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Five-Year Treatment Outcomes in the Ahmed Baerveldt Comparison Study

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Purpose: To compare the 5-year outcomes of the Ahmed FP7 Glaucoma Valve (AGV) (New World Medical, Cucamonga, CA) and the Baerveldt 101-350 Glaucoma Implant (BGI) (Abbott Medical Optics, Abbott Park, IL) for the treatment of refractory glaucoma.

Design: Multicenter, randomized, controlled clinical trial.

Participants: A total of 276 patients, including 143 in the AGV group and 133 in the BGI group.

Methods: Patients aged 18 to 85 years with previous intraocular surgery or refractory glaucoma and intraocular pressure (IOP) of $\geq$18 mmHg in whom glaucoma drainage implant (GDI) surgery was planned were randomized to implantation of an AGV or a BGI.

Main Outcome Measures: Surgical failure, IOP, visual acuity (VA), use of glaucoma medications, and complications.

Results: At 5 years, IOP (mean $\pm$ standard deviation [SD]) was 14.7$\pm$4.4 mmHg in the AGV group and 12.7$\pm$4.5 mmHg in the BGI group ($P = 0.015$). The number of glaucoma medications in use at 5 years (mean $\pm$ SD) was 2.2$\pm$1.4 in the AGV group and 1.8$\pm$1.5 in the BGI group ($P = 0.28$). The cumulative probability of failure during 5 years of follow-up was 44.7% in the AGV group and 39.4% in the BGI group ($P = 0.65$). The number of subjects failing because of inadequately controlled IOP or reoperation for glaucoma was 46 in the AGV group (80% of AGV failures) and 25 in the BGI group (53% of BGI failures; $P = 0.003$). Eleven eyes in the AGV group (20% of AGV failures) experienced persistent hypotony, explantation of implant, or loss of light perception compared with 22 eyes (47% of failures) in the BGI group. Change in logarithm of the minimum angle of resolution VA (mean $\pm$ SD) at 5 years was 0.42$\pm$0.99 in the AGV group and 0.43$\pm$0.84 in the BGI group ($P = 0.97$).

Conclusions: Similar rates of surgical success were observed with both implants at 5 years. The BGI produced greater IOP reduction and a lower rate of glaucoma reoperation than the AGV, but the BGI was associated with twice as many failures because of safety issues. *Ophthalmology 2015;122:308-316 © 2015 by the American Academy of Ophthalmology.*

*Supplementary material is available at www.aaojournal.org.

Glaucoma drainage implants (GDIs) have been used with increasing frequency in the management of glaucoma refractory to trabeculectomy, even in the era of antifibrotic agent use. Medicare data reveal a marked increase in the use of GDIs, from approximately 2000 in 1994 to approximately 12 000 in 2012 (Rich W III, personal communication, 2014). In addition, surveys of the membership of the American Glaucoma Society performed in 1996, 2002, and 2008 show a significant increase in the use of GDIs in patients who had undergone prior surgery or who had neovascular or uveitic glaucoma compared with trabeculectomy with mitomycin-C.[1–3] This shift in practice pattern has been validated by the results of the Tube Versus Trabeculectomy (TVT) Study,[4] which found that patients with prior trabeculectomy or cataract surgery had a higher success rate with GDI surgery compared with trabeculectomy with mitomycin-C.

Glaucoma drainage implants share a common design consisting of a tube that is inserted into the eye through a scleral fistula, which shunts aqueous humor to an end plate placed in the equatorial region. They differ with respect to the size and material composition of the end plate, as well as the presence or absence of a valve that restricts aqueous flow if the intraocular pressure (IOP) becomes too low. A limited number of studies comparing different implant designs exist, and most of these are retrospective case series.[5] A recent Ophthalmic Technology Assessment of GDIs performed by the American Academy of Ophthalmology's Technology Assessment Committee concluded that "Too few high-quality direct comparisons of various available shunts have been published to assess the relative efficacy or complication rates of specific devices…."[6] The Ahmed Baerveldt Comparison (ABC) and Ahmed Versus Baerveldt (AVB) studies were initiated to compare the safety and efficacy of the Ahmed FP7 glaucoma valve (AGV) (New World

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Medical, Cucamonga, CA) and the Baerveldt 101-350 glaucoma implant (BGI) (Abbott Medical Optics, Abbott Park, IL), the 2 most commonly used GDIs in the United States. These randomized prospective clinical trials have shown similar results through 3 years of follow-up.[7,8] Specifically, both studies showed a small difference in IOP (1.2−1.3 mmHg lower in the BGI group) on slightly fewer medications (0.5−0.7 in the BGI group), with more subjects failing because of elevated fewer IOP in the AGV group. The purpose of this study is to report the 5-year treatment outcomes in the ABC Study.

Methods

The institutional review board at each of 16 clinical centers approved the study protocol before recruitment was started, and each patient gave informed consent. The study was registered at www.clinicaltrials.gov (NCT00376363; accessed February 16, 2014). The design and methods of the ABC Study are described in detail in a baseline methodology article[9] and are summarized in the following sections.

Randomization and Treatment

Patients aged 18 to 85 years with refractory glaucoma and IOPs ≥18 mmHg in whom GDI surgery was planned were enrolled in the study. Patients with primary glaucomas with a previous failed trabeculectomy or other intraocular surgery were included. Also, patients without previous intraocular surgery were eligible if they had secondary glaucomas known to have a higher risk of trabeculectomy failure, such as neovascular glaucoma (NVG), uveitic glaucoma, or glaucoma associated with iridocorneal endothelial syndrome. Exclusion criteria included no light perception (NLP) at baseline, uveitic glaucoma secondary to juvenile rheumatoid arthritis, prior GDI or cyclodestructive procedure, need for concurrent or anticipated (within 6 months) nonglaucoma surgery (cataract, corneal, vitreoretinal), superotemporal scleral buckle, or retinal sponge precluding superotemporal placement of an implant), or inability to provide informed consent.

Eligibility was independently confirmed at the Statistical Coordinating Center at the Bascom Palmer Eye Institute. Individuals enrolled in the study were randomized to placement of an AGV or BGI according to a permuted variable block randomization scheme, stratified by surgeon within Clinical Center and type of glaucoma. Patients were allocated to 1 of 4 strata according to their type of glaucoma, as follows: (1) primary glaucomas with previous intraocular surgery; (2) high-risk secondary glaucomas (excluding uveitic glaucoma and NVG); (3) NVG; and (4) uveitic glaucoma. Neither the subject nor the investigator was masked to the randomization assignment. Only 1 eye of each patient was eligible for enrollment. Details of the inclusion and exclusion criteria, recruitment method, and surgical procedures for implantation of the AGV and BGI used in this study are described in the baseline article.[9]

Patient Visits

Follow-up visits were scheduled 1 day, 1 week, 1 month, 3 months, 6 months, 1 year, 18 months, 2 years, 3 years, 4 years, and 5 years postoperatively. Information about data obtained at baseline and follow-up visits is contained in the baseline article.[9]

Primary and Secondary Outcome Measures

The primary outcome measure was failure, based on consensus definitions contained in the World Glaucoma Association Guidelines on Design and Reporting of Surgical Trials.[10] These criteria for failure were defined prospectively as IOP >21 mmHg or less than a 20% reduction below baseline on 2 consecutive study visits after 3 months, IOP ≤5 mmHg on 2 consecutive study visits after 3 months, reoperation for glaucoma, loss of light perception, or removal of the implant for any reason. Reoperation for glaucoma was defined as additional glaucoma surgery requiring a return to the operating room. Cyclodestruction was counted as a reoperation for glaucoma, irrespective of whether the procedure was performed in the operating room. Interventions performed at the slit lamp, such as needling procedures, removal of occluding stents, or laser suture lysis, were not considered glaucoma reoperations. The IOP, use of glaucoma medications, visual acuity (VA), visual fields, and rates of surgical complications were secondary outcome measures in the ABC Study. Eyes that had not failed by the these criteria and were not receiving glaucoma medical therapy were considered complete successes, and those requiring adjunctive medical therapy were defined as qualified successes.

Statistical Analysis

Snellen VA measurements were converted to logarithm of the minimum angle of resolution (logMAR) VA equivalents for the purpose of data analysis, as reported previously.[11] The time to failure was defined as the time from GDI placement to reoperation for glaucoma, loss of acuity to NLP in the study eye, or the first of 2 consecutive follow-up visits after 3 months in which the patient had persistent hypotony (IOP ≤5 mmHg) or inadequately controlled IOP (IOP >21 mmHg or not reduced by 20%). Data on IOP and numbers of glaucoma medications were censored once a patient underwent a reoperation for glaucoma, explantation of the implant, or loss of light perception, but not after failure due to high IOP, hypotony, or reoperation for a complication. There was no censoring of VA results. Univariate comparisons between treatment groups were performed with the 2-sided Student *t* test for continuous variables and the chi-square test or Fisher exact test for categoric variables. Risk factors for treatment failure were assessed for statistical significance with the Kaplan−Meier survival analysis log-rank test. Multivariate analysis was performed with Cox proportional hazard regression analysis with forward stepwise elimination. Patients' data were analyzed in the group to which they were assigned during randomization (intent-to-treat analysis). A *P* value of 0.05 or less was considered statistically significant in our analyses.

Results

Recruitment and Retention

A total of 276 patients were enrolled between October 2006 and April 2008, including 143 patients (52%) who were randomized to placement of an AGV and 133 patients (48%) who were randomized to placement of a BGI. Protocol violations are described in the baseline article.[9]

The retention of patients in the study through 5 years of follow-up is shown in Figure 1. In the overall study group, 174 patients (63%) completed their 5-year visit. This included 87 patients (61%) in the AGV group and 87 patients (65%) in the BGI group. We compared the numbers of patients who did not complete a 5-year visit (n = 81) by treatment group, excluding from analysis those who had died before the end of the 5-year visit window (n = 21). No significant difference was observed in the proportion of patients