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Rationale and Design of a Registry in a Referral and Educational Medical Center in Tehran, Iran: Sina Hospital Covid-19 Registry (SHCo-19R)

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Abstract

Coronavirus disease 2019 (Covid-19) is caused by the novel coronavirus resulting in a highly contagious respiratory tract infection with an increased risk of acute respiratory distress syndrome (ARDS), which was first seen in Wuhan, China. Thus far, this virus has spread to many countries worldwide, including Iran. Multiple studies have assessed disease characteristics, viral genetics, and complications of Covid-19 in the Chinese population. However, there is limited data regarding patient characteristics and outcomes of infected cases outside of China. Besides, risk factors of adverse outcomes are poorly identified in different populations. Due to limited data in the Iranian population affected by the virus, we aimed to design a registry of patients with Covid-19 at Sina Hospital in Tehran, Iran [Sina Hospital Covid-19 Registry (SHCo-19R)] in this regard, to assess patient characteristics, imaging features, laboratory findings, management strategies, and adverse outcomes of Iranian patients with Covid-19 and their differences with other populations.

Key words: Covid-19; Iran; Registries; Severe Acute Respiratory Syndrome Coronavirus 2

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Introduction

In December 2019, several cases of pneumonia of unknown cause with subsequent acute respiratory distress syndrome (ARDS) first emerged in Wuhan, China [(1)]. A novel coronavirus was then identified to be the cause and was later named severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) by the World Health Organization (WHO) and the disease caused by it was called Covid-19 [(2)]. Thus far, the virus has spread to many countries. Multiple studies from China have shown that the new virus is highly contagious. Covid-19 is most commonly reported to present with fever, dry cough and myalgia [(3)]. Besides, it was shown that patients might develop dyspnea within one week of presentation with rapid deterioration of respiratory and end-organ failure [(4)].

There are limited data from infected regions other than china and there is an urgent need to identify specific patient characteristics and outcomes in different populations. Unfortunately, Iran is amongst the top countries with the highest number of cases outside China struggling to provide care for a large pool of patients with Covid-19. On this occasion, it is of utmost importance to implement high-quality researches on Covid-19 for better prevention, diagnosis, and treatment. Hence, we decided to start a registry of patients with Covid-19 at Sina hospital [Sina Hospital Covid-19 Registry (SHCo-19R)], which is one of the designated referral centers for COVID-19 cases in Tehran, the capital of Iran. We are registering clinical presentations, diagnostic workups, treatments, hospital course, and follow-up of our patients. We are going to report descriptive and analytic results soon; we believe that publishing this report enables us to receive comments from experts in the field from all over the world. Moreover, it can be a starting point for international collaborations on this topic.

Methods

Study design and setting

Sina Hospital Covid-19 Registry is an ongoing, prospective, hospital-based registry of patients diagnosed with Covid-19 presenting to emergency department (ED) of Sina Hospital, affiliated to Tehran University of Medical Sciences (TUMS). This study commenced patient enrollment in February 2020 after Sina hospital was declared a Covid-19 referral center in south Tehran. Enrolled

patients are followed during the hospitalization period and for one month after discharge. This registry is designed in compliance with the reporting standards of STROBE guidelines and in accordance with the Declaration of Helsinki Principles in term of all interventions [5, 6]. This project is approved by the Covid-19 research committee of Sina hospital and the ethical committee of TUMS.

Patients and data collection

Patients over 18 years of age with suggestive symptoms of Covid-19 infection (e.g. fever, cough, dyspnea) accompanied by chest computed tomography (CT) scan findings compatible with COVID-19 or definite diagnosis of Covid-19 with real-time polymerase chain reaction (RT-PCR) have been included [7, 8]. Data regarding demographic features, prehospital findings, chest CT scan findings, laboratory data, hospitalization and/or intensive care units (ICU) course, in-hospital outcomes, follow-up events, and complications are recorded on separate predesigned checklists or a web-based electronic report form by trained staff members.

After patient discharge or death, data from patient files and checklists are retrieved and entered into a specifically designed web-based electronic report form by trained nurses, physicians and researchers. After discharge, patients or designated family members are contacted alternately through telephone calls to assess the vital status, readmission and drug complications for one month.

Measures and outcomes

Figure 1 depicts the comprehensive algorithm of patient care for individuals presenting with

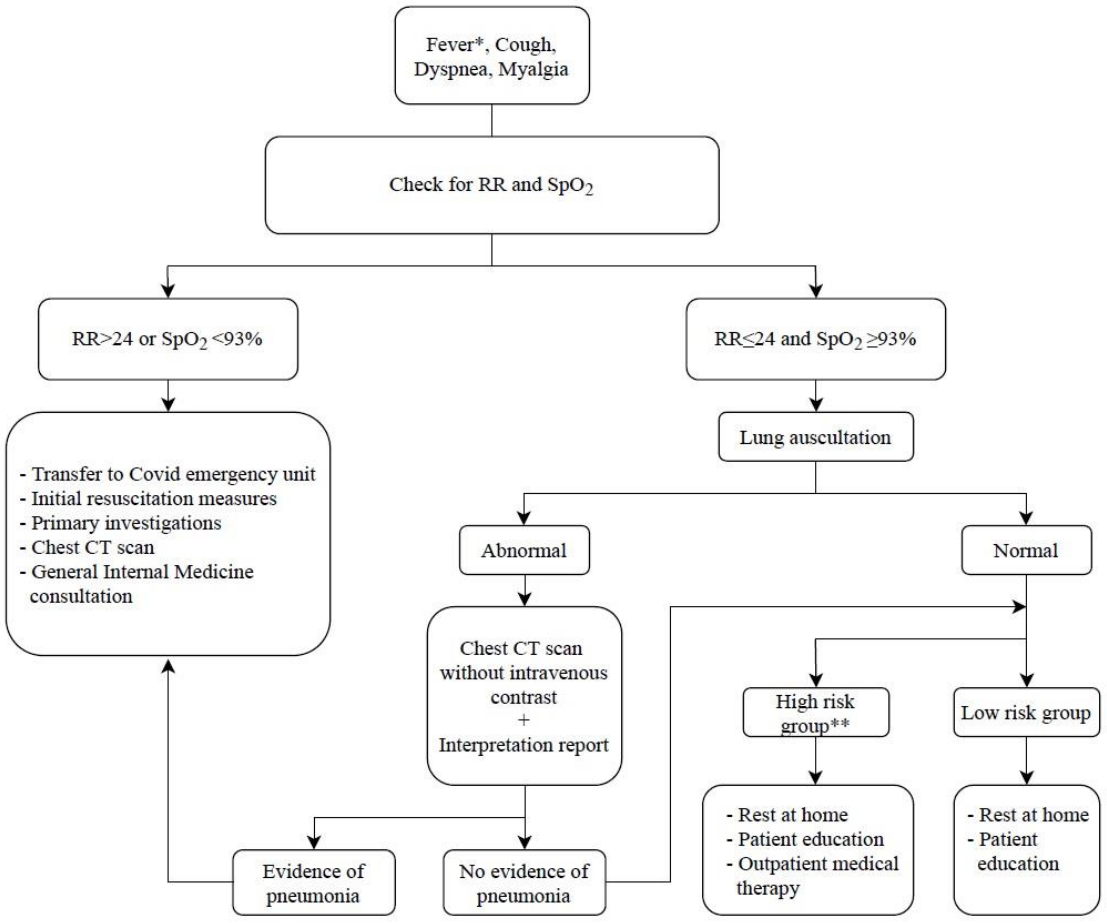

Figure 1: Algorithm of patient care for individuals presenting with respiratory symptoms to Sina hospital emergency department
RR: Respiratory rate; SpO2: Oxygen saturation; CT: computed tomography
* Fever: temperature ≥37.3 in the morning and ≥37.7 in the evening
** High-risk group: immunocompromised patients (chemotherapy, malignancy, organ transplant, corticosteroid use, HIV), cardiovascular disease, hypertension, diabetes, chronic respiratory disease, pregnancy, body mass index≥40, age more than 50 years, chronic kidney disease, cirrhosis

respiratory symptoms in to the ED after the outbreak of Covid-19. Patients diagnosed with Covid-19 are treated according to the latest national guidelines as these protocols are subject to change and are constantly being updated based on emerging new evidence. All patients with possible diagnosis of Covid-19 undergo a chest CT scan and laboratory testing for complete blood count with differential, C-reactive protein (CRP), serum creatinine, sodium, potassium, magnesium, vitamin D, liver function tests, troponin, ferritin, and blood group.

Further investigations are performed based on a predesigned protocol and at the discretion of attending physicians (Table 1). During hospitalization, patients are monitored for blood pressure, fever, respiratory symptoms, oxygen saturation, serum electrolytes, and drug complications, as well as adverse outcomes such as death, respiratory complications (such as ARDS and superimposed bacterial infections), cardiac complications (such as myocarditis, acute coronary syndrome, and arrhythmia) and renal complications (such as oliguria and decreased serum creatinine).

Bias and Quality Assurance

The retrospective nature of data retrieval from medical records might exert some bias on data entry. However, the use of predesigned Covid-19 checklists decreases the amount of missing data and bias. Besides, due to the unknown nature of the disease, national guidelines and protocols might change during the study. Hence, a committee of physicians is constantly monitoring national recommendations, issues in data collection, and accuracy of data entry.

Table 1: Further investigations in patients with Covid-19

Test	Findings
All patients	
Laboratory tests	Complete blood count with differential CRP Serum creatinine Na, K, Mg, vitamin D Liver function tests Troponin Ferritin Blood group
Electrocardiogram	ST-T change Arrhythmia
Chest CT scan	Density (ground-glass opacity, consolidative opacity, mixed) Internal characteristics of the lesion (crazy-paving, reversed halo sign) Axial location, Lobar location Shape (patchy, round-nodular, confluent) Other findings (tree-in-bud opacities, predominantly nodular opacities, predominantly reticular opacities, cavitation, mediastinal lymphadenopathy, pleural effusion)
If myocarditis suspected	
Laboratory tests	LDH CPK Pro-BNP
Echocardiography	Ventricular dysfunction Pericardial effusion
In ICU admitted patients	
Laboratory tests	PT, PTT, INR D-dimer
ICU course sheet	APACHE score, SOFA score Types of Oxygen therapy (reservoir bag, CPAP, NIV, intubation) Oxygenation status (SPO_2, PAO_2/FiO_2, PAO_2 during and after intubation) Lung dynamics (compliance, resistance) Advanced hemodynamic parameters with USCOM Complications and outcomes
If sepsis suspected	
Laboratory tests	Arterial blood gas Procalcitonin Blood culture (x2)

CPAP: Continuous positive airway pressure; CPK: Creatine kinase; CRP: C-reactive protein; CT: Computed tomography; INR: International normalized ratio; LDH: Lactate dehydrogenase; NIV: non-invasive ventilation; PAO_2/FiO_2: Arterial partial pressure of oxygen/ Fraction of inspired Oxygen; Pro- BNP: Pro-brain natriuretic peptide; PT: Prothrombin time; PTT: Partial thromboplastin time; SPO_2: Oxygen saturation, USCOM: Ultrasonic Cardiac Output Monitors; ICU: intensive care unit; APACHE: Acute Physiology And Chronic Health Evaluation; SOFA: Sequential Organ Failure Assessment

Discussion

SHCo-19R is an ongoing registry of patients with COVID-19 in Tehran, Iran, designed to evaluate patient characteristics, findings and etc. In the study by Guan et al. on 1099 patients with laboratory-confirmed Covid-19, it was shown that five percent of patients were admitted to ICU, 2.3% needed intensive mechanical ventilation, and 1.4% died. In addition, ARDS was the most common complication among patients presenting with severe disease with a prevalence of 15.6% followed by septic shock (6.4%) and acute kidney injury (2.9%) [9]. Similar studies have shown that ARDS, cardiac injury, secondary infection, and end-organ failure are among the most frequent complications of the disease [3, 10]. Besides, recent studies have proved the involvement of angiotensin-converting enzyme 2 in Covid-19, leading to an increased risk of cardiac myocyte injury [11, 12]. Overall, the same data are limited in the Iranian population. This study will provide valuable epidemiological knowledge on Iranian patients with Covid-19. These findings will be used to 1) identify patient characteristics, comorbidities, and previous risk factors; 2) evaluate outcome in these patients and a better understanding of risk factors associated with adverse events; 3) assess changes in laboratory findings of Covid-19 cases and their association with poor outcomes; 4) evaluate different treatment strategies and their potential efficacy and safety and 5) form a base for conduction of future therapeutic clinical trials.

Conclusions

Here, in this paper, we introduced SHCo-19R which is an ongoing, prospective, hospital-based registry of patients with Covid-19 admitted to Sina hospital, affiliated to TUMS, in Tehran, Iran.

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Authors' contribution

All the authors met the standard criteria of authorship based on the recommendation of International Committee of Medical Journal Editors.

Conflict of interest

The authors declare that there is no conflict of interest regarding the present study.

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Appendix 1: Members of the Covid-19 Crisis Committee of the Sina Hospital (in alphabetic order)

Name	Academic Degree	Affiliation
Aghamir, Seyed Mohammad Kazem	MD	Department of Urology
Arya, Pantea	MD	Psychiatrist
Ashraf, Haleh	MD	Department of Cardiology
Babaei, Soorya	MSc	Department of Nursing
Baratloo, Alireza	MD	Department of Emergency Medicine
Ebrahimi, Mehdi	MD	Department of Internal Medicine
Ghorbani, Mazaher	MD	Department of Forensic Medicine
Hadadi, Azar	MD	Department of Infectious Diseases
Kafan, Samira	MD	Department of Internal Medicine
Karbalai Saleh, Shahrokh	MD	Department of Cardiology
Khajavi, Mohammad Reza	MD	Department of Anesthesiology and Critical Care
Montazeri, Mahnaz	MD	Department of Infectious Diseases
Moradi Tabriz, Hedieh	MD	Department of Pathology
Najafi, Atabak	MD	Department of Anesthesiology and Critical Care
Najafi, Mina	MSc	Department of Nursing
Najmeddin, Farhad	PharmD	Department of Clinical Pharmacy
Payandeh Mehr, Pooya	MD	Department of Emergency Medicine
Pazouki, Marzieh	MD	Department of Internal Medicine
Sahraian, Mohammad Ali	MD	Department of Neurology
Salimzadeh, Ahmad	MD	Department of Internal Medicine
Shakouri Rad, Ali	MD	Department of Radiology
Shariat Moharari, Reza	MD	Department of Anesthesiology and Critical Care
Sotoodehnia, Mehran	MD	Department of Emergency Medicine
Talebpour, Mohammad	MD	Department of Surgery
Zafarghandi, Mohammad Reza	MD	Department of Vascular Surgery

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