Reactogenicity of COVID-19 vaccine in hemodialysis patients: a single-center retrospective study

Articoli originali

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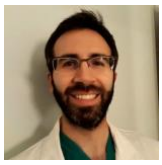
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ABSTRACT

Introduction: Some hemodialysis patients are reluctant to undergo COVID-19 vaccination for the fear of developing adverse events (AEs). The aim of this study was to verify the safety of the mRNA-1273 vaccine in hemodialysis patients.

Methods: We conducted a retrospective analysis of in-center hemodialysis patients who underwent mRNA-1273 vaccine from March 1st to April 30th, 2021. All AEs occurring after the first and the second doses were collected and classified as local or systemic.

Results: Overall, 126 patients on chronic maintenance dialysis without a prior COVID-19 diagnosis were vaccinated with two doses of mRNA-1273 vaccine. Mean age was 68 (IQR, 54,7-76) years and 53.6% of patients were aged ≥65 years. During the observational period of 68 (IQR, 66-70) days, AEs occurred in 57.9% and 61.9% of patients after the first dose and second dose, respectively. The most common AEs were: injection-site pain (61.9%), erythema (4.8%), itching (4.8%), swelling (16.7%), axillary swelling/tenderness (2.4%), fever (17.5%) headache (7.9%), fatigue (23.8%), myalgia (17.5%), arthralgia (12.7%), dyspnoea (2.4%), nausea/vomiting (7.1%), diarrhoea (5.6%), shivers (4%) and vertigo (1.6%). The rates of local AEs were similar after the first and second doses (P=0.8), whereas systemic AEs occurred more frequently after the second dose (P=0.001). Fever (P=0.03), fatigue (P=0.02) and nausea/vomiting (P=0.03) were significantly more frequent after the second dose of the vaccine. There were no age-related differences in the rate of AEs. Overall, vaccine-related AEs in hemodialysis patients seem to be lower than in the general population.

Conclusion: The RNA-1273 vaccine was associated with the development of transient AEs after the first and second doses in patients on chronic maintenance hemodialysis. They were mostly local, whereas systemic AEs were more prevalent after the second dose. Overall, all AEs lasted for a few days, without any apparent sequelae.

KEYWORDS: COVID-19, mRNA-1273, safety, vaccine, hemodialysis, HD, side effects, SARS-COV-2

Introduction

The Coronavirus Disease-2019 (COVID-19) is a novel infectious disease that carries a high burden of mortality and morbidity worldwide [1–3]. In the absence of a specific treatment for COVID-19, vaccination is currently the most effective strategy to prevent this disease [4]. Highly effective vaccines against SARS-CoV-2 infection have been developed and administered globally for a full-vaccine coverage strategy. To attain the goal of reducing mortality, current policies prioritize the vaccination of frail populations, including patients on maintenance hemodialysis [5]. This group of patients is particularly at risk of COVID-19-related complications because includes subjects with advanced age and compromised immunity [6–8], moreover, the thrice-a-week in-center haemodialytic treatment carries a high risk of cluster infection [9,10]. For these reasons, the immunization of hemodialysis patients has been recognized as a public health priority worldwide and a mass vaccination with RNA-platform such as mRNA-1273 vaccine (previously known as vaccine Moderna) has been soon conducted after the release of regulatory agencies' authorization. Safety and efficacy of mRNA-1273 vaccine have been tested in phase III clinical trial (ClinicalTrials.gov n. NCT04470427) recruiting 30.351 participants. The promising results showed 94.1% efficacy at preventing Covid-19 illness, including severe disease [11,12].

Vaccine-related adverse events (AEs) were usually mild or moderate in intensity and resolved within a few days [11]. The most commonly AEs were injection-site pain (92%), fatigue (70%), headache (64.7%), myalgia (61.5%), arthralgia (46.4%), shivers (45.4%), nausea/vomiting (23%), axillary swelling/tenderness (19.8%), fever (15.5%), swelling (14.7%) and erythema (10%).

Nevertheless, the fear of developing vaccine-related symptoms led patients to deny vaccination or additional booster doses. A recent nationwide vaccine acceptability survey conducted in 150 facilities in the United States reported that about half of patients who were vaccine-hesitant expressed concerns about vaccine-side effects [13]. This perception is contradicted by recent vaccine safety data reporting the incidence of severe AEs was similar in mRNA-1273 (1.0%, 147 events) and placebo (1.0%, 153 events) groups during the study period [14]. However, no studies have been conducted until now to evaluate the reactogenicity of the mRNA-1273 vaccine in patients on maintenance dialysis. To inform public health and clinical practice of the potential AEs of mRNA-1273 vaccine, we reported the symptoms occurring in the post-vaccine period in a cohort of hemodialysis patients.

Methods

The study population included patients aged ≥18 years on chronic maintenance hemodialysis at the University Hospital of Modena, Italy. Anti-SARS-CoV-2 vaccination was performed between March 1st and April 30th 2021 in all patients without a prior COVID-19 diagnosis and without signs of ongoing infection who provided written consent. All charts of these patients were reviewed retrospectively. This study has been authorized by the local Ethical Committee of Emilia Romagna (n. 839/2020).

RNA-1273 vaccine contains a molecule of mRNA carrying instructions encoding the spike protein, a protein on the surface of the SARS-CoV-2 virus which the virus needs to enter the body's cells. Once the human cells have produced the spike protein, the immune system recognizes this protein as foreign and produces antibodies and activates T cells to attack it.

This vaccine was found to be safe and effective (94.1%) in preventing symptomatic, laboratory-confirmed COVID-19 in a large, randomized-controlled trial [11] and subsequent observational studies [15,16]. To facilitate its availability and its use, the Food and Drug Administration (FDA) and the European Medicine Agency issued an emergency use authorization in the United States

(December 2020) and Europe (January 2020), respectively [14,17].

In our patients, RNA-1273 vaccine was administered as two intramuscular injections, 28 days apart, by dialysis nurses. Injection of the vaccines was provided 30 minutes before the start of the dialysis session on the non-arteriovenous fistula arm. To optimize the number of vaccine doses, some patients were vaccinated at the end of the dialysis session if no hemodialysis-associated complications (hypotension, nausea, vomiting) had occurred during the treatment. Patients were monitored on-site for at least 15 minutes after the vaccine injection. Subjects who had severe allergic reactions or any type of immediate allergic reaction to drugs were monitored for at least 30 minutes. Anticoagulant therapy was left unchanged when vaccination was performed before the dialysis session.

Adverse events

AEs were considered related to the vaccine when they occurred soon after the vaccination. The monitoring of local and systemic adverse events occurred for 7 days after each injection. The duration of the side effects was counted as a whole 24-hour period. Fever was classified as a symptom only when body temperature was above 37.5° C. The definition “any local AR” or “any systemic AR” denotes the number of patients with any local or systemic adverse reaction, respectively. Multiple ARs in the same patient were considered as a single event.

Statistical analysis

Baseline characteristics were described using median and interquartile range (IQR) or mean and standard deviation (SD). The percentage was used to describe categorical variables. The Student’s t-test and chi-square or Fisher’s test were used to comparing continuous compare and categorical variables between groups, respectively.

A p value of <0.05 was considered statistically significant. All statistical analyses were performed using the SPSS 24® statistical software.

Results

The RNA-1273 vaccine was administered by the dialysis healthcare workers to 126 patients (59.4%) of the 212 patients who regularly received hemodialysis. Sixteen (7.5%) patients refused vaccination for non-religious reasons. The remaining 70 (33%) patients underwent vaccination in other vaccination hubs and therefore were not enrolled in our study.

The baseline characteristics of participants are shown in Table I. The median age was 68 (IQR, 54.7-76) and more than half of the patients (53.6%) were aged ≥65 years. Seventy-one patients were male (53.6%) and the majority of the patients were of Caucasian origin (87.3%). The median observation time from the second dose of the vaccine to the end of the study was 68 (IQR, 66-70) days.

First dose

After the first dose of RNA-1273 vaccine, local AEs occurred in 68 (53,9%) hemodialysis patients whereas systemic AEs in only 20 of them (15.8%). As shown in Figure 1, the most common local symptoms were injection-site pain (50.7%) followed by local swelling (9.5%), erythema (3.1%) and itching (3.1%).

Fatigue (11.1%), myalgia (7.9%) fever (5.1%) and arthralgia (5.1%) were the most common systemic AEs experienced by hemodialysis patients.

Basal characteristics	All patients (n =126)
Age (yr)	68 (54.7-76)
range	19-92
≥65 yr (%)	71 (56.3)
Males, n. (%)	71 (56.31)
Ethnic origin, n. (%)	
Caucasian	110 (87.3)
African	15 (11.9)
Hispanic	1 (0.8)
Etiology of ESRD, n. (%)	
Nephrosclerosis	54 (42.9)
Glomerulonephritis	26 (20.6)
Diabetes	14 (11.1)
ADPKD	4 (3.2)
Nephrotoxic	4 (3.2)
Pyelonephritis	4 (3.2)
Interstitial	3 (2.4)
HIVAN	2 (1.6)
Others	10 (7.9)
NA	5 (4)
HD treatment schedule, n. (%)	
3 times per week	115 (91.2)
2 times per week	7 (5.5)
4 times per week	4 (3.1)
Infectious disease, n. (%)	
HBV	3 (2.3)
HCV	3 (2.3)
HIV	2 (1.5)
Time elapsed from the first to the second dose of vaccine, day	28 (28-28)
Follow-up, day	68 (66-70)
Note: ESRD denotes end-stage renal disease; HBV, hepatitis B virus; HCV, hepatitis C virus	

Table I: Demographic and clinical characteristics of hemodialysis patients who underwent RNA-1273 vaccine

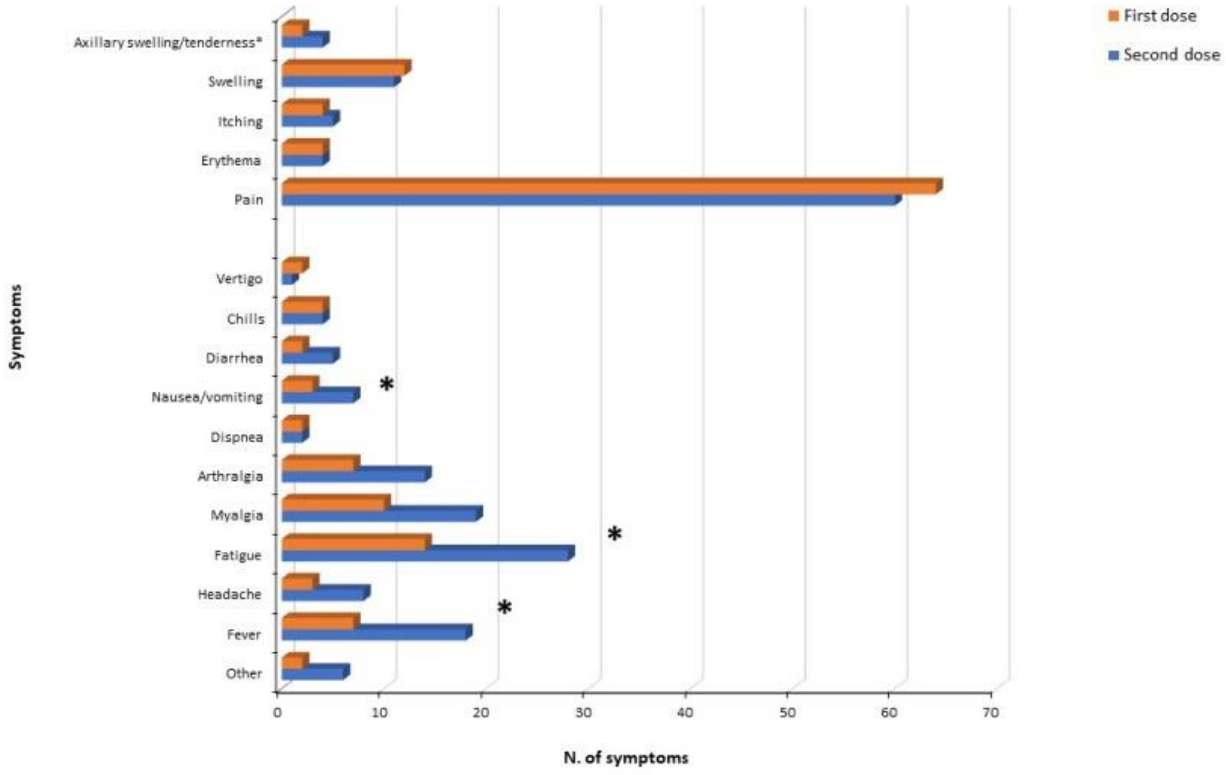


Figure 1. Patients who experienced AEs after the first and second dose of vaccination. The asterisks denote p <0.05

Second dose

The second dose was associated with local (51.6%) and systemic (34.1%) symptoms. The most common local AEs were injection site pain (47.6%) followed by local swelling (8.7%) and itching (3.9%). Systemic AEs included fatigue (22.2%), fever (14.2%) and myalgia (15.07%) (Figure 1).

Difference between first and second dose

The time elapsed between the first and the second dose was 28 days (IQR, 28-28). No differences were found in terms of local AEs between the first and second dose (P=0.8), whereas the second dose was significantly associated with more systemic AEs than the first (P=0.001).

As detailed in Table II and Figure 1, fever (P=0.033), fatigue (P=0.02) and nausea/vomiting (P=0.03) occurred more frequently after the second dose of vaccine.

Seventy-three (57.9%) patients reported at least one AE after the first dose and 78 (61.9%) at least one AE after the second dose. Analysis of the data detected statistically significant differences in the duration of axillary swelling/tenderness and diarrhea between the first and second doses of vaccine.

In both cases, these symptoms lasted longer after the second dose of the vaccine (Table III). No differences in terms of symptoms were found between younger participants (18 to <65 years of age) and older participants (≥65 years of age) (Supplementary figures 1-2).

	First dose		Second dose		p value
Any local AR, n. (%)	68	(53.9)	65	(51.5)	0.80
Pain, n. (%)	64	(50.7)	60	(47.6)	0.70
Erythema, n. (%)	4	(3.1)	4	(3.1)	>0.99
Itching, n. (%)	4	(3.1)	5	(3.9)	>0.99
Swelling, n. (%)	12	(9.5)	11	(8.7)	>0.99
Axillary swelling/tenderness, n. (%)*	2	(1.5)	4	(3.1)	>0.99
Any systemic AR, n. (%)	20	(15.8)	43	(34.1)	**0.001**
Fever, n. (%)	7	(5.1)	18	(14.2)	**0.03**
Headache, n. (%)	3	(2.3)	8	(6.3)	0.21
Fatigue, n. (%)	14	(11.1)	28	(22.2)	**0.02**
Myalgia, n. (%)	10	(7.9)	19	(15)	0.11
Arthralgia, n. (%)	7	(5.1)	14	(11.1)	0.17
Dispnea, n. (%)	2	(1.5)	2	(1.5)	>0.99
Nausea/vomiting, n. (%)	3	(2.3)	7	(5.5)	**0.03**
Diarrhea, n. (%)	2	(1.5)	5	(3.9)	0.44
Chills, n. (%)	4	(3.1)	4	(3.1)	>0.99
Vertigo, n. (%)	2	(1.5)	1	(0.7)	>0.99
Other, n. (%)	2	(1.5)	6	(4.7)	0.28

* Localized axillary swelling or tenderness ipsilateral to the vaccination arm

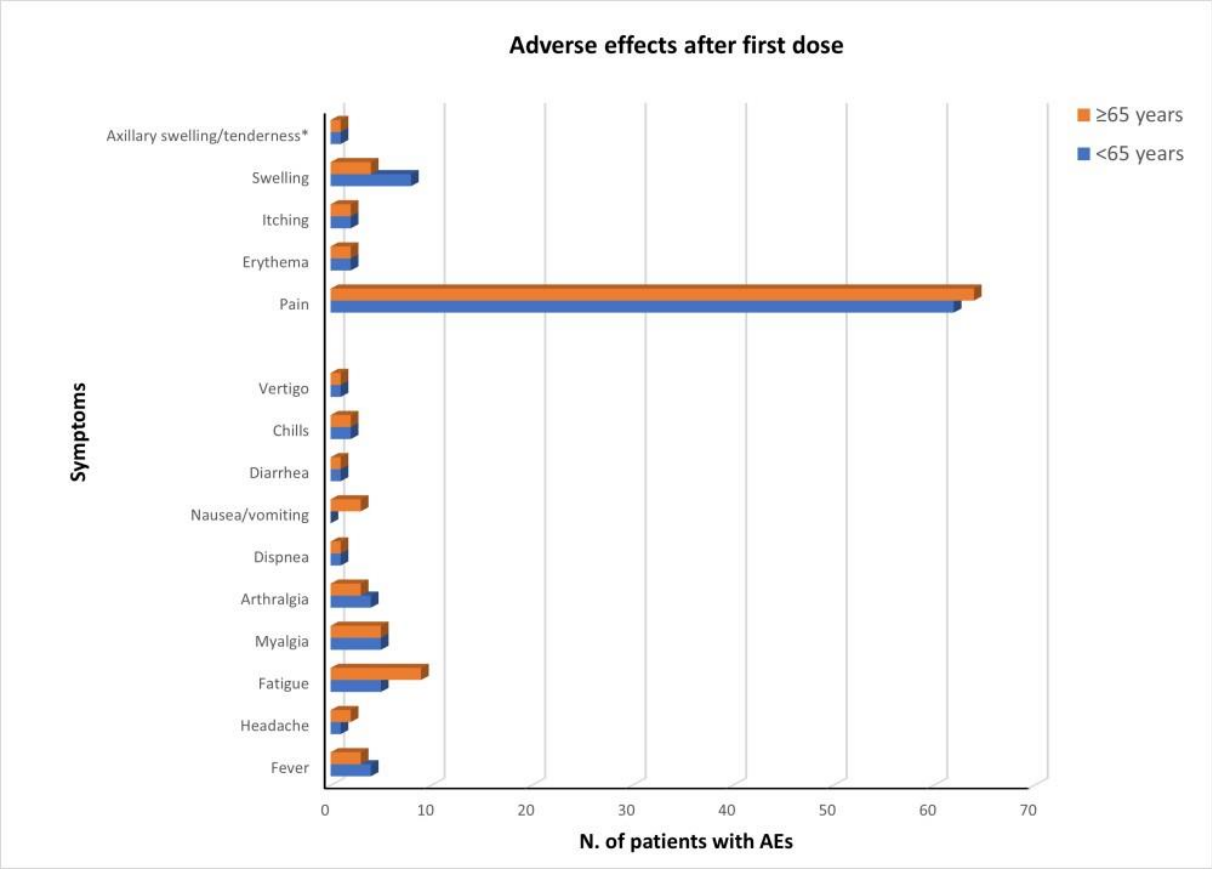
Table II: Rate of AEs after the first and second dose

Completed vaccination cycle

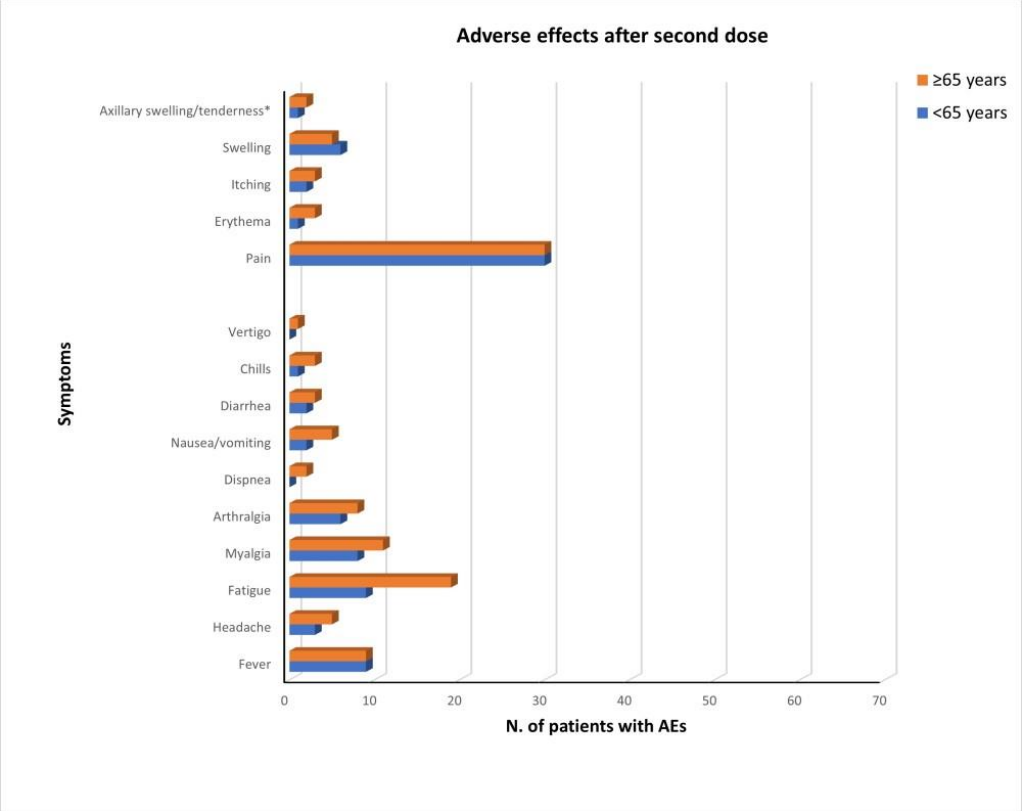
Overall, 71.4% of patients experienced vaccine-related AEs. In particular, the most commonly reported AEs were: injection-site pain (61.9%), erythema (4.8%), itching (4.8%), swelling (16.7%), axillary swelling/tenderness (2.4%), fever (17.5%) headache (7.9%), fatigue (23.8%), myalgia (17.5%), arthralgia (12.7%), dyspnoea (2.4%); nausea/ vomiting (7.1%), diarrhoea (5.6%), shivers (4%) and vertigo (1.6%).

	Duration of AEs in days				
	First dose *mean (±SD)*		**Second dose** *mean (±SD)*		**p value**
Pain	1.96	(1.02)	2.16	(1)	0.28
Erythema	1.75	(0.95)	3	(1.4)	0.2
Itching	2	(0.81)	2	(0.7)	>0.99
Swelling	1.75	(0.9)	2.27	(1.3)	0.26
Axillary swelling/tenderness*	1	(0)	3.3	(1.2)	**0.07**
Fever	1.14	(0.37)	1.22	(0.4)	0.65
Headache	1.33	(0.57)	2	(0.5)	0.10
Fatigue	1.85	(0.86)	2.03	(1)	0.58
Myalgia	1.8	(0.78	2.21	(1)	0.24
Arthralgia	2	(0.8)	2.42	(1.1)	0.32
Dispnea	2	(1.4)	2.5	(2.1)	0.81
Nausea/vomiting	1.33	(0.57)	1.57	(0.8)	0.61
Diarrhea	1	(0)	2.2	(0.4)	**0.016**
Chills	1.75	(0.5)	2.5	(1)	0.22
Vertigo	1.5	(0.7)	3		0.33
* Localized axillary swelling or tenderness ipsilateral to the vaccination arm.					

Table III: Duration of AEs after the first and second doses



Suppl. figure 1: Stratification according to the age of patients who experienced AEs after the first dose of vaccination



Suppl. figure 2: Stratification according to the age of patients who experienced AEs after the second dose of vaccination

Management of AEs occurred in outpatient settings without the need for hospitalization. Comparing these findings to the data of the previously mentioned phase III randomized trial [11,12] shows that hemodialysis patients reported a lower rate of AE compared to the general population after the first (57.9% vs. 84.2%) and the second dose (61.9% vs. 88.6%). Only one patient had herpes zoster reactivation after one week from the first dose. It healed after administering specific antiviral therapy. No cases of vein thrombosis or myocarditis were detected after vaccination in our cohort of patients.

Discussion

The mRNA-1273 vaccine is an effective tool to prevent the severe consequences of COVID-19. This type of vaccine, based on RNA platform technology, has shown short- and long-term safety and efficacy in preventing symptomatic, laboratory-confirmed COVID-19 in a phase III trial [11,12] and post-marketing studies [15,16]. Similar to other vaccines, RNA-1273 is associated with mild-moderate local and systemic AEs. Generally, these side effects develop within a few days after vaccination as a sign of an effective immune response against the foreign protein. At present, the reactogenicity of the mRNA-1273 vaccine is unknown in the hemodialysis population, given their exclusion from the pre-marketing clinical trial. The low response rate to the vaccine and the high rate of COVID-19 infection after vaccination [18,19] support the hypothesis that the rate of AEs might be even lower than the general population because this cohort of patients is believed to have defects in humoral and cellular immunity. In our study, we found that the mRNA-1273 vaccine was associated with local and systemic AEs in patients on in-center maintenance hemodialysis. About three-quarters (71.4%) of our patients experienced some type of AEs after the completion of the dual-dose SARS-CoV-2 vaccination. The rate of local reactions was higher than systemic AEs for both doses, without any statistically significant differences between the first and the second doses.

Injection-site pain, fatigue and myalgia were the most common side effects reported by our patients. Overall, these symptoms were transient and recovery occurred without sequelae within 2 days, on average, from the injection. As expected, the immune system of our patients, sensitized to the foreign protein, had a more robust response with the delivery of the second dose. A higher rate of AEs including fever (14.2% vs 5.1%), fatigue (22.2% vs 11.1%), myalgia (11.1% vs 22.2%), arthralgia (11.1% vs 5.1%) and headache (6.3%vs 2.3%) was indeed observed after the administration of the second dose. No cases of vein thrombosis or myocarditis were detected after vaccination in our cohort of patients. We also investigated the age-related reactogenicity of RNA-1273 in our patients, because injection-site and systemic AEs after this vaccine are shown elsewhere to be slightly less frequent in older participants than in younger ones. Our findings show that the rate and the duration of AEs were similar between the younger (18 to 64 years) and older (65-84 years) hemodialysis patients. The reasons why the RNA-1273 vaccine elicited no age-related differences in the development of AEs are unclear. Likely, the burden of immunodepression induced by ESRD heavily affects the immune system of hemodialysis patients and minimizes the differences due to aging. Taking all together, mild to moderate vaccine-related AEs are frequent in hemodialysis patients and, consequently, healthcare workers in the dialysis units must learn to cope with them. Generally, the detection of severe systemic symptoms (i.e., fever, dyspnoea, nausea or vomiting) requires immediate attention because these symptoms are common to a large spectrum of conditions including infections, fluid overload, and electrolytes disturbance as well as COVID-19. Thus, we suggest a prudential behavior in hemodialysis patients presenting with fever and fatigue after vaccination, in order to prevent a potential COVID-19 outbreak in the dialysis unit. Lastly, we noted a low rate of AEs in our cohort of hemodialysis patients after the first dose (57.9% vs. 84.2%) and second dose (61.9% vs. 88.6%) when compared to the data reported in the general population. This low-level reactogenicity could be partially due to the burden of comorbidities, advanced age and suboptimal immune response of hemodialysis patients against SARS-CoV-2 antigen. In support of this hypothesis, there is evidence that the effectiveness of hepatitis B [20], influenza [21] and SARS-CoV-2 vaccination [19,22] is reduced in this frail population. Some limitations of the study should be enunciated. The retrospective nature of the analysis and the small sample size could lead to unintended bias in the correct estimation of vaccine-related AEs. Measure of AEs magnitude were not collected in our patients. With regard to the severity of AEs, no patients required acute hospital in-patient care after the administration of the vaccine. Among the strengths of this study, our findings provide key information for healthcare workers to plan active surveillance on hemodialysis patients. This is particularly important for the management of hemodialysis patients since multiple doses of the vaccine are required to achieve optimal immunogenicity and efficacy.

Conclusion

In our experience, the RNA-1273 vaccine was associated with the development of transient AEs after the first (57.9%) and second dose (61.9%) in patients on chronic maintenance dialysis. These AEs were mostly local, whereas systemic AEs were more common after the second dose of vaccine than the first. The symptoms lasted for a few days, without any apparent consequences. These data confirm the safety of the RNA-1273 vaccine in hemodialysis patients and support the promotion of COVID-19 vaccination in hesitant patients.

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