

Confirmation of Safety of COVID-19 mRNA Vaccination for Cancer Patients

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ABSTRACT

Patients in the active phase of treatment for cancer are a population at risk of coronavirus disease-19 (COVID-19) with poor prognosis. While a majority of patients treated for cancer expressed their will to be vaccinated as early as December 2020 in a French survey, no data were available in terms of vaccine efficacy and tolerance, because they were excluded from initial registration trials. Several clinical facilities aimed to assess the safety and immunogenicity of the BNT162b2 (Pfizer–BioNTech) vaccine in patients with cancer. In patients with cancer, one dose of the BNT162b2 vaccine yields poor efficacy. Immunogenicity increased significantly in patients with solid cancer within 2 weeks of a vaccine boost at day 21 after the first dose. However, the anti-SARS-CoV-2 immune response was lower in patients with solid tumors who were vaccinated a second dose of BNT162b2 vaccine than in healthy individuals. These data support prioritization of patients with cancer for an early (day 21) second dose of the BNT162b2 vaccine.

KEYWORDS: COVID-19 mRNA vaccination, COVID-19, SARS-CoV-2, COVID-19 vaccine

Compared to healthy individuals, the immune response of cancer patients after or during treatment with systemic chemotherapy is reduced. Therefore, there is an increased risk of death from the new coronavirus infectious disease 2019 (COVID-19) in cancer patients who have been or are being treated with systemic chemotherapy (1). Therefore, cancer patients are a high priority group for COVID-19 vaccination. However, no safety and efficacy data are available for the COVID-19 vaccine in cancer patients. Recent clinical studies found that all responders, with the exception of a single responder with haematological cancer, could neutralise the wild-type strain. Conversely, an additional three responders with solid cancer could not neutralise the variant of concern B.1.1.7 strain; moreover, in healthy controls, neutralisation titres for the variant of concern B.1.1.7 strain were significantly lower than for the wild-type strain. Although anti-S IgG titres and neutralisation correlated strikingly for healthy controls and for patients with solid cancer, previous clinical studies have reported statistically lower anti-SARS-CoV-2 antibody titers ($p < 0.0001$) in cancer patients with COVID-19 mRNA (BNT162b2) vaccinated compared to healthy subjects (Figure 1) (2,3,4,5,7). In addition, cancer treatment experts have pointed out that COVID-19 vaccination may induce or enhance immune-related adverse events (irAEs) in patients,

which have been treating with immune checkpoint inhibitors (ICIs) (8).

In the guidelines of the Japan Society of Clinical Oncology, the following contents are expressed

In general, immune checkpoint inhibitors have a long half-life in the body of patient with cancer, so the antiviral efficacy and safety of COVID-19 mRNA (BNT162b2) vaccination are unlikely to be affected by the timing of COVID-19 mRNA (BNT162b2) vaccination. Therefore, at this time, COVID-19 mRNA (BNT162b2) vaccination for patients with cancer is recommended during treatment with immune checkpoint inhibitors. However, fever is observed a few days after the COVID-19 vaccination, so Patients should refrain from COVID-19 vaccination within a few days prior to the start of treatment with immune checkpoint inhibitors.

Considering the high mortality due to COVID-19 in patients with cancer who are being treated, the data obtained from recent clinical studies support current guidelines and call for vaccination of patients being treated with immune checkpoint inhibitors, especially during pandemic surges.

An increase in anti-SARS-CoV-2 antibody titer by COVID-19 mRNA (BNT162b2) vaccination is observed after the second dose COVID-19 mRNA (BNT162b2) vaccination (9). Therefore, a second dose of the COVID-19 mRNA

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(BNT162b2) vaccine is much more important in cancer patients than in healthy individuals to prevent the severe illness of COVID-19.

So that cancer patients can be vaccinated with COVID-19 mRNA vaccine (BNT162b2) with confidence, medical researchers must carry out clinical studies with large cohorts to obtain safety and efficacy data for the COVID-19 mRNA vaccine (BNT162b2) in patients with cancer. Until the results of these clinical studies are achieved, cancer patients, like the general public, need to continue to wear masks and maintain social distance.

Ethical approval and consent to participate

This study was reviewed and approved by the Central Ethics Review Board of the National Hospital Organization Headquarters in Japan (Tokyo Japan). The authors attended a 2020 educational lecture on medical ethics supervised by the Japanese government. The completion numbers of the authors are AP0000151756 AP0000151757 AP0000151769 AP000351128.

Author Contributions

T.H. wrote the manuscript. N.Y. and I.K. provided with information on clinical medicine and reviewed our manuscript.

Disclosure

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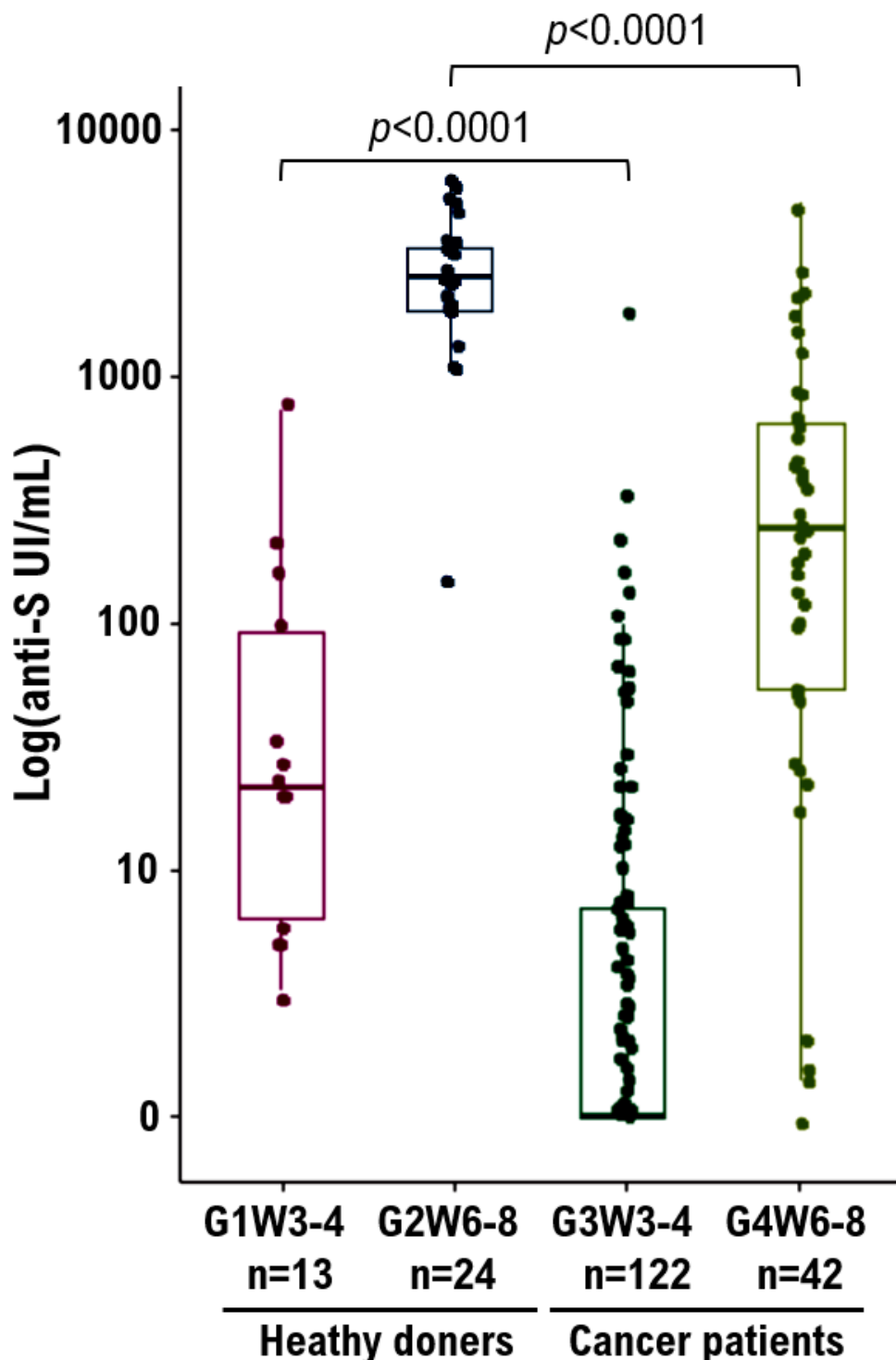


Figure 1 Humoral quantitative anti-spike (S) of SARS-CoV-2 antibody (logarithmic scale) response at week (w) 3-w4 and w6-w8 from dose 1 of BNT162b2 (Pfizer/BioNtech)messenger RNA (mRNA) vaccine in patients with active treatment for cancer group (G3 n 122 and G4 n 42) and in a healthy donors group (G1 n 24 and G2 42).G3W3-4: cohort of patients with active treatment for cancer at w3-w4/from dose 1 of BNT162b2 (Pfizer/BioNtech) mRNA vaccine (date of booster dose); G1W3-4:healthy donors group at w3-w4; G4W6-8: cohort of patients at w6-w8 from dose 1 of vaccine; G2W6-8: healthy donors group at w6-w8.