Original Article

Non-penetrating deep sclerectomy versus combined trabeculotomy–trabeculectomy in primary congenital glaucoma

Ibrahim Hassan Elabd [1], Ahmed A Elsayed [1], Akram Fekry Elgazzar [2], Ezzeldin Ramadan Ezzeldin [2], Mohamed Hassanein [1], Haitham Beshr Soliman [2], Ashraf Mohammed GadElkareem [3], Basheer Eltantawy [2], Mohamed Yahia Omran [2], Mohamed Gaber Okasha [1], Hatem Mahmoud [1], Ahmed Mohammed Madinah Alkady [1], Mahmoud H Abd Rbu [1], Hanan Saied Hegazy [4], Mona N Mansour [4] and Ehab Tharwat [2]

[1] *Department of Ophthalmology, Faculty of Medicine for Boys, Al-Azhar University, Cairo, Egypt*
[2] *Department of Ophthalmology, Faculty of Medicine, Al-Azhar University, Damietta, Egypt*
[3] *Department of Ophthalmology, Faculty of Medicine, Al-Azhar University, Assiut, Egypt*
[4] *Department of Ophthalmology, Faculty of Medicine for Girls, Al-Azhar University, Cairo, Egypt*

ABSTRACT

Background: The primary mode of therapy in children with primary congenital glaucoma (PCG) and mild or no corneal edema is goniotomy, which has a high success rate. However, in developing countries, the diagnosis of PCG is usually delayed, and corneal cloudiness interferes with goniotomy. Therefore, trabeculotomy may be the best choice in such eyes. We compared the short-term efficacy and safety of primary combined trabeculotomy–trabeculectomy (primary CTT) with that of non-penetrating deep sclerectomy (NPDS) in managing PCG.

Methods: This prospective, randomized, comparative study included patients with PCG referred to Al-Azhar University Hospitals within a 1-year period. Eyes were randomly allocated to one of two groups: eyes in *NPDS group* underwent NPDS, and those in *primary CTT group* underwent primary CTT. Baseline and frequent postoperative assessments of intraocular pressure (IOP), cup-to-disc ratio (C/D ratio), corneal diameter, and axial length were performed for up to 6 months. The success rates were recorded in both groups.

Results: Forty eyes of 26 patients were included, with 20 eyes allocated to each group. The mean (standard deviation) age of all patients was 12.9 (9.5) months, with comparable ages and sex ratios between groups (both $P > 0.05$). Both groups demonstrated a significant reduction in IOP and C/D ratio at each postoperative visit compared to the baseline visit (all $P < 0.001$), with no significant difference detected between the groups (all $P > 0.05$), except for a significantly lower IOP in NPDS group at 1 month ($P < 0.05$). The corneal diameter and axial length were comparable between groups at baseline and remained unchanged at all postoperative visits (all $P > 0.05$). The groups had comparable success rates ($P > 0.05$). No serious complications were detected.

Conclusions: CTT and NPDS both yielded reasonable IOP control and reversal of cupping in eyes with PCG. We observed equal effectiveness of the surgical procedures without major safety concerns. Further large-scale clinical trials with longer follow-up periods are needed to verify our preliminary findings.

KEYWORDS

primary congenital glaucoma type 3B, trabeculotomy, trabeculotomy, non-penetrating deep sclerectomy, intraocular pressures, optic disc, optic nerves, corneas, eye axial length

Correspondence: Ehab Tharwat, Department of Ophthalmology, Faculty of Medicine, Al-Azhar University, Damietta, Egypt.
Email: ehabtharwat71@gmail.com. ORCID iD: https://orcid.org/0000-0002-5917-2929

How to cite this article: Elabd IH, Elsayed AA, Elgazzar AF, Ezzeldin ER, Hassanein M, Soliman HB, GadElkareem AM, Eltantawy B, Omran MY, Okasha MG, Mahmoud H, Alkady AMM, Abd Rbu MH, Hegazy HS, Mansour MN, Tharwat E. Non-penetrating deep sclerectomy versus combined trabeculotomy–trabeculectomy in primary congenital glaucoma. Med Hypothesis Discov Innov Ophthalmol. 2023 Winter; 12(4): 168-176. https://doi.org/10.51329/mehdiophthal1483

Received: 07 December 2023; Accepted: 29 January 2024

INTRODUCTION

Congenital primary open-angle glaucoma is an autosomal recessive hereditary disorder featuring abnormal development of the trabecular meshwork with increased aqueous outflow resistance and a subsequent intraocular pressure (IOP) increase. Primary congenital glaucoma (PCG) is the commonest type of glaucoma in children and accounts for 0.01 – 0.04% of all childhood blindness. Its incidence is 1 in 10 000 to 1 in 20 000 live births in developed countries and 1 in 2500 live births in the Middle East [1-4]. It is typically bilateral; however, 25 – 30% of the patients may have unilateral involvement [4]. Infants born with a megalocornea (corneal diameter > 12 mm) are more likely to have PCG [5-7].

The first-line treatment of PCG is mainly surgical, although temporary medical treatment is used to decrease the IOP and corneal cloudiness to facilitate diagnosis and surgical procedures. Early surgical treatment is crucial in these children to restore and preserve good visual function [4]. The primary mode of therapy in children with mild or no corneal edema is goniotomy, which has a high success rate. However, in developing countries, the diagnosis of PCG is usually delayed, and corneal cloudiness interferes with goniotomy. Therefore, trabeculotomy may be the best choice in such eyes. Combined trabeculotomy–trabeculectomy is an alternative procedure in patients with poor trabeculotomy outcomes or in more advanced cases [3, 7].

Trabeculectomy with adjunctive antimetabolites, despite its reasonable success rate in children, is not the preferred choice because of its potential complications, and it is reserved for refractory congenital glaucoma [4, 8]. Studies have revealed a superior surgical outcome of combined trabeculotomy–trabeculectomy over primary trabeculectomy in the treatment of PCG with or without mitomycin-C (MMC) [9-12].

Because of the high success rate of the non-penetrating deep sclerectomy (NPDS) in adults with glaucoma, certain glaucoma specialists have considered it as an alternative procedure in PCG. In deep sclerectomy, the surgeon creates a partial-thickness flap in the sclera and removes the outer sections of both Schlemm's canal and the trabecular meshwork without opening the eye, leaving a thin trabeculo-Descemet's membrane. This membrane guards against early postoperative hypotony owing to the non-penetrating nature of the procedure [13, 14].

In this study, we compared the safety and efficacy of the primary combined trabeculotomy–trabeculectomy (primary CTT) with that of the NPDS in managing PCG.

METHODS

This prospective, randomized, comparative study included patients with PCG who were referred to Al-Azhar University Hospitals between February 2022 and February 2023. The study was conducted according to the standards of the Declaration of Helsinki and was approved by the Regional Ethical Committee The parents of each patient received detailed information about the surgical procedures and the expected outcomes, and they provided written informed consent.

We included 40 eyes of 26 consecutive patients with PCG. Eyes were randomly allocated to one of two groups: the eyes undergoing NPDS (*NPDS group*, 20 eyes) and the eyes undergoing primary CTT (*primary CTT group*, 20 eyes). (Figure 1). Randomization was accomplished using computer-generated random numbers placed in separate opaque envelopes that were opened by the study investigator [15].

PCG was diagnosed under general anesthesia on the clinical basis of increased IOP (> 21 mmHg), enlarged horizontal corneal diameter (in newborns, > 11 mm; in children aged < 1 year, > 12 mm; and in children aged > 1 year, > 13 mm), corneal haze, cup-to-disc ratio (C/D ratio) of > 0.5, significant intereye asymmetry of cupping (> 0.2), or abnormally increased axial length (3 months to 3 years: 19 – 22 mm). Only patients younger than 6 years with a horizontal corneal diameter of 12 – 14 mm were included in this study [16]. We excluded eyes with anterior segment anomalies, secondary glaucoma, or previous anterior segment surgeries.

A single observer performed examinations under general sevoflurane anesthesia using spontaneous ventilation [17]. All patients underwent complete preoperative ocular examinations including IOP measurement using Tono-Pen XL (Medtronic Solan, Jacksonville, FL, USA), corneal diameter measurement using a caliper, gonioscopy using a Koeppe goniolens (17 – 18 mm; Ocular Instruments, Inc., Bellevue, WA) under the operating microscope (all included corneas had adequate clarity to perform gonioscopy), optic disc evaluation using direct (Keeler, PA, USA) and indirect (Heine, Germany) ophthalmoscopy, and axial length measurement using A-scan ultrasonography (Quantel Medical and Lumibird Medical, France). These parameters were reassessed at 1 week, 1 month, 3 months, and 6 months after surgery.

Postoperatively, eyes were examined using a portable slit-lamp microscope (Handheld Slit Lamp XL-1; Rexxam, Shin-Nippon, Japan) and indirect ophthalmoscope (Heine) for evidence of serious complications such as endophthalmitis, blebitis, cataract, hyphema, choroidal detachment/effusion, or severe hypotony.

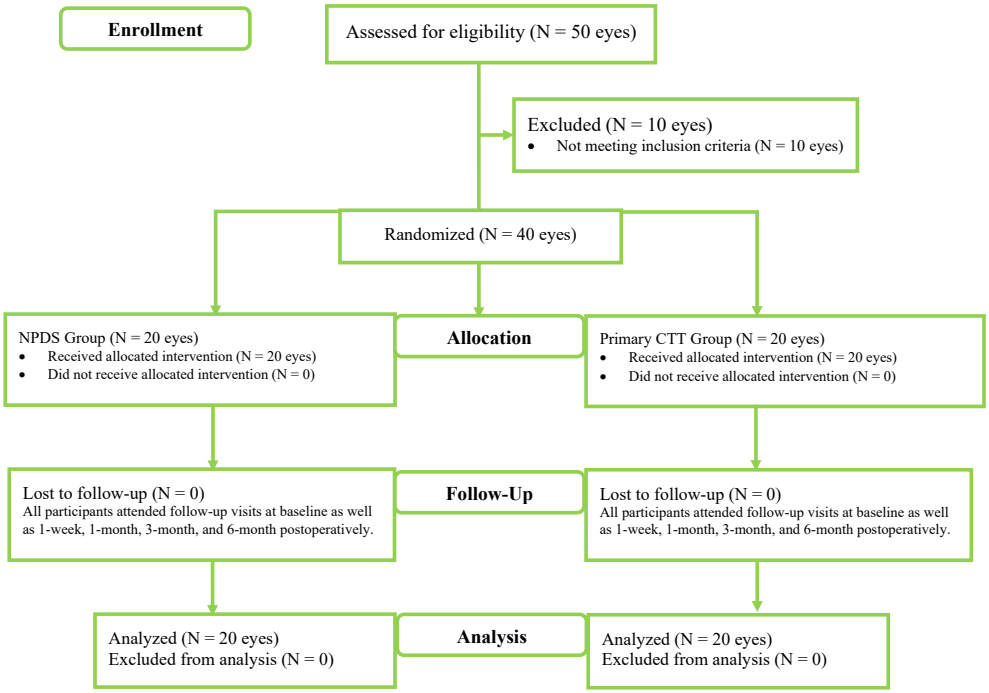

Figure 1. Patient allocation into non-penetrating deep sclerectomy (NPDS) or primary combined trabeculotomy–trabeculectomy (primary CTT) group. Abbreviations: N, number of eyes with primary congenital glaucoma

NPDS was performed under general anesthesia by a single glaucoma surgeon (I.H.E.). A fornix-based conjunctival flap was produced following placement of a superior rectus bridle suture using 6-0 silk. The superficial scleral flap measured 6 mm × 6 mm and accounted for one third of the scleral thickness. The surgical area was thoroughly rinsed with balanced salt solution after a 2-min application of a sponge saturated with MMC (0.2 mg/mL) (Naprod Life Sciences Pvt. Ltd., Mumbai, Maharashtra, India). A deep scleral flap measuring 4 mm × 4 mm was carefully created to expose Schlemm's canal and reveal trabeculo-Descemet's membrane. This increases outflow facility by 10-fold [18]. The deep scleral flap was then incised to create an intrascleral reservoir. The outer layer of tissue was stitched loosely at its back corners to the outer layer of sclera using 8-0 absorbable Vicryl sutures. The conjunctiva was subsequently stitched with 9-0 absorbable Vicryl sutures, providing a watertight seal. The primary objective of deep sclerectomy is to ensure adequate aqueous drainage through the trabeculo-Descemet's membrane into the intrascleral space, resulting in the formation of a subconjunctival bleb [19, 20].

Primary CTT was performed under general anesthesia by a single glaucoma surgeon (I.H.E.). After a 6-0 silk superior rectus bridle suture was placed, a fornix-based conjunctival flap was created. A 4 mm × 4 mm scleral flap, partially penetrating the cornea, was created and a sponge saturated with MMC (0.2 mg/mL) was applied for 2 min followed by thorough rinsing of the surgical field with balanced salt solution. A 2-mm radial incision was made, starting from the bluish area and extending to the white area of the sclera. Schlemm's canal was then externally accessed. The incision was progressively extended until it breached the external wall of Schlemm's canal and allowed the passage of aqueous humor. Schlemm's canal was dissected using a trabeculotome probe, with a 120° dissection in both the temporal and nasal directions. First, a pre-marked deep scleral flap measuring 1 mm × 2 mm was cut, followed by the creation of a peripheral iridectomy. Two 10-0 Nylon sutures were subsequently placed to secure the superficial scleral flap at its back corners. A watertight closure was achieved using 9-0 absorbable Vicryl sutures to seal the conjunctival flap.

Postoperative care included topical cyclopentolate HCl 1% eye drops (Plegica; Hikma Pharmaceuticals, Egypt) 2 times per day, along with moxifloxacin (Vigamox™;Alcon Inc., Hunenberg, Switzerland) and prednisolone acetate 1% (Econopred Plus; Alcon Laboratories, Inc., Fort Worth, TX, USA) eye drops 4 times per day for 6 weeks, with gradual tapering of the steroid regimen.

Surgical success was defined as follows: A) complete success was considered an IOP ≤ 18 mmHg without anti-glaucoma therapy, B) qualified success was considered an IOP ≤ 18 mmHg with anti-glaucoma therapy, and C) failure of surgery was defined as an IOP > 18 mmHg despite maximum tolerated anti-glaucoma therapy.

Table 1. Demographic data of the study participants

Variable	Total (n = 40 eyes)	NPDS Group (n = 20)	Primary CTT Group (n = 20)	*P*-value
Age (m), Mean ± SD	12.9 ± 9.5	16.5 ± 11.3	9.2 ± 5.4	0.2 [a]
Sex (Boy / Girl), n (%)	22 (55) / 18 (45)	11 (55) / 9 (45)	11 (55) / 9 (45)	> 0.99 [b]

Abbreviations: m, months; SD, standard deviation; n, number of eyes; %, percentage. Note: [a] *P*-value is derived from the independent-samples *t*-test; [b] *P*-value is derived from the chi-square test; NPDS Group, eyes with primary congenital glaucoma who underwent non-penetrating deep sclerectomy; Primary CTT Group, eyes with primary congenital glaucoma who underwent primary combined trabeculotomy–trabeculectomy.

Data were analyzed using GraphPad Prism 9 software (GraphPad Software, La Jolla, CA, USA). Normality of the data distribution was determined using the Shapiro – Wilk test. Data are presented as means and standard deviations (SDs) for continuous variables and as frequencies and percentages for categorical variables. Inferential analysis was performed using the chi-square test, repeated-measures analysis of variance (ANOVA), the independent-samples *t*-test, or the paired Student's *t*-test when relevant. *P*-values < 0.05 were considered statistically significant.

RESULTS

Forty eyes of 26 patients were allocated to either NPDS or primary CTT group. The groups had comparable mean ages and sex ratios (both $P > 0.05$) (Table 1) and baseline parameters (all $P > 0.05$) (Table 2).

We observed significant IOP reductions in either group throughout the study (both $P < 0.001$) (Table 2). Mean postoperative values were within the normal range; thus, we found no clinical value in pairwise comparisons between follow-up measurements. In both groups, we detected a significant decrease in the mean IOP at each postoperative visit compared with baseline values (all $P < 0.001$). We observed no significant difference in the mean IOP between groups (all $P > 0.05$), except for a significantly lower IOP in NPDS group at the 1-month postoperative visit ($P < 0.05$) (Table 2).

We observed a significant C/D ratio reduction in either group throughout the study (both $P < 0.001$) (Table 2). Because all postoperative values were within the normal range, we found no clinical value in pairwise comparisons between follow-up measurements. We detected a significant decrease in the mean C/D ratio in both groups at each postoperative visit compared with baseline values (all $P < 0.001$); however, C/D ratio was comparable between groups at each visit (all $P > 0.05$) (Table 2).

The mean corneal diameter and axial length were consistent in both groups throughout the study, with no significant differences between the groups at each visit or between the baseline and follow-up measurements in either group (all $P > 0.05$) (Table 2).

At the final visit, complete surgical success was detected in 14 eyes (70%) and 12 eyes (60%) in NPDS and primary CTT group, respectively. However, 4 eyes (20%) and 6 eyes (30%) in NPDS and primary CTT group, respectively, had surgical failure at the final visit. Two eyes (10%) in each group had qualified success (Table 3). No serious complications, such as endophthalmitis, blebitis, cataract, hyphema, choroidal detachment/effusion, or severe hypotony occurred in this study.

DISCUSSION

This randomized, prospective, comparative study found comparable efficacies and safety profiles for MMC-augmented NPDS and MMC-augmented primary CTT in patients with PCG. The only significant difference was a significantly lower IOP at the 1-month postoperative visit in NPDS group. At the final visit, a lower mean IOP reading in NPDS group did not reach statistical significance.

Glaucoma is a complex ocular disease and is the second leading cause of blindness worldwide. PCG has a variable incidence worldwide, with differing surgical outcomes. Its diagnosis and treatment are challenging. Although surgery is the standard therapy for congenital glaucoma, antiglaucoma medications have a minor and temporary preoperative role in controlling IOP and clearing corneal edema [16, 21-23]. Goniotomy and trabeculotomy are effective in treating early congenital glaucoma with clear corneas; however, primary trabeculotomy–trabeculectomy is optimal for advanced disease. Trabeculectomy combined with antimitotic medications and glaucoma drainage devices plays a crucial role in treating eyes with glaucoma that is unresponsive to other treatments [10, 11]. In our study, 40 eyes with PCG were treated using deep sclerectomy (20 eyes) or primary trabeculotomy–trabeculectomy (20 eyes). The age of onset in this study revealed a greater occurrence of PCG within the first 6 – 12 months after delivery (65%), a rate consistent with that of a previous report [24].

Table 2. Comparisons of IOP, C/D ratio, corneal diameter, and axial length between study groups

Variable	NPDS Group (n = 20)	[b] *P*-value	Primary CTT Group (n = 20)	[b] *P*-value	[c] *P*-value
IOP (mmHg), Mean ± SD					
Pre-operative	29 ± 3.2	-	29 ± 4.0	-	0.5
At 1 week post-op	12 ± 2.1	**< 0.001**	13 ± 2.1	**< 0.001**	0.6
At 1 month post-op	15 ± 1.8	**< 0.001**	18 ± 2.3	**< 0.001**	**0.001**
At 3 months post-op	17 ± 3.8	**< 0.001**	20 ± 4.5	**< 0.001**	0.06
At 6 months post-op	18 ± 2.9	**< 0.001**	21 ± 6.3	**< 0.001**	0.3
[a] ***P*-value**	**< 0.001**		**< 0.001**		
C/D ratio, Mean ± SD					
Pre-operative	0.5 ± 0.1	-	0.5 ± 0.2	-	0.7
At 1 week post-op	0.3 ± 0.1	**< 0.001**	0.3 ± 0.1	**< 0.001**	0.6
At 1 month post-op	0.3 ± 0.1	**< 0.001**	0.3 ± 0.1	**< 0.001**	0.07
At 3 months post-op	0.3 ± 0.1	**< 0.001**	0.3 ± 0.1	**< 0.001**	0.11
At 6 months post-op	0.3 ± 0.1	**< 0.001**	0.3 ± 0.1	**< 0.001**	0.08
[a] ***P*-value**	**< 0.001**		**< 0.001**		
Corneal diameter (mm), Mean ± SD					
Pre-operative	14 ± 0.9	-	14 ± 0.8	-	0.2
At 1 week post-op	14 ± 0.9	0.08	14 ± 0.8	0.08	0.1
At 1 month post-op	14 ± 0.9	0.08	14 ± 0.8	0.08	0.1
At 3 months post-op	14 ± 0.9	0.08	14 ± 0.8	0.08	0.11
At 6 months post-op	14 ± 0.9	0.08	14 ± 0.8	0.08	0.35
[a] ***P*-value**	0.8		0.8		
Axial length (mm), Mean ± SD					
Pre-operative	23 ± 1.3	-	23 ± 1.7	-	0.55
At 1 week post-op	23 ± 1.3	0.07	23 ± 1.7	0.07	0.57
At 1 month post-op	23 ± 1.3	0.07	23 ± 1.7	0.07	0.73
At 3 months post-op	23 ± 1.3	0.07	23 ± 1.7	0.07	0.73
At 6 months post-op	23 ± 1.3	0.07	23 ± 1.7	0.07	0.85
[a] ***P*-value**	0.9		0.9		

Abbreviations: IOP, intraocular pressure; C/D ratio, cup-to-disc ratio; n, number of eyes; mmHg, millimeter of mercury; SD, standard deviation; post-op, post-operative visit; mm, millimeter. Note: *P*-values < 0.05 are shown in bold; [a] *P*-value is derived from the repeated-measures analysis of variance (ANOVA); [b] *P*-value is derived from the paired Student's *t*-test comparing each post-operative value with baseline in NPDS or primary CTT Group; [c] *P*-value is derived from the independent-samples *t*-test comparing NPDS versus primary CTT group at each visit; NPDS Group, eyes with primary congenital glaucoma who underwent non-penetrating deep sclerectomy; Primary CTT Group, eyes with primary congenital glaucoma who underwent primary combined trabeculotomy–trabeculectomy.

Table 3. Comparison of surgical success rates between study groups

Success rates	NPDS Group (n = 20)	Primary CTT Group (n = 20)	*P*-value [a]
Complete success rate, n (%)	14 (70)	12 (60)	0.7
Qualified success rate, n (%)	2 (10)	2 (10)	
Rate of failure, n (%)	4 (20)	6 (30)	
Overall success rate, n (%)	16 (80)	14 (70)	-

Abbreviations: n, number of eyes; %, percentage. Note: [a] *P*-value is derived from the chi-square test; NPDS Group, eyes with primary congenital glaucoma who underwent non-penetrating deep sclerectomy; Primary CTT Group, eyes with primary congenital glaucoma who underwent primary combined trabeculotomy–trabeculectomy.

The sex distribution in our study was approximately equal (55% boys and 45% girls), which is consistent with the findings of Yassin et al. [25], who reported a similar sex distribution of 53% boys and 47% girls among patients with PCG [25]. However, other studies in patients with PCG found that boys outnumbered girls by a ratio of 3:2 [24, 26]. In our study, nearly two thirds of patients had bilateral involvement, which is consistent with other reports indicating a higher frequency of bilateral disease [26, 27]. However some studies demonstrated an equal distribution of bilateral and unilateral cases [28].

In eyes that underwent NPDS, the mean (SD) IOP decreased significantly from 29 (3.2) mmHg at baseline to 18 (2.9) mmHg at the end of follow-up, reflecting an approximated 38% reduction between the baseline and final measurements. However, in eyes that underwent primary CTT, the mean (SD) IOP decreased from 29 (4.0) mmHg at baseline to 21 (6.3) mmHg at the end of follow-up, representing a reduction of 27.6% from the baseline reading. This finding is similar to that of Yassin et al. [25], who demonstrated a 32.9% decrease in IOP following trabeculotomy and the combined trabeculotomy–trabeculectomy [25].

At the final visit, we detected complete surgical success in 70% and 60% of eyes with PCG in NPDS and primary CTT group, respectively. Qualified success was achieved in an approximated 10% of eyes in each group, and surgical failure occurred in 20% and 30% of eyes in NPDS and primary CTT group, respectively. The overall success rates were 80% and 70% in NPDS and primary CTT group, respectively. Papadopoulos et al. [26] observed that 94% of their patients with PCG experienced a drop in IOP to 21 mmHg or less after 12 months of follow-up. Among these patients, 34% required drug therapy, while 60% required no medications [26]. Mandal et al. [29] reported complete surgical success in 77.5% of PCG cases without antiglaucoma therapy, and when antiglaucoma medication was used, an 80.8% success rate was achieved [29]. Early diagnosis and surgical intervention for children with PCG could have led to a higher success rate in our study. In addition, the use of topical IOP-lowering eye drops before and after surgery in patients with IOP > 18 mmHg could be a contributing factor.

Zhang et al. [30] reported a success rate of 56.8% with and without antiglaucoma therapy when comparing different glaucoma surgeries in patients with PCG. Mohammedsaleh et al. [7] reported that IOP was controlled with antiglaucoma therapy in 88.88% of their cases; however, IOP was controlled without therapy in 11.11%. Farid et al. [31] achieved overall success in 72.7% and qualified success in 18.1% [31]. Al-Obeidan et al. [32] evaluated the safety and success rate of NPDS in childhood glaucoma. They achieved complete success in 79.7% and overall success in 82.4% of their cases, with a reduction in mean (SD) IOP from 31.9 (8.1) mmHg at baseline to 16.1 (5.3) mmHg at final visit, postoperatively [32]. Denis et al. [33] studied the effects of NPDS with the administration of 5-fluorouracil in 37 eyes affected by congenital glaucoma. They attained a 34% total success rate and an overall success rate of 82%. The wide range of success rates achieved in the different studies could be attributed to the variable numbers of patients included, different follow-up periods, varying definitions of surgical success, and the adjunctive use of antimetabolites. In addition, studies have demonstrated that early surgical intervention at the age of 2 – 12 months is associated with good IOP control and visual outcomes [25, 34].

In our study, we observed no significant differences between NPDS and primary CTT regarding IOP control or reversal of cupping, which implies that both are safe and effective surgical options for managing congenital glaucoma. For 36 months, Elhofi and Helaly [35] followed 80 eyes of 80 children with PCG who underwent NPDS or penetrating trabeculectomy under the age of 3 years. At the end of follow-up, they detected a comparative postoperative reduction in the IOP and overall success rate, with fewer postoperative complications, after NPDS [35]. In contrast, Chiselita reported a lower IOP after trabeculectomy than after NPDS, with a lower complication rate in the latter, in adults with primary open-angle glaucoma [36]. Correia Barbosa et al. reached a similar conclusion in a group of adults with open-angle glaucoma [37]. This observed difference may indicate variable efficacy of the NPDS for different age groups. This must be verified through large-scale studies of participants with a wide age range, comparing efficacy of the surgical procedure between eyes with PCG and those with open-angle glaucoma.

In this study, the mean (SD) corneal diameters were 14 (0.9) mm and 14 (0.8) mm in NPDS and primary CTT group, respectively, and they remained unchanged throughout the study, with no statistically significant difference between groups. In agreement with our results, Alsheikheh et al. [38] observed no statistically significant difference in the mean (SD) corneal diameter between the baseline (13.1 [0.9] mm) and final visits (13.4 [0.8] mm), and the corneal diameter remained constant after the first year of age [38]. Cronemberger et al. [39] observed a significant increase in the mean (SD) corneal diameter from 13.45 (1.00) mm at baseline to 13.98 (1.01) mm after surgery [39]. Another study demonstrated a significant increase in the mean (SD) corneal diameter from 12.63 (1.83) mm at baseline to 13.31 (1.13) mm at the last visit [7]. In our study, corneal diameter remained unchanged, which may indicate effective glaucoma control by either of the surgical interventions we used.

We observed a statistically significant difference between preoperative (0.5) and postoperative (0.3) mean C/D ratio in both groups, and it persisted until the final follow-up. The difference between the two groups was not significant. Several reports have demonstrated that successful IOP control in children after early surgical intervention conferred a higher chance of glaucomatous cupping reversal [7, 40]. However, Mohammedsaleh et al. [7] observed no significant difference in the mean (SD) C/D ratio between the initial (0.53 [0.37]) and final (0.45 [0.27]) follow-up measurements. In another study, the mean C/D ratio increased in 18 eyes, decreased in 19 eyes, and was unchanged in 24 eyes at the last follow-up visit [38]. Zhang et al. [30] also observed no significant difference between the preoperative and postoperative mean C/D ratio after trabeculotomy [30].

Axial length is an important parameter for diagnosis, long-term monitoring, and visual prognosis of congenital glaucoma [41]. An axial length > 20 mm at birth (normal: 16 – 17 mm) or 22.5 mm at 1 year (normal: 20.1 mm) suggests PCG [34]. Our patients in both groups had a constant axial length throughout the study. However, Alsheikheh et al. [38] reported an increase in the mean (SD) axial length, measuring 22.6 (1.8) mm at baseline and 24.4 (2.0) mm at the final visit [38].

In this prospective, randomized, comparative study, we observed that primary CTT and NPDS both offered reasonable efficacy and safety in eyes with PCG, with acceptable IOP control. The primary CTT has a slight upper hand in IOP control. The limitations of this study include the restricted number of patients, the short follow-up period, and the lack of visual acuity evaluation, as all included children were less than 3 years of age. Further large-scale randomized studies with longer follow-up and assessment of visual acuity, visual field testing, or other standard measures of visual function with structural changes [42] could provide more robust inferences concerning the efficacies of each surgical intervention in managing PCG.

CONCLUSIONS

NPDS and primary CTT yielded comparable outcomes and appear to be safe and efficient surgical alternatives in the management of PCG. Further large-scale clinical trials with longer follow-up periods are needed to verify our preliminary findings.

ETHICAL DECLARATIONS

Ethical approval: The study was conducted according to the standards of the Declaration of Helsinki and was approved by the Regional Ethical Committee. The parents of each patient received detailed information about the surgical procedures and the expected outcomes, and they provided written informed consent.
Conflict of interest: None.

FUNDING

None.

ACKNOWLEDGMENTS

None.

REFERENCES

1. Ho CL, Walton DS. Primary congenital glaucoma: 2004 update. J Pediatr Ophthalmol Strabismus. 2004;41(5):271-88; quiz 300-1. doi: 10.3928/01913913-20040901-11 pmid: 15478740
2. Sharifipour F, Arasteh E, Hajizadeh M, Mahdian-Rad A, Mirdehghan MS. Progression in pediatric glaucoma: lessons learnt from 8 years' follow-up. Med Hypothesis Discov Innov Ophthalmol. 2021;10(3):138-145. doi: 10.51329/mehdiophthal1432 pmid: 37641711
3. Badawi AH, Al-Muhaylib AA, Al Owaifeer AM, Al-Essa RS, Al-Shahwan SA. Primary congenital glaucoma: An updated review. Saudi J Ophthalmol. 2019;33(4):382-388. doi: 10.1016/j.sjopt.2019.10.002 pmid: 31920449
4. Mandal AK, Chakrabarti D. Update on congenital glaucoma. Indian J Ophthalmol. 2011;59 Suppl(Suppl1):S148-57. doi: 10.4103/0301-4738.73683 pmid: 21150027
5. Bayoumi N, Elsayed EN, Saber A. How many children with large clear cornea do not have glaucoma? Eur J Ophthalmol. 2023;33(6):2162-2169. doi: 10.1177/11206721231168147 pmid: 37021409
6. Kaur K, Gurnani B. Primary Congenital Glaucoma. 2023. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2024 Jan–. pmid: 34662067
7. Mohammedsaleh A, Raffa LH, Almarzouki N, Jubran RM, Al-Harbi A, Alluqmani AH, et al. Surgical Outcomes in Children With Primary Congenital Glaucoma: An Eight-Year Experience. Cureus. 2020;12(8):e9602. doi: 10.7759/cureus.9602 pmid: 32923206

8. Morales J, Al Shahwan S, Al Odhayb S, Al Jadaan I, Edward DP. Current surgical options for the management of pediatric glaucoma. J Ophthalmol. 2013;2013:763735. doi: 10.1155/2013/763735 pmid: 23738051
9. Mandal AK, Bhatia PG, Gothwal VK, Reddy VM, Sriramulu P, Prasad MS, et al. Safety and efficacy of simultaneous bilateral primary combined trabeculotomy-trabeculectomy for developmental glaucoma. Indian J Ophthalmol. 2002;50(1):13-9. pmid: 12090080
10. Mandal AK, Bhatia PG, Bhaskar A, Nutheti R. Long-term surgical and visual outcomes in Indian children with developmental glaucoma operated on within 6 months of birth. Ophthalmology. 2004;111(2):283-90. doi: 10.1016/j.ophtha.2003.05.027 pmid: 15019376
11. al-Hazmi A, Zwaan J, Awad A, al-Mesfer S, Mullaney PB, Wheeler DT. Effectiveness and complications of mitomycin C use during pediatric glaucoma surgery. Ophthalmology. 1998;105(10):1915-20. doi: 10.1016/S0161-6420(98)91041-7 pmid: 9787364
12. Mullaney PB, Selleck C, Al-Awad A, Al-Mesfer S, Zwaan J. Combined trabeculotomy and trabeculectomy as an initial procedure in uncomplicated congenital glaucoma. Arch Ophthalmol. 1999;117(4):457-60. doi: 10.1001/archopht.117.4.457 pmid: 10206572
13. Bayoumi NH. Deep sclerectomy in pediatric glaucoma filtering surgery. Eye (Lond). 2012;26(12):1548-53. doi: 10.1038/eye.2012.215 pmid: 23060025
14. Chen TC, Chen PP, Francis BA, Junk AK, Smith SD, Singh K, et al. Pediatric glaucoma surgery: a report by the American Academy Of Ophthalmology. Ophthalmology. 2014;121(11):2107-15. doi: 10.1016/j.ophtha.2014.05.010 pmid: 25066765
15. Kim J, Shin W. How to do random allocation (randomization). Clin Orthop Surg. 2014;6(1):103-9. doi: 10.4055/cios.2014.6.1.103 pmid: 24605197
16. Yu Chan JY, Choy BN, Ng AL, Shum JW. Review on the Management of Primary Congenital Glaucoma. J Curr Glaucoma Pract. 2015;9(3):92-9. doi: 10.5005/jp-journals-10008-1192 pmid: 26997844
17. Darlong V, Kalaiyarasan R, Baidya DK, Pandey R, Sinha R, Punj J, et al. Effect of airway device and depth of anesthesia on intra-ocular pressure measurement during general anesthesia in children: A randomized controlled trial. J Anaesthesiol Clin Pharmacol. 2021;37(2):226-230. doi: 10.4103/joacp.JOACP_55_19 pmid: 34349371
18. Lim R. The surgical management of glaucoma: A review. Clin Exp Ophthalmol. 2022;50(2):213-231. doi: 10.1111/ceo.14028 pmid: 35037376
19. Frączkiewicz-Skok M, Konopińska J, Mariak Z, Rękas M. Comparison of ExPress Implantation and Partial Deep Sclerectomy Combined with ExPress Implantation and Simultaneous Phacoemulsification. J Ophthalmol. 2019;2019:7424376. doi: 10.1155/2019/7424376 pmid: 31885894
20. Varga Z, Shaarawy T. Deep sclerectomy: safety and efficacy. Middle East Afr J Ophthalmol. 2009;16(3):123-6. doi: 10.4103/0974-9233.56223 pmid: 20142976
21. Pantalon A, Feraru C, Tarcoveanu F, Chiselita D. Success of Primary Trabeculectomy in Advanced Open Angle Glaucoma. Clin Ophthalmol. 2021;15:2219-2229. doi: 10.2147/OPTH.S308228 pmid: 34079219
22. Allison K, Patel D, Alabi O. Epidemiology of Glaucoma: The Past, Present, and Predictions for the Future. Cureus. 2020;12(11):e11686. doi: 10.7759/cureus.11686 pmid: 33391921
23. MacKinnon JR, Giubilato A, Elder JE, Craig JE, Mackey DA. Primary infantile glaucoma in an Australian population. Clin Exp Ophthalmol. 2004;32(1):14-8. doi: 10.1046/j.1442-9071.2004.00750.x pmid: 14746584
24. Aponte EP, Diehl N, Mohney BG. Incidence and clinical characteristics of childhood glaucoma: a population-based study. Arch Ophthalmol. 2010;128(4):478-82. doi: 10.1001/archophthalmol.2010.41 pmid: 20385945
25. Yassin SA, Al-Tamimi ER. Surgical outcomes in children with primary congenital glaucoma: a 20-year experience. Eur J Ophthalmol. 2016;26(6):581-587. doi: 10.5301/ejo.5000784 pmid: 27033964
26. Papadopoulos M, Cable N, Rahi J, Khaw PT; BIG Eye Study Investigators. The British Infantile and Childhood Glaucoma (BIG) Eye Study. Invest Ophthalmol Vis Sci. 2007;48(9):4100-6. doi: 10.1167/iovs.06-1350 pmid: 17724193
27. Alanazi FF, Song JC, Mousa A, Morales J, Al Shahwan S, Alodhayb S, et al. Primary and secondary congenital glaucoma: baseline features from a registry at King Khaled Eye Specialist Hospital, Riyadh, Saudi Arabia. Am J Ophthalmol. 2013;155(5):882-9. doi: 10.1016/j.ajo.2012.12.006 pmid: 23394909
28. Bayoumi NH. Surgical management of primary congenital glaucoma in Egypt. Journal of the Egyptian Ophthalmological Society. 2016;109(2):85-92. doi: 10.4103/2090-0686.193398
29. Mandal AK, Gothwal VK, Nutheti R. Surgical outcome of primary developmental glaucoma: a single surgeon's long-term experience from a tertiary eye care centre in India. Eye (Lond). 2007;21(6):764-74. doi: 10.1038/sj.eye.6702324 pmid: 16575414
30. Zhang X, Du S, Fan Q, Peng S, Yu M, Ge J. Long-term surgical outcomes of primary congenital glaucoma in China. Clinics (Sao Paulo). 2009;64(6):543-51. doi: 10.1590/s1807-59322009000600009 pmid: 19578658
31. Farid MF, Anany M, Awwad MA. Surgical Outcomes of Primary Congenital Glaucoma in Children Under One Year from the Nile Delta. Clin Ophthalmol. 2021;15:1145-1151. doi: 10.2147/OPTH.S299716 pmid: 33758497
32. Al-Obeidan SA, Osman Eel-D, Dewedar AS, Kestelyn P, Mousa A. Efficacy and safety of deep sclerectomy in childhood glaucoma in Saudi Arabia. Acta Ophthalmol. 2014;92(1):65-70. doi: 10.1111/j.1755-3768.2012.02558.x pmid: 23241279
33. Denis D, Pommier S, Coste R, Fogliarini C, Benso C, Cornand E. Glaucome congénital et sclérectomie profonde: résultats d'une étude sur plus de 3 années [Deep sclerectomy in congenital glaucoma: results of a study lasting more than 3 years]. J Fr Ophtalmol. 2008;31(2):173-9. French. doi: 10.1016/s0181-5512(08)70350-4 pmid: 18401318
34. Ghate D, Wang X. Surgical interventions for primary congenital glaucoma. Cochrane Database Syst Rev. 2015;1:CD008213. doi: 10.1002/14651858.CD008213.pub2. Update in: Cochrane Database Syst Rev. 2020;8:CD008213. pmid: 25636153
35. Elhofi A, Helaly HA. Non-Penetrating Deep Sclerectomy versus Trabeculectomy in Primary Congenital Glaucoma. Clin Ophthalmol. 2020;14:1277-1285. doi: 10.2147/OPTH.S253689 pmid: 32494118
36. Chiselita D. Non-penetrating deep sclerectomy versus trabeculectomy in primary open-angle glaucoma surgery. Eye (Lond). 2001;15(Pt 2):197-201. doi: 10.1038/eye.2001.60 pmid: 11339590

37. Correia Barbosa R, Gonçalves R, Bastos R, Alves Pereira S, Basto R, Viana AR, et al. Trabeculectomy Vs Non-penetrating Deep Sclerectomy for the Surgical Treatment of Open-Angle Glaucoma: A Long-Term Report of 201 Eyes. Clin Ophthalmol. 2023;17:1619-1627. doi: 10.2147/OPTH.S405837 pmid: 37304331
38. Alsheikheh A, Klink J, Klink T, Steffen H, Grehn F. Long-term results of surgery in childhood glaucoma. Graefes Arch Clin Exp Ophthalmol. 2007;245(2):195-203. doi: 10.1007/s00417-006-0415-2 pmid: 16983524
39. Cronemberger S, Calixto N, Avellar Milhomens TG, Gama PO, Milhomens EG, Rolim H, et al. Effect of intraocular pressure control on central corneal thickness, horizontal corneal diameter, and axial length in primary congenital glaucoma. J AAPOS. 2014;18(5):433-6. doi: 10.1016/j.jaapos.2014.05.012 pmid: 25439302
40. Quigley HA. Childhood glaucoma: results with trabeculotomy and study of reversible cupping. Ophthalmology. 1982;89(3):219-26. doi: 10.1016/s0161-6420(82)34803-4 pmid: 7088505
41. Al-Obaida I, Al Owaifeer AM, Ahmad K, Malik R. The relationship between axial length, age and intraocular pressure in children with primary congenital glaucoma. Sci Rep. 2020;10(1):17821. doi: 10.1038/s41598-020-74126-5 pmid: 33082416
42. Arede P, Przezdziecka-Dolyk J, Debowy F, Olszewski J, Fernandes C, Bruxelas C, Spohr H, Patricio S. Glaucomatous Macular Vasculature: A Quantitative Analysis. Med Hypothesis Discov Innov Ophthalmol. 2020;9(3):185-197. doi: 10.51329/mehdiophthal1403