Efficacy and Safety Results of Tenofovir DF (TDF) Treatment from the First Trimester in HBV Pregnant Women in Real-Life Clinical Practice

AASLD Liver*Learning*®. GANNE CARRIE N. Nov 3, 2013; 35905
Topic: Treatment and Clinical Trials

Disclosure(s): Pr Ganne, Dr Causse, Pr Zarski, Dr Riachi, Dr Roche, Pr Zoulim, Dr Desmorat, Dr Constant, Dr Fouchard-Hubert, Dr Cadranel, Dr Ouzon, Pr Marcellin: Gilead for VIREAL Study; Drs Libert, Terrier, and Stern are employees of and own stock in Gilead.

Prof. Nathalie GANNE CARRIE

ABSTRACT FINAL ID: 952
CURRENT CATEGORY: Hepatitis B
CURRENT DESCRIPTORS: I02. Treatment and Clinical Trials
SESSION TYPE: Poster
SESSION TITLE: HBV Trials and Treatments
PRESENTER: Kellie Chu

AUTHOR/INSTITUTIONS: N. Ganne-Carrie, Hôpital Jean Verdier, Bondy, FRANCE|X. Causse, Hôpital La Source, Orléans, FRANCE|J.H. Zarski, CHU Grenoble, Grenoble, FRANCE|G. Riachi, CHU Rouen, Rouen, FRANCE|B. Roche, Hôpital Paul Brousse, Villejuif, FRANCE|F. Zoulim, Hôp

SPONSORSHIP: Gilead Sciences.

ABSTRACT BODY:

Background/Aims: Mother to child transmission (MTCT) is one of the main routes of HBV transmission, especially if the pregnant woman has HBV-DNA >6-7logIU/mL at delivery. Antiviral therapy given during the last trimester of pregnancy, in association with serovaccination, can reduce the risk of MTCT. Nonetheless, TDF use from the first trimester has not been well documented in HBV mono-infected patients. The aim of this study was to analyze the efficacy and safety of TDF during pregnancy.
Methods: Among 441 HBV patients treated with TDF included in a French real-life cohort (VIREAL study), 14 cases of pregnancy were reported. Virologic data were collected at the beginning of pregnancy and at delivery. TDF treatment initiation and interruption were recorded. Serovaccination according to French guidelines (HBIg 100µg at birth plus 3 doses of HBV vaccine at 0, 1 and 6 months) was recommended for all babies. Safety data were analyzed during pregnancy, labor and follow-up. MTCT was evaluated by HBsAg status in infants after 9 months.
Results: Baseline characteristics (n=14) were: mean age 29 years, 43% African origin and 57% HBeAg-positive. Among patients with prior fibrosis evaluation (n=10), 40% had METAVIR stage F0-F1 and 60% had F2. Eight patients were already receiving TDF treatment at the beginning of pregnancy with undetectable HBV-DNA. The other 6 patients had a median HBV-DNA of 8 logIU/mL. Regarding TDF exposure, twelve, one and one patient(s) received TDF from the first, second and third trimester, respectively. The median duration of TDF exposure during pregnancy was 35 weeks (range: 5-39 weeks). HBV-DNA was assessed at delivery in 12 patients. Among these, 10 patients (83%) had HBV-DNA < 6 logIU/mL at delivery. Two cases of high HBV-DNA were associated with non-compliance and TDF discontinuation at week 9 of pregnancy. The median gestational age at delivery was 39 weeks (range: 34-40 weeks). No adverse events related to TDF and no cases of birth defects were observed. ***Five patients reported breastfeeding, and 3 of them breastfed while receiving TDF treatment without any consequence on the babies up to 1 year***. No cases of positive HBsAg were observed in infants. Additionally, among 5 infants with anti-HBs testing, all were anti-HBs positive (84–308mIU/mL).
Conclusions: In a HBV real-life cohort, TDF treatment from the first trimester of pregnancy was well tolerated. No cases of MTCT were observed. Moreover, no safety issues were reported for breastfeeding while on TDF up to 1 year.