# Seeing into the future: Ranibizumab for Retinopathy of Prematurity

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## Background

- The standard treatment of Retinopathy of Prematurity (ROP) in neonates is peripheral retinal laser photocoagulation which is not risk free.
- Ophthalmologists have successfully trialled vascular endothelial growth factor inhibitor ranibizumab (intravitreal formulation) on compassionate supply as an emerging alternative therapy to laser and non-intravitreal formulation of bevacizumab.

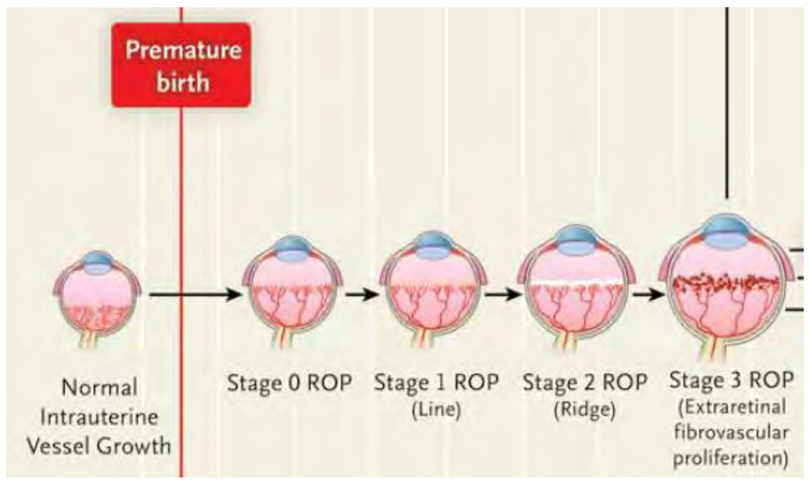


**Figure One: Stages of ROP (Mintz-Hittner et al. *New England Journal of Medicine*, February 2011)**

## Aim

- To audit the use, safety and efficacy of ranibizumab for ROP treatment at a tertiary paediatric hospital.

## Method

- Ethics approval obtained via SCHN Human Research Ethics Committee (2021/ETH11521).
- Conducted a retrospective chart review of medical and laboratory records from May 2019-June 2021 of patients who had received ranibizumab intravitreal injection for ROP.
- Indication, dose, duration, monitoring parameters, adverse effects, ophthalmologists review and projected cost were assessed.
- Additionally, completed a comprehensive literature review on the use of Ranibizumab for ROP.

## Results and Discussion

### Participant characteristics

- The 9 patients (n=5 males) included in the study were born at a median gestational age of 25 weeks (range 23–27 weeks) with a median birth weight of 635 g (range = 552 g–750 g).
- The patients received ranibizumab treatment at a median age of 79 days (range 57–148 days).
- Across the study period 17 doses (13 doses of 0.2 mg and 4 doses of 0.15 mg) of ranibizumab were given. One patient received ranbizumab treatment at another hospital and was admitted for follow-up.

### Disease State

- The disease state of patients included was stage 2 to 3 ROP with both pre-plus and plus disease. The most common disease state was stage 3 plus disease (50%). Patients treated had disease in zone 1 or 2.
- All patients had at least one existing co-morbidity. The most common co-morbidity recorded was chronic lung disease (78%)

| Disease State | Number of eyes |
|---|---|
| Stage 2/3 | 2 |
| Stage 3 | 10 |
| Plus | 7 |
| Pre-plus | 6 |

### Dosing

- Patients received 0.2 mg (68%) or 0.15 mg (21%) of intravitreal ranibizumab .
- The majority of patients required no further treatment (74%) for ROP after ranibizumab treatment, with some receiving laser therapy (21%) or an additional dose of ranibizumab (5%).

| Dose, n (%) | N = 19 |
|---|---|
| 0.15 mg | 4 (21%) |
| 0.20 mg | 13 (68%) |
| Unknown | 2 (11%) |

### Safety and tolerability

- Seven patients treated with ranibizumab required no further treatment for ROP. One patient required a follow-up treatment of laser therapy and another patient required an additional dose of ranibizumab in one eye.
- Adverse effects reported included swollen eyes and haziness of the cornea in 3 patients.

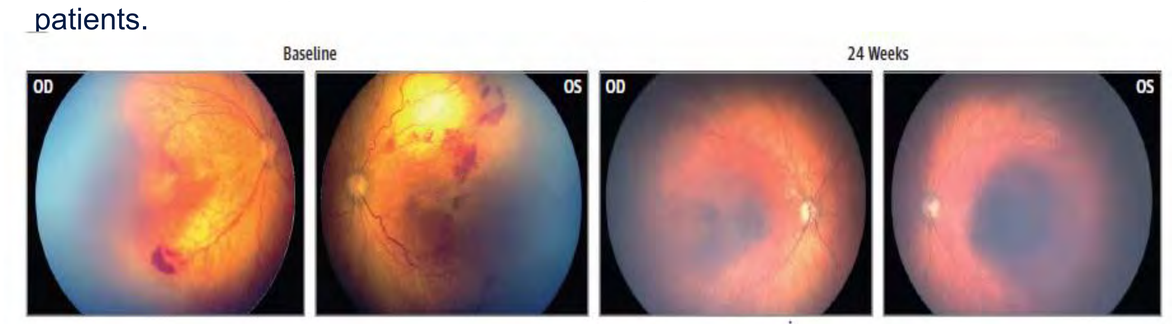


**Figure Two: Representative images of treatment response at Baseline & 24 Weeks (Stahl et al et al. *JAMA Pediatrics*, January 2018)**

### Cost

- The projected average cost of ranibizumab treatment per patient was $1967 in comparison to bevacizumab cost of $122.

## Conclusion

- In our patient cohort, ranibizumab was found to be safe and effective for ROP treatment with minimal adverse effects.
- Further investigation on long-term safety and developmental outcomes as well as comparison with bevacizumab and laser therapy in terms of safety, benefits and cost-effectiveness is required to support access and funding.

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