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QUESTION
What is the safety of oseltamivir during breastfeeding?

ANSWER

BACKGROUND
Oseltamivir phosphate is a pro-drug of oseltamivir carboxylate, an oral viral neuramidase inhibitor that prevents viral seeding from infected cells, and prevents viral aggregation. It is used for both the treatment of, and prophylaxis against, influenza virus types A and B [1,2].

Drug safety during breastfeeding is assessed by determining the magnitude of infant exposure i.e. the dose ingested through milk, infant pharmacokinetics, and the drug's inherent toxicity. The infant's dose (mg/kg) can be expressed as a percentage of the maternal dose (mg/kg). We generally consider that for drugs with relatively low toxicity, such as oseltamivir, that an infant dose of less than 10% of the maternal dose (weight-adjusted) is generally compatible with breastfeeding [3,4].

BREASTFEEDING
There are very limited data on the use of oseltamivir during human lactation. We found only one published case report that looked at concentrations of oseltamivir in human breast milk [5]. We found no data regarding the potential adverse effects, if any, to a suckling infant exposed to oseltamivir via breast milk.

The case report [5] involved a laboratory worker who had a needlestick injury with an influenza-contaminated needle. They were prescribed a precautionary five day course of oseltamivir (75mg twice daily). The worker was also breastfeeding a 9 month old infant at the time of the injury. Due to lack of safety data, breastfeeding was withheld during oseltamivir therapy. Samples of breast milk were collected to determine the concentrations of oseltamivir excreted into breast milk.

The maximum concentrations of oseltamivir and oseltamivir carboxylate in the breast milk were 38.2ng/mL and 43.4ng/mL, respectively, making a combined total of 81.6ng/mL. Assuming an average consumption of breastmilk by a suckling infant of 150mL/kg/day this would mean that the infant could potentially ingest 0.012mg/kg/day of oseltamivir, based on a worst case scenario. If we assume a maternal weight of 60kg, the maternal dose works out to 2.5mg/kg/day. This means that the infant could receive a maximum of 0.5% of a weight-adjusted maternal dose (WAMD).

CONCLUSIONS
There are very limited data of oseltamivir in human lactation. We found no data regarding the potential adverse effects, if any, to a suckling infant of oseltamivir exposure via breast milk. However, the single published case report that we located suggests that only very small concentrations of oseltamivir are excreted into breast milk (WAMD = 0.5%). The

decision to continue breastfeeding in a lactating mother who is prescribed oseltamivir is a clinical decision based on the potential risks of oseltamivir exposure to the suckling infant versus the benefits of continuing to breastfeed.

References

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