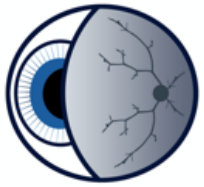
# PREVENT: Updated Report

Maziar Lalezary, MD



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## The Retina Society VR Meeting

September, 2020

THE RETINA SOCIETY 1968

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# Disclosures

- Research grant: Roche-Genentech
- Institutional review board approved Western IRB (May, 2014)
- Off-label use of ranibizumab

# Summary

- Eyes (N=108) with high-risk nonexudative AMD received sham (54) versus intravitreal ranibizumab (54) quarterly over 2 years.
- Conversion to exudative AMD occurred equally (13%) in sham and ranibizumab group over 2 years.
- Quarterly intravitreal ranibizumab was tolerated well but did not prevent nor reduce progression to exudative AMD in high-risk eyes.

# PREVENT:
# Prophylactic Ranibizumab for Exudative AMD in Vulnerable Eyes with Non-Exudative AMD Trial:
## A prospective controlled clinical trial

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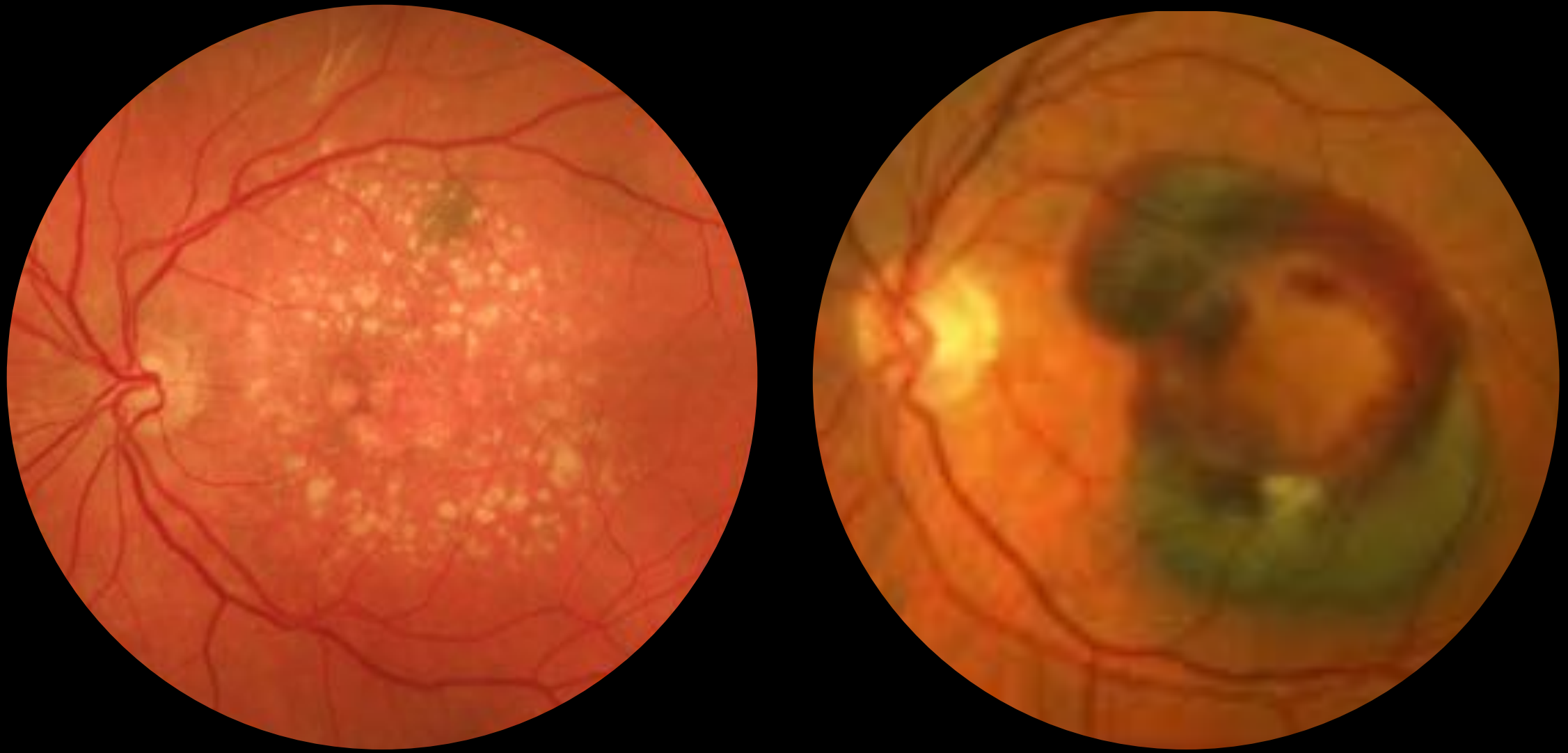
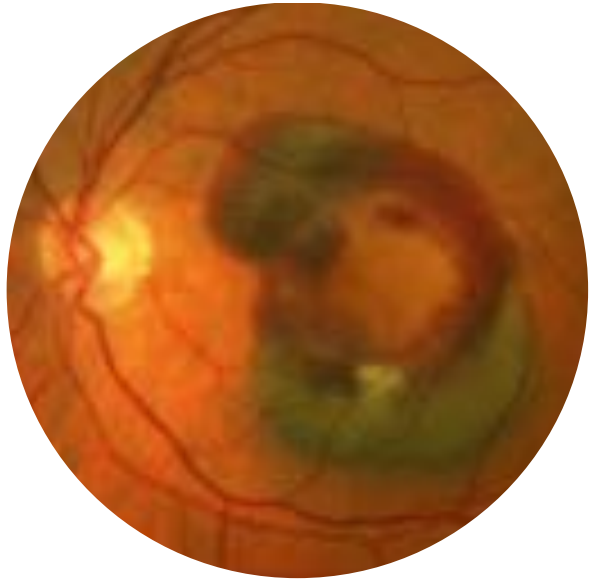
Doctor Retina, Beverly Hills, CA, Southern California Desert Retina Consultants, Palm Desert, CA, Loma Linda University, Loma Linda, CA, Black Hills Regional Eye Institute, Rapid City, SD, Elman Retina Group, Baltimore, MD, Northern California Retina Vitreous Associates, University of California, Davis, CA



# Natural History



## High-risk characteristics: AREDS

(Ferris et al. Arch Ophthalmol 2005)

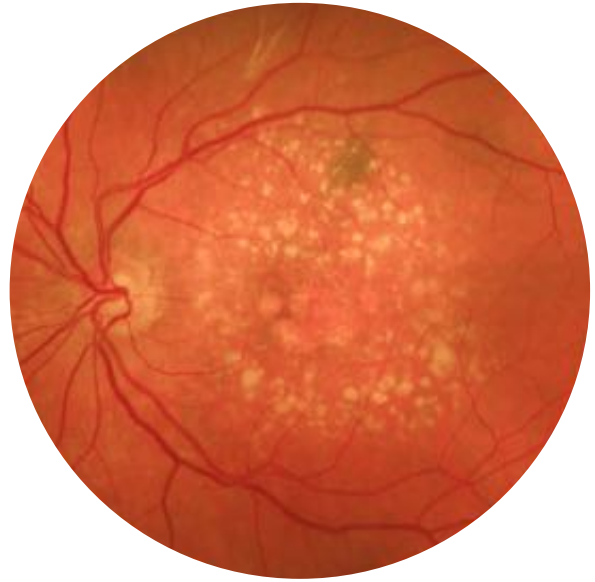
- Ocular features (large, soft drusen, pigmentary changes)
- Genetics factors

## Rate of conversion in fellow eyes

Range 17-35% in 2 years

- ANCHOR: 23.8%, MARINA: 35.1% *(Barbazetto et al, AJO 2010)*
- CATT: 20.6% (ranibizumab), 16.6% (bevacizumab), *(Maguire et al Ophthalmology 2013)*

# Anti-VEGF Therapy



Animal Models – Prevent *laser-induced* CNV

“Treat-and-Extend” – Prevent recurrence

Hypothesis – Prevent primary conversion

# Design

Multicenter, prospectively randomized, single-masked, controlled, phase I/II

Enrollment

- NE-AMD in the study eye (high-risk; large, soft drusen, pigmentary changes)
- Ex-AMD in the fellow eye (within 5 years)

Randomized (1:1)

- Sham injection (SHAM) Q3M
- Ranibizumab 0.5 mg (IVR) Q3M

# Methods

Baseline Exam, ETDRS BCVA, FP/AF/FA , SD-OCT, genetic testing

Fundus Reading Center (Diagnostic confirmation – Dr. G. Yiu)

OCT parameters monitored (Independent, masked grader – Dr. B. Lujan)

Quarterly visits conducted over 2 year study period.

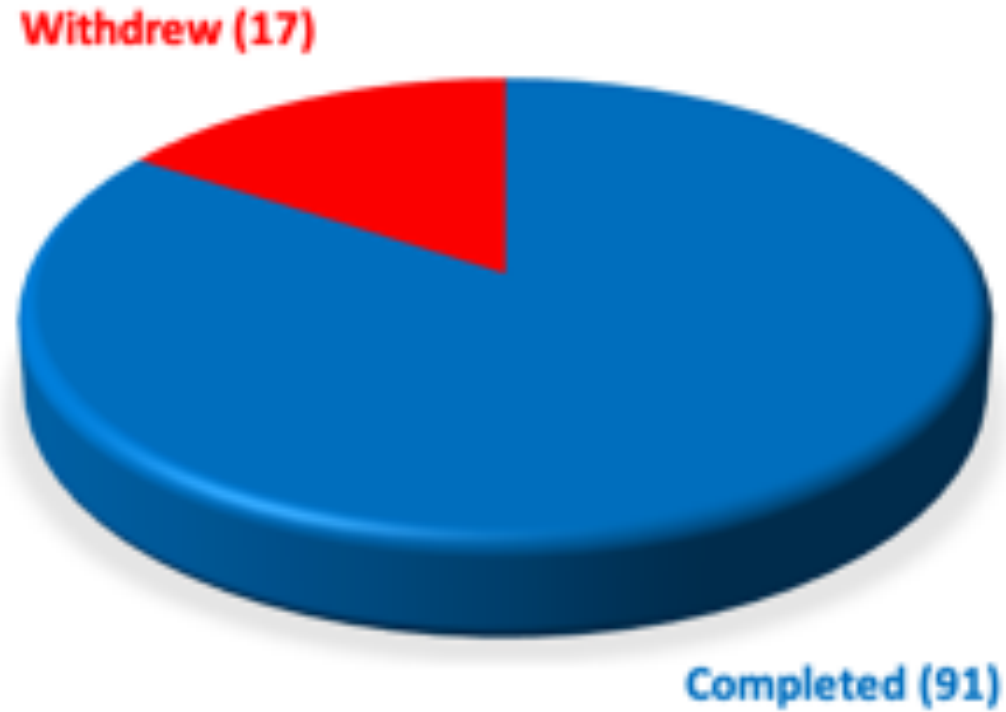
Primary outcome measure – Development of Ex-AMD

# Results – Baseline

- 108 eyes of 108 patients enrolled and completed
- 54 IVR, 54 SHAM
- All Caucasian, 61 female, mean age 78, mean BCVA 20/28 (78 ETDRS letters)
- Baseline characteristics (age, gender, vision) balanced

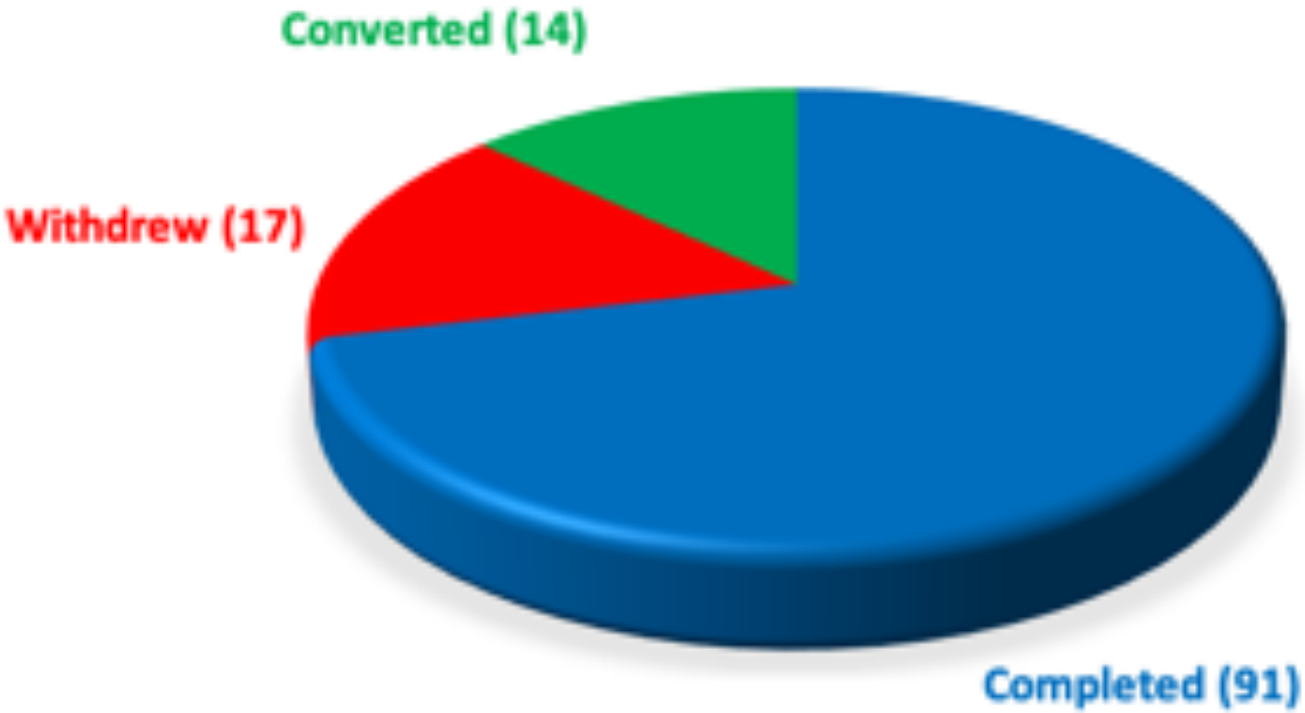
# Results – Census

- 108 Enrolled
- 91 Completed
- 17 Early Termination (8 IVR, 9 SHAM)
  - Choice – 11
  - Relocation – 1
  - Medical issues – 4 (2 IVR, 2 SHAM)
  - Death (unrelated)



# Results – Conversion

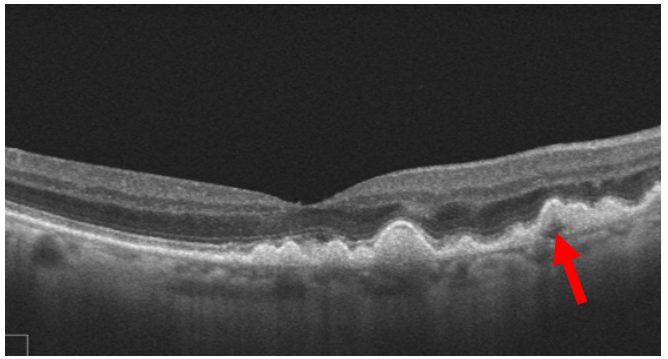
- 14 eyes progressed to Ex-AMD
  - SHAM – 7/54 (13%)
  - IVR – 7/54 (13%)
- Time to conversion (Months)
  - IVR – 3, 9, 9, 9, 15, 21, 24M
  - SHAM – 1, 3, 6, 12, 18, 18, 18M
- No ocular or systemic adverse events were reported



# Results – SD-OCT

Baseline parameters and signs (drusen volume, *“double layer sign”*)

- Balanced between SHAM and IVR groups
- Not predictive of conversion



# Conclusions

- Tolerated well
- Conversion occurred equally
- Not preventative
- PROCON (Heier et al)

# Discussion

- Continued Analysis
- Limitations
  - Suboptimal VEGF suppression
- Future?
  - Prediction or Prevention

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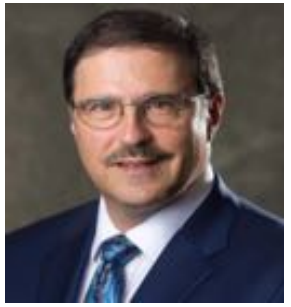

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