Study on the effect of two ways of cycloplegia on biological parameters of ciliary muscle

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Research Background

The ciliary muscle exhibited an inward-forward contraction during accommodation[1-3], resulting in a significant thickening of the anterior area of the ciliary muscle[3 4]. In addition to ultrasound biomicroscope (UBM), anterior segment optical coherence tomography (AS-OCT) is also commonly used to study morphological changes in the ciliary muscle. Studies using AS-OCT revealed that the posterior area of the ciliary muscle thinned during accommodation[3-8].

The morphology of the ciliary muscles differs in individuals with refractive errors. Many researchers found that the ciliary muscle became thicker with an increase of axial length (AL)[7 9-11]. Some studies suggested that myopia primarily affected the posterior area of the ciliary muscle[5 9 12-15].

Atropine has a ciliary muscle-paralysing effect and causes hyperopic drift. Besides, atropine has been proven to slow the progression of myopia [16 17]. Many studies have suggested that atropine can increase the thickness of the choroid[17-20]. However, few studies have discussed changes in the ciliary muscle after treatment with atropine or other cycloplegic agents. This study aimed to assess the difference in ciliary muscle morphology before and after two different cycloplegic agents and explored the influencing factors of ciliary muscle.

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Research purposes

1. To observe the anatomical position and morphological changes of ciliary muscle in myopic children under two cycloplegic methods

2. To analyze the correlation between the changes of ciliary muscle biological parameters and the changes of axial length, spherical equivalent, lens power, choroidal thickness, etc.

3. To provide clinical evidence for the role of regulatory factors in the occurrence and development of myopia

3. Research content

This study was designed as a prospective, randomized controlled clinical study

Grouping

72 people in the 1% atropine group

72 people in the tropicamide group

Children mainly from the optometry clinic of Shanghai Eye Disease Control Center

Inclusion criteria

1. Age from 6 to 12 years old, gender is not limited;

2. Both eyes are in line with the diagnosis of myopic refractive error and the myopia is 0.25D < myopia spherical lens <6.00D, astigmatism <2.00D, binocular anisometropia <3.00D, and the best corrected distance vision is at least 0.8, near vision at least 0.8;

3. A clear anterior segment image can be obtained through anterior segment OCT;

4. Have normal thinking and language communication skills, and can actively cooperate with the inspection process;

5. No contraindications to atropine treatment such as acute eye inflammation, dry eye, keratoconus, diabetes, etc.;

6. Written informed consent of the guardian and the child himself

Exclusion criteria

1. Combined with neurological diseases and have allergies or contraindications to cycloplegic drugs or other drugs;

2. Intraocular pressure ≥21mmHg; history of photosensitivity, glaucoma, blue eye syndrome, ocular hypertension, and retinal macular lesions or damage;

3. Patients with chronic eye diseases such as ocular trauma and allergic conjunctivitis;

4. Those who wear contact lenses and those who use myopia control-related drugs within 1 month, such as atropine and Xinliuding;

5. Patients with previous varus trichiasis, severe horn, conjunctiva infection and other eye diseases;

6. Insufficient image quality, such as inconsistent field of view, poor image exposure, inaccurate image focus, stains, shadows or crescent shadows, etc.;

7. There are systemic diseases;

8. Epilepsy, mental disorders unable to communicate normally;

9. Other circumstances judged by the investigator to be unsuitable to participate in the research

Interventions

The period of recruiting patients 3 months

the intervention period 1 week.

1. 1% atropine group: once a night for 7 consecutive days

2. Tropicamide group: once every 5 minutes, after 3 consecutive instillations, close the eyes for 20 minutes

Outcome

Main outcomes

Ciliary muscle thickness and position parameters before and after treatment

Secondary outcomes

Spherical equivalent and axial length before and after treatment

Other outcomes

Changes in uncorrected visual acuity, corrected visual acuity, intraocular pressure, pupil diameter, corneal thickness, anterior chamber depth, lens thickness, and choroid/retina thickness

security indicators

1. Observe changes in intraocular pressure, headache, nausea and vomiting, etc.

2. Questionnaire survey: self-perceived photophobia, near blurred vision and other side effects levels

3. Incidence of allergic reactions

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Research methods

Sample size

Select the ciliary muscle apex thickness difference after cycloplegia for sample size calculation

α (inspection level) = 0.05

β (test power) = 0.90

Lost to follow-up rate/dropout rate is 20%

The ratio of the two groups of samples is 1:1

The final calculated sample size is 72 (1% atropine group) + 72 (Tropicamide group) = 144 (total sample size)

grouping

Generate random numbers through a random number table, divide the random numbers by the number of groups, and group them according to the remainder

Technical Risk

After cycloplegia, near vision blurring may occur, and there may be temporary eye burning sensation, stinging pain, and photophobia; for people with near vision blurry, the phenomenon affecting reading needs to be explained patiently, and the subjects should be informed to keep correct reading distance.

1% atropine may cause dry mouth, dry skin and mucous membranes, nausea, facial flushing, palpitations and other symptoms after systemic absorption of atropine. Stop the drug

immediately.

A small number of patients have allergic reactions such as itching, redness, and conjunctival hyperemia of the eyelids, and the drug should be discontinued immediately.

In case of increased intraocular pressure, headache, eye pain and vomiting (manifestations of acute angle-closure glaucoma). The solution is to perform initial slit-lamp screening in all subjects before dilation, and patients with very narrow angles will not be dilated. If the subject has symptoms such as increased intraocular pressure, headache, eye pain, etc., timely drug treatment.

Expected results

To clarify the changes in the morphology and position of the ciliary muscle and its influencing factors by different methods of mydriasis in clinical practice