CASE REPORT

ALT CHANGES AND ADVERSE EVENTS OF TELBIVUDINE IN HEPATITIS-B PATIENTS-AN EXPERIENCE OF 11 PATIENTS

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Hepatitis-B virus (HBV) infection is a major global health problem**.** Of the two billion people who have been infected, more than 350 million have chronic hepatitis. It is estimated that 235,000–328,000 people die annually due to liver cirrhosis and hepatocellular carcinoma, we assessed the short term outcomes of treatment with telbivudine in 11 adults aged 14–41 years with HBeAg-positive or HBeAg-negative chronic hepatitis-B (CHB). Treatment of chronic hepatitis-B patients with telbivudine shows 43.1% reduction in serum ALT with no significant adverse effects.

Keywords: Telbivudine, Hepatitis-B Virus, Hepatocellular Carcinoma, HBeAg

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INTRODUCTION

Hepatitis-B virus (HBV) infection is a major global health problem.[1] Of the two billion people who have been infected, more than 350 million have chronic hepatitis.[2] It is estimated that between 235,000 and 328,000 people die annually due to liver cirrhosis and hepatocellular carcinoma, respectively.[3] Serum HBV DNA is a marker of viral replication, and several natural history studies have shown that high serum HBV DNA levels are associated with an increased risk of disease progression.[4–7] Telbivudine demonstrated potent activity against hepatitis-B with a significantly higher rate of response and superior viral suppression compared with lamivudine, the standard treatment.[8] Previous studies showed that after 1 year of treatment, telbivudine demonstrated better treatment outcomes as compared to other 4 oral nucleos(t)ide analogues available for treatment of chronic hepatitis-B.

The aim of the study was to assess the short term outcomes (03 months) of telbivudine in adults aged 14–41 years with HBeAg-positive or HBeAg-negative chronic hepatitis-B (CHB) patients.

CASE REPORTS

11 adults aged 14–41 years with HBeAg-positive or HBeAg-negative chronic hepatitis-B with no other liver problem like hepatitis C and D, alcoholic hepatitis, fatty liver, hepatocellular carcinoma patients who came to medicine department of Jinnah Post Graduate Centre between April 2014 and June 2014, were included in the study. Each patient was prescribed oral telbivudine 600 mg/d for 2 years and after 3 months changes in ALT and adverse events were observed. A total of 11 patients, 4 (36.4%) females and 7 (63.6%) males were treated with telbivudine. The treated population comprised 7 HBeAg-positive and 4 HBeAg-negative patients. Mean serum ALT was reduced from 129.6±30 iu/ml from first visit to 55.9±18 iu/ml after 3 months of treatment. The HBV DNA was positive in five (45.6%) patients from initial to final visit after 3 months of treatment.

Case-1:

A 30-year-old female was hospitalized in March 2014 for acute Hepatitis-B, followed by HBV viral persistence and CHB, characterized by hepatitis e antigen positivity and serum ALT 141 iu/ml. in March, telbivudine was started and after 3 months ALT dropped to 44 iu/ml without any significant adverse event.

Case-2:

A 14-year-old male with hepatitis e antigen negative, ALT 108 iu/ml was given telbuvidine and after 3 months ALT was dropped to 44 iu/ml. During treatment patient experienced a nausea and dizziness.

Case-3:

A 41-year-old male with hepatitis e antigen negative, ALT 167 iu/ml was given telbuvidine and after 3 months ALT was dropped to 83 iu/ml. During treatment patient experienced a headache.

Case-4:

A 34-year-old male with hepatitis e antigen negative, ALT 96 iu/ml was given telbuvidine and after 3 months ALT was dropped to 36 iu/ml. Patient reported nausea and headache occasionally.

Case-5:

A 30-year-old female with hepatitis e antigen negative, ALT 101 iu/ml was given telbuvidine and after 3 months ALT was dropped to 57 iu/ml. Drug was well tolerated during treatment.

Case-6:

A 28-year-old male with hepatitis e antigen positive, ALT 104 iu/ml was given telbuvidine and after 3 months ALT was dropped to 51 iu/ml. Drug was well tolerated during treatment.

Case-7:

A 19-year-old male with hepatitis e antigen positive, ALT 164 iu/ml was given telbuvidine and after 3

months ALT was dropped to 67 iu/ml. Drug was well tolerated during treatment.

Case-8:

A 33-year-old female with hepatitis e antigen positive, ALT 139 iu/ml was given telbuvidine and after 3 months ALT was dropped to 66 iu/ml. Drug was well tolerated during treatment.

Case-9:

A 40-year-old male with hepatitis e antigen positive, ALT 166 iu/ml was given telbuvidine and after 3 months ALT was dropped to 42 iu/ml. Drug was well tolerated during treatment.

Case-10:

A 27-year-old female with hepatitis e antigen positive, ALT 153 iu/ml was given telbuvidine and after 3 months ALT was dropped to 86 iu/ml. During treatment patient experienced a nausea and headache.

Case-11:

A 39-year-old male with hepatitis e antigen positive, ALT 87 iu/ml was given telbuvidine and after 3 months ALT was dropped to 39 iu/ml. Drug was well tolerated during treatment.

DISCUSSION

The results showed that at the end of three months treatment, telbivudine produced a reduction in ALT and also the reduction in Hepatitis virus detection. The result of the systematic review showed telbivudine had greater antiviral efficacy than did lamivudine and the frequencies of adverse events were more for patients who received telbivudine than for those who received lamivudine,and increased with the prolonged treatment.[9] Telbivudine was more effective in inhibiting HBV replication and promoting HBeAg seroconversion than lamivudine for CHB patients.[10] In GLOBE trial, the rates of normalization of serum ALT at week-52 were reported more than 70% in patients treated with telbivudine.[11]

CONCLUSION

Treatment of chronic hepatitis-B patients with telbivudine shows reduction in serum ALT without any significant adverse effects as reported during 03 months of treatment. The most common side effect of telbivudine in few patients was headache, nausea, and dizziness.

Conflicts of Interest: There was no funding of any sort either from pharmaceutical company, agency or from the hospital itself for the study. There were no disclosures either financial or personal to be made by any author involved in this study.

AUTHORS' CONTRIBUTION

ZA conceived, designed the study, collected data, supervised all the research process and also helped in preparing, editing and finalizing the manuscript for publication. NM, UZ and AS were involved in concept, study design, and manuscript review. A Khan analyzed the data and write up of manuscript.

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