Research Article

Establishment of a Longitudinal Registry of COVID-19 ICU Patients in Qom City, Iran: Retrospective Chart Review and Analysis of Laboratory Data

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Somayeh Mehrpour[1], Reihane Tabaraii[2]*, Hassan Safdari[3], Mansoureh Shakeri[4], Mojdeh Bahadorzadeh[5]

1   Assistant professor of ICU &critical care Department of anesthesiology &critical care, Qom university of Medical Sciences, Qom, Iran.

2   Clinical Research Development Center, Shahid Beheshti Hospital, Qom University of Medical Sciences, Qom, Iran.

3   Department of Anesthesiology and Perioperative Medicine, Tufts Medical Center.

4   PhD. student of Educational Management Clinical Research development center, Qom University of Medical Sciences, Shahid Beheshti Hospital, Qom, Iran.

5   Assistant Professor of Surgery, Department of Surgery, School of Medicine, Shahid Beheshti Hospital, Qom University of Medical Sciences, Qom , Iran.

*   **Correspondence**: Reihane Tabaraii. Clinical Research Development Center, Shahid Beheshti Hospital, Qom University of Medical Sciences, Qom, Iran. Email: Rt1356@yahoo.com

Abstract:

Objective: This study aimed to establish a registry of patients admitted to the COVID-19 ICU ward, in Qom city, Iran.

Methods: This was a retrospective chart review (RCR). The dataset of Longitiduanl laboratory data of Qom COVID-19 Intensive unit care (QCOVICU) was created based on the patients admitted to Shahid Beheshti-Amir al-Momenin Hospital of Qom city, in 2021. This registry includes information on COVID-19 patients, whose disease was confirmed based on the RT-PCR of SARS-COV2 between January 1, 2021, and December 31, 2021. Data were retrospectively collected from electronic medical records and medical notes of healthcare providers. The dataset includes age, gender, RT-PCR SARS-COV2 variant, dates of admission, ICU admission, discharge or death, and laboratory data. Laboratory data were collected longitudinally at each time of blood sampling (maximum 10 data for each item of laboratory data), based on the Iranian Health authority provided standard laboratory data request times.

Results: The dataset included a total of 200 patients in 2021, of which 94 were female and 106 were male. The mortality rate was 50.5% (101 deceased, 47 females and 52 males; mean age of 69.12±16.92). CBC data were collected for an average of more than 60 patients each time (10 separate time assessments). ESR, CRP, creatinine, CPK, and LDH were also collected till the 10th serial assessment.

Conclusion: The QCOVICU registry dataset has provided a longitudinal data set of CBC assessments of 200 COVID-19 patients with time-to-event data that could be utilized for survival analyses. Multiple assumptions and hypotheses could be evaluated on this registry data.

Keywords: Longitudinal Registry, COVID-19, ICU, Laboratory Data.

Introduction

On December 31, 2019, in the city of Wuhan, Hobicin, a new Coronavirus began to revolt, leading to an epidemic throughout China, and eventually reached several continents in just a month, with China late in the late one. February 2020 announced more than 78631 cases of the virus and 2747 deaths affected by the virus, and in February 2020 the World Health Organization (WHO) officially called it COVID-19 (1-5). The Coronavirus is from the Coronavir family, which is a large family of RNA viruses, commonly seen in animals and rarely transmitted to humans (6).

The virus transmission processes are not fully known, but the virus, like the influenza virus, is usually transmitted through respiratory droplets in close contact with the person. Its symptoms can vary from asymptomatic cases to respiratory distress syndrome and other critical patient conditions (respiratory failure, shock or disruption of multiple organs) and may require intensive care unit admission (5-8). The rate of death in different countries and ages may vary and most of the deaths are seen in old-age patients with a background risk such as cardiovascular disease, diabetes, hypertension, chronic pulmonary disease, chronic kidney disease, age 60 years, high body mass index, immunodeficiency and cancers (9 - 11).

The definitive diagnosis of the virus is using genomic tests (RT-PCRs) on nasopharynx specimens to determine the virus RNA, laboratory data, and CT-SCAN is very helpful in diagnosing the disease and prognosis determination (12-14). According to the Ministry of Health's protocol in the latest version (eleventh version), patients with Covid 19 are required in the special sector if hypoxia resistant to non-invasive treatment, reduced levels of consciousness, hemodynamic instability, and respiratory fatigue require care in the special sector (15).

Therefore a significant percentage of patients with COVID-19 during treatment have been found in special care and ICU, and new statistics on hospitalization in ICU and trends of laboratory data change of these patients are not assessed fully in Iran, this study was designed to collect longitudinal laboratory data of ICU admitted COVID-19 patients.

Methods

Study design, settings, and ethical considerations:

This was a retrospective chart review (RCR). The data abstractors referred to the Shahid Beheshti-Amir al-Momenin Hospital after approving the proposal and obtaining an ethics code from the University Ethics Committee.

Study population:

The study population was all COVID-19 patients admitted to Shahid Beheshti-Amir al-Momenin Hospital in Qom, Iran, from January 1, 2021, and December 31, 2021. Shahid Beheshti Hospital in Qom is a training, research, and medical center affiliated with Qom University of Medical Sciences. Currently, 463 active beds. The study sampling method was available sampling based on the inclusion criteria. The main criterion of entry into the present registry was patients with a positive RT-PCR test of the nasopharyngeal swab for SARS-COV2 at any age range and managed in ICU of this hospital based on the Ministry of Health's national protocol. Exclusion criteria were patients who did not have a positive PCR test and did not want to participate in the study; Patients with immunodeficiency.

Data collection:

If the medical record had entry criteria, patient information was recorded in a pre-specified checklist in accordance with ethics to maintain patient information. When extracting information from the

files, the patient's contact number was also registered to contact for further information collection. If the information collection was not possible by a phone interview, the case was excluded.

All patient information such as age, gender, RT-PCR SARS-COV2 variant, dates of admission, ICU admission, and discharge or death, and laboratory data of CBC, ESR, CRP, creatinine, CPK, and LDH, underlying diseases were sought to be extracted from patients' files and physician and nursing reports. The duration of hospitalization, the duration of hospitalization in the ICU, and the discharge status of patients (discharge) are also extracted from the electronic records.

Variables:

RT-PCR SARS-COV2 variant: a binary variable indicating variant of the SARS-COV2 infection (delta or Omicron).

The standard Delta and Omicron detection kits were provided by the Iranian Health authority.

Death: Any-cause in-hospital mortality as binary data.

Laboratory data: All laboratory data by the same machines used in the laboratory of Shahid Beheshti-Amir al-Momenin Hospital.

Based on the Iranian Health Authority, CBC and creatinine were being evaluated daily in COVID-19 ICU. ESR, CRP, LDH, and CPK were QOD.

Age: continuous, years of life.

Dates: recorded from medical records.

Statistical methods:

This is a descriptive study and does not include any inferential statistical analysis. Only numbers and percentages were used for categorical data and mean and SD for the continuous data.

Results

Description of patients based on the mortality:

The QCOVICU registry provides information about 200 individuals admitted to this hospital's ICU. The mortality rate of this period of time was 50.5% (99 survived and 101 deceased). There were 47 females and 52 males who survived and 47 females and 54 males who deceased. Mean age of patients in the group of surviving patients was 56.66 ±20.76 years old, while the victims' mean age was 69.12±16.92 years. This suggests that the COVID-19 victims had higher average age than survivors. The SARS-COV-2 variant was also evaluated, and the Delta variant accounted for 50.50% of cases in both the survived and deceased groups, while the Omicron variant accounted for 49.50% of cases in both groups. Mean length of hospitalization for surviving patients was 12.51±22.04 days and 13.41±10.53 days, respectively. The mean length of ICU hospitalization of patients was 4.6±18.48 days and 6.58 ±7.23 days, respectively (table 1).

Table 1. Characteristics of survived and deceased patients of QCOVICU

		Survived N=99		Deceased N=101	
		n/mean	%/SD	n/mean	%/SD
Gender	female	47	50.00%	47	50.00%
	male	52	49.10%	54	50.90%
Age		56.66	20.76	69.12	16.92
SARS-COV-2 variant	Delta	50	50.50%	50	49.50%
	Omicron	49	49.50%	51	50.50%
Hospitalization length, days		12.51	22.04	13.41	10.53
ICU hospitalization length, days		4.6	18.48	6.58	7.23

Description of patients based on the SARS-COV2 variant:

One hundred patients had Delta and 100 had Omicron variant. Delta variant infected patients (46 female and 54 male; mean age:59.9 ± 17.24 years) had hospitalization lengths longer than the Omicron variant infected patients (48 females and 52 males, mean age: 66.04 ± 21.82 years).

Table 2 provides information on ICU hospitalization, mortality rate, and laboratory data of LDH and CPK, levels of creatinine, platelets, ESR, WBC, lymphocytes and neutrophils. The Omicron variant has higher levels of and lymphocytes at first blood sample collection.

Missing data:

Serial laboratory data assessments were performed and data is collected. As some subjects were discharged or died earlier, there are a different number of laboratory data assessments that should be considered in the analysis of QCOVICU. The number of available records of each paramedical investigation at different times is presented in table 3.

Discussion

Since the registry system still does not exist at the level of our country and considering that the COVID-19 epidemic is still making tough situations in the country and the importance of screening and examination of samples, we established this registry. The study by Mohammad Haghigi et al. was conducted in 2020 with the aim of investigating paraclinical epidemiological findings and imaging in patients with covid-19 hospitalized in the intensive care unit of Rasht Hospital found that increased ESR, LDH, neutrophil percentage, and lymphopenia were the most common laboratory findings in COVID-19 patients (16). But, these laboratory data are not assessed continuously in most studies and this registry is aimed at longitudinal assessments. Currently, there are a growing number of COVID-19 patient registries getting established worldwide with different subjects.

Table 2. Characteristics of Delta and Omicron SARS-COV2 variant infected patients

		Delta		Omicron	
		n/mean	%/sd	n/mean	%/sd
Gender	female	46	23	48	24
	male	54	27	52	26
Age		59.9	17.24	66.04	21.82
hospitalization length		13.94	9.91	9.95	8.09
ICU hospitalization length		5.67	7.52	3.79	5.12
mortality	No	49	50	49	50
	Yes	50	49.5	51	50.5
First blood sample laboratory data results					
LDH, U/L		699.06	288	583.17	290.29
CRP, mg/L		66.63	35.21	58.68	37.24
CPK, mcg/L		425.97	640.28	519.51	1399.04
Creatinine, mg/dL		1.38	0.68	2.02	1.76
Platelet, count per microliter		183.30	81.90	214.48	90.4
ESR, mm/hr		42.65	25.81	48.37	32.32
WBC, count per microliter		9009	5199.77	9915.38	5801.87
Neutrophil, percentage		82.29	11.94	77.81	13.17
Lymphocyte, percentage		12.97	11.38	15.61	10.19

Table 3. Number of records in each time investigation

times	LDH	CRP	CPK	Creatinine	platelet	ESR	WBC	Neutrophil	Lymphocyte
1	98	97	33	93	80	72	100	90	99
2	85	85	11	91	78	24	99	94	96
3	70	72	8	89	76	16	97	92	92
4	55	56	6	76	73	8	80	71	71
5	52	49	4	68	70	8	76	64	66
6	45	45	3	64	66	-	71	57	59
7	40	42	3	58	59	-	63	49	50
8	38	39	2	54	55	-	59	44	45
9	35	36	2	51	52	-	56	32	35
10	34	34	2	48	48	-	52	29	32

While our sample size is low, this is a prevalent issue in new registries. global COVID-19 stroke registry was established with 172 patients (17). COVID-19 dermatological duration had 331 COVID-19 cases in their registry (18). A systematic review of registry studies by Karlsen et al. found 1303 interventional COVID-19 registries (19).

In case of novelty, this is the first longitudinal laboratory data registry in Iran; while there are statistical considerations for analysis of such data as patients getting die or censored get lost of the continuing serial measurements and later laboratory data measurements would have fewer observations than initial ones. This issue was tried to be solved in a study by Johnson et al. established a longitudinal data repository named MIMIC-III (20), on which multiple studies were published as well as the Chen et al. study (21)

Limitations:

This was a single-center study and its results could not be generalized to clinics. Also, data are being collected retrospectively so there is a high chance of missing data, and multiple known and unknown confounding factors. We had many missing data regarding the comorbidities as we were extracting them from the physician's notes.

Most importantly, mixed infections with other wild variants or mixed delta omicron are also possible that we could not be excluded. We also did not have data on vaccination type and doses.

Conclusion

This registry would be available for all potential stakeholders, the patients who might get benefits from the improved care results of this registry, healthcare providers for decision-making, researchers who need source data for their studies, public health for establishing any preventive measures, etc. The QCOVICU registry dataset has provided a longitudinal data set of CBC assessments of 200 COVID-19 patients with time-to-event data that could be utilized for survival analyses. Multiple assumptions and hypotheses could be evaluated on this registry data.

Declarations:

Funding:

Qom University of Medical Sciences

Conflicts of interest:

None

Authors' contributions:

SM and RT wrote the study protocol, collected datasets and HS, MS, MB, RT, and SM, performed statistical analyses, and wrote the manuscript.

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None.

Ethical considerations

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