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ORIGINAL ARTICLE
ORİJİNAL ARAŞTIRMA

Evaluation of SARS-CoV-2 Total Antibodies After Two Doses of Coronavac in Healthcare Workers: Retrospective and Observational Study

Sağlık Çalışanlarında İki Doz Coronavac Aşısı Sonrası SARS-CoV-2 Antikorlarının Değerlendirilmesi: Retrospektif ve Gözlemsel Çalışma

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ABSTRACT

Objevtive: During the pandemic process, physical distance, quarantine and isolation measures have been effective in limiting the number of infected people in the short term. However, special drugs and vaccines are required to be effective in the treatment and protection of COVID-19. In our study, it was aimed to compare antibody levels after inactivated Coronavac vaccine.

Material and Method: Our study included those who received two doses of CoronaVac vaccine from our hospital's healthcare workers. Blood antibody levels measured four weeks after the second dose of vaccine were compared according to age, gender, and units studied. Our study is a retrospective and observational study.

Results: A total of 491 healthcare employees were included in the study. Although no significant relations were detected between the total antibody levels, age, and gender, the antibody levels were significantly higher in those who had COVID-19 infection ($P < 0.001$). When the antibody levels of healthcare workers with COVID 19 infection are compared according to the units studied; the antibody levels of those working in risky units were statistically significantly higher than those working in these units. ($P < 0.001$)

Conclusions: The findings in our study showed that natural immunity supported by vaccination is more valuable than acquired immunity in terms of COVID-19.

Keywords: Antibody level, CoronaVac, healthcare workers, immunization, vaccination

ÖZ

Amaç: Pandemi sürecinde fiziksel mesafe, karantina ve izolasyon önlemleri kısa vadede enfekte olan insan sayısını sınırlamada etkili olmuştur. Ancak COVID 19 tedavi ve korunmasında etkili olacak özel ilaç ve aşılar gerekmektedir. Çalışmamızda inaktif Coronavac aşısı sonrası antikor düzeylerinin karşılaştırılması amaçlanmıştır.

Gereç ve Yöntem: Çalışmamıza hastanemizin sağlık çalışanlarından iki doz CoronaVac aşısı olanlar dahil edildi. İkinci aşı dozundan dört hafta sonra ölçülen kan antikor seviyeleri yaş, cinsiyet ve çalışılan ünitelere göre karşılaştırıldı. Çalışmamız retrospektif ve gözlemsel bir çalışmadır

Bulgular: Çalışmaya toplam 491 sağlık çalışanı dahil edildi. Toplam antikor seviyeleri, yaş ve cinsiyet arasında anlamlı bir ilişki saptanmamasına rağmen, COVID-19 enfeksiyonu olanlarda antikor seviyeleri anlamlı olarak daha yüksekti ($P < 0.001$). COVID 19 enfeksiyonu olan sağlık çalışanlarının antikor düzeyleri çalışılan birimlere göre karşılaştırıldığında; riskli birimlerde çalışanların antikor düzeyleri, bu birimlerde çalışmayanlardan istatistiksel olarak anlamlı derecede yüksekti. ($P < 0,001$)

Sonuç: Çalışmamızda elde edilen bulgular, COVID-19 açısından aşı ile desteklenen doğal bağışıklığın kazanılmış bağışıklıktan daha değerli olduğunu göstermiştir.

Anahtar Kelimeler: Antikor düzeyi, aşılama, CoronaVac, immunizasyon, sağlık çalışanları

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INTRODUCTION

The ongoing coronavirus disease 2019 (COVID-19) pandemic, which was caused by severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2), has caused high morbidity and mortality on a global scale. More than 497 million cases were detected worldwide from the onset of the pandemic to April 2022, and 6182000 people were lost (1). More than 6 million cases were detected in our country, and more than 98000 deaths were reported (2). The World Health Organization (WHO) has reported that healthcare employees, the elderly (> 60 years old), and those with underlying health problems are especially at high risk (1,3,4). Specific therapeutic agents and vaccines are needed urgently to decrease the burden of the disease and stop the spread of COVID-19 throughout the community (5).

There are currently more than 394 COVID-19 vaccine candidates under development worldwide, and 153 of these are at different stages of clinical trials by using different platforms (6). There are 12 vaccines with completed Phase 3, and they are currently in use. CoronaVac vaccine that was produced by the Sinovac Company, which is the first vaccine applied in our country among these vaccines, is an inactive vaccine, which has passed into Phase 4 (6). After the Phase 3 works, risk groups for COVID-19 vaccination were identified by the Ministry of Health of the Republic of Turkey. In this respect, according to the risk of exposure to the disease, risks of severe and transmission of the disease, and the risk groups, healthcare employees were vaccinated firstly.

Spike (S) and Nucleocapsid (N) proteins are the major antigenic structures in COVID-19 infection. The The antibodies against the Receptor-Binding Domain of the S (RBD-S) protein are more specific and have the feature of being neutralizing antibodies. Typically, seroconversion develops in the first 3 weeks (7-9). Although current serological tests are used as indicators of previous or ongoing infection, they do not assess the neutralizing ability of antibodies directly. However, it was shown that high immunoglobulin G (IgG) antibody titers detected with enzyme-linked immunosorbent assay (ELISA) are positively correlated with neutralizing antibodies (9, 10).

In this study, we aimed to compare the antibody responses that occur after the administration of two doses of inactivated SARS-CoV-2 vaccine (CoronaVac) in healthcare workers according to age, gender, department and previous COVID-19 status.

MATERIAL AND METHOD

The healthcare employees who received the CoronaVac vaccine between January and February 2021 were included in this retrospective and observational study, which was conducted in Kırıkhan State Hospital. Healthcare employees who had two doses of CoronaVac and whose antibody levels were checked with COVID-19 ELISA Test at least four weeks after the second dose were included in the study. The ethical approval of the study was obtained from the Ethics Committee of Hatay Mustafa Kemal University (Ethics Committee Decision N° 03; dated June 05, 2021). Those who had one single CoronaVac vaccine dose and those who had the COVID-19 vaccine but did not have their antibody levels checked were excluded from the study. The age, gender, COVID-19 infection status of the participants, their working in a risky unit status (emergency service, pandemic service, pandemic intensive care unit, polymerase chain reaction (PCR) laboratory) were recorded retrospectively from the hospital records. All of the cases that had COVID-19 were PCR positive. The antibody levels were compared according to age ranges, gender, previous COVID-19 infection, and units worked at.

The Elecsys Anti-SARS-CoV-2 Electrochemiluminescence Immunoassay of Cobas Company was used in our study. The Elecsys Anti-SARS-CoV-2 is an immunoassay for qualitative in vitro detection of the antibodies (including IgG) of the SARS-CoV-2 in human serum and plasma. The Elecsys Anti-SARS-CoV-2 Test uses a recombinant protein that represents the N antigen in double antigen sandwich assay format supporting the detection of high-affinity antibodies of SARS-CoV-2. Blood samples were taken and treated with the reagents and microparticles in line with the manufacturer's procedures, and >1 COI was considered positive as the threshold value in the evaluation of the results.

Statistical Analysis

The analyzes were made with the IBM SPSS Package Program version 22.0 (IBM Corporation, Armonk, New York, United States). The statistical significance level was taken as $P < 0.05$. The continuous variables were expressed as median (min.-max.), and the categorical data were expressed as numbers and percentages. The normality analyzes were performed with the Kolmogorov-Smirnov Goodness of Fit Test in the intergroup analysis of the continuous variables. Since the continuous variables were not found to be suitable for normal distribution, the Kruskal Wallis Test was used for the analyzes of more than two groups; and the Mann Whitney U test was used for the analysis of two groups. The categorical data were expressed as numbers and percentages. The McNemar test was used for the comparison of the categorical data between the dependent groups.

RESULTS

The results of the healthcare employees who received two CoronaVac vaccine doses and whose antibody levels were checked with the COVID-19 ELISA Test four weeks after the 2nd vaccine were evaluated in our study. There are a total of 625 healthcare employees in our hospital. A

total of 491 healthcare employees were included in the present study after 28 people were excluded because they had one single dose of the vaccine, and 106 people were excluded because they did not have antibody tests. The comparison of the total antibody levels according to the demographic data, units worked at, and COVID-19 infection status of the participants is shown in **Table 1**.

Table 1. Comparison of the antibody levels according to age, gender, and coronavirus disease 2019 (COVID-19) transmission status

	n; %	COVID-19 vaccine antibody level Median (min.-max.)	P
Age (years)			0.123*
18-30 years of age	175 (35.6)	35.13 (1.05-219.70)	
31-40 years of age	149 (30.4)	19.06 (1.03-211.10)	
41-64 years of age	167 (34.0)	41.91 (1.07-224.10)	
Gender			0.597**
Female	242 (49.3)	31.79 (1.19-224.10)	
Male	249 (50.7)	32.56 (1.03-211.70)	
Past COVID-19 infection			< 0.001**
Yes	105 (21.4)	81.54 (1.28-211.10)	
No	386 (78.6)	23.13 (1.03-224.10)	
Total	491 (100.0)	32.38 (1.03-224.10)	

*Kruskal Wallis Test; **Mann Whitney U Test. min.-max. = minimum-maximum.

A total of 35.6% of the healthcare employees who were examined in the scope of the present study were between the ages of 18-30, 34.0% were between the ages of 41-64, 50.7% were men, and 21.4% had COVID-19. According to our findings, no significant relations were detected between the total antibody levels, age, and gender, and the antibody level was significantly higher in those who had the COVID-19 infection (P < 0.001).

A total of 105 healthcare workers, 98 of whom before vaccinated, who participated in our study, had COVID 19 infection. Twenty-four of those who were vaccinated before and who had COVID 19 infection worked in units at risk for COVID-19. Among those who had COVID-19 infection before vaccination, 50 people had the infection less than one month before the vaccination, 42 people had it 60 days before the vaccination, and six people had it three-six months before. Only seven people had COVID-19 infection after the vaccination. It was found that these people had a COVID-19 infection in three-six months after the first dose of vaccine.

When the COVID-19 vaccine antibody levels were considered, it was found that the antibody levels of those working at risky units were higher than those not working at risky units, and the difference was close to a significant level (P = 0.082). The antibody levels of the healthcare employees working or not working at risky units who had COVID-19 infection were higher at statistically significant than those who did not have COVID-19 infection (P < 0.001) (**Table 2**).

Table 2. Comparison of the antibody levels according to the units worked at and coronavirus disease 2019 (COVID-19) infection status

	n; %	COVID-19 vaccine antibody level Median (min.-max.)	P
Working at a risky unit			0.082*
Yes	101 (20.6)	47.46 (1.19-219.70)	
No	390 (79.4)	30.30 (1.03-224.10)	
Total	491 (100.0)	32.38 (1.03-224.10)	
Those working at a risky unit			0.012*
Positive Covid infection	24 (23.8)	104.50 (1.64-205.60)	
Negative Covid infection	77 (76.2)	30.91 (1.19-219.70)	
Total	101 (100.0)	81.54 (1.28-211.10)	
Those not working at a risky unit			0.000042*
Positive Covid infection	81 (20.8)	75.96 (1.28-211.10)	
Negative Covid infection	309 (79.2)	21.60 (1.03-224.10)	
Total	390 (100.0)	30.30 (1.03-1.03	

*Mann Whitney U Test. min.-max. = minimum-maximum.

No statistically significant differences were detected in the comparison of those with and without COVID-19 infection according to the status of working at risky units (**Table 3**).

Table 3. The comparison of the antibody levels according to the units worked at and coronavirus disease 2019 (COVID-19) infection status

	n;%	COVID-19 vaccine antibody level Median (min.-max.)	P
Those with positive Covid infection			0.260*
Those working at a risky unit	24 (22.9)	104.51 (1.64-205.60)	
Those not working at a risky unit	81 (77.1)	75.96 (1.28-211.10)	
Total	105 (100.0)	81.54 (1.28-211.10)	
Those with negative Covid infection			0.230*
Those working at a risky unit	77 (19.9)	30.91 (1.19-219.70)	
Those not working at a risky unit	309 (80.1)	21.60 (1.03-224.10)	
Total	386 (100.0)		

*Mann Whitney U Test. min.-max. = minimum-maximum.

DISCUSSION

Detection of specific antibodies after active immunization in the COVID-19 pandemic; In addition to contributing to the vaccine development and approval processes, it is also important in the follow-up of the vaccinated people (11). It was also found that the total antibody levels of those who had COVID-19 infection were higher than those who did not (P < 0.001). Also, more than 70% of the 105 people infected with COVID-19 did not work in units at risk for COVID-19. When the antibody levels developed

after the COVID-19 vaccine, were considered, it was found that the antibody levels were higher in those working in the risky unit than in those who were not working in the risky unit, and the difference was close to significant (P = 0.082).

Inactivated virus vaccines, Nucleic Acid-Based Vaccines (mRNA and DNA vaccines), vector vaccines, and protein-based vaccines are the methods used commonly in COVID-19 vaccine works (6). A total of 12 vaccines among the COVID-19 vaccines, whose Phase 3 has been completed, can be examined under four headings. The part of the SARS-CoV-2 genome that encodes the Spike protein is inserted in the lipid nanoparticles with the mRNA molecule in the first mRNA vaccine group (12). In the second vector-based vaccines group, the SARS-CoV-2 Spike glycoprotein is immunogenic along with the non-replicative adenoviral vectors (13). The entire length of the SARS-CoV-2 Spike glycoprotein is used along with the matrix M adjuvant in recombinant protein-based vaccines (14). In the final group, which is the inactivated vaccines, inactivated viruses are used along with various adjuvants (15, 16). Twenty one of the 153 vaccine candidates examined in various clinical phases are inactivated virus vaccines (6).

When the efficacy rates were examined in a review that investigated COVID-19 vaccines in Phase 3 and advanced phases, RNA-based and protein-based vaccines stood out in terms of efficacy rates; but when safety, logistics, and storage conditions were evaluated, inactivated vaccines stood out (17). Inactivated vaccines are used widely for the prevention of respiratory diseases that emerged in previous years. Although there are early findings suggesting that inactivated vaccines developed in the COVID-19 pandemic have low efficacy when compared to mRNA vaccines, according to a WHO Guideline, they still provide protection at minimum 50% efficacy. In Phase 3 studies regarding the CoronaVac vaccine of the Sinovac Company, which were conducted in different countries, 91.25% efficacy rate was reported in our country, 65% in Indonesia, and 50.4% in Brazil (17). When these Phase 3 studies were examined, it was found that 12396 healthcare employees who were over the age of 18 participated in the Brazilian study. According to the antibody results that were measured 14 days after the two doses of the vaccine (0-14), it was detected that the vaccine was found to be effective at a rate of 50.4% to prevent asymptomatic-mild cases, 83.7% to prevent cases requiring treatment, and 100% to prevent hospitalization, severe, and fatal cases (18). In Phase 3 results in our country, a total of 7371 people were evaluated, which included 918 healthcare employees, and 6453 non-healthcare participants between the ages of 18-59. According to the antibody measurements that were made 14 days after the two doses of the vaccine, a 91.25% protection rate was detected (18).

In phase studies with CoronaVac and other inactivated vaccines at different dosages and doses, seroconversion was found to be over 90% (15, 16). In the phase 2 study of Che et al. with another inactivated SARS CoV-2 vaccine other than CoronaVac, both anti-S and anti-N proteins were measured separately. According to the data of the study, neutralizing antibody was induced by the vaccine in more than 90% of individuals in this adult population, and the resulting antibody response included anti-S and anti-N antibodies (19). The anti-N type antibodies were also measured in our study. The antibody levels of all healthcare employees who participated in our study were above the positive threshold value. When evaluated along with this phase study, it can be speculated that the seroconversion with neutralizing antibodies was 100%.

In the first study in the literature that evaluated the CoronaVac vaccine results in our country, the post-vaccination anti-spike IgG levels of 1072 healthcare employees were measured. Antibody rates was found to be higher in women than in men. In the present study, when the antibody levels of people who had and did not have COVID-19 before were compared, it was found that the antibody rates of those who had COVID-19 were 98.6%, and those who did not have it were 70.6% (20). In a study examining the antibody levels measured after the first and second dose vaccination of 276 healthcare workers, it was found that the mean antibody level obtained after the first dose of vaccination in people with COVID 19 infection was higher than the average antibody level obtained after the second dose of vaccination in people who did not have COVID-19 infection (21). Similarly, in the study of Özdemir et al., antibody titers in healthcare workers who had COVID-19 infection were higher than those who did not (22). In our study, the antibody levels of those who had COVID-19 were statistically significantly higher than the antibody rates of those who did not have COVID-19 ($P < 0.001$). The antibodies caused by natural immunity become detectable at high levels with one single dose of the vaccine. In our study, the antibody levels did not differ according to gender. In the study in which the anti-spike IgG levels were measured, it was found that the antibody response was higher in women. The fact that the antibody kit used in our study was not anti-spike may have caused this.

In the study that was conducted by Bayram et al., 213 of the 1072 healthcare employees were working at risky units which involved COVID-19 patients. No differences were detected in the antibody levels of these individuals when compared to those working at other units (20). In our study, the antibody levels of those who worked at risky units and those who worked at other units were close, which may indicate that the COVID-19 antibody levels are not associated with occupational exposure. However, the antibody levels of the healthcare employees who worked at risky units and those who had COVID-19 infection

were found to be statistically higher than those who did not in our study (P 0.012). It was found that, apart from occupational exposure, natural immunity significantly increases antibody levels as expected for COVID-19. In the study conducted by Bayram et al., antibody positivity was detected at a rate of 71.4% in people whose COVID-19 status was not known, which was considered to reflect community-acquired immunity as a result of unaware exposure in daily medical practice. When the antibody levels of those who had and did not have COVID-19 in our study were evaluated according to working at risky units status, no statistically significant differences were detected. It was observed in our study that occupational exposure and antibody levels of employees at risky units were not affected.

Our study had several limitations. First, it was a single-center study, and it was not sufficient to generalize the findings. Second, SARS-CoV-2 antibody levels were not tested in healthcare employees before the vaccinations. The antibody levels of asymptomatic COVID-19 cases or those who were not diagnosed with mild symptoms might have affected our results. However, the strengths of our study were that our data reflect the real-life data of the CoronaVac vaccine following Phase 3 studies. Also, the number of COVID-19 infections diagnosed after the vaccination decreased at significant levels, which shows the success of the CoronaVac vaccine in preventing the disease. We believe that our real-life data will contribute to the literature in terms of the protection of the CoronaVac vaccine.

Although social distancing, quarantine, and isolation measures in the COVID-19 pandemic are effective in limiting the number of people who are infected in the short term, vaccination studies must continue without slowing down to decrease the morbidity and mortality rates after the disease and to end the pandemic. When the side-effect profile, logistics, and storage conditions were considered, it was found that inactivated vaccines appear to be advantageous when compared to other mRNA, viral vector, and protein-based vaccines. Their effectiveness is adequate with Phase 3 studies and with the real-life data as in our study.

CONCLUSION

The findings of our study showed that natural immunity is more valuable than acquired immunity for COVID-19. However, it is necessary to provide herd immunity acquired by vaccination to avoid morbidity and mortality, which might occur with natural immunity. In addition, in COVID-19 infection; The level of antibody that provides protection or the duration of protection is not yet clear. Therefore, prospective studies are needed to determine how long the immunity provided by SARS-CoV-2 vaccines will continue..

ETHICAL DECLARATIONS

Ethics Committee Approval: The ethical approval of the study was obtained from the Ethics Committee of Hatay Mustafa Kemal University (Date: 05.06.2021, Decision No: 03).

Informed Consent: Because the study was designed retrospectively, no written informed consent form was obtained from patients.

Referee Evaluation Process: Externally peer-reviewed.

Conflict of Interest Statement: The authors have no conflicts of interest to declare.

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Author Contributions: All of the authors declare that they have all participated in the design, execution, and analysis of the paper, and that they have approved the final version.

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