Long-term Efficacy of Mitomycin C Augmented Trabeculectomy in a Mixed Pediatric Glaucoma Cohort

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Precis: This paper reports a retrospective consecutive case series investigating the efficacy of Mitomycin C-augmented trabeculectomy in the treatment of primary and secondary pediatric glaucoma in a mixed etiology, multiethnic cohort of patients.

Purpose: To evaluate the long-term efficacy and safety of Mitomycin C-augmented trabeculectomy in a mixed, tertiary-referral, pediatric glaucoma cohort.

Methods: Retrospective consecutive review of all children (37 eyes) undergoing Mitomycin C-augmented trabeculectomy by a single surgeon between 2008 and 2016. Seventeen eyes (45.9%) had primary congenital glaucoma, and 20 eyes (54.1%) had secondary glaucoma. The median age at surgery was 11 months (range, 2 to 146). The mean follow-up was 09.2 ± 4.7 months (range, 3.5 to 107.9).

Results: Overall, trabeculectomy was successful in 80.6% of eyes at 12 months, 60.5% at 3 years, and 57.5% at 5 years. 45.9% cases (17 eyes) required further laser or surgery for uncontrolled intraocular pressure (IOP) and were therefore deemed as failures. The time to failure ranged from 0.4 to 65.1 months (mean, 22.2 ± 5.1 mo). The proportion of children achieving visual acuity of 1.0 LogMAR equivalent or better increased from 43.2% preoperatively to 63.6% postoperatively at 1 year and 68% at 5 years. The mean IOP reduced from 24.85 ± 0.88 mm Hg preoperatively to 15.14 ± 0.94 mm Hg at 3 months (39% reduction) and 17.42 ± 1.08 mm Hg at 5 years (30% reduction). IOP-lowering medication requirement reduced from 4.14 ± 0.20 agents preoperatively to 0.84 ± 0.22 at 3 months (80% reduction) and 1.78 ± 0.36 at 5 years (57% reduction). There were no sight-threatening complications such as hyphaema, bleb leak, chronic hypotony, endophthalmitis, retinal detachment, or loss of light perception.

Conclusions: This study provides valuable evidence that Mitomycin C-augmented trabeculectomy is safe and effective as a treatment of primary or secondary pediatric glaucoma, with particularly encouraging results in cases of secondary glaucoma.

Glaucoma in childhood involves damage to the optic nerve secondary to elevated intraocular pressure (IOP) and may be caused by a range of disorders. The Childhood Glaucoma Research Network (CGRN) criteria for diagnosing childhood glaucoma are summarized in Table 1. Childhood glaucoma has been classified into glaucoma after cataract surgery, glaucoma associated with non-acquired systemic disease (eg, metabolic disorders, phacomatoses), glaucoma associated with acquired conditions (eg, trauma, uveitis, steroid use, neoplasm), primary congenital glaucoma (PCG), and juvenile open-angle glaucoma. PCG is the most common type of glaucoma during infancy and is mostly sporadic with 10% to 40% of cases being familial. CYP1B1 gene mutations account for 87% of familial cases and 27% of sporadic cases. The treatment of childhood glaucoma varies depending on the subtype, but the overall aim, by controlling IOP, is to provide a lifetime of vision. Although medical treatment has an important first-line role in temporizing or augmenting IOP control, surgery remains the mainstay of treatment and often needs to be repeated. Other than the subtype of glaucoma, factors such as corneal clarity and the surgeon’s experience influence the choice of intervention. There is still much debate around the optimal management strategy in this condition. This is evidenced by a Cochrane review of surgical interventions for PCG, which was unable to draw conclusions because of paucity of data. Similarly, in relation to secondary interventions, there is currently no consensus on ideal surgical management after failure of angle surgery.

Angle surgery in the form of goniotomy or trabeculotomy is considered the first-line surgical intervention for PCG. However, poorer outcomes have been reported after angle surgery in children with secondary glaucoma. Trabeculectomy has historically been considered after the failure of angle surgery. However, trabeculectomy is particularly challenging in the pediatric population, and the outcomes are less successful when compared with adults. The significant healing response observed in children requires the use of adjunctive antiscarring agents such as Mitomycin C (MMC), which confers an increased risk of complications including hypotony and bleb-related problems. However, even with MMC, the literature
TABLE 1. Summary Table of CGRN Criteria for Diagnosis of Childhood Glaucoma

| For a diagnosis of childhood glaucoma, ≥2 of the following must be present: |
|-----------------------------|
| intraocular pressure >21 mm Hg |
| Reproducible visual field defect that is consistent with glaucomatous optic neuropathy, with no other observable cause |
| Increased axial length with progressive myopia or myopic shift beyond that expected for normal growth |
| Corneal diameter >11 mm (newborn), >12 mm (child <1 y old), or >13 mm (child >1 y old); findings such as Haab striae |
| Progressive increase in cup-to-disc ratio, cup-disc asymmetry of ≥0.2, or focal rim thinning |

CGRN indicates Childhood Glaucoma Research Network.

TABLE 2. Summary Table of Demographic Information, Diagnoses and Pre-operative Parameters for All Patients

| No. patients | 26 |
| No. eyes | 37 |
| Age range, mean ± SE, median (mo) | 2–146, 33.5 ± 6.8, 11.0 |
| No. previous goniotomies, mean ± SE | 0.9 ± 0.1 |
| Diagnosis, n (%) | |
| Primary congenital glaucoma | 17 (45.9) |
| Anterior segment dysgenesis | 11 (29.7) |
| Sturge-Weber | 4 (10.8) |
| Uveitic | 1 (2.7) |
| Aphakic | 1 (2.7) |
| Aniridic | 1 (2.7) |
| Cutsis marmorata | 1 (2.7) |
| Aicardi syndrome | 1 (2.7) |
| Sex, n (%) | |
| Male | 24 (64.9) |
| Female | 13 (35.1) |
| Ethnicity, n (%) | |
| White | 28 (75.7) |
| Asian | 4 (10.8) |
| Mixed | 4 (10.8) |
| Black | 1 (2.7) |
| No. preoperative IOP-lowering medications, mean ± SE | 4.1 ± 0.2 |
| Preoperative IOP, mean ± SE (mm Hg) | 24.8 ± 0.9 |

IOP indicates intraocular pressure.

suggests disappointing results in children younger than 1 year of age11 and also when compared with glaucoma tube surgery.12 Children with glaucoma drainage devices (GDD) however are at risk of complications including tube migration requiring further surgery12 and chronic endothelial cell loss.13

It is known that childhood glaucoma significantly impacts a child’s quality of life and functional visual ability. One observational study14 reported similar health-related quality of life scores in pediatric glaucoma patients as those with severe congenital cardiac defects, those who have had liver transplantation, or who have acute lymphoblastic leukemia. Likewise, the outcome of surgery and visual morbidity can have a significant impact on the future quality of life in these children.15 This study aims to evaluate the long-term efficacy of MMC-augmented trabeculectomy in a mixed, tertiary-referral, pediatric glaucoma cohort.

METHODS

A retrospective case note review was undertaken on all children who underwent MMC-augmented trabeculectomy by a single surgeon (M.P.) between February 2008 and March 2016. Sequential surgery to both eyes was recorded by a single surgeon (M.P.) between February 2008 and March 2016. Sequential surgery to both eyes was recorded as separate data points in the analysis. The mean follow-up was 69.2 ± 4.7 months (range, 3.5 to 107.9). Baseline demographic data are summarized in Table 2.

Standard Surgical Technique

The standard surgical technique involved the creation of a superior fornix-based conjunctival peritomy and rectangular lamellar scleral flap 4 mm × 3 mm. MMC-soaked sponges (at a concentration of 0.2 mg/mL) were applied to the subconjunctival space, as well as under the scleral flap for 3 minutes. Four 100 nylon scleral sutures were preplaced (2 fixed, 2 releasable). A 1.0 to 1.5 mm sclerostomy was created, followed by surgical iridectomy. The scleral flap was sutured with the aim of achieving minimal flow of aqueous at the end of the procedure. The conjunctiva was closed with 8/0 Vicryl (Polyglactin 910, Ethicon Inc) or 100 nylon sutures, subconjunctival 5-fluorouracil (5-FU) injection 5 mg in 0.2 mL routinely at the first 2 EUs, and as required for the third EU. Further, EUAs were performed as required at other times. During EUA, removal or adjustment of releasable sutures, bleb massage, or bleb needling was performed depending on clinical need. Visual acuity was measured in an age-appropriate manner and recorded as LogMAR equivalent. IOP was measured in the clinic with either iCare rebound or Goldmann applanation tonometry (depending on the child’s level of cooperation) or in theater before anesthesia with Perkins applanation tonometry.

Outcome Measures

Success was defined as IOP ≤21 mm Hg with or without topical glaucoma medication. Failure was defined as IOP >21 mm Hg, the need for further glaucoma surgery, progressive optic nerve head cupping, or loss of light perception. Bleb massage, bleb needling with 5-FU, and removal or adjustment of releasable sutures were part of routine postoperative management and as such not included in the definition of surgical failure.

RESULTS

Thirty-seven consecutive eyes of 26 children underwent MMC-augmented trabeculectomy. Age at the time of surgery ranged from 2 to 146 months, with mean of 33.5 ± 6.8 months and median of 11 months. Other baseline demographic information is summarized in Table 2. Seventeen eyes (45.9%) had PCG, whereas the majority (20 eyes, 54.1%) had secondary glaucoma. Causes of secondary glaucoma were anterior segment dysgenesis (11 eyes, 29.7%), Sturge-Weber (4 eyes, 10.8%), uveitic glaucoma, aphakic glaucoma, aniridia, cutis marmorata,
and Aicardi syndrome (each 1 eye, 2.7%). The majority of eyes had undergone surgery before the trabeculectomy studied in this paper: goniotomy in 22 eyes (59.5%), trabeculectomy in 9 eyes (24.3%), MMC-augmented trabeculectomy in 8 eyes (21.6%), and lensectomy in 1 eye (2.7%). Eight eyes (21.6%) had undergone a previous trans-scleral cyclodiode laser. The mean preoperative IOP was 24.85 ± 0.88 mm Hg (n = 36) and was calculated from an average of the readings recorded at the 3 clinical assessments immediately before the trabeculectomy surgery. Patients were on an average of 4.14 ± 0.20 antihypertensive agents (including topical antihypertensive drops and oral acetazolamide) immediately before surgery.

**Surgical Success**

Overall, trabeculectomy was successful in 80.6% of eyes at 12 months, 60.5% at 3 years, and 57.5% at 5 years. At the last follow-up, the trabeculectomy was successful in 54.1% of cases. Surgical survival was graphically represented by a Kaplan-Meier curve for both cases of primary and secondary glaucoma (Fig. 1).

**Visual Acuity**

The proportion of children achieving visual acuity of 1.0 LogMAR equivalent or better increased from 16 of 37 (43.2%) preoperatively to 21 of 33 (63.6%) at 1 year and 17 of 25 (68%) at 5 years. The proportion of children achieving worse than 1.0 LogMAR equivalent decreased from 21 of 25 (84%) preoperatively to 8 of 33 (24.2%) at 1 year and 17 of 33 (51.5%) at 5 years. Overall, at the final follow-up, the mean visual acuity was 0.9 ± 0.1 LogMAR equivalent.

**IOP**

The mean IOP reduced to 15.14 ± 0.94 mm Hg (n = 36) at 3 months after surgery and was maintained at 15.42 ± 0.94 (n = 32) and 17.42 ± 1.08 mm Hg (n = 25) at 1 year and 5 years, respectively. This equates to a 39%, 38%, and 30% IOP reduction from baseline at 3 months, 1 year, and 5 years, respectively. When excluding failures, the mean IOP reduced to 12.9 (n = 19), 12.9 (n = 18), and 15.1 mm Hg (n = 12) at 3 months, 1 year, and 5 years, respectively.

Overall, 12 patients had a functioning bleb in at least one eye at 5 years of follow-up with a mean IOP of 15.1 mm Hg. It is interesting to note that 3 of these 12 patients had surgical failure in the other eye. Cup-to-disc (measurements were also documented: the mean cup-to-disc was 0.54 ± 0.05 (n = 32) preoperatively, 0.42 ± 0.05 (n = 36) at 3 months, 0.47 ± 0.04 (n = 31) at 1 year, and 0.55 ± 0.06 (n = 23) at 5 years.

**Medication Requirements**

The requirement for medication reduced to 0.84 ± 0.22 (n = 37), 0.76 ± 0.24 (n = 33), and 1.78 ± 0.36 (n = 28) at 3 months, 1 year, and 5 years, respectively. The corresponds to an 80%, 82%, and 57% reduction in antihypertensive medication from baseline at 3 months, 1 year, and 5 years, respectively.

**Postoperative Interventions**

The number of EUAs performed postoperatively ranged from 0 to 10 with an average of 4.5. Twenty-eight eyes (75.7%) had removal of releasable sutures. The number of bleb needlings ranged from 0 to 10 with an average of 4.5. Twenty-eight eyes (75.7%) had removal of releasable sutures. The number of bleb needlings ranged from 0 to 6 with an average of 1.8, and the number of 5-FU injections ranged from 0 to 7 with an average of 2.4.

**Reasons for Failure**

Seventeen eyes (45.9%) required further laser or surgery for uncontrolled IOP and were therefore deemed as failures. The time to failure ranged from 0.4 to 65.1 months with a mean of 22.2 ± 5.1 months. Of the failures, 2 eyes (5.4%) required trans-scleral cyclodiode laser, 2 eyes (5.4%) underwent further angle surgery, 3 eyes (8.1%) had a redo trabeculectomy, and 10 eyes (27.0%) had GDD surgery. Following further IOP-lowering intervention, the mean IOP at final follow-up in this group was 19.4 ± 1.4 mm Hg. Findings at the final follow-up, with sub-group analysis (success vs. failure), are summarized in Table 3.
Safety
Six eyes (16.2%) developed visually significant lens opacification and required lensectomy with or without intraocular lens, with a mean time to surgery of 16.2±4.3 months (range, 4.1 to 32.5). Four eyes (10.8%) required penetrating keratoplasty with a mean time to surgery of 7.3±2.7 months (range, 2 to 14). There were no cases of hyphaema, chronic hypotony, endophthalmitis, retinal detachment, or loss of light perception in this series.

DISCUSSION
There are numerous challenges to successful glaucoma surgery in children. This may in part be because of anatomic factors, such as buphthalmos or anterior segment dysgenesis. Surgical outcomes in children are also less favorable when compared with adults because of amplified healing response and resultant bleb failure. Furthermore, the rate of serious complications such as endophthalmitis and other bleb-related infections has traditionally been high, with rates of around 5% reported in the literature. Even after successful trabeculectomy surgery, to achieve the best long-term outcomes, regular follow-up reviews, adherence to intensive postoperative topical therapy, potentially numerous EUA, and repeated (often invasive) interventions are frequently required, imposing a significant burden on patients, their families, and eye departments. Long-term follow-up is required for all patients with childhood glaucoma; a study of patients with PCG who were followed-up for >20 years revealed that sight-threatening complications may occur after many years of stability.

There is evidence that surgical success and complication rates for trabeculectomy in childhood glaucoma have improved significantly with modern surgical techniques combined with MMC augmentation. A study by Jayaram et al19 at Moorfields reported cumulative probability of success at 1 year and 7 years of 78% and 60%, respectively, although the authors did acknowledge that their more favorable results could be because of a number of factors, including their study group being predominantly white, mostly PCG, with no previous lensectomy or surgery involving the conjunctiva. Our overall cumulative probability of success at 1 year and 5 years was 80.6% and 57.5%, respectively, which compares well with the Moorfields results given the heterogeneity of our group, with 20 eyes (54.1%) having secondary glaucoma and 8 eyes (21.6%) undergoing a redo trabeculectomy. Surgical management of secondary childhood glaucoma is notoriously difficult, but our study shows comparable outcomes between cases of primary and secondary glaucoma. Although there was an apparent early disparity between the cumulative probability of success (69.3% in PCG vs. 90.0% in secondary glaucoma at 1 y), survival at 5 years was essentially the same between the 2 groups, at 56.7% in PCG and 58.2% for cases of secondary glaucoma. However, age was an apparent predictor of success in the cohort overall; with a younger age at the time of surgery appearing to be strongly associated with failure: median age in the success group was 36 months compared with just 5 months in the failure group. Further analysis was not possible because of limited patient numbers in each subgroup.

GDD play an important role in the long-term management of childhood glaucoma, with 5-year success rates reported around 55% to 59%. The consistent low pressures achieved and high success rate can be attributed to the placement of the device posterior to the Spiral of Tillaux, which is a relatively avascular part of the sclera, with a lower risk of scarring compared with trabeculectomy. There is however a lag period of 6 to 8 weeks before the device can function in most cases, during which considerable damage can occur. In contrast, trabeculectomy produces a rapid lowering of IOP, minimizing optic nerve damage.

There is a recognized rate of complications from GDDs23 including hypotony within the first 6 months occurring in 39%, bleb encapsulation in 16%, and endophthalmitis in nearly 6%, requiring removal of the device. One of the most common complications is tube-endothelial touch, reported in one series15 to necessitate reoperation with tube repositioning surgery in more than one third of cases. Other reported complications include cataract, shunt extrusion, and retinal detachment.24 Long-term effects on endothelial cells have been studied, showing that although both trabeculectomy and GDD surgery result in a statistically significant reduction in corneal endothelial cell density, this effect was greater and persisted for longer in the GDD surgery group, with long-term risk of corneal decompensation. Another proposed benefit of trabeculectomy over GDD surgery is the immediate lowering of IOP with trabeculectomy compared with the lag period after GDD surgery. Childhood glaucoma is a lifelong disease, and it is not unusual for children to undergo multiple interventions. The longevity of any procedure is limited, and there may be advantages to delaying GDD surgery by performing trabeculectomy as an intermediate procedure.

There is ongoing research into the role of newer surgical options such as ExPRESS shunt25 (which shunts aqueous from the anterior chamber to a subconjunctival bleb), XEN gel stent,26 transluminal trabeculotomy,27 PRESERFLO MicroShunt,28 canaloplasty, Trabectome, and iStent that may provide further options for the management of pediatric glaucoma.

Poor visual outcomes in children with glaucoma are most commonly because of either amblyopia or glaucomatous optic neuropathy.29 A study into the long-term outcomes of visual function in children with glaucoma30 found that overall 29% of children achieved good visual acuity (defined as 6/6 to 6/12) and that appropriate amblyopia treatment was important in achieving this. In our group, the proportion of children with visual acuity 6/12 or better increased from 13.2% at baseline to 30.8% at 5 years. At the final follow-up, overall 24.3% achieved visual acuity 6/12 or better; 35.0% in those with successful surgery, and 11.8% in those where surgery failed. In any pediatric series reporting visual acuity outcomes, some change will be attributable to normal visual development and the natural history of improvement over time. Kargi et al38 suggested that a sustained IOP of ≤19 mm Hg resulted in long-term stabilization of visual function. In our group at the final follow-up, the mean IOP (with or without medication) was 16.9 mm Hg overall, 14.9 mm Hg in the success group, and 19.4 mm Hg in the failure group. These favorable visual outcomes further support the role of trabeculectomy in the management of childhood glaucoma.

Although this is a retrospective study, it provides valuable data for the outcomes of primary and secondary glaucoma treated with MMC-augmented trabeculectomy over the medium to long term. The success rate with trabeculectomy for secondary glaucoma is particularly encouraging, providing evidence that this procedure has the potential for delaying or avoiding GDD surgery altogether.
in a significant proportion of cases in the short to medium term. Trabeculectomy has the added benefit compared with primary tube surgery of allowing subsequent placement of a GDD, if required at a later date. In conclusion, MMC-adjunctive mitomycin-C in pediatric glaucoma is safe and effective as a treatment of primary or secondary pediatric glaucoma, as demonstrated in this mixed cohort with an overall surgical survival rate of 54.1% at the end of follow-up.

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