



# **AN OPEN LABEL SINGLE ARM CLINICAL STUDY ON VIBHITAKADI GHRITA EYE DROP AND PAANA IN THE MANAGEMENT OF PRATHAMPATALAGATATIMIRA (PRESBYOPIA)**

**Dr Hemalata Rajpurohit<sup>1</sup>**

*Post Graduate Scholar, Department of Shalakya Tantra, Shri Dharmasthala Manjunatheshwara College of Ayurveda and Hospital, Hassan, Karnataka, India*

**Dr Abhijith H N<sup>2</sup>**

*<sup>2</sup>Associate Professor, Department of Shalakya Tantra, Shri Dharmasthala Manjunatheshwara College of Ayurveda and Hospital, Hassan, Karnataka, India*

**Dr Ashwini M J<sup>3</sup>**

*<sup>3</sup>Professor and HOD, Department of Shalakya Tantra, Shri Dharmasthala Manjunatheshwara College of Ayurveda and Hospital, Hassan, Karnataka, India*

## **ABSTRACT**

*A total of 44 patients of Prathamapatagata timira / Presbyopia fulfilling the inclusion criteria were registered for this clinical study. 40 patients of presbyopia completed the clinical study irrespective of gender, socio-economic status and religion with an aim to know the efficacy of Vibhitakadi ghrita eye drop and paana. To present the study in scientific manner 3 criteria's were made for assessment and statistical evaluation. Finally favorable results were found. The symptoms were reduced and the results were significantly effective.*

**KEY WORDS:** *Vibhitakadi Ghrita, Prathamapatagata timira, Presbyopia*

## **INTRODUCTION**

Presbyopia is explained as age-related hardening of the lens substance and an associated inability of the lens to be molded by the tension exerted by capsular forces. Presbyopia, affects all primates, blurred vision and the inability to see fine details at the customary near working distance are the hallmarks of presbyopia. Without treatment, it becomes difficult or impossible to see fine details at

near distances. Presbyopia can be classified under five types, Incipient Presbyopia, Functional Presbyopia, Absolute Presbyopia, Premature Presbyopia, and Nocturnal Presbyopia. The concept of presbyopia belongs to modern ophthalmology but it resembles and almost is parallel to the concept of timira described in the chapters of drishtigata rogas by Sushruta Samhita and the subsequent authors.

## NEED FOR THE STUDY

Presbyopia is one of the outcomes of the changing life style, food habits and environment. Now a days there has been a drastic change in day today activities including life style, food habits, environmental pollution, industrial and occupational hazards. It has been observed that the person who indulges more in near work e.g., working on computer monitor, tailoring work, embroidery work, working on microscope and other professionals requiring fine work develops Presbyopia at an early age. Due to all these factors Presbyopia is increasing day by day.

The prevalence of Presbyopia is found to be 62% with increasing age. The global prevalence<sup>1</sup> of Presbyopia is predicted to increase from 1.4 billion in 2005 to 1.37 billion by 2020 and to 1.78 billion by 2050. It is the commonest aging defect affecting the eyes leading to impairment of near vision. It has been observed that the person who indulged more near work develops presbyopia at an early age<sup>2</sup>. There is no permanent cure for presbyopia<sup>3</sup>. But there are many ways to improve near vision. In contemporary science,

spectacles represent an effective measure which keeps varying as the condition advances<sup>4</sup>.

On overview of pathophysiology of Presbyopia, it may be compared to a Vata Kapha vitiation. Timira can be managed using Nasya, Tarpana, Ghritapana, Virechana, Anjana<sup>5</sup> therapies. Vibhitakadi Ghrita<sup>6</sup> is mentioned as Sarva Netraroga Hara by Yogaratnakara in Netrachikitsa Adyaya. The drugs in this yoga are having Rasayana, Chakshushya, Nadibalya Laghu Snigdha Guna and Tridosahara mainly Kaphahara as Karma. As the drugs are easily available, cost effective, easily administered without complications. Hence an attempt is made to study efficacy of Vibhitakadi ghrita picked up from Ayurveda classics.

## METHODOLOGY

To evaluate the effect of Vibhitakadi ghrita eye drop and paana in the management of Pratamapatalagata timira- Presbyopia. 40 Patients was selected from Out-patient department and In-patient department of Shalakyta Tantra, Shri Dharmasthala Manjunatheshwara college of Ayurveda and Hospital, Hassan.

### A. DIAGNOSTIC CRITERIA: Table no: 1

Sl.no	Subjective:	Objective:
1	Samipasta avyakta darshana (blurred near vision) <sup>7</sup>	Visual efficiency <sup>8</sup>
2	Shiroabhitapa/headache <sup>7</sup>	
3	Netrayasa/asthenopia <sup>7</sup>	

### B. INCLUSION CRITERIA

Patients aged between 35<sup>9</sup> to 45 years was selected irrespective of age, gender, occupation, religion and socio economic status .Patients who are ready to sign informed consent form

### C. EXCLUSION CRITERIA

Hypermetropia, Cycloplegia, Internal or total ophthalmoplegia, Ocular disease or trauma like removal or damage to lens, zonules, or ciliary muscle, Cataract, Patients who are using drugs like, alcohol, chlorpromazine, hydrochlorothiazide, anti-anxiety

agents, antidepressants, antipsychotics, antispasmodics, antihistamines, diuretics, Patient hypersensitive to the *Vibhitakadi ghrita*.

## STUDY DESIGN

40 patients fulfilling the criteria for diagnosis and inclusion was taken and treated as an open label single arm prospective interventional clinical study with pre and post-test design. During the course of treatment observation was done once in 15 days till the completion of study. Then follow up was done at an interval of 15 days for a period of one month.

Table no : 2 Intervention of medicine

Drug	Quantity of drug use	Dose	Duration Total
<i>Vibhitakadi ghrita</i> Eye Drop	2 drops in both eye	Twice a day	60 days
<i>Vibhitakadi ghrita Paana</i>	5ml <sup>10</sup> orally with milk	Twice a day	60 days

The drugs which is used for treating eye diseases should have *chakshushya rasayana balya* property. So *Vibhitakadi Ghrita* was selected for the present study as eye drop and *paana* which is specially mentioned by Yoga *Ratnakara* in the

context of *Sarva Netrarogahara* by *Yogaratnakara* in *Netrachikitsa Adyaya*.

The ingredients of *Vibhitakadi Ghrita* are *Vibhitaka*, *Shiva (Haritaki)*, *Dhatri (Amalaki)*, *Patola*, *Arista*, *Vasaka* and *Goghrita*. The drugs in this yoga are having *laghu snigdha guna* and *vata kaphahara* as

karma. Go Ghrita is also having the properties like *madhura rasa,balya, rasayana* etc.. Due to above properties the present combination is given in the

form of eye drop and *paana* to know its effect in treating *Prathamapatalagata Timira* (Presbyopia).

**Table no 3. Duration of treatment**

Baseline Assessment	During the Treatment				Follow up After the Treatment
1 <sup>st</sup> day	15 <sup>th</sup> day	30 <sup>th</sup> day	45 <sup>st</sup> day	60 <sup>th</sup> day	75 <sup>th</sup> day

**DISCUSSION ON OBSERVATIONS**

**AGE:** The age limit of the patients in the study was 35 to 45 years. Maximum numbers of patients 51.2% were belonging to the age group of 35 to 40 years followed by 48.2% to the age group of 41 to 45. *Dhatukshaya* and *indriya vishaya grahana asamarthya* occur by the influence of *kala swabhava* and it may be a cause to initiate presbyopic changes at this age group. Recent A-scan ultrasonography and magnetic resonance imaging (MRI) studies have shown that the lens capsule becomes less elastic after age 35<sup>11</sup>.

**GENDER:** Maximum number of patients were females 55.8% followed by males 44.2%. Earlier onset in females<sup>11</sup> (short stature, menopause). In women, the possible explanation is decrease in estrogen level at menopause cause increased risk of difficulty in vision<sup>12</sup>

**OCCUPATION:** Maximum numbers of patients (30.2%) were homemakers,14.0% Were teachers, 11.6% were agriculturist, 9.3% were businessmen and also people engaged in occupations like tailoring, 7.0% were doctors and laborers , 4.7 % were office workers and advocate, 2.3% of patients were drivers. In patients who indulged in more near work e.g., working on computer monitor, doing tailoring work,

embroidery work and other professionals involved in fine work develops presbyopia earlier. In those peoples *Sukshmanirikshana, malavarodha, chinta, krodhanidana sevanas* have been found more. Exposure to *atapa, ushnabhitaptasya-jalaprareshata* were observed in agriculturists and laborers. In home makers, *Divaswapna, Dhumanishevana* and *Ajirnashana* have been found more prone to the disease *Timira. Dhumanishevana* is found to be very common for the home makers and it has direct effect on the eyes.

**AGGRAVATING FACTORS:** In the present study, 46.5% of patients have reported prolonged reading as an aggravating factor, 39.5% have prolonged near work as aggravating factor, 7.0% have reported computer work and sunlight as an aggravating factor. Those who do visually demanding or prolonged near vision work develops *Timira/presbyopia* early. More over *Sukshmanireekshna, Dhumanishevana, Atapa sevana* are also considered as the triggering factors for *Timira* which are found to be more in home makers, teachers, office workers and in agriculturists.

**RESULTS**

**Table No. 4- Showing Friedman test on Results of subjective parameters**

Parameter	N	<sup>2</sup> X	P Value	Remark
Samipasta avyakta darshana	40	123.444	0.001	S
Shirobhitapa	11	46.994	0.001	S
Netrayasa	5	24.020	0.001	S

**Table No. 5: Showing the paired t test result on objective parameters**

Parameters	MEAN		Diff. Mean	SD	SE	T	P	Remarks
	BT	AT						
Near vision reading	89.0625	95.187	-6.125	11.745	1.313	-4.664	0.001	S
Manual efraction	2.125	1.937	0.187	0.167	0.264	7.081	0.001	S

## DISCUSSION ON RESULTS

### 1) EFFECT OF TREATMENT ON SAMIPASTHA AVYAKTA DARSHANA

It has been found that the effect of treatment on *Samipastha avyaktha lakshana*, on 30<sup>th</sup> day, 45<sup>th</sup> day, and BT-follow up with P value (< 0.001) revealed statistically significant results. *Vibhitakadi ghritha* helps to improve the elasticity of the lens and strengthens the ciliary muscles by *madhura tiktarasa* and *laghu snigdha guna*. *Ghritha* with its *snigdha guna* helps in softening of the lens substance by improving the metabolic activity of lens epithelium which in turn leads to proper accommodation.

### 2) EFFECT OF TREATMENT ON SHIROABHITAPA

It has been found that the effect of treatment on *Shiroabhitapa*, between BT-AT with P value (< 0.001) revealed statistically significant results. *Shiroabhitapa* occurs due to straining of ciliary muscles during excessive near work. So *Vibhitakadi ghritha* with its *Vatakaphahara* and *Vedhanasthapana karma* pacifies the vitiated *dosas* and relieves the strain thereby subsiding *Shiroabhitapa*.

### 3) EFFECT OF TREATMENT ON NETRAYASA

There was reduction in *Netrayasa* noticed after treatment in X<sup>2</sup> value (Friedman test) which is statically significant at the level of p value (< 0.001) As *netrayasa* occurs due to straining of ciliary muscles and extra ocular muscles during excessive near work, *Vibhitakadi ghritha* helps to strengthen the ciliary and extra ocular muscles. The drugs in this yoga are having analgesic and antispasmodic property which helps in relieving *netrayasa*.

## CONCLUSION

After completion of the study, it can be concluded that, the age, occupation, diet, habits and aggravating factors have a significant role in development of *Timira*/Early Presbyopia. The average onset of presbyopia is between 35-45 years. Effect of *Vibhitakadi Ghritha Eye drop* and *Paana* is found to be significantly effective on reducing the signs and symptoms of *Prathamapatalagata Timira/presbyopia*. Hence the Null Hypothesis is rejected and the Research Hypothesis can be accepted.

## BIBLIOGRAPHY

1. <http://www.medpagetoday.com/general/ophthalmology/12086>
2. J.Renu. *Basic ophthalmology*.3<sup>rd</sup> edition. New Delhi; Jaypee brothers Medical publishers; 2003.p.60.
3. <http://www.eyehalthweb.com/presbyopia/date-29/3/14>
4. Khurana.A.K. *Comprehensive ophthalmology*.4<sup>th</sup>edition. New delhi: New age international; 2007.p.49.

5. Acharya.J.T.*Susrutha samhita of Susrutha with Nibandhasangraha of Sri Dalhanacharya. Varanasi:Choukambha Orientalia;2009.p.625.*
6. Sreedhar Suja K. *A Textbook of Shalaky Tantra Part-1, 1<sup>st</sup> ed. Varansi:Chaukhamba Orientalia; 2016.p. 147*
7. Sreedhar Suja K. *A Textbook of Shalaky Tantra Part-1, 1<sup>st</sup> ed. Varansi:Chaukhamba Orientalia; 2016.p. 147*
8. <http://www.aoa.org/cpg-17>
9. Nancy B. Carlson, O.D., *Care of Patient with Presbyopia, American Optometric Association. December 2010.p.10*
10. Anonymous. *The Ayurveda Formulary of India. 2nd edition . New Delhi: Govt of India . Ministry of Health and Family welfare;2003*
11. Nancy B. Carlson, O.D., *Care of Patient with Presbyopia, American Optometric Association. December 2010.p.9* <http://www.aoa.org/cpg-17>
12. Glasser A, Croft MA, Kaufman PL. *Aging of the human crystalline lens and presbyopia. Int Ophthalmol Clin* 2001; 41:115. <https://www.ncbi.nlm.gov/pubmed/556127>