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Session PS2 - PS2. Poster Session 2

P414. Rituximab Exposure From Breastfeeding. A Case Series.

February 25, 2022, 5:30 PM - 6:00 PM | Exhibit Hall A

Authors

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Abstract

Background: Multiple sclerosis (MS) disproportionately affects women, and disease onset most frequently occurs during their reproductive years. Monoclonal antibodies are increasingly used as first-line disease modifying therapy (DMT), but the data on safety during breastfeeding is limited. For many, this implies a choice of breastfeeding or the use of DMT.

Objectives: To assess the extent of transfer of rituximab to mature breast milk, and to determine the exposure of RTX on the infant.

Methods: Six mothers with relapsing-remitting multiple sclerosis (RRMS) received 500 or 1,000 mg rituximab after giving birth. Serum and blood from mothers and infants, and breast milk from mothers, was collected at six time points: pre infusion, two days after infusion, after one week, and after one, three and five $T_{1/2}$ of rituximab. The samples were analyzed for rituximab (serum and breast milk), immunoglobulins (serum), complete cell counts and lymphocyte quantification (blood).

Results: The median average concentration (C_{avg}) in breastmilk was 0.041 µg/mL. The median relative infant dose (RID), the infant exposure as a percentage of the weight-adjusted maternal dose, based on the individual C_{avg} was 0.07%. All of the measurements of rituximab concentration in the infants' serum were below 0.01 µg/mL, and most of them below the lower limit of quantification, <0.005 µg/mL. No apparent abnormalities in white blood cell count, lymphocyte quantification or immunoglobulin levels were detected in the infants after rituximab infusion.

Conclusions: Rituximab exposure during breastfeeding led to a transfer of rituximab into breast milk with a RID far below the commonly accepted threshold of concern of 10%. The B cell counts and level of rituximab observed in the blood of the infants suggest that there are no clinically significant hematological effects after exposure to rituximab from breastfeeding.