Combined subconjunctival injection of dexamethasone for the management of acute primary angle closure: a randomised controlled trial

Wenbin Huang, Xingyi Li, Kai Gao, Xiulan Zhang

State Key Laboratory of Ophthalmology, Zhongshan Ophthalmic Center, Sun Yat-Sen University Zhongshan Ophthalmic Center, Guangzhou, China

Correspondence to
Professor Xiulan Zhang, Zhongshan Ophthalmic Center, Sun Yat-Sen University Zhongshan Ophthalmic Center, Guangzhou 510060, China; zhangxl2@mail.sysu.edu.cn

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ABSTRACT

Purpose To investigate whether the combined subconjunctival injection of dexamethasone can accelerate the decrease in intraocular pressure (IOP) in acute primary angle closure (APAC)-affected eyes.

Methods 42 patients with APAC were recruited for a randomised controlled trial. These patients were separated into two groups: the injection group (21 patients) and the control group (21 patients). The injection group was subjected to a subconjunctival injection with 2.5 mg dexamethasone. Other drug treatments were the same with the control group. The follow-up was at 0, 3, 6, 12 and 24 hours after injection. The outcome measures include IOP and intraocular inflammation variables.

Results The IOP was significantly decreased in both groups after treatment. However, 24 hours after the initial treatment, the IOP of the injection group was significantly lower compared with the control group ($p = 0.017$). Kaplan-Meier survival curve analysis showed that the total success rate of the injection group and the control group were 79.7% and 54.9% at 24 hours after treatment ($p = 0.027$), respectively. For the comparison of anterior chamber inflammation, the severity of conjunctival erythema, ciliary flush and pain in the injection group was also lower than that in the control group at 24 hours after treatment($p = 0.012$, $p = 0.048$ and $p = 0.013$, respectively). No statistical significance was found between the two groups regarding the anterior chamber cells, anterior chamber flare and photophobia.

Conclusion The combined subconjunctival injection of dexamethasone for the management of APAC eyes can significantly accelerate the relief of high IOP, and therefore, improve the success rate of treatment.

INTRODUCTION

Acute primary angle closure (APAC) is a well-known ophthalmic emergency, characterised by the sudden and excessive increases in intraocular pressure (IOP).[1] Previous studies have reported that APAC has a higher incidence with Chinese, seen in various parts in Asia, with 10.4 cases per 100 000 per year in Hong Kong and 12.2 per 100 000 per year in Singapore.[2] Because of excessive increases in IOP, severe episodes of APAC can lead to the development of visual field damage, chronic glaucoma and even blindness.[3 4] For example, anterior chamber inflammation is related to the increase in IOP. It is caused by an excessive increase in IOP that damages the blood barrier of the anterior chamber. As a result, inflammatory cells and inflammatory factors cause the anterior chamber inflammation. In turn, this will change the aqueous circulation and cause post-pupil adhesion, which leads to pupillary block.[5]

Studying the expression of inflammatory factors in the aqueous humour of APAC eyes is of great significance for understanding the pathogenesis of APAC and for guiding clinical practices. Therefore, we previously conducted a study on the expression of inflammatory factors in the anterior chamber of patients' eyes with APAC. Our results showed that the inflammatory response in the aqueous humour from APAC eyes was evident and that multiple inflammatory factors were elevated significantly.[6 7]

Since APAC has an increased IOP and a clear anterior chamber inflammation, it is necessary to strengthen the anti-inflammatory strategies during treatment. Anti-inflammatory treatments include topical non-steroidal anti-inflammatory eye drops, topical steroidal eye drops and systemic steroidal therapy, which are all strategies commonly used to treat APAC. To investigate whether the combination of anti-inflammatory eye drops is effective for the treatment of angle-closure glaucoma, a multicentre retrospective study with dogs suffering acute angle-closure glaucoma was previously performed. The study showed that a combination of topical anti-inflammatory eye drops was beneficial during treatment.[8] Although promising, there are currently no data regarding a randomised controlled trial that demonstrates the effectiveness of anti-inflammatory drugs for the treatment of human eyes suffering from APAC. Therefore, we performed a randomised controlled trial in this study to explore whether a combined subconjunctival injection of dexamethasone can alleviate the inflammation in human APAC eyes and accelerate the decrease in the IOP.

METHODS

The study was a randomised controlled trial approved by the Zhongshan Ophthalmic Centre Institutional Review Board of Sun Yat-sen University. The trial was registered at http://www.chictr.org.cn (identifier, ChiCTR-ICR-15006079) and conducted in accordance with the principles of the Declaration of Helsinki. Subjects affected by APAC were recruited between April 2015 and March 2017. Written informed consent was obtained from all participants.

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The study population consisted of subjects who were 40 years or older, diagnosed with APAC (defined below) and were experiencing APAC for the first time. APAC was defined based on the following criteria[2]: (1) the presence of at least two of the following symptoms: ocular or periocular pain, nausea and/or vomiting or an antecedent history of intermittent blurring of the vision with halos; (2) an IOP of at least 22 mm Hg (measured by the Goldmann applanation tonometer); (3) the presence of at least three of the following signs of conjunctival injection: corneal epithelial oedema, mid-dilated unreactive pupil or a shallow anterior chamber and (4) the presence of an occluded angle in the affected eye (verified by gonioscopy). All eyes underwent an ultrasound biomicroscopy (UBM) examination to confirm the existence of a narrow-angle pupillary block component.

Patients that were excluded included ones with any of the following criteria: (1) a secondary acute attack because of lens subluxation, uveitis, iris neovascularisation, trauma, tumour or any detectable cataract leading to an intumescent lens; (2) a history of previous ocular surgery (including laser treatment); (3) a known inflammatory, autoimmune or immunosuppressive disease; (4) a pre-existing ocular disease (eg, retinal vein occlusion, retinal artery occlusion, diabetic retinopathy or age-related macular degeneration); (5) parietes with diabetes; (6) a history of hypersensitivity against dexamethasone and its analogues; (7) a usage of topical anti-inflammatory drugs (including non-steroidal anti-inflammatory drugs and steroids); (8) pregnant women (9) and one-eyed and other disabled people.

As a baseline, a detailed demographic and medical history were collected using a questionnaire, and all the subjects underwent a standardised examination that included assessment of their best-corrected visual acuity (VA; Snellen VA chart), slit-lamp biomicroscopy, IOP measurement (Goldmann applanation tonometry), gonioscopy, fundus examination, UBM, A/B-scanning, visual field test analysis (SITA, standard algorithm with a 24–2 test pattern that uses the Humphrey Visual Field Analyzer II from Carl Zeiss Meditec, Dublin, CA, USA) and a refractive error examination that uses an auto kerato-refractometer (KR-8900 V.1.07, Topcon Corporation, Tokyo, Japan). For all patients, IOP was measured during every visit, and the same slit lamp and tonometer were used. Three consecutive readings were obtained, and the scale of the tonometer was concealed from the examiner. The IOP values were documented by an assistant, and the mean was computed.

Treatment assignment

Qualified patients were assigned to one of the two treatments using a table of computer-generated random numbers. The control group received four times daily 1% topical pilocarpine, two times daily topical beta-blocker (timolol 0.5%), two times daily brinzolamide (Azopt; Alcon Laboratories, Elkridge, MD, USA), two times daily topical alpha-2 agonists (Alphagan; Allergan, Irvine, CA, USA), three times daily 250 mg acetazolamide by oral intake and once 250 mL of 20% mannitol inserted intravenously. The injection group received a subconjunctival injection of 2.5 mg dexamethasone disodium phosphate. Other drug treatments for the injection group were the same as the control group. For the subconjunctival injection of dexamethasone, a 30-gauge needle was used to inject it 4 mm away from the limbus. The injection site was closed using a cotton wool tip for 10 s.

Measurement of the outcome

The patients were visited at the baseline moment and then 3, 6, 12 and 24 hours after the initial treatment (control group: drug treatments, injection group: drug treatments and the subconjunctival injection of 2.5 mg dexamethasone). During each visit, the VA, the IOP and the clinical assessment of intraocular inflammation were performed by a masked investigator who was unaware of the patient group status. Additionally, a masked statistician analysed the data.

The primary outcome measurements were IOP and the success rate after the subconjunctival injection of dexamethasone disodium phosphate. The success of treatment was reached when an IOP between 6 and 21 mm Hg without significant complications was determined. A failure of treatment was defined when an IOP of more than 21 mm Hg was determined. The secondary outcomes included the intraocular inflammation variables. Intraocular inflammation was evaluated by slit-lamp biomicroscopy without pupil dilation, according to a previously published grade system[9 10]: Anterior chamber cells were graded on a scale of 0–4, with 0 as none (no cells), 1 as mild (1–5 cells), 2 as moderate (6–15 cells), 3 as severe (16–30 cells) and 4 as very severe (>30 cells). Anterior chamber flare was also graded on a scale of 0–4, with 0 as none (no Tyndall effect), 1 as mild (a weak Tyndall effect), 2 as moderate (a moderate intensity of the Tyndall beam in the anterior chamber), 3 as severe (a strong intensity of the Tyndall beam) and 4 as very severe (a very strong intensity of the Tyndall beam with a white and milky appearance of the aqueous humour). Furthermore, additional efficacy variables included conjunctival erythema and ciliary flush. Patients were verbally asked whether they experienced symptoms of ocular inflammation such as a foreign body sensation, tearing, photophobia and pain. These variables were also evaluated on a scale of 0–4, with 1-grade increments, where 0 none and 4 very severe.

Finally, adverse events, VA, and other biomicroscopic and ophthalmoscopic findings were also documented. Throughout the study, any signs or symptoms of adverse events were recorded, graded for severity and assessed for their relationship to the study's medication.

Statistical analysis

By using the superiority test, a significance level below 0.05 was set and a power of 0.80 to detect an average IOP difference of 2.0 mm Hg with a 2.5 mm Hg SE between groups, it was estimated that 21 eyes in each group were needed. The data were processed and analysed statistically using SPSS (V.13.0, SPSS, Chicago, IL, USA). For categorical variables, the frequency distribution and percentages were calculated and compared using the χ^2 test. For numerical variables with a parametric distribution, the two-sample independent t-test was performed. The Mann-Whitney U test was used to evaluate variables with ordered-response categories and continuous responses. The success rates in both groups were compared using the Kaplan-Meier survival curves and the log-rank test. Statistical significance was accepted at $p<0.05$.

RESULTS

Baseline characteristics

The screening, recruitment and flow of randomisation of subjects are illustrated in figure 1. Of the 42 recruited subjects in this study, 21 (21 eyes) were randomised to the control group and 21 (21 eyes) randomised to the injection group. At the baseline (table 1), results for all parameters including age, gender, duration before recruitment, drug use, IOP, VA, spherical equivalent,

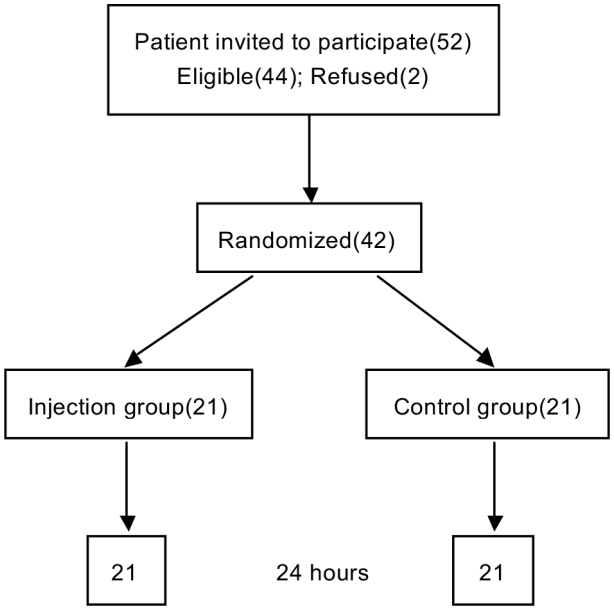

Figure 1 Flowchart showing screening, recruitment, and randomisation in the trial.

anterior chamber depth, lens thickness, vitreous chamber depth, axial length and visual field test were found to be similar between the two groups.

IOP and success rate

Table 2 and figure 2 show the mean IOP for all time intervals in both groups. Compared with the groups' IOP baseline, the two groups showed a statistically significant decrease in IOP at all follow-up intervals (all $p<0.05$). After 24 hours of subconjunctival injection of dexamethasone, the IOPs were significantly lower in the subconjunctival injection group than in the control group ($p=0.017$). Kaplan-Meier survival analysis showed the cumulative probabilities of the success rates for the injection group and the control group; the success rates were 79.7% and 54.9% at 24 hours, respectively. The success rate of the injection group after treatment completion was significantly higher than that of the control group ($p=0.027$, log-rank test; figure 3).

Table 1 Baseline patient characteristics

Characteristics	Injection group (n=21)	Control group (n=21)	P value
Age, years	59.6 (9.2)	64.0 (9.1)	0.131
Sex (No. [%])			
Male	4 (19%)	3 (14%)	0.682
Female	17 (81%)	18 (86%)	
Duration before recruitment, d	5.9 (5.8)	5.2 (5.5)	0.623
Drug	1.0 (1.3)	1.2 (1.5)	0.167
IOP, mm Hg	45.4 (9.8)	44.4 (7.4)	0.719
VA (LogMar)	1.4 (0.6)	1.4 (1.0)	0.686
SE, D	0.8 (3.8)	0.7 (2.4)	0.959
ACD, mm	2.02 (0.31)	2.04 (0.18)	0.834
LT, mm	5.20 (0.40)	5.36 (0.35)	0.214
VCD, mm	14.65 (0.68)	14.95 (0.95)	0.288
AL, mm	21.87 (0.63)	22.15 (0.75)	0.249
MD	−20.1 (10.0)	−15.7 (10.1)	0.233
PSD	5.3 (3.0)	6.2 (3.0)	0.431

The date are present with mean (SD).
IOP, intraocular pressure; VA, visual acuity; SE, spherical equivalent; D, diopter; ACD, anterior chamber depth; LT, lens thickness; VCD, vitreous chamber depth; AL, axial length; MD, mean deviation; PSD, pattern SD.

Table 2 The IOP between injection group and control group

Variable	Group	Baseline	3 hours	6 hours	12 hours	24 hours
IOP, mm Hg	Injection group	45.4 (9.8)	28.3 (10.3)	26.0 (11.0)	23.0 (11.4)	18.0 (8.5)
	Control group	44.4 (7.4)	33.8 (11.5)	30.0 (13.4)	29.0 (15.3)	26.6 (12.9)
	P value	0.719	0.114	0.306	0.164	0.017

The date are present with mean (SD).
IOP, intraocular pressure.

Intraocular inflammation variables

For the anterior chamber and its number of cells and flares, there were no statistically significant differences between the injection group and the control group during all time intervals. The data are summarised in table 3.

Regarding conjunctival erythema, ciliary flush and symptoms of ocular inflammation with pain, stronger improvements were seen—at 24 hours after subconjunctival injection of dexamethasone—in the subconjunctival injection group than in the control group ($p=0.012$, $p=0.048$ and $p=0.013$). There was no statistically significant difference in photophobia between the groups. The data are summarised in table 3.

Then for VA and corneal oedema, no statistically significant difference between the subconjunctival injection group and the control group was found. The data are summarised in table 4. In both groups, no adverse events were found.

DISCUSSION

According to the American Academy of Ophthalmology Preferred Practice Pattern guidelines on primary angle closure,[11] the current treatment process for APAC involves various steps. First, medical therapy is usually initiated to lower the IOP to reduce pain and clear corneal oedema. Then, iridotomy should be performed as soon as possible. When laser iridotomy is not

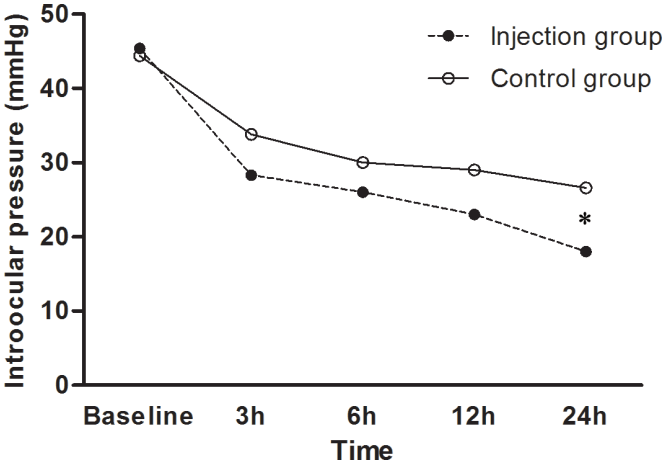

Figure 2 The mean IOP for both groups at each time interval. Compared with the groups' baseline IOP, the two groups showed a statistically significant IOP decrease at all follow-up intervals. *The IOPs were significantly lower in the injection group than in the control group at 24 hours (p=0.017). IOP, intraocular pressure.

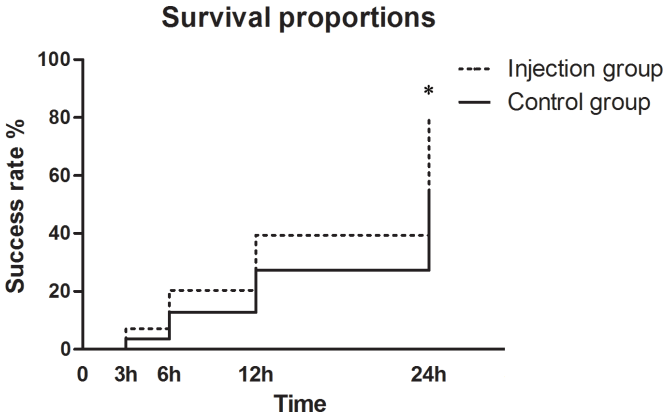

Figure 3 Cumulative survival curves show the cumulative probabilities of the treatment success rates for the injection and control groups. There was significant difference between the two groups (p=0.027).

possible or if the APAC cannot be medically improved, laser peripheral iridoplasty (even with a cloudy cornea), paracentesis and incisional iridectomy remain effective alternatives. Finally, when incisional iridectomy is required, and extensive synechial closure is recognised or suspected, simultaneous primary filtering surgery may be considered. However, the current treatment procedure described above does not provide a normative intervention for an inflammatory condition in APAC eyes.

Table 3 The intraocular inflammation variables between injection group and control group

Variable	Group	Baseline	3 hours	6 hours	12 hours	24 hours
AC cell	Injection group	2.3 (0.5)	2.1 (0.7)	1.5 (0.7)	1.2 (0.7)	0.9 (0.5)
	Control group	2.1 (0.7)	2.0 (0.8)	1.8 (0.6)	1.4 (0.9)	1.3 (0.8)
	P value	0.226	0.860	0.261	0.382	0.110
AC flare	Injection group	2.2 (0.5)	1.9 (0.7)	1.3 (0.7)	1.1 (0.6)	0.8 (0.4)
	Control group	2.1 (0.7)	2.0 (0.8)	1.7 (0.7)	1.3 (0.9)	1.2 (0.8)
	P value	0.575	0.555	0.050	0.487	0.068
Conjunctival erythema	Injection group	2.3 (0.5)	1.9 (0.5)	1.4 (0.5)	1.2 (0.4)	1.0 (0.3)
	Control group	2.2 (0.7)	2.1 (0.8)	1.7 (0.7)	1.6 (0.7)	1.5 (0.6)
	P value	0.792	0.399	0.208	0.040	0.012
Ciliary flush	Injection group	2.1 (0.5)	1.4 (0.5)	0.9 (0.5)	0.7 (0.5)	0.6 (0.5)
	Control group	1.9 (0.8)	1.7 (0.8)	1.5 (0.9)	1.2 (0.9)	1.0 (0.6)
	P value	0.512	0.173	0.030	0.059	0.048
Photophobia	Injection group	1.6 (0.9)	1.3 (0.9)	1.1 (0.9)	0.8 (0.9)	0.7 (0.8)
	Control group	1.6 (0.8)	1.5 (0.7)	1.2 (0.9)	1.1 (0.8)	1.0 (0.6)
	P value	0.739	0.583	0.475	0.152	0.161
Pain	Injection group	2.4 (0.9)	1.5 (0.9)	0.9 (0.7)	0.7 (0.7)	0.3 (0.5)
	Control group	2.2 (0.9)	1.9 (1.0)	1.5 (1.2)	1.3 (1.1)	1.0 (1.1)
	P value	0.509	0.263	0.097	0.093	0.013

The date are present with mean (SD).
AC, anterior chamber.

Table 4 The VA and cornea oedema between injection group and control group

Variable	Group	Baseline	3 hours	6 hours	12 hours	24 hours
VA	Injection group	1.4 (0.6)	1.3 (0.7)	1.2 (0.7)	1.2 (0.7)	1.0 (0.6)
	Control group	1.4 (1.0)	1.3 (1.0)	1.3 (1.0)	1.3 (1.0)	1.2 (1.1)
	P value	0.686	0.742	0.854	0.783	0.834
Cornea oedema	Injection group	1.9 (0.6)	1.6 (0.8)	1.2 (0.9)	0.9 (0.9)	0.7 (0.8)
	Control group	2.0 (0.8)	1.8 (0.9)	1.5 (0.9)	1.2 (0.8)	0.9 (0.8)
	P value	0.710	0.506	0.282	0.272	0.377

The date are present with mean (SD).
VA, visual acuity.

Before that, we previously conducted a study focused on the expression of inflammatory factors in the anterior chamber of APAC eyes. The results showed that the inflammatory reaction was evident, and multiple inflammatory factors were elevated.[6] However, there was no randomised controlled trial to demonstrate the effectiveness of anti-inflammatory therapy in the treatment of APAC, creating the necessity to conduct a clinical trial to explore its effectiveness. Recent studies have shown that the topical application of steroids for the treatment of APAC can reduce the postoperative inflammatory response, stabilise the blood-aqueous barrier, inhibit fibrin exudation, and reduce postoperative scarring and formation of iris adhesion.[12 13] In this regard, dexamethasone has been proven to be safe and effective and is widely used for clinical anti-inflammatory treatment. On the other hand, previous studies found that the subconjunctival injection of dexamethasone can achieve more effective concentrations in the aqueous humour and maintain higher levels for longer periods than the topical and systemic applications.[14 15] Therefore, in the present study, we use the method of combined subconjunctival injection of dexamethasone to explore its role in the treatment of APAC.

Our results showed that the treatment and control groups had a significant decrease in IOP after treatment and that the mean IOP at each follow-up time point was lower than their baseline. However, 24 hours after the treatment, the degree of IOP decrease in the combined subconjunctival injection of dexamethasone group was greater than that of the control group. Kaplan-Meier survival analysis showed that the total success rate of the combined injection group and the control group was 79.7% and 54.9%, respectively. After 24 hours of treatment, the combined injection group had a higher success rate. Regarding anterior chamber inflammation, the results showed that there was no significant difference in the AC cell, AC flare or photophobia between the two groups. In contrast, conjunctival erythema, ciliary flush and eye pain were significantly better at 24 hours after treatment in the injection group than those in the control group. These results indicate that combined subconjunctival injection of dexamethasone could accelerate the decrease in high IOP in a short period of time and may relieve the anterior chamber inflammation in APAC eyes.

Since APAC eyes have a high IOP during the expose, which can cause irreversible visual impairment in the short time, it is recommended to reduce the IOP rapidly as soon as possible. Both groups were treated with specific drugs during this study, and further treatment was needed when the treatment was ineffective to reduce the IOP in the short-term rapidly. As such, our follow-up time was designed to be short with only 24 hours after

the increase in IOP. We found that after this short period of time, a subconjunctival injection of dexamethasone significantly accelerated the relief of high IOP in APAC eyes, which is important and meaningful for guiding anti-inflammatory treatment of APAC.

Regarding complications, none occurred in both groups during this study. Previous studies, however, have reported a transient increase in IOP 5–7 days after the subconjunctival injection of triamcinolone acetonide in patients aged younger than 30 years.[16] Cataract is well documented regarding other approaches of steroid administration and was linked with only one case were a subconjunctival injection of triamcinolone acetonide was applied.[17–19] To avoid the occurrence of these complications, we used a subconjunctival injection of dexamethasone. The dexamethasone was water soluble and had a short half-life. As such, the subconjunctival injection of dexamethasone was less likely to cause IOP and lens opacity. Studies have further shown that with a subconjunctival injection of 2.5 mg dexamethasone, the anterior chamber concentration would reach the highest concentration of 858 ng/mL dexamethasone after 2.5 hours; and decrease to approximately 20 ng/mL after 24 hours,[15] which is similar to the concentration of frequently applied topical treatment (one drop every 1.5 hours).

Some potential limitations of our study should be mentioned. First, because subconjunctival injection is difficult to blind, the patients were not blinded in this study. The operators, however, were blinded for every examination. Second, the classification of anterior chamber inflammation is subjective, although this study was performed by the same experienced physician for the grading of anterior chamber inflammation; further research is needed to provide more objective data. Finally, another limitation of the study includes the sample size. The number of patients enrolled in our study was relatively low, and further studies with a larger sample size are needed to confirm our results further.

CONCLUSION

This study was performed to explore the role of combined subconjunctival injection of dexamethasone for the treatment of APAC eyes. We found that this approach can significantly accelerate the decrease in high IOP in APAC eyes and improve the success rate of treatment in the short term. This shows that the anti-inflammatory treatment of combined subconjunctival injection of dexamethasone for APAC eyes has significant clinical importance.

Contributors WH: design of the work, analysis and interpretation of data, wrote the manuscript. XL, KG: collect the data. XZ: design of the work, patient recruitment, wrote the manuscript.

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