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Hepatocellular carcinoma development risk of besifovir and other antiviral therapy for hepatitis B

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Backgrounds: Current antiviral therapy using nucleos(t)ide analogs (NAs), entecavir (ETV), tenofovir disoproxyl fumarate (TDF), tenofovir alafenamide (TAF), and besifovir (BSV), well suppress viral replication in patients with chronic hepatitis B (CHB), resulting in the risk reduction of hepatocellular carcinoma (HCC) development. We investigated whether there were differences in the HCC development according to the besifovir and other NA use.

Methods: The retrospective cohort study recruited treatment-naïve patients with active CHB or B-viral cirrhosis who started BSV (n=185), ETV (n=431), TDF (n=316), and TAF (n=281) in Severance Hospital between 2017 and 2022. Propensity score matching (PSM) was performed to reduce treatment selection bias between the two groups.

Results: Before matching, the incidence of HCC development per 1000 person-years (PYs) was 3.43 in BSV users, similar to those of the ETV (13.22, P=0.070), TAF (7.31, P=0.300), and TDF users (9.65, P=0.200). 1:1 PSM yielded well-matched 150 pairs for BSV vs. ETV users, 175 for BSV vs. TAF, 165 for BSV and TDF, and 248 for ETV vs. TAF users (all standard mean differences <0.2). BSV users had a significantly reduced incidence of HCC development compared to the ETV users (3.98 vs. 23.47 per 1000 PYs, P=0.016) and statistically similar incidence to the TAF (3.59 vs. 5.89 per 1000 PYs, P=0.470) and TDF users (3.81 vs. 10.64 per 1000 PYs, P=0.310). Univariate Cox regression analyses after matching showed the reduced risk of HCC development in BSV users compared to the matched ETV users (hazard ratio [HR] = 0.191, P=0.031), whereas the risk was similar to the matched TAF (HR=0.524, P=0.480) and TDF (HR=0.433, P=0.321) users. Matched TDF users did not show a significant difference in the incidence (9.78 vs. 15.41 per 1000 PYs, P=0.360) and risk of HCC development (HR=0.663, P=0.360) compared to ETV users.

Conclusion: Besifovir showed non-inferiority for HCC development in patients with CHB compared to the other NAs. A further large-scale study is warranted due to the small number of events.