Since January 2020 Elsevier has created a COVID-19 resource centre with free information in English and Mandarin on the novel coronavirus COVID-19. The COVID-19 resource centre is hosted on Elsevier Connect, the company's public news and information website.

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The prevalence of asymptomatic COVID-19 infection in cancer patients. A cross-sectional study at a tertiary cancer center in New York City

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ABSTRACT

Objective: Several factors raise concern for increased risk of COVID-19 in cancer patients. While there is strong support for testing symptomatic patients. The benefit of routine testing of asymptomatic patients remains contentious. We aim to evaluate the prevalence of asymptomatic COVID-19 infection in cancer patients.
Methods: Between June 1 and September 3, 2020, we obtained nasopharyngeal swab from asymptomatic cancer patients who were visiting a single tertiary-care cancer center, and tested the specimen for the presence or absence of SARS-CoV-2 RNA. We performed a descriptive statistic of data
Results: We tested a total of 80 patients, of which 3 (3.75%) were found positive for COVID-19. A significant proportion of the tested patients were on active immunosuppressive or immunomodulatory treatment, cytotoxic chemotherapy ($n = 34$), and immunotherapy ($n = 16$). However, all three COVID-19 positive patients were only actively on hormonal therapy. All three patients observed a minimum of 2 weeks home quarantine. None of the patients developed symptoms upon follow up and no changes were required to their treatment plan.
Conclusions: Despite published evidence that cancer patients may be at increased risk of severe COVID -19 infection, our data suggest that some infected cancer patients are asymptomatic. The overall prevalence of asymptomatic COVID-19 infection in this population of cancer patients was similar to that in the general population. Therefore, since asymptomatic infections are not uncommon in patients with cancer, we recommend universal COVID-19 testing to help guide treatment decisions and prevent the spread of the disease.

Introduction

The emergence of the coronavirus disease 2019 (COVID-19) quickly changed the care of cancer patients across the globe. New York was one of the first epicenters of the disease in the United States, and since the first reported case in March 2020, the rapid spread of the virus had resulted in more than 481,000 cases and 25,000 deaths in the New York region by October 2020 [1].

Patients with cancer are prone to a variety of infections primarily because of a potentially compromised immune system due to tumor or cancer treatment effect. In addition, cancer patients are frequently exposed to unavoidable contacts with family members, fellow citizens and the health care system for support, therapy, monitoring, rehabilitation or surveillance. All these factors in combination raise concern about an increased risk of COVID-19 in this particular group of patients. In fact, some data conclude an increased risk and worse outcomes in cancer patients with COVID-19 [2-4]. While there are numerous publications on the occurrence and risk factors for adverse outcomes in symptomatic and admitted cancer patients with COVID-19 [4-6], substantial data on asymptomatic patients with cancer is scarce, especially in the outpatient setting. The routine testing for COVID-19 in asymptomatic cancer patients also remains a topic of debate as it remains unclear whether it is beneficial in the cancer therapy decision-making process.

We therefore aim to identify the prevalence and clinical characteristics of asymptomatic COVID-19 in cancer patients by implementing a universal screening of cancer patients without symptoms of COVID-19 visiting our outpatient tertiary-care cancer center.

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Methods

Design

We conducted a prospective, single-institution, cross-sectional study between June 1, 2020 and September 3, 2020. The study was approved by Maimonides Medical Center Institutional Review Board and Research Committee, with designated ID: 2020–04–02-MMC, and conducted in accordance with the Declaration of Helsinki. All included patients agreed to participate and voluntarily provided a written informed consent.

Patients

Ambulatory adult patients over the age of 18 with confirmed diagnosis of cancer who are currently or had previously undergone systemic cancer treatment were offered to enroll in the study. Patients with prior diagnosis of COVID-19 were not eligible. At the time of consenting, patients were asked if they have had any COVID-19-like symptoms (cough, fever $\geq$ 100°F, dyspnea above baseline, myalgia, anosmia, headache or diarrhea) within the past months, and excluded if they answered, yes. Patients who tested positive were contacted by their physician again to get more details about their health and were followed closely by their treating physician and the study team for a duration of 4 months.

Testing

A trained health care worker, donned in personal protective equipment routinely obtained nasopharyngeal swabs from the participants. Hologic Aptima multitest swab specimen collection kit for SARS CoV-2 (by Hologic Inc, CA) was used for this testing. Specimens tested for SARS-COV-2 RNA were analyzed by Lenco labs (Lenco Diagnostic Labs, Brooklyn, NY) on their Hologic Molecular platform. All results were recorded and made available to the participants and their respective oncologists. If positive, the hospital's infectious disease control and state health department were also notified. Asymptomatic infection is defined as a positive nucleic acid test in an asymptomatic patient (absence of any of the symptoms mentioned above).

Definition of treatment regimens

Cytotoxic chemotherapy includes all routine chemotherapy drugs which have myelosuppressive and immunosuppressive potentials. Monoclonal antibodies (trastuzumab, bevacizumab) are not considered cytotoxic, but if combined with cytotoxic chemotherapy, the treatment regimen will be labelled as cytotoxic. Targeted therapies include monoclonal antibodies and oral small molecule drugs such as tyrosine kinase inhibitors, while hormonal treatments include luteinizing hormone releasing hormone (LHRH) agonists, fulvestrant, tamoxifen, and aromatase inhibitors. Immunotherapy refers to the immune checkpoint inhibitors that target PD-1 or PD-L1, such as pembrolizumab, nivolumab, durvalumab and CTLA4-directed agents. None of the patients in our cohort were on CAR-T, Cancer vaccines or cytokine therapies. Active treatment means receiving treatment within one week prior to consenting and testing, with scheduled treatment sessions thereafter. History of treatment means any type of treatment other than the current treatment the patient received prior to consenting.

Data

Electronic medical record was reviewed for demographics and clinical information. Study information was collected and stored on a secure electronic data capture platform: the research electronic data capture (REDCap)

Statistical analysis

Demographic variables that were continuous and normally distributed were demonstrated as means and standard deviation. Non- normally distributed continuous variables were demonstrated as medians and range. Categorical variables were demonstrated as counts and percentages. Analysis was performed using the IBM SPSS statistical software (version 27.0)

Results

Patient demographics

Between June 1 and September 3, 2020, Eighty cancer patients without symptoms or prior diagnosis of COVID-19 who visited our ambulatory cancer center, were enrolled and tested for the presence or absence of SARS-COV-2 RNA in their upper respiratory tract. Patient characteristics are listed in Table 1. There are 58 females (72.5%) and 22

Table 1.
Patient demographics.

			$N = 80$	%
Sex				
Male			22	27.50%
Female			58	72.50%
Age in years, median (range)		66 (33 - 86)	100%	
BMI in Kg/m^2, median (range)		28.2 (16.9 - 51.5)	97.50%	
Ethnicity				
White			41	51%
African American			25	31%
Asian			9	11%
Hispanic			3	4%
Others			2	3%
Comorbidities				
Smoking:	Never		45	56%
	Quit		23	29%
	Current		10	12%
Hypertension			38	47.50%
HLD			21	26.50%
DM			16	20%
CAD			9	11.20%
COPD			9	11.30%
Asthma			6	7.50%
Arrhythmia:	Atrial fibrillation		4	6.30%
	SVT		1	1.00%
Renal failure			2	2.50%
Cancer type				
Breast			41	51.30%
Lung			15	18.70%
GI			8	10%
Urogynecology			8	10%
Hematology			5	6.30%
Skin			2	2.50%
Brain			1	1.30%
Treatment type				
			Total (%)	Active[1] (%)
Cytotoxic Chemotherapy			68 (85%)	34 (50%)
Radiotherapy			30 (37%)	0 (0%)
Immunotherapy			22 (27.5%)	16 (72%)
Targeted therapy			17 (21.3%)	17 (100%)
Hormonal therapy			25 (31.3%)	18 (72%)

Abbreviations: BMI, body mass index; HLD, hyperlipidemia; DM, diabetes mellitus; CAD, coronary artery disease; COPD, chronic obstructive pulmonary disease; SVT, supraventricular tachycardia.

[1] Active therapy means ongoing treatment at the time of testing.

males (27.5%). Median age was 67 years (range, 33 – 86 years). Our sample represented diverse ethnic groups, majority being White ($n = 41$; 51%), followed by African American ($n = 25$; 31%). The main comorbidity noted was hypertension ($n = 38$; 47.5%), followed by hyperlipidemia ($n = 21$; 26.5%), then diabetes mellitus ($n = 16$; 20%). About 12% of the patients are current smoker. Median BMI was 28.2 kg/m^2(range, 16.9 – 51.5 kg/m^2).

Cancer and treatment status

The most common cancer diagnosis was breast cancer ($n = 41$; 51.3%), followed by lung cancer ($n = 15$; 18.7%), GI ($n = 8$; 10%) and urogynecology cancers ($n = 8$; 10%). At the time of COVID- 19 testing, 68 patients (85%) had received immunosuppressive therapy (chemotherapy), of which 34 (50%) were actively on chemotherapy. Sixteen patients were actively on immunotherapy, 17 patients were actively on targeted therapy, while 25 patients were actively on Hormonal therapy.

COVID-19 testing

SARS-CoV-2 RNA was detected in the respiratory tract of 3 of the 80 patients (3.75%). Their characteristics and outcome are presented in Table 2. All three patients were tested during the month of June 2020. Their median age was 64 (range, 62–73), and all three were nonsmokers. At the time of COVID-19 testing, all three patients denied having COVID-19-like symptoms in the prior months. However, upon further questioning after a positive test result, one of the patients recalled a history of chronic bronchitis with symptoms of cough that resolved with antibiotics three months prior to the test date. She otherwise was feeling well after that episode and never had a prior COVID-19 diagnosis. All three patients had a primary diagnosis of breast cancer and were only actively on adjuvant hormonal therapy. None of the patients developed COVID-19-like symptoms after further monitoring, and all observed 2 weeks of home quarantine. No changes were made to their treatment regimen. Upon 4 months follow up, all patients remained asymptomatic and none required an inpatient admission.

Discussion

The COVID-19 global pandemic has drastically impacted the care of cancer patients around the globe, posing challenges in diagnosis, treatment, surveillance and monitoring. As the pandemic continues, there is increasing evidence that cancer patients are particularly vulnerable to COVID-19 and may have poorer outcomes in comparison to the general population [2-4]. In response, physicians around the world are working to determine the best strategies to protect cancer patients from COVID-19. In this setting, the question of testing for SARS-Cov-2 RNA in all cancer patients came to light. While there is overwhelming support for testing patients with active COVID-19 symptoms and those with significant risk of exposure like hospitalized patients [7,8], testing all asymptomatic patients in the outpatient settings remains contentious.

Our prospective COVID-19 testing strategy for all asymptomatic cancer patients revealed that 3 out of 80 patients (3.75%) had COVID-19. This result is strikingly similar to the 3.8% overall incidence (both symptomatic and asymptomatic) of COVID- 19 in the New York region [1]. Our finding highlights the similarity of the prevalence of COVID–19 between cancer patients and the general population, further stressing the possibility and significance of missed infection in this vulnerable patient population. During the height of the pandemic, as a result of limited resources and test kits, The American Society of Clinical Oncology recommended a symptom-based screening [9]. However, the effectiveness of this method depends on the proportion of transmission that occurs before symptom onset, and testing only symptomatic and admitted cancer patients is potentially suboptimal in protecting the vulnerable cancer patient population, since further disease transmission from asymptomatic carriers remains a serious risk. Available evidence shows that viral shedding patterns are not yet well understood, and further investigation is needed to better understand the timing and quantity of viral shedding [10]. A study on universal screening of 215 pregnant patients admitted for delivery in New York City (NYC) between March 22 – April 14, 2020 (the height of the pandemic in NYC) showed that asymptomatic carriers were common. In fact, 13.5% of asymptomatic women admitted for delivery, tested positive [11]. A recent study of those aboard the diamond princess cruise ship shows that about 20–35% of those infected with SARS-CoV-2 were asymptomatic carriers [12].

From a public health standpoint, managing asymptomatic carriers remains a major challenge. Patients with asymptomatic or mild disease manifestations can be totally missed even if a more sensitive symptom-based surveillance system were in place. These patients might then spread the disease silently to other community members, caregivers, medical staff and patients given the frequent unavoidable contact specific to the cancer patient population [13]. Moreover, the symptoms of COVID-19, namely: fever; cough; sore throat; dyspnea; diarrhea; myalgia and arthralgia, could mimic symptoms related to patients' underlying malignancy or treatment side effects making symptoms-based screening a more problematic and complex approach. Among our patients who tested positive for the SARS-CoV-2 nucleic acid, none of them had clinical suspicion of COVID-19 upon evaluation by a physician. This indicates that clinical assessment and symptoms-based screening may be unreliable and only universal testing can provide accurate information about patients' infection status.

Other authors have also reported the prevalence of asymptomatic COVID-19 in cancer patients. Included, is a study conducted by Bi and colleagues between March 9 – April 7, 2020 at a major cancer center in Wuhan, China. The authors reported a 3.2% prevalence of asymptomatic COVID-19 in their cancer patient population [14]. It is noteworthy to mention that their symptoms screening was limited to the time of testing. Also, their definition of asymptomatic infection was different from ours (presence of antibody with negative SARS-COV-2 RNA). Patients were tested for antibodies (IgG and IgM) against SAR-Cov-2 by immunoassay, and only if positive, were then tested for the presence or absence of SAR-Cov-2 RNA. Despite the similarities of our findings, we believe that this group of patients would be better labelled as "recovered patients" instead of asymptomatic infected group. Our study looks particularly at cancer patients without COVID-19- like symptoms within months prior to screening and testing date. Another was a study conducted by Al-Shamsi and colleagues, between March 13 – April 4, 2020 at a cancer center in the United Arab Emirate. They reported a higher prevalence of (8%) asymptomatic COVID-19 in their cancer patients. Also, all of their patients later became symptomatic and some required hospital admission. The authors therefore concluded that a universal screening for COVID-19 in this particular high-risk patient group may facilitate earlier identification of cases and implementation of infection

Table 2
Characteristics of cancer patients with asymptomatic and COVID-19- positive. $N = 3$.

No.	Gender	Age	Comorbidities	Cancer type	Ongoing treatment	Pre- test COVID-19-like symptoms	Follow-up
1.	Female	73	HTN, HLD	Breast	Anastrozole	none	asymptomatic
2.	Female	64	HTN	Breast	Letrozole	Cough 3 months prior	asymptomatic
3.	Female	62	HLD	Breast	Anastrozole	none	asymptomatic

Abbreviations: HLD, hyperlipidemia; HTN, hypertension.

control strategies [15].

Maradriaga and colleague shared their hospital protocol detailing that all ambulatory patients considered at risk, or those who are receiving immunosuppressive therapies in whom knowledge of COVID-19 status would impact the decision to treat or defer, were all offered testing [16]. In this study, all asymptomatic cancer patients were offered testing regardless of treatment status. A significant proportion of the patients were on active systemic anti-cancer therapy with majority receiving immunosuppressive regimen. Interestingly, the three patients that tested positive for COVID-19 were only actively on adjuvant hormonal therapy (aromatase inhibitors) for breast cancer, suggesting that selective testing of only the patients on active immunosuppressive therapy, carries the risk of missing other possibly infectious patients. It is worth noting that while some studies have suggested that androgen deprivation therapies (ADT) may provide protection against COVID-19 infection or decrease its severity in patients with prostate cancer [17, 18], other studies did not show similar result [19]. Moreover, there is no knowledge of such correlation with aromatase inhibitors. So, it is unlikely that our observation of asymptomatic infection in the COVID-19 positive group is related to their hormonal therapy status, but just a coincidence due to high population of breast cancer patients in our cohort.

After a positive COVID-19 status is identified in an asymptomatic cancer patient, the clinical impact of this information remains a topic of interest. Whether to continue immunosuppressive treatment in this population, especially those who require it for the goal of cure or alleviation of cancer symptoms is a challenge both on medical liability [20], and from the public health point of view, as described above. The American Society of Clinical Oncology recommends delaying in-office care for 14 days after symptoms onset and obtaining 2 negative tests a minimum of 24 h apart before commencement of treatment. However, a recent guideline from the Memorial Sloan Kettering Cancer Center in New York, recognizes that certain patients remain asymptomatic and therefore recommends that resumption of antineoplastic therapy can be considered when at least 14 days have elapsed since the initial positive COVID-19 test and no symptoms have developed during this time [21]. Although this study is not powered to answer questions on treatment decisions, our approach to treatment modification and decision is case-by-case based, putting perceived patient benefit, patient's preference and risk factors into consideration. We have previously published our treatment modification strategy and decision-making process during the pandemic [22,23]. Given the health and treatment status of our COVID-19 positive cohort, there were no changes required to their treatment plan. They all observed a minimum of 2 weeks home quarantine as recommended and remained asymptomatic upon follow up at 4 months. Since they all remained asymptomatic and no treatment modification was required, they were not re-tested for virus clearance. We believe that our strategy of SARS-CoV-2 testing of all asymptomatic cancer patients presenting to our center allowed us to identify and isolate COVID-19 positive patients and thus prevent possible uncontrolled viral spread.

We encourage caution with the interpretation and generalizability of this study result, given its observational design, single center experience and limited sample size. Although RT-PCR is currently the recommended test method, it is still plagued by false negatives that we are unable to account for. Serologic antibody testing was also not performed in our study which makes it likely to have missed truly asymptomatic but recovered patient population. One of the strengths of our study is, it is a prospective study and result data were collected in real time. Also, our patient population represents a diverse group of active cancer patients with relevant comorbidities and on systemic immunosuppressive therapy. Larger studies are needed to gain better understanding of the questions at hand.

In conclusion, we advocate that regardless of symptoms or treatment status, Universal testing for COVID-19, when available, be considered and implemented in all cancer patients. We believe this will help detect asymptomatic virus carriers and potentially avoid uncontrolled virus spread. It will also provide physicians and patients with all information required in therapy decision making process. We further encourage observation of all safety measures, such as hand hygiene measures, wearing of protective masks and face covering, and social distance practice even in patients with negative test results.

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Declaration of Competing Interest

None to declare from all authors

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