



## Research Article

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### MYOPIA MANAGEMENT WITH AYURVEDIC OCULAR THERAPEUTICS: A CLINICAL STUDY

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#### ABSTRACT

An open-label double-arm randomised study was conducted to evaluate the efficacy of Drishtipradavarti Aschyotana (eye drops) with and without Mahatriphaladi ghrita Tarpana (a nourishing topical ocular therapy) in the management of simple myopia. The study was comprised of two groups with twenty subjects each. Group A subjects were administered Drishtipradavarti Aschyotana (eye drops), and subjects of group B were administered Drishtipradavarti Aschyotana and Mahatriphaladi ghrita Tarpana. The total duration of treatment in both groups was restricted to 90 days. Subjects under the age group of 18-25 years with refractive error up to - 6 D were included in the study; out of the 45 subjects registered for the study, 40 completed the treatment. The parameters, namely, visual acuity, clinical refraction, indistinct distant vision, headache and eye strain, were evaluated statistically before and after the treatment along with the axial length and corneal radius of curvature findings to observe if there is any reduction in axial length and corneal curvature, after the treatment. The results showed a statistically highly significant reduction in symptoms ( $p < 0.001$  and  $p < 0.01$ ) and visual acuity ( $p < 0.001$ ) and a significant reduction in clinical refraction ( $p < 0.05$ ) in both groups. Group B showed comparatively better results. No significant changes were noticed in axial length and corneal radius of curvature values after the treatment ( $p > 0.05$ ). The results indicate that this Ayurvedic management can be utilised as a safe and potent treatment to control Myopia.

**Keywords:** Myopia, Aschyotana, Tarpana, Drishtipradavarti, Mahatriphaladi ghrita

#### INTRODUCTION

Myopia is the most common refractive error and is said to be one of the common causes of visual disability throughout the world. The prevalence of myopia is increasing, and it has been predicted that by 2050, there will be 4758 million (49.8% of the world population) people with myopia.<sup>1</sup> It is reaching as high as 70-90% in some Asian populations.<sup>2</sup> The crude prevalence of myopia in India over the last four decades is 7.5% in the 5-15-year age group.<sup>3</sup>

Myopia or short sight is that form of refractive error wherein parallel rays of light come to focus in front of the sentient layer of the retina when the eye is at rest.<sup>4</sup> Myopia is also defined as a condition in which the spherical equivalent refractive error of an eye is  $\leq - 0.5D$ .<sup>5</sup> Simple myopia is the most common clinical variety, which includes low ( $<3D$ ) and medium ( $-3D$  to  $-6D$ ) degrees of myopia.<sup>6</sup> It is considered as a physiological error in the growth of the eyeball caused by an increase in the axial length of the eyeball or curvature of the cornea and or lens. Symptoms include diminution of vision for distance and asthenopic symptoms such as eye strain and headache in cases of mild refractive error.<sup>7</sup>

Myopia, even to a smaller degree, lowers academic performance and career opportunities. Even low and moderate myopia is associated with increased risks of myopic macular degeneration, retinal detachment, cataract and open-angle glaucoma.<sup>8</sup> Developing a safe and effective medical intervention for myopia is the need of the hour to prevent its progression and further visual impairment.

In Ayurvedic classics, visual disturbances similar to myopia are found under "Timira", one of the drishtigata netrarogas (diseases affecting vision), whose main feature is avyaktadarshana or indistinct vision when doshas afflict the first patala.<sup>9</sup> Vitiated doshas pervade through rupavaha siras and get localised in patalas inhibiting the nutritional supply by obstructing the channels.<sup>10</sup> Ayurveda contributes many formulations for vision-related problems, administered through simple and safe techniques called kriyakalpas (topical ocular therapeutics) like anjana, tarpana etc. Drishtipradavarti is an Anjana (collyrium) mentioned in Ayurvedic classics, which is said to restore vision even in the blind.<sup>11</sup> Mahatriphaladi ghrita, a medicated ghee, has been indicated in all vision abnormalities.<sup>12</sup> In this study, modification of the drug delivery has been undertaken by converting Drishtipradavarti Anjana into Aschyotana (topical drop instillation), to suit patient compliance and minimise ocular irritation.

The present study has been undertaken after appreciating the promising results of a pilot study on myopia with the administration of Drishtipradavarti in Aschyotana form. The study has been conducted to evaluate and compare the efficacies of Drishtipradavarti Aschyotana and Drishtipradavarti Aschyotana along with Mahatriphaladi ghrita Tarpana in the management of simple myopia.

#### MATERIALS AND METHODS

Subjects with clinical features of myopia approaching the Shalakya Tantra OPD of Sri Kalabhyraveswaraswamy Ayurvedic Medical College Hospital and Research Centre Bengaluru, India,

were screened and selected using simple random technique after receiving informed consent. The subjects were allowed to withdraw from the trial without giving any reason. It was an open-label active, randomised, double-arm clinical study. A total of 45 subjects were registered for the study and were divided into two groups (Group A - 23 subjects and Group B - 22 subjects). A case proforma containing all the necessary details pertaining to the study was prepared. The parameters considered for the study were scored as mentioned in the case proforma. The Institutional Ethics committee cleared the study with No. SKAMCH & RC/IEC/037/2019 having CTRI REF no 2019/06/026783.

#### **Inclusion criteria**

Subjects under the age group of 18-25 years with refractive error up to -6 dioptres and subjects with best corrected visual acuity - 6/6 were included in the study.

#### **Exclusion criteria**

Subjects with degenerative myopia and myopia associated with other ocular disorders like keratoconus, squint, retinal diseases, cataract etc., were excluded from the study.

#### **Trial Drugs**

Drishtipradavarti and Mahatriphaladi ghrita were prepared at Rasa Shastra and Bhaishajya Kalpana pharmacy, SKAMCH and RC, Bengaluru, by adopting the classical method of preparation after the identified raw drugs were authenticated by the department of Dravya guna.

**Drishtipradavarti:** Purified fine powders of Haritaki (*Terminalia chebula*), Vibhitaki (*Terminalia bellirica*), Amalaki (*Emblica officinalis*), Neelotpala (*Nymphaea stellata*), Vidanga (*Embelia ribes*) Samudraphena (cuttlefish bone) and Kukkutandatwak bhasma (incinerated egg shell), Kasisa bhasma (calcinated ferrous sulphate) and Loha bhasma (calcinated iron) were triturated with goat's milk, a fine paste obtained was applied on copper plate, removed after seven days and again triturated with goat's milk to make vartis (collyrium pills), which were later dried under shade and stored in sterile bottles.

**Preparation of Drishtipradavarti drops:** Drishtiprada varti was powdered and soaked in rose water overnight in 1:10 ratio in a sterile vessel. This liquid was then filtered through Whatman's filter paper and stored in sterilised dropper bottles under aseptic measures. Subjects were instructed to use the drops within 15 days of preparation.

#### **Intervention**

Group A- Drishtipradavarti Aschyotana, 2 drops twice daily, once in the morning and once in the evening.

Group B- Drishtipradavarti Aschyotana, 2 drops twice daily, once in the morning and once in the evening and Tarpana with Mahatriphaladi ghrita, 3 sittings of 5 days each, 1 sitting every month with a gap of 25 days. The procedure was done for 8-10 minutes with a sufficient quantity dosage (approximately 40-50 ml).

**Duration of the treatment:** The total duration of the treatment was restricted to 90 days in both groups, and one follow-up was done a month after the duration.

#### **Assessment criteria**

**Subjective** - Subjective assessment was done using parameters; Avyakta darshana (Indistinct distant vision), headache, eye strain and unaided visual acuity. Visual acuity was analysed statistically by applying the student's t-test after converting the values

obtained into decimals, and other subjective parameters were statistically analysed by using the Wilcoxon rank test within the groups and the Mann-Whitney U test between the groups after adopting a suitable scoring pattern.

**Objective:** Objective assessment was done using parameters; Clinical refraction (determined by both subjective and objective methods), axial length (measured using A-scan biometry) and corneal radius of curvature (measured using Keratometry). Data obtained was statistically analysed by applying a t-test.

The results obtained were considered highly significant for  $p = < 0.001$  and  $p = < 0.01$ , significant for  $p = < 0.05$ , and insignificant for  $p = > 0.05$

#### **OBSERVATIONS**

Out of the 45 subjects registered for the study, 40 (20 in each group) completed the treatment. 2 subjects in group A and 3 subjects in group B discontinued the treatment. General observations of all 45 subjects are as follows:

The majority (73.3%) of the subjects were students, as the age group considered was 18-25 years. Simple myopia usually begins in childhood, increases up to about 20 years with a slight increase in refractive error every year and later becomes stable. The maximum (77.7%) subjects were females. Though there is no gender predisposition mentioned for myopia, many research works have revealed female gender predisposition in myopia. A study reported that serum level of estrogen is closely related to the occurrence and development of juvenile myopia, and estrogen had a certain influence on corneal thickness, which was positively correlated to myopic diopter<sup>13</sup>

Most of the subjects (53.2%) exhibited a chronicity of 5 to 10 years, as most of them were diagnosed with myopia in their childhood. Family history of myopia was present in 33.3% of the subjects. Myopia is said to be a polygenic disease influenced by both genes and the environment.<sup>14</sup>

44.4% of the subjects revealed stress on assessing their retrospective evaluation. Melanie J *et al.* reported in their study that levels of myopia significantly increased following acute stress ( $p < 0.005$ ), in conjunction with elevated cortisol levels and an increase in IOP, which suggested that acute psychological stress may play a role in driving environmentally derived refractive errors.<sup>15</sup> It is said that continuous stress and elevated cortisol levels negatively impact the eye and brain due to sympathetic imbalance and vascular dysregulation.<sup>16</sup> Klesha (stress), shoka (grief) and other mental factors have also been mentioned as etiological factors for eye diseases in Ayurvedic classics.

The majority (69%) of the subjects were found to be involved in near work, which included prolonged reading and usage of computer screens and smartphones for more than 3 hours. According to the current theory, prolonged near work leads to myopia via the blurred retinal image that occurs during near focus.<sup>2</sup> Sukshma nireekshana or straining to see minute objects and prolonged reading of books, are also mentioned as some of the etiological factors for eye diseases in Ayurvedic classics.

Among the symptoms, 100% of subjects complained of indistinct distant vision, 53.3% and 82.2% of subjects complained of headache and eye strain respectively. Out of 90 eyes, there were 23 eyes (25.5%) with visual acuity  $< 6/60$ , 24 eyes (26.7%) with visual acuity between  $6/36 - 6/60$ , 17 eyes (18.9%) between  $6/18 -$

6/24 and 26 eyes (26.7%) with visual acuity between 6/9-6/12. 69 (76.7%) eyes had spherical refractive error ranging between -0.25D to -3D, and 29 (23.3%) had spherical refractive error between -3.25D to -5D.

In the present study, the anterior chamber depth (AC) of 90 eyes ranged between 3.30 mm - 4.30 mm, and the mean AC depth was 3.76 mm. Normal AC depth is said to be 2.5 mm - 3.5 mm<sup>17</sup>, and in simple myopia, the AC depth will be slightly deeper.

Axial length (AL) ranged between 22.50 mm - 26.50 mm, and the mean AL was 24.13 mm. The adult human eye's axial length or anteroposterior diameter is 24 mm.<sup>17</sup> There were 46 eyes with AL more than 24 mm.

The corneal radius of curvature (CRC) ranged between 7.20 mm - 8.20 mm, and the mean CRC was 7.63 mm. The anterior radius of curvature of the central part of the cornea is 7.8 mm.<sup>17</sup> There were 60 eyes with CRC <7.8 mm. This finding was consistent with a study which concluded that myopic eyes had been found to have steeper corneas.<sup>18</sup> It was also observed from the present study that eyes with shorter axial length had steeper corneal curvature than those with longer axial length, which had comparatively flatter corneas. Axial length and corneal radius of curvature findings provided etiological evidence for myopia in this study.

**RESULTS**

**Effect of therapies on symptoms**

In group A, the reduction observed was statistically highly significant in avyakta darshana (z = 2.828, p = < 0.001), significant in headache (z = 2.236, p = < 0.05), and highly significant in eye strain (z = 3.742, p = < 0.001).

In group B, the reduction observed was statistically highly significant in avyakata darshana (z = 3.557 p = < 0.001), headache (z = 3.166 p = < 0.001) and eye strain (z = 3.877 p = < 0.001)

**Effect of therapies on visual acuity**

A statistically highly significant reduction was observed in visual acuity in group A (t = 3.93, p = < 0.001) and in group B (t = 4.18, P = < 0.001).

**Effect of therapies on clinical refraction**

The effect of treatment on clinical refraction for the spherical lens (spherical dioptric power) showed a significant reduction in group A (t = 2.211, p = < 0.05) and in group B (t = 2.243, p = < 0.05). The effect of treatment on clinical refraction for the cylindrical lens (cylindrical dioptric power) was found to be statistically non-significant in group A (t = 1.639, p = > 0.05) while it showed a statistically highly significant reduction in group B (t = 3.007, p = < 0.01).

**Effect of therapies on axial length and corneal radius of curvature**

The effect of treatment on axial length and corneal radius of curvature was found to be non-significant within both groups (p = > 0.05).

**Intergroup comparison**

The effect of therapies on all the parameters was statistically non-significant between the groups after the treatment.

The mean rank (Refer to table 2) of group B for Avyakta darshana (18.45), headache (19.0) and eye strain (19.42) was found to be less than that of group A for Avyakta darshana (22.55), headache (22.00) and eye strain (21.58).

The mean difference (Refer to table 1) of group B for visual acuity (0.172), spherical dioptric power (0.050), and cylindrical dioptric power (0.100) was more than that of group A for visual acuity (0.064), spherical dioptric power (0.043), and cylindrical dioptric power (0.017).

Therefore, the results were comparatively better in group B.

**Follow-up:** In the follow-up period of one month, the relief obtained remained stationary without further improvement or deterioration in both groups.

**Table 1: Effect of therapies on assessment parameters within the groups**

Assessment Criteria	Group A						Group B					
	Wilcoxon rank test (BT - AT)						Wilcoxon rank test (BT - AT)					
	NR	PR	TIES	MR	Z	P	NR	PR	TIES	MR	Z	P
Indistinct distant vision	8	0	12	4.5	2.828	<0.01	14	0	6	7.5	3.557	<0.001
Headache	5	0	15	3.00	2.236	<0.05	12	0	8	6.5	3.166	<0.01
Eyestrain	14	0	6	7.5	3.742	<0.001	17	0	3	9.00	3.877	<0.001
	Unpaired t-test (BT - AT)						Unpaired t-test (BT - AT)					
	Mean BT AT	Mean difference	SD	SE	t value	p-value	Mean BT AT	Mean difference	SD	SE	t value	p-value
Visual acuity	0.3949 0.4595	0.0646	0.103	0.164	3.93	<0.001	0.1715 0.3435	0.1720	0.25	0.042	4.182	<0.001
Clinical refraction (Spherical dioptric power)	1.9688 1.9250	0.0438	0.125	0.019	2.211	<0.05	2.1938 2.1438	0.050	0.140	0.022	2.243	<0.05
Clinical refraction (Cylindrical dioptric power)	0.4050 0.3875	0.0175	0.067	0.010	1.639	>0.05	0.3438 0.2438	0.1000	0.210	0.033	3.007	<0.01
Axial length	23.99 24.00	0.01	0.039	0.006	1.898	>0.05	24.16 24.18	0.02	0.070	0.011	1.850	>0.05
Corneal radius of curvature	7.6295 7.6238	0.0057	0.037	0.005	0.969	>0.05	7.6647 7.6640	0.0007	0.031	0.004	0.150	>0.05

BT- Before treatment, AT- After treatment, NR- Negative rank, PR- Positive rank, MR- Mean rank, SD- Standard deviation, SE- Standard error

**Table 2: Effect of therapies on assessment parameters between the groups**

Assessment criteria	Group A		Group B		Mann-Whitney U	Z value	p-value
	Mean rank	Sum of ranks	Mean rank	Sum of ranks			
Indistinct distant vision	22.55	451.00	18.45	369.00	159.0	1.141	>0.05
Headache	22.00	440.0	19.0	380.0	170.0	1.77	>0.05
Eyestrain	21.58	431.50	19.42	388.50	178.5	0.837	>0.05
	<b>Mean</b>	<b>SD</b>	<b>Mean</b>	<b>SD</b>	<b>Mean difference</b>	<b>t value</b>	<b>p-value</b>
Visual acuity	0.45	0.65	0.34	0.23	0.11	1.89	>0.05
Clinical refraction (Spherical dioptric power)	1.92	1.32	2.14	1.46	0.22	1.890	>0.05
Clinical refraction (Cylindrical dioptric power)	0.387	0.268	0.243	0.486	0.144	1.635	>0.05
Axial length	24.00	1.00	24.18	0.87	0.18	0.703	>0.05
The corneal radius of curvature	7.62	0.220	7.66	0.269	0.04	0.799	>0.05

## DISCUSSION

Both groups showed significant results in subjective parameters and clinical refraction. Though there was a significant improvement in visual acuity in both groups, reduction of refractive error was not seen in all the eyes, which showed improvement in the same. Reduction in the dioptric power was also assessed by adopting the scoring pattern as unchanged or no reduction, mild improvement or 0.25D reduction, moderate improvement or 0.5D reduction and marked improvement or 0.75D or > 0.75D reduction. In this study, mild improvement was seen in 10 eyes (25%) of group A, and 12 eyes (30%) of group B and moderate improvement was seen in 2 eyes (5%) of group A and 6 eyes (15%) of group B within 90 days of treatment. Marked improvement was not seen in any of the eyes, and the dioptric power remained unchanged in the remaining eyes. Though the refractive status was unchanged in most subjects, the clarity of vision improved their academic performance and working efficiency. Few were reported to have enjoyed outdoor sports, swimming, etc., without wearing glasses. No significant changes were noticed in axial length and corneal radius of curvature values after treatment. The study demonstrated a mean axial length change of  $0.01 \pm 0.04$  in group A and  $0.02 \pm 0.07$  in group B and a mean corneal radius of curvature change of  $0.005 \pm 0.04$  in group A and  $0.001 \pm 0.03$  in group B.

### Probable mode of action of trial drugs and procedures

#### Drishtipradavarti aschyotana

The compound drug predominantly possesses kashaya, madhura, tikta rasa, sheeta virya, madhura vipaka, and laghu guna. The addition of taruni jala (rose water) further enhances sheeta guna, and hence it has both prasada (soothing) and ropana (healing) qualities. It increases drishtibala or visual capacity by its sneha and sheeta qualities. It is beneficial for soothing the doshas of drishti (drishti prasada). It has tridosha shamaka, chakshushya (wholesome to vision), deepana, pachana, lekhana and rasayana properties. The compound drug pacifies vitiated tridoshas, activates dhatwagni or metabolic enzymes, relieves dhatwagni mandya janya ama, clears sanga (obstruction of channels) and restores nutritional supply to dhatu of drishti patala, thus breaking the pathogenesis of Timira.

The drug contains vitamin C and minerals like Cu, Fe and Zn required for collagen synthesis. It is found that Vitamin C, a water-soluble antioxidant, plays a key role in collagen synthesis and strengthens the cornea by decreasing the distance between collagen fibrils by enhancing crosslinking *in vitro*. Cu, Fe, Zn, and Se are the co-factors of enzymes involved in collagen

synthesis, cross-linking, or antioxidant activity.<sup>19</sup> Therefore, the drug has a strengthening effect on the cornea and also the sclera since scleral tissue predominantly contains collagen. The drug contains calcium, and calcium is said to have a primary role in retinal function<sup>20</sup>. Polyphenolic compounds like flavonoids, Vitamin A, E and C present in the compound drug are strong antioxidants which protect the retina, cornea and other ocular tissues against free radical damage. A study reported the relation between oxidative stress and myopia and that damage to the retina by oxidative stress had been associated with hypoxia. This circumstance would exist chronically in this disease.<sup>21</sup>

**The Aschyotana procedure** consists of instilling eye drops into the conjunctival sac from a height of 2 angulas. The medicine, after instillation, enters into the channels of fornices of the eyes, head, nose and oral cavity, eliminating doshas localised in the upper part of the body.<sup>22</sup> Drishtipradavarti drops are in liquid dosage form containing fine particles of the drug. It has been reported that suspension particles retain in the pre-corneal pocket, thereby improving drug contact time and duration of action.<sup>23</sup> The drug contains lipids, as goat's milk is one of the ingredients; hence it is amphipathic (lipid and water soluble) and therefore, its active principles readily penetrate the cornea to get absorbed into ocular tissues.

#### Mahatriphaladi ghrita

The compound drug predominantly possesses madhura, tikta, kashaya rasa, sheeta veerya and madhura vipaka. It acts as tridosha shamaka and has chakshushya, deepana, pachana and rasayana properties. It enhances dhatwagni, clears obstruction of channels, improves microcirculation, and nourishes and strengthens the ocular tissues. The ghee-based medicine contains potent antioxidants which include vitamin A, D, E and phytoconstituents like flavonoids, saponins and, polyphenols. Vitamin A is required to maintain the integrity of the corneal epithelium.

**Tarpana:** Tarpana is said to be the best procedure to nourish the eye. Being amphipathic, the active principles of ghrita readily penetrate the cornea, and due to lipid solubility, these readily cross blood-ocular barriers and reach the target tissues. The high viscosity of the drug enhances its bioavailability by increasing its contact time. Since the drug's contact duration with the cornea is more (8-10 minutes), drug penetration through the cornea is increased.

Due to improved vision, eye strain and headache were reduced effectively in both groups, as these occur due to straining of ocular muscles to overcome the visual defect.

## CONCLUSION

Treatment in both groups provided significant results. Group B showed comparatively better results due to the combined effect of Drishtipradavarti Aschyotana and Mahatriphaladi ghrita Tarpana. No untoward effects were observed in any of the cases in the groups. Treatment of longer duration may be required to appreciate a significant reduction in refractive error, axial length, and corneal curvature. Since the treatment effect in both groups is promising, the same can be adopted to prevent and check the further progression of myopia. Further elaborative studies are required to standardise the modified ocular drug delivery system, like Aschyotana, in terms of preparation, dosage, etc.

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