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A Randomized Comparative Study between the Effect of Tenofovir Alafenamide and Entecavir in Treatment-naïve Chronic Hepatitis B Patients

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KEYWORDS
Chronic hepatitis B; Tenofovir alafenamide ; Entecavir; Antiviral therapy.

ABSTRACT:

Background: Chronic hepatitis B (CHB) remains a major global health problem and is associated with significant morbidity and mortality due to liver cirrhosis and hepatocellular carcinoma. Potent nucleos(t)ide analogues such as tenofovir alafenamide (TAF) and entecavir (ETV) are recommended as first-line antiviral therapies. However, comparative data regarding their efficacy and safety in treatment-naïve CHB patients in Bangladesh remain limited.

Objective: To compare the efficacy and safety of TAF and ETV in treatment-naïve CHB patients.

Methods: This randomized comparative study was conducted at the Hepatitis Clinic of the Department of Gastroenterology, Bangabandhu Sheikh Mujib Medical University (BSMMU), Dhaka, Bangladesh from January 2024 to December 2024. A total of 44 treatment-naïve CHB patients were enrolled and randomly allocated into two groups: TAF group (n=22) and ETV group (n=22). Patients received TAF 25 mg once daily or ETV 0.5 mg once daily for 48 weeks. Clinical assessment and laboratory investigations including HBV DNA, alanine aminotransferase (ALT), hepatitis B surface antigen (HBsAg), anti-HBe, and serum creatinine were performed at baseline, 24 weeks, and 48 weeks. Data were analyzed using SPSS version 27.

Results: Both treatment groups showed significant reduction of HBV DNA levels from baseline to 24 weeks and 48 weeks. ALT levels also decreased progressively in both groups, indicating improvement in biochemical response. No statistically significant difference was observed between TAF and ETV groups regarding virological suppression, ALT normalization, or serological response. However, serum creatinine levels at one year were significantly higher in the ETV group compared with the TAF group (p=0.028).

Conclusion: Both TAF and ETV are effective antiviral therapies for treatment-naïve CHB patients, achieving significant virological suppression and biochemical improvement. TAF demonstrated a relatively favorable safety profile, particularly regarding renal function. Larger studies with longer follow-up are required to evaluate long-term outcomes.

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INTRODUCTION

Hepatitis B virus (HBV) infection remains a major global public health problem. It is estimated that nearly two billion people worldwide have been infected with HBV at some point in their lifetime, and approximately 296 million people are living with chronic hepatitis B (CHB). HBV infection accounted for about 820,000 deaths globally in 2019, mainly due to complications such as liver cirrhosis and hepatocellular carcinoma (HCC). [12] the clinical manifestations of HBV infection vary widely, ranging from asymptomatic carrier state and acute self-limiting hepatitis to chronic hepatitis, cirrhosis, acute-on-chronic liver failure, and hepatocellular carcinoma. [3]

Bangladesh lies in the intermediate endemic zone of hepatitis B infection with an estimated prevalence of about 5–6% in the general population. [4] HBV infection is one of the major causes of both acute and chronic liver diseases in the country. Previous studies have reported that HBV is responsible for approximately 30% of acute hepatitis, about 75% of chronic hepatitis, around 60% of liver cirrhosis, and nearly 65% of hepatocellular carcinoma cases in Bangladesh.[4–6] Because of the substantial disease burden and the potential for serious complications, effective antiviral therapy is essential for the management of chronic hepatitis B and for preventing disease progression.

After infecting hepatocytes, the HBV genome enters the nucleus and forms covalently closed circular DNA (cccDNA), which serves as a stable template for viral replication. The persistence of cccDNA makes complete eradication of HBV difficult with currently available therapies.[7] Serum hepatitis B surface antigen (HBsAg) levels correlate with intrahepatic cccDNA levels and are therefore considered an important marker of viral activity and treatment response.[8] Studies have also demonstrated that higher HBsAg levels are associated with an increased risk of hepatocellular carcinoma, even in patients with relatively low viral loads.[9] Consequently, the main goal of antiviral therapy in chronic hepatitis B is sustained suppression of HBV replication and eventual loss of HBsAg, which is often referred to as a functional cure.[10]

The current treatment options for chronic hepatitis B include interferon therapy and nucleos(t)ide analogues (NAs). Among these agents, entecavir (ETV) and tenofovir disoproxil fumarate (TDF) are widely recommended as first-line antiviral therapies because of their potent antiviral activity and high genetic barrier to resistance. [11] These drugs inhibit the reverse transcription of HBV DNA and can effectively suppress viral replication, thereby reducing the risk of disease progression and complications. However, long-term treatment with entecavir has shown limited effectiveness in reducing serum HBsAg levels and may not completely eliminate the risk of hepatocellular carcinoma in patients with chronic hepatitis B.[12]

Although tenofovir disoproxil fumarate is highly effective in suppressing HBV replication, prolonged use has been associated with adverse effects such as renal dysfunction and reduction in bone mineral density. [13] to overcome these limitations, tenofovir alafenamide (TAF), a newer prodrug of tenofovir, has been developed. TAF has greater plasma stability and delivers the active metabolite more efficiently into hepatocytes at a much lower dose, resulting in similar antiviral efficacy but improved renal and bone safety profiles compared with TDF. [1314] Because of these advantages, TAF has recently been included among the recommended first-line antiviral agents for the treatment of chronic hepatitis B.[10]

Previous studies have suggested that tenofovir-based therapy may lead to greater reductions in HBsAg levels compared with entecavir therapy, indicating a potential advantage in long-term viral suppression and disease control. [15] However, direct comparative data between tenofovir alafenamide and entecavir remain limited, particularly in treatment-naïve patients and in developing countries such as Bangladesh. Moreover, local clinical evidence comparing the efficacy and safety of these two antiviral agents is still scarce.

Considering the high burden of chronic hepatitis B in Bangladesh and the limited comparative data regarding these commonly used antiviral therapies, further evaluation is required to determine the relative effectiveness and safety of tenofovir alafenamide and entecavir in treatment-naïve patients.

Therefore, the aim of this study was to compare the efficacy and safety of tenofovir alafenamide and entecavir in treatment-naïve chronic hepatitis B patients.

MATERIAL AND METHODS:

This randomized comparative study was conducted in the Hepatitis Clinic of the Department of Gastroenterology at Bangabandhu Sheikh Mujib Medical University (BSMMU), Dhaka, Bangladesh. The study was carried out over a period of one year from January 2024 to December 2024. The objective of the study was to compare the efficacy and safety of tenofovir alafenamide (TAF) and entecavir (ETV) in treatment-naïve patients with chronic hepatitis B.

The study population consisted of patients diagnosed with chronic hepatitis B who attended the Hepatitis Clinic of

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the Department of Gastroenterology, BSMMU. Patients aged 18 years or older with confirmed chronic hepatitis B infection were considered eligible for inclusion. Chronic hepatitis B was defined as persistence of hepatitis B surface antigen (HBsAg) for more than six months along with detectable HBV DNA levels. Patients fulfilling treatment criteria such as HBV DNA ≥2000 IU/ml with elevated alanine aminotransferase (ALT) or evidence of liver inflammation or fibrosis were included in the study. Patients with compensated cirrhosis with detectable HBV DNA were also considered eligible for treatment and inclusion.

Patients were excluded if they had received previous antiviral therapy, interferon, or immunosuppressive therapy. Pregnant or lactating women were also excluded. Patients with co-infection with hepatitis C virus or human immunodeficiency virus, decompensated liver disease, hepatocellular carcinoma, or severe systemic illness were excluded from the study. Patients who had a history of hepatitis B vaccination or had severe renal impairment were also excluded.

A total of 44 treatment-naïve chronic hepatitis B patients who met the inclusion and exclusion criteria were enrolled in the study. The patients were randomly divided into two treatment groups. Twenty-two patients were assigned to the tenofovir alafenamide (TAF) group and twenty-two patients were assigned to the entecavir (ETV) group.

Patients in the TAF group received tenofovir alafenamide 25 mg orally once daily with food, while patients in the ETV group received entecavir 0.5 mg orally once daily on an empty stomach. Both treatment groups received antiviral therapy for a duration of 48 weeks and were followed regularly during the study period.

Baseline demographic information including age and gender was recorded for all patients. Detailed clinical history and physical examination findings were also documented at enrollment. Baseline clinical variables included symptoms such as yellowish discoloration of eyes and urine, right upper quadrant pain, malaise, loss of appetite, abdominal swelling, weight loss, and history of liver disease or blood transfusion.

Laboratory investigations were performed at baseline for all participants. These included complete blood count, erythrocyte sedimentation rate (ESR), platelet count, serum bilirubin, alanine aminotransferase (ALT), aspartate aminotransferase (AST), prothrombin time, serum albumin, alpha-fetoprotein (AFP), and serum creatinine levels. Virological and serological markers including HBsAg, HBeAg, anti-HBe, and HBV DNA were also assessed. Ultrasonography of the whole abdomen and upper gastrointestinal endoscopy were performed when indicated to assess liver morphology and complications.

Follow-up assessments were conducted in 24 weeks and 48 weeks (one year) after initiation of therapy. During each follow-up visit, clinical symptoms, physical examination findings, and possible drug-related adverse effects were recorded. Laboratory investigations including ALT, HBsAg, anti-HBe, HBV DNA levels, and serum creatinine were repeated to assess treatment response and safety.

The primary outcome variables of the study included virological response, serological response, biochemical response, and drug safety. Virological response was defined as suppression of HBV DNA levels during treatment. Serological response included HBsAg loss, HBeAg loss, and development of anti-HBe antibodies. Biochemical response was defined as normalization of ALT levels. Safety of treatment was assessed by monitoring clinical side effects and changes in serum creatinine levels.

Statistical Analysis

All collected data was recorded in a pre-designed data collection sheet. Data were entered and analyzed using the Statistical Package for Social Sciences (SPSS) version 27. Quantitative variables were expressed as mean ± standard deviation, while categorical variables were expressed as frequency and percentage. Continuous variables between the two groups were compared using the unpaired t-test. Categorical variables were analyzed using the Chi-square test or Fisher's exact test where appropriate. A p-value of less than 0.05 was considered statistically significant.

Ethical Clearance:

Ethical approval for the study was obtained from the Institutional Review Board of Bangabandhu Sheikh Mujib Medical University. Written informed consent was obtained from all participants prior to enrollment in the study. Confidentiality of patient information was strictly maintained throughout the study period.

RESULTS

A total of 44 treatment-naïve chronic hepatitis B patients were enrolled in the study. Participants were randomly allocated into two groups: Tenofovir Alafenamide (TAF) group (n=22) and Entecavir (ETV) group (n=22). Baseline demographic characteristics, clinical features, laboratory findings, and treatment outcomes were analyzed and compared between the two treatment groups.

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Table 1. Demographic profile of the study subjects (n=44)

Variable	TAF (n=22)	ETV (n=22)	p value
Age (years)	37.59 ± 10.04	34.91 ± 10.85	0.400
Male	16 (72.7%)	18 (81.8%)	0.472
Female	6 (27.3%)	4 (18.2%)	

Table 1 resembles demographic profile of the study subjects. The mean age of the TAF group was 37.59±10.04 years, whereas the mean age of the ETV group was 34.91±10.85 years. Male participants predominated in both groups. There was no statistically significant difference in demographic characteristics between the groups.

Table 2. Baseline laboratory findings of the study subjects (n=44)

Parameter	TAF	ETV	p value
Serum Bilirubin (mg/dl)	1.54 ± 1.97	1.08 ± 0.74	0.315
ALT (U/L)	74.95 ± 73.21	55.77 ± 26.14	0.254
AST (U/L)	48.64 ± 32.25	50.18 ± 27.47	0.865
Serum Creatinine (mg/dl)	0.78 ± 0.16	0.85 ± 0.24	0.295

Table 2 shows baseline laboratory findings of the study subjects. There was no statistically significant difference between the two groups with respect to baseline biochemical parameters.

Table 3. HBV-DNA levels at baseline, 24 weeks, and 1 year (n=44)

Time	TAF	ETV	p value
Baseline	1585 ± 5935	724 ± 1309	0.520
24 weeks	2.99 ± 1.07	249.12 ± 621.38	0.184
1 year	2.62 ± 1.34	45.86 ± 127.94	0.326

Table 3 indicates HBV-DNA levels at baseline, 24 weeks and 1 year. Both treatment groups demonstrated a marked reduction in HBV-DNA levels during follow-up. However, the difference between the groups was not statistically significant.

Table 4. ALT levels at baseline, 24 weeks, and 1 year (n=44)

Time	TAF	ETV	p value
Baseline	74.95 ± 73.21	55.77 ± 26.14	0.254

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24 weeks	40.95 ± 17.97	48.50 ± 18.20	0.174
1 year	38.86 ± 14.41	42.52 ± 12.27	0.376

Table 4 shows ALT levels in the baseline, 24 weeks and 1 year. ALT levels gradually decreased in both treatment groups during follow-up, indicating improvement in biochemical response.

Table 5. Serological response (Anti-HBe positivity) (n=44)

Time	TAF	ETV	p value
Baseline	14 (63.6%)	19 (86.4%)	0.082
24 weeks	14 (63.6%)	15 (68.2%)	1.000
1 year	15 (68.2%)	15 (68.2%)	1.000

Table 5 resembles serological response. The proportion of Anti-HBe positive patients increased slightly in both groups during the study period, but no statistically significant difference was observed.

Table 6. Serum creatinine levels after 1 year of treatment (n=44)

Parameter	TAF	ETV	p value
Serum Creatinine (mg/dl)	0.72 ± 0.22	0.86 ± 0.20	0.028*

Table 6 indicates Serum creatinine levels were significantly higher in the ETV group after one year of treatment, suggesting possible differences in safety profile.

Figure 1. Trend of HBV-DNA reduction during treatment (n=44)

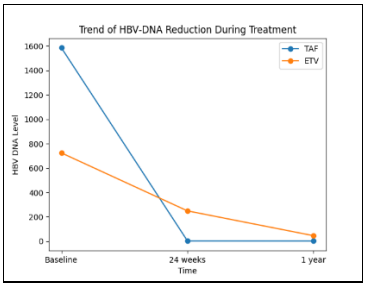

Figure 1 illustrates the trend of HBV-DNA reduction during treatment with tenofovir alafenamide (TAF) and entecavir (ETV). HBV-DNA levels decreased markedly in both groups from baseline to 24 weeks and further at 1 year of follow-up. The decline was more rapid in the TAF group, although both treatments demonstrated effective viral suppression over time.

Figure 2. Trend of ALT levels during treatment (n=44)

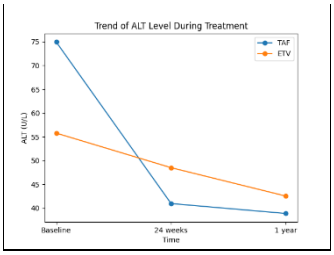

Figure 2 shows the trend of ALT levels during treatment with tenofovir alafenamide (TAF) and entecavir (ETV). ALT levels decreased progressively from baseline to 24 weeks and further at 1 year in both

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treatment groups, indicating improvement in biochemical response. The reduction appeared more pronounced in the TAF group compared to the ETV group over the follow-up period.

DISCUSSION

Chronic hepatitis B (CHB) remains a significant cause of liver-related morbidity and mortality worldwide. Long-term antiviral therapy with potent nucleos(t)ide analogues is the cornerstone of CHB management, as it effectively suppresses viral replication and reduces the risk of cirrhosis and hepatocellular carcinoma. [16] the present randomized comparative study was conducted to evaluate the efficacy and safety of tenofovir alafenamide (TAF) and entecavir (ETV) in treatment-naïve chronic hepatitis B patients.

In the present study, the baseline demographic characteristics of the participants were comparable between the two treatment groups. The mean age of the patients in the TAF group was slightly higher than that of the ETV group, although the difference was not statistically significant. Male patients predominated in both groups, which is consistent with previous studies reporting a higher prevalence of chronic hepatitis B among males. [17] the comparable baseline characteristics between the two groups ensured that the treatment outcomes observed during follow-up were unlikely to be influenced by demographic differences.

Both antiviral regimens demonstrated a significant reduction in HBV DNA levels during the follow-up period. In the TAF group, the mean HBV DNA level decreased markedly from baseline to 24 weeks and remained suppressed at one year. A similar trend was observed in the ETV group, although the reduction appeared relatively slower compared with TAF. These findings indicate that both drugs are effective in suppressing viral replication in treatment-naïve chronic hepatitis B patients. Previous clinical trials have also demonstrated potent antiviral activity of both TAF and ETV, with sustained viral suppression during long-term therapy. [18]

The reduction in HBV DNA observed in the TAF group was more pronounced during the early phase of treatment, which may suggest a rapid antiviral response with this drug. Similar observations have been reported in earlier studies where tenofovir-based therapy demonstrated strong viral suppression in chronic hepatitis B patients. [19] However, in the present study the difference between the two treatment groups was not statistically significant, suggesting that both medications provide comparable virological efficacy over time.

Biochemical response was also evaluated in the present study by measuring serum alanine aminotransferase (ALT) levels during follow-up. ALT levels decreased progressively in both groups from baseline to 24 weeks and further at one year, indicating improvement in hepatic inflammation following antiviral therapy. The reduction appeared more pronounced in the TAF group; however, the difference between the two groups did not reach statistical significance. Similar improvements in ALT normalization have been reported in previous studies comparing nucleos(t)ide analogues in chronic hepatitis B patients. [20]

Serological response is another important indicator of treatment effectiveness. In the present study, the proportion of patients with Anti-HBe positivity showed slight improvement during follow-up in both treatment groups. However, the rate of seroconversion was relatively low. This observation is consistent with earlier studies reporting that serological responses, particularly HBeAg or HBsAg seroconversion, occur gradually and often require longer durations of antiviral therapy. [21] Therefore, extended follow-up may provide better insights into long-term serological outcomes.

Regarding safety outcomes, both drugs were generally well tolerated by the study participants. However, serum creatinine levels in one year were significantly higher in the ETV group compared with the TAF group. Although the values remained within the normal range, this finding suggests a possible difference in renal safety profiles between the two treatments. Previous studies have demonstrated that TAF has improved renal and bone safety compared with earlier tenofovir formulations because it achieves high intracellular drug concentrations at lower systemic exposure. [22] These pharmacokinetic advantages may explain the relatively favorable safety profile observed with TAF in the present study.

Overall, the findings of this study suggest that both tenofovir alafenamide and entecavir are effective antiviral agents for the treatment of treatment-naïve chronic hepatitis B patients. Both drugs achieved substantial virological suppression and improvement in biochemical parameters during the one-year follow-up period. However, TAF showed a tendency toward more rapid viral suppression and a better renal safety profile compared with ETV.

LIMITATIONS:

The present study has some limitations. The sample size was relatively small, and the duration of follow-up was limited to one year. Larger multicenter studies

with longer follow-up periods are required to further evaluate long-term virological response, serological outcomes, and safety profiles of these antiviral agents. Despite these limitations, the findings provide valuable clinical information regarding the comparative efficacy and safety of TAF and ETV in Bangladeshi patients with chronic hepatitis B.

CONCLUSION:

Tenofovir alafenamide and entecavir both demonstrated effective antiviral activity in treatment-naïve chronic hepatitis B patients, resulting in significant reduction of HBV DNA levels and improvement of biochemical parameters during follow-up. Both therapies showed comparable virological and serological outcomes with good overall tolerability. Tenofovir alafenamide appeared to have a favorable safety profile, particularly regarding renal function. Further large-scale studies with longer follow-up are required to better evaluate long-term outcomes, seroconversion rates, and clinical benefits of these antiviral agents in diverse patient populations.

Conflict of Interest: no

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