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Review

Dosing Schedule Modification of COVID-19 Vaccine in Immunosuppressed and Cancer Patient: A Review of Current Suggestions

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Abstract: The effect of SARS-CoV-2 pandemic has been subsided significantly following the rapid development of vaccine. However, patients with cancer and immunosuppressed state, who are more prone to mortality and morbidity due to this infection, were excluded from majority of the vaccine trials. Moreover, suggested dose modification for cancer and immunosuppressed patients are often not followed because of lack of awareness or unavailability of vaccination schedule. This review will try to bridge this knowledge gap by summarizing the current suggestions of dose modification of COVID-19 vaccine for patients with cancer and immunosuppression.

Keywords: COVID-19; vaccine; immunosuppressed; cancer; vaccine efficacy

1. Introduction

COVID-19 is caused by a crown shaped, enveloped, RNA virus belonging to the family of Coronaviridae, the family which has been known since 1960s. [1] It has been discussed widely since 2019, when virus particle from this family was extracted from several patients with 'pneumonia of unknown etiology' at Wuhan, China in December, 2019. [2] This novel strain of corona virus apparently shared genetic component with SARS-CoV from Coronaviridae family. [3–5] Based on phylogenetic analyses, on February 11, 2020, the Coronavirdae Study Group of the International Committee on Taxonomy of Viruses named the newly detected beta coronavirus as SARS-CoV-2. [6] By the end of February 2020, nearly 82,000 infections with the virus had been confirmed, resulting in more than 2,800 deaths globally. [7] On March 11, the World Health Organization (WHO) formally named the disease as COVID-19 disease and declared the outbreak as a pandemic. [8]

Remarkably, within a year of the first outbreak, numerous successful vaccines against the virus were developed, and mass vaccination campaigns in several nations decreased COVID-19 disease incidence and severity among the general population after two doses of vaccination. [9,10] Analysis of COVID-19 related morbidity and mortality has suggested that certain risk factors, such as- age >80 years, BMI >40 kg/m^2, diabetes, severe asthma and immunosuppressing conditions like cancer are linked to high mortality due to COVID-19 infection. [11] Unfortunately, these high-risk groups were not appropriately represented at the clinical trials of most of the widely accepted COVID-19 vaccines. Despite having a higher risk of mortality due to COVID-19 among immunocompromised and cancer patients, these highly vulnerable groups were excluded from major clinical trials while developing effective vaccines, and thus the question of efficacy, safety, and durability of the available vaccines in this population remains unanswered. [12]

Comparing the waves of SARS-CoV-2 infection in European nations in 2021, it was observed that patients with both active cancer and SARS-CoV-2 infection suffered from significantly high mortality rates during the first wave, where the rate was estimated to be around 40% and declined to roughly 25% in the succeeding waves. [13–16] In addition to the direct effect of the pandemic, the death rate of cancer patients faced an upward

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trend due to modified guidelines and reduced screening as a result of the imposed social restrictions. [17,18] Subsequent analyses have established the necessity of prioritizing immunosuppressed and cancer patients in the ongoing vaccination program, an effort backed up by numerous international societies and organizations. [19,20]

However, information about effect of immunosuppressive state, cancer and anti-cancer treatment on efficacy of COVID-19 vaccine is not yet well-circulated. This lack of awareness along with limited availability of vaccine slots are hindering the suggested dose-schedule modification of COVID-19 vaccine in immunosuppressed and cancer patients that was recommended by organizations such as ESMO, CDC and NCCN. In this systemic review, we aim to bridge this knowledge gap. We discussed potential effect of COVID-19 vaccines on malignancy and summarized the recommended dose-schedule of COVID-19 vaccine in patients with cancer, chemotherapy and other immunosuppressive states. Goal of this study is to represent the recommendation that will ensure optimum outcome of vaccination in immunosuppressed individuals. Furthermore, we have linked these suggestions with practical implication and indicated the scopes of future studies in the relevant field.

2. Inclusion criteria

We searched PubMed for publications from inception to 8th September 2022 using the search terms ('covid 19 vaccines' [MeSH Terms] OR ('covid 19' [All Fields] AND 'vaccines' [All Fields]) OR 'covid 19 vaccines' [All Fields] OR 'covid 19 vaccine' [All Fields]) AND ('cancers' [All Fields] OR 'neoplasms' [MeSH Terms] OR 'neoplasms' [All Fields] OR 'cancer' [All Fields]) AND ('patients' [MeSH Terms] OR 'patients' [All Fields] OR 'patient' [All Fields]) ('immunosuppression' [MeSH Terms] OR 'immunosuppression' [All Fields]). We reviewed articles published in only English that had any of the three criteria: included any information about the timing to receive vaccines, any information on the effect of different cancer therapies on the vaccine and information about vaccination and COVID-19 vaccination in immunosuppressed state. Based on their applicability to the parameters of this evaluation, the final reference list was created.

3. Discussion

Effect of Covid-19 vaccine on Cancer-treatment and screening

According to the recommendation of Infectious Diseases Society of America (IDSA 2013 recommendations), immunization with any kind of vaccine should not be delayed in immune-compromised or chronic inflammatory disease patients because there is no evidence that it might cause a flare-up or a beginning of such diseases. [21] All the COVID-19 vaccines currently approved use several platforms such as mRNA, protein sub-unit, and viral vectors to trigger an immune response against the disease. [22,23] Since none of them has live viruses in their composition, the chance of virus shedding, and reactivation of the virus after vaccination is minimal. Similarly, studies conducted in the past on cancer patients who received vaccinations including all the platforms currently utilized in the COVID-19 vaccines revealed no issues and mentioned them as being safe for cancer patients. [24–26] Although COVID-19 vaccine response in cancer patients is nearly equivalent to that of general population in most cases, this response showed a rapid decline in cancer patients following 3-6 months of the second dose. [27] Both ESMO and ASCO declared that there is no safety issue for COVID-19 vaccines for patients who are receiving chemotherapy, immunotherapy, or radiation therapy because these vaccines do not clinically interfere with these treatments. [28,29] In this group, vaccinations seemed to be generally fairly safe, with mostly mild and moderate side effects observed. [30] Reactogenicity events were the most frequent adverse events following the BNT162b2 mRNA vaccine. Among these, the most common were injection-site pain, fatigue, and pyrexia. No death was documented as a result of vaccination. [31] During immunotherapy, the SARS-CoV-2 BNT162b2 vaccine appears to be secure and provides cancer patients with a satisfying

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serologic status. In cancer patients receiving anti-PD-1/PDL1 therapy, the vaccination was effective in eliciting both humoral and cell-mediated immune responses. [32]

An important adverse effect of COVID vaccines in cancer patients to take into account is reactive lymphadenopathy close to the vaccine injection site, which might mimic metastasis and cause a diagnostic dilemma. [33] Around 16% of patients self-reported 'lumps and bumps' following Moderna vaccination, [34] whereas 0.3% of patients receiving Pfizer-BioNTech reported such incidence [35] Most commonly, the supraclavicular and ipsilateral axillary lymph nodes are involved. Even after the size has shrunk, the involvement may still be identifiable on a radiological scan as the lymphadenopathy may persist for 4-8 weeks after the second dose. [36] Radiologists have advised that routine imaging should be performed prior to the start of treatment or six weeks after the second dose of the immunization because this lymphadenopathy may resemble malignant involvement. Notably, imaging should not be postponed because of a vaccine, and imaging should not be delayed because of this interaction from a diagnostic or prognostic standpoint. [37] Similar advice was provided by the Society of Breast Imaging, which recommended routine breast imaging for breast cancer patients to be scheduled for 4-6 weeks after the second dose of the vaccine "where it does not unreasonably delay therapy." [38]

Suggested dose schedule for individual with cancer and immunosuppressed state

In general, cancer therapy does not impact significantly on efficacy of vaccine. [39] Vaccination is also considered safe in general, with presence of mild or moderate adverse effect in some cases. [30] However, the effect cannot be excluded completely in certain groups. Most of the major vaccination guidelines have suggested the immunosuppressed individuals to vaccinate for SARS-Cov-2 at the earliest time when vaccine is available. [40] Considering the severity of the pandemic, it is understandable that vaccination should not be delayed for the sake of ongoing immunosuppressed state or immunosuppressing therapy. But modification of dosage schedule should be considered to optimize the outcome.

Several immunosuppressing agents and anticancer therapies alter the cellular and humoral immune response, and thus affect the outcome of vaccination. Thus, dose schedule modification should be considered in such condition to minimize the interaction and ensure favorable outcome. Some studies suggested to monitor immune response of the at-risk group following vaccination group, [40] although it is not yet applied at mass level. Taking the severity of disease outcome into account, it is suggested that SARS-CoV-2 vaccination should be prioritized over other ongoing therapy. In most cases, it is encouraged not to delay the vaccination, rather subjects with ongoing immunosuppressing therapy or immunosuppressed condition should be considered with priority in vaccination program and should be vaccinated at the earliest available time. [41]

In general, while administering vaccine to an immunosuppressed individual, vaccination is encouraged to be administered at the time when immunosuppression is at the lowest level [21] IDSA has also recommended not to consider a vaccine dose as 'valid' when it is given during immunosuppressive therapy and subsequently failed to attain satisfactory protective antibody level. [21] In case of SARS-CoV-2 vaccination, large scale cohort studies such as the **VOICE** ('vaccination against COVID-19 in cancer'; clinicaltrials.gov identifier, NCT04715438). and **CAPTURE (**Coronavirus disease 2019 (COVID-19) Antiviral Response in a Pan-tumor Immune Study; clinicaltrials.gov identifier, NCT03226886) have not considered immunosuppressive therapy as a prominent factor to alter immune response to this vaccine [20,40] However, our review has found the following suggestions that might be considered to ensure an optimum outcome of vaccination:

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Table 1. Different immunosuppressed conditions related to cancer, anticancer treatment and inflammatory conditions are mentioned. Their impact on immune reaction, vaccine efficacy and suggested modified dose are subsequently stated. Abbreviations: AED (Adverse effect of Drug), IMP (investigational medicinal product), BTKi (Burton's Tyrosine Kinase inhibitor), SLE (Systemic Lupus Erythematosus), CAR-T (Chimeric receptor antigen T-cell therapy), MOA (Mechanism of Action).

Immunosuppressing states	Interaction with vaccine and immunity	Suggested dose schedule modification	Comments	Ref.
B-cell depletion	May show immunosuppression in following 6 months of therapy	4 weeks before or 6 months after starting therapy	Monitoring of vaccine response might be considered	[42]
Cytotoxic chemotherapy	Seroconversion after vaccination was present in 83% of study subjects, which is less than healthy counterpart. (>99% seroconversion)	1-2 weeks before or after initiation of treatment	Dose interval may prevent the overlapping of adverse effect from vaccination and chemotherapy	[41,43]
Profound Immune suppressed state	Granulocyte and lymphocyte depletion may subside immune response	Vaccination is suggested following recovery of absolute neutrophil count	In immunosuppressed and granulocyte depleted patients, Blood Cell count can be used to decide the appropriate time of vaccination	[41]
Clinical trial of surgical treatment	Stressful event may impair immune response	1 week prior to surgery, or after the patient has recovered from post operative complication(s)	Clinical stability might be considered while starting vaccination	[41]
Urgent initiation of anti-cancer drug regime	Immunosuppression depends on MOA of drug	After the patient achieves clinical stability	AED may mimic side-effect of vaccination	[41]
Immunosuppression therapy	Cell receptor specific therapy may alter immune response	2 weeks prior to initiation or continuation of chemotherapy cycle	Schedule of chemotherapy should be considered while vaccinating	[44]
Anti CD-20 therapy	May cause impairment of T-cell response, antibody response is lower (around 70%) following vaccination than non-treatment group	6 months after completion of therapy	Early third vaccine dose or double vaccine dose during first injection is suggested	[30,45]
Cellular therapy/ CAR-T cell therapy/ Monoclonal antibody therapy	Antibody response is lower than healthy individual	3-6 months after receiving therapy or 2 weeks before initiation of treatment	Patients should be monitored after vaccination to ensure sufficient response	[28,46–48]
Stem cell transplantation	May cause slow bone marrow response to vaccination	3 months following transplantation Or 2 weeks before initiation of treatment	Graft Versus Host disease should be considered, dosage schedule can be modified according to clinical condition	[28,46,47]
BTKi therapy	Diminished antibody response is observed following second dose of vaccination	Vaccinate before starting therapy	Post vaccination monitoring should be considered	[32,49]
SLE	Reduced Pool of Naïve B-cell can be caused by SLE treatment.	No association with flare or increased side effect of vaccine	Medication of SLE such as – Methotrexate and Mycophenolate mofetil results in poorer immune response; monitoring should be done on case-by-case basis	[50]

Patient on anti PD-1/ PDL1 therapy	Vaccine appears to trigger both humoral and cell mediated immune response	Sustained immune response present with regular dose schedule	No dose schedule modification is suggested	[32]
Hormonal therapy	Appropriate immune response is noticed after 28 days of booster dose	No dose modification is suggested	Observed antibody response is close to healthy individual	[51]
Patient with indolent lymphoma or anti lymphoma therapy	May not develop antibody response if vaccinated during ongoing therapy	Should be revaccinated after completion of therapy	Booster dose with alternative vaccine can be considered	[52]
Patients starting IMP as a part of clinical trial		Start trial 2-4 weeks after 2nd dose of Covid-19 vaccination	Applied for patients in phase 2 and 3 clinical trial,	[49]
Ongoing IMP treatment		Administer vaccine after dose limiting toxicity period is over	Useful for differentiating of toxic effect of vaccine and medication	[49]
Chronic inflammatory diseases		No prove of diseases getting triggered by vaccination	Vaccine should not be deferred or delayed for such conditions	[21]
Simultaneous other vaccine administration		14 days gap between Covid-19 vaccine and other approved vaccine when appropriate		[46]

4. Conclusion

Overall, vaccination should be prioritized for patient with cancer and immunosuppression. Modification of dose schedule is necessary to optimize the outcome of vaccination. Endorsement of this modification will validate the generalized application of the vaccine and promote inclusion of the high-risk groups. It will also prevent vaccine hesitancy in this already vulnerable group.

First step of promoting this modification is acknowledgement and knowledge sharing. Our systemic review is an effort towards that. Accepting the necessity of specific strategy for vaccination to this specific group will ensure a favorable outcome. This guideline should be standardized with further study and propagated among the beneficiaries. Approximation of booster doses of vaccine will also be helpful to develop a favorable response in these individuals. Targeted awareness build-up in health workers, patients and their families should be considered to establish this modified dose schedule. In the future studies of vaccination, these vulnerable immunosuppressed subjects should not be excluded, rather prioritized to ensure an inclusive and comprehensive guideline.

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