

THE LITERATURE

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Five-Year Pooled Data Analysis of the Ahmed Baerveldt Comparison Study and the Ahmed Versus Baerveldt Study

Christakis PG, Zhang D, Budenz DL, et al; ABC-AVB Study Groups¹

ABSTRACT SUMMARY

This pooled analysis of two randomized controlled trials, the Ahmed Baerveldt Comparison (ABC) study and the Ahmed Versus Baerveldt (AVB) study, compared the safety and efficacy of the Ahmed Glaucoma Valve FP7 (AGV; New World Medical) and the Baerveldt 350-mm² glaucoma implant (Johnson & Johnson Vision) in the treatment of refractory primary and secondary glaucoma. The pooled analysis included 514 subjects. The average preoperative IOP was 31 mm Hg in each group.

After 5 years of follow-up, both the mean final IOP and the number of medications were significantly lower in the Baerveldt group than the AGV group (Table). The failure rate at 5 years was lower in the Baerveldt group than the AGV group (37% vs 49%; $P = .007$). The rate of further glaucoma surgery for high IOP was significantly greater in the AGV group than the Baerveldt group (16% vs 8%; $P = .002$). Elevated IOP was the main reason for failure in both groups, but hypotony-related failure was higher in the Baerveldt group than in the AGV group (4.5% vs 0.4%; $P = .002$).

DISCUSSION

Why did the Baerveldt 350-mm² implant result in better IOP control than the AGV?

Several factors could explain the higher success rate of the Baerveldt. First, the surface area of this implant is twice that of the AGV (350 vs 184 mm²). Studies of Molteno (Molteno Ophthalmic) and Baerveldt devices have demonstrated a positive relationship between surface area and final IOP: the larger the plate surface area, the lower the IOP.^{2,3} Second, although both the Baerveldt and the AGV are made of silicone, the latter has a rougher surface, which facilitates fibroblast adherence and, hence, a higher rate of encapsulation. Third, the presence of a valve in the AGV prevents early hypotony, but it also allows early aqueous flow.

Many surgeons believe aqueous flow is disadvantageous during the early postoperative period after the

implantation of a glaucoma drainage device for two reasons. For one thing, tissue contact with aqueous containing elevated levels of TGF- β may stimulate a greater healing response over the plate. For another, mechanical stretching of fibroblasts by the presence of fluid in the subconjunctival space may stimulate fibroblast contraction and healing. Paradoxically, nonvalved devices such as the Baerveldt largely avoid these effects, because these implants are occluded in the early postoperative period.

How might the results of this study influence surgeons' choice of glaucoma implant?

Both the AVB and the ABC clinical trials provide key information on the two most commonly used aqueous drainage devices. The FP7 model of the AGV and the Baerveldt 350-mm² implant differ in terms of their surface area and the presence of a flow restrictor. The AVB study, the ABC study, and the pooled analysis all demonstrated that the Baerveldt achieved a lower IOP with fewer glaucoma medications compared to the AGV FP7. Hypotony-related complications, however, were significantly more common with the Baerveldt. Surgeons must therefore exercise caution when using this device and have confidence in their technique of tube occlusion to prevent dangerous hypotony.



AT A GLANCE

- A pooled analysis of the Ahmed Baerveldt Comparison (ABC) study and the Ahmed Versus Baerveldt (AVB) study found that the Baerveldt 350-mm² glaucoma implant achieved lower IOPs with fewer glaucoma medications than the Ahmed Glaucoma Valve FP7, but hypotony-related failure was higher in the Baerveldt group.
- In the multicenter, randomized, controlled Effectiveness of Early Lens Extraction for the Treatment of Primary Angle-Closure Glaucoma (EAGLE) trial, the clear lens extraction group achieved a significantly lower IOP and was on fewer medications than the iridotomy and medical therapy group. A significantly larger proportion of patients randomized to medical therapy required further surgery.

TABLE. FINAL IOP AND NUMBER OF MEDICATIONS AT 5 YEARS IN THE AVB STUDY, ABC STUDY, AND POOLED AVB-ABC ANALYSIS

	AVB Study N = 238	ABC Study N = 276	Pooled AVB ABC Analysis N = 514
Final IOP 5 years			
Baerveldt 350 mm²	13.6 ±5.0 mm Hg	12.7 ±4.5 mm Hg	13.2 ±4.7 mm Hg
Ahmed FP7	16.6 ±5.9 mm Hg	14.7 ±4.4 mm Hg	15.8 ±5.2 mm Hg
P value	.001	.015	< .001
Final medication 5 years			
Baerveldt 350 mm²	1.2 ±1.3	1.8 ±1.5	1.5 ±1.4
Ahmed FP7	1.8 ±1.5	2.2 ±1.4	1.9 ±1.5
P value	.03	.28	.023

Abbreviations: ABC, Ahmed Baerveldt Comparison; AVB, Ahmed Versus Baerveldt. Ahmed Glaucoma Valve model FP7 (New World Medical) and Baerveldt glaucoma implant (Johnson & Johnson Vision).

Both drainage devices effectively lower the IOP. Patients with advanced glaucoma who require low target IOPs are more likely to achieve them with the Baerveldt implant. It is worth noting that most subjects in the AVB and ABC studies suffered from secondary glaucoma. The results of this research still apply to primary open-angle glaucoma, however, particularly to patients with failed previous trabeculectomies for whom the Baerveldt implant appears to achieve lower IOPs than the AGV. In patients with uncontrolled IOP and less advanced disease who do not necessarily require a very low IOP, the AGV will effectively lower pressure with fewer hypotony-related complications.

Effectiveness of Early Lens Extraction for the Treatment of Primary Angle-Closure Glaucoma (EAGLE): a Randomised Controlled Trial

Azuara-Blanco A, Burr J, Ramsay C, et al, for the EAGLE study group⁴

ABSTRACT SUMMARY

This multicenter randomized study compared the efficacy of clear lens extraction (CLE) to laser iridotomy and topical medication for the treatment of patients with early primary angle-closure glaucoma (PACG) who had an IOP greater than 21 mm Hg and patients with primary angle closure (PAC) who had an initial IOP greater than 30 mm Hg. Patients with a history of acute angle closure were excluded. The study included 419 patients, approximately 30% of whom were of Chinese origin.

After 3 years of follow-up, the CLE group had achieved a significantly lower IOP and was on fewer medications

than the iridotomy and medical therapy (IMT) group (16.6 ±3.5 mm Hg on 0.4 ±0.8 medications vs 17.9 ±4.1 mm Hg on 1.3 ±1.0 medications; $P = .004$ and $P < .001$, respectively). Significantly more IMT patients required further surgery compared to the CLE group (24 vs 3; $P < .001$). Sixteen of the 24 patients in the IMT group underwent lens extraction for clinically relevant cataract, and the rest underwent trabeculectomy or received the AGV. In the CLE group, one patient required trabeculectomy, one required a hyaloid-vitreotomy for malignant glaucoma, and one required IOL repositioning. There was no difference in visual field outcome and central corneal thickness between the two groups at 3 years of follow-up.

The quality of life and cost-effectiveness of the treatment were coprimary endpoints. Both a quality-of-life questionnaire and a cost-effectiveness analysis favored the CLE group.

DISCUSSION

How might the results of this study influence the management of angle-closure disease?

The EAGLE trial is one of few prospective studies on angle closure in a predominantly Caucasian population. The results support the benefit of CLE in patients with early PACG and in those with ocular hypertension from primary angle closure (PAC). Because the study protocol allowed the clinicians to escalate treatment in each arm to achieve their target IOP, the difference in IOP between the two groups was small. That said, the CLE group had a lower mean IOP with much less medication. Furthermore, fewer additional glaucoma procedures were required in the CLE group,

“ The results of the EAGLE study do not necessarily apply to patients with advanced PACG or to PAC suspects.”

suggesting better IOP control in these patients. Although there was no difference in visual field change between the two groups after 3 years of follow-up, the EAGLE study was not powered to detect a difference in visual field status.

Further studies will be required to evaluate the rate of glaucomatous progression after early lens extraction versus medical treatment in angle-closure glaucoma. Specifically, the results of the EAGLE study do not necessarily apply to patients with advanced PACG or to PAC suspects (narrow angle with normal IOP). CLE alone is unlikely to be sufficient in patients with advanced PACG. Patients with early PACG or PAC who have a high IOP will benefit from CLE despite the absence of a clinically significant cataract. That said, although the complication rate after CLE is low, malignant glaucoma is a potential risk. ■

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