

Three-year Treatment Outcomes in the Ahmed Baerveldt Comparison Study

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PURPOSE: To compare 3-year outcomes and complications of the Ahmed FP7 Glaucoma Valve (AGV) (New World Medical, Cucamonga, CA) and the Baerveldt Glaucoma Implant (BGI) 101-350 (Abbott Medical Optics, Abbott Park, IL) for the treatment of refractory glaucoma.

DESIGN: Multicenter, randomized, controlled clinical trial.

PARTICIPANTS: A total of 276 patients: 143 in the AGV group and 133 in the BGI group.

METHODS: Patients aged 18 to 85 years with refractory glaucoma and intraocular pressures (IOPs) ≥ 18 mmHg in whom an aqueous shunt was planned were randomized to an AGV or a BGI.

MAIN OUTCOME MEASURES: The IOP, visual acuity (VA) , supplemental medical therapy, complications, and failure (IOP >21 mmHg or not reduced by 20% from baseline, IOP RESULTS: At 3 years, IOP (mean \pm standard deviation) was 14.3 ± 4.7 mmHg (AGV group) and 13.1 ± 4.5 mmHg (BGI group) ($P = 0.086$) on 2.0 ± 1.4 and 1.5 ± 1.4 glaucoma medications, respectively ($P = 0.020$) . The cumulative probabilities of failure were 31.3% (standard error [SE], 4.0%) (AGV) and 32.3% (4.2%) (BGI) ($P = 0.99$) . Postoperative complications associated with reoperation or vision loss of >2 Snellen lines occurred in 24 patients (22%) (AGV) and 38 patients (36%) (BGI) ($P = 0.035$) . The mean change in the logarithm of the minimum angle of resolution VA at 3 years was similar (AGV: 0.21 ± 0.88 , BGI: 0.26 ± 0.74) in the 2 treatment groups at 3 years ($P = 0.66$) . The cumulative proportion of patients (SE) undergoing reoperation for glaucoma before the 3-year postoperative time point was 14.5% (3.0%) in the AGV group compared with 7.6% (2.4%) in the BGI group ($P = 0.053$, log rank) . The relative risk of reoperation for glaucoma in the AGV group was 2.1 times that of the BGI group (95% confidence interval, 1.0-4.8; $P = 0.045$, Cox proportional hazards regression) .

CONCLUSIONS: Implantation of the AGV was associated with the need for significantly greater adjunctive medication to achieve equal success relative to implantation of the BGI and resulted in a greater relative risk of reoperation for glaucoma. More subjects experienced serious postoperative complications in the BGI group than in the AGV group.

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