Original Article

Surgical Outcomes of Mitomycin C Augmented Trabeculectomy in Congenital Glaucoma

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Najia Uzair[1], Sumaira Altaf[2], Sarah Naveed Malik[3], Rabeeah Zafar[4], Shafaq Najmi[5]
[1-5]Al-Shifa Trust Eye Hospital, Rawalpindi

ABSTRACT

Purpose: To evaluate outcomes of augmented trabeculectomy in lowering IOP in eyes with Congenital Glaucoma and to report the post-operative complications.

Study Design: Retrospective chart review.

Place and Duration of Study: Al-Shifa Trust Eye Hospital, Rawalpindi from July 2022 to April 2024.

Methods: This study evaluated the outcomes of Mitomycin C-augmented trabeculectomy in 78 children (102 eyes) under 3 years of age with primary or secondary congenital glaucoma. All patients were followed for one-year post-surgery. Intraocular pressure (IOP) was measured under sedation using a hand-held Perkins applanation tonometer at various intervals up to 12 months. Surgical success was defined as achieving an IOP of ≤19 mm Hg, categorized into absolute success (without medications) and qualified success (with medications). Failure was defined as uncontrolled IOP despite topical therapy. Data was analyzed using SPSS version 23.

Results: Of the included eyes, 59.8% had primary congenital glaucoma (PCG) and 40.2% had secondary congenital glaucoma (SCG). The mean age was 18.24 ± 9.22 months, and 41% were boys. The mean IOP at 12 months was significantly reduced compared to baseline, with no significant difference between PCG and SCG groups (p=0.76). Postoperative complications were minimal; only 11.76% required further intervention, mostly anterior chamber reformation. One case each of retinal detachment and bleb leak was successfully managed.

Conclusion: Mitomycin C-augmented trabeculectomy is a safe and effective procedure for both PCG and SCG, with comparable success rates between the two groups at one year.

Keywords: Mitomycin C, Trabeculectomy, Primary Congenital Glaucoma, Secondary Congenital Glaucoma.

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Correspondence: Najia Uzair
Al-Shifa Trust Eye Hospital, Rawalpindi
Email: enjay27@hotmail.com

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INTRODUCTION

Congenital glaucoma is a blinding global disease.[1] It usually presents during the first year of life with epiphora, photophobia, and blepharospasm.[2] However, large eyeball size and hazy cornea may be the more common presenting features in the Indian subcontinent.[3] Primary congenital glaucoma (PCG) is caused by trabeculodysgenesis and is the most frequent cause of childhood glaucoma.[4] PCG can be sporadic, autosomal recessive or dominant. It is more commonly seen in geographical locations with higherconsanguinity.[5] Secondary congenital glaucoma (SCG) is associated with other ocular pathologies and includes anterior segment dysgenesis, lens-related congenital glaucoma, phacomatoses, Peters anomaly, aniridia, and Axenfeld-Rieger syndrome.[6]

Management of congenital glaucoma is surgical; medical management plays only a supportive role. Goniotomy is the preferred initial surgical technique in eyes with a clear cornea and good visualization of angle structures. However, in developing countries,

most patients present late with corneal haze and advanced disease and are therefore not amenable to goniotomy.[7,8] While trabeculotomy can be performed in cases with compromised corneal clarity, it may not provide satisfactory intraocular pressure (IOP) control when used as a stand-alone procedure. The use of glaucoma drainage devices, a preferred surgical option in developed countries when angle surgery fails, is hindered by cost and availability constraints in developing countries.[9] The procedure of choice in such cases is trabeculectomy or combined trabeculotomy and trabeculectomy (CTT). The eyes of paediatric patients are at a higher risk of post-operative inflammation leading to surgical failure, because of the enhanced proliferation of fibrovascular tissue in the Tenon capsule and conjunctiva. The use of antimetabolites, such as mitomycin C or 5-fluorouracil, with trabeculectomy, leads to improved surgical outcomes.[10]

The purpose of this study was to evaluate outcomes of Mitomycin C (MMC) augmented trabeculectomy in lowering IOP in eyes with PCG and SCG and to report the post-operative complications.

METHODS

The study was approved by the Institutional review board/Ethical review board **(ERC-06/AST-24)**. Medical records of 78 patients less than 3 years of age at the time of surgery with primary and secondary congenital glaucoma who underwent MMC augmented trabeculectomy by a single surgeon (SA) between July 2022 and April 2024(to allow for final follow-up at 1 year) were retrospectively reviewed. Informed consent was taken from the guardians of all patients. Eyes with a previous history of glaucoma surgery and eyes in which trabeculotomy was performed along with trabeculectomy were excluded from the study. Eyes that failed trabeculotomy and underwent augmented trabeculectomy alone were also included. Cases with a follow-up period of less than 12 months were excluded from the study. Pre-operative visual acuity was assessed according to the age and intellectual level of each child by Cardiff cards or Lea gratings.

All patients underwent examination under general anaesthesia. IOP was measured immediately after induction of anaesthesia. The type of glaucoma was documented as PCG or SCG. SCG cases were further classified as anterior segment dysgenesis, microspherophakia, aphakic glaucoma, glaucoma due to lens subluxation, or Sturge Weber Syndrome. Corneal diameters were measured with a calliper. A thorough fundus examination, which included assessment of the optic discs and documentation of the cup-to-disc ratio, was performed. Axial length measurements were taken, and B-scan was performed in eyes with hazy view of the posterior segment.

After passing a 7.0Vicryl corneal bridle suture, a fornix-based conjunctival flap was created. Gentle cautery was performed at the bare sclera. Sponges soaked in 0.2 mg/ml Mitomycin C were applied to the sclera. A partial thickness scleral flap measuring 4.5mm × 4.5mm was created. A15° blade was used to create an anterior chamber paracentesis. Another 1mm × 1mm full-thickness window was created using a 15° blade at the summit of the partial-thickness scleral flap, followed by iridectomy. The partial thickness scleral flap was placed back and sutured at its posterior ends. The site was checked with a sponge stick for excessive leakage, and further sutures were applied if needed. The conjunctiva was closed. IOP was digitally judged on the first post-operative day and documented as very soft, soft (satisfactory), or firm. IOP was documented in the clinic with a hand-held Perkins applanation tonometer at 1 week, 1 month, 3 months, 6 months, and 12 months after sedating the child with chloral hydrate syrup. Post-operative complications were documented as early or late depending on whether they occurred within or after the first 2 weeks of surgery.

Surgical success was defined as an IOP of 19 mm Hg or less. It was further defined as absolute success if no topical medications were needed to achieve this, and qualified success if this was achieved with anti-glaucoma medications post-operatively. Eyes with uncontrolled IOP, even with topical treatment, were considered a failure.

Data were analysed using Statistical Package for the Social Sciences (SPSS) program version 23.0 (IBM Corp., Armonk, New York, NY, USA). Frequencies and percentages were calculated for categorical data and means and standard deviations for numerical data. The primary outcome measure was defined as absolute success, qualified success, or failure at 12 months. Secondary outcome measures were intraocular pressure at the same intervals post-operatively, complications of the procedure, and post-operative interventions.

RESULTS

This study included 102 eyes of 78 children diagnosed with PCG or SCG who underwent Mitomycin C-augmented trabeculectomy. All patients were followed for a minimum of 12 months postoperatively. The mean age at the time of surgery was 18.24 ± 9.22 months. Of the 78 children, 46 (41.02%) were boys and 32 (58.97%) were girls. In terms of laterality, surgery was performed on the right eye in 29 children (37.17%), the left eye in 25 (32.05%), and both eyes in 24 children (30.76%). Among the operated eyes, 61 (59.8%) had PCG and 41 (40.2%) had SCG. Examination under anaesthesia showed mean horizontal corneal diameter of 13.45 ± 0.95mm (Range: 10-15mm) and mean axial length of 24.79 ± 2.17 (Range: 20-34mm). Other ocular findings are shown in Table 1.

Table 1: *Ocular findings of examination under anaesthesia.*

Ocular Examination	Number of eyes (%)
Anterior Segment Dysgenesis	32 (78.04)
Lens-related (Microspherophakia + subluxation)	6 (14.62)
Aphakic glaucoma	2 (4.87)
Sturge-Weber Syndrome	1 (2.43)
Haab striae	80(78.4%)
Clear cornea	10(9.8%)
Sclerocornea	8(7.8)
Decompensated cornea (bullae and scarring)	4(3.9)
Cup-Disc Ratio (CDR)	
0.2 - 0.3	12 (11.80)
0.4 - 0.7	62 (60.8)
0.8 - Absolute cup	20 (19.6)
Deep cup on B-Scan	8 (7.8)

Table 2 shows the pre-operative and post-operative IOP at different time intervals in both groups with the respective significance levels. Although IOP progressively increased with time in both the PCG and SCG groups, the mean IOP at 12 months after surgery was significantly lower than the pre-operative IOP. There was no statistically significant difference in IOP control at 12 months between the two groups(p=0.76).

Of the 102 operated eyes, 54 belonged to children younger than 18 months, while 48 were from children aged 18 months or older. In both age groups, postoperative IOP was significantly lower than preoperative IOP ($p < 0.001$). However, a Mann-Whitney test showed no significant difference in pre- or postoperative IOP at 12 months between the two groups ($U = 1091.5$, $p = 0.169$).

Regarding axial length (AXL), only 8 eyes had a preoperative AXL of less than 21 mm, while 94 eyes had an AXL of 21 mm or greater. In both groups, postoperative IOP was significantly reduced compared to preoperative values (AXL < 21 mm: $p = 0.012$; AXL ≥ 21 mm: $p < 0.001$). Again, no statistically significant difference in pre- or postoperative IOP at 12 months was found between the two AXL groups based on the Mann-Whitney test ($U = 320.5$, $p = 0.489$).

Table 2: *Intraocular pressure (IOP) at different time intervals in Primary and Secondary congenital glaucoma groups,*

Primary Congenital Glaucoma		
IOP	**Mean ±SD(Range)**	**P value**
Pre-operative	24.87± 4.57 (18-36)	
1 month (post-op)	12.10± 2.67 (6-21)	<0.001∗
3 months (post-op)	13.75± 2.91 (7-22)	<0.001∗
6 months (post-op)	14.79±2.70 (8-23)	<0.001∗
12 months (post-op)	16.54±2.64 (8-24)	<0.001∗
Secondary Congenital Glaucoma		
Pre-op IOP	24.73± 4.09 (16-34)	
1 month (post-op)	12.22± 2.93 (8-19)	<0.001∗
3 months (post-op)	14.71± 3.63 (7-25)	<0.001∗
6 months (post-op)	16.00±2.95 (8-23)	<0.001∗
12 months (post-op)	17.05±2.99 (11-24)	<0.001∗

∗Wilcoxon Signed Rank Test

Only 11.76% of eyes (n=12) needed post-operative intervention. Ten eyes, out of 15 with shallow anterior chamber (AC), underwent AC reformation within the first two weeks of surgery with good outcomes. One eye with retinal detachment was referred to vitreo-retinal surgeon and bleb leak in one eye was managed with re-suturing at the third post-op day. Other complications were Hyphema and choroidal detachment in one eye each.

The line graph in *Figure 1*illustrates the surgical outcomes for the entire study population at 1, 3, 6, and 12 months. Overall surgical success at 1 month was observed in 99% of eyes. This gradually declined, reaching 84.3% at 12 months. Of the 84.3% of eyes that achieved surgical success at 12 months, absolute success (blue line-representing satisfactory post-operative IOP control without topical medication) was observed in 41.2% of eyes, while qualified success (orange line- indicating requirement of topical medication for IOP control) was seen in 43.1% of eyes. Surgical failure at the end of 12 months was recorded in 15.7% of eyes. There was no statistically significant difference in pre-operative IOP among eyes

that resulted in success, qualified success, or failure according to the Kruskal-Wallis test (p=0.614).

At 12 months post-operatively, the success rates were comparable between the PCG group (42.6%) and the SCG group (39%), with no statistically significant difference identified by the chi-square test (p=0.68). The chi-square test also did not reveal any statistically significant difference in failure rates 12 months post-operatively between the PCG group (13.1%) and the SCG group (19.5%) (p=0.38).

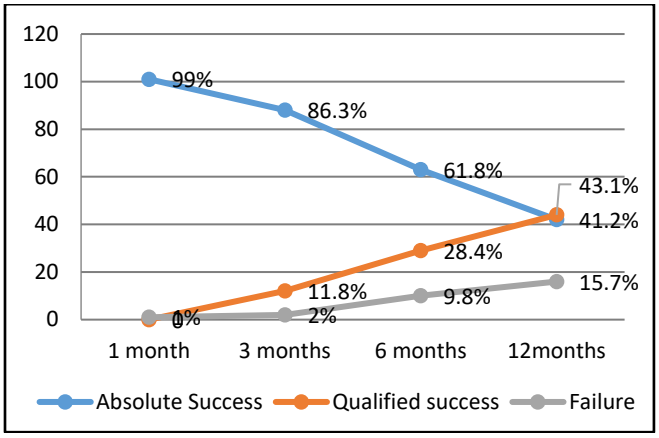

Figure 1: Surgical results in the whole study population represented by a line graph.

DISCUSSION

Trabeculectomy is the most widely performed surgical procedure for the treatment of congenital glaucoma in Pakistan because of late presentation with severe disease.[11] Use of antimetabolites like MMC improves the surgical success at 1 year to up to 78%.[12,13.]

In the entire study population in this study, overall surgical success at 12 months was observed in 84.3% of eyes, with absolute success in 41.2% and qualified success in 43.1%. In PCG cases, successful outcomes were achieved in 86.9% of eyes, with 42.6% achieving absolute success and 44.3% achieving qualified success. Two similar studies reported success rates of augmented trabeculectomy that are comparable to our findings, with a 75.7% success rate in PCG and an 80.6% success rate in a mixed cohort of PCG and SCG at 12 months.[4,14]

In cases of SCG, overall success was achieved in 80.5% of eyes in this study, comprising 39.0% absolute success and 41.5% qualified success. Similarly, Ehrlich et al, reported a comparable success rate of 86% for the procedure in paediatric glaucomacases.[15]

The mean post-operative IOP in the whole study population in this study at 12 months (16.75 ± 2.78 mm Hg) was significantly lower than the pre-op IOP (24.81 ± 4.37 mm Hg). In a prospective study of children aged less than 2 years with primary congenital glaucoma only, Jabeen S et al, reported that IOP after 12 months of Mitomycin C augmented trabeculectomy reduced from 27.3 ± 4.2 mm Hg to 17.9 ± 6.3 mm Hg.[4] Gurney SP et al, reported that IOP reduced from 24.85 ± 0.88 mm Hg to 17.42 ± 1.08 mm Hg at 5 years. Although the follow-up duration was longer in their study, the results were comparable.[14]

The mean age at the time of surgery in our study was 18.24 ± 9.22 months. Raza A et al, had reported similar results in a Pakistani cohort.[16] However, other Asian literature reports variable ages at surgery, with a mean age of 26 months in an Indian study and as low as 6.18 months in a study conducted in Egypt.[17,18] Operating on very young children can be beneficial because it lowers IOP before corneal complications set in.[19] On the other hand, such eyes have exaggerated post-operative inflammation causing episcleral fibrosis and early bleb failure, leading to raised IOP over time.[20] Khairy MA et al, report a higher failure rate in children operated before 6 months of age, attributing this to the fact that earlier presentation corresponds to more severe disease.[18] Research from Denmark reveals that 62.7% of patients with congenital glaucoma underwent surgery within the first year, typically between 3 to 12 months of age.[21] In our study, patients presented late with severe disease. Most were from far-flung villages in Pakistan, with their local ophthalmologists not being adequately trained for such surgeries. In this study, there was no statistically significant difference in IOP control in children operated before or after 18 months of age.

In this study a post-operative follow-up of12 months is reported. In contrast, Mandal AK et al, reported follow up of 20 years.[22] Cases of congenital glaucoma warrant a longer follow-up as the success of filtration surgery declines over time.

In this study, there was no statistically significant difference in IOP control between eyes with axial length greater than or less than 21mm. Most eyes were of higher axial lengths (range 20-34mm). On the other hand, Vimalanathan M et al, reported greater surgical success in eyes with smaller axial lengths, as it corresponds to earlier presentation.[23] A longer follow-

up is needed to evaluate this in our patient population.

Post-operative complications in this study were minimal, and most were managed conservatively. Complications in another study were reported to be hypotony, Hyphema, cataract, choroidal effusion, and Descemet's membrane detachment.[24] In this study, choroidal detachment was seen in only one eye. A higher incidence of postoperative choroidal detachment has also been reported in the literature.[4] The authors deduce that the low percentage of choroidal detachment in this study could be due to intra-operative meticulous rechecking of the wound for leakage and application of further scleral flap sutures if over-filtration is suspected. Further studies are needed to validate this.

Small sample size, retrospective design, and short follow up are the limitations of this study which can be addressed in future studies.

CONCLUSION

This study has shown Mitomycin C augmented trabeculectomy to be a useful and safe surgical procedure to lower IOP in both primary and secondary congenital glaucoma. Studies comparing surgical outcomes of the procedure in both groups over a longer period are needed to further validate this.

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Conflict of Interest: Authors declared no conflict of interest.

Ethical Approval: The study was approved by the Institutional review board/Ethical review board **(ERC-06/AST-24)**.

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Authors Designation and Contribution

Najia Uzair; Assistant Professor: *Concepts, Design, Literature Search, Data Acquisition, Manuscript Preparation, Manuscript Editing.*

Sumaira Altaf; Professor and Head of Department: *Concepts, Literature Search, Manuscript Review.*

Sarah Naveed Malik; Senior Registrar: *Concepts, Design, Manuscript Review.*

Rabeeah Zafar; Assistant Professor: *Data Analysis, Statistical Analysis.*

Shafaq Najmi; Senior Registrar: *Literature Search, Data Acquisition, Data Analysis, Statistical Analysis.*