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SARS-COV-2 AND CANCER

1557O Adaptive immunity to SARS-CoV-2 infection and vaccination in cancer patients: The CAPTURE study

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Background: Patients with cancer are at increased risk of severe outcomes from COVID-19. Understanding the impact of SARS-CoV-2 infection and vaccination induced-immunity is an area of unmet need.

Methods: CAPTURE (NCT03226886) is a prospective longitudinal cohort study of COVID-19 vaccine or SARS-CoV-2 infection-induced immunity. SARS-CoV-2 infections were confirmed by RT-PCR and ELISA. Neutralising antibody titres (NAbT) against wild-type (WT) SARS-CoV-2 and variants of concern (VOC; Alpha, Beta, Delta) and SARS-CoV-2 specific T-cells (SsT-cells) were quantified.

Results: 118 patients (89% solid malignancy, [SM]) were SARS-CoV-2-positive (median follow-up: 154 days). 85% patients were symptomatic; 2 died of COVID-19. 82% had S1-reactive antibodies, of whom 89% had neutralising antibodies (NAbs); NAbT were lower against all VOCs. While S1-reactive antibody levels declined over time, NAbT remained stable up to 329 days. Most patients had detectable SsT-cells (76% CD4+, 52% CD8+). Haematological malignancy (HM) patients had impaired immune responses that were disease and treatment-specific (anti-CD20), but with evidence suggestive of compensation from T-cells. 585 patients were evaluated following 2 doses of BNT162b2 or AZD1222 vaccines, administered 12 weeks apart. Seroconversion rates after 2 doses were 85% and 54% in patients with SM and HM, respectively. A lower proportion of patients had detectable NAbs against SARS-CoV-2 VOC (Alpha 62%, Beta 54%, Delta 49%) vs WT (84%), with corresponding significantly lower NAbT. Patients with HM were more likely to have an undetectable NAb and had lower NAbT vs solid malignancies to both WT and VOCs. Seroconversion showed poor concordance with NAbTs against VOCs. Prior SARS-CoV-2 infection boosted NAbT including against VOCs. Anti-CD20 treatment was associated with severely diminished NAbTs. Vaccine-induced T-cell responses were detected in 80% of patients, with no differences between vaccines or cancer types.

Conclusions: Patients with HM had blunted humoural responses to infection and vaccination, particularly against VOCs, but preserved cellular responses might contribute to protection. Our results lend support to prioritisation of all cancer patients for further booster vaccination.

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1558O COVID-19 vaccine in participants (ptcpts) with cancer: Subgroup analysis of efficacy/safety from a global phase III randomized trial of the BNT162b2 (tozinameran) mRNA vaccine

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Background: Patients with cancer are at higher risk of developing COVID-19 disease, adverse outcomes, and increased mortality. Phase III COVID-19 vaccine trials have demonstrated safety/efficacy against COVID-19 and prevented hospitalizations and deaths; however, most excluded ptcpts with cancer. We present phase 3 tozinameran mRNA COVID-19 vaccine trial results from ptcpts with a cancer history at baseline, either ongoing or not, per the Charlson Comorbidity Index and up to 6 months of follow-up.

Methods: Between Jul 2020-Jan 2021, 46429 ptcpts ≥12 y at 152 sites in 6 countries were randomized in a placebo-controlled, observer-blinded trial of 2-dose tozinameran, showing 95% protection against COVID-19 and favorable safety (Polack et al *NEJM*, Dec 2020). After emergency use authorization, ptcpts were allowed to unblind and placebo recipients received vaccine. Data prior to unblinding for crossover up to 13 Mar 2021 are presented for ptcpts ≥16 y for safety and ≥12 y for efficacy. Adverse event (AE) data are controlled for follow-up time before unblinding and reported as incidence rate (IR) per 100-person-y of follow-up.

Results: Of ptcpts ≥16 y, 1647 had a prior diagnosis of cancer and were not on active immunosuppressive treatment (755 M; 892 F; median age 66 y [range 22-91]). Most common solid cancers included breast (n=458), prostate (n=360), and melanoma (n=210). AEs were reported at IRs of 94.0 (vaccine) and 49.3 (placebo) per 100-person-y; most common AEs were reactogenicity events (injection-site pain [IR: 40.2 vaccine; 4.2 placebo]; fatigue [IR: 21.4 vaccine; 7.6 placebo]; pyrexia [IR: 19.8 vaccine; 0.7 placebo]). 1 vaccine ptcpt withdrew due to a vaccine-related AE. No vaccine-related deaths were reported. Among ptcpts ≥12 y with cancer, 3 vaccine and 27 placebo recipients developed COVID-19 from 7 days post-Dose 2; vaccine efficacy (VE) was 89.7% (95% CI 66.5-98.0%). This compares favorably with overall VE of 91.1%. Updated results will be presented.

Conclusions: Tozinameran has similar efficacy/safety in ptcpts with cancer as in the overall population. These results inform tozinameran use in COVID-19 and in future trials in patients with cancer.

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