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# **RESEARCH ARTICLE - MEDICAL TECHNIQUES**

# Comparison of IgG and Neutralizing Antibody Response After Pfizer BioNTech COVID-19 Vaccine Among Iraqi Individuals

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Article Info.	Abstract		
Article history:	SARS-C0V-2 has quickly caused a pandemic. The distribution of vaccines is presently underway in an effort to stop the viral transmission and stop fatalities, several vaccinations have been created to decrease COVID virus disease, in 2019.		
Received 21 February 2023	the development of vaccine-induced population immunity is an important global strategy. Review of the anti-spike protein receptor-binding domain (S-RBD) a person's level of immune response to antibody strategy can be used to assess SARS-CoV-2 viral infection in 2019. Their efficacy, safety, and immunogenicity in various population are not thoroughly		
Accepted 18 May 2023	understood. The objective of this study was to evaluate the vaccinations adverse effects as well as determine the immunogenicity of the messenger ribonucleic acid (mRNA) BNT162b2 vaccines through the production of IgG and neutralizing antibodies against the protein s subunit. A total of 41 vaccinated individuals with Pfizer-BioNTech COVID-		
Publishing 30 June 2023	19 vaccine, as well as (10) non-vaccinated were included in the study. Measurements of Neutralizing antibody (Nab) levels and CoV-IgG levels were tested by fluorescence Immunochromatographic assay. IgG and Nab levels showed a significant difference between its level in the sera of vaccinated and controls (p<0.05). This means the majority of immunization recipients between the ages of 18 -50 years can develop an immunological response to the SARS-Cov-2 vaccine.		

Keywords: SARS-CoV2; COVID-19; IgG Level; Neutralizing Antibody; Vaccination.

# 1. Introduction

The serious acute respiratory infection coronavirus pandemic, a severe acute respiratory infection, which started end of 2019, was mostly brought on by the single-stranded RNA virus known as coronavirus -2 [1-3]. The primary goal of vaccination is to induce a humoral immune response to stop the spread of disease [4]. Through several mechanisms, coronavirus-2 vaccinations promote both innate and adaptive immunity. The Pfizer/BioNTech BNT162b2 vaccination demonstrated 95% effectiveness against COVID-19. The FDA approved the emergency use of two SARS-CoV-2 mRNA vaccines with a two-dose schedule in December 2020: BNT162b2/Pfizer and mRNA-1273/Moderna [5].

The majority of COVID vaccinations require two doses given 3 to 12 weeks apart to adequately immunize the recipient. The SARS-CoV-2 spike protein is encoded by the mRNA vaccines, and when administered, it is absorbed and translated in the host cell, producing the spike protein, which is then exposed on the cell surface to B and T-cells, inducing an immunological response [6]. After the initial dose, this immune response (T-lymphocytes and antibody levels) gradually decreases, leaving just a tiny pool of memory B and T cells to protect against attacks from the same pathogen in the future [7]. A second dose results in a stronger immunological response, which gradually diminishes with time. However, more memory B cells remain, aiding in the future staging of a more thorough and swifter immune response against the same disease [8]. Our primary concern with adaptive immunity stems from the fact that it involves a B cell-mediated antibody response, this causes the development of certain antibodies that bind to the spike protein in order to prevent viral entrance into cells and provide protection against severe acute respiratory syndrome coronavirus-2 infection [9]. Due to some technological advantages, the COVID-19 vaccines based on mRNA technology were the first to be approved and delivered in several Western countries. These vaccines are either already approved for clinical use or are in the advanced stages of development [10]. The Pfizer-BioNTech and Moderna vaccines to prevent COVID-19 in the US were given an Emergency Use Authorization (EUA) in December 2020 by the US Food and Drug Administration (FDA). and to safeguard those who are at high risk for consequences [11,12].

The receptor-binding domain of spike protein (RBD), which has a lot of neutralizing epitopes, is targeted by SARS-CoV-2 vaccines to elicit a strong immunological reaction to the protein in spike [13]. In general, COVID-19 vaccinations trigger innate and adaptive immunity through

Nomenclature & Symbols				
COVID-19	Coronavirus disease- 2019	RNA	Ribonucleic acid	
Nab	Neutralizing antibody	RBD	Receptor binding domain	
IgG	Immunoglobulin G	N-protein	Nucleocapsid protein	
FDA	Food and Drug Administration	S-protein	Spike protein	

several pathways. Adaptive immunity involves both the (cellular (T cells) and antibody (B cells) responses) and can lead to the production of antibodies specific for several SARS-CoV-2 antigens [14]. When determining vaccine immunogenicity, one should consider both the humoral and cellular antivaccine immune response because the integrated adaptive immunity and defence against SARS-CoV-2 are aided by neutralizing antibodies that can restrict illness severity [15]. Numerous serological diagnostic assays for COVID-19 have recently been established [16,17]. They make a diagnosis of the illness based on the discovery of antibodies to all or a subset of the N or S proteins of SARS-CoV-2. Notably, due to their neutralizing action analyzing S-RBD IgG antibodies is the most important step in determining the degree of protection. against SARS-CoV-2 infection [18]. IgG and response levels will be measured and compared in the current investigation of a neutralizing antibody after Pfizer-BioNTech COVID-19 Vaccine among Iraqi individuals.

## 2. Materials and Methods

## 2.1. Study design

The study included fifty-one volunteers who were selected from those attending the model health center (Ahmed Al-Maliki). A total of fortyone individuals after 14 days of the second Pfizer-BioNTechCOVID-19 vaccine dose, and ten individuals not taking the vaccine. They were 15 men and 24 women, their ages ranging from (18- 50) years during the period (from April / 2022 until- August /2022). From each subject; (5 mL) of blood was drawn by vein puncture and transferred into a simple tube with disposable syringes placed to clot at room temperature in a plane tube, then separated by centrifuge at 2500 rounds/minute(rpm) for 10 minutes to obtain the serum. Neutralizing antibody (Nab) levels and Cov-IgG levels were tested by fluorescence Immunochromatographic assay technique by the manufacturer's protocol (AeHealth, Germany).

## 2.2. Statistical analysis

The social sciences statistics program was utilized. to conduct the study's statistical analysis. (Version 21 SPPS). Data were presented as Mean±SD for the quantitative variable to compare the means of study groups with each other. Relations were studied using the ROC Curve.

# 3. Results

This study had 41 volunteers who received the Pfizer COVID-19 vaccine and 10 unvaccinated controls. Fig. 1 demonstrates that after the second dose of the Pfizer-BioNTech COVID-19 vaccine, there is a statistically highly significant difference between Cov-Nab levels among the vaccinated groups ( $73.766\pm 30.19$  IU/ml), and non-vaccinated groups ( $29.580\pm 5.29$  IU/mL) (P < 0.001).

While the serum levels of Cov-IgG among the same groups shows highly significant difference  $(4.322 \pm 0.46 \text{ IU/mL})$  and the non-vaccinated group  $(1.020 \pm 0.71 \text{ IU/mL})$  are presented in Fig. 2.

The area under the receiver operating characteristic curve (ROC) for Cov-IgG was 0.959 (95% CI 0.881-10000 p<0.0001). while for Cov-Nab was 0.704 (95% CI 0.463-0.944, p<0.063). To determine CoV-IgG the optimum parameter that could be relied on to distinguish between groups that had received vaccinations and those that hadn't, receiver operating characteristic curve (ROC) analyses were carried out (as shown in Fig. 3). ROC program was applied which showed that most of the studied parameters were significantly differentiated between the users of vaccinated from non-vaccinated for Cov-IgG and Cov-Nab.

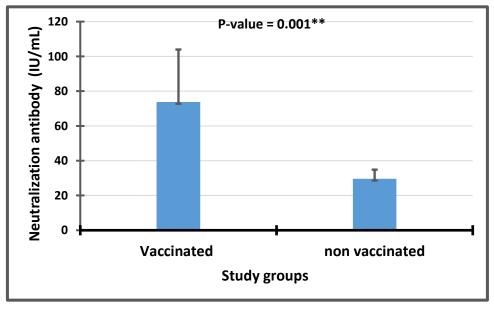


Fig. 1. Distribution of Cov-Nab in study groups

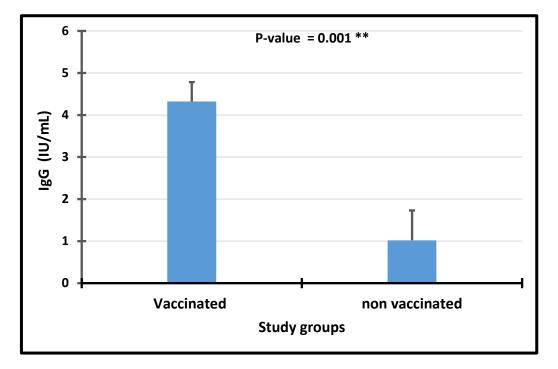


Fig. 2. Distribution of Cov-IgG in study groups

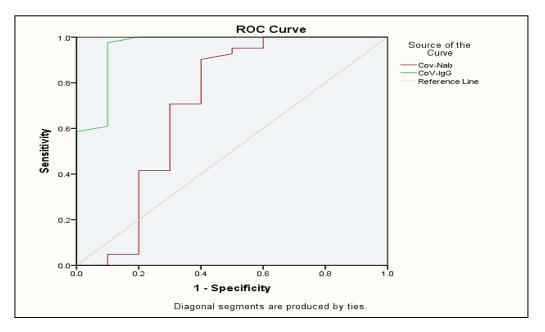


Fig. 3. Receiver operating characteristic curve for both antibodies Cov-Nab &Cov-IgG between vaccinated and non-vaccinated groups

#### 4. Discussion

Coronavirus Disease 2019 is brought on by the SARS-CoV-2 virus (COVID-19), and is susceptible to being prevented from spreading by messenger RNA (Pfizer) vaccinations [19-21]. In the present study IgG Ab is increased in vaccinated as compared to non-vaccinated individuals which agreed with previous research who assumed that mRNA vaccines induce cellular and humoral responses, vaccinations caused the production of IgG antibodies [22]. Neutralizing antibodies are measured as part of the evaluation of vaccines to determine the quantity and quality of the antibodies produced Neutralizing antibodies (Nabs) play an important role in the virus's clearance and have been consider a key immune correlated for the production or treatment against viral disease. Viral-specific Nabs can prevent viral infection when they are produced as a result of infection or immunization [23,24].

In our study, Nabs are measured as part of the evaluation of vaccines to determine the quantity and quality of the antibodies produced and the results detected that Nab had a significant increase in vaccinated as compared to non-vaccinated individuals. In the present study, Cov-Nab levels a significant with a p-value (0.001) the same result was shown by other studies which found that there is a significant Nabs level difference

between the vaccinated group and the non-vaccinated [25]. Researchers discovered that those who had previously contracted SARS-CoV-2 had neutralizing antibody titers that were 2-4 times higher in the first two months following vaccination [26].

ROC analyses were used to analyze Cov-IgG and Nab levels. In the present study, Cov-IgG value has been reported to correlate with neutralization, our data showed different antibody responses after the second dose of mRNA vaccine.

#### 5. Conclusion

Our research reveals that the majority of immunization recipients between the ages of 18 and 50 can develop an immunological response to the SARS-Cov-2 vaccine.

#### **Ethical Approval**

The ethical review board of the Iraqi Ministry of Health gave its clearance for this study (no.3289).

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#### References

- [1] JM Dan, J Mateus, Y Kato, KM Hastie, ED Yu, CE Faliti, A Grifoni, SI Ramirez, Haupt, A Frazier, C Nakao, V Rayaprolu, SA Rawlings, B Peters, F Krammer, V Simon, EO Saphire, DM Smith, D Weiskopf, A Sette, S Crotty. "Immuno-logical memory to SARS-CoV-2 assessed for up to 8 months after infection". Science 371: eabf4063. 2021 https://doi.org/10.1126/science.abf4063.
- [2] MR Shurin, A Morris, A Wells, SE Wheeler. "Assessing immune response to SARS-CoV-2 infection. Immunotargets" Ther 9:111–114. 2020 https://doi.org/10.2147/ITT.S264138.
- [3] HB Najeb, AJ Mohamed, EM Rasheed Effect of Covid-19 Vaccine on Women's Fertility Hormones. Journal of Techniques, ISSN: 2708-8383, Vol. 4, No. Special Issue, November 2022, Pages 139-144.
- S Kashte, A Gulbake, SF El-Amin III, A Gupta A. COVID-19 vaccines: Rapid development, implications, challenges and future prospects. Human Cell 2021, 34, 711–733.
- [5] EE Walsh, RW Frenck, AR Falsey, N Kitchin, KNeuzil, A Gurtman, S Lockhart, M J. Mulligan, R Bailey, K A. Swanson, P Li, K Koury, W Kalina, D Cooper, C F-Garfias, PY Shi, Ö Türeci, K R. Tompkins, K E. Lyke, V Raabe, P R. Dormitzer, K U. Jansen, U Şahin, and W C. Gruber. Safety and Immunogenicity of Two RNA-Based Covid-19 Vaccine Candidates. New England gournal of Medicine. 2020; 383:2439-2450.
- [6] L Dai, GF Gao G.F. Viral targets for vaccines against COVID-19. Nat. Rev. Immunol. 2021, 21, 73-82.
- [7] Iwasaki, A.; Omer, S.B. Why and how vaccines work. Cell 2020, 183, 290–295. https://doi.org/10.1016/j.cell.2020.09.040.
- [8] Z Wang, F Schmidt, Y Weisblum, F Muecksch, CO Barnes, S Finkin, c, Viant, cGaebler. Naturally enhanced neutralizing breadth against SARS-CoV-2 one year after infection. Nature 2021, 595, 426–431.
- [9] Z Wang, F Muecksch, D Schaefer-Babajew, S Finkin. Naturally enhanced neutralizing breadth against SARS-CoV-2 one year after infection.Nature2021,595,426–431.
- [10] Y Wu, F Wang, C Shen, W Peng, D Li, C Zhao, Z Li, S. Li, Y. Bi, Y. Yang, "A noncompeting pair of human neutralizing antibodies block COVID-19 virus binding to its receptor ACE2". Science, 368, 1274–1278. 2020.
- [11] E Dolgin. "How COVID unlocked the power of RNA vaccines". Nature;5 89:189-91. 2021.
- [12] Food and Drug Administration. "Pfizer COVID-19 vaccine emergency use authorization". U.S. Food and Drug Administration, Silver Spring, MD. 2020.
- [13] Food and Drug Administration. "Moderna COVID-19 vaccine emergency use authorization". U.S. Food and Drug Administration, Silver Spring, MD. 2020.
- [14] CO Barnes, CA Jette, ME Abernathy, KA Dam, SR Esswein, HB Gristick, AG Malyutin, NG Sharaf, KE Huey-Tubman, YE Lee, DF Robbiani, MC Nussenzweig, AP West, PJ Jr, Bjorkman. "SARS-CoV-2 neutralizing antibody structures inform therapeutic strategies". Nature 588:682–687. 2020. https://doi.org/10.1038/s41586-020-2852-1.
- [15] B Lo Sasso, R V Giglio, M Vidali, C Scazzone, G Bivon, C M Gambino, A M Ciaccio, L Agnello and M Ciaccio, "Evaluation of Anti-SARS-Cov-2 S-RBD IgG Antibodies after COVID-19 mRNA BNT162b2 Vaccine". Diagnostic 11(7):1135 Jun-2021.
- [16] C. RydyznskiModerbacher, S.I. Ramirez, J.M. Dan, A. Grifoni, K.M. Hastie, D. Weiskopf, "Antigen-specific adaptive immunity to SARS-CoV-2 in acute COVID-19 and associations with age and disease severity Cell, 183, pp. 996-1012.e19 2020.
- [17] B Lo Sasso, C.M Gambino, N Scichilone, R. V Giglio, G Bivona, C. Scazzone, R. Muratore, S. Milano, M Barbagallo, L. Agnello, "Clinical Utility of Midregional Proadrenomedullin in Patients with COVID-19". Lab. Med. 2021.
- [18] C.M Gambino, B Lo Sasso, C. Colomba, R. V Giglio, L. Agnello, G. Bivona, M. Ciaccio, "Comparison of a rapid immunochromatographic test with achemiluminescence immunoassay for detection of anti-SARS-CoV-2 IgM and IgG". Biochem.Med., 30(3): 030901. 2020.
- [19] L Baden, et al., "Efficacy and safety of the mRNA-1273 SARS-CoV-2 vaccine". N. Engl. J. Med. 384, 403–416 2021.
- [20] F. Polack, et al. "Safety and efficacy of the BNT162b2 mRNA Covid-19 vaccine". N. Engl. J. Med. 383, 2603–2615 2020.
- [21] AS Abd, IA AL-Rayahi A Study of Some Biochemical Parameters in COVID-19 Patients with Diabetes Mellitus: Comparative Study. Journal of Techniques, ISSN: 2708-8383, Vol. 4, No. Special Issue, November 2022, Pages 1-6.
- [22] M.J. Mulligan, K.E Lyke, N. Kitchin, J. Absalon, A. Gurtman, S. Lockhart, K. Neuzil, V. Raabe, R. Bailey, K.A Swanson, et al. "Phase I/II study of COVID-19 RNA vaccine BNT162b1 in adults". Nature, 586, 589–593. 2020.

- [23] D.S Khoury, D. Cromer, A. Reynaldi, T.E. Schlub, A.K. Wheatley, J.A. Juno, K. Subbarao, S.J Kent, J.A Triccas, M.P Davenport, "Neutralizing antibody levels are highly predictive of immune protection from symptomatic SARS-CoV-2 infection." Nat.Med., 27, 1205– 1211, 2021.
- [24] F Wu, A Wang, M Liu, Q Wang, J Chen, S Xia, Y Ling, Y Zhang, J Xun, L Lu, S Jiang, H Lu, Y Wen, J Huang 2020 "Neutralizing antibody responses to SARS-CoV-2 in a COVID-19 recovered patient cohort and their implications" doi: https://doi.org/10.1101/2020.03.30.20047365.
- [25] A R. Demonbreun, A Sancilio, M P. Velez, D T. Ryan, R Saber, L A. Vaught, N L. Reiser, R R. Hsieh, R T. D'Aquila, B Mustanski, E M. McNally, T W. McDade. "Comparison of IgG and neutralizing antibody responses after one or two doses of COVID-19 mRNA vaccine in previously infected and uninfected individuals." E Clinical Med. Vol. 38 101018 2021.
- [26] F Krammer, K Srivastava, H Alshammary, AA Amoako, MH Awawda, KF Beach, et al. "Antibody Responses in Seropositive Persons after a Single Dose of SARS-CoV-2 mRNA Vaccine" N Engl J Med, 384, pp. 1372 1374, 2021 10.1056/nejmc2101667.