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The Ahmed Versus Baerveldt Study

Five-Year Treatment Outcomes

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Purpose: To compare 2 frequently used aqueous shunts for the treatment of glaucoma.

Design: International, multicenter, randomized trial.

Participants: Patients aged 18 years or older with uncontrolled glaucoma despite maximum tolerated medical therapy, many of whom had failed or were at high risk of failing trabeculectomy.

Methods: Eligible patients were randomized to receive an Ahmed-FP7 valve implant (New World Medical, Inc, Rancho Cucamonga, CA) or a Baerveldt-350 implant (Abbott Medical Optics, Inc, Santa Ana, CA) using a standardized surgical technique.

Main Outcome Measures: The primary outcome was failure, defined as intraocular pressure (IOP) outside the target range (5−18 mmHg) or reduced <20% from baseline for 2 consecutive visits after 3 months, severe vision loss, or de novo glaucoma surgery. Secondary outcomes measures included IOP, medication use, visual acuity, complications, and interventions.

Results: A total of 238 patients were randomized; 124 received the Ahmed-FP7 implant, and 114 received the Baerveldt-350 implant. Baseline characteristics were similar between groups. Mean preoperative IOP was 31.4±10.8 mmHg on 3.1±1.0 glaucoma medications. At 5 years, the cumulative failure rate was 53% in the Ahmed group and 40% in the Baerveldt group ($P = 0.04$). The main reason for failure in both groups was high IOP, and the cumulative de novo glaucoma reoperation rate was 18% in the Ahmed group and 11% in the Baerveldt group ($P = 0.22$). Hypotony resulted in failure in 5 patients (4%) in the Baerveldt group compared with none in the Ahmed group ($P = 0.02$). Mean IOP was 16.6±5.9 mmHg in the Ahmed group (47% reduction) and 13.6±5.0 mmHg in the Baerveldt group (57% reduction, $P = 0.001$). Mean medication use was 1.8±1.5 mmHg in the Ahmed group (44% reduction) and 1.2±1.3 mmHg in the Baerveldt group (61% reduction, $P = 0.03$). The 2 groups had similar complication rates (Ahmed 63%, Baerveldt 69%) and intervention rates (Ahmed 41%, Baerveldt 41%). Most complications were transient, and most interventions were slit-lamp procedures.

Conclusions: Both implants were effective in reducing IOP and the need for glaucoma medications. The Baerveldt group had a lower failure rate and a lower IOP on fewer medications than the Ahmed group, but had a small risk of hypotony that was not seen in the Ahmed group. *Ophthalmology 2016;123:2093-2102 © 2016 by the American Academy of Ophthalmology.*

Supplemental material is available at www.aaojournal.org.

The mainstay of glaucoma treatment is reducing intraocular pressure (IOP) to prevent disease progression and vision loss.[1,2] Treatment often begins with the use of topical medications and laser trabeculoplasty, with surgery reserved for advanced or refractory cases, or for patients at high risk of failing medical therapy.[3] Traditional filtration surgery is trabeculectomy, which removes a block of limbal tissue to allow aqueous humor to flow through a scleral flap to an adjacent subconjunctival bleb. However, rates of failure of approximately 10% per year have been reported, as well as complications including hypotony.[4−6]

Patients who have failed trabeculectomy with antimetabolite or who have high risk disease (i.e., neovascular or uveitic glaucoma) may benefit from aqueous shunts.[4,7] These implants shunt aqueous humor from the anterior chamber using a long tube connected to a subconjunctival equatorial end-plate that drains into the venous plexus. The 2 most commonly used aqueous shunts are the Ahmed valve (New World Medical Inc, Rancho Cucamonga, CA) and the Baerveldt implant (Abbott Medical Optics, Santa Ana, CA). These shunts differ in that the Ahmed valve implant has a built-in Venturi-based flow restrictor designed to prevent postoperative hypotony and its complications. However, the

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Ahmed implant has been associated with bleb encapsulation, resulting in inadequate IOP reduction and the need for postoperative glaucoma medications or additional glaucoma surgery.[8,9] The Baerveldt implant lacks built-in flow restriction and requires the surgeon to create a temporary tube ligature to allow for healing to occur around the end plate to regulate flow. This limits postoperative flow until the ligature dissolves or is removed, at which point the Baerveldt implant achieves excellent IOP control because of its large end-plate surface area (350 mm^2).[4,7] However, there is a risk of hypotony should there be inadequate healing around the plate to regulate flow when the tube opens.[10,11]

A 2008 American Glaucoma Society survey showed a significant change in practice patterns between 1996 and 2008, with trabeculectomy use decreasing from 81% to 46% and aqueous shunt use increasing from 18% to 51%.[12] The impetus for this change may be based on the results of the Tube Versus Trabeculectomy (TVT) study, a multicenter randomized trial that showed that Baerveldt-350 implantation had a higher success rate with fewer complications than trabeculectomy with mitomycin C after 5 years.[4,5] Furthermore, a 2015 meta-analysis comparing Ahmed valve implantation with trabeculectomy showed similar success rates, IOP reduction, and medication use, with fewer adverse effects seen in the Ahmed group.[13]

Until recently, selecting which aqueous shunt to use was dependent on surgeon and site preference given the lack of prospective data comparing the devices. Retrospective studies have yielded inconclusive results and have had modest sample sizes, and pooling them is difficult given their heterogeneous patient populations, use of different device models, and varying success criteria.[9,14–16] The Ahmed Versus Baerveldt (AVB) study is an international, multicenter, randomized trial that has provided evidence to support a surgeon's choice.[17–19] Three-year results demonstrated that the Baerveldt implant achieves a lower IOP on fewer medications, but may have more safety issues, including hypotony.[19] This article will present the 5-year treatment results of the AVB study.

Methods

The AVB study methodology is described in detail in our baseline article[17] and will be summarized in the current article. Institutional review board approval was obtained at each clinical center, and the study protocol is registered on www.ClinicalTrials.gov (NCT00940823).

Inclusion Criteria

1. Age 18 years or older.
2. Inadequately controlled glaucoma defined as IOP greater than clinical target despite maximum tolerated medical and laser therapy.
3. Failed trabeculectomy with antimetabolite or disease at high risk of failing trabeculectomy (e.g., neovascular or uveitic glaucoma) and scheduled for aqueous shunt implantation.
4. Eyes with prior surgeries or significant conjunctival scarring were included.
5. One eye enrolled per patient.

Exclusion Criteria

1. Requires an additional procedure at the time of implantation (e.g., cataract surgery, corneal transplant).
2. Unwilling or unable to provide informed consent or adhere to the study requirements, including implant randomization and follow-up visits.

Recruitment and Treatment

Patients were recruited from 6 international clinical centers by 9 surgeons from 2005 to 2009 and randomized to an Ahmed-FP7 valve implant or a Baerveldt-350 implant (Appendix, available at: www.aaojournal.com). The surgical technique was standardized, and Baerveldt implants were ligated intraoperatively with a dissolvable or releasable suture. Tube fenestrations were placed anterior to the ligation at the discretion of the performing surgeon in cases deemed requiring immediate postoperative IOP reduction. Follow-up occurred at scheduled intervals, including 9 appointments in the first postoperative year, 2 appointments in the second year, and annually through 5 years. At each visit, IOP, glaucoma medication use, visual acuity, and any complications or interventions related to the implant were recorded.

Outcome Measures

The primary outcome was failure, defined as any one of the following:

1. IOP out of target range (5−18 mmHg inclusive) or <20% reduction from baseline for 2 consecutive visits after 3 months.
2. De novo glaucoma surgery required (e.g., cyclodestructive procedure, additional tube shunt).
3. Removal of the implant.
4. Severe vision loss related to the surgery (endophthalmitis, suprachoroidal hemorrhage with vision loss, enucleation, evisceration, or phthisis bulbi) or progression to no light perception for any reason.

Success was the absence of failure and was further classified as complete or qualified. Complete success required IOP to be within target range (5−18 mmHg) at all visits after 3 months without the use of glaucoma medications, without any additional surgical interventions, and without significant vision loss (within 2 Snellen lines). Qualified success allowed nonconsecutive visits to be outside of the target IOP range, allowed the use of glaucoma medications, and allowed surgical interventions (including revisions), provided they were not de novo glaucoma procedures.

Alternate IOP success criteria of ≤21 mmHg and ≤14 mmHg also were analyzed as recommended by the World Glaucoma Association.[20] Secondary analyses compared groups on the basis of IOP, medication use, visual acuity, postoperative complications, and interventions required.

Data Censoring

Patients meeting the criteria for failure were included in secondary analyses unless they underwent de novo glaucoma procedures or device explantation, or experienced severe vision loss affecting treatment goals. In these cases, IOP and medication use were censored to prevent confounding, but visual acuity, complications, and interventions related to the original surgery were included. Patients who underwent evisceration or enucleation, or progressed to no light perception vision had their visual outcome carried forward for analysis.