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Prevention and control of COVID-19 outbreak in a hemodialysis center

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ABSTRACT

Background: *The prevention and control of SARS-CoV-2 infection in hemodialysis (HD) units is challenging.* ***Aim:*** *To describe the clinical characteristics and outcome of patients with chronic kidney disease (CKD) on HD with COVID-19, between March 2020 and January 28, 2021, attending a single HD unit in Bogotá, Colombia.* ***Material and Methods****: In this prospective observational study, incidence, prevalence, and case-fatality rate were estimated, including screening results with RT-PCR and anti-SARS-CoV-2 IgG and IgM antibodies in all patients and health personnel in the HD unit.* ***Results:*** *Among patients and health workers, 55 and 9 cases of COVID-19 were identified, respectively. The median age of patients was 63 years (84% males). Fifty five percent of patients were symptomatic, with fever, cough and/or myalgia. The most common comorbidities were hypertension, type 2 diabetes mellitus, and coronary heart disease. The cumulative incidence of infection was 30.2%, population seroprevalence was 24.9%, and fatality was 9.1%.* ***Conclusions****: The incidence of SARS-CoV-2 infection in this HD unit was high. Strict biosafety protocols are required to prevent outbreaks.*

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Key words: *COVID-19; Kidney Failure, Chronic; Renal Dialysis; SARS-CoV-2.*

Prevención y control de un brote de COVID-19 en una unidad de hemodiálisis

Introducción*: La prevención y el control de la infección por SARS-CoV-2 en las unidades de hemodiálisis (HD) es un desafío.* ***Objetivo****: Describir las características clínicas y la evolución de los pacientes con enfermedad renal crónica (ERC) en HD con COVID-19, entre marzo de 2020 y el 28 de enero de 2021, que acudieron a una unidad de HD en Bogotá, Colombia.* ***Material y Métodos****: Estudio observacional prospectivo con estimación de incidencia, prevalencia y letalidad, incluyendo los resultados del cribado con RT-PCR y anticuerpos IgG e IgM anti-SARS-CoV-2 en todos los pacientes y personal sanitario de la unidad de HD.* ***Resultados:*** *Se identificaron 55 casos de pacientes en HD y 9 casos de trabajadores de salud con COVID-19. La mediana de edad de los pacientes fue de 63 años y 84% eran hombres. Cincuenta y cinco por ciento de los pacientes eran sintomáticos, con fiebre, tos y/o mialgia. Las comorbilidades más frecuentes*

fueron hipertensión arterial, diabetes mellitus tipo 2 y enfermedad coronaria. La incidencia acumulada de infección fue del 30,2%, la seroprevalencia poblacional del 24,9% y la letalidad del 9,1%. ***Conclusiones:*** *La incidencia de infección por SARS-CoV-2 en esta unidad de HD fue alta. Se requieren de protocolos estrictos de bioseguridad para evitar brotes.*

Palabras clave: *COVID-19; Diálisis Renal; Fallo Renal Crónic; SARS-CoV-2.*

At the end of 2019, a new disease caused by the SARS-CoV-2 coronavirus, which was first reported in Wuhan (China), rapidly spread worldwide, and was declared as a pandemic by the WHO on March 11, 2020. Patients with chronic kidney disease (CKD) constitute a high-risk population due to multimorbidity and age, among other factors[1]. In Colombia, it is estimated that 10% of the population has some degree of CKD[2]. According to the 2019 report of the High Cost Account, 34,658 patients were on dialysis, of whom 25,510 (73.6%) received in-center hemodialysis (HD)[3].

Following the declaration of the SARS-CoV-2 pandemic and the national order of mandatory confinement in Colombia, the scientific societies and the institutions providing dialysis services, joined efforts in order to prevent the dissemination of the virus. A series of recommendations based on the limited evidence available at that time were published, and were applied by consensus in the vast majority of Colombian dialysis units[4]. In the small areas designated for HD, it is particularly challenging to ensure adequate physical distancing. Furthermore, patients have to remain in these poorly ventilated areas for an average of 4 hours and they usually attend these centers 3 times per week. These circumstances, combined with the high comorbidity and age, resulted in an increased risk of serious disease and deaths from COVID-19[5]. The objective of this study was to describe the confirmed cases of COVID-19 in patients with chronic kidney disease in a hemodialysis unit, as well as the public health intervention strategies for prevention and control, achieved between March 2020 and January 28, 2021, at the Renal Unit of Bogota, Colombia.

Methods

This was a prospective observational study conducted in a hemodialysis center in Bogota, Colombia. All adult patients with stage 5 CKD on HD therapy between March 1, 2020, and January 28, 2021, and with a confirmed diagnosis of COVID-19 by RT-PCR test were consecutively included. Each case was followed-up for 3 months after the diagnosis. Patients with acute kidney disease requiring in-center hemodialysis were excluded.

The sociodemographic and clinical characteristics of the patients are described through absolute and relative frequencies, as well as by measures of central tendency and dispersion, after the bivariate analysis. Timelines of the cases and their orientation in space are presented; the case fatality rate was estimated, defined as the ratio between the number of confirmed fatal cases of COVID-19 (RT-PCR or specific antibodies) and the number of confirmed cases of COVID-19.

Population screening within the unit was used as a strategy for infection control and documented. Screening involved performing RT-PCR by nasal swab on January 18 and 19, 2021, and measuring anti- SARS-CoV-2 IgG and IgM antibodies in all patients and healthcare personnel of the renal unit.

The real-time reverse transcriptase polymerase chain reaction or PCR performed for diagnosis and screening, amplifies the fragments of E, N, and RdRP genes, the latter being specific for SARS-CoV-2 using Allplex Assay technology by Seegene. The amplifications are detected with probes labeled with FAM, QUASAR 670, RED 610, respectively, and are analyzed on a Bio Rad CFX96 platform using the exclusive 2019-nCov Viewer software; with a sensitivity of 100 copies/reaction. The technique for measurement of antibodies in peripheral blood was the lateral chromatography immunoassay method, with a qualitative report and a cut-off point of titers of 25 U/ml.

Results

Between March 1, 2020, and January 28, 2021; a average of 182 patients (IQR: 173-191) were

treated on the in-center HD unit, by 28 health professionals (8 nurses, 7 nursing assistants, 2 general physicians, 3 nephrologists, 4 administrative assistants and 4 individuals of the general services). Including those detected by active screening in January 2021, a total of 55 cases of COVID-19 was documented in patients and 9 in the staff. The median age in the patient group was 63 years (IQR: 28-90) and 83.6% of patients were male. Among the health personnel of the unit, median age was 29 years (IQR: 22-42) and one third of participants were male. Overall, 62.5% of participants were symptomatic (58% of the patients and 88% of the health worker).

The most commonly reported symptoms among the patients were fever, cough and myalgia (Table 1).

Of the 55 patients diagnosed during the study period, 90.9% had a diagnosis of hypertension, 50.9% had a diagnosis of type 2 diabetes mellitus, 29% had an antecedent of coronary heart disease, and 9.09% were recipients of kidney transplant. The mean body mass index was 25.6 Kg/m2, with a baseline albumin prior to infection of 3.98 g/dL (±0.39), and 25.4% of patients had residual renal function, defined as the presence of diuresis greater than 250 ml per day (Table 2).

Among the 32 symptomatic patients, the median duration on hemodialysis until the date of onset of COVID-19 symptoms was 38.5 months (IQR: 20.7-62.3), median age was 63.5 years (IQR: 50.5-73), and the majority of patients were male. In 27 patients, laboratory information was available because they required attended at the home or the emergency medical services (Table 3).

In total, 20 patients (62.5% of symptomatic patients) required hospital admission and 6 patients (18.7%) required admission to the intensive care unit. Overall, 19.05% of the patients died during hospitalization. The median length of hospital stay was 13 days (IQR 2-48). Corticosteroids were administered to 13 (59%) patients and antibiotics were administered to 13 (59%) patients. Among the six patients requiring ICU admission due to severe hypoxemia, the median stay was 2 days (IQR: 1-15), and 2 patients died (33.3%); the non-renal SOFA score was 8 points (IQR: 6-15), the APACHE II score in the first 24 hours after admission was 15 (IQR 13-33). Only 2 cases (33.3%) presented with shock requiring vasopressor support, the same proportion was managed with mechanical ventilation, during 4 and 7 days each case. One patient was transiently managed with continuous renal replacement therapy for 3 days.

A 71-year-old female patient with a history of hypertension, coronary heart disease and diabetes was documented as a case of reinfection,

Table 1. Symptoms reported by patients in the hemodialysis unit

Variable	Patients (n = 55)			Staff (n = 9)
	Total	Survival (n = 50)	Dead (n = 5)	
Age median (R)- yr	63 (28-90)	61 (28-90)	71 (62-76)	29 (22-42)
Male - no. (%)	46 (83.6)	41 (82)	5 (100)	6 (66.6)
Afro-Colombian - no. (%)	2 (3.12%)	2 (4%)	0	0
Symptoms, no. (%)				
Fever	20 (36.3)	16 (32)	4 (80)	4 (44.4)
Cough	18 (32.7)	14 (28)	4 (80)	4 (44.4)
Sore throat	9 (16.3)	8 (16)	1 (20)	1 (11)
Dyspnea	13 (23.6)	11 (22)	2 (40)	0
Diarrhea	10 (18.1)	9 (18)	1 (20)	1 (11)
Myalgia	16 (29)	14 (28)	2 (40)	5 (55.5)
Anosmia	3 (5.4)	2 (4)	1 (20)	2 (22.2)
Headache	7 (12.7)	6 (12)	1 (20)	5 (55.5)

Source: Own elaboration. N: number, R: range.

Table 2. Basal characteristics of patients

Variable	Patients (n = 55)		
	Total	Symptomatic (n = 32)	Asymptomatic (n = 23)
Age median (Range)-yr	63 (28-90)	63.5 (50.5- 73)	60 (51-68)
Distribution- n. (%)			
< 65 yr	39 (60.9)	25 (62.5)	14 (58.33)
65-80	20 (31.25)	11 (27.5)	9 (37.5)
≥ 80	5(7.81)	4 (10)	1 (4.17)
Male - n. (%)	46 (83.6)	28 (87.5)	18 (78.26)
Afro-Colombian- n. (%)	2 (3.12)	1 (2)	1 (2)
Vintage median (IQR) –yr	40.2 (19.2-48)	38.5 (20.7-62.3)	43.5 (24.1 -47.67)
Previous kidney transplant - no. (%)	5 (9.09)	1 (4.12)	4 (17.39)
Coronary disease - no. (%)	16 (29)	10 (31.25)	6 (26.1)
Hypertension- no. (%)	50 (90.9)	28 (87.5)	22 (95.6)
Diabetes- n. (%)	28 (50.9)	18 (56.25)	10 (43.5)
COPD- n. (%)	1 (1.8)	1 (3.12)	0
Cardiac failure - n. (%)	12 (21.8)	8 (25)	4 (17.4)
Neoplasm- n. (%)	6 (10.9)	3 (9.4)	3 (13)
Autoimmune disease - no. (%)	5 (9)	3 (9.4)	2 (8.7)
ECAi/RAA - n. (%)	28 (51	15 (46.8)	13 (56.5)
Corticosteroids- n. (%)	4 (7.2)	4 (12.5)	0
Immunosuppression- n. (%)	4 (7.2)	2 (6.25)	2 (8.7)
Anticoagulation- n. (%)	5 (9)	2 (6.25)	3 (13)
Weigh median- Kg	71.7 (±11.3)	71.4 (±12.3)	72.16 (±10)
BMI median- Kg/m^2	25.6 (±3.2)	26.3 (±3)	25.2 (±3.3)
Residual function- n. (%)	14 (25.4)	10 (31.25)	4 (17.4)
Baseline albumin median- g/dL	3.98 (±0.39)	3.9 (±0.4)	3.9(±0.3)

Source: Own elaboration. N= number, IQR: interquartile range, BMI: body mass index, ECAi/RAA: Angiotensin-converting enzyme inhibitors/ Renin-angiotensin antagonists COPD: Chronic obstructive pulmonary disease. Yr; years. G= grams, Kg: kilograms, dL: deciliter. M=meters.

with symptoms in July 2020 and in December 2020; a RT-PCR test was performed confirming SARS-CoV-2 infection. During follow time, 5 patients dead, with a mean age of 69.2 ±5.97 years. All fatal cases were men and hypertensive. Four patients had a diagnosis of diabetes and a history of coronary heart disease; two patients had lymphopenia on admission, median values for the following variables were: ferritin 2340 (IQR: 1687-28310) ng/mL, D-dimer 1017 (819-1076) ng/mL, troponin 105.7 (IQR: 67.2-129) ng/L, C- reactive protein 293 (IQR: 135.6-335.4) mg/L, and LDH 364 (IQR: 247-540) U/L.

Screening results

Due to the increase in positive COVID-19 cases during the second wave of infections in Colombia, massive screening of the entire hemodialysis population was conducted. In January 2021, 186 patients undergoing hemodialysis services were reported, 8 patients were hospitalized during the screening period and 2 commenced renal replacement therapy after the screening dates. Therefore, 176 patients were included for screening, 155 (88%) were screened with RT-PCR (11 patients did not consent to screening and 10 patients were recorded as cases of infection confirmed by PCR

Table 3. Labs in 27 with medical attention

Variable	Total (n = 27)	Hospital admission (n = 20)	At home (n = 7)
Hemoglobin- median (IQR), g/dL	12.1 (11.3-13.2)	12 (11.35-12.9)	12.3 (9.8-13.4)
Leucocytes- median (IQR) cel/uL	5990 (5040-7260)	6420 (5480-7520)	4600 (4556 – 6720)
Lymphocytes- median (IQR) cel/uL	660 (350-1020)	560 (335-910)	980 (620-1140)
Ferritin- median (IQR) ng/mL	1849 (43.6-53791)	2015 (1260-3532)	832.5 (491-1546)
D-dimer- median (IQR) ng/mL	1022 (150-30262)	1137.5 (690.5-1857)	458 (193-465)
Lactate dehydrogenase- median (IQR) U/L	266.2 (170-617)	298.5 (229-505)	231.1 (182.9-266)
Troponin- median (IQR) ng/L	58.2 (3-345)	67.2 (38-6-105.7)	50.8 (33.3-64.9%)
C reactive protein- median (IQR) mg/L	51.3 (1.8-348)	102.15 (22.8-261.35)	16.3 (7.8-13.6)
PaO2/FiO2 at admission- median (IQR)	281 (224-296)	273.5 (220-296)	290 (281-362)
Oxygen supplementation- n. (%)	23 (85%)	20 (100%)	3 (42-8%)
Corticosteroids- n. (%)	14 (51.8%)	14 (70%)	0
Antibiotic - no. (%)	13 (28.1%)	13 (65%)	0

Source: Own elaboration. N = number, IQR: interquartile range, G = grams, dL: deciliter. ml = milliliters L: liters.

in the last 3 months). Ten days after collecting the samples for the RT-PCR test, samples for antibodies level tests were taken from the entire population. The average age of this screened cohort of patients was 62.1 ± 17.2 years (range 19-93 years) and 68.9% of the patients were male and 46.3% had a diagnosis of diabetes.

The results of the screening with RT-PCR showed that 6.4% (n = 10) of the patients were positive (asymptomatic), 25% (n = 44) were positive for IgG, 26.5% were positive for IgM, 25% of patients were positive for IgG and IgM, in 10 cases (22.7%) patients had no history of symptoms or positive PCR test. Among the patients with positive IgG and IgM, the mean age was 58.6 ±15.4 years and 22.7% were female. The 3 cases with positive IgM and negative IgG, no symptoms, and with recent negative PCR, were considered false positives. All patients detected as positive cases by PCR at screening also had positive antibodies. For biosafety, the asymptomatic cases detected by PCR screening were isolated for 10 days.

Considering the median population at risk, the cumulative incidence of infection among patients on the hemodialysis unit was 30.2%; of the symptomatic cases, 68.7% seroconverted, with a median time of 175 days (IQR: 101-222.2) between the onset of symptoms and the date on which the sample for antibodies was taken. The population seroprevalence with a cut-off date on January 28, 2021, was 24.9%. The estimated mortality rate corresponds to 9.1%. Regarding the human resource, the cumulative incidence was 32% during the same period.

Preventive strategies implemented

Among the transversal interventions for the prevention of COVID-19 in the HD unit, they are in accordance with the recommendations published in the Colombian consensus[4] such as:

1. Re-education on hand washing and technique supervision.
2. Mandatory and correctly use of a disposable face-mask.
3. Tele-medicine.
4. Structured telephone triage of symptoms on the non-hemodialysis day and/or at the entrance to dialysis.
5. HD temperature measurement
6. HD seat distancing of 1.8 meters.
7. Waiting room limit.
8. Fixed HD seat point and schedule for each patient, in order to guarantee the same contiguous person in the HD machine.
9. HD room natural ventilation (opening windows).

10. Route and room isolation for confirmed case, different to suspected case for HD session.
11. Diagnosis prioritization for HD suspected patients.
12. The time of isolation by risk of transmissibility.
13. Health professionals used N95 masks, glasses and exclusive clothing for COVID 19 patient assistance.

The timeline cases and their specific orientation by sequence and location in the HD room is available in the supplementary material 1 and 2. We considered 2 cases were health care-associated on HD room. Given the nature of the virus and its transmissibility in the community, it was difficult to determine the presence of other outbreaks inside the center. (See supplementary material).

Discussion

Since SARS-CoV-2 pandemic emergency declaration on March 2020, our medium-sized HD center in Bogota, Colombia,established rigorous biosafety protocols and prevention guidelines under international and national guidelines[4]. In order to mitigate the risks of viral transmission, strategies for grouping patients in the available space according to their epidemiological and serological characterization were established. For example, individuals with a history of infection or seroconversion were placed next to higher-risk patients, such as older adults without antecedent of infection or positive antibodies. At the same time, a SARS-CoV-2 epidemiological surveillance program was in place, and a cumulative COVID-19 incidence of 30.2% was reported, including asymptomatic individuals detected by screening with PCR on January 2021 and antibodies during the same time frame; among symptomatic cases, 62.5% of patients required hospital admission and 18.7% required admission to the ICU.

Our data confirm the susceptibility of patients on HD to SARS-CoV-2 infection. Reports from Europe and the United States show that the population requiring in-center hemodialysis was 5 to 16 times more likely to be diagnosed with COVID-19 disease compared with the general population and approximately 20% of patients undergoing in-center hemodialysis were positive for SARS-CoV-2 infection, particularly in countries with high rates of viral circulation and in multimorbid populations[6,7,8].

In Barranquilla, the initial focus of the pandemic in Colombia, seven positive cases for SARS-CoV-2 infection were described in patients with CKD on hemodialysis requiring hospitalization[9]. Meantime, in 65 hemodialysis centers in Wuhan, China, the original focus of the epidemic, show that of 7154 patients, a diagnosis of COVID-19 was confirmed in 154 patients, average age was 63.2 years, 57% of patients were male, and the majority had cardiovascular comorbidity (68.7%). And reported mortality rate of 2%, slightly higher than the mortality rates reported among the general population in Wuhan at the same time[10]information about this population of patients is limited. Using data retrospectively collected from a registration system that included 7154 patients undergoing hemodialysis at 65 hospitals in Wuhan, China, the authors found that 154 patients had laboratory-confirmed COVID-19. In a detailed analysis of epidemiologic and clinical characteristics for 131 COVID-19 patients who provided oral consent, they showed that hemodialysis centers are high-risk settings for COVID-19, and described interventions that effectively prevented COVID-19 spread among patients at such centers. These measures included requiring patients to wear a medical mask during dialysis and in public, conducting universal screening for the infection, and isolating infected patients and directing them to designated hemodialysis centers.Background Reports indicate that those most vulnerable to developing severe coronavirus disease 2019 (COVID-19.

Different outcomes were reported in a cohort of patients in New York including 57 patients on hemodialysis and 59 on peritoneal dialysis with confirmed COVID-19 who required hospitalization. The patients had a high prevalence of hypertension (98%) and type 2 diabetes (69%). The most frequent symptoms were fever (49%) and cough (39%). During the follow-up time, 18 patients died (31%) after an average of 6 days of hospitalization, including 75% of those who required mechanical ventilation[11]the outcomes for COVID-19 in this patient population are not clear. In their study of 59 patients with ESKD and COVID-19 receiving dialysis at a New York City

medical center, the authors found that although the presentation of patients on dialysis with COVID-19 was similar to that of the general population, these patients have poor outcomes, including 31% overall mortality and 75% mortality among those requiring mechanical ventilation. In addition, higher levels of inflammatory markers associated with severe disease. This information will help inform care of patients on dialysis who develop COVID-19 and reinforces the importance of infection control measures when treating this vulnerable population.Background The relative immunosuppression and high prevalence of comorbidities in patients with ESKD on dialysis raise concerns that they may have an elevated risk of severe coronavirus disease 2019 (COVID-19).

In France, the national registry of patients on dialysis (*French REIN registry*) provides a more robust source of data to identify the number of confirmed cases of COVID-19 infection used as the denominator for the case fatality rate[7]. A total of 1621 patients with confirmed COVID-19 infection were reported between March 16 and May 4, 2020. Of these, 344 died, estimating an incidence of < 1% to 10% among the different regions. The probability of infection was higher among men, patients with diabetes, and among patients with limited functionality and it was less frequent among patients undergoing dialysis at home compared to that requiring in-center hemodialysis. The mortality rate among patients with a positive diagnosis of COVID-19 was 21%. Age, hypoalbuminemia, and the presence of coronary heart disease were independently the risk factors for mortality[7].

Patients on HD are susceptible to infection, and have an increased mortality risk of 130% compared to patients with COVID-19 without CKD[12,13,14]. In our cohort, the mortality rate was 9.1% over the 10 month-observation period among patients with hypertension, diabetes, and coronary heart disease. These finding conflicts with the 16-32% mortality rate reported among patients with well-established risk factors for death from COVID-19, such as hypertension, obesity, diabetes, and heart disease[14,15,16,17]. Explaining a little bit the divergence of information on the frequency of infection and mortality, a significant burden of asymptomatic cases within the HD centers has been observed.

In our center, sero-prevalence after the second wave of transmission in Colombia was 25%, which is consistent with 28%-36% reported in studies involving HD units in the United Kingdom and New York[18,19].

Finally, and to get the most information, derived from the DOPPS registry, we can obtain the global effect of the COVID-19 pandemic on the patients on dialysis, including 15 countries from Europe, Asia and America. In this study, it was possible to identify positive cases by population, which vary by more than 100 times among the participating countries, with the highest number of cases reported in the USA, followed by Belgium. Mortality rates ranged from 10 to 30%, with the highest number of deaths per population recorded in Belgium[20].

Conclusions

The findings of this study show a high frequency (~25%) and mortality (9.1%) of SARS-CoV-2 infection on HD. Our data are consistent with results reported in other centers. The frequency of asymptomatic and/or pauci-symptomatic patients is important, and may be explained by the immunological biology of the patients on dialysis.

List of abbreviations

SARS-CoV-2: severe acute respiratory syndrome by coronavirus 2.

HD: hemodialysis

CKD: chronic kidney disease.

COVID-19: coronavirus infectious disease 2019

RT-PCR: reverse transcription - polymerase chain reaction

IgG: Immunoglobulin G

IgM: Immunoglobulin M

WHO: world health organization

IQR: Interquartile range

CRP: C-reactive protein

ICU: intensive care unit

SOFA: Sequential Organ Failure Assessment

APACHE: Acute Physiology and Chronic Health disease Classification System II

LDH: lactate dehydrogenase

DOPPS: Dialysis Outcomes and Practice Patterns Study

USA: United States of America

Declarations

Ethics approval and consent to participate: The research protocol was approved by the Research Ethics Committee of the Sanitas University Foundation (CEIFUS 087-21). The study complies with the Declaration of Helsinki, the ethical guidelines for biomedical research prepared by the Council for International Organizations of Medical Sciences (CIOMS) and Habeas Data Law 1581 of 2012. The research is categorized as risk-free, according to Resolution 8430 of 1993 of the Colombian Ministry of Health and did not require informed consent.

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