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ORIGINAL ARTICLE

Exposure to novel coronavirus in patients on renal replacement therapy during the exponential phase of COVID-19 pandemic: survey of the Italian Society of Nephrology

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Abstract

Background Between February and April 2020, Italy experienced an overwhelming growth of the COVID-19 pandemic. Little is known, at the country level, where and how patients on renal replacement therapy (RRT) have been mostly affected.

Methods Survey of the network of Nephrology centers using a simplified 17 items electronic questionnaire designed by Italian Society of Nephrology COVID-19 Research Group. We used spatial epidemiology and geographical information systems to map SARS-CoV-2 spread among RRT patients in Italy.

Results On April 9th 2020, all nephrology centers (n = 454) listed in the DialMap database were invited to complete the electronic questionnaire. Within 11 days on average, 365 centers responded (80.4% response rate; 2.3% margin of error) totaling 60,441 RRT patients. The surveyed RRT population included 30,821 hemodialysis (HD), 4139 peritoneal dialysis (PD), and 25,481 transplanted (Tx) patients respectively. The proportion of SARS-CoV-2 positive RRT patients in Italy was 2.26% (95% CI 2.14–2.39) with significant differences according to treatment modality ($p < 0.001$). The proportion of patients positive for SARS-CoV-2 was significantly higher in HD (3.55% [95% CI 3.34–3.76]) than PD (1.38% [95% CI 1.04–1.78] and Tx (0.86% [95% CI 0.75–0.98]) ($p < 0.001$), with substantial heterogeneity across regions and along the latitude gradient ($p < 0.001$). In RRT patients the highest rate was in the north-west (4.39% [95% CI 4.11–4.68], followed by the north-east (IR 2.06% [1.79–2.36]), the center (0.91% [0.75–1.09]), the main islands (0.67% [0.47–0.93]), and the south (0.59% [0.45–0.75]. During the COVID-19 pandemic, among SARS-Cov-2 positive RRT patients the fatality rate was 32.8%, as compared to 13.3% observed in the Italian population as of April 23rd.

Conclusions A substantial proportion of the 60,441 surveyed RRT patients in Italy were SARS-Cov-2 positive and subsequently died during the exponential phase of COVID-19 pandemic. Infection risk and rates seems to differ substantially across regions, along geographical latitude, and by treatment modality.

Keywords COVID-19 · Hemodialysis · Peritoneal dialysis · Renal transplant · Survey

Introduction

Italy was among the countries most severely affected by COVID-19 pandemic [1–3], with an unprecedented and overwhelming growth of active cases and mortality, one of the highest in the world [4]. The first Italian patient with COVID-19 was confirmed on February 21st, 2020 at Codogno Hospital in Lombardy. By early March, the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection had spread rapidly, yet heterogeneously, throughout the country. A substantial latitude gradient had been reported, with the highest spread in the Northern regions and

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the lowest in the Southern regions and in the main Islands [5].

The relationship between SARS-CoV-2 infection and comorbidity is complex, multifaceted, and further complicated by an unknown number of asymptomatic cases [6]. Nonetheless, severe and deadly cases are most often reported in elderly patients, especially in those with comorbidities [7]. Patients with renal failure are often old and with major comorbidities, thus at increased risk for COVID-19 morbidity and mortality [8, 9]. Additionally, they often have high levels of contact with health-care facilities and providers for dialysis sessions, clinical monitoring, and supportive care. According to a recent report of the Italian National Institute of Health (Istituto Superiore di Sanità [ISS]), among the most common comorbidities of COVID-19 patients dying in Italy, chronic kidney disease and dialysis are found in 21% and 2% of deceased patients respectively [10].

In Italy, preliminary studies confirmed that patients on renal replacement therapy (RRT), especially those on hemodialysis (HD), are particularly vulnerable for severe and fatal COVID-19 [11–15]. Thus far, while several reports and editorials focused on this fragile population [8, 11–15], no large-scale country level study addressed the COVID-19 epidemiology in RRT patients. The urgent need for a better understanding of the epidemic in RRT patients was immediately evident, and therefore we designed a survey of the Nephrology centers in Italy, aimed to capture the main features, impact and geographical distribution of SARS-CoV-2 spread in over 60,000 prevalent RRT patients during the exponential phase of the COVID-19 pandemic in Italy. We also sought to explore whether RRT modality-specific risks exist for SARS-CoV-2 infection and its consequences.

Methods

Survey oversight and design

On March 24th the Italian Society of Nephrology (SIN) Board of Directors constituted a task force and research group (The SIN COVID-19 Research Group) to promote and coordinate, at the national level, epidemiologic studies on the impact of COVID-19 pandemic on Italian Nephrology centers and patients.

As a first initiative to define the impact of the pandemic, the research group designed a fast-response cross-sectional survey. Such design was chosen because it allows to gather data in a narrow time interval and to assemble large amounts of information on a pre-defined number of items, thereby ensuring adequate statistical power and low margin of error. The sampling strategy was based on a convenience sample made of nephrology centers, the primary sampling units (PSU), listed in the DialMap database [16] with implicit aggregation of prevalent RRT patients within each PSU [17–19].

Instrument and key measures

All centers were invited to complete a short electronic questionnaire, an instrument designed to obtain 17 key information about patient, workforce and facilities during the exponential phase of COVID-19 pandemic. The questionnaire was internally developed by consensus, and explores five domains: (1) center characteristics (2) test positivity by treatment modality, (3) outcome by treatment modality, (4) preventive measures adopted, (5) policies for SARS-Cov-2 testing.

After an initial pilot study [19] in selected centers [20], the final version of the survey questionnaire was approved by SIN Board of Directors and sent by e-mail on April 9th 2020. The survey deadline date was set for April 23rd 2020. All centers were instructed to input cumulative counts and define the actions taken since February 24th 2020. The study flow-chart and a copy of the questionnaire can be found in the supplementary material (Online Resource 1—Figure S3 and Survey Questionnaire).

Laboratory testing

In all centers positive cases were identified using a reverse transcriptase–polymerase chain reaction (RT-PCR) test on samples obtained from the upper respiratory tract by nasopharyngeal or oropharyngeal swab. All samples were processed in regional certified laboratories according to procedures specified by the ISS Working Group Diagnostics and Microbiological Surveillance of COVID-19 [21].

Data acquisition and statistical analysis

For database handling and analysis, we used Microsoft Excel® (Microsoft, WA, USA) and STATA version 15 (StataCorp LLC, TX, USA).

To evaluate the quality and precision of the survey we calculated the response rate (the ratio of respondents to non-respondents) and the margin of error (the maximum expected difference between true population parameters and survey estimates) [18].

Test positive rates, by treatment modality and overall, were estimated using the number of positive cases as numerator and the number of patients as denominator. To calculate fatality rates we divided the number of deaths in persons who tested positive for SARS-CoV-2 by the number of SARS-CoV-2 cases, in keeping with the report of Italian National Institute of Health [3]. Confidence intervals for rates and proportions were calculated using the exact method

[22]. Poisson regression models were used to explore the association between case counts with region and latitude [23].

Geospatial analysis

Geographical information system (GIS) technology was used to manage geographic data.

A spatial database was created, with GIS layers of administrative units (regions and provinces) using the Istituto Nazionale di Statistica (ISTAT) shapefiles [24] and the SIN COVID-19 survey observations. A series of GIS-supported procedures were implemented to geocode and aggregate data in the corresponding regions. Geospatial mapping, in choropleth style maps, was conducted using R Software Ver 3.6.3 (R Foundation for Statistical Computing, Vienna, Austria) with centers and RRT patients grouped at the region level [25].

Results

Centers

On April 9th 2020, all nephrology centers (n = 454) listed in the DialMap database [16] were invited to complete the electronic questionnaire. By the deadline date (April 23rd 2020) 365 centers responded (80.4% response rate; 2.3% margin of error). The national distribution of participating centers is shown in the left panel of Fig. 1.

Preventive measures were adopted by all surveyed centers using personal protective equipment (PPE) and gloves for all patients and staff. Diagnostic testing policies varied across centers (Online Resource 1—Figure S1). The surveyed centers adopted a "test-all" policy more frequently for health care professional (30%) than for patients (16%; $p < 0.001$ for the proportions difference). Conversely, patients were more likely to be tested than health-care professionals if symptomatic (58% vs. 42% respectively; $p < 0.001$ for the proportions difference). All surveyed centers did in person triage and modified access policies, while 227 centers, out of 365, systematically contacted patients (telephone triage) during the interdialytic interval. The vast majority of the centers (321/365; 88%) modified transport policies, using individual transport for suspected and/or confirmed cases in HD patients.

SARS-Cov-2 positive cases

The survey population included 30,821 hemodialysis (HD), 4139 peritoneal dialysis (PD), and 25,481 kidney transplant (Tx) patients, totaling 60,441 RRT patients (Fig. 1, right panel). There were 1368 SARS-CoV-2 positive cases out of the 60,441 RRT patients surveyed (Fig. 2) with an overall rate of 2.26% (95% CI 2.14–2.39). There were significant differences ($p < 0.001$) according to treatment modality. As shown in Table 1, the number

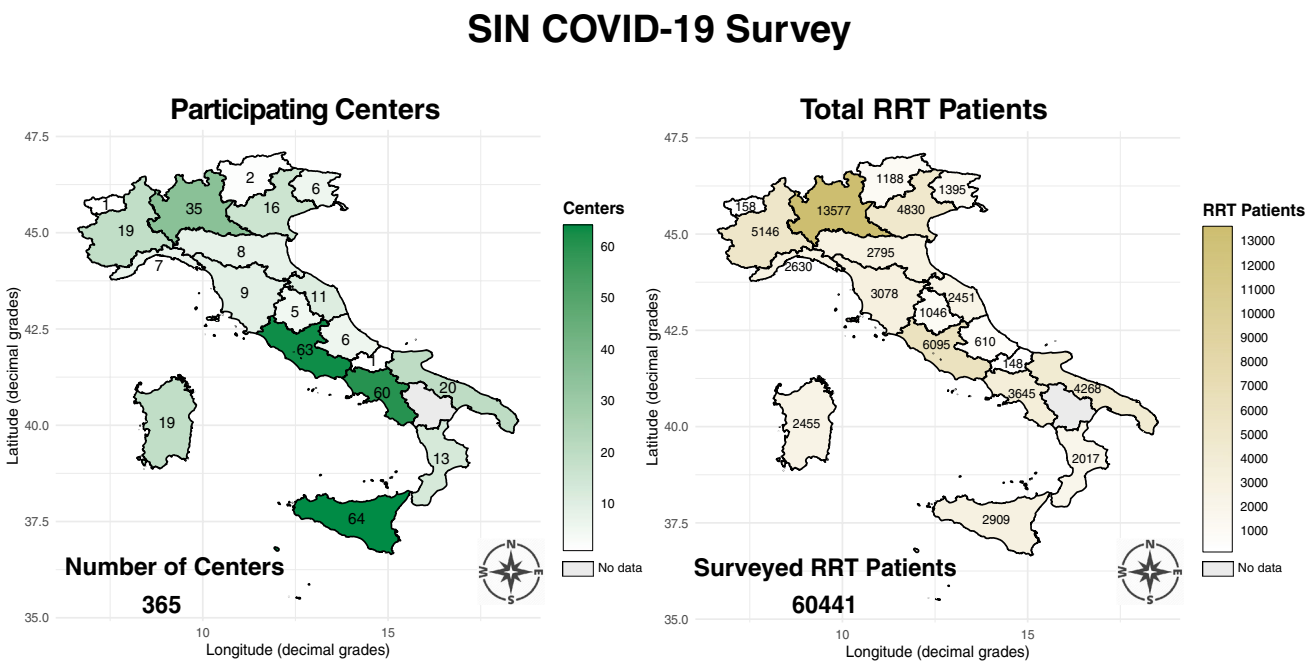

Fig. 1 Choropleth map of the regional distribution of the 365 surveyed centers (left panel) and the 60,441 surveyed patients on renal replacement therapy (RRT) (right panel)

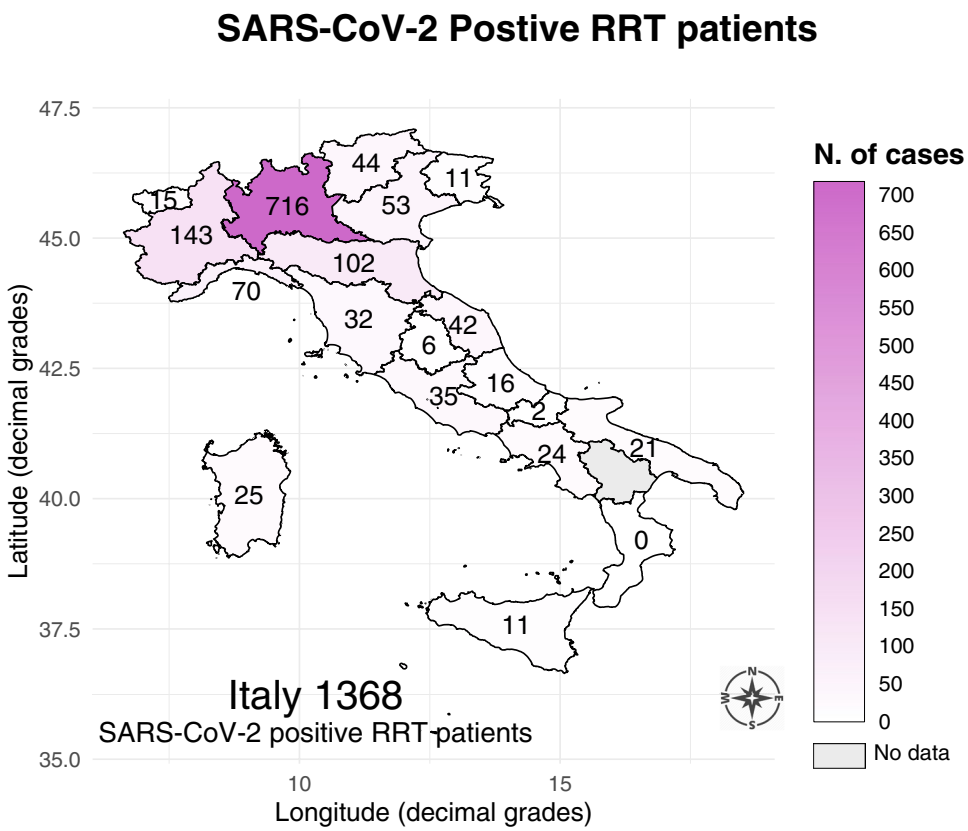

Fig. 2 Map of SARS-CoV-2 positive cases in the 60,441 surveyed renal replacement therapy (RRT) patients observed from February 24th to April 23rd 2020

Table 1 Exposed patients, SARS-CoV-2 positive cases and incidence rate by treatment modality and overall

Treatment modality	Exposed patients	SARS-CoV-2 positive cases	IR per 100	95% CI	
HD	30,821	1093	3.55	3.34	3.76
PD	4139	57	1.38	1.04	1.78
Tx	25,481	218	0.86	0.75	0.98
RRT	60,441	1368	2.26	2.14	2.39

HD hemodialysis, *PD* peritoneal dialysis, *Tx* transplant, *RRT* renal replacement therapy, *IR* incidence rate

of positive cases was higher in HD (1093/30,821) than PD (57/4139) and Tx (218/25,481) respectively. The rate of positive cases exhibited substantial and significant heterogeneity along the latitude gradient ($p < 0.001$). In RRT patients the highest rate was in the north-west (4.39% [95% CI 4.11–4.68]), followed by the north-east (2.06% [1.79–2.36]), the center (0.91% [0.75–1.09]), the main islands (0.67% [0.47–0.93]), and the south (0.59% [0.45–0.75]). At finer level of geographical aggregation, significant heterogeneity ($p < 0.001$) persisted for all treatment modalities (Fig. 3).

Hemodialysis

In the north-west regions SARS-CoV-2 positivity rates in HD were higher than the national average (7.65% vs. 3.55%; $p < 0.001$) but with substantial heterogeneity (Table 2; Fig. 3 panel A). Interestingly, north-east regions had lower rates than the north-west ones (3.30% vs. 7.65%; $p < 0.001$). In central Italy SARS-CoV-2 positivity rate was, on average, 1.39% (95% CI 1.12–1.71) but rates higher than expected were observed in Toscana (3.42% [95% CI 2.27–4.94]) and Marche (2.50% [95% CI 1.63–3.66]). Starting from Umbria down south, and across the main islands, rates were generally lower than 1% with two notable extremes: Calabria with no SARS-CoV-2 positive cases, and Abruzzo with the highest positivity rate (4.67% [95% CI 2.62–7.71]).

Peritoneal dialysis

Compared to HD, SARS-CoV-2 positive cases were less frequent among PD patients (1.38% vs 3.55%; $p < 0.001$; Table 3; Fig. 3 panel B) with 57 total cases, out of which two thirds were observed in four regions: Lombardia (17), Veneto (8), Piemonte (7) and Marche (6). In six regions no cases were registered.

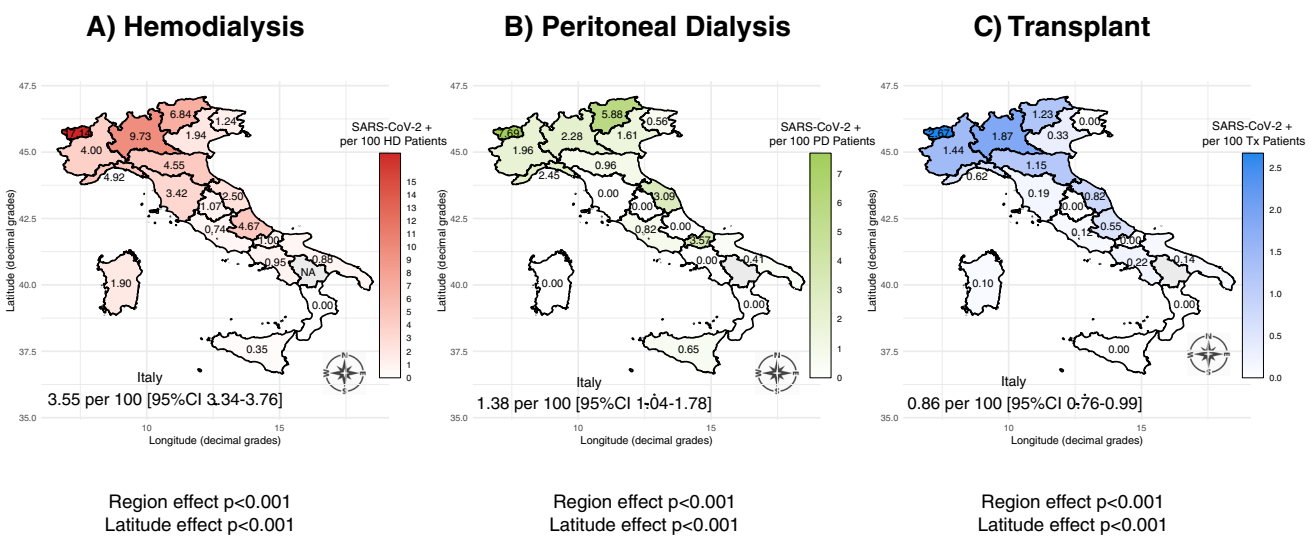

Fig. 3 Map of the regional distribution of SARS-CoV-2 infection rates by renal replacement modality: **a** hemodialysis (HD); **b** peritoneal dialysis (PD); **c** transplant (Tx)

Table 2 SARS-CoV-2 incidence rates in hemodialysis patients by geographical macro-region and nationally

Macro-region	Exposed HD patients	IR per 100	95% CI	
North-West	9717	7.65	7.11	8.22
North-East	5242	3.30	2.83	3.83
Center	6462	1.39	1.12	1.71
South	5567	0.97	0.73	1.27
Main Islands	3833	0.86	0.59	1.21
Italy	30,821	3.55	3.34	3.76

HD hemodialysis, *IR* incidence rate

Table 3 SARS-CoV-2 incidence rates in peritoneal dialysis patients by geographical macro-region and nationally

Macro-region	Exposed PD patients	IR per 100	95% CI	
North-West	1281	2.26	1.52	3.25
North-East	952	1.58	0.88	2.60
Center	791	1.14	0.52	2.16
South	626	0.32	0.04	1.15
Main Islands	489	0.41	0.05	1.48
Italy	4139	1.38	1.04	1.78

PD peritoneal dialysis, *IR* incidence rate

Table 4 SARS-CoV-2 incidence rates in transplant patients by geographical macro-region and nationally

Macro-region	Exposed Tx patients	IR per 100	95% CI	
North-West	10,513	1.64	1.40	1.90
North-East	4014	0.55	0.34	0.83
Center	5417	0.29	0.17	0.48
South	4495	0.16	0.06	0.32
Main Islands	1042	0.10	0.00	0.53
Italy	25,481	0.86	0.75	0.98

Tx transplant patients, *IR* incidence rate

Kidney transplant

The north-to-south geographical gradient of SARS-CoV-2 positive cases was confirmed also for Tx patients (Table 4; Fig. 3 panel C), even though the overall rate (0.86% [95% CI 0.76–0.99]) was the lowest observed among treatment modalities. About three-quarters of the 218 SARS-Cov-2 positive Tx patients were observed in two regions: Lombardia (131) and Piemonte (31). In five regions no cases were registered.

Case fatality

There were 449 deaths among 1368 SARS-CoV-2 positive RRT patients, with an overall case fatality rate (CFR) of 32.82% (95% CI 29.9–36.0). However, there were substantial

Table 5 Number of deaths and fatality rates in 1368 SARS-CoV-2 positive patients by treatment modality and overall

Treatment	SARS-CoV-2 positive patients	Deaths	Fatality rate per 100	95% CI	
HD	1093	369	33.76	30.43	37.42
PD	57	26	45.61	29.80	66.83
Tx	218	54	24.77	18.61	32.32
RRT	1368	449	32.82	29.86	36.00

HD hemodialysis, *PD* peritoneal dialysis, *Tx* transplant, *RRT* renal replacement therapy

and significant differences (Table 5) among treatment modalities ($p < 0.001$). Specifically, CFR was 33.76% in HD, 45.61% in PD, and 24.77% in Tx patients.

Hemodialysis

Out of 1069 SARS-CoV-2 positive HD, 369 died.

The geographical distribution of fatality rates among SARS-CoV-2 positive HD patients (Fig. 4) was not influenced by latitude ($p = 0.653$) or region-specific effect ($p = 0.243$). Restricting the analysis to the regions where at least 10 deaths were observed, accounting for 333 fatal cases (86.6%), the rates remained well above 25% (Online Resource 1—Table S1). Only two regions reported no deaths among SARS-CoV-2 positive HD patients.

Peritoneal dialysis

Out of 57 SARS-CoV-2 positive PD patients, 26 died (Table 5). Although on sparse counts (Online Resource 1—Table S2), this was the highest national fatality rate (CFR 45.61% [95% CI 29.80–66.83]).

Kidney transplant

Out of 218 SARS-CoV-2 positive Tx patients 54 died with a 24.77% fatality rate, the lowest among treatment modalities (Table 5). The highest toll was paid by Lombardia (26) and Piemonte (13), collectively 39 out of 54 total deaths (Online Resource 1—Table S3).

Discussion

In the last few months, Italian nephrologists have been contrasting the overwhelming COVID-19 pandemic with all available means and strategies, including stringent containment measures, extensive diagnostic testing, especially in high risk patients, and by sharing the latest information transparently and promptly [8, 10, 26].

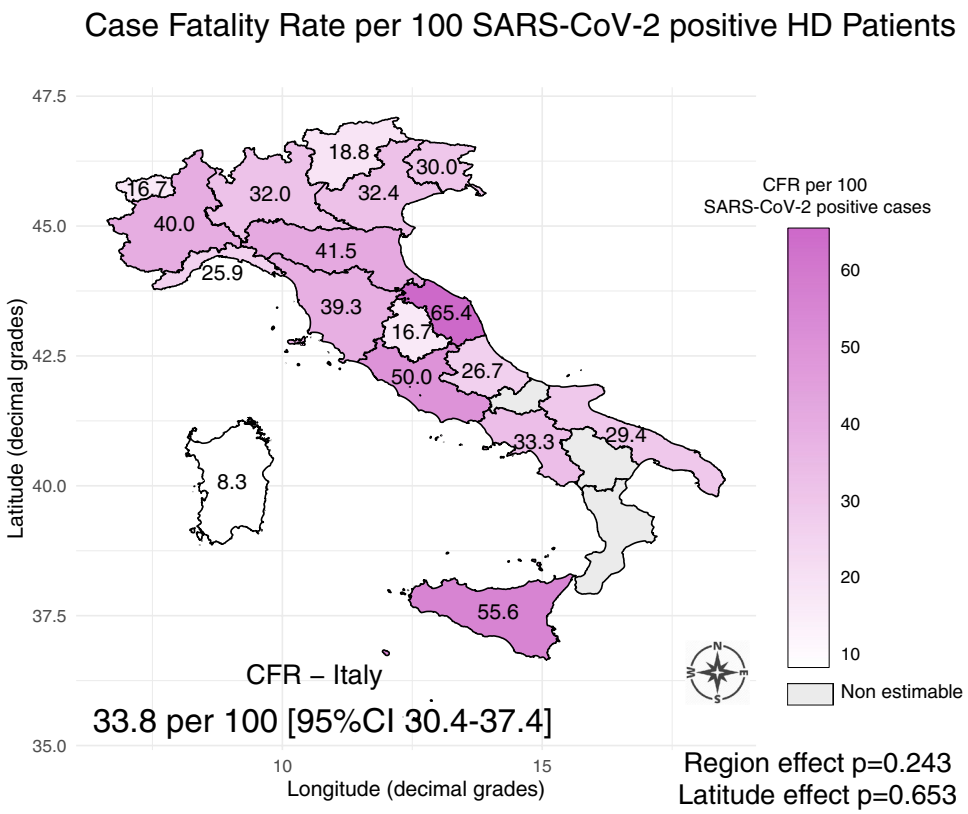

Fig. 4 Regional map of case fatality rates (CFR) in SARS-CoV-2 positive hemodialysis (HD) patients

The impact and burden of COVID-19 pandemic on the Nephrology community in Italy was indeed a "life-changing experience" [27]. Recommendations to contain the spread of infection in RRT patients have been quickly posted [28–30], but little is known on the outcomes at the country and regional levels, where the pandemic appears to spread with varying degrees of intensity [11, 12, 14, 31].

The Italian Society of Nephrology COVID-19 Survey is the first initiative fostering a national research collaboration on the pandemic impact on RRT patients and centers.

Overall, the survey shows that a significant proportion of RRT patients are SARS-Cov-2 positive, in settings where most of the tests were done in symptomatic patients. Positivity rates showed significant heterogeneity among regions ($p < 0.001$) as well as along the country latitude gradient ($p < 0.001$). Such heterogeneity might depend upon several factors including the local rate of infection spread and burden, the type and effectiveness of containment measures, and the testing strategies adopted. Besides, the scattering of local outbreaks along the latitude, temperature, and humidity gradients is fairly consistent with the spread of seasonal respiratory virus infections [32, 33]. Nonetheless, our descriptive findings deserve further investigation, since, if causal links will be established, they might have significant impact on future containment and lockdown policies.

Fewer PD and Tx patients tested positive for SARS-CoV-2. Unlike HD, PD and Tx patients refer to nephrology centers for scheduled visits, typically a few weeks apart, while continuing treatment at home, thus limiting the exposure [11, 12, 15]. Moreover, home treated patients, as well as their caregivers, are usually well trained and acquainted with effective measures to reduce infection risk. Incidentally, telemedicine and remote consulting [28, 34] might have further contributed to reduce the risks in these cases.

The fatality rate was impressively high: 34% among HD patients with no substantial differences across and along the country. Such figure is 2.5 times higher than the 13.3% overall case-fatality rate estimated in Italy as of April 23rd [5]. Interestingly, even though the absolute number of deaths in central and southern regions was lower than in northern Italy, the regional rates were larger than expected. The huge death toll paid by HD patients in the first 2 months of the pandemic is likely due to the inherent clinical characteristics of HD patients such as advanced age, major comorbidities and frailty status. Of note, fatality rates remained substantially higher than expected, even though with wide confidence intervals, also among PD and Tx patients (45% and 25% respectively). With all due caution, our findings collectively suggest that even at low infection rates, as observed in PD and Tx, fatal outcomes are common among SARS-Cov-2 positive RRT patients.

Finally, while hospitals and facilities were tackling an overwhelming pandemic, Nephrologists had also to treat COVID-19 related acute kidney injury (AKI) [35, 36]. The surveyed centers reported 607 AKI cases requiring RRT in intensive care units (Online Resource—Figure S2). The prompt response of nephrology teams in emergency settings must be recognized [37], and we believe that the timely recommendations endorsed by the Italian Society of Nephrology [26] provided a comprehensive and continuously updated guidance.

The present survey has the strength of covering the majority of the RRT centers and patients in a nation that was heavily confronted by the COVID-19 pandemic, but also has some limitations. The findings should be interpreted judiciously because the centers database, on which the study was built, is primarily used for administrative management rather than research. Given the limited resources available and the time-sensitivity of the COVID-19 pandemic, we adopted a non-probability sampling strategy. Nonetheless, since the survey response rate was over 80%, with a small margin of error (2.3% at the 95% confidence level), and covered over 90% of the country territory, the estimates can be considered reliable and precise with low uncertainty.

Conclusions

Nationwide and international collaboration, such as the Italian Society of Nephrology COVID-19 Research project, are extremely important to support the development of effective strategies to reduce the burden of severe and potentially fatal disease among RRT patients [8, 28]. The Italian Society of Nephrology COVID-19 survey confirms and extends previous preliminary observations suggesting that RRT patients, especially those on HD, are at increased risk of developing severe SARS-Cov-2 infections. Conversely, home treated patients are at lower risk of being infected. While positivity rates showed a significant latitude and region effect, in keeping with what was observed in the general population, these factors did not affect death rates, suggesting that fatality is inherently linked to RRT status and related comorbidities. Our findings support and reinforce the current recommendations of the Italian Society of Nephrology [28, 31] on prompt, effective and meticulous care of RRT patients, to reduce the risk of SARS-Cov-2 infection and its adverse prognostic implications [12–14, 28, 30, 31].

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Compliance with ethical standards

Conflict of interest The authors declare that there is no conflict of interest.

Ethical approval All data used in this study were collected anonymously and in accordance with the ethical standards of the institutional and regional research committees, with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards. The study did not require formal individual consent because it was conducted on aggregate data.

Appendix

Italian Society of Nephrology COVID-19 Research Group

1. **Italian Society of Nephrology Board of Directors**
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   Maurizio Postorino, Aurelio Limido
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