NEI Press Release

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Blacks, Whites Benefit from Different Surgical Glaucoma Treatments

Researchers supported by the National Institutes of Health have discovered that black and white patients with advanced glaucoma respond differently to two surgical treatments for the disease. A paper detailing these findings is published in the July 1998 issue of *Ophthalmology*.

Scientists found that blacks with advanced glaucoma benefit more from a regimen that begins with laser surgery, and whites benefit more from one that begins with an operation called a trabeculectomy.

> "This is the first evidence that members of two racial groups benefit from different treatments for glaucoma," said Carl Kupfer, MD, director of the National Eye Institute (NEI), one of the Federal government's National Institutes of Health and the sponsor of the study. "Doctors now have better information to recommend treatment programs, depending on the patient's race. This will give people with advanced glaucoma a better chance to preserve and prolong their vision."

A leading cause of irreversible vision loss in the United States, glaucoma affects about three million Americans, about half of whom may be unaware they have the disease because of its lack of early symptoms. The disease is three to four times as common in blacks as in whites, and blindness from glaucoma is six times as common in blacks than in whites.

Glaucoma is a group of diseases that damages the eye's optic nerve and can lead to blindness. It tends to worsen over time. Open-angle glaucoma, the most common form and the one examined in this study, usually occurs when the normal fluid pressure inside the eye progressively increases. This increased pressure can lead to optic nerve damage and reduced peripheral (side) vision. As the disease worsens, the field of vision gradually narrows and blindness may result.

Treatment aimed at lowering the pressure within the eye is believed to slow progression of the disease. In its early stages, glaucoma is usually treated with daily eye drops. In some patients, the beneficial effect of the eye drops wears off with time, and "advanced glaucoma" develops. At this point, doctors usually recommend laser surgery, irrespective of race, and supplement it with eye drops as needed. If the beneficial effect of the laser surgery wears off, doctors usually recommend a trabeculectomy, and, if its effect wears off, a second trabeculectomy.

The major purpose of the study, called the Advanced Glaucoma Intervention Study (AGIS), was to find out which of two advanced glaucoma treatment regimens better preserves vision. Over a four-year period, researchers enrolled 332 black patients (451 eyes), and 249 white patients (325 eyes). All eyes

involved in the AGIS had advanced glaucoma. The patients' eyes were assigned randomly to one of two treatment regimens: one beginning with laser surgery, the other beginning with the trabeculectomy surgery.

After seven years of follow-up on these patients, the study results revealed that blacks and whites differed in the way they benefited from the two treatment programs. More specifically:

- The vision in eyes of black patients with advanced glaucoma tended to be better preserved in the program that started with the laser surgery. From initial treatment through seven years of follow-up, the average percent of eyes in black patients with decrease of vision was 28 percent in the program starting with laser surgery, as compared with 37 percent in the program starting with a trabeculectomy.
- Through the first four years, the vision in eyes of white patients with advanced glaucoma tended to be better preserved in the program starting with laser surgery. Thereafter, however, the reverse was true; seven years after the initial treatment, the average percent of eyes in white patients with decrease of vision was 31 percent in the program starting with a trabeculectomy, as compared with 35 percent in the program starting with laser surgery.

"Based on the study results, it is recommended that black patients with advanced glaucoma begin a treatment program that starts with laser surgery, which is consistent with current medical practice," said study co-chairman Douglas E. Gaasterland, MD, of Georgetown University. "In contrast, white patients with advanced glaucoma who have no life-threatening health problems should begin a treatment program that starts with trabeculectomy. This recommendation is inconsistent with current medical practice."

Dr. Gaasterland also said that it is "important to note that not all patients responded to the treatments in the same way. The vision of most, but not all, black patients was better preserved if their program started with laser surgery. Four years after the first surgical treatment of white patients, the vision of most, but not all, was preserved better if their program started with trabeculectomy."

Because glaucoma is a life-long disease, long-term information is important. The AGIS patients will continue to be followed for up to four more years.

The Advanced Glaucoma Intervention Study is being conducted in 12 medical centers and affiliated doctors' offices in the United States. A list of the study centers is attached.

The National Eye Institute, part of the National Institutes of Health, is the Federal government's lead agency for vision research, and supports between 70 to 80 percent of basic and applied vision research in the United States.

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Background

The Advanced Glaucoma Intervention Study (AGIS)

About Glaucoma

Glaucoma, called the "thief of vision" because of its lack of early symptoms, is a leading cause of irreversible vision loss in the United States and affects an estimated three million Americans. It is estimated that as many as 120,000 Americans are now blind from the disease.

In normal vision, a clear fluid flows continuously in and out of a space in the front of the eye called the anterior chamber. This fluid nourishes nearby tissues. The fluid leaves the anterior chamber at the angle where the iris and cornea meet. When the fluid reaches this open angle, it flows through a spongy meshwork, like a drain, and leaves the eye. Open-angle glaucoma gets its name because for unknown reasons, the fluid passes too slowly through the meshwork drain. As the fluid builds up, the pressure inside the eye rises. Unless the pressure at the front of the eye is controlled, it can damage the optic nerve and cause vision loss.

Groups at high risk of developing the disease are everyone over the age of 60, blacks over the age of 40, and people who have a family history of glaucoma. The Baltimore Eye Survey, supported by the National Eye Institute, shows that by age 70, about one in 50 whites has the disease. In blacks, the problem is more severe — by age 70, one in eight has the disease. Open-angle glaucoma tends to develop earlier in blacks than in whites, and progresses more rapidly.

It is believed that early treatment can substantially reduce the likelihood of severe vision loss or blindness. However, many people at high risk for blindness from glaucoma are unaware of the importance of early detection, or are not having their eyes examined on a regular basis for the disease. Increased public awareness of the potential benefits of a regular, comprehensive eye examination with dilated pupils may serve to reduce the enormous social and personal costs of open-angle glaucoma.

About the Advanced Glaucoma Intervention Study

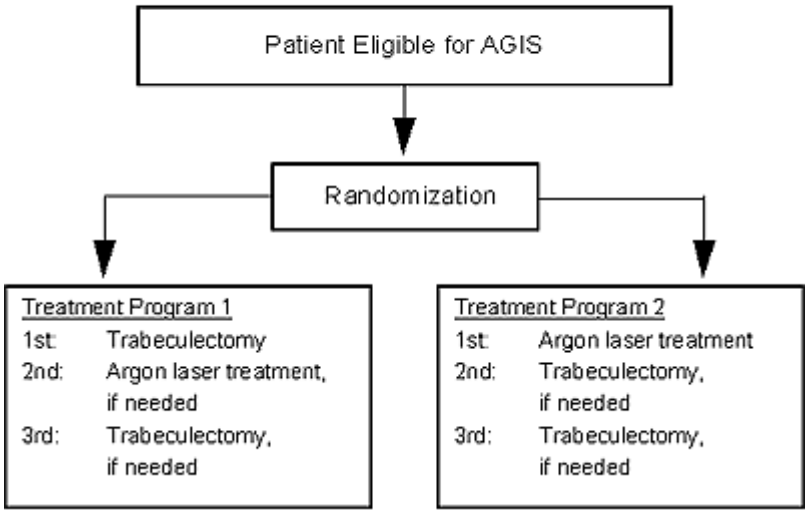
The Advanced Glaucoma Intervention Study (AGIS) is a randomized clinical trial designed to determine which of two advanced glaucoma surgical treatment programs — one beginning with laser surgery, the other beginning with an operation called trabeculectomy (see figure) — better preserves vision. The study is being conducted in 12 medical centers and affiliated doctors' offices in the United States.

Laser surgery for glaucoma involves using a high energy beam of light to make 50-100 evenly-spaced burns in the meshwork inside the eye. These tiny burns open up the drainage area, allowing for better outflow of the fluid. This procedure, often done in the doctor's office, requires only local anesthesia. In a trabeculectomy procedure, a small opening is made in the front chamber of the eye, providing a new drainage pathway for the fluid inside the eye. This procedure, done in an operating room, requires local or general anesthesia.

Researchers followed patients for seven years after their initial surgery for advanced glaucoma. In 28 percent of the cases, the beneficial effect of the initial surgical treatment (either the laser surgery or the trabeculectomy) wore off. When this happened, eyes were treated according to their study protocol assignment, as follows:

1. If the treatment beginning with the trabeculectomy lost its effect, patients' eyes would then receive the laser surgery. If, in these eyes, the laser surgery lost its effect, the eyes would receive a second trabeculectomy.
2. If the treatment beginning with the laser surgery lost its effect, patients' eyes would then receive the trabeculectomy surgery. If, in these eyes, the trabeculectomy lost its effect, the eyes would receive a second trabeculectomy.

TWO TREATMENT PROGRAMS COMPARED IN AGIS



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After seven years of follow-up on these patients, the study results revealed that blacks and whites differed in the way they benefited from the two treatment programs.

Study investigators also observed that cataract operations were performed in a somewhat larger fraction of eyes that initially received trabeculectomy than in those that initially received laser surgery. Further, on the average, more supplemental medications were needed to control glaucoma in eyes that initially received laser surgery than in those that initially received trabeculectomy.

About the National Eye Health Education Program

As part of its mission to address glaucoma as a public health problem, the National Eye Institute has established the National Eye Health Education Program (NEHEP). The NEHEP is coordinated by the NEI in partnership with more than 50 public and private organizations who plan and implement eye health education programs targeted to a variety of high-risk audiences. The focus of the NEHEP is on public and professional education programs that encourage early detection and timely treatment of glaucoma and diabetic eye disease.

As part of the NEHEP, the National Eye Institute, along with 25 other eye care organizations, annually promotes Glaucoma Awareness Month in January. This public service campaign highlights the importance of eye care and good vision, and urges those people at high risk for glaucoma to have a dilated eye exam at least every two years.

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