

The Literature

BY KEVIN KAPLOWITZ, MD

THE AHMED VERSUS BAERVELDT STUDY: ONE-YEAR TREATMENT OUTCOMES

Christakis PG, Kalenak JW, Zurakowski D, et al¹

Abstract Summary

Are Baerveldt and Ahmed tube shunts equally effective and safe?

The main question proposed in the Ahmed Versus Baerveldt (AVB) Study concerns the failure rates and safety of the two glaucoma drainage devices most commonly used today, the Baerveldt glaucoma implant (Abbott Medical Optics Inc.) and the Ahmed Glaucoma Valve (New World Medical, Inc.). Compared with the Baerveldt implant, the valve in the Ahmed device allows for earlier IOP control but has a smaller plate, permitting less out-flow. The latter device has also been noted to have higher encapsulation rates.²

The AVB Study enrolled 238 patients, and the surgical steps were standardized to minimize differences in technique among the 10 surgeons. The main outcome of the study was prospectively defined failure. This was similar to the main outcome of the Tube Versus Trabeculectomy (TVT) Study, which focused on a final IOP of between 5 and 18 mm Hg while avoiding a second surgery or a vision-threatening complication.³

What do the comparative data show about the Baerveldt and Ahmed devices?

In both groups of the AVB Study, the baseline characteristics were statistically similar, including a baseline IOP of 31.1 mm Hg in the Ahmed eyes and 31.7 mm Hg in the Baerveldt eyes. The final IOP at 1 year was lower with the Baerveldt implant (13.6 mm Hg, a 56% decrease from baseline) versus the Ahmed device (16.5 mm Hg, a 47% decrease from baseline). The IOP was actually lower with the Ahmed implant through the first month. This finding confirms the benefit of implanting a valved device that can begin draining aqueous as soon as it is implanted. The final number of medications was also lower with the Baerveldt than the Ahmed device (1.2 vs 1.6).

The main outcome measure of the AVB Study was prospectively defined failure rates, although the reason for failure in a majority of both groups was inadequate IOP control. At 1 year, the Baerveldt eyes had fewer failures than the Ahmed eyes (28% vs 43%). Even after changing the IOP cutoff value for failure up to 21 mm Hg or down to 14 mm Hg, the Baerveldt group still had fewer failures.

Although the absolute number of complications that occurred was similar (107 for Ahmed vs 105 for Baerveldt), they occurred in only 44% of the Ahmed patients compared with 54% of the Baerveldt patients. The most common complication was a shallow anterior chamber. One interesting complication noted was encapsulation, found in 14 Ahmed eyes but only three Baerveldt eyes. The complications required intervention in 42% of the Baerveldt patients versus 26% of the Ahmed patients. The most common intervention in the Ahmed group was reformation of the anterior chamber (performed 13 times), whereas it was a paracentesis in the Baerveldt group (performed 16 times). Among the Baerveldt eyes, anterior chamber reformation, paracentesis, phacoemulsification, and tube adjustments accounted for just over half of the interventions.

The AVB Study also looked at the risk factors for failure. A man was three times more likely to experience failure of an Ahmed than a Baerveldt implant. The only variable to persist in multivariate analysis was implantation of the Ahmed device.

Discussion

Did one tube have conclusively better results?

The AVB Study was a very well-designed, randomized, controlled trial comparing the failure rates of two drainage devices. The Baerveldt had a statistically significantly lower failure rate than the Ahmed (43% vs 28%; $P = .02$). The number of complications in each group was similar, but the absolute number and percentage of patients needing intervention for a complication were higher with a Baerveldt implant. These findings are in line with previous studies, which had suggested that, although Ahmed devices provide a lower IOP early on, Baerveldt implants achieve lower final IOPs. The largest earlier comparative-outcome study by Goulet et al also showed a higher success rate with the Baerveldt.⁴ One interesting complication noted was the increased rate of encapsulation with the Ahmed. This finding is in line with previous studies, which seems to suggest that the early flow permitted by this device may allow proinflammatory mediators access from the anterior chamber into the bleb. That could explain the higher rates of hypertensive phase and later bleb encapsulation observed.⁵

The AVB Study was the first prospective trial on the subject. Although the number of complications in the two study groups was statistically similar, the lower rates of failure with the Baerveldt implant came at the cost of

a higher intervention rate for complications. This finding implies that the choice of tube will still be an individual decision based on factors such as the IOP target for a particular patient. Further analysis is expected during the designed 5-year follow-up period.

TREATMENT OUTCOMES IN THE AHMED BAERVELDT COMPARISON STUDY AFTER 1 YEAR OF FOLLOW-UP

Budenz DL, Barton K, Feuer WJ, et al;
Ahmed Baerveldt Comparison Study Group⁶

Abstract Summary

What Are the Long-Term Outcomes of the Implantation of Two Glaucoma Drainage Devices?

The Ahmed Baerveldt Comparison (ABC) Study had an overall goal similar to that of the AVB Study. The main objective was to compare the failure rates and safety of the Baerveldt glaucoma implant and the Ahmed Glaucoma Valve. Both studies were randomized controlled trials.

At 31.2 mm Hg in the Ahmed group and 31.8 mm Hg in the Baerveldt group, the baseline mean IOPs for the two treatment arms in the ABC Study were similar, and they were nearly the same values as in the AVB Study. The main outcome measure of the ABC Study was prospectively defined failure almost identical to in the AVB Study, except the IOP target was set under 21 mm Hg in the former rather than 18 mm Hg.

The IOP comparisons in the ABC Study showed that, for the first 2 weeks, the Ahmed implant produced lower IOPs. For the rest of the first year, however, the Baerveldt group had lower IOPs. The final mean IOP measured 15.4 mm Hg (a 51% decrease from baseline) in the Ahmed eyes versus 13.2 mm Hg (a 58% decrease from baseline) for the Baerveldt eyes. In terms of failure rates—the primary outcome measure—the two study groups had similar results (Baerveldt failure, 16% vs Ahmed failure, 14%; $P = .61$). When the investigators looked instead at the number of nonfailures who were able to avoid the use of any glaucoma medication postoperatively, the Baerveldt group had greater success than the Ahmed group (31% vs 19%). The complication rate, however, was significantly higher during the first 3 months postoperatively with a Baerveldt versus an Ahmed device (58% vs 43% of patients). In addition, the complications with a Baerveldt implant were more severe; surgical intervention was required in 13% of patients versus 5% of those in the Ahmed group.

Discussion

Were the Results of the Two Studies Similar?

The results of the ABC Study were similar to those of the AVB Study. The Baerveldt implant lowered the IOP to

a greater degree than the Ahmed device at 1 year. Although the rates of failure were not statistically different, the number of successes off all medication was higher with the Baerveldt implant. The rate of complications with the Baerveldt was higher only for the first 3 months, but more surgical reintervention was necessary in these patients than in the Ahmed group. As in the AVB Study, the ABC Study demonstrated that lower IOP with a Baerveldt implant came at the cost of a higher rate of complications.

SUBCONJUNCTIVAL BEVACIZUMAB VERSUS MITOMYCIN C ADJUNCTIVE TO TRABECULECTOMY

Nilforushan N, Yadgari M, Kish SK, Nassiri N⁷

Abstract Summary

Can Using Adjunctive Bevacizumab With Trabeculectomy Provide Similar Outcomes to Mitomycin C?

Given that vascular endothelial growth factor (VEGF) promotes wound healing (specifically fibroblast formation), surgeons may use anti-VEGF medications to delay fibrosis of the bleb, the most common cause of trabeculectomy failure. The anti-VEGF agent bevacizumab has already been shown to be effective in cases of neovascular glaucoma (NVC),⁸ and it has shown promise for bleb-needling procedures.⁹ The study by Nilforushan and colleagues focused on primary open-angle glaucoma (POAG).

The investigators randomized 34 patients to two groups: one underwent trabeculectomy with mitomycin C (MMC), and the other underwent trabeculectomy with bevacizumab (an off-label use). On average, the patients were observed for 8 months. A single surgeon performed all of the trabeculectomies using a fornix-based approach. Either sponges soaked with MMC 0.2 mg/mL for 3 minutes were applied after the flap was created, or bevacizumab 2.5 mg was injected subconjunctivally over the flap at the end of the case. There were no statistically significant differences in baseline characteristics. Although the study enrolled almost twice as many men as women, this proportion was maintained in both study groups. All patients had either POAG or pseudoexfoliation glaucoma.

The IOP decreased from 23 to 9.6 mm Hg at the last visit with MMC (a 58% reduction) and from 22 to 13.6 mm Hg with bevacizumab (a 38% reduction). The mean number of medications also decreased more with MMC (2.6-0 vs 2.7-0.22 with bevacizumab). There were no statistically significant differences in the extent, height, or vascularization of the blebs at the last visit. With relatively stringent criteria for success (IOP $\leq$ 21 mm Hg and 20% reduction), MMC again was superior in terms of lowering IOP (88% vs 61% for bevacizumab). The only complication noted in the bevacizumab group was one persistent leak that needed to be resealed.

Discussion

The study's authors concluded that bevacizumab in POAG or pseudoexfoliation glaucoma successfully and safely lowered the IOP at 6 months. IOP control, however, was better with MMC in terms of a decrease in pressure and the number of medications. This study was well designed to answer an extremely interesting question of whether bevacizumab would be helpful in POAG.

To date, the drug has mostly been studied in NVG. In a case series of four patients with secondary glaucoma other than NVG, bevacizumab injected after a trabeculectomy with MMC adequately controlled the IOP.¹⁰ The only previous randomized study to compare the injection of bevacizumab at the end of a trabeculectomy with the injection of saline found no significant difference in IOP at 3 months.¹¹

In the study by Nilforushan and colleagues, the main outcome measure of IOP was superior with MMC. Although bevacizumab may effectively avoid the fibrosis that constitutes the most common reason for a trabeculectomy to fail, further studies with longer follow-up and more patients are needed. □

Section Editor James C. Tsai, MD, is the Robert R. Young professor of ophthalmology and visual science and the chair of the Department of Ophthalmology & Visual Science at Yale School of Medicine in New Haven, Connecticut. Dr. Tsai may be reached at (203) 785-2020; james.tsai@yale.edu.

Kevin Kaplowitz, MD, is a clinical glaucoma fellow in the Department of Ophthalmology & Visual Science at Yale School of Medicine in New Haven, Connecticut. He acknowledged no financial interest in the products or companies mentioned herein. Dr. Kaplowitz may be reached at kevin.kaplowitz@yale.edu.

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