• Clinical Research •

Viscocanalostomy combined with trabeculotomy and mitomycin C in the treatment of primary congenital glaucoma

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Abstract

• AIM: To evaluate the long-term outcome of viscocanalostomy combined with trabeculotomy and mitomycin C in the treatment of primary congenital glaucoma.

• METHODS: This is a retrospective study. Forty-two eyes of 26 patients with primary congenital glaucoma were enrolled. Intraocular pressure (IOP), corneal diameter (mm) and cup/disc (C/D) were measured before and after the surgery respectively. Follow-up period was 30mo.

• RESULTS: The mean preoperative IOP was 30.6±7.35 mm Hg. Of the 42 eyes, 2 eyes were required conversion to trabeculectomy for the absence of Schlemm's canal. Of remained 40 eyes, 38 eyes (95%) achieved successful IOP control. The average postoperative IOP was 11.69±4.18 mm Hg at 12mo. The mean reduction was 18.91 mm Hg (P<0.0001). Eighteen (75%) eyes presented a reduction in corneal diameter, and 25 (62.5%) eyes presented a C/D ratio reversal after the surgery. There was no serious complication in any patients over the follow-up period.

• CONCLUSION: Viscocanalostomy combined with trabeculotomy and mitomycin C is useful in the management of primary congenital glaucoma.

• KEYWORDS: glaucoma; treatment surgery; intraocular pressure; congenital eye disorders

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INTRODUCTION

Primary congenital glaucoma (PCG) is characterized by significantly increased intraocular pressure (IOP) with accompanied symptoms and signs. Recently, surgical intervention remains the main option for the initial treatment of PCG. The conventional therapies include goniotomy, trabeculotomy, combined trabeculotomy-trabeculectomy and trabeculectomy. Non-penetrating filtering surgery (NPFS) began in 1962 with the first sinusotomy performed by Kraznov[1]. Viscocanalostomy was one of non-penetrating filtering firstly described by Stegmann in 1999. This surgery has been considered to be quite effective in lowering IOP, with less risks of complication[2]. The operator did viscocanalostomy, and combined with trabeculotomy and mitomycin C for the PCG's treatment. The aim of this study was to demonstrate the IOP lowering effects and the potential complications of viscocanalostomy combined with trabeculotomy (VCT) and mitomycin C in patients with PCG.

SUBJECTS AND METHODS

Patients This study has been approved by the Ethics Committee of the First Affiliated Hospital of Nanjing Medical University. The study was conducted on the patients' records. Twenty-six Chinese patients (20 males, 6 females), 42 eyes with uncontrolled PCG were enrolled in this study. Patient's age ranged from 3 to 36mo (mean 10.7mo). All the relevant data were collected from 2012 to 2015, and every child's parents had signed the informed consent.

The inclusion criteria were: 1) the IOP is greater than 21 mm Hg in one eye as measured by applanation tonometry on at least two occasions is considered abnormally elevated; 2) enlargement of the globe (axial length); 3) increased corneal diameter; 4) anomalously cup/disc (C/D) ratio.

The exclusion criteria were: 1) patients who had previous surgery; 2) secondary glaucoma; 3) Axenfeld-Rieger syndrome; 4) Aniridia or Sturge-Weber syndrome.

Baseline examinations: at the baseline visit, all patients had a full ocular examination under anesthesia by ketamine to confirm the diagnosis.

Methods The following examinations were performed at the baseline visit: IOP (TONO-Pen AVIA, Reichert, NY, USA), corneal diameters (with Caliphers), the presence of corneal

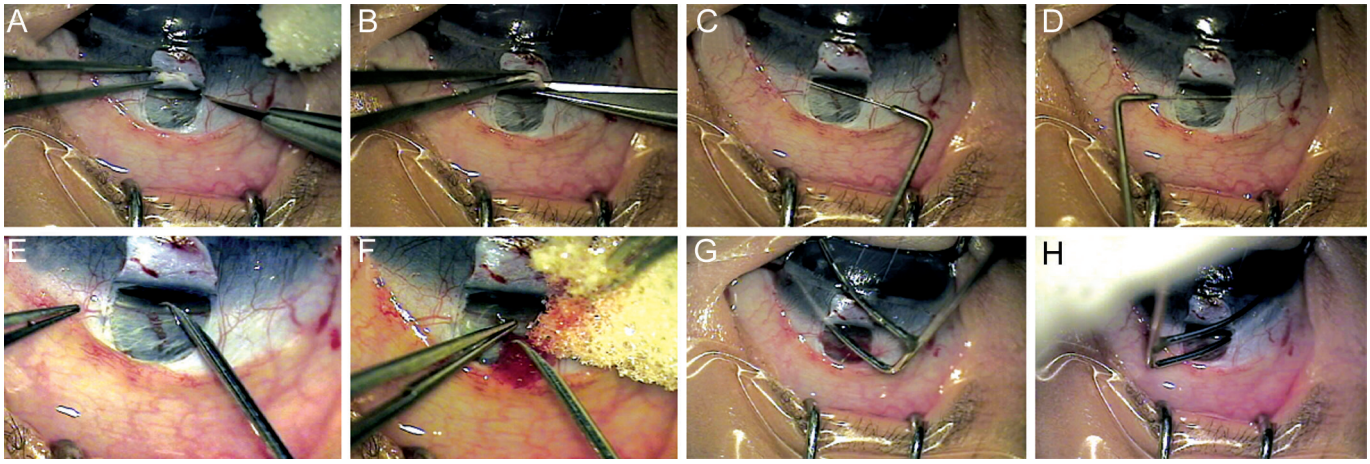

Figure 1 The main procedures of viscocanalostomy A, B: A deeper scleral flap was fashioned 0.5 mm inside the border of superficial scleral flap, about two-thirds of scleral thickness, leaving a thin translucent layer over the choroids. Cut apart the deeper scleral flap from its base. C, D: High molecular weight sodium hyaluronate was injected into the ostia of Schlemm's canal each for five times. E, F: Peel away the internal layer of Schlemm's canal and juxtacanalicular connective tissue carefully. G, H: The trabeculotome (Sourdille-Paufique, Moria®) was inserted into the ostia of Schlemm's canal, checking for obstacles to the advancement into the canal.

opacification, Habb's striae, the depth of the anterior chamber, iris structure, lens transparency, pupil reactivity and shape, optic disc evaluation, the C/D ratio measurement. The gonioscopy and biomicroscopy were also performed. All the examinations were conducted by the same glaucoma specialist under anesthesia before the surgery and every child's parents had signed the informed consent for it. As the patients were too young, the authors did not do visual acuity on patients.

Surgical Procedures The operations were started under general anesthesia and also that there's an informed consent process each time. All surgeries were performed by 1 experienced senior surgeon follow standard techniques: a corneal traction suture (8-0 nylon suture) was placed in the nasal cornea to enhance exposure. The conjunctiva and Tenon's capsule was opened at the limbus to expose sclera. A 5×4 mm tongue-shaped, one-third thickness superficial scleral flap was prepared at the 12th and 1st clock where there were no large penetrating vessels and dissected 1.5-2 mm into clear cornea. At this stage, 0.2 mg/mL of mitomycin-C was applied with a sponge under the scleral flap for three minutes before dissecting the deeper scleral flap[3]. This area was then flushed with balanced salt solution (BSS®). A deeper scleral flap was fashioned 0.5 mm inside the border of superficial scleral flap, about two-thirds of scleral thickness, leaving a thin translucent layer over the choroids. Cut apart the deeper scleral flap from its base (Figure 1A, 1B). High molecular weight sodium hyaluronate was injected into the ostia of Schlemm's canal each for five times (Figure 1C, 1D), and then peel away the internal layer of Schlemm's canal and juxtacanalicular connective tissue carefully (Figure 1E, 1F). In the cases when the aqueous humor outflow was not sufficient, the surgery was converted to a trabeculectomy by cutting apart a 1 mm× 3 mm trabecular block and creating a peripheral iridectomy[4]. Before thetrabeculotomy, a "side port" incision was made to inject some high molecular weight sodium hyaluronate. The trabeculotome (Sourdille-Paufique, Moria®) was inserted into the ostia of Schlemm's canal, checking for obstacles to the advancement into the canal (Figure 1G, 1H). Then rotated carefully towards the anterior chamber, crossed the internal side of Schlemm's canal, and breaked the angle's embrionary tissue, including the trabecular mesh. With a cut of 120°-150°, Healon GV (Healon GV solution for intraocular use) was injected beneath the first flap, the wound was seamed tightly with 10-0 nylon sutures[5]. The conjunctival flap was seamed with 10-0 nylon sutures, too.

After surgery, patients were prescribed to tobramycin and dexamethasone (Tobradex, Alcon-Couvreur, Puurs, Belgium) 0.1% eye drops four times daily for 4wk.

Postoperative patients were measured IOP at 1wk, 3, 6mo and thereafter every 6mo. Corneal diameter (mm), C/D ratio, however, was only measured at 1wk, 6mo and at the last reported follow-up.

Statistical Analysis Paired-samples *t*-test was used to analyze the results using SPSS V 16.0 (SPSS Inc., Chicago, Illinois, USA) and *P* values equal or less than 0.05 were considered as statistically significant. Cumulative probabilities of success were determined in accordance with Kaplan-Meier survival analysis.

RESULTS

Forty-two eyes from 26 patients were enrolled into the study. Two eyes were required conversion to trabeculectomy the absence of Schlemm's canal. This patient's data was excluded. Total of 40 eyes were analyzed from 26 patients including 20 males (76.9%) and 6 females (23.1%). The mean (SD) age at the time of undergoing VCT for each eye was 10.7 (9.70) mo, with a range of 3 to 36mo. The disease was bilateral in

16 children (61.5%) and unilateral in 10 children (38.5%). In unilateral cases the left eye accounted for 66.7%. The mean (SD) number of glaucoma medications used prior VCT was 1.1 (0.56). One patient (two eyes) had glaucoma family history, his mother also suffered from congenital glaucoma (Table 1).

Suspicion of congenital glaucoma was based on enlarged corneal size (24 eyes; 60.0%), corneal edema (26 eyes; 65%), tearing (8 eyes; 20.0%) (Figure 2). Follow-up time lasted from 3 to 30mo, with a mean value of 11.79mo.

Intraocular Pressure The preoperative and postoperative IOP recordings are listed in Table 2, Figure 3. The mean preoperative IOP (±SD) under glaucoma medication was 30.6±7.35 mm Hg. The mean postoperative IOP was 8.83±2.82 mm Hg at the first week, 12.55±7.26 mm Hg at 3mo, 12.43±7.17 mm Hg at 6mo, 11.69±4.18 mm Hg at 12mo, 13.44±4.49 mm Hg at 24mo, and 14.48±2.10 mm Hg at 30mo. The mean deduction of IOP at week 1 postoperation compared to preoperation was 21.77 mm Hg.

Success Probabilities Qualified success was defined through the following criteria: alleviation of corneal edema, stabilisation or reduction in horizontal corneal diameter, reversal of disc cupping, an IOP measurement equal or less than 21 mm Hg. When medications were not required, it was defined as a complete success. When IOP was >21 mm Hg with three kinds of glaucoma medications, the operation was considered as a failure.

Our results presented a 100% qualified success rate at 12mo, 95.5% at 24mo, 68.6% at 30mo. The success was complete in 97.4% of cases at 6mo, in 88.5% at 12mo, and in 70.4% at 24mo and 53.8% at 30mo. The cumulative probability curves for complete and qualified success were depicted in Figures 4 and 5[6]. However, only 6 patients had completed 30mo of follow-up. There were three patients (four eyes) who failure with VCT and required a secondary surgery to achieve pressure control.

Corneal Diameter and Cup/Disc Ratio The corneal diameter and C/D ratio did not change significantly in the first week after postoperative[6]. However, a significant reversal was observed after 6mo (Table 3). There were 18 eyes presented a reduction in corneal diameter, and 25 eyes presented a C/D ratio reversal. The mean corneal diameter was 13.81±0.77 mm preoperative and 12.59±0.78 postoperative (t=7.60, P=0.000). The mean C/D ratio was 0.75±0.12 preoperative and 0.55±0.17 postoperative (t=6.70, P=0.000).

Complications There was no sight threatening intraoperative and postoperative complication. The shallow anterior chambers were found in 2 (5.0%) eyes and recovered spontaneously. Four (10.0%) eyes developed hyphema, and 2 (5.0%) eyes had an inadvertent small hole in the Descemet's membrane. There were no severe complications such as retinal detachment, choroidal haemorrhage, late bleb leakage, blebitis and endophthalmitis in any patient intraoperatively and postoperatively.

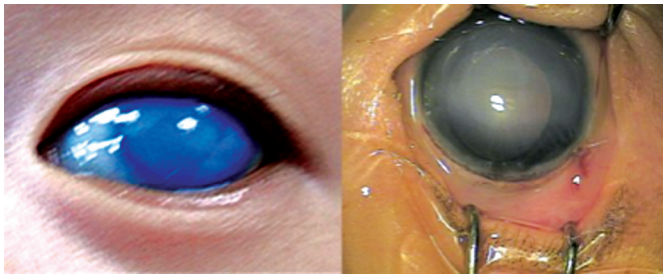

Figure 2 The two children's cornea was enlarged obviously and the edema was severe that the iris was hardly to be seen.

Table 1 Patients demographics

Characteristics	Value
Patients, *n*	26
Sex, *n* (%)	
M	20 (76.9)
F	6 (23.1)
Eyes, *n* (%)	40
R	18 (45)
L	22 (55)
Age at surgery, mo	
Mean (SD)	10.7 (9.70)
Range	3-36
Median	6
Preoperative IOP, mm Hg	
Mean (SD)	30.6±7.35
Range	21.0-55.9
Preoperative medications used, mean±SD	1.1±0.56
Family history	2 (5%)

Table 2 Preoperative and postoperative IOP undergoing VCT

Characteristic	No. of eyes	Mean IOP (SD) (mm Hg)	Mean IOP decrease (mm Hg)	[a]*P*
Preoperative	40	30.6 (7.35)		
Postoperative				
1wk	40	8.83 (2.82)	21.77	<0.001
3mo	35	12.55 (7.26)	18.05	<0.001
6mo	39	12.43 (7.17)	18.17	<0.001
12mo	30	11.69 (4.18)	18.91	<0.001
18mo	26	12.05 (3.08)	18.55	<0.001
24mo	21	13.44 (4.49)	17.16	<0.001
30mo	6	14.48 (2.10)	16.12	<0.001

[a]Paired-samples Student's *t*-test.

DISCUSSION

As medical therapy for PCG is hardly effective, PCG is almost managed surgically[7]. Although the conventional operation therapy for congenital glaucoma such as goniotomy, trabeculotomy, trabeculectomy, effective pressure control can be acquired in up to 90%[8-11]. However, all of them have

Table 3 Preoperative and postoperative corneal diameter and C/D ratio undergoing VCT

Characteristic	Preoperative	Post-6mo	*n*	*t*	[a]*P*
Corneal diameter (mm)	13.81±0.77	12.59±0.78	27	7.6	<0.05
C/D ratio	0.75±0.12	0.55±0.17	35	6.7	<0.05

C/D: Cup/disc. [a]Paired-samples Student's *t*-test.

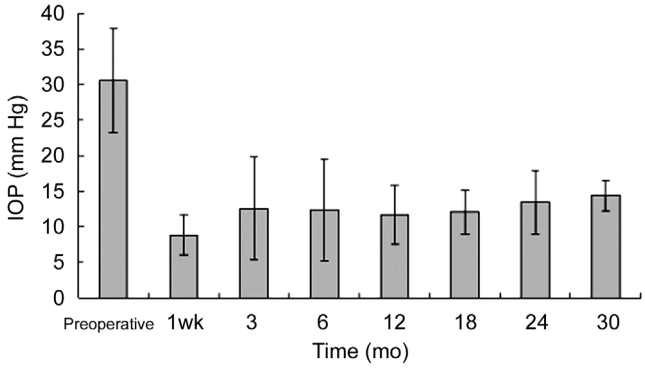

Figure 3 Mean IOP over time in eyes having viscocanalostomy combined with trabeculotomy The decline of the IOP at each follow-up point was statistically obvious.

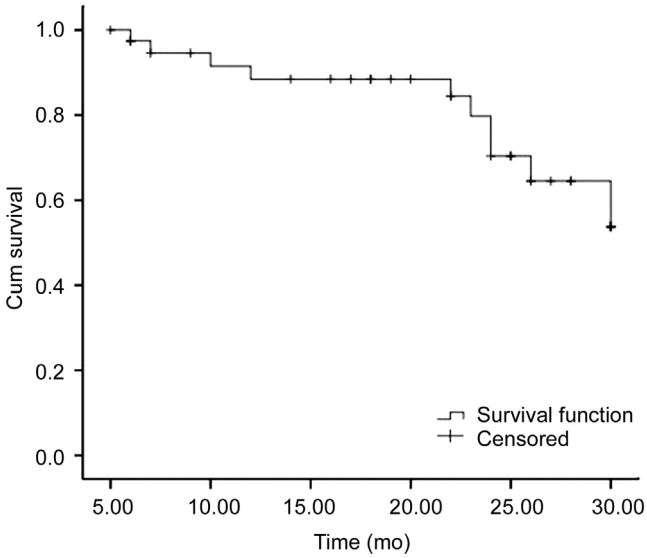

Figure 4 The cumulative probability curves for complete success The complete success rate was 97.4% at 6mo, 88.5% at 12mo, 70.4% at 24mo and 53.8% at 30mo.

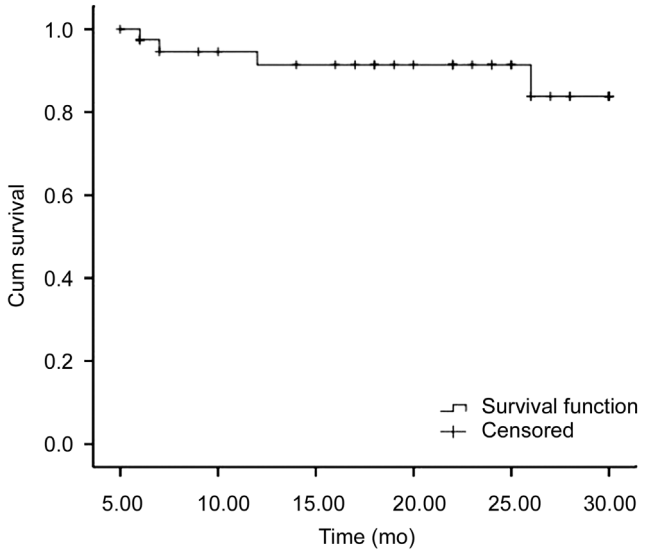

Figure 5 The cumulative probability curves for qualified success The qualified success rate was 100% at 12mo, 95.5% at 24mo, 68.6% at 30mo.

disadvantages. Goniotomy which need transparent corneas is the main choice for the western surgeons, because patients may not have serve corneal edema at the time for treatment[12]. While in China, quite a few patients present with clouding because of limited medical conditions and goniotomy is technically impossible[13]. In our study, there are 26 (65%) eyes present with cornea edema. External trabeculotomy's main advantage over goniotomy is its relatively ignore the transparency of the cornea[14]. As an initial procedure, goniotomy has lower success rate than external trabeculotomy in China[15]. But for locating Schlemm's canal exactly is difficult, the complications of external trabeculotomy hardly can be avoided: hyphema, peripheral anterior synechia of iris, Descemet's detachment, marginal ulcer corneal, prolapse of iris. Tube drainage surgery is another choice for PCG because it offers the best opportunity of long-term IOP control[16]. While people often didn't choose this surgery as the initial treatment for the reason of the complications like tube exposure, infectious endophthalmitis, retinal detachment and high costs which couldn't be afford by many rural patients in China[17-18].

In primary open angle glaucoma, viscocanalostomy is said to be rather effective in lowering IOP, with less risks of complication than full-thickness filtering surgery[19]. After someone used it to treat infantile glaucoma and proved that it could maintain a considerably lower IOP during a long-time follow-up period[1]. Some of the results have indicated that when the child's angle was poorly developed, viscocanalostomy without breaking the trabecular mesh and the angle's embrionary tissue is insufficient. So we also combined trabeculotomy for infantile glaucoma[20]. As the use of mitomycin C is a safe and effective therapy during nonpenetrating filtering surgery[21]. VCT with mitomycin C provided a significant reduction of IOP in congenital glaucoma in this study. It demonstrated a 100% overall success rate at 12mo, 95.5% at 24mo, 68.6% at 30mo.

VCT included two steps, the first step was viscocanalostomy, shaped a scleral lake separated from the anterior chamber only by Descemet's membrane, dilated the Schlemm's canal with high-molecular-weight viscoelastic substance to keep

its open, aqueous humor then permeated into a scleral lake from the Descemet's window, and finally into the Schlemm's canal[22-23]. The second step was trabeculotomy, breaked the angle's embrionary tissue, sliced the whole thickness of trabecular mesh, made the anterior chamber and Schlemm's canal be linked together. Aqueous could flow into Schlemm's canal directly even the child's angle was poorly developed. So VCT creates two exit ways for aqueous humor. And that's why our researches have high success rates in IOP control. Circle aqueous humor goes through the permeable trabeculo-descemetic membrane to the intrascleral space, and then it's absorbed by several pathways.

The main cause of failure of infantile glaucoma filtration surgery is postoperative scar formation[3]. The operator had took some measures to inhibiting wound healing. First, mitomycin C was being applied to the scleral bed for three minutes[20]. In addition, we don't use cautery during this surgery. Moreover, some high molecular weight sodium hyaluronate should be injected under the first scleral flap, which can decrease the risk of wound's fibrosis after operation. That's why this surgery has an acute effect in reducing IOP and works quite well in infantile glaucoma. Shallow filtration blebs were observed postoperatively in 10 cases, however, bleb formation wasn't crucial factors of IOP control. In this study, we found that VCT is at least as successful in reducing pressure as multiple standard procedures. After viscocanalostomy was being done, the baseline IOP (±SD) had significantly decreased at the last follow-up visit for each patient (paired-samples *t*-test, $P<0.001$). Our results presented a 100% qualified success rate at 12mo, 68.6% at 30mo. Because of the non-compliant patients, only 6 patients have completed 30mo of follow-up, and that's why a large drop in the success rate was noted from 24 to 30mo.

The advantage of the procedures include that when viscocanalostomy was being done, we could confirm the Schlemm's canal's locating. Second, high molecular weight sodium hyaluronate was injected into the ostia of Schlemm's canal each for five times during the surgery so that the trabeculotome can be inserted into it smoothly. Also some high molecular weight sodium hyaluronate should be injected into the anterior chamber before trabeculotomy. Thus, it doesn't lead to sharp decrease of IOP, which can cause choroids detachment, shallow anterior chamber, expulsive choroidal haemorrhage and some other severe complications[24].

However, there are certain disadvantages. It may be that more time will be cost to do the operation. More likely, VCT is more difficult than either goniotomy or trabeculotomy ab externo in technique. The main difficulty encountered in VCT is dissection of the scleral flap. Although we can dissect the superficial scleral flap easily by an experienced doctor, but it's difficult to grasp the deeper flap's thickness accurately. These infantile eyes' limbal sclera is relatively thinner than adults have. So two-thirds of scleral thickness was hardly decided, we must dissect it carefully. So surgeon should invest time and effort to overcome the relatively long learning curve associated with it. Complications may also be higher when surgeons have no previous experience. The most common intraoperative complication is trabeculo-Descemet's membrane perforation, which essentially converts viscocanalostomy to a trabeculectomy.

Other studies have reported delayed-onset hyphema, retinal detachment and endophthalmitis occured in the surgery for pediatric glaucoma[25-26]. In contrast, our study showed that after taking VCT, only four cases developed a spontaneously reabsorbed (within 48h) microhyphema, two cases had shallow anterior chamber and recovered in 48h, two cases had an inadvertent small hole in the Descemet's membrane, others all had no complications. So it seems to be a safer procedure for a child who has infantile glaucoma. Because of the less risk of surgical complications, viscocanalostomy has gained more interests from ophthalmologists.

In summary, our study has demonstrated that VCT is effective and safe in controlling infantile glaucoma, and it could be an alternative choice for infantile glaucoma procedure in the future although the controlled studies with large subject numbers and long follow-up period are needed.

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