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Stop COVID Cohort: An Observational Study of 3480 Patients Admitted to the Sechenov University Hospital Network in Moscow City for Suspected Coronavirus Disease 2019 (COVID-19) Infection

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Background. The epidemiology, clinical course, and outcomes of patients with coronavirus disease 2019 (COVID-19) in the Russian population are unknown. Information on the differences between laboratory-confirmed and clinically diagnosed COVID-19 in real-life settings is lacking.

Methods. We extracted data from the medical records of adult patients who were consecutively admitted for suspected COVID-19 infection in Moscow between 8 April and 28 May 2020.

Results. Of the 4261 patients hospitalized for suspected COVID-19, outcomes were available for 3480 patients (median age, 56 years; interquartile range, 45–66). The most common comorbidities were hypertension, obesity, chronic cardiovascular disease, and diabetes. Half of the patients (n = 1728) had a positive reverse transcriptase–polymerase chain reaction (RT-PCR), while 1748 had a negative RT-PCR but had clinical symptoms and characteristic computed tomography signs suggestive of COVID-19. No significant differences in frequency of symptoms, laboratory test results, and risk factors for in-hospital mortality were found between those exclusively clinically diagnosed or with positive severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) RT-PCR. In a multivariable logistic regression model the following were associated with in-hospital mortality: older age (per 1-year increase; odds ratio, 1.05; 95% confidence interval, 1.03–1.06), male sex (1.71; 1.24–2.37), chronic kidney disease (2.99; 1.89–4.64), diabetes (2.1; 1.46–2.99), chronic cardiovascular disease (1.78; 1.24–2.57), and dementia (2.73; 1.34–5.47).

Conclusions. Age, male sex, and chronic comorbidities were risk factors for in-hospital mortality. The combination of clinical features was sufficient to diagnose COVID-19 infection, indicating that laboratory testing is not critical in real-life clinical practice.

Keywords. cohort; COVID-19; mortality risk factors; Russia; SARS-CoV-2.

In Russia, the first confirmed cases of coronavirus disease 2019 (COVID-19) were reported by the state authorities in early March 2020 [1]. Since then, the Russian Federation climbed into the top 3 nations in the world affected by COVID-19, surpassing 400 000 cases by the end of May 2020.

The rate of infections in Moscow and the Moscow metropolitan area, with its high population density and number of inhabitants (20 million), has exceeded 180 000 confirmed cases, accounting for half of all the COVID-19 cases in Russia [2].

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The clinical characteristics of COVID-19 have been described in studies from China [3], Italy [4], the United States [5–7], and the United Kingdom [8]. At present, no information on the clinical epidemiology, including clinical course, and outcomes of patients with COVID-19 in the Russian population is available. A recent editorial in *The Lancet* highlighted a surprisingly low mortality rate (~1%) in Russia [9]. With no academic data, perspectives on the COVID-19 pandemic in Russia are mainly based on media reports and briefs from Russian officials.

This study aimed to present demographic characteristics, symptoms, comorbidities, clinical test results, outcomes, and risk factors associated with mortality in a cohort of consecutively admitted patients with COVID-19 at the Sechenov University Hospital Network in Moscow. Secondarily, we aimed to test whether patients presenting with symptoms and radiological findings consistent with COVID-19 but without laboratory confirmation of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) have outcomes similar to those with positive reverse transcriptase–polymerase chain reaction (RT-PCR).

METHODS

Study Design and Ethics

StopCOVID is an observational cohort study that took place at 4 large adult tertiary university hospitals in Moscow, Russia. All persons aged 18 years or olrder admitted to any of 4 Sechenov University Hospital Network hospitals between 8 April and 28 May 2020 with suspected COVID-19 infection were included in the study. RT-PCR to SARS-CoV-2 was the recommended mode of testing by the Russian Ministry of Health and was used throughout the study period in all the hospitals (Supplementary Box 1). We enrolled all patients with confirmed or suspected COVID-19 infection, due to concerns of a high false-negative rate from RT-PCR results [10].

This study was approved by the Sechenov University Institutional Review Board on 22 April 2020 (protocol number 08–20).

Data Collection Process

The data were collected between 22 April and 6 June 2020. We reviewed electronic medical records for signs and symptoms on admission, baseline comorbidities, computed tomography (CT) imaging, and laboratory results for all admitted patients. Weight and height were self-reported by the patients to the clinical staff.

The data extraction was performed by a group of 40 medical students and resident doctors who went through personal protocol explanation webinars and data entry training prior to the beginning of the study. The team was supervised by senior academic staff members. The baseline characteristics were collected using the case report form (CRF) that was developed by the International Severe Acute Respiratory and Emerging Infection Consortium (ISARIC) and the World Health Organization (WHO) for use in outbreak investigations [11]. REDCap (Research Electronic Data Capture; Vanderbilt University, Nashville, TN, USA, hosted at Sechenov University) was used for data collection, storage, and management [12, 13].

Study Definitions

Patients were defined as having confirmed COVID-19 if the diagnosis was confirmed by laboratory testing (at least 1 SARS-CoV-2 RT-PCR positive result).

Patients were defined as having "clinically diagnosed COVID-19" if laboratory confirmation was inconclusive or not available. Details of COVID-19 case definitions, criteria for hospitalization, grading of severity, and recommended treatment approaches are presented in Supplementary Box 1.

We reviewed radiology reports of chest CT imaging during hospitalization. The data on the presence/absence of ground-glass opacities, consolidation, and severity of radiologic changes were retrieved. Incomplete reports containing no information on severity were excluded from the analysis. The severity of changes was graded by radiologists as per national COVID-19 guidelines using the modified visual assessment scale by Inui et al [14] (Supplementary Table 1). The primary outcome in this study was in-hospital mortality.

Statistical Analysis

Descriptive statistics were calculated for baseline characteristics. Continuous variables were summarized as medians (interquartile range) and categorical variables as frequencies (percentage). The chi-square test or Fisher's exact test was used for testing differences in proportions between individuals. The Wilcoxon rank-sum test was used to test for differences in laboratory test results between the groups.

We first ran univariate analysis to investigate associations between demographic characteristics and comorbidities with mortality. Then, we performed a multivariable logistic regression model, which included all statistically significant (at $P = .001$) potential predictors from the univariate analysis.

A Bonferroni correction was used to adjust for multiple comparisons, such that P values less than or equal to .001 were considered statistically significant for the analysis of symptoms and comorbidities and P values less than .001 were considered statistically significant for laboratory markers. All routine clinical laboratory measurements were used in the analysis, except the ones which were available for less than 10 deceased patients. Statistical analysis was performed using R version 3.5.1 (R Core Team).

RESULTS

A total of 4261 adults with suspected COVID-19 infection were admitted to the hospitals. Primary outcome data were available for 3535 patients who were discharged, died, or transferred to another hospital. The study primary endpoint was available for

all but 55 individuals transferred to other hospitals; thus, 3480 (82%) individuals were included in the statistical analysis.

Half of the patients (n = 1728) had positive RT-PCR results, while the second half (n = 1748) were negative on RT-PCR but had clinical symptoms and CT signs suggestive of COVID-19. No differences were noted in the baseline demographic and clinical characteristics and laboratory and radiologic findings of those with RT-PCR–confirmed versus clinically diagnosed COVID-19 (Table 1, Supplementary Tables 2, 4, 5, 7).

Baseline Characteristics

Table 2 and Supplementary Table 2 present an overview of baseline characteristics, stratified by the primary outcome and the RT-PCT result, respectively. The median age of all patients at admission was 56 years (interquartile range, 45–66; range, 18–100 years). Similar numbers of men (50.5%, n = 1758) and women (49.5%, n = 1722) were admitted to the hospitals (P = .55). The median age of patients who died in the hospital was higher, 72 (61.5–81) years compared with 55 (44–65) years in survivors. Time from hospitalization to discharge/death was 14.5 (11.8–17.7) days, with shorter hospital stay in patients who died. Severity at admission was recorded as mild in 632 (18.2%), moderate in 2634 (75.7%), severe in 204 (5.9%), and critical in 7 (0.2%) patients, respectively.

Only 218 (6.3%) patients required admission and/or transfer to the intensive care unit (ICU), with some patients requiring noninvasive ventilation and/or invasive mechanical ventilation: 80 (2.3%) and 171 (5.0%), respectively. Although the proportion discharged alive from the ICU facilities was 42.5%, among all patients who received care in the ICU during the hospital stay, 57 (26.1%) were discharged from the hospital alive. Eight (4.7%) patients who received invasive mechanical ventilation during the hospital stay were discharged alive.

Data on symptoms and comorbidities at the time of hospital admission were available in 3382 (97%) patients. The most common symptoms in the medical records were fever (3157, 93.3%), fatigue/malaise (2684, 79.4%), cough (2476, 73.2%), and shortness of breath (2013, 59.5%). We also found a significant overlap between the top 3 most common symptoms, with 1912 (56.5%) patients having all 3 symptoms (Figure 1). Shortness of breath, altered consciousness, and inability to walk were present significantly more often in patients who died, while anosmia, sore throat, fever, and muscle pain were found more frequently in those discharged alive (Supplementary Table 3). Symptoms at admission did not differ significantly between the patients with laboratory-confirmed and clinically diagnosed COVID-19 (Supplementary Table 4).

Detailed information on comorbidities in our cohort is presented in Table 3, Supplementary Table 5, and Figure 1. The most common comorbidities were hypertension (1539, 45.5%), obesity (1129, 33.4%), chronic cardiovascular disease (621, 18.4%), and diabetes (predominantly type 2; 459, 13.6%). One in 10 patients reported current (139, 4.1%) or former (235, 6.9%) smoking. There was little overlap between the top 3 most common comorbidities, with only 145 (4%) patients having all 3, while 965 (28.5%) did not report any comorbidities.

Clinical Investigations

Most patients (71.6%) had significant changes on chest CT, equivalent to CT-2–CT-3 severity grade. Ground-glass opacity was found in over 95% of the patients and 77.95% had lung consolidation in accordance with the radiologist's reports.

We reviewed routine clinical test measurements at admission and found abnormal changes to the coagulation profile, greater median levels of C-reactive protein (CRP), erythrocyte sedimentation rate (ESR), aspartate aminotransferase (AST), and lactate dehydrogenase and decreased iron levels. Those patients who died in the hospital had more abnormal changes to their coagulation profile (D-dimer, international normalized ratio, prothrombin time, ferritin, fibrinogen), lymphocytopenia, and neutrophilia, and much higher levels of CRP and ESR, high blood urea nitrogen, AST, and γ-glutamyltransferase when compared with survivors (Table 4). Platelet to lymphocyte ratio was associated with a higher in-hospital mortality odds ratio (1.003; 95% confidence interval, 1.002–1.004) adjusted for age and sex.

Results of the laboratory tests routinely performed in the clinical setting did not differ significantly between patients with confirmed and clinically diagnosed COVID-19 for 48 out of 51 parameters (Table 1). Platelets, leukocytes, and neutrophil count were significantly lower in patients with confirmed COVID-19, but the differences were unlikely to be relevant, being within the normal reference ranges for both groups.

Patient Outcomes and Risk Factors

Among the 3480 patients who were discharged or died during hospitalization, the overall mortality was 5.5%, with a total number of 191 people who died.

In a univariate analysis, chronic cardiovascular disease, hypertension, chronic pulmonary disease, chronic kidney disease, chronic neurological disorder, malignant neoplasm, diabetes, and dementia significantly differed between survivors and patients who died (Table 3). In multivariable analysis, older age was a predictor of in-hospital mortality with an odds ratio (per 1-year increase) of 1.05 (95% confidence interval, 1.03–1.06). Other predictors associated with in-hospital mortality were male sex (1.71; 1.24–2.37), chronic kidney disease (2.99; 1.89–4.64), diabetes (2.1; 1.46–2.99), chronic cardiovascular disease (1.78; 1.24–2.57), and dementia (2.73; 1.34–5.47) (Figure 2). The same risk factors were significantly associated with the admission/transfer to the ICU, with only dementia not reaching statistical significance (Supplementary Figure 1).

When including COVID-19 laboratory-confirmed/suspected status as a covariate in the multivariable logistic regression model we found no evidence that it was associated with mortality (odds ratio, 1.22; 95% confidence interval, .89–1.69)

Table 1. Laboratory Test Results (Median [IQR]) in Patients With Clinically Diagnosed COVID-19 Infection (RT-PCR Negative) and Patients With RT-PCR–Confirmed COVID-19 Infection

Marker Name (COVID-19)	Reference Range	Unit	Confirmed COVID-19	Clinically Diagnosed COVID-19	*P*
% PT (quick)	70–130	%	79 (71–86), n = 606	78 (70–85), n = 600	.246
Activated partial thromboplastin time (APTT)	0.75–1.25	Ratio	1.05 (0.97–1.12), n = 482	1.03 (0.96–1.115), n = 455	.333
D-dimer, quantitative	0–0.5	µg/mL	0.57 (0.33–1.015), n = 151	0.59 (0.39–1.08), n = 137	.114
International normalized ratio (INR)	0.9–1.16	…	1.17 (1.11–1.26), n = 606	1.17 (1.12–1.27), n = 600	.307
Prothrombin time	9.4–12.5	Seconds	12.8 (12.1–13.7), n = 606	12.9 (12.2–13.8), n = 600	.304
Ferritin	7–200	µg/L	253.7 (150.875–464.35), n = 108	252.8 (159.13–510), n = 105	.318
Fibrinogen	1.8–4	g/L	5.33 (4.32–6.84), n = 776	5.59 (4.51–7), n = 793	.016
Hemoglobin (HGB)	117–180	g/L	137 (126–148), n = 1201	137 (127–146), n = 1188	.902
Mean corpuscular hemoglobin (MCH)	27–38	pg	29.2 (28.1–30.3), n = 1201	29.2 (28–30.2), n = 1188	.854
Mean platelet volume (MPV)	8.7–9.6	fL	9.3 (8.925–9.775), n = 170	9.3 (8.9–9.8), n = 170	.782
Plateletcrit (PCT)	0.14–0.28	%	0.16 (0.13–0.198), n = 170	0.17 (0.13–0.21), n = 169	.182
Platelets (PLT)	150–450	$\times 10^9$/L	181 (146–228), n = 1201	195 (156.75–246), n = 1188	**<.001**
Red blood cells (RBC)	3.8–6.1	$\times 10^{12}$/L	4.71 (4.34–5.07), n = 1201	4.69 (4.37–5.03), n = 1188	.963
Red cell distribution width (RDW)	10.5–18	%	13.6 (13.1–14.3), n = 1201	13.6 (13–14.3), n = 1188	.304
White blood cells (WBC)	4–11	$\times 10^9$/L	4.97 (3.9–6.3), n = 1201	5.4 (4.2–7), n = 1188	**<.001**
No. of basophils	0–0.1	$\times 10^9$/L	0.02 (0.01–0.03), n = 427	0.02 (0.01–0.04), n = 476	.868
No. of lymphocytes	1–3.7	$\times 10^9$/L	1.1 (0.8–1.5), n = 1200	1.2 (0.9–1.6), n = 1188	.003
No. of monocytes	0–0.7	$\times 10^9$/L	0.4 (0.25–0.5), n = 1197	0.4 (0.3–0.5), n = 1187	.026
No. of neutrophils	1.5–7	$\times 10^9$/L	3.2 (2.2–4.5), n = 1200	3.5 (2.4–4.9), n = 1188	**<.001**
No. of eosinophils	0–0.4	$\times 10^9$/L	0.04 (0.01–0.1), n = 545	0.06 (0.01–0.1), n = 637	.053
Hematocrit (HCT)	35–52	%	41.6 (38.525–44.8), n = 1202	41.5 (38.8–44.4), n = 1189	.65
Mean corpuscular hemoglobin concentration (MCHC)	300–380	g/dL	323 (311–331), n = 1201	322 (307.75–331), n = 1188	.106
Mean cellular volume (MCV)	80–99	fL	88.8 (85.5–92.1), n = 993	88.7 (85.325–91.5), n = 986	.31
Erythrocyte sedimentation rate (ESR)	…	mm/hour	32 (21–40), n = 1173	32 (22–41), n = 1161	.499
Color index	0.8–1.05	…	0.88 (0.84–0.91), n = 1201	0.88 (0.84–0.91), n = 1188	.79
Eosinophils %	0–5	%	0.4 (0.2–0.8), n = 1183	0.4 (0.2–1), n = 1177	.416
Basophils %	0–2	%	0.4 (0.2–0.5), n = 1200	0.4 (0.2–0.5), n = 1187	.343
Lymphocytes %	18–44	%	23.4 (16.5–32), n = 1200	23.2 (16.6–31.125), n = 1188	.513
Monocytes %	2–12	%	7.1 (5.2–9.4), n = 1200	6.9 (5.2–9.1), n = 1188	.357
Neutrophils %	45–72	%	65.8 (55.375–74.8), n = 1200	65.8 (56.5–74.625), n = 1188	.402
C-reactive protein	0–5	mg/L	40 (14–84), n = 1213	44 (17–87.25), n = 1208	.175
Urea nitrogen	3.2–8.2	mmol/L	5.3 (4.3–7), n = 803	5.2 (4.2–6.9), n = 737	.503
Alanine aminotransferase (ALT)	10–49	U/L	32 (22–47), n = 1162	33 (22–50), n = 1134	.486
Aspartate aminotransferase (AST)	0–34	U/L	36 (28–50), n = 1171	37 (27–52), n = 1148	.569
Total protein	57–82	g/L	71.25 (67.4–74.8), n = 952	70.9 (67.475–74.4), n = 924	.647
Total bilirubin	3–21	µmol/L	9.5 (7.4–12.725), n = 1020	10.4 (7.7–13.4), n = 1005	.002
Direct bilirubin	0–5	µmol/L	3 (2.2–4), n = 534	3.2 (2.3–4.2), n = 445	.186
γ-Glutamyltransferase (GGT)	0–73	U/L	43 (26–72.25), n = 172	48 (26–88), n = 165	.443
Potassium	3.5–5.5	mmol/L	4.4 (4.1–4.9), n = 1080	4.5 (4.1–4.8), n = 1030	.891

Table 1. Continued

Marker Name (COVID-19)	Reference Range	Unit	Confirmed COVID-19	Clinically Diagnosed COVID-19	*P*
Calcium	2.08–2.65	mmol/L	2.12 (2.05–2.21), n = 91	2.07 (1.95–2.18), n = 65	.122
Creatinine	44–115	µmol/L	95.4 (83.7–109.5), n = 1195	94.1 (81.57–106.968), n = 1170	.044
Creatine kinase (CK)	0–190	U/L	134 (75–252), n = 294	117 (70–206), n = 314	.081
Lactate dehydrogenase (LDH)	240–480	U/L	476 (372–609), n = 745	492.5 (382.75–623), n = 796	.113
Uric acid	145–415	µmol/L	313 (247–396), n = 405	306 (247–388), n = 347	.676
Sodium	132–150	mmol/L	141 (138–144), n = 1053	141 (138.25–145), n = 990	.09
Chloride	99–109	mmol/L	102 (98–106), n = 141	102 (97–105), n = 102	.335
Cholesterol	3.2–5.6	mmol/L	4.01 (3.36–4.66), n = 367	4.08 (3.47–4.81), n = 333	.342
Albumin	32–48	mmol/L	40.4 (37.6–43.2), n = 924	40.2 (37.9–42.6), n = 849	.185
Amylase	30–118	U/L	46.9 (34.8–58.35), n = 231	47 (35–65.5), n = 195	.41
Glucose	4.1–5.9	mmol/L	5.4 (4.9–6.3), n = 1159	5.4 (4.8–6.2), n = 1134	.194
Iron	9–30.4	µmol/L	3.8 (2.1–6.4), n = 218	4.1 (2.5–7.8), n = 165	.207

Statistically significant results at P values <.001 are presented in bold. The number of patients is presented for each parameter.

Abbreviations: COVID-19, coronavirus disease 2019; IQR, interquartile range; RT-PCR, reverse transcriptase–polymerase chain reaction.

Table 2. Baseline Characteristics of Patients Admitted to Sechenov University Hospitals, Stratified by Outcome

Variable	Total (N = 3480)	Discharged Alive (n = 3289)	Died (n = 191)
Age at admission, y			
Median (IQR)	56 (45–66)	55 (44–65)	72 (61.5–81)
Age groups, n (%)			
18–39 years	574 (16.5)	570 (17.3)	4 (2.1)
40–49 years	621 (17.8)	614 (18.7)	7 (3.7)
50–59 years	865 (24.9)	837 (25.4)	28 (14.7)
60–69 years	728 (20.9)	687 (20.9)	41 (21.5)
70–79 years	402 (11.6)	349 (10.6)	53 (27.7)
≥80 years	290 (8.3)	232 (7.1)	58 (30.4)
Male sex, n (%)	1758 (50.5)	1653 (50.3)	105 (55)
Temperature at admission, median (IQR), °C	37.4 (37–38)	37.5 (37–38)	37.7 (37–38)
ICU care during hospital stay,[a] n (%)	218 (6.3)	57 (26.1)	161 (73.9)
Invasive mechanical ventilation during hospital stay,[a] n (%)	171 (5.0)	8 (4.7)	163 (95.3)
Noninvasive ventilation during hospital stay,[a] n (%)	80 (2.3)	31 (38.8)	49 (61.2)
Time from hospitalization to discharge/death, median (IQR), days	14.5 (11.8–17.7)	14.6 (12–17.7)	9.5 (5.4–15.5)
RT-PCR COVID-19–positive patients, n (%)	1728 (49.7)	1618 (49.2)	110 (57.6)

Abbreviations: COVID-19, coronavirus disease 2019; ICU, intensive care unit; IQR, interquartile range; RT-PCR, reverse transcriptase–polymerase chain reaction; PT, Prothrombin.
[a]The proportion of patients in each subgroup is calculated from the total number of patients receiving a particular type of care (ICU, noninvasive ventilation, and invasive mechanical ventilation). Calculations were performed for each type of care, regardless of whether patients were discharged/died within the ICU facilities or were transferred to the ward and were discharged/died there.

and it did not have major impact on the effect size and significance of other predictors (Supplementary Figure 2).

We did not find any statistically significant association of CT severity grade with in-hospital mortality, adjusting for age and sex (Supplementary Table 6). With respect to CT imaging, no evidence of difference was found between the patients with confirmed and clinically diagnosed COVID-19 (Supplementary Table 7).

Treatment

Hydroxychloroquine was the most frequently used (84%) medication, followed by antibiotics (azithromycin [77.7%] and ceftriaxone [30.3%]), heparin (56.4%), paracetamol (34.4%), mucolytics (25.4%), lopinavir/ritonavir (16.2%), and systemic corticosteroids (10.4%), respectively (Supplementary Table 8). There was a significant overlap between the top 3 most commonly used medications, with hydroxychloroquine, azithromycin, and heparin used in 1322 patients (Supplementary Figure 3).

DISCUSSION

To our knowledge, StopCOVID cohort is the first large-scale study of consecutively hospitalized patients with COVID-19 in Russia assessing clinical characteristics and risk factors for

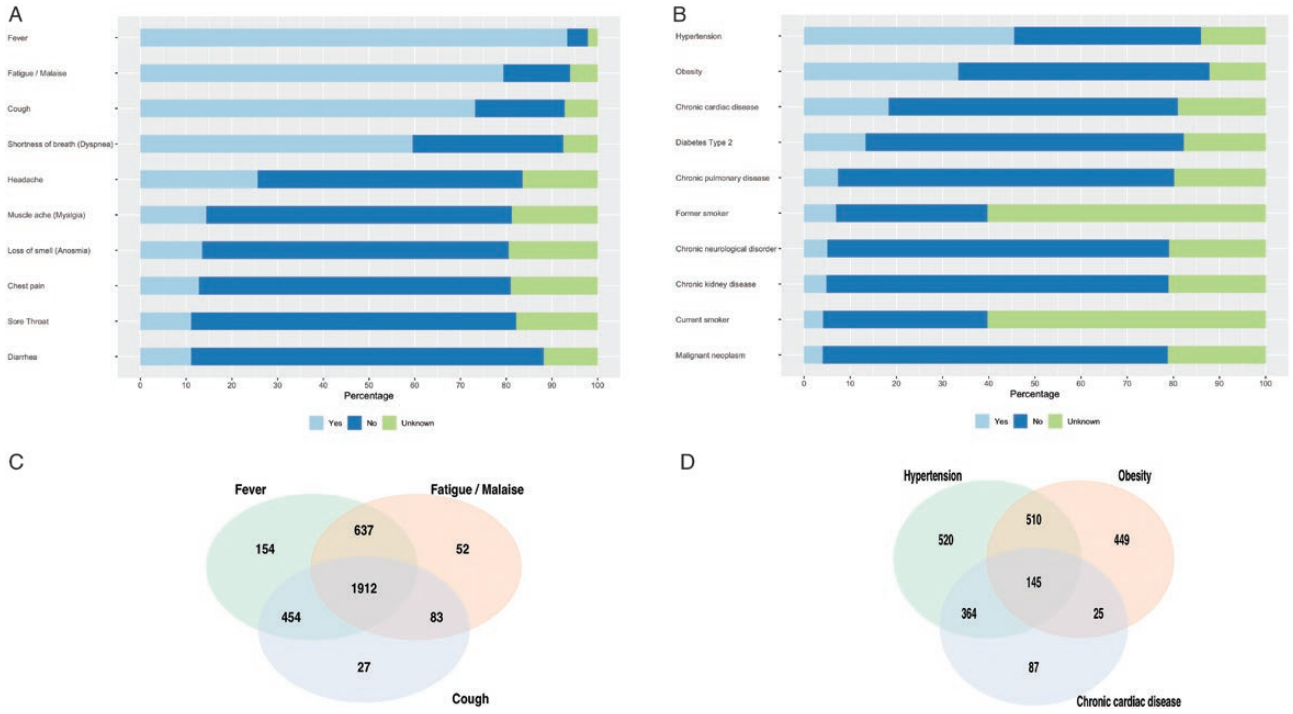

Figure 1. Stacked bar charts presenting the (*A*) top 10 most common symptoms and (*B*) most common comorbidities. Venn diagrams showing the coexistence of the (*C*) top 3 symptoms and (*D*) top 3 comorbidities at the time of hospital admission.

in-hospital mortality. This is also the first large cohort, including both RT-PCR–confirmed COVID-19 cases and patients, diagnosed with COVID-19 based on clinical and radiological presentation in the absence of the SARS-CoV-2 RT-PCR confirmation. We found that older age and male sex as well as existing comorbidities were associated with in-hospital mortality. We found no significant difference between patients with clinical COVID-19 and laboratory-confirmed COVID-19, either in clinical presentation or in clinical measurements and risk factors for in-hospital mortality. We feel it is entirely appropriate to treat patients with clinical and radiological signs of COVID-19 who do not have an alternative diagnosis to explain their symptoms equivalently to PCR-confirmed cases. Sequential RT-PCR testing can identify patients with COVID-19 whose initial result was false-negative [15]. In settings where repeat testing is not performed, it can also be appropriate to include patients with clinical and radiological COVID-19 alongside those with laboratory-confirmed disease.

Patients in our study were of an age very similar to the New York cohort [6] and of a much lower median age than similar cohorts in Italy [4] and the United Kingdom [8]. This may be partly explained by a lack of a clear message from the authorities to the public with regard to whom should present to a hospital. Healthcare-seeking behavior may further explain a younger age at admission, which differs between the countries. Russian people are known for active specialist-seeking behavior [16], particularly in the presence of distrust of media sources [17] and easy access to free healthcare. It is, however, more likely to be a reflection of varying approaches from health services in different countries.

Patients in Moscow typically presented with fever, fatigue, cough, and shortness of breath, which is in agreement with the previously reported symptom patterns in other countries [5, 8, 18]. Among symptoms, anosmia was associated with a more favorable outcome, which is similar to the data from Hopkins et al [19], which showed rapid improvement in patients with COVID-19 presenting with a loss of smell.

Similar to other cohorts, cardiological conditions, hypertension, obesity, and diabetes were common problems in the hospitalized population. The lower median age of the patients in our cohort may explain the lower comorbidity rate when compared with some other studies [6, 8]. We recorded a much lower number of patients with chronic pulmonary diseases, which is in agreement with data from Richardson et al [7] but in contrast to other US [6] and particularly UK [8] cohorts. We also found low rates of asthma in our cohort, which did not exceed the prevalence in the general population, which has been reported previously [20].

Patient age, male sex, and the presence of major comorbidities were all predictors of in-hospital mortality. These findings are in line with other international cohorts [6, 21], including a UK ISARIC study using a similar data-collection protocol [8]. We also found common changes in the coagulation profile [6] and previously reported clinical patterns, such as lymphocytopenia,

Table 3. Patient-reported Comorbidities at the Time of Hospital Admission and Chest Computed Tomography Imaging Stratified by Outcome

Characteristics	Total (N = 3382)	Discharged Alive (n = 3191)	Died (n = 191)	*P*
Chronic cardiovascular disease	621 (18.4)	518 (16.2)	103 (53.9)	**<.001**
Hypertension	1539 (45.5)	1388 (43.5)	151 (79.1)	**<.001**
Peripheral and/or coronary artery revascularization	108 (3.2)	101 (3.2)	7 (3.7)	.67
Chronic pulmonary disease[a]	249 (7.4)	220 (6.9)	29 (15.2)	**<.001**
Asthma (physician diagnosed)	127 (3.8)	120 (3.8)	7 (3.7)	1.0
Chronic kidney disease	164 (4.8)	121 (3.8)	43 (22.5)	**<.001**
Obesity[b]	1129 (33.4)	1062 (33.3)	67 (35.1)	.67
Moderate or severe liver disease	21 (0.6)	19 (0.6)	2 (1)	.33
Mild liver disease	71 (2.1)	66 (2.1)	5 (2.6)	.60
Asplenia	11 (0.3)	10 (0.3)	1 (0.5)	.47
Chronic neurological disorder	170 (5)	139 (4.4)	31 (16.2)	**<.001**
Malignant neoplasm	135 (4)	114 (3.6)	21 (11)	**<.001**
Chronic hematologic disease	27 (0.8)	21 (0.7)	6 (3.1)	.003
AIDS/HIV				
Yes—on ART	5 (0.1)	5 (0.2)	0 (0)	1.0
Yes—not on ART	7 (0.2)	7 (0.2)	0 (0)	1.0
Diabetes				
Yes—type 1	9 (0.3)	8 (0.3)	1 (0.5)	.41
Yes—type 2	450 (13.3)	389 (12.2)	61 (31.9)	**<.001**
Rheumatological disorder	102 (3)	100 (3.1)	2 (1)	.13
Dementia	53 (1.6)	33 (1)	20 (10.5)	**<.001**
Tuberculosis	5 (0.1)	5 (0.2)	0 (0)	1
Malnutrition	19 (0.6)	15 (0.5)	4 (2.1)	.02
Smoking				
Yes	139 (4.1)	128 (4)	11 (5.8)	.32
Former smoker	235 (6.9)	227 (7.1)	8 (4.2)	.14
CT grade (n = 3187)				
CT-0	93 (2.9)	87 (2.9)	6 (3.6)	.85
CT-1	608 (19.1)	575 (19.1)	33 (19.5)	
CT-2	1245 (39.1)	1176 (39)	69 (40.8)	
CT-3	1034 (32.4)	981 (32.5)	53 (31.4)	
CT-4	207 (6.5)	199 (6.6)	8 (4.7)	
Ground-glass opacity (n = 3165)				1.0
Yes	3020 (95.4)	2864 (95.5)	156 (94.5)	
No	145 (4.6)	136 (4.5)	9 (5.5)	
Consolidation (n = 2813)				.45
Yes	2194 (77.9)	2076 (77.8)	118 (80.8)	
No	621 (22.1)	593 (22.2)	28 (19.2)	

Statistically significant results at *P* values ≤.001 are presented in bold.

Abbreviations: ART, antiretroviral therapy; CT, computed tomography; HIV, human immunodeficiency virus.

[a]Excluding asthma.

[b]Obesity defined as body mass index based on electronic medical records data, and if data on height and weight were missing, records were screened for obesity definition by clinical staff.

neutrophilia, and very high levels of CRP and ESR in patients who subsequently died from COVID-19. The platelet to lymphocyte ratio has been previously reported to be associated with higher severity and mortality in patients with COVID-19 [22]. Our findings agree with previous research but require further validation.

The proportion of patients admitted to the ICU in our cohort study was much lower than in the similar cohorts from the United Kingdom (17%) [8] and the United States (14.2%) [7], but similar to published data from China [18]. The decision for ICU admission within the Sechenov University Hospital Network is normally based on a joint opinion of a multidisciplinary team of respiratory physicians and intensivists. Due to good access to high-flow oxygen and noninvasive ventilation within the COVID-19 wards, only critical patients were transferred into the ICU, which may explain the lesser need for ICU admission in our cohort. Active use of noninvasive ventilation on the wards may explain the low in-hospital mortality in this group of patients. As only the most severely unwell patients were admitted for invasive mechanical ventilation, this may explain the high mortality recorded in ICU patients. The overall mortality rate in our cohort was similar to the average worldwide estimate [23] but much lower than in other international cohorts of hospitalized individuals, which may be a direct reflection of their

Table 4. Laboratory Test Results (Median [IQR]), Stratified by Outcome

Test	Marker Name	Reference Range	Unit	Total	Discharged	Died	*P*
Coagulation profile	% PT (quick)	70–130	%	78 (71–86), n = 1207	78 (71–86), n = 1131	70 (61.75–81.25), n = 76	**<.001**
Coagulation profile	Activated partial thromboplastin time (APTT)	0.75–1.25	Ratio	1.04 (0.97–1.12), n = 938	1.04 (0.97–1.12), n = 869	1.05 (0.91–1.13), n = 69	.668
Coagulation profile	D-dimer, quantitative	0–0.5	µg/mL	0.58 (0.36–1.04), n = 288	**0.525 (0.33–0.928)**, n = 246	**1.075 (0.575–2.125)**, n = 42	**<.001**
Coagulation profile	International normalized ratio (INR)	0.9–1.16	…	**1.17 (1.12–1.27)**, n = 1207	**1.17 (1.11–1.26)**, n = 1131	**1.25 (1.157–1.38)**, n = 76	**<.001**
Coagulation profile	Prothrombin time	9.4–12.5	Seconds	**12.8 (12.2–13.8)**, n = 1207	**12.8 (12.1–13.7),** n = 1131	**13.6 (12.6–15)**, n = 76	**<.001**
Coagulation profile	Ferritin	7–200	µg/L	**252.8 (155.4–482.1)**, n = 213	**249.5 (150.933–483.525)**, n = 194	**290.55 (217.55–360.65)**, n = 19	.619
Coagulation profile	Fibrinogen	1.8–4	g/L	**5.45 (4.4–6.93)**, n = 1570	**5.45 (4.4–6.93)**, n = 1488	**5.645 (4.602–7.572)**, n = 82	.187
Complete blood count	Hemoglobin (HGB)	117–180	g/L	137 (126–147), n = 2392	137 (127–147), n = 2255	131 (120–142), n = 137	**<.001**
Complete blood count	Mean corpuscular hemoglobin (MCH)	27–38	pg	29.2 (28.1–30.3), n = 2392	29.2 (28.1–30.3), n = 2255	29.2 (28.3–30.4), n = 137	.512
Complete blood count	Mean platelet volume (MPV)	8.7–9.6	fL	9.3 (8.9–9.8), n = 340	9.3 (8.9–9.8), n = 313	9.3 (8.9–10.35), n = 27	.454
Complete blood count	Plateletcrit (PCT)	0.14–0.28	%	0.16 (0.13–0.2), n = 339	0.16 (0.14–0.2), n = 312	0.15 (0.105–0.19), n = 27	.017
Complete blood count	Platelets (PLT)	150–450	$\times 10^9$/L	188 (151–237), n = 2392	188 (152–238), n = 2255	171 (134–228), n = 137	.005
Complete blood count	Red blood cells (RBC)	3.8–6.1	$\times 10^{12}$/L	4.7 (4.35–5.05), n = 2392	4.72 (4.37–5.06), n = 2255	4.45 (4.14–4.76), n = 137	**<.001**
Complete blood count	Red cell distribution width (RDW)	10.5–18	%	13.6 (13.1–14.3), n = 2392	13.6 (13–14.3), n = 2255	14.2 (13.8–15), n = 137	**<.001**
Complete blood count	White blood cells (WBC)	4–11	$\times 10^9$/L	5.175 (4.038–6.7), n = 2392	5.1 (4.015–6.6), n = 2255	6 (4.15–8.6), n = 137	**<.001**
Complete blood count	No. of basophils	0–0.1	$\times 10^9$/L	0.02 (0.01–0.04), n = 904	0.02 (0.01–0.04), n = 846	0.015 (0.01–0.03), n = 58	.093
Complete blood count	No. of lymphocytes	1–3.7	$\times 10^9$/L	1.2 (0.895–1.51), n = 2391	1.2 (0.9–1.58), n = 2254	**0.8 (0.59–1.08)**, n = 137	**<.001**
Complete blood count	No. of monocytes	0–0.7	$\times 10^9$/L	0.4 (0.29–0.5), n = 2387	0.4 (0.3–0.5), n = 2250	0.3 (0.2–0.42), n = 137	**<.001**
Complete blood count	No. of neutrophils	1.5–7	$\times 10^9$/L	3.3 (2.3–4.7), n = 2391	3.3 (2.3–4.6), n = 2254	4.7 (2.98–7.3), n = 137	**<.001**
Complete blood count	No. of eosinophils	0–0.4	$\times 10^9$/L	0.05 (0.01–0.1), n = 1184	0.05 (0.01–0.1), n = 1122	0.02 (0.01–0.075), n = 62	**<.001**
Complete blood count	Hematocrit (HCT)	35–52	%	41.55 (38.7–44.6), n = 2394	41.6 (38.8–44.7), n = 2256	40.5 (37.2–43.475), n = 138	.001
Complete blood count	Mean corpuscular hemoglobin concentration (MCHC)	300–380	g/dL	323 (310–331), n = 2392	323 (310–331), n = 2255	315 (301–329), n = 137	.006
Complete blood count	Mean cellular volume (MCV)	80–99	fL	88.7 (85.4–91.7), n = 1982	88.65 (85.4–91.6), n = 1884	90 (86.2–94.175), n = 98	.002
Complete blood count	Erythrocyte sedimentation rate (ESR)	…	mm/hour	**32 (21–40)**, n = 2337	**32 (21–40)**, n = 2203	**36 (23–45)**, n = 134	.014
Complete blood count	Color index	0.8–1.05	…	0.88 (0.84–0.91), n = 2392	0.88 (0.84–0.91), n = 2255	0.87 (0.85–0.91), n = 137	.492
Complete blood count	Eosinophils %	0–5	%	0.4 (0.2–0.9), n = 2363	0.4 (0.2–1), n = 2230	0.3 (0.1–0.5), n = 133	**<.001**
Complete blood count	Basophils %	0–2	%	0.4 (0.2–0.5), n = 2390	0.4 (0.2–0.5), n = 2253	0.3 (0.2–0.4), n = 137	**<.001**
Complete blood count	Lymphocytes %	18–44	%	23.3 (16.6–31.4), n = 2391	24 (17.225–31.875), n = 2254	**13.8 (7.7–21.1)**, n = 137	**<.001**
Complete blood count	Monocytes %	2–12	%	7 (5.2–9.2), n = 2391	7.2 (5.4–9.4), n = 2254	4.9 (3.3–6.3), n = 137	**<.001**
Complete blood count	Neutrophils %	45–72	%	65.8 (56.05–74.7), n = 2391	65 (55.3–73.7), n = 2254	**78.6 (71–86.6)**, n = 137	**<.001**
Metabolic panel	C-reactive protein	0–5	mg/L	**42 (15.135–87)**, n = 2424	**39 (14–81)**, n = 2293	**107 (64–160.5)**, n = 131	**<.001**
Metabolic panel	Urea nitrogen	3.2–8.2	mmol/L	5.3 (4.25–6.9), n = 1543	5.2 (4.2–6.7), n = 1445	**8.75 (5.75–12.575)**, n = 98	**<.001**
Metabolic panel	Alanine aminotransferase (ALT)	10–49	U/L	32 (22–49), n = 2299	32 (22–48), n = 2175	35 (23–54.25), n = 124	.202
Metabolic panel	Aspartate aminotransferase (AST)	0–34	U/L	**36 (27–51)**, n = 2322	**36 (27–50)**, n = 2194	**50 (38–75)**, n = 128	**<.001**
Metabolic panel	Total protein	57–82	g/L	71.1 (67.4–74.6), n = 1879	71.2 (67.6–74.7), n = 1772	68.6 (64.05–72.65), n = 107	**<.001**
Metabolic panel	Total bilirubin	3–21	µmol/L	10.1 (7.5–13.2), n = 2027	10 (7.6–13.1), n = 1912	10.3 (7–14.2), n = 115	.94
Metabolic panel	Direct bilirubin	0–5	µmol/L	3.1 (2.3–4.1), n = 981	3 (2.3–4), n = 927	3.8 (2.375–4.675), n = 54	.017
Metabolic panel	γ-Glutamyltransferase (GGT)	0–73	U/L	46 (26–79), n = 338	45 (26–73), n = 315	**93 (34.5–143)**, n = 23	.023
Metabolic panel	Potassium	3.5–5.5	mmol/L	4.5 (4.1–4.9), n = 2113	4.5 (4.1–4.9), n = 1996	4.4 (4–5), n = 117	.736
Metabolic panel	Calcium	2.08–2.65	mmol/L	2.105 (2–2.203), n = 156	2.11 (2.012–2.21), n = 138	**2.055 (1.88–2.18)**, n = 18	.114

Table 4. Continued

Test	Marker Name	Reference Range	Unit	Total	Discharged	Died	*P*
Metabolic panel	Creatinine	44–115	µmol/L	94.805 (82.797–108.305), n = 2368	94.4 (82.523–107.362), n = 2240	106.565 (88.785–133.765), n = 128	**<.001**
Metabolic panel	Creatine kinase (CK)	0–190	U/L	127 (71–233), n = 608	122 (70–222), n = 561	**207 (117.5–350)**, n = 47	.003
Metabolic panel	Lactate dehydrogenase (LDH)	240–480	U/L	**484 (376–616)**, n = 1543	**481 (378–609.75)**, n = 1446	**575 (1.591–764)**, n = 97	.044
Metabolic panel	Uric acid	145–415	µmol/L	310 (246.75–395), n = 752	307 (244–388), n = 691	343 (284–442), n = 61	.008
Metabolic panel	Sodium	132–150	mmol/L	141 (138–144), n = 2046	141 (138–144), n = 1933	141 (138–145), n = 113	.679
Metabolic panel	Chloride	99–109	mmol/L	102 (97–105.5), n = 243	102 (98–105), n = 217	101.5 (95.25–105.5), n = 26	.799
Metabolic panel	Cholesterol	3.2–5.6	mmol/L	4.03 (3.38–4.69), n = 701	4.055 (3.413–4.72), n = 654	3.67 (3.015–4.32), n = 47	.006
Metabolic panel	Albumin	32–48	mmol/L	40.3 (37.8–42.925), n = 1776	40.5 (38.1–43.1), n = 1673	37.2 (35–39.7), n = 103	**<.001**
Metabolic panel	Amylase	30–118	U/L	46.9 (35–60), n = 427	47 (35–59.4), n = 397	40.55 (27.1–70.975), n = 30	.473
Metabolic panel	Glucose	4.1–5.9	mmol/L	5.4 (4.8–6.3), n = 2296	5.4 (4.8–6.2), n = 2170	**6.25 (5.4–8.325)**, n = 126	**<.001**
Other	Iron	9–30.4	µmol/L	**4 (2.2–6.9)**, n = 385	**4.1 (2.375–7.2)**, n = 356	**1.9 (1.8–4.8)**, n = 29	.001

Statistically significant results at *P* values <.001 and parameters with levels higher/lower than the reference range are presented in bold. The number of patients is presented for each variable.

Abbreviations: IQR, interquartile range; PT, Prothrombin.

much younger age and moderate state of disease at the time of admission in most of the patients.

Half of the patients admitted to the Sechenov University Hospital Network did not have positive RT-PCR test results, despite having clinical features of COVID-19 infection. Our findings are similar to the US data, with 42% [5] to 51.8% [6] of individuals having negative RT-PCR test results. The false-negative rate of the RT-PCR tests varies between 20% and 66% depending on the day since symptom onset [10], meaning that results must be cautiously interpreted [24], which represents a major concern related to control of the pandemic [25]. Previous research suggests that a negative RT-PCR test result does not exclude the possibility of COVID-19. Repeated testing and sampling were shown to improve the sensitivity of RT-PCR [15]. To our knowledge, previous studies of patients with COVID-19 excluded those with suspected COVID-19 infection in the absence of a positive test result [3–8]. However, this approach differs from pragmatic clinical practice, in which, in the absence of an alternative diagnosis, patients with a clinical diagnosis of COVID-19 are treated equally to laboratory-confirmed cases. When evaluating radiological findings in COVID-19, it must be born in mind that some patients may present with clinical symptoms or extrapulmonary manifestations, such as hepatic, cardiovascular, or kidney injury, but initially will have normal CT findings [26]. In our study we did not solely rely on CT findings for clinical diagnosis of COVID-19. However, new approaches to minimize the exclusion of patients with false-negative RT-PCR results should be sought, as highlighted in a recent report suggesting real-time lung ultrasound as an auxiliary method to rule-in COVID-19 during screening [27].

Limitations

This cohort study has some limitations. First, the study population only included patients within Moscow. Second, the data were collected retrospectively from the electronic medical records with no access to additional information that could be potentially retrieved from the medical notes. Third, half of the patients in our cohort did not have RT-PCR–confirmed COVID-19 infection, although this is unlikely to affect the outcomes as we failed to find any significant differences between clinically diagnosed and laboratory-confirmed cases. Fourth, endpoint outcome data were available for 83% of admitted patients. Patients admitted and/or transferred to the ICU and receiving invasive mechanical ventilation can spend a significant amount of time attached to the machine [7, 8]. The absence of data on patients (18%) who remained in the hospital at the time of data analysis completion may lead to bias and may influence overall mortality calculations. Fifth, morbidity related to invasive procedures or sequelae in clinically suspected and/or laboratory-confirmed cases has not been recorded. Sixth, the definition of "clinically diagnosed COVID-19" implies changes on chest CT and nonspecific signs and symptoms, which may

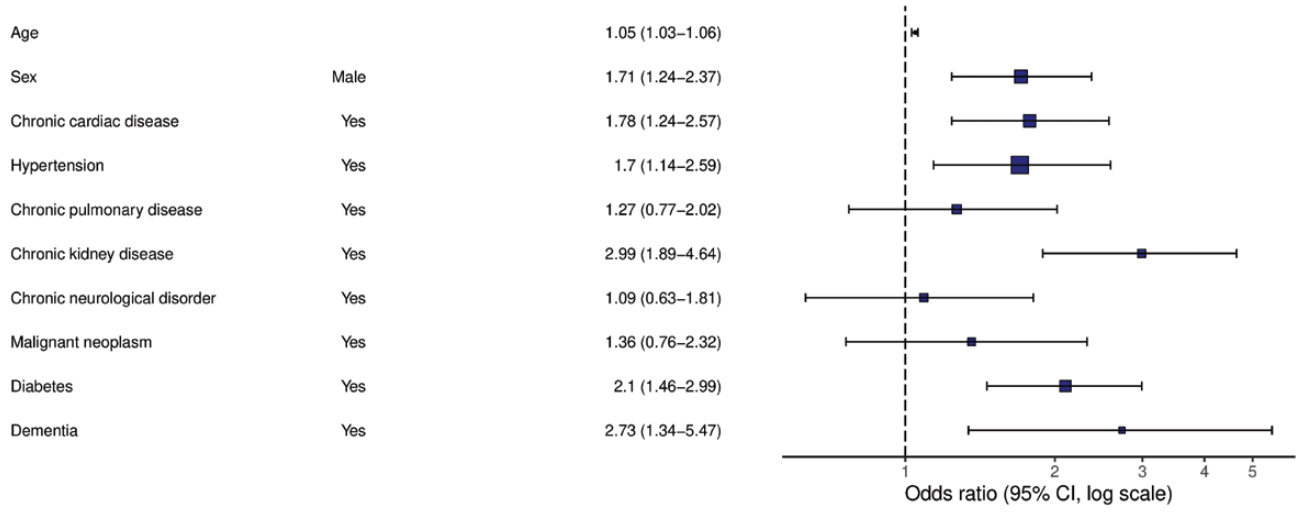

Figure 2. Odds ratios and 95% CIs for in-hospital mortality from a multivariable logistic regression model. Abbreviation: CI, confidence interval.

be present in other respiratory viral illnesses. The scoring system used for radiological signs is able to differentiate between symptomatic and asymptomatic cases of COVID-19 but is not fully able to differentiate between COVID-19 from other similar conditions.

Conclusions

The clinical features, chest CT, and blood test results did not differ between test-confirmed and clinically diagnosed patients. Furthermore, clinical outcomes were also identical. Our study results suggest that in order to assess the full impact of this pandemic on populations, all clinically diagnosed patients should be included. Comorbidities associated with death were similar to other published studies on COVID-19. Mortality in our cohort was low, which may have been due to the mean age of patients being lower than in some other published studies. Anosmia was associated with milder disease while asthma did not appear to pose an increased risk of adverse outcome. As with other studies, manifestations of nonrespiratory problems including coagulopathy, immune deficiency, hyperinflammation and renal deficits were associated with higher risks of death. The data collection within StopCOVID cohort is continuing and further analysis focused on predictive models of adverse outcomes for routine clinical practice is in progress.

Supplementary Data

Supplementary materials are available at *Clinical Infectious Diseases* online. Consisting of data provided by the authors to benefit the reader, the posted materials are not copyedited and are the sole responsibility of the authors, so questions or comments should be addressed to the corresponding author.

Notes

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