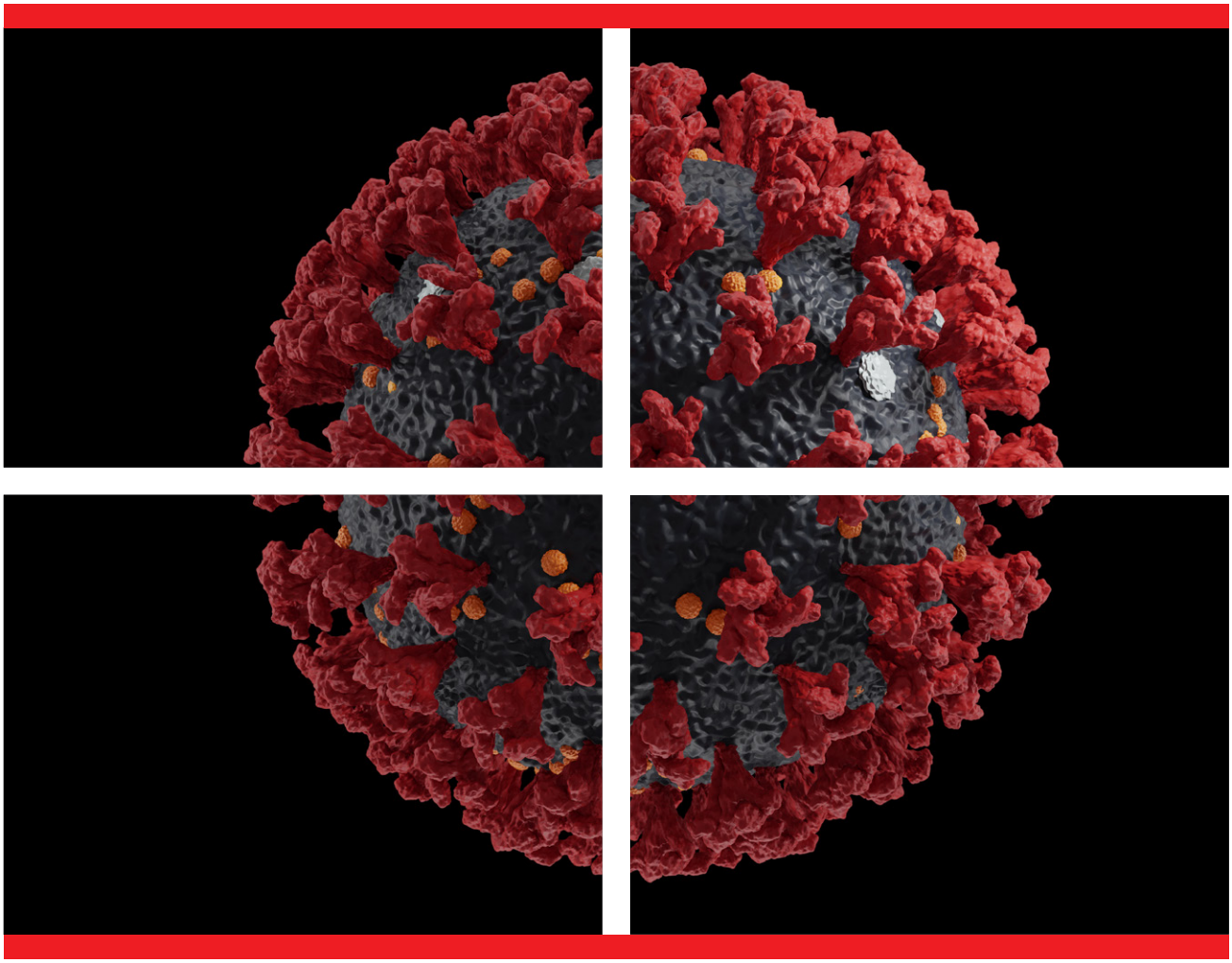
Publication List
COVID-19



Human
Diagnostics Worldwide

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The content has been compiled to the best of our knowledge and belief and makes no claim to completeness or correctness.

Content

COVID-19: Disease state and related laboratory abnormalities

Epidemiological and clinical characteristics of 99 cases of 2019 novel coronavirus pneumonia in Wuhan, China: a descriptive study

Nanshan Chen, Min Zhou, Xuan Dong, Jieming Qu, Fengyun Gong, Yang Han, Yang Qiu, Jingli Wang, Ying Liu, Yuan Wei, Jia'an Xia, Ting Yu, Xinxin Zhang, Li Zhang

– Lancet 2020; 395: 507–13 –

Summary

Background

In December, 2019, a pneumonia associated with the 2019 novel coronavirus (2019-nCoV) emerged in Wuhan, China. We aimed to further clarify the epidemiological and clinical characteristics of 2019-nCoV pneumonia.

Methods

In this retrospective, single-centre study, we included all confirmed cases of 2019-nCoV in Wuhan Jinyintan Hospital from Jan 1 to Jan 20, 2020. Cases were confirmed by real-time RT-PCR and were analysed for epidemiological, demographic, clinical, and radiological features and laboratory data. Outcomes were followed up until Jan 25, 2020.

Results

Of the 99 patients with 2019-nCoV pneumonia, 49 (49%) had a history of exposure to the Huanan seafood market. The average age of the patients was 55·5 years (SD 13·1), including 67 men and 32 women. 2019-nCoV was detected in all patients by real-time RT-PCR. 50 (51%) patients had chronic diseases. Patients had clinical manifestations of fever (82 [83%] patients), cough (81 [82%] patients), shortness of breath (31 [31%] patients), muscle ache (11 [11%] patients), confusion (nine [9%] patients), headache (eight [8%] patients), sore throat (five [5%] patients), rhinorrhoea (four [4%] patients), chest pain (two [2%] patients), diarrhoea (two [2%] patients), and nausea and vomiting (one [1%] patient). According to imaging examination, 74 (75%) patients showed bilateral pneumonia, 14 (14%) patients showed multiple mottling and ground-glass opacity, and one (1%) patient had pneu mothorax. 17 (17%) patients developed acute respiratory distress syndrome and, among them, 11 (11%) patients worsened in a short period of time and died of multiple organ failure.

Conclusions

The 2019-nCoV infection was of clustering onset, is more likely to affect older males with comorbidities, and can result in severe and even fatal respiratory diseases such as acute respiratory distress syndrome. In general, characteristics of patients who died were in line with the MuLBSTA score, an early warning model for predicting mortality in viral pneumonia. Further investigation is needed to explore the applicability of the MuLBSTA score in predicting the risk of mortality in 2019-nCoV infection.

Clinical predictors of mortality due to COVID-19 based on an analysis of data of 150 patients from Wuhan, China

Qiurong Ruan, Kun Yang, Wenxia Wang, Lingyu Jiang, Jianxin Song

– Intensive Care Med 2020; https://doi.org/10.1007/s00134-020-05991-x –

Abstract

Introduction

The rapid emergence of COVID-19 in Wuhan city, Hubei Province, China, has resulted in thousands of deaths [1]. Many infected patients, however, presented mild flu-like symptoms and quickly recover [2]. To effectively prioritize resources for patients with the highest risk, we identified clinical predictors of mild and severe patient outcomes. Using the database of Jin Yin-tan Hospital and Tongji Hospital, we conducted a retrospective multicenter study of 68 death cases (68/150, 45%) and 82 discharged cases (82/150, 55%) with laboratory-confirmed infection of SARS-CoV-2. Patients met the discharge criteria if they had no fever for at least 3 days, significantly improved respiratory function, and had negative SARS-CoV-2 laboratory test results twice in succession. Case data included demographics, clinical characteristics, laboratory results, treatment options and outcomes. For statistical analysis, we represented continuous measurements as means (SDs) or as medians (IQRs) which compared with Student's t test or the Mann–Whitney–Wilcoxon test. Categorical variables were expressed as numbers (%) and compared by the $\chi 2$ test or Fisher's exact test.

Asymptomatic carrier state, acute respiratory disease, and pneumonia due to severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2): Facts and myths

Chih-Cheng Lai, Yen Hung Liu, Cheng-Yi Wang, Ya-Hui Wang, Shun-Chung Hsueh, Muh-Yen Yen, Wen-Chien Ko, Po-Ren Hsueh

– Journal of Microbiology, Immunology and Infection, https://doi.org/10.1016/j.jmii.2020.02.012 –

Abstract

Since the emergence of coronavirus disease 2019 (COVID-19) (formerly known as the 2019 novel coronavirus [2019-nCoV]) in Wuhan, China in December 2019, which is caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), more than 75,000 cases have been reported in 32 countries/regions, resulting in more than 2000 deaths worldwide. Despite the fact that most COVID-19 cases and mortalities were reported in China, the WHO has declared this outbreak as the sixth public health emergency of international concern. The COVID-19 can present as an asymptomatic carrier state, acute respiratory disease, and pneumonia. Adults represent the population with the highest infection rate; however, neonates, children, and elderly patients can also be infected by SARS-CoV-2. In addition, nosocomial infection of hospitalized patients and healthcare workers, and viral transmission from asymptomatic carriers are possible. The most common finding on chest imaging among patients with pneumonia was ground-glass opacity with bilateral involvement. Severe cases are more likely to be older patients with underlying comorbidities compared to mild cases. Indeed, age and disease severity may be correlated with the outcomes of COVID-19. To date, effective treatment is lacking; however, clinical trials investigating the efficacy of several agents, including remdesivir and chloroquine, are underway in China. Currently, effective infection control intervention is the only way to prevent the spread of SARS-CoV-2.

COVID-19-associated nephritis: early warning for disease severity and complications?

Oliver Gross, Onnen Moerer, Manfred Weber, Tobias B Huber, Simone Scheithauer
– The Lancet 2020; https://doi.org/10.1016/S0140-6736(20)31041-2 –

Abstract

Among patients with coronavirus disease 2019 (COVID-19), parameters for the prediction of the need for admission to intensive care units (ICUs) are urgently needed to enable appropriate resource allocation. Here we report that analysis of a urine sample on admission to hospital can be used to detect systemic capillary leak syndrome, which can be a predictor of fluid overload, respiratory failure, need for ICU admission, and death. At our medical centre (University Medical Center Göttingen, Göttingen, Germany), we identified abnormalities in the urine samples of patients with COVID-19 who became very sick within a few days. Three of these patients had coincidentally submitted urine samples in the few weeks before their infection with severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). These urine samples had been normal. However, on March 21, 2020, since becoming infected with SARS-CoV-2, the urine sample of one of these three patients was also positive for SARS-CoV-2 RNA. The urine samples of the other two patients have not been tested because of safety concerns.

Epidemiology and transmission of COVID-19 in 391 cases and 1286 of their close contacts in Shenzhen, China: a retrospective cohort study

Qifang Bi, Yongsheng Wu, Shujiang Mei, Chenfei Ye, Xuan Zou, Zhen Zhang, Xiaojian Liu, Lan Wei, Shaun A Truelove, Tong Zhang, Wei Gao, Cong Cheng, Xiujuan Tang, Xiaoliang Wu, Yu Wu, Binbin Sun, Suli Huang, Yu Sun, Juncen Zhang, Ting Ma, Justin Lessler, Tiejian Feng

– The Lancet 2020; https://doi.org/10.1016/S1473-3099(20)30287-5–

Abstract

Background

Rapid spread of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in Wuhan, China, prompted heightened surveillance in Shenzhen, China. The resulting data provide a rare opportunity to measure key metrics of disease course, transmission, and the impact of control measures.

Methods

From Jan 14 to Feb 12, 2020, the Shenzhen Center for Disease Control and Prevention identified 391 SARS-CoV-2 cases and 1286 close contacts. We compared cases identified through symptomatic surveillance and contact tracing, and estimated the time from symptom onset to confirmation, isolation, and admission to hospital. We estimated metrics of disease transmission and analysed factors influencing transmission risk.

Results

Cases were older than the general population (mean age 45 years) and balanced between males (n=187) and females (n=204). 356 (91%) of 391 cases had mild or moderate clinical severity at initial assessment. As of Feb 22, 2020, three cases had died and 225 had recovered (median time to recovery 21 days; 95% CI 20–22). Cases were isolated on average 4·6 days (95% CI 4·1–5·0) after developing symptoms; contact tracing reduced this by 1·9 days (95% CI 1·1–2·7). Household contacts and those travelling with a case were at higher risk of infection (odds ratio 6·27 [95% CI 1·49–26·33] for household contacts and 7·06 [1·43–34·91] for those travelling with a case) than other close contacts. The household secondary attack rate was 11·2% (95% CI 9·1–13·8), and children were as likely to be infected as adults (infection rate 7·4% in children <10 years vs population average of 6·6%). The observed reproductive number (R) was 0·4 (95% CI 0·3–0·5), with a mean serial interval of 6·3 days (95% CI 5·2–7·6).

Conclusions

Our data on cases as well as their infected and uninfected close contacts provide key insights into the epidemiology of SARS-CoV-2. This analysis shows that isolation and contact tracing reduce the time during which cases are infectious in the community, thereby reducing the R. The overall impact of isolation and contact tracing, however, is uncertain and highly dependent on the number of asymptomatic cases. Moreover, children are at a similar risk of infection to the general population, although less likely to have severe symptoms; hence they should be considered in analyses of transmission and control.

Clinical course and risk factors for mortality of adult inpatients with COVID-19 in Wuhan, China: a retrospective cohort study

Fei Zhou, Ting Yu, Ronghui Du, Guohui Fan, Ying Liu, Zhibo Liu, Jie Xiang, Yeming Wang, Bin Song, Xiaoying Gu, Lulu Guan, Yuan Wei, Hui Li, Xudong Wu, Jiuyang Xu, Shengjin Tu, Yi Zhang, Hua Chen, Bin Cao

– The Lancet 2020; https://doi.org/10.1016/S0140-6736(20)30566-3 –

Abstract

Background

Since December, 2019, Wuhan, China, has experienced an outbreak of coronavirus disease 2019 (COVID-19), caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). Epidemiological and clinical characteristics of patients with COVID-19 have been reported but risk factors for mortality and a detailed clinical course of illness, including viral shedding, have not been well described.

Methods

In this retrospective, multicentre cohort study, we included all adult inpatients (≥18 years old) with laboratoryconfirmed COVID-19 from Jinyintan Hospital and Wuhan Pulmonary Hospital (Wuhan, China) who had been discharged or had died by Jan 31, 2020. Demographic, clinical, treatment, and laboratory data, including serial samples for viral RNA detection, were extracted from electronic medical records and compared between survivors and non-survivors. We used univariable and multivariable logistic regression methods to explore the risk factors associated with in-hospital death.

Results

191 patients (135 from Jinyintan Hospital and 56 from Wuhan Pulmonary Hospital) were included in this study, of whom 137 were discharged and 54 died in hospital. 91 (48%) patients had a comorbidity, with hypertension being the most common (58 [30%] patients), followed by diabetes (36 [19%] patients) and coronary heart disease (15 [8%] patients). Multivariable regression showed increasing odds of in-hospital death associated with older age (odds ratio 1·10, 95% CI 1·03–1·17, per year increase; p=0·0043), higher Sequential Organ Failure Assessment (SOFA) score (5·65, 2·61–12·23; p<0·0001), and d-dimer greater than 1 µg/L (18·42, 2·64–128·55; p=0·0033) on admission. Median duration of viral shedding was 20·0 days (IQR 17·0–24·0) in survivors, but SARS-CoV-2 was detectable until death in non-survivors. The longest observed duration of viral shedding in survivors was 37 days.

Conclusions

The potential risk factors of older age, high SOFA score, and d-dimer greater than 1 µg/L could help clinicians to identify patients with poor prognosis at an early stage. Prolonged viral shedding provides the rationale for a strategy of isolation of infected patients and optimal antiviral interventions in the future.

Clinical Characteristics of Coronavirus Disease 2019 in China

W. Guan, Z. Ni, Yu Hu, W. Liang, C. Ou, J. He, L. Liu, H. Shan, C. Lei, D.S.C. Hui, B. Du, L. Li, G. Zeng, K.-Y. Yuen, R. Chen, C. Tang, T. Wang, P. Chen, J. Xiang, S. Li, Jin-lin Wang, Z. Liang, Y. Peng, L. Wei, Y. Liu, Ya-hua Hu, P. Peng, Jian-ming Wang, J. Liu, Z. Chen, G. Li, Z. Zheng, S. Qiu, J. Luo, C. Ye, S. Zhu, N. Zhong

– N Engl J Med 2020; DOI: 10.1056/NEJMoa2002032 –

Abstract

Background

Since December 2019, when coronavirus disease 2019 (Covid-19) emerged in Wuhan city and rapidly spread throughout China, data have been needed on the clinical characteristics of the affected patients.

Methods

We extracted data regarding 1099 patients with laboratory-confirmed Covid-19 from 552 hospitals in 30 provinces, autonomous regions, and municipalities in mainland China through January 29, 2020. The primary composite end point was admission to an intensive care unit (ICU), the use of mechanical ventilation, or death.

Results

The median age of the patients was 47 years; 41.9% of the patients were female. The primary composite end point occurred in 67 patients (6.1%), including 5.0% who were admitted to the ICU, 2.3% who underwent invasive mechanical ventilation, and 1.4% who died. Only 1.9% of the patients had a history of direct contact with wildlife. Among nonresidents of Wuhan, 72.3% had contact with residents of Wuhan, including 31.3% who had visited the city. The most common symptoms were fever (43.8% on admission and 88.7% during hospitalization) and cough (67.8%). Diarrhea was uncommon (3.8%). The median incubation period was 4 days (interquartile range, 2 to 7). On admission, ground-glass opacity was the most common radiologic finding on chest computed tomography (CT) (56.4%). No radiographic or CT abnormality was found in 157 of 877 patients (17.9%) with nonsevere disease and in 5 of 173 patients (2.9%) with severe disease. Lymphocytopenia was present in 83.2% of the patients on admission.

Conclusions

During the first 2 months of the current outbreak, Covid-19 spread rapidly throughout China and caused varying degrees of illness. Patients often presented without fever, and many did not have abnormal radiologic findings.

Clinical Characteristics of 138 Hospitalized Patients With 2019 Novel Coronavirus Infected Pneumonia in Wuhan, China

Dawei Wang, Bo Hu, Chang Hu et al.

– JAMA. 2020;323(11):1061-1069 –

Abstract

Background

In December 2019, novel coronavirus (2019-nCoV)–infected pneumonia (NCIP) occurred in Wuhan, China. The number of cases has increased rapidly but information on the clinical characteristics of affected patients is limited.

Methods

Retrospective, single-center case series of the 138 consecutive hospitalized patients with confirmed NCIP at Zhongnan Hospital of Wuhan University in Wuhan, China, from January 1 to January 28, 2020; final date of follow-up was February 3, 2020.

Results

Of 138 hospitalized patients with NCIP, the median age was 56 years (interquartile range, 42-68; range, 22-92 years) and 75 (54.3%) were men. Hospital-associated transmission was suspected as the presumed mechanism of infection for affected health professionals (40 [29%]) and hospitalized patients (17 [12.3%]). Common symptoms included fever (136 [98.6%]), fatigue (96 [69.6%]), and dry cough (82 [59.4%]). Lymphopenia (lymphocyte count, 0.8 × 109/L [interquartile range {IQR}, 0.6-1.1]) occurred in 97 patients (70.3%), prolonged prothrombin time (13.0 seconds [IQR, 12.3-13.7]) in 80 patients (58%), and elevated lactate dehydrogenase (261 U/L [IQR, 182-403]) in 55 patients (39.9%). Chest computed tomographic scans showed bilateral patchy shadows or ground glass opacity in the lungs of all patients. Most patients received antiviral therapy (oseltamivir, 124 [89.9%]), and many received antibacterial therapy (moxifloxacin, 89 [64.4%]; ceftriaxone, 34 [24.6%]; azithromycin, 25 [18.1%]) and glucocorticoid therapy (62 [44.9%]). Thirty-six patients (26.1%) were transferred to the intensive care unit (ICU) because of complications, including acute respiratory distress syndrome (22 [61.1%]), arrhythmia (16 [44.4%]), and shock (11 [30.6%]). The median time from first symptom to dyspnea was 5.0 days, to hospital admission was 7.0 days, and to ARDS was 8.0 days. Patients treated in the ICU (n = 36), compared with patients not treated in the ICU (n = 102), were older (median age, 66 years vs 51 years), were more likely to have underlying comorbidities (26 [72.2%] vs 38 [37.3%]), and were more likely to have dyspnea (23 [63.9%] vs 20 [19.6%]), and anorexia (24 [66.7%] vs 31 [30.4%]). Of the 36 cases in the ICU, 4 (11.1%) received high-flow oxygen therapy, 15 (41.7%) received noninvasive ventilation, and 17 (47.2%) received invasive ventilation (4 were switched to extracorporeal membrane oxygenation). As of February 3, 47 patients (34.1%) were discharged and 6 died (overall mortality, 4.3%), but the remaining patients are still hospitalized. Among those discharged alive (n = 47), the median hospital stay was 10 days (IQR, 7.0-14.0).

Conclusions

In this single-center case series of 138 hospitalized patients with confirmed NCIP in Wuhan, China, presumed hospital-related transmission of 2019-nCoV was suspected in 41% of patients, 26% of patients received ICU care, and mortality was 4.3%.

Laboratory abnormalities in patients with COVID-2019 infection

Giuseppe Lippi, Mario Plebani

– Clin Chem Lab Med 2020; https://doi.org/10.1515/cclm-2020-0198 –

Abstract

Introduction

Coronavirus disease 2019 (COVID-19), a form of respiratory and systemic zoonosis caused by a virus belonging to the Coronaviridae family, originated from the town of Wuhan in China, is still spreading around the world, thus assuming the dramatic features of a pandemic emergency [1]. According to the recent statistics of the World Health Organization (WHO), the disease has already involved all continents, with over 80,000 diagnosed cases in 34 different countries, and nearly 2700 deaths until February 26, 2020 [2]. Despite the severity of COVID-19 seems lower than that of the two previous coronavirus diseases, i.e. SARS (severe acute respiratory syndrome) and MERS (Middle East respiratory syndrome), the long incubation period and the relatively low pathogenicity compared to that of the two previous homologous viruses are contributing to sustain and amplify the outbreak inside and outside China. Therefore, the aim of this article is to provide a brief overview on the most frequent laboratory abnormalities encountered in patients with COVID-2019 infection.

COVID-19: Diagnosis and treatment strategies

Therapeutic and triage strategies for 2019 novel coronavirus disease in fever clinic

Jinnong Zhang, Luqian Zhou, Yuqiong Yang, Wei Peng, Wenjing Wang, Xuelin Chen
– Lancet Vol 8,2020; https://doi.org/10.1016/S22132600(20)300710 –

Introduction

In December, 2019, numerous unexplained pneumonia cases occurred in Wuhan, China. This outbreak was confirmed to be caused by severe acute respiratory syndrome corona virus 2 (SARSCoV2), belonging to the same family of viruses responsible for severe acute respiratory syndrome (SARS) and Middle East respiratory syndrome (MERS).1 The SARS epidemic in 2003 was controlled through numerous measures in China. One effective strategy was the establishment of fever clinics for triaging patients. Based on our firsthand experience in dealing with the present outbreak in Wuhan, we have established the following clinical strategies in adult fever clinics.

Diagnosis and Treatment Protocol for Novel Coronavirus Pneumonia

– National Health Commission & State Administration of Traditional Chinese Medicine on March 3, 2020 –

Abstract

Introduction

Since December 2019, multiple cases of novel coronavirus pneumonia (NCP) have been identified in Wuhan, Hubei. With the spread of the epidemic, such cases have also been found in other parts of China and other countries. As an acute respiratory infectious disease, NCP has been included in Class B infectious diseases prescribed in the Law of the People's Republic of China on Prevention and Treatment of Infectious Diseases, and managed as an infectious disease of Class A. By taking a series of preventive control and medical treatment measures, the rise of the epidemic situation in China has been contained to a certain extent, and the epidemic situation has eased in most provinces, but the incidence abroad is on the rise. With increased understanding of the clinical manifestations and pathology of the disease, and the accumulation of experience in diagnosis and treatment, in order to further strengthen the early diagnosis and early treatment of the disease, improve the cure rate, reduce the mortality rate, avoid nosocomial infection as much as possible and pay attention to the spread caused by the imported cases from overseas.

COVID-19 and hemostasis

Chinese expert consensus on diagnosis and treatment of coagulation dysfunction in COVID-19

Jing-Chun Song, Gang Wang, Wei Zhang, Yang Zhang, Wei-Qin Li, Zhou Zhou

– *Military Medical Research (2020) 7:19; https://doi.org/10.1186/s40779-020-00247-7* –

Abstract

Since December 2019, a novel type of coronavirus disease (COVID-19) in Wuhan led to an outbreak throughout China and the rest of the world. To date, there have been more than 1,260,000 COVID-19 patients, with a mortality rate of approximately 5.44%. Studies have shown that coagulation dysfunction is a major cause of death in patients with severe COVID-19. Therefore, the People's Liberation Army Professional Committee of Critical Care Medicine and Chinese Society on Thrombosis and Hemostasis grouped experts from the frontline of the Wuhan epidemic to come together and develop an expert consensus on diagnosis and treatment of coagulation dysfunction associated with a severe COVID-19 infection. This consensus includes an overview of COVID-19-related coagulation dysfunction, tests for coagulation, anticoagulation therapy, replacement therapy, supportive therapy and prevention. The consensus produced 18 recommendations which are being used to guide clinical work.

COVID-19 cytokine storm: the interplay between inflammation and coagulation

Ricardo J Jose, Ari Manuel

– *The Lancet 2020; https://doi.org/10.1016/S2213-2600(20)30216-2* –

Abstract

Coronavirus disease 2019 (COVID-19) has spread rapidly throughout the globe. It is associated with significant mortality, particularly in at-risk groups with poor prognostic features at hospital admission. The spectrum of disease is broad but among hospitalised patients with COVID-19, pneumonia, sepsis, respiratory failure, and acute respiratory distress syndrome (ARDS) are frequently encountered complications. The pathophysiology of severe acute respiratory syndrome coronavirus (SARS-CoV-2)-induced ARDS has similarities to that of severe community-acquired pneumonia caused by other viruses or bacteria. The overproduction of early response proinflammatory cytokines (tumour necrosis factor [TNF], IL-6, and IL-1β) results in what has been described as a cytokine storm, leading to an increased risk of vascular hyperpermeability, multiorgan failure, and eventually death when the high cytokine concentrations are unabated over time. Therefore, therapeutic strategies under investigation are targeting the overactive cytokine response with anticytokine therapies or immunomodulators, but this must be balanced with maintaining an adequate inflammatory response for pathogen clearance.

Abnormal coagulation parameters are associated with poor prognosis in patients with novel coronavirus pneumonia

Ning Tang, Dengju Li, Xiong Wang, Ziyong Sun

– J Thromb Haemost. 2020;00:1–4 –

Abstract

Background

In the recent outbreak of novel coronavirus infection in Wuhan, China, significantly abnormal coagulation parameters in severe novel coronavirus pneumonia (NCP) cases were a concern.

Methods

Conventional coagulation results and outcomes of 183 consecutive patients with confirmed NCP in Tongji hospital were retrospectively analyzed.

Results

The overall mortality was 11.5%, the non-survivors revealed significantly higher D-dimer and fibrin degradation product (FDP) levels, longer prothrombin time and activated partial thromboplastin time compared to survivors on admission ($P < .05$); 71.4% of non-survivors and 0.6% survivors met the criteria of disseminated intravascular coagulation during their hospital stay.

Conclusions

The present study shows that abnormal coagulation results, especially markedly elevated D-dimer and FDP are common in deaths with NCP.

ISTH interim guidance on recognition and management of coagulopathy in COVID-19

Jecko Thachil, Ning Tang, Satoshi Gando, Anna Falanga, Marco Cattaneo, Marcel Levi, Cary Clark, Toshiaki Iba

– doi: 10.1111/JTH.14810 –

Abstract

Introduction

The novel corona virus infection (now classified as COVID-19), first identified in December 2019 in Wuhan, China, has contributed to significant mortality in several countries with the number of infected cases increasing exponentially worldwide. The majority of the most severely ill patients initially present with single organ failure (i.e. respiratory insufficiency) but some of them progress to more systemic disease and multiple organ dysfunction. One of the most significant poor prognostic features in those patients is the development of coagulopathy. In patients who develop sepsis from various infectious agents, development of coagulopathy is one of the key and persistent features which is associated with poor outcomes. In this context, the role of International Society of Thrombosis and Haemostasis (ISTH) would be crucial in guiding health care professionals how to manage the coagulopathy of COVID-19. A simple and easily follow-able algorithm for the management of COVID-19 coagulopathy would currently be useful in both the well-resourced and less-resourced settings as a guide in managing this complication. This pragmatic statement should clearly be considered as an interim guidance since the clinical experience of managing this pandemic is increasing. The authors are certain that this statement will be modified with developing knowledge and therapeutics in managing COVID-19. The aim of this guidance document is to provide a risk stratification at admission for a COVID-19 patient and management of coagulopathy which may develop in some of these patients, based on easily available laboratory parameters.

D-dimer is Associated with Severity of Coronavirus Disease 2019: A Pooled Analysis

Giuseppe Lippi, Emmanuel J. Favaloro

– Thrombosis and Haemostasis April 2020; https://doi.org/ 10.1055/s-0040-1709650 –

Abstract

Introduction

A new infective outbreak, sustained by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) and defined coronavirus disease 2019 (COVID-19), is now spreading all around the world.[1] The clinical course of this respiratory disease is complicated in up to 15% of infected patients by onset of interstitial pneumonia, evolving toward acute respiratory distress syndrome needing mechanical ventilation or admission to the intensive care unit (ICU), and is also often accompanied by multiorgan failure.[2] Since there is now incontrovertible evidence that laboratory hemostasis provides an essential contribution to decision-making and care of the vast majority of human pathologies,[3] we aimed to explore here whether increased D-dimer values—which are a frequent occurrence in patients with COVID-19[4]—may be associated with disease severity.

Prominent changes in blood coagulation of patients with SARS-CoV-2 infection

Huan Hana, Lan Yanga, Rui Liu, Fang Liu, Kai lang Wu, Jie Li, Xing-hui Liu, Cheng-liang Zhu
– Clin Chem Lab Med 2020; https://doi.org/10.1515/cclm-2020-0188 –

Abstract

Background

As the number of patients increases, there is a growing understanding of the form of pneumonia sustained by the 2019 novel coronavirus (SARS-CoV-2), which has caused an outbreak in China. Up to now, clinical features and treatment of patients infected with SARS-CoV-2 have been reported in detail. However, the relationship between SARS-CoV-2 and coagulation has been scarcely addressed. Our aim is to investigate the blood coagulation function of patients with SARS-CoV-2 infection.

Methods

In our study, 94 patients with confirmed SARS-CoV-2 infection were admitted in Renmin Hospital of Wuhan University. We prospectively collect blood coagulation data in these patients and in 40 healthy controls during the same period.

Results

Antithrombin values in patients were lower than that in the control group ($p < 0.001$). The values of D-dimer, fibrin/fibrinogen degradation products (FDP), and fibrinogen (FIB) in all SARS-CoV-2 cases were substantially higher than those in healthy controls. Moreover, D-dimer and FDP values in patients with severe SARS-CoV-2 infection were higher than those in patients with milder forms. Compared with healthy controls, prothrombin time activity (PT-act) was lower in SARS-CoV-2 patients. Thrombin time in critical SARS-CoV-2 patients was also shorter than that in controls.

Conclusions

The coagulation function in patients with SARS-CoV-2 is significantly deranged compared with healthy people, but monitoring D-dimer and FDP values may be helpful for the early identification of severe cases.

A New Predictor of Disease Severity in Patients with COVID-19 in Wuhan, China

Ying Zhou, Zhen Yang, Yanan Guo, Shuang Geng, Shan Gao, Shenglan Ye, Yi Hu, Yafei Wang
– medRxiv; https://doi.org/10.1101/2020.03.24.20042119 –

Abstract

Background

Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) broke out in Wuhan, Hubei, China. This study sought to elucidate a novel predictor of disease severity in patients with coronavirus disease-19 (COVID-19) caused by SARS-CoV-2.

Methods

Patients enrolled in this study were all hospitalized with COVID-19 in the Central Hospital of Wuhan, China. Clinical features, chronic comorbidities, demographic data, and laboratory and radiological data were reviewed. The outcomes of patients with severe pneumonia and those with non-severe pneumonia were compared using the Statistical Package for the Social Sciences (IBM Corp., Armonk, NY, USA) to explore clinical characteristics and risk factors. The receiver operating characteristic curve was used to screen optimal predictors from the risk factors and the predictive power was verified by internal validation.

Results

A total of 377 patients diagnosed with COVID-19 were enrolled in this study, including 117 with severe pneumonia and 260 with non-severe pneumonia. The independent risk factors for severe pneumonia were age [odds ratio (OR): 1.059, 95% confidence interval (CI): 1.036–1.082; $p < 0.001$], N/L (OR: 1.322, 95% CI: 1.180–1.481; $p < 0.001$), CRP (OR: 1.231, 95% CI: 1.129–1.341; $p = 0.002$), and D-dimer (OR: 1.059, 95% CI: 1.013–1.107; $p = 0.011$). We identified a product of N/L*CRP*D-dimer as having an important predictive value for the severity of COVID-19. The cutoff value was 5.32. The negative predictive value of less than 5.32 for the N/L*CRP*D-dimer was 93.75%, while the positive predictive value was 46.03% in the test sets. The sensitivity and specificity were 89.47% and 67.42%. In the training sets, the negative and positive predictive values were 93.80% and 41.32%, respectively, with a specificity of 70.76% and a sensitivity of 89.87%.

Conclusions

A product of N/L*CRP*D-dimer may be an important predictor of disease severity in patients with COVID-19.

Anticoagulant treatment is associated with decreased mortality in severe coronavirus disease 2019 patients with coagulopathy

Ning Tang, Huan Bai, Xing Chen, Jiale Gong, Dengju Li, Ziyong Sun

– doi: 10.1111/JTH.14817 –

Abstract

Background

A relatively high mortality of severe coronavirus disease 2019 (COVID-19) is worrying, the application of heparin in COVID-19 has been recommended by some expert consensus due to the risk of disseminated intravascular coagulation and venous thromboembolism. However, its efficacy remains to be validated.

Methods

Coagulation results, medications and outcomes of consecutive patients being classified as severe COVID-19 in Tongji hospital were retrospectively analysed. The 28-day mortality between heparin users and nonusers were compared, also in different risk of coagulopaphy which was stratified by the sepsis-induced coagulopathy (SIC) score or D-dimer result.

Results

There were 449 patients with severe COVID-19 enrolled into the study, 99 of them received heparin (mainly with low molecular weight heparin, LMWH) for 7 days or longer. The D-dimer, prothrombin time and age were positively, and platelet count was negatively, correlated with 28-day mortality in multivariate analysis. No difference on 28-day mortality was found between heparin users and nonusers (30.3% vs 29.7%, P=0.910). But the 28-day mortality of heparin users were lower than nonusers In patients with SIC score ≥4 (40.0% vs 64.2%, P=0.029), or D-dimer > 6 fold of upper limit of normal (32.8% vs 52.4%, P=0.017).

Conclusions

Anticoagulant therapy mainly with LMWH appears to be associated with better prognosis in severe COVID-19 patients meeting SIC criteria or with markedly elevated D-dimer.

Thrombocytopenia is associated with severe coronavirus disease 2019 (COVID-19) infections: A meta-analysis

Giuseppe Lippi, Mario Plebani, Brandon Michael Henry

– Clinica Chimica Acta 506 (2020); 145–148 –

Abstract

Background

Coronavirus disease 2019 (COVID-19) is a novel infectious disease with lack of established laboratory markers available to evaluate illness severity. In this study, we investigate whether platelet count could differentiate between COVID-19 patients with or without severe disease. Additionally, we evaluate if thrombocytopenia is associated with severe COVID-19.

Methods

An electronic search in Medline, Scopus and Web of Science was performed to identify studies reporting data on platelet count in COVID-19 patients. A meta-analysis was performed, with calculation of weighted mean difference (WMD) of platelet number in COVID-19 patients with or without severe disease and odds ratio (OR) of thrombocytopenia for severe form of COVID-19.

Results

Nine studies with 1779 COVID-19 patients, 399 (22.4%) with severe disease, were included in the metaanalysis. The pooled analysis revealed that platelet count was significantly lower in patients with more severe COVID-19 (WMD −31 × 109/L; 95% CI, from −35 to −29 × 109/L). A subgroup analysis comparing patients by survival, found an even lower platelet count was observed with mortality (WMD, −48 × 109/L; 95% CI, −57 to −39 × 109/L. In the four studies (n = 1427) which reported data on rate of thrombocytopenia, a low platelet count was associated with over fivefold enhanced risk of severe COVID-19 (OR, 5.1; 95% CI, 1.8–14.6).

Conclusions

Low platelet count is associated with increased risk of severe disease and mortality in patients with COVID-19, and thus should serve as clinical indicator of worsening illness during hospitalization.

Prominent changes in blood coagulation of patients with SARS-CoV-2 infection

Huan Han, Lan Yang, Rui Liu, Fang Liu, Kai-lang Wu, Jie Li, Xing-hui Liu, Cheng-liang Zhu
– Clin Chem Lab Med 2020; https://doi.org/10.1515/cclm-2020-0188 –

Abstract

Background

As the number of patients increases, there is a growing understanding of the form of pneumonia sustained by the 2019 novel coronavirus (SARS-CoV-2), which has caused an outbreak in China. Up to now, clinical features and treatment of patients infected with SARS-CoV-2 have been reported in detail. However, the relationship between SARS-CoV-2 and coagulation has been scarcely addressed. Our aim is to investigate the blood coagulation function of patients with SARS-CoV-2 infection.

Methods

In our study, 94 patients with confirmed SARSCoV-2 infection were admitted in Renmin Hospital of Wuhan University. We prospectively collect blood coagulation data in these patients and in 40 healthy controls during the same period.

Results

Antithrombin values in patients were lower than that in the control group ($p < 0.001$). The values of D-dimer, fibrin/fibrinogen degradation products (FDP), and fibrinogen (FIB) in all SARS-CoV-2 cases were substantially higher than those in healthy controls. Moreover, D-dimer and FDP values in patients with severe SARS-CoV-2 infection were higher than those in patients with milder forms. Compared with healthy controls, prothrombin time activity (PT-act) was lower in SARS-CoV-2 patients. Thrombin time in critical SARS-CoV-2 patients was also shorter than that in controls.

Conclusions

The coagulation function in patients with SARS-CoV-2 is significantly deranged compared with healthy people, but monitoring D-dimer and FDP values may be helpful for the early identification of severe cases.

Risk Factors Associated With Acute Respiratory Distress Syndrome and Death in Patients With Coronavirus Disease 2019 Pneumonia in Wuhan, China

Chaomin Wu, Xiaoyan Chen, Yanping Cai et al.

– JAMA Intern Med. Published online March 13, 2020. doi:10.1001/jamainternmed.2020.0994 –

Abstract

Background

Coronavirus disease 2019 (COVID-19) is an emerging infectious disease that was first reported in Wuhan, China, and has subsequently spread worldwide. Risk factors for the clinical outcomes of COVID-19 pneumonia have not yet been well delineated.

Methods

Retrospective cohort study of 201 patients with confirmed COVID-19 pneumonia admitted to Wuhan Jinyintan Hospital in China between December 25, 2019, and January 26, 2020. The final date of follow-up was February 13, 2020.

Results

Of 201 patients, the median age was 51 years (interquartile range, 43-60 years), and 128 (63.7%) patients were men. Eighty-four patients (41.8%) developed ARDS, and of those 84 patients, 44 (52.4%) died. In those who developed ARDS, compared with those who did not, more patients presented with dyspnea (50 of 84 [59.5%] patients and 30 of 117 [25.6%] patients, respectively [difference, 33.9%; 95% CI, 19.7%-48.1%]) and had comorbidities such as hypertension (23 of 84 [27.4%] patients and 16 of 117 [13.7%] patients, respectively [difference, 13.7%; 95% CI, 1.3%-26.1%]) and diabetes (16 of 84 [19.0%] patients and 6 of 117 [5.1%] patients, respectively [difference, 13.9%; 95% CI, 3.6%-24.2%]). In bivariate Cox regression analysis, risk factors associated with the development of ARDS and progression from ARDS to death included older age (hazard ratio [HR], 3.26; 95% CI 2.08-5.11; and HR, 6.17; 95% CI, 3.26-11.67, respectively), neutrophilia (HR, 1.14; 95% CI, 1.09-1.19; and HR, 1.08; 95% CI, 1.01-1.17, respectively), and organ and coagulation dysfunction (eg, higher lactate dehydrogenase [HR, 1.61; 95% CI, 1.44-1.79; and HR, 1.30; 95% CI, 1.11-1.52, respectively] and D-dimer [HR, 1.03; 95% CI, 1.01-1.04; and HR, 1.02; 95% CI, 1.01-1.04, respectively]). High fever (≥39 °C) was associated with higher likelihood of ARDS development (HR, 1.77; 95% CI, 1.11-2.84) and lower likelihood of death (HR, 0.41; 95% CI, 0.21-0.82). Among patients with ARDS, treatment with methylprednisolone decreased the risk of death (HR, 0.38; 95% CI, 0.20-0.72).

Conclusions

Older age was associated with greater risk of development of ARDS and death likely owing to less rigorous immune response. Although high fever was associated with the development of ARDS, it was also associated with better outcomes among patients with ARDS. Moreover, treatment with methylprednisolone may be beneficial for patients who develop ARDS.

Clinical features and treatment of COVID-19 patients in northeast Chongqing

Suxin Wan, Yi Xiang, Wei Fang, Yu Zheng, Boqun Li, Yanjun Hu, Chunhui Lang, Daoqiu Huang, Qiuyan Sun, Yan Xiong, Xia Huang, Jinglong Lv, Yaling Luo, Li Shen, Haoran Yang, Gu Huang, Ruishan Yang

– J Med Virol. 2020;1–10 –

Abstract

The outbreak of the novel coronavirus in China (SARS-CoV-2) that began in December 2019 presents a significant and urgent threat to global health. This study was conducted to provide the international community with a deeper understanding of this new infectious disease. Epidemiological, clinical features, laboratory findings, radiological characteristics, treatment, and clinical outcomes of 135 patients in northeast Chongqing were collected and analyzed in this study. A total of 135 hospitalized patients with COVID-19 were enrolled. The median age was 47 years (interquartile range, 36-55), and there was no significant gender difference (53.3% men). The majority of patients had contact with people from the Wuhan area. Forty-three (31.9%) patients had underlying disease, primarily hypertension (13 [9.6%]), diabetes (12 [8.9%]), cardiovascular disease (7 [5.2%]), and malignancy (4 [3.0%]). Common symptoms included fever (120 [88.9%]), cough (102 [76.5%]), and fatigue (44 [32.5%]). Chest computed tomography scans showed bilateral patchy shadows or ground glass opacity in the lungs of all the patients. All patients received antiviral therapy (135 [100%]) (Kaletra and interferon were both used), antibacterial therapy (59 [43.7%]), and corticosteroids (36 [26.7%]). In addition, many patients received traditional Chinese medicine (TCM) (124 [91.8%]). It is suggested that patients should receive Kaletra early and should be treated by a combination of Western and Chinese medicines. Compared to the mild cases, the severe ones had lower lymphocyte counts and higher plasma levels of Pt, APTT, d-dimer, lactate dehydrogenase, PCT, ALB, C-reactive protein, and aspartate aminotransferase. This study demonstrates the clinic features and therapies of 135 COVID-19 patients. Kaletra and TCM played an important role in the treatment of the viral pneumonia. Further studies are required to explore the role of Kaletra and TCM in the treatment of COVID-19.

Diagnostic utility of clinical laboratory data determinations for patients with the severe COVID-19

Yong Gao, Tuantuan Li, Mingfeng Han, Xiuyong Li, Dong Wu, Yuanhong Xu, Yulin Zhu, Yan Liu, Xiaowu Wang, Linding Wang

– J Med Virol. 2020;1–6. –

Abstract

Background

The role of clinical laboratory data in the differential diagnosis of the severe forms of COVID-19 has not been definitely established. The aim of this study was to look for the warning index in severe COVID-19 patients. We investigated 43 adult patients with COVID-19. The patients were classified into mild group (28 patients) and severe group (15 patients). A comparison of the hematological parameters between the mild and severe groups showed significant differences in interleukin-6 (IL-6), d-dimer (d-D), glucose, thrombin time, fibrinogen, and C-reactive protein ($P < .05$). The optimal threshold and area under the receiver operator characteristic curve (ROC) of IL-6 were 24.3 and 0.795 μg/L, respectively, while those of d-D were 0.28 and 0.750 μg/L, respectively. The area under the ROC curve of IL-6 combined with d-D was 0.840. The specificity of predicting the severity of COVID-19 during IL-6 and d-D tandem testing was up to 93.3%, while the sensitivity of IL-6 and d-D by parallel test in the severe COVID-19 was 96.4%. IL-6 and d-D were closely related to the occurrence of severe COVID-19 in the adult patients, and their combined detection had the highest specificity and sensitivity for early prediction of the severity of COVID-19 patients, which has important clinical value.

COVID-19 and laboratory diagnostics

Antibody Tests in Detecting SARS-CoV-2 Infection: A Meta-Analysis

Panagiota I. Kontou, Georgia G. Braliou, Niki L. Dimou, Georgios Nikolopoulos, Pantelis G. Bagos
– Diagnostics 2020, 10, 319; doi:10.3390/diagnostics10050319 –

Abstract

The emergence of Coronavirus disease 2019 (COVID-19) caused by SARS-CoV-2 made imperative the need for diagnostic tests that can identify the infection. Although Nucleic Acid Test (NAT) is considered to be the gold standard, serological tests based on antibodies could be very helpful. However, individual studies are usually inconclusive, thus, a comparison of dierent tests is needed. We performed a systematic review and meta-analysis in PubMed, medRxiv and bioRxiv. We used the bivariate method for meta-analysis of diagnostic tests pooling sensitivities and specificities. We evaluated IgM and IgG tests based on Enzyme-linked immunosorbent assay (ELISA), Chemiluminescence Enzyme Immunoassays (CLIA), Fluorescence Immunoassays (FIA), and the Lateral Flow Immunoassays (LFIA). We identified 38 studies containing data from 7848 individuals. Tests using the S antigen are more sensitive than N antigen-based tests. IgG tests perform better compared to IgM ones and show better sensitivity when the samples were taken longer after the onset of symptoms. Moreover, a combined IgG/IgM test seems to be a better choice in terms of sensitivity than measuring either antibody alone. All methods yield high specificity with some of them (ELISA and LFIA) reaching levels around 99%. ELISA- and CLIA-based methods perform better in terms of sensitivity (90%–94%) followed by LFIA and FIA with sensitivities ranging from 80% to 89%. ELISA tests could be a safer choice at this stage of the pandemic. LFIA tests are more attractive for large seroprevalence studies but show lower sensitivity, and this should be taken into account when designing and performing seroprevalence studies.

Assay Techniques and Test Development for COVID-19 Diagnosis

Linda J. Carter, Linda V. Garner, Jeffrey W. Smoot, Yingzhu Li, Qiongqiong Zhou, Catherine J. Saveson, Janet M. Sasso, Anne C. Gregg, Divya J. Soares, Tiffany R. Beskid, Susan R. Jervey, Cynthia Liu
– ACS Cent. Sci. 2020, 6, 591−605 –

Abstract

An ongoing theme of the COVID-19 pandemic is the need for widespread availability of accurate and efficient diagnostic testing for detection of SARS-CoV-2 and antiviral antibodies in infected individuals. This report describes various assay techniques and tests for COVID-19 diagnosis. Most tests for early detection of SARS-CoV-2 RNA rely on the reverse transcription-polymerase chain reaction, but isothermal nucleic acid amplification assays, including transcription-mediated amplification and CRISPR-based methodologies, are promising alternatives. Identification of individuals who have developed antibodies to the SARS-CoV-2 virus requires serological tests, including enzyme-linked immunosorbent assay (ELISA) and lateral flow immunoassay. This report also provides an overview of current development in COVID-19 diagnostic techniques and products to facilitate future improvement and innovation.

Towards the next phase: evaluation of serological assays for diagnostics and exposure assessment

Corine H. GeurtsvanKessel, Nisreen M.A. Okba, Zsofia Igloi, Carmen W.E. Embregts, Brigitta M. Laksono, Lonneke Leijten, Janette Rahamat-Langendoen, Johannes P.C. van den Akker, Jeroen J.A. van Kampen, Annemiek A. van der Eijk, Rob S. van Binnendijk, Bart Haagmans, Marion Koopmans
– medRxiv; https://doi.org/10.1101/2020.04.23.20077156 –

Abstract

The world is entering a new era of the COVID-19 pandemic in which there is an increasing call for reliable antibody testing. To support decision making on the deployment of serology for either population screening or diagnostics, we present a comprehensive comparison of serological COVID-19 assays. We show that the assay detecting total immunoglobulins against the receptor binding domain of SARS CoV-2, had optimal characteristics for antibody detection in different stages of disease.

Evaluation of nine commercial SARS-CoV-2 immunoassays

Ria Lassaunière, Anders Frische, Zitta B. Harboe, Alex C.Y. Nielsen, Anders Fomsgaard, Karen A. Krogfelt, Charlotte S. Jørgensen
– medRxiv; https://doi.org/10.1101/2020.04.09.20056325 –

Abstract

Due to urgency and demand, numerous severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) immunoassays are rapidly being developed and placed on the market with limited validation on clinical samples. Thorough validation of serological tests are required to facilitate their use in the accurate diagnosis of SARS-CoV-2 infection, confirmation of molecular results, contact tracing, and epidemiological studies. This study evaluated the sensitivity and specificity of nine commercially available serological tests. These included three enzyme-linked immunosorbent assays (ELISAs) and six point-of-care (POC) lateral flow tests. The assays were validated using serum samples from: i) SARS-CoV-2 PCR-positive patients with a documented first day of disease; ii) archived sera obtained from healthy individuals before the emergence of SARS-CoV-2 in China; iii) sera from patients with acute viral respiratory tract infections caused by other coronaviruses or non-coronaviruses; and iv) sera from patients positive for dengue virus, cytomegalovirus and Epstein Barr virus. The results showed 100% specificity for the Wantai SARS-CoV-2 Total Antibody ELISA, 93% for the Euroimmun IgA ELISA, and 96% for the Euroimmun IgG ELISA with sensitivities of 90%, 90%, and 65%, respectively. The overall performance of the POC tests according to manufacturer were in the rank order of AutoBio Diagnostics > Dynamiker Biotechnology = CTK Biotech > Artron Laboratories > Acro Biotech ≥ Hangzhou Alltest Biotech. Overall, these findings will facilitate selection of serological assays for the detection SARS-CoV-2-specific antibodies towards diagnosis as well as sero-epidemiological and vaccine development studies.

Kinetics of the humoral immune response to SARS-CoV-2: comparative analytical performance of seven commercial serology tests

Pauline H. Herroelen, Geert A. Martens, Dieter De Smet, Koen Swaerts, An-Sofie Decavele
– medRxiv; https://doi.org/10.1101/2020.06.09.20124719 –

Abstract

Background

SARS-CoV-2 serology tests are clinically useful to document a prior SARS-CoV-2 infection in patients with no or inconclusive PCR results and suspected COVID-19 disease or sequelae. Data are urgently needed to select the assays with optimal sensitivity at acceptable specificity.

Methods

A comparative analysis of analytical sensitivity was performed of seven commercial SARS-CoV-2 serology assays on 171 sera from 135 subjects with PCR-confirmed SARS-CoV-2 infection, composed of 71 patients hospitalized for COVID-19 pneumonia and 64 healthcare workers with paucisymptomatic infections. The kinetics of IgA/IgM/IgG seroconversion to viral N- and S-protein epitopes were studied from 0 to 54 days after symptom onset. Specificity was verified on 57 pre-pandemic samples.

Results

Wantai SARS-COV-2 Ab ELISA and Orient Gene COVID-19 IgG/IgM Rapid Test achieved a superior overall sensitivity. Elecsys Anti-SARS-CoV-2 and EUROIMMUN Anti-SARS-CoV-2 combined IgA/IgG also showed acceptable sensitivity (>95%) versus the consensus result of all assays from 10 days post symptom onset. Optimal specificity (>98%) was achieved only by Wantai SARS-COV-2 Ab ELISA, Elecsys Anti-SARS-CoV-2 assay and Innovita 2019-nCoV Ab rapid test. LIAISON SARS-CoV-2 S1/S2 IgG showed a significantly lower sensitivity as compared to all other assays. Lack of seroconversion by any test was seen in 1.4% of hospitalized and 4.7% of paucisymptomatic infections. Within 10 days from symptom onset, only the Wantai SARS-COV-2 Ab ELISA showed acceptable sensitivity.

Conclusions

Wantai SARS-COV-2 Ab ELISA and Elecsys Anti-SARS-CoV-2 assays are suitable for sensitive and specific screening of a SARS-CoV-2 infection from 10 days after symptom onset.

Diagnostic performances and thresholds: the key to harmonization in serological SARS-CoV-2 assays?

Mario Plebani, Andrea Padoan, Davide Negrini, Benedetta Carpinteri, Laura Sciacovelli
– medRxiv; https://doi.org/10.1101/2020.05.22.20106328–

Abstract

Background

The evaluation of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) specific antibody (Ab) assay performances is of the utmost importance in establishing and monitoring virus spread in the community. In this study focusing on IgG antibodies, we compare reliability of three chemiluminescent (CLIA) and two enzyme linked immunosorbent (ELISA) assays.

Methods

Sera from a total of 271 subjects, including 64 reverse transcription-polymerase chain reaction (RT-PCR) confirmed SARS-CoV-2 patients were tested for specific Ab using Maglumi (Snibe), Liaison (Diasorin), iFlash (Yhlo), Euroimmun (Medizinische Labordiagnostika AG) and Wantai (Wantai Biological Pharmacy) assays. Diagnostic sensitivity and specificity, positive and negative likelihood ratios were evaluated using manufacturers' and optimized thresholds.

Results

Optimized thresholds (Maglumi 2 kAU/L, Liaison 6.2 kAU/L and iFlash 15.0 kAU/L) allowed us to achieve a negative likelihood ratio and an accuracy of: 0.06 and 93.5% for Maglumi; 0.03 and 93.1% for Liaison; 0.03 and 91% for iFlash. Diagnostic sensitivities and specificities were above 93.8% and 85.9%, respectively for all CLIA assays. Overall agreement was 90.3% (Cohen's kappa = 0.805 and SE = 0.041) for CLIA, and 98.4% (Cohen's kappa = 0.962 and SE = 0.126) for ELISA.

Conclusions

The results obtained indicate that, for CLIA assays, it might be possible to define thresholds that improve the negative likelihood ratio. Thus, a negative test result enables the identification of subjects at risk of being infected, who should then be closely monitored over time with a view to preventing further viral spread. Redefined thresholds, in addition, improved the overall inter-assay agreement, paving the way to a better harmonization of serologic tests.

Viral Kinetics and Antibody Responses in Patients with COVID-19

Wenting Tan, Yanqiu Lu, Juan Zhang, Jing Wang, Yunjie Dan, Zhaoxia Tan, Xiaoqing He, Chunfang Qian, Qiangzhong Sun, Qingli Hu, Honglan Liu, Sikuan Ye, Xiaomei Xiang, Yi Zhou, Wei Zhang, Yanzhi Guo, Xiu-Hua Wang, Weiwei He, Xing Wan, Fengming Sun, Quanfang Wei, Cong Chen, Guangqiang Pan, Jie Xia, Qing Mao, Yaokai Chen, Guohong Deng

– medRxiv; https://doi.org/10.1101/2020.03.24.20042382 –

Abstract

Background

A pandemic of coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) has been spreading over the world. However, the viral dynamics, host serologic responses, and their associations with clinical manifestations, have not been well described in prospective cohort.

Methods

We conducted a prospective cohort and enrolled 67 COVID-19 patients admitting between Jan 26 and Feb 5, 2020. Clinical specimens including nasopharyngeal swab, sputum, blood, urine and stool were tested periodically according to standardized case report form with final follow-up on February 27. The routes and duration of viral shedding, antibody response, and their associations with disease severity and clinical manifestations were systematically evaluated. Coronaviral particles in clinical specimens were observed by transmission electron microscopy (TEM).

Results

The median duration of SARS-CoV-2 RNA shedding were 12 (3-38), 19 (5-37), and 18 (7-26) days in nasopharyngeal swabs, sputum and stools, respectively. Only 13 urines (5.6%) and 12 plasmas (5.7%) were viral positive. Prolonged viral shedding was observed in severe patients than that of non-severe patients. Cough but not fever, aligned with viral shedding in clinical respiratory specimens, meanwhile the positive stool-RNA appeared to align with the proportion who concurrently had cough and sputum production, but not diarrhea. Typical coronaviral particles could be found directly in sputum by TEM. The anti-nucleocapsid-protein IgM started on day 7 and positive rate peaked on day 28, while that of IgG was on day 10 and day 49 after illness onset. IgM and IgG appear earlier, and their titers are significantly higher in severe patients than non-severe patients ($p<0.05$). The weak responders for IgG had a significantly higher viral clearance rate than that of strong responders ($p= 0.011$)

Conclusions

Nasopharyngeal, sputum and stools rather than blood and urine, were the major shedding routes for SARS-CoV-2, and meanwhile sputum had a prolonged viral shedding. Symptom cough seems to be aligned with viral shedding in clinical respiratory and fecal specimens. Stronger antibody response was associated with delayed viral clearance and disease severity.

Performance of SARS-CoV-2 antibody assays in different stages of the infection: Comparison of commercial ELISA and rapid tests

Traugott M., Aberle SW., Aberle JH., Griebler H., Karolyi M., Pawelka E., Puchhammer-Stöckl E., Zoufaly A., Weseslindtner L.

– The Journal of Infectious Diseases, jiaa305, https://doi.org/10.1093/infdis/jiaa305 –

Abstract

We comparatively assessed sensitivities and specificities of 4 commercial enzyme-linked immunosorbent assays (ELISAs) and 2 rapid tests in 77 patients with polymerase chain reaction–confirmed severe acute respiratory syndrome coronavirus 2 infection, grouped by interval since symptom onset. Although test sensitivities were low (<40%) within the first 5 days after disease onset, immunoglobulin (Ig) M, IgA, and total antibody ELISAs increased in sensitivity to >80% between days 6 and 10 after symptom onset. The evaluated tests (including IgG and rapid tests) provided positive results in all patients at or after the 11th day after onset of disease. The specificities of the ELISAs were 83% (IgA), 98% (IgG), and 97% (IgM and total antibody).

Herd immunity is not a realistic exit strategy during a COVID-19 outbreak

Ed Slot, Boris M. Hogema, Chantal B.E.M. Reusken, Johan H. Reimerink, Michel Molier, Jan H.M. Karregat, Johan IJlst, Věra M.J. Novotný, René A.W. van Lier, Hans L. Zaaijer

– doi: 10.21203/rs.3.rs-25862/v1–

Abstract

The world is combating an ongoing COVID-19 pandemic1-4. Health-care systems, society and the economy are impacted in an unprecedented way. It is unclear how many people have contracted the causative coronavirus (SARS-CoV-2) unknowingly. Therefore, reported COVID-19 cases do not reflect the true scale of outbreak5-9. Natural herd immunity has been suggested as a potential exit strategy during COVID-19 outbreaks, which may arise when 50-67% of a community has been infected10. Here we present the prevalence and distribution of antibodies to SARS-CoV-2 in a healthy adult population of a highly affected country using a novel immunoassay, indicating that one month into the outbreak (i) the seroprevalence in the Netherlands is 2.7% with substantial regional variation, (ii) the hardest-hit areas show a seroprevalence of up to 9.5%, (iii) the seroprevalence is sex-independent throughout age groups (18-72 years), (iv) antibodies are significantly more often detected in younger people (18-30 years), and (v) the number of immune individuals in the current epidemic stage is far below the herd immunity threshold. This study provides vital information on the extent of virus spread in a country where social distancing is in place, concluding that herd immunity to SARS-CoV-2 is not a realistic short-term exit strategy option.

Comparison of diagnostic accuracies of rapid serological tests and ELISA to molecular diagnostics in patients with suspected coronavirus disease 2019 presenting to the hospital

D.S.Y. Ong, S.J. de Man, F.A. Lindeboom, J.G.M. Koeleman

– Clinical Microbiology and Infection; https://doi.org/10.1016/j.cmi.2020.05.028 –

Abstract

Background

To assess the diagnostic performance of rapid lateral flow immunochromatographic assays (LFAs) compared with an ELISA and nucleic acid amplification tests (NATs) in individuals with suspected coronavirus disease 2019 (COVID-19).

Methods

Patients presenting to a Dutch teaching hospital were eligible between 17 March and 10 April 2020, when they had respiratory symptoms that were suspected for COVID-19. The performances of six different LFAs were evaluated in plasma samples obtained on corresponding respiratory sample dates of NATs testing. Subsequently, the best performing LFA was evaluated in 228 patients and in 50 sera of a historical patient control group.

Results

In the pilot analysis, sensitivity characteristics of LFA were heterogeneous, ranging from 2/20 (10%; 95% CI 0%–23%) to 11/20 (55%; 95% CI 33%–77%). In the total cohort, Orient Gene Biotech COVID-19 IgG/IgM Rapid Test LFA had a sensitivity of 43/99 (43%; 95% CI 34%–53%) and specificity of 126/129 (98%; 95% CI 95%–100%). Sensitivity increased to 31/52 (60%; 95% CI 46%–73%) in patients with at least 7 days of symptoms, and to 21/33 (64%; 95% CI 47%–80%) in patients with C-reactive protein (CRP) ≥100 mg/L. Sensitivity and specificity of Wantai SARS-CoV-2 Ab ELISA was 59/95 (62%; 95% CI 52%–72%) and 125/128 (98%; 95% CI 95%–100%) in all patients, respectively, but sensitivity increased to 38/48 (79%; 95% CI 68%–91%) in patients with at least 7 days of symptoms.

Conclusions

There is large variability in diagnostic test performance between rapid LFAs, but overall limited sensitivity and high specificity in acutely admitted patients. Sensitivity improved in patients with longer existing symptoms or high CRP. LFAs should only be considered as additional triage tools when these may lead to the improvement of hospital logistics.

Diagnostic value and dynamic variance of serum antibody in coronavirus disease 2019

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– *International Journal of Infectious Diseases 94 (2020) 49–52; https://doi.org/10.1016/j.ijid.2020.03.065–*

Abstract

Background

To investigate the diagnostic value of serological testing and dynamic variance of serum antibody in coronavirus disease 2019 (COVID-19).

Methods

This study retrospectively included 43 patients with a laboratory-confirmed infection and 33 patients with a suspected infection, in whom the disease was eventually excluded. The IgM/IgG titer of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) was measured by chemiluminescence immunoassay analysis.

Results

Compared to molecular detection, the sensitivities of serum IgM and IgG antibodies to diagnose COVID-19 were 48.1% and 88.9%, and the specificities were 100% and 90.9%, respectively.In the COVID-19 group, the IgM-positive rate increased slightly at first and then decreased over time; in contrast, the IgG-positive rate increased to 100% and was higher than IgM at all times. The IgM-positive rate and titer were not significantly different before and after conversion to virus-negative. The IgG-positive rate was up to 90% and not significantly different before and after conversion to virus-negative. However, the median IgG titer after conversion to virus-negative was double that before, and the difference was significant.

Conclusions

Viral serological testing is an effective means of diagnosis for SARS-CoV-2 infection. The positive rate and titer variance of IgG are higher than those of IgM in COVID-19.

Antibody responses to SARS-CoV-2 in patients of novel coronavirus disease 2019

Juanjuan Zhao, Quan Yuan, Haiyan Wang, Wei Liu, Xuejiao Liao, Yingying Su, Xin Wang, Jing Yuan, Tingdong Li, Jinxiu Li, Shen Qian, Congming Hong, Fuxiang Wang, Yingxia Liu, Zhaoqin Wang, Qing He, Zhiyong Li, Bin He, Tianying Zhang, Shengxiang Ge, Lei Liu, Jun Zhang, Ningshao Xia, Zheng Zhang

– *medRxiv; https://doi.org/10.1101/2020.03.02.20030189* –

Abstract

Background

The novel coronavirus SARS-CoV-2 is a newly emerging virus. The antibody response in infected patient remains largely unknown, and the clinical values of antibody testing have not been fully demonstrated.

Methods

A total of 173 patients with confirmed SARS-CoV-2 infection were enrolled. Their serial plasma samples (n = 535) collected during the hospitalization period were tested for total antibodies (Ab), IgM and IgG against SARS-CoV-2 using immunoassays. The dynamics of antibodies with the progress and severity of disease was analyzed.

Results

Among 173 patients, the seroconversion rate for Ab, IgM and IgG was 93.1% (161/173), 82.7% (143/173) and 64.7% (112/173), respectively. Twelve patients who had not seroconverted were those only blood samples at the early stage of illness were collected. The seroconversion sequentially appeared for Ab, IgM and then IgG, with a median time of 11, 12 and 14 days, respectively. The presence of antibodies was < 40% among patients in the first 7 days of illness, and then rapidly increased to 100.0%, 94.3% and 79.8% for Ab, IgM and IgG respectively since day 15 after onset. In contrast, the positive rate of RNA decreased from 66.7% (58/87) in samples collected before day 7 to 45.5% (25/55) during days 15 to 39. Combining RNA and antibody detections significantly improved the sensitivity of pathogenic diagnosis for COVID-19 patients ($p < 0.001$), even in early phase of 1-week since onset ($p = 0.007$). Moreover, a higher titer of Ab was independently associated with a worse clinical classification ($p = 0.006$).

Conclusions

The antibody detection offers vital clinical information during the course of SARS-CoV2 infection. The findings provide strong empirical support for the routine application of serological testing in the diagnosis and management of COVID-19 patients.

A serological assay to detect SARS-CoV-2 seroconversion in humans

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– medRxiv; https://doi.org/10.1101/2020.03.17.20037713–

Abstract

Introduction

SARS-Cov-2 (severe acute respiratory disease coronavirus 2), which causes Coronavirus Disease 2019 (COVID19) was first detected in China in late 2019 and has since then caused a global pandemic. While molecular assays to directly detect the viral genetic material are available for the diagnosis of acute infection, we currently lack serological assays suitable to specifically detect SARS-CoV-2 antibodies.

Methods

Here we describe serological enzyme-linked immunosorbent assays (ELISA) that we developed using recombinant antigens derived from the spike protein of SARS-CoV-2. These assays were developed with negative control samples representing pre-COVID 19 background immunity in the general population and samples from COVID19 patients.

Results

The assays are sensitive and specific, allowing for screening and identification of COVID19 seroconverters using human plasma/serum as early as 3 days post symptom onset. Importantly, these assays do not require handling of infectious virus, can be adjusted to detect different antibody types and are amendable to scaling.

Conclusions

Serological assays are of critical importance to determine seroprevalence in a given population, define previous exposure and identify highly reactive human donors for the generation of convalescent serum as therapeutic. Sensitive and specific identification of coronavirus SARS-Cov-2 antibody titers will also support screening of health care workers to identify those who are already immune and can be deployed to care for infected patients minimizing the risk of viral spread to colleagues and other patients.

Antibody responses to SARS-CoV-2 in patients with COVID-19

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– Nat Med 26, 845–848 (2020). https://doi.org/10.1038/s41591-020-0897-1 –

Abstract

We report acute antibody responses to SARS-CoV-2 in 285 patients with COVID-19. Within 19 days after symptom onset, 100% of patients tested positive for antiviral immunoglobulin-G (IgG). Seroconversion for IgG and IgM occurred simultaneously or sequentially. Both IgG and IgM titers plateaued within 6 days after seroconversion. Serological testing may be helpful for the diagnosis of suspected patients with negative RT–PCR results and for the identification of asymptomatic infections.

Interpreting Diagnostic Tests for SARS-CoV-2

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– JAMA. 2020;323(22):2249-2251. doi:10.1001/jama.2020.8259 –

Abstract

The pandemic of coronavirus disease 2019 (COVID-19) continues to affect much of the world. Knowledge of diagnostic tests for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) is still evolving, and a clear understanding of the nature of the tests and interpretation of their findings is important. This Viewpoint describes how to interpret 2 types of diagnostic tests commonly in use for SARS-CoV-2 infections—reverse transcriptase–polymerase chain reaction (RT-PCR) and IgM and IgG enzyme-linked immunosorbent assay (ELISA)—and how the results may vary over time.

CT Features of Coronavirus Disease 2019 (COVID-19) Pneumonia in 62 Patients in Wuhan, China

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– AJR Am J Roentgenol. 2020 Mar 05 –

Abstract

Background

The purpose of this study was to investigate 62 subjects in Wuhan, China, with laboratory-confirmed coronavirus disease (COVID-19) pneumonia and describe the CT features of this epidemic disease.

Methods

A retrospective study of 62 consecutive patients with laboratory-confirmed COVID-19 pneumonia was performed. CT images and clinical data were reviewed. Two thoracic radiologists evaluated the distribution and CT signs of the lesions and also scored the extent of involvement of the CT signs. The Mann-Whitney U test was used to compare lesion distribution and CT scores. The chi-square test was used to compare the CT signs of early-phase versus advanced-phase COVID-19 pneumonia.

Results

A total of 62 patients (39 men and 23 women; mean [± SD] age, 52.8 ± 12.2 years; range, 30–77 years) with COVID-19 pneumonia were evaluated. Twenty-four of 30 patients who underwent routine blood tests (80.0%) had a decreased lymphocyte count. Of 27 patients who had their erythrocyte sedimentation rate and high-sensitivity C-reactive protein level assessed, 18 (66.7%) had an increased erythrocyte sedimentation rate, and all 27 (100.0%) had an elevated high-sensitivity C-reactive protein level. Multiple lesions were seen on the initial CT scan of 52 of 62 patients (83.9%). Forty-eight of 62 patients (77.4%) had predominantly peripheral distribution of lesions. The mean CT score for the upper zone (3.0 ± 3.4) was significantly lower than that for the middle (4.5 ± 3.8) and lower (4.5 ± 3.7) zones ($p = 0.022$ and $p = 0.020$, respectively), and there was no significant difference in the mean CT score of the middle and lower zones ($p = 1.00$). The mean CT score for the anterior area (4.4 ± 4.1) was significantly lower than that for the posterior area (7.7 ± 6.3) ($p = 0.003$). CT findings for the patients were as follows: 25 patients (40.3%) had ground-glass opacities (GGO), 21 (33.9%), consolidation; 39 (62.9%), GGO plus a reticular pattern; 34 (54.8%), vacuolar sign; 28 (45.2%), microvascular dilation sign; 35 (56.5%), fibrotic streaks; 21 (33.9%), a subpleural line; and 33 (53.2%), a subpleural transparent line. With regard to bronchial changes seen on CT, 45 patients (72.6%) had air bronchogram, and 11 (17.7%) had bronchus distortion. In terms of pleural changes, CT showed that 30 patients (48.4%) had pleural thickening, 35 (56.5%) had pleural retraction sign, and six (9.7%) had pleural effusion. Compared with early-phase disease (≤ 7 days after the onset of symptoms), advanced-phase disease (8–14 days after the onset of symptoms) was characterized by significantly increased frequencies of GGO plus a reticular pattern, vacuolar sign, fibrotic streaks, a subpleural line, a subpleural transparent line, air bronchogram, bronchus distortion, and pleural effusion; however, GGO significantly decreased in advanced-phase disease.

Conclusions

CT examination of patients with COVID-19 pneumonia showed a mixed and diverse pattern with both lung parenchyma and the interstitium involved. Identification of GGO and a single lesion on the initial CT scan suggested early-phase disease. CT signs of aggravation and repair coexisted in advanced-

phase disease. Lesions presented with a characteristic multifocal distribution in the middle and lower lung regions and in the posterior lung area. A decreased lymphocyte count and an increased high-sensitivity C-reactive protein level were the most common laboratory findings.

Molecular immune pathogenesis and diagnosis of COVID-19

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– Journal of Pharmaceutical Analysis, https:// doi.org/10.1016/j.jpha.2020.03.001 –

Abstract

Coronavirus disease 2019 (COVID-19) is a kind of viral pneumonia with an unusual outbreak in Wuhan, China, in December 2019, which is caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). The emergence of SARS-CoV-2 has been marked as the third introduction of a highly pathogenic coronavirus into the human population after the severe acute respiratory syndrome coronavirus (SARS-CoV) and the Middle East respiratory syndrome coronavirus (MERS-CoV) in the twenty-first century. In this minireview, we provide a brief introduction of the general features of SARS-CoV-2 and discuss current knowledge of molecular immune pathogenesis, diagnosis and treatment of COVID-19 on the base of the present understanding of SARS-CoV and MERS-CoV infections, which may be helpful in offering novel insights and potential therapeutic targets for combating the SARS-CoV-2 infection.

COVID-19 and Postinfection Immunity

Robert D. Kirkcaldy, Brian A. King, John T. Brooks
– JAMA. 2020;323(22):2245-2246. doi:10.1001/jama.2020.7869 –

Abstract

In the absence of effective treatment or biomedical prevention, efforts to control the coronavirus disease 2019 (COVID-19) pandemic have relied on nonpharmaceutical interventions such as personal preventive actions (eg, handwashing, face covers), environmental cleaning, physical distancing, stay-at-home orders, school and venue closures, and workplace restrictions adopted at the national, state, and local levels. In addition to these public health interventions, development of herd immunity could also provide a defense against COVID-19. However, whether immunity occurs among individuals after they have recovered from COVID-19 is uncertain. Many human infections with other viral pathogens, such as influenza virus, do not produce a durable immune response.

Differences in antibody kinetics and functionality between severe and mild SARS-CoV-2 infections

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– medRxiv; https://doi.org/10.1101/2020.06.09.20122036 –

Abstract

We determined and compared the humoral immune response in severe, hospitalized and mild, non-hospitalized COVID-19 patients. Severe patients (n=38) develop a robust antibody response to SARS-CoV-2, including IgG and IgA antibodies. The geometric mean 50% virus neutralization titer is 1:240. SARS-CoV-2 infected hospital personnel (n=24), who developed mild symptoms necessitating leave of absence, self-isolation, but not hospitalization, 75 % develop antibodies, but with low/absent virus neutralization (60% < 1:20). While severe COVID-19 patients develop a strong antibody response, mild SARS-CoV-2 infections induce a modest antibody response. Long term monitoring will show whether these responses predict protection against future infections.

What policy makers need to know about COVID-19 protective immunity

Daniel M Altmann, Daniel C Douek, Rosemary J Boyton

– The Lancet; jiaa305, https://doi.org/10.1016/S0140-6736(20)30985-5 –

Abstract

About a third of the world is under lockdown as a public health measure to curb the spread of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), the virus that causes coronavirus disease 2019 (COVID-19). Policy makers are increasingly pressed to articulate their rationales and strategies for moving out of lockdown; the process of re-emergence is already cautiously starting in Austria, Switzerland, Denmark, Wuhan, and some US states. As the counterpoise between further disease spread and socioeconomic costs is debated, it is essential that policy makers in all affected countries have the best possible data and understanding to inform any course of action.

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