The Ahmed Versus Baerveldt Study: Three-Year Treatment Outcomes

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OBJECTIVE: To compare 2 commonly used aqueous drainage devices for the treatment of refractory glaucoma.

DESIGN: International, multicenter, randomized trial.

PARTICIPANTS: Patients aged 18 years or older with uncontrolled or high-risk glaucoma refractory to maximum medical therapy, many of whom had failed trabeculoplasty and trabeculectomy.

METHODS: Eligible patients were randomized to 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 of the target range (5-18 mmHg, with ≥20% reduction from baseline) for 2 consecutive visits after 3 months, vision-threatening complications, de novo glaucoma procedures, or loss of light perception. Secondary outcome measures include IOP, medication use, visual acuity, complications, and interventions.

RESULTS: A total of 238 patients were enrolled and randomized; 124 received the Ahmed implant and 114 received the Baerveldt implant. Baseline characteristics were similar in both groups. Half the study group had secondary glaucoma, and 37% had previously failed trabeculectomy. The mean preoperative IOP was 31.4±10.8 mmHg on 3.1±1.0 glaucoma medications. Median baseline Snellen visual acuity was 20/100. At 3 years, the cumulative probability of failure was 51% in the Ahmed group and 34% in the Baerveldt group (P = 0.03). Mean IOP was 15.7±4.8 mmHg in the Ahmed group (49% reduction) and 14.4±5.1 mmHg in the Baerveldt group (55% reduction; P = 0.09). Mean number of glaucoma medications was 1.8±1.4 in the Ahmed group (42% reduction) and 1.1±1.3 in the Baerveldt group (65% reduction; P = 0.002). There was a moderate but similar decrease in visual acuity in both groups (P<0.001). The 2 groups had similar complication rates (52% Ahmed, 62% Baerveldt; P = 0.12); however, the Baerveldt group had a higher rate of hypotony-related vision-threatening complications (0% Ahmed, 6% Baerveldt; P = 0.005). More interventions were required in the Baerveldt group, although the difference did not reach statistical significance (38% Ahmed, 50% Baerveldt; P = 0.07). Most complications were transient, and most interventions were slit-lamp procedures.

CONCLUSIONS: Both devices were effective in reducing IOP and glaucoma medications. The Baerveldt group had a lower failure rate and required fewer medications than the Ahmed group after 3 years, but it experienced more hypotony-related vision-threatening complications.

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