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Immune Response to SARS-Covid 19 Vaccine in Patients with Cancer: Prospective Study at the Oncology-Radiotherapy Department/Oncology and Hematology Hospital of Marrakech

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Abstract **Original Research Article**

The world has experienced the SARS-Covid 19 virus disease pandemic since 2019, which has required the implementation of multiple preventive measures aimed at protecting against this infection may be serious in patients at risk, in particular cancer patients (high incidence of immunosuppression and comorbidities). In Morocco, the anti-Covid 19 vaccination started in January 2021. The scientific committee recommended the vaccination of all cancer patients using two doses except for under-vaccinated patients. We carried out a prospective observational study with 30 patients followed in our center and received an anti-Covid 19 vaccination for a period of four months. The objectives of our study were to evaluate the qualitative immunological response in this population at risk and to review the tolerance of vaccination. We conducted a prospective observational study about 30 patients followed in the Oncology-Radiotherapy department at the Hospital of Oncology and Hematology of Marrakech, a recruitment from different sites of our department was done: medical consultation, outpatient clinic, hospitalization unit and at the radiotherapy technical platform for a period of four months (from May 3, 2021 to August 31, 2021). We recruited 36 patients from different departments of our center, the average age of our patients was 49 years [38-67]. Breast location was dominant (22%) followed by UCNT (16%). The localized stage of the disease was the most frequent (88%). At the time of recruitment, 44% of patients were undergoing radiotherapy, 38% were receiving chemotherapy, 16% hormone therapy and 11% of patients were undergoing post-treatment follow-up. Six of our patients (16%) had seropositivity before receiving the first vaccine dose indicating a latent infection and were excluded from our series. All our patients received the Synopharm® vaccine. After the first vaccine dose, 04 patients (13%) showed positive serology in favor of a vaccine response, while 07 patients (23%) showed positivity after the second vaccine dose. Most of our patients showed good tolerance to vaccination with mild side effects: Asthenia (16%), headaches (5%), myalgia (5%) resolving after an average period of 02 days. Our study highlights the good tolerance of the anti-SARS Cov-19 vaccine in cancer patients, the response rate in our study remains average (36%), additional doses may be necessary in order to achieve better protection.

Keywords: SARS-Covid 19 virus, anti-Covid 19 vaccination, hospitalization, Synopharm® vaccine.

INTRODUCTION

The world experienced the Corona virus disease (Covid-19) pandemic since 2019, which necessitated the introduction of multiples preventive measures aimed at the protection against this infection which can be severe in patients at risk, especially cancer patients. Patients who have cancer are predisposed to an increased incidence of immune defiscience, cardiovascular disease, abnormal kidney function, and pulmonary insufficiency, all of which may affect the severity of Covid-19 infection and complications [1]. Vaccines have been developed and shown to be efficacious and are already being deployed worldwide, but patients with cancers were excluded from COVID-19 vaccine clinical trials, there is many concern about efficacy and the safety profile of vaccines in this population of patients [2]. In Morocco, anti Covid 19 vaccination began in January 2021 and the scientific committee recommended vaccination for all patients

with cancer using two doses except for patients undergoing chemotherapy. We perform a prospective observational study about 30 patients followed in our department unit and receiving an anti-Covid 19 vaccination for a period of four months. The objectives of our study were to assess the qualitative immunological response to the vaccination and its safety in these patients.

PATIENTS AND METHODS

We conducted a prospective observational study about 30 patients followed in the department of Oncology-Radiotherapy at the Oncology and Hematology Hospital of Marrakech. Recruitment was from the different sites of our department: medical consultation, outpatient clinic, hospitalization unit and radiotherapy technical platform for a period of four months (from 03 Mai 2021 to 31 August 2021).

Inclusion Criteria

- Voluntary patient in our department for histologically confirmed cancer regardless of the location and the stage of the disease

Exclusion Criteria:

- Patients with previous Covid infection
- Poor performance status (WHO 3)

Design:

- Three qualitative serological assays were performed for each patient (IgG-like antibodies):
  - 1st: at requirement
  - 2nd: three weeks after the first vaccine dose
  - 3rd: Three weeks after the second vaccine dose

Data collection was done by completing an individual information sheet for each patient, then recorded on Excel® software.

RESULTS

During a period of four months, we sign-up 36 patients from different departments of our center, average age of our patients was 49 years old (38-67). Breast cancer location was dominant (22,2%) followed by nasopharyngeal cancer (16,7%).

The localized stage of disease was the most frequent (89%) while metastatic disease was present in 11% of patients. At the moment of recruitment, 44% of patients were undergoing radiotherapy, 38% were receiving chemotherapy (in between chemotherapy treatment), 16% endocrine therapy and 11% of patients were undergoing post-treatment follow-up (Table1).

Table 1: Locations, stage and current treatment of patients of our study

Cancer location	N (%)	Stage	Current treatment
Breast	8 (22,2%)	Localized: 75% Metastatic: 25%	Radiotherapy: 4 Chemotherapy: 2 Follow-up: 2
Nasopharyngeal	6 (16,7%)	Localized : 100%	Radiotherapy: 5 Chemotherapy: 5 Follow-up: 1
Sarcoma	4 (11,1%)	Localized : 100%	Chemotherapy: 2 Follow-up: 2
Cervix	4 (11,1%)	Localized : 100%	Radiotherapy: 4 Chemotherapy: 4
Uterus	2 (5,5%)	Localized : 100%	Chemotherapy: 1 Follow-up: 1
Vulva	1 (2,8%)	Localized : 100%	Radiotherapy: 1
Glioblastoma	1 (2,8%)	Localized : 100%	Radiotherapy: 1
Prostate	3 (8,4%)	Localized : 100%	Radiotherapy: 3 Endocrine therapy: 3
Lung (SCLC)	4 (11,1%)	Localized: 75% Metastatic: 25%	Radiotherapy: 2 Chemotherapy: 2
Parotid gland	1 (2,8%)	Localized : 100%	Radiotherapy: 1
stomach	2 (5,5%)	Localized: 50% Metastatic : 50%	Chemotherapy: 2

The first serological test was performed before receiving any vaccine dose, it was positive in 6 of our patients (16,7%), indicating a latent infection, those patients were excluded from next serological tests. Regardless of the various types of vaccines available in the vaccination centers, all of our patients have received the Sinopharm® vaccine. Three weeks after the first vaccine dose, 04 patients (13,3%) presented a positive serology in favor of a vaccine response, while 07 patients (23,3%) presented a positivity after the second vaccine dose making a total of positive response rate of 36,6%. Most of our patients showed good tolerance to

vaccination with mild side effects: asthenia (16%), headaches (5%), myalgia (5%) resolving after an average period of 02 days (Table 2).

Table 2: Results of serological test before and after dose of vaccine

Serological test	Before vaccine dose	After 1st vaccine dose	After 2nd vaccine dose	Total
Positive	6 (16,7%)	4 (13,3%)	7 (23,3%)	11 (36,6%)
Negative	30 (83,3%)	26 (86,7%)	23 (76,7%)	19 (63,4%)

DISCUSSION

The COVID-19 pandemic has highlighted the issue of whether patients with cancer; either receiving active treatment or having survived cancer; are more vulnerable to the virus disease and its aftereffects than people without cancer.

Due to the complexity of health issues in cancer patients, the diversity of malignancies and treatments and the limited number of individuals with both COVID-19 infection and cancer, the risk of death and serious complications due to the virus has been a challenge to define.

Oncologists and their patients have had to make difficult decisions aimed at limiting potential exposure to the COIVD-19 virus, that sometimes, have influenced treatment choices and in some cases, clinical outcomes [1]. Because of that, vaccinating this category of patients at high risk for severe COVID takes priority.

Considerations of expected safety and efficacy differ by each therapy, based on their general mechanisms and associated immune alterations [3]:

- For patients treated with cytotoxic chemotherapies: with the exception of during periods of intensive chemotherapy, patients undergoing chemotherapy are expected to generate protective responses with COVID-19 vaccination [3].
- For patients treated with targeted therapies, it is reasonable to expect that patients being treated with targeted therapies will generate protective responses with COVID-19 vaccination [3].
- For patients treated with immune checkpoint inhibitors, we expect that patients on immune checkpoint inhibitor therapy should make protective responses with COVID19 vaccination. Whether Immune-related adverse events (IRAEs) increase after COVID19 vaccinations warrants close study. In the meantime, it might be more safe, from a cancer treatment perspective, to delay treatment with immune checkpoint inhibitors in some circumstances [3, 4].
- For patients treated with radiation therapy, commonly used for patients with malignancies in both curative and palliative settings. While it is known that radiation involving a large part of the body can indeed have impact on the bone marrow, it is rare for radiation to impact significatively the immune system to the point where vaccination would not be recommended. The main situation for radiation to affect immune cell generation is in case of total body irradiation (TBI) given for marrow suppression prior to stem cell transplantation or other rare situations where patients are receiving total lymph node or spine irradiation. Therefore, most patients treated with radiation should generate protective immunity responses to COVID-19 vaccines [3].

Because cancer patients were excluded from COVID-19 vaccine clinical trials, there is concern about efficacy and the safety profile of vaccines in this setting [2]. Publications focusing on patients with cancer reported weak immunogenicity after a single dose[5], but efficient immunogenicity after two doses of the BNT162b2 COVID-19 vaccine [6, 7], as well as lower rates of neutralizing antibodies after 1 dose of the vaccine in patients receiving checkpoint inhibitors [8]. However, limited data are available for patients enrolled in early-phase clinical trials. We thus aimed to assess safety and immunogenicity of the vaccine in a cohort of earlyphase trial oncology patients [2].

Malissen *et al*., [2] reported a study of data from patients who received 2 doses of the BNT162b2 COVID-19 vaccine, between January 2021 and April 2021. COVID-19 immunization had been monitored, as part of routine care: samples were taken before the first dose (T0), before the second dose (T1) and one month after the second dose of the vaccine (T2) with a 21- to 28-day interval between the doses, as recommended in France. The vaccine was injected in between experimental treatment administrations, except for patients on a continuous regimen. Polymerase chain reaction swab tests were performed at each patient's venue to rule out asymptomatic SARS-Cov-2 infections. Serum samples were tested for quantitative detection of anti- SARS-Cov-2 spike (S1) IgG antibodies/). In samples with an enzyme linked immunosorbent assay ratio 0.7, neutralizing antibodies against SARS-Cov-2 were detected using a virus neutralization test (VNT100). The study was approved by the data protection committee of APHM.

Seroconversion rates were 37% at T1 and 77% at T2. Among patients who seroconverted, 2 of 8 had positive neutralizing antibodies at T1, whereas 16 of 20 had positive neutralizing antibodies at T2. We could identify no difference depending on the patient's age, treatment type or lymphocyte count. The 77% seroconversion rate achieved after 2 doses of the vaccine in our cohort is in line with the data reported in other oncology patients treated with this vaccine

scheme, without unexpected toxicity or treatment delay. This is lower than reported in a small series of adolescents and young adults [9]. The lower rate of neutralizing antibodies among seropositive patients might be explained by differences in assays.

Most cancer therapies will not inhibit the generation of protective responses by the vaccine. Lymphodepleting and intensive myelosuppressive chemotherapies will blunt the humoral and/or cell-mediated responses that are likely important for full protection against COVID-19. Nevertheless, some protection is likely beneficial. Depending on the phase and urgency of a patient's cancer treatment, there may be flexibility to optimize the timing of COVID-19 vaccinations (e.g., COVID-19 vaccination followed by anti-B cell therapy several weeks later) as is sometimes practiced for other vaccines [3].

CONCLUSION

In conclusion, our study showed an average rate of response to vaccination against Covid-19, several factors may be incriminated: immunodeficiency status, type of administered vaccine, number and time between doses.

We strongly recommend vaccination for cancer patients; doses must be received in between treatments.

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