

The Determination of Tenofovir Level in Breast Milk of Nursing Mothers Under Tenofovir Therapy

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Abstract Text

Background:

In this study, we aimed to determine of tenofovir concentration in maternal plasma, breast milk and plasma of infants and factors affecting drug levels in chronic hepatitis B (CHB) patients using tenofovir disoproxil fumarate (TDF) during breastfeeding period.

Methods: Patients followed up or transferred to Istanbul University Cerrahpasa Medical Faculty Infectious Diseases and Clinical Microbiology Department for CHB and who had received TDF at least for one month during breastfeeding period between 2014-2017 years were enrolled in this study. A total of 11 mother infant pairs had been included in this study. Maternal blood, breast milk and infant blood samples were obtained simultaneously from mother and infant pairs. Tenofovir concentrations were determined by liquid chromatography tandem mass spectrometry (LC-MS / MS) method

Results: Tenofovir concentrations were determined at a range of 4-600 ng / mL. The median concentrations of tenofovir in maternal plasma and breast milk samples were 88,44 (IQR: 62,47-116,17) ng / mL, 6,69 (IQR: 4,88-7,03) ng /mL, respectively. Tenofovir concentrations in all of the infant plasma samples were determined as 0 ng/mL. The ratio of tenofovir concentration in breast milk/maternal plasma was determined as 0,07. There was a strong and statistically significant relationship between the concentration of tenofovir in breast milk and maternal plasma ($r: 0,7$ $p < 0,05$). There was no significant relationship between tenofovir concentrations and age, height and weight of the mothers, infant's age, duration of TDF use and time of the last TDF dose.

Conclusion:

This study demonstrated that TDF use during breastfeeding due to CHB, leads to passage of small amount of tenofovir to the breast milk and no any detectable drug is present in the infant's systemic circulation. These results suggest that use of TDF is safe during the breastfeeding period, but a wider cohort study evaluating whether any side effects will develop or not in the long term in infants is required.

Number of Patients	Concentration of tenofovir in maternal blood (ng/mL)	Concentration of tenofovir in breast milk (ng/mL)	Concentration of tenofovir in infant blood (ng/mL)
1	88.443	6.95	0
2	79.001	4.88	0
3	93.431	4.44	0
4	49.890	5.05	0
5	115.836	8.10	0
6	116.175	7.03	0
7	57.788	6.75	0
8	62.475	5.71	0
9	87.719	4.86	0
10	162.621	10.00	0
11	133.994	6.69	0

Disclosures

The following people have nothing to disclose: Umrans Sumeysse Erturk, Bahar Kacmaz

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