Original Article

The safety and efficacy of modified minimally invasive trabeculectomy for the treatment of primary chronic angle-closure glaucoma

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Background: Primary chronic angle-closure glaucoma (PCACG) is one of the main types of glaucoma in China. Trabeculectomy is the most commonly used glaucoma filtration surgery for glaucoma in the world. Conventional trabeculectomy is prone to anesthesia-related complications intraoperative and operation-related complications postoperative in PCACG treatment. Modified minimally invasive trabeculectomy maybe can reduce the incidence of complications.

Methods: We conducted a prospective case series study and performed modified fornix-based trabeculectomy in 27 patients (30 eyes) under topical anesthesia; we then observed intraoperative anesthesia and cooperation effect, intraoperative and postoperative complications, preoperative and postoperative visual acuity, intraocular pressure (IOP), visual field, and the use of ocular hypotensive drugs. The patients were followed up for at least 12 months.

Results: All operations were completed successfully with no intraoperative complications. All 27 patients (30 eyes) were followed up for at least 12 months. No significant decrease in visual acuity was observed at days 1 or 7 and at months 1, 3, 6, and 12 after operation; however, a significant decrease in IOP was observed at days 1 and 7 and at months 1, 3, 6, and 12 after operation. Moreover, no significant progression in visual field mean defect was observed at month 12 after operation, and the number of ocular hypotensive drugs required was significantly reduced at months 6 and 12 after operation. By month 12 after operation, the overall success rate was 93.33% (28/30).

Conclusions: Modified minimally invasive trabeculectomy is safe and effective for the treatment of PCACG.

Keywords: Trabeculectomy; modified; minimally invasive; primary chronic angle-closure glaucoma (PCACG)

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Glaucoma is the second leading cause of blindness worldwide (1), and primary chronic angle-closure glaucoma (PCACG) is one of the main types of glaucoma in China (2). Currently, trabeculectomy is the most commonly used glaucoma filtration surgery (3,4). PCACG present the biological structure such as short eye axial and shallow anterior chamber (5). Conventional trabeculectomy is prone to anesthesia-related complications intraoperative and shallow anterior chamber, low intraocular pressure (IOP) and malignant glaucoma postoperative in PCACG treatment (6-9). Based on the concept that minimally invasive surgery helps to reduce operation complications, we modified

conventional trabeculectomy and used a less invasive surgical approach and instruments; a smaller scleral flap was prepared to reduce the incidence of complications by reducing postoperative scarring. A patent aqueous humor filtration channel was established, and watertight scleral sutures were used. The anterior chamber was reconstructed at the end of the operation. The results are reported below.

Materials and methods

Information and subjects

Subjects

A total of 27 patients (30 eyes) with PCACG, who were treated at the Department of Glaucoma, The Joint Shantou International Eye Center (JSIEC) of Shantou University and the Chinese University of Hong Kong from February 2012 to May 2014, were included in this study [11 females and 16 males, aged 50-69 (60.19±5.94)]. Thirteen right eyes and 17 left eyes were affected. All operations (minimally invasive trabeculectomy) were performed by the same physician, and patients less than 60 years also received mitomycin C during the operation.

Inclusion criteria (8,10)

(I) IOP >21 mmHg, typical glaucomatous disc and visual field changes, goniosynechia and closure > 1/2; (II) patient unable to tolerate ocular hypotensive drugs or requiring at least two ocular hypotensive drugs; (III) daily vision >0.3, no plan to have cataract surgery.

Exclusion criteria: (I) acute angle-closure glaucoma, secondary glaucoma or other types of glaucoma; (II) other concurrent fundus conditions; (III) history of eye surgery; (IV) did not consent to the study operation or had plans to have cataract surgery.

This prospective case series study followed the Declaration of Helsinki and was approved by the Academic Committee and the Ethics Committee of JSIEC.

Methods

Surgical approach

At 15 minutes before operation, 0.5% proparacaine hydrochloride eye drops (Alcaine; Alcon, USA) were added to the affected eye(s) (every 5 minutes; for a total of 3 times) for topical anesthesia. During operation, the patient was instructed to look in the direction of his/her heel, and no suture was used to fix the eye(s). A pair of non-invasive forceps was used to grip the conjunctiva, and a pair of toothed forceps was used to grip the sclera. The surgical procedures were as follows:

(I) A fornix-based conjunctival flap was prepared as follows: the bulbar conjunctiva was cut at the junction of the cornea and sclera along the 11-1 o'clock direction, followed by sharp separation of the bulbar conjunctiva and fascia. The bleeding at the scleral surface was stopped using interval cautery hemostasis and sponge thermal hemostasis;

(II) A tunnel scalpel was then used to prepare a square scleral flap 2.5×3 mm^2 in size, approximately half of the scleral thickness and 0.5 mm into the clear cornea. For patients less than 60 years old, hemostatic sponge preps that were soaked in mitomycin C solution (2 mg/10 mL) were placed under the scleral flap for 1 minute; then, the scleral flap was rinsed with 500 mL of saline;

(III) A 15° scalpel was used to make a side incision in the clear cornea to release a small amount of aqueous humor;

(IV) A 15° scalpel was used to make a puncture into the anterior chamber at the junction of the clear cornea and the trabecular tissue under the scleral flap. A trabecular cutter was then used to cut and remove approximately 1×2 mm^2 of trabecular tissue, followed by peripheral iridectomy;

(V) 10/0 nylon sutures were used for prepare two interrupted diagonal sutures of the scleral scalp; 10/0 nylon sutures were used for one interrupted half purse-string suture on each side of the bulbar conjunctival wound, until the wound was just watertight;

(VI) Balanced salt solution was injected through the side corneal incisions to form the anterior chamber, until diffuse bulging of filtering blebs was observed. A hemostatic sponge was used to check any leakage of the conjunctival flap; then, the operation was completed.

Postoperative medication

A total of 0.3% tobramycin and dexamethasone ophthalmic ointment (Tobradex ointment; Alcon, USA) was used to cover the operated eye(s) and was removed the next day. The patient was routinely given 0.3% ofloxacin eye drops (Tarivid; Daiichi Pharmaceuticals, Japan) every 2 hours, 1% prednisolone acetate eye drops (pred Forte; Allergen, USA) every 2 hours, and 0.3% tobramycin and dexamethasone

ophthalmic ointment or 0.3% ofloxacin ophthalmic ointment (Tarivid) nightly at bedtime. Based on the eye conditions, the medications and dosing schedule were adjusted and recorded as appropriate.

Parameters recorded

(I) Before operation—ophthalmic biological parameters, visual acuity, IOP, medications, chamber angle, eye condition, visual field; (II) during operation—patient cooperation, pain and complications; (III) after operation—visual acuity, IOP, medications, eye condition, visual field, filtering blebs.

An ultrasound device (Quantel; Cinescan, France) was used to measure ophthalmic biological parameters including anterior chamber depth, lens thickness, eye axial length, daily visual acuity (standard vision chart). On postoperative day 1, a non-contact pneumatonometer (Canon TX-F, Japan) was used to measure IOP; on postoperative day 2 and subsequent days, IOP was measured using a Goldmann tonometer (Goldmann AT900, Switzerland). IOP was measured 3 times, and the average was used for subsequent analysis. Chamber angle was examined using a four-angle goniolens (Zeiss, Germany) and ultrasound biomicroscopy (UBM, PARADIGM P40, USA). Visual field was examined using Humphrey perimetry.

Evaluation of surgical outcome

Patient-rated intraoperative anesthesia effect

At the end of operation, the patient was asked to use the visual analog scale (VAS) (11) to rate the anesthesia effect (0-10 points indicated "no pain" to "maximum pain").

Surgeon-rated intraoperative patient cooperation

Surgeon-rated intraoperative patient cooperation was rated as "good", "fair", or "poor": good—good eye cooperation, allowing successful completion of the operation; fair—involuntary eye movement, and the operation was completed using additional topical anesthesia; poor—lack of eye cooperation, anesthesia was administered by injection or the eye was fixed with sutures.

Inflammatory response of the anterior chamber

Inflammatory response of the anterior chamber was rated as mild, moderate, or severe according to the literature (12): mild—aqueous flare 0-1+ or aqueous cells 0-0.5+; moderate—aqueous flare 2+ or aqueous cells 1-2+; severe—aqueous flare 3-4+ or aqueous cells 3-4+.

Anterior chamber

Anterior chamber depth was compared before and after the operation using the Spaeth method (8) as follows: shallow I—the central anterior chamber is formed, and the iris periphery is in contact with the corneal endothelium; shallow II—except for the anterior lens capsule at the pupil area, the surface of the iris is in contact with the corneal endothelium; shallow III—the anterior chamber is lost, the entire surface of the iris and the anterior lens capsule are in contact with the corneal endothelium. In cases less than shallow I, the depth is compared to the preoperative level.

Filtering blebs

Filtering blebs are classified as one of four types according to the Kronfeld classification (8): type I (micro-fluid cysts)—diffuse cystic bulging filtering blebs with thin walls and surface anemia; type II (diffuse flat type)—diffuse, slightly bulging filtering blebs with slightly thicker walls and mild anemia or new thin vessels on the surface; type III (absence type)—flat filtering blebs, with scleral adhesions and rich neovascularization on the surface; type IV (encapsulation type)—localized encapsulated highly bulging filtering blebs having clear boundaries with the surrounding conjunctiva, thick walls, solid and indurated scarring, and rich neovascularization on and around the surface.

Criteria for surgical success

Criteria for surgical success is no need for ocular hypotensive drugs after operation, IOP of the operated eye ≤18 mmHg (13), and no progression in visual field; relative success: use of one ocular hypotensive drug, IOP of the operated eye ≤18 mmHg, and no progression in visual field; failure: use of more than one ocular hypotensive drug and IOP of the operated eye >18 mmHg. Visual field was analyzed using the glaucoma progression analysis (GPA) software provided with the Humphrey perimetry equipment, and glaucoma was considered to have progressed if the visual field mean defect had increased by ≥1 dB since the previous visit.

Statistical analysis

The data were analyzed using SPSS 17.0 software. In the statistical analysis, visual acuity was converted to the logarithm of the minimum visual angle of resolution (LogMAR) (14). General information and endpoints of the subjects are expressed as $\bar{x}\pm s$, and the following parameters were compared using analysis of variance (ANOVA) of repeated measures: visual acuity, IOP, visual field mean defect, and the number of drugs used at various time points. The Greenhouse-Geisser correction was used if sphericity test criteria were not satisfied. A multiplex pairwise *t*-test

was performed for pairwise comparison of repeat measures at various time points (Bonferroni method). A χ^2 test was performed to compare the surgical success rate at various time points. Differences with P<0.05 were considered statistically significant.

Results

Twenty-seven patients (30 eyes) were enrolled and completed the operation; mitomycin C was used on ten eyes. All patients were followed up for at least 12 months. The preoperative information of the enrolled patients is shown in *Table 1*.

Visual acuity, IOP, and visual field

No significant decrease in visual acuity was observed at days 1 and 7 and at months 1, 3, 6, and 12 after operation (P>0.05); however, a significant decrease in IOP was observed at days 1 and 7 and at months 1, 3, 6, and 12 after operation (P<0.01). Moreover, no significant progression in visual field mean defect was observed at months 6 and 12 after operation (P>0.05) (*Table 2*).

Table 1 Preoperative general information of the enrolled patients

Parameters	Value
Gender (male/female) (n)	16/11
Age $\bar{x}$±s [years]	60.19±5.94 [50-69]
Eye (left/right) (n)	17/13
Stage (10)	
Early (n)	2
Progression (n)	9
Late (n)	19
Anterior chamber depth $\bar{x}$±s (mm) [range]	2.62±0.29 [1.96-3.12]
Lens thickness $\bar{x}$±s (mm) [range]	4.86±0.39 [4.09-5.55]
Axial length $\bar{x}$±s (mm) [range]	22.71±0.86 [20.58-23.96]

Use of ocular hypotensive drugs

Before operation, 30 eyes (100%) required the use of ocular hypotensive drugs. At month 6 after operation, four eyes (13.33%) required the use of ocular hypotensive drugs, and at month 12 after operation, seven eyes (23.33%) required the use of ocular hypotensive drugs. The number of ocular hypotensive drugs required was significantly reduced at months 6 and 12 after operation (P<0.05). More ocular hypotensive drugs were required at month 12 after operation than at month 6 after operation, but the difference was not statistically significant (P>0.05) (*Tables 2,3*).

Intraoperative cooperation

All operations were successfully completed under topical anesthesia; among these, 13.3% (4/30) of operations required additional topical anesthesia. Patient-rated anesthetic effect was 0.53±1.02 (range, 0-3.0). Surgeon-rated patient cooperation was "good" (86.7%, 26/30) and "fair" (13.3%, 4/30).

Intraoperative complications

No intraoperative complications were observed.

Postoperative inflammatory response of the anterior chamber

All 30 eyes are in mild response.

Table 2 Change in visual acuity, IOP, visual field, and medications before and after operation ($\bar{x}$±s) (n=30)

Time	Visual acuity (LogMAR)	IOP (mmHg)	Visual field mean defect (dB)	Number of ocular hypotensive drugs (n)
Before surgery	0.34±0.32	24.26±8.59	–22.70±7.41	2.20±1.06
1 day after surgery	0.37±0.31	14.32±7.04	–	–
7 days after surgery	0.33±0.20	11.20±3.18	–	–
1 month after surgery	0.33±0.23	13.85±4.01	–	–
3 months after surgery	0.35±0.24	13.53±4.26	–	–
6 months after surgery	0.37±0.27	13.70±4.19	–21.75±7.50	0.23±0.57
12 months after surgery	0.37±0.27	13.85±4.01	–21.98±7.63	0.33±0.61

IOP, intraocular pressure.

Table 3 The number of ocular hypotensive drugs used before and after operation (n=30)

Number of ocular hypotensive drugs	Before operation (number of eyes)	6 months after operation (number of eyes)	12 months after operation (number of eyes)
0	0	26	23
1	7	2	5
2	9	2	2
≥3	14	0	0

Postoperative complications

During the first week after operation, four eyes (13.3%) exhibited shallowing of the anterior chamber (not reaching shallow I), which improved 2-4 days after the dosing of 1% prednisolone acetate eye drops was adjusted to 3-4 times/day; one eye (3.33%) exhibited conjunctival flap leakage and shallow anterior chamber (shallow I). The anterior chamber depth returned to normal after a soft bandage contact lens was worn for 3 days; the contact lens was removed 7 days later, and no incision leakage was observed. Three eyes (10%) exhibited IOP >21 mmHg during the first week after operation, during which one eye underwent laser removal of scleral stitches, and two eye received massage. IOP was under control. No complications (such as malignant glaucoma, choroidal detachment, or filtering bleb infection) were observed.

Filtering blebs

At month 12 after operation, 13.33% (4/30), 83.33% (25/30), 3.33% (1/30), and 0% (0/30) of eyes were of types I, II, III, and IV, respectively.

Surgical success rate

At month 6 after operation, the surgical success rate was 86.7% (26/30), and the overall success rate was 93.33% (28/30); at month 12 after operation, the surgical success rate was 76.67% (23/30), and the overall success rate was 93.33% (28/30). No significant difference was observed in the surgical success rate between months 6 and 12 after operation (χ^2=1.47, P=0.48).

Discussion

In this study, we introduced minimally invasive trabeculectomy to minimize tissue damage in the surgical field during trabeculectomy. All patients in this study successfully underwent operation under topical anesthesia without the need for sutures to fix the eye. Moreover, patient-rated anesthesia was good, suggesting that topical anesthesia was safe and feasible while minimizing pain. In addition, we used a trabecular cutter during the operation for the precise resection of trabecular tissue. While replacing the iris, we advantageously used a scleral flap rather than an iris replacer, which helped to reduce postoperative inflammation. Consequently, only mild inflammation was observed after operation.

Patients enrolled in this study had angle-closure glaucoma that was characterized by a shallow anterior chamber, thick lens and short axial length. Using watertight scleral sutures and intraoperative reconstruction of the anterior chamber, during operation and the first week after operation, four eyes (12.5%) exhibited shallowing of the anterior chamber (not reaching shallow I) that was resolved, and one eye (3.12%) had conjunctival flap leakage and shallow anterior chamber (shallow I) that recovered after wearing a soft bandage contact lens. Thus, the incidence of complications was lower than that reported by Edmunds *et al*. (15), where the incidence of intraoperative bleeding in the anterior chamber, postoperative shallow anterior chamber, and conjunctival flap leakage was 24.6%, 23.9%, and 17.8%, respectively. Moreover, in this study, no other complications (such as malignant glaucoma, choroidal detachment and endophthalmitis) were observed, suggesting that the modified procedure is safe for PCACG and reduces the incidence of postoperative complications, such as shallow anterior chamber and low IOP.

In this study, during the first week after operation, three eyes (10.52%) exhibited IOP >21 mmHg and this was primarily due to tight scleral sutures. Specifically, one eye underwent laser removal of scleral sutures, and two eyes received massage. Consequently, IOP was rapidly controlled. However, two eyes exhibited long-term high IOP, suggesting that it is important to avoid tight sutures during operation and that patients with elevated IOP during

the early stage after operation should be closely monitored and receive interventions if needed to ensure long-term treatment outcome.

In this study, we used less invasive surgical approaches and instruments, such as non-invasive forceps and trabecular cutters, to reduce surgical damage (16); we used topical anesthesia to avoid complications that are associated with postbulbar anesthesia or beneath-the-fascia anesthesia (11); to reduce eye muscle or corneal damage, we did not use sutures to fix the eye; we used non-invasive forceps to grip the conjunctiva with a smaller conjunctival flap and reduce conjunctival damage; we used thermal hemostasis with a hemostatic sponge to mitigate the thermal reaction of the scleral surface caused by direct burning; and we used a scleral tunnel scalpel to make a (smaller) scleral flap to reduce damage to the scleral tissue and the surrounding vessels, thereby reducing the wound healing response of filtration surgery and postoperative scarring and facilitating the establishment of good filtration pathways (17). In this study, at month 12 after operation, 83.33% of the operated eyes had type II filtering blebs, and 96.67% (29/30) had a functional bleb morphology. No complications (such as filtering bleb infection) were observed.

In this study, the patients were followed up for at least 1 year, and no significant decrease in visual acuity was observed after operation; IOP was significantly reduced after operation, no significant progression was observed in visual field mean defect at months 6 and 12 after operation, and the number of ocular hypotensive drugs used was significantly reduced at months 6 and 12 after operation. The surgical success rate observed was higher than that reported by Edmunds *et al.* (18), who reported a 1-year absolute surgical success rate of 66.6% and an overall success rate of 71.0%. Collectively, these findings suggest that our modified procedure improved the surgical success rate. In this study, some patients required ocular hypotensive drugs at months 6 and 12 after operation, mainly because these patients had advanced visual field changes caused by glaucoma before operation, thus requiring a lower IOP target.

This study has some limitations, including small sample size, short follow-up time, and lack of a suitable control. In future studies, we will enroll more patients and use a longer-term follow-up period to further investigate long-term IOP management after operation.

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Footnote

Conflicts of Interest: The authors have no conflicts of interest to declare.

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