

Efficacy of Akshitarpana and Pana of Mahatriphaladi Ghrita in the Management of Timira (Simple Myopia) - An Open Labelled Randomized Comparative Clinical Trial

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Abstract

Background: *Acharya Sushruta* has mentioned *Timira* as a *Drishtigata Roga* affecting the *Patala*¹. *Timira* is considered as a disease affecting the *Drishti* which left untreated causes *Drishtinasha*. When *Apathya Ahara-Vihara* has been continued for a long period, it leads to *Khavaigunya* and vitiated *Dosha* takes place in the *Prathama Patala* can complain of “*Avyakta Darshana*” which can be correlated with complain of difficulty in seeing far object or all the external objects appears dim and hazy to the sight. When it occurs in the *Dwitiya Patala*, there are complaints of “*Vihwala Darshana*” can be correlated with confused visual perception and seeing false image. According to the dominancy of *Dosha* among all the vitiated *Doshas* when reach to the *Prathama* and *Dwitiya Patala*; it causes *Vataja-Pittaja-Kaphaja-Raktaja-Sannipataja Timira* accordingly. *Rupa* of *Doshika Timira* occurs according to vitiated *Dosha* in *Sansthan*². According to *Acharya Sushruta*, *Prathama Patalagata Timira* is *Sadhya* (curable) and *Dwitiya Patalagata Timira* is *Krichchhasadhya* (curable with difficulty)³.

In modern science, *Timira* can be co-related with clinical findings of Simple Myopia. Also called physiological myopia. simple myopia is the commonest variety. Various surveys in India have found myopia prevalence ranging from 6.9% to 19.7%⁴. Corrective lenses are just providing an aid to diminished vision.

Aim: To assess the efficacy of *Akshitarpana* and *Pana* of *Mahatriphaladi Ghrita* in the management of *Timira* (Simple Myopia).

Material and Methods: Total 40 patients on the basis of signs and symptoms of the disease *Timira* (Simple Myopia) were registered and were randomly allocated into two groups adopting computerised randomisation technique as follows with Group A (n = 20): *Pana* and *Akshitarpana* with *Mahatriphaladi Ghrita* and Group B (n = 20): *Akshitarpana* with *Mahatriphaladi Ghrita*.

Results: Group A shows better percentage of relief in *Durastha Avyakta Darshana* i.e., 70.31% in comparison to Group B i.e., 32%. Group A shows better percentage of relief in *Vihwala Darshana* i.e., 76.92% in comparison to Group B i.e., 33.33%. Group A shows 83.31% relief in *Shiroabhitapa* and 90%

relief in *Netrasrava* in compare to Group B. The comparative data was statistically insignificant ($p > 0.05$) in chief complain while statistically significant ($p < 0.05$) in associated complain.

Conclusion: *Mahatriphaladi Ghrita Pana* along with *Mahatriphaladi Ghrita Akshitarpana* is more effective than *Mahatriphaladi Ghrita Akshitarpana* alone in Simple Myopia.

Keywords: *Timira*, *Mahatriphladi Ghrita*, Simple Myopia

Introduction

Eye is the most specialized sense organ serving the most vital function providing sight to living creature Good. Vision is crucial for social and intellectual development. *Acharya Sushruta* has clearly mentioned that prevention of eye diseases should be the utmost aim rather than its curative aspect ⁵ and if neglected or improperly treated, these diseases may ultimately lead to the total loss of vision ⁶.

Acharya Sushruta discoursed on the chapter seven - *Drishtigata Roga Vijnaniya* which deals with the *Rupa*, *Samprapti*, *Pathya-Apathya*, *Chikitsa* of the diseases which are peculiar to the *Drishti* of the eye. Among them the present study deals with the details of the disease named as *Timira* affecting the *Patala* ⁷. *Timira* is considered as a disease affecting the *Drishti* which left untreated causes *Drishtinasha*. When *Apathya Ahara-Vihara* has been continued for a long period, it leads to *Khavaigunya* and vitiated *Dosha* takes place in the *Prathama Patala* can complain of “*Avyakta Darshana*” which can be correlated with complain of difficulty in seeing far object or all the external objects appears dim and hazy to the sight. When it occurs in the *Dwitiya Patala*, there are complaints of “*Vihwala Darshana*” can be correlated with confused visual perception and seeing false image of *Makshika* (fly), *Mashakana* (insect), *Keshana* (hair), *Jalani* (web), *Mandalani* (circles), *Pataka* (flag), *Mariachi* (mirage), *Pariplavacha* can be correlated with seeing unexciting objects and floaters. *Acharya Vagbhata* added other complaints are “*Bhutam Tu Yatnata Aasnna*” and “*Dure Sukshuma Cha Na Ikshate*” in the *Dwitiya Patala* can be correlated with difficulty for near and distance vision ⁸. According to the dominancy of *Dosha* among all the vitiated *Doshas* when reach to the *Prathama* and *Dwitiya Patala*; it causes *Vataja-Pittaja-Kaphaja-Raktaja-Sannipataja Timira* accordingly. *Rupa* of *Doshika Timira* occurs according to vitiated *Dosha* in *Sansthan* ⁹.

According to *Acharya Sushruta*, *Prathama Patalagata Timira* is *Sadhya* (curable) and *Dwitiya Patalagata Timira* is *Krichchhasadhya* (curable with difficulty) ¹⁰. Local as well as systemic management of the disease *Timira* is necessary evident from the *Chikitsa Sutra* described in classics. In *Timira*, therapies such as *Snehana*, *Raktamokshana*, *Pana*, *Nasya*, *Murdha Basti*, *Basti kriya*, *Tarpana*, *Anjana*, *Bidalaka*, *Lepa* is advocated to be given according to *Dosha* involved.

According to clinical features of *Prathama* and *Dwitiya Patalagata Timira*, in Modern science can be correlated with clinical findings simple myopia. Also called physiological myopia. It is dioptric condition of the eye in which with the accommodation at the rest incident parallel rays come to a focus anterior to the light sensitive layer of retina. Among the four varieties classified clinically, simple myopia is the commonest variety. Various surveys in India have found myopia prevalence ranging from 6.9% to 19.7% ¹¹. Simple Myopia has been implicated as the 6th leading cause of vision impairment. In Asia, prevalence of simple myopia is higher ranging 40% in general population and 80% in students. As regards to prognosis low or

moderate degree of simple myopia are not likely to progress. Only widely used corrective lenses are just providing an aid to diminished vision. Surgical measures are carried out if required other than the glasses or contact lenses which has its own risks and complications apart from being expensive.

- **Aim:** To assess the efficacy of *Akshitarpana* and *Pana* of *Mahatriphaladi Ghrita* in the management of *Timira* (Simple Myopia).
- **Objective:** To assess the efficacy of *Mahatriphaladi Ghrita Pana* and *Akshitarpana* in the management of *Timira* (Simple Myopia).

Materials and Methods

Institutional Ethics Committee (IEC) approval was taken prior to initiation of research. No any adverse drug reaction has been recorded during the course of the trial. Study was registered in Clinical Trial Registry of India CTRI/2020/11/029217. Patient information sheet was prepared and the patient informed consent was taken before starting the treatment.

Total 40 patients of *Timira* (Simple Myopia) were registered from outpatient department and inpatient department of Shalaky Tantra, IPGT&RA, Jamnagar. They were randomly allocated into two groups adopting computerised randomisation technique as follows:

Group A (n = 20): *Pana* and *Akshitarpana* with *Mahatriphaladi Ghrita*.

Group B (n = 20): *Akshitarpana* with *Mahatriphaladi Ghrita*

The patients were given treatment for a period of 30 days. After completion of the treatment, the patients were followed up for 1 month at the interval of 15 days.

Raw herbal drug of *Mahatriphaladi Ghrita* was procured from Pharmacy, Gujarat Ayurved University, Jamnagar and authenticated in Pharmacognosy laboratory, IPGT and RA, Gujarat Ayurved University, Jamnagar. Then the medicines were prepared adopting the standard API methods *Ghrita*.

Criteria of Selection

Inclusion Criteria

- Patient within the age group of 10-25 years with normal fundus were included in the study.
- Patients having signs and symptoms of *Timira* (Simple Myopia) described as per *Ayurveda* and Modern science.
- Myopia up to -6D were included in the study.

Exclusion Criteria

- Patient below age of 10 years and above 25 years.
- Patient having any other known ocular pathology.
- Patient having myopia more than -6D.
- Patient having myopic degenerative changes.

Investigations

Haematological examinations (Hb%, TC, DLC, ESR), Urine analysis (Physical, Chemical and Microscopic) and Biochemical-RBS has been carried out before treatment to rule out any systemic disease. Lipid profile analysis (S. Cholesterol, S. Triglycerides, S. HDL, S. LDL, S. VLDL) has been carried out before treatment to rule out any systemic disease and after treatment to note any changes in these parameters.

Criteria for Assessment

Assessment was done on the basis of scoring pattern applied for subjective and objective parameters both before and after treatment.

Subjective Criteria

Symptoms of Simple myopia i.e.

- *Vihwala Darshana* (Blurred Vision)
- *Durastha Avyakta Darshana* (Diminished Distant Vision)
- *Netrasrava* (Watery Discharge)
- *Shiroabhitapa* (Headache)

Objective Criteria

Routine Examination and investigations:

- Visual Acuity with Snellen’s Chart
- Direct and Indirect Ophthalmoscopy
- Wet Retinoscopy (if required)
- Keratometry
- A-Scan

The details of the score adopted for the main signs and symptoms in this study are as follows:

<i>Durastha Avyakta Darshana: (Diminished Distant Vision)</i>	Score
No feeling of Diminished distant vision	0
Occasional Diminished distant vision	1
Regular Diminished distant vision without disturbing routine work	2
Regular Diminished distant vision disturbing day to day work	3

<i>Vihwala Darshana: (Blurred Vision)</i>	Score
No such problem	0
Occasional blurring or disturbance of vision	1
Regular blurring without disturbing routine work	2
Regular blurring disturbing day to day work	3

<i>Netrasrava: (Watery Discharge)</i>	Score
No watery discharge	0

Mild watery discharge	1
Moderate watery discharge	2
Severe watery discharge	3

Shirobhitapa: (Headache)	Score
No headache	0
Very occasional headache	1
Irregular attacks of frequent headache	2
Regular headache	3

Objective Criteria

Scoring of Distant Vision Acuity with (Snellen’s Distance Vision Chart)	Score
Distant Vision Acuity (Snellen’s Distance Vision Chart)	6/6 -0
	6/9 -1
	6/12 -2
	6/18 -3
	6/24 -4
	6/36 -5
	6/60 -6
	< 6/60 -7

Statistical Analysis

The data obtained in clinical study were subjected to statistical analysis by evaluating the significance of the interventions using paired and unpaired t tests. After obtaining the P value, it was observed as insignificant $P > 0.05$, significant $P < 0.05$, highly significant was $P < 0.01$.

Observation

Among all the participants in this clinical trial 80% had complaints of *Durastha Avyakta Darshana* (Indistinct distant vision) and 47.5% had complaints of *Vihwala Darshana* (Blurred vision), 50% had complaints of *Shiroabhitapa* (Headache) and 47.5% had complains of *Netrasrava* (Eye discharge).

Results

In the present study total 40 patients were registered, 20 in group A and 20 in Group B, and all of them completed the course of study. The effect of therapy in 40 patients of OSMF is presented below.

Effect of Therapies on Chief Complaints

Subjective Parameters

Chief Complaints

In Group A, mean score of *Durastha Avyakta Darshana* was reduced from 1.58 to 0.47 with percentage of relief 70.31% which was statistically highly significant ($p < 0.001$). While, mean score of *Vihwala Darshana* was reduced from 1.083 to 0.250 with percentage of relief 70.31% which was statistically highly significant ($p < 0.001$).

In Group B, mean score of *Durastha Avyakta Darshana* was reduced from 1.60 to 1.13 with percentage of relief 32% which was statistically significant ($p < 0.001$). While, mean score of *Vihwala Darshana* was reduced from 1.70 to 1.33 with percentage of relief 33.33% which was statistically significant ($p < 0.001$).

Associated Complaints

In Group A, mean score of *Shiroabhitapa* was reduced from 1.08 to 0.18 with percentage of relief 83.31% which was statistically highly significant ($p < 0.001$). While, mean score of *Netrasrava* was reduced from 1.00 to 0.00 with percentage of relief 90% which was statistically highly significant ($p < 0.001$).

In Group B, mean score of *Shiroabhitapa* was reduced from 1.0 to 0.63 with percentage of relief 36.36% which was statistically significant ($p < 0.05$). While, mean score of *Netrasrava* was reduced from 1.0 to 0.30 with percentage of relief 58.33% which was highly statistically significant ($p < 0.001$).

Objective Parameters

Visual Acuity

In Group A, mean score of Right Eye Visual Acuity was reduced from 4.30 to 3.45 with percentage of relief 19.76% which was statistically highly significant ($p < 0.001$). While, mean score of Left Eye Visual Acuity was reduced from 4.450 to 3.45 with percentage of relief 22.47% which was statistically highly significant ($p < 0.001$).

In Group B, mean score of Right Eye Visual Acuity was reduced from 4.90 to 4.45 with percentage of relief 8.33% which was statistically highly significant ($p < 0.001$). While, mean score of Left Eye Visual Acuity was reduced from 4.90 to 4.45 with percentage of relief 9.18% which was statistically highly significant ($p < 0.001$).

Refraction

In Group A, mean score of dioptric power of spherical lens in Right eye was reduced from 1.71 to 1.40 with percentage of relief 17.36% which was statistically highly significant ($p < 0.001$). While, mean score of dioptric power of spherical lens in Left Eye was reduced from 1.66 to 1.37 with percentage of relief 16.52% which was statistically highly significant ($p < 0.001$).

In Group B, A, mean score of dioptric power of spherical lens in Right eye was reduced from 1.76 to 1.55 with percentage of relief 12.05% which was statistically significant ($p < 0.005$). While, mean score of dioptric power of spherical lens in Left Eye was reduced from 2.06 to 1.76 with percentage of relief 12.05% which was statistically significant ($p < 0.05$).

Keratometry

In Group A, keratometry in right eye K1 and K2 has no mean difference with percentage of relief 0.025% and left eye K1 was reduced from 43.92 to 41.89 with percentage of relief 5.14% and in K2 was reduced from 44.03 to 43.98 with percentage of relief 0.13%. Both eye K1 and K2 results were statistically insignificant in Group A.

In Group B, keratometry in right eye K1 and K2 has no mean difference with 0% of relief while in left eye K1 has mean difference of -0.05 i.e., 0.13% percentage of relief and in K2 mean difference of -0.02 i.e., 0.06% percentage of relief. No Keratometry change was found in Group B. Both eye K1 and K2 results were statistically insignificant in Group B.

Axial Length

In Group A, Axial length of right eye mean score reduced from 23.420 to 23.395 with percentage relief 0.116% and in left eye mean score reduced from 23.482 to 23.470 with percentage relief 0.059% were found. Both eye Axial length results were statistically insignificant in Group A.

In Group B, Axial length of right eye mean score reduced from 23.561 to 23.59 with percentage relief 0.004% and in left eye mean score reduced from 23.572 to 23.57 with percentage relief 0.002% were found. Both eye Axial length results were statistically insignificant in Group B.

Table 1: Comparative Effect of Therapy on Chief Symptoms of *Timira* (Simple Myopia)

Chief Complaints (B/L Eye)	Group	N	Mean Diff.	S.D. ±	S.E. ±	‘t’	P	Sign.
<i>Durastha Avyakta Darshana</i>	A	17	1.118	0.600	0.146	0.0616	> 0.05	IS
	B	15	1.133	0.834	0.21			
<i>Vihwala Darshana</i>	A	11	0.909	0.302	0.090	1.511	> 0.05	IS
	B	08	0.625	0.518	0.183			

Group A shows better percentage of relief in *Durastha Avyakta Darshana* i.e., 70.31% in comparison to Group B i.e., 32%. Group A shows better percentage of relief in *Vihwala Darshana* i.e., 76.92% in comparison to Group B i.e., 33.33%.

The data reveals that Group A showed better percentage of relief in comparison to Group B in all symptoms of the disease *Timira* (Simple Myopia) but comparison between both the groups shows statically insignificant result ($p > 0.05$).

Table 2: Comparative Effect of Therapy on Associated Complaints of *Timira* (Simple Myopia)

Associated Complaints	Group	N	Mean Diff.	S.D. ±	S.E. ±	‘t’	‘P’	Sign.
<i>Shiroabhitapa</i>	A	10	1	0.47	0.14	2.714	< 0.05	S
	B	10	0.40	0.51	0.16			

Netrasrava	A	9	1	0.00	0.00	2.838	< 0.05	S
	B	10	0.500	0.52	0.16			

Group A shows 83.31% relief in *Shiroabhitapa* and 36.36% in Group B. Group A shows 90% relief in *Netrasrava* and 58.33% in Group B. The data reveals that Group A showed better percentage of relief in comparison to Group B in all above symptoms of the disease *Timira* (Simple Myopia) but comparative data between both the groups shows statically significant result ($p < 0.05$).

Table 3: Comparative Effect of Therapy on Visual Acuity in *Timira* (Simple Myopia)

Parameter	Eye	Group	N	M.D.	S.D. ±	S.E. ±	't'	P	Sign.
Visual Acuity	RE	A	20	0.850	0.366	0.081	2.869	< 0.05	S
		B	20	0.400	0.598	0.134			
	LE	A	20	1	0.459	0.103	3.584	< 0.001	HS
		B	20	0.450	0.510	0.114			

Group A shows better percentage of improvement in Left Eye in compare to Right Visual Acuity i.e., 22.471% in left eye and 19.76% in right eye in comparison to Group B i.e., 9.183% in left eye and 8.33% in right eye. The comparative data is statistically highly significant ($p < 0.001$) in Left eye and statistically significant in right eye ($p < 0.05$).

Table 4: Comparative Effect of Therapy on Visual Refraction in *Timira* (Simple Myopia)

Parameter	Eye	Group	N	M.D.	S.D. ±	S.E. ±	't'	P	Sign
Visual Refraction	RE	A	20	0.30	0.21	0.04	1.20	< 0.05	S
		B	20	0.21	0.28	0.06			
	LE	A	20	0.28	0.18	0.041	0.98	< 0.05	S
		B	20	0.21	0.28	0.063			

In Group A, dioptric power of spherical lens was reduced better percentage in Right and Left Eye Visual Refraction i.e., 17.36% in right eye and 16.52% in left eye in comparison to Group B i.e., 12.056% in both right and left eye. The comparative data is statistically significant ($p < 0.05$) in all these parameters.

Table 5: Overall Effect of Therapy

Assessment of Result	Group A		Group B	
	No. of Patients	Percentage (%)	No. of Patients	Percentage (%)
Cured	15	75%	04	20%
Marked Improvement	0	0%	02	10%
Moderate Improvement	4	20%	05	25%
Mild Improvement	0	0%	04	20%

Unchanged	1	5%	05	25%
Total	20	100%	20	100%

In Group A, 75% of patient's patient got complete remission, 20% of patients got moderate improvement, 5% patients remained unchanged. While no patients got marked improvement.

In Group B, 20% of patient's patient got complete remission, 10% of patients got marked improvement, 25% of patients got moderate improvement, 20% of patients got mild improvement and 25% patients remained unchanged.

No any adverse effect found in the present study till the follow- up period.

Discussion

Probable Mode of Action of *Mahatriphaladi Ghrita Akshitarpana*

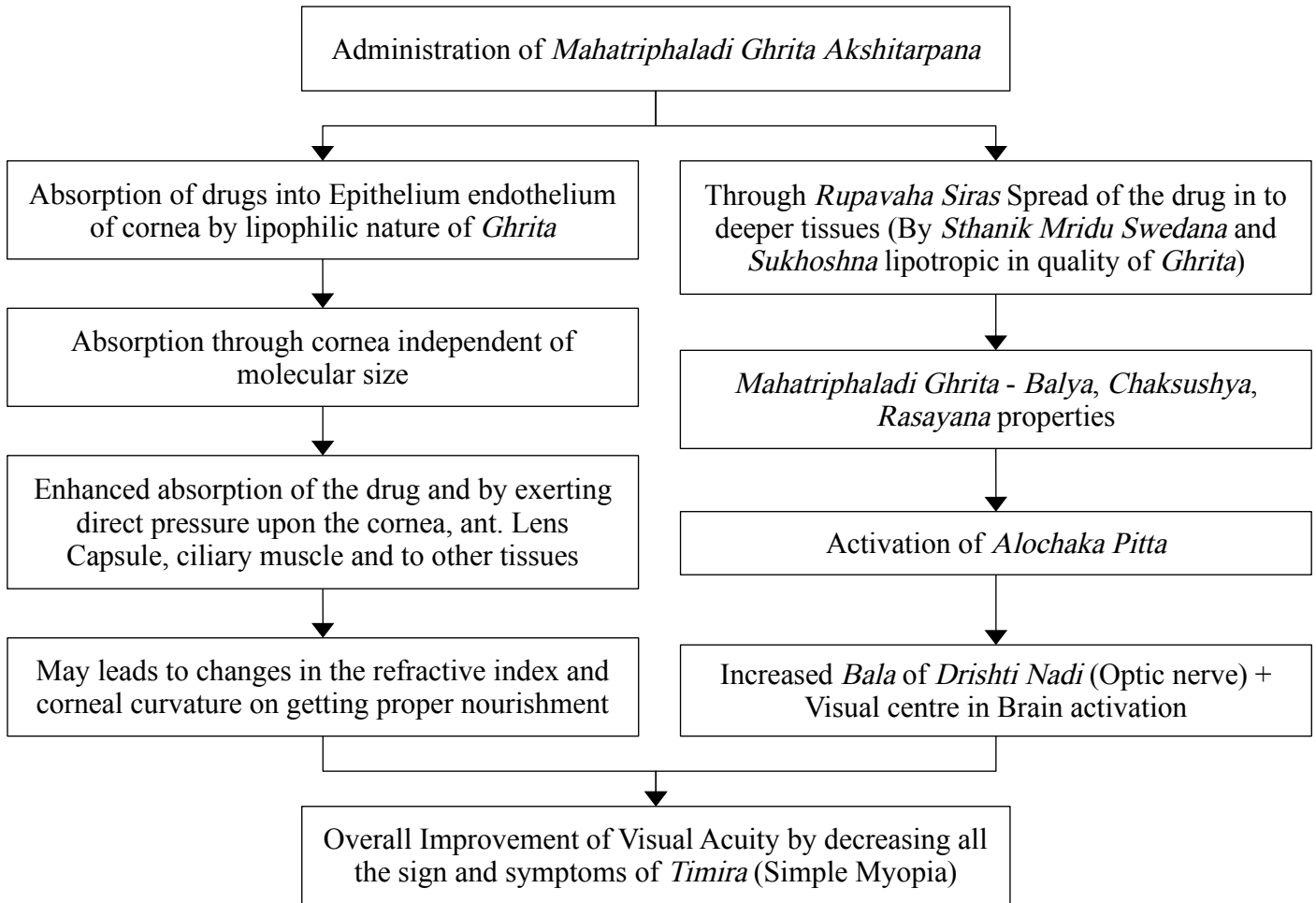
Akshitarpana (ocular therapy) is one of the local therapeutic procedures aimed to give nourishment to the eye through Medicated *Ghrita*, *Ghritmanda*, *Vasa*, *Majja* etc. which made stagnant in the eye for a specular time period in a particular formed frame which if promptly used reveal an objective piece of evidence of excellent responses are already been mentioned by *Acharyas*.

Akshitarpana acts as a prophylactic and curative therapy for maintaining the natural acuity and condition of eyes. It has *Brimhana* quality. It cherishes the eyes, improves and invigorates the *Drishti Shakti*. It is preventive and remedial procedure in *Vataja* and *Pittaja Vikara*.

The drugs used in *Akshitarpana* procedure is the combination of *Ghrita* and medicines, hence the drug can easily cross the corneal epithelium (being lipophilic) and endothelium (being hydrophilic). Also due to more contact time the active component of drug used in *Akshitarpana* will be absorbed more and may leads to cure the diseases by providing proper nourishment to the structures.

In *Ayurveda*, *Mahatriphaladi Ghrita* described as *Rasayana* having *Sheeta Virya* and *Balya*, *Brimhana* property to protect body from various diseases. The *Ghrita* has trespassing into minutest channels of the body and enters into deeper layer of *Dhatu*s through *Rupavaha Siras* and purifies every minutest part of channels while pacifying *Pitta dosha*. So, it is highly effective in *Drishtigata Roga* having dominancy of *Alochaka Pitta*.

Flowchart of Probable Mode of Action of *Mahatriphaladi Ghrita Akshitarpana*



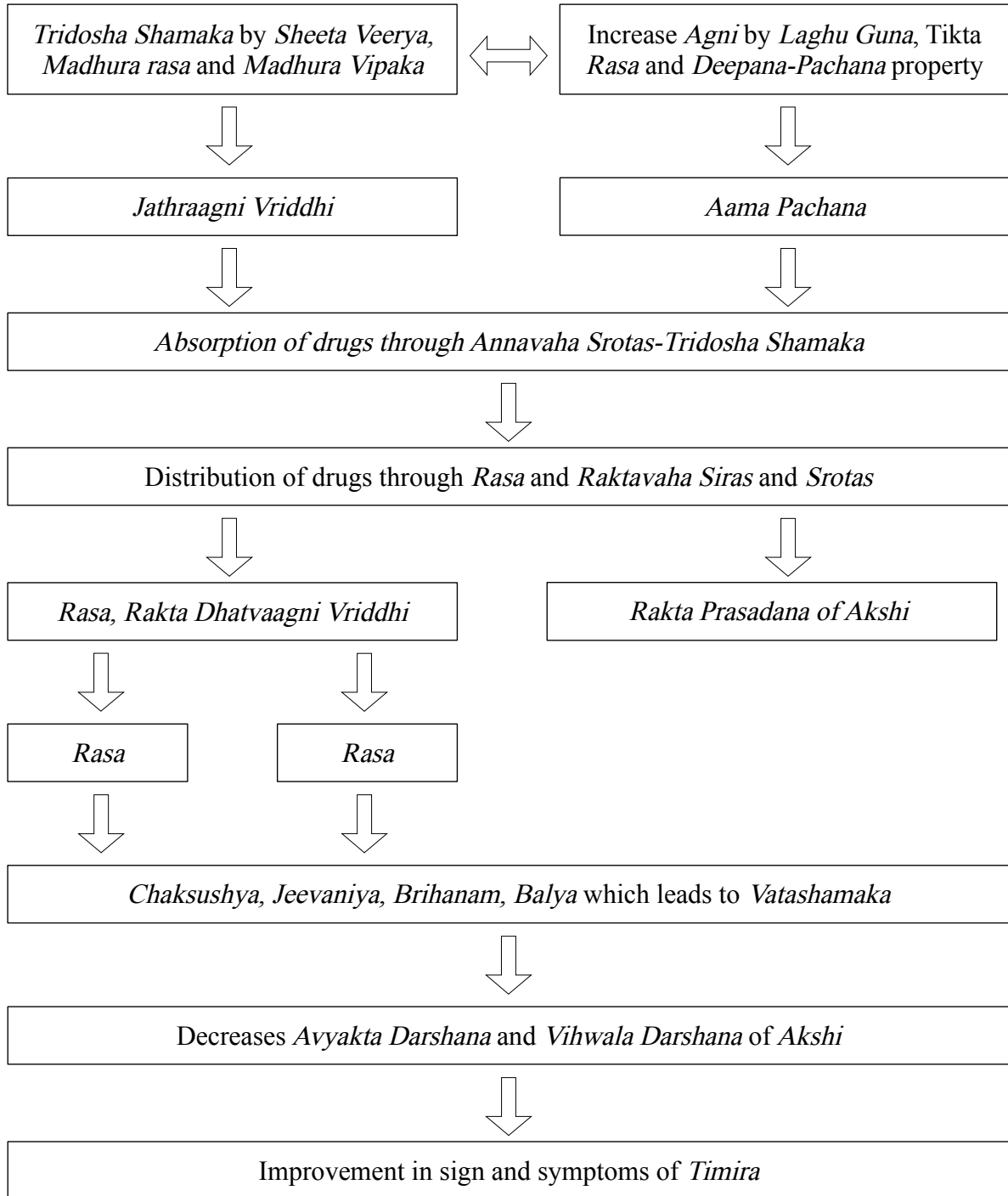
Probable Mode of Action of *Mahatriphaladi Ghrita Pana*

In the present study, the selected formulation - *Mahatriphaladi Ghrita* must have the *Guna* (Properties - Molecular structure) to break down the *Samprapti* (Pathogenesis) of the *Roga - Timira*. The *Samprapti* of *Timira* is not sufficient enough according to *Samhitas*. In Ayurveda, the *Rasapanchaka* plays an important role to know any drug in detail. On the basis of *Rasapanchaka*, the probable mode of the action of the *Mahatriphaladi Ghrita* is as follows - The drug is having *Madhura, Amla, Katu, Tikta* and *Kashaya Rasas, Snigdha, Guru, and Mridu Guans, Sheeta* (Mainly) and *Ushna Veerya, Madhura Vipaka*. In the *Samprapti* of *Timira* it is having *Tridosha Prakopa*, were major constituents of *Mahatriphaladi Ghrita* has *Tridoshashamak* property.

Due to *Ama Utpatti*, which causes *Rupavaha Sira Srotorodha* – can be break down by drugs of *Mahatriphaladi Ghrita* having *Deepana - Pachana Gunas* and by *Chhedana Guna* of *Tikta rasa* with respect to *Tikshna Guna* of *Katu Rasa in Marga Vivarana*. *Ushna Veerya* has *Rasayana, Shodhana, Chaksushya* and *Kapha- Vatashamaka* effect which gives *Bala* to *Alochaka Pitta* responsible for visual perception while *Sheeta Veerya* of other drugs maintains the *Sheeta Satmya* of the *Drishti*. *Madhura Rasa* and *Madhura Vipaka* of *Mahatriphaladi Ghrita* drug have *Jeevaniya, Rasayana, Chaksushya* properties, a prime source of nourishment of *Dhatus* of the *Patalas* and *Drishti*, thus by enlightening *Netra-Sharir*. *Mahatriphaladi Ghrita* has *Sheeta Veerya* and *Madhura* in *Vipaka*. At last, *Samprapti - Ghataka* achieved by *Tridosha Shamaka*

Karma of *Mahatriphaladi Ghrita* which ultimately helpful in *Vata Pradhan Tridosaja Vikar – Timira*. Apart from these properties, all the content of *Mahatriphaladi Ghrita* has *Balya*, *Chaksushya*, *Rasayana*, and *Brimhana* which will strengthen the *Drishti* and *Patala* of *Netra* for better vision.

Flow Chart of Probable Mode of Action of *Mahatriphaladi Ghrita Pana*



Conclusion

After analysis of all the data, it can be concluded that group A shows statistically significant result than that of group B that was Oral administration of *Mahatriphaladi Ghrita* along with *Akshitarpana* is more effective

as that of *Mahatriphaladi Ghrita Akshitarpana* alone in the management of *Timira* (Simple Myopia). The duration of the treatment is short; so, further long-duration studies are needed. It is recommended that the study should be carried out on a large number of patients with longer duration to evaluate and analyse the efficacy of drugs.

Financial Support and Sponsorship

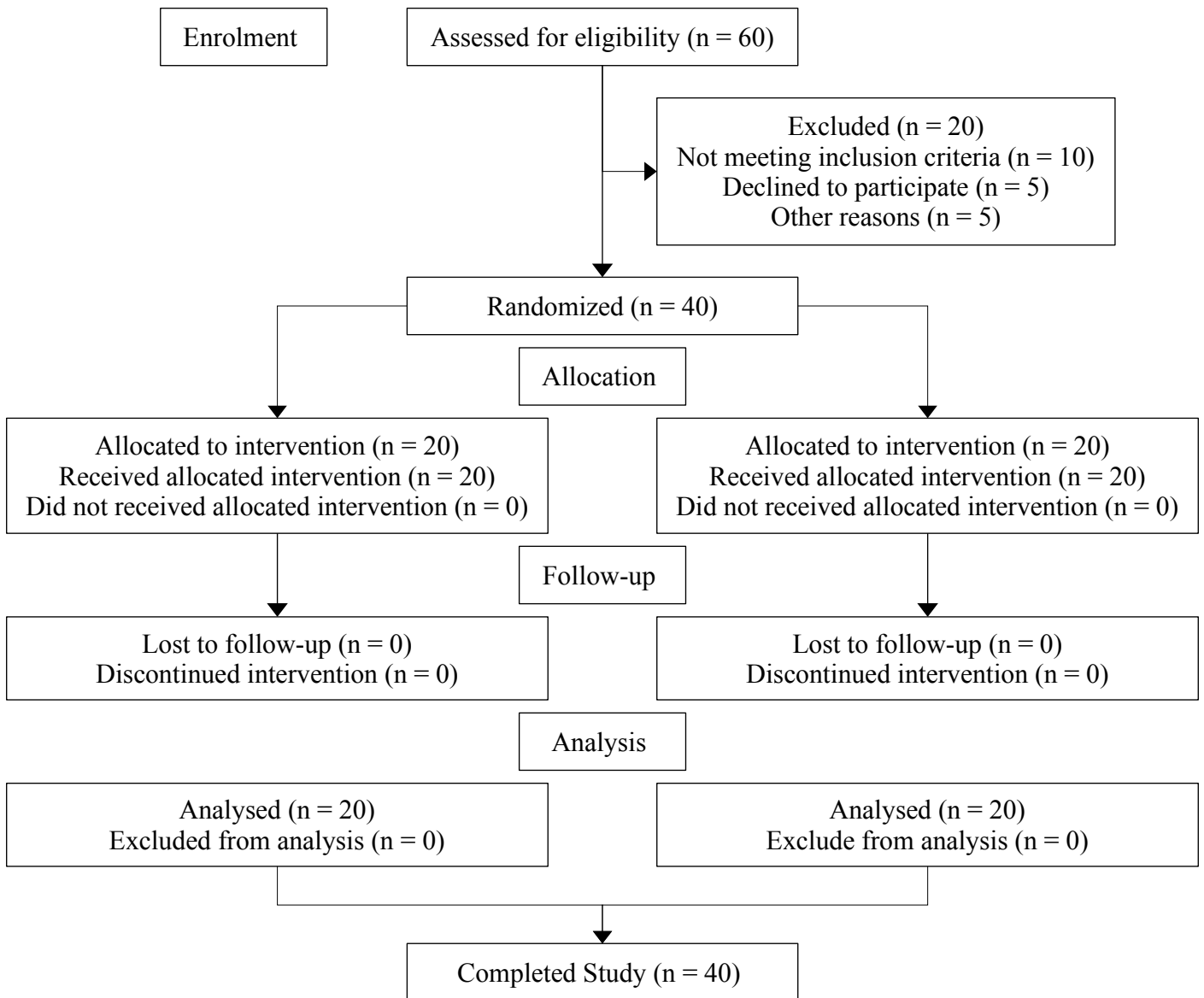
IPGT and RA, Gujarat Ayurved University, Jamnagar, Gujarat, India.

Conflicts of Interest

There is no conflict of interest.

Consort flowchart of this study is described in Figure 1.

Figure 1: Consort Flowchart



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