Universal Screening of Patients with Cancer for COVID-19: Results from an Observational, Retrospective Cohort Study in Kerala, India

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Abstract

Introduction There is high risk of contracting coronavirus disease 2019 (COVID-19) among patients with cancer with risk of mortality and morbidity being high. Limited data is available on the outcomes of universal screening of cancer patients with asymptomatic severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection from lower-middle-income countries (LMICs).

Objectives Our goal was to determine the prevalence of asymptomatic SARS-CoV-2 infection in patients with cancer attending the medical oncology department of a tertiary care hospital in Kerala and protect both patients and health care workers before proceeding with the systemic anticancer treatment.

Materials and Methods This was a retrospective cohort study of screening patients receiving systemic anticancer therapy for COVID-19 among hospitalized patients from August 1, 2020, and both outpatients and hospitalized patients from September 1 to November 15, 2020. After clinical triaging, patients were subjected to universal screening with rapid antigen tests and/or reverse transcriptase-polymerase chain reaction (RT-PCR).

Results A total of 1,722 SARS-CoV-2 tests (321 RT-PCR and 1,401 antigen tests) were performed among 1,496 asymptomatic patients before their scheduled chemotherapy/immunotherapy. Eight hundred forty-eight patients were screened more than twice. The patient cohort's median age was 59 years (range 01–92 years);

Keywords
- SARS-CoV-2 antigen testing
- RT-PCR
- universal screening
- LMIC

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44.98% of patients were males, and 55.01% were females. 58.77% of patients were on adjuvant or neoadjuvant chemotherapy and 41.22% on chemotherapy for metastatic cancer. The most common malignancy was breast cancer (26.53%), followed by lung (8.35%) and gastrointestinal (16.4%) cancers. The prevalence of asymptomatic infections in our study was 0.86%. Only one patient who had undergone chemotherapy after a negative SARS-CoV-2 test developed confirmed COVID-19 during subsequent testing. From these index cases, none of the other patients, health care workers, or their caretakers contracted COVID-19.

Conclusion The prevalence of asymptomatic COVID-19 infections in our study was low (0.86%). With proper health education, clinical triaging, and screening of the high-risk group, it is possible to continue cancer treatment during the peak of the COVID-19 pandemic, even in LMICs.

Introduction

Cancer patients are at an increased risk for contracting coronavirus disease 2019 (COVID-19)[1–3] relative to the general population and its complications due to various host, disease, or treatment factors.[4,5] The risk is amplified for patients with hematologic and lung cancers.[5] However, not all studies are consistent.[6,7] A study from Memorial Sloan Kettering Cancer Center (MSKCC) suggested that specific subsets such as those on immunotherapy may be more prone.[8] International agencies such as the American Society of Clinical Oncology (ASCO),[9] European Society of Medical Oncology (ESMO),[10] Infectious Disease Society of America (IDSA),[11] and National Comprehensive Cancer Network (NCCN)[12] recommend screening every patient undergoing chemotherapy to identify casualties early and isolate them to prevent infection to other patients as well as to health care workers.[13] Following the COVID-19 infection, an asymptomatic period lasts 2 weeks, during which viral transmission occurs.[14,15] The percentage of asymptomatic infection ranges from 20 to 31%, and such asymptomatic persons can transmit the infection to others.[16] Hence, screening is vital for patients with cancer. It also helps increase the confidence of health workers and promotes the safe and timely administration of chemotherapy to maintain the efficacy of chemotherapy in the era of COVID-19.[17] The curative-intent cancer care will need to continue, given that further delays may affect the outcome. There is limited data from low-middle-income countries (LMICs) where the management of the pandemic and cancer itself have unique challenges. Data on the prevalence of asymptomatic COVID-19 cases in our patient population and their clinical characteristics would enable the development of better protocols in the smooth and safe delivery of treatment for cancer, adding to the wealth of information available. In the state of Kerala, the first case of COVID-19 was reported on January 30, 2020, in a student who had returned from Wuhan.[18] In the initial period (February, March), severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection could be contained through lockdowns, quarantine, contact tracing, and other preventive measures. Later, the numbers started increasing steadily and peaked in August-September and plateaued. On July 30, 2020, one of our patients scheduled for chemotherapy tested positive, following which, we implemented universal screening of all our patients scheduled for systemic anticancer treatment. However, the Indian Council of Medical Research (ICMR) recommends COVID-19 testing only for asymptomatic hospitalized patients or those admitted for chemotherapy.[19] Prior to these developments, only telephonic triaging and clinical screening were conducted. Patients were also advised to follow basic hygiene measures (using masks and washing hands) and social distancing recommended by the governmental authorities. There were no specific recommendations for screening patients who were planned for systemic anticancer therapy on a daycare basis or conducting repeat testing before each subsequent cycle of systemic therapy.

Materials and Methods

A retrospective cohort study was conducted on patients scheduled for systemic anticancer treatment at the medical oncology department of a tertiary care hospital in Kerala. All asymptomatic patients who have attended the department for systemic anticancer therapy were screened for the SARS-CoV-2 infection using nasopharyngeal (NP) swabs and were included in this analysis. Patients were regarded as asymptomatic if they had no fever (fever being defined as body temperature $\geq$38°C for more than 5 days), no symptoms of COVID-19—such as cough, headache, loss of taste, and shortness of breath or high-risk exposure (e.g., contact with a COVID-19 positive patient, visit by a family member from abroad or hospitalization) within 2 weeks. Symptomatic patients were excluded (►**Fig. 1**).

A total of 1,722 asymptomatic SARS-CoV-2 tests were performed in 1,496 consecutive patients before their scheduled chemotherapy/immunotherapy between August 1, 2020, and November 15, 2020. These included hospitalized patients from August 2020 and outpatient and hospitalized patients from September 1 to November 15, 2020. The primary outcome of the study was to determine the

prevalence of asymptomatic SARS-CoV-2 in patients with cancer. Demographic and clinical details were retrieved from the electronic medical records, and the COVID-19 diagnosis was confirmed using the SARS-CoV-2 NP swab polymerase chain reaction (PCR) testing and SARS-CoV-2 nucleocapsid antigen.

For consultations and other outpatient facilities, the rapid chromatographic immunoassay-based SARS-CoV-2 antigen test was used. Patients admitted for chemotherapy or supportive care were instructed to undergo the SARS-CoV-2 antigen and reverse transcriptase-polymerase chain reaction (RT-PCR). Both were utilized to avoid delays in initiating treatments. If the antigen test was negative, they were admitted to a particular ward, and chemotherapy started. If the RT-PCR was also negative, they were shifted to the general ward. The testing was performed before the start of chemotherapy and at each visit if the interval was more than 14 days. For those who were tested positive treatment was restarted once the RT-PCR test became negative. ►**Fig. 1** depicts the workflow for COVID-19 screening in the Oncology out-patient services (OPS).

The NP swabs were tested by the RT-PCR for SARS CoV-2 targeting RdRP and E-gene regions (ViroQ SARS-CoV-2 Kit, BAG Diagnostics, GmbH, Germany). They were also tested for SARS CoV-2 nucleocapsid antigen using the STANDARD Q COVID-19 AgTest (SD Biosensor, Inc., Republic of Korea).

Statistical Analysis:

The rates of positive SARS-CoV-2 PCR and antigen tests were analyzed and reported using the two-sided Clopper-Pearson (exact) test with a 95% confidence interval. The statistical analyses were conducted using IBM SPSS version 22.

Ethics

The procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation and with the Helsinki Declaration of 1964, as

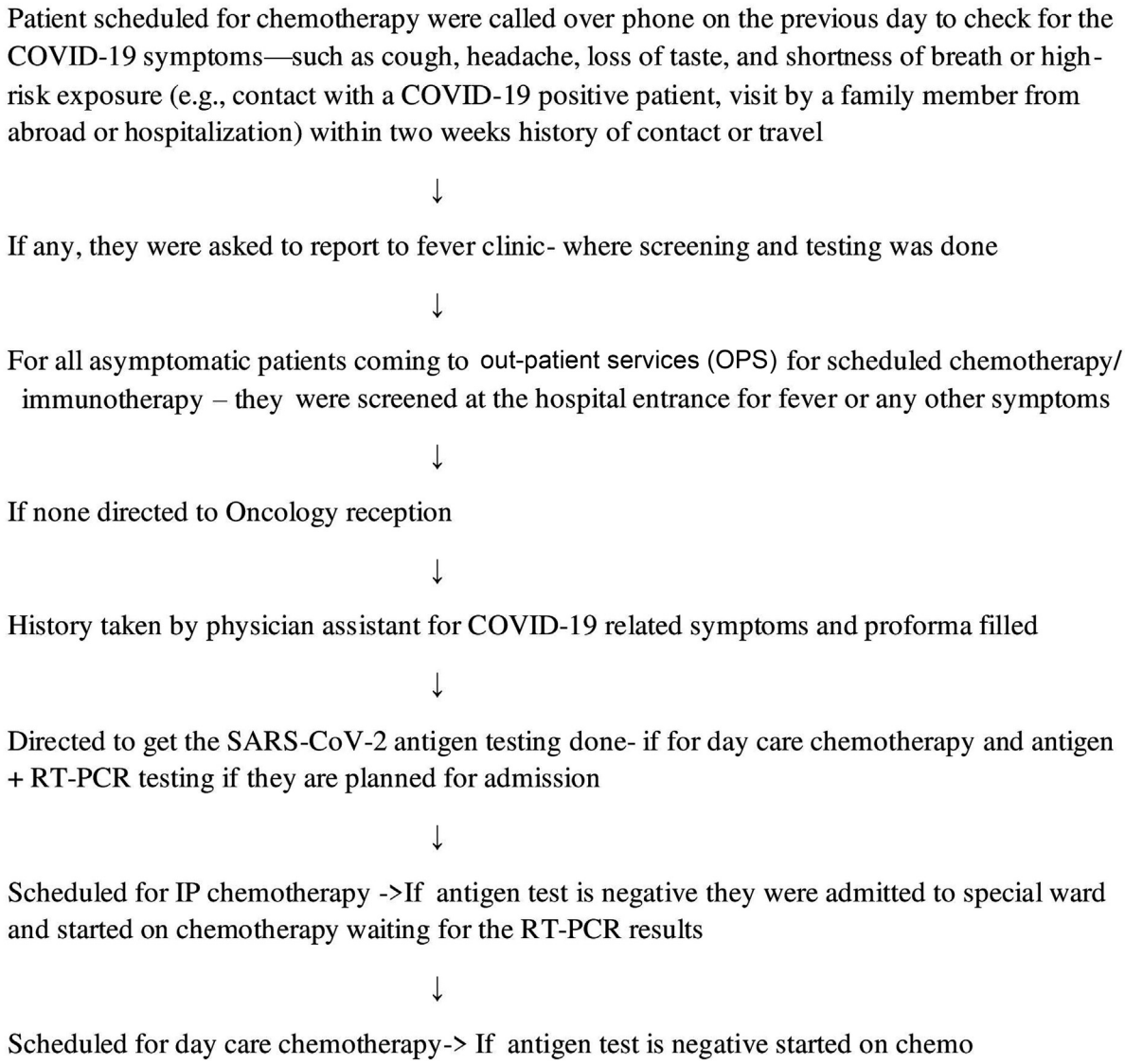

Fig. 1 Work flow for COVID-19 screening in the Oncology OPS. COVID-19, coronavirus disease 2019; OPS, out-patient services.

revised in 2013. The study was conducted after obtaining approval from the Institutional Review Board of Amrita Institute of Medical Sciences (IRB-AIMS-2020-342) dated December 15, 2020. A waiver of informed consent was obtained due to the retrospective nature of the study. The study was carried out in compliance with the protocol.

Results

A total of 1,722 SARS-CoV-2 tests were performed on 1,496 consecutive asymptomatic patients scheduled for chemotherapy/immunotherapy. During this period, 321 RT-PCR and 1,401 antigen tests were conducted, and 848 patients were screened for the SARS-CoV-2 infection more than twice. The median age of this patient cohort was 59 years (range 01–92 years); 652 (44.2%) patients were males, and 823 (55.78%) were females. The number of patients on adjuvant or neo-adjuvant chemotherapy were 885 (59.15%), and 611 (41.5%) patients were on chemotherapy for metastatic disease. The most common malignancy was breast cancer ($n = 397$, 26.5%) followed by gastrointestinal ($n = 246$, 16.4%) and lung ($n = 125$, 8.3%) cancers. The clinical characteristics of the study population are detailed in ►**Table 1**.

Among the 1,496 patients screened, 13 were found to be positive for the SARS-CoV-2 infection. All these patients were asymptomatic at the time of testing, giving an asymptomatic infection prevalence of 0.86% (95% confidence interval 0.3–1.2). The clinical and laboratory characteristics for the 13 patients are given in ►**Table 2**.

Table 1a Clinical characteristics of the study population

Population characteristics	$N = 1,496$ (%)
Median age, years (Range)	59 (01-92)
Sex	
Male	673 (44.98%)
Female	823 (55.01%)
Tested positive	13 (0.86%)
Solid tumors	
Breast	397 (26.53%)
Lung	125 (8.35%)
Esophagus, stomach, pancreas, biliary	100 (6.6%)
Colorectal	146 (9.75%)
Head and neck	37 (2.47%)
Gynecological	107 (7.15%)
Genitourinary	82 (5.48%)
Sarcoma	21 (1.4%)
Hepatocellular	42 (2.8%)
Brain	22 (1.4%)
Other solid tumors	132 (8.8%)
Haematological malignancies	
Lymphoma	128 (8.5%)
Leukemia	38 (2.5%)
Multiple myeloma	96 (6.4%)
Other hematological	23 (1.5%)

Table 1b Clinical characteristics of the study population

Population characteristics	$N = 1,496$
Solid tumors	
Breast	397
Lung	125
Esophagus, stomach, pancreas, biliary	100
Colorectal	146
Head and neck	37
Gynecological	107
Genitourinary	82
Sarcoma	21
Hepatocellular	42
Brain	22
Other solid tumors	132

The SARS-CoV-2 infection was detected using RT-PCR in 10 cases and rapid antigen testing in three other cases. The median age of the SARS-CoV-2 infection positive patients was 53 years (range: 17–64 years), out of which six were male, and seven were female. The most common malignancies among the SARS-CoV-2 infection positive patients were breast cancer ($n = 5$, 38%) followed by gastrointestinal ($n = 2$, 15%) and lung ($n = 2$, 15%) cancers. The abnormalities in complete blood counts observed among the patients were as follows: neutropenia ($n = 2$; one grade 1 and one grade 2), neutrophilia ($n = 1$, 10%), anemia ($n = 1$, grade 1), and thrombocytopenia ($n = 1$, grade 1). The hematological changes were all grade 1 or 2 and not clinically significant.

Out of the 13 patients, five were receiving chemotherapy when tested positive for the SARS-CoV-2 antigen. We carried out contact tracing for all these patients but could not identify the source of infection. Considering these patients as high-risk contacts, 11 were quarantined at home and two in the hospital. None of the caregivers, health care workers or other contacts caring for them developed the COVID-19 infection. All except two patients could resume anti-tumor therapy within 30 days (average delay of 27 days). ►**Fig. 2** outlines the delay in anti-tumor therapy among the SARS-CoV-2 infection positive patients.

None of them had any clinically apparent tumor progression due to the delay in treatment. RT-PCR negativity was attained in 14 to 30 days. During the serial screening, where 848 patients underwent screening two or more times, only one patient turned out to be positive. The total number of tests repeated is listed in ►**Table 3**.

Discussion

People with active cancer and cancer survivors are at an increased risk of COVID-19 and its complications, including

Table 2 Patient characteristics of asymptomatic SARS-CoV-2 positive patients

Patient demographics	Patients ($N = 13$)
Median age, years (range)	53 (17–64)
Sex	
Male	6
Female	7
Test used to detect SARS-CoV-2 infection.	
RT-PCR	10
Rapid antigen test	3
Diagnosis	
Breast cancer	5
Lung cancer	2
Gastrointestinal cancer	2
Head and neck cancer	1
Sarcomas	1
Hepatocellular	1
Lymphoma	1
Treatment	
Adjuvant/neoadjuvant	10
Metastatic	3
Average number of delay for anti-tumor treatment (days)	27
Anti-tumor therapy used	
Chemotherapy	10
Targeted therapy	2
Immunotherapy	1
Anticancer treatment used before COVID-19 infection	
Nil—newly diagnosed	4
Cytotoxic chemotherapy	6
Immunotherapy	1
Targeted therapy	2
Anticancer treatment used after COVID-19 infection	
Cytotoxic chemotherapy	7
Immunotherapy	1
Hormonal therapy	1
Targeted therapy	2
Radiation therapy	1
Surgery	1

hospitalization and 30-day mortality than the general population, due to factors like old age, smoking, comorbidities (diabetes, asthma, other respiratory, cardiac, neurological, renal, and liver diseases) and the effects of cancer treatment. Patients with cancer who are hospitalized are at a higher risk of severe COVID-19 infection compared to non-cancer controls.[20,21] About 30% of the people with COVID-19 are asymptomatic, and at least 50% of the transmission is estimated to happen from persons without symptoms.[22] These findings suggest that protective measures and strategic testing of asymptomatic patients will be necessary for slowing the spread of COVID-19 until a majority of the people are vaccinated.

Before getting admitted into a ward or a closed enclosure such as the daycare chemotherapy unit, screening all asymptomatic patients would be the best way to prevent the inter-patient spread of the SARS-CoV-2 infection and maintain confidence among health care workers. In previously reported studies, screening was conducted by three methods—RT-PCR, antibody testing, or antigen testing. We screened our daycare chemotherapy patients with the SARS-CoV-2 antigen testing. Although RT-PCR would have been ideal because of its higher sensitivity, this was not viable in our setting because of the two reasons—the cost of the test and the time taken for the RT-PCR report (more than 6 hours). This would necessitate patients staying back 1 day whereas, with rapid antigen testing, the results would be available within 1 hour, reducing delays in inpatient care.

In resource-poor settings, molecular testing results may take a few days or are altogether unavailable.[23] A recent study revealed comparable sensitivity (98.33%) and specificity (98.73%) for rapid SARS-CoV-2 antigen test with the real-time RT-PCR assay.[24] This was the same kit that we also used. Therefore, this rapid SARS-CoV-2 antigen detection test has enormous potential in resource-poor settings. In three previous studies, a serologic test was used.[25] In one, the rapid serological testing was not useful—it failed to detect the active asymptomatic COVID-19 infection and increased the cost of care and delayed therapy administration.[26] However, a similar study found it helpful in identifying the silent carriers and triaging patients for safe continuation of anticancer therapies.[27]

The prevalence of asymptomatic infections in our study was low (0.86%). The test positivity rate in the state of Kerala at the time of this study was 10 to 11%. In a similar study from Chennai, India, the testing of 761 patients was planned for chemotherapy using RT-PCR, out of which 11 (1.45%) patients were positive for COVID-19.[28] Our data was comparable to the low prevalence reported from developed nations like the United States of America (New York: 0.64%),[29] United Kingdom (Birmingham: 0.6%),[17] and Austria (Vienna: 0.4%).[30] The low prevalence of asymptomatic infections in our patients with cancer could be because they were more cautious and followed social distancing, hygiene, and masking rigorously. Additionally, Kerala's higher literacy rate of 96.2% probably helped, as educating our patients was easier.

In comparison, data from Germany reported an asymptomatic infection rate of 6.1% in their cancer patient population.[31] Similarly, in the study by Al-Shamsi et al from the United Arab Emirates (UAE), the RT-PCR positivity was 8.24% (7/85 patients).[32] All the RT-PCR positive cases later developed the symptomatic disease, two with severe illness,

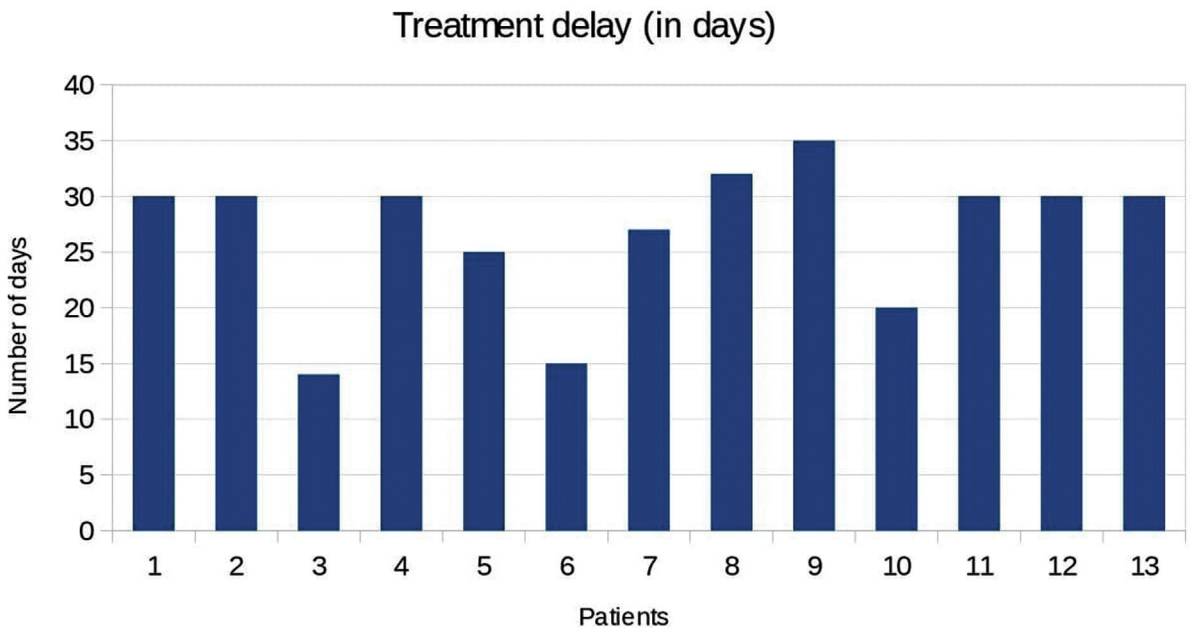

Fig. 2 Treatment delay in days.

Table 3 Number of times tests repeated

Number of tests done	Frequencies
1	648
2	493
3	187
4	112
5	37
6	19

requiring admission in the intensive care unit. In our cohort, only one patient developed the symptomatic disease.

The most prevalent cancers in our study were breast cancer, followed by gastrointestinal and lung cancers. In comparison, the most common diagnoses were gastrointestinal cancers in the study from New York[26] and breast cancer in the series from the UAE and Vienna.[30] In a study using serial testing from UAE, 25 (78.1%) were diagnosed in the asymptomatic state, and seven (21.9%) developed symptoms after an initial negative RT-PCR test. Although initially asymptomatic, the majority (84.4%) of patients with COVID-19 subsequently developed the symptomatic disease.[33] This was in sharp contrast with our study, where only one patient was positive on subsequent testing.

Similar to the study by Berghoff et al, our study also provides information on the SARS-CoV-2 prevalence in patients undergoing active anticancer therapy.[33] The universal screening of all patients in our department for the SARS-CoV-2 infection allowed us to identify positive patients and their contacts quickly. This helped prevent the spread of COVID-19 to health care workers as well as other patients.

Another factor we sought to explore in our study was the delay in therapy due to the pandemic. The delay becomes significant in patients undergoing curative-intent therapy and probably might be less concerning in metastatic diseases. Prior studies have documented that more than 4 weeks of treatment delay may affect outcomes across all cancer treatment modalities.[34] In our cohort of 13 patients who tested positive, 10 were on adjuvant therapy and three had metastatic disease. The median delay in initiation or continuation of cancer treatment was 30 days. The delay of more than 4 weeks occurred in eight patients. The curative intent adjuvant cytotoxic therapy was delayed for more than 4 weeks for seven patients. This was similar to other studies. We conducted contact tracing among all our patients but could not identify the source of infection for any. The possible source of infection or contact tracing was not mentioned in any of the previous studies.

There are some limitations in our study. Ideally, screening with RT-PCR SARS-CoV-2 testing would be preferable as it has higher sensitivity for COVID-19 detection than the available serological tests and rapid antigen tests. We used rapid antigen testing in most patients because of the shorter turnaround time and cost. As the sensitivity of this test is low, it would have missed some patients. However, a recent study by Chaimayo et al showed that the sensitivity and specificity were comparable with the real-time RT-PCR assay.[25] Given the results, antigen testing may be used in resource-poor settings. To the best of our knowledge, ours is the first study that used antigen testing from an LMIC. Our study included only patients who presented to the hospital for systemic anticancer treatment. The prevalence may differ in the community and the public sector hospital as the population of patients seeking treatment is different. Prevalence can also vary during the different periods of the year. Another limitation of our study is the retrospective study

design. However, our sample size was large. Based on these findings screening of high-risk patients (age ≥60 years, performance status ≥2, patient on prolonged immunosuppressive regimens and with comorbidities—cardiovascular, chronic obstructive pulmonary disease, diabetes, renal failure) and universal testing when the community prevalence is high may be a more cost-effective strategy.

Ongoing studies are needed to understand better the efficacy and safety of COVID-19 treatment approaches in cancer patients, comorbidities, and clinical outcomes. Patients with cancer and COVID-19 included in various studies were small in number and a heterogeneous group. Clinical outcomes and the biological basis for the comorbidity of cancer and COVID-19 remain to be resolved. Cancer treatment cannot be delayed, so we need to find ways to deliver cancer care on time by implementing screening strategies among the high-risk group and augmenting the vaccination drive.

Conclusion

Our study presents the findings of the universal screening strategy conducted for screening of COVID-19 among patients receiving anti-cancer treatment. The prevalence of asymptomatic COVID-19 infections in our study was low (0.86%). Our study results reflect that with proper health education, clinical triaging, and screening, it is possible to continue cancer treatment during the peak of the COVID-19 pandemic, even in LMICs.

Summary Points

We aimed to determine the prevalence of asymptomatic SARS-CoV-2 in patients with cancer planned for systemic anticancer treatment from an LMIC using rapid antigen tests and/or RT-PCR. In total, 1,722 asymptomatic SARS-CoV-2 tests were performed among 1,496 patients. The prevalence of asymptomatic COVID-19 infections in the study reported was low (0.86%). Clinical triaging with screening can detect asymptomatic cases and help continue planned anti-cancer treatment without any interruption.

Authors' Contributions
The authors were fully responsible for all content, and editorial decisions were involved at all stages of manuscript development and they approved the final version.

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None.

Conflict of Interest
None declared.

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