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COVID-19 Vaccine-Related Adverse Events in Solid Cancer Patients Treated with Immunotherapy

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ABSTRACT

Little data are available regarding the effects of COVID-19 vaccine in cancer patients undergoing immunotherapy. Thereby, COVID-19 vaccine-related adverse events were monitored through a short questionnaire in solid cancer patients receiving immunotherapy. A total of 95 patients were included in this study. Two doses of vaccines were administered to cancer patients which mainly received Pembrolizumab (51.1%). Respectively 78.2% and 62.2% of patients reported no adverse events after the first and the second dose regardless of the type of vaccine used. Considering the high mortality rate due to COVID-19 among cancer patients, this study demonstrated the good tolerance of COVID-19 vaccine.

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Introduction

Immune checkpoint inhibitors (ICIs) have become a part of cancer treatment, and demonstrated impressive survival results in several malignancies. These blocking antibodies are particularly used in melanoma, lung, and bladder cancer, head or neck squamous and renal carcinoma. Immunotherapy induces immune system activation leading to cancer cells destruction. These checkpoints inhibitors targeted (i) PD-1 (programmed cell death1 protein: Pembrolizumab (Keytruda), Nivolumab (Opdivo), Cemiplimab (Libtayo)), (ii) PD-L1 (programmed cell death-ligand1: Atezolizumab (Tecentriq), Avelumab (Bavencio), Durvalumab (Imfinzi)), and CTLA-4 (cytotoxic T-lymphocyte-associated protein 4: Ipilimumab (Yervoy)). These molecules are known to induce immune-related adverse events (irAEs) (1). According to a recent retrospective review, the frequency of all grades of irAEs is estimated at 44.63%, resulting in treatment discontinuation in 11.73% of cases (2).

Cancer patients infected with SARS-CoV-2 are more likely to have severe events, requiring invasive ventilation or intensive care unit admission according to a nationwide analysis in China (3). Furthermore, cancer patients had worse endpoints from severe acute respiratory SARS-CoV-2 disease (4,5). Mortality rate for infected cancer patients ranged from 3.7 to 61% depending on cancer location (6,7). Indeed, this fatality rate was higher in patients with hematological malignancies compared to patients with solid tumors (37 vs. 25%). The probability of death in this population was 25.6% (95% CI: 22.0–29.5%; $I^2 = 48.9\%$) in a pooled analysis of 25 studies (8). However, the pooled in-hospital mortality risk among patients with COVID-19 and cancer was 14.1% in Zarifkar meta-analysis (9).

Two mRNA-based vaccines (BNT162b2, Pfizer Inc./BioNTech SE; mRNA-1273, Moderna Inc.) and chimpanzee adenovirus vectored vaccine ChAdOx1 nCoV-19 (AZD1222) have been approved by the European Medicines Agency (EMA) (10). Based on scientific data, several studies and recommendations support the priority to provide COVID-19 vaccine to patients with active cancer (11–13). To date, little data are

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available regarding the effects of COVID-19 vaccine in cancer patients. A recent observational study showed that SARS-CoV-2 mRNA vaccines were generally well tolerated in cancer patients (14). In the same study, no toxicities were reported in 54% of cancer patients receiving the first dose of BNT162b2 (14). Moreover, a recent retrospective study which included 81 patients treated with ICIs showed no increased risk of irAEs onset after mRNA COVID-19 vaccines (15). Thus, the aim of this study was to analyze the frequency of adverse events in cancer patients treated with ICIs and who received COVID-19 vaccine.

Materials and methods

We performed this study to analyze the frequency of irAEs in cancer patients treated with ICIs and who received COVID-19 vaccine. The ethical approval was obtained from the representative of the General Data Protection Regulation of the Saint Etienne university hospital. According to clinical trials legislation, all included patients provided their oral consent to participate to this research.

Study population

Patients were identified from the prescription software provided by the pharmacy department. All patients treated for solid cancer in medical oncology department with immunotherapy between 1 March 2021 and 31 May 2021and who received two doses of COVID-19 vaccine were included in this study. Patients with COVID-19 history and who received only one dose of COVID-19 vaccine according to the recommendation was also included. The French COVID-19 vaccination campaign of cancer patients began on December 2020. Patients who have not received COVID-19 vaccine as well as patients who received the first dose of vaccine before immunotherapy initiation were excluded from this study. Furthermore, patients treated for hematological cancer were not included, because they are not treated in our department.

Assessment

Demographic data and medical history were collected from the patient's medical file. The clinical research associate collected through a short questionnaire the dates of the two injections (first and second dose), the type of vaccines received as well as the adverse events reported by patients one week after the vaccine injection. The rate of the toxicities was analyzed at two time-points: after the 1st and after the 2nd dose of vaccine.

Statistical analysis

Patient characteristics were described using numbers and proportions for categorical variables and using mean, standard deviation, median, and interquartile range for continuous variables. Subgroup descriptions according to the type of vaccine and immunotherapy were also performed. Factors associated with the occurrence of post-vaccination adverse events (either after the first or second dose) were studied using Wilcoxon-Mann-Whitney tests for continuous variables and Chi-2 or Fisher tests for categorical variables. Patients who received only one injection during the study period or had missing data on adverse events after one of the two vaccine doses were excluded from this analysis. Studied factors were the time from the start of immunotherapy to the first vaccine injection, PD-L1 status, presence of bronchopulmonary metastasis, presence of hypertension, diabetes, dyslipidaemia, peripheral arterial disease, anxiety or depressive syndrome, type of vaccine (messenger RNA or adenovirus), use of immunotherapy with Pembrozilumab, Nivolumab, and Atezolizumab.

All results are presented as odds ratios and all tests were performed with a two-sided alpha risk of 5%. Statistical analyses were performed with R software version 4.0.2.

Results

Patient characteristics

A total of 95 of patients (34 men and 61 women), received COVID-19 vaccine while receiving immunotherapy were included in this study (Figure 1). The median age of this cohort was 69

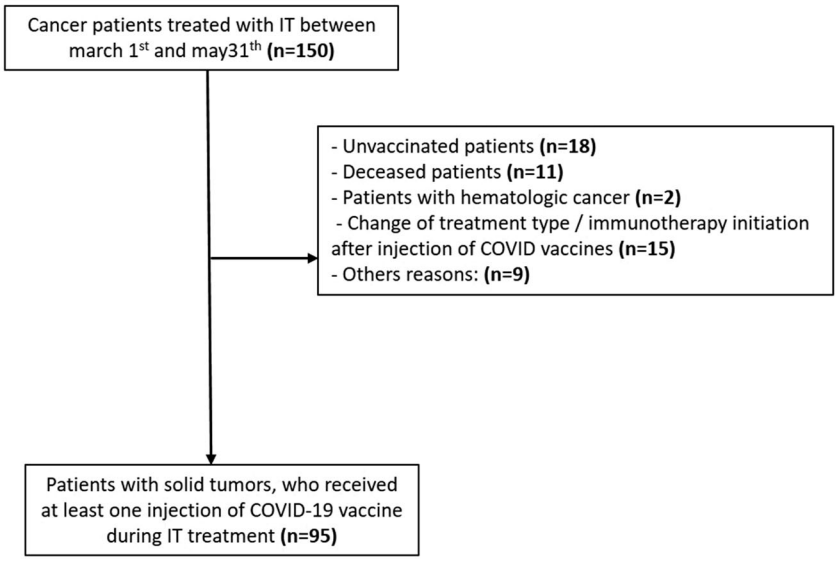

Figure 1. Flowchart of the study.

(IQR, 63.5–74). Regarding to body mass index (BMI), 40% of patients were overweight, while 14.5% were obese (Table 1). Seventy percent of patients had at least one comorbidity. Seventy eight percent of patients had cardiovascular disease, while 7.4% had chronic pulmonary disease. Most of patients (51.5%) included in this cohort had lung cancer, followed by kidney cancer (14.8%) and bladder cancer (11.6%). Among all patients, 85.3% had a metastatic disease. The main metastatic sites were lymph nodes (38.9%), bronchopulmonary system (26.3%), and bone (26.3%). In this cohort, 16.8% were active smokers, while 57.9% were ex-smokers. Of note, nine patients had a history of COVID-19. All patients' characteristics are summarized in Table 1.

Treatment characteristics

The two doses of vaccines were given to cancer patients receiving mainly either Pembrolizumab (51.1%), Nivolumab (18.75%) or Atezolizumab (11.3%). The Pfizer-BioNTech vaccine was mostly used (54.7% at 1st dose), followed by Moderna (33.6% at 1st dose) and finally AstraZeneca, for which the 1st dose was administered only to three patients. The median duration between immunotherapy initiation and the first dose of the COVID-19 vaccine was 146.5 days [IQR: 32.75–333.25]. The median duration between the first and second dose of vaccine was 28 days [IQR: 27–31] (Table 2).

Adverse events assessment

After the first dose of COVID-19 vaccine, 78.2% of patients declared no vaccine related adverse events. Injection site pain (11.5%), hyperthermia (4.6%), and asthenia (4.6%) were the main adverse events reported by patients. Furthermore, 62.2% of patients reported no adverse events after the second dose of vaccine. Hyperthermia (17.1%), asthenia (15.8%), and injection site pain (8.5%) were the main adverse events reported by patients after the second dose of vaccine injection. Only one patient reported an increase of blood pressure associated with high levels of thyroid stimulating hormone (TSH) (Table 3). Only one suspected case of pancreatitis requested a pharmacovigilance survey on the accountability of either immunotherapy or possibly the second dose of Pfizer-BioNTech vaccine (Table 4).

Univariate analysis

An univariate logistic regression was performed to identify any potential predictor factor correlated with high rate of the adverse events. No factor was significantly associated with an increase in vaccine related adverse events. Comorbid conditions (High blood pressure [OR: 0.83(0.33–2.08) $p = 0.68$)], diabetes [OR: 0.98 (0.29–3.17) $p = 0.97$)], cardiovascular diseases [OR: 0.86 (0.20–3.29) $p = 1$)]) were not associated with a higher rate of vaccine related adverse

Table 1. Patients' characteristics.

Patient characteristics ($n = 95$)	*N* (%)
Gender	
Female	61 (64.2)
Male	34 (35.8)
Age (years)	
Median [Q1–Q3]	69 [63.5–74]
BMI (kg/cm^2)	
Underweight	6 (6.3)
Normal range	37 (38.9)
Overweight	38 (40)
Obesity class I	10 (10.5)
Obesity class II	4 (4.3)
Comorbidities (1 pathology and more)	
Yes	67 (70.5)
No	28 (29.5)
If comorbidities	
Cardiovascular disease	74 (78)
Hypercholesterolemia/dyslipedemia	24 (25.3)
Diabetes	17 (17.9)
Depression	14 (14.7)
Chronic pulmonary disease	7 (7.4)
Renal failure	5 (5.3)
Dysthyroidism	2 (2.1)
Digestive diseases	3 (3.3)
Other	10 (13)
Smoking status	
Current smoker	16 (16.8)
Ex-smoker	55 (57.9)
Never smoker	17 (17.9)
Not specified	7 (7.4)
Alcohol drinking status	
Current drinker	12 (12.6)
Ex-drinker	6 (6.3)
Non-drinker	37 (39)
Not specified	40 (42.1)
Solid cancer localization	
Lung	49 (51.5)
Kidney	14 (14.8)
Bladder	11(11.6)
Head and neck	8 (8.4)
Melanoma	4 (4.2)
Colon	2 (2.1)
Liver	2 (2.1)
Breast	2 (2.1)
Ovarian	1 (1.1)
Pineal gland	1 (1.1)
Stomach	1 (1.1)
Metastatic cancer	
Yes	81 (85.3)
No	14 (14.7)
Metastasis localization	
Lymph node	37 (38.9)
Bronchopulmonary	25 (26.3)
Bone	25 (26.3)
Liver	15 (15.8)
Adrenal gland	16 (16.8)
Central nervous system	16 (16.8)
Mediastinum	12 (12.6)
Peritoneum	5 (5.3)
Pleura	5 (5.3)
Diaphragm	2 (2.1)
Other	9 (9.7)
COVID-19 history	
Yes	9 (9.7)

Table summarizing patient's demographic and clinical characteristics. BMI: body mass index.

events. Likewise, the presence of bronchopulmonary metastasis [OR: 1.25 (0.43–3.60) $p = 0.67$)] or the type of immunotherapy administered had no impact on the frequency of vaccines-related – adverse-events (Table 5).

Discussion

Few studies investigate the efficacy of vaccination for cancer patients receiving immunotherapy (16). Inactivated vaccines seem to induce humoral response and may raise irAEs in cancer patients treated with ICIs (16,17). Little data are available regarding the safety of COVID-19 vaccine in cancer patients undergoing active immunotherapy treatment. This study did not report an increased frequency of toxicities after COVID-19 vaccination among cancer patients treated with ICIs, therefore supporting previous retrospective studies (15,17). This study was characterized by the prospective dimension in the collection of toxicities related to the vaccine. Indeed, after the first dose of COVID-19 vaccine, 78.2% of patients declared no toxicities related to the vaccine. Similarly, the short-safety of BNT126B2 was observed in a cohort of 134 cancer patients receiving ICIs (18). Interestingly, 2 patients of this cohort received a combination of two ICIs. The patients who received Durvalumab and Tremelimumab experienced only injection site pain, and the second patient who received Nivolumab and Ipilimumab association had hyperthermia, sweats and asthenia. However, serological studies in this population are lacking in this study. They should be performed to analyze the immune response following COVID-19 vaccine, given that cancer patients were largely excluded from the initial clinical trials testing the vaccines. Indeed, 46% of patients with various hematological malignancies did not produce antibodies and were considered as vaccine non-responders (19). Furthermore, one dose of the BNT162b2 vaccine had poor efficacy in cancer patients (14). Indeed, after 3 weeks of a single dose vaccination, immunogenicity was low in 38% of patients with solid tumor, and in 18% of patients with hematological cancer (14). Moreover, in this cohort, cancer patients with COVID-19 history well tolerated the single dose of COVID-19 vaccine. In this cohort, vaccine hesitancy was estimated at 10.5%. This parameter is multifactorial consisting of cognitive, psychologic, socio-

Table 2. Treatment characteristics.

		First COVID-19 vaccine dose ($n = 87$) N (%)	Second COVID-19 vaccine dose ($n = 82$) N (%)
Immunotherapy	Pembrolizumab	49 (51.6)	46 (50.5)
	Nivolumab	16 (16.8)	17 (20.7)
	Atezolizumab	11 (11.6)	9 (11)
	Avelumab	4 (4.2)	4 (4.9)
	Durvalumab	4 (4.2)	3 (3.7)
	Cemipilimab	2 (2.1)	2 (2.4)
	Durvalumab + Tremelimumab	1 (1.1)	–
	Nivolumab + ipilimumab	–	1 (1.2)
Vaccines	Type of vaccine	($n = 87$)	($n = 82$)
	Pfizer-BioNTech	52 (54.7)	50 (52.6)
	Moderna	32 (33.6)	31 (32.6)
	Astrazeneca	3 (3.15)	1 (1.05)
	Vaccine not done	($n = 8$)	($n = 13$)
	IT not yet started	8 (8.4)	–
	COVID-19 history	–	9 (9.5)
	Switch to another treatment	–	4 (4.2)

Median duration between IT initiation to the first dose of vaccine in days [Q1–Q3]: 146.5 [32.75–333.25].
Median duration between first and second dose of vaccine in days [Q1–Q3]: 28 [27–31].
Table summarizing the different immunotherapies and COVID-19 vaccines administered in the cohort. (IT: immunotherapy).

Table 3. Adverse events assessment. Table summarizing all the different adverse events reported by the patients receiving COVID-19 vaccine during immunotherapy treatment.

	First COVID-19 vaccine dose ($n = 87$)			Second COVID-19 vaccine dose ($n = 82$)		
	N (%)			N (%)		
Vaccine type/adverse events reported by patients (1 week after injection)	Pfizer-BioNTech	Moderna	AstraZeneca	Pfizer-BioNTech	Moderna	AstraZeneca
None	41 (78.8)	24 (75)	3 (100)	34 (68)	16 (51.6)	1 (100)
Asthenia	3 (5.8)	1 (3.1)	0	5 (10)	8 (25.8)	0
Hyperthermia	2 (3.8)	4 (12.5)	0	5 (10)	9 (29)	0
Myalgia	2 (3.8)	1 (3.1)	0	2 (4)	2 (6.5)	0
Injection site pain	7 (13.5)	3 (9.4)	0	6 (12)	1 (3.2)	0
Hematoma	0	2 (6.3)	0	–	–	–
Headache	2 (3.8)	0	0	4 (8)	1 (3.2)	0
Erythema	0	1 (3.1)	0	1 (2)	0	0
Chills /tremor	1 (1.9)	0	0	0	4 (13)	0
Drowsiness	0	1 (3.1)	0	–	–	–
Vomiting	1 (1.9)	0	0	–	–	–
Abdominal pain	–	–	–	2 (4)	1 (3.2)	0
Anorexia	–	–	–	0	1 (3.2)	0
Confusion	–	–	–	0	1 (3.2)	0
Watering	–	–	–	1 (2)	0	0
High blood pressure	–	–	–	0	1 (3.2)	0
Hypothyroidism	–	–	–	0	1 (3.2)	0
Nausea	–	–	–	1 (2)	0	0
Sweats	–	–	–	0	2 (6.5)	0

Table 4. Description of suspected adverse events that requested a pharmacovigilance survey.

Sex	Cancer	Antineoplastic drugs	Vaccine	Time to onset of symptoms after vaccination	Diagnosis	irAE evolution	Comment
F	Lung	Alimta + pembrolizumab	Moderna	18 days	Acute pancreatitis	Regression	Patient with no comorbidities

irAEs: immune-related adverse events.

demographic, political and cultural factors (20,21). In this context, larger studies are needed to identify barriers to vaccine acceptance particularly in patients with chronic diseases.

A real-world digital cohort with 19,586 participants demonstrated that serious COVID-19 vaccine adverse events were rare. The strongest factors associated with adverse events were vaccine dose, vaccine brand, age, and female sex and history of COVID-19 (22). Conversely, no factor was significantly associated with an increase in vaccine related adverse events in this cohort. The main limitations of this study are the short duration of the follow-up, the small sample size and

Table 5. Univariate statistical analysis.

		Adverse events			
Variables	Modalities	*N* (*n* = 42)	*Y* (*n* = 32)	OR (IC95%)	*p* Value
High blood pressure	N	19 (54.3)	16 (45.7)	Ref	–
	Y	23 (59.0)	16 (41.0)	0.83 (0.33–2.08)	0.68
Diabetes	N	34 (56.7)	26 (43.3)	Ref	–
	Y	8 (57.1)	6 (42.9)	0.98 (0.29–3.17)	0.97
Dyslipidemia	N	30 (55.6)	24 (44.4)	Ref	–
	Y	12 (60.0)	8 (40.0)	0.83 (0.29–2.35)	0.73
Heart disease	N	36 (56.2)	28 (43.8)	Ref	–
	Y	6 (60.0)	4 (40.0)	0.86 (0.20–3.29)	1
Anxiety and/or depression	N	37 (58.7)	26 (41.3)	Ref	–
	Y	5 (45.5)	6 (54.5)	1.71 (0.47–6.50)	0.51
Nivolumab (at the first and/or second injection)	N	32 (54.2)	27 (45.8)	Ref	–
	Y	10 (66.7)	5 (33.3)	0.59 (0.17–1.88)	0.38
Pembrozilumab (at the first and/or second injection)	N	21 (65.6)	11 (34.4)	Ref	–
	Y	21 (50.0)	21 (50.0)	1.91 (0.75–5.04)	0.17
Atezolizumab (at the first and/or second injection)	N	37 (56.9)	28 (43.1)	Ref	–
	Y	5 (55.6)	4 (44.4)	1.06 (0.24–4.35)	1
Type of vaccine	Messenger RNA	13 (48.1)	14 (51.9)	Ref	–
	Adenovirus	29 (61.7)	18 (38.3)	0.58 (0.22–1.50)	0.25
Time between Immunotherapy – first injection	–	279.1 (292.6)	233.9 (315.2)	1 (1.00–1.00)	0.32
Bronchopulmonary metastasis	N	32 (58.2)	23 (41.8)	Ref	–
	Y	10 (52.6)	9 (47.4)	1.25 (0.43–3.60)	0.67

Y: Yes; N: No; OR: odd ratio.

the lack of serological measurements. Considering the high mortality rate from COVID-19 among cancer patients, this study promotes COVID-19 vaccines in patients undergoing ICIs treatments as no serious adverse events were reported. Further prospective studies are needed to investigate serological protection of COVID-19 vaccines and the frequency of irAEs in cancer patients.

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