

For treating retinopathy of prematurity, research proves that ranibizumab is safe

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James Reynolds, MD, Jerald and Ester Bovino Professor and Chair of the Department of Ophthalmology in the Jacobs School, has been conducting critical research on retinopathy of prematurity for decades. Credit: University at Buffalo

A University at Buffalo researcher who is a leading expert on

retinopathy of prematurity (ROP) has published a study that could change the standard of care for the condition. ROP occurs in low birthweight premature babies; if not treated, it can lead to blindness.

The [study](#), published in *eClinicalMedicine*, answers a longstanding concern about which is the safest, most effective agent for treating ROP.

The international randomized clinical trial, called RAINBOW, compared ranibizumab to [laser therapy](#) for the treatment of very low birthweight infants with ROP.

Laser therapy vs. anti-VEGF

For several decades, laser therapy has been the primary treatment method for ROP. Laser treatment involves burning the infant's peripheral retina to stop the proliferation of the abnormal blood vessels that occur in ROP.

The procedure is physically demanding for both the clinician and the baby, typically takes at least 60 minutes per eye and may require general anesthesia or heavy sedation. Infants who have undergone laser treatment as infants have been found to develop nearsightedness as [young children](#); they may also lose their peripheral vision.

In 2011, the BEAT-ROP study was published in the *New England Journal of Medicine*. That study revealed that agents called anti-vascular endothelial growth factor (anti-VEGF) agents may also be effective and can be administered into the infant's vitreous at the bedside in just minutes with only topical anesthesia, thus avoiding the need for prolonged heavy sedation with intubation. Those agents work by suppressing the excessive levels of VEGF that occur in ROP.

"That paper caused a sensation," recalls James D. Reynolds, MD, senior

author on the new paper and Jerald and Ester Bovino Professor and Chair of the Department of Ophthalmology in the Jacobs School of Medicine and Biomedical Sciences at UB. He wrote the editorial that accompanied the *NEJM* publication in 2011.

The BEAT-ROP study found that intravitreal injection of an anti-VEGF agent called bevacizumab was as effective as laser therapy. These agents are often used to treat adult eye disorders such as age-related macular degeneration (AMD).

"Many doctors then switched to intravitreal bevacizumab," says Reynolds, who is also president of the Ross Eye Institute/UBMD Ophthalmology. "But there was a huge controversy regarding safety."

He explains that anti-VEGF molecules can get into the bloodstream from the eye and from there could potentially cause harm.

"The major concern was, can they harm the developing brain?" says Reynolds.

So laser therapy has remained the gold standard. Until now.

The proven safe agent

"Our study using ranibizumab should end this safety controversy," says Reynolds. "Ranibizumab is a smaller molecule whose serum half-life is many times shorter than bevacizumab, and ranibizumab does not lower plasma VEGF."

"Intravitreal ranibizumab (IVR) is at least as effective as laser," he continues. "It may even be superior to laser and it is systemically safe. Ranibizumab is now the proven safe agent."

Of the 201 children enrolled, 156 of them were followed for five years. It was the first time that visual acuity—the ability to differentiate objects and shapes at a distance—was tested after anti-VEGF treatment. The researchers found that [visual acuity](#) in these 5-year-old children was at least as good in those who received [ranibizumab](#) as it was in those who received the laser therapy.

No adverse effects were observed in visual function and a broad range of non-ocular outcomes, including neurodevelopment, gross motor function, growth, blood pressure or respiratory function.

Reynolds is currently conducting research on imaging in ROP and its impact on treatment timing.

More information: Neil Marlow et al, Ranibizumab versus laser therapy for the treatment of very low birthweight infants with retinopathy of prematurity (RAINBOW): five-year outcomes of a randomised trial, *eClinicalMedicine* (2024). [DOI: 10.1016/j.eclinm.2024.102567](#)

Provided by University at Buffalo

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