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Antibody Responses to COVID-19 Vaccination or Infection in Actively Treated Cancer Patients: A Prospective Cohort Study

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ABSTRACT

Studies have indicated that individuals with compromised immune systems display substantially weaker antibody reactions to COVID-19 vaccines. Patients suffering from solid malignancies exhibit decreased immunogenicity following COVID-19 vaccination or infection. The current investigation examined antibody reactions to COVID-19 infection and/or the Pfizer-BioNTech BNT162b2 mRNA vaccine in individuals with cancer undergoing active therapy. Additionally, prior publications were surveyed to pinpoint patient subgroups potentially benefiting from an additional vaccine dose. Levels of anti-SARS-CoV-2 S1/S2 IgG antibodies were determined in a group of 202 patients with cancer actively treated with chemotherapy (96 cases), immunotherapy (52), targeted biologic agents (46), or endocrine therapy (12) for either localized (n = 66, 32.7%) or advanced (n = 136, 67.3%) malignancy. Of these participants, 172 completed a two-dose vaccination series, whereas 30 experienced natural COVID-19 infection (including 20 who also received a single vaccine dose). For cases yielding borderline anti-S1/S2 findings, anti-receptor-binding domain antibodies were assayed separately. Seropositivity for SARS-CoV-2 antibodies reached 89.1% (180/202) in cancer patients after either vaccination or infection, and 87.2% (150/172) in vaccinated individuals without prior infection—significantly lower than the 100% rate observed in 30 healthy healthcare workers ($P < 0.001$). Chemotherapy emerged as an independent predictor of impaired antibody production after infection or vaccination, yielding an 81.3% positivity rate compared to 96.2% among those on alternative therapies ($P = 0.001$). In chemotherapy recipients who were vaccinated, seropositivity stood at 77.5%. Multivariable regression revealed higher likelihood of robust neutralizing titers (>60 AU/ml) with immunotherapy (odds ratio 2.44) and lower likelihood with chemotherapy (odds ratio 0.39). Taken together, both the BNT162b2 vaccine and prior SARS-CoV-2 infection provoke substantial antibody production in most cancer patients. Nonetheless, this work pinpoints individuals on chemotherapy as exhibiting markedly impaired seroconversion and reduced titer magnitudes. Such evidence advocates for intensified viral and antibody monitoring in this population, alongside preferential allocation of booster vaccinations, especially amid the rise of more transmissible viral strains.

Keywords: COVID-19, Cancer, Solid tumors, Vaccine, Serologic response, Chemotherapy

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Introduction

The World Health Organization designated COVID-19, triggered by SARS-CoV-2, a worldwide pandemic in March 2020. Individuals with cancer receiving ongoing treatment appear particularly vulnerable to severe disease courses [1-6].

Intensive international initiatives led to emergency authorization by the U.S. Food and Drug Administration for multiple SARS-CoV-2 vaccines, among them the Pfizer-BioNTech BNT162b2 mRNA platform. The pivotal phase III trial showed 95% protection against symptomatic COVID-19 [95% confidence interval (CI) 90.3% to 97.6%] after two doses spaced 21 days apart, alongside a strong safety record [7]. Real-world data from Israel's

national rollout corroborated these efficacy figures [8]. That said, modestly diminished protection was evident in those with concomitant illnesses [8].

Immunity against infection or vaccination commences with rapid production of antibodies targeting viral surface proteins, detectable via assays for anti-spike or anti-nucleocapsid IgG in convalescent cases. Sustained protection depends on memory B- and T-lymphocytes, which exhibit pronounced amplification following even one vaccine dose in previously infected persons [9]. Healthy vaccinees consistently achieve 98%-100% seroconversion across reports [10-12]. By contrast, multiple investigations have documented attenuated antibody responses in immunocompromised cohorts [10-13]. In hematological cancers, diminished rates have been noted in chronic lymphocytic leukemia [10], multiple myeloma [11], and notably among recipients of potent immunosuppressants like BTK inhibitors, anti-CD20 monoclonal antibodies, or post-allogeneic transplantation [12, 13]. Evidence regarding solid tumor subgroups remains comparatively sparse. Available data suggest seroconversion approaching 90% overall in this population [12-17]. Constraints including limited participant numbers and occasional admixture with blood cancers have hampered precise delineation of impacts from chemotherapy, immune checkpoint inhibitors, or targeted biologics in pure solid tumor cohorts.

Here, we report serological outcomes after natural COVID-19 exposure and/or BNT162b2 vaccination in patients with solid malignancies on diverse ongoing regimens, seeking to delineate subgroups with modified reactivity linked to tumor extent or therapeutic modality. Findings are further contextualized against earlier publications.

Materials and Methods

In order to investigate the antibody response of oncology patients to COVID-19 exposures, we measured serological reactivity following administration of the BNT162b2 mRNA vaccine, prior SARS-CoV-2 infection, or both in individuals on ongoing anticancer regimens. From April to May 2021, individuals receiving care at the ambulatory oncology units of Hadassah Hebrew University Medical Center were invited to join the study. Information on patient age, sex, tumor stage (localized versus metastatic), treatment modality [chemotherapy, targeted biologics, immunotherapy limited to immune checkpoint inhibitors, or hormone therapy], and timing of vaccination or infection was gathered through patient interviews and review of clinical records.

Serum specimens were obtained at a median interval of 77 days after completion of the two-dose vaccine series (range 21-97 days) or 121 days post-infection (range 44-271 days). Samples were processed in the institutional virology lab using a quantitative assay for IgG directed against the SARS-CoV-2 spike protein S1/S2 domains (Liaison SARS-CoV-2 S1/S2 IgG assay, DiaSorin, Saluggia, Italy), detecting levels from 3.8 to >400 AU/ml. Titers exceeding the assay ceiling were reported as >400 AU/ml, which may underestimate true peak values. Interpretation thresholds were <12 AU/ml negative, 12-19 AU/ml borderline, and ≥19 AU/ml positive. A level >60 AU/ml was designated as probable neutralizing activity, corresponding to the median titer observed in individuals with verified positive neutralization tests [18]. Seven participants with borderline S1/S2 readings underwent supplementary testing for anti-receptor-binding domain IgG (SARS-CoV-2 IgG II Quant assay, Abbott Park, IL).

Findings from patients were benchmarked against results from 30 vaccinated healthcare workers without prior infection at the same institution [19], with comparable timing of blood draws relative to vaccination (median 77.5 days, range 6-118 days after the second dose).

Every participant and control subject provided signed informed consent under a protocol approved by the local ethics committee.

Statistical analyses

Group comparisons for continuous parameters employed the Student's t-test, while categorical parameters used the chi-square test. Data processing utilized IBM SPSS version 27 (Armonk, NY) and R software (R Foundation for Statistical Computing, Vienna, Austria), the latter also for graphic generation. Distributions of anti-S1/S2 titers across subgroups were displayed as combined dot, box, and violin plots created with the 'ggplot2' package; significant pairwise comparisons were overlaid via the 'ggsignif' package. A logistic regression model was built using achievement of titer ≥60 AU/ml as the dependent variable and receipt of chemotherapy, immunotherapy, or biologic therapy as covariates, producing adjusted odds ratios with 95% confidence intervals. Non-parametric correlations were evaluated with Spearman's rank coefficient and corresponding P values.

Results and Discussion

Initially, 238 oncology patients completed anti-SARS-CoV-2 S1/S2 antibody testing. Exclusions totaled 36 cases: 7 tested after a single vaccine dose, 6 within 21 days of the second dose, 19 lacked documented vaccination or infection dates, and 4 had neither vaccination nor infection history. The final cohort therefore comprised 202 patients. Demographic and oncologic features are detailed in **Table 1.** Median age was 62.1 ± 14.1 years (range 23-91 years). Metastatic involvement was documented in 136 cases (67.3%). Primary sites included breast (66), lung (38), gastrointestinal (36), genitourinary (22), gynecologic (10), and miscellaneous (30). Ongoing therapies consisted of chemotherapy for 96 patients (47.5%), immune checkpoint blockade for 52 (25.7%; including 17 combined with chemotherapy), targeted biologics for 46 (22.8%), and endocrine therapy for 12 [monotherapy in 5, combined with CDK4/6 inhibitors in 6, or everolimus in 1]. At the time of vaccination, 42 patients were treatment-free, 37 commenced therapy afterward, and 5 were managed with palliative support alone.

Table 1. Patients' baseline demographics and disease characteristics

Characteristic	Value
Age	Mean ± SD
	62.1 ± 14.1
	>65 years old, % (n)
	52.0 (105)
Sex: Males, % (n)	44.1 (89)
Primary cancer site, % (n)	
Breast	32.7 (66)
Genitourinary	10.9 (22)
Lung	18.8 (38)
Gynecological	5.0 (10)
Gastrointestinal	17.8 (36)
Other	14.9 (30)
Presence of metastatic disease, % (n)	67.3 (136)
Treatment received, % (n)	
No treatment*	18.8 (37)
Chemotherapy	47.5 (96)
Targeted therapy	22.8 (46)
Hormonal therapy	5.9 (12)
Immunotherapy	25.7 (52)
Best supportive care only	2.5 (5)
History of prior COVID-19 infection, % (n)	14.9 (30)
Days from second vaccine dose	Mean ± SD
	83.7 ± 42.0
	1st Quartile
	22–60
	2nd Quartile
	60–80
	3rd Quartile
	80–89
	4th Quartile
	90–315

SD, standard deviation.

aThese patients started treatment after vaccination.

Of nine individuals with equivocal S1/S2 results, follow-up RBD testing was negative in two and positive in seven. Consequently, detectable anti-SARS-CoV-2 antibodies (S1/S2 or RBD) were present in 89.1% (180/202)

of the cohort after vaccination and/or infection, and in 87.2% (150/172) of vaccinated patients without preceding infection. By comparison, seropositivity reached 100% among 30 uninfected vaccinated healthcare workers (P < 0.001) [19]. **Figure 1** depicts antibody titer trends over time in both groups. Controls maintained stable titers across post-vaccination time quartiles, whereas patients showed a small but statistically significant decrease between the earliest and latest quartiles. Titers in controls exceeded those in patients at every quartile (all pairwise t-tests P < 0.05).

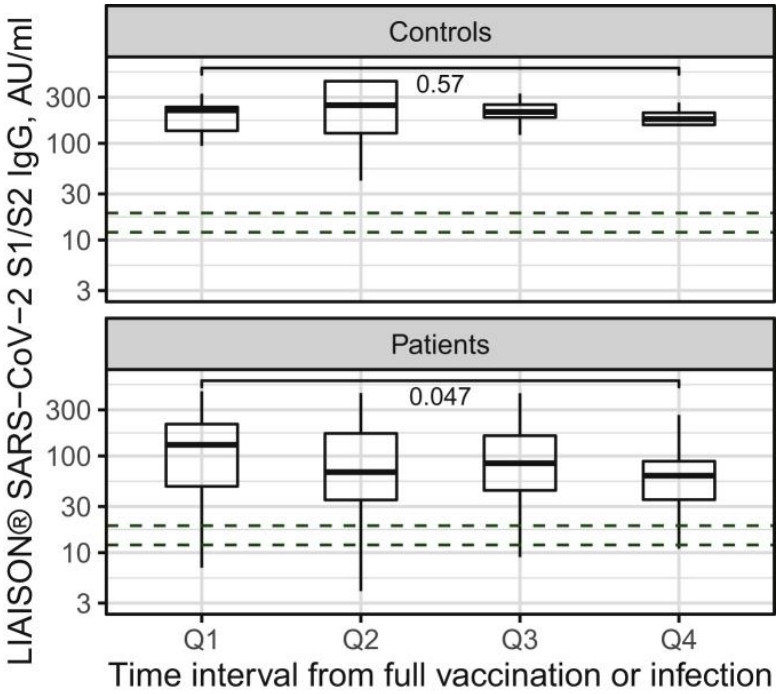

Figure 1. Anti-S1/S2 titers in controls (top panel) and patients (bottom panel) at the specified time interval quartiles after full vaccination or disease.
Interval Q1 ≤ 58 days, interval Q2 59 to 80 days, interval Q3 81 to 93 days, and interval Q4 ≥ 94 days.

Table 2 illustrates the correlations between antibody positivity and clinical characteristics in cancer patients without prior SARS-CoV-2 infection who completed two doses of the BNT162b2 mRNA COVID-19 vaccine (n = 172). Unadjusted analyses revealed that chemotherapy was the sole factor strongly linked to diminished antibody response after vaccination, with rates of 77.5% (62/80) in chemotherapy-treated patients versus 95.7% (88/92) in those without chemotherapy (OR 6.39, 95% CI 2.06-19.79, P < 0.001). Similar findings in the full group of 202 patients (incorporating 30 with previous infection), **(Table 3)** showed response rates of 81.3% during chemotherapy and 96.2% otherwise (OR 5.89, 95% CI 1.91-18.09, P = 0.001). No significant links emerged for variables like age, cancer stage, advanced versus localized malignancy, or therapies involving immunotherapy, hormones, or biologics. All 30 post-infection patients achieved seropositivity (including 20 who got one vaccine dose), versus 87.2% (150/172) in uninfected cases (P = 0.038) **(Table 3).**

Table 2. Univariate analysis of antibody response rate in cancer patients after two BNT162b2 vaccinations (n = 172)

Characteristic	Category	Positive Serological Response, n (%)	Negative Serological Response, n (%)	P-value	Odds Ratio (95% CI)
Age	<65 years	74 (87.1)	11 (12.9)	1.0	1.03 (0.42–2.5)
	≥65 years	76 (87.4)	11 (12.9)		
Sex	Male	62 (83.8)	12 (16.2)	0.26	1.70 (0.69–4.21)
	Female	88 (89.8)	10 (10.2)		
Time from vaccination	<4 weeks	2 (66.7)	1 (33.3)	0.28	3.52 (0.30–40.6)

	≥4 weeks	148 (87.6)	21 (12.4)		
Cancer status	Early	47 (82.5)	10 (17.5)	0.20	0.55 (0.20–1.36)
	Metastatic	103 (89.6)	12 (10.4)		
Treatment					
Any treatment	Yes	119 (85.6)	20 (14.4)	0.20	0.38 (0.90–1.73)
	No	31 (93.9)	2 (6.1)		
Chemotherapy	Yes	62 (77.5)	18 (22.5)	<0.001	6.39 (2.06–19.8)
	No	88 (95.7)	4 (4.3)		
Targeted biological therapy	Yes	34 (87.2)	5 (12.8)	1.0	1.03 (0.35–2.92)
	No	116 (87.2)	17 (12.8)		
Hormonal therapy	Yes	9 (90.0)	1 (10.0)	0.78	0.75 (0.09–6.19)
	No	141 (87.0)	21 (13.0)		
Immunotherapy	Yes	42 (91.3)	4 (8.7)	0.33	0.57 (0.18–1.80)
	No	108 (85.7)	18 (14.3)		
Best supportive care only	Yes	3 (75.0)	1 (25.5)	0.46	2.33 (0.23–23.5)
	No	147 (87.5)	21 (12.5)		

Table 3. Univariate analysis of antibody response rate in cancer patients after COVID-19 infection and/or vaccination (n = 202)

Characteristic	Category	Positive Serological Response, n (%)	Negative Serological Response, n (%)	P-value	Odds Ratio (95% CI)
History of COVID-19 infection	Yes	30 (100.0)	0 (0.0)	0.038	—
	No	150 (87.2)	22 (12.8)		
Chemotherapy	Yes	78 (81.3)	18 (18.8)	0.001	5.89 (1.91–18.09)
	No	102 (96.2)	4 (3.8)		

For deeper insight into particular therapy regimens **(Table 4),** antibody positivity rates and titers are detailed across subgroups. In the 172 vaccinated patients, positivity stood at 77.5% for chemotherapy alone, 83.3% for chemotherapy combined with immunotherapy, and 94.1% for immunotherapy with or without biologics. **Figure 2** depicts anti-SARS-CoV-2 S1/S2 antibody titer distributions in the complete 202-patient cohort, categorized by chemotherapy-based regimens, immunotherapy-based regimens, combined chemo-immunotherapy, or absence of either, with associated P values. Chemotherapy correlated with reduced average titers relative to no chemotherapy or immunotherapy ($P = 0.00067$). Average titers were markedly higher under immunotherapy than chemotherapy ($P = 0.0017$), but comparable to no-treatment groups **(Figure 2).** Multivariable logistic regression indicated higher odds of reaching a presumed protective titer (>60 AU/ml) [18] with immunotherapy (OR 2.44, $P < 0.05$) and lower odds with chemotherapy (OR 0.39, $P < 0.05$).

Table 4. Summary of previously reported SARS-CoV-2 antibody response rate among patients with solid tumors receiving various treatments

Publication and Therapy Subgroup		Positive / Total (n)	Serologic Response Rate (%)
Studies including only patients with solid tumors			
Massarweh *et al.* [15]	All	92/102	90

	All chemotherapy combinations	55/64	85.8
	All immunotherapy combinations	36/41	87.8
	IC only (22) or + biologic (5)	26/27	96.2
	Immunotherapy + chemotherapy	10/14	71.4
Goshen-Lago *et al*. [16]	All	187/218	85.8
	All chemotherapy combinations	102/125	81.6
	Biologic therapy	70/77	90.9
	All immunotherapy combinations	8/79	89.9
Barrière *et al*. [14]	All	42	95.2
Grinshpun, Rottenberg *et al*. (present study)	All	150/172	87.2
	All chemotherapy combinations	63/80	77.5
	All immunotherapy	4/46	91.3
	Immunotherapy only	32/34	94.1
	Immunotherapy + chemotherapy	10/12	83.3
Studies that included hematologic patients (data shown are extracted for solid tumor patients only; specific treatment subgroups may include hematologic patients)			
Thakkar *et al*. [12]	All solid tumor patients	136	98
	Chemotherapy	112	93
	Immunotherapy	31	97
	Other	47	100
Addeo *et al*. [13]	All solid tumor patients	101	98
	Cytotoxic chemotherapy	30	93
	Immunotherapy	14	92.8
	Other	63	98.4
Iacono *et al*. [17] (>80 years old)	All solid tumor patients	26	96

Chemo, chemotherapy; IC, immunotherapy; immune, immunotherapy.

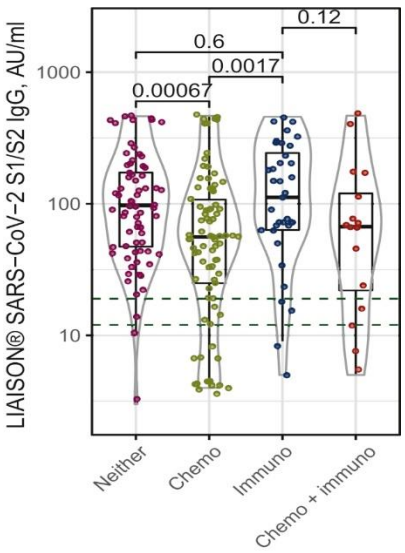

Figure 2. Anti-SARS-CoV-2 S1/S2 levels distribution among cancer patients with solid tumors treated with chemotherapy, immunotherapy, neither, or both.
Chemo, chemotherapy; immune, immunotherapy.

Within the study group, two individuals contracted COVID-19 after their initial vaccine dose, while another—with metastatic breast cancer on concurrent chemo-immunotherapy—recently tested positive during Israel's delta variant surge. This patient had a titer of 62 AU/ml three months before severe symptomatic infection requiring intensive care.

The results of this study demonstrate robust overall immunogenicity, evidenced by antibody responses to the BNT162b2 mRNA COVID-19 vaccine or prior SARS-CoV-2 infection, achieving around 90% seroconversion in patients with solid tumors undergoing active treatment. While this figure is notably lower than the 99%-100% observed in our healthy healthcare worker control group [18] and in published control populations [10-12], it substantially exceeds rates seen in other immunocompromised populations, including patients with chronic lymphocytic leukemia [10] (39%), liver transplant recipients [20] (52.5%), and kidney transplant recipients (44%) [19].

Chemotherapy emerged as an independent predictor of markedly diminished humoral immunity following vaccination or infection, with seropositivity of 77.5% in chemotherapy recipients versus >95.7% in those on alternative therapies. Notably, seroconversion reached 100% among chemotherapy patients with prior COVID-19 infection, though this may indicate selection bias. Antibody responses in patients treated with checkpoint inhibitors—either alone or combined—showed no significant deviation from other cohorts: 94.1% (32/34) for immunotherapy without chemotherapy and 83.3% (10/12) for combined immunotherapy-chemotherapy. Antibody titers were considerably lower in chemotherapy-treated patients compared to all other categories (immunotherapy, biologic therapy, or no active treatment). In contrast, immunotherapy exerted an opposing influence, yielding an adjusted odds ratio of 2.44 for achieving antibody levels >60 AU/ml, while chemotherapy yielded an OR of 0.39. This suggests that immunotherapy may enhance antibody responses to potentially more protective thresholds when a response occurs—a hypothesis previously proposed in routine vaccination settings [21, 22].

Table 4 provides an overview of prior reports on serologic responses to two doses of SARS-CoV-2 vaccines in solid tumor patients. An Israeli study by Massarweh *et al*. [15] focused exclusively on solid tumors and documented 90% seropositivity among 102 actively treated patients, with rates of 85.8% for chemotherapy alone or combined, 96.2% for immunotherapy ± biologics, and 71.4% (10/14) for chemo-immunotherapy. Only the chemo-immunotherapy combination significantly correlated with reduced titers.

Another Israeli investigation by Goshen-Lago *et al*. [16] described seropositivity of 81.6% (102/125) in chemotherapy recipients and 89.9% (8/79) in immunotherapy recipients, without distinguishing immunotherapy subgroups by chemotherapy co-administration.

Three further studies [12-14] encompassed both solid and hematologic malignancies, reporting 96%-98% seropositivity among solid tumor cases. These included substantial numbers of patients on hormonal therapy or observation, with 98%-100% seropositivity in those subgroups—indicating responses comparable to the general population for non-chemotherapy treatments, irrespective of disease stage. Chemotherapy subgroups in these reports achieved 93% seropositivity. Thakkar *et al*. [12] observed 97% seropositivity in 31 immunotherapy patients, while Addeo *et al*. [13] noted 93% (13/14). Intriguingly, Thakkar *et al*. [12] reported 100% seropositivity but lower titers in five patients on CDK4/6 inhibitors; in contrast, our five CDK4/6 inhibitor-treated patients exhibited high titers, underscoring the requirement for larger cohorts in such subgroup evaluations.

Subgroup sizes across these investigations were often limited, and differences frequently lacked statistical significance. Collectively with our data, however, they indicate consistently high seropositivity in solid tumor patients on hormonal/biologic therapy or surveillance, versus approximately 80% in those receiving chemotherapy.

One limitation of our study is the absence of neutralizing antibody assays. Nevertheless, IgG levels have demonstrated strong correlation with neutralization capacity [7, 20, 23].

Regarding checkpoint inhibitor immunotherapy, the potential for enhanced vaccine immunogenicity—as suggested by the elevated OR for >60 AU/ml titers—aligns with prior observations in influenza vaccination programs [21, 22] and merits additional investigation in larger immunotherapy-treated cancer cohorts.

Conclusion

This investigation indicates a strong overall antibody response exceeding 90% to the BNT162b2 mRNA COVID-19 vaccine or infection in actively treated cancer patients. Our findings build on earlier reports by confirming that chemotherapy is linked to a decreased serologic response of around 80% in solid tumor patients, independent of disease stage or concomitant therapies. Conversely, patients on non-chemotherapy regimens exhibit responses akin to the general population. Accordingly, intensive virological and serological monitoring is recommended for chemotherapy recipients to facilitate prompt diagnosis and appropriate care. Furthermore, this population should be prioritized for booster (third-dose) vaccination as novel, highly transmissible SARS-CoV-2 variants continue to appear.

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