



BRIEF REPORT

Examining reporting and representation of patients with cancer in COVID-19 clinical trials

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Abstract

Background: Patients with cancer are particularly vulnerable in the current COVID-19 pandemic. Emerging evidence suggests that patients with a cancer diagnosis are three times more likely to die from COVID-19 compared to non-cancer patients. Due to these observed risks, it is critical that emerging COVID-19 therapies demonstrate safety and efficacy among patients with cancer.

Aim: This study sought to examine reporting and representation of patients with cancer among published COVID-19 treatment-related research studies.

Methods and results: All published COVID-19 treatment-related clinical research studies published from March 1 to August 20, 2020 recruiting from North America and Europe were identified. The date published, study design, therapeutics studied, and study population were evaluated. Of the 343 studies identified through initial search and researcher knowledge, 55 (16%) reported on COVID-19 treatments. Twenty-one COVID-19 therapeutic studies (n = 15, prospective; n = 6, retrospective) that recruited from the United States and Europe were identified. Among these studies, eight (38%) reported on the number of trial participants with a cancer diagnosis in the publication and two (10%) specified tumor type. Four of the studies (19%) did not collect cancer history. Among studies where cancer history was available, patients with a cancer diagnosis participated at a proportion higher than overall cancer prevalence and greater than the known proportion of COVID-19 patients with cancer.

Conclusion: This study observed that cancer history was not uniformly collected or reported among published COVID-19 therapeutic studies. Among reported publications, we observed that patients with a cancer diagnosis were generally overrepresented. However, patients with a cancer diagnosis were notably underrepresented in outpatient COVID-19 therapeutic studies.

KEYWORDS

cancer, clinical research participants, clinical trials, COVID-19, disparities

1 | INTRODUCTION

A large number of clinical trials testing a broad variety of interventions to treat SARS-CoV-2 infected patients have been reported since the onset of the global COVID-19 pandemic. In studies reported from the United States, the characteristics of study participants in COVID-19 treatment trials often do not reflect the distribution of the COVID-19 disease burden among the general population. In particular, racial and ethnic minorities face higher infection and mortality rates from COVID-19¹ yet are underrepresented in COVID-19 therapeutic clinical research.² It is not known if other vulnerable populations, such as patients with a cancer diagnosis, are also underrepresented in these trials. The inclusion of cancer patients in COVID-19 therapeutic trials is of importance, as cancer patients may develop cancer- or treatment-related symptoms that may influence a clinician's ability to diagnose COVID-19.³ Furthermore, cancer treatments may also increase the risk of severe respiratory symptoms that can be seen with SARS-CoV-2 infection.⁴

Due to the potential additional risks associated with SARS-CoV-2 infection among patients with a cancer diagnosis, inclusion of patients with a cancer diagnosis in clinical trials testing COVID-19 therapeutic interventions is essential. This study sought to examine the extent to which COVID-19 therapeutic clinical trials have reported on the

comorbidity of cancer diagnosis and, when available, achieved representation among participants.

2 | METHODS

COVID-19 treatment-related clinical research studies published from March 1 to August 20, 2020 were identified by searching "COVID-19 drug therapy" on PubMed and searching "COVID-19" using the Clinical Query filter. As shown in Figure 1, 343 articles were identified through initial search and researcher knowledge. Fifty-five of these (16%) reported on COVID-19 treatments. Twenty-one COVID-19 therapeutic studies ($n = 15$, prospective; $n = 6$, retrospective) were identified that recruited from the United States and Europe were identified. The date published, study design, treatment studied, eligibility criteria, the primary endpoint, study site, sample size, and the number of participants with a cancer diagnosis and their tumor types were noted for each eligible study. Investigators contacted all first authors of published studies seeking to identify the number of patients with a cancer diagnosis included in the sample and their tumor types, if not published. A univariate statistical descriptive analysis was employed.

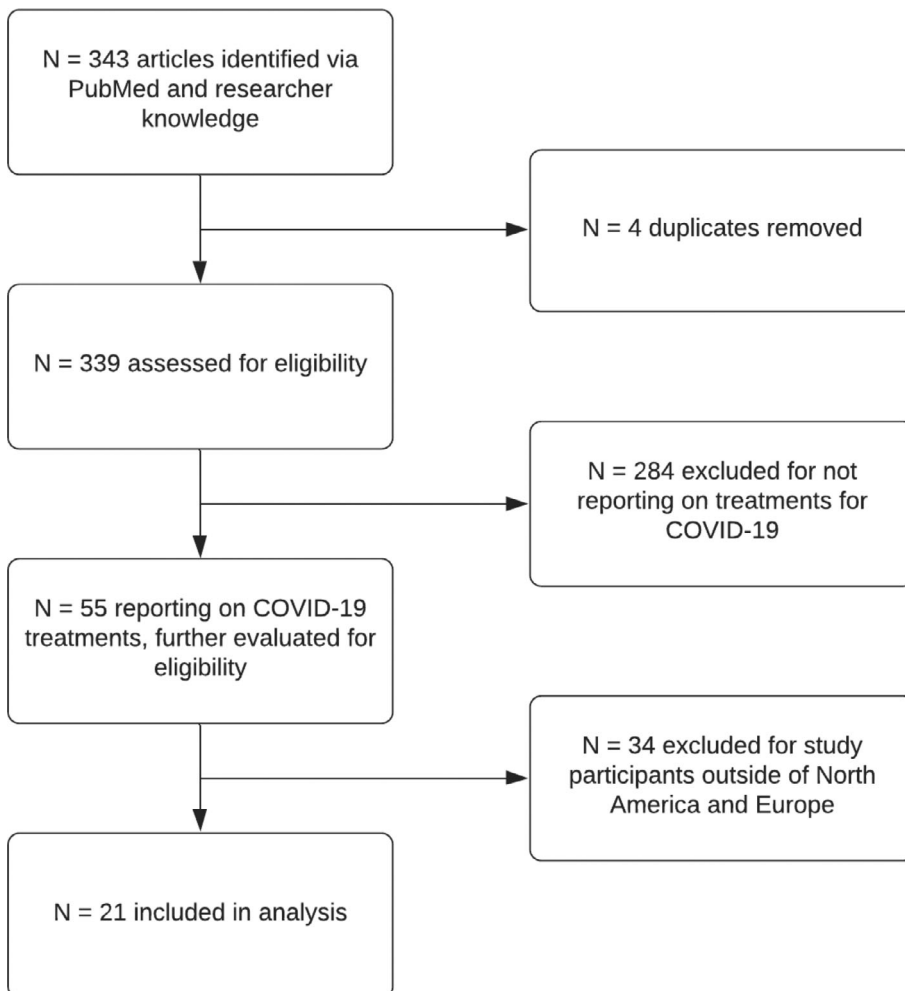


FIGURE 1 CONSORT diagram of COVID-19 treatment studies in North America and Europe

TABLE 1 Cancer patients in COVID-19 clinical studies

Treatment	Design	Setting	Primary endpoint	Total (N)	Cancer (N)	Tumor type	Location
Remdesivir ⁵	Prospective	Inpatient	Change in clinical status	35	1 (2.9%)	Breast ^a	Europe (Luigi Sacco Hospital, Milan, Italy)
Colchicine ⁶	Prospective	Inpatient	High-sensitivity cardiac troponin level and C-reactive protein; change in clinical status	105	Unknown		Europe (16 tertiary care hospitals, Greece)
Hydroxychloroquine and azithromycin ⁷	Retrospective	Inpatient	Change in clinical status, contagiousness	80	5 (6.3%)	Unknown	Europe (University Hospital Institute Méditerranée Infection, Marseille, France)
Auxora (a novel CRAC channel inhibitor) ⁸	Prospective	Inpatient	Change in clinical status	30	1 (3.3%) ^a	Hairy cell leukemia ^a	North America (California, Michigan, Minnesota, Texas, and Virginia, USA)
Hydroxychloroquine ⁹	Prospective	Outpatient	Reduction of viral RNA load; change in clinical status	293	1 (0.3%) ^a	Breast ^a	Europe (Catalonia, Spain)
Convalescent Plasma ¹⁰	Prospective	Inpatient	Change in clinical status	10	0 ^a	N/A	North America (Centro de Hematología y Medicina Interna, of the Clínica Ruiz, Puebla, Mexico)
Hydroxychloroquine and tocilizumab ¹¹	Retrospective	Inpatient	Change in clinical status	176	Unknown		North America (Abington Hospital–Jefferson Health, Pennsylvania, USA)
Inhibition of bruton tyrosine kinase ¹²	Prospective	Inpatient	Change in clinical status	19	2 (10.5%)	Prostate, CLL	North America (USA)
Hydroxychloroquine ¹³	Prospective	Outpatient	Change in clinical status	423	Not collected ^a		North America (multisite, USA, Canada)
Low-dose tocilizumab ¹⁴	Prospective	Inpatient	Fever resolution and CRP response	32	1 (3.1%) ^a	CLL ^a	North America (University of Chicago, Illinois, USA)
Anticoagulation prior to infection ¹⁵	Retrospective	Inpatient and outpatient	All cause mortality	3772	Not collected ^a		North America (Mount Sinai, New York City, New York, USA)
Enhanced platelet inhibition ¹⁶	Prospective	Inpatient	Change in PaO ₂ , PaO ₂ /FiO ₂ ratio and alveolar-arterial oxygen (A-a O ₂) gradient	10	1 (10%)	Rectal (successfully treated 6 y prior)	Europe (Intermediate Respiratory Care Unit of L. Sacco University Hospital, Milano, Italy)
Ruxolitinib ¹⁷	Retrospective	Inpatient	CIS reduction	14	1 (7.1%) ^a	Lung ^a	Europe (Schwarzwald-Baar-Klinikum Villingen-Schwenningen, Germany)
Hyperimmune plasma ¹⁸	Prospective	Inpatient	7 days mortality rate	46	7 (16%)	Unknown	Europe (Two university hospitals and one general hospital in Northern Italy)
Remdesivir ¹⁹	Prospective	Inpatient	Time to recovery	1059	71 (7.7%)	Not collected ^a	Multisite (73 sites in USA, Denmark, UK, Greece, Germany, Korea, Mexico, Spain, Japan, and Singapore)

(Continues)

TABLE 1 (Continued)

Treatment	Design	Setting	Primary endpoint	Total (N)	Cancer (N)	Tumor type	Location
Hydroxychloroquine as postexposure prophylaxis ²⁰	Prospective	Outpatient	Incidence of Covid-19 within 14 days	821	1 (0.2%)	Not collected ^a	North America (Minneapolis, Minnesota, USA, and Montreal, Quebec, Canada)
Hydroxychloroquine and azithromycin ²¹	Prospective	Inpatient	Presence/absence of virus	36	Unknown		Europe (Marseille, Nice, Avignon, and Briançon centers, South France)
Hydroxychloroquine ²²	Retrospective	Inpatient	Time from study baseline to intubation or death	1376	176 (12.8%)	30 different tumor types ^a	North America (NYP-CUIMC, New York, USA)
Remdesivir ²³	Prospective	Inpatient	Change in clinical status	53	Not collected ^a		Multisite (22 subjects in the United States, 22 in Europe or Canada, and 9 in Japan)
Hydroxychloroquine with or without concomitant azithromycin ²⁴	Retrospective	Inpatient	Change in QT interval	90	Not collected ^a		North America (Boston, Massachusetts, USA)
Remdesivir ²⁵	Prospective	Inpatient	Change in clinical status	397	Unavailable ^a		Multisite (55 hospitals in the USA, Italy, Spain, Germany, Hong Kong, Singapore, South Korea, and Taiwan)

^aCancer and tumor type information captured by contacting study's corresponding author.

3 | RESULTS

As shown in Table 1, there have been 21 COVID-19 therapeutic studies ($n = 7$, randomized clinical trial; $n = 5$, single arm; $n = 6$, observational; $n = 3$, compassionate use) published to date with participants in North America and Europe. Thirty-eight percent ($n = 8$) reported the number of trial participants with a cancer diagnosis in the publication. Two of those publications specified the type of malignancy. Investigators were able to obtain the number of patients with cancer included in five additional studies by contacting authors directly, of which four also shared data on tumor type. Four first authors confirmed that cancer history information was not collected for their published studies. Two of the studies reported the number of participants with cancer but did not collect data on tumor type. Investigators were unable to determine the existence of cancer data beyond that which was published for five of the studies. Of the studies for which data were available, 6.2% of study participants carried a cancer diagnosis.

Patients with a cancer diagnosis comprised a small subset of COVID-19 clinical research participants. An average of 5% of study participants in North America, 7.1% of study participants in Europe, and 7.7% of multisite study participants had a cancer diagnosis. Figure 2A summarizes the distribution of cancer patients across the studies surveyed and compares it with the reported cancer prevalence in those populations. The cancer prevalence is 5.34% in North America and 1.92% in Europe, an average of 3.63% across all study sites included in our analysis.²⁶ Patients with cancer are underrepresented

in COVID-19 clinical research studies in North America (5% of study participants vs 5.34% cancer prevalence). However, patients with a cancer diagnosis were overrepresented in Europe (7.1% of study participants vs 1.92% cancer prevalence) and multisite studies (7.7% of study participants vs 3.63% cancer prevalence). In a meta-analysis of 32 studies involving 46 499 COVID-19 patients, 3.82% (1776 patients) had cancer.²⁷ Figure 2B illustrates that patients with cancer were overrepresented in both prospective (5.4%) and retrospective (8.73%) studies based on the overall percentage of COVID-19 patients with cancer (3.82%). While patients with cancer were overrepresented in inpatient studies (7.24%), as shown in Figure 2C, they were significantly underrepresented in outpatient studies (0.25%).

4 | DISCUSSION

The potential impact of a cancer diagnosis on COVID-19 outcomes, and conversely the impact of SARS-CoV-2 infection on cancer outcomes, underscores the importance of inclusion of cancer patients in COVID-19 therapeutic trials. Achieving full representation of patients with cancer in COVID-19 therapeutic trials would provide stronger safety and efficacy data among these vulnerable patients.

This study demonstrates that cancer history is inconsistently collected and reported among COVID-19 therapeutic research studies, as only 38% of the studies analyzed reported the number of participants with a cancer diagnosis. While patients carrying a cancer

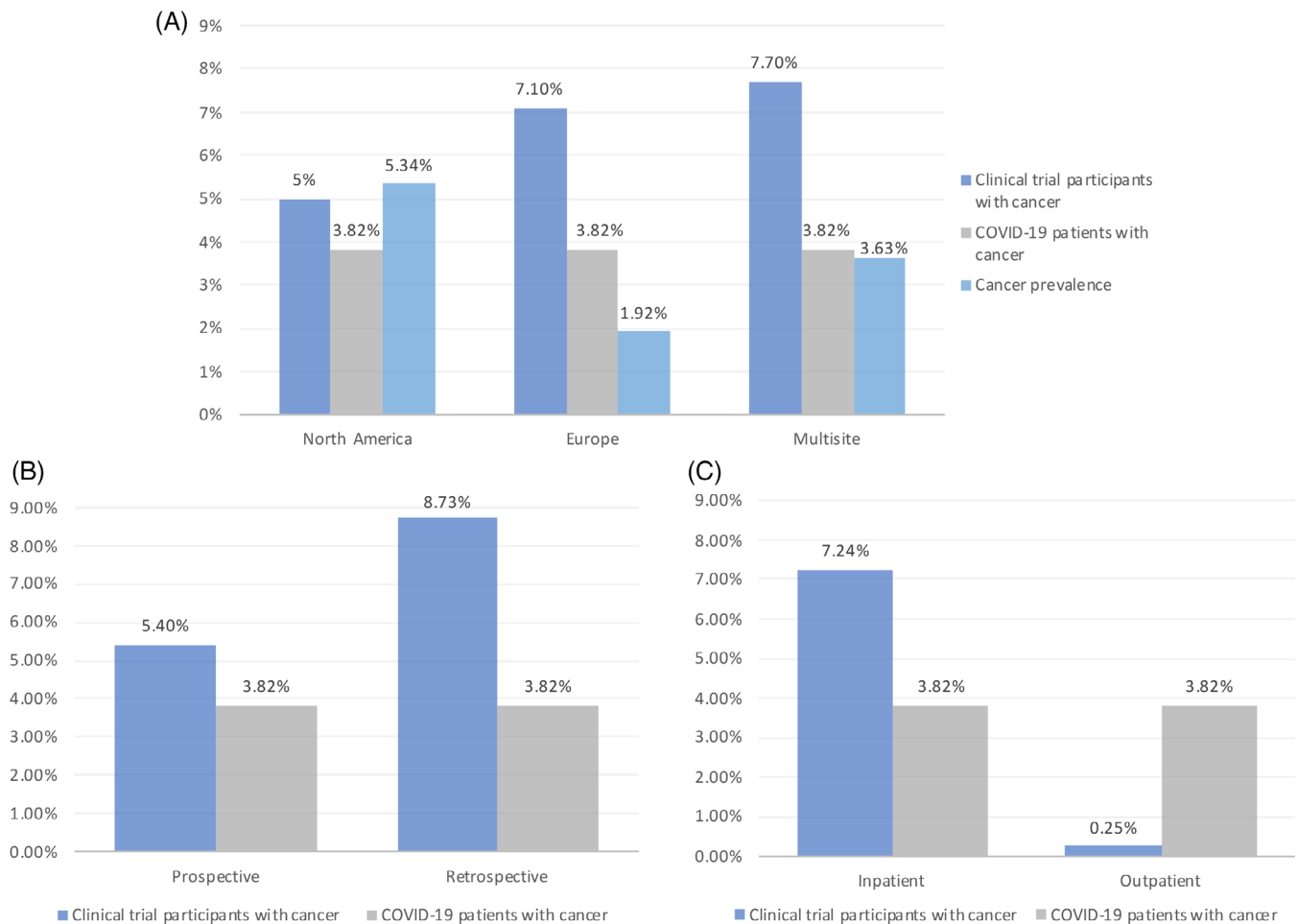


FIGURE 2 Comparison of representation of patients with cancer diagnosis by: (A) Regional comparison (North America vs Europe vs Multisite); (B) Study design comparison (prospective vs retrospective); (C) Study clinical setting comparison (inpatient vs outpatient)

diagnosis were generally overrepresented in COVID-19 therapeutic studies, they were notably underrepresented in outpatient studies as only 0.25% of participants in outpatient COVID-19 therapeutic studies had a cancer diagnosis.

Patients with cancer are more susceptible to infection than those without cancer due to immunosuppression caused by malignancy and/or anticancer treatments.²⁸ In general, patients with cancer seem to be at a higher risk both of being infected with SARS-CoV-2, and if infected, of becoming severely ill. Thirty-six point 5% of COVID-19 patients with cancer reach a critical/severe status compared to 19% of the general COVID-19 population.²⁹ An early analysis from China reported that 1% of COVID-19 patients had a history of cancer, an incidence higher than that of cancer in the general Chinese population (0.29%). These patients suffered severe events—defined as requiring mechanical ventilation or death—during their COVID-19 illness at a rate 3.5 times that of the general population.³⁰ Overall, patients with cancer have an increased risk of all severe outcomes from COVID-19, including ICU admission, developing severe symptoms, requiring mechanical ventilation, and death.³¹ Furthermore, patients with cancer in China experienced a fatality rate from COVID-19 of 28.6%,³² compared to the overall COVID-19 fatality

rate in China of 2.3%.³³ A review of publications on the impact of COVID-19 on patients with cancer worldwide found reported mortality rates among patients with cancer range from 9% to 33.3%, compared to an overall 3% to 6% fatality rate.³⁴ One recent study found that patients with cancer and COVID-19 face an increased likelihood of in-hospital death compared to COVID-19 patients without cancer (31.7% vs 20.0%, respectively).³⁵ Additionally, an early report of COVID-19 fatalities in Italy found that patients with active cancer accounted for 20.3% of the deceased.³⁶ Thus, the overrepresentation of patients with cancer in inpatient studies likely reflects the higher likelihood of hospitalization in COVID-19 patients with cancer. Since most of the studies analyzed (18 of 21) included hospitalized participants, this may also explain the overall overrepresentation of patient with cancer in COVID-19 clinical research studies.

Given this vulnerability, it is even more important to carefully consider the treatment of patients with cancer during the COVID-19 pandemic. Any treatment must be based on a discussion of the risks and benefits with the patient per recently published European and American guidelines.^{37,38}

Although it is clear that patients with a cancer diagnosis are particularly vulnerable to COVID-19 and that cancer pathology may



affect COVID-19 illness, only one trial included in this study published a stratified analysis detailing the differences in treatment outcome in patients with cancer. Considering the unique relationship between COVID-19 and cancer, it is especially important that the effects of potential COVID-19 treatments be analyzed in patients with cancer.

Eligibility criteria for participation in COVID-19 therapeutic trials are not consistent across clinical research studies. Patients with a cancer diagnosis were systematically excluded from several of the published studies reviewed due to immunosuppressed status as a result of concurrent medications. Notably, two of the three outpatient trials analyzed excluded patients receiving active cancer treatment. This exclusion likely contributed to the observed underrepresentation of patients with a cancer diagnosis in outpatient trials. While this exclusion may be appropriate given potential interactions between antiviral therapeutics and antineoplastic agents, it limits the ability to draw conclusions in this group of patients.

The limitations of this study include the small sample size and the diversity in study designs assessed. Only 21 clinical research studies were assessed. Over twice as many were excluded based on geography. While this exclusion is a significant limitation, we chose to select studies only from North America and Europe because the methodology for determining cancer prevalence and, as a result, its accuracy, varies widely. For this first analysis, we thus intentionally selected studies from North America and Europe, which have reasonably homogenous cancer reporting processes. Furthermore, this analysis included a variety of study designs, both prospective and retrospective. We pooled articles without regard for their heterogeneity, allowing the possibility of inaccurate conclusions from combining dissimilar studies. Additionally, the rush to find COVID-19 treatments also has meant that many trials are not developed, conducted, and analyzed as rigorously as usual.³⁹ New research on COVID-19 therapeutics is published daily, making it difficult to capture an up-to-date portrait of study participants worldwide. We employed a search in the PubMed database in order to render clinical-relevant literature. However, this research approach leads to potential bias toward US-based studies.

The exclusion and subsequent underrepresentation of patients with a cancer diagnosis in outpatient studies of COVID-19 therapeutics is concerning, given the vulnerability of patients with cancer to COVID-19. Developing safe and effective outpatient treatments for COVID-19 that prevent hospitalization is critical in reducing death rates,⁴⁰ so this underrepresentation of patients with a cancer diagnosis, particularly in outpatient COVID-19 clinical studies, is of concern. Inadequate evaluation of potential outpatient therapies in patients with cancer may result in less effective treatments since the SARS-CoV-2 virus, COVID-19 illness, and potential treatments may be affected by cancer pathology and treatments. To date, there are 135 outpatient COVID-19 clinical trials recruiting in North America and Europe.⁴¹ It is important that these trials include a significant proportion of patients with a cancer diagnosis and that all COVID-19 clinical trials report a stratified analysis of their results focused on their participants with a cancer diagnosis.

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CONFLICTS OF INTEREST

The authors have stated explicitly that there are no conflicts of interest in connection with this article.

AUTHOR CONTRIBUTIONS

Conceptualization, M.R., H.B.; *Data Curation*, M.R., P.T., H.B.; *Investigation*, M.R.; *Supervision*, S.Z., E.J.S., H.B.; *Visualization*, M.R.; *Writing-Original Draft*, H.B.; *Writing-Original Draft*, M.R.; *Writing-Review & Editing*, C.W., S.Z., E.J.S., H.B.

ETHICAL APPROVAL

All study procedures received institutional ethical approval.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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