

WHEN GLAUCOMA THERAPY FAILS



Recent studies highlight the risks and benefits of two interventions for refractory glaucoma.

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TRANSSCLERAL CYCLOPHOTOCOAGULATION WITH MICROPULSE LASER VERSUS AHMED VALVE IMPLANTATION IN PATIENTS WITH ADVANCED PRIMARY OPEN-ANGLE GLAUCOMA

Fili S, Kontopoulou K, Vastardis I, et al¹

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ABSTRACT SUMMARY

A prospective randomized clinical trial assessed the outcomes and complications of treating advanced primary open-angle glaucoma (POAG) that was refractory to medical management with either micropulse transscleral cyclophotocoagulation (MP-CPC) or an Ahmed Glaucoma Valve (AGV; New World Medical). Absolute success was defined as an IOP reduction of 30% or more from baseline or an IOP between 6 and 15 mm Hg with the same or a reduced number of postoperative antiglaucoma medications. A qualified success was defined as an IOP reduction of 20% or more from baseline or an IOP between 6 and 18 mm Hg irrespective of the number of postoperative medications.

Thirty eyes of 30 patients with advanced refractory POAG were randomly assigned to receive either MP-CPC or an AGV. There were no statistically significant differences in baseline demographic data between the groups. Of note, 66.67% and 93.33% of eyes in the MP-CPC and AGV groups, respectively, had already undergone a glaucoma procedure; one eye (6.67%) in the MP-CPC group had received an AGV.

At 12 months, the absolute success rates were 33.33% and 73.33% for the MP-CPC and AGV groups, respectively. The qualified success rates were 46.67% and 80% for the MP-CPC and AGV groups, respectively. Eight eyes (53.33%) that underwent MP-CPC required additional procedures secondary to elevated IOP postoperatively, whereas no additional procedures were required in the AGV group.

DISCUSSION

Is an AGV a reasonable first choice for surgical intervention in patients with medically refractory POAG?

Trabeculectomy is generally the preferred surgical procedure to lower IOP in patients with medically refractory POAG.² The current study and the

Primary Tube Versus Trabeculectomy (PTVT) study had similar patient populations. The PTVT study reported similar IOP outcomes among eyes that underwent trabeculectomy with mitomycin C compared to those that received a Baerveldt 350-mm² glaucoma implant (Johnson & Johnson Vision), with a cumulative 5-year failure rate of 35% and 42%, respectively.³ Trabeculectomy, however, tends to require frequent follow-up visits during the postoperative period to achieve optimal results.

Comparisons of the AGV and Baerveldt glaucoma implants have shown them to have a similar ability to lower IOP,^{4,5} although trabeculectomy is generally considered the best surgical procedure for achieving a low IOP.⁶

STUDY IN BRIEF

- ▶ A prospective randomized clinical trial of patients with advanced primary open-angle glaucoma refractory to medical management compared 12-month outcomes with micropulse transscleral cyclophotocoagulation (MP-CPC) versus an Ahmed Glaucoma Valve (AGV; New World Medical). The AGV group achieved greater reductions in IOP and the number of antiglaucoma medications than the MP-CPC group.

WHY IT MATTERS

Previous studies have compared outcomes with continuous-wave transscleral CPC versus glaucoma drainage devices. MP-CPC uses pulsed thermal energy to decrease IOP, which reduces tissue damage in adjacent structures, decreases complication rates, and allows the procedure to be performed earlier in the glaucoma disease process.² The improved side effect profile of MP-CPC notwithstanding, the study authors concluded that AGV implantation was more effective in eyes with advanced, refractory primary open-angle glaucoma.

Based on data from the study by Fili et al,¹ however, it may be reasonable to consider the AGV in cases of medically refractory glaucoma when single-digit target IOPs are not necessary and frequent postoperative follow-up is a concern.

Is MP-CPC a better option than continuous-wave transscleral CPC?

MP-CPC is an innovation in CPC therapy with a better safety profile

than continuous-wave transscleral CPC (CW-TSCPC); the former uses more energy-efficient on/off cycles that are thought to be less destructive to tissue.⁷ Energy delivery can be titrated to an individual patient based on the audible “pop” in CW-TSCPC, but this generally is not true with MP-CPC. In the study by Fili et al, the treatment parameters were the same for all patients in the MP-CPC group,¹ which might have led to variable treatment

outcomes depending on the type of glaucoma, preoperative IOP, and treatment history. Although some studies have demonstrated similar or superior efficacy with MS-CPC compared to CW-TSCPC, further research is required to define optimal treatment parameters given that the current literature on MP-CPC consists mainly of heterogeneous, noncomparative case series with relatively short follow-up periods (≤ 2 years).⁷

OUTCOMES OF THE SECOND AQUEOUS SHUNT IMPLANT VERSUS TRANSSCLERAL CYCLOPHOTOACOAGULATION TREATMENT STUDY (ASSISTS): A RANDOMIZED COMPARATIVE TRIAL

Feldman RM, Chuang AZ, Mansberger SL, et al⁸

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ABSTRACT SUMMARY

A prospective, randomized, multicenter clinical trial compared the outcomes and complications of

CW-TSCPC and placement of a second glaucoma drainage device (SGDD) in eyes with medically refractory glaucoma despite previous GDD surgery. Treatment failure was defined as an IOP reduction that was less than 20% below baseline, a final IOP of 5 mm Hg or less or greater than 18 mm Hg, a loss of light perception, or a need for additional glaucoma surgery.

The final analysis included 42 eyes of 42 patients; 22 eyes received an SGDD, and 20 underwent CW-TSCPC. The mean follow-up period was 18.6 and 20.3 months for the SGDD and CW-TSCPC groups, respectively. There were no statistically significant differences in baseline demographic characteristics between groups. The SGDDs implanted were a Baerveldt 350 mm² (73%), a Baerveldt 250 mm² (18%), and an AGV model FP7 (9%).

At 12 months, the success rates were 79% and 88% in the SGDD and CW-TSCPC groups, respectively. At 3 years, the success rates were 63% and 88% in the SGDD and CW-TSCPC groups, respectively. There were 14 complications in the SGDD group versus eight in the CW-TSCPC group ($P = .29$). Further surgery was required in nine eyes in the SGDD group and one eye in the CW-TSCPC group. The number of office visits required during the first 3 months after surgery was significantly greater in the SGDD group compared to the CW-TSCPC group (3.7 ± 2.5 vs 0.9 ± 1.2).

DISCUSSION

Should CPC be considered earlier in the management of refractory glaucoma?

TSCPC is often reserved for patients with refractory glaucoma who have poor or no visual potential because of concern about significant postoperative complications such as hypotony, macular edema, and phthisis bulbi due to excess thermal damage.⁹ In ASSISTS, the success rate was higher (although the difference was not statistically significant) in patients who, following a failed initial GDD, received CW-TSCPC versus an SGDD, with no significant differences in final IOP, number of postoperative glaucoma medications, pain, or adverse events.⁸ Only one patient in the CPC group needed additional surgery in the follow-up period versus 11 patients in the SGDD group ($P = .003$). There were no irreversible complications such as sympathetic ophthalmia or phthisis bulbi in either group during the study period. There was, however, a nonstatistically significant decline in visual acuity from baseline in the CPC patients compared to the SGDD patients; the reason for this finding is unclear.

When considering the results, it should be noted that the study was underpowered and did not meet its recruitment goals.⁸ Overall, however, the data suggest that it may be reasonable to consider CPC earlier in the glaucoma treatment paradigm,

STUDY IN BRIEF

- A randomized, prospective, multicenter clinical trial compared the outcomes of a second glaucoma drainage device (SGDD) versus continuous-wave transscleral cyclophotocoagulation in patients with uncontrolled glaucoma and a preexisting GDD. Although both treatment groups demonstrated a high rate of success, the SGDD group required more postoperative office visits and additional glaucoma surgical procedures.

WHY IT MATTERS

Approximately 33% to 53% of initial GDDs fail within the first 5 years, and there is no consensus on the best subsequent intervention.^{10,11} The Second Aqueous Shunt Implant Versus Transscleral Cyclophotocoagulation Treatment Study (ASSISTS) is the first randomized clinical trial to compare continuous-wave transscleral cyclophotocoagulation and an SGDD in patients with uncontrolled glaucoma after initial GDD surgery. High success rates were found with both procedures in this setting.

especially for patients at high risk of requiring incisional surgery.

What factors could account for the differing conclusions of the study by Fili et al¹ and ASSISTS?⁸

On the surface, these prospective randomized trials appear to reach different conclusions about whether clinicians should opt for a GDD or CPC when treating refractory glaucoma. ASSISTS presents a more favorable view of CW-TSCPC; although the SGDD group had a similarly high rate of success, these patients also experienced more complications and required more office visits. In contrast, Fili and colleagues reported a greater IOP reduction with an AGV than MP-CPC.

Several factors may account for the differences. Both studies compared the outcomes of a GDD versus CPC in refractory glaucoma, but baseline patient characteristics and the selection criteria differed notably. First, ASSISTS patients had various types of glaucoma (not just POAG) and a previous GDD that had failed.⁸ In contrast, Fili et al evaluated strictly advanced POAG irrespective of previous surgical history, including

canaloplasty and trabeculectomy. Also, only one eye in that study had a previous GDD.¹

Second, many published studies have suggested that MP-CPC and CW-TSCPC have similar outcomes,⁷ but that does not necessarily mean that the efficacy of CW-TSCPC in ASSISTS is comparable to that of MP-CPC in all scenarios given the heterogeneity of clinical indications and procedural settings used in other studies.

Third, the preferred SGDD in ASSISTS was the nonvalved Baerveldt 350 mm², which has been more frequently associated with hypotony and other complications in some studies compared with valved GDDs such as the AGV FP-7, which was used exclusively in the study by Fili et al.^{9,10}

Lastly, mean baseline IOP was higher for both groups in the study by Fili et al (31.27 mm Hg for MP-CPC and 30.4 mm Hg for GDD)¹ than for the ASSISTS groups (26.2 mm Hg for CPC and 27.6 mm Hg for SGDD).⁸ This difference might skew results more favorably toward an outflow procedure (AGV) at higher IOPs versus an aqueous-suppressing procedure (CPC). ■

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