



Research Article

A CLINICAL STUDY ON THE EFFICACY OF *TIMIRHAR LAUHA* AND *BALADI GHRIT TARPANA* IN THE MANAGEMENT OF *TIMIRA* WITH SPECIAL REFERENCE TO MYOPIA

Abhishek Jain^{1*}, Shamsa Fiaz², Pankaj kundal³

¹AMO, Ayush Department, Govt. Ayurved College, Burhanpur, M.P., India.

²Professor & HOD., Department of Shalakya Tantra, National Institute of Ayurveda, Jaipur, India.

³Assistant Professor, Department of Shalakya, All India Institute of Ayurveda, New Delhi, India.

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ABSTRACT

Myopia is a refractive error which affects every age group person around the world. Specially in modern age when the use of mobile screen and computer is increased so much, this error has become horrible. The symptoms of myopia closely resembles with the disease *Timir*. It involves *Pratham* and *Dwitiya patala* of *Netra*. In the present study, 35 clinically diagnosed patients of *Timira/Myopia* were selected and randomly divided into two groups (Group-A-18 patients, Group-B-17patients) out of these, 30 patients completed the trial. Patients of group A were administrated *Timirhar Lauha* orally. While patients of group B were topically administrated *Baladi Ghritha* for *Tarpana* and *Timirhar Lauha* orally. The study shows that *Timirhar Lauha* (systemic drug) alone was effective in all symptoms of *Timira /Simple Myopia* but combination of the drug *Timirhar Lauha* (systemic drug) with *Baladi Ghritha* (*Tarpana*/topical application) had much greater potential to ameliorate the symptoms of *Timira /Simple Myopia*.

*Address for correspondence

Dr Abhishek Jain

AMO, Ayush Department,

Govt. Ayurved College,

Burhanpur, M.P., India.

Email:

drabhishek211@gmail.com

Ph: 9982253037

INTRODUCTION

Timira is the *Drishtigata Rog* explained by all the *Acharyas*. *Timira* is a disease, which starts with simple visual disturbance (*Avyakta Darshana*) but if unattended it may lead to ends in complete loss of vision (*Linganasha*). Due to this reason all the *Acharyas* have paid special attention to this disease. The clinical features of *Timira* (first *Patalashrita- Avyakta Darshana*- indistinct distance vision and second *Patalashrita- Vihwala Darshana*- blurred vision) can be correlated symptomatically with refractive errors.

Myopia or short-sightedness is type of refractive error in which parallel rays of light coming from infinity are focused in front of the retina when accommodation is at rest^[1]. Myopia is a highly significant problem not only because of its high prevalence, but also because it can contribute to visual morbidity and increase the risk for vision-threatening conditions (e.g. retinal breaks and detachment, glaucoma etc.).

In Ayurveda, various treatment formulations are advocated for *Timira Roga* for enhancement of vision. Here *Timirhar Lauha* (Ref. *Rasendrasara samgrah*^[2]) was selected for present study along with local therapy of *Akshi Tarpana* with *Baladi ghritha* (Ref. *Yogratnakar*^[3]).

As the disease *Timira* (Myopia) is degenerative in nature, the *Chakshushya*, *Rasayana* and *Tridosha* mitigating action might be helpful in such type of disorders. Majority of *Rasayana* drugs work on multiple areas and helps in achievement of *Vyadhikshamatwa* through its *Dipana*, *Pachana*, *Medhya* and non specific immune booster properties. *Chakshushya* term indicate for regeneration of eye sight. *Ghritha* is one among the best *Rasayana* drug and *Triphala* (which is main content of both selected drug) is one among the best *Chakshushya* drug. Thus a drug having both *Chakshushya* and *Rasayana* properties might be helpful for treating the disease *Timira* (myopia). According to *Charaka*, *Ghritha* improves *Dhatu*s and is overall booster for *Ojas*^[4].

Therefore, a clinical study was planned to study the efficacy of *Timirhar Lauha* orally and *Baladi ghrita Tarpana* for evaluating the efficacy of above therapies in reduction of dioptric power and visual improvement.

The researches in Ayurveda are being carried out in different institutions all over the India with special attention to *Timira* and also to myopia. The present study is a step forward in that direction to find out the remedial measure for this problem with the topic entitled 'A clinical study on the efficacy of *Timirhar Lauha* and *Baladi Ghrita Tarpana* in the management of *Timira* with special reference to Myopia'.

This clinical trial is interventional, randomized study and approved by Institutional Ethical committee NIA, Jaipur with letter number ICE/ACA/2015/88.

MATERIALS AND METHODS

Patients Selection

Patients attending the O.P.D. & I.P.D. of P.G. Department of Shalaky Tantra, NIA, Hospital, Jaipur, Rajasthan, with signs and symptoms of myopia/*Timira*.

35 patients of myopia, who attended O.P.D./I.P.D. during this period were selected for present study.

Inclusion Criteria

1. Patients presenting with signs and symptoms of *Timira*, described as per Ayurvedic and modern science.
2. Patients diagnosed with simple myopia were selected for the trial.

Exclusion Criteria

1. Patients not willing for the trial were excluded.
2. Patients having any other ocular pathology, e.g., cataract, corneal opacity, iridocyclitis, retinal disease etc. were excluded.
3. Patients suffering from systemic diseases.
4. Patients aged below 08 years and above 40 years.
5. Patients having a dioptr power more than -6.00 dioptr (Pathological myopia) were also excluded.

Grouping of Patients

In the present study 35 clinically diagnosed patients of *Timira*/Myopia were selected and randomly divided into two groups (Group-A-18 patients, Group-B-17patients) out of these 35 patients 30 patients completed the trial.

Group A: 18 patients of *Timira*/Myopia were advised *Timirhar Lauha* orally. **Group B:** 17

patients of *Timira*/Myopia were advised *Baladi Ghrita* for *Tarpana* and *Timirhar Lauha* orally. All the cases were examined initially in O.P.D. and were selected for study on the basis of clinical presentation and diagnostic criteria.

Laboratory Investigations

Hb gm%, TLC, DLC, ESR, RBS and Serum Cholesterol were advised to all the patients to rule out any sever pathology and to note the changes, if any.

Drug Schedule

Timirhar Lauha orally

Dose: 500mg once a day with honey.

Mode: oral

Duration: 30 days

Follow up: were done once in 15 days for a period of 45 days.

Baladi Ghrita for *Tarpana*

Poorva Karma

- Purification of body by *Avipathikara churana*.
- *Snehana* with *Dashmoola taila* followed by *Swedana* up to *Samyak Swinna Lakshana Nasya* with 6-6 drops of *Anu taila* for 3 days
- *Kavala Dharana* with warm saline water.

Pradhana Karma

- Mild fomentation with a cotton soaked in lukewarm water
- *Tarpana* with *Baladi ghrita* after 3 days of *Nasya*

Dose: Q. S.

Mode: *Tarpana*

Tarpana kala/ Aushadh dharan kal

1000 *Vak Matra* (30 minutes approx.)

Duration: 3 sittings of 5 days *Tarpana* each with interval of 5 days between the sittings.

Follow up: were done once in 15 days for a period of 45 days after completion of trial.

Criteria of Assessment

Subjective

The patients were subjectively assessed based on the symptoms- *Avyakta Darshana* (indistinct distant vision), *Vihwala Darshana* (blurred vision), *Dwidha Darshana/* (Diplopia), *Shirobhitapa* (headache), *Netrasrava* (watering), *Netrayasa* (eye strain), and *Netradaha* (burning sensation) - by adopting the scoring pattern.

Objective

- (1) Visual Acuity/LogMAR Value
- (2) Autorefractometry/Retinoscopy
- (3) Ophthalmoscopy
- (4) A scan

Grading**Awyakta Darshna (Indistinct distance vision)**

- 0- No feeling of blurring of the vision
- 1- Occasional blurring of the vision
- 2-Routine blurring which affected routine work
- 3- Regular blurring disturbing routine work
- 4- Complete darkness before the eyes

Vihwala Darshna/ (blurred vision)/ Makshikadi Abhuta Dravya Darshan (Floaters)

Visualization of non existing objects like flies, gnats, hairs, webs, circles, flags, mirage and ear rings.

- 0- No such problem
- 1- Occasional visualization of any such objects
- 2- Irregular visualization of two to four kinds of the above mentioned objects
- 3- Regular visualization of two to four kinds of the above mentioned objects
- 4- Regular visualization of more than four kinds of the above mentioned objects

Dwidha Darshana (Diplopia)

- 0 - No diplopia
- 1 - Occasional diplopia
- 2 - Regular diplopia without disturbing routine work
- 3 - Regular diplopia disturbing day-to-day work

Shirobhitapa (Headache) - Scored on the frequency of attacks

- 0 - No headache
- 1 - Occasional headache
- 2 - Irregular attacks of frequent headache
- 3 - Regular attacks of Headache

Netrayasa (Eye Strain) - It was recorded on the basis of minimum time taken to produce eye strain after near work

- 0 - More than 6 hrs of near work
- 1 - After 4- 6 hrs of near work
- 2 - After 2- 4 hrs of near work
- 3 - Before 2 hrs of near work.

Netrasrava (Watering)

- 0 - No Watering
- 1 - Occasional Watering
- 2-Regular Watering without disturbing routine work
- 3 - Regular Watering disturbing routine work

Netradaha (Burning sensation)

- 0-No Burning sensation
- 1-Occasional Burning sensation
- 2-Regular Burning sensation without disturbing routine work

3-Regular Burning sensation disturbing routine work

Statistical Analysis

Various observations made and results obtained were computed statistically using Student t - test, Wilcoxon matched pairs signed ranks test and Mann Whitney test on graph Pad InStat 3 software.

The results obtained were considered Extremely Significant for p value <0.0001, Very significant for <0.001, significant for p value <0.01 and insignificant for p value >0.05.

Observation

In present study 45.17% patients were found in the age group of 17-24 years. According to a survey in Taiwan population there was an increasing prevalence of myopia with age, from 4 percent at age of 6 years to 40 percent at age of 12 years further, more than 70 percent at the age of 15 years, and more than 75 percent at age 18 years^[5]. Only 2 patients were found in age group of 33-40 years, some studies showed the decreasing prevalence of myopia with age (between the ages of 43 and 84 years)^[6].

The percentage of female was 57.14% whereas male was 42.86%. Thus studies showed that the prevalence rate was higher in females than males^[7,8,9].

In present study, among 35 patients, 77.14% patients were Hindu, 14.28% others and 8.57% patients were Muslims. This might have occurred due to the dominance of the Hindu community in this region. However, this data is not suggestive of any confirmed finding regarding the disease.

Majority of the patients were unmarried (80%). This only signifies that most of the patients belonged to younger age group and were students.

Majority of patients 54.28% were graduates and 14.28% were post graduates. Duration and level of education is highly correlated with time spent on reading and writing. Educational level and intelligence are strongly related to amount of close up work and are probably not independent risk factors but surrogates for close up work^[10,11,12].

In occupation wise distribution of patients, out of 35 patients majority of the patients i.e. 91.42% were students, it may be due to the fact that students had a higher prevalence of myopia^[13].

In this study most of the patient belonged to upper middle (54.28%) and middle economical class (37.14%). It reflects that the area of study is predominantly represented by upper middle

economic class. This may be due to maximum subjects spending more time on computer and gadgets.

Maximum numbers of patients were on Vegetarian diet (77.14%). This is because maximum patients were from Hindu community and they used to take vegetarian diet. So we cannot say clearly that the vegetarian diet may promote the development of the disease.

Majority of patients were having good appetite 54.28%. Majority of patients (85.71%) were having regular bowels. Maximum number of patients, 94.28% were having normal micturition. Maximum number of patients 68.57% were of *Vata Pittaja Prakriti*.

Maximum no. of patients showed *Madhyama Sara* (77.14%), *Samhanana* (74.28%), *Pramana* (82.85%), *Satva* (71.42%), *Satmaya* (74.28%). No specific relation can be established between them and the disease myopia from this small number of data.

Maximum no. of patients showed *Madhyama Abhyavaharana* and *Jarana Shakti* both were 74.28%. 77.14% patients were having *Madhyama Vyayama Shakti*.

Maximum patients 94.28% were of *Bala Vaya* (up to 30 years according to *Acharya Charaka*).

In the present study 91.42% patients were having addiction to tea while 8.58% patients were

having no addiction. This indicates general trend of drinking tea as beverage.

Maximum number of patients spent 5-6 hours in front of Visual Display Screen (51.42%) followed by 37.14% patients spent 3-4 hours in front of visual Display. In Ayurveda, *Atiyoga* or *Sookshmanireekshnat* is a main etiological factor for eye diseases. According to modern science, close up work encompasses tasks of high accommodative demand, such as reading, writing, computer work, close television viewing, play video games and use of mobile phone. There are several theories which attribute close up work to the increase in axial length that causes myopia. One of the most widely held theories is the accommodation theory, wherein there is an increase in pressure in the posterior part of the eye during accommodation which is poorly resisted by the sclera, resulting in increased ocular length^[14].

All the patients, 100% were from urban areas. According to previous studies, it was observed that in urban areas myopia rates are higher than in rural areas^[15,16].

Maximum number of patients, (82.85%) had sound sleep. Maximum numbers of patients, 57.14% were having positive family history. Parental myopia is considered as a marker for both genes and a shared family environmental exposure. Myopic parents are more likely to create myopigenic environments such as more intensive education or less time spent outdoors.^[17,18]

Table 1: Incidence of Positive Symptoms in 35 Patients

Parameters	Group A	Group B	Total	Percentage
<i>Avyakta Rupa Darshan/ Duram na pashyate</i> (Indistinct distance vision)	18	17	35	100%
<i>Vihwala Darshana</i> (Blurred vision) and <i>Makshikadi abhuta dravya darshan</i> (Floaters)	07	12	19	54.28%
<i>Dwidha/ Bahuvridha darshan</i> (Diplopia/ Polypia)	0	0	0	0%
<i>Shirobhitapa</i> (Headache)	13	13	26	74.28%
<i>Netrayasa</i> (Eye strain)	16	15	31	88.57%
<i>Netrasrava</i> (Watering)	7	5	12	34.28%
<i>Netradaha</i> (Burning sensation)	9	13	22	62.85%

RESULTS AND DISCUSSION

Effect of Therapy on Subjective Parameters

Relief in the symptom of *Avyakta Darshana* was observed 27.71% in Group A ($p=0.0012$), and 68.66% in Group B ($p<0.0001$), there was extremely significant difference between BT and AT scoring of two groups, Group B showed 40.95% more relief than Group A. which indicated that the combined effect of *Tarpana* and *Timirhar Lauha* is

better than only *Timirhar Lauha* on visual feeling. Relief in the symptom of *Vihwala Darshana/ Makshikadi Abhuta Dravya Darshana* was 15% in Group A ($p=0.5000$), and 64.51% in Group B ($p<0.0001$) and these values were statistically not significant in Group A and extremely significant in Group B. So there was extremely significant ($P<0.0001$) difference found between BT and AT

scoring of two groups, even though Group B showed 49.51% better relief than Group A. Relief in the symptom of *Shiroabhitapa* was observed 56.15% in Group A (p=0.0020), and 86% in Group B (p=0.0005) and these values were statistically very significant in group A and extremely significant in group B. Relief in the symptom of *Netrayasa* was 26.19% in Group A (p=0.0020), and 88.49% in Group B (p<0.0001) and these values were statistically very significant in Group A and

extremely significant in Group B. in the symptom of *Netrasrava* was 33.33% in Group A (p=0.0020), and 82.50% in Group B (p=0.0020) these values were statistically significant in Group A and very significant in Group B. Relief in the symptom of *Netradaha* was 31.50% in Group A (p=0.0313), and 78.30% in Group B (p<0.0001) these values were statistically significant in Group A and extremely significant in Group B.

Table 2: Comparison of Relief in Terms of Percentage in Two Groups

S.No.	Symptoms	Percent Relief	
		Group A	Group B
1	<i>Avyakta Darshana</i>	27.71	68.66
2	<i>Vihwala Darshana/ Makshikadi abhuta dravya darshana</i>	15.00	64.51
3	<i>Shiroabhitapa</i>	56.15	86.00
4	<i>Netrayasa</i>	26.19	88.49
5	<i>Netrasarva</i>	33.33	82.50
6	<i>Netradaha</i>	31.50	78.30
7	LogMAR Value	12.28	23.17
Average percentage of relief		28.88	70.26

Table 3: Intergroup Comparison of Subjective Parameters of Myopia /Timira (Mann Whitney test)

S.No.	Symptoms	Mean		S.D.		S.E.		U	P	Results
		G _A	G _B	G _A	G _B	G _A	G _B			
1	<i>Avyakta Darshana</i>	0.56	1.6	0.56	0.62	0.10	0.11	774	<0.0001	ES
2	<i>Vihwala Darshana/ Makshikadi abhuta dravya darshana</i>	0.06	0.60	0.25	0.49	0.04	0.09	210	<0.0001	ES
3	<i>Netrayasa</i>	0.30	1.00	0.46	0.52	0.08	0.09	723	<0.0001	ES
4	<i>Shiroabhitapa</i>	0.73	0.86	0.59	0.51	0.15	0.13	126.50	0.4988	NS
5	<i>Netrasrava</i>	0.26	0.33	0.44	0.47	0.08	0.08	480	0.5827	NS
6	<i>Netradaha</i>	0.20	0.83	0.48	0.53	0.08	0.09	713	<0.0001	ES

On the basis of above results we can say that the improvements in the subjective feeling are better in Group B. Therefore we infer that the drug *Timirhar Lauha with Baladi Ghrit Tarpan* is very effective for the improvement of subjective feeling like *Avyakta Darshana, Vihwala Darshana/ Makshikadi Abhuta Dravya Darshana, Shiroabhitapa, Netrayasa, Netrasrava* and *Netradaha*.

Effect of Therapy on Objective Parameters

Statistically extremely significant relief were found in LogMAR value of 12.28% in Group A (p<0.0001), and 23.17% in Group B (p<0.0001). However there was extremely significant difference between BT and AT scoring of two groups

(p<0.0001) with Group B showing 10.89% better relief than Group A. In this trial insignificant result was observed in K₁ and K₂ in intra group comparison before treatment and after treatment. In this study insignificant results were observed in A Scan in intra group comparison before treatment and after treatment. Effect on dioptric power/ clinical refraction was found to be significant result (p=0.0117) in group A (3.70%), while it was extremely significantly (p<0.0001) in group B (19.53%). However there was Not significant difference between two groups (p=0.2741) statistically with Group B showing 15.83% more relief than Group A.

Table 4: Intergroup Comparison on Objective Parameter of *Timira* (Student unpaired 't' test)

S.No.	Objective parameter	Mean		S.D.		S.E.		t	P	Result
		G _A	G _B	G _A	G _B	G _A	G _B			
1	LogMAR Value	0.07	0.19	0.09	0.12	0.01	0.02	4.22	<0.001	ES
2	K ₁	-0.20	0.21	0.29	0.28	0.05	0.05	0.71	0.9436	NS
3	K ₂	-0.14	0.23	0.29	0.28	0.05	0.05	1.28	0.2057	NS
4	A Scan	0.13	0.17	0.14	0.12	0.02	0.02	1.15	0.2514	NS
5	Dioptric Power/ Clinical Refraction	0.02	0.01	0.12	0.48	0.02	0.08	1.10	0.2741	NS

Effect of Therapy on Laboratory Parameters

In this trial, insignificant results were observed in Hb, TLC, Neutrophils, Lymphocytes, Eosinophils, Monocytes, ESR, Random Blood Sugar and Serum Cholesterol in intra group and inter group comparison

Table 5: Intergroup Comparison of Laboratory Parameter of *Timira* (Student unpaired 't' test)

S.No.	Laboratory parameter	Mean		S.D.		S.E.		t	P	Result
		G _A	G _B	G _A	G _B	G _A	G _B			
1	HB	0.56	0.56	0.55	0.80	0.14	0.20	2.15	>.9999	NS
2	TLC	1080.01	1393.31	1191.8	1086.6	307.71	280.56	0.75	0.4581	NS
3	Neutrophils	8.33	10.06	6.33	7.58	1.63	1.95	0.67	0.5024	NS
4	Lymphocytes	4.60	7.93	7.92	5.78	2.04	1.49	1.315	0.1990	NS
5	Eosinophils	2.80	2.86	4.14	4.50	1.07	1.16	0.04	0.9666	NS
6	Monocytes	2.06	2.26	2.31	1.90	0.59	0.49	0.258	0.7980	NS
7	ESR	5.33	3.86	4.25	4.82	1.09	1.24	0.88	.3846	NS
8	RBS	13.00	11.13	16.98	14.80	4.38	3.82	0.32	0.7507	NS
9	Serum cholesterol	21.46	20.46	19.51	14.74	5.04	3.80	0.15	0.8753	NS

Probable mode of action of trial drug

Contents of *Timirhar lauha*- *Triphala, Loha bhasma, Yasthimadhu, Padmakamal.*

***Anupan*-** *Madhu*

Contents of *Baladi Ghrita*- *Bala, Triphala, kakoli, (Ashwagandha), Shatavari, Saileyaka, Sita, Go-ghrita*

Contents of both formulations have *Chakshushya, Rasayana* and *Tridoshshamak* properties. *Triphala, Yasthimadhu, Loha bhasma, Ashwagandha* and *Shatavari* are well established *Chakshushya* and *Rasayana* drugs. *Bala* is *Balya* and best for *Vatashaman*. *Padmakamal* and *Saileyaka* are *Pittashamak* they reduce *Daha* (burning sensation) which is a very important associated symptom in *Timir/ Myopia*. *Goghrita* is also having above said properties. *Ghrita* due to its *Sansakaranuvartana* quality easily imbibes the properties of other drugs processed with it without leaving its own properties. According to *Bhavprakash Madhu* is best *Anupan* and have *Vata Pittahara, Graahi, Lekhana, Chakshushya, Saukumaryakara, Dipana, Srotovishodhana, Yogavahi, Medhakara, Vrishya,*

Rochana, Prasadajanaka properties. Thus *Timir* which is a *Vatapitta* dominating *Tridoshaja Vyadhi* and considering its associated symptoms like *Netradaha* (Burning sensation), *Shirobhitapa* (Headache), *Netrayasa* (Eye strain), *Netrasrava* (Watering) etc. *Timirhar Lauha* and *Baladi Ghrita* are selected for the study. After analyzing the content of both formulations we can say that they are helpful to mitigating *Vatapitta* and may cure the associated symptoms.

Probable Mode of Action of *Tarpana*

The disease *Timira* is *Vata Pradhana Tridoshaja vyadhi* so compound drug employed should also have *Tridoshaghna* qualities that can counteract vitiated *Doshas* to disintegrate the pathology of the disease. In eye diseases, *Acharyas* gave special emphasis to *Kapha Dosha* hence *Kapha* should be controlled first, for this purpose *Nasya* is the best treatment and after that *Tarpana* should be advised with medicated *Ghrita* for *Vata* and *Pitta Shamana*^[19]. In the description of *Drishti, Sushruta* has mentioned that *Sheeta Dravyas* are *Satmya* for

Drishhti. Ghrita is also *Sheeta Virya*, hence the eye being the site of *Alochaka Pitta* can be effectively managed by topical administration of *Ghee* in *Tarpana*. *Ghrita* contains properties like *Balya*, *Brimhaṇa* and *Rasayana*, so it gives strength to the overall tissues of the eyeball as well as to the nervous tissues. According to *Charaka*, *Timira* is a *Vata Nanatmaja Vyadhi*, so mainly *Vata* aggravating causative factors are responsible for *Timira*. *Sneha* is the best drug to pacify the vitiated *Vata*. *Acharya Charaka* considered *Tarpana* as one of the *Sneha-Pravicarana*. *Tarpana* provides *Vatasamaka* effect and nourishment to the eyes thus improves visual acuity. Among all *Kriyakalpas*, *Netra Tarpana* is the foremost procedure for eye disorders. It acts as both preventive and curative therapy for maintaining normal healthy condition of eyes. All the ingredients of *Baladi Ghrita* are having *Chakshushya* and *Rasayana* properties; therefore *Baladi Ghrita* was selected for *Tarpana*.

CONCLUSION

Features related to visual disturbances have been described under *Drishtigata Rogas*. *Timira* comes under this group of diseases. *Timira* is a disease when the vitiated *Doshas* are situated in the first and second *Patala*. On the basis of similarities in symptoms, involvement of anatomical structures, aetiology and prognosis, *Timira* can be correlated with the refractive errors in general including myopia. The modern counterpart has made wonderful and remarkable progress in the field of ophthalmology but no satisfactory and universally accepted treatment for myopia is available. Ayurvedic text enumerates number of treatment modalities for the treatment of eye diseases, including both localized and systemic measures.

Topical applications play essential role, may be due to the limitation of systemic formulations to reach the target organ due to blood ocular barriers.

The study shows that *Timirhar Lauha* (systemic drug) alone was effective in alleviating symptoms of *Timira*/Simple Myopia but combination of the drug *Timirhar Lauha* (systemic drug) with *Baladi Ghrita* (*Tarpana*/topical application) had much greater potential to ameliorate the symptoms of *Timira* /Simple Myopia. Thus study showed that local therapy combined with systemic therapy give better result in *Timira*/Simple Myopia. No adverse effects were seen in both the groups.

However, the results of this study and the conclusion drawn there upon need to be further clarified by conducting a large scale placebo controlled clinical trial.

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