

Landmark Tube Trials

A review of key findings from recent multicenter randomized clinical trials involving tube shunts.

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As a glaucoma surgeon, it is tempting to make surgical decisions based on my own most recent anecdotal experiences: a bleb leak that is difficult to repair, challenging diplopia after a tube shunt surgery, a trabeculectomy-related case of endophthalmitis, or perhaps a perfect outcome after a trabeculectomy or tube shunt surgery. These most recent experiences loom large in my mind and may cloud my judgment when deciding on the best approach for my next surgical patient. Although our own experiences inform our decision making, large randomized controlled trials provide a rigorous basis to put our own experiences into a larger context. Thankfully, we now have the results of several trials to help shape our decision making for patients with difficult-to-control glaucoma who require a trabeculectomy or a tube shunt surgery. I thank Ambika Hogue, MD, and Steven J. Gedde, MD, for their excellent summary of the Ahmed Baerveldt Comparison (ABC) Study, Ahmed Versus Baerveldt (AVB) Study, and the Tube Versus Trabeculectomy (TVT) Study to help us compare and digest the key findings from these trials.

—Barbara Smit, MD, PhD, section editor

Tube shunts, or glaucoma drainage implants, are being used more frequently in the surgical management of glaucoma. Medicare claims data demonstrated that the number of trabeculectomies decreased by 43% and tube shunt surgery increased by 184% between 1995 and 2004.¹ Practice patterns in glaucoma surgery were also evaluated with sequential surveys of the members of the American Glaucoma Society, and the selection of tube shunts as the preferred surgical approach increased from 17.5% in 1996² to 50.8% in 2008.³

Several recent multicenter randomized clinical trials involving tube shunts have provided valuable information for glaucoma surgeons. Major conclusions can be derived from a critical analysis and interpretation of data from these trials. This article reviews key findings from the ABC, AVB, and TVT Studies.

ABC AND AVB STUDIES

The ABC and AVB Studies are both multicenter randomized clinical trials designed to compare the surgical

outcomes of the Ahmed Glaucoma Valve (New World Medical) and Baerveldt glaucoma implant (Abbott Medical Optics), the two most popular shunts worldwide.^{4,5} Both studies recruited patients with refractory glaucoma requiring tube shunt surgery and randomized them to receive an Ahmed implant (model FP-7) or a Baerveldt 350-mm² implant. The ABC Study included 276 patients from 16 clinical centers, and the AVB Study included 238 patients from seven clinical centers. Similar results were reported in the ABC and AVB Studies during 3 years of follow-up, allowing validation of each trial by the other.⁶⁻⁹ Key findings from both studies include the following.

1. **Ahmed implantation produced a greater IOP reduction immediately postoperatively, but Baerveldt implantation tended to result in a lower IOP with longer follow-up.** Table 1 shows IOP data at baseline and at follow-up visits in the ABC and AVB Studies. The mean IOP was significantly lower in the Ahmed group compared with the Baerveldt group at study visits during the first few weeks postoperatively in both studies.^{6,7} The Baerveldt group, however, achieved a greater IOP reduction relative to the Ahmed group with longer follow-up.^{8,9} Lower mean IOPs were observed in the Baerveldt group compared with the Ahmed group after 1 month postoperatively, and these differences were statistically significant at several follow-up visits in the ABC Study (3 months, 1 year, and 18 months) and the AVB Study (1 year and 18 months).⁶⁻⁹

2. **Fewer glaucoma medications were required long term after placement of a Baerveldt implant compared with an Ahmed implant.** Table 1 provides data on medical therapy in the ABC and AVB Studies. The mean number of glaucoma medications was greater in the Ahmed group than in the Baerveldt group from 2 months and 6 months onward in the AVB and ABC Studies, respectively.⁶⁻⁹

3. **The Baerveldt implant demonstrated a higher rate of surgical success relative to the Ahmed implant.** Kaplan-Meier survival curves for the AVB and ABC Studies are shown in Figures 1 and 2. There were slight differences in the criteria for failure in the ABC Study⁴ (IOP > 21 mm Hg or not reduced $\geq$ 20% from baseline, IOP $\leq$ 5 mm Hg additional

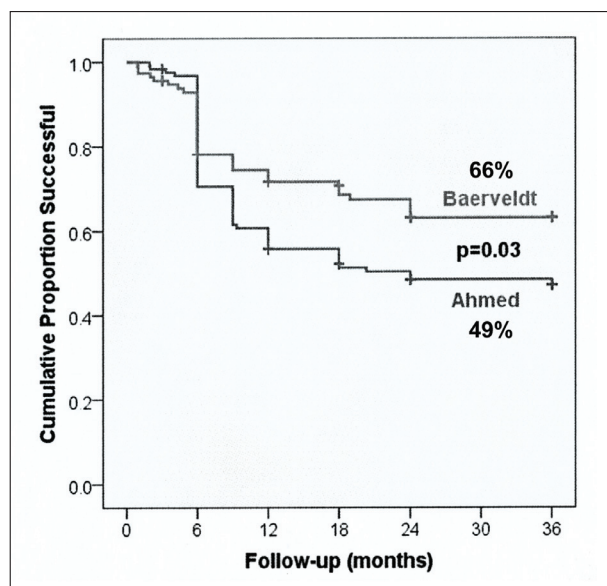


Figure 1. Kaplan-Meier plots of the probability of failure (IOP > 18 mm Hg or not reduced $\geq 20\%$ from baseline, IOP ≤ 5 mm Hg, vision-threatening complications, additional glaucoma procedures, or loss of light perception vision) in the AVB Study. Adapted from Christakis et al.⁹

glaucoma surgery, removal of the implant, or loss of light perception vision) and the AVB Study⁵ (IOP > 18 mm Hg or not reduced $\geq 20\%$ from baseline, IOP < 5 mm Hg, vision-threatening complications, additional glaucoma procedures, or loss of light perception vision). Using these failure criteria (Figure 1), the cumulative probability of failure was 51% in the Ahmed group and 34% in the Baerveldt group 3 years postoperatively in the AVB Study ($P = .03$).⁹ Similar rates of surgical failure were observed at 3 years in the ABC Study in accordance with the primary failure criteria.⁸ Several post hoc analyses were performed in the ABC Study applying more stringent criteria to define success and failure. When failure was defined as an IOP greater than 14 mm Hg (Figure 2), the failure rate was 67.2% in the Ahmed group and 52.6% in the Baerveldt group 3 years postoperatively ($P = .005$).

4. Serious postoperative complications occurred more frequently after Baerveldt implantation than Ahmed implantation. The ABC Study defined serious complications as those that were associated with the loss of 2 or more lines of Snellen visual acuity and/or required a reoperation to manage the complication. The rate of serious complications was significantly higher in the Baerveldt group (36%) compared with the Ahmed group (22%) through 3 years of follow-up ($P = .035$).⁸ The AVB Study reported that hypotony-related vision-threatening complications developed more frequently in the Baerveldt group (6%) than the Ahmed group (0%) after 3 years of follow-up ($P = .005$).⁹

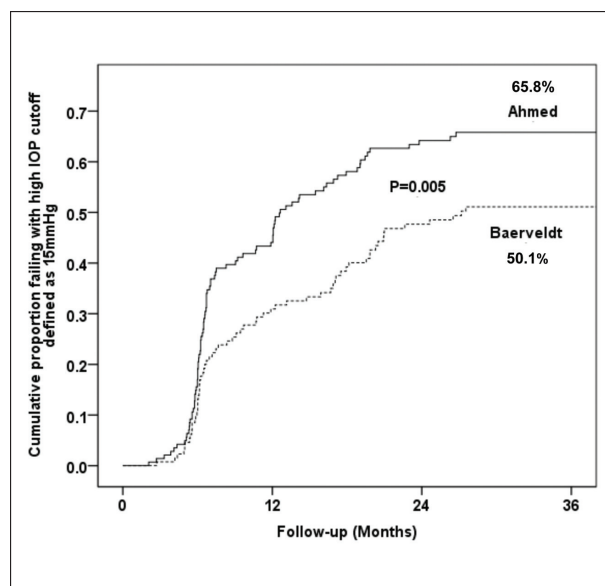


Figure 2. Kaplan-Meier plots of the probability of failure (IOP > 14 mm Hg or not reduced $\geq 20\%$ from baseline, IOP ≤ 5 mm Hg, additional glaucoma surgery, removal of the implant, or loss of light perception vision) in the ABC Study in post hoc analysis.

5. Vision loss occurred at a similar rate with the Ahmed and Baerveldt implants. No significant difference in change in Snellen visual acuity was seen between the Ahmed and Baerveldt groups during 3 years of follow-up in the ABC Study.⁸ The rate of 2 or more lines of loss of Snellen visual acuity was similar in the Ahmed group (35%) and Baerveldt group (30%) at 3 years ($P = .46$). A similar decrease in Snellen visual acuity from baseline to 3 years was observed in both treatment groups in the AVB Study.⁹

TVT STUDY

The TVT Study is a multicenter randomized clinical trial comparing the safety and efficacy of tube shunt surgery to trabeculectomy with mitomycin C (MMC) in patients with previous ocular surgery.¹⁰ A total of 212 patients were enrolled at 17 clinical centers who had prior cataract and/or glaucoma surgery, and they were randomly assigned to treatment with a Baerveldt 350-mm² glaucoma implant or trabeculectomy with MMC (0.4 mg/mL for 4 minutes). Major conclusions from the TVT Study are as follows.

1. Trabeculectomy with MMC and tube shunt surgery produced a sustained IOP reduction to the low teens throughout 5 years of follow-up. Data regarding IOP at baseline and at follow-up visits in the TVT Study are presented in Table 2. The trabeculectomy group achieved significantly lower mean IOPs than the tube group at all follow-up visits during the first 3 months post-

operatively,¹¹ but no significant difference in the degree of IOP reduction persisted between treatment groups after 3 months.¹¹⁻¹³ A recent Ophthalmic Technology Assessment by a panel of glaucoma specialists provided an evidence-based summary of aqueous shunts by

reviewing the peer-reviewed literature.¹⁴ The Ophthalmic Technology Assessment concluded that, "if a very low IOP goal range is desirable, an aqueous shunt may be a poor choice for IOP control Generally, the IOP will settle at higher levels (approximately 18 mm Hg) than after

TABLE 1. IOP AND MEDICAL THERAPY IN THE ABC STUDY AND AVB STUDY^{8,9}

	ABC Study			AVB Study		
	Ahmed Group (n = 143)	Baerveldt Group (n = 133)	P Value	Ahmed Group (n = 124)	Baerveldt Group (n = 114)	P Value
Baseline						
IOP (mm Hg)	31.2 ±11.2	31.8 ±12.5	.71	31.1 ±10.5	31.7 ±11.1	.71
Glaucoma medications	3.4 ±1.1	3.5 ±1.1	.34	3.1 ±1.0	3.1 ±1.1	.60
1 d						
IOP (mm Hg)	10.0 ±7.9	18.6 ±13.7	< .001	10.1 ±7.3	17.4 ±14.7	< .001
Glaucoma medications	—	—	—	0.8 ±1.4	1.2 ±1.7	.029
1 wk						
IOP (mm Hg)	10.6 ±5.6	17.2 ±12.0	< .001	10.9 ±8.2	16.5 ±11.9	< .001
Glaucoma medications	0.2 ±0.7	0.9 ±1.4	< .001	0.8 ±1.4	1.5 ±1.7	.002
2 wk						
IOP (mm Hg)	—	—	—	16.2 ±11.1	19.7 ±10.8	.029
Glaucoma medications	—	—	—	1.0 ±1.5	1.5 ±1.7	.026
1 mo						
IOP (mm Hg)	20.7 ±9.7	18.0 ±10.0	.026	19.1 ±8.3	19.2 ±12.6	.94
Glaucoma medications	0.5 ±1.1	1.3 ±1.5	< .001	1.1 ±1.4	1.5 ±1.6	.059
2 mo						
IOP (mm Hg)	—	—	—	18.6 ±8.3	17.7 ±9.7	.49
Glaucoma medications	—	—	—	1.3 ±1.4	0.9 ±1.2	.028
3 mo						
IOP (mm Hg)	18.8 ±8.2	16.7 ±8.2	.044	18.6 ±8.0	17.1 ±9.7	.24
Glaucoma medications	1.4 ±1.3	1.2 ±1.3	.28	1.5 ±1.4	1.0 ±1.2	.008
6 mo						
IOP (mm Hg)	15.7 ±5.5	14.8 ±6.8	.27	16.7 ±5.1	15.0 ±6.4	.053
Glaucoma medications	1.8 ±1.3	1.3 ±1.3	.010	1.6 ±1.3	1.0 ±1.2	< .001
1 y						
IOP (mm Hg)	15.4 ±5.5	13.4 ±6.9	.018	16.5 ±5.3	13.6 ±4.8	< .001
Glaucoma medications	1.8 ±1.3	1.5 ±1.4	.078	1.6 ±1.3	1.2 ±1.3	.027
18 mo						
IOP (mm Hg)	14.8 ±4.6	13.3 ±4.6	.034	16.7 ±5.5	14.0 ±5.7	.002
Glaucoma medications	1.8 ±1.4	1.4 ±1.4	.068	1.6 ±1.4	1.1 ±1.2	.016
2 y						
IOP (mm Hg)	14.5 ±5.5	14.2 ±6.0	.76	16.1 ±6.5	14.4 ±6.5	.090
Glaucoma medications	1.9 ±1.3	1.4 ±1.5	.020	1.8 ±1.4	1.0 ±1.2	< .001
3 y						
IOP (mm Hg)	14.3 ±4.7	13.1 ±4.5	.086	15.7 ±4.8	14.4 ±5.1	.088
Glaucoma medications	2.0 ±1.4	1.5 ±1.4	.020	1.8 ±1.4	1.1 ±1.3	.002
Data are presented as mean ±standard deviation. Statistically significant P values are highlighted.						

trabeculectomy.” This observation is contradicted by the TVT Study, which found a mean IOP reduction to the low teens in both treatment groups throughout the 5-year duration of the study.¹³ Furthermore, 63.9% of patients in the tube group and 63.5% of patients in the trabeculectomy group had an IOP of 14 mm Hg or less 5 years postoperatively ($P = 1.00$). The more favorable IOP results with tube shunts in the TVT Study relative to prior reports may relate to the enrollment of eyes at lower risk of surgical failure than have traditionally undergone tube shunt surgery (eg, eyes with only previous clear corneal cataract extraction) and the exclusion of several secondary glaucomas with a poorer surgical prognosis (eg, neovascular glaucoma) that were included in other case series of tube shunts.

2. Tube shunt surgery required more glaucoma medications than trabeculectomy with MMC during the first 2 years of the study, but use of medical therapy equalized with longer follow-up. Medical therapy data from the TVT Study are shown in Table 2. The need for supplemental medical therapy was significantly greater in the tube group during the first 2 postoperative years.^{11,12} The use of glaucoma medications, however, progressively increased in the trabeculectomy group and remained stable in the tube group such that the mean number of medications did not differ between treatment groups at 3 years and thereafter.¹³

3. Trabeculectomy with MMC had a higher failure rate compared with tube shunt surgery. Kaplan-Meier survival curves for the TVT Study are shown in Figure 3. The cumulative probability of failure (IOP > 21 mm Hg or not reduced $\geq 20\%$ from baseline, IOP ≤ 5 mm Hg, additional glaucoma surgery, or loss of light perception vision) was 29.8% in the tube group and 46.9% in the trabeculectomy group at 5 years ($P = .002$; hazard ratio [HR], 2.15; 95% CI, 1.30-3.56).¹³ No significant difference in the distribution of reasons for treatment failure was observed between treatment groups ($P = .43$). Significantly higher failure rates in the trabeculectomy group compared with the tube group were still seen when the upper IOP level defining success was 17 mm Hg (31.8% in the tube group vs 53.6% in the trabeculectomy group; $P = .002$; HR, 2.04; 95% CI, 1.29-3.24) and 14 mm Hg (52.3% in the tube group vs 71.5% in the trabeculectomy group; $P = .017$; HR, 1.57; 95% CI, 1.09-2.26) in post hoc analyses. Because the difference in treatment outcomes was present using a broad range of IOP success criteria, the study results seem applicable to patients with early or advanced glaucomatous damage.

4. Trabeculectomy with MMC had a higher rate of reoperation for glaucoma than tube shunt surgery. The 5-year cumulative reoperation rate for glaucoma in the TVT Study using Kaplan-Meier survival analysis was 9% in the tube group and 29% in the trabeculectomy group ($P = .025$).¹³ Placement of a tube shunt was selected as the glaucoma reoperation in 94% of cases in the trabeculectomy group.

TABLE 2. IOP AND MEDICAL THERAPY IN THE TVT STUDY¹³

	Tube Group (n = 107)	Trabeculectomy Group (n = 105)	P Value
Baseline			
IOP (mm Hg)	25.1 $\pm$ 5.3	25.6 $\pm$ 5.3	.56
Glaucoma medications	3.2 $\pm$ 1.1	3.0 $\pm$ 1.2	.17
1 d			
IOP (mm Hg)	21.3 $\pm$ 11.8	16.8 $\pm$ 10.4	.004
Glaucoma medications	-	-	
1 wk			
IOP (mm Hg)	19.0 $\pm$ 9.8	14.0 $\pm$ 8.5	< .001
Glaucoma medications	1.2 $\pm$ 1.4	0.2 $\pm$ 0.7	< .001
1 mo			
IOP (mm Hg)	18.5 $\pm$ 9.8	12.6 $\pm$ 7.3	< .001
Glaucoma medications	1.3 $\pm$ 1.3	0.1 $\pm$ 0.6	< .001
3 mo			
IOP (mm Hg)	16.2 $\pm$ 6.4	13.7 $\pm$ 6.6	< .006
Glaucoma medications	1.1 $\pm$ 1.1	0.5 $\pm$ 1.0	< .001
6 mo			
IOP (mm Hg)	13.5 $\pm$ 4.2	12.8 $\pm$ 5.9	.32
Glaucoma medications	1.2 $\pm$ 1.2	0.6 $\pm$ 1.1	< .001
1 y			
IOP (mm Hg)	12.5 $\pm$ 3.9	12.7 $\pm$ 5.8	.73
Glaucoma medications	1.3 $\pm$ 1.3	0.5 $\pm$ 0.9	< .001
2 y			
IOP (mm Hg)	13.4 $\pm$ 4.8	12.1 $\pm$ 5.0	.101
Glaucoma medications	1.3 $\pm$ 1.3	0.8 $\pm$ 1.2	.016
3 y			
IOP (mm Hg)	13.0 $\pm$ 4.9	13.3 $\pm$ 6.8	.78
Glaucoma medications	1.3 $\pm$ 1.3	1.0 $\pm$ 1.5	.30
4 y			
IOP (mm Hg)	13.5 $\pm$ 5.4	12.9 $\pm$ 6.1	.58
Glaucoma medications	1.4 $\pm$ 1.4	1.2 $\pm$ 1.5	.33
5 y			
IOP (mm Hg)	14.4 $\pm$ 6.9	12.6 $\pm$ 5.9	.12
Glaucoma medications	1.4 $\pm$ 1.3	1.2 $\pm$ 1.5	.23
Data are presented as mean $\pm$ standard deviation. Statistically significant P values are highlighted.			

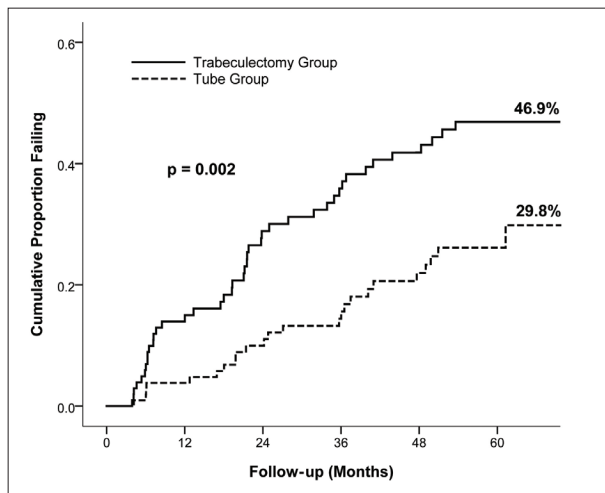


Figure 3. Kaplan-Meier plots of the probability of failure (IOP > 21 mm Hg or not reduced $\geq 20\%$ from baseline, IOP ≤ 5 mm Hg, additional glaucoma surgery, or loss of light perception vision) in the TVT Study. Adapted from Gedde et al.¹³

tomy group. Half of the patients in the tube group who underwent additional glaucoma surgery had placement of a second tube shunt, and the other half underwent cyclodestructive procedures.

5. Vision loss occurred at a similar rate with tube shunt surgery and trabeculectomy with MMC. A reduction in visual acuity was observed in both the tube and trabeculectomy groups during 5 years of follow-up in the TVT Study, but Snellen and Early Treatment Diabetic Retinopathy Study visual acuity were similar between treatment groups at baseline and 5 years postoperatively.¹³ The rate of loss of 2 or more lines of Snellen visual acuity was not significantly different between the tube group (46%) and the trabeculectomy group (43%) after 5 years ($P = .93$). Many of the causes of vision loss in both treatment groups, such as macular degeneration and diabetic retinopathy, were not directly attributable to the surgical procedures under study.

6. Early postoperative complications developed more frequently after trabeculectomy with MMC relative to tube shunt surgery, but both procedures had similar rates of late postoperative and serious complications. Early postoperative complications in the TVT Study, defined as complications occurring in the first month after surgery, were significantly more common in the trabeculectomy group (37%) than the tube group (21%; $P = .012$).¹⁴ The rate of late postoperative complications developing after 1 month was similar in the tube group (34%) and trabeculectomy group (36%) through 5 years of follow-up ($P = .81$).¹⁵ All complications were not equal in severity, and the frequency of serious com-

plications requiring a reoperation to manage and/or producing loss of 2 or more Snellen lines of visual acuity was not significantly different between the tube group (22%) and trabeculectomy group (20%) at 5 years ($P = .79$). Wound leaks ($P = .004$), bleb leaks ($P = .014$), and dysesthesia ($P = .018$) were significantly more common in the trabeculectomy group compared with the tube group during 5 years of follow-up. New postoperative motility disturbances developed more frequently in the tube group (9.9%) than in the trabeculectomy group (0%) after 1 year ($P = .005$).¹⁶

CONCLUSION

Similar results were reported in the ABC Study and ABV Study.⁶⁻⁹ Both studies observed significantly greater long-term IOP reduction and less need for glaucoma medical therapy with the Baerveldt implant compared with the Ahmed implant. The larger end plate of the Baerveldt implant likely explains its greater efficacy, as plates with a larger surface area are associated with greater pressure reduction.¹⁷ Ahmed implantation was associated with a significantly lower rate of serious postoperative complications in the ABC Study⁸ and hypotony-related vision-threatening complications in the AVB Study⁹ relative to Baerveldt implantation. The valve mechanism in the Ahmed implant appears to provide an additional level of safety by minimizing the risk of hypotony-related complications in the immediate period after surgery.

The TVT Study supports the expanding use of tube shunts beyond the surgical management of refractory glaucoma. Tube shunt surgery was shown to be effective in a patient population at lower risk of surgical failure than has traditionally been designated for this procedure.¹¹⁻¹³ The study results have prompted another multicenter randomized clinical trial comparing tube shunt surgery and trabeculectomy with MMC as an initial surgical procedure in low-risk eyes (Primary Tube Versus Trabeculectomy Study). The TVT Study also demonstrated that low levels of IOP could be achieved with tube shunts in this patient group, which challenges the conventional wisdom.¹⁸

Each of the landmark randomized clinical trials involving tube shunts has provided useful information to assist in surgical decision making for similar patient groups. Other factors must be considered when selecting a surgical procedure, however, including the surgeon's skill and experience with each operation and the characteristics of the individual patient. We look forward to additional follow-up data from these clinical trials. ■

(Continued on page 26)

(Continued from page 22)

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