Kidney360

COVID-19 Antibodies and Outcomes among Outpatient Maintenance Hemodialysis Patients

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Abstract

Background Patients on maintenance hemodialysis are particularly vulnerable to infection and hospitalization from severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). Due to immunocompromised patients and the clustering that occurs in outpatient dialysis units, the seroprevalence of COVID-19 antibodies in this population is unknown and has significant implications for public health. Also, little is known about their risk factors for hospitalization.

Methods Three outpatient maintenance hemodialysis units affiliated with a major teaching hospital in the New York area were studied. We determined rates of SARS-CoV-2 positivity *via* nasopharyngeal, real-time, reverse-transcriptase PCR (RT-PCR); SARS-CoV-2 IgG seropositivity; hospitalization; and mortality.

Results Of 367 patients, 28% had either SARS-CoV-2 seropositivity or PCR positivity. Prevalence across the three respective units was 7%, 32%, and 70%. Those who were either antibody or PCR positive were significantly younger (65 versus 69 years, $P=0.05$), and had a higher prevalence of Black race (43% versus 30%, $P=0.001$) and Hispanic ethnicity (32% versus 12%, $P<0.001$) compared with those who tested negative. Higher positivity rates were also observed among those who took taxis and ambulettes to and from dialysis, compared with those who used personal transportation. Antibodies were detected in all of the patients with a positive PCR result who underwent serologic testing. Of those that were seropositive, 32% were asymptomatic. The hospitalization rate on the basis of either antibody or PCR positivity was 35%, with a hospital mortality rate of 33%. Aside from COPD, no other variables were more prevalent in patients who were hospitalized.

Conclusions We observed significant differences in rates of COVID-19 infection within three outpatient dialysis units, with universal seroconversion. Among patients with ESKD, rates of asymptomatic infection appear to be high, as do hospitalization and mortality rates.

KIDNEY360 2: 263–269, 2021. doi: https://doi.org/10.34067/KID.0006292020

Introduction

The severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) has brought on a worldwide pandemic with lethal consequences. Those at highest risk for adverse outcomes include the elderly and those with preexisting health conditions (1,2), such as CKD, which is a well-established risk factor for mortality and morbidity in the general population and in those with coronavirus disease 2019 (COVID-19) (3,4). The risk for adverse outcomes may be especially high among individuals with ESKD, because they are at high risk for infection-related complications (5). Moreover, in-center patients on maintenance hemodialysis also have frequent encounters with the healthcare system, and at least one study has shown they have a higher risk of contracting SARS-CoV-2 compared with those performing home hemodialysis (6).

Much remains unknown about the incidence of COVID-19 infections, risk factors, and outcomes in this highly vulnerable population. Studies from China, Italy, and England have reported a broad COVID-19 incidence rate of 2%–30% among outpatient hemodialysis centers, with mortality up to 30% (6–8). These studies identified cases on the basis of clinical features and/or positive quantitative, real-time, reverse-transcriptase PCR (RT-PCR) assays of nasopharyngeal swabs, which were mostly performed on patients who were symptomatic. These PCR tests are prone to false-negative results (9) and, unfortunately, asymptomatic transmission of SARS-CoV-2 is also common (10). Therefore, the true incidence of COVID-19 infection in this medically vulnerable group is unknown. Serologic SARS-CoV-2 IgG antibody testing has been used to detect prior infections, with reported sensitivity and specificity of some assays approaching 100%, depending on the timing postinfection (11). Antibody testing in outpatient hemodialysis units has been limited, but may help provide a better assessment of SARS-CoV-2 epidemiology.

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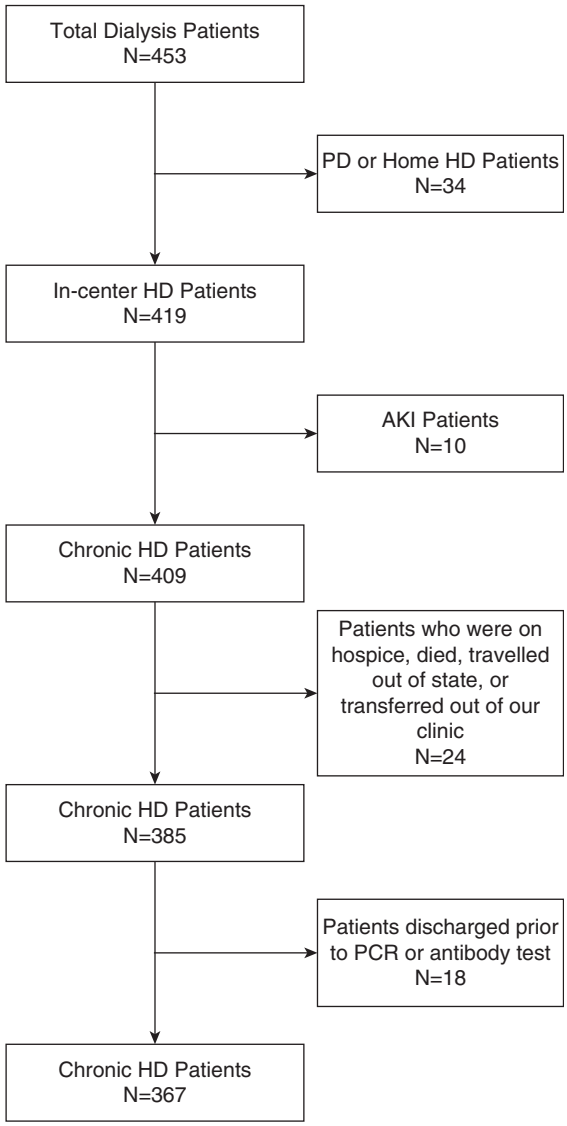

Figure 1. | **Derivation of study cohort.** HD, hemodialysis; PD, peritoneal dialysis.

One study from a small pediatric population in Indiana (12) demonstrated high rates of asymptomatic seroconversion in both patients (23%) and healthcare workers (44%). Reports from outpatient dialysis units in China and England, using serologic testing, found rates of asymptomatic infection of 51% and 40%, respectively (13,14). These studies have been limited by restricted demographics and comorbidities, utilization of data from community-based (as opposed to nursing home–based) dialysis units only, and lack of hospitalization and mortality data. It is vital to understand the extent of spread (both symptomatic and asymptomatic) within a dialysis unit, with important ramifications from an infection prevention and control standpoint. Additionally, although risk factors for more serious consequences of COVID-19 have been elucidated in the general population, it is unclear whether the same risk factors hold true for patients on in-center dialysis. Finally, it is also not clear what is the full extent of seroconversion in a relatively immunosuppressed ESKD population.

To date, no study has addressed all of these issues in a multiethnic cohort. We addressed this limitation by analyzing data from diverse outpatient dialysis units in the New York City region. Between March and May 2020, New York was the epicenter of the American COVID-19 pandemic, and dialysis facilities had significant rates of COVID-19 infection. With near-universal antibody testing, we were able to explore asymptomatic transmission within these units, estimate rates of seroconversion, and determine characteristics associated with COVID-19 infection and hospitalization.

Materials and Methods

Study Population

Patients were examined from three outpatient dialysis units in the New York University (NYU) Winthrop Outpatient Dialysis Network. All units are affiliated with NYU Winthrop Hospital, which is a teaching hospital within the NYU Langone Healthcare system and located just outside New York City in Mineola, New York. Two of the three units are stand-alone units (Mineola and Bethpage), whereas a third is centered within a subacute rehabilitation facility (Sun Harbor). Inclusion criteria included all patients with ESKD on in-center hemodialysis who were active at one of these units as of February 1, 2020, because COVID-19 may have been undergoing community transmission in the New York region as early as February 2020 (D. Stadlbauer *et al.*, unpublished observations). Exclusion criteria were all patients on home dialysis (peritoneal dialysis and home hemodialysis), because their risks of SARS-CoV-2 acquisition are vastly different, and any patients who did not undergo either SARS-CoV-2 antibody or PCR testing due to passing away, transfer to another dialysis unit, or other circumstances (see Figure 1). Follow-up was available through August 25, 2020. This study was approved with a waiver of informed consent and a Health Insurance Portability and Accountability Act waiver by the NYU Grossman School of Medicine Institutional Review Board.

Data

Data were extracted from a unified electronic health record (EHR) that spanned all three dialysis units. Variables used in these analyses were obtained using established reporting algorithms within the EHR and included age, race, sex, SARS-CoV-2 antibody titer and PCR results, dialysis vintage, and key comorbidities (congestive heart failure, hypertension, vascular disease, diabetes mellitus, chronic obstructive pulmonary disease [COPD]). Transportation-modality details were maintained in the EHR, with any missing data provided by social workers at each dialysis unit. Results of SARS-CoV-2 PCR testing were obtained by the dialysis unit on all patients who were tested, even if testing occurred outside of the NYU system. Additionally, any positive SARS-CoV-2 PCR results were recorded separately from the EHR, as an added layer of redundancy. Early during the pandemic when COVID-19 testing was limited, anyone who presented with potential symptoms and could not be tested was labeled as a "person under investigation" and was empirically isolated, as were any patients who tested positive. SARS-CoV-2 IgG antibody testing was performed universally on all patients on in-center hemodialysis starting from May 2020, and the only

patients missing tests were those who were discharged from our dialysis centers before testing. All serologic tests were exclusively performed at NYU Winthrop Hospital and were performed on the basis of the Abbott chemiluminescent microparticle immunoassay, which detects antibodies against the nucleocapsid protein of SARS-CoV-2. This assay has a sensitivity of 100% and a specificity of 99.9% in patients 17 days after symptom onset (11).

Outcomes

There were four outcomes of interest: (*1*) overall prevalence of SARS-CoV-2 IgG seropositivity in the three in-center hemodialysis units; (*2*) proportion of patients testing positive for SARS-CoV-2 RT-PCR who went on to develop antibodies; (*3*) proportion of patients who were asymptomatic who developed antibodies; and (*4*) severity of COVID-19 disease, defined as requiring hospitalization. Hospitalization was ascertained *via* EHR if it occurred at an NYU hospital, whereas hospitalizations at other institutions were recorded by the dialysis unit in a separate record. We only counted hospitalizations for which the patient was admitted specifically for COVID-19, and did not include hospitalizations for other reasons, during which SARS-CoV-2 PCR positivity may have been an incidental finding. We believe this increases the validity of using hospitalization as a surrogate for more severe COVID-19. In addition, we found that all positive PCR tests were performed within 7 days of hospitalization, with many performed on the day of hospital admission. Mortality was also tracked at each dialysis unit.

Statistical Analyses

Baseline characteristics were grouped by those who had either SARS-CoV-2 IgG antibody or PCR positivity (classified as "COVID-19 positive") versus those who had neither, and was summarized using medians with interquartile ranges for continuous variables and frequencies for levels of categoric variables. The same was done for characteristics of patients positive for COVID-19 who were hospitalized versus those who were not. Continuous variables were assessed for normality using the Kolmogorov–Smirnov test and visual graphs, such as histograms and Q-Q plots. The Wilcoxon rank-sum test was used to test for differences between continuous variables, and the chi-squared or Fisher exact tests were used to test for differences between categoric variables. Two-sided $P<0.05$ was considered to be statistically significant. All analyses were performed with SAS version 9.4 (SAS Institute, Cary, NC).

Results

Baseline Characteristics of Patients with and without COVID-19

Of 385 patients registered at our units as of February 1, 2020, 367 met the inclusion criteria and had either SARS-CoV-2 PCR ($N=156$) or IgG antibody ($N=343$) tests and were included in the analyses. Characteristics of this cohort categorized by COVID-19 status are shown in Table 1. Median age for the overall cohort was 68 years (interquartile range, 56–77 years); 44% were female, 45% were White, 34% were Black, and 17% were Hispanic. Those who were COVID-19 positive were significantly younger (65 versus 69 years), and were more likely to be Black (43% versus 30%) or Hispanic (32% versus 12%). Black patients had a disproportionate positive test rate (37% versus 21% of White patients), as did Hispanic patients (52% versus 23% of non-Hispanic patients). Transportation modality to and from the dialysis center was also associated with COVID-19 status, because those who tested positive were more likely to use taxis and ambulettes, and less likely to use personal transportation. A total of 104 patients (28%) had either a positive PCR or IgG test, but there was significant variability in COVID-19 positivity between the three dialysis units. The subacute rehabilitation facility–based unit (Sun Harbor) had the highest disease prevalence, with 70% of patients affected. There was also a large difference in prevalence between the two stand-alone, community-based dialysis units: 32% of patients were affected at the Mineola center, whereas only 7% were affected at the Bethpage center. Demographics between these two units likely explains the discordance, with the Mineola unit having a higher percentage of Black (44% versus 6%) and Hispanic patients (22% versus 6%) compared with the Bethpage unit, despite the latter having more comorbidities, including older age, vascular disease, and COPD (see Table 2).

Characteristics of Patients with COVID-19 Stratified by Hospitalization Status

Table 3 shows the characteristics of patients with COVID-19 categorized by outpatient versus inpatient management. Of 104 patients on outpatient hemodialysis who tested positive for COVID-19, 36 (35%) were hospitalized. When only considering patients who were symptomatic (PCR positive [$N=67$] or person under investigation who later tested IgG positive [$N=9$]), the hospitalization rate was 36/76 (47%). A total of 15/104 (14%) of patients with COVID-19 passed away. With the exception of greater prevalence of COPD in the hospitalized group (14% versus 3%), there were no significant differences among patients who required hospitalization compared with those who did not. There was a trend for older age among patients who were hospitalized (68.5 years versus 62.5 years), but this did not reach significance ($P=0.10$). SARS-CoV-2 IgG antibody titers did not differ between groups either. The hospitalization mortality rate was 12/36 (33%).

Performance of Antibody Testing

There was universal seroconversion among patients who tested positive for COVID-19 by PCR ($N=67$) and who underwent IgG antibody testing ($N=51$), because there were 16 patients who had a positive PCR test but no antibody testing. Among those who had IgG antibodies ($N=88$), 51 (58%) had a positive PCR test, whereas the other 37 had no PCR test ($N=29$) or tested negative ($N=8$). Asymptomatic transmission—which was defined as patients who had IgG antibodies and either were not given a PCR test (no indication) or were a person under investigation with a negative PCR result—occurred in 28 of 88 (32%) patients.

Discussion

In this study of three in-center maintenance hemodialysis units located within the initial epicenter of the COVID-19

Table 1. Characteristics of patients testing positive versus negative for SARS-CoV-2 PCR or IgG antibodies

Characteristics	COVID-19 Positive (*N*=104)	COVID-19 Negative (*N*=263)	Overall (*N*=367)	*P* Value
Age (yr), median (IQR)	65.0 (53.0–74.5)	69.0 (56.0–78.0)	68.00 (56.0–77.0)	0.05
Female sex, *n* (%)	51 (49)	112 (43)	163 (44)	0.26
Race, *n* (%)				0.001
White	35 (34)	129 (49)	164 (45)	
Black	45 (43)	78 (30)	123 (34)	
Asian	5 (5)	30 (11)	35 (10)	
Other/unknown	19 (18)	26 (10)	45 (12)	
Ethnicity, *n* (%)				<0.001
Hispanic	33 (32)	31 (12)	64 (17)	
Non-Hispanic	70 (67)	230 (87)	300 (82)	
Unknown	1 (1)	2 (0.8)	3 (0.8)	
Hypertension, *n* (%)	104 (100)	258 (98)	362 (99)	0.16
Diabetes, *n* (%)	67 (64)	157 (60)	224 (61)	0.40
Vascular disease, *n* (%)	41 (39)	121 (46)	162 (44)	0.25
Congestive heart failure, *n* (%)	40 (39)	82 (31)	122 (33)	0.18
COPD, *n* (%)	7 (7)	24 (9)	31 (8)	0.46
Dialysis vintage (mo), median (IQR)	28.5 (13.5–60.5)	32.0 (11.0–63.0)	31.0 (13.0–62.0)	0.55
Transportation, *n* (%)				0.02
Taxi	21 (20)	37 (14)	58 (16)	
Self	42 (40)	103 (39)	145 (40)	
Family	20 (19)	89 (34)	109 (30)	
Ambulette/ambulance	21 (20)	34 (13)	55 (15)	

SARS-CoV-2, severe acute respiratory syndrome coronavirus 2; IQR, interquartile range; COPD, chronic obstructive pulmonary disease.

pandemic in the United States, we found that asymptomatic COVID-19 infection was common among patients on maintenance hemodialysis, and that hospitalization and mortality rates were high. Many questions remain about the role of antibody testing for COVID-19, including whether antibodies are protective, how long they persist, and what antibody threshold level is needed for protection. It is reassuring, however, that patients on dialysis—who generally have impaired immunity, blunting of antibody response, and delayed clearance of SARS-CoV-2 (15)—all developed seropositivity. We noted this robust antibody response in a population with a significant diversity of age, races/ethnicities, and comorbidities. Interestingly, antibody titers were similar among patients who were hospitalized (and presumably had more severe infections). This is in contrast to another study that showed patients admitted to intensive care had higher IgG titers compared with those who did not (16).

The exact role of antibody testing in a dialysis unit remains unknown. Although, theoretically, antibody positivity suggests some level of protection from further SARS-CoV-2 infections, its effect on immunity has yet to be definitively established. Additionally, those with less severe infection may have waning antibody levels. Two reports demonstrated that SARS-CoV-2 antibodies decline early in the convalescent phase among those with mild or asymptomatic infection, and the rate of decline was faster than the

Table 2. Characteristics of patients by dialysis facility

Characteristics	Mineola (*N*=254)	Bethpage (*N*=90)	Sun Harbor (*N*=23)	Overall (*N*=367)	*P* Value
Age (yr), median (IQR)	68.0 (54.0–75.0)	73.0 (59.0–80.0)	68.0 (59.0–77.0)	68.0 (56.0–77.0)	0.02
Female sex, *n* (%)	112 (44)	39 (43)	12 (52)	163 (44)	0.74
Race, *n* (%)					<0.001
White	84 (33)	70 (78)	10 (44)	164 (45)	
Black	111 (44)	5 (6)	7 (30)	123 (34)	
Asian	24 (9)	8 (9)	3 (13)	35 (10)	
Other/unknown	35 (14)	7 (8)	3 (13)	45 (12)	
Ethnicity, *n* (%)					<0.001
Hispanic	56 (22)	5 (6)	3 (13)	64 (17)	
Non-Hispanic	196 (77)	84 (93)	20 (87)	300 (82)	
Unknown	2 (0.8)	1 (1)	0 (0)	3 (0.8)	
COVID-19 positive, *n* (%)	82 (32)	6 (7)	16 (70)	104 (28)	<0.001
Hypertension, *n* (%)	249 (98)	90 (100)	23 (100)	362 (99)	0.52
Diabetes, *n* (%)	154 (61)	53 (59)	17 (74)	224 (61)	0.41
Vascular disease, *n* (%)	101 (40)	45 (50)	16 (70)	162 (44)	0.01
Congestive heart failure, *n* (%)	80 (32)	31 (34)	11 (48)	122 (33)	0.27
COPD, *n* (%)	16 (6)	11 (12)	4 (17)	31 (8)	0.05
Dialysis vintage (mo), median (IQR)	30.0 (10.0–62.0)	32.0 (16.0–62.0)	36.0 (11.0–71.0)	31.0 (13.0–62.0)	0.74

IQR, interquartile range; COVID-19, coronavirus disease 2019; COPD, chronic obstructive pulmonary disease.

Table 3. Characteristics of patients hospitalized with COVID-19

Characteristics	Hospitalized (*N*=36)	Not Hospitalized (*N*=68)	Overall (*N*=104)	*P* Value
Age (yr), median (IQR)	68.5 (58.0–77.0)	62.5 (50.0–73.0)	65.0 (53.0–74.5)	0.10
Female sex, *n* (%)	16 (44)	35 (52)	51 (49)	0.50
Race, *n* (%)				0.67
White	15 (42)	20 (29)	35 (34)	
Black	14 (40)	31 (46)	45 (43)	
Asian	1 (3)	4 (6)	5 (5)	
Other/unknown	6 (17)	13 (19)	19 (18)	
Ethnicity, *n* (%)				0.28
Hispanic	14 (39)	19 (28)		
Non-Hispanic	22 (61)	48 (71)		
Unknown[a]	0 (0)	1 (2)		
Clinic, *n* (%)				>0.99
Bethpage	2 (6)	4 (6)	6 (6)	
Mineola	29 (81)	53 (78)	82 (79)	
Sun Harbor	5 (14)	11 (16)	16 (15)	
Hypertension, *n* (%)	36 (100)	68 (100)	104 (100)	—
Diabetes, *n* (%)	25 (69)	42 (62)	67 (64)	0.44
Vascular disease, *n* (%)	16 (44)	25 (37)	41 (39)	0.45
Congestive heart failure, *n* (%)	17 (47)	23 (34)	40 (39)	0.18
COPD, *n* (%)	5 (14)	2 (3)	7 (7)	0.05
COVID-19 IgG level, median (IQR)[b]	5.8 (4.8–6.7)	6.7 (5.1–7.4)	6.5 (5.1–7.2)	0.08
Dialysis vintage (mo), median (IQR)	31.0 (17.0–60.5)	27.0 (8.50–60.5)	28.50 (13.50–60.5)	0.40

COVID-19, coronavirus disease 2019; IQR, interquartile range; COPD, chronic obstructive pulmonary disease.
[a]Unknown category was excluded (*N*=1) from statistical testing.
[b]*N*=16 patients did not have IgG levels available.

antibody levels observed with the previous SARS-CoV-1 (17,18). Despite the uncertainties and pitfalls of so-called "immunity passports," knowledge of the serologic status of patients with ESKD in a dialysis unit may be valuable. Routine serologic testing could be used to cohort certain patients in the event of future COVID-19 waves. Durability of immunity needs to be confirmed, however, especially in more immunocompromised populations, such as those with ESKD.

We also found significant differences between patients who acquired COVID-19 and those who did not. Importantly, as has been reported in the general population, we found that Blacks and Hispanic patients with ESKD experienced an excess burden of COVID-19 as compared to White patients (19). This was a driving factor in the discordant prevalence between the two community-based, standalone dialysis units, because one unit had a significantly greater Black and Hispanic population. It is unclear if there may have been other factors that could have contributed to the disparity between the two units, such as dialysis unit layout or staff infections. Our study and others (6) demonstrated clustering of infections by dialysis units, and we had three separate units with very different prevalence rates of COVID-19. We noted an especially high rate of infections at the subacute rehabilitation facility–based dialysis unit, which mirrors the fact that these types of facilities in general were hard hit by the COVID-19 pandemic in the New York area. Transportation status was also a factor, with greater use of taxis and ambulettes in those with COVID-19 positivity. It is unclear whether this is due to increased exposure risk or underlying comorbidities and socioeconomic status.

Risk factors for more severe COVID-19 have been well documented, and include age, a high prevalence of comorbidities, obesity, and racial/ethnic characteristics. However, the significance of these risk factors in a dialysis population has not been fully examined. Patients on dialysis may have different clinical presentations than patients who do not have ESKD, including less fever and cough (20), suggesting data from the general population are less generalizable to the dialysis community. This may, partly, be due to an impaired immune response and reduced cytokine storm (21). In our study, we did not find different rates of most risk factors between those who were hospitalized and those who were not, with the exception of an increased prevalence of COPD in the COVID-19–positive group.

Asymptomatic transmission in the general population varies on the basis of comorbidities and age, and little is known about asymptomatic spread in more vulnerable populations, including among individuals who are immunosuppressed, such as those with ESKD. On the basis of serology, we found 32% of all COVID-19 cases among patients on in-center dialysis were asymptomatic. This is compatible with studies from China and England that reported an asymptomatic rate of between 21% and 51% among patients on maintenance hemodialysis (7,13,14). Using serologic testing, the overall prevalence of COVID-19 of 28% in these three dialysis units is significantly higher than results from a Chinese study, reporting a seroprevalence rate of 10% (13), but less than that from a study from England, which had a seroprevalence rate of 36% (14). Nearly half of our patients who were symptomatic went on to be hospitalized, which is much higher than hospitalization rates observed in the general population, which vary by age, but is similar to the hospitalization rates described among residents of a Washington state long-term care facility (22). This likely reflects the age and higher burden of comorbidities seen in ESKD. Additionally, a third of our

patients with ESKD who were hospitalized died, which is similar to the 31% mortality rate reported at another New York–area hospital (23).

Our study has several strengths, including completeness of the medical record and meticulous tracking of patients with symptoms, thereby allowing for a more complete capture of the extent of asymptomatic spread. Moreover, longitudinal and extended follow-up of patients, including hospitalizations, allowed for a more accurate epidemiologic assessment. Inclusion of both a subacute rehabilitation facility–based dialysis unit and community units with significant racial and ethnic diversity increases the generalizability of our findings. We also performed serologic testing on nearly our entire dialysis population, minimizing risks of bias. However, this study also has several limitations. The accuracy of serologic testing needs to be confirmed in larger studies, and we cannot rule out either false positives or false negatives. Also, patients on home dialysis were not included, and we cannot make assertions between different dialysis modalities and antibody response or clinical presentation. We did not have data on rates of infection among dialysis staff, or whether proximity to other patients may have played a role in acquisition of COVID-19 infection within units. Additionally, the sample size may also have been too small to detect significant associations for COVID-19 acquisition, associated hospitalization risk factors, and antibody titers.

In conclusion, we found that all patients on dialysis mounted an antibody response to symptomatic infection, and there was a significant rate of asymptomatic spread in dialysis units, as determined on the basis of serologic testing. There were high rates of hospitalization of patients who were symptomatic and subsequent mortality, and there were also substantial racial/ethnic disparities in this population as well. The durability and efficacy of antibodies need to be confirmed in larger and longer studies.

Disclosures

N. Ali reports receiving honoraria from CareDx. J. Divers reports receiving honoraria from the National Institutes of Health and Oak Ridge Associated Universities. P. Dutka reports receiving research funding from Akebia, Bayer, GlaxoSmithKline, and Novo Nordisk; being on the editorial board of the *Nephrology Nursing Journal*; and having consultancy agreements with, receiving honoraria from, and being on a speakers bureau for Rockwell Medical. C. Grant reports receiving research funding from Novo Nordisk. N. Masani reports having ownership interest in AbbVie, Bristol Meyers Squibb, General Electric, and Siemens; receiving research funding from Cara Therapeutics, GlaxoSmithKline, and Novo Nordisk; being a scientific advisor for, or member of, Rockwell Medical; and being a member of Renal Physicians Association. All remaining authors have nothing to disclose.

Funding

None.

Acknowledgments

The authors would like to acknowledge the thousands of patients admitted to NYU Hospitals with COVID-19 and the staff for the care extended to them.

The funding source had no input into analysis, collection of data, or manuscript writing.

Each author contributed important intellectual content during manuscript drafting or revision, accepts personal accountability for the author's own contributions, and agrees to ensure that questions pertaining to the accuracy or integrity of any portion of the work are appropriately investigated and resolved. All authors read and approved the final version of the manuscript. M. Khatri has had full access to the data in the study and final responsibility for the decision to submit for publication.

Author Contributions

N. Ali, P. Dutka, M. Khatri, and N. Masani conceptualized the study; N. Ali, C. Grant, and N. Masani were responsible for data curation; J. Divers, C. Grant, and S. Islam were responsible for formal analysis; J. Divers, N. Masani, and M. Khatri provided supervision; C. Grant was responsible for software; C. Grant, M. Khatri, and N. Masani were responsible for investigation, methodology, and project administration; M. Khatri wrote the original draft; and all authors reviewed and edited the manuscript.

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Received: October 19, 2020 **Accepted:** December 9, 2020

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