

## A RANDOMIZED DOUBLE-BLIND PLACEBO CONTROLLED CLINICAL STUDY ON ANTI - CATARACT EFFECT OF SHWETHA PALANDU EYE DROP IN THE MANAGEMENT OF KAPHAJA TIMIRA (IMMATURE CATARACT): A PILOT STUDY

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Published online: November 2019

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### ABSTRACT

**Introduction:** *Kaphaja Timira* is a disease of the *Drushti Mandala* which presents with blurred vision initially and if left untreated may lead to conditions like *Kacha* and *Linganasha* associated with complete loss of vision. Cataract is an important cause of visual impairment and blindness, affecting approximately 3.8 million people in India each year. With a motto of reducing lenticular opacity and to prevent cataract surgery, this study on anti-cataract effect of *Shwetha Palandu* eye drops in *Kaphaja Timira* is taken up. *Palandu* is *Kaphahara*, *Drushti Sak-tivardhaka* and good in *Drstimandya* was taken for the study as *Lekhana* eye drops. **Objective of the Study** is to evaluate the anti-cataractous effect of *Shwetha Palandu Arka* eye drop in *Kaphaja Timira*. **Material and Methods:** Randomized double-blind placebo controlled clinical study on Anti cataract effect of *Shwetha Palandu* eye drop in the management of *Kaphaja Timira* in immature cataract was done for 30 patients in two groups. Two eye study design' was used for both the eye for data collection. 'Worst Eye Study Design' was takes up the eye with lowest visual acuity for analysis when both eyes are involved. **Results:** Mean distant vision improved from 55.20 % to 67.33 % which was highly significant ( $p = 0.006$ ). Mean near vision improved from 32.42 % to 59.46 % which was highly significant ( $p = 0.005$ ). Visual Function improved from 66.8 to 71.4 which is highly significant ( $p = 0.005$ ). The mean grading of glare was reduced from 1.77 to 1.18 which is highly significant ( $p = 0.001$ ). **Conclusion:** The medicine had shown significant improvement in both distant and near vision improvement in cortical type of immature cataract.

**Keywords:** *Kaphaja Timira*, *Shwetha Palandu*, Cataract.

### INTRODUCTION

*Kaphaja Timira* is a disease of the *Drushti Mandala* which presents with blurred vision initially and if left

untreated may lead to conditions like *Kacha* and *Linganasha* associated with complete loss of vision. Var-

ious medical measures have been advised for treating *Kaphaja Timira* in the initial stage. *Aschyotana* is the process of instilling liquid medicine into the eyes drop by drop. As lens is deep seated structure of eye, a period of two months treatment protocol was selected. As eye drops was easiest method of administration in outpatient basis, eye drop has been selected as the treatment of choice.

**Need for the study:** Cataract is an important cause of visual impairment and blindness, affecting 12 to 15 million people worldwide. In Indian, approximately 3.8 million person becomes blind from cataract each year<sup>1</sup>. The most recent estimates from WHO reveal that 47.8% of global blindness is due to cataract and in South Asia region which includes India, 51% of blindness is due to cataract.<sup>2</sup> Since cataract is a major cause of avoidable blindness in the developing countries, to go in hand with Global Vision 2020: the right to sight, this study was taken in cataract.<sup>3</sup> There is no time tested and proven medical treatment to delay, prevent or reverse the development of cataract. The treatment of choice in cataract is surgery. Owing to the increased rate of incidence of cataract, non-availability of effective medical measures and the possible complications and contraindications of surgery, Ayurveda offers an avenue of research for the need of drugs which can effectively manage this condition. Surgery is mentioned in the final stage of *Kaphaja Linganasha* where there is total loss of vision<sup>4</sup>. Considering the signs, symptoms and histological changes in the lens, different stages of cataract can be compared to *Kaphja Timira*, *Kacha* and *Linganasha*. With a motto of reducing lenticular opacity and to prevent surgery, this study on anti- cataract effect of *Shwetha Palandu* eye drops in *Kaphaja Timira* is taken up.

**Shwetha Palandu or White Onion:** *Palandu* is *Kaphahara*, *Drushti Saktivardhaka* and good in *Drstimandya* was taken for the study as *Lekhana* variety of eye drops. Properties of *Shwetha Palandu*: Botanical Name: *Allium Cepa* (white variety), Part used: Bulb, Rasa - *Katu*, *Madhura*, Guna - *Guru Snigdha*, *Tikshna*, *Veerya* - *Isat Usna*, *Doshaghna* - *Vata Kaphahara*, good in *Drishtimandyaharavikaras*<sup>5</sup>. Sulfur in onion improves the health of eye lens. Sulfur

stimulates the production of a protein named Glutathione, which act as an antioxidant. Higher level of Glutathione reduces the risk of lens degeneration<sup>6</sup>. White onion contains higher amount of Sulfur content than other varieties and hence white onion was taken for study.

**Arka or Distillation method:** *Shwetha Palandu Swarasa* is a folklore practice for cataract in south India. *Swarasa* of *Shwetha Palandu* causes irritation in eye and may not be acceptable for more patients. Hence *Arka*, distilled form of drug was selected in this study as it was more potent, less irritant, more resident time in eye, thus more absorption and more acceptability by patients. *Arka* shows enhanced effect of the drug.

**Review of Literature:** *Timira* is one among *Dhristigata Roga*<sup>7</sup>. According to Acharya Vagbhata person sees objects as *Snigdha* and *Shwetha* in color<sup>8</sup>. He will perceive as if the objects are covered by *Kunda*, *Kumuda* or *Sankha*<sup>9</sup>. According to Acharya Susruta person will be able to see only large objects and will not be able to perceive smaller ones. Person will feel as if some heavy objects are covered in front of his eyes and may perceive objects as if seen through water<sup>10</sup>. Acharya Vangasena explains person will be able to see *Jalakas*<sup>11</sup>.

**Pathophysiology of Immature cataract:** In senile cataract there are two biochemical process take place inside the lens which result in cataract. Frist change happens in lens is hydration followed by opacification. The strength of the epithelium of lens decreases as the age increases. In *Vridhdha Avastha* there will be *Vata Dosha Pradhana*. *Sigdha Guna* in lens will be decreased due to *Vata Dosha* which increases *Rooksha Guna*. Nature of *Sigdha Guna* is to provide strength to the lens. Normally when *Sigdha Guna* in the epithelium decreases leading to loss of strength of the ion's channels and other guards in the anterior epithelium and capsule of the lens dehydrated. Another phase hydration of lens take place due to *Kleda Guna Vruddhi* or *Abhishyanda* of lens and due to this denaturation of proteins occurs. The *Jala Mahabootha* impregnated in lens is expelled out and the fibers start getting denatured there by getting opacified. As a result, transparent white fibers turn to dense white opac-

ity in senile cortical cataract. In nuclear cataract lens fibers become *Khatina* (hard), *Sthira* (firm), *Shosha* (dehydrated) as a result of *Rooksha guna vriddhi* in the lens due to *Kaphavata Doshapradhana*. In Posterior sub-capsular cataract epithelial hyperplasia and abnormal differentiation of cells occur due to *Vata prakopa*. Increase in number and mass of cells which results in *Kaphavridhi*. This abnormal division is very fast which results in rapid loss of vision without any visible colour changes in lens of posterior subcapsular cataract<sup>12</sup>.

**Kaphaja Timira and Immature cataract:** First and second *Patalagatha Kaphaja Timira Lakshanas* can be considered as immature condition of cataract. Person experience blurred vision for both distant and near vision. Patient experiences floaters, glare, polyopia, diplopia and difficulty in threading a needle, sees all the objects as white. Person sees the object covered by like *Kumuda*-white lily flower, *Shankha* (Conch Shell), *Indu* (Moon), *Kunda* (Jasmine). The subjective symptoms mentioned by Acharya Vagbhata can be objectively seen with the help of slit lamp on dilation of pupil. Early stages of nuclear cataract and posterior sub capsular cataract have veiling luminance and produce contrast sensitivity without any visible colour changes in lens. Frist stage of *Dosha* in *Rasa Dhatu* may be taken as immature cataract in the stage of lamellar separation and incipient stage which is reversible.

**Treatment Principle:** Lens has the property of transmitting and refracting the incident light. It is possible only when all the *Mahabhootas* are in normalcy with increased *Jala Mahabootha*. If *Prithvi mahabhootha* increases, then refracting property of the lens changes. Poor transmitter of light rays due to compactness leads to diminished vision. Cataract can be compared to *Kapha Avrutha Vata*.ie. *Prithvi Mahabhoota* having *Avarana* with the movement of light rays passing through the lens. Principal of treatment of cataract is reduction or removal of *Kapha* and if done will normalize the movement of light into retina thereby increasing vision. *Kaphahara Chikithsa* and *Lekhana* of lens can reduce cataract.

**Objective of the study** was to evaluate the anti-cataractous effect of *Shwetha Palandu Arka* eye drop in *Kaphaja Timira*.

**Material and Methods:** The patients with lenticular opacity were screened and selected from OPD and IPD of Department of Shalakya Tantra, Sri Dharma-shala Manjunatheshwara Institute of Ayurveda and Hospital, Anchepalya, Kumbalgodu, Bengaluru, for the clinical study. Data has been collected using specially prepared Case Report Forms of 30 cases that fulfills the clinical features of *Kaphaja Timira* (immature cataract) were randomly selected irrespective of gender, religion, economic status, and marital status.

**Diagnostic criteria:** Patients with *Snigdha Darshana* (Glare), Patients with feeling of *Tanucailavrutopama* (Blurred Vision), Patients with *Jalaka Darshana* (Floaters), Patients with *Dvididha Darshana* (Diplopia).

**Inclusion Criteria:** Patients of age group of 30 to 70 years, Visual Acuity of 6/60 or less and informed consent form was taken from all patients.

**Exclusion Criteria:** Patients with senile mature and hyper mature cataract, pregnant and lactating mothers, congenital, developmental, traumatic, complicated or metabolic cataract and any other ocular pathology that can cause diminution of vision was excluded from the study.

**Study Design:** Current study was two arms randomized double blind placebo controlled clinical study on Anti cataract effect of *Shwetha Palandu* eye drop in the management of *Kaphaja Timira* in immature cataract was conducted. A combination of 'before and after design' to compare the effect of trail drug and placebo drug before and after treatment in 2 groups were used. 'Two eye study design' was used for both the eye for data collection as cataract occurs in both the eye. 'Worst Eye Study Design' was taken up in which the eye with lowest visual acuity for analysis when both eyes are involved. To assess the actual effect of the trail drug in improving visual acuity this design was taken. Improvement in worst eye helped to interpret potency and effect of the trial drug. Sampling Technique used was convenience sampling method. Random allocation of participants was generated by

computer method for treatment group and control group. Thirty medicine boxes with 4 bottles of eye drop in each box was numbered prior to study. Fifteen days once 1 bottle of eye drops was dispensed to the patient. Double blind placebo controlled clinical trial was chosen for the study.

**Method of Preparation:** *Arka* is a liquid preparation obtained by distillation of certain liquids or drugs soaked in water using the *Arka Yantra* or any convenient modern distillation apparatus.<sup>13</sup> White onion were cleaned; the external scaly layer was removed. They were crushed and transferred into *Arka Yantra* and was boiled. The vapors were condensed and collected in a receiver which contains the essential principle of onion.

**Treatment protocol:** Thirty patients with the classical features of *Kaphaja Timira* (immature cataract) were selected for the study. Study Group of 15 patients with *Shwetha Palandu Arka* eye drop and control group of 15 patients with *Jala Arka* eye drop were given. Dosage was 3 drops 3 times daily. Duration of treatment was 60 days. Assessment during treatment was done on the 15<sup>th</sup> day, 30<sup>th</sup> day, 45<sup>th</sup> day, 60<sup>th</sup> day. Follow up after treatment was done on 75<sup>th</sup> day and 90<sup>th</sup> day, 15 days once twice in a month.

**Procedure of Treatment:** The patient was advised to open the eye by the left hand and from the right hand the medicine was instilled drop by drop (3 drops) into the open eyes from a height of 2 Angulas<sup>14</sup>. Primary outcome was done Visual acuity, Refraction, Direct ophthalmoscopy, Auto refractometry and slit lamp examination. Secondary outcome and subjective parameters were taken as blurred vision, glare and floaters. Periodic assessment of the patients on 15<sup>th</sup> day, 30<sup>th</sup> day, 45<sup>th</sup> day, 60<sup>th</sup> day, 75<sup>th</sup> day, and 90<sup>th</sup> day was done.

**Objective parameter:** Visual acuity by LogMAR chart, contrast sensitivity test by Pelli Robson chart, refraction by Auto Refractometer readings with manual correction, examination of lens by Slit lamp, type of cataract by direct Ophthalmoscope, anterior segment photography for cataract with Retro illumination camera. Lens Opacity Classification System LOCS III

grading, scale for grading glare, grading of floaters, and grading for diplopia was done.

**Observations:**

Age: 2 patients were in the age group of 30-40 years(6%), 6 patients were in the age group of 41-50 years (18%), 8 patients were in the age group of 51-60 years (24%)and 14 patients were in the age group of 61-70 years (42%). Gender: Males were 19 (57%) and females were 11(33%). Religion: Hindus were 24 patients (72%), Muslims were 4 (12%), and Christians were 2 patients (6%). Socio- economic Status: 9 belong to upper middle class and 21 belonged to lower class. Nature of Diet: 13 were vegetarians (39%) and 20 were consuming mixed diet (60%). BMI- 22 patients were overweight (66%). Incidence of Diabetics – 18 were diabetic (54%). *Prakruti – Vata Pitta* -14 patients (42%), *Pitta Kapha* – 10 patients (30%) *Vata Kaphaja* - 6 patients (18%).Incidence of type of cataract based on slip lamp observation: Among 60 eye screened 56 eyes had immature cataract, 38 eyes (68%) were having cortical cataract, 14 eyes (26%) had nuclear cataract, 4 eyes (6%) had posterior sub-scaphular cataract.

**Results:**

**Effect on vision in Distant vision:** Mean distant vision improved from 55.20 % to 67.33 % which was highly significant (p = 0.006). **Pin Hole improvement** - Mean distant vision using a pinhole improved from 79.37 % to 81.24 which is not significant (p = 0.612). **Near Vision** - Mean near vision improved from 32.42 % to 59.46 % which was highly significant (p = 0.005). **BCVA (Best Corrected Visual Acuity) DV** - Mean BCVA DV improved from 87.17% to 89. 12% which was not statistically significant (p = 0.589). **BCVA NV** - Mean BCVA NV improved from 91.50% to 92.25% which was not statistically significant (p = 0. 297). **Visual Function** - Visual Function improved from 66.8 to 71.4 which is highly significant (p = 0.005). **Effect on glare:** The mean grading of glare was reduced from 1.77 to 1.18 which is highly significant (p = 0.001)

**In Cortical Cataract:** Effect before treatment and after treatment and effect on vision was seen highly significant by *Shwetha Palandu* eye drops. Mean dis-

tant vision improved from 58.54 % to 79.68 % which was highly significant ( $p = 0.005$ ). Mean distant vision using a pinhole improved from 84.78 % to 88.75% which is not significant ( $p = 0.147$ ). Mean near vision improved from 31.89 % to 59.20 % which was highly significant ( $p = 0.025$ ). Mean BCVA DV improved from 93.37% to 95.14 % which was not statistically significant ( $p = 0.192$ ). Visual Function improved from 69.76 % to 78.49 % which is highly significant ( $p = 0.005$ ). Parameters which are not statistically significant are not mentioned here.

**Effect of treatment on lenticular opacity based on LOCS III in Cortical Lenticular Opacity:** The mean grade of Cortical type of lenticular opacity of Right eye was reduced from 2.569 to 2.008 which were highly significant ( $p = 0.004$ ). The mean grade of Cortical type of lenticular opacity of Left eye was reduced from 2.558 to 2.166 which was highly significant ( $p = 0.006$ ).

## DISCUSSION

Maximum numbers of patients were from the age group of 60-70 years. Cataract is essentially an age-related disease and is usually found after the age of 50 years. It is universal after 70. But depending upon the work nature, nutrition status, smoking habits it may come early. Majority people were doing agriculture. Working in the farmlands increases the exposure to UV rays of the sun thus increase in the incidence of cataract. Maximum number of patients is in overweight group. Increased BMI increases the occurrence and affects progression of cataract. Diabetic is a precipitating cause of early onset of cataract which is been seen in the study. In *Prakruthi* analysis *Pitta Kaphaja* and *Vata Pittaja Prakruti* were more seen. *Pitta* is common in both. *Pitta* is the causative factor for transformation, i.e. it is the procedure that converts the clear lens to opacified lens.

## CONCLUSION

With regards to senile cataract, the medicine had shown significant improvement in both distant vision and near vision in cortical cataract. In nuclear cataract there was only a mild improvement in vision which

was insignificant. In posterior sub capsular cataract, the vision remains the same. Hence, it can be concluded that *Shwetha Palandu* eye drops is effective in improving vision for in cortical type of senile cataract.

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**Source of Support: Nil**

**Conflict Of Interest: None Declared**

How to cite this URL: Divya Stuvvert et al: A Randomized Double-Blind Placebo Controlled Clinical Study On Anti-Cataract Effect Of Shwetha Palandu Eye Drop In The Management Of Kaphaja Timira (Immature Cataract) - A Pilot Study. International Ayurvedic Medical Journal {online} 2019 {cited November 2019} Available from: [http://www.iamj.in/posts/images/upload/2017\\_2022.pdf](http://www.iamj.in/posts/images/upload/2017_2022.pdf)