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15590 Efficacy and toxicity of BNT162b2 vaccine in cancer patients

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Background: Efficacy and safety profile of COVID-19 vaccines had been acquired from phase III studies. Nevertheless, cancer patients were not represented in these trials. In 1/2021 mass vaccination of high-risk population, including cancer patients, was initiated in Israel. We aimed to prospectively evaluate efficacy, immunogenicity and safety of BNT162b2 vaccine in cancer patients.

Methods: Cancer patients on active treatment were prospectively enrolled following first dose of BNT162b2 or after a second dose. Serum was collected after each dose and additionally in case of seronegativity. An age-matched cohort of healthcare workers served as controls. Questionnaires regarding sociodemographics and adverse reactions were employed at serum collection. FDA-approved assay was used to assess IgG at all time-points. Patients' electronic medical records were reviewed for documentation of COVID-19 infection, blood counts, liver enzymes and imaging studies.

Results: The study included 232 cancer patients and 261 controls. Following first dose 29% of patients were seropositive compared with 84% of controls ($p < 0.001$). Following second dose seropositive rate reached 86%. Rate per 1000-person days after first dose were 12.5 for patients and 48.5 for controls. Chemotherapy reduced immunogenicity (OR 0.41 [95%CI 0.17-0.98]). In seronegative patients, rate of documented leukopenia reached 39%. No COVID-19 cases were documented throughout the study period except two cases following the first dose. Reported adverse events resembled former published studies.

Conclusions: Our results indicate the BNT162b2 appear to be safe and effective in cancer patients. There is a pronounced lag in antibody production compared with non-cancer controls, however seroconversion occurred in most patients after the second dose. Future real-world data is warranted to determine the long-term efficacy of the vaccine with regard to type of anti-cancer treatment.

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15600 Prevalence and impact of COVID-19 sequelae on treatment pathways and survival of cancer patients who recovered from SARS-CoV-2 infection

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Background: The long-term impact of COVID-19 in cancer patients (pts) is undefined.

Methods: Among 2795 consecutive pts with COVID-19 and cancer registered to OnCovid between 01/2020 and 02/2021, we examined clinical outcomes of pts reassessed post COVID-19 recovery.

Results: Among 1557 COVID-19 survivors, 234 (15%) reported sequelae including respiratory symptoms (49.6%), fatigue (41%) and cognitive/psychological dysfunction (4.3%). Persisting COVID-19 sequelae were more likely found in males ($p = 0.0407$) aged ≥ 65 years ($p = 0.0489$) with ≥ 2 comorbidities ($p = 0.0006$) and positive smoking history ($p = 0.0004$). Sequelae were associated with history of prior hospitalisation

($p < 0.0001$), complicated disease ($p < 0.0001$) and COVID-19 therapy ($p = 0.0002$). With a median post-COVID-19 follow up of 128 days (95%CI 113-148), multivariable analysis of survival revealed COVID-19 sequelae to be associated with an increased risk of death (HR 1.76, 95%CI 1.16-2.66) after adjusting for sex, age, comorbidities, tumour characteristics, anticancer therapy and COVID-19 severity. Out of 473 patients who were on systemic anticancer therapy (SACT) at COVID-19 diagnosis; 62 (13.1%) permanently discontinued therapy and 75 (15.8%) received SACT adjustments, respectively. Discontinuations were due to worsening performance status (45.1%), disease progression (16.1%) and residual organ dysfunction (6.3%). SACT adjustments were pursued to avoid hospital attendance (40%), prevent immunosuppression (57.3%) or adverse events (20.3%). Multivariable analyses showed permanent discontinuation to be associated with an increased risk of death (HR 4.2, 95%CI: 1.62-10.7), whereas SACT adjustments did not adversely affect survival.

Conclusions: Sequelae post-COVID-19 affect up to 15% of patients with cancer and adversely influence survival and oncological outcomes after recovery. SACT adjustments can be safely pursued to preserve oncological outcomes in patients who remain eligible to treatment.

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15610 The future of the oncology workforce since COVID-19: Results of the ESMO Resilience Task Force survey series

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Background: The ESMO Resilience Task Force has investigated wellbeing since COVID-19 in relation to work, lifestyle and support factors in oncology professionals globally. We reported on the significant impact of the initial surge of the pandemic on wellbeing and job performance (Banerjee et al. 2021). As the pandemic continues, it is imperative to understand experiences and concerns to better inform support measures for the oncology workforce.

Methods: Three anonymous online surveys were conducted during the COVID-19 pandemic (S1, Apr/May 2020; S2, Jul/Aug 2020; S3, Feb/Mar 2021). Longitudinal analysis of responses at these timepoints were conducted. Here, we present responses to questions on job demands and resources, and perceived job performance since COVID-19 (JP-CV).

Results: We analysed 3894 individual responses (S1, n=1520; S2, n=942; S3, n=1432): 53% (n=1961/3731) female, 45% (n=1679/3731) ≤ 40 years, 31% (n=1132/3692) non-white ethnicity, >100 countries. There has been significant increases from S1 to S3 ($p < 0.001$) in feeling overwhelmed with workload (29% vs 45%); COVID-19-related clinical (14% vs 58%) and research (16% vs 64%) work; out-of-hours work (16% vs 41%), shift work (12% vs 26%) and overall working hours (17% vs 47%); and inadequate time for personal/family life (35% vs 45%). 59% (n=1156/1946) were

unable to take allocated annual leave. While JP-CV has improved (34% vs 49%, $p < 0.001$), there remained concerns about the negative impact of the pandemic on career development/training (43%), job security (37%) and international fellowship opportunities (76%). Overall, less than half had felt supported by their work management, professional societies or government, and/or had access to wellbeing support services. 25% ($n = 266/1086$) were considering changing their future career with 38% ($n = 100/266$) contemplating leaving the profession.

Conclusions: Since COVID-19, oncology professionals have reported increased job demands, concerns over career development/training and job security, and inadequate time for personal life. There is a real threat of potential attrition in the current workforce. National and international stakeholders must act together to ensure robust recovery plans as we emerge from the COVID-19 crisis.

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1562MO Effectiveness of COVID-19 vaccination in cancer patients: A nationwide Veterans Affairs study

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Background: Data is lacking about SARS-CoV-2 vaccination effectiveness in patients with cancer, particularly those on systemic therapy. This retrospective cohort study in the US national Veterans Affairs (VA) healthcare system reports the effectiveness of SARS-CoV-2 vaccination in cancer patients on and off active therapy during the first 140 days following administration.

Methods: This is a multicenter study of SARS-CoV-2 infection among vaccinated and unvaccinated Veterans vaccinated during the period from 12/15/2020 to 5/4/2021. Veterans with solid or hematologic malignancy who received systemic cancer-directed therapy at the VA at least one time between 8/15/2010 to 5/4/2021 were included. Vaccinated patients were exactly matched 1:1 to an unvaccinated control on race, VA facility, rurality of home address, cancer type, and treatment timing and modality with minimum distance matching on age. The primary exposure was receipt of a SARS-CoV-2 vaccine. The primary outcome was laboratory-confirmed SARS-CoV-2 infection. Vaccination effectiveness was defined as 1 minus the risk ratio of SARS-CoV-2 infection for vaccinated individuals compared to unvaccinated controls.

Results: 184,485 patients met eligibility criteria and 113,796 were vaccinated during the study period. Of these, 29,152 vaccinated patients were matched 1:1 to 29,152 unvaccinated or not yet vaccinated controls. As of a median 47 days of follow-up, overall vaccine effectiveness in the matched cohort was 58% (95% CI, 39 to 72%) starting 14 days after the second dose. Patients on chemotherapy within three months prior to first vaccination dose exhibited a 14-day post-second dose effective-

tiveness of 57% (95% CI -23 to 90%), versus 76% (95% CI 50 to 91%) for those on endocrine therapy and 85% (95% CI 29 to 100%) for those off systemic therapy for at least six months prior.

Conclusions: Vaccination is an effective strategy for preventing COVID-19 in cancer patients. However, effectiveness may be reduced in patients actively receiving immunosuppressive systemic therapy. Future study is needed to determine if these patients would benefit from post-vaccination serologies and/or a booster vaccination following completion of therapy.

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1563MO CoVigi phase IV multicentric trial evaluating COVID-19 vaccination adverse events and immune response dynamics in cancer patients: First results on antibody and cellular immunity

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Background: SARS-CoV-2 infection may be a threat for those undergoing active anti-cancer therapy. We aim to study adverse events, efficacy, and immune response in Covid-19 vaccinated patients focusing on possibly interfering therapy.

Methods: CoVigi is a prospective open-label multicentric phase 4 clinical study (EudraCT 2021-000566-14) enrolling patients on anti-cancer treatment. Vaccines from Pfizer-BioNTech, AstraZeneca, Johnson&Johnson, or Moderna are considered. Data on vaccination side effects, the onset and course of Covid-19, and quantitative analysis of anti-S and anti-N SARS-CoV-2 antibodies (Roche) and SARS-CoV-2 specific cellular response evaluated by IFN-gamma-release assay (Qiagen) and CD69 expression are recorded as follows: at the baseline (prior to the vaccination), prior to the 2nd dose, 4–8 weeks, 3, 6 and 12 months after the first dose.

Results: The trial was initiated on March 22th. As of May 4th, 152 solid cancer and 103 hemato-oncology patients were enrolled. From preliminary baseline data, 22% of solid cancer and 29% of hemato-oncology patients had detectable levels of anti-S antibodies with a median of 106 U/ml (range 1.4–3666) and 84 U/ml (range 0.75–2528), respectively ($p = 0.888$). Surprisingly, only 44% solid cancer and 53% of hemato-oncology patients with detectable antibodies prior to the vaccination referred on covid-19 in medical history. In the Ab-positive cohort, the IFN-gamma level upon both CD4 and CD8 stimulation was 0.04 pg/ml (IQR 0.02–0.13), the CD69 expression on NKT-like cells increased to 10.9% (IQR 6.6–17.3), whereas in the Ab-negative cohort was 0.00 pg/ml (IQR 0.00–0.01 and to 7.5% (IQR 4.0–10.1), respectively ($p < 0.001$ and $p = 0.079$).

Conclusions: Substantial number of cancer patients experienced SARS-CoV-2 infection during active anti-cancer treatment prior to vaccination, often with asymptomatic course. In SARS-CoV-2-immunized patients, we observed SARS-CoV-2 positive cellular response. The preliminary results with dynamics of immune response with 3-month follow-up will be presented at the conference. Acknowledgment: CZECRIN LM2018128, Roche Diagnostics, MMCI00209805, MHCZ/DRO (FNBR, 65269705).

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