·Clinical Research·

Cyclopexy versus vitrectomy combined with intraocular tamponade for treatment of cyclodialysis

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Abstract

• AIM: To compare the effects and complications of direct cyclopexy (DC) versus vitrectomy, endophotocoagulation, and gas/silicone oil endotamponade (VEE) treatment in patients with cyclodialysis and persistent hypotony.

• METHODS: This is a prospective, comparative, non-randomized clinical trial which includes 52 patients with cyclodialysis and persisting hypotony. Fifty-two patients suffering from cyclodialysis and persistent hypotony in one eye were divided into 2 groups (groups DC and VEE) and treated, respectively, with direct cyclopexy or vitrectomy, endophotocoagulation, and gas/silicone oil endotamponade. The patients were followed up for 12 months. Assessments included best corrected visual acuity (BCVA), intraocular pressure (IOP), anterior chamber depth (ACD), anterior chamber volume (ACV) and subjective rating of the pain caused by the treatments.

• RESULTS: After a follow-up of 12 months, significant improvement was seen in postoperative mean BCVA, IOP, ACD and ACV in both treatment groups (which were not significantly different from each other). The success rates for the treatments were not significantly different (DC: 50.0% *vs* VEE: 62.5%, P=0.383). Postoperative morbidity of cataract and subjective pain rating were significantly higher in the VEE group *vs* the DC group (P=0.003 and P<0.001 respectively).

• CONCLUSION: DC and VEE were effective surgical procedures in treating patients with cyclodialysis and persistent hypotony. Patients had better tolerance to DC treatment and VEE was more likely lead to cataract complications. Taking into consideration the ease of the operation, success rate, and patient comfort, DC treatment seems preferable to VEE treatment in patients with simple cyclodialysis. While VEE has the advantage of treating patients with cyclodialysis combined with vitreous hemorrhage.

• **KEYWORDS:** cyclodialysis; ocular hypotony; cyclopexy; vitrectomy

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INTRODUCTION

Cyclodialysis cleft is a relatively rare condition in which there are areas of disinsertion of the meridional ciliary muscle from its attachment at the scleral spur [1]. Usually, a cyclodialysis cleft occurs after severe blunt ocular trauma [2, 3] or intraocular surgery, such as trabeculectomy, phacoemulsification and intraocular-lens insertion or vitrectomy [4-7]. An abnormal secondary pathway for the drainage of aqueous humor into the suprachoroidal space is established resulting in a severe persistent ocular hypotony and an associated intraocular pressure (IOP) which is often lower than 5mmHg. Hypotony leads to a number of complications, such as corneal edema, cataract, shallow anterior chamber, hyperopic shift, choroidal effusion, retinochoroidal folds, optic disc oedema, macular oedema, and permanent loss of vision. Untreated cyclodialysis cleft persists for an extended period of time, it might lead to choroidal or retinal detachment, or even atrophy of eyeball. Anatomic closure of the cleft helps to raise IOP, improving the visual prognosis [2,4,8]. Nonincisional interventions include the application of various lasers and cryotherapy in the vicinity of the cleft. The traditional approach of direct cyclopexy has more recently been complemented by recent reports of employing modified external plombage procedures, vitrectomy and gas assisted endotamponade. There are insufficient studies formally evaluating these techniques to be able to assess their safety and efficacy. However, the effects and complications have not been analyzed [1]. Therefore, we conducted a prospective, comparative trial to compare the anatomical and functional results of these two surgical procedures.

SUBJECTS AND METHODS

Included patients We enrolled 52 eyes of 52 consecutive patients suffering from cyclodialysis and persistent hypotony in one eye visiting the ophthalmology department of the Chinese People's Liberation Army (PLA) General Hospital, Beijing between June 1, 2006 and May 30, 2012. The study patients were divided into 2 groups (groups DC and VEE) and treated, respectively, with direct cyclopexy or vitrectomy, endophotocoagulation, and gas/silicone oil endotamponade. The protocol for this prospective, comparative, nonrandomized clinical trial was approved by

the Ethics Committee of "Chinese People's Liberation Army General Hospital", in accordance with the principles set forth in the Helsinki Declaration and the International Conference on Harmonisation guidelines for Good Clinical Practice.

Inclusion and exclusion criteria The inclusion criteria in the DC treatment group were as follows: 1) gonioscopy and UBM examinations showed a cyclodialysis cleft; 2) preoperative IOP ≤8mmHg; 3) binocular indirect ophthalmoscope and B-mode ultrasonography examinations showed no vitreous hemorrhages or retinal detachment; 4) the cyclodialysis cleft was not caused by penetrating ocular trauma. The criteria inclusion in the VEE treatment groups was similar to that of DC treatment group, except article 3. In the VEE treatment group, binocular indirect ophthalmoscope examination and B-mode ultrasonography examination showed vitreous hemorrhages (with minimal or no retinal detachment). Patients with a perforating injury and/or rupture of the eyeball, normal IOP, secondary glaucoma, or patients with severe and complicated retinal detachment (*i.e.* patients needing special retinal reattachment surgery) were excluded from the study. All patients were adequately informed and signed consent forms were obtained. The patients had the option to refuse to participate in the procedure even though the surgical procedure was considered necessary by the consulting ophthalmologist.

Detecting parameter During all pre- and post-surgical visits, each patient underwent a complete ocular examination, including slit-lamp photography, gonioscopy, fundus photography, UBM, measurement of the mean best corrected visual acuity (BCVA), IOP measurements (applanation tonometry, Gold-mann), anterior chamber depth and volume assessment (ACD, ACV respectively; Pentacam), and a record of the location and extent of the cyclodialysis cleft. All the patients filled a questionnaire developed with relevant questions pertaining to the feeling about the entire therapeutic process on a likert scale of 0-10. A score of 0 meant that the patients felt the surgical and recovery procedure was completely painless, while a score of 10 score meant that the patients felt the surgical and recovery procedure was very painful.

The normal range of IOPs in the Chinese population is 11-21mmHg [9]. Feng *et al* [10] performed an international, multicenter study to obtain normative data from various countries worldwide and reported a range from 2.04mm (0.15%) to 4.18mm (0.15%) of normal ACD values. Fu *et al* [11] evaluated healthy Chinese subjects and reported an ACV of 165.56±34.86μL. Positive treatment effect was defined when the following standards were achieved simultaneously: 1) UBM examination confirmed that the cyclodialysis cleft was closed; 2) postoperative IOP showed ≥11mmHg and ≤21mmHg; 3) postoperative ACD ≥2.04mm and ≤4.18mm; 4) postoperative ACV >130.7μL; 5) postoperative BCVA ≥ preoperative BCVA.

Surgical techniques All operations were performed using retrobulbar anesthesia and by the same surgeon. DC was performed as described by Demeler [12] with some improvements. Briefly, a limbic conjunctival flap was fashioned over the extent of the cyclodialysis and viscoelastic substance was injected into the anterior chamber. A partial thickness scleral flap was formed by making a 3mm incision from the limbus and dissecting the flap towards the cornea. The remaining sclera was incised 1mm from the limbus to expose the cleft. Under gonioscopic control, the ciliary body was sutured to the scleral spur by interrupted 10-0 nylon sutures. The cleft was totally sutured at one surgical procedure.The needle distance was 2.0mm. However, in the whole cleft extent, there must be at least one needle distance was 4mm. In the VEE group, 23-gauge transconjunctival pars plana vitrectomy was performed using a three-port technique and thoroughly cutting the vitreous. After the vitrectomy, a fluid-gas exchange and endophotocoagulation were performed throughout the pars plana. Energy of the endophotocoagulation laser was 350-750mW and the time was 0.1-0.2 second. The laser spots were arranged around the extent location with 2-3 ranks. Then the vitreous cavity filled with gas or silicone oil. The principle behind the surgical technique relied on the mechanical apposition of the detached ciliary muscle to the scleral spur by the gas/silicone bubble and subsequent scar induction by the endophotocoagulation. No intraoperative complications were encountered in either group.

After surgery, all patients received an identical regimen of a topical corticosteroid and antibiotic for one week. Patients in the VEE group were asked to keep a fixed head position for at least one week to ensure that the gas/silicone oil bubble maintained pressure on the detached ciliary muscle in the region of the surgery.

Follow-up Postoperative follow-up examinations were performed daily for a week and then at 1, 3, 6 and 12 months after surgery. Eyes with reversible IOP spikes received antihypertensive eye drops, oral medicines or paracentesis of anterior chamber. In DC group, two patients (2/26, 7.7%) with very low postoperative IOP (lower than 4mmHg) and unclosed cyclodialysis clefts required a repeat DC. Similarly, two patients (2/26, 7.7%) in VEE group required a repeat VEE. In the VEE group, eyes that received a silicone oil endotamponade had the oil removed by six to nine months of their follow up by a three-port process.

Statistical Analysis Data of the last follow up time point (12 months after the surgery) were used for analyzing. Chi-square and independent sample *t* tests were used to compare categorical data and difference between means respectively, between the DC and VEE groups. Paired sample *t* tests were used to compare the pre and postoperative measurements. The corresponding Nonparametric Tests were used to compare quantitative variables which did not obey normal distribution. The statistical level of significance was preset at 0.05 and all the eligible data were analyzed using SPSS version 18.0 statistical software (SPSS Inc, Chicago, Illinois, USA).

RESULTS

Preoperative findings The sample consisted of 41 males

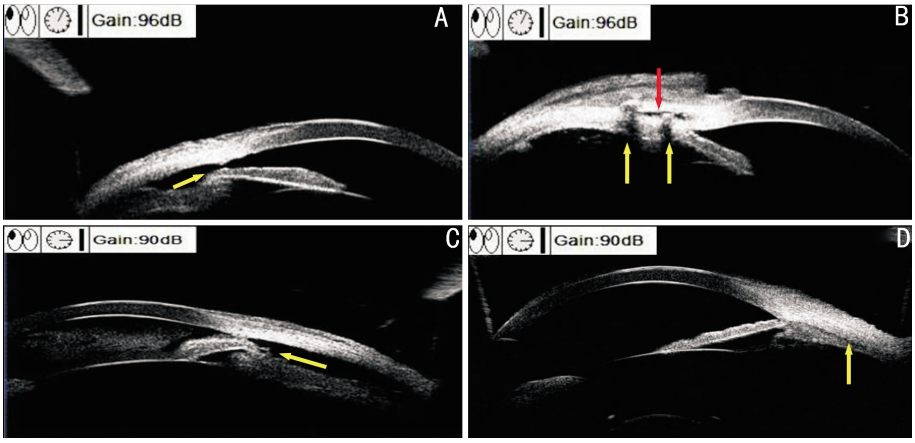

Figure1 Pre – and postoperative ulrtasound biomicroscopy (UBM), images of direct cyclopexy (DC) and gas/silicone oil endotamponade (VEE) A: Before DC surgery UBM showed a cyclodialysis cleft at 2 o'clock (yellow arrow), with the cleft extension from 12 o'clock to 4 o'clock (anterior chamber is to the right); B: Two months after DC surgery the cyclodialysis cleft was closed. The yellow arrows show the location of sutures in the cleft. The red arrow indicates the position of small residual cleft at 1 o'clock; C: Prior to surgery there was a cyclodialysis cleft at 3 o'clock extending from 2 o'clock to 5 o'clock (yellow arrow; anterior chamber is to the right); D: Two months after VEE surgery the cyclodialysis cleft was closed and the gas endotamponade had been completely absorbed.

Table 1 Clinical characteristics in patients with cyclodialysis undergoing DC or VEE $\overline{x} \pm s$

	DC	VEE	*P*
Number of eyes	26	26	
Age (a)	40.96±12.37	41.88±12.62	0.800
Gender (male/female)	20/6	21/5	0.719
Cause (trauma/surgery)	24/2	21/5	0.191
Cyclodialysis extent (o'clock)	2.58±1.44	2.79±1.22	0.772
[1]Injury history (week)	19.43±42.28	5.82±3.29	0.043
Preoperative BCVA (logMAR)	1.00±0.53	1.87±0.53	0.000
Preoperative IOP (mmHg)	6.85±1.82	6.34±2.07	0.367
Preoperative ACD (mm)	2.15±0.45	2.15±0.57	0.966
Preoperative ACV (μL)	84.63±21.93	77.75±23.10	0.296
Preoperative cataract morbidity rate	10/26 (37.5%)	12/26 (45.8%)	0.558
Papilledema	15/26(57.7%)	23/26(88.5%)	0.012
Macular fold	12/26(46.2%)	20/26(76.9%)	0.023
Macular edema	8/26(30.8%)	15/26(57.7%)	0.051
Retinal break	0/26(0%)	5/26(19.2%)	0.019

[1]Injury history means the interval of time between injury and surgical repair. DC: direct cyclopexy; VEE: gas/silicone oil endotamponade.

and 11 females with a mean age of 41.42 ±12.37 years (range, 25-77 years). These included 26 eyes in the DC group (24 post-traumatic and 2 post-surgical) and 26 eyes in the VEE group (21 post-traumatic, 5 post-surgical). Of the patients whose cyclodialysis was secondary to intraocular surgery, which included, phacoemulsification (1/7, 14.3%), trabeculectomy (2/7, 28.6%) and vitrectomy (4/7, 57.1%). No statistically significant differences existed between the two groups in terms of age, gender, cyclodialysis cleft extent, preoperative mean BCVA, IOP, ACD and ACV. The data of the 52 patients (52 eyes) were showed in Table 1. Two eyes (2/26, 7.7%) in the DC group underwent two cyclopexy procedures for complete repair; two eyes (2/26, 7.7%) in VEE group underwent repeat endophotocoagulation and silicon oil endotamponade procedures for complete repair. A follow-up of 12 months was achieved for all patients. Cyclodialysis clefts for all the patients were closed at the end of follow-up period (Figure 1).

DC treatment In the DC group, postoperative mean BCVA (logMAR) was 0.83±0.58, mean IOP was 13.03±4.15mmHg, mean ACD was 2.84±0.6mm and mean ACV was 164.63±50.91μL. Significant improvements were observed in all of the four parameters. The *P* value was 0.028, <0.001, <0.001 and <0.001, respectively. The data were showed in Table 2.

VEE treatment In the VEE group, 17 patients (17/26, 65.38%) received silicon oil tamponade and 9 patients (9/26, 34.62%) received sterilized C3F8 tamponade. Silicon oil of all the 17 patients was removed at the end of follow-up period. Postoperative mean BCVA (logMAR) was 1.46±0.61, mean IOP was 12.72±3.51mmHg, mean ACD was 2.76±0.39mm and mean ACV was 152.71±44.09μL. Significant improvements were observed and the *P* value was 0.0003, <0.001, <0.001 and <0.001, respectively. The data were showed in Table 3.

Table 2 Pre- and Postoperative values comparison of DC group $\bar{x} \pm s$

	Preoperative	Postoperative	Paired differences	*P*
BCVA (logMAR)	1.00±0.53	0.83±0.58	-0.17±0.36	0.028
IOP (mmHg)	6.55±1.61	13.03±4.15	6.47±4.36	0.000
ACD (mm)	2.15±0.45	2.84±0.60	0.69±0.74	0.000
ACV (μL)	84.63±21.93	164.63±50.91	80.00±54.20	0.000

Paired differences: Postoperative values *vs* preoperative values.

Table 3 Pre- and Postoperative values comparison of VEE group $\bar{x} \pm s$

	Preoperative	Postoperative	Paired differences	*P*
BCVA (logMAR)	1.87±0.53	1.46±0.61	-0.40±0.60	0.003
IOP (mmHg)	5.96±1.66	12.72±3.51	6.75±3.57	0.000
ACD (mm)	2.15±0.57	2.76±0.39	0.61±0.67	0.000
ACV (μL)	77.75±23.10	152.71±44.09	74.96±50.52	0.000

Paired differences: Postoperative values *vs* preoperative values.

Table 4 Postoperative values comparison between DC and VEE groups $\bar{x} \pm s$

	DC	VEE	*P*
Postoperative BCVA (logMAR)	0.83±0.58	1.46±0.61	0.003
Postoperative IOP (mmHg)	13.03±4.15	12.72±3.51	0.266
Postoperative ACD (mm)	2.84±0.60	2.76±0.39	0.056
Postoperative ACV (μL)	164.63±50.91	152.71±44.09	0.295
Success rate	13/26 (50.0%)	16/26 (62.5%)	0.383
[1]Subjective pain rating	3.42±0.83	6.67±1.37	<0.001
IOP Spike incidence	11/26 (42.3%)	3/26 (11.5%)	0.023
Postoperative cataract morbidity rate	14/26(53.8%)	24/26 (92.3%)	0.003

[1]Scale from 0 to 10. A score of 0 meant that the patients felt the surgical and recovery procedure was completely painless, while a score of 10 score meant that the patients felt the surgical and recovery procedure was very painful (even if the surgical procedure was recommended by the consulting ophthalmologist, the patient would refuse it).

DC *vs* VEE treatment Postoperative mean IOP, ACD and ACV were not significantly different between the two treatments groups. However, the postoperative BCVA of the DC group was significantly better than that of the VEE group. The success rates of the two types of surgical procedures were not significantly different. However, subjective rating of the pain caused by the treatments was significantly different. The data were showed in Table 4.

After VEE and DC treatment, morbidity rate of cataract was noticeably higher in the VEE group compared to the DC group (Table 4). Of the 38 cataract cases, new cataract developed in 19 cases (20/38, 52.6%) and progressed cataract developed in 18 cases (18/38, 47.4%) after the primary surgical treatment. Eight (8/26, 30.8%) and 16 (7/26, 26.9%) patients in the DC and VEE group respectively received phacoemulsification combined with IOL implantation after the primary surgery. After receiving cataract extraction surgery, all of the 24 cases had visual improvement.

The incidence rate of transient IOP spike was noticeably lower in the VEE group compared to the DC group (Table 4). In the DC group, transient IOP spikes occurred between the 1st and 9th days following the surgery, whereas, it was between the 2nd and the 7th days after surgery in the VEE group. However, the time range of postoperative IOP spike was not significantly different between the two treatments groups (DC 2.00±0.47 *vs* VEE 1.67±1.15 day, P=0.67). There were no cases of secondary glaucoma reported during the follow-up period.

DISCUSSION

To the best of our knowledge, there are no studies reporting the comparison of the DC and VEE as treatment for cyclodialysis. Kato *et al*[13] reported the effective ratio of DC was 4/5 and Küchle *et al* [14] reported that 86% of treated eyes had improved visual acuity. Hoerauf *et al*[15] reported that vitrectomy, cryotherapy, and gas endotamponade was useful in treating traumatic cyclodialysis. It was hard to realize randomization from the viewpoint of ethics. Patients with a perforating injury, rupture of the eyeball, incised injury, or secondary glaucoma were excluded from the study, as were patients with severe retinal detachment needing special retinal reattachment surgery. Usually, patients with these severe complications need more than one surgical procedure. The surgical procedures that were compared in this study may not be sufficient to deal with all these complications. Similarly, the poor preoperative condition of the eye might produce a bias and will make the comparison of the postoperative parameters unreliable. We excluded patients with cyclodialysis cleft and normal IOP because these patients did not need immediate surgical intervention.

Patients with cyclodialysis clefts that were successfully sealed by laser photocoagulation without the necessity of surgical DC or VEE were excluded.

Cyclodialysis secondary to intraocular surgery, were primarily caused by vitrectomy (4/7, 57.1%), trabeculectomy (2/7, 28.6%) and phacoemulsification (1/7, 14.3%), which suggests that vitrectomy was the commonest iatrogenic reason for cyclodialysis. However, larger number of cases should be analyzed to get a more convincible conclusion.

It is recommended to suture the cyclodialysis cleft at two surgical procedures if the cleft extent was more than 200 degrees, avoiding ischemia of the anterior ocular segment. To avoid pupillary blocking, it is better to implement peripheral iridectomy in the condition of large cleft extent (90-120 degrees). In our study, the direct cyclopexy was performed in an improved way. The cleft was fully sutured at one surgical procedure, but the needle distance was 2mm, which was sparse. Besides, there is one especially large needle distance (4mm) in the whole cleft extent. Thus, postoperative IOP spike could be avoided.

We did not considered the closure of cyclodialysis clefts as the only criteria for success since cleft closure often do not correspond to normal IOP, ACD or ACV. This implies that the dysfunction of ciliary body and aqueous production may exist even if ciliary body has been restored anatomically[16]. The aim of this study was not only to assess anatomical but also functional outcome of the two surgical procedures. We wanted to assess not only anatomical but also functional results of the two surgical procedures.

Postoperative mean BCVA of both groups did get significant improvement (Tables 2,3), but the postoperative BCVA was still unfavorable. Besides, mean postoperative BCVA of VEE group was significantly lower than that of DC group. This may be due to vitreous hemorrhage, retinal detachment and other fundus manifestations (Table 1). Of 20 patients (20/26, 75.0%) in DC group and 10 patients (10/26, 37.5%) in VEE group, interval of time between injury and surgery was longer than 4 weeks. A functional ciliary body is essential for retaining the eye globe and structure of eye globe could not be anatomically restored if the ciliary body was seriously damaged. Abnormal globe structure and hypotony existing for such a long time resulted in irreversible structural and functional changes in the globe. Visual loss was inevitable in such a condition [17]. Our findings were similar to the findings reported by Feng *et al*[16], who concluded that ciliary body damage after injury is destructive to both visual outcome and anatomic outcome. Several studies have documented poor prognosis attributing to vitreous hemorrhage [17,18]. The mechanism of retinal damage caused by vitreous hemorrhage is complex. The toxic effect of whole blood and hemoglobin on the retina[19,20], mechanical damage of infusion fluid [21] and light-induced damage from ophthalmic operating microscope [22] are all destructive to postoperative visual acuity. Cataract was the second reason for the unfavorable postoperative visual acuity. Cataract progression is one of the most frequently reported complications of intraocular tamponade [23-26], which usually requires surgical treatment after the primary vitrectomy and intraocular tamponade [27,28]. Preoperative morbidity of cataract was not significantly different between the two groups (Table 1), while postoperative morbidity of cataract was significantly higher in the VEE group (Table 4). In VEE group, cataract morbidity increased significantly after the surgical procedure (P=0.001). In addition, progression of cataract was much severe in the operated eye in comparison to the fellow eye. This finding was in keeping with the reports that trauma and silicon oil/gas tamponade are the risk factors for the development of cataract[25, 29]. After receiving cataract extraction surgery, all of the 24 cases had significant visual improvement. This means that cataract extraction surgery helped patient to get better visual acuity.

Both DC and VEE groups showed significant improvement in postoperative mean BCVA, IOP, ACD and ACV (Table 2 and Table 3). Thus, either treatment is effective in improving anterior chamber structure and improving IOP.

Overall, 56.3% (29/52) of the surgery was considered successful. The other 23 patients (23/52, 44.2%) failed to meet all of the 5 parts criteria for success simultaneously. Sixteen patients (16/52, 30.8%), 14 patients (14/52, 26.9%), 7 patients (7/52, 13.5%) and 4 patients (4/52, 7.7%) failed to meet normal ACV, IOP, BCVA and ACD respectively. Nine eyes (10/26, 38.5%) in DC group and seven eyes (8/26, 30.8%) in VEE group did not reach normal ACV respectively, P=0.540. These data indicated that it was difficult to realize normalization of ACV after surgical repair. We inferred that the scar at the cyclodialysis cleft position contracted and minimized the volume of anterior chamber. Since the scar located at peripheral anterior chamber, it influenced the central depth of anterior chamber very weakly. Most of eyes (48/52, 92.3%) reached normal ACD after surgeries. Who did not receive any further surgical intervention, in a subset of patients, cyclodialysis clefts were closed and IOP were normal, but ACD and/or ACV failed to meet the normal criteria. In another subset, IOP were stable after following for more than 6 months though they were slightly below 11mmHg. Further surgical procedures were not necessary for them.

Subjective pain rating was significantly higher in VEE group. Thus it appears that the VEE treatment causes significantly more discomfort than the DC treatment. Information from the questionnaire showed that all of the 26 patients (26/26, 100%) in VEE group felt uncomfortable about fixing head position after the surgery. Of the 17 patients who received silicon oil tamponade, 12 patients (12/26, 46.2%) felt that silicone oil removal added pain to the whole treatment process. This means that patients had better tolerance to DC.

In the past, reversible pressure spikes in the early postoperative course have been reported after successful closure of the cyclodialysis cleft [30-34]. However, if left untreated, uncontrolled postoperative IOP spikes can result in pain, corneal edema, glaucomatous nerve damage [35,36] and anterior ischemic optic neuropathy[37] Postoperative IOP spike

incidence was significantly lower in VEE group (Table 4), which may have less harm to optic nerve and globe structure. The success rate of the two treatments in this study were found to be similar, which may, in part, be due to the relatively small sample size of the treatment groups, given the rarity of the condition.

In conclusion, both of DC and VEE were effective in treating patients with cyclodialysis and hypotony. In cases with cyclodialysis combined with vitreous hemorrhage, VEE is, in a sense, irreplaceable. Thus given the reduced patient discomfort, ease of surgical completion and equal effectiveness of DC, this might be considered as a preferred treatment in cases of cyclodialysis without vitreous hemorrhage. In addition, cataract extraction operation helped patients to get better visual acuity.

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