

COVID and Immunotherapy

625 COVID-19 VACCINATION IN PATIENTS WITH RENAL CANCER OR MELANOMA RECEIVING IMMUNE CHECKPOINT INHIBITORS

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Background Patients with cancer are at high risk for severe COVID-19 disease and mortality¹; however, patients on active cancer treatment, including immune checkpoint inhibitors (ICI), were excluded from COVID-19 vaccine trials.^{2, 3} Thus, safety and efficacy of COVID-19 vaccination in patients receiving ICIs is not well described.

Methods We identified patients with renal cell carcinoma (RCC) or melanoma who received at least one dose of an FDA-authorized COVID-19 vaccine (vax+), with or without being on ICI, between the dates of December 1, 2020 and April 1, 2021, and had at least 3 months of documented follow up at Duke Cancer Center. Retrospective chart abstraction of patient encounters during three months following vaccination was performed. Patient characteristics included demographics and oncologic treatments. Primary outcome was adverse events attributed to vaccination; other outcomes included immune related adverse events (IRAE) following vaccination and subsequent COVID-19 infection.

patients (4%) and 0 patients developed COVID-19 infection after one and two vaccine doses, respectively.

Conclusions Amongst a heterogeneous population of patients receiving ICI therapy, COVID-19 vaccination appears to be well tolerated and safe. The higher rate of symptoms reported post-vaccination in patients receiving ICI therapy is likely related to more frequent follow up intervals versus control. The rate of new or worsening IRAEs post-vaccination is no higher than historically reported.^{4, 5} An update of this data with a larger cohort will be presented. Larger cohort studies of patients receiving ICIs are needed to fully assess the safety and efficacy of COVID-19 vaccination in this population; however, these data support the safety of vaccination in patients receiving ICIs.

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Abstract 625 Table 1 Baseline characteristics of ICI and control populations

Characteristic	Vax+ with ICI	Vax+ not on active treatment
Age, years		
Median (range)	70 (33 - 93)	72 (35-88)
Primary Cancer (N, %)		
Renal Cell Carcinoma	25, 49%	12, 52%
Melanoma	26, 51%	11, 48%
Gender (N, %)		
Male	38, 75%	8, 35%
Female	13, 25%	15, 65%
Treatment Regimen (N, %)		
Ipilimumab + Nivolumab	13, 25%	NA
Nivolumab	19, 37%	NA
Nivolumab + Cabozantinib	6, 12%	NA
Pembrolizumab	9, 18%	NA
Pembrolizumab + Axitinib	3, .9%	NA
Pembrolizumab + Lenvatinib	1, 2%	NA
COVID-19 Vaccine (N, %)		
Pfizer	34, 67%	18, 78%
Moderna	16, 31%	4, 17%
Johnson and Johnson	1, 2.0%	1, 4.3%

Results 51 study patients (vax+ with ICI) and 23 control patients (vax+ not on active treatment) were initially identified. Baseline characteristics are in table 1. 27.5% of ICI patients (N = 14/51) reported symptoms attributed to vaccination. Common symptoms reported by the ICI group were fever (9.8%; N = 5), chills (7.8%; N = 4), arm pain (7.8%; N = 4), myalgias (7.8%; N = 4), lymphadenopathy (7.8%; N = 4), headache (5.9%; N = 3), and diarrhea (3.9%; N = 2). None of these were reported in the control group. One patient in the ICI group developed a rash at the injection site, and one developed porokeratoses following the second dose. From the control group, one patient developed a stye and one patient developed PVCs. Five ICI patients (9.8%) developed a new or worsening IRAE requiring systemic steroids and/or treatment hold. These IRAEs included: colitis (N = 2), hepatitis, rash, and concurrent pancreatitis/colitis. Two ICI

<http://dx.doi.org/10.1136/jitc-2021-SITC2021.625>