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Case Report

Tenofovir Overdosage-A Rarely Reported Phenomenon in Literature

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Abstract

Introduction: Hepatitis B virus (HBV) has infected affected thirty three percent of the world population, two billion have been infected worldwide and out of them, 350 million suffer from chronic HBV infection. Out of these, approximately 15–40% of patients will develop cirrhosis, liver failure and hepatocellular carcinoma. The most common side effects of tenofovir are nausea, vomiting, diarrhea, bloating, flatulence, indigestion, loss of appetite, headache, weakness (asthenia), dizziness, insomnia, rash, itching, back pain, pain, renal failure, lactic acidosis, alopecia and osteoporosis. There is paucity of research regarding overdosage of tenofovir. Hence, the need of this case report.

Case Report: We are reporting a thirty-year-old male of chronic hepatitis B who was in active phase thus was put on Tenofovir disoproxil fumarate (TDF) 300 mg daily once. The six -month therapy was issued to him free of cost under National viral hepatitis control program (NVHCP). As the six bottles of tenofovir were of different time period of expiry, hence they were numbered from 1-6, for ease of patient, so that number 1 bottle is finished first and number 6 was to be taken in last. It was clearly explained to him that only one tablet has to be taken in a day. There were no accompanying family members at the time of dispensing of drugs. The patient reported after one month with complaints of irritability, vertigo, restlessness, red eyes, feeling of radiation of heat from body and headache. We have never seen these kinds of side effects with tenofovir in 2500 patients in last 13 years who are on regular treatment and follow-up. There was no history of any kind of drug intake with tenofovir, alteration in food habits, any kind of drug or alcohol abuse in last one month when tenofovir was started. On probing further, he admitted that he was taking six tablets of tenofovir per day. The reason given was that by mistake on reading number 6 written on one bottle, he understood that six tablets per day are to be taken in a day. The reality is that number 6 was written on that particular bottle for depicting that this bottle has to be used in last i.e. in sixth month. The patient all biochemical labs including liver function & renal function, blood sugar, thyroid profile, serum electrolytes, serum calcium and phosphorus levels, urine complete examination, ECG, chest x-ray and ultrasonogram abdomen was essentially normal. He was immediately shifted on daily once dosage of tenofovir. All his symptoms subsided within a week.

Conclusion: Every drug has well documented side effects but it is not necessary that manifestations due to overdosage are available for all the available drugs. Similarly, there is scarcity of data regarding overdose of tenofovir which occurred in our case. The relieving side was that patient did not develop life threatening complications like lactic acidosis and renal failure. Our case report re-affirms the need of repeatedly explaining to the patients about proper dosage of drugs.

Keywords: Tenofovir, Allergic Reaction, Irritability, Vertigo, Restlessness, Red Eyes.

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Introduction

Hepatitis B virus (HBV) has infected affected thirty three percent of the world population, two billion have been infected worldwide and out of them, 350 million suffer from chronic HBV infection. Out of these, approximately 15–40% of patients will develop cirrhosis, liver failure and hepatocellular carcinoma [1-4]. The prevalence of Hepatitis B surface antigen (HBsAg) > 8% of the population is termed high, between 2-7% is called intermediate and < 2%) is labelled as low [5]. It is estimated that around 40million HBV carriers are present in India which amounts for10–15% of total pool of HBV carriers of the world. One lakh people in India die due to HBV infection in India [6,7] and HbsAg positivity ranges between 2–4.7% [8-9]. Tenofovir and Entecavir are two main drugs which are used for treatment of chronic hepatitis B. The most common side effects of tenofovir are nausea, vomiting, diarrhea, bloating, flatulence, indigestion, loss of appetite, headache, weakness

(asthenia), dizziness, insomnia, rash, itching, back pain, pain, renal failure, lactic acidosis, alopecia and osteoporosis. The overdosage of tenofovir is limitedly reported in literature and lactic acidosis & renal injury are two main dreaded complications of the same.

Case Report

We are reporting a thirty-year-old male of chronic hepatitis B who was in active phase thus was put on Tenofovir disoproxil fumarate (TDF) 300 mg daily once. The six -month therapy was issued to him free of cost under National viral hepatitis control program (NVHCP). As the six bottles of tenofovir were of different time period of expiry, hence they were numbered from 1-6, for ease of patient, so that number 1 bottle is finished first and number 6 was to be taken in last. It was clearly explained to him that only one tablet has to be taken in a day. There were no accompanying family members at the time of dispensing of drugs. The patient reported after one month with complaints of irritability, vertigo, restlessness, red eyes, feeling of radiation of heat from body and headache. We have never seen these kinds of side effects with tenofovir in 2500 patients in last 13 years who are on regular treatment and follow-up. There was no history of any kind of drug intake with tenofovir, alteration in food habits, any kind of drug or alcohol abuse in last one month when tenofovir was started. On probing further, he admitted that he was taking six tablets of tenofovir per day. The reason given was that by mistake on reading number 6 written on one bottle, he understood that six tablets per day are to be taken in a day. The reality is that number 6 was written on that particular bottle for depicting that this bottle has to be used in last i.e. in sixth month. The patient all biochemical labs including liver function & renal function, blood sugar, thyroid profile, serum electrolytes, serum calcium and phosphorus levels, urine complete examination, ECG, chest x-ray and ultrasonogram abdomen was essentially normal. He was immediately shifted on daily once dosage of tenofovir. All his symptoms subsided within a week.

Discussion

Limited clinical experience at doses higher than the therapeutic dose of tenofovir 300 mg is available. In Study 901, 600 mg tenofovir disoproxil fumarate was administered to 8 subjects orally for 28 days. No severe adverse reactions were reported. The effects of higher doses are not known. If overdose occurs the patient must be monitored for evidence of toxicity, and standard supportive treatment applied as necessary. Tenofovir is efficiently removed by hemodialysis with an extraction coefficient of approximately 54%. Following a single dose of tenofovir 300 mg, a four-hour hemodialysis session removed approximately 10% of the administered tenofovir dose. The various common side effects documented with TDF are diarrhea, headache, depression, rash, itching, fever, difficulty falling asleep or staying asleep, gas, heartburn, indigestion and weight loss. The uncommon severe side effects reported with TDF are decreased urination, swelling of feet and ankles, ongoing or worsening bone pain, myalgias, dizziness or light headedness, fast or irregular heartbeat, shortness of breath and cold or blue-coloured hands & feet [10]. Malhotra et al showed that TDF 300 mg has minimal side effects like dyspepsia, allergic rash, anxiety, generalized weakness and constipation. The most common side effect noted was dyspepsia which was seen in 15 patients (39.47%), followed by allergic rash in 9 patients (23.68%), anxiety in 8 patients (21.05%), generalized weakness in 3 patients (7.89%) and constipation in 3 patients (7.89%) [11]. An overdose of tenofovir requires immediate medical attention, typically involving monitoring for renal failure or lactic acidosis. High doses may cause severe, sometimes irreversible, acute kidney injury and renal tubular dysfunction. Tenofovir's primary route of elimination is through the urine, where it is excreted largely via glomerular filtration and proximal tubular secretion [12-14].

Conclusion

Every drug has well documented side effects but it is not necessary that manifestations due to overdosage are available for all the available drugs. Similarly, there is scarcity of data regarding overdose of tenofovir which occurred in our case. The relieving side was that patient did not develop life threatening complications like lactic acidosis and renal failure. Our case report re-affirms the need of repeatedly explaining to the patients about proper dosage of drugs.

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