中文題目：Fofnir®對慢性乙型肝炎病人接受口服抗病毒藥物治療，在轉換使用和初次使用群體中的有效性之回顧性研究

英文題目：A real-world retrospective study of Fofnir® effectiveness in both transition and naive cohorts of chronic hepatitis B patients

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Background:

Viread® (300 mg tenofovir disoproxil fumarate) is an effective antiviral agent for chronic hepatitis B worldwide, and has been approved by the National Health Insurance (NHI) since 2011 under certain conditions. Fofnir®, a generic drug of *Viread*®, has also been approved as treatment for chronic hepatitis B by the Ministry of Health and Welfare because of similar bioavailability. However, Fofnir® has not been widely used in real world scenario, and lacks validation from large-scale clinical trials. Due to financial policies, *Viread*® was replaced with Fofnir® in our hospital (Chi-Mei Medical Center) since October 2018, and patients receiving *Viread*® were transitioned to Fofnir® since then. Naive patients were also administered with Fofnir® therapy as indicated by NHI. This study aims to evaluate the real-world effectiveness and safety of Fofnir® in patients with chronic hepatitis B who have been receiving on-going treatment for over 2 years.

Methods:

This single-center retrospective study enrolled 181 patients (31 naive and 150 transitioned) who have received on-going Fofnir® treatment in Chi Mei Medical Center and Chi Mei Hospital, Liuying, from October 2018 to October 2020. Patients who have received interferon-αor thymosin-αwithin 24 weeks prior to initiating Fofnir® therapy were excluded. Patients who refused transition, or those that failed to complete a 2-year-treatment were also excluded. Serum hepatitis B viral load (HBV DNA), quantity hepatitis B surface antigen (qHBsAg), alanine aminotransferase (ALT), and other routine laboratory tests were measured at baseline and every 24 weeks to evaluate the effectiveness of Fofnir®. Clinical adverse events (AEs) were reviewed through medical chart to evaluate the safety and tolerability throughout the course of treatment

and follow up.

Results :

31 cases in the naive cohort and 150 cases in the transition cohort received Fofnir® treatment for more than 2 years. The demographics and biochemistry responses of both cohorts will be presented in the poster.

Virologic responses including HBV DNA levels and qHBsAg levels declined progressively in both groups.

In the Naive cohort, HBV DNA decline rates were 5.11 $\log_{10}$ IU/mL at 48wk and 5.80 $\log_{10}$ IU/mL at 96wk.

In the Transition cohort, HBV DNA decline rates were 0.40 $\log_{10}$ IU/mL at 48wk and 0.49 $\log_{10}$ IU/mL at 96wk.

In the Naive cohort, qHBsAg decline rates were 0.65 $\log_{10}$ IU/mL at 48wk and 0.7 $\log_{10}$ IU/mL at 96wk.

In the Transition cohort, qHBsAg decline rate were 0.16 $\log_{10}$ IU/mL at 48wk and 0.24 $\log_{10}$ IU/mL at 96wk.

No breakthrough hepatitis or resistant viral response was noted in either cohorts. No adverse reactivation was mentioned in the medical records of both cohorts.

Conclusions:

In our real-world experience, Fofnir® was capable of maintaining adequate virologic response in both the Naive cohort and the Transition cohort from Viread® for up to 48 weeks and 96 weeks without any significant adverse events.