Clinical Outcomes After Ahmed Glaucoma Valve Implantation for Pediatric Glaucoma After Congenital Cataract Surgery

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Précis: Ahmed valve success for glaucoma following congenital cataract surgery lasts at least 5 years in most eyes, and >10 years in some cases. The procedure is a valuable option for these patients.

Purpose: The aim of the study was to report on the results of Ahmed valve implantation in children with glaucoma following congenital cataract surgery.

Patients and Methods: Medical records were reviewed for 41 pediatric eyes (27 patients) with glaucoma after congenital cataract surgery with Ahmed glaucoma valve (AGV) implantation between 2007 and 2018. The primary outcome measure was surgical success, defined as intraocular pressure (IOP) ≤22 mm Hg (with or without glaucoma medications) on 2 consecutive follow-up visits, without glaucoma reoperation, and without significant visual complications during the follow-up period.

Results: Median age at the time of AGV implantation was 80 months (range: 14 to 146 mo) and the mean follow-up period was 61.1 ± 46.5 months. The cumulative probability of surgical success was 95.1%, 89.8%, 83.1%, and 72.6% at 12, 24, 60, and 84 months, respectively. IOP significantly decreased from 35.8 ± 7.4 mm Hg before valve implantation to 18.7 ± 6.5 mm Hg at the last recorded visit (P < 0.0001). Most eyes (79%) required medications for pressure control. Complications occurred in 14 eyes (34%), with 12 of these remaining successful. Early hypotony was the most common complication (19.5%). Retinal detachment occurred in 1 eye.

Conclusions: Despite a decrease in surgical success over time, AGV implantation was successfully used for IOP control in the majority of our pediatric eyes with glaucoma after congenital cataract surgery. Most complications were managed effectively and surgical success was maintained.

Key Words: Ahmed glaucoma valve, aphakic glaucoma, congenital cataract, childhood glaucoma

Glaucoma is a known complication of congenital cataract surgery. Its rate reportedly ranges between 10% and 25%. Young age at cataract surgery, particularly below 4 weeks and reoperation increase the risk of glaucoma. These studies are biased by lack of control for very young age at the time of surgery, a key risk factor for the development of glaucoma. Moreover, the studies that controlled for age did not elucidate the protective effect.

Glucoma that develops after a congenital cataract surgery (GFCS) often requires a surgical intervention for adequate control of intraocular pressure (IOP). Nonetheless, there is no consensus on the best surgical approach. Angle surgery, trabeculectomy with mitomycin C, and cyclodestructive procedure have been used. In addition, glaucoma drainage devices are increasingly being utilized for the management of pediatric aphakic glaucoma, with the Ahmed glaucoma valve (AGV; New World Medical, Rancho Cucamonga, CA) being the most common.

The study presented herein describes the results of AGV implantation in pediatric eyes with GFCS, expanding on previous studies by including a larger sample size and a longer follow-up period.

PATIENTS AND METHODS

This is a retrospective evaluation of consecutive eyes with GFCS that underwent AGV implantation in our ophthalmology clinic between 2007 and 2018. The study was approved by the Institutional Review Board of the Carmel Medical Center, Haifa, Israel.

The inclusion criteria for participant selection were as follows: age 18 years and younger at the time of AGV implantation, IOP uncontrolled by medical therapy or a previous trabeculectomy, and postoperative follow-up information for at least 12 months. Eyes with other types of glaucoma (congenital glaucoma, anterior segment dysgenesis, and secondary glaucomas), before use of a glaucoma drainage device, or patients who underwent a cyclodestructive procedure were excluded from the study. None of the eyes had previously undergone angle surgery (goniotomy or trabeculotomy). IOPs were measured in the clinic with an iCare tonometer (iCare Finland Oy, Helsinki, Finland) in small children, whereas Goldmann applanation tonometer (Haag-Streit, Köniz, Switzerland) was used with older children.

We used the AGV (model FP7; New World Medical Inc.) due to its availability in Israel. All operations were performed by one surgeon (O.G.). The implant was located superior-temporally or superior-nasally. A fornix-based conjunctival pocket was created. Then the implant plate was inserted under the conjunctival pocket and secured to the sclera 8 to 9 mm posterior to the limbus by 8-0 Prolene sutures (Ethicon US LLC, Somerville, NH). A partial thickness rectangular scleral-based flap was cut near the limbus. Following injection of sodium hyaluronate into the anterior chamber, the tube was inserted into the anterior
chamber in front of the iris through a 23 G needle tract, at 2 to 3 mm beyond the limbus, close to the base of the scleral flap. The tube was ligated with 7-0 Vicryl (Ethicon US LLC) to prevent early postoperative hypotony, and then fixed to the sclera with 10-0 nylon. The scleral flap was placed above the tube, and secured with 10-0 Vicryl. The conjunctiva was closed with an 8-0 Vicryl running sutures.

After surgery, the patients were prescribed a topical antibiotic-steroid combination that was tapered off over 2 months. Glaucoma medications were added to maintain an IOP of ≤ 18 mm Hg during follow-up.

Information was obtained from the medical records on demographic variables, age at the time of cataract surgery and AGV implantation, before trabeculectomy, location of implant, duration of follow-up, IOP, and number of glaucoma medications before surgery and at the last follow-up visit, and complications. Fixed combination eye drops were counted as 1 medication.

Surgical success was defined as IOP ≤ 22 mm Hg (with or without glaucoma medications) on 2 consecutive visits, without the need for glaucoma reoperation and without significant visual complications. When these criteria were met without the use of glaucoma medications, success was defined as complete; and if medications were used to achieve success it was defined as qualified. Operative failure was defined as the success criteria not being met.

**Statistical Analysis**

Data were analyzed using SPSS statistical software, version 24 (IBM Corp., Armonk, NY). Continuous variables are presented as mean, SD, and median. Categorical variables are given in percentages. Kaplan-Meier survival analysis was used to assess cumulative surgical success rate. Cox proportional hazard ratio models were used to explore the potential predictors of treatment failure. A P-value <0.05 was considered statistically significant.

**RESULTS**

Our study included 41 eyes of 27 patients who met the inclusion criteria. A 2-month-old boy with rhizomelic chondroplasia punctata died 16 months after surgery and his data were retained in the analysis. Another 12-month-old infant underwent secondary intracocular lens implantation in a different hospital, 2 years after the AGV surgery. He developed secondary membrane proliferation with visual field loss. Considering no association between his visual complication and the AGV surgery, we set his follow-up period as the median follow-up of the entire group (41 eyes) and 80% (95% CI: 65%-95%) when including the first operated eye only (34 eyes). In addition, we analyzed alternative IOP criteria to determine their effects on success. Using 18 and 14 mm Hg as the upper IOP limits, the success rate at the last follow-up visit was 68% and 34%, respectively. Six eyes (14.6%) failed due to inadequate IOP reduction (IOP >22 mm Hg), while 2 eyes (4.9%) failed due to surgical complications. Age at cataract surgery, age at AGV implantation, sex, previous trabeculectomy, aphakia, pseudophakia, preoperative IOP, and number of medications were not significantly associated with treatment failure.

Mean IOP before AGV implantation was 35.8 ± 7.4 and 18.7 ± 6.5 mm Hg at the last recorded visit, a significant median reduction from baseline of 51.4% (P < 0.0001). The mean number of glaucoma medications decreased from 3.1 ± 1.3 at baseline to 1.6 ± 1.0 at the last visit (P < 0.0001). Most eyes (84%) required only 1 medication for pressure control, with fixed dorzolamide-timolol combination being the most common.

There were no intraoperative complications. Despite the occurrence of postoperative complications in 14 eyes, 83.1%, 72.6% at 12, 24, 60, and 84 months, respectively. In addition, it was 85.4% at a median follow-up of 43.1 months. All 8 eyes that were followed up for >7 years maintained the surgical success. Of these eyes, 6 have been followed for >10 years.

Seven patients (34.1% of eyes) underwent surgery in both eyes. Considering the introduction of bias because of the presence of both eyes of 1 patient, we performed a separate survival analysis, including the first operated eye of each patient for bilateral cases [comparison of the 95% confidence intervals (CIs) of the medians]. There was no significant difference in cumulative survival at median follow-up between the groups: 83% (95% CI: 70%-96%) for the entire group (41 eyes) and 80% (95% CI: 65%-95%) when including the first operated eye only (34 eyes). In addition, we assessed alternative IOP criteria to determine their effects on success. Using 18 and 14 mm Hg as the upper IOP limits, the success rate at the last follow-up visit was 68% and 34%, respectively. Six eyes (14.6%) failed due to inadequate IOP reduction (IOP >22 mm Hg), while 2 eyes (4.9%) failed due to surgical complications. Age at cataract surgery, age at AGV implantation, sex, previous trabeculectomy, aphakia, pseudophakia, preoperative IOP, and number of medications were not significantly associated with treatment failure.

## Table 1. Demographic and Ocular Characteristics of Eyes Undergoing Ahmed Valve Implantation for Glaucoma Following Congenital Cataract Surgery

| Eyes (patients) (n) | 41 (27) |
|---------------------|---------|
| Age at cataract surgery (mo) | Mean ± SD 4.6 ± 4.4 Median (range) 2.2 (1.5-6.5) |
| Age at Ahmed valve implantation (mo) | Mean ± SD 94.8 ± 87.9 Median (range) 80 (14-146) |
| Female [n (%)] | 27 (66) |
| Lens status [n (%)] | Aphakia 36 (88) Pseudophakia 5 (12) |
| Prior trabeculectomy [n (%)] | 7 (17) |
| Implant location | Superior-temporally 36 (88) Superior-nasally 5 (12) |
| Follow-up (mo) | Mean ± SD 61.1 ± 46.5 Range 12-159 Median 43.1 |

## Table 2. Surgical Outcomes at Last Follow-up

| Overall Success | Complete Success | Qualified Success |
|----------------|-----------------|------------------|
| No. eyes [n (%)] | 33 (80.5) | 7 (21) | 26 (79) |
TABLE 3. Complications, Management, and Surgical Success

| Complications                                | No. Eyes (% of 41 Eyes) | Management                  | Ahmed Glaucoma Valve Surgery Success |
|----------------------------------------------|-------------------------|------------------------------|-------------------------------------|
| Early hypotony (in the first postoperative week) | 2 (4.8)                 | Choroidal drainage           | Successful                          |
| Choroidal and retinal effusion               | 6 (14.6)                | Anterior chamber reformation | Successful                          |
| Shallow anterior chamber                     | 3 (7.3)                 | Autologous scleral patch     | 2 successful                        |
| Tube exposure                                |                         | Implant removal              | 1 failure                           |
| Infiltrate in the tube lumen                 | 2 (4.8)                 | Oral and topical steroids    | Successful                          |
| Tube-cornea touch                            | 1 (2.4)                 | Transcameral suture          | Successful                          |
| Retinal detachment with vision deterioration  | 1 (2.4)                 | Pars plana vitrectomy        | Failure                             |
| All complications*                           | 14 (34.1)               |                              |                                     |

*One eye had 2 complications.

(34.1%), 12 of these (85.7%) maintained success (Table 3). Eight eyes (19.5%) reported hypotony (IOP <5 mm Hg) during the first postoperative week: 2 eyes of 2 patients with choroidal and retinal effusion needed choroidal drainage; and the other 6 (14.6%) with corneal touch that persisted for 72 hours despite application of topical atropine 1% twice daily required anterior chamber reformation. One of the 6 eyes developed tube-corneal touch 12 months later, and was treated with transcameral suture. Tube exposure in 3 eyes (7.3%) was managed with autologous scleral grafts: 2 eyes (4.9%) remained successful; and 1 eye (2.4%) reported 2 recurrences of tube exposure requiring valve removal. Two eyes of 2 patients developed a dense white infiltrate that filled the tube lumen and a mild anterior chamber inflammation. Nonetheless, there was no tube exposure or conjunctival erosion. On suspecting low-grade tube infection, we administered 0.5% topical moxifloxacin (Vigamox; Novartis AG, Basel, Switzerland) hourly, for 1 week. As no improvement was seen, the treatment was changed to 1% topical prednisolone acetate 4 times daily, combined with oral prednisone (1 mg/kg/d). The tube infiltrate and anterior chamber inflammation gradually resolved over the next 2 weeks, following which the medications were tapered off over 1 month. There was no recurrence of tube infiltrate during 12 months’ follow-up. Another eye (2.4%) developed retinal detachment that resulted in a significant deterioration of vision despite successful anatomic repair.

**DISCUSSION**

AGV implantation is commonly used for the management of pediatric GFCS. However, few studies have directly addressed the outcomes of this practice. Kirwan et al15 reported on 18 of 19 eyes achieving an IOP ≤15 mm Hg during a mean follow-up of 13 months. Pakravan et al16 reported on 15 eyes with an overall success of 86.7% during 32 months of follow-up, while Esfandiari et al13 examined 14 eyes with a success rate of 93% and 71% at a follow-up of 1 and 4 years, respectively. Furthermore, Pakravan et al17 analyzed 33 eyes and reported on 90% and 71.5% success rate at a follow-up of 1 and 5 years, respectively. However, our study comprised a larger sample size, a longer follow-up, a similar success rate (95.1%) at 1 year, and a greater success rate (83.1%) at 5 years. Nonetheless, our success rate decreased over time, consistent with the aforementioned studies. Noteworthy, all eyes that were followed up for 7 years or more, including those with >10 years follow-up, maintained success as defined by our study criteria. The main reason for failure in our cohort was inadequate IOP reduction. However, no specific predictor of failure was found.

We used an IOP target of ≤22 mm Hg because young patients generally do not have severe disease and can withstand IOPs in upper normal or mildly elevated ranges without disease progression.11 We observed a lower rate of surgical success (34%) when IOP success was stringently defined as an IOP ≤14 mm Hg.

The degree of IOP reduction reflects the therapeutic success for glaucoma. In addition, it is an important measure of surgical success. The total IOP reduction from baseline was 51.4% in our study, similar to that described by Pakravan and colleagues (51.4% and 45%).16,17 However, it was greater than that reported by Esfandiari et al (36%).13 The discrepancy with the latter study can be attributed to the greater severity of disease and younger age at the time of operation. Despite achieving success in 80.5% of the eyes at the last follow-up visit, many (79%) required medications to attain the target IOP ≤18 mm Hg. Nevertheless, AGV was clearly effective in reducing the number of glaucoma medications needed.
Postoperative complications occurred in 34% of the eyes. Retinal detachment was reported in one eye resulting in vision deterioration. However, we could effectively manage the complications in most eyes while maintaining surgical success. Hypotony in the early postoperative period was the most frequent complication (19.5%). It was higher than the rates previously reported, following AGV implantation in pediatric aphakic glaucoma.13,15–17 It should be noted that hypotony in our cases occurred despite complete tube ligation and it is therefore an AGV implant valve failure was unlikely its cause. The leakage of aqueous around the tube was the likely reason for the complications in our study. We used a 23 G needle for creating the anterior chamber entry tract that might have resulted in a peritubular leakage.19 Considering the tube implantation under a scleral flap, the needle track passed through the half-thickness sclera. Extremely young children with glaucoma have stretched eyes and a thin sclera. A short needle track that passes through the half-thickness sclera results in the 23 G needle creating a larger entry. This eventually results in peritubular leakage. Use of either a smaller gauge needle, such as 25 G for creating the entry tract, or a longer needle track, or passing through a full thickness sclera and using a patch, the leakage and hypotony would likely get eliminated.

The tube-related complications included tube exposure and tube-coneal touch. These complications occurred in few patients and have been reported in previous studies.15,17 We observed a white infiltrate in the tube lumen with mild inflammation in the anterior chamber of 2 eyes. It occurred in the absence of a tube exposure or conjunctival erosion as a possible source of infection. Moreover, the infiltrate resolved with steroid therapy, which is unusual in infective settings. Thus, it indicated an inflammatory reaction, triggered by the AGV implant. Sterile endophthalmitis has been reported in a patient with an unexposed Ahmed tube implant.20 Recently, Lee et al21 observed a similar white inflammatory material in the lumen of the AGV tube. However, the pathology was caused by infection from an exposed tube in the aforementioned study. Another reason for the infiltrate observed in our patients could be a lens-related inflammation, triggered by a small, undetected residual piece that remained after the cataract surgery and was exposed following placement of the tube.

The success rate of AGV (92.7% at 3 y) in our previous study on glaucoma after cataract surgery in adults22 was similar to this study (86.3% at 3 y). However, adults had a lower rate of hypotony within the first 2 weeks after surgery (7%). This supports the association between hypotony in infants to stretched eyes, as discussed above. To the best of our knowledge, there are no previous studies comparing the results of glaucoma drainage device implantation following cataract surgery between children and adults. Our study had 2 main limitations. The retrospective study design was the first limitation. However, all surgeries being performed by one surgeon using a standard AGV implantation protocol increased the reliability of our results. Second, inclusion of both eyes of bilateral cases might have introduced bias. However, the results of survival analysis including only the first operated eye per patient for bilateral cases were similar to those for the complete set of eyes.

The major strengths of our study included the extensive follow-up period, the large sample size, and the absence of loss to follow-up.

In summary, our study on pediatric GFCS found that AGV implantation resulted in a significant and prolonged decrease in IOP. The surgical success lasted for at least 5 years in most eyes, and > 10 years in some cases. Despite a decrease in this success over time, we could efficiently manage the complications while maintaining a successful surgical outcome in most cases. Therefore, our results clearly support previous work indicating that AGV implantation is a valuable procedure, in both first-line and second-line settings, for the management of pediatric glaucoma following congenital cataract surgery.

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