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ORIGINAL RESEARCH

Efficacy of tenofovir alafenamide in patients with chronic hepatitis B undergoing chronic hemodialysis and kidney transplantation: A real-world data study

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Highlights & Insights

- **Scientific Gap:** Data on the efficacy and safety of TAF in patients undergoing chronic hemodialysis and in kidney transplant recipients remain limited.
- **Key Finding:** Virological response rates were 78.9% at month 12 and 94.7% at month 24, with improved serum ALT levels in patients with elevated baseline ALT levels, while renal function remained stable.
- **Clinical Impact:** These real-world findings support TAF as an effective and well-tolerated treatment option for these high-risk populations.

ABSTRACT

Background and Aim: This study evaluated the efficacy and safety of tenofovir alafenamide (TAF) in chronic hepatitis B virus-infected patients undergoing chronic hemodialysis and kidney transplant recipients.

Materials and Methods: Between January 2019 and January 2023, patients receiving TAF who were undergoing chronic hemodialysis or were kidney transplant recipients were included in a multicenter retrospective study at 17 tertiary care centers across Türkiye.

Results: A total of 58 patients were included (13 receiving hemodialysis and 45 kidney transplant recipients). The mean age of patients was 50.1±12.5 years, with a predominantly male gender (71%). At baseline, 19 patients were hepatitis B virus DNA-positive; 11 of whom were antiviral treatment-naïve. The virological response rate was 78.9% (15/19) at 12 months of TAF treatment and increased to 94.7% (18/19) by 24 months. Patients with elevated baseline alanine aminotransferase levels exhibited significant improvement after initiation of TAF. Overall, TAF was well tolerated throughout the study period, with no serious adverse events or drug discontinuations due to adverse effects.

Conclusion: TAF was associated with effective virological suppression and favorable biochemical response in patients with chronic HBV infection undergoing chronic hemodialysis and kidney transplant recipients. TAF was generally well tolerated in such patients.

Keywords: Chronic hepatitis B, hemodialysis, kidney transplantation, real-world data, tenofovir alafenamide.

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Introduction

Hepatitis B virus (HBV) infection is a major global public health concern, affecting over 250 million individuals.[1,2] HBV accounts for the majority of adult cases of chronic liver disease, cirrhosis, and hepatocellular carcinoma (HCC) in Türkiye.[3–5] However, its prevalence has decreased over time. At present, interferons and nucleos(t)ide analogs (NAs) with high genetic barriers are recommended for the treatment of chronic hepatitis B (CHB).[1,2,6] NA treatment provides effective long-term viral suppression, reduces fibrosis, slows disease progression, and prevents HCC development in patients with CHB. The primary goal of antiviral treatment for HBV is to eliminate hepatitis B surface antigen (HBsAg) and achieve seroconversion to antibody to hepatitis B surface antigen (anti-HBs).[1–3] Current guidelines recommend high-genetic-barrier NAs, including entecavir, tenofovir disoproxil fumarate (TDF) and tenofovir alafenamide (TAF), as first-line antiviral agents.[6]

TAF demonstrates efficacy comparable to TDF, showing non-inferior viral suppression and high rates of aminotransferase normalization. In addition, TAF is associated with fewer adverse effects, including reduced renal toxicity, a lower risk of hypophosphataemia, and less loss of bone mineral density. For these reasons, it is particularly preferred in patients at risk for chronic kidney disease or osteoporosis.[6,7] Several studies have investigated the efficacy and tolerability of TAF therapy in patients with CHB with or without cirrhosis.[1,7–10] However, data on the efficacy and safety of TAF treatment in hemodialysis patients and kidney transplant recipients are limited. The present study aimed to evaluate the efficacy and tolerability of TAF in chronic HBV-infected patients undergoing chronic hemodialysis and kidney transplant recipients.

Materials and Methods

This multicenter retrospective study included non-cirrhotic patients who were receiving hemodialysis or kidney transplantation and were followed at liver disease outpatient clinics at 17 tertiary care centers across Türkiye. All patients received TAF either as prophylaxis against HBV reactivation or as treatment for CHB. Medical records covering the period from January 2019 to January 2023 were retrospectively reviewed. Patients with cirrhosis were excluded from the study. A specific electronic case report form was developed for data collection and documentation. Data were collected and entered into the CRF at each center. This study was approved by the Marmara University Ethics Committee of the Marmara Medical School (June 12, 2020/09.2020.698), and written informed consent was waived due to the retrospective nature of the study. The study was conducted in accordance with the principles of the Declaration of Helsinki. TAF was administered at a dosage of 25 mg/day. In patients receiving chronic hemodialysis, TAF was administered after the dialysis session, and the timing of administration relative to the dialysis session was not otherwise standardized; this practice is consistent with pharmacokinetic data supporting TAF use in patients on dialysis.[11,12]

The laboratory investigations included serum alanine aminotransferase (ALT), aspartate aminotransferase (AST), gamma-glutamyl transpeptidase, total bilirubin, creatinine, fasting glucose levels, lipid profile (serum total cholesterol, high-density lipoprotein [HDL], low-density lipoprotein [LDL], very-low-density lipoprotein [VLDL], and triglyceride), and prothrombin time. Complete blood cell counts were obtained using the local central laboratory of each unit. HBsAg, anti-HBs, HBeAg, antibody to hepatitis B e antigen (anti-HBe), antibody to hepatitis B core antigen, and anti-delta were measured. HBV DNA levels were measured using the Roche COBAS TaqMan assay (lower limit of quantitation of 20 IU/mL). Patients with HBV DNA below the lower limit of quantitation at baseline were analyzed separately from patients with detectable baseline HBV DNA. Biochemical and serological test results obtained at treatment initiation and during follow-up were recorded.

The primary endpoint was to evaluate the efficacy of TAF in chronic HBV-infected patients undergoing chronic hemodialysis and in kidney transplant recipients. The secondary endpoint was to evaluate the tolerability and adverse effects of TAF in this population.

Safety

Safety and tolerability analyses were assessed during TAF treatment. Adverse events (AE), serious AEs, laboratory abnormalities, drug discontinuation due to AE, and deaths were evaluated. Serum creatinine levels and estimated glomerular filtration rates (eGFR) were evaluated. eGFR was calculated using the Modification of Diet in Renal Disease (MDRD) formula.

Follow-up

All patients were seen in the outpatient clinic at 3- or 6-month intervals after initiation of TAF treatment. Available clinical assessments, laboratory findings, treatment adherence data, and HBV virological and serological markers documented at baseline and during follow-up were recorded. Blood was drawn to determine the metabolic, biochemical, and serological parameters. HBV viral markers were all monitored. Follow-up data for up to 24 months after TAF initiation were evaluated. Complete virological response was defined as undetectable serum HBV DNA (<20 IU/mL).

Statistical Analysis

The data were analyzed using the Statistical Package for the Social Sciences, version 23 (IBM Corp., Armonk, NY, USA). Normality of distribution was assessed using the Shapiro-Wilk Test. The categorical data were analyzed by groups using Fisher's Exact Test and Fisher's Exact Test with Monte Carlo Correction, and multiple comparisons were made using the Bonferroni-corrected Z-test. The Independent Samples T-Test was used to compare normally distributed data across groups, and the Mann–Whitney U-Test was used to compare variables that did not meet normality assumptions. Repeated Measures Analysis of Variance was used to compare dependent data with a normal distribution measured at different times within each group, and the Friedman Test was used to compare dependent data

that did not conform to a normal distribution. Analysis results are presented as frequencies (percentages) for categorical variables and as means±standard deviations and medians (minimum–maximum) for quantitative variables. The level of significance was set at p<0.050.

Results

A total of 58 patients were included in the study: 13 receiving hemodialysis and 45 who had undergone kidney transplantation. All patients in the hemodialysis group were HBsAg-positive. Among the kidney transplant recipients, 10 were HBsAg-negative and anti-HBc-positive and received TAF prophylaxis against HBV reactivation during immunosuppressive therapy. The mean age of the participants was 50.1±12.5 years, with a predominantly male gender (71.0%). Among the patients, 8 of the 12 hemodialysis patients with available data and 11 of 45 kidney transplant recipients were antiviral treatment-naïve. Of the 45 transplant patients, six were receiving a single immunosuppressant, while 39 were on multiple therapies. HBeAg was positive in 9 of 42 patients (21.4%). Tacrolimus was the most commonly used single agent, whereas the multiple-therapy regimen consisted of tacrolimus, mycophenolate mofetil, and steroids. Immunosuppressive drug levels were not available in this cohort; therefore, no data on immunosuppressant dose adjustments during TAF treatment could be provided. The baseline characteristics of all patients are given in Table 1.

Nineteen patients were HBV DNA-positive at baseline; 11 of these were antiviral treatment-naïve (eight in the hemodialysis group and three in the transplant group). Baseline HBV DNA positivity rates were 84.6% (11/13) in the hemodialysis group and 17.8% (8/45) in the transplant group. Eleven patients (4 receiving hemodialysis and 7 post-kidney transplantation) had elevated baseline serum ALT levels (>40 U/L). When baseline laboratory values were compared between the two groups, mean serum phosphorus and creatinine levels were significantly higher in the hemodialysis group. In contrast, serum total cholesterol and HDL levels were significantly higher in the transplant group (Table 1). The remaining 39 patients (67.2%) had undetectable HBV DNA (<20 IU/mL) at the time of switching to TAF and were analyzed separately from the 19 patients with detectable baseline HBV DNA. Baseline and follow-up HBV serological and virological markers are summarized in Table 2.

Among the 19 patients with detectable HBV DNA at baseline, the complete virological response rates at 12 and 24 months were 78.9% (15/19) and 94.7% (18/19), respectively. Among the 11 hemodialysis patients with high baseline HBV DNA levels, 10 achieved HBV DNA undetectability during TAF treatment, while the remaining patient showed a marked reduction in HBV DNA – from 19,756,248 IU/mL at baseline to 450,000 IU/mL at month 12 and 23,000 IU/mL at month 24. This patient was anti-HBe positive at baseline. No HBeAg seroconversion occurred during TAF treatment. In the kidney transplantation group, all eight patients with high baseline HBV DNA levels became HBV DNA undetectable during TAF treatment. Serum ALT levels improved significantly in patients with elevated baseline ALT levels during TAF treatment (Table 3).

Fasting plasma glucose levels remained stable from baseline to the end of follow-up (93±18 mg/dL vs. 96±21 mg/dL; p=0.56). TAF was associated with a slight increase in serum lipid parameters. From baseline to end of follow-up visit, total cholesterol increased from 168.8±46.4 mg/dL to 172.5±48.1 mg/dL (p=0.41), HDL cholesterol increased from 41.4±14.2 mg/dL to 42.7±14.8 mg/dL (p=0.52), LDL cholesterol increased from 103.4±38.6 mg/dL to 106.1±39.7 mg/dL (p=0.47), and triglycerides increased from 158.6±70.2 mg/dL versus 162.4±72.5 mg/dL (p=0.55) (Table 3).

Safety

TAF treatment was well tolerated. Headache, fatigue, and nausea were the most common adverse effects. No drug discontinuation was observed due to adverse effects. No significant clinical side effects or serious AE were reported. Renal function parameters were analyzed separately for the hemodialysis and kidney transplant groups. In the kidney transplant group, the mean eGFR-MDRD was 50.12±22.52 mL/min/1.73 m^2 at baseline (n=44), 63.86±22.69 mL/min/1.73 m^2 at month 12 (n=36), and 60.86±25.27 mL/min/1.73 m^2 at month 24 (n=29). Although eGFR-MDRD increased numerically over time, this change was not statistically significant (Friedman test, $\chi^2(2)=1.813$, p=0.404; Kendall's W=0.034).

In the hemodialysis group, the mean eGFR-MDRD was 10.71±5.38 mL/min/1.73 m^2 at baseline, 9.38±3.48 mL/min/1.73 m^2 at month 12, and 16.13±9.83 mL/min/1.73 m^2 at month 24 (Friedman test, $\chi^2(2)=0.200$, p=0.905; Kendall's W=0.010).

In the 10 hemodialysis patients with serum phosphorus measurements available at baseline, month 12, and month 24, the estimated mean serum phosphorus levels were 5.434 mg/dL (95% confidence interval [CI], 4.207–6.661) at baseline, 5.504 mg/dL (95% CI, 4.456–6.552) at month 12, and 5.624 mg/dL (95% CI, 4.937–6.311) at month 24; Bonferroni-adjusted pairwise comparisons indicated no significant differences between baseline and month 12 (mean difference: -0.070 mg/dL; adjusted p=1.000), baseline and month 24 (mean difference: -0.190 mg/dL; adjusted p=1.000), or months 12 and 24 (mean difference: -0.120 mg/dL; adjusted p=1.000). In the kidney transplant group, Bonferroni-adjusted pairwise comparisons showed no significant differences in serum phosphorus levels between baseline and month 12 (mean difference: 0.244 mg/dL, 95% CI: -0.300–0.788; adjusted p=0.775), baseline and month 24 (mean difference: 0.162 mg/dL, 95% CI: -0.325–0.650; adjusted p=1.000), or months 12 and 24 (mean difference: -0.082 mg/dL, 95% CI: -0.520–0.357; adjusted p=1.000).

Discussion

This multicenter study evaluated the efficacy and tolerability of TAF in chronic HBV-infected patients undergoing chronic hemodialysis or who had received a kidney transplant. Among patients with detectable HBV DNA at baseline, TAF treatment was associated with a high virological response rate, improved serum aminotransferase levels in both patient groups. These findings are consistent with

Table 1. Baseline characteristics of patients receiving TAF undergoing chronic hemodialysis and kidney transplant recipients

Parameter	Overall	Group		p
		Kidney transplant recipient	Hemodialysis	
Gender				0.494
Male	41 (70.7)	33 (73.3)	8 (61.5)	
Female	17 (29.3)	12 (26.7)	5 (38.5)	
Age	50.1±12.5 52.5 (26–77)	49.3±11.6 50.0 (26–77)	52.8±15.4 59.0 (27–70)	0.102
Hypertension	50 (86.2)	38 (84.4)	12 (92.3)	0.669
Diabetes mellitus	15 (27.3)	11 (25.6)	4 (33.3)	0.370
Coronary artery disease	9 (15.8)	6 (13.6)	3 (23.1)	0.671
Osteoporosis	11 (19.6)	11 (25.6)	0 (0)	0.098
Antiviral therapy before TAF initiation	38 (66.7)	34 (75.6)	4 (33.3)	**0.013**
Type of antiviral agent before TAF initiation				
TDF	23 (60.5)	21 (61.8)	2 (50)	0.447
Entecavir	9 (23.7)	7 (20.6)	2 (50)	
Lamivudine	6 (15.8)	6 (17.6)	0 (0)	
Baseline HBV DNA positivity (n)	19 (32.8)	8 (17.8)	11 (84.6)	**<0.001**
Serum HBV DNA Level (Log10 IU/ml)	3.4 (2.77–6.15)	2.82 (2.08–4.20)	3.73 (3.14–7.30)	0.102
Serum ALT (U/L)	42.1±98.5 18 (4–746)	29.7±28.6 18 (4–121)	85.0±201.3 16 (5–746)	0.538
Serum AST (U/L)	30.1±56.8 18 (7–422)	21.2±11.3 18 (8–66)	58.2±112.6 20 (7–422)	0.612
Fasting plasma glucose (mg/dL)	93±18 92 (80–105)	94±18 92 (80–105)	92±17 90 (78–102)	0.79
Total cholesterol (mg/dL)	168.8±46.4 172 (90–248)	177.6±45.6 184 (94–248)	143.3±40.5 143 (90–232)	**0.033**
HDL (mg/dL)	41.4±14.2 38 (10.5–80)	44.1±14.3 40 (10.5–80)	32.6±9.9 31 (21–53)	**0.005**
LDL (mg/dL)	103.4±38.6 101 (19.4–177)	108.9±38.5 107 (19.4–177)	85.9±35.0 79 (40–153)	0.085
Triglyceride (mg/dL)	158.6±70.2 147 (58–356)	159.5±76.8 142.5 (58–356)	155.73±44.9 156 (88–233)	0.811
Serum creatinine (mg/dL)	3.1±2.6 1.6 (0.8–10.1)	2.0±1.5 1.5 (0.8–7)	6.6±2.4 6.5 (3.1–10.1)	**<0.001**
Serum phosphorus (mg/dL)	3.8±1.5 3.5 (1.9–7.9)	3.3±0.9 3.3 (1.9–6.0)	5.7±1.7 6.0 (3.4–7.9)	**<0.001**

Mean±standard deviation, Median (minimum–maximum). *Data were missing for diabetes mellitus in 3 patients (2 kidney transplant recipients and 1 hemodialysis patient), for coronary artery disease in 1 kidney transplant recipient, for osteoporosis in 2 kidney transplant recipients, and for prior antiviral therapy in 1 hemodialysis patient. Percentages are based on the number of patients with available data. HDL: High-density lipoprotein; LDL: Low-density lipoprotein; AST: Aspartate aminotransferase; ALT: Alanine aminotransferase; HBV: Hepatitis B virus; TAF: Tenofovir alafenamide; TDF: Tenofovir disoproxil fumarate.

prior studies demonstrating a high virological response rate following initiation of TAF therapy in both immunocompetent and immunosuppressed populations.[1,9,13]

Long-term treatment with NA, particularly TDF, has been associated with renal dysfunction in some studies.[9,12–15] Consequently, TAF treatment is often preferred over TDF for older patients, those with renal impairment, and those with bone disease.[1,8-10,16] In the present study, no significant changes were observed in mean eGFR or serum creatinine levels from baseline to 24 months of TAF treatment in either the hemodialysis or the kidney transplant group. Serum phosphate levels were stable in most patients, and no major TAF-related renal AE were detected among kidney transplant

Table 2. HBV serological and virological markers at baseline and during follow-up

HBV marker	Baseline positive n/N (%)	Month 12 positive n/N (%)	Month 24 positive n/N (%)
HBsAg	46/56 (82.1)	17/21 (81.0)	11/13 (84.6)
Anti-HBc	47/52 (90.4)	13/15 (86.7)	4/4 (100.0)
HBeAg	9/42 (21.4)	2/13 (15.4)	1/5 (20.0)
Anti-HBe	29/40 (72.5)	10/13 (76.9)	4/5 (80.0)
Anti-HBs	3/22 (13.6)	4/15 (26.7)	0/7 (0.0)
HBV DNA	19/58 (32.8)	4/45 (8.9)	2/44 (4.5)

Data are presented as n/N (%), where N represents the number of patients with a known positive or negative test result at the corresponding time point. Unknown and missing results were excluded from percentage calculations. HBV: Hepatitis B virus; HBsAg: Hepatitis B surface antigen; anti-HBc: Antibody to hepatitis B core antigen; HBeAg: Hepatitis B e antigen; anti-HBe: Antibody to hepatitis B e antigen; Anti-HBs: Antibody to hepatitis B surface antigen; DNA: Deoxyribonucleic acid.

recipients. These findings support the renal safety and stability of TAF treatment in these high-risk populations.

Some studies have demonstrated that TAF treatment, particularly a switch from TDF to TAF, is associated with weight gain, adverse changes in lipid profiles, and increases in cardiovascular risk scores.[6–8,12,15] However, other studies have not confirmed these findings.[1,9,17–19] Calcineurin inhibitors, including cyclosporine and tacrolimus, suppress hepatic LDL receptor expression and reduce LDL clearance, contributing to hyperlipidemia; this effect is particularly pronounced with cyclosporine.[20] Corticosteroids induce hyperlipidemia through multiple mechanisms, including promotion of insulin resistance with increased hepatic free fatty acid reuptake and augmented VLDL synthesis.[20] They also lower LDL receptor activity and promote VLDL-to-LDL conversion. Mammalian target of rapamycin inhibitors, such as sirolimus and everolimus, impair lipolysis by inhibiting lipoprotein lipase activity, further contributing to dyslipidemia.[20] As expected, in the present study, total serum cholesterol and HDL levels were higher in the transplant group than in the hemodialysis group, likely reflecting the effects of immunosuppressive therapy. TAF did not significantly change lipid profiles in either the hemodialysis or kidney transplant group from baseline to the end of the follow-up period.

The multicenter, real-world design of this study enhances the clinical generalizability and reliability of the findings. However, several limitations should be acknowledged. These include the retrospective design, insufficient data to classify the natural-history phases of chronic HBV infection, laboratory data at certain time points, irregular follow-up in some patients who did not return to the center regularly, a relatively small sample size, and the lack of bone mineral density data during TAF treatment. In addition, the uncontrolled study design, without a comparator arm, limits causal inference regarding the observed renal outcomes attributable to TAF treatment.

Table 3. Changes in laboratory values over 24 months by group

Variables	Group	Baseline	3-months	6-months	12-months	24-months	p
ALT (U/L), patients with baseline ALT >40 U/L*	Overall	229.4±290.4	26.2±9.3	26.2±15.2	27.6±13.7	22.6±9.0	**0.024**
ALT (U/L)	Overall	42.1±98.5	28.3±34.1	26.2±29.8	27.6±31.5	24.8±28.4	**0.001**
Fasting plasma glucose levels (mg/dL)	Overall	93±18	94±19	95±20	95±21	96±21	0.56
Total cholesterol (mg/dL)	Overall	168.8±46.4	170.2±47.1	171.4±48.0	173.0±49.2	172.5±48.1	0.41
LDL (mg/dL)	Overall	103.4±38.6	104.5±39.2	105.3±39.8	106.8±40.5	106.1±39.7	0.47
HDL (mg/dL)	Overall	41.4±14.1	41.9±14.5	42.3±14.9	42.8±15.2	42.7±14.8	0.52
Triglyceride (mg/dL)	Overall	158.6±70.2	160.1±71.5	161.8±72.4	163.5±73.2	162.4±72.5	0.55
Creatinine (mg/dL)							
Kidney transplant recipients		2.2±1.6	1.4±0.5	1.5±0.6	1.5±0.5	1.5±0.6	0.826
Hemodialysis patients		6.7±2.3	4.8±2.7	6.3±2.7	6.7±2.2	5.4±3.2	0.419
eGFR-MDRD (mL/min/1.73 m^2)							
Kidney transplant recipients		50.1±22.5	58.9±22.1	61.8±21.7	63.9±22.7	60.9±25.3	0.404
Hemodialysis patients		10.7±5.4	15.3±9.3	10.7±6.3	9.4±3.5	16.1±9.8	0.905
Phosphorus (mg/dL)							
Kidney transplant recipients		3.2±1.2	3.3±0.8	3.0±0.7	3.1±0.5	3.3±0.7	0.321
Hemodialysis patients		5.4±1.7	4.8±1.3**	5.5±1.2	5.5±0.7	5.6±1.0	0.944

Data are presented as mean ± standard deviation (SD). HDL: High-density lipoprotein; LDL: Low-density lipoprotein; ALT: Alanine aminotransferase; * This subgroup includes 11 patients with baseline ALT levels >40 U/L; eGFR-MDRD: Estimated glomerular filtration rate - modification of diet in renal disease, Phosphorus values in the hemodialysis group are based on the 10 patients with measurements at baseline, month 12, and month 24. **The 3-month phosphorus measurement was unavailable only in one patient (9 patients). Baseline values in Table 1 include all 12 patients with available data and therefore differ slightly.

Conclusion

TAF treatment was associated with effective virological suppression and favorable biochemical responses in patients with chronic HBV infection receiving chronic hemodialysis and in kidney transplant recipients. TAF was well tolerated in these patients.

Ethics Committee Approval: The study protocol was approved by the Marmara University Clinical Research Ethics Committee (date: June 12, 2020, number: 09.2020.698) and the study was conducted in accordance with the principles of the Declaration of Helsinki.

Informed Consent: Written informed consent was waived due to the retrospective nature of the study.

Conflict of Interest: The authors did not have any conflicts of interest to declare.

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