Serologic Status and Toxic Effects of the SARS-CoV-2 BNT162b2 Vaccine in Patients Undergoing Treatment for Cancer

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BACKGROUND

The COVID-19 pandemic has been associated with inferior clinical outcomes in patients with cancer, owing to altered delivery of care and potential high-risk for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection in distinct subpopulations.[1,2] The BNT162b2 vaccine, which is administered in 2 doses at a 21-day interval, was found to be safe and efficient in preventing COVID-19 in the general population.[3,4] However, patients with cancer under active treatment were not represented in these trials. In this study, the authors prospectively evaluated the serologic status and safety of the SARS-CoV-2 BNT162b2 vaccine in a cohort of patients with solid tumors who were receiving active anticancer treatments, compared with age-matched healthcare workers who served as vaccinated controls.

METHODS

In January 2021, mass SARS-CoV-2 vaccination of high-risk populations, including patients with cancer, was initiated in Israel. This cohort study prospectively enrolled and followed up patients with cancer and healthy participants between 15th January and 14th March 2021. The study was conducted at the Division of Oncology of Rambam Health Care Campus, the major tertiary (referral) medical centre in Haifa, Israel. Participants included 232 patients with cancer who were receiving active treatment after their first and second doses of the BNT162b2 vaccine, and 261 healthy, age-matched healthcare workers, who served as controls. Serum samples were collected after each vaccine dose and in cases of seronegativity. Questionnaires regarding sociodemographic characteristics and adverse reactions were administered at serum collection. A regulatory agencies–approved assay was used to assess IgG at all time points. Patients' electronic medical records were reviewed for documentation of COVID-19 infection and results of blood cell counts, liver enzyme levels, and imaging studies.

RESULTS

Of the 232 patients undergoing treatment for cancer, 132 were males (57%); mean (standard deviation) age was 66 (12.09) years. Cancer types included mostly gastrointestinal (27%), genitourinary (21%), lung (19%), and breast (18%) cancers. After the first dose of BNT162b2 vaccine, 29% (n=25) patients were seropositive compared with 84% (n=220) of the controls (p<0.001). After the second dose, the seropositive rate reached 86% (n=187) in the patients group. Testing rate ratios per 1,000 people days after the first dose were 12.5 (95% confidence interval

(CI): 3.4–45.7) for the patients, and 48.5 (95% CI: 37.2–63.2) for the controls. Patients undergoing chemotherapy showed reduced immunogenicity (odds ratio: 0.41; 95% CI: 0.17–0.98). No COVID-19 cases were documented throughout the study period; however, two cases in the patient cohort were noted immediately after the first dose. Reported adverse events were in concordance with previous reports comprising mostly healthy individuals. Elevation of liver enzyme levels was documented in 10.5% of patients with cancer. Newly documented axillary or cervical lymphadenopathy was noted in 5% of CT and PET scans that were performed as part of routine cancer care.

CONCLUSION

The SARS-CoV-2 BNT162b2 vaccine was found to be safe and achieved satisfactory serologic status in patients with cancer in this cohort study. A pronounced lag in antibody production was noted in patients with cancer compared with controls who do not have cancer; however, after the second dose, seroconversion occurred in most patients. Additional real-world data is required to determine the long-term efficacy of the vaccine with regard to type of anticancer treatment. ■

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