A CLINICAL COMPARATIVE STUDY ON THE EFFECT OF SHATAHWADI GHrita TARPANA WITH OR WITHOUT BHRRINGARAJA TAILA NASYA IN THE MANAGEMENT OF TIMIRA W.S.R. TO MYOPIC ASTIGMATISM

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ABSTRACT

Background & Objectives: Timira is one among the Drishtigata roga. It can be compared to Astigmatism based on the clinical features. Astigmatism is a type of refractive error wherein the refraction varies in different meridians of the eye. At present surgical treatment is the only satisfactory approach; recurrence after surgical intervention is common. Considering a non-surgical management, glasses and contact lenses are the most common methods to correct astigmatism, which neither stop nor prevent the progression of the condition. The Ayurvedic approach of the disease mainly concentrates on preventing the progression of the disease. With this aim clinical study was undertaken. The objective of the study was to compare the effect of Shatahwadi ghrita tarpana with and without Bhringaraja taila nasya in the management of myopic astigmatism. Methods: In this study 30 patients were randomly selected and divided into 2 groups, with 15 patients each. In Group A, patients were treated with Shatahwadi ghrita tarpana and Bhringaraja taila nasya for two sittings of 5 days each with a gap of 10 days. Group B were treated with only Shatahwadi ghrita tarpana for two sittings of 5 days each with a gap of 10 days. The research was a mixed methods study (quantitative & qualitative analysis). The parameters were tested for significance at p= 0.05. Results: There is statistically significant effect of Bhringaraja taila nasya with Shatahwadi ghrita tarpana in the management of Timira on comparative analysis within the groups before and after treatment at p=0.01. The calculated data shows the comparative result is insignificant (p> 0.05) between the groups. Interpretation & Conclusion: Myopic Astigmatism (Timira) is result of various structural changes in eye. Vata dosha is responsible for any structural changes in the body. Both the drugs Bhringaraja taila and Shatahwadi ghrita used for the treatment, possess vatashamaka, balya, rasayana and chakshushya properties. Which helped in alteration disease process of Myopic Astigmatism (Timira) resulting in improvement in objective parameters along with subjective parameters.

Keywords: Myopic Astigmatism, Timira, Tarpana, Nasya, Shatahwadighrita, Bhringarajataila.

INTRODUCTION
Timira\(^1\) means darkness or blurriness\(^3\). The condition with blurriness as symptom is called as timira roga in Ayurveda under drishtigata roga. Its clinical features includes, avyaktani-sarupani-sarvanyeva-prapashyati (whatever the person see is bluer)\(^2\), avyaktama-ikshate (not clear vision), vyaktama-api-animitatah (sometimes it is clear without any reason). There is also diminution of vision for distant objects (doorsookshmama cha naekshate), the vision is severely or deeply distorted (drishtir-bhrishamama-vihavalati), difficulty in perceiving the correct image (yatna-aasannama) even when person subjectively tries to accommodate by tilting head, squinting/ squeezing eyes, etc., and arunaa-bhasam, i.e. the red color will appear brighter than usual. These may cause eye strain, headache and fatigue\(^3\).

Prathama patalagata Timira is sadhya i.e. curable and dvitiya patala gata timira is yapya i.e. relievable/treatable Vyadhi (Vataya type).\(^4\)

Sushruta has advocated various forms of snehana viz, nasya and panca for vata-predominant drishti-gata vyadhi.\(^5\) The snehana, shodhana & chakshushya properties of the drugs used for nasya and tarpana procedures help in preehana (nourishment) of the patalas by supplementing the nutrition and help in establishment of prasanna-netra (clear vision).

Astigmatism is a type of refractive error wherein the refraction varies in the different meridian of the eye. Consequently, the rays of light entering in the eye cannot converge to a point focus but form focal lines. Patient usually have blurred or distorted vision in significant amounts of astigmatism and in mild astigmatism, there is complaint of headache, eye strain, fatigue, or blurred vision at only certain distances. Astigmatism is corrected using cylindrical lenses for spectacles, contact lenses and surgical procedures like vision corrected surgery with Phakic refractive lenses, Refractive Lens Exchange, LASIK and Photo astigmatic Refractive Keratotomy.\(^6\) All these treatment procedures (though less time consuming and mostly safe) have some specific complications that may or may not be managed post-surgery. Besides, many people with the diagnosed condition are not fit and/ or willing for the surgery.

The clinical features of Prathama patalagata, dvitiya patala gata and vataja types of timira are similar to simple and compound types of regular myopic astigmatism.

Nasya is the best modality to approach urdhwa jatrugata rogas\(^7\) and Tarpana for Timira.\(^8\) Thus in order to find out a solution to the problem timira (myopic astigmatism) without surgical intervention, this work was taken for clinical evaluation with Shatahwadi ghrita\(^9\) tarpana with or without Bhringaraja taila\(^10\) nasya, both having snehana, triidosha shamaka and chakshushya properties and analyzed statistically.

**AIM OF THE STUDY:**
A clinical comparative study on the effect of shatahwadi ghrita tarpana with or without bhringaraja taila nasya in the management of timira w.s.r. to myopic astigmatism

**OBJECTIVES OF THE STUDY:**
1. To evaluate the efficacy of shatahwadi ghrita tarpana with bhringaraja taila nasya in the management of myopic astigmatism.
2. To evaluate the efficacy of Shatahwadi ghrita tarpana without Bhringaraja taila nasya in the management of myopic astigmatism.
3. To compare the effect of Shatahwadi ghrita tarpana with and without Bhringaraja taila nasya in the management of myopic astigmatism.

**STUDY DESIGN:** Open labeled Comparative Clinical Study.

**ETHICAL CLEARANCE:** The Ethical Clearance for the study was taken from Institutional Clinical Ethical Committee SJGAMC & HOSPITAL, KOPPAL, India with ref. no. SJGAMCHKPL/ICEC/16-17/34.

**MATERIALS & METHODS:**

**SOURCE OF DATA:** Sample source: The sample size was 30 in total. The patients were screened from the outpatient department of Shalakya Tantra, Shree Jagadguru Gavisiddheshwara Ayurvedic Medical College and hospital, Koppal, Karnataka; the patients fulfilling the selection criteria were selected irrespective
of their sex, caste and socio economic status and occupation and allotted to two groups by a method of simple random sampling procedure.

**Drug source:** All the raw materials were collected from the local medicine herb dealer and their authentication was done from Dravyaguna department of SJGAMC Koppal.

**METHODOLOGY:** Method of drug preparation:
The medicines were prepared according to classical preparation methods of ghrita (medicated ghee) and taila (medicated oil) in Rasa Shastra Bhaishajya Kalpapana Department of SJGAMC Koppal..

**Ingredients of Shathahwadi ghrita:**
- Powders of Shatapushpa (Anethum sowa), Kusta (Saussurea lappa), Jatamamsi (Nardostachys jatamansi), Kakoli (Lilium polyphyllum), KsheeraKakoli (Fritilaria roylei), Yastimadhu (Glycercrhiza glabra), Prapoundarika (Saccharum officinarum), Sarala (Pinus roxburghii), Pippali (Piper longum), Devadaru (Cedrus deodar) – 50gms each
  - Cow’s ghee - (Moorchitha Go Ghrit) – 500gms
  - Cow’s milk – 4 liters;
  - Water- 2 liters

**Ingredients of Bhringaraja taila:**
- Bhringaraja swarasa = 2.5 Liters
- Tila taila = 500 ml
- Mulethi kalka = 60 grams
- Cow’s milk = 2.5 Liters

**Method of Drug Administration:**

**POSOLOGY:**

<table>
<thead>
<tr>
<th>Group A (SHATAHWADI GHRTA)</th>
<th>Group B (BHRINGARAJA TAILA)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Mode Of Administration &amp; Duration</strong></td>
<td>Two sittings of 5days Netra tarpana with the gap of 10 days each.</td>
</tr>
<tr>
<td><strong>Advice And Regimen To Be Followed After The Procedure.</strong></td>
<td>Not to go under sun, rub eyes, or strain eyes (reading, watching television) just after the procedure. He/she should not gaze at bright flames, wind, sky, mirror and shining objects and should adhere to healthy food and activities for double the number of days of these therapies.</td>
</tr>
</tbody>
</table>

**Assessment:** Patients were assessed on before treatment and 6th, 16th & 21st day during treatment and the Clinical observations were recorded systematically and thoroughly in Case Record Form prepared for the study.

**Follow up:** 30 days (every 15th day). Patients were advised for follow up twice, after 15 days and 30 days respectively.

**Method of study design:** An open label clinical comparative study of 30 patients fulfilling the inclusion criteria; will be allocated at random to receive one of the two comparative clinical interventions divided into two groups of 15 patients each.

**SELECTION CRITERIA:**
The selection of patients was based on clinical features of timira mentioned in Ayurveda as well as astigmatism of modern ophthalmology.

(a) **INCLUSION CRITERIA:**
1. Patients complaining of Avyakta (blurriness) and vihvala (distorted) drushti.
2. Patients presenting with the clinical symptoms of simple and compound myopic astigmatism namely defective vision, blurring of objects with or without asthenopic symptoms.
3. Patients between age group of 10 to 30 years.
4. Refractive error ranging from -0.25D to -1.50D (cylindrical and spherico-cylindrical)
(b) EXCLUSION CRITERIA:
1. All other drishtigatavikaras including timira affecting 3rd, and 4thpatalas.
2. Patients having lenticular or corneal opacity and any other known ocular pathology.
3. Simple and compound hypermetropic; irregular astigmatism.

GRADATION PARAMETER:
To assess the effect of therapy, all the signs and symptoms were given scoring depending upon their severity as below:

SUBJECTIVE CRITERIA-
1. Ayyaktadarshana/ vihvaladrushti: subjective blurring of vision as assessed on visual acuity even though patient may / may not read the line; and complains of blurring of vision while driving, or recognizing distant objects and known people at distant graded verbally on the scale of 1 to 10.
2. Eye strain (On the basis of Visual Analogue Scale)
3. Head ache (On the basis of VAS scale)

OBJECTIVE CRITERIA-
1. Visual efficiency by Visual Acuity: Snellen’s chart reading
2. Auto refraction instrument reading and Clinical refraction- Total refraction by the dioptric power required for full optical correction.

Grading of parameters:
Table 2: Grading of subjective parameters

<table>
<thead>
<tr>
<th>Grade</th>
<th>Blurring of vision</th>
<th>Headache/ VAS points</th>
<th>Eye strain</th>
<th>Snellen’s chart reading</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>Never</td>
<td>NO PAIN(0)</td>
<td>Never</td>
<td>6/6</td>
</tr>
<tr>
<td>1</td>
<td>Very little</td>
<td>VERY LITTLE(1-2)</td>
<td>Little</td>
<td>6/9</td>
</tr>
<tr>
<td>2</td>
<td>Little</td>
<td>LITTLE(3-4)</td>
<td>Much</td>
<td>6/12</td>
</tr>
<tr>
<td>3</td>
<td>Moderate</td>
<td>MODERATE(5-6)</td>
<td>Never</td>
<td>6/18</td>
</tr>
<tr>
<td>4</td>
<td>Much</td>
<td>MUCH(7-8)</td>
<td>Little</td>
<td>6/24</td>
</tr>
<tr>
<td>5</td>
<td>Very much</td>
<td>VERY MUCH (9-10)</td>
<td>Much</td>
<td>6/36</td>
</tr>
<tr>
<td>6</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>6/60</td>
</tr>
</tbody>
</table>

Table 3: Cylindrical and spherical power of auto refraction instrument and clinical correction

<table>
<thead>
<tr>
<th>Cylindrical values</th>
<th>Grade:</th>
<th>Cylindrical values</th>
<th>Grade:</th>
<th>Cylindrical values</th>
<th>Grade:</th>
</tr>
</thead>
<tbody>
<tr>
<td>-0.25D</td>
<td>Grade 1</td>
<td>-0.75D</td>
<td>Grade 3</td>
<td>-1.25D</td>
<td>Grade 5</td>
</tr>
<tr>
<td>-0.50D</td>
<td>Grade 2</td>
<td>-1.0D</td>
<td>Grade 4</td>
<td>-1.50D</td>
<td>Grade 6</td>
</tr>
<tr>
<td>Spherical values:</td>
<td>Grade:</td>
<td>Spherical values</td>
<td>Grade:</td>
<td>Spherical values</td>
<td>Grade:</td>
</tr>
<tr>
<td>-0.25D</td>
<td>Grade 0</td>
<td>-2.0D</td>
<td>Grade 7</td>
<td>-3.75D</td>
<td>Grade 14</td>
</tr>
<tr>
<td>-0.50D</td>
<td>Grade 1</td>
<td>-2.25D</td>
<td>Grade 8</td>
<td>-4.0D</td>
<td>Grade 15</td>
</tr>
<tr>
<td>-0.75D</td>
<td>Grade 2</td>
<td>-2.50D</td>
<td>Grade 9</td>
<td>-4.25D</td>
<td>Grade 16</td>
</tr>
<tr>
<td>-1D</td>
<td>Grade 3</td>
<td>-2.75D</td>
<td>Grade 10</td>
<td>-4.50D</td>
<td>Grade 17</td>
</tr>
<tr>
<td>-1.25D</td>
<td>Grade 4</td>
<td>-3.0D</td>
<td>Grade 11</td>
<td>-4.75D</td>
<td>Grade 18</td>
</tr>
<tr>
<td>-1.50D</td>
<td>Grade 5</td>
<td>-3.25D</td>
<td>Grade 12</td>
<td>-5.0D</td>
<td>Grade 19</td>
</tr>
<tr>
<td>-1.75D</td>
<td>Grade 6</td>
<td>-3.50D</td>
<td>Grade 13</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Assessment of overall response:
To evaluate the effect of treatment on individual parameters in Group A and Group B independent sample t test, repeated measures ANOVAs and post-hoc bonferroni were applied. The tests were applied as follows:
1. Comparison between the groups on individual parameters using independent sample t test.
2. Comparison of the groups at different time intervals using repeated measures anova.
3. Post-hoc bonferroni for multiple comparisons results between the different time intervals to evaluate the significance in specific time intervals.
4. Comparison of right and left eye using paired sample t test on individual parameters.

The test of significance was set at p= 0.05.

INVESTIGATIONS: - Nil –

OBSERVATIONS & RESULTS:

Demographic analysis:
Based on socio-economic status: Among 30 patients (group A and Group B), maximum patients were middle class (66.66%).

According to education: Out of total 30 patients in Group A and Group B, maximum patients were graduated i.e. 17 (56.6%).

According to occupation: Out of total 30 patients in Group A and Group B, maximum patients were found to be students, 19(63.33%). In Group A, 2(13.3%) were housewives, 9(60%) were students and 4(26.6%) were office workers [including 1(6.7%) advocate, 1(6.7%) engineer and 2(13.3%) teacher]. In Group B 1(6.7%) was housewife, 1(6.7%) was manager, 1(6.7%) was mechanic, 10(66.7%) were students and 2(13.3%) were teachers.

While observing family history: In group A family history was present in 5 patients (33.3%), while in group B it was found in 4 patients (26.7%)

Disease analysis:
While observing subjective parameters: Out of total 30 patients in group A & B, all the subjective parameters were found in both the groups except eyestrain, which was present in 14(93.3%) subjects and absent in 1(6.7%) subject in group B.

Assessment of results:

<table>
<thead>
<tr>
<th>MEAN DISTRIBUTION OF GROUPS FOR BLURRING OF VISION</th>
</tr>
</thead>
<tbody>
<tr>
<td>RE Group A</td>
</tr>
<tr>
<td>3.67</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>MEAN DISTRIBUTION OF GROUPS FOR EYE STRAIN</th>
</tr>
</thead>
<tbody>
<tr>
<td>RE Group A</td>
</tr>
<tr>
<td>3.27</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>MEAN DISTRIBUTION OF GROUPS FOR HEADACHE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Day 1</td>
</tr>
<tr>
<td>3.2</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>MEAN DISTRIBUTION OF GROUPS FOR DISTANT VISION</th>
</tr>
</thead>
<tbody>
<tr>
<td>RE Group A</td>
</tr>
<tr>
<td>3.73</td>
</tr>
</tbody>
</table>
RESULTS:
1. Both Shatahwadi Ghrita Tarpana with or without Bhringaraja Taila Nasya gave symptomatic relief in all subjects.
2. The calculated data shows the comparative result is insignificant (p> 0.05) between the groups.
3. Comparative analysis within the groups before and after treatment was statistically significant at p=0.01.
4. Multiple comparisons results for the effect of varied duration (before, during & after treatment and follow up) on efficacy of treatment within the two groups (group A and group B) was statistically significant at p=0.05.
5. The comparative inference between the right and left eye for different parameters is statistically found to be insignificant.

DISCUSSION
I. On disease:
The samples of the study were majorly from student age group and of lower-middle socio economic status. This indicates major disease process of Timira takes place in student age group because of exposure to bright light (laptops, smart phones, etc), reading and writing, late night activities and less sleep. Even the low value nutrition level of lower-middle socio economic status has impact in this.

II. On drugs and procedure:
1. Shatahavadi ghrita tarpana:
Tarpana provides nourishment to eye and strengthens the ocular structures because of its higher tissue contact time and bio availability. The ghee used in tarpana takes the absorbed medicines to cells of eye structures because of lipophilic action.

Ingredients of shatahavadi ghrita possess vatashamaka, balya, rasayana and chakshushya properties, which helped in alteration disease process. Ghrita also contains properties like balya, brimhana, and rasyana, so it gives strength to the overall tissues of the eyeball as well as the nervous tissues. Ghrita contains vitamin A, D, E, K and carotene in it. Vitamins A and E are antioxidants and Vitamin A also keeps the outer lining of the eyeball moist.

2. Bhringaraja taila nasya:
Nasya karma is a therapeutic measure in which the medicated drug is administered through nasal route mainly to eliminate or extinguish the vitiated Doshas situated in head and its constituent parts, curing the diseases of that part. (Urdhvajatrugatavikaras).
In Bhringarajataila, the base tilataila was used as a media or vehicle and by virtue of properties vyavayi (quick spread), sookshma (minuteness), Saraguna(flow) it can reach to every minute channel. The cow milk itself is chakshushya(good for eye) and also helps in pacifying doshas.
Other ingredients also possess tridosha-hara, rasyana, chakshushya and balya, which help in altering the disease process.

III. On result:
1. Comparison between Group A and Group B:
The comparative statistics was done to evaluate the efficacy of Shatahwadi ghrita tarpana with or without Bhringaraja taila nasya i.e. Myopic Astigmatism as expressed by three subjective parameters (blurring of vision, eye strain and headache) and objective parameters (autorefractometer reading and visual acuity testing).
The calculated data shows the comparative result is insignificant (p> 0.05) between the groups.
The mean value, however, was found higher for Group A (Group A > Group B) in overall assessment which is suggestive that there was mean difference between the groups. For example, during before verses after evaluation of the treatment, on 6th day after 1st sitting of the treatment protocol, the mean difference in right eye was found 1.13 and 0.53 in Group A and Group B respectively. This clearly shows Group A has better result after 6 days of the treatment (Group A > Group B); if we increase sample size then we might obtain significant results. Therefore, further research is needed with large sample size.

2. Comparison within the groups at different time intervals:

Comparative analysis of effect of Shatahwadi Ghrita Tarpana with or without Bhringaraja Taila Nasya (group A and group B) within the groups before and after treatment was statistically significant at p=0.01. There was no significance in results between first and second sitting protocol of the treatment. But second sitting helps in reduction of power clinically (as checked through visual acuity and autorefractometer).

3. Comparison of right and left eye using paired sample t test:

In Group B, when we started with the treatment, the difference in characteristic presentation of blurring of vision between the two eyes was statistically significant at p= 0.05. But during & after treatment there was no significant change observed between right eye and left eye. It was found non-significant for Group A in all the durations irrespective of the eye. Henceforth, the original values and the changes observed after the completion of procedures in the two groups statistically insignificantly varied between the two eyes in overall assessment of the subjects. The comparative inference between the right and left eye for the eye strain is statistically found to be insignificant.

CONCLUSION

Both Shatahwadi Ghrita Tarpana with or without Bhringaraja Taila Nasya are effective in management of Timira. It is beneficial to administer nasya along with tarpana procedure in order to have a satisfying result with respect to improvement in vision and correcting the refractive error i.e. Myopic Astigmatism.

FUTURE SCOPE AND LIMITATIONS:

- Multi centric trial can be carried out with larger sample size.
- Histopathology study to prove the mechanism of healing of Astigmatism with nasya and tarpana can be done.
- There is a need of further study in choosing the quality of ghrita to be used in Tarpana procedure.

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Source of Support: Nil
Conflict Of Interest: None Declared