

# A Clinical Study on the Efficacy of Phalatrikadi Ghrita (Tarpana and Orally) on Timira - Presbyopia

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**ABSTRACT :** The diseases of the eye are much more important than any other physical disability since the loss of vision completely disables the patient. The most disastrous result of ocular disease is blindness. Of all the ocular diseases, *Timira* is considered to be the most important one, causing difficulty in vision. A good deal of care is required to be exercised in carrying out its proper diagnosis and treatment. It has been observed that the person who indulged in more near work e.g. working on computer monitor, tailoring work, embroidery work, working on microscope and other professionals requiring fine work develop Presbyopia at an early age. Due to all these factors Presbyopia is increasing day by day. The disease *Timira* - Presbyopia is *Vata* predominant *Tridoshaja* condition described under *drishtigata rogas* by various *acharyas*. The study was done on 37 patients of *Timira*-Presbyopia. *Phalatrikadi ghrita* was given in Group A Orally and *Phalatrikadi ghrita* was used in Group B as Tarpana & Orally. After enrollment of the patients in the study, cardinal symptoms of *Timira* - Presbyopia such as *samipastha avyakta darshana*, *vihwala darshana*, *netrayasa* and *shirobhitapa* etc. were studied before and after the treatment. Amongst the registered patients, 30 patients completed the course of the treatment. Comparatively more relief in signs and symptoms was found in combined group.

**Key words :** *Timira*, Presbyopia, *Phalatrikadi ghrita* and *Samipastha avyakta darshana*.

## INTRODUCTION

*Timira roga* is *Vata* predominant *Tridoshaja* disease. The disease is produced when the vitiated *doshas* are situated in the first and second *patala* due to different type of *achakshushya nidana* sevana<sup>1</sup>. The pathological events of *Timira* began with the increment of *doshas* at their respective sites. The *vimarga gamana* of these increased *doshas* towards *drishti* through *siras* is said to be the main event in the pathogenesis of *Timira*. Dalhana opines that the word '*sira*' here denotes *rupavaha sira* and *drishti* indicate inner part of *drishti*. As already described, the progress of pathogenesis includes involvement of successive *patalas*. The localization of *doshas* in the *patalas* further prevents the functional capacities of *patalas* and leads to blurred vision or *avyakta darshana*. It further inhibits the nutritional supply by obstructing the channels responsible for it. The further progression leads to *vihwala darshana* due to the involvement of *pishitashrita* and *medoashrita Patalas*.

The involvement of *patala* by various *doshas* is responsible for the development of different kinds of refractive errors and Presbyopia. The term Presbyopia means "old eye" and is a vision condition involving the

loss of the eye's ability to focus on close objects. Presbyopia is a very common eye disease affecting middle age, usually beginning in the 40s of both sex & prevalent worldwide. It is not an error of refraction but condition of physiological insufficiency of accommodation, leading to failing vision for near<sup>2</sup>. It may be because of hardening of the lens, weakening of ciliary muscle and suspensory ligament<sup>3</sup>. It has been observed that the persons who are indulged in more near work e.g. working on computer monitor, tailoring work, embroidery work, working on microscope and other professionals requiring fine work develop Presbyopia at an early age.

Many of the clinical features described for *Timira* are having similarities with Presbyopia like indistinct near vision, blurring of vision, eye strain and headache. No remedial measures for the prevention and care of this pathology prevails in the domain of modern ophthalmology; opening the door to the other systems of medicine to suggest, experiment and contribute the drugs to alleviate or to check the deterioration.

Promotion of the visual acuity was considered as one of the priorities in the branch of *Shalakyas* of *Ayurveda*. Sushruta, the Father of ancient Indian surgery, has recommended '*Kriyakalpa*' for the management of *Timira*, along with other forms of treatment. *Tarpana karma* has been indicated in several eye diseases by various *acharyas* but the main emphasis has been given on *Timira*. The word "*Tarpana*" is derived from root '*Trup*' that means to

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become satisfied. In *ayurveda*, the *chakshushya* properties of certain drugs like *Triphala*, *Saptamrita lauha* etc. are proven. So a combination of the *chakshushya* drugs i.e. *Phalatrikadi ghrita* has been selected for the present study in the form of *ghrita* for *Tarpana* and as oral supplement<sup>4</sup>. According to Charaka *ghrita* is effective in subsiding *Pittaja* and *Vataja* disorders; it improves *dhatu*s and is over all booster for improving *Ojas*<sup>5</sup>. According to Sushruta, along with above said properties it provides strength to the eye sight<sup>6</sup>. Bhavaprakasha has also described *ghrita* as *rasayana*, good for the eyes and protects body from various diseases<sup>7</sup>. The formulation under trial has *tridoshashamaka* properties due to *Madhura vipaka*. These properties of formulation help to break down the *samprapti* - pathogenesis of the disease *Timira* - Presbyopia. Apart from these properties all ingredients are *Chakshushya*, *Rasayana*, *Brimhana* and *Balya* which will strengthen the *patala* and improve the vision. Keeping all these points in mind the present study was conducted with following aims and objectives :

#### Aims and Objectives :

1. Review of aetiopathogenesis of *Timira* in *ayurveda* as well as in modern literature and to establish a correlation between *Timira* and Presbyopia.
2. To assess the local and systemic effect of *Phalatrikadi ghrita* in the management of *Timira*.
3. To explain the probable mode of action of *Kriyakalpa* and develop the S.O.P. of *Kriyakalpa*.

#### MATERIAL AND METHODS

**Study design :** Open randomized clinical trial was conducted on 37 patients fulfilling the criteria for the diagnosis of the disease *Timira* - Presbyopia in the present study. Among these, 07 patients left the treatment before the completion of the therapy. The patients were selected from the O.P.D. of Dept. of *Shalakyas* of I.P.G.T. & R.A., G.A.U., Jamnagar hospital.

**Inclusion Criteria :** The patients of age 30 years and above, and those having the signs and symptoms of *Timira* - Presbyopia, were included.

**Exclusion Criteria :** Patients having any other known ocular pathology. e.g. Cataract, Corneal opacity, H/o Iridocyclitis, Chorio retinitis etc. were excluded.

**Ethical clearance :** The study was cleared by the ethical committee of the Institute. Written consent was taken from each patient willing to participate before

the start of the study. Patients were free to withdraw their name from the study at any time without giving for any reason.

**Diagnosis or Identification Phase :** The diagnosis of *Timira* - Presbyopia was done on both the modern and *ayurvedic* basis. For this purpose a special research proforma was prepared as per the modern and *ayurvedic* view. After taking ophthalmic and systemic history, the best corrected vision was recorded. Then pupillary area was examined with torch light in oblique illumination. Pupils were dilated maximally using Tropicamide eye drops. After maximal pupillary dilatation the lens was studied, using retinoscopic mirror and direct ophthalmoscope. Routine blood, urine and stool investigations, fasting blood sugar and serum cholesterol examination were done to rule out the associated pathology.

**Intervention Phase :** The study was intervened by the treatment with *Phalatrikadi ghrita* as oral supplement and *Tarpana* with *Phalatrikadi ghrita* along with internal use. Patients were advised to follow the *pathya ahara* as explained in classics.

#### Grouping Posology :

**Group - A :** *Phalatrikadi ghrita* by oral route.

Dose : 10 grams twice a day.

Duration : 45 days.

**Group -B :** *Tarpana* with *Phalatrikadi ghrita* & *Phalatrikadi ghrita* internally by oral route.

**Tarpana - Dose :** 40 grams per day for 1 course. *Tarpana* was done once daily for 7 days. Such 3 courses of 7 days of *Tarpana* were given and 7 days gap were kept between 2 courses.

Duration : 45 days.

Oral dose : Same as Group A.

**Follow Up :** A minimum period of two months was planned for the follow up study.

#### Criteria For Assessment :

The assessment was done on improvement in signs and symptoms with the help of suitable scoring method ranging from 0 - 4 e.g. (1) *avyakta darshana* (*samipastha* and *durastha*), (2) *vihwala darshana*, (3) *netrayasa* (Eye strain), (4) *shirobhitapa* (Headache), (5) watery discharge, (6) photophobia, (7) visual Acuity. Over all assessment of result was done as follows:

- ◆ Cured : 100% relief in signs and symptoms and no recurrence during follow up study.
- ◆ Marked Improvement: More than 76-99% improvement in signs and symptoms.
- ◆ Moderate Improvement: 51-75% improvement in signs and symptoms.
- ◆ Mild Improvement: 26-50% improvement in signs and symptoms.
- ◆ Unchanged: Up to 25% reduction in signs and symptoms.

## OBSERVATIONS

Total 37 patients registered in present study, 30 completed and 07 discontinued. Among them, in each group 15 patients had completed the treatment and 07 left against medical advice. General observations of all 37 patients are described as follows:

Maximum number of patients i.e. 62.16% belonged to the age group of 41 - 50 years. Majority of patients i.e. 67.57% were males, 89.18% patients were Hindus, 40.54% patients were from service class & 51.35% were from middle class. Maximum number of patients i.e. 43.24% had *Vataja* variety of *Timira*. As chief symptoms maximum numbers of patients i.e. 100% were having *Samipastha avyakta darshana* (difficulty for near vision), while 91.89% patients had *vihwala darshana*, while 54.05% patients had *netrayasa* (*Eye strain*) and 48.65% patients had *shirobhitapa* (*Headache*). In associated symptoms, 35.14% patients had *durastha avyakta darshana* (difficulty for distant vision), 29.73% patients were having watery discharge and 16.22% patients had Photophobia. In Maximum i.e. 83.78% of eyes of patients visual acuity for *distant vision* was in the range of 6/9 to 6/6 and 62.16% of eyes of patients were reported to have visual acuity of N/18 for *near vision*. Maximum number of eyes i.e. 24.32% were having dioptric power of 0.00 - 1.00 D hypermetropic correction for *distant vision*, 64.86% eyes were having Emmetropic eye (normal vision) for distant and 62.16% eyes were having dioptric power of 1.25 - 2.00 D hypermetropic correction for *near vision*.

## RESULTS

In group A, the mean score of *Samipastha avyakta darshana* was reduced from 2.33 to 1.53 with 34.29% relief and in group B it was reduced from 2.33 to 1.46 with 42.11% relief. Both the results were statistically

highly significant ( $p < 0.001$ ). In group A, the mean score of *vihwala darshana* was reduced from 2.0 to 1.43 with 28.57% relief. It was statistically significant ( $p < 0.01$ ). In group B, it was reduced from 2.38 to 1.54 with 35.48% relief. It was statistically highly significant ( $p < 0.001$ ). In group A the mean score of Eyestrain (*netrayasa*) was reduced from 1.55 to 0.88 with 42.86% relief. It was found to be statistically significant ( $p < 0.01$ ). In group B it was reduced from 1.3 to 0.4 with 69.23% relief which was statistically highly significant ( $p < 0.001$ ). In group A, the mean score of headache (*shirobhitapa*) was reduced from 1.85 to 0.85 with 53.85% relief which was statistically significant ( $p < 0.01$ ). In group B, it was reduced from 1.77 to 0.55 with 68.75% relief which was statistically highly significant ( $p < 0.001$ ). In group A, the mean score of *durastha avyakta darshana* was reduced from 1.2 to 1.0 with 16.66% relief. In group B, it was reduced from 1.2 to 0.8 with 33.33% relief. In group A, the mean score of Watery Discharge was reduced from 1.25 to 0.5 with 60% relief. In group B, it was reduced from 1.4 to 0.6 with 57.14% relief. In group A the mean score of Photophobia was reduced from 1.0 to 0.5 with 50% relief. In group B it was reduced from 1.25 to 0.5 with 60% relief. In Both groups the results were statistically insignificant ( $p > 0.05$ ).

On Visual Acuity for Distant Vision, in group A an average 1.59 % improvement was observed in both the eyes which was statistically insignificant ( $p > 0.05$ ). In group B, an average 1.21% improvement was observed in both the eyes which was statistically insignificant ( $p > 0.05$ ). On Visual Acuity for Near Vision, in group A an average 35.63% improvement was observed in both the eyes which was statistically significant ( $p < 0.01$ ). In group B an average 42.86% improvement was observed in both the eyes which was statistically highly significant ( $p < 0.001$ ). On Clinical Refraction for Distant Vision, in both the groups, no change was observed in dioptric power of myopic spherical glasses and also in myopic cylindrical glasses. An average 16.66% and 41.66% decrease in the power of hypermetropic spherical glasses were observed for both the eyes in group A and group B respectively which was statistically insignificant ( $p > 0.05$ ). On Clinical Refraction for Near Vision, an average 26.32% and 28.76% decrease in dioptric power of hypermetropic spherical glasses were observed for both the eyes (15 patients- 30 eyes) in group A and group B respectively which was statistically highly significant ( $p < 0.001$ ). No change was observed in dioptric power of myopic cylindrical glasses in both the groups which was statistically insignificant ( $p > 0.05$ ).

**TABLE NO. 1 : EFFECT OF PHALATRIKADI GHRITA (ORAL) ON CHIEF COMPLAINTS IN THE GROUP OF 15 PATIENTS (30 EYES) OF TIMIRA - PRESBYOPIA (GROUP A) :**

Chief complaints	No. of Pts.	Mean score		Mean ± SE	%	S.D.	't'	p
		BT	AT					
<i>Samipastha</i>								
<i>Avyakta Darshana</i>	15	2.33	1.53	0.8 ± 0.174	34.29	0.676	4.58	<0.001
<i>Vihwala Darshana</i>	14	2	1.43	0.57 ± 0.137	28.57	0.513	4.16	<0.01
<i>Netrayasa</i>	09	1.55	0.88	0.66 ± 0.166	42.86	0.5	4.0	<0.01
<i>Shirobhitapa</i>	07	1.85	0.85	1.0 ± 0.218	53.85	0.577	4.58	<0.01

**TABLE NO. 2 : EFFECT OF PHALATRIKADI GHRITA (TARPARANA + ORAL) ON CHIEF COMPLAINTS IN THE GROUP OF 15 PATIENTS (30 EYES) OF TIMIRA - PRESBYOPIA (GROUP B) :**

Chief complaints	No. of Pts.	Mean score		Mean ± SE	%	S.D.	't'	p
		BT	AT					
<i>Samipastha</i>								
<i>Avyakta Darshana</i>	15	2.33	1.46	1.06 ± 0.118	42.11	0.457	9.02	<0.001
<i>Vihwala Darshana</i>	13	2.38	1.54	0.85 ± 0.104	35.48	0.375	8.12	<0.001
<i>Netrayasa</i>	10	1.3	0.4	0.9 ± 0.179	69.23	0.567	5.01	<0.001
<i>Shirobhitapa</i>	09	1.77	0.55	1.22 ± 0.146	68.75	0.440	8.31	<0.001

**TABLE NO. 3 : OVERALL EFFECT OF THERAPIES ON 30 PATIENTS (60 EYES) OF TIMIRA - PRESBYOPIA ON NEAR VISION.**

Overall Effect	Group A		Group B	
	No. of Eyes	%	No. of Eyes	%
Cured	00	00.00	00	00.00
Marked Improvement	00	00.00	00	00.00
Moderate Improvement	02	06.67	04	13.33
Mild Improvement	16	53.33	20	66.67
Unchanged	12	40.00	06	20.00

Overall effect of Therapies on 30 patients (60 eyes) of Timira - Presbyopia on Near Vision is shown in Table No. 1. In group A (*Phalatrikadi ghrita - orally*), Cured and marked improvement was not observed in any eye (0.00%), moderate improvement was observed in 02 eyes (6.67%), mild improvement in 16 eyes (53.33%) and in 12 eyes (40.00%) no change was observed. In group B (*Phalatrikadi ghrita - Tarpana & orally*), Cured and marked improvement was not observed in any eye moderate improvement was observed in 04 eyes (13.33%), mild improvement in 20 eyes (66.67%) and in 06 eyes (20.00%) no change was observed in near vision.

## DISCUSSION

**Disease :** There are differences in opinion regarding the disease *Timira* in different *Ayurvedic* texts. *Timira* is a disease, which is included under *drishtigata vikaras* by all the *acharyas*. According to Sushruta, *Timira*, *Kacha* and *Linganasha* are the progressive stages of the disease *Linganasha*. But Vagbhatta considers *Timira*, *Kacha* and *Linganashas* as separate

clinical entities. When the vitiated *Doshas* are situated in the first and second *patala* the condition is termed as *Timira*. When the vitiated *doshas* affect the third *patala*, it is termed as *Kacha*; and when it involves the fourth *patala*, it is *Linganasha*.<sup>8</sup>

### Involvement of Patala in Timira - Presbyopia :

The involvement of *patalas* by various *doshas* is responsible for the development of different kinds of refractive errors including Presbyopia. *Acharya* Sushruta has quoted a similar clinical picture under the broad caption of *Timira*, a small fraction of which can be correlated to Presbyopia on the basis of following facts -

- [1] *Avyakta darshana* (Indistinct vision) especially for near, a symptom produced due to affliction of first *patala*.
- [2] Cardinal symptoms of Presbyopia i.e. difficulty in near vision is there in *Timira* when the vitiated *doshas* are lodged in lower part of eye.

- [3] *Vihwala darshana* (Blurring of vision) symptom is produced due to affliction of second *Patala*. Sushruta mentioned that when the second *patala* is affected by *doshas* the vision becomes more confusing and the patient is unable to put the thread in a needle. This condition occurs only due to impairment of near vision, which is one of the classical symptom of Presbyopia as described in the modern literature.
- [4] *Timira* is a progressive disease ultimately causing *Linganasha* i.e. complete loss of vision if not treated properly.
- [5] *Timira* is a disease in which *patala* or fine membranes, nourished by *Teja, Jala, Mamsa, Meda* and *Asthi* are held responsible which may probably be related to various intraocular structures participating in accommodation and convergence. The Presbyopia also involves the physiological insufficiency to accommodate the eye for near vision due to hardening of the lens and weakening of ciliary muscle.

**Drug :** *Phalatrikadi ghrita* was selected for the present study which is specially mentioned by Chakradatta in context of *Timira chikitsa*<sup>4</sup>. The ingredients of *Phalatrikadi ghrita* are *Haritaki* (*Terminalia chebula* Retz.), *Bibhitaki* (*Terminalia bellirica* (Gaertn.) Roxb.), *Amalaki* (*Phyllanthus emblica* Linn.), *Shatavari* (*Asparagus racemosus* Willd.), *Yashtimadhu* (*Glycyrrhiza glabra* Linn.) and *Goghrita*. This drug contains 33.33% of *Madhura rasa*, 28.57% *Guru guna*, 66.66% *Sheeta veerya* and 100% of *Madhura vipaka*. The *Phalatrikadi ghrita* was prepared by classical method of *ghrita paka*. All the ingredients of *Phalatrikadi ghrita* are available in their authentic forms, having *Chakshushya, Rasayana* and *Balya* properties. *Goghrita* is also having above said properties.

*Doshakarmata* of the combination is dominantly *Vatashamaka* (40.00%), *Pittashamaka* (40.00%), and *Kaphashamaka* (20.00%) by virtue of its *rasa, guna, veerya* and *vipaka*<sup>9,10</sup>. Thus, the overall effect of the compound drug is *Tridoshashamaka* and hence it disintegrates the pathology of the disease *Timira*, which is *Vata pradhana Tridoshaja* in its manifestation.

#### Clinical study :

**Observations :** In the present study maximum number of patients i.e. 62.16 % belonged to age group of 41 - 50 years. In the age group of 41 - 50 years *dhatukshaya* and *indriya vishaya grahana*

*asamarthya* occur by the influence of *kala svabhava* and it may be a cause to initiate more Presbyopic changes at this age group. But in this study it was found that 27.03% cases of Presbyopia were of the age group of 30 to 40 years. The possible explanation is that these patients were engaging themselves in close and eye straining work. It was observed in the present clinical study that maximum number of patients i.e. 78.38% belonged to urban area and 21.62% of the patients belonged to rural area. Probably change in most of dietary habits; life styles, working conditions and environment have resulted in increased incidence of Presbyopia.

#### CONCLUSION

From the observations and results which were received from this study it can be concluded that Group B *Phalatrikadi ghrita* (Tarpana & Orally) provided better results in chief & associated complaints like *Samipastha avyakta darshana, vihwala darshana, netrayasa* (Eye strain) and *shirobhitapa* (Headache), also provided better results in complaints like Indistinct distant vision and Photophobia. In Group B, *Phalatrikadi ghrita* was given *Tarpana & Orally*, shown better results in improvement of visual acuity on near vision, reduction in dioptric power on distant and especially near vision. No change was observed in dioptric power of myopic cylindrical glasses in both groups on distant and near vision also. In Group A, *Phalatrikadi ghrita* (Orally) provided good results in watery discharge and improvement of visual acuity on distant vision than group B.

In nutshell, the present clinical study has established that *Phalatrikadi ghrita* can be used in Presbyopia and better results are obtained when it is administered orally as well as locally as *Tarpana*.

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## हिन्दी सारांश

### तिमिर पर फलत्रिकादि घृत (तर्पण एवं आभ्यन्तर प्रयोग) के प्रभाव का चिकित्सकीय अध्ययन

दिनेश सिंह गौर, रुचि गुप्ता, मंजूषा राजगोपाल एवं पीयूष डी. माटलिया

नेत्र रोग शरीर के अन्य रोगों से अधिक महत्वपूर्ण हैं, क्योंकि दृष्टिनाश से रोगी अक्षम हो जाता है। नेत्र रोगों का अंतिम परिणाम अन्धापन है। सभी नेत्र रोगों में तिमिर महत्वपूर्ण है, क्योंकि इसमें देखने में कठिनाई होती है। नेत्र रोगों के बचाव के लिए व्यायाम, उचित निदान एवं चिकित्सा आवश्यक है। जो व्यक्ति अधिक नजदीक का कार्य जैसे, कम्प्यूटर वर्क, टेलरिंग, एम्ब्रॉयडरी, माइक्रोस्कोपिक वर्क करते हैं तथा अन्य ऐसे व्यवसाय जिसमें नजदीकी कार्य जरूरी है, ऐसे व्यक्तियों में कम उम्र में प्रेसबायोपिया विकसित हो जाता है। इन सभी कारणों से प्रेसबायोपिया दिन प्रतिदिन बढ़ रहा है। विभिन्न आचार्यों ने तिमिर-प्रेसबायोपिया को वात प्रधान त्रिदोषज दृष्टिगत रोग माना है। यह अध्ययन तिमिर-प्रेसबायोपिया के ३७ रुग्णों पर किया गया है। वर्ग 'क' में फलत्रिकादि घृत आभ्यन्तर प्रयोगार्थ एवं वर्ग 'ख' में फलत्रिकादि घृत तर्पण और आभ्यन्तर प्रयोग किया गया है। अध्ययन में रुग्णों के पंजीकरण के पश्चात् तिमिर-प्रेसबायोपिया के मुख्य लक्षणों जैसे समीपस्थ अव्यक्त दर्शन, नेत्रायास व शिरोभिताप का चिकित्सा पूर्व एवं चिकित्सा पश्चात् अध्ययन किया गया। अपेक्षाकृत वर्ग 'ख' में अधिक लाक्षणिक सुधार पाया गया।

गुजरात आयुर्वेद युनिवर्सिटी