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Original Article

Antibody levels of COVID-19 vaccine: A comparison between healthy subjects and psychiatric patients on antidepressants

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ABSTRACT

This study compares the serological antibody level post-COVID-19 vaccine among healthy subjects and psychiatric patients on antidepressant therapy. It also examines the difference in antidepressants' side effects experienced by psychiatric patients following the completion of two vaccine doses. A comparative posttest quasi-experimental study was conducted among healthy subjects and psychiatric patients on antidepressant medication in a teaching hospital in Malaysia. Elecsys Anti-SARS-CoV-2 assay was used to detect the antibody titre between weeks 4 and 12 post vaccination. The antidepressant side-effect checklist (ASEC) was used to monitor the occurrence of antidepressant-related side effects pre- and post-vaccination. 24 psychiatric patients and 26 healthy subjects were included. There was no significant difference in the antibody level between the patients (median = 1509 u/ml) and the healthy subjects (median = 995 u/ml). There was no significant worsening in the antidepressant-related side effects. The antibody level post-COVID-19 vaccine did not differ significantly between patients on antidepressant therapy and healthy subjects. Additionally, there was no change in the antidepressant side effects experienced by the patients following the completion of the vaccine.

KEYWORDS: COVID-19 vaccination, depression, antidepressant, serology antibody level, side effect.

INTRODUCTION

The COVID-19 pandemic, also known as the coronavirus disease 2019, is an ongoing global epidemic caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). The World Health Organisation (WHO) declared it a pandemic in March 2020 [1]. Since then, the pandemic has significantly impacted human civilization. Worldwide, people continue to face threats to their health and well-being rooted in social, economic, political, and environmental determinants of health—this exposed inequalities regarding age, sex, comorbidity, socioeconomic status, and geographic location.

Globally, several vaccines were developed against the SARS-CoV-2, which primarily rely on producing antibodies that neutralize specific viral proteins such as the S protein [2]. In December 2020, the WHO granted the Pfizer BioNTech vaccine emergency use listing (EUL) [3]. Later in October 2021, the Global Advisory Committee on Vaccine Safety (GACVS) COVID-19 subcommittee concorded that mRNA COVID-19 vaccines have clear benefits in all age groups, including reduced hospitalizations and deaths [4].

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Accordingly, health authorities across the globe created public health measures upon which millions of people get vaccinated every day. In Malaysia, the government initiated the COVID-19 vaccination programme to achieve herd immunity and curb the spread of COVID-19 [5]. Under this campaign, several types of vaccines were made accessible to the general public. Among these, the Pfizer COMIRNATY® is a messenger RNA (mRNA) vaccine that works by instructing the cell to produce proteins of the S antigen (a piece of the spike protein unique to SARS-CoV-2) to stimulate an immune response. Clinical trials involving participants with or without evidence of prior infection with SARS-CoV-2 and who received two doses demonstrated approximately 95% efficacy based on a median follow-up of two months [6].

Although the need for vaccination cannot be overemphasized, it is all the more necessary for individuals enduring mental health illnesses. A nationwide analysis of the US electronic health record database showed that individuals with a recent diagnosis of a mental health disorder had a significantly higher risk of contracting COVID-19 [7]. Additionally, the hospitalization and death rates among COVID-19 patients with mental health disorders, 27.4% and 8.5%, were higher than those without such a diagnosis, 18.6% and 4.7% [7]. Furthermore, the level of acquired immunity among this patient cohort is yet to be determined. Data from vaccination research against other infectious agents suggests that patients with depression might exhibit a reduced immune response. One study showed that adults with depression were less likely to test seropositive for measles than controls that were not depressed, and thus, adults with depression have an increased risk of infection. This is probably due to impaired maintenance of vaccine protection against measles [8].

Beyond that, a meta-analysis of studies on antidepressant therapy among major depressive disorder patients revealed that these medications reduced the concentration of several pro-inflammatory cytokines, resulting in a compromised inflammatory response [9]. Most psychotherapeutic drugs have been shown to alter immunological markers, and some of these agents even interact with the proteins to which SARS-CoV-2 binds [10]. Yet, there seems to be a dearth of research on the COVID-19-related vaccine-psychotropics/ psychotropics-vaccine interactions.

Against this backdrop, we aim to compare the effectiveness of the Pfizer COMIRNATY® mRNA vaccine among healthy individuals and patients on antidepressant therapy as well as assess the interaction of the vaccine with antidepressant medications. The information generated from this research ought to fill the knowledge gap mentioned above.

MATERIALS AND METHODS

This is a comparative posttest quasi-experimental study conducted among healthy subjects and psychiatric patients who completed two doses of the Pfizer COMIRNATY® vaccine at the University Malaya Medical Centre (UMMC). The study was conducted from July 2021 until October 2021. The participants were recruited following convenience sampling from the UMMC psychiatric clinic.

On the vaccine appointment day, all the patients were given a self-administered standardized questionnaire with instructions and assisted by a trained research assistant when necessary. The antidepressant side effect pre- and post-vaccination was assessed using the antidepressant side effect checklist (ASEC), which was developed by Hodgson *et al*. as part of the GENDEP study [11]. Serum serology antibody for COVID-19 was done 4 to 12 weeks after the second dose. Blood was collected from the study participants in a plain tube and sent to the laboratory on the same day.

In this study, we used the Elecsys® Anti-SARS-CoV-2 test to determine the participants' immune reaction to the vaccine. This is an immunoassay test for the *in vitro* quantitative determination of antibodies (including IgG) for the SARS-CoV-2 spike (S) protein receptor-binding domain (RBD) in human serum and plasma. The assay uses a recombinant protein representing the RBD of the S antigen in a double-antigen sandwich assay format, which favours the detection of high-affinity antibodies against SARS-CoV-2. The test is intended as an aid to assess the adaptive

humoral immune response to the SARS-CoV-2 S protein [12]. Quantification of the antibody response can help to determine the specific antibody, the specific titer and to aid in longitudinal monitoring of the dynamics of the antibody response in individual patients. The threshold for antibody positivity is more than 0.8 U/ml [12].

The inclusion criteria for the patient group were (1) psychiatric patients who are on antidepressant therapy, (2) completed two doses of Pfizer COMIRNATY® vaccine (within 4 to 12 weeks), (3) able to read and understand English or Malay, and (4) able to give consent. For the control group, the inclusion criteria were (1) individuals with no prior diagnosis of mental illness, (2) completed two doses of Pfizer COMIRNATY® vaccine (within 4 to 12 weeks), (3) able to read and understand English or Malay, and (4) able to give consent. Exclusion criteria for both patient and control group were (1) below 18 years of age, (2) medically unstable or actively psychotic.

The collected data were entered in a dedicated password-protected computer, with exclusive access to relevant study researchers. Patients were assigned study numbers, and their identities were removed to ensure anonymity. Statistical Package for Social Sciences (SPSS) version 25 was used for data analysis. The level of significance was set at a p-value < 0.05. Descriptive analysis was done using mean and median values, comparison of categorical variables by using Chi-square test and, Fisher-Exact test while the comparison of numerical variables was done by using independent T-test and Mann-Whitney U test, and comparison of proportion difference in paired variables by using Wilcoxon signed-rank test. Normality of the data was examined using Kolmogorov Smirnov test.

RESULTS

The socio-demographic characteristics of the patient and control group are shown in Table 1. Fifty subjects were included in the study, 24 in the patient group and 26 in the control. The mean age for the patients was 39.4 ± 16.3 years, while for the control, it was 36.6 ± 13.1 years. There were seven males and 17 females in the patient group, while 12 males and 14 females were in the control group. There were no significant differences between the groups in terms of age and gender. On the other hand, for the ethnicity, there was a statistically significant difference between the groups, with a Malay majority in the patient group and a Chinese majority in the control group. As for the marital status, education level, employment status and family household income no statistically significant difference was detected between the patient and control group.

Table 2 demonstrates the distribution of the antidepressant therapy among the study participants. Most of the patients were on Escitalopram; three patients were on combination therapy.

Figure 1 shows that both the patient and control group produce antibodies above the threshold for positivity. The level of antibody was higher than the patients on antidepressants but the difference was not statistically significant.

Table 3 compares the COVID-19 vaccine serum antibody levels between the patient and control group. The median for the patient group was 1509 with an interquartile range from 671.8 to 2220, while for the control group, the median was 995 with an interquartile range from 769.3 to 1664.5. However, the Mann-Whitney U test shows that a p-value of 0.30 was not statistically significant.

Table 4 demonstrates the common antidepressant side effects pre- and post-vaccination among patients who were on antidepressant therapy. Wilcoxon signed-rank test was done, and there was no significant difference in the side effects experienced by the patients before and after the vaccination.

DISCUSSION

The purpose of this study was to better understand the effectiveness of the COVID-19 vaccine among healthy individuals and psychiatric patients who are on antidepressant therapy using post-vaccination serology antibody levels. Furthermore, it examined the worsening of antidepressant-related side effects experienced by the patients following the completion of the two doses. To our knowledge, this is the first study to address these objectives.

Our results demonstrated no significant difference in the immune response between the psychiatric patients and the healthy subjects. Mann-Whitney

Table 1. Socio-demographic characteristics of the sample.

	Patient (n = 24)	**Control (n = 26)**	**p-value**
Age[◊]	39.4 ± 16.3	36.6 ± 13.1	0.510[d]
Gender[¥] Male Female	 7 (29.2.8%) 17 (70.8%)	 12 (46.2%) 14 (53.8%)	0.220[a]
Ethnicity[¥] Malay Chinese India Others	 13 (54.2%) 6 (25.0%) 4 (16.7%) 1 (4.2%)	 4 (15.4%) 15 (57.7%) 7 (26.9%) 0	0.020[a]
Marital status[¥] Single Married Divorced	 13 (54.2%) 11 (45.8%) 0	 13 (50%) 12 (46.2%) 1 (3.8%)	1.000[b]
Education level[¥] Primary Secondary Tertiary	 1 (4.2%) 4 (16.7%) 19 (79.2%)	 0 2 (7.7%) 24 (92.3%)	0.300[b]
Employment status[¥] Unemployed Housewife Student Employed Retired	 2 (8.3%) 2 (8.3%) 6 (25.0%) 11 (45.8%) 3 (12.5%)	 0 2 (7.7%) 3 (11.5%) 19 (73.1%) 2 (7.7%)	0.300[b]
Family income[¥] B40 M40	 13 (54.2%) 11 (45.8%)	 11 (42.5%) 15 (57.7%)	0.400[a]
Comorbidities[¥] Yes No	 9 (37.5%) 15 (62.5%)	 1 (3.8%) 25 (96.2%)	0.003[a]
Duration post-vaccination[◊]	8.4 ± 2.3	7.6 ± 2.1	0.182[d]

Note: a = Chi Square, b = exact test, c = Fisher's exact test, d = independent T-test, ◊ = mean ± standard deviation, ¥ = frequency (percentage).

Table 2. Types of antidepressants used by the patients (N = 24).

Antidepressant drugs[¥]	**(N = 24)**
Escitalopram	15 (62.5%)
Agomelatine	2 (8.3%)
Sertraline	2 (8.3%)
Mirtazapine	1 (4.2%)
Vortioxetine	1 (4.2%)
Combination therapy	3 (12.5%)

¥ = frequency (percentage).

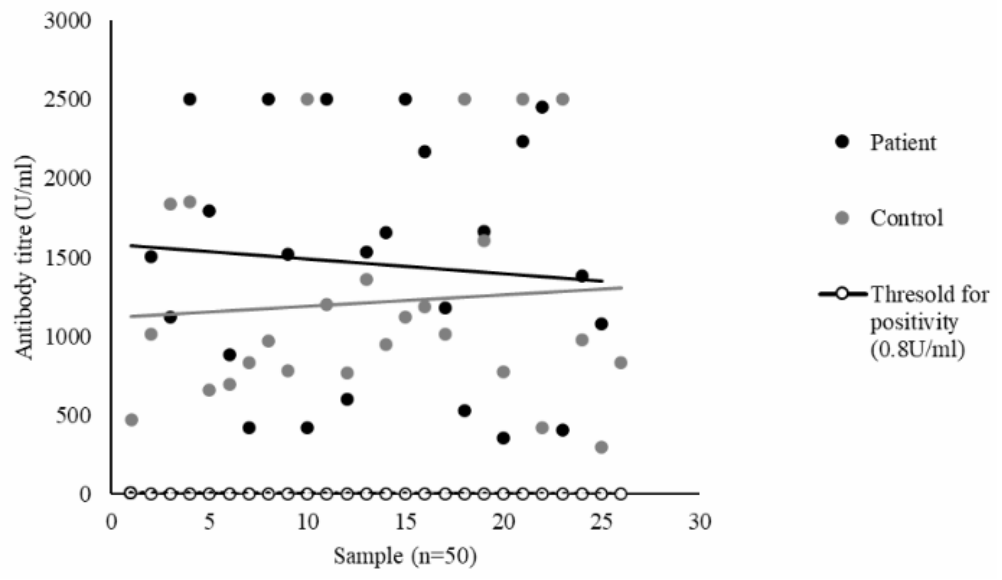

Figure 1. Scatter plot of antibody titre level in u/ml between patient and control group.

Table 3. Comparison of post-COVID-19 vaccine serology antibody level between patients on antidepressant and control group.

	Patient	**Control**	**p-value**
Antibody level (U/ml)[§]	1509 (671.8 – 2220.0)	995 (769.3 – 1664.5)	0.30[e]

Note: e = Mann-Whitney U Test, § = median (interquartile range).

U test shows that there is no difference (p-value = 0.3) in antibody level between the patient and control group. However, most of the participants were taking Escitalopram (62.5%). This antidepressant belongs to the selective serotonin receptor inhibitor (SSRI) drug class. Multiple studies have discussed the significant modulating effect of SSRI on immunity and immune cell functioning. Canan *et al*. reported that Escitalopram treatment causes considerable lymphocyte proliferation, and therefore, the management of depression with Escitalopram must be carried out with caution among patients with immunological disturbances [13]. Hernández *et al*. showed an increment in IL-2 and IL-1b after 52 weeks of SSRI treatment [14]. Another study of the same research team, Hernandez *et al*. concluded a significant increase in NK cells and B-cell numbers following SSRI treatment [15]. Furthermore, in a graded dose-dependent study of citalopram, Shenoy *et al*. showed that citalopram has a potent suppressive effect on cytokine production in the thymus, which helps to ameliorate clinical autoimmune diseases and to reduce inflammation [16]. Last but not least, there was no worsening of antidepressant side effects post-vaccination which was monitored by using ASEC in the current study. Wilcoxon signed-rank test was done, and there was no significant difference in symptoms of side effects for antidepressants before and after vaccination.

The major limitation of this study is the small sample size and therefore it is difficult to determine significant relationships from the data. Further study with larger sample size recruitment is needed for stronger evidence. In addition, there are multiple types of vaccine available and this study only analyses one type of vaccine, which is the Pfizer COMIRNATY® vaccine. Last but not least, there are varieties of antidepressants that were not included in the study. However, this is

Table 4. Adverse side effect checklist among patients on antidepressant before and after vaccine, based on antidepressant side effect checklist (ASEC).

ASEC	Before vaccine	After vaccine	p-value
Dry mouth[¥]			
Absent	7 (29.2%)	7 (29.2%)	
Mild	11 (45.8%)	9 (37.5%)	0.16[a]
Moderate	5 (20.8%)	5 (20.8%)	
Severe	1 (4.2%)	3 (12.5%)	
Drowsiness[¥]			
Absent	14 (58.3%)	12 (50%)	
Mild	6 (25%)	6 (25%)	0.26[a]
Moderate	2 (8.3%)	4 (16.7%)	
Severe	2 (8.3%)	2 (8.3%)	
Insomnia[¥]			
Absent	8 (33.3%)	7 (29.2%)	
Mild	3 (12.5%)	4 (16.7%)	0.41[a]
Moderate	10 (41.7%)	9 (37.5%)	
Severe	3 (12.5%)	4 (16.7%)	
Blurred vision[¥]			
Absent	18 (75%)	19 (79.2%)	
Mild	4 (16.7%)	3 (12.5%)	0.56[a]
Moderate	2 (8.3%)	2 (8.3%)	
Severe	0	0	
Headache[¥]			
Absent	11 (45.8%)	13 (54.2%)	
Mild	8 (33.3%)	5 (20.8%)	1.0[a]
Moderate	3 (12.5%)	3 (12.5%)	
Severe	2 (8.3%)	3 (12.5%)	
Constipation[¥]			
Absent	17 (70.8%)	18 (75%)	
Mild	4 (16.7%)	3 (12.5%)	0.56[a]
Moderate	2 (8.3%)	2 (8.3%)	
Severe	1 (4.2%)	1 (4.2%)	
Diarrhea[¥]			
Absent	19 (79.2%)	21 (87.5%)	
Mild	3 (12.5%)	2 (8.3%)	0.18[a]
Moderate	1 (4.2%)	1 (4.2%)	
Severe	1 (4.2%)	0	
Increase appetite[¥]			
Absent	12 (50%)	13 (54.2%)	
Mild	8 (33.3%)	4 (16.7%)	0.43[a]
Moderate	3 (12.5%)	4 (16.7%)	
Severe	1 (4.2%)	3 (12.5%)	
Decrease appetite[¥]			
Absent	16 (66.7%)	16 (66.7%)	
Mild	6 (25%)	6 (25%)	0.66[a]
Moderate	1 (4.2%)	2 (8.3%)	
Severe	1 (4.2%)	0	

Table 4 continued..

ASEC	Before vaccine	After vaccine	p-value
Nausea or vomiting[¥]			
Absent	16 (66.7%)	16 (66.7%)	
Mild	5 (20.8%)	6 (25%)	0.32[a]
Moderate	2 (8.3%)	2 (8.3%)	
Severe	1 (4.2%)	0	
Problems in urination[¥]			
Absent	20 (83.3%)	20 (83.3%)	
Mild	2 (8.3%)	2 (8.3%)	1.0[a]
Moderate	2 (8.3%)	2 (8.3%)	
Severe	0	0	
Problems in sexual function[¥]			
Absent	15 (62.5%)	14 (58.3%)	
Mild	4 (16.7%)	5 (20.8%)	0.32[a]
Moderate	5 (20.8%)	5 (20.8%)	
Severe	0	0	
Palpitations[¥]			
Absent	9 (37.5%)	11 (45.8%)	
Mild	9 (37.5%)	9 (37.5%)	0.28[a]
Moderate	5 (20.8%)	2 (8.3%)	
Severe	1 (4.2%)	2 (8.3%)	
Feeling light-headed on standing[¥]			
Absent	10 (41.7%)	9 (37.5%)	
Mild	11 (45.8%)	13 (54.2%)	0.56[a]
Moderate	3 (12.5%)	1 (4.2%)	
Severe	0	1 (4.2%)	
Feeling like the room is spinning[¥]			
Absent	16 (66.7%)	16 (66.7%)	
Mild	7 (29.2%)	8 (33.3%)	0.32[a]
Moderate	1 (4.2%)	0	
Severe	0	0	
Sweating[¥]			
Absent	14 (58.3%)	12 (50%)	
Mild	3 (12.5%)	5 (20.8%)	0.26[a]
Moderate	4 (16.7%)	3 (12.5%)	
Severe	3 (12.5%)	4 (16.7%)	
Increased body temperature[¥]			
Absent	14 (58.3%)	14 (58.3%)	
Mild	5 (20.8%)	4 (16.7%)	0.32[a]
Moderate	3 (12.5%)	4 (16.7%)	
Severe	2 (8.3%)	2 (8.3%)	
Tremor[¥]			
Absent	14 (58.3%)	16 (66.7%)	
Mild	6 (25%)	6 (25%)	0.16[a]
Moderate	3 (12.5%)	1 (4.2%)	
Severe	1 (4.2%)	1 (4.2%)	

Table 4 continued..

ASEC	Before vaccine	After vaccine	p-value
Disorientation¥			
Absent	14 (58.3%)	15 (62.5%)	
Mild	7 (29.2%)	7 (29.2%)	0.32[a]
Moderate	2 (8.3%)	1 (4.2%)	
Severe	1 (4.2%)	1 (4.2%)	
Yawning¥			
Absent	13 (54.2%)	13 (54.2%)	
Mild	7 (29.2%)	6 (25%)	0.56[a]
Moderate	4 (16.7%)	5 (20.8%)	
Severe	0	0	
Weight gain¥			
Absent	12 (50%)	11 (45.8%)	
Mild	3 (12.5%)	4 (16.7%)	0.32[a]
Moderate	6 (25%)	5 (20.8%)	
Severe	3 (12.5%)	4 (16.7%)	

Note: a = Wilcoxon signed-rank test, ¥ = frequency (percentage).

the first study that contributes to our understanding of the effectiveness of the COVID-19 vaccine based on antibody level among psychiatric patients on antidepressants. In addition, measurement of antibody level is based on an established method as discussed earlier.

CONCLUSION

There was no difference in COVID-19 serum antibody level between psychiatric patients on antidepressants and the control group. Furthermore, no difference in antidepressant side effects was experienced by psychiatric patients who are on antidepressants post-COVID-19 vaccination.

CONFLICT OF INTEREST STATEMENT

The authors of this manuscript declare no conflict of interest.

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