Published in final edited form as:

J Glaucoma. 2019 January ; 28(1): 1–6. doi:10.1097/IJG.0000000000001116.

Microcatheter-assisted trabeculotomy for primary congenital glaucoma after failed glaucoma surgeries

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Abstract

Purpose: To evaluate the effectiveness of microcatheter-assisted trabeculotomy (MAT) to treat primary congenital glaucoma(PCG) after failed prior glaucoma surgeries.

Methods: Retrospective, non-comparative, interventional case series conducted at Beijing Tongren Eye Center, China. Outcome measures were compared between three groups: Successful and complete (≥330-degrees) MAT; successful and partial (<330-degrees) MAT; or cases converted to traditional trabeculotomy when Schlemm's canal could not be catheterized > 180-degrees. Success was defined as final intraocular pressure ≤21 mmHg, with (qualified success) or without (complete success) glaucoma medications.

Results: Seventy-four eyes of 63 consecutive patients were included. MAT was performed in 50 eyes (67.6%). Post-operative intraocular pressure and number of glaucoma drops (17.7 ± 8.6 mmHg, 0.6 ± 1.2 medications) was significantly less than the pre-operative values (35.3 ± 7.2 mmHg, 2.7 ± 0.8 medications; $P < 0.001$). Cumulative probabilities of qualified and complete success were 84.0% and 80.0% at 3-year follow-up with no difference between complete and partial trabeculotomies. MAT was not successfully performed in 24 eyes (32.4%), requiring conversion to traditional trabeculotomy and associated with greater incidence of previous surgeries ($P < 0.001$), earlier age of disease onset ($P = 0.024$) and worse corneal transparency ($P = 0.010$). Cumulative probabilities of qualified and complete success were 37.0% and 29.2% at 3-year follow-up.

Conclusions: Both complete and partial MAT achieved significant pressure reduction in cases of PCG with previous failed glaucoma surgeries in intermediate-term.

Keywords

childhood glaucoma; primary congenital glaucoma; trabeculotomy; illuminated microcatheter; 360 degree

Introduction

The most common cause of glaucoma in the pediatric population is primary congenital glaucoma (PCG) which can have devastating visual consequences.^{1, 2} The pathogenesis of PCG is thought to be related to a developmental abnormality of the trabecular meshwork leading to an obstruction of the aqueous humor outflow pathways.³ Angle surgeries, including goniotomy and trabeculotomy ab externo, are the surgical mainstay for PCG and target rehabilitation of outflow by removing the obstruction.^{4, 5} Specifically, in cases of hazy corneas, trabeculotomy ab externo is easier and often the preferred initial surgery.^{6, 7}

While angle surgeries can lower intraocular pressure (IOP), angle surgery alone fails to control IOP in 6.5% to 52.2% of PCG cases.^{6, 8} Children with PCG who are unresponsive to conventional angle surgery then have difficult to manage IOP and often poorer prognosis.⁹ Repeat trabeculotomy is then also challenging because of reduced availability of un-operated regions on the eye to perform additional surgery. Filtering surgery is typically less successful in younger patients due to an exuberant healing response.¹⁰ Glaucoma drainage devices offer IOP control, but there is a risk of implant-related complications over time.^{11, 12}

Microcatheter-assisted trabeculotomy has been recently introduced and has shown significantly improved results compared to traditional angle surgeries as the initial procedure for treating PCG.^{13–16} For eyes with previously failed surgery, MAT continues as a viable option¹⁷ since it uses a small incision and because it targets the entire circumferential outflow pathways, especially the inferior angle that is untreated by traditional goniotomies and trabeculotomies.

Therefore, the purpose of this current study is to report the intermediate-term effectiveness and safety of the MAT in PCG refractory to prior conventional surgeries and to identify ocular and patient features related to success.

Materials and Methods

Study design

This retrospective study included PCG patients at Beijing Tongren Eye Center (February 2014 to June 2016) who underwent trabeculotomy using an ophthalmic microcatheter (iTRACK 250A; iScience Interventional, Menlo Park, CA, USA) after failed glaucoma surgery. The previous failed glaucoma surgeries included one or more traditional trabeculotomies or any filtering surgery. Patients included in the analysis had examinations consistent with the diagnosis of PCG, including isolated trabeculodysgenesis without any other ocular or systemic abnormalities, elevated IOP, increased corneal diameter, corneal edema, increased axial length, and glaucomatous cupping of the optic nerve. Patients were

excluded from this study if they had undergone any ophthalmic surgery other than glaucoma surgeries.

A detailed history was elicited for all patients, and each subject had an initial examination under anesthesia with 80-MHz ultrasound biomicroscopy (iUltrason, iScience Interventional) to evaluate suitability for trabeculotomy. Cases with more than 180° of peripheral anterior synechiae were excluded. All cases had a minimum of 18 months of follow-up. Written informed consent was obtained from the parents of eligible subjects after thoroughly explaining the risks and benefits of the procedure. This study was approved by the Ethics Committee of Beijing Tongren Eye Center and was registered under the Chinese Clinical Trials Registry (ChiCTR-OCC-15005789). This study conformed to the tenets of the Declaration of Helsinki.

Surgical procedure and postoperative care

Surgery was performed under general anesthesia by either HW or NW in accordance with standard procedures that have been described previously.^{13, 16, 18} Briefly, a ~60-degrees fornix-based conjunctival flap was made lateral to the previous flap (or bleb, if present) to avoid areas of possible Schlemm's canal damage from prior surgeries. Schlemm's canal was exposed by either a scleral cut down under a superficial scleral flap or by direct unroofing of a deep scleral flap. The microcatheter was then placed into one cut end of the canal and gradually advanced, with the illuminated tip providing the precise location of the catheter. If successful, 360-degree catheterization was achieved, and the two ends of the microcatheter were grasped and pulled toward one another like a purse string that would create an opening from Schlemm's canal through the trabecular meshwork into the anterior chamber. In some cases, the microcatheter would reach an obstruction or become misdirected. The conjunctiva was then incised and a scleral cut down was performed over the illuminated catheter tip, which was retrieved at the point of obstruction. Both ends of the catheter were then grasped and pulled, performing a partial trabeculotomy. If the microcatheter could not be passed at least 180-degrees within the canal in either clockwise or counterclockwise direction, a traditional trabeculotomy was performed using Harms metal trabeculotomies which were placed into the presumed canal beneath the original scleral flap. In all cases, the scleral flap and overlying conjunctiva were securely sutured with 10–0 nylon sutures. Gentle anterior chamber irrigation was performed via a paracentesis for rare occasions of significant hyphema. Tobramycin-dexamethasone ophthalmic ointment (TobraDex, Alcon, Rijksweg, Belgium) was administered, and the eye was patched at the end of each case.

Postoperatively, tobramycin-dexamethasone and pranoprofen (Pranopulin, Senju Pharmaceutical, Osaka, Japan) drops were used 4 times daily for 2–4 weeks. Pilocarpine 2% (Bausch & Lomb, Rochester, NY, USA) drops were used 3 times daily for 3 months to limit the development of peripheral anterior synechiae.

Outcome measures and statistical analysis

Baseline patient history and ocular characteristics were obtained from the chart or exam under anesthesia. IOP was measured at baseline and at follow-up examinations using an

Icare tonometer (Icare TA01i, Icare Finland Oy, Espoo, Finland) under chloral hydrate (CH) sedation if the patients could not cooperate. The median dosage of

CH given was 75 mg/kg (range: 50–100 mg) with either oral or rectal administration). Corneal transparency was scored as follows: 1+, complete corneal transparency; 2+, mild corneal opacity with visible iris; 3+, severe opacity blocking the iris; 4+, severe corneal opacification with neovascularization. In addition, 0.5 points were added to the corneal opacity score when accompanied by Haab's striae.¹⁹ Surgical success was defined as IOP ≤ 21 mmHg, not requiring further glaucoma surgery and absence of complication -- with (qualified success) or without (complete success) topical glaucoma medications. A complete trabeculotomy referred to a ≥ 330 -degree trabeculotomy (avoiding the previous surgical incision by ~ 30 -degrees). A partial trabeculotomy was < 330 -degrees.

Demographic and clinical characteristic data were reported as the mean $\pm$ standard deviation with the range specified. The data of the clinical features were compared between two subsets (Successful Group: successfully performed MAT and Failed Group: unsuccessful MAT requiring conversion to traditional trabeculotomy) using either a 2-tailed unpaired *t*-test with Welch's correction or a Mann-Whitney U test depending on whether the populations fit a Gaussian distribution as shown by the Shapiro-Wilk normality test. The pre-operative and last post-operative (ie, at the last follow-up visit or when failure criteria were reached) IOP was compared using the Mann-Whitney U test. Kaplan-Meier life table analyses were performed to evaluate complete and qualified success. Survival curves between groups were compared using the log-rank (Mantel-Cox) test with the chi-square significance test. Results were considered significant when $P < 0.05$. All statistical tests were performed using SAS (Statistical Analysis System, North Carolina State University) software.

Results

Patient demographics and surgical procedure

Seventy-four eyes of 63 patients with PCG, who had previously failed glaucoma surgeries, were operated on within the designated study period. The follow-up period ranged from 18 to 48 months (31.0 ± 7.9 mo). Twenty-two of the 74 eyes were reported in our prior study with short-term follow-up.²⁰ MAT was performed (Successful Group) in 50 (67.6%) of the 74 eyes, with complete circumferential trabeculotomy achieved in 22 eyes and partial circumferential trabeculotomy achieved in 28 eyes ($246.4 \pm 44.2^\circ$, range: 180° – 330°). MAT was not successfully performed (Failed Group) in the remaining 24 (32.4%) eyes, and they all underwent traditional trabeculotomy (Table 1).

The demographics and ocular characteristics were compared between those cases in which MAT was successfully performed (Successful Group) and cases in which the initial MAT failed (Failed Group; Table 1). The Failed Group had undergone a significantly higher number of previous surgeries, compared with the Successful Group ($P < 0.001$). Among the total 74 eyes, 39 (52.7%) had undergone only a single previous surgery, among which 15 eyes had trabeculotomy, 15 eyes had trabeculotomy combined with trabeculectomy, and 9 eyes had trabeculectomy with antimetabolite. Among the 39 eyes, MAT was successfully

performed in 34 (87.2%) eyes, specifically 14 of 15 with trabeculotomy, all 9 of those with trabeculectomy, and 11 of 15 with trabeculotomy combined with trabeculectomy. Thirty-five (47.3%) among the total 74 eyes received more than one prior operation (trabeculotomy, trabeculectomy, drainage device, cyclodestruction, or a combination of these). Among these 35 eyes, MAT was successfully performed in 16 (45.7%) eyes.

In addition to the number of previous surgeries, the Successful and Failed Groups differed significantly with regard to the age of disease onset and corneal transparency (Table 1). Patients for whom MAT was not successfully performed developed PCG at an earlier age ($P = 0.024$) and had worse corneal transparency ($P = 0.010$). There was no significant difference with respect to horizontal corneal diameter ($P = 0.233$), cup-to-disc ratio ($P = 0.320$), and preoperative IOP ($P = 0.178$) between the two subsets (Table 1). Measurement of the cup-to-disc ratio was only possible in 43 of 74 eyes due to corneal clouding (27/50 in the Successful Group and 16/24 in the Failed Group).

IOP Change and Success Rate

Among the 50 eyes successfully treated by MAT (Successful Group), mean IOP prior to surgery was 35.3 ± 7.2 mmHg. At last follow-up or time of failure, mean IOP was 17.7 ± 8.6 mmHg (decreased $47.6 \pm 27.6\%$ from baseline; $P < 0.001$ compared with pre-operative IOP; Fig. 1). The post-operative number of topical glaucoma medications (0.6 ± 1.2) was significantly lower than that of the pre-operative number (2.7 ± 0.8 ; $P < 0.001$). The cumulative rates of qualified success were 84.0%, at both 12 and 36 months postoperatively (Fig. 2, right dotted line). The cumulative rates of complete success were 80.0%, both at 12 and 36 months (Fig. 2, left dotted line). All failures occurred within postoperative months 6–9, with 4 cases failing at 1 month postoperatively, 4 cases failing at 6 months postoperatively. TWO eyes required medication at 3 months and 9 months respectively to help control IOP.

In 24 eyes where MAT was not successfully performed (Failed Group) and that underwent traditional trabeculotomy with a rigid probe, IOP prior to surgery was 33.1 ± 6.3 mmHg. At the last follow-up or time of failure, the IOP was 25.8 ± 10.0 mmHg (decreased $21.1 \pm 31.4\%$ from baseline; $P = 0.004$ compared with pre-operative IOP; Fig. 1). The number of glaucoma medications was reduced to 2.0 ± 1.4 from a pre-operative number of 3.0 ± 0.7 ($P = 0.002$). There was 55.8% qualified and 33.3% complete success at 12 months postoperatively (Fig. 2 solid lines) and 37.0% qualified and 29.2% complete success at 36 months postoperatively (Fig. 2 solid lines).

Complete MAT Compared to Partial MAT

In 22 eyes that underwent complete circumferential trabeculotomy, there was 86.4% qualified and 77.3% complete success at both 12 and 36 months postoperatively. In 28 eyes that underwent partial trabeculotomy, there was 82.2% qualified and 82.2% complete success at both 12 and 36 months postoperatively. All patients were completely successful. The success rate was not significantly different between these two 2 groups (Fig. 3 left, complete success $P = 0.96$; Fig. 3 right, qualified success $P = 0.76$).

Complications

Blood reflux was noted intraoperatively, and minimal-to-little hyphema was seen on the first postoperative day in all patients. At the 1-month follow-up examination, no patient had any evidence hyphema. One eye (traditional trabeculotomy group) had a transient shallow anterior chamber 1–2 days after surgery which recovered spontaneously 2 days later, and no persistent hypotony. No choroidal detachment was found in the B-ultrasound 2 weeks after the operation. There were no cases of iris tears, Descemet's tears, or persistent hypotony.

Discussion

Goniotomy or trabeculotomy ab externo remains the primary surgical therapy for PCG which have success rates ranging from 80% to 90% after a mean follow-up of 1–3 years.⁶ However, over 30% PCG require multiple operations.²¹ Children unresponsive to standard surgical therapy have a poorer prognosis for long-term pressure control. Zagora et al. reported in a 23-year follow-up study that there was 60.9%, 53.5%, 18.2% surgical success for the first, second, and third procedures for PCG, respectively.⁹ Success was not noted after the fourth procedure.⁹

In the current study, all eyes had undergone previous failed glaucoma surgeries with 47.3% of the eyes having undergone more than one procedure. After successful MAT, a significant reduction in IOP and medication burden was achieved with an overall cumulative survival rate of 84.0% after 3 years (with or without medication). However, some eyes failed initial attempt at MAT and required conversion to traditional trabeculotomy. While not as successful as eyes that did not require conversion, significant reduction in IOP and medication burden was still seen. In an intent-to-treat analysis, where the planned treatment strategy consisted of the primary intention of MAT with conversion to rigid probe trabeculotomy for select cases, the overall cumulative probabilities of survival (based on the final number of cases successfully treated by either MAT or rigid probe trabeculotomy) still reached 70.1% by the end of the follow-up period. This was similar to our prior short-term study which included 22 eyes with PCG after failed angle surgery.²⁰

Our results were also comparable to variable success seen in other surgical approaches for these challenging patients but with less complication. Trabeculectomy had a success rate between 32% to 100% at one year (most studies reporting 50–87%), but surgical efficacy decreased over time.^{10, 22, 23} Young patients also tended to have worse outcomes. The frequency of trabeculectomy complications varied and could be as high as 66.6% in cases utilizing mitomycin C.²² Glaucoma drainage devices, often chosen for PCG after previous failed surgery, had an overall success rate of 53–63% after 2 years.^{11, 12} However, during the same time period, rates of complications ranged from 26.7% to 45.7% and included corneal decompensation, retinal detachment, hypotony, phthisis, and other tube-related complications.^{11, 12}

Compared with previous studies which mainly focused on MAT as an initial treatment,^{15, 18} there was a higher rate of failure to catheterize Schlemm's canal in the current study. These eyes required conversion to traditional trabeculotomy and had worse outcomes compared to eyes that had successful microcatheter-associated trabeculotomy. Increased difficulty in

performing MAT was likely related to Schlemm's canal damage and restriction of catheter passage because of the greater number of prior failed glaucoma surgeries seen in this group (Table 1). Other factors related to failed MAT were an earlier age of disease onset and worse initial corneal transparency. Li et al.²⁴ had reported that eyes with PCG-related corneal haze had 1.3-fold greater risk of surgical failure compared to eyes without the haze and suggested that corneal haze was an indicator of generally more severe disease. Therefore, intrinsic factors related to greater baseline disease severity of abnormal anatomy could explain both the increased difficulty to catheterize Schlemm's canal in the overall group and worse outcomes seen when conversion to traditional trabeculotomy was required.

The debate regarding the minimum degree of angle opening required for successful IOP reduction in PCG is controversial. In our study, we found no difference in success between complete or partial MAT (Fig. 3). This is consistent with the study of Girkin et al.¹⁴. However, Sarkisian¹⁸ reported that eyes with complete 360-trabeculotomy had significantly lower IOP compared with those with partial trabeculotomy. This difference may be explained by half of Sarkisian's partial trabeculotomy group being rigid probe trabeculotomies rather than partial microcatheter-assisted trabeculotomies. A major advantage of MAT, even when done partially, is that the illuminated tip facilitates the placement and advancement of the microcatheter. This allows for more accurate placement of the catheter for a precise opening of the inner wall of Schlemm's canal. In fact, 14 eyes in this study that had undergone previous rigid probe trabeculotomy achieved complete catheterization. This indicated that Schlemm's canal was still intact either because the initial rigid probe trabeculotomy had fully healed shut or that Schlemm's canal had not been opened during the first surgery due to inaccurate placement of the rigid probe. It has been reported that aqueous humor outflow is segmental and that only a handful of aqueous veins account for the majority of aqueous outflow at any given time.^{25–29} Therefore, it makes sense that partial opening of Schlemm's canal may be sufficient to lower IOP so long as it is performed accurately.

In this study, use of the microcatheter resulted in no complications other than transient hyphema which resolved spontaneously by post-operative day 7. This is consistent with previous studies on microcatheter-assisted trabeculotomies.^{13–16, 18, 20} Using the illuminated tip to continuously verify the catheter location within the Schlemm's canal, complications caused by misdirection and tissue disruption³⁰ can be avoided and thereby improve the safety of the procedure.

In conclusion, this study showed that MAT was an effective option for the management of complicated PCG patients who had previously failed glaucoma surgeries. After successful MAT, PCG patients had significant IOP reduction and lower medication burden. The rate of success was further related to patient characteristics such as the age of disease onset, level of corneal haziness, and the number of prior failed glaucoma surgeries.

Acknowledgments

Financial Support: This study was partially supported by the Beijing Municipal Science & Technology Commission, PR China (Grant number is Z161100000516081) and National Natural Science Foundation of China

(Grant number is 11571031). The sponsors or funding organizations had no role in the design or conduct of this research. Partially supported by RPB Career Development Award (AH) and NIH K08EY024674 (AH)

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Figure 1.

Box-whisker plot of preoperative vs postoperative intraocular pressure (IOP) in cases in which microcatheter-assisted trabeculotomy (MAT) was successfully performed (Successful Group) and cases in which the initial MAT failed (Failed Group). The median (50th percentile) is represented by the horizontal centerline, and the 25th and 75th percentiles as the lower and upper limits of the box. The upper and lower horizontal bars represent the maximum and minimum values, respectively, of a 1.5 interquartile range. The '+' symbols represent outliers. Outliers were denoted in the figure because they resided outside of the 1.5 interquartile range. These cases were included in all results calculations such as averages and survival rates. There was a significant reduction in IOP in each group as compared to pre-operative values. (Successful Group: $n = 50$, Failed Group: $n = 24$). IOP = intraocular pressure.

Figure 2.

Kaplan-Meier survival plot over 36 months of the cumulative probability of success for the cases in which microcatheter-assisted trabeculotomy (MAT) was successfully performed (Successful Group, $n = 50$; dotted line) and cases in which the initial MAT failed (Failed Group, $n = 24$; solid line). Left: complete success, Right: qualified success.

Figure 3.

Kaplan-Meier survival plot of the cumulative probability of success for complete circumferential trabeculotomy ($n = 22$; solid lines) and partial trabeculotomy ($n = 28$; dotted lines) with microcatheter-assisted trabeculotomy over 36 months. The 2 curves were not significantly different when compared using the log-rank (Mantel-Cox) test. Left: complete success, $P = 0.96$. Right: qualified success, $P = 0.76$.

Table

Demographics and ocular characteristics of eyes where microcatheter-assisted trabeculotomy was successfully (Successful Group) or not successfully (Failed Group) performed.

Parameter	Total	Successful Group	Failed Group
No. of patients	63	42	21
No. of eyes (%)	74(100%)	50(67.6%)	24(32.4%)
Sex, no. of patients			
Male	46	31	15
Female	17	11	6
Age at surgery (months)			
Mean±SD	58.3±44.2	56.8±38.0	61.6±55.9 b
Range	7-252	7-163	12-252
Age of onset (months)			
Mean±SD	12.4±21.1	15.0±23.0	7.1±15.5 b*
Range	0-84	0-84	0-60
Horizontal Corneal diameter (mm)			
Mean±SD	13.4±1.1	13.3±1.2	13.7±1.0a
Corneal transparency Score			
Mean±SD	2.0±0.7	1.8±0.5	2.3±0.7 b*
Cup-to-disc ratio			
Mean±SD	0.84±0.14	0.84±0.16(n =27)	0.83±0.11(n =16) b
No. of previous surgeries			
Mean±SD	1.7±1.1	1.5±1.2	2.2±0.8 b*
Preoperative IOP (mmHg)			
Mean±SD	34.6±7.1	35.3±7.2	33.1±6.3a
Preoperative medications			
Mean±SD	2.8±0.8	2.7±0.8	3.0±0.7 b
Follow-up (months)			
Mean±SD	31.0±7.9	29.6±8.2	33.8±6.8
Range	18-42	18-42	18-42