



Effectiveness of the Pfazer vaccine against COVID-19 patients in chronic diseases.

Jihan Qais Dakhal AL-lamy¹

^{1,2}Department of Biology, College of Science, Wasit University, Iraq
Correspondence author; jihan.Qais1986@gmail.com

Ahmed D. Jabbar²

^{1,2}Department of Biology, College of Science, Wasit University, Iraq

ABSTRACT

Corona viruses belong in the corona family and are part of the nidovirales order. The family of closed-cell, positive-sense, single-stranded RNA viruses known as coronaviruses (CoVs) possesses a diverse variety of traits. The respiratory, digestive, hepatic, and neurological systems are all affected, and they cause a wide range of health issues in both people and animals. In this study, individuals who received the Pfizer vaccine had their IgG and IL6 levels measured. The study includes 167 cases, They were distributed on the basis of age and sex into four groups, The first group included 47 patients, which is the control group, the second group included 42 patients diseases only, the third group included 39 patients with Covid-19 only, and the fourth group included 39 patients Covid-19 and diseases. The study indicated a significant increase in ($p < 0.01$) in IgG for patients with Covid and chronic diseases with chronic diseases compared to other groups. The study we obtained indicated a significant increase in ($P < 0.01$) in IL6 ratio in relation to gender and age groups. According to these findings, the Corona virus may have an impact on and pose a threat to everything that results in the body's critical organs failing.

Keywords:

Covid 19 ; IgG Level Measurement , Effectiveness of pfazer vaccine

Introduction

In late December 2019, Wuhan, Hubei Province, China, saw an outbreak of an unknown disease identified as pneumonia of unclear etiology. [1]. the outbreak had infected 9720 people in China, resulting in 213 deaths, and 106 persons in 19 other countries. [2]. China alerted the World Health Organization of the outbreak on December 31st. The virus was recognized as a coronavirus on January 7th, having >95% homology with the bat coronavirus and >70% resemblance to the SARS-CoV. The virus was also found in environmental samples from the Huanan Sea food market, indicating that it originated there, [3]. Several independent laboratories identified

the primary agent of this unusual pneumonia as a new coronavirus (nCoV) a few days later[4]. The World Health Organization has temporarily designated the causal virus as severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) and the corresponding infected disease as coronavirus disease 2019 (COVID-19) [5]. Coronaviruses are members of the Coronavirinae subfamilyde . Coronaviridae, coupled with Torovirinae, make up the order Nidovirales' Coronaviridae family.[6]. Since April 2012, the Middle East Respiratory syndrome CoV (MERS-CoV) has emerged as a new betacoronavirus lineage C member, closely related to the bat coronaviruses HKU4 and HKU5 [7]. Coronaviruses are encased positive

sense RNA viruses with spike-like projections on their surface that give them a crown-like appearance under the electron microscope, hence the name coronavirus. Coronaviruses have a spherical shape with a ring of huge, bulbous projections on the surface. Coronaviruses infect cells largely by connecting their spike protein to the cell receptors of their host[8]. Coronaviruses are enveloped positive-strand RNA viruses with 30–32 kb RNA

genomes, the biggest known. (Fig. 1)The replicase locus is encoded in the 5' end of the genome, and the structural proteins are encoded in the 3' third of the genome, in the following order: hemagglutinin esterase (HE), if present (HE is only present in some betacoronaviruses), spike (S), small membrane (E), membrane (M), nucleocapsid (N), and internal (I) protein, encoded within the N gene. (Fig. 1) [9].

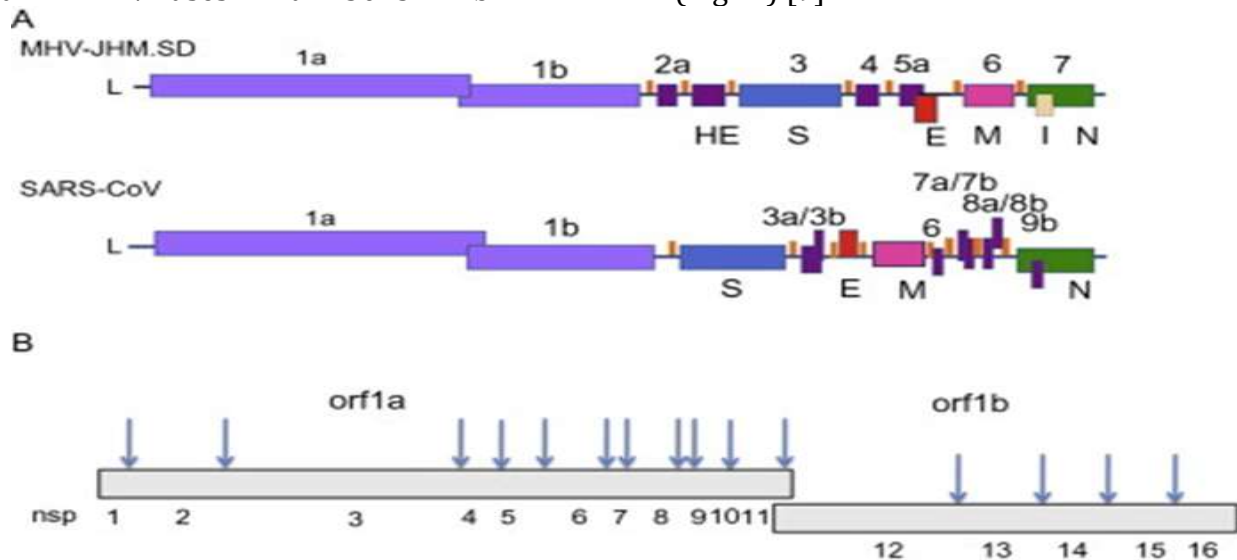


Figure 1. Genome organization and replicase encoded nonstructural proteins. (A) The genomes of MHV-JHM.SD and SARS-CoV are diagrammed. L, leader; ORF1a/1b, replicase; structural genes: HE, hemagglutinin-esterase; S, spike; E, small membrane envelope; M, membrane; N, nucleocapsid; I, internal. orfs encoding accessory genes are designated with numbers. (B). Arrows indicate cleavage sites for orf1a, orf1ab encoded polypeptides and numbers indicate individual nsp cleavage products.

Materials and Methods

Study design and samples collection:

This a case- control study from patients from November 2021 to February 2022, at Al-Kindi Teaching Hospital in Baghdad. After obtaining the approval of the Ministry of Health for the study.As well as the consent of the patients who are unable to give blood,as well as for the lack of sufficient information for collection the sample.We have collected 167 samples from patients who under went the

pfazer vaccine after confirming them through the vaccination card,a blood sample was taken 21 days after receiving the vaccine or more.They were divided into four groups: Group1:included 47 people who had received the Pfizer vaccine, without previously infected with corona and without chronic diseases. Group 2: included 42 peoples who had received the pfazer vaccine, without previously infected with corona and had chronic diseases. Group 3; included 39 peoples who had received the pfazer vaccine,who were previously infected with corona and without chronic diseases. Group 4: included 39 people who received the pfazer vaccine, who were previously infected with corona and chronic diseases

Samples collection :

Venus blood of 10 ml was drawn using a sterile syring, which can be disposed of after use.We distributed the blood into two tubes, I put 3ml of blood into EDTA tube for RT PCR genetic testing, the sample was left for 15 minutes at a temperatureof (20-25 C) after which the

sample was placed in the freezer at a freezing point -20 C. The second tube was placed 7 ml of blood in a tube gel for the purpose of the immunological study (ELISA) enzyme-linked immune-sorbent assay and left the sample for 15 minutes at room temperature (20-25 C) after that we put the samples in a centrifuge approximately 2500-3000 cycles per minute and for 5 minutes to obtain the serum, We distribute the serum into three eppendorf tubes, after which the tubes were placed in the freezer at a freezing degree of -20C.

Anti-SARS-CoV-2 IgG kIT

1. A sufficient amount of microtiter was prepared wells for the standards, controls and samples as well as for a substrate blank.
2. I took 100 μ l each of the diluted (10:990) samples and the ready-to- use standards and controls respectively into the wells. Leave one well empty for the substrate blank
3. Cover plate with the re-usable plate cover and incubate at room temperature for 30 minutes.
4. Empty the wells of the plate (dump or aspirate) and add 300 μ L of diluted washing solution. This procedure is repeated totally three times. Rests of the washing buffer are

afterwards removed by gentle tapping of the microtiter plate on a tissue cloth.

5. Pipet 100 μ L Anti IgG each of the wells. Leave one well empty for the substrate blank.
6. Cover plate with the re-usable plate cover and incubate at room temperature for 30 minutes.
7. Empty the wells of the plate (dump or aspirate) and add 300 μ L of diluted washing solution. This procedure is repeated totally three times. Rests of the washing buffer are afterwards removed by gentle tapping of the microtiter plate on a tissue cloth.
8. Pipet 100 μ L substrate each of the wells. This time also the substrate blank is pipetted.
9. Cover plate with the re-usable plate cover and incubate at room temperature for 15 minutes in the dark.(fig 2).
10. To terminate the substrate reaction, pipet 50 μ L stop solution into the wells. Pipet also the substrate blank.(fig 3).
11. After thorough mixing and wiping the bottom of the plate, perform the reading of the absorption at 450 nm (optionally reference wavelength of 620 nm). The color is stable for at least 60 minutes.



Figure 2: IgG assay by ELISA method, where the blue color shows positive IgG

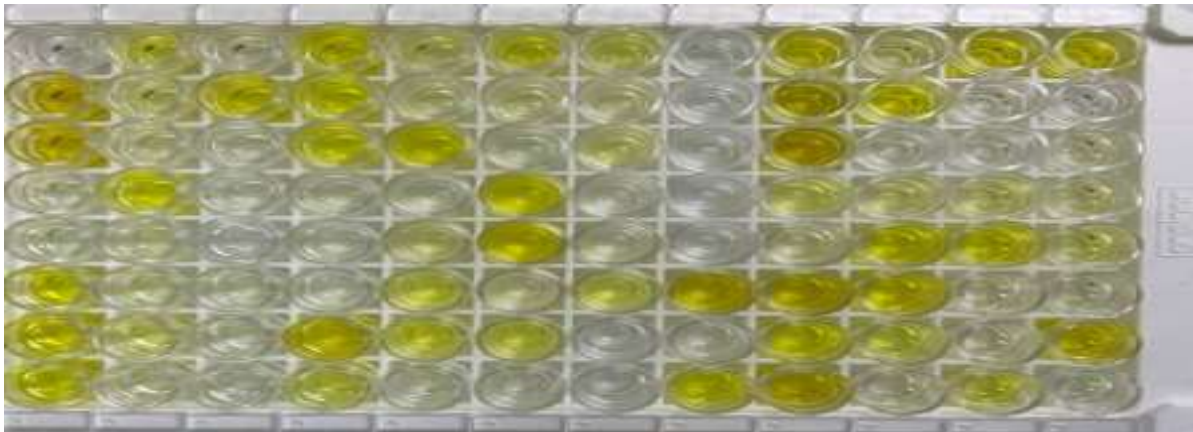


Figure 3: IgG assay by ELISA method, where the yellow color shows positive IgG after adding a stop solution.

Statistical analysis

Data were analyzed using SPSS statistical software, version 23. ANOVA test was performed for independent samples between patients, recovery and control groups, and the resulting values were expressed as mean and standard deviation (SD). Statistical tests were significant at $p < 0.05$ and highly significant at $p < 0.01$ with 95% confidence interval. ROC CURVE was carried out for the studied parameters and the area under the curve (AUC) was determined. The sensitivity and specificity

of the above-mentioned analyzes were also determined, and the cut-off value was determined.

Results and Discussion

Antibodies are measured in relation to gender and age groups. We compared the ratio of antibodies between males and females, as it was found that the percentage of IgG for males is higher than for females. (Fig 4).

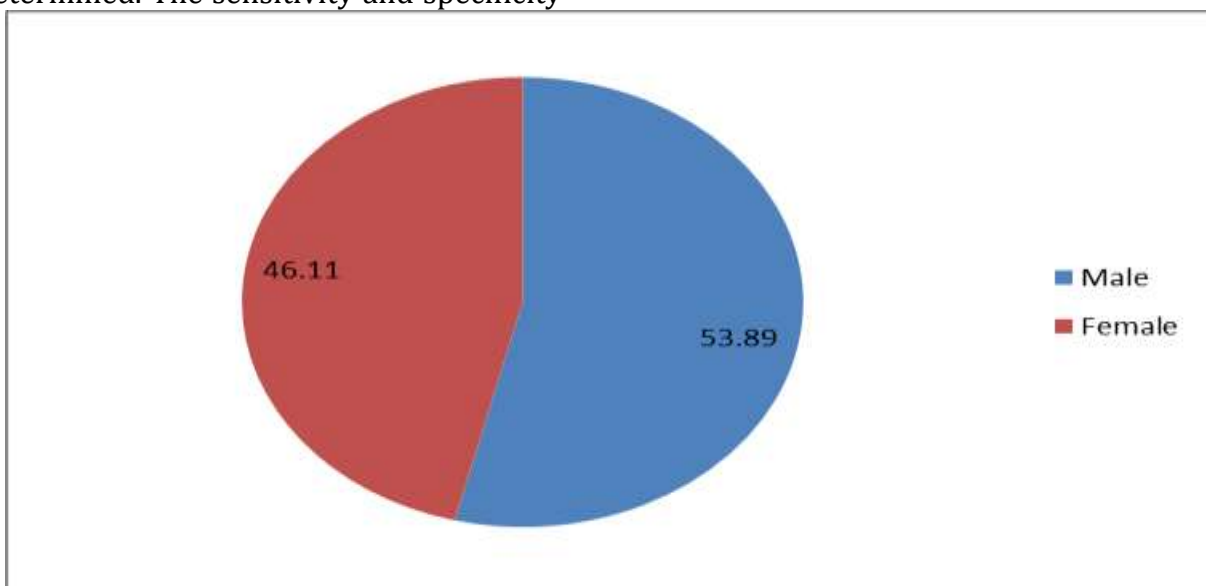


Figure 4: The pie chart shows the groups participating in the research classification by gender

The percentage of antibodies was calculated among the age groups, where the highest percentage of IgG was found, ranging between

the age group (20-30) years, and the lowest percentage of IgG ranging between the age group (50- > 60) years.(Fig 5).

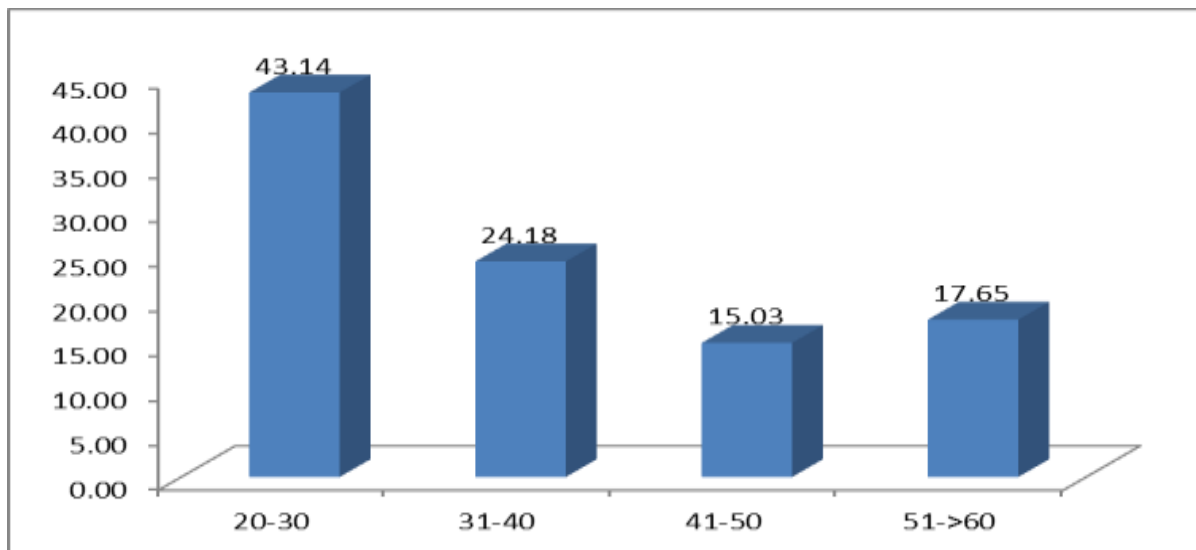


Fig.5 The percentage of antibodies

Table (1): Comparison of antibody values among the groups participating in the research.

| Group IgG | Control Mean+SD | Disease only Mean+SD | With COVID only Mean+SD | COVID+D. Mean+SD | P- value | Sign. |
|--------------------|-----------------------|----------------------------|-------------------------------|---------------------|--------------------------|--------------|
| IgG | C 2.2144±0.5 78 | C 2.47±0.803 | B 16.801±4.929 | A 26.695±4.779 | 0.000 4 | Sign. |
| Sensitivity | 93.51 | | | | | |
| Specificity | 95.35 | | | | | |

Examining the reasons why men have more coronavirus damage than women. Researchers still know very little about this novel coronavirus. However, according to the most recent data, men are significantly more likely to get infected than women are, and women's immune systems appear to be stronger.[10]. One study published in The Lancet showed that elderly men, particularly those who already have conditions like heart disease and diabetes, are disproportionately affected by the coronavirus fatality rate. It's important to remember that a comparable circumstance existed during the SARS pandemic, which killed 780 lives over 20 years ago. [11]. Researchers found that male mortality rates were 22% and female mortality rates were 13% after studying 1800 SARS patients. According to a 2019 study on MERS, the fatality rate was as high as 32%

for males and 26% for women. Differences in smoking habits, testing procedures, and immunological responses associated to sex are only a few potential causes for such discrepancies. It may be thought that hormones, particularly estrogen, are crucial. [12]. describes the presence of anti-COVID IgG that was either brought on by the SARS-COV-2 infection or as a result of receiving the Pfizer—BioNtech vaccine (BNT162b2 mRNA).[13]. In all of the patients who got two doses of the BNT162b2 mRNA vaccine, the serum COVID IgG levels were quite high[14] . IgG concentrations had a favorable relationship with the amount of time since the vaccination. Anti-immunoglobulinemia criteria were established for Pfizer vaccine recipients and age groups (20-> 60). In contrast to antibody levels, serum Igg levels in young patients were

comparable to or somewhat greater than those in older subjects. There is proof that as people age, their fraction of S IgG declines. The seventh, eighth, and ninth decades of life saw an increase in IgG levels. The levels of various immunoglobulin classes appeared to be significantly connected, and there was a propensity for correlation between IgG type antibodies and serum IgG levels. To describe the humoral immune status of older patients and to comprehend the origins as well as the diagnostic and prognostic importance of old age "imbalances," complex examinations, including quantification of antibodies to extrinsic and intrinsic antigens and serum immunoglobulins, are proposed. [15]. An effective method for determining a person's level of protection against SARS-CoV-2 infection is the assessment of SARS-CoV-2 S-RBD IgG titers. It should be noted that due to their seroconversion activity, the examination of antibodies against S-RBD IgG is crucial to determining the level of protection against SARS-CoV-2 infection. However, because SARS-CoV-2 is a recently discovered virus, little is known about the antibody reactions in COVID-19 patients and, particularly, in people who have received vaccinations. After receiving the full COVID-19 vaccine in our trial, DOC patients displayed decreased levels of antibodies compared to HC, which became more noticeable after six months.[16]. Since antibody levels were lower in older than in younger people, there was also a second linear effect of aging on antibody responses in both groups. Our results partially support those of Muller et al.[17]. who demonstrated that older patients' antibody levels were considerably lower than those of young subjects. Lo Sasso et al. observed an effectiveness antibody response following vaccination with age- and time-related differences in a large observational research. [18]. In order to study immunological activity and reactivity in this group of patients, we opt to evaluate the post-vaccination IgG titer. Therefore, there are two key benefits to examining the COVID-19 vaccine's effectiveness in DOC patients: (a) show that a subset of patients who are typically regarded as immunocompromised have adaptive

responses despite having beginning clinical severity, a high frequency of complications from neurosurgery, infections, and long-term bed rest[19]; and (b) encourage additional research using bigger samples to find out if patients who have suffered a stroke, been in an accident, or are anoxic share the same pattern of anti-S-RBD IgG levels.[20].

Conclusion

This study evaluates some important vital signs of Covid-19 patients. The results of this study showed an increase in antibody indicators in Covid-19 patients and the effectiveness of the vaccine.

Conflict of Interest: None

Funding: Self

Ethical Clearance: Not required

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