Effect of Fumigation with Dibazol Eye Drops on Adolescent Moderate and Low Myopia

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To explore the clinical efficacy and safety of fumigation with Dibazol eye drops in the treatment of juvenile middle and low myopia. From January 2019 to January 2020, a total of 158 adolescent patients with moderate and low myopia were randomly divided into control group and observation group, with 79 cases in each group. The observation group was treated with ultrasonic atomization fumigation of 10 times diluted Dibazol eye drops, once a day. The patients in the control group were treated with Dibazol eye drops once a day for 30 d. The uncorrected visual acuity and best corrected visual acuity of the control group and the observation group were measured before and after treatment. The diopter and astigmatism of the two groups were detected by comprehensive refractometer. The therapeutic effect and adverse reactions of the two groups were compared after treatment. The total effective rate of the observation group was 75.95 %, which was significantly higher than 56.96 % of the control group ($p<0.05$). The uncorrected visual acuity and best corrected visual acuity of the two groups after treatment were higher than those before treatment ($p<0.05$), and the uncorrected visual acuity of the observation group after treatment was higher than that of the control group ($p<0.05$). The diopter of the two groups after treatment was higher than that before treatment ($p<0.05$) and the diopter of the observation group after treatment was significantly better than that of the control group ($p<0.05$). After treatment, the astigmatism of the observation group was lower than that before treatment, the difference was statistically significant ($p<0.05$), but there was no significant difference in the astigmatism of the control group before and after treatment ($p>0.05$). After treatment, there was no significant difference in astigmatism between the observation group and the control group ($p>0.05$). The incidence of eye irritation in the observation group was 2.53 %, which significantly alleviated the incidence of adverse reactions ($p<0.05$). The total adverse reaction rate of the observation group was 6.33 %, which was significantly lower than 17.72 % of the control group ($p<0.05$). Compared with eye drops, atomization fumigation of Dibazol eye drops can significantly improve the uncorrected visual acuity, improve the diopter after mydriasis, and reduce the incidence of eye irritation and eye fever, which is a potential treatment for myopia.

Key words: Dibazol eye drops, fumigation, pseudomyopia, adolescent

Myopia is the most common eye disease in the world and it has become the main cause of global visual impairment. With the increasing burden of eye habits and the increased burden of eye use, the incidence rate of myopia has been increasing worldwide which has become an important factor hindering the development of physical and mental development of young people[1]. Limited ophthalmic care opportunities and insufficient intervention are one of the main factors for the increasing number of people with myopia and the aggravation of myopia[2]. The pathological reason of pseudomyopia is that the ciliary muscle can't adjust the shape of lens. Ciliary muscle is the smooth muscle and suspensory ligament around the lens, which can regulate the thickness of the lens[3]. Dibazol eye drops is a kind of smooth muscle relaxant used in the treatment of juvenile pseudomyopia. Dibazol eye drops can relax the smooth muscle and dilate the anterior ciliary artery and vein, promote the blood supply to the ciliary body, improve the ciliary muscle nutrition and its regulatory function, and achieve the effect of inhibiting the rapid growth of myopia, and has the characteristics of non-mydriasis[4]. However, Dibazol has eye irritation to some patients, and the drug compliance needs to be improved. Ultrasonic atomization fumigation therapy combines traditional Chinese medicine diagnosis and

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treatment ideas with modern technology and has the advantages of economy, simple operation, noninvasive and easy acceptance by patients[5]. Aerosol fumigation can improve ciliary microcirculation, promote drug absorption and has the potential to improve the efficacy and compliance of Dibazol eye drops[6]. In the case of few treatment options for myopia, the combination of Dibazol eye drops and fumigation therapy may become an innovative prevention and control option to slow down the aggravation of juvenile pseudomyopia and there are few reports of Dibazol eye drops fumigation in the treatment of juvenile middle and low myopia. In order to analyze the effect of fumigation with Dibazol eye drops on the control of middle and low myopia in adolescents, we carried out a prospective control analysis on the efficacy and safety of 236 eyes of 118 adolescents with middle and low myopia.

A total of 158 adolescent patients with moderate and low myopia admitted to the General Hospital of Tianjin Medical University from January 2019 to January 2020 were selected as subjects. All the participants met the diagnostic criteria of pseudomyopia of Ophthalmology branch of Chinese Medical Association: the near vision of adolescents was within the normal range, the far vision was lower than normal, the far vision returned to normal after giving drugs to paralyze the ciliary muscle and even the clinical manifestations of mild hyperopia were considered as pseudomyopia. Inclusive criteria- age 6-18 y old; informed consent form signed by patients and their families voluntarily; diopter <-3.00 d or astigmatism <-1.00 d after first mydriasis; binocular best corrected visual acuity ≥1.0; normal intraocular pressure, pupil and fundus, binocular best corrected visual acuity >1.0. Exclusion criteria- no history of eye treatment and eye surgery within 6 mo except for single frame glasses; patients with dry eye, keratitis and other eye diseases; patients with allergic to Dibazol; patients with poor compliance, unable to accept fumigation treatment and timely review; patients with systemic diseases and immune deficiency. The above 158 patients were randomly divided into control group and observation group, 79 cases in each group. There were 36 males and 43 females in the control group, with an average age of (10.54±2.52) y and an average visual acuity of (4.13±0.54). There were 38 males and 41 females in the observation group, with an average age of (11.21±2.36) y and an average visual acuity of (4.25±0.46). There was no significant difference in gender, age and average visual acuity between the two groups ($p>0.05$). The two groups were comparable. This study was approved by the ethics committee of our hospital. All patients and their families agreed and signed the informed consent. Dibazole eye drops (Sichuan Heyi Pharmaceutical Co., Ltd., approval number: Guoyao Zhunzi H20174085, specification: 8ml: 8mg). Ultrasonic nebulizer: dry eye treatment system (nebulizer, Shanghai, model: vgr-001a). Fumigation method of the observation group: Take 8 ml of Dibazol eye drops, add 10 times of sterilization dilution and fumigate with ultrasonic atomization through the ophthalmic treatment instrument until there is steam. Find the right posture of the patient, put the eyes on the ophthalmic therapeutic apparatus and steam them. During the fumigation, keep a distance of about 10 cm from the apparatus, 20 min each time. Once a day for 30 d. The patients in the control group were given 1-2 drops of Dibazol eye drops every night before going to bed for 30 d. Before treatment (0 d) and 30 d after treatment, full-time optometrists measured the uncorrected visual acuity, best corrected visual acuity, refractive power and astigmatism of all patients. The treatment effects of the two groups were compared: after 30 d of treatment, the uncorrected visual acuity ≥5.0, and the discomfort symptoms such as discomfort around the eyes, dizziness, reading difficulty, etc. were completely disappeared, which were judged to be markedly effective; after treatment, the uncorrected visual acuity improved by more than 2 lines, and the discomfort symptoms such as discomfort around the eyes, dizziness, reading difficulty were significantly improved, which were judged to be effective; after treatment, the uncorrected visual acuity improved by less than 2 lines or discomfort Such as dizziness, eye discomfort, reading difficulty obviously did not improve, or even aggravated, can be judged as invalid. Total effective rate=(markedly effective+effective)/ total cases×100 %. Compare the incidence of adverse reactions between the two groups after treatment. All data were analyzed by spssv22.0 software. The measurement data are represented by ($\bar{x}\pm s$) and t-test is used. The count data were expressed as n (%) and chi square test was used. $p<0.05$ was considered statistically significant.The total effective rate of observation group was 56.96 % and the total effective rate of observation group was significantly higher than that of the control group ($p<0.05$), as shown in Table 1. There was no significant difference in uncorrected visual acuity and best corrected visual acuity between the two groups before treatment ($p>0.05$); the uncorrected visual acuity and best corrected visual acuity of the two groups after treatment were higher than those before treatment ($p<0.05$), and the two methods of topical Dibazol eye

drops were effective in improving visual acuity. After treatment, the uncorrected visual acuity of the observation group was higher than that of the control group ($p<0.05$), as shown in Table 2. There was no significant difference in diopter and astigmatism between the two groups before and after treatment ($p>0.05$). The diopter of the two groups after treatment was higher than that before treatment ($p<0.05$), indicating that the two methods of using Dibazol eye drops have curative effect on improving diopter. After treatment, the diopter of the observation group was significantly better than that of the control group ($p<0.05$). After treatment, the astigmatism of the observation group was lower than that before treatment ($p<0.05$), but there was no significant difference in the astigmatism of the control group before and after treatment ($p>0.05$). As shown in Table 3. The main adverse reactions were eye irritation, eye fever and dry eye. 13 % of the patients in the control group developed eye irritation after medication, while the incidence of eye irritation in the observation group was only 2.53 %, which significantly alleviated the incidence of adverse reactions ($p<0.05$). The total adverse reaction rate of the observation group was 6.33 %, which was significantly lower than 17.72 % of the control group ($p<0.05$). The results are shown in Table 4. The typical symptoms of myopia are loss of distant vision and fatigue of vision. With the increase of myopia, there will be visual symptoms such as axial length, abnormal color vision, abnormal light vision, and flying mosquito. The most common refractive error problem in the world[7]. According to the world vision report published by World Health Organization (WHO) in 2019, myopia is the most common eye disease among adolescents. 312 million of them are children under 19 y old, and the incidence rate of myopia in East Asia[8]. The incidence

TABLE 1: COMPARISON OF THERAPEUTIC EFFECT BETWEEN THE TWO GROUPS [N (%)]

Group	N	Markedly effective	Effective	Ineffective	Total effective rate (%)
Observation group	79	24	36	19	75.95 %
Control group	79	21	24	34	56.96 %
U/x^2		U=5.56			x^2=6.398
p		p=0.018			p=0.012

TABLE 2: COMPARISON OF UNCORRECTED VISUAL ACUITY AND BEST CORRECTED VISUAL ACUITY BEFORE AND AFTER TREATMENT (x̄±S)

Group	N	Uncorrected visual acuity (LogMar)		t	p	Best corrected visual acuity (LogMar)		t	p
		Before treatment	After treatment			Before treatment	After treatment		
Control group	79	0.67±0.15	0.74±0.10	3.451	0.001	-0.15±0.07	-0.18±0.06	2.892	0.004
Observation group	79	0.68±0.14	0.82±0.17	5.65	0	-0.13±0.09	-0.17±0.12	2.37	0.019
t		0.433	3.605			1.559	0.662		
p		0.665	0			0.121	0.509		

TABLE 3: COMPARISON OF REFRACTIVE AND ASTIGMATISM OF ASTIGMATISM BEFORE AND AFTER TREATMENT (x̄±S)

Group	N	Diopter (D)		t	p	Astigmatism (D)		t	p
		Before treatment	After treatment			Before treatment	After treatment		
Control group	79	-2.11±0.27	-1.27±0.21	21.827	0	-0.41±0.12	-0.43±0.17	0.854	0.394
Observation group	79	-2.05±0.31	-0.93±0.24	25.392	0	-0.40±0.10	-0.46±0.14	3.1	0.002
t		1.297	9.476			0.569	1.211		
p		0.196	0			0.57	0.228		

TABLE 4: COMPARISON OF ADVERSE REACTIONS BETWEEN THE TWO GROUPS [N(%)]

Group	N	Eye irritation	Eye fever	Dry eye	Total adverse reaction rate (%)
Control group	79	8 (10.13 %)	4 (5.06 %)	2 (2.53 %)	14(17.72 %)
Observation group	79	2 (2.53 %)	1 (1.27 %)	2 (2.53 %)	5(6.33 %)
x^2		3.843	1.859	0	4.846
p		0.043	0.173	1	0.0277

of myopia in China is about 33 % which is 1.5 times of the world average[9]. The high incidence of myopia in teenagers is mainly due to heavy learning pressure, long-term close eye use time, poor eye hygiene, and the popularity of electronic products, resulting in sustained fatigue and tension of ciliary muscles. According to the pathological mechanism, myopia can be divided into pseudomyopia, true myopia and mixed myopia. Pseudomyopia is mainly caused by excessive use of the eye, resulting in persistent spasm of ciliary muscle and increase of lens thickness, resulting in blurred vision. Most pseudomyopia will develop into true myopia if not treated in time. Methods of clinical treatment for pseudomyopia include cycloplegic agents, myopia therapeutic apparatus, etc. Traditional Chinese Medicine (TCM) External Therapy is widely used in pseudomyopia, which is based on the basic theory of TCM, and has the functions of clearing away heat, removing dampness, promoting blood circulation and dredging collaterals, removing the haze and improving eyesight. Common techniques include fumigation, atomization, bloodletting at ear tip, acupuncture and massage. Atomization method is to fumigate the eyes with ultrasonic or heated mist; atomization method can make the blood flow in the eyes smooth, disperse pathogenic factors and lead to stagnation, and can also directly act on the eyes through different drugs, so as to dredge the meridians and increase the efficacy. According to the characteristics of adolescent pseudomyopia, this study selected adolescent patients with moderate to low myopia as the research object, and randomly compared the clinical efficacy and safety of atomization therapy and eye drop therapy of dibazolomide eye drops. The results showed that the total effective rate of the observation group was 75.95 % higher than that of the control group and the uncorrected visual acuity, best corrected visual acuity and diopter after mydriasis of the atomization treatment group were higher than those of the control group. These results indicate that the atomization therapy of dibazolomide eye drops can improve the curative effect of adolescent middle low vacation myopia, effectively relieve the clinical symptoms of pseudomyopia, improves the uncorrected visual acuity and diopter after mydriasis. This study also compared the incidence of adverse reactions between atomization therapy and eye drops therapy. The results showed that atomization therapy can significantly reduce the incidence of eye irritation and eye fever, which may be due to the lower concentration, more uniform distribution and less eye irritation of atomization therapy. To sum up the atomization fumigation of Dibazol eye drops in the treatment of adolescent middle and low vacation myopia can significantly improve the vision of patients, improve the diopter after mydriasis, ensure the safety of treatment and improve the treatment effect, which has high clinical reference significance.

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Conflict of interest:

The authors report no conflicts of interest.

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