

Diabetes Retinopathy Study (1971-1975)

Purpose

- Primary research question(s):
 - Does laser photocoagulation prevent loss of visual acuity in patients with proliferative diabetic retinopathy?
 - Is there a difference between the two treatment types – argon laser and xenon arc?
 - Are there stages of diabetic retinopathy during which treatment with photocoagulation is more or less effective or harmful?
- Primary endpoint
 - Best corrected visual acuity: Severe visual loss defined as visual acuity less than 5/200 at 2 consecutive 4 month follow-up visits.
- Perceived clinical importance
 - Diabetic retinopathy is a major cause of blindness in the US.

Background and Context

- Improvements in the management of diabetes have increased the lifespan of diabetic patients resulting in an increase in diabetic complications. One such complication, diabetic retinopathy, has become the leading cause of blindness in persons 20 to 74.
- Treatment (photocoagulation) was introduced in 1959 but not evaluated by RCTs with adequate sample size.
- There was limited understanding of the natural history of diabetic retinopathy and increased use of photocoagulation in its management, in spite of limited evidence.

Date and Place Conducted

- Enrollment: 1971-1975
- 15 medical centers in the US

Principal Investigators

- Diabetic Retinopathy Study Research Group

Sponsored by/Source of funding

- National Eye Institute, NIH

Size and Design

- Number of participants: 1742 subjects
- Type of participants: patients with bilateral retinopathy; visual acuity 20/100 or better at enrollment; both eyes suitable for photocoagulation.
- Design:
 - Random assignment of eyes to photocoagulation or no treatment. The type of photocoagulation was randomly assigned as scatter laser by xenon arc or argon laser.

Issues Encountered During the Trial

- Some side effects from treatment. Most notable, was loss of peripheral vision in about 10% of argon-treated eyes and in about 20% of xenon-treated eyes.
- Protocol changed in 1976 to treat all untreated eyes with high risk characteristics. Eyes in the observation group without clear risk factors remained untreated.

Findings

- Two-year findings: severe visual loss in 14% of untreated eyes vs. 6.2% of treated eyes.
- Five-year findings: severe visual loss in 33% of untreated eyes and 13.9% in treated eyes.
- Xenon appeared to have greater treatment effect than argon but the difference was not statistically significant.
- The study identified four risk factors to identify those patients most likely to benefit from this treatment: presence of hemorrhage; presence of new vessels; new vessels on or near disc; and, moderate or severe new vessels.

Impact

- Favors treatment of proliferative retinopathy with photocoagulation.
- Provides model for other trials in ophthalmology.

Unresolved issues

- Does not resolve important clinical question of whether treatment should be immediate or delayed.

Summary

Photocoagulation was effective in reducing the occurrence of severe visual loss in patients with all stages of diabetic retinopathy. Treatment is recommended in patients with proliferative diabetic retinopathy and high-risk characteristics. In such cases, a 50-60% reduction in risk of severe visual loss outweighs the potential side-effects of photocoagulation. Careful follow-up is recommended for patients without high-risk characteristics.

References

1. Diabetic Retinopathy Study Group. Photocoagulation treatment of proliferative diabetic retinopathy: the second report of diabetic retinopathy study findings. *Ophthalmology*, 1978; 85: 82-106.
2. Fine, SL; Patz, A. Ten years after the Diabetic Retinopathy Study. *Ophthalmology*, 1987; 94: 739-740.
3. Fine, SL. Clinical Trials and the practice of ophthalmology. *Archives of Ophthalmology*, 1984; 102: 1282-1285.