

THE LITERATURE



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The Ahmed Versus Baerveldt Study: Five-Year Treatment Outcomes

Christakis P, Kalenak J, Tsai JC, et al¹

ABSTRACT SUMMARY

This prospective, randomized, international, multicenter, controlled trial compared the effectiveness and complication rates of the Ahmed Glaucoma Valve (New World Medical) and Baerveldt glaucoma implant (Abbott) among patients in whom trabeculectomy had failed or was likely to fail. Two hundred thirty-eight eyes were randomized to receive the Ahmed Glaucoma Valve model FP7 ($n = 124$) or the Baerveldt 350 ($n = 114$) device and were monitored for 5 years. The baseline characteristics of the two groups were similar, and their follow-up rates during that period were nearly identical. Failure was defined as any one of the following: IOP out of target range (5-18 mm Hg) or less than a 20% reduction from baseline, de novo glaucoma surgery required, removal of the implant, or severe vision loss related to the surgery.

At 5 years, the cumulative rate of failure was 53.2% in the Ahmed group and 40.0% in the Baerveldt group ($P = .037$). The most common cause of failure in both groups was high IOP, resulting in 56 (45%) of the Ahmed failures and 26 (23%) of the Baerveldt failures. The Baerveldt group experienced a greater IOP reduction from baseline than did the Ahmed group (57% vs 47%, $P = .001$). The Baerveldt group also had a lower mean postoperative IOP compared with the Ahmed group (13.6 \pm 5.0 vs 16.6 \pm 5.9 mm Hg). In addition, the Baerveldt group had a greater percentage reduction in medication use compared to the Ahmed group (61% vs 44%, $P = .03$).

Complication rates were comparable and significant between the two groups (Ahmed 63% and Baerveldt 69%). The Baerveldt group had five cases of hypotony failure, whereas the Ahmed group had none. Most patients in both groups required medication after surgery to maintain adequate IOP lowering.

DISCUSSION

What are potential explanations for the greater reduction of IOP and lower postoperative medication use with the Baerveldt implant versus the Ahmed Glaucoma Valve?

The 5-year results of this randomized study show mean IOP to be 3 mm Hg lower with the Baerveldt implant versus

the Ahmed Glaucoma Valve (13.6 vs 16.6 mm Hg, $P = .001$). The Baerveldt group also had lower medication use than the Ahmed group (1.2 vs 1.8, $P = .03$). The investigators provided some explanations by citing studies in the literature.

The Baerveldt has a larger endplate size than the Ahmed—350 mm² versus 184 mm², respectively. Clinical studies have shown a positive relationship between a larger endplate size and better filtration.

In addition, this study (and others) found a higher rate of clinical bleb encapsulation in the Ahmed than in the Baerveldt group. The cause of this well-known encapsulation with the Ahmed device is not entirely clear. Previous investigators in the studies cited by Christakis and colleagues have postulated that early exposure of the Ahmed Glaucoma Valve bleb to surgically induced inflammatory cytokines stimulates encapsulation and fibrosis.² The researchers also cited an interesting study showing that, although both implants are made of silicone, the Ahmed Glaucoma Valve topography under electron microscopy has 10-fold greater roughness than the Baerveldt implant.³ In vitro, this resulted in greater Tenon fibroblast adhesion that could conceivably promote fibrous encapsulation.

How might the results of this study influence which glaucoma drainage device to choose for patients?

It is important to note that, in this study, both glaucoma drainage devices effectively lowered IOP from baseline, the Ahmed from a mean preoperative IOP of 31.1 mm Hg to a mean postoperative IOP of 16.6 mm Hg (47% reduction) and the Baerveldt from a mean preoperative IOP of 31.7 mm Hg to a mean postoperative IOP of 13.6 mm Hg (57% reduction). In other words, both implants can be useful for patients.

One might consider the Ahmed Glaucoma Valve when the preoperative IOP is very high and an early, significant reduction is needed. Certainly, venting slits can be placed in a Baerveldt tube anterior to the ligature for some early postoperative IOP relief, but the effect on IOP can be unpredictable. The Ahmed device quite reliably provides early IOP lowering when needed in such cases.

The Baerveldt glaucoma implant seems to offer improved long-term IOP lowering compared to the Ahmed device, so the former might be a better choice when lower target pressures are needed. This is particularly true when the eventual target IOP is low and the clinician considers the preoperative IOP to be tolerable during the few weeks needed for the tube to open. The Baerveldt is also favored as a second tube when a first Ahmed has failed.



ATA GLANCE

In terms of complications, both devices fared equally in this study with one exception: the five cases of hypotony failure in the Baerveldt group. The valved Ahmed device might therefore have an advantage in patients prone to hypotony, most notably those with uveitic glaucoma. We have found this to be particularly true in patients who have had multiple sub-Tenon capsule steroid injections. In these eyes, the needed capsule can fail to form around a Baerveldt endplate, resulting in significant hypotony.

Treatment Outcomes and Prognostic Factors of Selective Laser Trabeculoplasty for Open-Angle Glaucoma Receiving Maximal-Tolerable Medical Therapy

Miki A, Kawashima R, Usui S, et al⁴

ABSTRACT SUMMARY

This retrospective consecutive study evaluated the effect of 360° selective laser trabeculoplasty (SLT) on Japanese patients with glaucoma who were receiving maximally tolerated medical therapy (MTMT). The investigators reviewed the records of 75 eyes of 59 patients that met inclusion criteria and had completed at least 1 year of follow-up after SLT treatment. For analysis, patients were grouped based on disease type: primary open-angle glaucoma (POAG, n = 39), exfoliation glaucoma (n = 23), and secondary open-angle glaucoma (SOAG, n = 13).

Baseline characteristics were statistically analyzed relative to treatment success and failure using a mixed-effects Cox proportional hazards model. Failure (assessed using Kaplan-Meier survival analysis) was defined as meeting one of two criteria: (1) an IOP equal to or greater than baseline or (2) less than a 20% IOP reduction from baseline at two consecutive visits.

After 1 year of follow-up, the overall success ratio was 45.3% by criterion 1 and 14.2% by criterion 2. These two criteria also included a loss of light perception, repeat SLT, or incisional surgery as failure. The main cause of failure was a need for incisional surgery (85.4% of failures). Patients with POAG fared better than those with exfoliation glaucoma, who in turn did better than those with SOAG. A higher preoperative IOP and a diagnosis of SOAG were significantly associated with treatment failure.

DISCUSSION

How might the results of this study influence the management of patients?

The limitations of this study include its retrospective design and the exclusively Japanese study cohort. Nevertheless, the investigators tried to identify predictors of SLT success in patients on MTMT, which represents a common real-world clinical dilemma. In this study, the overall efficacy of SLT in patients on MTMT was low. Baseline predictors of failure in univariate analysis were the type of glaucoma (SOAG), a higher preoperative IOP, and more preoperative medicines. Conversely, analysis showed that a diagnosis of

- A prospective, randomized, international, multicenter, controlled trial found comparable and significant complication rates with the Ahmed Glaucoma Valve and Baerveldt glaucoma implant among patients in whom trabeculectomy had failed or was likely to fail.
- A retrospective consecutive study evaluated the effect of 360° selective laser trabeculoplasty on Japanese patients with glaucoma who were receiving maximally tolerated medical therapy. Investigators found the procedure's overall success to be low, but it was less likely to fail in cases of primary versus secondary open-angle glaucoma.

POAG, a lower preoperative IOP, and a lower number preoperative medications were significantly associated with treatment success.

Whenever a patient is on MTMT and a further decrease in IOP is needed, by definition of MTMT, some type of procedure is required. The study's main clinical question is really whether or not SLT in this setting keeps patients out of the OR. In most cases, it did not. The primary cause of failure in the study (85% of failures) was incisional surgery. When one considers the inherent risk of SLT versus incisional surgery, however, it might be reasonable to consider whether SLT is worth a try, so to speak, especially in high-risk surgical patients. Despite the generally unfavorable results of the study, the data suggest that SLT might be a reasonable option in individuals whose POAG is progressing on MTMT, whose IOP is moderate, and who are on fewer medications before the procedure. ■

1. Christakis PG, Kalenak JW, Tsai JC, et al. The Ahmed Versus Baerveldt Study: five-year treatment outcomes. *Ophthalmology*. 2016;123(10):2093-2102.
2. Mahale A, Othman MW, Shahwan A, et al. Altered expression of fibrosis genes in capsules of failed Ahmed Glaucoma Valve implants. *PLoS One*. 2015;10:e0122409.
3. Choritz L, Koyunov K, Renieri G, et al. Surface topographies of glaucoma drainage devices and their influence on human Tenon fibroblast adhesion. *Invest Ophthalmol Vis Sci*. 2010;51:4047-4053.
4. Miki A, Kawashima R, Usui S, et al. Treatment outcomes and prognostic factors of selective laser trabeculoplasty for open-angle glaucoma receiving maximal-tolerable medical therapy. *J Glaucoma*. 2016;25(10):785-789.

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