short review

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Vaccination against SARS-CoV-2 in adults with a diagnosis of cancer: a short review

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Summary Compared to individuals without cancer, patients with a diagnosis of malignancy bear a higher risk of becoming infected with SARS-CoV-2, suffer more frequently from disease-related complications, and are more likely to die due to coronavirus disease 2019 (COVID-19). Depending on the type of cancer and the treatment received, the immune response to vaccination may also be affected in patients with certain types of malignancy. Therefore, there is a need for more specific COVID-19 vaccination recommendations in individuals with a diagnosis of cancer. Furthermore, pre-exposition prophylaxis should be considered for some patients. This short review summarizes some challenges in prevention of (severe) COVID-19 in individuals with a diagnosis of cancer and compares guidelines given by the US *National Comprehensive Cancer Network*, German *Robert Koch-Institut*, and Austrian *Nationales Impfgremium*.

Keywords COVID-19 · Monoclonal antibodies · Malignancies · Immune response · Prophylaxis

Introduction

Already early on in the pandemic and long before vaccines were available, it became clear that patients with a diagnosis of cancer are at significantly higher risk of becoming infected with SARS-CoV-2 [1]. In an analysis of electronic health record (EHR) data from the USA, patients with active cancer (diagnosis of cancer within the last year) were found to be even more receptive to an infection than the overall population of patients with a diagnosis of cancer [1]. In fact, adjusted odds of an infection (adjustment for gender, age, race, coronavirus disease 2019 [COVID-19] risk factors, cancer treatments, transplantation, stay in a nursing home) were higher for patients with non-Hodgkin lymphoma, lung cancer, breast cancer, colorectal cancer, and prostate cancer, while patients with leukemia (adjusted odds ratio [aOR] 12.16) appeared to be at the highest risk of an infection compared to patients without cancer. The higher vulnerability of patients with an active cancer diagnosis furthermore extends to having a severe disease course resulting in a higher likelihood of hospitalization and mortality [1]. Various mechanisms may be responsible for this observation, including but not limited to higher expression of ACE2 (angiotensin-converting enzyme 2) in various types of cancer (therefore making the entry into the cell easier for the virus), cancer's immune evasion mechanisms (e.g., lower number and response of T-cells), higher likelihood of cytokine storm (due to higher levels of IL-6 in patients with cancer), and/or bone marrow suppression by chemotherapy [2].

Here we provide a brief review of the literature related to safety and efficacy of SARS-CoV-2 vaccination against infection and/or a severe COVID-19 disease course in patients with cancer.

Clinical and antibody response to vaccination in cancer patients

SARS-CoV-2 vaccinations have substantially reduced infection risk as well as complications and death

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due to COVID-19. Data about efficacy of vaccination specifically in patients with cancer are still incomplete, but indicate the same protective effects, though these might be lower and of shorter duration compared to individuals without a diagnosis of cancer [3, 4]. In a registry-based case–control study, Lee et al. investigated the efficacy of two doses of SARS-CoV-2 vaccination in individuals with and without a diagnosis of cancer. The dataset included a large sample of patients registered in the UKCCEP (UK Coronavirus Cancer Evaluation Project) in the United Kingdom between 08 December 2020 and 15 October 2021 and comprise therefore mainly infections with the Delta variant. In individuals with hematological malignancy (vaccinated individuals $n = 64{,}577$), the highest protection against being tested SARS-CoV-2 positive was observed in patients with myeloma compared to substantially lower vaccination effectiveness rates in patients with leukemia or lymphoma (63.9% versus 18.5% and 12.8% 3–6 months after second vaccination, respectively). In vaccinated individuals with solid cancer ($n = 700{,}745$), the highest effectiveness against being tested positive within 3–6 months after the second vaccination was observed in patients with lung cancer (61.4%) compared to noncolorectal gastrointestinal (60.5%), prostate (55.7%), colorectal gastrointestinal (52.8%), urinary tract (52.5%), gynecological (50.6%), central nervous system (49.3%), breast (44.2%), and endocrine glands (43.6%). The protection of vaccination against infection within 3–6 months was also influenced by the time passed since the diagnosis of cancer (51.3% vaccine effectiveness for those with a diagnosis of cancer > 12 months prior to data cut-off vs 44.2% ≤ 12 months prior), timing of systemic anticancer therapy (42.5% > 12 months prior vs 35.4% ≤ 12 months prior), and time elapsed since radiotherapy (48.8% > 12 months prior vs 36.6% ≤ 12 months prior). Although effectiveness was waning, 3–6 months after the second vaccination the vaccine's effectiveness was still 47.0% against breakthrough infection, 74.6% against hospitalization, and 90.3% against death. A more pronounced waning of protection was observed in patients with lymphoma, leukemia, or colorectal cancer compared to prostate, lung, or breast cancer. Both breakthrough infections and waning of effectiveness were less likely in a population without cancer [3].

While further research is being performed about the role and clinical value of the cellular response to vaccination, determining the antibody titer is currently considered the standard for estimating an individual's protection against the virus. Although there is no antibody titer at which an individual's protection can be assumed, the neutralizing antibody titer against SARS-CoV-2 seems to correlate well with the protection against symptomatic, complicated, and lethal infections [5]. However, patients with a diagnosis of cancer, compared to healthy individuals, appear to have a lower antibody response to vaccination. Importantly, in some individuals the cellular immune response might lower the risk of severe COVID-19, even in the absence of seroconversion after vaccination [6–8].

In a clinical trial, including 637 immunocompromised individuals (due to a diagnosis of solid or hematologic cancer, solid organ transplant, or autoimmune disease, 399 being under active systemic treatment at the time of vaccination) and 204 healthy controls, immunocompromised patients were more likely to lack seroconversion 1 month after the second mRNA vaccination, which was administered on average 31 days (range 19–131 days) after the first vaccination [9]. While healthy controls and patients with untreated solid cancer showed a seroconversion rate of 100%, the numbers were lower for participants with solid cancer receiving active cancer treatment (98.3%) and even lower in patients with untreated or treated hematologic cancer (95 and 86%, respectively), as well as autoimmune diseases (81.8%) or solid organ transplanted individuals (65.5%). Also, the mean level of produced antibodies differed between groups, being significantly lower in patients with autoimmune diseases, those with hematologic cancers receiving active treatment, or solid organ transplants, compared to healthy controls [9].

A meta-analysis investigating the influence of anticancer treatment on humoral response to SARS-CoV-2 vaccination supported the previously described negative correlation. Including data from 39 studies with a total of 11,075 patients, the likelihood of no seroconversion was significantly higher in patients with an active cancer treatment compared to patients without an ongoing treatment (OR 2.55). In the analysis of different groups of treatments, the odds of seronegativity were significantly higher in patients with active chemotherapy (OR 3.04) or targeted therapy (OR 4.72), but not in patients with immunotherapy (OR 1.23) or hormonal therapy (OR 1.16). Treatment with anti-CD20 antibodies was associated with higher odds of seronegativity compared to treatment with BTKi (Bruton tyrosine kinase inhibitor) or BCL2i (B-cell lymphoma 2 inhibitor). Interestingly, cancer status (stable disease, progressive disease, or remission) but not metastatic status (metastatic versus early disease) was significantly associated with immune response. The odds ratio for no seroconversion was significantly higher in stable disease or progressive disease versus remission [6].

Depending on the vaccination used and the SARS-CoV-2 variant tested for, the magnitude of neutralizing antibodies produced differs [9, 10]. The Omicron variant is currently the most prevalent variant worldwide. A lower level of antibodies against the Omicron variant after vaccination compared to wild type, their faster decline, and differing neutralization of subvariants are factors that might influence the vaccination efficacy [10]. In an investigation of Mair et al. [11], antibody concentrations were lower against the recep-

tor-binding domain of SARS-CoV-2 variants Delta and Omicron than against wildtype, with the lowest levels observed against Omicron. Furthermore, the authors reported overall lower antibody titers in cancer patients compared to those without cancer. The lowest levels were found in patients with hematologic cancer under B-cell-depleting therapy, followed by hematologic patients without B-cell-depleting therapy and patients with solid cancer, respectively [11].

Adapted vaccines, repeated boosters, and/or shorter intervals between doses of vaccination might improve antibody response in this context [9, 10]. One way of mounting the antibody level also against variants with a high level of immune evasion is the administration of multiple boosters. Studies have demonstrated seroconversion in some previously seronegative patients after administration of a third or fourth SARS-CoV-2 vaccination [8, 12, 13]. In a recent meta-analysis, the antibody response following a third vaccination in patients with cancer was studied. The authors reported seroconversion rates of 44 and 80% after a third vaccination (median time of about 6 months between second and third vaccination) in patients with hematological and solid cancer, respectively [12]. Though rising antibody levels could be observed after the third vaccination in patients with solid cancer and hematologic cancer without B-cell-depleting therapy, the third vaccination did not have an effect on the antibody level in patients with hematologic cancer undergoing B-cell-depleting therapy [14].

Ehmsen et al. extended these observations by studying the response to a fourth vaccination in patients with solid or hematologic cancer (mean time between third and fourth vaccination 140 days) [13]. The authors invited 530 participants (214 solid cancer, 316 hematologic cancer) of a previously performed study on the antibody response after three vaccinations against SARS-CoV-2. In all, 359 patients received the fourth vaccination (139 solid cancer, 256 hematologic cancer), 94% of these had blood drawn after 1 month and 83% at 3 months after the fourth vaccination, which was analyzed for anti-S IgG (IgG against spike protein of SARS-CoV-2) levels. A small proportion of patients included in that report received active oncological treatment. Nineteen patients with solid cancer were receiving chemotherapy, 6 immunotherapy, 57 other, and 55 no therapy. Of the patients with hematologic cancer, 6 were receiving chemotherapy, 22 anti-CD20, 11 anti-BTK, 56 other, and 167 no therapy. Antibody levels increased by a mean 1.7 times following the fourth vaccination. The decline in antibody level over the course of 3 months after the fourth vaccination was similar to the response observed within 3 months after the third vaccination. However, the calculated persistence of a protective antibody level was longer after the fourth vaccination compared to the third vaccination, given the initially higher antibody titer. The observations in that report may further be influenced by recruitment bias. Patients with rather high antibody titer after the third vaccination did not receive a fourth vaccination. Also, patients were not tested for previous infection (and thus boosted immune response) before the fourth vaccination [13]. Thus, the numbers should be interpreted carefully, though the general benefit of a fourth vaccination is concordant with other studies [13]. A fourth vaccination might lead to a significantly improved inhibition of interaction between the receptor-binding domain of the Omicron subvariants BA.1, BA.4, and ACE2, respectively, implying better protection against infection also in patients with hematologic malignancies [15]. In a recent report of 21 patients with solid and 33 patients with hematologic cancer by Mair et al., however, patients with hematologic malignancies benefited less from the fourth vaccination than patients with solid cancer [15]. Similar to previous observations, the vaccination's benefit in patients under B-cell-depleting therapy was lower than in patients with hematologic malignancies without B-cell-depleting therapy [15].

The lower immune response to vaccination in individuals under chemotherapy brings up the question of timing of vaccination in relation to chemotherapy. In a trial including 122 patients with solid cancer, no relevant difference of immune response after SARS-CoV-2 vaccination was observed in patients receiving the vaccination within 48 h before or after administration of chemotherapy [16]. In contrast, an analysis of immune response to influenza vaccination performed by Keam et al. did show a higher antibody titer after vaccination having been performed on day 11 compared to day 1 (the day on which chemotherapy was administered) in patients with breast cancer, however, no difference in other patient groups with solid cancer [17]. In another study of patients with breast cancer ($n=38$), higher antibody levels after vaccination against influenza were recorded on day 5 after chemotherapy compared to day 16 [18]. As the benefit of delaying vaccination due to chemotherapy is highly questionable, patients with solid cancer should be vaccinated as soon as possible, independently from chemotherapy.

The data presented above demonstrate the even higher vulnerability of patients with hematologic cancer compared to patients with solid cancer during the COVID-19 pandemic. Patients with hematologic cancer not only bear a higher risk of infection [1], but also have a lower chance of seroconversion even after multiple vaccinations [9, 12], with a tendency to lower antibody response [15, 19] and higher risk of break-through infection [20] compared to patients with solid cancer. Due to the central role of B-cells in the immune system's reaction to a COVID-19 infection, but also in building immunity after vaccination [21], patients with hematologic cancer receiving B-cell-depleting therapy (anti-CD20 therapy, BTKi) appear to be the most vulnerable of cancer patients [6, 15, 19]. Taking into account the absence of adequate

Table 1 Vaccination scheme and anticancer treatment related recommendations by NCCN [22]

Patient group	Recommendation
Vaccination scheme for patients with hematologic cancer, solid cancer under treatment or solid cancer receiving treatment within a year of initial vaccination	Primary series 3 doses of mRNA-vaccine + 1 bivalent[a] booster ≥ 2 months after primary series[b]
Already boostered once or twice with monovalent booster	Bivalent[a] booster ≥ 2 months after monovalent booster
B-cell-depleting therapy	≥ 6 months after treatment start of revaccination[c]
Hematopoietic cell transplantation/cellular therapy (e.g., CAR T cell therapy)	≥ 3 months after treatment start of revaccination[c]
Neutropenia due to chemotherapy in hematologic malignancies	Delay until absolute neutrophil count recovery or for those not expected to recover, vaccination as soon as possible[d]
Solid cancer surgery	A few days/14 days between surgery and vaccination[e]

[a]Bivalent vaccines: updated vaccines including a component of 2 virus strains (currently available a combination of the original virus strain and a component of the omicron variant) vs. monovalent vaccines which include components of one virus strain
[b]Former recommendation 3 doses primary series + 2 boosters, bivalent vaccine currently approved for single application
[c]Revaccination: 3 doses primary series + 1 booster, due to loss of immunity
[d]Recovery of absolute neutrophil count: surrogate marker for recovery of adequate immunocompetence to respond to vaccines
[e]For easier differentiation between infection and vaccination as cause for postoperative fever, differing timing depending on the extent of surgery

immune memory function, the impaired likelihood to produce antibodies after vaccination while receiving B-cell-depleting therapy, the US NCCN (National Comprehensive Cancer Network) recommends full revaccination ≥ 6 months after B-cell-depleting therapy [22] (details and further information about timing of vaccination in Table 1). Due to impacted antibody response, pre-exposure prophylaxis with monoclonal antibodies against SARS-CoV-2 does play a more central role in patients with hematologic malignancies especially for those with B-cell-depleting therapy.

Monoclonal antibody treatment as pre-exposure prophylaxis

Monoclonal antibodies (mAb) against SARS-CoV-2 may provide protection against infection and/or a severe disease course in patients with an insufficient immune response to vaccination. These may be used either as pre-exposure prophylaxis, post-exposure prophylaxis, or as treatment in patients with cancer.

Recent data, however, have demonstrated overall lower efficacy of mAb against the Omicron variant and its subvariants [15, 23, 24], also lowering the neutralizing effect in patients with hematologic malignancies [15]. An in vitro study by Takashita et al. showed absence of neutralization of BA.5, the currently most dominant subvariant [25], with tixagevimab, casirivimab or s309 (precursor to sotrovimab), while cilgavimab and imdevimab still had a neutralizing effect [24]. Tixagevimab/cilgavimab is a combination of monoclonal antibodies that currently is recommended as pre-exposure prophylaxis by various organizations [22, 26, 27]. To compensate for lower neutralization of Omicron variant compared to wildtype, a higher dose of administration (300 mg versus 150 mg) than initially authorized, has been approved by the US Food and Drug Administration (FDA) [28]. Furthermore, the FDA has approved prophylactic administration of tixagevimab/cilgavimab every 6 months [29]. The European Medicines Agency (EMA), on the other hand, until today (13 November 2022) has only authorized the initially approved dose of 150 mg tixagevimab/150 mg cilgavimab as prophylaxis and so far has not specified the timing of readministration [30].

What do guidelines recommend on immunization of cancer patients

Many institutions do not give recommendations specifically for patients with a diagnosis of cancer and the recommendations given hardly differentiate between subgroups of cancer patients or types of treatment. A rather detailed recommendation is given by the US *National Comprehensive Cancer Network* (NCCN), to which, among other institutions, the CDC (Center for Disease Control) and ASCO (American Society of Clinical Oncology) refer. Tables 1 and 2 summarize the NCCN recommendations for oncological patients as given on 22 September 2022 [22]. In Table 3 the recommendations of the German *Robert Koch-Institut* (RKI) [26] and the Austrian national vaccination assembly (Nationales Impfgremium, NIG) [27, 31] are compared. All three organizations recommend a bivalent vaccine as booster and, if indicated, tixagevimab/cilgavimab as a pre-exposure prophylaxis. While RKI and NIG refer rather unspecifically

Table 2 Monoclonal antibodies as pre-exposure prophylaxis recommendations by the US *National Comprehensive Cancer Network* (NCCN) [22]

Patient group	Recommendation
Unable to receive vaccines or may not mount adequate immune response	Tixagevimab/cilgavimab[a] every 6 months
Specific immunocompromised patients[b]	Tixagevimab/cilgavimab[a] (no substitute for vaccination)
After vaccination	≥ 2 weeks delay of tixagevimab/cilgavimab[a]
After pre-exposure prophylaxis	No delay of vaccination

[a]300 mg of tixagevimab and 300 mg of cilgavimab
[b] e.g. active treatment for solid or hematologic malignancies, receipt of CAR T-cell therapy or hematopoietic cell transplantation (within 2 years of transplantation or during immunosuppressive therapy)

Table 3 Comparison of vaccination recommendations by the German Robert Koch Institut (RKI) [26] and by the Austrian national vaccination assembly (Nationales Impfgremium, NIG) [27, 31]

	RKI	NIG
Vaccination scheme	2 doses primary series +2 to 3 boosters	3 doses primary series +2 boosters
Timing of boosters[a]	≥6 months after last vaccination, individually 2nd booster earlier (≥4 months), disease or under therapy which reduces immune response (e.g. chemotherapy) booster(s) ≥3 months after last vaccination	≥4 months after last vaccination
Testing of immune response to vaccination	≥4 weeks after primary series	
Insufficient immune response	Additional doses primary series ≥4 weeks after last vaccination[b]	
Pre-exposure prophylaxis	Expected or proven lack or insufficient[c] immune response	

[a]Both organizations recommend a bivalent booster (including a component of the original virus strain and a component of the omicron variant)
[b]RKI: consider higher dose or different types of vaccine
[c]Insufficient immune response: not further classified

to 'cancer under immune suppressive, antineoplastic therapy' they point out that decisions should be made according to individual circumstances [27, 31], whereas the NCCN gives more specific recommendations regarding different vaccination schemes for some anticancer treatments [22].

The above-mentioned recommendations already include adaptions in order to cover for the most recent circulating Omicron variants BA.4 and BA.5. With ongoing research and new variants, continuous changes in recommendations are expected.

Conclusion

To compensate for cancer patient's elevated risk of complications due to COVID-19, their lower antibody response to vaccination, and the immune escape mechanisms of variants, an adapted vaccination scheme and prioritization is recommended. Cancer patients might profit from more frequent vaccinations, as this might preserve and improve the neutralizing antibody titer also against variants with immune escape. As there is lack of evidence for a benefit in delaying vaccination due to chemotherapy, patients should be immunized as soon as possible. Revaccination (primary series and boosters) should be performed in specific patient groups (e.g., after anti-CD 20 therapy). In patients with hematologic malignancies, ongoing chemotherapy or targeted therapy testing for seroconversion should be performed after basic immunization, as these patient groups may benefit from additional doses. Individuals with risk of impaired seroconversion or low immune response should be offered pre-exposition prophylaxis, considering the variant's resistances against monoclonal antibodies. As these patients may continue to benefit from a cellular response, vaccination should still be performed. Development of vaccines and antibody treatments adapted to current (sub-)variants is essential for improving and maintaining the best possible protection against COVID-19 morbidity and mortality. Due to changes in the viral mutational landscape, developments in preventive medication and an improved understanding of individualized prevention, regular re-evaluation of recommendations is warranted.

Conflict of interest W.E. Huf and A. Valipour declare that they have no competing interests.

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