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EDITORIAL

- 3185 Device-assisted enteroscopy: Are we ready to dismiss the spiral?
Mussetto A, Merola E, Casadei C, Salvi D, Fornaroli F, Cocca S, Trebbi M, Gabbrielli A, Spada C, Michielan A
- 3193 Reactivation of hepatitis B virus infection – an important aspect of multifaceted problem
Morozov S, Batskikh S
- 3198 Non-participation of asymptomatic candidates in screening protocols reduces early diagnosis and worsens prognosis of colorectal cancer
Pérez-Holanda S
- 3201 Digesting gluten with oral endopeptidases to improve the management of celiac disease
Durham K, Ince MN
- 3206 Tumor-related factor complement C1q/TNF-related protein 6 affects the development of digestive system tumors through the phosphatidylinositol 3-kinase pathway
Kong MW, Li XR, Gao Y, Yang TF

ORIGINAL ARTICLE**Retrospective Cohort Study**

- 3210 Yield of alarm features in predicting significant endoscopic findings among hospitalized patients with dyspepsia
Ibrahim L, Basheer M, Houry T, Sbeit W

Retrospective Study

- 3221 Is it necessary to stop glucagon-like peptide-1 receptor agonists prior to endoscopic procedure? A retrospective study
Ghazanfar H, Javed N, Qasim A, Sosa F, Altaf F, Khan S, Mahasamudram J, Jyala A, Kandhi SD, Shin D, Mantri N, Sun H, Hanumanthu S, Patel H, Makker J, Balar B, Dev A, Chilimuri S

Basic Study

- 3229 Loss of monopolar spindle-binding protein 3B expression promotes colorectal cancer malignant behaviors by activation of target of rapamycin kinase/autophagy signaling
Sun J, Zhang JX, Li MS, Qin MB, Cheng RX, Wu QR, Chen QL, Yang D, Liao C, Liu SQ, Huang JA

CASE REPORT

- 3247 Early detection of multiple endocrine neoplasia type 1: A case report
Yuan JH, Luo S, Zhang DG, Wang LS

LETTER TO THE EDITOR

- 3253** Mean nocturnal baseline impedance in gastro-esophageal reflux disease diagnosis: Should we strictly follow the Lyon 2 Consensus?

Voulgaris TA, Karamanolis GP

- 3257** Photo-activated microtubule targeting drugs: Advancing therapies for colorectal cancer

Singh N, Sharma S

- 3261** Effectiveness and safety of tenofovir amibufenamide in chronic hepatitis B patients

Meng LY, Yang CT, Bao JF, Huang JS

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Effectiveness and safety of tenofovir amibufenamide in chronic hepatitis B patients

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Abstract

This letter to the editor relates to the study entitled "Tenofovir amibufenamide *vs* tenofovir alafenamide for treating chronic hepatitis B: A real-world study", which was recently published by Peng *et al.* Hepatitis B virus infection represents a significant health burden worldwide and can lead to cirrhosis and even liver cancer. The antiviral drugs currently used to treat patients with chronic hepatitis B infection still have many side effects, so it is crucial to identify safe and effective drugs to inhibit viral replication.

Key Words: Tenofovir amibufenamide; Chronic hepatitis B; Non-alcoholic fatty liver disease; Alanine transaminase normalization; Virological response

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Core Tip: It is well known that every chronic hepatitis B (CHB) patient should receive antiviral therapy. Although nucleos(t)ide analogs are still the first choice for CHB treatment, they are associated with many side effects, such as renal damage, osteoporosis, and lipid metabolism disorders. Therefore, as a new antiviral drug in China, tenofovir amibufenamide (TMF) is as effective as tenofovir alafenamide (TAF) in treating CHB and has comparable safety profiles, which suggests that TMF may be a viable alternative to TAF for CHB treatment.

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TO THE EDITOR

We read with interest the retrospective study by Peng *et al*[1] titled “Tenofovir amibufenamide *vs* tenofovir alafenamide for treating chronic hepatitis B: A real-world study” published in the *World Journal of Gastroenterology*. The results of this study highlight the effectiveness and safety of tenofovir amibufenamide (TMF) for 48 weeks in patients with chronic hepatitis B (CHB). TMF may replace tenofovir alafenamide (TAF) for CHB treatment.

CHB remains the leading cause of liver cirrhosis and cancer in China[2]. Nucleos(t)ide analogs (NAs) are still the first choice for CHB treatment. Most patients receiving antiviral therapy can achieve long-term hepatitis B virus (HBV) DNA suppression. However, long-term follow-up studies have revealed that drugs that inhibit HBV replication, such as those aimed at reducing the risk of renal damage and osteoporosis and affecting lipid metabolism, are still ineffective[3]. Therefore, it is still important to find new drugs with the best antiviral effects and the fewest side effects. TMF is a newly launched antiviral drug in China, and there is still a lack of real-world research data in the Chinese population. Therefore, we endorse this literature to evaluate the safety and effectiveness of TMF in the treatment of patients with CHB patients in China, which has made outstanding contributions to the treatment of patients with CHB. We want to emphasize the following points about this study. First, this retrospective study has inherent limitations: The nonrandom selection of antiviral drugs can impact the clinical prognosis under investigation.

Second, the exclusion of CHB patients with concomitant nonalcoholic fatty liver disease (NAFLD) deserves consideration in research studies. While the study exclusion criteria (study design and patient selection) did mention CHB concurrent with NAFLD, data from “Table 1: Baseline characteristics of the study population” revealed that there were percentages of CHB patients with NAFLD in the TMF and TAF groups. Consequently, this study did not exclude CHB patients with NAFLD from its analysis. The findings from a retrospective study suggest that the presence of NAFLD can compromise the effectiveness of NA therapy in hepatitis B e antigen-positive CHB patients, leading to diminished rates of biochemical response and fibrosis improvement[4]. Additionally, liver biopsy is the most accurate modality for diagnosing and staging the severity of liver fibrosis, but this method is invasive and associated with potential complications. As a noninvasive alternative, liver stiffness measurement based on FibroScan was utilized to diagnose liver cirrhosis in this study[5]. However, it should be noted that the reliability of diagnosing cirrhosis based on liver stiffness measurement may be compromised by severe hepatic steatosis. The presence of significant hepatic steatosis affects the degree of hepatic fibrosis and reduces the specificity of liver fibrosis detection[6]. Therefore, the exclusion of CHB patients with NAFLD is imperative due to the detrimental impact of hepatic steatosis on the progression of fibrosis and compromised antiviral effectiveness. It is recommended to compare the effectiveness of this antiviral between CHB patients with and without NAFLD if CHB patients with NAFLD cannot be excluded.

Moreover, it is essential to note that NAs require time to inhibit the replication of HBV[7]. Therefore, in attempts to protect patient safety, researchers have explored combining NAs with various liver protection drugs. However, this approach may impact the accuracy of the study results. It is important to recognize that different liver protection drugs can have varying effects on outcomes, such as the alanine aminotransferase normalization rate and blood lipid metabolism. To increase the validity of the findings and ensure greater comparability between groups, we recommend using the same liver protection drugs for the TMF and TAF groups.

Peng *et al*[1] have made a significant contribution to the effectiveness and safety profile of TMF in CHB patients. We agree with the limitations of demonstrating the safety of TMF, as clearly described by the author. The points we propose are all related to the antiviral effectiveness of TMF in this study. Nonetheless, because of some influencing factors, the effectiveness of TMF remains to be further demonstrated. It is advisable to exclude CHB patients with NAFLD and reduce the impact of different hepatoprotective drugs.

FOOTNOTES

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