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RESEARCH ARTICLE

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The efficacy of BNT162b2 (Pfizer–BioNTech) and CoronaVac vaccines in patients with cancer

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Abstract

Although vaccination is efficacious and prevents infection in the general population, there is limited data about Coronavirus disease-19 (Covid-19) occurrence after vaccination in cancer patients. It was aimed to evaluate the efficacy of BNT162b2 (Pfizer–BioNTech) and CoronaVac vaccines against Covid-19 in patients with cancer. In this single-center, retrospective, cross-sectional, and descriptive study, the data of cancer patients referred to the medical oncology clinic of a university hospital were analyzed. The sample of the study consisted of cancer patients who had Covid-19 or were vaccinated against Covid-19. A total number of 2578 patients were included in the study. Of the patients, 2000 have never been infected with severe acute respiratory syndrome coronavirus and 578 patients have had a positive reverse-transcription polymerase chain reaction (RT-PCR) for Covid-19. It was found that 2094 patients (81.2%) were fully vaccinated, and 484 patients (18.8%) did not receive full-dose vaccination. A statistically significant difference in Covid-19 occurrence was found between the patients who had full-dose vaccination or not ($p = 0.000$). In in-group comparisons of full-dose vaccinated patients, while no difference was observed between two doses of BNT162b2 (Pfizer–BioNTech) and three doses of CoronaVac ($p = 0.432$), a statistically significant difference was observed between all other groups ($p < 0.005$). When the data of 578 patients who experienced Covid-19 was analyzed, a statistically significant difference was observed between the groups who were full-dose vaccinated and those who were not ($p = 0.000$). It is recommended that this vulnerable patient group should be prioritized in vaccination programs, and full-dose vaccination (at least two doses of vaccines) should be completed as soon as possible.

KEYWORDS
cancer, COVID-19, SARS-CoV-2, vaccination

1 | INTRODUCTION

The novel severe acute respiratory syndrome coronavirus (SARS-CoV-2) has been first reported at the end of the year 2019 in China[1] and has emerged as a global pandemic.[1,2] The course of Coronavirus disease-19 (Covid-19) in elderly patients or in patients with comorbidities is more severe and the mortality rate is higher.[3] It was reported that multiple comorbidities or cancer diagnoses showed a higher risk for Covid-19 infection and poor prognosis.[4]

After the development of various types of vaccines against Covid-19, vaccination programs were initiated in many countries worldwide to provide asymptomatic or mildly symptomatic Covid-19 and to prevent mortality.[5,6] Immunosuppressive status due to cancer itself and cancer treatments is related to more aggressive infection and poor prognosis and may lessen vaccine effect.[7,8] We know from randomized controlled trials that vaccines against Covid-19 are efficacious and infection in the general population is lower than in the unvaccinated population.[5,6] But for patients with a cancer diagnosis, there is limited data on Covid-19 occurring after full dose vaccination and the efficacy of vaccines. This might be because these patients were underrepresented in clinical trials during the pandemic.

Cancer patients are more vulnerable to Covid-19 than the general population and experience serious complications when they are infected.[9] The evaluation of Covid-19 occurrence and the efficacy of vaccination schedules is a necessity in patients with malignancies. This study aimed to evaluate the efficacy of BNT162b2 (Pfizer–BioNTech) and CoronaVac vaccines against Covid-19 in patients with cancer.

1.1 | Two doses of CoronaVac and one dose of BNT162b2 (Pfizer–BioNTech)

H_1: Single-dose vaccination is insufficient for the prevention of Covid19 infection in cancer patients.

H_2: Two doses of either CoronaVac or BNT162b2 (Pfizer–BioNTech) vaccination is effective in preventing Covid19 infection in cancer patients.

H_3: Two doses of BNT162b2 (Pfizer–BioNTech), two doses of CoronaVac and one dose of BNT162b2 (Pfizer–BioNTech), and three doses of CoronaVac are more effective than two doses of CoronaVac in the prevention of Covid19 infection in cancer patients.

2 | METHODS

2.1 | Study design and type

This is a single-center, retrospective, cross-sectional, and descriptive study conducted in a medical oncology clinic of a university hospital between March 2020 and December 2021. The study was conducted according to the CONSORT flow chart (Figure 1).

2.2 | Participants

This study consisted of cancer patients referred to the medical oncology clinic of a university hospital during the planned time. The sample consisted of patients who met the inclusion criteria of the study. The study was completed with 2578 patients whose data about vaccination status and Covid-19 exposure status were reached. The inclusion criteria were having a cancer diagnosis, having had Covid-19, or being vaccinated against Covid-19. The patients whose vaccination status or the exact date of vaccination was unknown or who received the vaccine after SARS-CoV-2 infection were excluded.

2.3 | Data collection tools

"The data collection form" that has three sections was used in the study. Descriptive information about patients, such as gender and cancer type, was placed in Section 1, information about Covid-19 in Section 2, and information about vaccination against Covid-19 in Section 3.

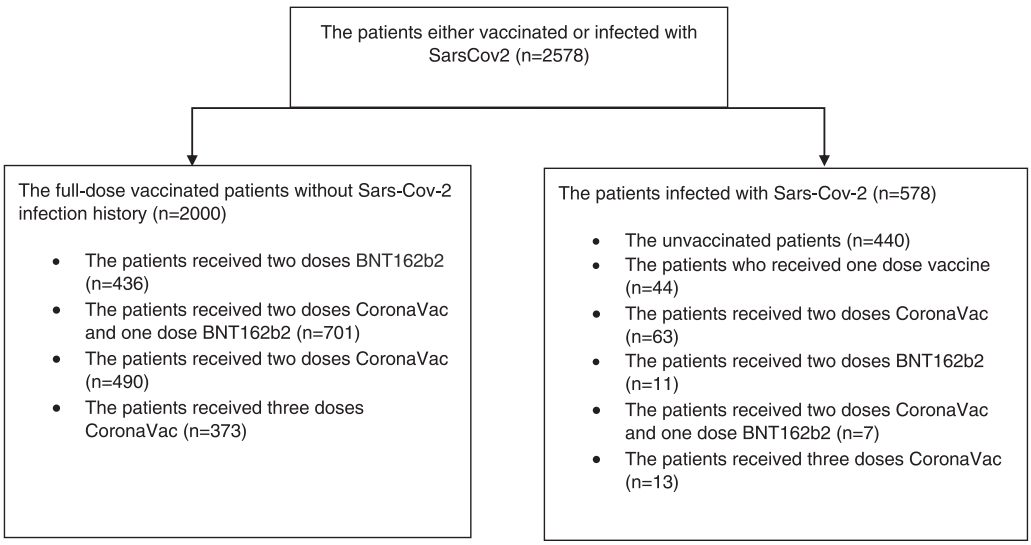

FIGURE 1 The CONSORT flow chart of the study.

2.4 | Data collection

Data were collected by researchers from patient files, patient information systems, and the database of the Ministry of Health. Data from 2578 cancer patients were compiled and recorded on data collection forms.

Full-dose vaccination was accepted as receiving at least two doses of either CoronaVac or BNT162b2 (Pfizer–BioNTech) 4 weeks apart. The patients who received at least one dose of vaccination and developed Covid-19 but did not meet the previous criteria were considered partially vaccinated. Unvaccinated patients were defined as having no known prior exposure to Covid-19 vaccination before Covid-19 diagnosis. The patients were grouped according to vaccination status as unvaccinated, not full-dose vaccinated (patients who received only one dose vaccine), and full-dose vaccinated (patients who received two doses of BNT162b2 (Pfizer–BioNTech) or two doses of CoronaVac or two doses of CoronaVac and one dose of BNT162b2 (Pfizer–BioNTech) or three doses of CoronaVac). The Covid-19 diagnosis was considered as a positive reverse-transcription polymerase chain reaction (RT-PCR) for Covid-19 28 days after the last dose of vaccination.

2.5 | Ethical aspects of the research

The local ethics committee's approval was obtained before the study. The study data was preserved in a computer that only the researchers could reach. This study complied with the Helsinki Declaration.

2.6 | Data analysis

Statistical Package for Social Sciences version 25 (SPSS, v25) was used in the statistical analysis of the data (IBM Company). While the mean values for continuous variables were taken, number and percentage ratios were used for categorical variables. Fischer's exact test, Mann–Whitney *U* test, and Kruskal–Wallace tests were used according to normality distributions for in-group and intergroup comparisons. Significance was $p < 0.05$ at 95% confidence interval.

3 | RESULTS

Of 2578 patients, 2000 have never been infected with SARS-CoV-2 and 578 patients have had a positive RT-PCR for Covid-19. The descriptive characteristics of the patients are shown in Table 1.

When the data of the study population was analyzed, it was found that 2094 patients (81.2%) were fully vaccinated, and 484 patients (18.8%) did not receive full-dose vaccination. In terms of having Covid-19, a statistically significant difference was found between two patient groups who had full-dose vaccination or not ($p = 0.000$). In in-group comparisons of full-dose vaccinated patients, no statistically significant difference was determined between the groups that received two doses of BNT162b2 (Pfizer–BioNTech) and three doses of CoronaVac in terms of having Covid-19 ($p = 0.432$). Contrarily, a statistically significant difference was observed between all other groups in terms of having Covid-19 ($p < 0.005$) (Table 2). Two doses of BNT162b2 (Pfizer–BioNTech), two doses of CoronaVac and one dose of BNT162b2 (Pfizer–BioNTech), and three doses of CoronaVac were all related to less Covid-19 occurrence than two doses of CoronaVac. Similarly, two doses of CoronaVac and one dose of BNT162b2 (Pfizer–BioNTech) were found to be more effective than both two doses of BNT162b2 (Pfizer–BioNTech) or three doses of CoronaVac.

When the data of 578 patients who experienced Covid-19 was analyzed, it was found that there was a statistically significant difference between the groups who were full-dose vaccinated or not in terms of having Covid-19 ($p = 0.000$). However, no statistically significant difference was observed when the full-dose vaccinated groups were compared with each other ($p > 0.05$).

TABLE 1 The descriptive characteristics of the patients.

Characteristics		*n*	%
Gender	Female	1554	60.3
	Male	1024	39.7
Diagnosis	Breast cancer	857	33.2
	NSCLC	325	12.6
	HNC	114	4.4
	CRC	484	18.8
	Non-CRC GIS	295	11.4
	GUS cancer	366	14.2
	STS	47	1.8
	Other	90	3.5
Vaccination status	Unvaccinated	440	17.1
	One dose of vaccine	44	1.7
	Two doses of CoronaVac	554	21.5
	Two doses of BNT162b2 (Pfizer–BioNTech)	447	17.3
	Two doses of CoronaVac and one dose of BNT162b2 (Pfizer–BioNTech)	708	27.5
	Three doses of CoronaVac	385	14.9
Covid-19 history	Yes	578	22.4
	No	2000	77.6
Total	2578	100	

Abbreviations: CRC, colorectal cancer; GIS, gastrointestinal system; GUS, genitourinary system; HNC, head and neck cancer; NSCLC; nonsmall cell lung cancer; STS, soft tissue sarcoma.

TABLE 2 The comparison of the vaccination status of the patients.

Characteristics			Patients with Covid-19						Test value
			Yes		No		Total		
			n	%	*n*	%	*n*	%	*p*
Full-dose vaccination		No	484	83.7	0	0	484	18.8	2061.8* **p = 0.000**
		Yes	94	16.3	2000	100	2094	81.2	
Vaccine groups	Unvaccinated (unvaccinated and single-dose vaccinated)[a]		484	100	0	0	484	83.7	577.000** **p = 0.000**
	Two doses of CoronaVac[b]		0	0	63	67	63	10.9	
	Two doses of BNT162b2[c]		0	0	11	11.7	11	1.9	
	Two doses of CoronaVac and one dose of BNT162b2[d]		0	0	7	7.5	7	1.3	
	Three doses of CoronaVac[e]		0	0	13	13.8	13	2.2	
		***b > a; *p* = 0.000			c > a; *p* = 0.000				
		d > a; *p* = 0.000			e > a; *p* = 0.000				
Vaccines	Two doses of CoronaVac[a]		63	67	490	24.5	553	26.5	86.803** **p = 0.000**
	Two doses of BNT162b2[b]		11	11.7	436	21.8	447	21.3	
	Two doses of CoronaVac and one dose of BNT162b2[c]		7	7.5	701	35	708	33.8	
	Three doses of CoronaVac[d]		13	13.8	373	18.7	386	18.4	
		***b > a; *p* = 0.000			c > a; *p* = 0.000		d > a; *p* = 0.000		
		c > b; *p* = 0.049			b = d; *p* = 0.432		c > d; *p* = 0.005		

Note: All the *p* values were statistically significant. *p* = 0.000 means *p* value is lower than 0.05 and this result is statistically significant.

*Fisher's exact test.

**Kruskal–Wallis test.

***Mann–Whitney *U* test; $p < 0.05$.

TABLE 3 The distribution of the patients on active chemotherapy at the time of vaccination.

Characteristics		CT status						Test value
		Yes		No		Total		
		n	%	*n*	%	*n*	%	*p*
Vaccines	Two doses of CoronaVac[a]	83	15	471	85	554	26.4	7.758* *p* = 0.051
	Two doses of BNT162b2[b]	72	16.2	375	83.8	447	21.3	
	Two doses of CoronaVac and one dose of BNT162b2[c]	78	10	630	89	708	33.8	
	Three doses of CoronaVac[d]	48	12.5	337	87.5	385	18.5	

Abbreviation: CT, chemotherapy.

*Kruskal–Wallis test; $p < 0.05$.

When the time between the date of cancer diagnosis and the date of first vaccination was analyzed, no statistically significant difference was observed between the patients with a cancer diagnosis of more than 5 years ($n = 592$, 27.7%) and less than 5 years ($n = 1546$, 72.3%) in terms of vaccine types and number of vaccine doses ($p > 0.05$). As chemotherapy has very well-known negative effects on immune response, it was evaluated if there was a relation between the vaccine types and vaccine doses administered during chemotherapy in patients who have received full-dose vaccination (Table 3). None of the patients with cancer received regular corticosteroid treatment during the study period.

The time between the date of last vaccine dose and the date of Covid-19 occurrence was found as a mean of 3.88 ± 2.24 months and a median of 3.8 (0.5–9.4) months for patients who had received two doses of vaccination, and a mean of 2.79 ± 1.32 and median 2.5 (1.1–5.6) months for patients who had received three doses of vaccination.

4 | DISCUSSION

As vaccination is one of the most effective methods to prevent infections, it has an important role in minimizing the serious complications of Covid-19, especially in cancer patients who have a worse prognosis than the general population.[4,10] Although the high efficacy rates with vaccines against SARS-CoV-2 were reported in clinical trials,[5,6] effect of these vaccines in cancer patients is still not clear. Low seroconversion rates after full-dose vaccination were reported in patients with malignancies than in healthy controls were reported.[8,11]

It is known that only one dose of the BNT162b2 (Pfizer–BioNTech) vaccine is insufficient to provide an effective immune response in patients with a cancer diagnosis, and most of these patients are unprotected against Covid-19. It was reported that a boost dose of BNT162b2 (Pfizer–BioNTech) 14 days after the first vaccine dose leads to an increased immune response in patients with solid malignancies, thus the authors commented that cancer patients should have priority in vaccination programs.[7] Like these findings, in this study, it was determined that cancer patients who were vaccinated with two doses of BNT162b2 (Pfizer–BioNTech) experienced Covid-19 less than the patients who were not full-dose vaccinated ($p = 0.000$). Also, it was observed that all other full-dose vaccinated cancer patients (two doses of CoronaVac, two doses of CoronaVac and one dose of BNT162b2 [Pfizer–BioNTech], and three doses of CoronaVac) had less Covid-19 compared to the patients without full-dose vaccination ($p = 0.000$). No other trials conducted on this subject were found in the literature search. This lack of data may be overcome with future studies that will evaluate the efficacy of different vaccination programs in cancer patients.

In the clinical trial conducted by our group, we evaluated the Spike immunoglobulin G antibodies against SARS-CoV-2 levels after CoronaVac, and we found that the seropositivity rate was lower in the cancer patient group than in the control group.[12] But the correlation between antibody response to vaccination and Covid-19 occurrence is not clear, and measurement of immunoglobulin levels after full-dose vaccination is not a routine attitude in daily practice. Thus, the only way to evaluate the efficacy of vaccination against SARS-CoV-2 is to observe patients for Covid-19 occurrence after receiving vaccines. In this present study, the antibody titers against SARS-CoV-2 after completion of vaccination were not measured.

Although a suboptimal vaccine efficacy with BNT162b2 (Pfizer–BioNTech) in elderly or immunocompromised patients was reported,[13] in this present study it was found that full-dose vaccination is effective in preventing cancer patients from Covid-19. Although the exact definition of full-dose vaccination is not clear yet, at least two doses of CoronaVac or BNT162b2 (Pfizer–BioNTech) seem to have sufficient effect. In a clinical trial, approximately 50 patients with a gynecological cancer diagnosis and who were receiving chemotherapy were evaluated. The authors of the study suggested that protection against Covid-19 could be achieved with further early booster vaccine doses.[14] In another trial, it was reported that more than two doses of COVID-19 vaccines might boost immune response, especially in the immunocompromised population or individuals who had comorbidities or increased Covid-19 exposure risk.[15] Booster doses for BNT162b2 (Pfizer–BioNTech) and Moderna vaccines is recommended a minimum of 6 months from completion of initial vaccination for risky population, including individuals older than 65 years old, who live in long-term care facilities, have comorbidities, or have jobs or live in environments with high-risk for Covid-19.[16] It is thought that the most effective vaccination schedule will be clearer soon, which may include booster doses or mixed administration of different vaccines.

5 | STRENGTHS OF THE STUDY

The primary strength of this current study is the evaluation of two different vaccines administered in various schedules. Another strength of the study is its large sample size. One other strength of this study is knowing the exact date of Covid-19 diagnosis with a positive RT-PCR test and the dates of vaccinations.

6 | LIMITATIONS OF THE STUDY

The first limitation of this study is its retrospective single-center design; the second is that the data of Covid-19 variants that infected the cancer patients in this study could not be reached.

7 | CONCLUSION

In conclusion, it is obvious that vaccination is the most important factor in the prevention of Covid-19 in cancer patients as in the general population. But the role of public health measures, such as vaccination of close contacts of cancer patients, maintenance of social distance, and mask-wearing outside the house should not be forgotten. In concordance with the data in the literature, it was found in this present study that Covid-19 risk decreased with booster shots against Covid-19. Although experience is limited to the Covid-19 pandemic, booster doses of vaccines against microorganisms that would lead to new pandemics in the future should be considered for cancer patients. It is recommended that this vulnerable patient group should be prioritized in vaccination programs, and full-dose vaccination (at least two doses of a vaccine type) should be completed as soon as possible.

AUTHOR CONTRIBUTIONS

Melih Simsek: data curation, investigation, validation, writing—original draft, and writing—review and editing. Ayse I. Yasin: data curation, investigation, methodology. Mehmet Besiroglu: formal analysis, software, and visualization. Atakan Topcu: formal analysis and methodology. Zehra S. Isleyen: software and validation. Mesut Seker: conceptualization, project administration, supervision, and

visualization. H. M. Turk: conceptualization, project administration, supervision, writing—original draft, and writing—review and editing.

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CONFLICTS OF INTEREST

The authors declare no conflicts of interest.

DATA AVAILABILITY STATEMENT

The data used to support the findings of this study are included within the article. The data and materials in the current study are available from the corresponding author on reasonable request.

ETHICS STATEMENT

Ethics Committee of Bezmialem Vakif University, Istanbul, Turkey (Date: 24.02.2021, Approval number: 02/28) and with the Helsinki declaration and its later amendments or comparable ethical standards. All procedures performed in experiments involving human participants were in accordance with the ethical standards of the Institutional committe.

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