An Observational Study of Risk Factors for SARS-CoV 2 Infection in Patients with Cancer

Sonam Singla, Teena Wadhwa, Charu Yadav, Manish Singh, Smita Sarma, Nitin Sood, and Ashok Vaid

ABSTRACT

Introduction: Cancer patients are regarded as a highly vulnerable population in Coronavirus Disease 2019 (COVID-19) pandemic due to their systemic immunosuppressive state. The aim of the study was to investigate the prevalence of SARS-CoV-2 (severe acute respiratory syndrome coronavirus 2) infection in asymptomatic cancer patients attending the oncology clinic.

Methods: We conducted a retrospective observational study from May-November 2020. The patients who tested positive for SARS-CoV-2 RT PCR were followed up to study the risk factors, clinical presentation, and outcome. The ethical approval from institutional review board was done. Chi-square test was used to compare qualitative variables and logistic regression model was used to estimate the odds ratio (OR) of having COVID-19 infection.

Results: We included 334 cancer patients who were tested for COVID-19 infection. The prevalence of SARS-CoV-2 infection was 28.4%. COVID-19 infection was more common in solid organ malignancy than hematological cancer (29.2% vs. 26.1%). The risk of COVID-19 infection was associated with comorbidity (p = 0.002). Time since diagnosis of malignancy and the type of anticancer treatment received did not increase the risk of COVID-19 infection. However, patients receiving anticancer therapy in the last 4 weeks of testing positive for SARS-CoV-2 RT PCR had a higher risk for COVID-19 infection (p<0001). The oncological treatment was continued after resolution of symptoms and with negative RT-PCR. The multi variable regression model revealed that females, patients having both hypertension and diabetes mellitus and patients receiving chemotherapy within the last 4 weeks had higher odds of COVID-19 infection (p<0.05).

Conclusion: We observed that active oncologic treatment does not represent a risk factor for SARS-CoV-2 infection in cancer patients. However delaying anticancer treatment to avoid SARS-CoV-2 transmission may lead to malignancy related complications. The approach of routine COVID 19 testing in cancer patients seems preferable in detecting asymptomatic virus carriers.

Keywords: Anti-cancer therapy, cancer, chemotherapy, COVID-19, hematological malignancy.

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S. Singla *

Department of Microbiology, Medanta -The Medicity, India

(e-mail: drsonamsingla@gmail.com)

T. Wadhwa

Department of Microbiology, Medanta -The Medicity, India

(e-mail: teenawarora@gmail.com)

C. Yadav

Department of Biochemistry, Medanta - The Medicity, India

(e-mail: Charu.yadav@medanta.org)

M. Singh

Institute of Clinical Research, Medanta -The Medicity, India

(e-mail: Manish.Singh1@Medanta.org)

S. Sarma

Department of Microbiology, Medanta -The Medicity, India

(e-mail: sarma.smita@yahoo.com)

N. Sood

Department of Hematology & Stem Cell Transplant, Medanta - The Medicity, India (e-mail: Nitin.Sood@Medanta.org)

A. Vaid

Department of Medical Oncology & Hemato Oncology, Medanta - The Medicity, India (e-mail Ashok.vaid@medanta.org)

*Corresponding Author

I. INTRODUCTION

The novel Corona virus 2019 (COVID-19), also known as SARS-CoV-2 (severe acute respiratory coronavirus-2) has become a worldwide threat and healthcare concern [1]. It was first reported from Wuhan, China, in December 2019. Since then the virus has spread globally and has led to the implementation of some of the most serious health policies around the world [2]. The World Health Organization (WHO) on 30th January 2020 declared it a public health emergency [3].

The human transmission of the virus occurs through respiratory droplets and through direct contact with an infected patient or indirect contact with fomites [1]. SARS-CoV-2 infection appears to be more common in elderly individuals and those with co-morbidities like chronic lung disease, cardiovascular disease, hypertension, and diabetes mellitus [4].

Patients with cancer are more susceptible to infection than individuals without cancer because of their systemic immunosuppressive state caused by the malignancy and anticancer treatment such as chemotherapy or surgery [5]. Also due to their regular follow up visits to the hospital for anti-neoplastic therapy, cancer patients are exposed to unavoidable social contacts. These factors give reason for concern about an increased risk for SARS-CoV-2 infection in patients with cancer. On the other hand, delaying medical health visits to healthcare facilities due to COVID-19 symptoms could increase cancer-related deaths [6].

Few studies conducted in China indicate an increased risk for SARS-CoV-2 infection and a severe disease course in patients with cancer [5]. However, due to the relatively small sample size of the studies with limited clinical information and variable course of the disease, many critical issues concerning COVID-19 infected cancer patients remain

Hence, there is an urgent need to answer certain questions, including whether COVID-19 infected cancer patients will have distinct clinical courses and worse outcomes, such as death from infection or severe pneumonia, and whether cancer patients should continue receiving their anticancer treatments as usual during COVID-19 pandemic.

Therefore, this study was conducted on COVID-19 infected cancer patients (both hematological and solid organ malignancies) in a tertiary care hospital in North India to study the risk factors, clinical presentation, and prognosis of COVID-19 infection in such patients.

II. MATERIALS AND METHODS

A. Study Design

This was a retrospective observational study conducted in a tertiary care hospital for a period of seven months (May 2020 to November 2020). The study was approved by the institutional ethical committee (MICR- 1149/2020 -Academic). A total of 334 patients with active cancer (hematological and solid organ malignancies) visiting oncology clinic were enrolled in the study. COVID-19 reverse transcriptase polymerase chain reaction (RT PCR) was done for each patient who was on active anticancer treatment or about to start the treatment at the oncologic clinic. The patients who tested positive for SARS-CoV-2 RT PCR were followed up to study the risk factors, clinical presentation, and outcome.

The patients who were suspected to have COVID-19 infection based on radiological findings but not tested for SARS-CoV-2 infection by RT PCR were not included in the study.

The patients were divided into different age groups to study any predilection of a particular age group towards acquiring COVID-19 infection. The co morbidities assessed were diabetes mellitus, hypertension and patients having both diabetes mellitus and hypertension.

We evaluated risk factors associated with COVID-19 infection mainly categorized as follows:

- 1) Time since diagnosis of malignancy in relation to testing positive by SARS-CoV-2 RT PCR: It was grouped into three categories, those diagnosed with malignancy in less than 12months, within 12-59 months and more than 60months from testing positive for COVID-19 infection by RT PCR.
- 2) Type of anticancer treatment received: The type of anticancer treatment received by the patients was grouped into chemotherapy, radiotherapy, chemo radiation, surgery and immunotherapy.
- 3) History of hospitalization for anticancer treatment in previous 4 weeks from date of testing positive for SARS-CoV-2 infection: The patients were grouped as those having a history of hospitalization in less than 4 weeks of testing positive for SARS-CoV-2 RT PCR and those not having a

history of hospitalization in less than 4 weeks.

B. Sample Collection and Processing of Sample

Nasal and/or oropharyngeal swabs were tested for SARS-CoV-2 RNA with RT-PCR assay. RNA extraction was done using Promega Maxwell RSC. After RNA extraction, PCR reaction was set up using Thermo fisher Taqpath SARS-CoV-2 qualitative PCR kit. The cut-off of cycle threshold (Ct) for RT PCR was taken as 38 as per the manufacturer's recommendations. The results were analyzed and patients were grouped into COVID -19 positive and negative based on SARS-CoV-2 RT PCR test.

C. Statistical Analysis

Chi-square test was used to compare qualitative variables and Student's t test was used for quantitative variables. The logistic regression model was used to estimate the odds ratio (OR) of having COVID-19 infection. Data were analyzed in SPSS-24 software and the significance level of the tests was considered at 5%.

III. RESULTS

A total of 334 patients with malignancies visiting oncology clinic for therapeutic intervention or follow up from May 2020-Nov 2020 were enrolled for the study. They were tested for SARS-CoV-2 infection by RT PCR. The mean age was 53 years (range 46-64 years) with maximum patients 46.7% in age group 41-60years followed by 35.6% in age group >60years. There were 195 (58.4%) males and 139(41.6%) females.

In patients with solid organ cancers, 31.6% patients had malignancy of gastro-intestinal tract followed by 18.8% with breast cancer, 16% had oral cavity cancer, 13.6% had genital tract cancer, 6% with lung cancer, 5.6% with central nervous system (CNS) cancer, and 17.6% with other malignancies. B cell lymphoma (32.1%) was the most common hematological malignancy followed by myeloma (27.3%), and acute myeloid leukemia (AML) (15.4%) and acute lymphoblastic leukemia (ALL) (15.4%) [Table I].

SARS-CoV-2 RT PCR was positive in 28.4% of patients (95/334). COVID-19 infection was observed in 50.5% of males and 49.5% of females. The prevalence of COVID-19 infection was 49.4% in 41-60 yrs. age group followed by 34.7% in 61-80 years. (Table I).

In our study cohort among 250 patients with solid cancers, 73(29.2%) were positive for SARS-CoV-2 RT PCR while in 84 patients with hematological malignancies, 22(26.1%) were COVID-19 positive. We thus observed a slightly higher incidence of SARS-CoV-2 infection in solid organ malignancy than hematological cancer (29.2% vs. 26.1%).

Amongst 73 COVID-19 infected patients with solid organ malignancies, 19(26%) patients had breast malignancy followed by 24.6% with malignancy of gastro-intestinal tract (GIT) and 13.6% with genital tract malignancy. In 22 COVID-19 infected patients with hematological malignancies, 13(59%) were of B cell lymphoma followed by AML patients (18.2%) However no statistically significant difference was observed with the type of malignancy and risk of COVID-19 infection (p= 0.597) (Table I).

The co-morbid conditions associated with COVID 19

positive patients were hypertension observed in 26(45.6%) patients, diabetes mellitus in 23(41%) patients while 16(59.2%) patients had both hypertension and diabetes mellitus. The risk of COVID-19 infection was associated with comorbidity (p = 0.002).

TABLE I: DEMOGRAPHICS AND BASELINE CHARACTERISTICS OF PATIENTS WITH CANCER AND COVID-19 INFECTION

PATIENTS WITH CANCER AND COVID-19 INFECTION								
	COVID 19	COVID 19	Total subjects					
Parameter	positive cases	negative (n=	(n= 334)					
	(n= 95)	239)	(II= 334)					
Age group(chi 0.067, p =0.796)								
≤20 years	6 (6.3%)	14(5.8%)	20 (6.0%)					
21-40 years	9 (9.5%)	30 (12.5%)	39 (11.7%)					
41-60 years	47 (49.4%)	109 (45.6%)	156 (46.7%)					
>60 years	33 (34.7%)	86 (35.9%)	119 (35.6%)					
Sex (chi = 3.373, p = 0.066)								
Male	48 (50.5%)	147 (61.5%)	195 (58.4%)					
Female	47 (49.5%)	92 (38.4%)	139 (41.6%)					
Type of Malignancy ($chi = 0.280$, $p = 0.597$)								
Hematological	22(26.2%)	62	84					
ALL	1(4.5%)	12(19.3%)	13(15.4%)					
AML	4(18.1%)	9(14.5%)	13(15.4%)					
B-Cell	12(50.00()	14(22.50()	27/22 10/					
Lymphoma	13(59.0%)	14(22.5%)	27(32.1%)					
CLL	1(4.5%)	3(4.8%)	4 (4.7%)					
CML	1(4.5%)	1(1.6%)	2 (2.3%)					
T-Cell	0	2(2.20()	2 (2 20()					
Lymphoma	0	2(3.2%)	2 (2.3%)					
Myeloma	2(9.1%)	21(33.8%)	23 (27.3%)					
Solid organ	73(29.2%)	177	250					
Breast	19 (26.0%)	28(15.8%)	47(18.8%)					
Gastro-								
intestinal tract	18 (24.6%)	61(34.4%)	79(31.6%)					
(GIT)								
Oral cavity	6 (8.2%)	34(19.2%)	40(16.0%)					
CNS	3 (4.1%)	11(6.2%)	14(5.6%)					
Lung	3 (4.1%)	12(6.7%)	15(6.0%)					
Genital tract	10 (13.6%)	24(13.5%)	12(4.8%)					
Others(includin	, ,	` '	` '					
g renal and	14(19.1%)	30(16.9%)	44(17.6%)					
liver)	` '	` '	` '					

The other risk factors associated with SARS-CoV-2 infection included in our study population are described below:

A. Time since Diagnosis of Malignancy

Among 95 patients with SARS-CoV-2 infection, 62 (65.3%) patients were diagnosed with malignancy in the last 12 months, 26(27.4%) were diagnosed within 12 to 59 months and 7(7.3%) patients were diagnosed within more than 60 months. (p <0.760) However, it was observed that the time since diagnosis of malignancy does not influence the risk of acquiring COVID-19 infection.

B. Type of Anticancer Treatment Received

In patients who had COVID-19 infection, 44(46.3%) patients were on chemotherapy, 23(24.2%) were treated with chemo radiation and 16(16.8%) were receiving radiotherapy for their malignancy. However, no statistically significant difference was noted with the type of anticancer treatment received in patients with COVID-19 infection (p=0.116) (Table II).

C. History of Anticancer Treatment in the Last 4 Weeks of COVID-19 Infection

We observed that among 95 COVID-19 positive patients, 65(68.4%) had received anticancer therapy within the last 4

weeks while 30(31.5%) patients did not receive any anticancer treatment in the last 4 weeks. The patients who had received anti-cancer treatment in the last 4 weeks were found to have a significantly higher prevalence (68.4%) of acquiring COVID-19 infection as compared with those who received therapy for more than 4 weeks (31.5%) and p-value was also found to be significant (p<0.001) [Table II].

TABLE II: RISK FACTORS IN CANCER PATIENTS ASSOCIATED WITH

	SARS-COV-2 INFECTION							
	COVID 19 COVID 19		Total					
	positive cases	negative	subjects					
	(n=95)	(n=239)	(n=334)					
Time since diagnosis (chi =0.093, p=0.760)								
Less than 12 months	62 (65.2%)	154 (64.4%)	216					
12 to 59 months	26 (27.4%)	73 (30.5%)	99					
More than								
equal to 60	7 (7.3%)	11 (4.6%)	18					
months								
Anti-cancer treatment modality(chi =7.410, p=0.116)								
Chemotherapy	44 (46.3%)	145 (64.4%)	189					
Radiotherapy	16 (16.8%)	21 (8.7%)	37					
Surgery	8 (8.4%)	18 (7.5%)	26					
Immunotherapy	notherapy 4 (4.2%) 7 (2.9%)		11					
Less than 4 week hospitalization (chi =19.214, $p < 0.001$)*								
Yes	65 (68.4%)	100 (41.8%)	165					
No	30 (31.5%)	139 (58.2%)	169					

D. Clinical Presentation and Outcome

The clinical characteristics of COVID-19 infected cancer patients were also assessed. The patients were mostly asymptomatic, symptoms were observed in 31.5% of patients. The most common symptom was fever (26.3%), cough (14.7%), and shortness of breath (7.4%). Hospital admission was required in 11.5% of patients; however, only 2 patients required ICU admission. The admitted patients were managed with hospital COVID-19 treatment protocol. The anticancer treatment was continued after the resolution of COVID-19 symptoms and with negative RT-PCR result.

The study cohort was followed up for six months to observe any COVID-19 related complications or mortality in the study population. We observed that 12% (40/334) patients died in our study group during the follow-up period, of these 7 patients had COVID-19 infection. Statistically, there was no significant association of COVID-19 infection with mortality in patients with malignancies (p < 0.102).

The mortality in patients with hematological malignancy was 6.8% (23/334) while it was 5% (17/334) in solid organ malignancy patients.

We compared mortality with COVID-19 status and with recent history of hospitalization. We observed that there was no significant association between mortality with COVID-19 infection and history of hospitalization (p=0.98).

We further studied multivariable regression analysis and included variables i.e. sex, co-morbidity, cancer type, receipt of chemotherapy within the last 4 weeks, type of anticancer therapy received, and time since cancer diagnosis. We observed that females had higher odd for COVID-19 infection (OR 0.568[0.329-0.981], p=<0.043) as compared to males. The patients having both hypertension and diabetes mellitus had higher odds of COVID-19 infection (OR 0.2, [95% CI 0.078- 0.508], p=<0.001). Patients with

TABLE III: MULTIPLE LOGISTIC REGRESSION ANALYSIS OF FACTORS ASSOCIATED WITH INCREASED RISK FOR COVID-19 INFECTION

Variable	COVID 19 positive (n=95) % within parameter	COVID 19 negative (n= 239) % within study group		p-value	Adjusted OR	95% Confidence Interval (lower limit, upper limit)
	<=20	6 (6.3%)	14 (5.8%)		1	
Age (in years)	21-40	9 (9.5%)	30 (12.5%)	0.662	1.339	0.362, 4.955
	41-60	47 (49.4%)	109 (45.6%)	0.781	1.176	0.374, 3.696
	>60	33 (34.7%)	86 (35.9%)	0.385	1.688	0.518, 5.503
	Male	48 (50.5%)	147 (61.5%)		1	
Sex	Female	47 (49.5%)	92 (38.4%)	0.043*	0.568	0.329, 0.981
Maliananav	Hematological	22 (26.2%)	62 (73.8%)		1	
Malignancy type	Solid organ	73 (29.2%)	177 (70.8%)	0.356	1.398	0.686, 2.850
Co-morbidity	Hypertension (HTN)	26 (45.6%)	31(54.4%)	0.573	0.771	0.313, 1.9
	Diabetes mellitus(DM)	23 (41.0%)	33(59%)	0.862	1.09	0.412, 2.882
	Both HTN & DM	16 (59.2%)	11(40.8%)	0.001*	0.2	0.078,0.508
	None	62 (25.0%)	186 (75.0%)	1.0		
T:	Less than 12 months	62 (65.3%)	154 (64.4%)	1.0		
Time since cancer diagnosis	12 to 59 months	26 (27.4%)	73 (30.5%)	0.909	0.965	0.526,1.770
	More than equal to 60months	7 (7.3%)	11 (4.6%)	0.337	0.584	0.195,1.751
Anti-cancer treatment modality	Chemo radiation	23 (24.2%)	48 (20.08%)	1.0		
	Chemotherapy	44 (46.3%)	145 (64.4%)	0.360	1.391	0.686,2.822
	Radiotherapy	16 (16.8%)	21 (8.7%)	0.173	0.530	0.213,1.322
	Surgery	8 (8.4%)	18 (7.5%)	0.513	0.688	0.224,2.113
	Immunotherapy	4 (4.2%)	7 (2.9%)	0.734	0.770	0.171,3.468
Less than 4	Yes	65 (68.4%)	100 (41.8%)	<0.001*	3.751	2.121, 6.634
week hospitalization	No	30 (31.5%)	139 (58.2%)	1.0		

solid organ malignancy have higher odds of having COVID-19 infection. (OR 0.356, [95% CI 0.686-2.850] p=<0.356). There was no correlation between the time since cancer diagnosis and the type of anticancer treatment. Receiving chemotherapy within last 4 weeks before symptom onset (OR 3.751 [95% CI 2.121- 6.634]; p=<0.001) was associated with increased risk for COVID -19infection (Table III).

IV. DISCUSSION

COVID-19 pandemic had a remarkable impact on cancer patient's care in terms of diagnosis, treatment schedules, and follow-up visit. The patients were losing their valuable clinic visits due to quarantine. This study was undertaken to assess the nature of COVID-19 disease in immunocompromised patients due to malignancy, focusing on the risk factors, clinical manifestation, and outcome of COVID-19 infection in patients who were on active anticancer treatment.

In our study, the prevalence of SARS-CoV-2 infection was similar in both sexes (50.5% males and 49.5% females).

In a study by reference [7] wherein they enrolled 205 patients for the study cohort, females had a higher rate of infection (53%) as compared to males.

In a study by reference [8] males (60.7%) were infected more as compared to females however their study group included only 28 patients.

We found that the prevalence of SARS-CoV-2 infection was higher in patients with solid organ malignancies as compared to hematological malignancy (29.2% vs. 26.1%). Amongst solid organ malignancies, patients with breast cancer had a higher rate of COVID-19 infection followed by

colorectal cancer. The higher prevalence of solid organ malignancies could be due to more number of patients with solid organ malignancies (74.8%) included in the study.

This finding corresponds with reference [7] where they reported a higher infection rate in solid organ malignancies (89%) as compared to hematological malignancy. They also observed a higher infection rate in patients with breast cancer (20%) followed by colorectal cancer (14%) [7].

In another cohort study of 105 patients by reference [9] they observed COVID-19 infection was more common in patients with lung cancer (20.9%) followed by gastrointestinal cancer (12.4%) and breast cancer (10.5%) [9].

The co-morbidities associated with increased risk for COVID-19 infection were patients having both hypertension and diabetes mellitus (59.2%). In a large study of 1590 patients (of whom 399 had at least one underlying co-morbid condition), a higher risk of SARS-CoV- 2 infection in patients with co-morbidities was observed. They reported a higher risk in patients with hypertension (16.9%) followed by diabetes mellitus (8.2%). They also observed that patients with two or more co-morbidities were at higher risk of having severe COVID-19 infection as compared to patients with a single co-morbidity [10]. This was similar to our study wherein patients having both hypertension and diabetes mellitus were at higher risk of acquiring COVID-19 infection.

The cancer patients included in our study had received different modalities of anticancer treatment, but it was found that there was no specific association between any type of anti-treatment with the risk of acquiring COVID-19 infection. Also, time since diagnosis of malignancy does not contribute to the risk for SARS-CoV-2 infection.

However, we observed that among COVID-19 positive patients, 68.4% of patients had received anti-cancer therapy within the last four weeks of acquiring COVID-19 infection. This was comparatively higher and statistically significant than those who received antitumor therapy more than four weeks before getting infected with COVID-19 disease (p<0.001).

This finding corresponds with a retrospective cohort study of 28 COVID-19 infected cancer patients with laboratory confirmed COVID-19 from three hospitals in China, where antitumor treatment within the last 14 days seemed to significantly increase the risk of severe outcome (hazard ratio (HR) = 4.079, 95% confidence interval (CI) 1.086–15.322, p = 0.037) [7].

The overall mortality rate seen in the study population was 12% (40/334). The mortality was seen more in patients with hematological malignancy as compared to solid organ (6.8% vs. 5%) irrespective of their COVID-19 status. This was similar to a study by reference [9] wherein they found that patients with hematological malignancies due to immune compromised state had a higher mortality rate as compared to patients with solid organ malignancies. The increase case fatality rate in hematological malignancies was also observed by reference [11].

The high risk of adverse events in patients with hematological malignancies could be related to immune dysregulation and immune-suppression as compared to patients with solid organ malignancies making them more prone to the risk of acquiring opportunistic infections and complications following the superseded infections.

The immune-compromised state leads to a downstream disease course with severe consequences, such as cytokine storm and multi-organ failure. Hence patients with hematologic cancer have high severity and death rates [9], [11].

We observed that mortality in COVID-19 positive patients was not related to a history of hospitalization in the past 4 weeks before SARS-CoV-2 infection.

Reference [12] studied combined outcome like death and/or admittance to hospital due to COVID-19. They found significant two-fold increased risk estimates for patients diagnosed with cancer less than one year ago (OR 2.08, 95% CI 1.14–3.80), for those treated with anti-cancer drugs during the past three months (OR 1.80, 95% CI 1.07-3.01) and for patients undergoing major surgery during the past three months (OR 2.19, 95% CI 1.40–3.44) [12].

In a study by reference [11] after adjusting for age, gender, and co-morbidities, they found that chemotherapy in the past four weeks had no significant effect on mortality from COVID-19 disease when compared to patients with cancer who had not received recent chemotherapy (1.18 [0.81–1.72]; p=0.380). They also found no significant effect on mortality for patients with immunotherapy, hormonal therapy, targeted therapy, radiotherapy use within the past four weeks [11].

Reference [13] found that the mortality rate among 281 patients with active cancer who had received chemotherapy four weeks before getting infected with SARS-CoV-2 infection was 27% vs 29% in patients who did not receive chemotherapy in the last four weeks. Also, the type of anticancer therapies received like immunotherapy, hormonal therapy, chemotherapy and targeted therapies did not seem to influence the mortality rate [13].

We conducted this study during the beginning of the pandemic when the information and data related to the course of the disease was limited particularly in relation to immunocompromised patients and policies were not well defined. The limitations of our study were that the sample size was not large and we were not able to study the factors related to COVID-19 related mortality in detail. The statistical tests due to small size could not be computed.

Additional studies will be needed to clarify whether continual anticancer therapy in cancer patients with persistent shedding of SARS-CoV-2 RNA is safe and feasible and whether delaying anticancer treatment because of COVID-19 infection is associated with insufficient tumor control [6].

V. CONCLUSION

Though recent hospitalization was a significant risk factor for acquiring COVID-19 infection in our study the patients were affected more due to malignancy related complications and delayed anti-cancer treatment. This signifies that continuation of anticancer treatment in the epidemic area during the COVID-19 pandemic seems feasible and can be continued without disruption provided adequate and astringent infection control measures are practiced. More studies need to be conducted in cancer patients with COVID-19 infection which may help in guiding the anticancer therapy of oncology patients in near future. The approach of routine SARS-CoV-2 testing in patients with cancer as a part of safety policies seems preferable in detecting asymptomatic virus carriers. It may also avoid undesirable viral spread in susceptible population of patients with cancer and to ensure the safe continuity of oncology treatment.

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CONFLICT OF INTEREST

Authors declare that they do not have any conflict of interest.

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