Effectiveness and safety of immune response to SARS-CoV-2 vaccine in patients with chronic kidney disease and dialysis: A systematic review and meta-analysis

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Abstract. The coronavirus disease 2019 (COVID-19) vaccination is the most effective way to prevent COVID-19. However, for chronic kidney disease patients on long-term dialysis, there is a lack of evidence regarding the efficacy and safety of the immune response to the vaccine. The present meta-analysis explores the efficacy and safety of COVID-19 vaccine in the immune response of patients with chronic kidney disease (CKD) undergoing dialysis. PubMed, Web of Science, Science Direct, and Cochrane Library databases were systematically searched from January 1, 2020, to December 31, 2022. Data analysis was performed using REVMAN 5.1s and Stata14 software. Baseline data and endpoint events were extracted, mainly including age, sex, dialysis vintage, body mass index (BMI), vaccine type and dose, history of COVID-19 infection, seropositivity rate, antibody titer, pain at injection site, headache and other safety events. The meta-analysis included 33 trials involving 81,348 patients. The immune efficacy of patients with CKD and dialysis was 80% (95 CI, 73-87%). The seropositivity rate of individuals without COVID-19 infection was 76.48% (3,824/5,000), while the seropositivity rate of individuals with COVID-19 infection was 80.82% (1,858/2,299). The standard mean difference of antibody titers in CKD and dialysis patients with or without COVID-19 infection was 27.73 (95% CI, -19.58-75.04). A total of nine studies reported the most common adverse events: Pain at the injection site, accounting for 18% (95 CI, 6-29%), followed by fatigue and headache, accounting for 8 (95 CI, 4-13%) and 6% (95 CI, 2-9%), respectively. COVID-19 vaccine benefitted patients with CKD undergoing dialysis with seropositivity rate ≥80%. Adverse events such as fatigue, headache, and pain at the injection site may occur after COVID-19 vaccination but the incidence is low.

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Introduction

The coronavirus disease 2019 (COVID-19) pandemic has caused social, economic, and political chaos worldwide (1). The effectiveness of antibody treatments varies depending on the variation of the virus strain (2). The World Health Organization (WHO) has identified α, β, γ, δ and o as severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) virus variants of concern (3). These variants notably decrease the effectiveness of vaccines, thus escalating the threat to global public health. Nevertheless, vaccines continue to demonstrate high efficacy in preventing severe illness, hospitalization and death against these variants (3,4). Without effective treatment, the virus can cause serious respiratory disease, similar to SARS and Middle East respiratory syndrome. Some cases of COVID-19 involve acute respiratory distress syndrome or septic shock, which causes pressure and challenges to the global medical and health system and consumes limited medical resources (5). Countries worldwide are actively responding to the COVID-19 pandemic and have formulated policies, such as wearing masks in public, social distancing and quarantining communities and cities. Despite these measures, the COVID-19 pandemic continues. Certain studies suggest vaccination may be the most effective measure to prevent COVID-19 infection (6,7). At present, most COVID-19 vaccines are based on recombinant subunit proteins, virus-like particles, messenger RNA, DNA and viral vectors (8).

Although COVID-19 infection primarily causes respiratory symptoms, the virus may also damage other organs and the kidney is one of the main sites of complications (9). Studies have shown that coronavirus infection increases serum creatinine levels and acute tubular necrosis, which may lead to impaired renal function (10,11). Clinical studies have shown that patients with COVID-19 have acute renal injury (10,12). At the same time, studies have shown that chronic kidney disease (CKD) is a risk factor for COVID-19 death (13,14). The mortality rate among patients with CKD and COVID-19 is significantly higher than that of non-nephrotic patients and non-dialysis CKD patients with COVID-19. Additionally, the severity of the disease is more pronounced in elderly patients (15-17). With the rapid mutation rate of the virus,

there are still some doubts about the effectiveness and safety of existing vaccines (18-20). The present study aimed to systematically analyze the efficacy and safety of the immune response of patients with CKD receiving hemodialysis (HD) and COVID-19 vaccine.

Materials and methods

Search strategy. An electronic search was performed in PubMed (pubmed.ncbi.nlm.nih.gov/), Web of Science (https://www.webofscience.com/wos/), Science Direct (https://www.sciencedirect.com/), and Cochrane Library (cochranelibrary.com/) from January 2019 until December 31, 2022, to identify eligible trials without any publication status restrictions. Data S1 shows the detailed search strategy for each database. Of the 327 identified articles, 33 fulfilled our inclusion criteria (Fig. 1).

Study selection. Inclusion criteria were as follows: i) Prospective cohort study, randomized controlled trial or cross-sectional study; ii) reported the effectiveness of COVID-19 vaccine response and iii) studies reporting adverse events and COVID-19 vaccine safety.

Data extraction. A total of two investigators independently performed the literature search and data selection. Discrepancies were resolved by the third reviewer. Extracted data included number of participants, occurrence of endpoints of interest, mean age at baseline, percentage of male participants, body mass index (BMI), dialysis vintage and vaccine.

Quality assessment. The study used a Risk Of Bias In Non-randomized Studies - of Interventions (ROBINS-I) tool for bias detection (21), which includes seven component (bias due to confounding, bias in selection of participants into the study, bias in classification of Interventions, bias due to deviations from intended interventions, bias due to missing data, bias in measurement of outcomes, and bias in selection of the reported result. Overall bias was identified as low, medium or serious bias.

Statistical analysis. The present study summarized the seropositivity rate and adverse events of patients with CKD undergoing dialysis who received the COVID-19 vaccine as outcome indicators. Heterogeneity was evaluated using the I^2 statistic as follows: 0-40, no significant heterogeneity; 30-60, moderate heterogeneity; 50-90 substantial heterogeneity and 75-100%, considerable heterogeneity (22). If I^2 statistic ≥50%, the random benefit model was used; otherwise, a fixed-effects model was used. Data reported as median and interquartile range were converted to mean and SD as previously described (23). Data were analyzed using Review Manager 5.1 (revman.cochrane.org/info) and STATA 18.0 (stata.com/). $P<0.05$ was considered to indicate a statistically significant difference.

Results

Study characteristics. A total of 327 studies were initially retrieved. Of these, 294 were excluded due to lack of relevant outcomes, patients who did not have CKD or receive dialysis or COVID-19 vaccine and articles published in a language other than English. Finally, 33 trials with a total of 81,348 patients were included in the meta-analysis (24-56) and mean dialysis vintage was 2.1 years. Details of age, BMI, dialysis vintage, and vaccine name included in the analysis are presented in Table I. At baseline, the mean age was 64.9 years and the mean percentage of male participants was 59.4%.

Quality assessment. ROBINS-I (21) was used by two independent authors to evaluate the quality of studies; the overall quality of was good. Of the 33 trials, 21 were considered low, 10 medium and two serious risk of bias (Table SI).

Endpoints. Seropositivity rate of patients with CKD and dialysis after vaccination was 80% (95 CI, 73-87%) and the heterogeneity was I^2=98.9% (Fig. 2). After removing Bielopolski *et al* (45) and Stumpf *et al* (37) due to large sample size, the sensitivity analysis found that the seropositivity rate remained unchanged but the heterogeneity was reduced (I^2=96.4%; Fig. S1). Seropositivity rate of patients without a history of COVID-19 infection was lower than that of patients with a history of infection [Fig. 3; 76.48% (3,824/5,000) of uninfected and 80.82% (1,858/2,299) of patients with a history of infection]. In addition, the antibody titers of patients with CKD and dialysis who had a history of COVID-19 infection were compared; SMD was 27.73 (95% CI, -19.58-75.04), indicating no significant difference (Fig. 4).

A total of nine trials reported adverse events. Safety outcomes assessed were as follows: Pain at injection site, redness, swelling, fatigue, headache and diarrhea (Table II). Pain at injection site was the most common adverse event, accounting for 18% (95 CI, 6-29%; Fig. 5). Other common adverse events were fatigue and headache, accounting for 8 (95 CI, 4-13%) and 6% (95 CI, 2-9%), respectively (Figs. S2 and S3).

Discussion

The present meta-analysis showed that the immune efficacy and safety of the COVID-19 vaccine in patients with CKD undergoing dialysis was good and the seropositivity rate was 80%. Individuals with a history of COVID-19 infection had higher seropositivity rate. The primary adverse events were pain at the injection site and fatigue after vaccination but the overall safety was high. Therefore, administering the COVID-19 vaccine significantly enhances protection against severe outcomes.

In recent years, CKD has become an increasingly serious global health problem (57,58). It is defined as kidney injury or glomerular filtration rate <60 ml/min/1.73 m^2 for ≥3 months (59). When patients with end-stage renal disease develop uremia, they need regular dialysis to survive. Studies have shown that COVID-19 invasion of the kidney can impair renal function (60-62). Effective vaccination strategies are crucial for patients with CKD, as the decreased efficiency of the immune system impairs vaccine-induced immunization (63). The COVID-19 pandemic has prompted research on the immune response to SARS-CoV-2 vaccines in patients with CKD and kidney transplant recipients with the aim of improving efficacy (64). In patients with CKD, the seroconversion rate is reduced after two doses of SARS-CoV-2 vaccine

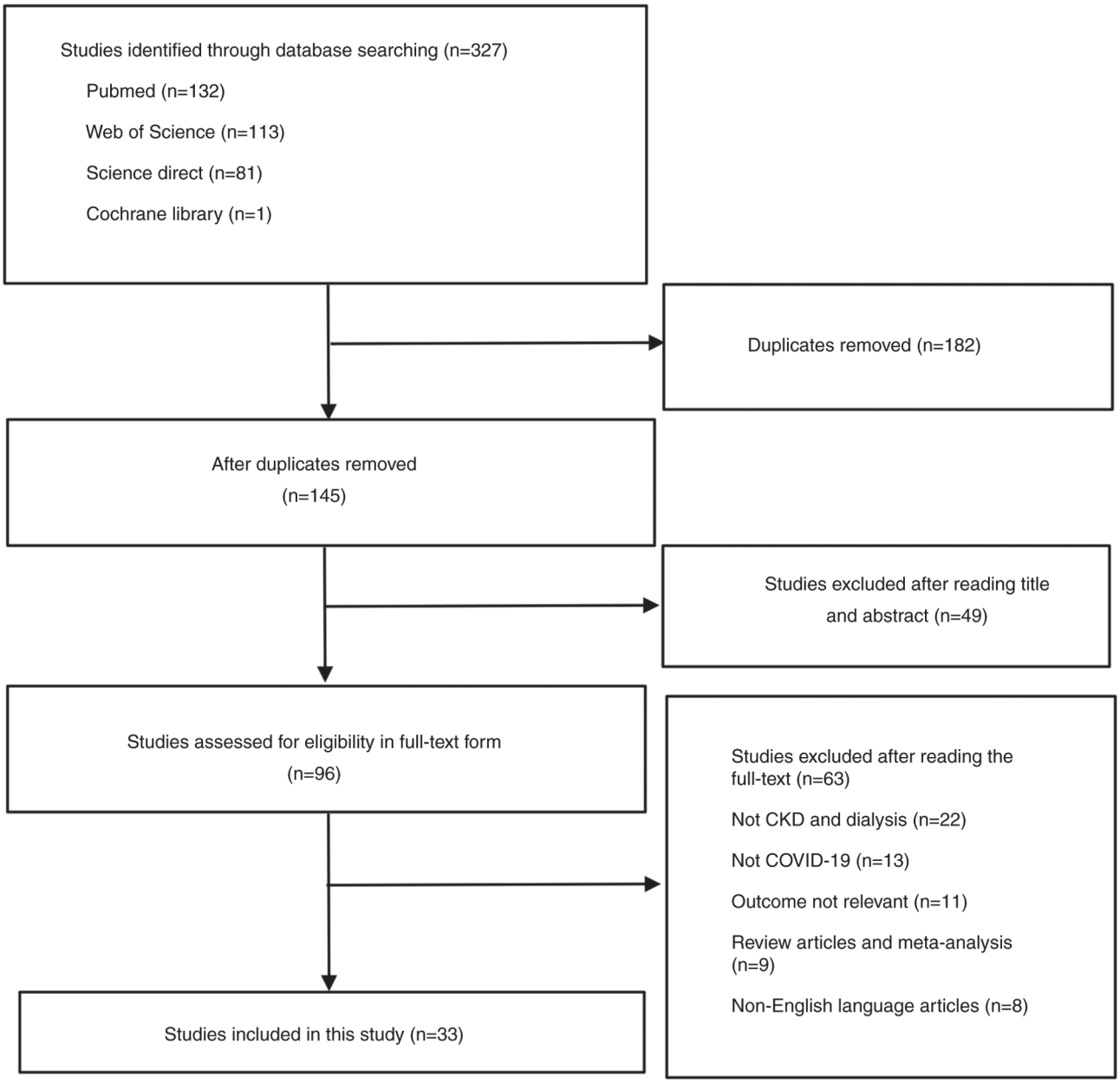

Figure 1. Flowchart of study selection for meta-analysis. CKD, chronic kidney disease; COVID-19, coronavirus disease 2019.

and anti-spike antibody titers are lower than those in healthy individuals (65,66). According to Babel *et al* (67) in patients with CKD, immunological aging and persistent inflammation decreases the efficacy of vaccination. Patients with CKD, especially those who have renal failure, are at high risk of experiencing severe adverse effects of COVID-19 (68). After receiving two doses of mRNA vaccine, most kidney transplant recipients do not establish humoral immunity despite seroconversion rates comparable to those of persons with normal renal function (69). However, some people continue to have a T cell response unique to the vaccination, which may protect against severe COVID-19. Studies have shown that elderly patients, especially men and those with cardiovascular or chronic liver disease, hypertension and CKD, are more likely to be infected with COVID-19, and the disease severity and death risk are also high (70,71). COVID-19 vaccine has a notable impact on the immune status of patients. Some studies have shown that patients undergoing renal dialysis patients may exhibit a weaker vaccine-induced immune response (72-74). According to studies, age and sex also affect immune response (75,76). Seropositivity rate of patients aged >60 years following vaccination is lower than that of those aged <60 years, which may be due to relatively strong immune system in young people leading to higher vaccine efficacy (77,78). Relevant studies have demonstrated out that sex affects seropositivity rate: The antibody response of female patients to virus infection and vaccines is usually higher than that of males (76,79,80). Studies have shown that patients who have been infected with COVID-19 have a higher seropositivity rate, indicating that history of infection can increase the concentration of antibodies (81,82). As the virus further, protective efficiency of vaccines also decrease. This can also explain why there is no significant difference between antibody levels of patients with a history of COVID-19 and those without a history of

Table I. Characteristics of the baseline population included in trials.

First author/s	Year	Country	Sample size	Population	Prior COVID infection	Mean age, years	Male, %	Mean BMI, kg/m^2	Mean dialysis vintage, months	Vaccine	Dose	(Refs.)
Agur *et al*	2021	Israel	122	HD/PD	No	71.6	33.6	26.7	39.7	BNT162b2	2	(24)
Alkadi *et al*	2022	Switzerland	782	HD	Mixed	57.0	64.1	NR	NR	BNT162b2/mRNA-1273	3	(43)
Ben-Dov *et al*	2022	Italian	175	HD	Mixed	65.1	60.0	NR	32.0	BNT162b2	2	(44)
Bielopolski *et al*	2022	Israel	67,861	CKD	No	76.0	48.0	29.0	NR	BNT162b2	2	(45)
Broseta *et al*	2021	Spain	78	HD	No	67.1	67.9	NR	94.3	mRNA-1273	2	(25)
Butt *et al*	2022	USA	6,076	HD	No	69.0	96.7	27.8	NR	BNT162b2/mRNA-1273	2	(46)
Clavero *et al*	2022	Switzerland	81	HD	Mixed	62.6	58.3	NR	NR	BNT162b2/Corona Vac	2	(56)
Cserep *et al*	2021	UK	83	HD	No	73.0	60.0	29.5	27.0	BNT162b2	2	(36)
Davidovic *et al*	2022	Austria	36	HD	No	66.9	66.7	NR	35.0	BNT162b2/Ad26COVS1	3	(48)
Duarte *et al*	2021	Portugal	67	HD/PD	No	67.8	59.5	NR	NR	BNT162b2	2	(47)
Ducloux *et al*	2021	France	45	HD	Mixed	NR	NR	NR	NR	BNT162b2	2/3	(51)
Espi *et al*	2021	France	106	HD/PD	No	64.9	65.0	26.5	50.7	BNT162b2	2	(52)
Fernando *et al*	2021	India	42	HD	No	NR	NR	NR	NR	ChAdOx1-nCoV-19/ BBV152	2	(53)
Frantzen *et al*	2021	France	326	HD	No	71.3	70.0	NR	NR	BNT162b2	2	(54)
Goupil *et al*	2021	Canada	131	HD	Mixed	70.0	77.0	NR	45.6	BNT162b2	1	(55)
Labriola *et al*	2021	Belgium	79	HD	Mixed	80.7	44.0	NR	NR	BNT162b2	2	(26)
Lesny *et al*	2021	Germany	23	HD	No	69.3	55.6	27.9	29.7	BNT162b2/ ChAdOx1-nCoV-19	1	(27)
Longlune *et al*	2021	France	82	HD	No	64.0	68.8	NR	39.0	BNT162b2	2	(28)
Quiroga *et al*	2022	Spain	1,116	HD	Mixed	65.0	64.0	NR	NR	BNT162b2/mRNA-1273/ ChAdOx1-S/Ad26.COV.2	2	(49)
Rincon-Arevalo *et al*	2021	Germany	41	HD	No	71.3	70.0	NR	66.0	BNT162b2	2	(29)
Sattler *et al*	2021	Germany	26	HD	No	67.4	65.4	NR	82.4	BNT162b2	2	(30)
Schrezenmeier *et al*	2021	Germany	36	HD	No	74.0	69.4	NR	64.0	BNT162b2	2	(31)
Simon *et al*	2021	Austria	81	HD	No	67.0	55	NR	NR	BNT162b2	2	(32)
Speer *et al*	2021	Germany	30	HD	No	78.7	60	25.3	37.3	BNT162b2	2	(33)
Speer *et al*	2021	Germany	43	HD	No	83.0	63	26.0	8.0	BNT162b2	2	(34)
Strengert *et al*	2021	Germany	81	HD	No	69.0	58	NR	NR	BNT162b2	2	(35)
Stumpf *et al*	2021	Germany	3,100	HD	No	67.6	65.1	27.5	68.4	mRNA-1273/BNT162b2	2	(37)

Table I. Continued.

First author/s	Year	Country	Sample size	Population	Prior COVID infection	Mean age, years	Male, %	Mean BMI, kg/m^2	Mean dialysis vintage, months	Vaccine	Dose	(Refs.)
Torreggiani *et al*	2021	France	132	HD	No	68.9	59	NR	30.8	BNT162b2	2	(38)
Trakarnvanich *et al*	2022	Thailand	12	CKD	No	63.1	75	22.5	NR	ChAdOx1-nCoV-19	2	(50)
Tylicki *et al*	2021	Poland	91	HD	No	69.3	61.5	25.7	36.0	BNT162b2	2	(39)
Weigert *et al*	2021	Portugal	156	HD	No	64.0	67.8	NR	NR	BNT162b2	2	(40)
Yanay *et al*	2021	Israel	160	HD	No	69.7	63	NR	40.8	BNT162b2	2	(41)
Zitt *et al*	2021	Austria	48	HD	No	67.6	68	NR	NR	BNT162b2	2	(42)

HD, hemodialysis; PD, Peritoneal dialysis; CKD, Chronic kidney disease; NR, Not reported .

Figure 2. Forest plot of seropositivity rate of patients with chronic kidney disease undergoing dialysis receiving coronavirus disease 2019 vaccine. DL, DerSimonian-Laird.

infection (83). In addition, when condition of patients with CKD is stable, COVID-19 vaccine is recommended. Studies have shown that the mRNA-1273 vaccine can induces higher antibody levels than the BNT162b2 vaccine, but the incidence of adverse events is also higher, requiring care in vaccine selection (84,85). Repeated doses of the COVID-19 vaccine improve the antibody levels and serum conversion rate of patients with kidney disease. Therefore, it is important to enhance vaccination programs, which is an important means of preventing COVID-19 infection (86-88). A recent investigation by Puspitasari *et al* (89) assessed the immunogenicity and safety of inactivated COVID-19 vaccines in individuals with end-stage renal disease undergoing HD. The aforementioned study observed no noteworthy distinctions in all measures of immunogenicity between 75 patients receiving HD and 71 healthy controls: The findings revealed no significant variations in anti- receptor-binding domain immunoglobulin G, neutralizing antibodies (NAbs) inhibition and seroconversion rates between the two groups. The incidence of adverse events also showed no significant difference. The study concluded that primary administration of inactivated SARS-CoV-2 vaccination generates an effective antibody response and can be safely administered to individuals undergoing HD. Moreover, a systematic review (90) examining the safety and efficacy of COVID-19 vaccination in patients with CKD undergoing maintenance HD revealed that two doses of COVID-19 vaccines were effective: Seroconversion rates for humoral response were 81-97% and T cell responses were observed in 67-100% of cases. COVID-19 vaccinations demonstrated no significant adverse effects and can be considered safe. In most HD studies, a single dose does not enhance the humoral immune response, but a double dose was improves seroconversion rates and humoral immune response (26,56). If the patient is in the stage of acute and chronic nephritis and takes hormone and immunosuppressive drugs for a long time, it is

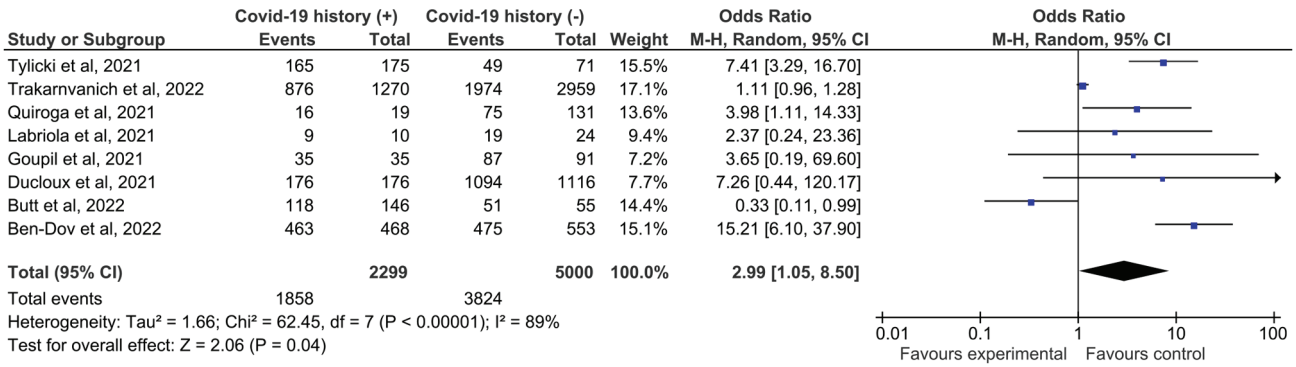

Figure 3. Forest plot of seropositivity rate of patients with or without coronavirus disease 2019 infection. M-H, Mantel-Haenszel.

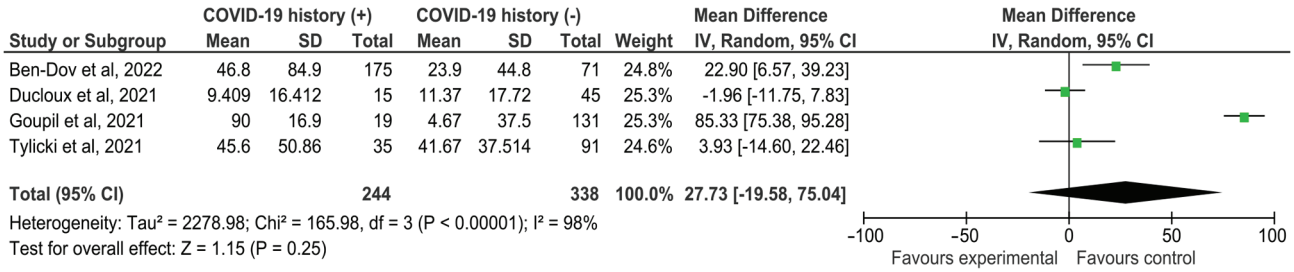

Figure 4. Forest plot of antibody titers of patients with chronic kidney disease and dialysis with or without COVID-19 infection. COVID-19, coronavirus disease 2019; IV, weighted mean difference.

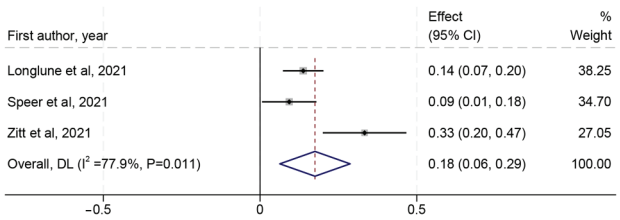

Figure 5. Forest plot of pain at the injection site after receiving coronavirus disease 2019 vaccine.

not recommended to administer the COVID-19 vaccine (91). In addition, the inactivated COVID-19 and recombinant protein vaccine are recommended for nephrotic patients; the vaccination should not be administered to patients allergic to the COVID-19 vaccine and its components (92).

Injection site pain and local injection site reactions are some of the most common reactions (93). Following COVID-19 vaccination, the body exhibits an immune response and the muscles at the injection site may become inflamed, leading to pain (94). In addition, some inactivated vaccines use aluminum hydroxide as an adjuvant to strengthen immunity. Certain scholars believe that aluminum hydroxide is related to the pain at the injection site after inoculation (95,96). The present results show that there is a fatigue reaction following injection of the COVID-19 vaccine, which may be due to brain hypoxia caused by excessive tension, which leads to muscle weakness and fatigue. If the patient has headaches after COVID-19 vaccination, the first thing to consider is psychological factors such as fear, mistrust, and conspiracy beliefs. Usually, after a few hours, the headache disappears when the individual relaxes. This is consistent with previous studies on major adverse events following COVID-19 vaccine injection (97,98).

The present study has limitations. First, most of the studies included were inpatient cases, which may not fully represent all infected people in the region, especially asymptomatic cases. In addition, the included studies did not obtain information about the characteristics, onset time, duration and acute treatment response of side effects. Finally, further research is needed to determine the protection level of naturally acquired antibodies against mutant strains and the durability of protection. Therefore, further research with a larger sample size is required, considering the specific immune and physical conditions of patients.

In conclusion, immune response of patients with CKD undergoing dialysis was effective, which indicated that COVID-19 vaccine injection can reduce the incidence of COVID-19 in patients. In addition, there were few common adverse events and there were no potentially vaccine-related serious adverse events. Therefore, the COVID-19 vaccine should be administered, considering the individual immune levels of patients.

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Table II. Adverse events after vaccination in patients with chronic kidney disease undergoing dialysis.

First author/s	Year	Sample size	New infection (%)	Death (%)	Pain at the injection site (%)	Redness (%)	Swelling (%)	Fatigue (%)	Headache (%)	Diarrhea (%)	(Refs.)
Cserep *et al*	2021	83	0 (0.0)	0(0.0)	NR	NR	2 (2.4)	9 (10.8)	7 (8.4)	1 (1.2)	(36)
Fernando *et al*	2021	38	2 (5.3)	NR	NR	NR	NR	NR	NR	NR	(53)
Longlune *et al*	2021	109	0 (0.0)	NR	15 (13.8)	NR	NR	15 (13.8)	NR	NR	(28)
Quiroga *et al*	2022	1116	NR	8 (0.7)	NR	NR	NR	NR	NR	NR	(49)
Simon *et al*	2021	81	NR	NR	NR	NR	NR	NR	NR	NR	(32)
Speer *et al*	2021	43	NR	NR	4 (9.3)	NR	NR	2 (4.6)	2 (4.6)	NR	(34)
Strengert *et al*	2021	81	NR	NR	NR	NR	NR	NR	NR	NR	(35)
Yanay *et al*	2021	160	6 (3.75)	NR	NR	NR	NR	NR	NR	NR	(41)
Zitt *et al*	2021	48	NR	NR	16 (33.4)	NR	NR	2 (4.2)	2 (4.2)	1 (2.1)	(42)

NR, not reported.

Availability of data and materials

The data generated in the present study are included in the figures and/or tables of this article.

Authors' contributions

KJ, YX and HY conceived and designed the study. XS and BS designed the search strategy and performed quality assessment. XS and BS confirm the authenticity of all the raw data All authors analyzed data and wrote the manuscript. All authors have read and approved the final manuscript.

Ethics approval and consent to participate

Not applicable.

Patient consent for publication

Not applicable.

Competing interests

The authors declare that they have no competing interests.

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