Microcatheter-assisted circumferential trabeculotomy in primary congenital glaucoma

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Access this article online



Website: www.saudijophthalmol.org DOI: 10 4103/1319-4534 337864

Abstract:

PURPOSE: To study circumferential trabeculotomy for congenital glaucoma using Glaucolight illuminated microcatheter.

METHODS: This was a prospective, uncontrolled, consecutive interventional study of 25 eyes of 25 patients with primary congenital glaucoma (PCG) underwent circumferential trabeculotomy done with an illuminated microcatheter through a period of 18–24 months in ophthalmology department, faculty of medicine, Minia University, Egypt. Patients' data of 12 months' follow-up were recorded. The primary target was the mean intraocular pressure (IOP) study in which complete success was defined as an IOP ≤ 21 mm Hg and at least a 30% reduction without the use of antiglaucoma drugs and a qualified success when medications were used to reach this aim. The secondary target was studying the corneal diameter and cup disc ratio change.

RESULTS: The mean IOP (mm Hg) was reduced from 27.28 ± 3.46 preoperatively to 17.50 ± 5.09 at the final postoperative visit (P < 0.001). The mean follow-up period length was (18 months). A qualified success rate was reached to 88%, complete success in 76% and failure in 12%. No serious surgical complications were observed.

CONCLUSION: Circumferential trabeculotomy accomplished by an illuminated microcatheter achieved a significant IOP lowering with either qualified or complete success in most of eyes with no significant ocular complications and it can be the first option in pediatric PCG surgery.

Keywords:

Glaucolight microcatheter- primary congenital glaucoma- intraocular pressure.

INTRODUCTION

The management of primary congenital glaucoma (PCG) is almost always surgical and it can be surgical also in secondary glaucoma. The opening of the Schlemm's canal (SC) and trabecular meshwork is the preferred surgical procedure.^[1] Trabeculotomy is an ab-externo angle surgery performed in children with glaucoma in whom goniotomy has failed because of cloudy cornea or disease advancement.^[2] Verner-Cole *et al.* 2006 reported success rate of (87%–93%) for 6-0 suture 360° trabeculotomy.^[3] Its disadvantage was possible false direction in the suprachoroidal space.^[4] The rate of success of Harms

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trabeculotomy for congenital glaucoma ranged from (73% to 90%).^[5,6]

Recently, illuminated microcatheter has emerged and becomes one of the first alternative operative interferences for pediatric congenital glaucoma. In 2010, Sarkisian used an illuminated flexible microcatheter to be visualized in the SC and he performed 360° trabeculotomy for 16 children eyes that had PCG and reported reduction of intraocular pressure (IOP) by 46% at 6 months follow-up period without any microcatheter false passage.^[7] More recent studies reported success rate of (83%–91%) for this procedure at the end of follow-up period of 6 to 12 months.^[8-11]

The aim of our study was to report the 12 months results of this prospective study of illuminated

How to cite this article: M. Elwan SA, A.Abdallah RM, Abdelhalim AS. Microcatheter-assisted circumferential trabeculotomy in primary congenital glaucoma. Saudi J Ophthalmol 2021;35:117-21.

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microcatheter 360° trabeculotomy in the treatment of pediatric PCG.

Methods

This was a prospective study of 25 eyes of 25 patients with PCG underwent circumferential 360° trabeculotomy done with an illuminated microcatheter (DORC International, Zululand, Netherlands) through a period of 24 months from June 2017 to May 2019. Twenty patients were unilateral cases, out of them 12 were right eyes and 8 were left eyes while five patients were bilateral cases and only the right eyes were chosen to be included in the study and their left eyes underwent the same procedure but not included. The child parents were informed by the procedure and signed consent as well as the study was approved from Ethical Committees and was in accordance with the Declaration of Helsinki.

Inclusion criteria

The study included children aged below 6 years with PCG with or without antiglaucoma medications and not had previous antiglaucoma surgery with complete 360° trabeculotomy.

Exclusion criteria

Eyes that needs combined operation or had previous antiglaucoma procedure.

Preoperative examinations

Routine ocular examination or under general anesthesia (GA) for younger children were done after history taking including, age, sex, laterality, family history and consanguinity, antiglaucoma drugs. The ocular examinations includes IOP with Perkins tonometer, slit lamp, corneal clarity, measurement of horizontal corneal diameter (CD), axial length by ultrasonography in some of patients and fundus examination

Table	1:	Patients	demographic data	
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Parameters	Descriptions	
Eyes (n)	25	
Age (month), mean±SD (range)	14.28±12.25 (2-48)	
Sex (male/female)	15/10	
Bilaterality, <i>n</i> (%)	5 (20) only one eye included in the study	
Consanguinity, n (%)	10 (40)	
Family history, n (%)	5 (20)	
Mean IOP (mm Hg), mean±SD (range)	27.28±3.46 (22-35)	
Cup disc ratio, mean±SD (range)	0.6±0.2 (0.3-0.8)	
Corneal clarity		
Moderate cloudy cornea, n (%)	14 (56)	
Corneal diameter (mm), mean±SD (range)	12.32±0.76 (11-13.5)	
Number of anti-glaucoma drugs, n (%)		
No drugs	7 (28)	
Beta blockers	8 (32)	
Beta blockers + dorzolamide	6 (24)	
Beta blockers + dorzolamide + Prostaglandins	4 (16)	

IOP=Intraocular pressure; SD=Standard deviation

with the assessment of cup to disc ratio. The demographic data were registered as in [Table 1].

Surgical procedure

All cases were done under GA, routine ophthalmology scrubbing, and sterilization were done. Eye speculum was inserted then:

- Conjunctival peritomy with fornix-based flap was done in the upper nasal quadrant
- Superficial rectangular scleral flab 3.5 mm × 4.5 mm and deep scleral flab 2 mm × 3 mm with identification of SC were done
- Cutting SC and exposure of its ostia and dilatation of the ostia by injection of Healon
- Paracentesis to lower IOP and injection of Miochol for miosis and Healon to keep anterior chamber stable and deep
- Introducing the illuminated catheter into one of the SC ostium and advanced through the whole SC 360° circumference
- When the atraumatic tip of the catheter appeared from the other ostium, both ends were pulled in opposite direction to make 360° trabeculotomy
- Gentle A/C irrigation was performed if needed through the Paracentesis in case of marked significant hyphema
- Both Scleral flaps were closed with interrupted 10/0 nylon suture and Conjunctival flap with contentious 10/0 nylon suture
- Injection of sub conjunctival steroid and antibiotic, then eye dressing.

Postoperative management

The patients were prescribed topical tobradex (tobramycin-dexamethasone) eye drops QID and tapering through 4–6 weeks and topical cycloplegic eye drops TID for 3 days. Scheduled follow-up visits were advised next postoperative day, 1 week, monthly for 3 months then each 3 months till 1 year. Each visit, the child subjected to full ophthalmological examinations previously mentioned and antiglaucoma medications were prescribed when needed (IOP>21 mmHg) or appearing of signs of glaucoma progression starting by one drug beta blockers and adding dorzolamide or prostaglandin to reach the target IOP.

Patients' data of 12 months' follow-up were recorded. The primary target was mean IOP study in which complete success was defined as an IOP \leq 21 mm Hg and at least a 30% reduction without the use of antiglaucoma drugs, a qualified success when medications were used to reach this aim and failure if the target IOP would not reached in spite of full antiglaucoma medications and the child needs another antiglaucoma procedure. The secondary target was studying the CD and cup to disc (C/D) ratio change. The results of 1 week, 3 months, 6 months, and 1 year were included in the statistical analysis.

Statistical analysis

Data were collected and entered for statistical analysis done by SPSS (statistical package for the social sciences) version 20. Descriptive statistics data, mean and standard deviation were done. Statistical analysis using Wilcoxon signed ranks test for comparison of two related parameters preoperative and postoperative. *P* value was considered statistically significant if ≤ 0.05 for all tests.

RESULTS

Twenty-five eyes of 25 patients were enrolled in our study as shown in Table 1 in which the mean children age at time of surgery was (14.28 ± 12.25) with range (2-48) months. Fifteen were females and 10 were males. Five patients (20%) had bilateral PCG but only one eye included in the study in bilateral disease. Consanguinity was positive in 10 (40%), and positive family history in 5 (20%) of patients. The mean preoperative IOP was 27.28 ± 3.46 , range (22–35) mmHg and the mean vertical cup disc ratio was 0.6 ± 0.20 , range (0.3–0.8). The mean horizontal CD was 12.32 ± 0.76 , range (11-13.5) mm and cornea was cloudy in 14 (56%) of cases. The number of anti-glaucoma drugs were 8 eyes (32%) on only beta blockers 0.5%, 6 eyes (24%) on (beta blockers 0.5% + dorzolamide 2%) combination, 4 eyes (16%) on prostaglandin (latanoprost 0.005%) + (beta blockers 0.5% + dorzolamide 2% combination), while 7 eyes (28%) with no medications at presentation.

Intraoperative complications were mild hyphema in 17 (68%) and it was marked in 8 (32%) of cases, all were controlled and resolved gradually on the early postoperative days. Postoperative minor complications are shown in Table 2 in which mild inflammatory membrane was present in 3 (12%), mild corneal edema in 5 (20%), mild hyphema in 6 (24%) of eyes, shallow anterior chamber in one eye (4%), mild hyphema with mild epithelial toxicity in 2 eyes (8%), while 8 eyes (32%) had no postoperative complications. All of these minor complications were resolved and controlled with medical treatment with no sequally and there were no serious postoperative ocular

Table 2: Postoperative complications

	Frequency (%)
No	8 (32)
Mild inflammatory membrane	3 (12)
Mild corneal edema	5 (20)
Mild hyphema	6 (24)
Shallow anterior chamber	1 (4)
Mild hyphema + mild epithelial toxicity	2 (8)
Total	25 (100)

complications such as endophthalmitis, retinal detachment, choroidal detachment, suprachoroidal hemorrhage, cyclodialysis cleft, or secondary cataract formation.

The mean IOP, as shown in Table 3, was 27.28 ± 3.46 preoperatively and reduced to 17.50 ± 5.09 after 12 months' follow-up with (64%) reduction and it was highly significant different at all visits in comparison to the preoperative measurement (P < 0.001). The mean number of medications was reduced from 1.2 ± 0.8 to 0.6 ± 0.4 at 1 week with high significant difference (P < 0.001) and continued in reduction throughout the following visits to reach 0.3 ± 0.25 at 1 year visit.

Table 4 demonstrates the rate of success at different visits in which complete success obtained in 19 eyes (76%), qualified success in 22 eyes (88%) and failure in 3 eyes (12%) at the last follow up visit. The three eyes that failed surgery underwent another antiglaucoma operation in which trabeculectomy was done 4–8 months from the initial microcatheter trabeculotomy because their IOP was higher than 25 mmHg in spite of full antiglaucoma medications.

Table 5 shows the mean change in CD and C/D ratio overtime in which the mean preoperative horizontal CD reduced from 12.32 ± 0.76 mm to 11.44 ± 0.60 and 11.32 ± 0.74 with about 1 mm (9%) difference and it was statistically significant at 6 and 12 months visits, respectively (P < 0.001). Regarding the mean vertical C/D ratio it was reduced from 0.6 ± 0.2 to 0.48 ± 0.34 and 0.45 ± 0.55 with 0.12 mm (20%) and 0.15 mm (25%) reduction from the preoperative value at 6 and 12 months visits, respectively (P < 0.01 and < 0.001).

DISCUSSION

To avoid the complications of hard instrument trabeculotomy, bleb-associated complications and anti-metabolites use in glaucoma surgery we used this new procedure in the management of PCG with current results comparable with many retrospective studies^[7,9-14] and few prospective studies^[8,15,16] such as our study.

In this study, the mean IOP was 27.28 ± 3.46 preoperatively and reduced to 17.50 ± 5.09 at 12 months follow-up with (64%) reduction with high significant difference at all visits in comparison to the preoperative measurement (P < 0.001) as well as the mean number of medications were reduced from 1.2 ± 0.8 to 0.6 ± 0.4 at 1 week with high significant difference (P < 0.001) and continued in reduction throughout

Table 3: Intraocular	pressure and	number of	anti-glaucoma	medications

IOP (mmHg)	Mean±SD	P-value from preoperative	<i>P</i> -value from previous follow up visit	Number of medications	<i>P</i> -value from previous follow up visit
Preoperative	27.28±3.46			1.2±0.8	
1 week	17.7±6.3	< 0.001*	< 0.001*	$0.6{\pm}0.4$	<0.001*
3 months	17.2 ± 4.9	< 0.001*	0.678	0.5 ± 0.44	0.9
6 months	17.3±4.8	< 0.001*	1	0.2±0.3	0.01*
1 year	17.5 ± 5.09	< 0.001*	0.799	0.3±0.25	0.4

IOP=Intraocular pressure; SD=Standard deviation

the following visits to reach 0.3 ± 0.25 at 1 year visit and these findings were comparable to that of Sarkisian 2010^[7] who is the first one to use this procedure and obtained reduction of IOP from 30.1 ± 5.4 to 13.5 ± 0.7 at 6 months follow up with (47%) reduction and reduction in the mean number of medications from $(1.3 \pm 0.9 \text{ to } 0.00)$ at 1 year in his retrospective study of 16 eyes of PCG only 12 that had complete 360° trabeculotomy. The difference in the percentage of reduction of IOP between his and ours may be attributed to the nature of study design retrospective, with small number of eyes (12) and prospective, (25 eyes), race difference Caucasian (14)-Hispanic (2) versus all Egyptian children and the younger mean children age $(0.7 \pm 0.6 \text{ vs. } 14.28 \pm 12.25)$ months for him versus for us, respectively. In addition, our results were comparable to the results of El Sayed and Gawdat, $2017^{[8]}$ in which the mean IOP was reduced from 25.1 ± 6.4 to 11.8 ± 4.4 at 12 months' follow-up with (47%) reduction and reduction in the mean number of medications from (0.6 ± 0.9) to 0.2 ± 0.6) at 1 year in their prospective study of 62 eyes (30 eyes for microcatheter and 32 for rigid probe trabeculotomy) whoever, their patients were younger in which the mean age was 5.6 ± 7.3 and complete 360° trabeculotomy were on 50%of eyes in the microcatheter group and this finding postulated that when the age is younger the percentage of reduction of IOP will be lower due to severe angle anomalies and poor outcome when glaucoma had early onset in this younger age.

Our results for IOP reduction were also comparable with Toshev *et al.*, $2018^{[11]}$ in which the mean IOP was reduced from 28.6 \pm 0.5 to 13 \pm 2.7 with (54.5%) reduction and reduction in the mean number of medications from (0.8 to 0.3) at 15.3 months' follow-up in their retrospective study for Group 1 (PCG) with complete 360° trabeculotomy.

Our results viewed complete success in 76%, qualified success in 88% and failure in 12%, these finding were comparable with Toshev *et al.*, $2018^{[11]}$ in which complete success was 80% and qualified success was 100% and comparable with El Sayed and Gawdat, $2017^{[8]}$ in which complete success was 67%, qualified success 85% and failure 15% in microcatheter

Table 4: Success an	d failure rate over time
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	Number of eyes	Complete success (%)	Qualified success (%)	Failure
1 week	25	19 (76)	24 (96)	1
3 months	25	17 (68)	23 (92)	2
6 months	25	18 (72)	22 (88)	3
1 year	25	19 (76)	22 (88)	3

Group 1 and in comparison to slightly higher results of Girkin *et al.*, 2012^[17] in which complete success was reached in 81.8%, qualified success in 90.1% and it increased to 87.5 and 100% if eyes with previous angle surgery were excluded however, their study involved only 11 eyes with PCG or secondary childhood glaucoma and 3 of them had previous angle surgery and used another type of illuminated microcatheter (iTRACK 250A; iScience Interventional, Menlo Park, CA) and shorter follow-up period.

Regarding to CD, it was reduced from 12.32 ± 0.76 mm to 11.44 ± 0.60 and 11.32 ± 0.74 with about 1 mm (9%) difference and it was statistically significant at 6 and 12 months' visits, respectively (P < 0.001) and the mean vertical C/D ratio was reduced from 0.6 ± 0.2 to 0.48 ± 0.34 and 0.45 ± 0.55 with 0.12 mm (20%) and 0.15 mm (25%) reduction from the preoperative value at 6 and 12 months' visits, respectively (P < 0.01and < 0.001) and this finding was in agreement with that of Tanuj Dada *et al.*, $2014^{[18]}$ in which they reported in their series 17.5% reduction in cup disc ratio at 12-month follow-up. The previous findings demonstrate the efficacy of this procedure in prevention of glaucoma progression.

In comparison of the results of microcatheter procedure and other antiglaucoma operations, it was superior in many studies. It was superior to rigid probe trabeculotomy in series of Shakrawal et al.,^[15] in which the complete success rate was 80% versus 60% and the qualified success was 90% versus 70% and with El Sayed and Gawdat^[8] in which the complete success rate was 67% versus 47% and qualified success was 85% versus 50% and failure rate was 15% versus 50%. When it was used for ab-interno transluminal gonioscopy assisted trabeculotomy in PCG. IOP reduced from 31 mmHg with mean 1.5 antiglaucoma drugs to 19.5 mmHg without drug use as demonstrated by Grover et al.,^[19] However, it was comparable to combined trabeculotomy-trabeculectomy with Mitomycin C (MMC) in which IOP reduction was 46.92% versus 46.61% as reported by Temkar et al.,[16] Unlike goniotomy, it can be easily done in cloudy cornea as 14 eyes (56%) of our cases had cloudy cornea.

In this study, intraoperative complications were mild hyphema in 17 (68%) and it was marked in 8 (32%) of cases, all cases resolved gradually on the early postoperative days and there were minor postoperative complications that were resolved and controlled with medical treatment with no sequally and there were no serious postoperative ocular complications such as endophthalmitis, retinal detachment, choroidal

Table 5: Corneal diameter (mm) and cup to disc ratio over time

CD (mm)	$Mean \pm SD$	Range	Р	Cup/disc ratio, mean±SD	Range	Reduction (%)	Р
Preoperative	12.32±0.76	11-13.5		0.6±0.2	3-8		
1 week	12.42±0.76	11-13	0.98	0.6±0.3	3-8	0 (0)	1
3 months	11.84 ± 0.68	11-13	0.62	0.55±0.3	3-6	0.05 (8.3)	0.9
6 months	11.44 ± 0.60	11-12.5	< 0.001*	$0.48{\pm}0.34$	3-5.5	0.12 (20)	0.01*
1 year	11.32 ± 0.74	11-12	< 0.001*	0.45 ± 0.55	3-4.5	0.15 (25)	< 0.001*

Number of patients=25 for both of CD and C/D ratio. CD=Corneal diameter; C/D=Cup to disc ratio

detachment, suprachoroidal hemorrhage, cyclodialysis cleft or secondary cataract formation as the illuminated atraumatic catheter tip make the procedure easy and under vision during cannulation and hence less serious complication from false passage.

CONCLUSION

Circumferential 360° trabeculotomy accomplished by an illuminated microcatheter achieved a significant IOP lowering with either qualified or complete success in most of eyes with no significant ocular complications and it would be advised as one of the first choices in treatment of PCG as well as it can be easily used in cloudy cornea. Further studies were needed to evaluate this procedure with more number of patients and long follow-up period.

Acknowledgments

Authors would like to acknowledge the overwhelming support from all of my colleges in Ophthalmology Department, Minia University, Egypt, with special concern to the Glaucoma team. Also to the nurse stuff and the health workers who contributed to the field work.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

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