

# Long-term outcome of combined trabeculotomy–trabeculectomy by a single surgeon in patients with primary congenital glaucoma

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## Abstract

**Purpose** Assess long-term outcome of combined trabeculotomy–trabeculectomy (CTT) in primary congenital glaucoma (PCG). **Methods** Data of PCG patients treated with CTT by a single surgeon between 1976 and 1993 were reviewed for reduction in intraocular pressure (IOP), visual acuities, surgical success rates, and need for repeat surgeries at last follow-up (FU). At the last FU, IOP < 21 mm Hg without any topical antiglaucoma medication (TAM) was complete success and with 1–2 TAMs was qualified success. IOP reduction  $\geq 30\%$  without any TAM was modified complete success and with 1–2 TAMs was modified qualified success. IOP > 21 mm Hg, IOP reduction < 30%, or use of > 2 TAM at last FU, or need for additional surgery was considered as failure.

**Results** Two hundred thirty eyes of 121 patients had been followed up for 21.5–38 years (mean  $28.87 \pm 2.77$  years). Eyes that were pthisical (3), had immeasurable IOP (2), or IOP < 6 mm Hg (3) were excluded from the success analysis. At last FU, mean IOP reduction was  $22.71 \pm 11.28$  mm Hg and TAM score was 1.71 (0–4). Complete success was achieved in 14 (6.3%), modified complete success in 14 (6.3%), qualified success in 148 (66.7%), and modified qualified success in 140 (63.1%). Success probability was 95% till 25 years and 92, 90, 85, 79 and 68% at 26, 27, 28, 29, and 30 years, respectively. Severe visual impairment or functional blindness was found in only 13 (10.7%) patients.

**Conclusion** CTT shows long-term success in PCG patients. All patients must be monitored for IOP control to avoid need for repeat surgeries.

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## Introduction

The most prevalent glaucoma in the paediatric population is primary congenital glaucoma (PCG), also called isolated goniodysgenesis.<sup>1,2</sup> In PCG, the intraocular pressure (IOP) increases due to isolated maldevelopment of the ocular trabecular meshwork or the angle of the anterior chamber with no other developmental anomaly in the eye or any systemic congenital anomaly.<sup>1–3</sup> Most cases are sporadic. Due to autosomal recessive transmission, the incidence may be much higher in groups where consanguineous marriages are common. Generally, PCG becomes apparent at birth or early childhood (<3 years of age).<sup>2</sup>

This study assesses the long-term outcome of combined trabeculotomy–trabeculectomy (CTT) performed by a single surgeon in PCG patients seen over a mean period of 28.9 years.

## Materials and methods

We analysed the medical records of all patients with PCG who had been treated with CTT performed by a single surgeon between 1976 and 1993 at a tertiary glaucoma centre in India. The study adhered to the tenets of the Declaration of Helsinki with appropriate safeguards for patient confidentiality, after approval from the Ethics Committee.

## Examination procedure

**Intraocular pressure** Preoperative IOP had been measured with a Perkin's handheld applanation tonometer during the early phase of anaesthesia. In the postoperative follow-up (FU) period, IOP was measured by Goldmann applanation

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tonometer in patients who cooperated for a slit-lamp examination.

**Visual function** Quantitative assessment of visual function was not possible in the preoperative phase as the children were too young. During the postoperative and FU periods, Snellens chart was used to assess visual function.

### Review of data

Gender, right or left eye, consanguinity, family history of glaucoma, and the presence of systemic illnesses were noted. We noted the category of PCG diagnosed. We also noted the corneal diameter and clarity at presentation, the preoperative IOP and the age at surgery.

For each patient, we noted the total number of years of FU and whether any repeat surgery was needed after the first glaucoma surgery done at our centre. Other parameters reviewed included the visual acuity, presence of bleb, IOP, the number of topical antiglaucoma medications (TAMs) being used, the visibility of the optic nerve head, and the refractive error at the last FU.

Patients were excluded from the study if they had a secondary paediatric glaucoma or an acquired diagnosis, <20 years of FU, incomplete FU, or initial surgery by another surgeon. We also excluded patients whose preoperative data were not available.

### Outcome measures

We based our diagnosis of PCG on increased corneal diameter, loss of corneal transparency/Haab's striae, photophobia, and raised IOP. Outcome measures analysed included reduction in IOP, visual acuities, surgical success rates, and the need for repeat surgeries.

### Surgical technique

All the surgeries were done by a single surgeon (NNS). Combined trabeculotomy–trabeculectomy (CTT) was done in all patients as the primary procedure. Where needed, bilateral surgery was performed during the same sitting to avoid repeated anaesthesia. Under general anaesthesia and aseptic technique, a limbus-based conjunctival flap was raised. A partial thickness triangular scleral flap was dissected. The Schlemm's canal was then dissected and trabeculotomy ab externo (Harms trabeculotome) was performed on either side of the radial incision, 180 degrees of the angle was treated. Then, trabeculectomy was performed and the scleral flap was sutured back. After completing the surgery on the first eye, the surgeon operated on the second eye using similar

technique but with a new set of instruments, drapes, drops, gown, gloves, and so on.

### Success criteria

Success rates were defined prior to data analysis.

Complete success was defined as an IOP <21 mm Hg without any TAM at the last FU. Qualified success was defined as an IOP <21 mm Hg with 1–2 additional TAM at the last FU. Failure was defined as an IOP >21 mm Hg with or use of more than two TAM at the last FU, or the need for additional surgery. A modified classification was also used. Modified complete success was considered if 30% drop in IOP was achieved without any TAM.

Modified qualified success was considered if target IOP was achieved with 1–2 TAM. Failure was considered if more than two TAMs were used or the target IOP was not achieved. The need for a repeat glaucoma surgery or diode laser transscleral cyclophotocoagulation was also considered as failure.

### Statistical analysis

All statistical analysis was performed by MS-Excel 2007 and SPSS-16 (SPSS Inc. Released 2007. SPSS for Windows, Version 16.0. Chicago, SPSS Inc., Chicago, IL, USA) software. Quantitative variables were expressed as mean and standard deviation (SD) and qualitative variables by frequencies and percentages. Chi-square test examined the association between two or more qualitative variables. Student *t*-test was used for comparison of quantitative data. Logistic regression analysis was used for predicting the better prognostic factor. For all statistical analysis,  $P < 0.05$  was considered as statistically significant. Kaplan–Meier survival analysis was done to estimate the cumulative success probability of the surgery.

## Results

### Preoperative findings

Complete data was available for 230 eyes of 121 patients. The patient characteristics are summarised in Table 1. There were 172 (75%) eyes diagnosed with newborn glaucoma and 58 (25%) eyes with infantile glaucoma. The affliction was bilateral in most cases (90%).

None of the infants had any associated systemic illnesses. Family history of glaucoma was present in only 5% (6/121) of the patients. Consanguineous marriages in the family were also uncommon (seen in the case of only three of the patients). The mean preoperative IOP was  $37.29 \pm 10.72$  mm Hg (range, 19–65 mm Hg) and the mean age of the patients at the primary CTT surgery was

**Table 1** Baseline demographic characteristics of 230 eyes of 121 patients with primary congenital glaucoma

Characteristic	Parameter	Value
Age at surgery ( <i>n</i> (%))	Up to 28 d	122 (53.0)
	28 d–3 years	108 (47.0)
	>3 y	0 (0)
Gender ( <i>N</i> (%))	Male	81 (66.9)
	Female	40 (33.1)
Affliction ( <i>N</i> (%))	Unilateral	12 (9.9)
	Bilateral	109 (90.1)
Family history of glaucoma	<i>N</i> (%)	6 (5.0)
Consanguineous marriages in the family	<i>N</i> (%)	3 (2.5)
Associated systemic illness	<i>N</i> (%)	0 (0)
Corneal diameter at the time of surgery	Mean ± SD (Range)	13.10 ± 1.38 (10–17)
	10–12 mm ( <i>n</i> (%))	81 (35.2)
	13–14 mm ( <i>n</i> (%))	112 (48.7)
	15–16 mm ( <i>n</i> (%))	35 (15.2)
	>16 mm ( <i>n</i> (%))	2 (0.9)
Corneal transparency	Clear ( <i>n</i> (%))	66 (28.7)
	Oedema ( <i>n</i> (%))	32 (13.91)
	Haab's striae ( <i>n</i> (%))	90 (39.13)
	Opacity ( <i>n</i> (%))	42 (18.26)

Abbreviations: d, days; *n* (%), number of eyes (percentage); *N* (%), number of patients (percentage); y, years.

**Table 2** Time to repeat surgery following primary CTT in 230 eyes

Time since primary CTT	1st repeat surgery ( <i>n</i> )	2nd repeat surgery ( <i>n</i> )	3rd repeat surgery ( <i>n</i> )	4th repeat surgery ( <i>n</i> )	5th repeat surgery ( <i>n</i> )	6th repeat surgery ( <i>n</i> )
Less than 1y	5	1	0	0	0	0
1–5y	10	5	0	0	0	0
5–10y	9	4	1	0	0	0
10–20y	12	5	4	1	0	0
20–30y	5	1	1	1	2	1
30–40y	0	0	0	0	0	0

Abbreviations: CTT, combined trabeculotomy–trabeculectomy; *n*, number of eyes; y, year.

51.3 ± 61.6 (4–300) days. The 165 eyes with PCG-related corneal haze had a mean IOP of 38.1 mm Hg (19–65 mm Hg), while the 65 eyes with clear cornea had a mean IOP of 35.3 mm Hg (21–61 mm Hg). Preoperative visualisation of the angle outflow structures on gonioscopy was not possible in most cases.

### Surgery algorithm

CTT was the primary surgery done on all 230 eyes. In 53% of cases, it was done within 28 days of birth. The first repeat surgery was done in 41 (17.8%) eyes at a mean of 111.32 ± 95.78 months after the first surgery. Second and third repeat surgeries were required in 16 (mean of 103.3 months after primary CTT) and six eyes (mean of 173.3 months after primary CTT), respectively. Most common repeat surgery was trabeculectomy with mitomycin C (TMMC). Two eyes needed a fourth surgery after a mean duration of 241.5 months from primary surgery; one was a TMMC while the other was a cyclocryotherapy. A fifth intervention was needed in only

two eyes (mean of 276 months after primary CTT). Cyclocryotherapy was repeated in one while the other needed an Ahmed glaucoma valve (AGV). At 335 months, a sixth surgery was also needed in the eye undergoing cyclocryotherapy and an AGV was implanted.

### Time of repeat surgery

In the first year since the primary CTT, five eyes needed a second surgery while one eye needed a third surgery (Table 2). Only 11/68 repeat surgeries were needed after 20 years following the primary surgery.

### Findings at the last follow-up visit

The FU period ranged from 21.5 years to 38 years (mean 28.87 ± 2.77 years). Three of the eyes had undergone atrophy, the IOP was immeasurable in three and <6 mm Hg in two. These eight eyes were excluded from the analysis of success based on IOP or medication scores.

For the 222 eyes analysed, the mean IOP at the last FU was  $14.64 \pm 3.17$  mm Hg (6–32 mm Hg), mean reduction in IOP was  $22.71 \pm 11.28$  mm Hg (1 to 55 mm Hg) and average percentage reduction in IOP was 57.44% (4.76–86.67%). IOP was reduced by at least 30% in 208/222 (93.7%) eyes. The TAM score in these 222 eyes was 1.71 (0–4). Twenty eyes (9%) did not require any TAM, 166 eyes (74.8%) required 1–2 TAMs, and 36 (16.2%) required more than two TAMs.

At the last FU visit, the visual acuity assessed by the Snellen chart was available for all 230 eyes. Out of the 230 eyes, 66 (28.7%) had best corrected visual acuity (BCVA)  $\geq 20/40$  in the affected eye and 109 (47.4%) had BCVA of 20/40–20/200. Fifty-five eyes (23.9%) had BCVA  $< 20/200$ .

There was a statistically significant association between the preoperative corneal diameter ( $P = 0.014$ ) and the visual acuity at the last FU (Table 3). The association between preoperative corneal clarity and visual acuity at the last FU was also significant ( $P = 0.013$ ).

#### Success rates

Success analysis was done for 222 of the 230 eyes. On the basis of predefined success criteria, complete success was achieved in 14 eyes (6.3%) and qualified success in 148 (66.7%) eyes (Table 4). Additional glaucoma surgery was needed in 33 eyes considered for success analysis.

Modified complete success was achieved in 14 eyes, modified qualified success in 140 (63.1%) eyes, and failure occurred in 68 (30.6%) eyes. Kaplan–Meier survival analysis (Figure 1) revealed success probability of 95% till 25 years and then it was 92, 90, 85, 79 and 68% at 26, 27, 28, 29, and 30, years respectively.

#### Bleb characteristics

At the last FU, diffuse, low to moderately cystic blebs were present in 8 (3.5%) eyes, while the blebs were flat in 222 (96.5%) eyes.

#### Optic nerve head

The optic nerve head could not be viewed in 112/230 eyes (48.7%) at last FU because of poor corneal clarity. The vertical cup to disc ratio was  $\leq 0.6$  in 77/230 eyes (33.5%) and  $> 0.6$  in 41/230 eyes (17.8%).

#### Refractive errors

Data for refractive errors at the last FU was available for all 230 eyes. Eighty (34.8%) eyes were myopic and nine (3.9%) eyes were hyperopic.

**Table 3** Correlation between preoperative factors and the visual acuity in eyes with primary congenital glaucoma ( $n = 230$ )

Parameters	Visual acuity			Total number of eyes	P-value
	$> 20/40$	20/40–20/200	$< 20/200$		
<i>Pre-operative IOP (mm Hg)</i>					
$< 20$	0	0	2	2	0.301
20–30	9	20	11	40	
30–40	30	46	26	102	
40–50	21	24	8	53	
$> 50$	8	15	10	33	
Total	68	105	57	230	
<i>Corneal diameter (at time of surgery)</i>					
10–12 mm	30	43	8	81	0.014*
13–14 mm	29	48	35	112	
15–16 mm	9	14	12	35	
$> 16$	0	0	2	2	
Total	68	105	57	230	
<i>Diagnosis (n)</i>					
New born glaucoma	49	83	40	172	0.543
Infantile glaucoma	19	22	17	58	
Total	68	105	57	230	
<i>Corneal clarity (n)</i>					
Clear	28	28	10	66	0.013*
Haab's striae	26	39	25	90	
Oedema	10	17	5	32	
Opacity	4	21	17	42	
Total	68	105	57	230	

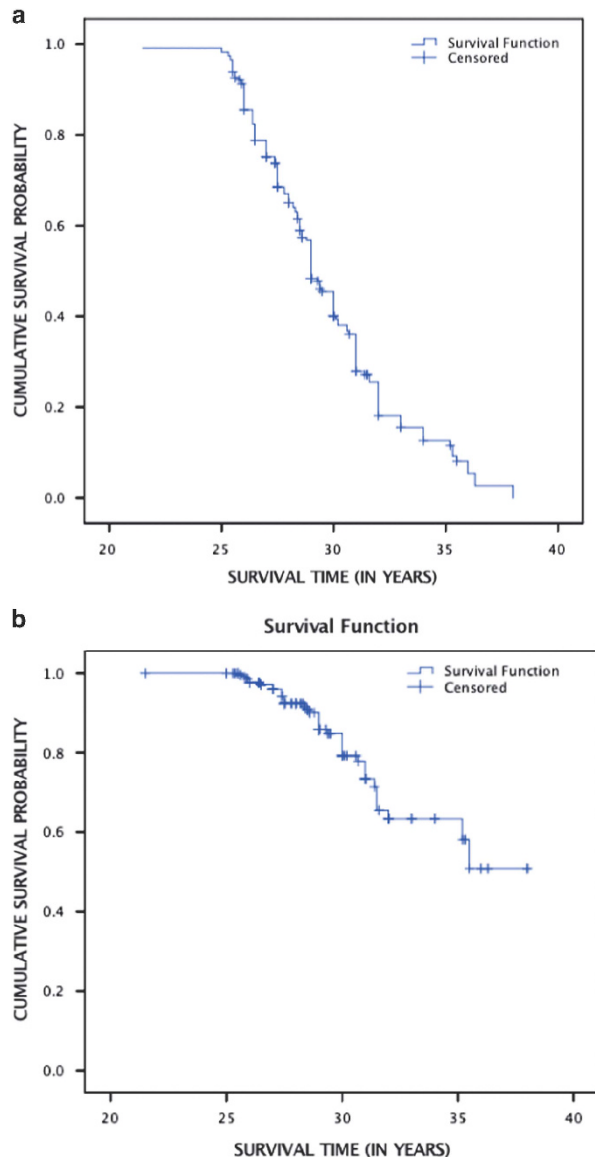
\*P value was significant ( $P < 0.05$ ).

**Table 4** Success rate of combined trabeculotomy–trabeculectomy in 222 eyes with primary congenital glaucoma

Success criteria	No. of eyes	Percentage
<i>Based on IOP at last follow-up</i>		
Complete success	14	6.3
Qualified success	148	66.7
Failure	60	27
<i>Based on percentage reduction in IOP at last follow up</i>		
Modified complete success	14	6.3
Modified qualified success	140	63.1
Modified failure	68	30.6

#### Discussion

Treatment of PCG focuses on removing the obstruction to aqueous flow due to structural abnormalities in the anterior chamber. An internal approach such as goniotomy or an external approach such as trabeculotomy or trabeculectomy may be tried. Unlike



**Figure 1** Kaplan-Meier survival analysis charts showing cumulative success probability of eyes with complete success (a) and complete plus qualified success (b).

goniotomy, trabeculotomy and trabeculectomy can be done even when the cornea is cloudy and the glaucoma is advanced.<sup>4</sup>

In 1983, NNS had found that congenital glaucoma in Indian children was commonly associated with corneal opacity and evaluated the efficacy of various surgical techniques.<sup>5,6</sup> During the early 1970 s, NNS had tried goniotomy, goniopuncture, Scheie's operation, anterior sclerectomy, and iridencleisis to treat congenital glaucoma. Though there was reduction in IOP in most cases in the immediate postoperative period, the IOP started increasing with time and the success was no more than 55.5%. He tried trabeculectomy in 55 eyes and got

slightly better results of 63.4%. Later, he tried CTT (which was a newer technique at that time) on 19 eyes. Seventeen eyes (89.5%) had well controlled IOP at a FU ranging between 6 months and 2 years.<sup>6</sup> He concluded that CTT was safe and effective in controlling IOP in the congenital glaucoma cases he operated upon and made it the standard for patients with newborn and infantile types of PCG at his glaucoma center.

Mandal *et al*<sup>7</sup> had reported the surgical outcome of primary CTT by a single surgeon in 624 eyes of 360 consecutive patients with PCG. However, the mean FU period in our study is longer and the success rate higher.

Clinical criteria to establish a diagnosis of PCG include an IOP of >21 mm Hg in one or both eyes, infantile buphthalmos, increased corneal diameter, isolated angle anomalies and mild congenital iris anomalies.<sup>8</sup> However, the angle structures could not be adequately evaluated because of corneal haziness and opacities.<sup>5</sup> Subcategories are based on the age at onset. In our case series of 230 cases, there were 172 newborn glaucoma (0–1 month), 58 infantile glaucoma (>1–24 months) and no late onset PCG (>2 years). The type of PCG did not significantly affect the visual acuity at last FU.

PCG is typically bilateral with 25–30% being unilateral.<sup>1,2,4,9–12</sup> However, as in another report,<sup>13</sup> <10% of our cases were unilateral. Some studies report an even sex distribution<sup>4,9,11</sup> but most report a male preponderance<sup>1,2,10,12,14</sup> as seen in our study. Higher rate of consanguinity is associated with a more severe disease and poorer outcomes with surgery.<sup>13</sup> At just 2.5%, the rate of consanguinity in our patients was rather low.

During CTT, the trabeculotomy procedure cut through the total thickness of the trabecular mass and helped create a direct continuity between the anterior chamber and Schlemm's canal. Trabeculectomy created a supplementary fistula and the aqueous humour could bypass Schlemm's canal to be drained out of the anterior chamber. Further, CTT is helpful in those cases where visualisation of the angle becomes difficult due to corneal haziness (71% of the eyes in this study).

CTT showed good long-term success rates with either complete or qualified success in 162/222 (73.0%) eyes over a mean of 28.9 years of FU, good control of IOP (at least 30% reduction at last FU in 93.7% (208/222) of the eyes) and a low rate of new surgical interventions (only 41/230 eyes, 17.8% required repeat surgeries). In other studies, surgical success rates varied between 65 and 90%.<sup>11,12,15–18</sup> Such a wide variance in the success rates could be due to the difference in the number of eyes studied, the length of FU, and the definitions for surgical success. In addition, in some of these studies, CTT was augmented by an adjunctive antimetabolite such as 5-fluorouracil. As a result, success rates in some studies may have been higher than ours.



Our study found a success probability of 95% till 25 years and then of 92, 90, 85, 79, and 68% at 26, 27, 28, 29, and 30 years, respectively, which is better than several other studies.<sup>12,18,19</sup>

There was no major difference in the mean preoperative IOP of the eyes with or without corneal haze. The postoperative visual acuity, however, seemed to be significantly affected by the degree of corneal clarity ( $P=0.013$ ). A recent study, however, reported more severe presentation but similar post management outcomes in eyes with PCG-related haziness as compared to eyes without haze.<sup>14</sup>

Preoperative visual acuity could not be checked in most of the children. Of the 230 eyes studied, 28.7% had a BCVA  $\geq 20/40$  at last FU, 47.4% had low vision (BCVA of 20/40–20/200) and 23.9% with BCVA  $< 20/200$  were considered blind. However, World Health Organization currently defines visual impairment with respect to the BCVA of the better eye of the patient.<sup>20</sup> At the last FU visit, out of the 121 patients, only 13 (10.7%) had severe visual impairment or were functionally blind with BCVA  $< 20/200$  in the better eye. Over 47% had mild or no visual impairment and 42% had low vision with moderate visual impairment. Functional visual outcome was thus, much better than the encouraging results seen in earlier studies in Indian children.<sup>7,12,19</sup>

In a study by Mandal *et al*,<sup>19</sup> myopia was reported in over half the patients while a quarter had hyperopia. Dubey *et al*<sup>12</sup> reported myopia in 76% of the eyes and hyperopia in 24%. Our study reported only 34.8% of the eyes being myopic (24,  $> 6$  dioptres, 33 between 2 and 6 dioptres and 23 upto 2 dioptres) and 3.9% of the eyes being hyperopic (1,  $> 6$  dioptres, 5 between 2 and 6 dioptres and 3 upto 2 dioptres) at last FU. For the rest, refraction though attempted was limited by corneal opacities/Haab's striae. For optimum visual rehabilitation, refractive changes and amblyopia developing during the course of the disease need to be adequately managed. Amblyopia may develop due to corneal haze leading to stimulus deprivation or due to anisometropia. Usual treatment is by patching.

The study is limited by its retrospective design and the limited documentation of the postoperative changes in corneal diameter and cloudiness.

CTT is a viable option for initial procedure in PCG patients. However, all patients must be monitored for a long term for IOP control. Failure of adequate IOP control may necessitate repeat filtration surgeries or the use of glaucoma drainage devices. Optical correction of refractive errors occurring in the natural course of the disease and aggressive amblyopia therapy are also highly recommended.

## Summary

### What was known before

- Infantile and newborn glaucomas are difficult to treat.

### What this study adds

- Combined trabeculotomy with trabeculectomy is a viable option as an initial procedure in PCG patients. Periodic monitoring and repeat filtration surgeries enhance long-term outcome.

## Conflict of interest

The authors declare no conflict of interest.

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