A prospective cohort of clinical and epidemiological characteristics of COVID-19 patients post-discharge in Tehran, Iran (Tele-COVID-19): Research protocol and baseline findings

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Abstract

Background: Coronavirus disease 2019 (COVID-19) was declared a pandemic on March 11, 2020. Given the severe shortage of hospital beds leading to early discharges and insufficient patient education regarding home care routines and isolation protocols, close follow-up with patients and their immediate relatives is an integral part of care transition from hospital to home among COVID-19 patients.

Objective: We designed the Tele-COVID-19 prospective cohort to follow-up COVID-19 patients in Tehran, Iran in order to help improve healthcare delivery and recording of patients' clinical profile post-discharge.

Methods: All adult patients admitted to COVID-19 wards of teaching hospitals of Tehran, Iran are eligible to participate. In the baseline wave, patients were recruited from four major hospitals from March 9, 2020 to May 20, 2020. Telephone follow-ups led by volunteer medical students were made on days 1, 2, 3, 5, 7, 10, and 14 post-discharge. Data was collected on a range of socio-demographic, epidemiological, and clinical characteristics using a standard questionnaire.

Results: Out of 950 confirmed COVID-19 patients who were approached, 823 consented and were enrolled in the cohort (response rate = 86.6%). A total of 449 (54.5%) participants were male and the mean (SD) age of participants was 50.1 (12.6).

Conclusions: Tele-COVID-19 will provide the patients with sufficient education on homecare and isolation as well as medical advice on care and proper use of drugs. In addition, by preventing unnecessary hospital returns and diagnosis of household transmissions at the earliest stages, this cohort would help disease management in resource restricted settings. Clinical Trial: NA

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were recorded.

Conclusion: Tele-COVID-19 will provide the patients with sufficient education on homecare and isolation as well as medical advice on care and proper use of drugs. In addition, by preventing unnecessary hospital returns and diagnosis of household transmissions at the earliest stages, this cohort would help with effective disease management in resource-restricted settings.

KEYWORDS: Cohort studies; COVID-19; Healthcare delivery; Iran; Medical Education; Telemedicine

Introduction

Coronavirus disease 2019 (COVID-19), caused by severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2), was declared a pandemic on March 11th, 2020. Based on the existing evidence, the risk appears to be relatively low for the general population, although senior citizens, immunocompromised people, and those with underlying health conditions such as cardiovascular diseases are at elevated risk of morbidity and mortality [1] . As of December 11, 2020, 71,088,688 confirmed COVID-19 patients and 1,595,096 deaths have been reported across the globe [2]. To date, effective treatment options for COVID-19 are unavailable; however, 2500+ trials and studies have been conducted and are ongoing worldwide to develop and evaluate different therapeutic options for COVID-19 [3]. Taking swift community-centered preventive measures, timely diagnosis and treatment initiation, along with contact tracing, successful isolation of patients at home, and reducing household transmissions of the virus among COVID-19 patients' close contacts have been at the core of recommended strategies for tackling the disease [4-6].

Despite the extensive efforts at controlling the pandemic worldwide, the constantly rising patient load and limited supplies of personal protective equipment (PPE) have overwhelmed healthcare systems across the globe; however, the toll has been heavier for low- and middle-income settings where healthcare systems are already underfunded, understaffed, and overstretched. Iran is one of the hardest-hit countries by COVID-19 outbreaks. The first confirmed COVID-19 patient was reported on February 19, 2020 at the city of Qom which is 200 Km away from the capital city of Tehran. As of December 11th, 2020, 1,092,407confirmed COVID-19 patients and 51,727deaths have been reported in the country [7]. Iran's initial response to the pandemic included physical distancing control policies that aimed to minimize close contacts within communities as well as individual-level (e.g., quarantine, isolation) and community-level (e.g., closure of educational and recreational

settings, non-essential businesses, and cancellation of public/mass/crowded gatherings) restrictions. Nevertheless, economic sanctions, inadequate financial and human resources, inefficient leadership, and limited hospital capacities for the rapidly growing number of COVID-19 patients requiring hospitalizations have created real and significant challenges for controlling the epidemic [8-10]. As >98% of the population have access to mobile or landline phones [11], one of the cost-effective ways that could help reduce the community transmission of SARS-CoV-2 and manage the influx of COVID-19 patients in the hospital settings in Iran could be managing the discharged patients or those with less critical conditions via routine telephone follow-ups. Indeed, telemedicine has been proposed as an effective approach in responding to health emergencies and could not only ensure that the limited hospital beds are occupied by those who need them most, but would also provide patients and their families with access to medical care without unnecessary referrals to healthcare facilities [12, 13]. Therefore, we designed a prospective cohort study (i.e., Tele-COVID-19) to follow-up COVID-19 patients discharged from teaching hospitals in Tehran to help assess the overall spread of SARS-CoV-2 in the community. The specific objectives of Tele-COVID-19 are as follow: i) Telephone-based follow-up of patients admitted to the coronavirus emergency departments across certain hospitals in Tehran, ii) Precise monitoring of the patients' signs and clinical symptoms post-discharge, iii) Providing patients with sufficient education on homecare and isolation principles as well as medical advice on care and proper use of drugs, iv) Preventing unnecessary hospital returns and timely diagnosis of within-household transmission of SARS-CoV-2, and v) Timely referral of patients in critical conditions post-discharge to the emergency department (ER) and facilitating their readmission when necessary. We hereby present the overall characteristics of Tele-COVID-19 and preliminary baseline characteristics of the first round of patients recruited in the cohort.

METHODS

Study Design

Tele-COVID-19 is a prospective cohort study that was designed to follow-up COVID-19 patients post-discharge for a two-week period in Tehran, Iran. At baseline, data collection was completed by a volunteer group of medical students established on February 22, 2020, under the supervision of clinical professors [14]. Baseline data collection was completed between March 9, 2020, to May 20, 2020. Given the prospective nature of the cohort, a 'top-up' sample of participants will be included in the sampling frame in the subsequent waves of data collection. Due to the emerging nature of SARS-CoV-2, a prospective sample size calculation was not determined and the recruitment of the patients would depend on the spread of the disease in Tehran with no specific end date at this point.

Setting

Four major teaching hospitals in Tehran (i.e., Shohada Tajrish Hospital, Ayatollah Taleghani Hospital, Shahid Modarres Hospital, and Loghman Hakim Hospital) were included at baseline. Collectively, these hospitals have 1652 beds, 136 primary care clinics, 100+ specialties and over 3000 employees. Three of them are located in the northern districts of Tehran and one in the southern district (**Figure 1**).

Eligibility Criteria

Eligible participants were adult (i.e., >18 years of age) hospitalized cases of COVID-19 with a positive SARS-CoV-2 PCR result who were treated and discharged from respective COVID-19 wards. Participants were excluded if contact information were wrong or missing. All patients who did not respond to follow-up phone calls or declined providing consent were also excluded. Participants were briefed about the study aims and objectives both in-person inside the hospital and over the phone post-discharge. All participants provided verbal consent and each patient received a unique

national identification code to avoid potential biases that could arise from patients referring to several other healthcare facilities post-discharge.

Data Collection

At baseline, telephone follow-ups led by volunteer medical students were conducted on days 1, 2, 3, 5, 7, 10, and 14 post-discharge following a predetermined protocol and under the supervision of clinical professors. The calls were made to patients' cell phones or landline phones from 10 am to 4 pm. In the case of non-response, calls were repeated three times with two-hour intervals until the end of the calling time. Patients were excluded if they could not be reached by the end of the day. The first round of the interviews was made by medical clerks. If the patient was assessed as being in a concerning or critical condition, the follow-up phone call was made by a senior medical intern —in consultation with clinical professors— for further assessment. Data were recorded on a secure and password-protected online platform. Each medical clerk signed a non-disclosure agreement before enrollment to ensure the security and confidentiality of the data. Medical clerks could only observe the data collected by themselves and not that of other team members. By the end of each patient's 14-day follow-up period, all data were extracted from the online platform and stored on a password-protected external hard drive.

Data were collected using a pilot-tested comprehensive COVID-19 risk assessment questionnaire informed by the Center for Disease Control and Prevention (CDC) and national guidelines in the Ministry of Health and Medical Education on the following areas: Socio-demographic information (e.g., age, sex), history of potential exposures to SARS-CoV-2 (e.g. travel history to China, city of Qom, exposure history to COVID-19 patients), signs and clinical symptoms (e.g., fever, dry cough, dyspnea, nausea, diarrhea), medical history for underlying conditions (e.g., history of diabetes, cardiovascular disorders, chronic lung disease, chronic renal disease, immunodeficiency), habitual history (e.g., current smoker, former smoker, nonsmoker), prescribed drugs post-discharge (e.g.,

hydroxychloroquine, lopinavir/ritonavir), history of non-COVID-19 related medications (e.g., nonsteroidal anti-inflammatory drug [NSAIDs], statin), and household close contact information (e.g., high risk household contacts, household transmission).

Interview Process

Interviewers were enrolled if they were 4th to 7th-year medical students and were registered in the respective medical schools at the time of interviews. There were two main groups of interviewers: a) medical clerks (i.e., those in their 4th and 5th year of training), and b) medical interns (i.e., those in their 6th and 7th year of training). Under the supervision of clinical professors, medical interns were mentored by the faculty and helped supervise medical clerks. All interviewers completed a 40-hour crash course. Educational topics in the course were tailored towards COVID-19 related prevention, care, and treatment and consisted of complete history taking and physical examination, practice essentials for COVID-19, guidance on precautionary measures during home care and isolation for patients and other household members, and assessment of high-risk conditions and referral guide for each medical condition. Data collection procedures were pilot-tested with patients and through role-play to ensure consistency throughout data collection. During the phone calls, patients and their household members were educated on homecare procedures and isolation guidelines. All clinical signs and symptoms were examined closely and recorded. Treatment regimen and procedures were adjusted accordingly and patients were guided to stay at home or return to the emergency room if critical symptoms were mentioned by the patient or household members.

Statistical Analysis

Data entries were double-checked and cleaned using STATA (Version 15, College Station, Texas, USA). For the purpose of the present study, descriptive statistics including relative frequencies for categorical variables, along with mean and standard deviation (SD) for quantitative variables were

reported. However, for the purpose of future studies deriving from this cohort, associations will be examined using appropriate regression analyses.

Results

A total of 950 confirmed COVID-19 patients were approached at the initial phase of the study; 823 of whom consented and were successfully enrolled in the study (261 from Shohada Tajrish Hospital [31.7%], 213 from Loghman Hakim Hospital [25.9%], 233 from Ayatollah Taleghani Hospital [28.3%] and 116 from Shahid Modarres Hospital [14.1%]). Baseline characteristics of the patients are presented in **Table 1**.

Table 1. Baseline characteristics of the coronavirus disease 2019 (COVID-19) patients in the Tele-COVID-19 in Tehran, Iran

Characteristics	n (%)†
Hospital (N=823)	
Loghman Hakim	213 (25.9)
Shohada Tajrish	261 (31.7)
Shahid Modarres	116 (14.1)
Ayatollah Taleghani	233 (28.3)
Sex (N=823)	
Male	449 (54.6)
Female	374 (45.4)
Mean (SD) age (N=823)	50.1 (12.6)
Healthcare worker (N=821)	
Yes	65 (7.9)
No	756 (92.1)

Travel history in the previous 14 days (N=821)	
China	1 (0.1)
Qom province	10 (1.2)
Gilan province	8 (0.9)
No travel history	802 (97.6)
Exposure to confirmed COVID-19 patients in the previous 14 days (N=818)	
Yes	176 (21.5)
No	642 (78.5)
Reason for hospital visit (N=814)	
Suspicious clinical signs and symptoms	701 (86.2)
Exposure to a probable COVID-19 patient	59 (7.2)
Other	54 (6.6)
Smoking history (N=811)	
Current smoker	77 (9.5)
Former smoker	90 (11.1)
Non-smoker	644 (79.4)
Chronic respiratory conditions* (N=818)	
Yes	81 (9.9)
No	737 (90.1)
Diabetes mellitus (N=820)	
Yes	159 (19.4)
No	661 (80.6)

Cardiovascular conditions (N=817)	
Yes	181 (22.2)
No	636 (77.8)
Chronic renal conditions (N=821)	
Yes	57 (6.9)
No	764 (93.1)
Chronic liver conditions (N=821)	
Yes	23 (2.8)
No	798 (97.2)
Immunodeficiency (N=818)	
Yes	25 (3.1)
No	793 (96.9)
Underlying neurological conditions‡ (N=819)	
Yes	52 (6.5)
No	767 (93.5)
Mean (SD) days of hospitalization	5.32 (4)
Clinical signs and symptoms (N=676)	
Fever	364 (53.8)
Chills	327 (48.4)
Myalgia	225 (33.3)
Headache	306 (45.3)
Cough	466 (68.9)
Respiratory distress	394 (58.3)
Nausea and vomiting	270 (39.9)

Diarrhea	239 (35.4)
Loss of appetite	289 (42.8)
Loss of weight	69 (10.2)
Abdominal pain	144 (21.3)
Anosmia	127 (18.8)
Ageusia	134 (19.8)
Rhinorrhea	117 (7.9)
Sore throat	171 (17.3)
Consciousness alterations	95 (14.1)
Severity¤ (N=676)	
Mild to moderate	647 (95.7%)
Severe	29 (4.3%)

†Percentages are rounded up to one decimal point; *Asthma/Emphysema/COPD (Chronic obstructive pulmonary disease); ‡Chronic neurological diseases, neurodevelopmental/Intellectual disability; ¤Severe cases were those who were admitted to intensive care unit or had a O2 saturation level below 90%.

A total of 449 (54.5%) participants were male and the mean (SD) age of participants was 50.1 (12.6). Overall, 65 (7.9%) of participants were healthcare workers and 19 (2.3%) reported travelling to known epicenters of COVID-19 in the previous 14 days. A total of 471 (57.6%) patients reported prior exposure to a COVID-19 patient in the past 14 days of the interview. A total of 701 (86.2%) patients visited the hospital due to suspicious signs and symptoms whereas 59 (7.2%) of them sought medical attention due to their exposure to other probable cases. Overall, 167 (20.6%) of the participants were current/former smokers. Most patients did not have any underlying diseases and only 25 (3.1%) were immunodeficient. Mean (SD) length of hospitalization was 5.23 (4).

Data on detailed baseline clinical symptoms was available for 676 patients. Among the baseline clinical presentations, the three most common symptoms were cough (68.9%), respiratory distress

(58.3%), and fever (53.8%). Only a small proportion of patients had severe conditions (i.e., admitted to an intensive care unit or O2 saturation level <90%). Most patients reported that they would be able to self-isolate post-discharge.

During the initial data collection phase, >5000 phone calls were made. Overall, 577 reports were recorded in the daily critical case report sheets, where patients were followed directly by medical interns and clinical professors for more specific medical care. Patients with serious conditions (n = 69) were referred to the ER in coordination with hospital staff, 40 of whom were re-hospitalized. Patients with minor conditions who primarily intended to revisit the hospital were successfully managed over the phone, leading to the prevention of unnecessary hospital visits (n = 296). A total of 60 patients who reported experiencing adverse reactions to medications were managed through phone calls.

Discussion

Tele-COVID-19 cohort provided a platform to effectively follow-up COVID-19 patients after their hospitalization. Our prospective cohort study presents a cost-effective way of managing COVID-19 patients post-discharge and supporting them and their family members on their path to full recovery. Tele-COVID-19 was designed and run by a group of volunteer medical students and could successfully follow-up 823 COVID-19 patients post-discharge in its baseline wave. Given the burden of COVID-19 on healthcare systems globally and in resource-limited settings such as Iran, telephone-based follow-up studies involving medical students could not only enhance patient care, but would also enhance medical education for medical students who are often left out of the COVID-19 response due to concerns about limited resources of PPE and students' safety [15]. Early telephone follow-up calls post-discharge have indeed been previously shown to improve patients' health outcomes and reduce their chance of readmission or developing critical conditions in the first

month after discharge [16-19].

Limitations

We acknowledge the limitations of our study that are common among studies of this nature. First, our non-random sample of participants from major hospitals in Tehran may not be generalizable to COVID-19 patients in other parts of Tehran or Iran. However, it is likely that the characteristics of the participants recruited in our cohort are not considerably different than patients in other hospitals in Tehran who were not in our study. Second, participants' self-reported responses to potential risk factors or underlying comorbidities are prone to social desirability and reporting biases. Third, we did not collect any data on the mental health profile of the patients which could be considered for future waves of data collection. Forth, most patients in our cohort were mild or moderate cases of COVID-19 with no adverse underlying conditions and therefore, do not provide a complete clinical picture of severe cases in our hospitals.

Conclusions

Tele-COVID-19 is a unique student-led cohort that could provide an effective platform to improve our evolving understanding of COVID-19 care and treatment in Iran. Such cohort studies assist the medical community in reducing the medical complications among people recovering from COVID-19, understanding the details of the clinical course of the disease, identifying potential drug interactions and adverse effects of pharmacotherapies, reducing household transmission and secondary attack rates of SARS-CoV-2, timely referral of discharged patients who are in critical conditions, reducing patients’ anxiety, and preventing unnecessary hospital visits. Moreover, cohorts like Tele-COVID-19 provide a cost-effective and rapidly implementable platform to improve our understanding of COVID-19 resource-limited settings.

Ethics

The study protocol was reviewed and approved by the ethics committee of Shahid Beheshti University of Medical Sciences (Ethics approval reference number: IR.SBMU.RETECH.REC.1399.114).

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All authors contributed to the development of the Cohort. LJK and MV prepared the first draft under the supervision of MK. All authors reviewed, revised, and approved the final draft. We are grateful to all participants and their families who spent their valuable time and participated in this research despite the difficult times they were going through. We are also thankful to the tireless efforts of the academic staff at Shahid Beheshti University of Medical Sciences and volunteer medical students who devoted their time to the project. MK is a member of the Pierre Elliot Trudeau Foundations COVID-19 impact committee and is supported by the Pierre Elliott Trudeau Foundation Doctoral Scholarship. MS is supported by a Canadian Institute of Health Research (CIHR) post-doctoral award.

Conflicts of Interest

All Authors declared that they have no conflict of interest.

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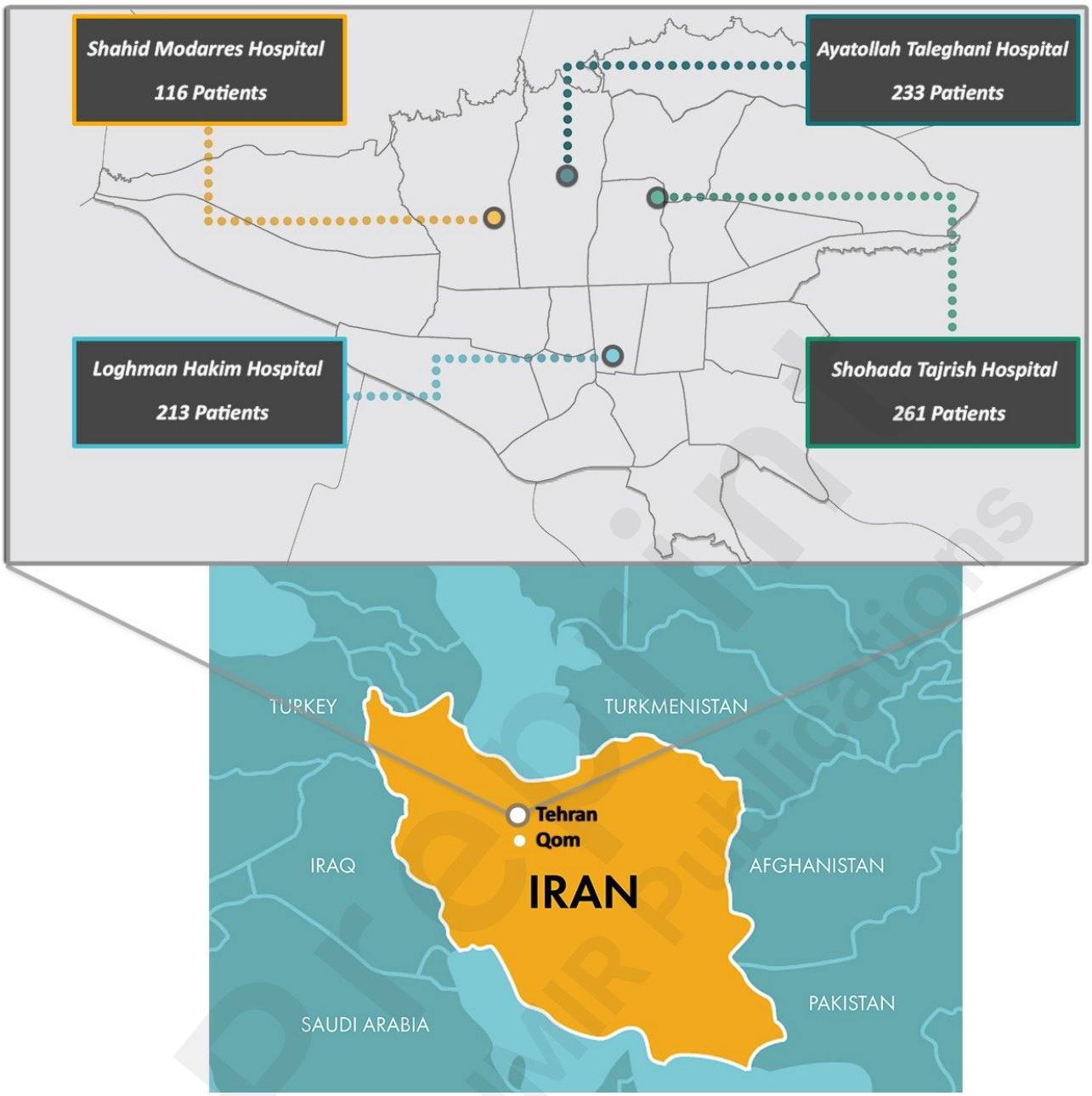
Figure 1. Hospitals included in the first phase of recruitment for Tele-COVID-19 cohort


Shahid Modarres Hospital
116 Patients
Ayatollah Taleghani Hospital
233 Patients
Loghman Hakim Hospital
213 Patients
Shohada Tajrish Hospital
261 Patients
TURKEY
TURKMENISTAN
Tehran
Qom
IRAQ
IRAN
AFGHANISTAN
PAKISTAN
SAUDI ARABIA

Supplementary Files

Figures

Hospitals included in the first phase of recruitment for Tele-COVID-19 cohort.