Clin. Lab. 2026;72:XXX-XXX

ORIGINAL ARTICLE

Effects of mRNA Vaccination on the Progression of Chronic Kidney Disease

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ABSTRACT

Introduction: **During the coronavirus disease 2019 (COVID-19) pandemic, messenger ribonucleic acid (mRNA) vaccines, developed using a novel technology distinct from conventional vaccines, were widely administered. Compared to classical vaccines, mRNA vaccines are known to induce more pronounced immune responses. This study aimed to investigate whether mRNA and inactivated COVID-19 vaccines accelerate the progression of chronic kidney disease (CKD).**
Methods: **A total of 140 patients with chronic kidney disease who were followed at Bursa City Hospital were retrospectively analyzed. Serum creatinine levels and glomerular filtration rate (eGFR) values were recorded at three different time points: the pre-vaccination period (-24 months), the vaccination period, and the post-vaccination period (+24 months). Glomerular filtration rate was calculated using the Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) equation. Due to the dependent nature of pre- and post-vaccination comparisons, the paired *t*-test was used for parametric data, and the Wilcoxon signed-rank test for nonparametric data. Furthermore, we applied a One-Way ANOVA with Bonferroni post-hoc correction for intergroup comparisons. A p-value of less than 0.05 was considered statistically significant.**
Results: **When stratified by vaccine type, all three subgroups (BioNTech-only, ınactivated-only, and mixed vaccination) exhibited significant within-group declines in eGFR and elevations in serum creatinine ($p < 0.001$ for all). Importantly, inter-group comparison using post-hoc analysis revealed no statistically significant difference in the magnitude of renal function change (delta eGFR or delta creatinine) between the different vaccine types ($p > 0.05$).**
Conclusions: **The findings of this five-year retrospective cohort study indicate that neither mRNA-based nor inactivated COVID-19 vaccines accelerate the progression of chronic kidney disease. These results support the renal safety of both vaccine types in patients with chronic kidney disease and may help reduce concerns about vaccination-related deterioration in kidney function in this vulnerable population.**
(Clin. Lab. 2026;72:xx-xx. DOI: 10.7754/Clin.Lab.2026.260204)

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Manuscript accepted April 12, 2026

KEYWORDS

mRNA vaccines and kidney function, eGFR, creatinine and BioNTech vaccine

INTRODUCTION

In patients with chronic kidney disease (CKD), the prevention and treatment of the underlying etiologic condition, slowing or halting disease progression, and preservation of residual renal function constitute the main the-

rapeutic goals [1]. Viral infections may directly impair renal function and, through immune-mediated and inflammatory mechanisms, can activate underlying kidney diseases and contribute to the progression of CKD [2].

The coronavirus disease 2019 (COVID-19) pandemic, which emerged at the end of 2019, was associated with severe macrophage activation syndrome (MAS) [3] and resulted in high morbidity and mortality, particularly among individuals with chronic comorbid conditions [4,5]. Beyond its acute clinical impact, the potential influence of COVID-19 on the progression of chronic kidney disease has been of considerable clinical concern [6].

The rapid global spread of COVID-19 and its high mortality rate necessitated the development of accelerated vaccination strategies, which led to the introduction of novel messenger RNA (mRNA) vaccines. Because vaccines produced using conventional methods require longer development and production times, mRNA vaccines were introduced into clinical practice earlier than traditional vaccine platforms.

Following reports that mRNA vaccines, like viral infections, can stimulate the immune system after administration and induce the production of proinflammatory cytokines, concerns were raised about their safety and potential systemic effects [7]. Most studies in the literature have focused on vaccine-related nephrotoxicity and the risk of acute kidney injury. However, data regarding the long-term effects of COVID-19 vaccination on chronic kidney disease progression remain limited.

Therefore, rather than investigating acute renal adverse effects, the present study aimed to evaluate whether mRNA-based and inactivated COVID-19 vaccines accelerate the progression of chronic kidney disease over the long term.

MATERIALS AND METHODS

A retrospective cohort study was conducted to evaluate the impact of COVID-19 vaccination on disease progression in patients with chronic kidney disease who were followed at the Nephrology Clinic of Bursa City Hospital between 2019 and 2024. In Türkiye, BioNTech (mRNA vaccine), Sinovac (inactivated vaccine), and Turkovac (inactivated vaccine) were administered during the vaccination period.

Approximately 2,500 patients with chronic kidney disease were screened from hospital records. Among nearly 450 patients who had remained under follow-up and received COVID-19 vaccination, 140 patients for whom complete data were accessible and who met the inclusion criteria were deemed eligible and subsequently enrolled in the study. The study design diagram and patient selection flow are presented in Figure 1.

A post-hoc power analysis was performed using G*Power 3.1.9.7 to assess the adequacy of the sample size. With N = 140 and an effect size of 0.30, the achieved statistical power was 0.88, confirming that the study had sufficient sensitivity to detect relevant clinical changes.

Renal function was assessed using serum creatinine levels and estimated glomerular filtration rate (eGFR). Serum creatinine levels were measured in the hospital laboratory using the kinetic Jaffe method with Roche Diagnostics (Mannheim, Germany) reagents on the Roche Cobas C702 Analyzer. The assay was traceable to the Isotope Dilution Mass Spectrometry (IDMS) reference method and calibrated accordingly. Estimated glomerular filtration rate (eGFR) was calculated using the CKD-EPI equation (2009) based on serum creatinine values, with the coefficient applied as 1 (non-Black), as originally described by Levey AS et al. and revised by Inker LA et al. [8,9].

Measurements were recorded at three predefined time points: the pre-vaccination period, covering the two years before vaccination; the vaccination period; and the post-vaccination period, covering at least two years following vaccination. Thus, renal function was longitudinally evaluated over approximately five years for each patient.

Patients were included if they were between 18 and 80 years of age, had regular nephrology follow-up for at least two years both before and after vaccination, had a baseline pre-vaccination eGFR between 30 and 90 mL/minute/1.73 m², and had received at least two doses of a COVID-19 vaccine.

Patients with a history of acute kidney injury, dialysis treatment, kidney transplantation, COVID-19-related hospitalization, immunosuppressive drug use, pregnancy, or any other newly developed conditions that could potentially affect renal function were excluded. In addition, patients whose treatment regimens were modified prior to vaccination or who had new therapies initiated for any reason were excluded from the study.

Clinical and laboratory data were retrospectively obtained from the hospital information system. Only patients with regular follow-up visits, defined as visits occurring at intervals of no more than 6 months, were included.

For each patient, mean serum creatinine and mean eGFR values were calculated separately for the pre-vaccination, vaccination, and post-vaccination periods. Differences in renal function parameters were determined by comparing the vaccination-period values with those of the pre- and post-vaccination periods. The patients were stratified into three subgroups: those receiving the BioNTech COVID-19 vaccine, those receiving inactivated vaccines, and those receiving mixed vaccination. These comparisons were conducted for the overall cohort and for subgroups receiving only the BioNTech COVID-19 Vaccine, exclusively inactivated vaccines, or mixed vaccination.

Statistical analyses were performed using SPSS version 26.0. Data distribution was assessed using the Kolmogorov-Smirnov and Shapiro-Wilk tests. Because the measurements before and after vaccination were paired,

Table 1. Baseline demographic and clinical characteristics of the study population.

Characteristic	BioNTech-only (n = 38)	Inactivated-only (n = 25)	Mixed vaccination (n = 77)	n	p-value *
Age (years), mean ± SD	54.5 ± 9.6	66.1 ± 10.9	67.3 ± 9.4		< 0.001 [a]
Gender (male), n (%)	22 (57.9%)	9 (36.0%)	44 (57.1%)		0.114
HbA1c (%), mean ± SD	6.11 ± 1.03	6.74 ± 1.30	6.71 ± 1.50		0.052
HbA1c 5.7 - 6.4 %, prediabetes, n	13	5	29	47	
HbA1c ≥ 6.5 %, diabetes, n	11	13	29	53	
Prediabetes + diabetes, n	24	18	58	100	
Baseline CKD stage, n (%)					
- Stage 2 (eGFR 60 - 90)	22 (57.9%)	9 (36.0%)	32 (41.6%)		0.018 [b]
- Stage 3a (eGFR 45 - 60)	13 (34.2%)	7 (28.0%)	28 (36.4%)		
- Stage 3b (eGFR 30 - 45)	1 (2.6%)	8 (32.0%)	15 (19.5%)		
- Stage 4 (eGFR 15 - 30)	2 (5.3%)	1 (4.0%)	2 (2.6%)		
Baseline eGFR	67.37 ± 14.87	57.84 ± 18.97	57.56 ± 13.26		0.002 [c]
Baseline Creatinine (mg/dL)	1.18 ± 0.23	1.23 ± 0.35	1.24 ± 0.26		0.325

CKD: Chronic kidney disease, eGFR: Estimated glomerular filtration rate (mL/minute/1.73m²), HbA1c: Glycated hemoglobin.
According to the American Diabetes Association (ADA), HbA1c levels are categorized as normal (< 5.7%), prediabetes (5.7 - 6.4%), and diabetes (≥ 6.5%).
Data are presented as mean ± standard deviation (SD) for continuous variables and frequency (percentage) for categorical variables.
*** p-values represent inter-group comparisons via ANOVA or Kruskal-Wallis. [a] Post-hoc Bonferroni: BioNTech vs. inactivated ($p < 0.001$) and BioNTech vs. mixed ($p < 0.001$) are significant. [b] Significant difference in stage distribution between groups ($p = 0.018$). [c] Post-hoc: BioNTech group had significantly higher baseline eGFR than inactivated and mixed groups ($p < 0.05$).**

Table 2. Changes in renal function parameters pre- and post-vaccination according to vaccine type.

Group/parameter	Baseline (mean ± SD)	Post-vaccination (mean ± SD)	95% CI of the mean	p-value †
Overall cohort (n = 140)				
- Serum creatinine (mg/dL)	1.22 ± 0.27	1.60 ± 0.38	[1.536, 1.659]	< 0.001
- eGFR (mL/min/1.73m²)	60.27 ± 15.56	42.22 ± 11.23	[40.35, 44.09]	< 0.001
BioNTech-only (n = 38)				
- Serum creatinine (mg/dL)	1.18 ± 0.23	1.60 ± 0.37	[1.477, 1.719]	< 0.001
- eGFR (mL/min/1.73m²)	67.37 ± 14.87	45.16 ± 10.37	[41.75, 48.56]	< 0.001
Inactivated-only (n = 25)				
- Serum creatinine (mg/dL)	1.23 ± 0.35	1.64 ± 0.46	[1.453, 1.829]	< 0.001
- eGFR (mL/min/1.73m²)	57.84 ± 18.97	38.47 ± 10.18	[34.27, 42.68]	< 0.001
Mixed vaccination (n = 77)				
- Serum creatinine (mg/dL)	1.24 ± 0.26	1.59 ± 0.37	[1.508, 1.677]	< 0.001
- eGFR (mL/min/1.73m²)	57.56 ± 13.26	42.02 ± 11.32	[39.46, 44.59]	< 0.001

CI: Confidence interval, eGFR: Estimated glomerular filtration rate (mL/minute/1.73m²).
eGFR was calculated using the CKD-EPI equation (2009) (chronic kidney disease epidemiology collaboration) with the coefficient applied as 1 (non-Black). 95% Confidence intervals (CI) for the mean change were calculated to demonstrate the precision of the estimates.
p-values were calculated using the Wilcoxon signed-rank test or Paired *t*-test to compare pre- and post-vaccination values within each group.
An inter-group comparison of the magnitude of change (delta) between the BioNTech, inactivated, and mixed groups showed no statistically significant difference ($p > 0.05$).

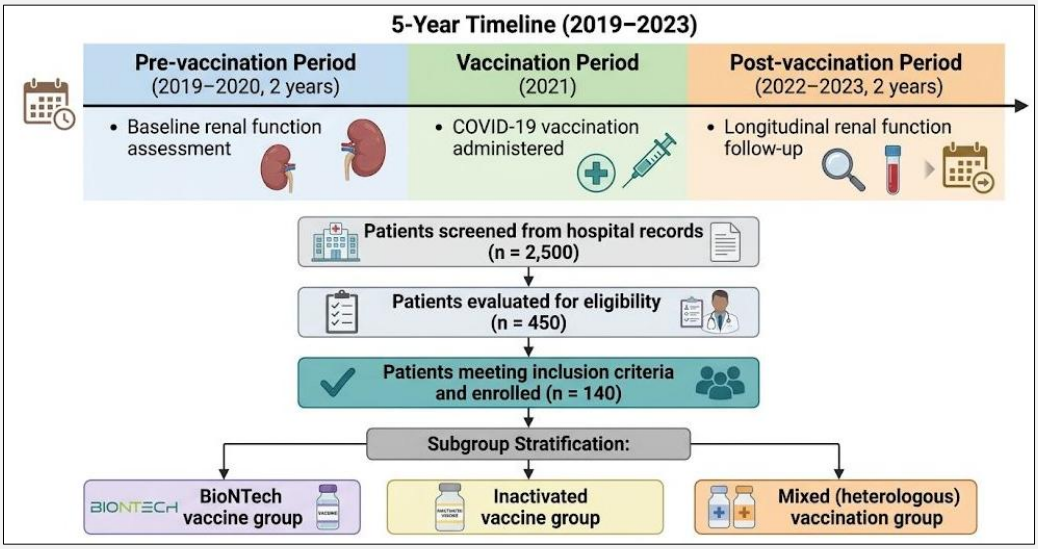

Figure 1. Study design and patient selection flow.

the paired-samples *t*-test was used for normally distributed variables, and the Wilcoxon signed-rank test was used for non-normally distributed variables. Furthermore, we applied a One-Way ANOVA with Bonferroni post-hoc correction for intergroup comparisons. A p-value of less than 0.05 was considered statistically significant.

The study protocol was approved by the Bursa City Hospital Scientific Research Ethics Committee (Approval No.: 2024-20/2; Date of Approval: November 27, 2024).

RESULTS

Baseline Characteristics of the Study Population

A total of 140 patients with chronic kidney disease (CKD) stages 2 to 4 were included in the final analysis. The demographic and baseline clinical data are summarized in Table 1. The mean age of the overall cohort was significantly lower in the BioNTech-only group (54.5 ± 9.6 years) compared to the inactivated-only (66.1 ± 10.9 years) and mixed vaccination (67.3 ± 9.4 years) groups ($p < 0.001$). Post-hoc analysis confirmed that these age differences were statistically significant between the BioNTech group and both the inactivated and mixed groups ($p < 0.001$ for both).

Regarding baseline renal function, the mean eGFR for the entire cohort was 60.27 ± 15.56 mL/minute/1.73m². Consistent with the age distribution, the BioNTech-only group presented with a higher baseline eGFR (67.37 ± 14.87 mL/minute/1.73m²) than the inactivated-only (57.84 ± 18.97 mL/minute/1.73m²) and mixed (57.56 ± 13.26 mL/minute/1.73m²) groups ($p = 0.002$). Baseline serum creatinine levels and HbA1c values were comparable across the three groups ($p = 0.325$ and $p = 0.052$, respectively).

Impact of Vaccination on Renal Function Parameters

The longitudinal changes in serum creatinine and eGFR from pre-vaccination to post-vaccination are detailed in Table 2. In the overall cohort, a statistically significant increase in mean serum creatinine was observed, rising from 1.22 ± 0.27 mg/dL to 1.60 ± 0.38 mg/dL ($p < 0.001$; 95% CI [1.536, 1.659]). Correspondingly, the mean eGFR for the total population showed a decline from 60.27 ± 15.56 mL/minute/1.73m² to 42.22 ± 11.23 mL/minute/1.73m² ($p < 0.001$; 95% CI [40.35, 44.09]). When stratified by vaccine type, all three subgroups (BioNTech-only, inactivated-only, and mixed vaccination) exhibited significant within-group declines in eGFR and elevations in serum creatinine ($p < 0.001$ for all). Specifically, the mean eGFR decreased to 45.16 ± 10.37 mL/minute/1.73m² (95% CI [41.75, 48.56]) in the BioNTech group, 38.47 ± 10.18 mL/minute/1.73m² (95% CI [34.27, 42.68]) in the inactivated-only group, and 42.02 ± 11.32 mL/minute/1.73m² (95% CI [39.46, 44.59]) in the mixed vaccination group.

Importantly, inter-group comparisons using post-hoc analysis revealed no statistically significant difference in the magnitude of renal function change (delta eGFR

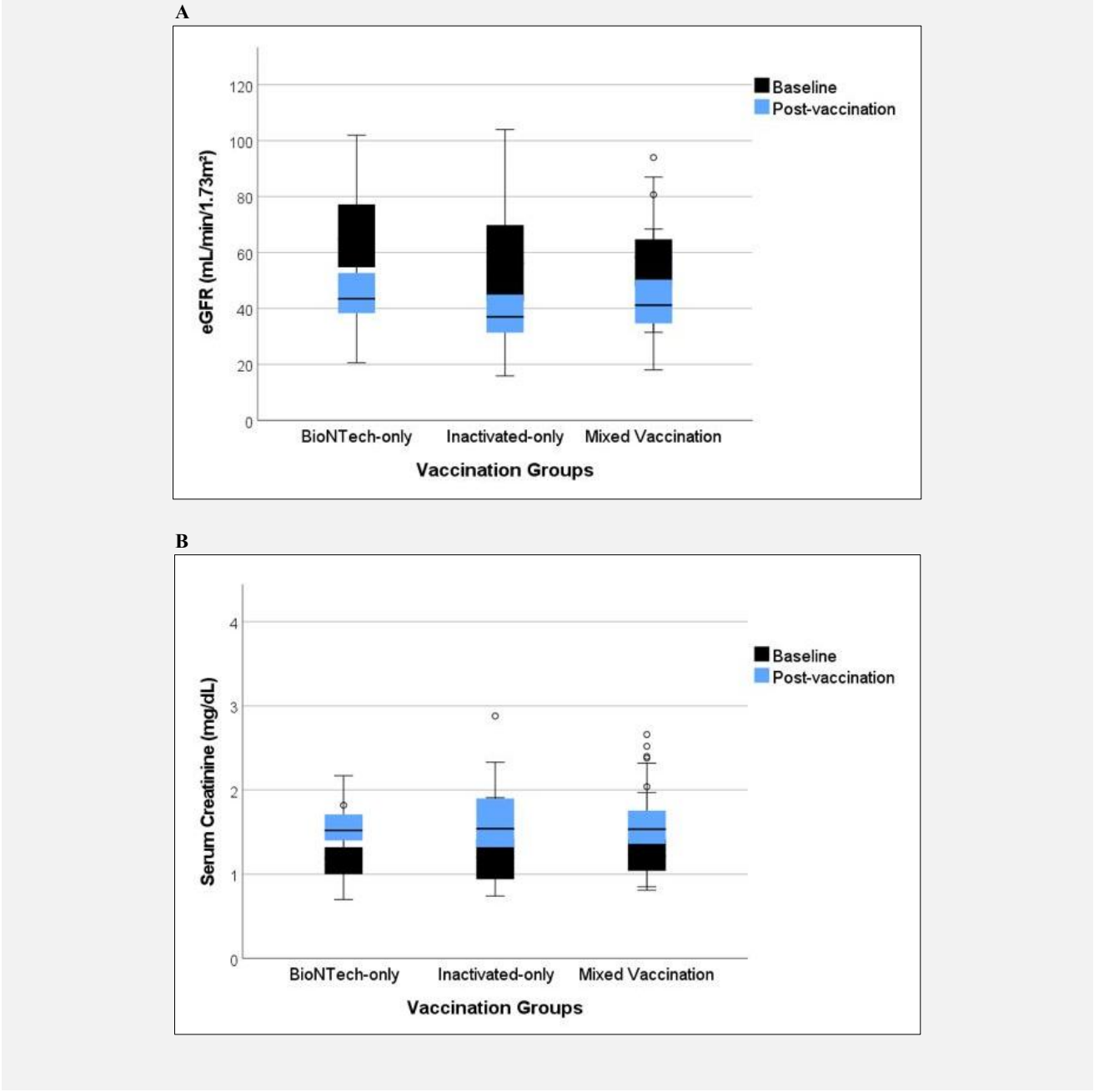

Figure 2. Longitudinal Assessment of Renal Function Parameters Across Different COVID-19 Vaccine Platforms.

A: eGFR Distribution: Clustered box-plot illustrating the estimated glomerular filtration rate (eGFR) at baseline (pre-vaccination) and post-vaccination for BioNTech-only, inactivated-only, and mixed vaccination groups.
B: Serum Creatinine Distribution: Clustered box-plot illustrating serum creatinine levels at the same timepoints.
The horizontal line within each box represents the median value, the box represents the interquartile range (IQR), and the whiskers indicate the 1.5x IQR. Outliers are represented by individual points. The high degree of overlap between baseline and post-vaccination distributions across all three platforms visually confirms the stability of renal function following vaccination ($p > 0.05$ by One-way ANOVA with Bonferroni post-hoc correction for inter-group comparisons).

or delta creatinine) between the different vaccine types ($p > 0.05$). This suggests that the type of vaccine platform (mRNA vs. inactivated) did not differentially impact the rate of CKD progression during the study period.

The longitudinal analysis of renal function parameters showed no clinically significant impairment following COVID-19 vaccination across the study cohort (N = 140). Baseline eGFR levels were well maintained post-vaccination across all three vaccine platforms (BioN-

Tech-only, inactivated-only, and mixed), with no significant inter-group differences in the magnitude of change ($p > 0.05$; Figure 2A). Similarly, serum creatinine levels remained stable from baseline to post-vaccination follow-up across all groups. The mean change in creatinine did not differ significantly among the BioNTech, inactivated, and mixed platforms ($p > 0.05$; Figure 2B). These findings were further supported by the 95% confidence intervals (CI), which showed extensive overlap among the vaccination groups (see Table 2).

DISCUSSION

In the present study, longitudinal analysis within each vaccination group revealed a significant expected physiological variation in eGFR and creatinine levels compared to baseline; however, the primary objective - inter-group comparison - demonstrated no statistically significant difference in the magnitude of eGFR decline or creatinine elevation between the cohorts. These findings suggest that the mRNA-based BioNTech vaccine does not exert a disproportionate adverse effect on renal function compared to inactivated vaccines. Furthermore, the lack of significant functional divergence in the heterologous (mixed) vaccination group indicates that combining different vaccine platforms is not associated with additive nephrotoxicity, although this observation warrants further validation through larger, specifically powered prospective trials.

The findings reported in the literature are consistent with those of our study. Wang et al [11] reported that COVID-19 vaccination did not adversely affect renal function in individuals with a history of glomerular disease and that pre- and post-vaccination eGFR slopes were similar. Chen et al. [12] likewise reported that although a mild decline in eGFR may be observed in the short term, this difference disappears during long-term follow-up. These findings are in line with the eGFR stability observed in our study.

Additionally, Nagatsuji et al. [13] reported transient fluctuations in renal function following vaccination in patients with IgA nephropathy, while Li et al. [14] similarly demonstrated that renal events occurring after COVID-19 vaccination are generally associated with a favorable prognosis and are reversible.

Rodríguez Y et al. [7] reported that mRNA vaccines induce a proinflammatory cytokine response through toll-like receptor (TLR) activation, which may lead to transient changes in renal function in some susceptible patients.

In addition, Pethő et al. [15] emphasized that mRNA vaccines may rarely trigger autoimmune glomerulonephritis following immune activation; however, these effects are mostly transient and respond well to treatment. Imhof et al. reported the development of anti-Human Leukocyte Antigen (HLA) antibodies in a renal transplant recipient after vaccination [16].

Zhang et al. [17] reported that COVID-19 vaccination preserves renal function and reduces mortality in patients undergoing hemodialysis, while Ma et al. [18] demonstrated high vaccine safety.

However, some studies have reported modest changes following vaccination: Cheng et al. [19] observed hematuria and proteinuria after vaccination, and Sun et al. [20] noted a transient increase in proteinuria levels.

Overall, there is strong consensus in the literature that COVID-19 vaccines do not cause severe or permanent deterioration of renal function in patients with chronic kidney disease; on the contrary, renal stability is generally maintained [11-14,17,19,20].

In our study, rather than investigating whether it causes harm, we examined whether it accelerates the progression of the disease. Although the aims of our study differ, the findings reported in the literature support our results.

The differing results reported across studies may be explained by variations in patient characteristics, comorbidity burden, and follow-up duration.

A major strength of our study is that each patient served as their own control, allowing for a comparison of pre- and post-vaccination data within the same individuals. Although the study is retrospective, it includes a relatively long follow-up period of approximately 4 - 5 years, which enhances the robustness of the findings.

The limitations of this study include small number of study patients, the retrospective design, which precludes the establishment of a direct causal relationship; the lack of data on proteinuria, inflammatory markers, and immune response parameters; the absence of post-vaccination renal biopsy data.

Another limitation of this study is the absence of a detailed subgroup analysis based on the primary etiology of renal failure. Although the majority of patients (100/140) were classified as prediabetic or diabetic, the potential impact of different underlying primary renal diseases on vaccine response could not be adequately evaluated due to the retrospective design of the study and the limited sample sizes within certain etiological subgroups.

CONCLUSION

Within the limitations of this five-year retrospective cohort study, the negative median values observed suggest a relative slowing in the rate of increase in serum creatinine and a deceleration in the rate of decline in eGFR. These findings further indicate that neither the BioNTech COVID-19 vaccine nor inactivated COVID-19 vaccines appear to be associated with an increased risk of chronic kidney disease progression. Nevertheless, these results should be interpreted with caution, and confirmation through larger-scale prospective studies is warranted.

But these findings may help reduce concerns about vaccination-related renal impairment in this vulnerable

population, especially for BioNTech vaccines that use a new method.

Acknowledgment:
All authors declared that they have no conflict of interest. Approval for the study was obtained from the Scientific Research Ethics Committee of Bursa City Hospital (Decision No.: 2024-20/2, Date: 11/27/2024).

Declaration of Generative AI in Scientific Writing:
During the preparation of this manuscript, generative artificial intelligence (AI) tools were used solely for language editing and improvement of clarity. The AI tool was not used for data analysis, interpretation of results, or generation of scientific content. All scientific content, analyses, and conclusions presented in this manuscript are the sole responsibility of the authors.

Declaration of Helsinki:
The study was conducted in accordance with the principles of the Declaration of Helsinki.

Declaration of Interest:
The authors declare that they have no conflicts of interest related to this study.

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