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.

COVID-19 in patients with thoracic malignancies (TERAVOLT): first results of an international, registry-based, cohort study

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Summary

Background Early reports on patients with cancer and COVID-19 have suggested a high mortality rate compared with the general population. Patients with thoracic malignancies are thought to be particularly susceptible to COVID-19 given their older age, smoking habits, and pre-existing cardiopulmonary comorbidities, in addition to cancer treatments. We aimed to study the effect of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection on patients with thoracic malignancies.

Methods The Thoracic Cancers International COVID-19 Collaboration (TERAVOLT) registry is a multicentre observational study composed of a cross-sectional component and a longitudinal cohort component. Eligibility criteria were the presence of any thoracic cancer (non-small-cell lung cancer [NSCLC], small-cell lung cancer, mesothelioma, thymic epithelial tumours, and other pulmonary neuroendocrine neoplasms) and a COVID-19 diagnosis, either laboratory confirmed with RT-PCR, suspected with symptoms and contacts, or radiologically suspected cases with lung imaging features consistent with COVID-19 pneumonia and symptoms. Patients of any age, sex, histology, or stage were considered eligible, including those in active treatment and clinical follow-up. Clinical data were extracted from medical records of consecutive patients from Jan 1, 2020, and will be collected until the end of pandemic declared by WHO. Data on demographics, oncological history and comorbidities, COVID-19 diagnosis, and course of illness and clinical outcomes were collected. Associations between demographic or clinical characteristics and outcomes were measured with odds ratios (ORs) with 95% CIs using univariable and multivariable logistic regression, with sex, age, smoking status, hypertension, and chronic obstructive pulmonary disease included in multivariable analysis. This is a preliminary analysis of the first 200 patients. The registry continues to accept new sites and patient data.

Findings Between March 26 and April 12, 2020, 200 patients with COVID-19 and thoracic cancers from eight countries were identified and included in the TERAVOLT registry; median age was 68·0 years (61·8–75·0) and the majority had an Eastern Cooperative Oncology Group performance status of 0–1 (142 [72%] of 196 patients), were current or former smokers (159 [81%] of 196), had non-small-cell lung cancer (151 [76%] of 200), and were on therapy at the time of COVID-19 diagnosis (147 [74%] of 199), with 112 (57%) of 197 on first-line treatment. 152 (76%) patients were hospitalised and 66 (33%) died. 13 (10%) of 134 patients who met criteria for ICU admission were admitted to ICU; the remaining 121 were hospitalised, but were not admitted to ICU. Univariable analyses revealed that being older than 65 years (OR 1·88, 95% 1·00–3·62), being a current or former smoker (4·24, 1·70–12·95), receiving treatment with chemotherapy alone (2·54, 1·09–6·11), and the presence of any comorbidities (2·65, 1·09–7·46) were associated with increased risk of death. However, in multivariable analysis, only smoking history (OR 3·18, 95% CI 1·11–9·06) was associated with increased risk of death.

Interpretation With an ongoing global pandemic of COVID-19, our data suggest high mortality and low admission to intensive care in patients with thoracic cancer. Whether mortality could be reduced with treatment in intensive care remains to be determined. With improved cancer therapeutic options, access to intensive care should be discussed in a multidisciplinary setting based on cancer specific mortality and patients' preference.

Funding None.

Introduction

COVID-19, a respiratory tract infection caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), emerged in Wuhan, China, in late 2019.[1] Its rapid global spread led WHO to declare a pandemic in early March, 2020,[2] with more than 7 360 200 confirmed

Research in context

Evidence before this study

We searched PubMed on March 16, 2020, using the search terms ("novel coronavirus" OR "SARS-CoV-2" OR "COVID-19") AND ("cancer" OR "carcinoma" OR "tumor" OR "thoracic cancer" OR "NSCLC" OR "lung cancer") for articles in English that documented the risk factors for morbidity and mortality from COVID-19 in patients with and without cancer. Data on the impact of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection on patients with cancer is scant and predominantly from retrospective series emerging from China. Although previous reports on patients with cancer infected with SARS-CoV-2 have suggested a higher mortality rate compared with the general population, the applicability of such data is hampered by small sample sizes, including 1–2% of the total patient population with multiple different tumour types, at a single institution. Among them, patients with thoracic malignancies are thought to be particularly vulnerable.

Added value of this study

To our knowledge, this is the first report of the effect of SARS-CoV-2 infection on patients with thoracic cancers, using a global database (TERAVOLT) that aims to understand the effect of SARS-CoV-2 infection on this patient group. To date, we have obtained data from 200 patients with thoracic cancers in eight countries, predominantly in Europe, with most patients on active treatment at the time of infection. We report a 33% mortality rate and a low proportion of patients receiving intensive care or mechanical ventilation. Only smoking seems to significantly correlate with higher death rates.

Implications of all the available evidence

Overall, patients with thoracic malignancies have a higher mortality compared with that reported for the general population, in line with previous reports from China. As most patients were on therapies that have been shown to improve survival at the time of SARS-CoV-2 infection, a diagnosis of thoracic malignancy alone should not be an exclusion criteria for ICU admission and care. Also, the effect of smoking—both former and current—should be further investigated. TERAVOLT will continue to register patients to identify those with higher risk of severe SARS-CoV-2 infection and the effect of specific COVID-19 therapies on outcomes.

cases and 416 000 deaths as of June 11.[3] Due to limited testing capacity, the true global infection and mortality rates are likely to far exceed the confirmed cases.[4]

One of the first publications describing patients infected with SARS-CoV-2 came from The National Health Commission of China and reported on 1099 patients from 552 hospitals.[5] They noted that 24% of patients had comorbidities associated with a more severe SARS-CoV-2 infection. In patients admitted to hospital, the median duration of hospital stay was 12 days, 5% required an admission to the intensive care unit (ICU), 2·3% required mechanical ventilation and 1·4% died. The most common presenting symptoms at time of hospital admission were cough and fever. In the largest report from Italy on 1591 patients with COVID-19 admitted to the ICU, 88% required mechanical ventilation and 68% had at least one comorbidity, with hypertension in 49% of patients.[6] At the time of publication, 16% of patients had been discharged and 26% had died, with age being the most significant risk factor for mortality. Many other reports describe similar clinical features of patients presenting with COVID-19.[7–11] The differences in patients' demographics and mortality between the reports from China and those from Italy and other countries have not yet been fully explained. Data on how the virus affects patients living with cancer has also emerged. A report of 1524 patients with cancer who were screened at Zhongnan Hospital in Wuhan identified COVID-19 in 12 (0·8%) patients, seven of whom had non-small-cell lung cancer (NSCLC) and more than half of whom were on active therapy. One patient required ICU admission and three patients died, leading the authors to conclude that patients with cancer had a higher risk of mortality compared with the community.[12] A second report from Wuhan on 1590 hospitalised patients with COVID-19 noted a higher incidence and risk for ICU admission or mortality in patients with cancer.[13] These publications are limited by their small sample size and the inherent bias that patients with cancer were more likely to be tested for the virus by nature of their symptoms and frequency of contacts with the medical system.[14,15]

In a recent commentary, Lipsitch and colleagues posed several important questions that need to be answered to characterise the impact of this new virus on patients, including elucidating the full spectrum of the disease, ranging from asymptomatic to fatal.[16] They also emphasised the need to identify subgroups most likely to have poor outcomes, thereby deserving specific prevention and therapy efforts.[16] Many scientific societies have provided clinical recommendations for the management of patients with cancer, revisiting standards of care and allowing for a better risk–benefit ratio in this period of rapid viral circulation, including minimising hospital visits, which have been identified as a contamination risk.[17,18] Regarding systemic treatments, a particular emphasis has been placed on immune checkpoint inhibitors, which have been assumed to result in more complications in patients who are infected with SARS-CoV-2, albeit without any reliable scientific evidence.[19]

Unfortunately, epidemiological data suggest that the pandemic will continue for months if not for years.[20] The improvement in lung cancer mortality reported in 2020 is thought to be due to major advances in the treatment of patients with advanced-stage NSCLC, who are treated

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See Online for appendix

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with tyrosine kinase inhibitors (TKIs) and immune checkpoint inhibitors.[21] The fear and anxiety created by the outbreak of COVID-19 has resulted in a major shift in cancer care delivery, with hospitals reducing patient visits and implementing telemedicine while delaying surgery, systemic therapy, and routine follow-up. Screening rates allowing for earlier detection of cancers have also undoubtedly dropped as many health-care systems have postponed elective imaging procedures, as has been dramatically observed for breast, colon, and cervical cancer screenings.[22] While such strict measures are necessary in the short term to protect patients from SARS-CoV-2 infection, prolonged treatment delays could lead to an increase in cancer-related mortality. Therefore, it is crucial to understand the impact of COVID-19 on patients with cancer to ensure optimal care. The Thoracic Cancers International COVID-19 Collaboration (TERAVOLT) is the first global registry aimed at understanding the effect of SARS-CoV-2 infection on patients with thoracic malignancies.

Methods

Study design and participants

This study is composed of a cross-sectional component and a longitudinal cohort component. The cross-sectional part describes the patients and disease characteristics both for cancer and for COVID-19 disease, including treatment received and complications due to therapy; the longitudinal component is related to the association between potential prognostic factors and outcome.

Institutions from around the world were invited via email to collaborate. Almost 200 centres have expressed interest in collaborating on the database; to date, 87 have received Institutional Review Board approval and have contributed data (appendix pp 12–13). Main eligibility criteria were patients with thoracic cancer (NSCLC, small-cell lung cancer, mesothelioma, thymic epithelial tumours, and other pulmonary neuroendocrine neoplasms) with a COVID-19 diagnosis defined as any of the following: laboratory confirmed (using RT-PCR techniques) COVID-19; suspected COVID-19 with at least one of the following symptoms: fever higher than 37·5°C, decrease of oxygen saturation of at least 5%, cough, diarrhoea, otitis, dysgeusia, myalgia, arthralgia, conjunctivitis, and rhinorrhoea, and, when available, known exposure to a person with confirmed COVID-19; or radiologically suspected cases with lung imaging features consistent with COVID-19 pneumonia and symptoms. Asymptomatic patients found positive for SARS-CoV-2 were included in this analysis; these patients were tested although asymptomatic according to local and institutional policies or owing to known exposure to a person with confirmed COVID-19. Patients of any age, sex, histology, or stage were considered eligible, including those in active treatment and clinical follow-up. Full eligibility criteria are listed in the study protocol (appendix pp 14–20). Participating centres were asked to enrol consecutive patients with these characteristics.

Local Institutional Review Board approval is required for each centre before data entry. For those institutions that required consent, when possible written informed consent was obtained. A waiver was allowed for those who were not able to sign. All study procedures were in accordance with the precepts of Good Clinical Practice and the declaration of Helsinki. According to the regulation (EU) 2016/679 of the European Parliament and of the Council of April 27, 2016, the following requirements regarding personal data were guaranteed: pseudonymisation and encryption, confidentiality, integrity, availability, resilience of treatment systems and services, and the ability to restore the availability and access of data in the event of a physical or technical accident.

Procedures

Data are entered into a de-identified REDCap (Research Electronic Data Capture) database, with each institution assigned a unique number. REDCap is a secure web platSform for building and managing online databases and surveys; it provides easy data handling (with audit trails for reporting, monitoring, and querying patient records) and an automated export mechanism to common statistical packages (SPSS, SAS, Stata, R/S-Plus).

Clinical data were extracted from medical records of consecutive patients from Jan 1, 2020, and will be collected until the end of pandemic declared by WHO. Data are divided into four main categories: demographics, oncological history and comorbidities, COVID-19 diagnosis, and course of illness and clinical outcomes (appendix p 2). Oncological outcomes will be collected until the end of the study for all patients included to evaluate the effect of this pandemic on treatment delays. Initial case report form variables were chosen according to available data from the literature and are updated on the basis of emerging evidence.[23]

Basic demographic characteristics, including age, sex, smoking status, race, stage of disease at COVID-19 diagnosis (American Joint Committee on Cancer clinical stages), type of thoracic malignancy, current oncological treatment, comorbidities, concomitant medications, method for COVID-19 diagnosis, and need for hospital admission, were recorded; a complete list can be found in the appendix (p 2). For hospitalised patients, the length of hospital stay and need for admission to ICU were also recorded. Criteria for ICU admission were defined as needing a higher level of care including more intense monitoring, ventilation, and resuscitation.

Statistical analysis

Descriptive statistics of patients' demographics (eg, age, sex) and clinical characteristics (eg, comorbidities, severe events, therapy) were reported as frequencies (proportions) for categorical variables and median (IQR) for

continuous variables. Summary measures for association between demographic and clinical characteristics and outcomes (hospitalisation, prolonged hospitalisation [>8 days], and death) were assessed by univariable logistic models; the association with risk of death was also assessed with multivariable logistic models. Results are given as odds ratios (ORs) with 95% CIs. In multivariable analysis of factors associated with risk of death, we included sex, age (>65 years *vs* ≤65 years), smoking status (current or former *vs* never), hypertension, and chronic obstructive pulmonary disease (COPD)—all factors known from the literature to be associated with COVID-19 outcomes in general patient populations. Patients with missing values were excluded from univariable and multivariable analyses. All analyses were done using R (version 3.6).

No power analysis was done to calculate the sample size, and the aim was descriptive in nature, focusing on estimation rather than hypothesis testing. With about 150 centres contributing data and about five patients from every centre, a sample size of approximately 750 patients can produce a CI of ±2% for estimates of proportion. In this study, we present preliminary data on the first 200 consecutive patients enrolled; the cutoff number was not dependent on previous knowledge of results but was driven by the emergency and the lack of data provided in this setting so far. This report of the first 200 patients was not prespecified in the protocol but was written to disseminate information quickly during the pandemic. With a CI of less than 14%, we believe the results can assure a reasonably precise preliminary estimate for the purpose of our study.

Role of the funding source

There was no funding source for this study. The corresponding author had full access to all of the data and the final responsibility to submit for publication.

Results

Between March 26 and April 12, 2020, data on the first 200 patients were entered into the TERAVOLT registry, from 42 institutions across eight countries (Italy, Spain, France, Switzerland, Netherlands, USA, UK, and China).

180 (91%) of the 198 patients with COVID-19 diagnosis information were diagnosed with COVID-19 by RT-PCR, five (3%) were diagnosed on the basis of clinical symptoms (with fever >37·5°C [n=4] and dyspnoea [n=4] in most patients), and 13 (7%) had radiological findings that were highly suggestive of COVID-19. The remaining two patients were missing data on COVID-19 diagnostic tests. Median follow-up since COVID-19 diagnosis was 15 days (IQR 8–24). Median age was 68·0 years (61·8–75·0). The majority of patients were male, white, or current or former smokers (table 1). The most common histology was NSCLC, followed by small-cell lung cancer. Most patients had stage IV disease, and 147 (74%) patients were currently undergoing treatment, of whom 144 were receiving systemic therapy (table 1). The most common treatments were chemotherapy alone, immune checkpoint inhibitors alone, TKIs alone, and chemotherapy in combination with immune checkpoint

	All patients (n=200)	Hospitalised (n=152)	Not hospitalised (n=48)
Age, years	68·0 (61·8–75·0)	68·5 (62·0–75·2)	66·0 (59·0–71·5)
<50	12 (6%)	8 (5%)	4 (8%)
50–65	66 (33%)	47 (31%)	19 (40%)
>65	122 (61%)	97 (64%)	25 (52%)
Sex			
Female	59 (30%)	42 (28%)	17 (35%)
Male	141 (70%)	110 (72%)	31 (65%)
Smoking status			
Current	48/196 (24%)	38/148 (26%)	10 (21%)
Former	111/196 (57%)	84/148 (57%)	27 (56%)
Never	37/196 (19%)	26/148 (18%)	11 (23%)
Race			
White	184/195 (94%)	142/149 (95%)	42/46 (91%)
Other	11/195 (6%)	7/149 (5%)	4/46 (9%)
Region			
Europe	196 (98%)	149 (98%)	47 (98%)
USA	3 (2%)	2 (1%)	1 (2%)
Asia	1 (1%)	1 (1%)	0
Country			
Italy	118 (59%)	86 (57%)	34 (71%)
Spain	36 (18%)	34 (22%)	2 (4%)
France	26 (13%)	19 (12%)	7 (15%)
Switzerland	8 (4%)	5 (3%)	3 (6%)
Netherlands	6 (3%)	5 (3%)	1 (2%)
USA	3 (2%)	2 (1%)	1 (2%)
UK	2 (1%)	1 (1%)	1 (2%)
China	1 (1%)	1 (1%)	0
Cancer stage at COVID-19 diagnosis			
I	15 (8%)	11 (7%)	4 (8%)
II	2 (1%)	2 (1%)	0
III	36 (18%)	28 (18%)	8 (17%)
IV	147 (74%)	111 (73%)	36 (75%)
Cancer diagnosis			
NSCLC	151 (76%)	111 (73%)	40 (83%)
Small-cell lung cancer	29 (15%)	23 (15%)	6 (13%)
Thymoma or thymic carcinoma	8 (4%)	7 (5%)	1 (2%)
Carcinoid or neuroendocrine	4 (2%)	3 (2%)	1 (2%)
Malignant pleural mesothelioma	8 (4%)	8 (5%)	0
ECOG performance status			
0	63/196 (32%)	63/196 (32%)	63/196 (32%)
1	79/196 (40%)	79/196 (40%)	79/196 (40%)
2	35/196 (18%)	35/196 (18%)	35/196 (18%)
3	16/196 (8%)	16/196 (8%)	16/196 (8%)
4	3/196 (2%)	3/196 (2%)	3/196 (2%)
Currently undergoing treatment			
Yes	147/199 (74%)	106/151 (70%)	41 (85%)
No	52/199 (26%)	45/151 (30%)	7 (15%)

(Table 1 continues on next page)

	All patients (n=200)	Hospitalised (n=152)	Not hospitalised (n=48)
(Continued from previous page)			
Line of therapy			
0	42/197 (21%)	37/149 (25%)	5 (10%)
1	112/197 (57%)	78/149 (52%)	34 (71%)
2	25/197 (13%)	21/149 (14%)	4 (8%)
≥3	18/197 (9%)	13/149 (9%)	5 (10%)
Current therapy			
TKI alone	28/147 (19%)	17/106 (16%)	11/41 (27%)
Chemotherapy alone	48/147 (33%)	35/106 (33%)	13/41 (32%)
Immune checkpoint inhibitors alone	34/147 (23%)	26/106 (25%)	8/41 (20%)
Chemotherapy and immune checkpoint inhibitors	20/147 (14%)	16/106 (15%)	4/41 (10%)
Other*	17/147 (12%)	12/106 (11%)	5/41 (12%)
Comorbidities			
Any	166/198 (84%)	134/151 (89%)	32/47 (68%)
Autoimmune disease	6/198 (3%)	6/151 (4%)	0/47
Chronic hepatitis	3/198 (2%)	2/151 (1%)	1/47 (2%)
Chronic kidney insufficiency	15/198 (8%)	13/151 (9%)	2/47 (4%)
COPD	51/198 (26%)	44/151 (29%)	7/47 (15%)
Diabetes	29/198 (15%)	20/151 (13%)	9/47 (19%)
Hypertension	93/198 (47%)	76/151 (50%)	17/47 (36%)
Lung fibrosis	3/198 (2%)	3/151 (2%)	0/47
History of cerebrovascular disease	10/198 (5%)	8/151 (5%)	2/47 (4%)
History of ischaemic heart disease	30/198 (15%)	23/151 (15%)	7/47 (15%)
History of tuberculosis	3/198 (2%)	3/151 (2%)	0/47
History of viral hepatitis B	8/198 (4%)	6/151 (4%)	2/47 (4%)
History of viral hepatitis C	5/198 (3%)	5/151 (3%)	0/47
Other	93/198 (47%)	77/151 (51%)	16/47 (34%)
Number of comorbidities			
None	32/198 (16%)	17/151 (11%)	15/47 (32%)
1	60/198 (30%)	44/151 (29%)	16/47 (34%)
2	53/198 (27%)	45/151 (30%)	8/47 (17%)
≥3	53/198 (27%)	45/151 (30%)	8/47 (17%)
Concomitant medications			
ACE inhibitors	30/195 (15%)	23/148 (16%)	7/47 (15%)
Angiotensin II receptor blockers	25/195 (13%)	21/148 (14%)	4/47 (9%)
NSAID	2/195 (1%)	1/148 (1%)	1/47 (2%)
Steroids (>10 mg of prednisone)	42/195 (22%)	31/148 (21%)	11/47 (23%)
Immunosuppressive drugs	2/195 (1%)	2/148 (1%)	0/47
Aspirin	39/195 (20%)	30/148 (20%)	9/47 (19%)
Anticoagulants	50/195 (26%)	42/148 (28%)	8/47 (17%)
Other chronic therapy	98/195 (50%)	76/148 (51%)	22/47 (47%)
None	35/195 (18%)	25/148 (17%)	10/47 (21%)

Data are n (%), n/N (%), or median (IQR). NSCLC=non-small-cell lung cancer. ECOG=Eastern Cooperative Oncology Group. TKI=tyrosine kinase inhibitor. COPD=chronic obstructive pulmonary disease. NSAID=non-steroidal anti-inflammatory drug. ACE=angiotensin-converting enzyme. *Other includes additional combinations of treatment modalities: chemotherapy, immune checkpoint inhibitors, and radiotherapy (n=2); chemotherapy and radiotherapy (n=6); immune checkpoint inhibitors and cementoplasty (n=1); immune checkpoint inhibitors and other unknown (n=1); radiotherapy (n=3); TKI and chemotherapy (n=1); TKI, chemotherapy, and immune checkpoint inhibitors (n=1); TKI, chemotherapy, immune checkpoint inhibitors, and radiotherapy (n=1); and TKI and radiotherapy (n=1).

Table 1: **Demographic and clinical characteristics**

inhibitors; the majority of patients were on first-line treatment with therapy administered a median of 7 days (IQR 0–17) before COVID-19 diagnosis (table 1). 32 (16%) of 198 patients had no comorbidities; in those with comorbidities, the most common were hypertension and COPD (table 1). 50 (26%) of 195 patients were on anticoagulants and 42 (22%) were on steroids (table 1).

The most common presenting symptoms were fever, dyspnoea, and cough (table 2). There were a median of 5 days (IQR 2–7) between onset of symptoms and diagnosis and a median 7 days (2–13) of hospitalisation. Of 200 patients, 143 had developed complications by April 12, 2020, with 92 (46%) patients still hospitalised at the time of data cutoff. The most common complications were pneumonia or pneumonitis and acute respiratory distress syndrome (table 2). 24 (12%) of 198 patients were asymptomatic; 13 (54%) of these patients were tested in hospitals due to known exposure to a patient with confirmed SARS-CoV-2 infection, whereas six (25%) had secondary findings on routine imaging for anticancer therapy or surveillance; details on the remaining five patients are unknown.

Of the 152 hospitalised patients, 134 (88%) met criteria for ICU admission, but only 13 (10%) of these patients were admitted to the ICU, nine of whom were mechanically ventilated (table 3). Predominantly, the reasons for patients not being admitted to ICU was reported as not indicated, which included institutional policy against ICU admission, underlying cancer diagnosis and decision not to escalate to ICU, or not indicated due to severity of COVID-19 illness and physician recommendation not to escalate to ICU for futility in patients with advanced-stage cancer; only six (5%) of 114 patients with data available that were offered ICU-level care declined ICU admission (table 3). 31 (53%) of 58 hospitalised patients with data on complete length of stay had a prolonged hospitalisation, defined as longer than 8 days. Of the 66 (33%) patients who died, 52 (79%) deaths were listed as due to complications from COVID-19 only, seven (11%) as cancer progression only, three (5%) as complications from COVID-19 and cancer progression, one (2%) as complications from cancer therapy, one (2%) as cancer progression and other reasons, and one (2%) as other reasons. Cause of death for one patient was not listed. 52 (79%) patients died in hospital, eight died in the ICU (12%), and three (5%) died at home; details are unknown for the three (5%) remaining deaths.

Univariable analyses revealed that being older than 65 years (OR 1·88, 95% 1·00–3·62), being a current or former smoker (4·24, 1·70–12·95), receiving treatment with chemotherapy alone (2·54, 1·09–6·11), and the presence of any comorbidities (2·65, 1·09–7·46) were associated with increased risk of death. Dyspnoea was also associated with increased risk of death (6·20, 3·10–13·23), whereas experiencing no symptoms at the time of diagnosis was associated with decreased risk (0·08, 0·00–0·38; appendix pp 3–7). Although the

number of patients is small (n=28), patients treated with TKIs alone were less likely to be hospitalised (0·24, 0·08–0·71) than patients not on therapy, whereas patients with fever (2·46, 1·27–4·80) and dyspnoea (2·66, 1·37–5·32) were more likely to be hospitalised, as were patients with any comorbities (3·70, 1·66–8·21), including COPD (2·35, 1·03–6·09). Full univariable analyses for the risk of hospitalisation, prolonged hospitalisation, and death are in the appendix (pp 3–7). In multivariable analysis for risk of death, only smoking history (3·18, 1·11–9·06) was associated with increased risk of death (table 4).

Discussion

TERAVOLT is a global consortium that was formed to characterise the effects of SARS-CoV-2 infection on patients with thoracic cancers. Our initial report from the first 200 patients entered into the registry suggests that the mortality in patients with thoracic cancer is 33%, and might be as high as previously reported for patients in China.[12–13,17] In multivariable analysis, only smoking habits maintained a significant association with death. Comorbidities such as hypertension or ischaemic heart disease, which are associated with increased risk of death in the general population, did not appear to be predictors for poor outcomes in our patient population. The question as to whether smoking exacerbated the effect of other clinically associated variables (such as COPD and other comorbidities) or there is a net effect of smoking merits further investigation. However, these are preliminary data and we acknowledge that more events are needed to observe and confirm effects.

While most deaths occurred during hospitalisation, only 13 (9%) of 147 patients in our cohort were admitted to the ICU, nine of whom received mechanical ventilation. This is in contrast with previous reports in which 16% of hospitalised patients were cared for in the ICU, 88% of whom received endotracheal intubation and mechanical ventilation,[6] as well as a report from New York City (NY, USA) showing that patients with all types of cancer were frequently intubated for COVID-19 treatment.[24] Part of this could be explained by the geographical locations included in this initial cohort, which were mainly European (Italy, France, and Spain). All of these regions were particularly hard hit and they have universal health systems that might differ from other countries. In addition, our database includes heterogeneity among types of hospitals (comprehensive cancer centres and general hospitals).

We tried to capture the reasons for the low rate of ICU admission. Difficult decisions were made limiting ICU admissions for patients with cancer and others with terminal illness due to equipment and personnel shortages. However, we are aware that behind these choices there might also be patients' decisions and cultural and institutional choices that our work is unable to properly capture. Given that our database is longitudinal, future reports from TERAVOLT will evaluate the effect of SARS-CoV-2 infection outcomes on patients in hospital systems that are not under as much as stress. Nonetheless, as targeted therapy and immunotherapy have dramatically shifted the paradigm of care and life expectancy for patients with metastatic NSCLC, the decision to escalate care should be decided in a multidisciplinary setting and not on the basis of old preconceptions limiting access to aggressive care for these patients.

Importantly, our data suggest that the type of systemic therapy, including TKIs, chemotherapy, and immunotherapy, did not affect survival in patients with COVID-19. Although the number of patients is small, patients treated with TKIs alone were at decreased risk for hospitalisation, and despite initial concerns of increased mortality, immunotherapy did not worsen outcomes for

	All patients (n=200)	Hospitalised (n=152)	Not hospitalised (n=48)
Symptoms			
Fever (>37·5°C)	127/198 (64%)	104/150 (69%)	23 (48%)
Dyspnoea	106/198 (54%)	89/150 (59%)	17 (35%)
Cough	103/198 (52%)	83/150 (55%)	20 (42%)
Fatigue	54/198 (27%)	46/150 (31%)	8 (17%)
Headache	13/198 (7%)	10/150 (7%)	3 (6%)
Diarrhoea	10/198 (5%)	10/150 (7%)	0
Myalgia	10/198 (5%)	9/150 (6%)	1 (2%)
Nasal congestion	6/198 (3%)	5/150 (3%)	1 (2%)
Anosmia*	7/198 (4%)	4/150 (3%)	3 (6%)
Dysgeusia	7/198 (4%)	4/150 (3%)	3 (6%)
Loss of smell or taste*	6/198 (3%)	4/150 (3%)	2 (4%)
Shivers	4/198 (2%)	4/150 (3%)	0
Conjunctival congestion	1/198 (1%)	0/150	1 (2%)
Otitis	0/198	0/150	0
Other	19/198 (10%)	17/150 (11%)	2 (4%)
None (asymptomatic)	24/198 (12%)	9/150 (6%)	15 (31%)
Diagnostic test			
RT-PCR	180/198 (91%)	140/150 (93%)	40 (83%)
Clinical findings	5/198 (3%)	2/150 (1%)	3 (6%)
Radiological findings	13/198 (7%)	8/150 (5%)	5 (11%)
Complications			
Any complications	143/157 (91%)	123/127 (97%)	20/30 (67%)
Pneumonia or pneumonitis	125/157 (80%)	90/127 (71%)	16/30 (53%)
Acute respiratory distress syndrome	42/157 (27%)	40/127 (31%)	2/30 (7%)
Multi-organ failure	12/157 (8%)	11/127 (9%)	1/30 (3%)
Sepsis	8/157 (5%)	7/127 (6%)	1/30 (3%)
Coagulopathy	8/157 (5%)	8/127 (6%)	0/30
Bacterial infection	6/157 (4%)	6/127 (5%)	0/30
Arrhythmia	3/157 (2%)	3/127 (2%)	0/30
Heart failure	1/157 (1%)	1/127 (1%)	0/30
Other	15/157 (10%)	12/127 (9%)	3/30 (10%)
No complications	14/157 (9%)	4/127 (3%)	10/30 (33%)

*Data obtained as two separate questions.

Table 2: **COVID-19 clinical presentation and symptoms**

	All patients (n=200)
Hospitalisation	
Yes	152 (76%)
No	48 (24%)
ICU admission*	
Yes	13/147 (9%)
No	134/147 (91%)
Received mechanical ventilation*	
Yes	9/147 (6%)
No	138/147 (94%)
Prolonged hospitalisation (>8 days)†	
Yes	31/58 (53%)
No	27/58 (47%)
Death (during hospitalisation, ICU, or at home)‡	
Yes	66 (33%)
No	125 (63%)
Reasons why patients were not admitted to the ICU§	
Not indicated¶	97/114 (85%)
No resources available	4/114 (4%)
Institutional policy	7/114 (6%)
Patient declined	6/114 (5%)

ICU=intensive care unit. *Calculated on number of hospitalised patients with data on ICU admission. †Calculated on number of hospitalised patients with data on complete length of stay. ‡The outcome (dead or alive) is unknown for nine patients. §Calculated on number of patients eligible for ICU who were not admitted for whom the reason for non-admission was available. ¶Not indicated includes several factors: not indicated due to mild or moderate COVID-19 symptoms; not indicated due to underlying cancer diagnosis and decision not to escalate to ICU; or not indicated due to severity of COVID-19 illness and physician recommendation not to escalate to ICU for futility. For the majority of sites, it also included institutional policy concerning patients with lung cancer.

Table 3: **Hospitalisation and mechanical ventilation use**

	Odds ratio (95% CI)
COPD	1·18 (0·59–2·37)
Hypertension	1·16 (0·61–2·21)
Female sex (*vs* male)	0·69 (0·33–1·44)
Age >65 years (*vs* ≤65 years)	1·53 (0·77–3·03)
Current or former smoker (*vs* never smoker)	3·18 (1·11–9·06)

Outcome includes death during hospitalisation, in the intensive care unit, or at home. COPD=chronic obstructive pulmonary disease.

Table 4: **Multivariable model of factors associated with death**

patients with cancer with COVID-19 in our analysis. These findings suggest that withholding or discontinuing such therapy for a patient out of fear of COVID-19 might not be warranted. We note, however, that more data with larger patient numbers are needed to make a final verdict on the role of treatments. Moreover, it is important to acknowledge that previous studies have suggested that frequent contact with the health-care environment increases risk of SARS-CoV-2 infection and thus a goal of minimising such contact, especially during cancer therapy, is important.[7,17]

The most common presenting symptoms for patients with thoracic cancer and COVID-19 are also those symptoms frequently noted by patients with thoracic cancer without COVID-19, including dyspnoea, cough, and fatigue. However, very few patients died due to progressive disease, with most dying of complications of COVID-19 itself. Furthermore, the majority of our patients had a stage IV disease (74%) and a large proportion were on active oncological treatment (74%) at the time of SARS-CoV-2 infection; in particular, 57% of patients were on first line with therapy administered a median of 7 days before COVID-19 diagnosis. The patients included in this analysis could represent a selected population since this initial cohort did not capture many patients after surgery or radiotherapy; efforts will be made to expand TERAVOLT participation beyond medical oncologists to include other thoracic cancer disciplines (eg, thoracic surgeons and radiation oncologists). Furthermore, we recognise that this is a preliminary report, written to provide more information to clinicians at a crucial time, but that it does not yet have the statistical power to give final answers in terms of subgroup analyses.

While the data presented here are representative of mainly symptomatic patients with NSCLC stage IV disease on systemic therapy and importantly only include a small fraction of patients who were managed at home for their COVID-19 illness, data are urgently needed to plan the optimal diagnostic and therapeutic pathways for patients with cancer in an environment where SARS-CoV-2 is still in circulation, often accompanied with only mild or no symptoms. Although consecutive inclusion of patients controls the risk of selection bias, thus assuring a correct description of patients' characteristics and outcomes, major limitations in the estimation and correct interpretation of associations were related to control of confounding factors. More data on the prevalence and outcomes of COVID-19 on asymptomatic patients with thoracic cancer could emerge as hospital systems implement broader testing on all patients seeking care.

TERAVOLT is a unique effort aimed at providing real-time data to support the optimal diagnostic and therapeutic pathways for all patients with thoracic cancer. Given our findings suggest a high risk of severe infection or death for patients with thoracic malignancies, a tailored approach is needed. Calabró and colleagues have proposed routine testing for patients with cancer on active therapy;[25] the continued shortage of testing kits and variances across countries makes such an approach difficult to achieve universally, but it could indeed be the optimal approach once an effective therapy for COVID-19 has been found. For now, emphasising social distancing and encouraging measures such as wearing face masks in the community might help to minimise a surge of cases, allowing the medical system to keep up with testing and decreasing the need for physicians to triage care on the basis of age and comorbidities. Protecting all

susceptible members of our societies with protective measures supported by our current knowledge of SARS-CoV-2 must remain a priority, while also respecting the needs of each individual, including optimal care management.

We believe that a multidisciplinary approach to the treatment of patients with thoracic cancer and SARS-CoV-2 infection should consider both the individual cancer-specific mortality and risk of a morbidity or mortality from COVID-19. At this time, it is not clear if intubation and more aggressive care in patients with cancer could improve COVID-19-specific survival, or if such an approach would simply prolong the process of dying. However, in the absence of clear data, the integration of patients' preferences could provide a benefit, especially in decisions in which uncertainty is high.[26] In this perspective, a shared decision-making paradigm will allow both patients and clinicians to recognise and pursue the option that best fits the individual.

Contributors

FA, RB, GB, ACB, EB, JB, MB, CC, EF, CG, RG, FeG, FrG, VG, SI, SVL, NLV, Y-LW, DM-S, EM, GM, GP, AP, ES, VS, PS, LV, and SZ collected data. FB collected data and participated in study design, data interpretation, and reviewing the manuscript. JC collected data and reviewed the manuscript. AC, MCG, AT, LH, VT, VP, and JGW participated in study design, data analysis and interpretation, and manuscript writing. PG, A-MD, JM, ADT, and GV participated in study design, data collection and interpretation, and manuscript writing. GF participated in data collection and patient enrolment. L-CH participated in data analysis and interpretation. VP participated in study design, data analysis and interpretation, and manuscript writing. SP participated in literature searching; study design; data collection, analysis, and interpretation; and writing and reviewing the manuscript. MT collected data and participated in data interpretation and manuscript writing. OM participated in development of the electronic case report form and reviewing the manuscript. JVM participated in data collection, analysis, and interpretation and reviewing the manuscript. HW participated in conception and design of the database, literature searching, and data analysis and interpretation and manuscript writing.

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All declarations of interest are outside of the submitted work, unless stated otherwise. MCG received grants, personal fees, and other financial support from Merck Sharp & Dohme, AstraZeneca, Novartis, Roche, Pfizer, Celgene; grants and other financial support from Tiziana Sciences, Clovis, GlaxoSmithKline, Spectrum, and Blueprint; personal fees and other financial support from Eli Lilly and Bristol Myers Squibb; grants from Merck and Bayer; personal fees from Boheringer, Otsuka Pharma, Incyte, Inivata, Takeda, Bayer, Sanofi, Seattle Genetics, and Daichii Sankyo; and other financial support from Merck Serono. GLB received personal fees from Jannsen-Cilag, Boheringer/Ingelheim, and Roche; and non-financial support from Bristol Myers Squibb, AstraZeneca/medimmune, Pierre Fabre, and Ipsen. RB has been on the advisory board for AstraZeneca, Boerhinger/Ingelherim, Lilly, Merck Sharp & Dohme, and Otsuka and has received institutional funding from Novartis, Lilly, and AstraZeneca. 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Data sharing

Due to privacy laws, individual participant data will not be made available to others. The data dictionary of the case report form will be made available upon request to the corresponding author. The study protocol and table of case report form elements are included in the appendix (pp 2, 14–20). VUMC and INT have a proper DTA for anonymised data sharing available on private request.

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