Introduction

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Hepatitis B virus (HBV) infection, a significant source of liver-related morbidity and mortality, has reached endemic proportions in the Asia-Pacific region. When left untreated, chronic hepatitis B (CHB) can lead to progressive liver damage, culminating in cirrhosis or hepatocellular carcinoma (HCC) in a substantial number of patients. In the Asia-Pacific region, CHB remains a serious health problem where most individuals acquire the virus early in life increasing the risk of serious liver-related complications. The burden of disease has spurred efforts to identify patients who require treatment and develop more effective treatment strategies to optimize therapeutic outcomes. Over the last decade, the availability of highly sensitive assays and more potent anti-HBV agents has resulted in a substantial improvement in the management of CHB. These advances have paved the path for the identification of predictors of response and on-treatment monitoring strategies that may lead to more effective or optimal therapeutic outcomes. Additionally, a better understanding of the natural history of the infection has improved the management of special patient populations, including women of childbearing age.

The articles in this supplement have been prepared by a group of recognized hepatology experts and provide clinicians with relevant information on the latest research. The purpose is to provide clinicians with an insight into the importance of these new advances and their role in the daily clinical management of patients with CHB.

The first article, written by Drs. Tin Nguyen, Paul Desmond, and Stephen Locarnini, reviews the serologic

markers of HBV infection during the natural course of CHB and the role of quantitative serology in the management of the disease. As with hepatitis C virus infection, the availability of highly sensitive quantitative assays for markers of HBV infection, including serum HBV DNA, hepatitis B surface antigen (HBsAg), and hepatitis B e antigen (HBeAg) levels, has facilitated investigation of the role of on-treatment quantitative serology in predicting and optimizing response to treatment. Substantial evidence from large natural history studies investigating quantitative serum HBV DNA levels in patients with CHB has shown a positive correlation between these levels and an increased risk for the development of cirrhosis and HCC. More recently, analyses of on-treatment quantitative serum HBV DNA levels have shown that the levels measured at week 24 can be used to predict virologic response and risk for the development of antiviral resistance. Similarly, the recent introduction of highly sensitive assays for HBeAg and HBsAg has allowed the assessment of early kinetics of these markers during therapy and the role of on-treatment serologic quantification as a predictor of response to anti-HBV therapy. These clinical investigations indicate that the presence of HBsAg, in addition to HBV DNA level, may predict which patients are likely to respond to treatment. The application of quantitative serology into the daily management of CHB may lead to more effective and optimal therapy, allowing the identification of patients who are likely to require on-treatment therapeutic adjustments and patients who can stop treatment. Current studies have provided the foundation for the more effective treatment of patients with CHB, although additional studies are needed to determine the best strategy and relevant settings for on-treatment HBsAg and HBeAg assessment.

The second article, authored by Dr. Ting-Tsung Chang, reviews the emerging body of evidence demonstrating the

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value of on-treatment serum HBV DNA levels in predicting response to oral nucleos(t)ide analog (NA) therapy. The magnitude of suppression of hepatitis B viral load correlates with favorable histologic, biochemical, and serologic responses in clinical trials of patients with CHB. The ability to identify patients who will not experience durable viral suppression in response to a specific antiviral regimen permits early treatment modification to optimize outcomes and avoid the development of antiviral resistance. Dr. Chang reviews the substantial body of evidence regarding the value of on-treatment serum HBV DNA measurement in predicting response to antiviral therapy with older oral NAs (e.g., lamivudine, adefovir) as well as more recently approved agents (e.g., entecavir, telbivudine, tenofovir). Evidence from clinical studies has validated on-treatment serum HBV DNA levels at week 24 as an appropriate predictor of durable viral suppression for lamivudine, adefovir, entecavir, and telbivudine, whereas week 48 appears to be a more suitable time point for predicting response to tenofovir therapy. The value of the earlier time point needs to be explored. The incorporation of on-treatment monitoring to assess response to therapy and the development of antiviral resistance in society guidelines for the management of CHB are also discussed.

In the final article of the supplement, Dr. Nancy Leung reviews the prevalence of CHB in Asian women of

childbearing age and the effect of CHB on pregnancy. The author also addresses the unique role of women in the prevention of HBV transmission, with an emphasis on how the prevention of vertical transmission from CHB-infected mothers to their children and horizontal transmission to sexual partners and other household members will reduce long-term HBV-related mortality. This review includes a discussion of current treatment options for patients with CHB and society guidelines for the management of CHB in women of childbearing age and during pregnancy.

The articles in this supplement provide a useful overview of important developments in our understanding of CHB, offering new perspectives on the natural history and pathogenesis of the disease, molecular diagnostics, and strategies to diminish the impact of HBV infection on human health. Application of this knowledge to everyday practice may allow for more individualized treatment and ultimately pave the way for more optimal and cost-effective strategies for the management of CHB, particularly in geographic areas such as the Asia-Pacific region, where it is so disproportionately prevalent.

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