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# A COMPARATIVE CLINICAL TRIAL TO EVALUATE THE EFFICACY OF VIMALA VARTHI ANJANA WITH AND WITHOUT VAASADI GHRITA TARPANA IN KAPHAJA TIMIRA WITH SPECIAL REFERENCE TO SENILE IMMATURE CATARACT

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## ABSTRACT

### Introduction

Senile Immature Cataract is a leading cause of blindness, especially among individuals over 40. In Ayurveda, this condition can be correlated with *Kaphaja Timira*, marked by vision blurring and other visual impairments. While surgical interventions are often recommended for cataract management, the cost and accessibility issues make it imperative to explore alternative treatments.

### Objectives

The primary aim is to compare the efficacy of *Vimala Varthi Anjana* with and without *Vaasadi Ghrita Tarpana* in managing *Kaphaja Timira* (Senile Immature Cataract). The study seeks to evaluate which treatment method yields better clinical outcomes in terms of visual improvement and disease progression.

**Materials and Methods**

A randomized clinical trial was conducted with 40 patients diagnosed with Senile Immature Cataracts. Patients were divided into two groups:

- Group A: Received *Vimala Varthi Anjana* along with *Vaasadi Ghrita Tarpana*.

- Group B: Received *Vimala Varthi Anjana* alone.

Both groups were treated for 13 days with a follow-up period of 28 days. The efficacy of treatment was assessed using subjective parameters and objective measures.

**Results**

Preliminary observations suggest a significant improvement in both subjective and objective parameters in Group A compared to Group B. Improvement is more prominent in patients receiving combined therapy.

**Conclusion**

The combination of *Vimala Varthi Anjana* and *Vaasadi Ghrita Tarpana* appears to be more effective in managing *Kaphaja Timira* (Senile Immature Cataract) compared to *Vimala Varthi Anjana* alone. These results indicate a promising non-surgical approach for delaying cataract progression, aligning with Ayurveda's holistic health approach. Further studies with larger sample sizes are recommended to confirm these findings.

**Keywords**: Kaphaja Timira, Senile Immature Cataract, Anjana, Tarpana

## INTRODUCTION

The eye is the most vital sensory organ gifted to Human beings by God. *"Sarvendriyanam Nayanam Pradhanam"*[(1)] Eye is the main *indriya* among all the *indriyas*. It is given utmost importance among all the indriyas, 80% of what we perceive comes through our sense of sight[(2)]. So, the existence and status of a person in the universe are directly influenced by eyes.

Vision 2020, an International initiative by the World Health Organisation (WHO), was started to decrease the number of people having preventable blindness. According to National Blindness and Visual Impairment Survey of India (2015-19) Cataract is the principal cause of blindness for people above 50 years in India. Cataract causes 66.2 % of cases of blindness, 80.7 % of cases of severe visual impairment, and 70.2% of cases of moderate visual impairment in this age group. Cost is the biggest barrier to accessing a cataract surgery it is the reason for 22.1% of blindness cases and due to lack of awareness 18.4% of people do not feel any need for surgery[(3)], So the clinical study on Senile immature cataract is most essential as we found more cases of blurred vision and partial blindness in surrounding of Bagalkot district, and effort is made to prevent and cure the Senile Immature Cataract.

Increased incidence of cataracts in elderly people, lack of effective medical procedures, potential complications, and contraindications to surgery. Ayurveda may provide avenues for research on the need for medication to effectively manage the condition.

There is no direct mention of senile cataracts in Ayurveda. Considering the signs, symptoms, and histological changes in the lens, different stages of senile cataracts may be compared to *Kaphaja Timira, Kacha,* and *Linganasha*. Various medical measures have been advised in different authoritative textbooks of Ayurveda to correct *Kaphaja Timira* in the initial stage. Surgery is mentioned only in the final stage of *Kaphaja Linganasha* where there is total loss of vision. [(4)] Hence, any potential intervention that could delay the progression of cataracts can be negotiated to be incorporated into the Vision 2020 program to provide an Ayurveda wave of vision care to millions of sufferers.

Explaining the treatment of *timira*, the *Acharya Vagbhata* says that *Kaphaja timira* is a *sadhya vyadhi,*

*Kaphaja kacha* as *yapya*, and *Kaphaja Linganasha* as *Sastra Sadya*. The *Acharya Vagbhata* mentioned *Vimala Varthi Anjana*[5] And *Acharya Yogaratnakara* mentioned *Vaasadi Ghrita*[6] in the treatment *of Kaphaja timira*. All the medicine is cost-effective and easily available. Hence, The present study is entitled **"A comparative clinical trial to evaluate the efficacy of Vimala varthi Anjana with and without Vaasadi Ghrita Tarpana in Kaphaja timira with special reference to Senile Immature Cataract".**

# METHODOLOGY

The present clinical study entitled **"A COMPARATIVE CLINICAL TRIAL TO EVALUATE THE EFFICACY OF VIMALA VARTHI ANJANA WITH AND WITHOUT VAASADI GHRITA TARPANA IN KAPHAJA TIMIRA WITH SPECIAL REFERENCE TO SENILE IMMATURE CATARACT"** was carried out withthe following procedures.

**MATERIALS AND METHODS:**

**SOURCE OF DATA:**

**(A)Patient Source:**

- The patient with the classical signs and symptoms of Kaphaj Timira will be selected from OPD and IPD of Shalakya Tantra Department, **R P KARADI Ayurvedic Hospital** of SVM Ayurvedic Medical College ILKAL, Medical camps, and other referrals.

**(B)Literary Source:**

- Literature for the study will be collected from contemporary and classical ayurvedic texts, as well as from websites and recently published medical journals.

**(C)Drug Source:**

- Raw materials will be identified and collected from local areas and markets with the help of the Dravyaguna and Rasashastra departments and procured from certified suppliers.

**Method of Collection of Data:**

**(A)Sample Size:**

A minimum diagnosed 40 patients of Kaphaj Timira fulfilling inclusion criteria will be randomly divided into two groups Group 'A' and Group 'B' with 20 patients in each group for the present clinical comparative study.

Group A- Application of Vimala varthi Anjana with madhu and vaasadi ghrita tarpana in 2 sittings for 5 days with intervals of 3 days.

Group B- Application of Vimala Varthi Anjana with Madhu for 13 days.

**(B)Diagnostic criteria:**

- Patient with lens changes as seen through the slit lamp the findings like a greyish color lens and iris shadow.
- Patient with pupil changes as seen through Direct ophthalmoscope the findings like diminished red reflex or irregularity in red reflex.

**(C)Inclusion criteria:**

- Patients who are diagnosed with kaphaja timira.
- Patients who are fit for Tarpana and Anjana.
- Patients of the age group of 40 to 60 years.
- Patient of either gender.
- Visual acuity of 6/60 or less (Snellen's Chart).

## (D)Exclusion criteria:

1. Patients with Senile mature and hyper matured cataracts, and other complicated eye diseases are excluded.
2. Patient with other congenital, traumatic, complicated, metabolic cataracts is excluded.
3. Patients with systemic diseases like renal disease, hyperlipidemia, cardiovascular diseases, and hypertension are excluded.
4. Other Ocular pathology that causes diminished vision.
5. Visual Acuity <6/60(Snellen Chart)

## SAMPLE SIZE ESTIMATION

## Study design:

40 patients satisfying the diagnostic and inclusion criteria were randomly selected and divided into groups, Group 'A' and Group 'B'.The study was carried out for 28 days duration.

Group A- Application of Vimala varthi Anjana with madhu and vaasadi ghrita tarpana in 2 sittings for 5 days with

intervals of 3 days.

Group B- Application of Vimala Varthi Anjana with Madhu for 13 days.

Assessment was done on the 14th day, the 28th day of the treatment(observation between treatments), and on 28 th day (follow-up).

**Nature of the study:**

The study was purely clinical in three phases. The patients were informed of the nature of the research and prior consent was taken before including in the study. The three phases of the study are as follows.

A. Diagnostic Phase

B. Interventional Phase

C. Assessment Phase

**Diagnostic Phase**

Selected patients were subjected to a complete examination; findings were recorded in the specially designed case proforma for KaphajaTimira.

Examination as per Ayurveda and Modern parameters. The examinations which are

- carried out are: Visual acuity using Snellen's chart
- WHO Simplified Cataract Grading System was used through the Slit-lamp Examination.

**Interventional phase**

| GROUP | A | B |
|---|---|---|
| **Treatment** | Vimala varthi Anjana with Madhu and Vaasadi Ghrita Tarpana in 2 sittings for 5 days with an interval of 3 days. | Vimala varthi Anjana with Madhu |
| **Time of administration** | Morning | Morning |
| **Duration of treatment** | 13 days | 13 days |
| **After treatment Follow-up** | 14th day | 14th day |
| **1st Follow-up (after treatment)** | 28th day | 28th day |
| **Total duration of treatment** | 28 days | 28 days |

**Treatment protocols:**

- Following treatment protocol was executed in enrolled patients with standard operative
- procedures.

**Assessment phase**

For assessing the effect of trial drug in a standard protocol, the kaphaja timira lakshanas were equated to standard parameters used for immature senile cataract assessment in wide-scale research Hence, these Kaphaja Timira Lakshanas were assessed based on their corresponding standard parameters. The effect of treatment was assessed based on both subjective criteria and the objective parameter in the following schedule.

**Subjective parameters:**

Symptoms of Kaphaja Timira were subjectively assessed based on whether it is Present or absent as perceived by the patient.

| SI no | Symptoms | Observations | Gradings |
|---|---|---|---|
| 01 | Pashyet asookshmaanyatartham (Blurred Vision for Distant Objects) | Absent | 0 |
| | | Mild | 1 |
| | | Moderate | 2 |
| | | Severe disturbing day-to-day life | 3 |
| 02 | Yatnavaanapi soochi paasham na pashyati | Absent | 0 |

| | | | |
|---|---|---|---|
| | (Blurred vision for near objects) | Occasional perception | 1 |
| | | Perception without disturbing routine work | 2 |
| | | Severe disturbing day-to-day work | 3 |
| 03 | Jaalaka darshanam (Floaters) | Absent | 0 |
| | | Mild floaters (2-3dots/thread) | 1 |
| | | Moderate floaters (4-8dots/threads) | 2 |
| | | Severe Floaters (>8 dots/threads) | 3 |

## Objective Parameters:

| SI no | Symptoms | Observations | Gradings |
|---|---|---|---|
| 01 | Visual acuity | 6/6 | 0 |
| | | 6/9 | 1 |
| | | 6/12 | 2 |
| | | 6/18 | 3 |
| | | 6/24 | 4 |
| | | 6/36 | 5 |
| | | 6/60 | 6 |
| 02 | Near vision by Jaeger's chart | N6 | 0 |
| | | N8 | 1 |
| | | N10 | 2 |
| | | N12 | 3 |
| | | N18 | 4 |
| | | N24 | 5 |
| | | N36 | 6 |
| 03 | LOCS (Grading of lens opacity) | Grade 0 – No Opacity | 0 |
| | | Grade 1 – Grayish Opacity | 1 |

| | | | |
|---|---|---|---|
| | | Grade 2 – Pearly Opacity | 2 |

**STATISTICAL ANALYSIS**

The obtained data were statistically assessed using the Mann-Whitney U test, Wilcoxon Signed Rank test, and Repeated Measures ANOVA on ranks to calculate values within the groups.

| Signs and Symptoms | Group A (Mean ± SD) | Group B (Mean ± SD) | Mean Difference | Mann-Whitney U Test (p-value) | Significance |
|---|---|---|---|---|---|
| **Blurred Vision (Distant Objects)** | 3.00 ± 0.44 | 2.45 ± 0.50 | 0.55 | U = 2211, p = 0.0204 | Significant (S) |
| **Blurred Vision (Near Objects)** | 2.75 ± 0.51 | 2.60 ± 0.60 | 0.15 | U = 1955, p = 0.3704 | Not Significant (NS) |
| **Floaters** | 3.00 ± 0.69 | 2.85 ± 0.62 | 0.15 | U = 1452, p = 0.0532 | Approaching Significance |
| **Visual Acuity** | 3.00 ± 0.77 | 2.95 ± 0.70 | 0.05 | U = 1568, p = 0.2116 | Not Significant (NS) |
| **Near Vision (Jaeger's Chart)** | 3.00 ± 0.93 | 2.80 ± 0.88 | 0.20 | U = 1940.5, p = 0.4465 | Not Significant (NS) |
| **LOCS Grading (Lens Opacity)** | 2.73 ± 0.37 | 2.65 ± 0.42 | 0.08 | U = 1328, p = 0.0046 | Significant (S) |

**Remarks**

Group A (treated with Vimala Varthi Anjana and Vaasadi Ghrita Tarpana) showed significant improvements in key areas. Blurred vision for distant objects improved with a mean difference of 0.55 and a p-value of 0.0204. Lens opacity (LOCS grading) also improved significantly, with a p-value of 0.0046, indicating clearer lenses in Group A compared to Group B.

For floaters, Group A showed improvement close to significance (p-value 0.0532), suggesting that the combined treatment may be more effective, though further research is needed.

In other parameters such as blurred near vision, visual acuity, and near vision (Jaeger's chart), both groups showed similar improvements, with no significant difference.

Overall, although Group B had a slightly higher marked response rate (55%) compared to Group A (50%), Group A showed more consistent moderate improvements, particularly in distant vision and lens clarity.

**Discussion:**

This study aimed to evaluate the effectiveness of Vimala Varthi Anjana with and without Vaasadi Ghrita Tarpana for managing Kaphaja Timira (Senile Immature Cataract). The results indicated that Group A, which received the combined treatment, showed significant improvements. Specifically, Group A demonstrated better improvement in blurred vision for distant objects ($p = 0.0204$) and lens opacity ($p = 0.0046$), suggesting that adding Vaasadi Ghrita Tarpana enhances the treatment's effectiveness. Although improvement in floaters was observed in Group A, the result was not statistically significant ($p = 0.0532$). There was no significant difference between the two groups in terms of blurred vision for near objects, visual acuity, or near vision, indicating that both treatments had similar effects on these parameters. Overall, while both treatments showed positive outcomes, Group A showed more consistent improvements in key areas. This supports the potential use of the combined treatment as an effective approach for managing early-stage cataracts. Further research with larger sample sizes is recommended to confirm these findings.

**Conclusion:**

The combination of Vimala Varthi Anjana with Vaasadi Ghrita Tarpana (Group A) proved to be more effective in managing Kaphaja Timira (Senile Immature Cataract) compared to Vimala Varthi Anjana alone (Group B). Significant improvements were observed in critical areas, such as blurred vision for distant objects and lens opacity, supporting the potential of the combined treatment in enhancing visual function. Although there was no significant difference for some parameters like blurred vision for near objects and visual acuity, the results indicate that the addition of Vaasadi Ghrita Tarpana may offer added benefits in managing the condition. These findings suggest that the combined Ayurvedic treatment could serve as a promising non-surgical alternative for the early stages of cataracts. Further studies with larger sample sizes are needed to confirm these results and explore the long-term benefits.

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