Published in final edited form as:
Ophthalmology. 2011 March ; 118(3): 435–442. doi:10.1016/j.ophtha.2010.07.015.

The Ahmed Baerveldt Comparison Study: Methodology, Baseline Patient Characteristics, and Intraoperative Complications

Keith Barton, MD[1], **Steven J. Gedde, MD**[2], **Donald L. Budenz, MD, MPH**[2], **William J. Feuer, MS**[2], **Joyce Schiffman, MS**[2], and **for the Ahmed Baerveldt Comparison Study Group**

[1]NIHR Biomedical Research Centre for Ophthalmology, Moorfields Eye Hospital, London, U.K

[2]Department of Ophthalmology, Bascom Palmer Eye Institute, University of Miami, Miller School of Medicine, Miami, FL, USA

Abstract

Purpose—The Ahmed Baerveldt Comparative (ABC) Study compares the long-term outcomes and complications of the Ahmed Glaucoma Valve (AGV), model FP7, and the Baerveldt Glaucoma Implant (BGI), model 101–350.

Design—Multicenter randomized controlled clinical trial.

Participants—276 glaucoma patients at 16 clinical centers worldwide, aged 18–85 years with inadequately controlled intraocular pressure (IOP ≥ 18 mm Hg) in whom placement of an aqueous shunt was planned.

Methods—Study patients were randomized to undergo implantation of an AGV or a BGI.

Main Outcome Measure—Failure, defined as IOP > 21 mm Hg or not reduced by 20% below baseline IOP ≤ 5 mm Hg (2 consecuteive visits after 3 months), additional glaucoma surgery, removal of the implant or loss of light perception vision

Results—A total of 276 patients were enrolled between October 2006 and April 2008, including 143 in the AGV group and 133 in the BGI group. The age of patients enrolled was 63 ± 14 years (mean ± standard deviation, SD), and 52% were male. The baseline IOP was 31.5 ± 11.8 mmHg (mean ± SD). Except for a 13% higher prevalence of hypertension in the AGV group, no significant differences in baseline demographic or ocular characteristics were observed between the study groups. Intraoperative complications occurred in 11 (8%) patients in the AGV group and 16 (12%) patients in the BGI group (p = 0.31).

Conclusions—The ABC study should yield valuable prospective data comparing two commonly used aqueous shunts in clinical practice.

CORRESPONDENCE: Donald L. Budenz, MD, MPH, Bascom Palmer Eye Institute, University of Miami, Miller School of Medicine, 900 NW17th St, Miami, Florida 33136, USA.

FINANCIAL DISCLOSURES: Mr. Barton has received fees for lecturing from New World Medical, Inc, and Abbott Medical Optics, Inc. Drs. Brandt and Samuelson have received fees for consulting from Abbott Medical Optics.

INTRODUCTION

Aqueous shunts have traditionally been reserved for treatment of the most refractory glaucomas. However, more recent studies have suggested that aqueous shunts offer similar outcomes to trabeculectomy with Mitomycin C in eyes that are at a lower risk of failure, ie., in patients with primary glaucomas who are pseudophakic or who have had one failed trabeculectomy.[1–5] Consequently, aqueous shunts have been increasingly used in the management of medically uncontrolled glaucoma.

The two principal aqueous shunts in common use at the present time are the Ahmed Glaucoma Valve (AGV, New World Medical, Los Ranchos, CA, USA) and the Baerveldt Glaucoma Implant (BGI, Advanced Medical Optics, Santa Ana, CA, USA). Both the AGV and BGI share a common design consisting of a tube that shunts aqueous humour to an end-plate located in the equatorial region of the eye. These two shunts differ in two important respects. Firstly, the AGV has a flow-restrictor that limits flow through the device when the intraocular pressure (IOP) becomes low, and this is intended to limit early hypotony without the need for additional external ligation. Secondly, the end-plates differ significantly in terms of plate characteristics. The surface area of the BGI (350 mm^2) is almost double that of the AGV (184 mm^2). The absence of a flow resistor also permits the BGI to have a lower profile than the AGV. However. some surgeons believe that the large surface area necessitates implantation of the wings of the end-plate under adjacent rectus muscles.

There are differing opinions regarding the most appropriate implant to use in recalcitrant glaucoma, and no prospective comparative data have been reported. The Ahmed Baerveldt Comparison (ABC) Study is a prospective randomized clinical trial, the primary objective of which is to compare the long-term outcomes and complications of the AGV (model FP7) with the BGI (model 101–350) for surgical management of refractory glaucomas.

METHODS

The Institutional Review Board at each Clinical Center approved the study protocol before initiating recruitment. An effort was made to recruit consecutively every eligible patient into the study. Written informed consent was obtained in all patients.

Study Organization

Participating centers and committee members are listed in the Appendix. Investigators at 16 Clinical Centers have been responsible for screening all potential study patients, enrolling eligible patients, and following the patients according to the study protocol set forth in detail in the *Manual of Procedures of the ABC Study*. An independent Safety and Data Monitoring Committee (SDMC) has yearly meetings to monitor the conduct of the study and confers by phone or email as necessary to resolve study issues. A primary responsibility of the SDMC is to review the differences in failure rates and the occurrence of adverse events between treatment groups with a view to halting randomization early if treatment benefit or risk is so great for one treatment group that continuation of patient recruitment is deemed unethical. However, no formal stopping rule was adopted as recruitment was expected to be complete before noteworthy differences could emerge between these two drainage implants which are already in common use. The Statistical Coordinating Center (SCC) receives, edits, processes, analyzes, and stores all study data. The SCC coordinates activities at the Clinical Centers and monitors adherence to the study protocol. The Steering Committee (SC) is composed study chairmen (KB and DLB) and the head biostatistician (WJF). The SC provides leadership for the study, and this committee has overall responsibility for directing activities and formulating policy for the study.

Selection of Participating Surgeons

At the outset of the study, there was a concern that variable surgical experience with each of the implants could potentially influence the study results. Our intention, in this study, was to identify differences in outcomes after implantation of these two shunts, while minimizing other confounding influences such as surgical experience. Specific surgeons were therefore invited to participate in the study based on their volume of aqueous shunt surgery and history of recruitment in previous aqueous shunt studies (i.e., The Tube Versus Trabeculectomy Study). Participating surgeons were asked to declare their prior surgical experience with each implant. All surgeons indicated that they had performed at least 20 implantation procedures with one or other study implant. Surgeons reporting less than 5 procedures using one type of implant were required to submit a video demonstrating their surgical technique with that device, which was reviewed by a study chairman (DLB) prior to enrollment of any patients in the ABC Study. In all videos reviewed, the surgical procedure was deemed to be of a satisfactory standard, and no surgeons were rejected from the study on this basis.

Eligibility Criteria

Patients between ages 18 and 85 years inclusive, with inadequately controlled glaucoma on maximum tolerated medical therapy, with IOP greater than 18 mmHg, and who had an aqueous shunt as the planned surgical procedure were included. 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 high failure rate with trabeculectomy such as neovascular, uveitic, or iridocorneal endothelial syndrome-associated glaucoma.

Investigators were instructed to recruit consecutively all eligible patients from their clinics. No form of advertising was used to recruit patients. Patients were excluded if they lacked light perception vision, were unwilling or unable to give informed consent, lived out of the area and were expected to be unavailable for follow-up visits, had previous cyclodestructive procedure or previous aqueous shunt implanted in the same eye, prior scleral buckling procedure or other external impediment to supero-temporal drainage device implantation, presence of silicone oil, vitreous in the anterior chamber sufficient to require a vitrectomy, uveitis associated with a systemic condition like juvenile rheumatoid arthritis, nanophthalmos, Sturge-Weber syndrome or other conditions associated with elevated episcleral venous pressure, or needed aqueous shunt surgery combined with other ocular procedures. For patients in whom two eyes were eligible for enrollment, only the first eligible eye to be implanted was enrolled. Investigators were not asked to keep a record of eligible patients who were not enrolled.

Treatment Assignment

After informed consent was given and confirmation of eligibility by the SCC, each enrolled patient was assigned a study number and randomized to one of the two treatment arms according to a permuted variable block randomization scheme, stratified by surgeon within Clinical Center and type of glaucoma. Enrolled patients were allocated to one of 4 strata according to their type of glaucoma, as follows: (1) Primary glaucomas with previous intraocular surgery; (2) Secondary glaucomas (excluding uveitic and neovascular glaucomas); (3) Neovascular glaucoma; (4) Uveitic glaucoma.

Surgical Procedures

The surgical procedures under investigation in the ABC Study were standardized in order to ensure consistency in certain aspects of each procedure, while permitting sufficient latitude for the operation to be performed in a manner with which the surgeon was comfortable.

Aqueous shunt implantation – both treatment groups—Certain critical parts of the implantation procedure that applied to both types of shunt were standardized for the purposes of the study. The protocol specified that: (1) all shunts should be implanted in the supero-temporal quadrant; (2) the conjunctiva and Tenon's capsule should be dissected to permit placement; (3) the end-plate should be sutured to sclera at a measured distance 8–10 mm posterior to the limbus; (4) the anterior chamber entry should be made with a 23-gauge needle at the posterior limbus parallel to the iris plane; (5) the tube should be trimmed bevel up to extend several millimeters into the anterior chamber; (6) the tube should be inserted through the needle track and positioned in the anterior chamber away from the corneal endothelium and above the iris; (7) the limbal portion of the tube should be covered with a donor patch of sclera, cornea or pericardium; (8) the conjunctiva should be sutured closed. Other parts of the procedure were left to the surgeon's discretion.

AGV implantation—The ABC study protocol specified that the model FP7 AGV should be used in all cases randomized to the AGV treatment group. A 30 gauge cannula was used to prime the flow restrictor in the AGV. Occlusion of the AGV tube with a ligature was not permitted. The use of a viscoelastic was permitted at the conclusion of the surgery at the surgeon's discretion.

BGI implantation—The ABC study protocol specified that the model 101–350 BGI should be used in all cases randomized to the BGI group. The BGI end-plate was positioned under or over the superior rectus and lateral rectus muscles, depending on the surgeon's usual practice. The BGI tube was completely occluded in all cases in order to restrict aqueous flow to the plate until it became encapsulated. The method of tube occlusion was left to the discretion of the surgeon, including ligation of the tube with a polyglactin suture near the tube-plate junction, ligation with a polypropylene suture which is inserted into the anterior chamber with the tube, or internal occlusion of the tube using a "rip-cord" technique. A 30-gauge cannula was used to cannulate the end of the tube and confirm complete occlusion of the tube. Tube fenestration was permitted, and the method of tube fenestration was left to the discretion of the surgeon. The use of a viscoelastic was permitted at the conclusion of the surgery at the surgeon's discretion.

Follow-up Schedule and Study Measurements

The study measurements to be made at each planned follow-up visit are listed in Table 1 (available at http://aaojournal.org). Following the surgery, an appointment schedule was generated for each patient by the SCC and sent to the patient's Clinical Center. The study entry date was recorded as the date of surgery, and follow-up visit windows calculated from this date. All patients are to have planned postoperative follow-up examinations scheduled at 1 day, 1 week, 1 month, 3 months, 6 months, 1 year, 18 months, 2 years, 3 years, 4 years, and 5 years after surgery. All measurements are made according to standard operating procedures as outlined in the *Manual of Procedures for the ABC study*. This is an unmasked study and study visit measurements and outcome measures will be judged by participating physicians.

Visual acuity—Snellen visual acuity is measured before pupil dilation, tonometry, gonioscopy, or other technique that could affect vision. Snellen visual acuity is measured at the Qualifying Assessment and at every follow-up visit.

Refraction—Subjective refraction is performed prior to formal measurement of visual acuity at the Qualifying Assessment and the annual follow-up visits.

Slit-lamp biomicroscopy—Examination of the anterior segment using slit lamp biomicroscopy is performed at the Qualifying Assessment to document preoperative status, and at all follow-up examinations to detect any changes during the course of the study which may be attributable to the disease or treatment. Aqueous shunts have been implicated in long-term damage to the cornea. Tube position and length within the anterior chamber in relation to the cornea and iris, on slit-lamp examination, will therefore be documented at each study visit.

IOP—Goldmann applanation tonometry is used to measure IOP, except when irregular corneal astigmatism, corneal scarring, or corneal edema precludes accurate measurement. In these cases, the Tono-Pen (Tonopen XL, Reichert Ophthalmic Instruments, Depew, NY, USA) is used. In either case, IOP readings are repeated until 2 measurements are obtained that differ by 1 mm Hg or less. The average of these 2 readings is recorded as the IOP measurement for the visit.

Pachymetry—As a surrogate measure of corneal function that is simple to acquire, central corneal thickness using ultrasonography will be measured before surgery and at the annual follow-up visits.

Gonioscopy—Gonioscopy is performed at the slit lamp using either a Zeiss-type indentation gnoioprism or a Goldmann-type non-indentation gonioprism. The purpose of the preoperative examination of the anterior chamber angle is to document neovascularization, peripheral anterior synechiae, the presence of silicone oil in the angle, and to identify an appropriate implantation site for the tube.

Motility assessment—Transient diplopia following aqueous shunt implantation is not uncommon. Permanent restrictive diplopia is less common and of uncertain incidence, but nevertheless a significant complication. This has been studied prospectively with the BGI in the Tube versus Trabeculectomy (TVT) Study after one year of follow-up,[6] but is unknown for the AGV. To address this issue, a formal motility assessment is performed in all patients at baseline and at the 1-year and 5-year follow-up visits. Additionally, motility assessment is performed in those patients with diplopia at the 6-month follow-up visit or after.

During each motility examination, the cover-uncover and alternate cover tests will be performed in primary gaze, as well as in upgaze, downgaze, left gaze, and right gaze. Motility examination is performed for distance and near in order to identify any heterophoria or heterotropia, and the deviation measured with a hand-held prism. In patients who are unable to fixate for cover testing, the deviation is measured by centering the corneal light reflexes with a prism using the modified Krimsky method.

Perimetry—Threshold perimetry is performed using the Humphrey Field Analyzer. Visual field testing is performed before tonometry, gonioscopy, or other technique that could affect vision. A visual field will be attempted in any eye that has sufficient vision to permit finger counting at a distance of two feet. Perimetry will be performed using a 24-2 threshold test in all patients using a size III white stimulus. Both the Swedish Interactive Threshold Algorithm (SITA) and full threshold strategies are permitted, with the proviso that the same testing strategy be used in any one patient throughout the duration of the study. Visual fields are performed preoperatively (within one month of enrollment in the study) and annually thereafter.

Dilated fundus examination—A dilated fundus examination is performed at the Qualifying Assessment to determine the preoperative status of the eye, and at all postoperative follow-up examinations to detect any changes in ocular status produced by the disease or treatment. At the Qualifying Assessment, particular attention is paid to detect signs of proliferative retinopathy, retinal neovascularization, vitreous hemorrhage, or preretinal hemorrhage. At all postoperative follow-up visits, ophthalmoscopy is performed to look for posterior segment complications of surgery. Structural changes in the optic disc were not recorded as part of the study as progression of glaucoma was not an end-point and satisfactory images would be difficult to obtain in a sufficient number of patients.

Sample Size Calculations

A recent retrospective comparison from Singapore reported an 83% success rate for the Baerveldt and 67% for the Ahmed.[7] This study was powered to detect a true difference in success rates of this size. Setting the power at 80% and alpha at 5%, 125 patients in each group were required to detect this difference. The overall study size of 275 was determined to allow for a 10% dropout rate.

Outcome Measures

The primary outcome measure will be failure, defined by any of the following criteria:

1. IOP > 21 mm Hg or not reduced by 20% below baseline on two consecutive visits after 3 months
2. IOP ≤ 5 mm Hg on two consecutive visits after 3 months
3. Additional glaucoma surgery
4. Removal of implant
5. Loss of light perception vision

Eyes with successfully controlled intraocular pressures (≤ 21 mm HG and >5 mmHg and reduced by at least 20% from baseline) will be considered complete successes if medications are not used at the relevant follow-up visits and will be considered qualified successes otherwise. Qualified success, that is, pressure controlled with or without medications, is considered successful in survival analyses.

Two alternative IOP cut-offs 18 mm Hg and 15 mmHg, will be used in secondary analyses as suggested by the World Glaucoma Association's Guidelines on Design and Reporting of Surgical Trials.[8] All other criteria for failure will be the same as in the primary analysis as outlined above.

Successful repair of an exposed shunt, unblocking or resiting of a retracted or occluded shunt will not be considered a failure, though all complications will be listed and analysed. It is intended that the ABC study will permit comparison of the two shunts with regard to specific issues of safety including the risks of complications as recommended by the Cochrane Collaboration review of Aqueous Shunts.[9]

Investigators in the ABC Study recorded intraoperative complications at the time of surgery, and postoperative complications were documented at each follow-up visit on standardized forms. The data forms listed several complications that were designated as present or absent, and blank spaces were also included for recording complications that did not appear on the list. Intraoperative complications listed on the data form included hyphema, suprachoroidal hemorrhage, and scleral perforation. Postoperative complications that were listed on the data forms included tube occlusion with iris/vitreous, choroidal effusion, suprachoroidal

hemorrhage, cystoid macular edema, shallow anterior chamber, hypotony maculopathy, endophthalmitis, cataract, diplopia, corneal edema, and tube or shunt erosion, uveitis and tube malposition. Investigators were asked to report any complications that were present at the scheduled follow-up visit or between study visits.

RESULTS

Patients Recruited

A total of 276 patients were enrolled in the ABC study at 16 clinical centers between October 2006 and April 2008. One hundred forty three patients were randomized to the AGV and 133 to the BGI. Demographic characteristics of the study population at baseline are shown in Table 2. The mean age of the study group was 63.8 ± 13.7 years (mean ± standard deviation, SD), and 52% were male. Forty nine percent were white and 25% were black. Notably 41% of the overall group was diabetic and 57% had systemic hypertension. No significant differences in any of the demographic features were observed between the AGV group and the BGI group except for a 13% higher prevalence of hypertension in the AGV group (p=0.039)(Table 2).

Ocular Characteristics

The ocular characteristics of the study group are presented in Table 3. Fifty four percent of operated eyes were right eyes. The overall baseline IOP was 31.5 ± 11.8 mmHg (mean ± SD) on an average of 3.4 ± 1.1 glaucoma medications. The median preoperative visual acuity was 20/80 (range, 20/15 to light perception). Seventy two percent of eyes had a preoperative visual acuity of less than 20/30 and glaucoma was documented to be the cause of this reduction in acuity in 67% of patients. The average preoperative central corneal thickness was 551 ± 56 μm (mean ± SD).

The most common preoperative glaucoma diagnoses were primary open angle glaucoma (POAG, 40%), neovascular glaucoma (NVG, 29%), primary angle closure glaucoma (PACG, 7%), and uveitic (7%). Sixty one percent of eyes were pseudophakic with a posterior chamber intraocular lens implant (PCIOL), and 33% were phakic at enrollment. Only 6% were aphakic or had an anterior chamber intraocular lens (ACIOL). Forty two percent had previously undergone trabeculectomy (Table 4). Twenty percent had not undergone any form of incisional surgery before enrollment. Overall, 49% had undergone either laser iridotomy, trabeculoplasty or other laser procedure. No significant differences in the baseline ocular characteristics were seen between the two study groups.

The numbers and classes of glaucoma medication used by each patient at baseline are presented in Table 5 (available at http://aaojournal.org), and these did not significantly differ between the two study groups. The most commonly used classes were beta-blockers (84%), prostaglandin analogues (81%), topical carbonic anhdrase inhibitors (72%) and alpha-agonists (71%). Twenty nine percent of patients were also taking systemic carbonic anhydrase inhibitors.

Randomized Patients Who Did Not Receive Surgery

A total of 286 eligible patients were randomized. Of these, 10 withdrew consent between randomization and surgery for the following reasons: one patient became compliant with their prescribed glaucoma medications after the qualifying visit and surgery was cancelled; two patients had to cancel surgery due to systemic medical conditions that contraindicated eye surgery; seven patients elected to seek care from another physician or had insurance problems. This resulted in surgical treatment of 276 patients, despite an initial target of 275,

because one patient who had been randomized and consented and had cancelled surgery, eventually underwent surgery after a subsequent patient had been enrolled.

Protocol Violations

Four (1.4%) patients received the wrong device as follows: one patient randomized to the AGV group received a non-FP7 Ahmed (model S2); two patients randomized to the BGI group received Ahmeds because Baerveldts were not available at the time of surgery; one patient randomized to the BGI group received an Ahmed due to surgeon error. One patient with an IOP of 16mmHg at the qualifying assessment visit was randomized into the study due to an SCC error. According to the study protocol, all recruited patients will be included in the analysis according to the implant to which they were randomized, irrespective of whether or not they received the correct implant.

Surgical Experience

Table 6 details prior surgical experience with each device in terms of numbers implanted. Twenty five surgeons participated in the study. All surgeons had implanted at least one type of implant in more than 20 patients. Sixty percent of surgeons had implanted each type of implant in more than 20 cases before the study. There were 2 surgeons (8%) who had performed fewer than 5 AGV implantations, though both were experienced BGI surgeons. There were 5 surgeons (20%) who had performed fewer than 5 BGI procedures, but all 5 were experienced AGV surgeons. A greater number of cases randomized to the AGV group (120, or 84%), were operated on by surgeons having performed 20 or more prior procedures with the same implant, compared with cases randomized to the BGI group, (95 cases or 71%) (p=0.014, Fisher exact).

Recruitment by Stratum—Recruitment by stratum is presented in Table 7. There was no difference in distribution by strata between the two groups (P = 0.88, Chi-square test).

Operative Data

Table 8 (available at http://aaojournal.org) presents a summary of operative techniques and perioperative injections used in the AGV and BGI groups. More subjects in the AGV group (56%) had a viscoelastic injected after conclusion of the surgery than in the BGI group (13%, P < 0.001, Chi-squared test). There were no differences in the type of patch graft material used or postoperative medications give. Three subjects in the AGV group received an intravitreal anti-angiogenic injection compared to none in the BGI group. Table 9 (available at http://aaojournal.org) provides details of operative techniques unique to the BGI group. Six (5%) subjects in the BGI group were implanted over, rather than under the muscles. Viscoelastic material was left in the anterior chamber at the end of the operation in 81 (57%) of AGV procedures compared to 18 (14%) of BGI procedures (P < 0.001).

Intra-operative Complications

Surgical complications in the ABC study are presented in Tables 10 (according to treatment group) and Table 11 (according to surgical experience with the type of shunt implanted, available at http://aaojournal.org). The overall surgical complication rate was 10%. Hyphema was the most common intraoperative complication, accounting for 79% of intraoperative complications. No significant difference was observed in the frequency of intraoperative complications between inexperienced surgeons (i.e., surgeons with less than 20 cases experience with the device implanted) and experienced surgeons.

DISCUSSION

Extensive past experience with the Molteno implant highlighted two impediments to achieving safe, predictable, physiological, long-term IOP levels with aqueous shunts. The first is difficulty in achieving a physiological IOP level in the early postoperative period, and the second is loss of long-term pressure control due to encapsulation of the end-plate portion of the shunt.

A number of modern aqueous shunts, including the AGV and BGI adhere to the basic design of the original Molteno implant in that they consist of a silicone tube of approximately 600 μm external diameter and 300μm internal diameter that shunts aqueous from either anterior chamber, ciliary sulcus or vitreous cavity, to the equatorial sub-conjunctival space where an end-plate attached to the distal end of the tube and secured to sclera, prevents fibrous ingrowth from obstructing the tube orifice, and determines the surface area of aqueous absorption. Although the AGV and BGI are similar in these respects, they differ in other respects and opinion is divided as to which is the most appropriate for the treatment of refractory glaucoma. The AGV contains a flow restrictor that is intended to reduce the frequency of early hypotony, the unpredictability of the early postoperative course, and also the complexity of the implantation technique. However, with the AGV, flow is restricted rather than abolished and the sub-conjunctival space is exposed to aqueous humor immediately after implantation. It has been suggested that this might expose subconjunctival tissues to greater levels of inflammatory cytokines than is the case with ligated shunts, where aqueous flow does not occur until 5 – 6 weeks after surgery. Some believe that such exposure provides a greater stimulus for end-plate encapsulation than is the case with a ligated non-valved implant such as the BGI. However, there are no prospective clinical data to support this hypothesis.

The degree to which the plate encapsulates is the main determinant of longer-term shunt function. All shunt end-plates develop a surrounding capsule to some degree.[10–12] In non-valved shunts, the capsule is the main point of resistance to aqueous flow and hence the main determinant of longer-term IOP level. The factors that influence encapsulation are therefore of interest. These probably include plate surface area, thickness, material, and flexibility. The AGV and BGI differ in surface area and thickness. The larger surface area of the BGI 101–350 provides a greater potential drainage bleb area for aqueous absorption. However, the width of the end-plate extends to more than two clock hours of circumference when placed on the equatorial sclera, and in most eyes are placed under the adjacent rectus muscles. Despite this increasing popularity of shunts, non-randomized retrospective studies provide the majority of comparative data between the AGV and BGI.[7,13–16]

Although the surface area of the external plate is only one of a number of variables that might influence encapsulation, and hence the major determinant of long-term IOP control, the importance of plate surface area has been demonstrated in 2 randomized controlled trials,[17, 18] supported by other non-randomized clinical series. While larger plate surface area is associated with lower mean postoperative IOP levels, there seems to be a higher cost in terms of hypotony, with larger plate surface area.[19] A retrospective study by Seah et al comparing 70 BGI (350 mm^2) with 54 BGI (250 mm^2) implants in Asian eyes, found very little difference in IOP reduction between the two groups after a mean follow-up of 33 months.[20]

Although there is some evidence that shunt size represents a trade-off between smaller plate size and higher long-term pressures, or large plate size, with better long-term IOP control, and a higher risk of sequelae from hypotony, there are other differences between the AGV

and BGI, that may influence the relative outcomes and complications rates of these two implants.

Despite wider eligibility criteria than the TVT study,[3] a majority of enrolled patients, albeit a small majority (51%, Table 7), suffered from a primary (stratum 1) rather than a secondary glaucoma (strata 2 – 4) with neovascular glaucoma (stratum 3) being the second most common diagnosis (29% of enrolled patients). It is conceivable that the most appropriate shunt for one stratum of glaucoma patient may not be the most appropriate for others and ABC study should provide important comparative data in this regard.

A concern in the design of this study was the possibility that investigators who were surgically inexperienced with one or other implant might introduce significant bias towards a higher risk of surgical complications and poorer outcomes with that respective shunt. A number of steps were taken in the study design in order to minimize this. First, investigators and study centers were selected that had extensive experience with aqueous shunt implantation in general. As it would not be possible to select only investigators who had extensive experience with both implants, investigators were selected so that experience with the two implants was equally represented. Table 6 shows that 5 investigators with significant previous AGV experience, had implanted fewer than 5 BGI prior to the study and for 2 investigators, the opposite was true. In order to protect the safety of the patients enrolled, investigators who had implanted fewer than 5 of one particular study implant were asked to provide a video of their implantation technique which was reviewed by one of the principal investigators (DLB). Second, balanced randomized treatment assignment lists were prepared for each surgeon. Despite these efforts, more patients randomized to AGV had the device implanted by a surgeon with 20 or more prior AGV cases than were patients receiving BGI. However there was no indication that operative complications were more common in cases for which the surgeon had relatively less experience with the randomized drainage implant.

It is worth noting from Table 10 that hyphema accounted for 22 out of 27 intraoperative complications and that no patient suffered an intra-operative supra-choroidal hemorrhage. At 9.8%, the intra-operative complication rate was similar to the TVT study (7.0%). The percentage of patients experiencing an intraoperative complication other than hyphema was 2.1% in this study compared with 5.6% for TVT.[5] Additionally, the intra-operative complication rate was not higher in surgeons who had implanted fewer than 5 cases of one type of implant. It is anticipated that the ABC study will also provide interesting insights into the influence of surgical experience on postoperative outcomes.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

Acknowledgments

SUPPORTED BY: NIH P30 EY014801 and unrestricted grants from New World Medical and Research to Prevent Blindness

References

1. Wilson MR, Mendis U, Smith SD, Paliwal A. Ahmed glaucoma valve implant vs trabeculectomy in the surgical treatment of glaucoma: a randomized clinical trial. Am J Ophthalmol 2000;130:267–273. [PubMed: 11020403]
2. Wilson MR, Mendis U, Paliwal A, Haynatzka V. Long-term follow-up of primary glaucoma surgery with Ahmed glaucoma valve implant versus trabeculectomy. Am J Ophthalmol 2003;136:464–470. [PubMed: 12967799]

3. Gedde SJ, Schiffman JC, Feuer WJ, et al. Tube Versus Trabeculectomy Study Group. The Tube versus Trabeculectomy Study: design and baseline characteristics of study patients. Am J Ophthalmol 2005;140:275–287. [PubMed: 16086949]
4. Gedde SJ, Schiffman JC, Feuer WJ, et al. Tube Versus Trabeculectomy Study Group. Treatment outcomes in the Tube versus Trabeculectomy study after one year of follow-up. Am J Ophthalmol 2007;143:9–22. [PubMed: 17083910]
5. Gedde SJ, Herndon LW, Brandt JD, et al. Tube Versus Trabeculectomy Study Group. Surgical complications in the Tube versus Trabeculectomy Study during the first year of follow-up. Am J Ophthalmol 2007;143:23–31. [PubMed: 17054896]
6. Rauscher FM, Gedde SJ, Schiffman JC, et al. Tube Versus Trabeculectomy Study Group. Motility disturbances in the Tube versus Trabeculectomy Study during the first year of follow-up. Am J Ophthalmol 2009;147:458–466. [PubMed: 19038375]
7. Wang JC, See JL, Chew PT. Experience with the use of Baerveldt and Ahmed glaucoma drainage implants in an Asian population. Ophthalmology 2004;111:1383–1388. [PubMed: 15234141]
8. Heuer, DK.; Barton, K.; Grehn, F., et al. Consensus on definitions of success. In: Shaarawy, TM.; Sherwood, MB.; Grehn, F., editors. Guidelines on Design and Reporting of Surgical Trials. Amsterdam, The Netherlands: Kugler; 2008 [Accessed June 16, 2010]. p. 15-24.Available at: http://www.worldglaucoma.org/
9. Minckler DS, Vedula SS, Li TJ, et al. Aqueous shunts for glaucoma. Cochrane Database Syst Rev 2006;(2):CD004918. [PubMed: 16625616]
10. Molteno AC. New implant for drainage in glaucoma: clinical trial. Br J Ophthalmol 1969;53:606–615. [PubMed: 4900144]
11. Molteno AC. New implant for drainage in glaucoma: animal trial. Br J Ophthalmol 1969;53:161–168. [PubMed: 5813407]
12. Lloyd MA, Baerveldt G, Nguyen QH, Minckler DS. Long-term histologic studies of the Baerveldt implant in a rabbit model. J Glaucoma 1996;5:334–339. [PubMed: 8897233]
13. Tsai JC, Johnson CC, Dietrich MS. The Ahmed shunt versus the Baerveldt shunt for refractory glaucoma: a single-surgeon comparison of outcome. Ophthalmology 2003;110:1814–1821. [PubMed: 13129882]
14. Syed HM, Law SK, Nam SH, et al. Baerveldt-350 implant versus Ahmed valve for refractory glaucoma: a case-controlled comparison. J Glaucoma 2004;13:38–45. [PubMed: 14704542]
15. Tsai JC, Johnson CC, Kammer JA, Dietrich MS. The Ahmed shunt versus the Baerveldt shunt for refractory glaucoma II. Ophthalmology 2006;113:913–917. [PubMed: 16751034]
16. Goulet RJ III, Phan AD, Cantor LB, WuDunn D. Efficacy of the Ahmed S2 glaucoma valve compared with the Baerveldt 250-mm2 glaucoma implant. Ophthalmology 2008;115:1141–1147. [PubMed: 18164068]
17. Heuer DK, Lloyd MA, Abrams DA, et al. Which is better? One or two? A randomized clinical trial of single-plate versus double-plate Molteno implantation for glaucomas in aphakia and pseudophakia. Ophthalmology 1992;99:1512–1519. [PubMed: 1454316]
18. Britt MT, LaBree LD, Lloyd MA, et al. Randomized clinical trial of the 350-mm2 versus the 500-mm2 Baerveldt implant: longer term results: is bigger better? Ophthalmology 1999;106:2312–2318. [PubMed: 10599663]
19. Molteno AC. The optimal design of drainage implants for glaucoma. Trans Ophthalmol Soc N Z 1981;33:39–41. [PubMed: 6942574]
20. Seah SK, Gazzard G, Aung T. Intermediate-term outcome of Baerveldt glaucoma implants in Asian eyes. Ophthalmology 2003;110:888–894. [PubMed: 12750085]

Table 2

Summary of Demographic Characteristics of Study Patients at Baseline in the Ahmed Baerveldt Comparison Study

	Overall Group (n = 276)	**AGV Group (n =143)**	**BGI Group (n =133)**	**P-value**
Age (years)				
Mean ± SD	63.8 ± 13.6	65.4+12.8	62.2 ± 14.2	0.053[a]
Range	24, 85	24, 85	24, 85	
Gender, n (%)				
Male	142 (51%)	73 (51%)	70 (52 %)	0.91[b]
Race, n (%)				0.12[c]
White	134 (49%)	66 (46%)	68 (51%)	
Black	68 (25%)	43 (30%)	25 (19%)	
Hispanic	33 (12 %)	12 (8%)	21 (16%)	
Asian	33 (12%)	17 (12%)	16 (12%)	
Other	8 (3%)	5 (4%)	3 (2%)	
Hypertension, n (%)	157 (57%)	90 (63%)	67 (50%)	0.039[b]
Diabetes mellitus, n (%)	113 (41%)	62 (43%)	51 (38%)	0.46[b]

[a] Student *t*-test

[b] Fisher Exact test

[c] Chi-square test

AGV = Ahmed Glaucoma Valve; BGI = Baerveldt Glaucoma Implant, SD = standard deviation.

Table 3

Summary of Ocular Characteristics at Baseline in the Ahmed Baerveldt Comparison Study

	Overall Group (n = 276)	AGV (n =143)	BGI (n = 133)	P-value
Study eye, n (%)				
Right	148 (54%)	83 (58%)	65 (49%)	0.15[a]
Snellen Visual Acuity				
Median	20/80	20/80	20/70	0.78[b]
Range	20/15, LP	20/15, LP	20/15, LP	
IOP (mm Hg)				
Mean ± SD	31.5 ± 11.8	31.2±11.2	31.8 ± 12.5	0.71[c]
Range	16, 78.5	18, 67	16, 78.5	
Number of classes of glaucoma medications, n (%)				0.40[d]
0	4 (1%)	4 (3%)	0 (0%)	
1	10 (4%)	4 (3%)	6 (5%)	
2	32 (12%)	17 (12%)	15 (11%)	
3	91 (33%)	48 (34%)	43 (32%)	
4	99 (36%)	52 (36%)	47 (35%)	
≥ 5	40 (15%)	18 (13%)	22 (17%)	
Mean ± SD	3.4±1.1	3.4 ± 1.1	3.5 ± 1.1	0.34[c]
Central Corneal thickness				
Mean ± SD	551.1±55.6	552.0±60.5	550.2 ± 50.0	0.79[c]
Range	417, 984	434, 984	417, 675	
Diagnosis, n (%)				0.88[d]
POAG	111 (40%)	58 (41%)	53 (40%)	
PACG	18 (7%)	10 (7%)	8 (6%)	
Neovascular	80 (29%)	41(29%)	39 (29%)	
Uveitic	18 (7%)	11 (8%)	7 (5%)	
Other	49 (18%)	23 (16%)	26 (20%)	
VA < 20/30, n (%)	198 (72%)	101 (71%)	97 (73%)	0.69[a]
Reason for VA < 20/30, n (%)				
Glaucoma	133 (67%)	63 (62%)	70 (72%)	0.094[a]
Macular disease	45 (23%)	26 (26%)	19 (20%)	0.32[a]
Cataract	21 (11%)	13 (13%)	8 (8%)	0.36[a]
Other	66 (33%)	31 (31%)	35 (36%)	0.45[a]
Unknown	2 (1%)	0	2 (2%)	0.24[a]

[a] Fisher Exact test

[b] Mann-Whitney test

[c] t-test

[d] Chi-squared test

AGV = Ahmed Glaucoma Valve,; BGI = Baerveldt Glaucoma Implant; LP = Light perception; IOP = Intraocular Pressure; SD = Standard Deviation; POAG = Primary Open Angle Glaucoma; PACG = Primary Angle Closure Glaucoma; VA = Visual Acuity.

Table 4

Summary of Previous Interventions at Baseline in the Ahmed Baerveldt Comparison Study

	Overall Group (n = 276)	AGV (n =143)	BGI (n = 133)	P-value
Lens status, n (%)				0.50[d]
Phakic	91 (33%)	47 (33%)	44 (33%)	
PCIOL	169 (61%)	90 (63%)	79 (59%)	
ACIOL	11 (4 %)	5 (4%)	6 (5%)	
Aphakic	5 (2%)	1 (1%)	4 (3%)	
Previous laser therapy, n (%)				
None	141 (51%)	70 (49%)	71 (53%)	0.47[a]
Laser trabeculoplasty	47 (17%)	27 (19%)	20 (15%)	0.42[a]
Laser iridotomy	25 (9%)	15 (11%)	10 (8 %)	0.41[a]
Other laser procedures	74 (27%)	41 (29%)	33 (25%)	0.50[a]
Previoius incisional surgery				
None	54 (20%)	28 (20%)	26 (20%)	1.00[a]
Cataract	152 (55%)	79 (55%)	73 (55%)	1.00[a]
Trabeculectomy	83 (30%)	42 (29%)	41 (31%)	0.80[a]
Combined Cataract and trabeculectomy	32 (12%)	16 (11%)	16 (12%)	0.85[a]
Other	60 (22%)	31 (22%)	29 (22%)	1.00[a]

[a] Fisher Exact test

[b] Mann-Whitney test

[c] t-test

[d] Chi-squared test

AGV = Ahmed Glaucoma Valve,; BGI = Baerveldt Glaucoma Implant; PCIOL = Posterior Chamber Intraocular Lens Implant; ACIOL = Anterior Chamber Lens Implant

Table 6

Surgeon experience with the study devices

		Prior surgical procedures with BGI		
		0–4*	**20+**	**Total**
Prior surgical cases with AGV	0–4*	0	2 (8%)	2 (8%)
	5–9	0	2 (8%)	2 (8%)
	10–19	0	1 (4%)	1 (4%
	20+	5 (20%)	15 (60%)	20 (80%)
	Total	5 (20%)	20 (80%)	25 (100%)

* Surgeons with less experience than five prior cases with a device were required to submit a video of a non-study case undergoing implantation with that device to be certified by one principle investigator (DLB).

BGI = Baerveldt Glaucoma Implant; AGV = Ahmed Glaucoma Valve

Table 7

Enrollment by Stratum in the Ahmed Baerveldt Comparison Study*

	Overall (n = 276)	AGV (n = 143)	BGI (n = 133)
Primary glaucoma with previous surgery (Stratum 1)	141 (51%)	72 (50%)	69 (52%)
Secondary glaucomas (excluding neovascular and uveitic glaucomas) (Stratum 2)	37 (13%)	19 (13%)	18 (14%)
Neovascular glaucoma (Stratum 3)	80 (29%)	41 (29%)	39 (29%)
Uveitic glaucoma (Stratum 4)	18 (6.5%)	11 (8%)	7 (5%)

*No difference in distribution of strata between treatment groups (p=0.88, Chi-Squared)

AGV = Ahmed Glaucoma Valve; BGI = Baerveldt Glaucoma Implant

Table 10

Intraoperative complications by treatment group

n (%)	Overall	AGV	BGI	p (Fisher exact)
Hyphema	22 (8%)	8 (6%)	14 (11%)	0.18
Supra-choroidal hemorrhage	0	0	0	0
Scleral perforation	1 (0.4%)	1 (1%)	0	1.00
Other complication	5 (2%)	2 (1%)[a]	3 (2%)[b]	0.68
Any complication	27 (10%)	11 (8%)	16 (12%)	0.31

[a] capsule over previous trabeculectomy opened and aqueous percolated through conjunctival hole;

[b] leakage from a preexisting corneal graft

AGV = Ahmed Glaucoma Valve; BGI = Baerveldt Glaucoma Implant