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One Year Experience of COVID-19 Disease on 700 Chronic Dialysis Patients from Ecuadorian Highlands

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1. Abstract

1.1. Introduction: In December 2019, first Covid-19 disease cases were reported. The pandemic spread with 114.217.365 cases and 2.533014 deaths worldwide in March 2021, with 286.155 cases and 15.811 deaths in Ecuador. The aim of this work is to share COVID-19 disease impact on 700 chronic dialysis patients from Ecuadorian highlands, which represents almost 7% of Ecuadorian dialysis population, after one year of pandemic.

1.2. Materials and Methods: Observational-prospective-multicenter study on 700 Latin-American chronic dialysis patients of five different cities from Ecuadorian highlands. Patients were followed since February first, 2020 until 31 January 2021. Patients with COVID-19 symptoms were identified and diagnosis was made exclusively with positive nasopharyngeal swabs PCR testing. Oxygen saturation below 90% at presentation (LOS) classified disease presentation as severe, moderate if symptoms without LOS and asymptomatic if no symptoms. Hospital-stay, time until negative PCR, mortality and laboratory findings were collected.

1.3. Results: Two-hundred and five patients (29%) presented COVID-19 disease related symptoms; 115 patients tested positive (16%), 60% were men (p=0.03). Twenty-five patients died (22%). Mortality was related with age above 64 years old, saturacion<90% and severe disease presentation (p=0.03), previous pulmonary pathology and hospitalization (p=0.01). Hospitalization was needed in 74 patients (64%) with hospital stay 11 days (4-15), days until death during hospitalization of 12 days (4-19) and time until negative PCR 20 days (10-25). Symptomatic time was 16 days (11-26).

1.4. Conclusion: COVID-19 disease was more frequent in men and has added up to 22% of extra mortality to chronic dialysis population. Patients older than 64 years old, previous pulmonary pathology, LOS at presentation are at higher risk of mortality which demands a closer follow-up in this subgroup. Health care burden due to COVID-19 is high in dialysis population suggesting that vaccination programs must include dialysis patients and staff involved in their care to diminish mortality, infections and health care burden produced by the disease.

2. Introduction

First patients with COVID-19 disease were reported in Wu-

han-China in December 2019 [1,2]. The first COVID-19 case reported by Ecuadorian government was in a 70-year-old woman who arrived from Spain together with her sister and both died of the disease [3], then the pandemic spread worldwide and locally at great speed, producing a big mortality in countries like Italy, Spain, USA, and Brazil. Nowadays, after more than one year of pandemic, reports by March 2021 gives a total of 114.217.365 cases and 2.533014 deaths worldwide with 286.155 cases and 15.811 deaths in Ecuador [4].

Ecuador is a South American development-country with an estimated prevalence of Chronic Kidney Disease (CKD) of 11% [5] with almost 10.000 patients on renal replacement therapy [6]. "Menydial Kidney Clinics" are private dialysis units that have provided dialysis treatments, Peritoneal Dialysis (PD) and Hemodialysis (HD) for more than 40 years in Ecuador. By February 2020, the dialysis centers served to 700 patients in five different cities of Ecuadorian highlands who had to face the pandemic with low social incomes, adding one more comorbidity to End Stage Renal Disease (ESRD) [7]. This probably has worsened Ecuadorian dialysis patient's prognosis significantly.

The aim of this work is to share COVID-19 disease impact on 700 chronic dialysis patients from Ecuadorian highlands, which represents almost 7% of Ecuadorian dialysis population, after one year of pandemic, share population characteristics, clinical presentation, clinical outcomes, public health system burden of those who suffered the disease after one year of follow-up.

3. Methods

Observational-prospective-multicenter study in 700 Latin-American dialysis patients (HD and PD) of five different cities from Ecuadorian highlands who were receiving dialysis treatment in Menydial Kidney Clinic. Two-hundred and five consecutive patients (29%) were suspicious of COVID-19 disease after presenting any of the symptoms linked with COVID-19 disease [8] and were followed between February, first 2020 until 31 January 2021. COVID-19 disease confirmation was made exclusively positive testing on PCR nasopharyngeal swabs. Demographics, clinical data, comorbidities, hospital stay, time until death after hospitalization, symptomatic time, days until negative PCR were collected in those with confirmed disease from medical-record program (Nefrosoft®) and analyzed with SPSS statistics® 24.0 version. Complementary tests were collected: basic hemogram with platelet count, lymphocyte count, C reactive protein, chest x-ray, and oxygen saturation were obtained in all patients and recorded for analysis. Severity of disease presentation was classified according to COVID-19 disease guidelines [9] and was severe if patient presented with oxygen saturation below 90%, moderate if symptoms present without LOS and asymptomatic if no symptoms present. Continuous with normal distribution variables were expressed as mean and standard deviation or were indicated as median and interquartile range if asymmetric. P-values were calculated with T student test in quantitative variables with normal distribution, U-Mann-Whitney for those quantitative asymmetric variables, chi square and Fisher´s exact test for qualitative variables. Study was approved by ethics committee of the center.

4. Results

Demographics and baseline characteristic of studied population are described in (Table 1). Seven-hundred chronic dialysis patients from five cities of Ecuadorian highlands who were receiving dialysis treatment in Menydial Kidney Clinic initiated follow up. Two-hundred five patients (29%) presented COVID-19 disease related symptoms, 115 (16%) tested positive on PCR tests, 69 (60%) were male (p=0.03) and 114 (99%) were on HD technique Twenty-nine patients (3%) were negative. Baseline characteristics of COVID-19 confirmed patients as well as co-morbidities, clinical presentation and other variables studied are described at (Table 2). A quarter of patients presented gastrointestinal symptoms at disease presentation (abdominal cramps/pain, diarrhea).

Complementary tests were obtained, and most frequent findings were abnormal chest X ray in 71 patients (62%), oxygen saturation <90% in 66 (57%) patients, with median value of 77% (66-89%), 36 patients (31%) presented lymphopenia and 16 subjects (14%) with C-reactive protein levels above 40 mg/l (x8 above normal value). Complementary tests findings PCR are described in (Table 3).

Patients with hospitalization where significantly older when compared with those with ambulatory treatment (61±14 vs 54.4±13.2 years; p=0.01). Patients older than 55 years old presented oxygen saturation <90%, severe disease at presentation (p<0.001) and hospitalization (p=0.03) significantly more when compared with younger patients.

Hospital stay was 11 days (4-15 days) with no differences when compared for gender (p=0.26), age (p=0,07), abnormal chest x-ray (p=0.14), lymphopenia (p=0.27) and severe disease presentation (p=0.94).

Twenty-five patients with positive PCR test died during the study (22%), 21 died at hospital, 3 at home and one at dialysis session. Fifteen were male (p=0.07), one from PD with significative difference in mortality in patients older than 64 years old (p=0.03), previous pulmonary disease (p=0.01), hospitalization (p=0.01), oxygen saturation and severe disease at presentation (p=0.03). Quito and Ibarra were cities with most deaths occurred, with ten deaths each. (Figure 1) shows mortality distribution around five cities studied.

Time until death after hospitalization was 12 days (4-19) with a hospital-stay of 11 days (4-15) and 20 days (10-25) until negative PCR.

Sixty-four patients (54%) had contact with symptomatic people

and 10% were infected by other dialysis fellow while sharing transportation to treatment. Contagious rate from all 5 clinics was 16 cases for each 100 patients exposed with the highest rate found in capital Quito (Ecuador´s capital). (Figure 2) shows contagious rate per center during follow-up.

In 69 patients (10%) PCR swabs were not possible to be performed due to local/economical limitations, 36 (52%) were male (p=0.7), with a median age of 61 years (50-71). Twelve patients died (2%) with a mean age of 67 years with no influence in mortality (p=0.51).

Number of positive cases per month and per unit are shown in (Figure 3). July had the highest peak of contagious with 30 new cases followed by August and June with 18 and 17 patients, respectively. To note, we had a total of 182 patients that received their treatment on isolation room, with the highest peak in July with 44 individuals followed by August and June with 31 and 21 subjects, respectively.

Table 1: Demographic and baseline characteristics of total population of dialysis center.

Population studied (N=700)	Results
Age	63 (± 11.3 años)
Sex	
-Male	397 (58%)
BMI	25.55 (± 6.2 Kg/m^2)
Etiology of CKD	
-Diabetes Mellitus	32%
-Others	68%
Co-morbidites	
-Hypertension	38%
-Diabetes Mellitus	30%
-Pulmonary disease	20%
-Ischemic heart disease	12%
-Immunocompromised	22%
-Co-morbidites	
Vascular access	
-Catheter	10%
-Native fistula	79%
-Prosthetic fistula	11%
Dialysis Modality	
-HD	697
-DP	3

HD: Hemodialysis; DP: Peritoneal dialysis; BMI: Body mass index; CKD: Chronic Kidney disease

Table 2: Demographic features and outcomes in dialysis patients with confirmed COVID-19 disease

Patients Characteristics (n=115)	Results
Age	63 (± 5.3 years)
Sex	
Male	69 (60%)
BMI	23.5 (± 4.2 Kg/m2)
Time in Dialysis*	3 (1.5-6.5 years)
Dialysis Modality	
-HD	114 (99%)
-PD	1 (1%)
Co-morbidites	
-Hypertension	105 (91%)
-Diabetes Mellitus	47 (41%)
-Pulmonary disease	39 (34%)
-Immunocompromised	31 (27%)
Clinical Presentation	
-Asymtomatic	10 (9%)
-Mild	79%
-Severe	11%
Most Frequent Symptoms	
-Cough	96 (83%)
-Fever	90 (78%)
-Myalgia/Athralgia	67 (58%)
-Gastrointestinal symptoms	29 (25%)
-Anosmia	15 (13%)
-Dysgeusia	19 (16%)
Hospitalized Paients	74 (64%)
Outcomes	
-Recovered	90 (78%)
-Death	25 (22%)
Global Contagious rate	16/100 patients
Previous contact with suspects	64 (54%)
Symptomatic time*	16(11-26) days
Time until negative PCR*	20 (10-25) days
Time until death*	12 (4-19) days
Hospital stay*	11 (4-15) days

*Values expressed as median and interquartile range. BMI: Body mass index, HD: Hemodialysis. PD: Peritoneal dialysis; PCR: Polymerase chain reaction test. +: p<0.05

Table 3: Complementary tests findings in dialysis patients with confirmed COVID-19 disease

Complementary tests (n=115)	Results
Pathological chest X-ray	71 (62%)
Lymphopenia (<1000 mm3)	36 (31%)
Lymphocytes count per L	1221,8 (700-1260)*
Oxygen saturation ≤ 90%, n (%)	66 (57%)
Oxygen saturation value, (%)	77 (66-89)*
C-reactive protein (mg/L)	54 (23-188)*
C-reactive protein above 40 mg/L	16 (14%)

*Values expressed in median and interquartile range.

Table 4: Studied variables in dialysis patients with confirmed COVID-19 disease and p-values

*Mortality	p-value
Age ≥ 64 years	0.03
Severe disease presentation	0.03
Previous pulmonary pathology	0.01
Low oxygen saturation (<90%)	0.03
Hospitalization	0.01
Lymphopenia	0.2
Hypertension	0.35
Diabetes	0.2
Inmunocompromised status	0.89
Abnormal chest-x-ray	0.84
**Age > 55 years old	
Severe disease at presentation	<0.001
Low oxygen saturation at presentation	<0.001
Hospitalization	0.03
+Male	
COVID-19 infection	0.03

*p-value calculated between groups who died vs those who survived.
**p-value calculated between population below 55 years old and older.
+ p value calculated between both genders.

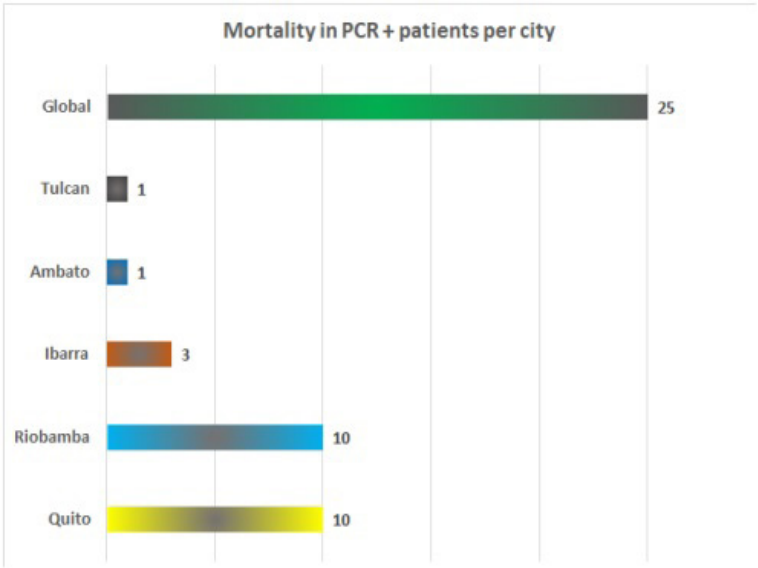

Figure 1: Mortality in patients with confirmed disease patients per city.

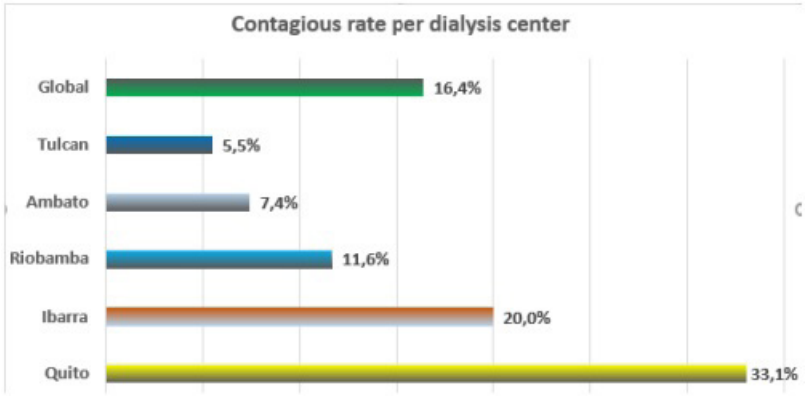

Figure 2: Contagious rate per center during follow-up period

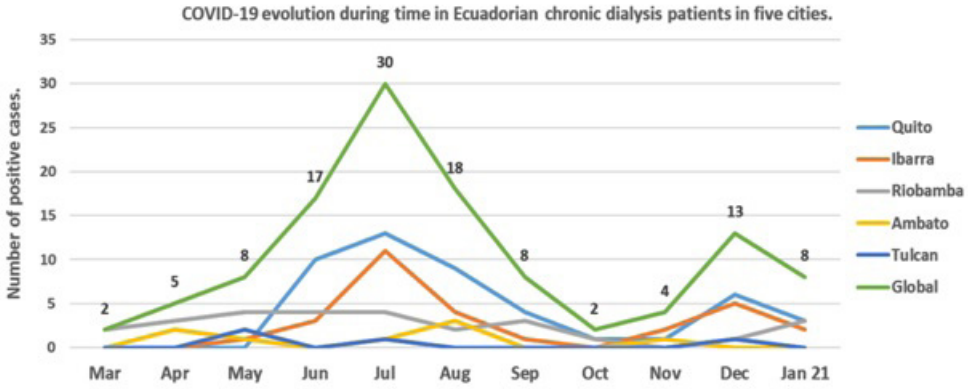

Figure 3: Number of positive COVID-19 cases per month, per city and globally during follow-up in chronic dialysis patients from 5 different cities from Ecuadorian highlands.

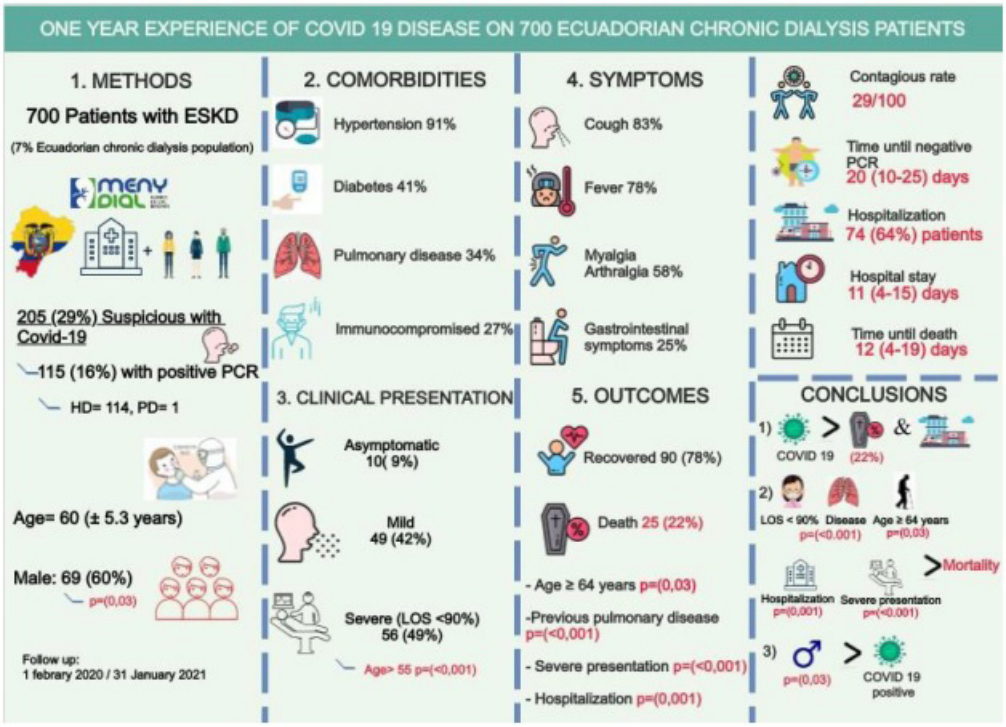

Figure 4: Visual abstract of original investigation

5. Discussion

This study denotes COVID-19 disease evolution and impact on 700 chronic dialysis patients (7% of local dialysis population) from five different cities throughout Ecuadorian highlands who were attending to a private Nephrology care center network (Menydial Kidney Clinic) during one year of pandemic outbreak. COVID-19 disease incidence in chronic in-center HD patients is variable among different countries, for example in one HD center in Madrid-Spain was 41.1% [10], 16% in other series reported in Wuhan-China [11] and 23% in previous local reports [12] with global prevalence along five cities after one year of follow-up was 16.4%. More Latin-American data is needed to compare different realities. Quito had the highest contagious rate when compared to other cities in part due to its better diagnostic capacity with PCR tests, low rural population, and is the city with the highest infection rate of Ecuador [13].

Male patients were infected significantly more than women without differences in mortality although p-value suggest that differences might be seen if more population were studied. This gender predilection has been analyzed in other series and several factors may explain this phenomenon such as sex hormones, differences in coagulation pattern, higher cardiovascular disease risk in male population, different smoking/drinking habits and differences in immune system activity between gender [14,15].

Clinical presentation and percentage of asymptomatic patients were similar as other studies [16,17]. Gastrointestinal symptoms must be taken in count when identifying and isolating suspicious patients for diminishing COVID 19 transmission because up to a quarter of patients presented gastrointestinal symptoms at disease presentation like in other studies [18,19]. It is known that CKD represents a key risk factor for severe COVID-19 disease and that dialysis population have up to 5-20 times higher infection risk when compared to general population, higher case-mortality rate (up to 32%) and up-to 430 higher mortality risk, depending on age, when compared to general population [20,21]. This is consistent with our findings where half of patients of our series presented with severe disease and more than half required hospitalization producing a high health care burden to public health system and a rise in mortality in this population.

After first COVID-19 case was reported in Ecuador measures to prevent and diminish contagious spread were taken immediately after knowing the Spanish experience where there were more than 65.000 health caregiver infected at initiation of pandemic outbreak [22]. Protective personal equipment, N95 masks, facial shields, daily fourth-generation quaternary ammonium spread in all centers, bi-monthly COVID-19 antibody screening to workers and patients as well as standard general measures to prevent contagious spread were distributed to all center workers constantly, even so, a quarter of workers from five centers were infected during pandemic. Detailed results of COVID-19 impact on health care and administrative workers from dialysis centers will be published elsewhere.

Pandemic has distributed along time in five centers studied with peaks and valleys as seen in healthy local population, indicating that periods of time where there are massive events and people interaction (deconfinement, Christmas and new year's festivi-

ties, president elections, national or local holidays) must alert health-workers of a fast increase of suspicious cases, some of them asymptomatic, and patients to take all measures in their familiar environment.

The highest peak of positive cases occurred in July 2020, by that time we faced an exponential grow of suspected/confirmed cases by creating isolation rooms in all centers from different cities fast enough and with enough capacity to cover the quick and continuous demand with the accomplishment of all bio-security measures without any disturbance to the non-suspicious patients. Nowadays, in March 2021, we are entering in the third peak just after carnival holidays and presidential elections without receiving yet massive vaccination to chronic dialysis population and workers.

Initially, isolation time in confirmed patients was decided by one negative result on PCR nasopharyngeal swabs after testing positive, concluding with our results that each patient needed at least 2 weeks of isolation, some cases more, something to notice when organizing time, shifts and staff for that area. Nowadays the CDC guidance for SARS-COV-2 infection in health care settings in "symptom-based strategy for discontinuing transmission-based precautions" section mentions that in asymptomatic patients with mild to moderate disease who are not severely immunocompromised 10 days after first symptom appear and at least 24 hours have passed since last fever without the use of fever-reducing medications with symptoms improvement. In those with severe disease or severely immunocompromised isolation may be necessary for at least 10 days and up to 20 days since symptoms first appeared and at least 24 hours have passed since last fever without the use of fever-reducing medications and symptoms improvement [23]. These strategies clearly diminish isolation time when compared with time until negative PCR.

Mortality was inferior to other series reported [24-27]. This may be due to younger population when compared with industrialized countries such as USA, Spain. Measures taken in the dialysis centers to face pandemic like constant medical assessment, isolation if clinical suspicion or ambulatory symptomatic contact, ambulatory follow-up with phone calls, complementary tests when needed, prompt treatment initiation if needed (steroids, antibiotics, prophylactic-dose-anticoagulation, oxygen supplementation during treatment and home) avoidance of shared transportation to treatment if disease suspicious. Majority of deaths were in July when contagious peak reached to our country and to five different cities indicating that public health services saturation may have an important role in mortality [28]. In our series we noted that mortality was more common in elderly patients (>64 years old), previous pulmonary pathology, hospitalization, low oxygen saturation at presentation and severe disease at presentation (common in patients older than 55 years old), findings that must encourage us to have a more conscious care to this sub-group of patients. We didn´t find any complementary test to be related with death or fatal event, however recent studies have shown that early and significant reduction in C-reactive protein levels after steroid therapy is associated with reduced mortality in patients with COVID-19 disease [29]. Lymphopenia was developed in one third of patients as in other papers30 and it could be a marker of suspicion and more severe disease in symptomatic population (Xiong F). Riobamba, a city with low economical and health resources, high rural and indigenous population equals in deaths to Quito, suggesting that social factors like poorness, low local health care resources and low education might be related and influence in mortality.

COVID 19 disease is known to increase health care burden to public health system [31] complicating the use of health resources to other patients due to prolonged burden of hospital services. This is especially relevant when our data, that only represents 7% of chronic dialysis from Ecuador, shows that more than half of dialysis patients diagnosed of COVID-19 disease had a median hospital-stay up to two weeks, or more in those with more severe disease. This high health care burden could be dramatically reduced if massive vaccination programs would consider dialysis population as a priority group to receive immunization, which would reduce the number of seriously ill patients in hospitals, health care burden and improvement of health care services after hospital decongesting. This could represent an economic saving to local state, as seen in Israel after initiation of massive vaccination programs [32] and Asturias after vaccination in elderly residences [33]. Recent reports showed chemoprophylaxis to be an effective measure to combat and diminish widespread of infection among patients with kidney disease as well as their contacts[34], strategy thar could be consider locally if as another measure to diminish local infection widespread.

Local limitations (south American development country) were important during pandemic outbreak. The prolonged waiting time for definite PCR results with public health system at initiation of pandemic outbreak, taking up to 15 days in some cases for a definite result prolonging unnecessarily isolation time in some patients. This situation forced the use of private laboratories to process PCRs due to their efficiency and speed in swabs processing (mean time 72 hours) even though most of time patients had low social incomes and didn´t have resources to afford them with the clinic having to pay for them or as in some cases described PCR could not be performed.

Another important local limitation is the low percentage of population in domiciliary-dialysis technique. By 2015 only 10% of total local dialysis patients where on PD [35] which is also reflected in our series where PD reflects only 1% of studied population. In the Spanish registry by the Spanish Nephrology Society, PD population patients where less infected (3%) and had less mortality (15%) when compared with in-center HD and kidney transplanted patients [36]. In terms of facing pandemic after viewing the results achieved in other publications [36, 37], PD or home-based dialysis

techniques are a powerful tool to fight pandemic to reduce disease spread and mortality in low-income countries where it is not expected massive vaccination programs soon. Local authorities must encourage and promote these home-based techniques as a state policy to save lives and protect local economy when is known that pandemic will last much more time in countries that delay massive immunization for any reason.

Limitans of the study were a small sample size of peritoneal dialysis patients which difficult the knowledge of outcomes in home-based-techniques patients extrapolating findings only to in-center HD patients. Another weakness of the study was difficulty to perform PCR swabs to all suspicious patients which clearly diminish diagnostic capacity and more exact results. This happened especially in rural cities where there is lack of economic and health care resources. Dialysis centers studied are second level health-care-centers with basic tools for attention as basic laboratory, X-ray studies only in some centers which complicated performing more complementary tests to analyze their association with outcomes. Measures and treatments received during hospitalization were not share with medical staff from our centers when patients were discharged which difficulted us to analyze in-hospital treatments and outcomes.

Strengths of the study are a homogenous sample with a sample size studied that represents a good external validity that represents local reality as well as reliable data collection.

6. Conclusions

COVID-19 disease was more frequent in men and has added up to 22% of extra mortality to chronic dialysis population. Patients older than 64 years old, previous pulmonary pathology and oxygen saturation below 90% at presentation are at higher risk of mortality which demands a closer follow-up in this subgroup. Health care burden, disease severity and mortality due to COVID-19 disease is high in dialysis population suggesting that massive vaccination programs must include chronic dialysis patients and staff involved in their care to diminish mortality, high-rate infections, and burden on the health care system. Domiciliary therapies (PD, domiciliary-hemodialysis) must be strengthened by local authorities to diminished COVID-19 disease spread and mortality in this population. Quick diagnosis confirmation by PCR nasopharyngeal swabs is critical to organize health and human resources which are short in developing countries with weak public health system.

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