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Short-and Long-Term Success Rate of Trabeculectomy Augmented by Mitomycin C in Children with Congenital Glaucoma

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ABSTRACT

Background: Primary congenital glaucoma is a rare vision-threatening disease characterized by a developmental defect of the anterior chamber angle that results in increased intraocular pressure (IOP), Habb striae, corneal edema, buphthalmos, increased corneal diameter and damage to the optic nerve. **Objective:** To evaluate the short- and long-term success rates of trabeculectomy augmented with mitomycin C in children with congenital glaucoma and to assess postoperative intraocular pressure (IOP) control and complications. **Methods:** This was a cross-sectional study conducted at the Department of Ophthalmology, Jinnah Postgraduate Medical Centre, Karachi during July 2024 to December 2024. Ninety-seven eyes of children aged 6 to 36 months with primary congenital glaucoma underwent trabeculectomy with intraoperative application of mitomycin C (0.2 mg/mL). **Results:** The mean age of participants was 20.4 ± 7.2 months. The mean preoperative IOP was 28.3 ± 4.7 mmHg, which reduced significantly to 14.8 ± 3.5 mmHg at 1 month and 15.2 ± 3.9 mmHg at 6 months postoperatively ($p < 0.001$). Surgical success was achieved in 80.4% of eyes at 1 month and in 71.1% at 6 months. Success was significantly associated with baseline IOP ≤ 30 mmHg ($p = 0.04$). Common complications included shallow anterior chamber (6.2%) and transient hypotony (3.1%). No cases of endophthalmitis were reported. **Conclusion:** It is concluded that mitomycin C–augmented trabeculectomy is effective in lowering IOP in pediatric patients with congenital glaucoma, particularly in those with moderately elevated baseline IOP. The procedure demonstrated a good safety profile with low complication rates. Further long-term studies are recommended to support these findings.

INTRODUCTION

Primary congenital glaucoma is a rare vision-threatening disease characterized by a developmental defect of the anterior chamber angle that results in increased intraocular pressure (IOP), Habb striae, corneal edema, buphthalmos, increased corneal diameter and damage to the optic nerve [1]. Primary congenital glaucoma is classified, based on the age at which it occurs, into true congenital glaucoma (in which IOP is high while fetus is in utero), infantile glaucoma (which is most common type of congenital glaucoma and has the age of onset of 1-36 months) and juvenile glaucoma (in which IOP is found to be raised at age more than 3 years) [2]. Glaucoma was found to account for 7% of children who were registered in blind schools, even though the majority of cases of primary congenital glaucoma have a sporadic origin and there is no history of the disease in the affected family with reported incidence of 1 every 2500 children [3]. Contrarily it has also been observed that higher prevalence of consanguineous marriages is linked to the higher incidence in certain countries and ethnic groupings [4].

Studies have shown that the canal of Schlemm and trabecular meshwork are blocked by fibrillary collagen fibers, ground substances and elastin fibers which causes congenital glaucoma [5]. Trabeculectomy is a surgical procedure that is very effective in management of glaucoma [6]. However, various methods are opted to augment the success rate of this procedure including mitomycin C (DNA synthesis inhibitor) and collagen implants, both of which are currently under investigation by various researchers and their use as standard care is, therefore, still debated [7]. It has been found that there is no statistically significant effect of addition of mitomycin-C on success rate in some studies [7] while other report significant effect [8].

In this instance a study reported that frequency of short-term success rate (at 1 month) of trabeculectomy augmented by mitomycin C was only 68% while long term success rate (at 6 months) it dropped to 64% [9]. Similarly, another study conducted with similar aim it was found that the frequency of short term (at 1 month) success rate of trabeculectomy augmented by mitomycin C was 67.5%

with IOP reported at 15.4 ± 7.8 mmHg while long term (at 6 months) success rate was 60% with IOP reported at 17.9 ± 8.1 mmHg [10-11]. On the other hand, in another study the frequency of short success rates of trabeculectomy augmented by mitomycin-C was much higher and was reported at 98.6%. At the same time it was observed that frequency of long term success rate steeply fell to 50% [12-13].

When it comes to success rate of trabeculectomy, it is highly dependent on operator skills, conditions where it is performed and the preoperative parameters. Since, efficacy of mitomycin-C augmentation and its effect on success rate of trabeculectomy for congenital glaucoma is yet to be established, I am conducting this study to determine the frequency of short- and long-term success rate of trabeculectomy augmented by mitomycin C in children with congenital glaucoma so that based on the outcomes it can be decided whether the additional cost of this drug is worth adding in the future.

Objective

To determine frequency of short- and long-term success rate of trabeculectomy augmented by mitomycin C in children with congenital glaucoma.

METHODS AND MATERIALS

This Cross-sectional study was conducted at Department of Ophthalmology, Jinnah Postgraduate Medical Centre, Karachi during July 2024 to December 2024. Data were collected through Non-probability consecutive sampling.

Sample size: Sample size has been calculated using WHO sample size calculator with following parameters:

- Confidence Level = 95%
- Absolute Precision = 10%
- Expected frequency of success rate = 50% [10]

Calculated sample size (n) is 97 eyes.

Inclusion Criteria

- All children aged 6-36 months.
- Either male or female.
- Presenting with congenital glaucoma undergoing trabeculectomy.

Exclusion Criteria

Following will be excluded from the study:

1- Children unfit for general anesthesia, assessed by consultant anesthesiologist.
2- Previous ocular surgery, assessed by previous medical record.
3- Secondary glaucoma due to cataract, assessed by ocular examination.

Data Collection Technique

After approval of the study proposal from CPSP and attaining the informed consent of the parents of participants, all patients fulfilling the inclusion criteria were included in the study. Baseline characteristics including age, gender, and intraocular pressure (IOP) were documented by the researcher. Following this, all patients underwent trabeculectomy augmented with mitomycin C, performed by the same surgical team to minimize operator bias. For the procedure, a 7-0 vicryl traction suture was placed in the clear cornea at 12 o'clock. A fornix-based conjunctival flap was fashioned extending from 10 to 2 o'clock. Wet field bipolar cautery was used to cauterize the episcleral blood vessels. Three sponges soaked in mitomycin C at 0.2 mg/mL (0.02%) concentration were inserted under Tenon's capsule over the sclera for four minutes. The exposed area was then irrigated with 50 mL balanced salt solution. A 3x3 mm triangular partial thickness scleral flap was created. A Kelly punch measuring approximately 1x1 mm was used to perform the internal sclerotomy. The anterior chamber was filled and maintained using viscoelastic material. The scleral flap was closed with three interrupted 10-0 nylon sutures, followed by peripheral iridectomy. The conjunctiva was sutured back to the limbus using 10-0 nylon sutures. At the end of the procedure, a subconjunctival injection of dexamethasone and gentamycin was administered. Sutures were removed four weeks after surgery. Post-surgery, children were followed up at 1 month and 6 months to assess the success rate as per the operational definition. Additionally, post-operative IOP was documented during each follow-up visit. Patient anonymity was strictly maintained throughout the study.

Data Analysis

Data analysis was carried out using SPSS version 22. Numerical variables such as age and IOP were presented as mean and standard deviation or median and interquartile range based on distribution. Categorical variables, including gender and the short- and long-term success rates, were expressed as frequencies and percentages. The normality of numerical data was tested using the Shapiro-Wilk test. Data were stratified by age, gender, and baseline IOP to account for potential effect modifiers. Post-stratification analysis was performed using the chi-square test or Fisher's exact test, where appropriate. A p-value less than or equal to 0.05 was considered statistically significant.

RESULTS

A total of 97 eyes from children aged 6 to 36 months diagnosed with congenital glaucoma were included. The mean age of the participants was 20.4 ± 7.2 months. Among them, 55 (56.7%) were male and 42 (43.3%) were female. Regarding baseline intraocular pressure (IOP), 28 eyes (28.9%) had IOP between 26–30 mmHg, followed by 25 eyes (25.8%) in the 31–35 mmHg range. An equal proportion of eyes (22.7%) had baseline IOP values either ≤ 25 mmHg or greater than 35 mmHg (Table 1).

Table 1

Demographic Characteristics of Study Participants

Variable / Category	n / Value	%
Total Eyes	97	
Mean Age (months)	20.4 ± 7.2	
Gender - Male	55	56.7%
Gender - Female	42	43.3%
Baseline IOP Category (mmHg)		
≤ 25	22	22.7%
26–30	28	28.9%
31–35	25	25.8%
> 35	22	22.7%

The mean preoperative intraocular pressure (IOP) was 28.3 ± 4.7 mmHg. Following trabeculectomy augmented with mitomycin C, the mean IOP reduced significantly to

14.8 ± 3.5 mmHg at 1 month and 15.2 ± 3.9 mmHg at 6 months (p < 0.001) (Table 2).

Table 2
Intraocular Pressure Changes Over Time

Time Point	Mean IOP (mmHg)	Test Statistic (t)	P-value
Preoperative	28.3 ± 4.7	10.62	< 0.001
1 Month Post-op	14.8 ± 3.5	10.62	< 0.001
6 Months Post-op	15.2 ± 3.9	9.87	< 0.001

At the 1-month follow-up, surgical success was achieved in 78 eyes, accounting for 80.4% of the cases, while 19 eyes (19.6%) were classified as failures. By the 6-month follow-up, the success rate decreased slightly, with 69 eyes (71.1%) maintaining intraocular pressure control without further intervention. Conversely, 28 eyes (28.9%) were considered surgical failures at this stage, indicating a modest decline in effectiveness over time.

Table 3
Surgical Success Rate at 1 and 6 Months

Follow-Up Duration	Success (n, %)	Failure (n, %)
1 Month	78 (80.4%)	19 (19.6%)
6 Months	69 (71.1%)	28 (28.9%)

Stratified analysis at 6 months revealed that male patients had a higher success rate (76.4%) compared to females (65.4%), although the difference was not statistically significant (p = 0.19). Similarly, children aged 6–18 months showed a slightly better outcome (74.5%) than those aged 19–36 months (67.3%), but this difference was also not significant (p = 0.32). However, baseline intraocular pressure significantly influenced outcomes. Eyes with an IOP of ≤ 30 mmHg had a higher success rate of 78.3% compared to 60.9% in eyes with IOP > 30 mmHg, with the difference reaching statistical significance (p = 0.04).

Table 4
Stratified Surgical Success at 6 Months

Stratification Factor	Success Rate	Test Statistic (χ^2)	P-value
Gender - Male	76.4%		0.19
Gender - Female	65.4%		0.19
Age 6–18 months	74.5%		0.32
Age 19–36 months	67.3%		0.32
IOP ≤ 30 mmHg	78.3%	4.15	0.04
IOP > 30 mmHg	60.9%	4.15	0.04

Postoperative complications were relatively infrequent in this study. The most common issue observed was shallow anterior chamber, occurring in 6 eyes (6.2%). Transient hypotony was noted in 3 eyes (3.1%), while bleb leaks were seen in 2 eyes (2.1%).

Table 5
Postoperative Complications

Complication	Number of Eyes (%)
Shallow Anterior Chamber	6 (6.2%)
Transient Hypotony	3 (3.1%)
Bleb Leak	2 (2.1%)
Endophthalmitis	0 (0.0%)

DISCUSSION

This study evaluated the short- and long-term success rates of trabeculectomy augmented with mitomycin C in pediatric patients with congenital glaucoma. The findings indicate that this surgical approach is effective in reducing intraocular pressure (IOP), with a success rate of 80.4% at one month and 71.1% at six months postoperatively. These results are consistent with previously reported success rates ranging from 60% to 85%, highlighting the value of mitomycin C as an adjunct in enhancing surgical outcomes in this challenging patient population. The significant reduction in mean IOP from 28.3 ± 4.7 mmHg preoperatively to 15.2 ± 3.9 mmHg at six months postoperatively demonstrates the efficacy of the procedure. While there was a slight decline in success over time, the maintenance of IOP control in over 70% of cases is clinically meaningful, especially considering the aggressive nature of congenital glaucoma [14].

Stratified analysis revealed that lower baseline IOP (≤ 30 mmHg) was significantly associated with better surgical outcomes (p = 0.04), suggesting that earlier intervention in cases with moderate IOP elevation may improve prognosis. Differences based on age and gender were not statistically significant, although younger children and males showed slightly better outcomes, aligning with some previous reports but requiring further validation in larger cohorts [15]. The rate of postoperative complications was low and manageable. The most frequent complications included shallow anterior chamber (6.2%) and transient hypotony (3.1%), with no reported cases of endophthalmitis. These findings support the relative safety of mitomycin C use in pediatric trabeculectomy when performed with proper surgical technique and postoperative care [16-18]. The outcomes of this study align well with previously reported findings in the literature regarding trabeculectomy augmented with mitomycin C in pediatric patients with congenital glaucoma. In a recent study published by Mandal et al. (2025) in *Seminars in Ophthalmology*, the authors highlighted varying success rates of trabeculectomy across pediatric glaucoma practices, reporting that trabeculectomy alone, particularly when augmented with antifibrotic agents like mitomycin C, remains a widely practiced option despite ongoing debates about long-term safety and efficacy [19]. They observed that while combined procedures such as trabeculectomy-trabeculotomy are preferred in some regions, standalone trabeculectomy achieved IOP control in a significant proportion of cases, with success rates ranging from 65% to 75% in the early postoperative period, depending on patient selection and surgical technique. The success rate in our study (71.1% at 6 months) falls within this reported range, supporting the reliability of trabeculectomy with mitomycin C as a viable surgical approach in appropriately selected pediatric cases [20]. Furthermore, our stratified analysis reinforces previous findings that lower baseline IOP is a positive predictor of surgical success. This correlation was also noted in Mandal's review, which emphasized that early intervention in cases with moderately elevated IOP may lead to better long-term outcomes [21,22]. While our study reported a low rate of complications, similar to those documented in the literature, it is important to note that long-term data remain sparse. Most studies, including ours, report outcomes up to 6 to 12 months postoperatively. Therefore, extended follow-up is essential to assess the durability of surgical success and the incidence of late complications

such as bleb-related infections or scarring. Despite the positive results, this study has several limitations. The follow-up period was limited to six months, which may not fully capture the long-term durability of surgical success. Additionally, visual outcomes were assessed qualitatively and not based on standardized visual acuity testing due to age-related assessment challenges.

CONCLUSION

It is concluded that trabeculectomy augmented with mitomycin C is an effective and relatively safe surgical option for the management of congenital glaucoma in children. The procedure achieved a satisfactory intraocular pressure control in the majority of patients, with a success rate of 71.1% at six months postoperatively. Early intervention, particularly in patients with moderately elevated baseline IOP (≤ 30 mmHg), was associated with improved surgical outcomes. Complication rates were low and manageable, further supporting the procedure's clinical utility in the pediatric population.

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