of possible instant infection or possible vaccine side effect.

REFERENCES

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