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Study finds certain drugs used to treat eye diseases excreted into human breast milk

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Certain drugs used to treat retinal diseases are excreted into breast milk, raising possible safety concerns for developing infants, suggests a first-of-its-kind study led by St. Michael's Hospital in Toronto and published

in *Ophthalmology*.

Ranibizumab and aflibercept are medications used to treat several retinal diseases. They contain an agent called anti-vascular endothelial growth factor (anti-VEGF), which blocks the eye's production of vascular endothelial growth factor (VEGF). VEGF is a protein that stimulates the development of blood vessels but is associated with retinal diseases in high quantities.

VEGF is present in breast milk and plays an important role in the development of an infant's digestive system. As a result, anti-VEGF drugs in a nursing mother raise concerns about possible adverse events in a developing infant if the drugs were to pass into breast milk and suppress VEGF.

"As retina specialists, we often tell our pregnant or nursing patients that there's a risk of a small amount of these drugs making its way into the breast milk, but we can't be sure," said Dr. Rajeev Muni, co-lead author, a vitreoretinal surgeon at St. Michael's and a project investigator at the hospital's Li Ka Shing Knowledge Institute.

"We don't want these patients to lose their vision so we make a decision, despite limited information."

Hoping to change this, Dr. Muni and Dr. Verena Juncal, co-lead author and a retinal fellow at St. Michael's, measured the concentrations of retinal medications in the breast milk of three lactating patients following injection of anti-VEGF therapy. Each patient represented a different scenario—one continued to breastfeed while receiving therapy, one discontinued breastfeeding, and one never started.

The team found that the drugs were secreted into the breast milk within the first couple days following injection, with a corresponding reduction

in VEGF levels.

They also found that the amount of medication detected in the patient who continued to breastfeed was significantly lower than the other two patients, suggesting that the medication was constantly excreted and ingested by the infant.

"These results definitively show us that the drug reaches the breast milk," said Dr. Juncal. "We realize that some readers may question the small sample size, but if the drug reaches the breast milk in three patients, it'll reach in 30 patients because it's the same biological process."

As the first study to evaluate the presence of Health Canada approved anti-VEGF therapy in human breast milk, these results provide a resource for ophthalmologists and retina specialists counselling pregnant and nursing patients.

"I'm comforted knowing that other pregnant or nursing mothers with retinal diseases will have the information needed to make an educated decision about whether to consider nursing while receiving these medications," said Lisa, one of the three study participants, who didn't want to reveal her surname.

Next, the researchers hope to collaborate with a team of paediatricians to find out whether the drug passes from the breast milk through the infant's digestive system and into the blood stream.

"If we can measure the levels of these drugs in the infant's blood, we can figure out the exposure over a long period of time," said Dr. Muni. "That's what's really important here—the possible effect of these drugs on the infant over a long period of time."

More information: Verena R. Juncal et al, Ranibizumab and Aflibercept Levels in Breast Milk after Intravitreal Injection, *Ophthalmology* (2019). DOI: 10.1016/j.ophtha.2019.08.022