

MEDICAL SCHOOL

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INTRAVITREAL RANIBIZUMAB AS A PRIMARY OR A COMPLEMENTARY TREATMENT FOR AP-ROP IN ZONE I AND POSTERIOR ZONE II RETINOPATHY OF PREMATURITY (ROP)

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BACKGROUND WHAT DO WE KNOW ABOUT ?

- **Aggressive posterior retinopathy of prematurity (AP-ROP) is a severe and rapidly progressive disease with unfavorable outcome in around 50% when treated by laser photocoagulation.**
- **AP-ROP, when not promptly diagnosed and treated, usually progresses to retinal detachment and blindness (stage 5 of ROP).**
- **The characteristic features of AP-ROP are its posterior location (zones I or posterior zone II), prominence of plus disease with flat neovascularization, retinal hemorrhages, intraretinal shunting without ridge tissue formation, and ill-defined nature of the retinopathy without progression through classic stages 1 to 5 of ROP.**

PURPOSES

- **This study reports on a cohort of patients with AP-ROP in zones I and posterior zone II treated with intravitreal anti-VEGF ranibizumab (IVR) as monotherapy or as a complementary treatment after failure of the laser photocoagulation.**



SETTING / VENUE

- This is a prospective institution-based, interventional and non-comparative cohort study conducted from July 2009 to June 2012 in University Hospital of Maracaibo, Venezuela.

PATIENTS

- Were included all preterm infants with AP-ROP, defined according to the International Classification of ROP revisited from 2005, that were submitted for treatment in the Institution during the study period.

INTERVENTIONS

- Anti-VEGF therapy with IVR, 0.25 mg (0.025 ml) was performed in each eye. Injection site was located 1.5 mm posterior to the corneal limbus. Treatment was always performed in surgical room under topical anesthesia with proparacaine eye drops.
- Diode laser photocoagulation was performed in surgical room under general anesthesia or sedation.



OUTCOMES

- Favorable outcome was considered regression of the AP-ROP after treatment (regression of retinal neovascularization and plus disease) and good retinal anatomical aspect.
- Unfavorable outcome was registered if occurrence of evolution to stages 4A, 4B or 5.
- Ocular and systemic short- and long term (after 1 year follow) adverse effects were registered.

ETHICS

- The study protocol was approved by the Research Ethics Committee of the University Hospital of Maracaibo and it was consistent with the principles of the Helsinki Declaration of 1995 (revised in Edinburgh in 2000).
- The parents or their representatives have signed a consent term before the treatment.

- A total of 29 patients (57 eyes) were included in the study.
- All patients presented AP-ROP in zone I or in posterior zone II.
- 17 patients were female.
- Mean gestational age (GA) at birth was 29.4 ± 2.2 weeks (range 25-33 weeks).
- Mean birth weight (BW) was $1,272 \pm 255$ grams (range 900-1,900 grams).
- Mean postconceptional age (PCA) at ROP diagnosis was 36 ± 2.7 weeks
- Mean PCA at treatment was 37.7 ± 2.6 weeks.
- 16 eyes from 8 patients comprised group 1 (patients treated only with IVR)
- 41 eyes from 21 patients comprised the group 2 (patients that received IVR and laser photocoagulation).

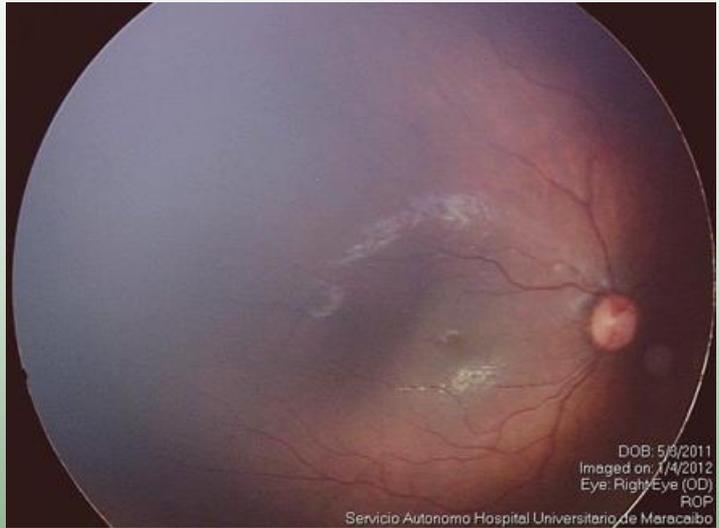
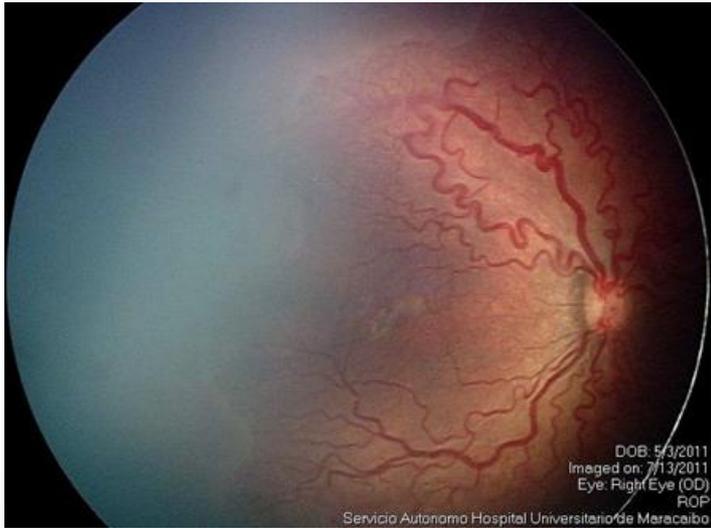


GROUP 1

- . A total of 14 eyes (7 patients) achieved favorable outcome after the use of only one IVR injection in each eye (87.5%).
- . It was remarkable that all of the eyes that achieved favorable outcome remained with peripheral vascular immaturity at around 6 months after treatment.

GROUP 2

- . A total of 29 eyes (15 patients) achieved favorable outcome after combined treatment (70.7%).
- . 28 eyes received laser photocoagulation by the first treatment and IVR was used after laser failure.
- . 13 eyes received IVR as the first treatment and, after failure by plus disease reactivation, received laser photocoagulation in zones II and III.



We reported very good anatomical results after the use of IVR, as monotherapy or combined to laser photocoagulation, to treat severe cases of AP-ROP in zone I and posterior zone II.

Final favorable outcome of regression of retinal neovascularization and good retinal anatomical aspect was obtained in 43 eyes (75.4%).

At 1 year follow-up no ocular or systemic complications were registered in our patients but new studies are necessary to evaluate the ideal doses of anti-VEGF therapy that should be used to minimize systemic long term consequences.