



TENOFOVIR-INDUCED ACUTE KIDNEY INJURY IN A PATIENT ON LONG-TERM TLD THERAPY: A CASE REPORT

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ABSTRACT

Tenofovir is a common antiretroviral agent that is employed in the management of HIV infection; nevertheless, its long-term use may result in kidney dysfunction and acute kidney injury (AKI). Here we describe the case of a 54-year-old lady who was admitted in the nephrology department with complaints of bilateral edema of lower limbs for the last one week and face puffiness for three days. She had been diagnosed with type 2 diabetes mellitus, hypertension, and retroviral disease (RVD) on tenofovir-based TLD for the past ten years. On examination, lab investigations revealed raised serum creatinine levels (7.5 mg/dL), elevated blood urea levels (151 mg/dL), hyperphosphatemia, metabolic acidosis, anemia, and poor renal function indicative of acute kidney injury (AKI). Considering the medical history of the patient and clinical features, tenofovir-induced AKI was suspected. The patient was managed conservatively using supportive care, glycemic control, antihypertensive drugs, correction of metabolic

imbalances, and renal monitoring. Repeat laboratory investigations showed progressive improvement of her renal indices while in the hospital. Considering time sequence, clinical findings, and absence of alternative etiology, the ADR was considered to be probable according to Naranjo causality assessment score. It clearly shows that regular monitoring of renal function is vital for people who are undergoing prolonged treatment with tenofovir in cases of co-morbid diseases like diabetes mellitus and hypertension.

KEYWORDS: Tenofovir, acute kidney injury, nephrotoxicity, adverse drug reaction, HIV, pharmacovigilance, case report.

1. INTRODUCTION

Tenofovir disoproxil fumarate (TDF) is a type of nucleotide reverse transcriptase inhibitor that is frequently administered in highly active antiretroviral therapy (HAART) in the management of HIV infection due to its remarkable antiviral efficacy, tolerability, and simple once daily dosing schedule. It is frequently combined with other antiretrovirals in fixed dose combinations like TLD regimen composed of tenofovir, lamivudine, and dolutegravir. Although tenofovir is effective in managing HIV infections, it has been reported to cause a variety of side effects, including nephrotoxicity, which is considered one of the serious consequences of its administration.^[1] The development of tenofovir-induced nephrotoxicity may lead to a wide spectrum of disorders such as proximal renal tubular dysfunction, Fanconi syndrome, chronic kidney disease, and acute kidney injury (AKI), especially among individuals who have received prolonged treatment or those predisposed to the condition due to other risk factors.^[2]

Renal toxicity due to tenofovir is known to occur via the accumulation of the drug in proximal tubule cells causing mitochondrial injury and tubular cell dysfunction through the processes of oxidative stress. Nephrotoxicity associated with tenofovir use includes high serum creatinine levels, presence of protein in urine, electrolyte imbalances, metabolic acidosis, low glomerular filtration rate, and edema. Acute kidney injury refers to the sudden onset of renal impairment that results in poor clearance of body's metabolic waste, fluid, electrolyte and acid-base balance abnormalities.^[3]

The patients who have various medical conditions including type 2 diabetes mellitus and hypertension are more susceptible to the adverse effects on renal function caused by nephrotoxic drugs owing to their existing poor renal function and physiological reserves. It is important that regular testing for the renal function tests like serum creatinine, blood urea nitrogen, eGFR, and electrolytes be done in all patients who are under long-term treatment with Tenofovir. In the presented case report, an episode of acute kidney injury following the use of tenofovir in a patient with retroviral disease on long-term treatment with TLD is reported.^[4]

2. CASE PRESENTATION

A 54-year-old female patient presented at the nephrology ward with chief complaints of bilateral lower limb swelling for one week and puffy face for three days. She is known as a case of RVD being on ART with TLD regimen comprising of tenofovir, lamivudine, and dolutegravir for ten years. The patient is also known as a case of type 2 diabetes mellitus and hypertension with regular treatment. There was no previous history of chronic kidney disease, renal calculi, or use of other nephrotoxic drugs. The patient had generalized weakness, anorexia, and decreased urinary output during the course of admission. On physical examination, bilateral pedal edema, puffy face, pallor, and mild dehydration were found. Her vital signs revealed raised blood pressure, whereas pulse rate and respiratory rate remained stable. No focal neurological signs or features of cardiac failure were noted on systemic examination.

Laboratory tests showed increased renal parameters including serum creatinine level of 7.5 mg/dL and serum urea level of 151 mg/dL consistent with AKI. The patient had hyperphosphatemia with metabolic acidosis based on serum electrolytes. There were hematological findings indicative of anemia with decreased hemoglobin concentration. Proteinuria was evident in the urine findings with renal dysfunction features indicative of nephrotoxicity. Hyperglycemia was noted in this diabetic patient. Imaging tests using ultrasonography showed features consistent with renal parenchymal disease but without signs of obstruction in the urinary tract. Diagnosis of AKI secondary to tenofovir therapy was made considering the clinical manifestation, long-term tenofovir use, laboratory results, and exclusion of other causes.

The patient was put on conservative management with fluid replacement therapy, input-output balance measurement, electrolyte correction, antihypertensive treatment, glycemic management, monitoring of renal function, and supportive measures. Medication history of any nephrotoxic drug intake was obtained and changes in the antiretroviral therapy were also considered. While the patient was in the hospital, tests conducted from time to time revealed gradual improvement in his renal parameters and relief of symptoms. There was marked reduction of his edema, increase in urination, and decreased serum creatinine levels.

Table 1: Initial Laboratory Evaluation of the Patient.

Parameter	Obtained Value	Normal Range
Hemoglobin (Hb)	10.4 gm%	11.9–15 gm%
ESR	120 mm/hr	0–20 mm/hr
PCV	30.8%	36–46%
TRBC	3.32 million/cumm	3.8–4.8 million/cumm
RDW-CV	15%	11.6–14%
Serum Urea	151 mg/dL	18–45 mg/dL
Serum Creatinine	7.5 mg/dL	0.6–1.1 mg/dL
Chloride	107 mEq/L	96–105 mEq/L
Phosphorus	8.2 mg/dL	2.5–4.5 mg/dL
Bicarbonate	14.7 mEq/L	22–28 mEq/L

Table 2: Day-wise Serum Creatinine and Urea Values.

Day	Serum Urea (mg/dL)	Serum Creatinine (mg/dL)
Day 1	151	7.5
Day 2	165	8.3
Day 3	172	7.7
Day 4	172	8.0
Day 5	170	7.6
Day 6	169	7.0
Day 7	168	6.0

3. DISCUSSION

Tenofovir disoproxil fumarate (TDF) has become widely used as a potent nucleotide reverse transcriptase inhibitor for Human Immunodeficiency Virus (HIV) infection due to its significant antiviral effect and effectiveness in treatment. Prolonged administration of tenofovir leads to nephrotoxicity, regarded as the most dangerous adverse reaction related to this drug. The development of tenofovir nephrotoxicity occurs because the accumulation of the drug in renal proximal tubule epithelial cells results in mitochondrial toxicity, oxidation, and other cellular disturbances. Tenofovir nephrotoxicity can cause different diseases related to renal disorders, such as proximal tubulopathy, Fanconi syndrome, chronic kidney disease, and acute kidney injury (AKI).^[5]

In the current case, the patient was taking a TLD regimen based on tenofovir for almost ten years and has presented with signs of acute kidney injury due to high serum creatinine level, high blood urea, edema, puffy face, metabolic acidosis, hyperphosphatemia, and proteinuria. The occurrence of renal impairment in the wake of long-term tenofovir treatment was indicative of tenofovir-related nephrotoxicity. In addition to that, the patient had several risk factors such as type 2 diabetes and hypertension. Both these conditions are associated with an

increased risk of renal damage, and they aggravate the adverse effects of nephrotoxic medications.^[6]

The underlying mechanism of AKI caused by tenofovir includes defective synthesis of mitochondrial DNA in proximal tubule cells resulting in tubular cell necrosis and decreased glomerular filtration rate. Symptoms of the condition range from mild elevations in serum creatinine to severe cases that necessitate renal replacement therapy. The timely recognition of signs of deteriorating renal function and prompt pharmacovigilance assessment enabled detection of the adverse drug reaction at an early stage in the patient before causing permanent damage to the kidneys.^[7] Other possible etiologies of AKI such as obstruction, dehydration, septic shock, and other forms of nephrotoxic drugs were considered during evaluation and ruled out. The treatment strategy for tenofovir induced nephrotoxicity is based on prompt identification of the cause, discontinuation or adjustment of drug therapy, supportive measures, hydration, and electrolyte correction. In this case, conservative approach comprising of intravenous fluid replacement, management of glycemia and hypertension, and serial measurement of renal markers led to gradual improvement of the symptoms and laboratory indices. The patient experienced successful treatment as evidenced by alleviation of edema, increased urine output, and normalization of serum creatinine levels.^[7]

The causality assessment of the drug reaction with the use of Naranjo Adverse Drug Reaction Probability Scale classified the reaction as “Probable” adverse drug reaction, confirming the link between long-term use of tenofovir and occurrence of acute kidney injury. This patient case underscores the significance of regular kidney function tests among patients undergoing long-term tenofovir therapy especially those with concurrent diseases such as diabetes mellitus and hypertension. Early pharmacovigilance is necessary for proper management and to prevent any further complications in the kidneys due to prolonged antiretroviral therapy.

S. No	Question	Yes	No	Don't Know/NA	Score
1	Are there previous conclusive reports on this reaction?	+1	0	0	+1
2	Did the adverse event appear after the suspected drug was administered?	+2	-1	0	+2
3	Did the adverse reaction improve when the drug was discontinued or a specific antagonist was administered?	+1	0	0	+1
4	Did the adverse reaction reappear when the drug was re-administered?	+2	-1	0	0

5	Are there alternative causes other than the drug that could on their own have caused the reaction?	-1	+2	0	+1
6	Did the reaction reappear when a placebo was given?	-1	+1	0	0
7	Was the drug detected in blood (or other fluids) in concentrations known to be toxic?	+1	0	0	0
8	Was the reaction more severe when the dose was increased or less severe when the dose was decreased?	+1	0	0	0
9	Did the patient have a similar reaction to the same or similar drugs in any previous exposure?	+1	0	0	0
10	Was the adverse event confirmed by any objective evidence?	+1	0	0	+1

TOTAL SCORE = 6

CAUSALITY CATEGORY: PROBABLE ADR

Interpretation

- ≥ 9 = Definite ADR
- 5–8 = Probable ADR
- 1–4 = Possible ADR
- 0 = Doubtful ADR

4. CONCLUSION

Acute renal dysfunction as a consequence of tenofovir is considered an important adverse effect due to extended use of antiretroviral drugs, especially in patients suffering from existing conditions, such as diabetes mellitus and hypertension. In the current case study, an acute kidney injury caused by the use of TLD regimen, which includes tenofovir, was identified. The development of acute kidney dysfunction associated with high levels of serum creatinine, elevated blood urea levels, edema formation, metabolic changes, and renal impairment suggests that the use of this medication might be associated with tenofovir-induced nephrotoxicity in a patient aged 54 years old. Early diagnosis of the adverse effect of the drug helped prevent serious consequences and progression of kidney failure and permanent organ damage. Conservative treatment and pharmacovigilance helped avoid adverse effects of the adverse drug reaction and achieved a gradual improvement in the patient's condition. According to the Naranjo causality scale, the reaction can be classified as "Probable" adverse drug reaction.

CONSENT

As per institutional guidelines, patient consent was obtained prior to preparation of this case report.

ETHICAL APPROVAL

Not applicable.

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