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Two – Arm, Randomized, Open Labeled, Comparative, Prospective Clinical Study to Assess the Efficacy of *Amalaki Ghrita Aashchyotana* versus Hydroxypropyl Methylcellulose Eye Ointment in Dry Eye Syndrome with special reference to *Shushkaakshipaka*

Research Article

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Abstract

Background: Increased computer work hours, reduced blinking and effect of light rays and radiation lead to raised number of cases of dry eye. *Amalaki Ghrita Aashchyotana* can be useful in the management of dry eye. Objectives: to compare the clinical efficacy of *Amalaki Ghrita Aashchyotana* with Hydroxypropyl Methylcellulose (HPMC) eye ointment as a surface lubricant in dry eye syndrome with special reference to *Shushkaakshipaka.* Methods: In an open labeled, comparative, randomized, prospective clinical study, 60 patients of Dry eye syndrome were randomly selected randomly and categorized into 2 groups, each comprising 30 patients each. Patients in trial group were given *Amalaki Ghrita Aashchyotana* while patients in the control group were given local application of HPMC eye ointment for consecutive 90 days. Patients were assessed on various clinical parameters before and after the treatment. The data generated through clinical study was subjected to appropriate statistical tests. Results: On treatment of *Amalaki Ghrita Aashchyotana* in trial group and HPMC eye ointment in control group for 90 days showed significant difference in all objectives as well as subjective parameters on intra-group comparison. The statistically insignificant inter-group comparison shows that both the treatments were equivalent. No adverse events during or after the completion of study in any of the groups. Conclusion: *Amalaki Ghrita Aashchyotana* is equally efficient as HPMC eye ointment in Dry eye syndrome and has more advantage over HPMC ointment, as it also can help to improve visual acuity.

Key Words: *Shushkaakshipaka, Amalaki Ghrita Aashchyotana,* Dry eye, Hydroxypropyl Methylcellulose.

Introduction

There is ample research work available on vision than on any other sensory modality because vision is our most important and most complex sense. (1) Acharya Sushruta has explained the importance of the *Chakshurindriya* (eye) in *Uttaratantra*.(2) In the current era, working on various gadgets for longer hours has become inevitable in all age groups which is a highly vision demanding task and it exposes eyes to continuous light emission. The eyes may find it difficult to cope up with the demand of digital work, leading to ocular and systemic discomfort. Digital eye strain (DES), also known as computer vision syndrome, encompasses a range of ocular and visual symptoms, and estimates suggest its prevalence may be 50% or more among computer users. Symptoms fall into two main categories: those linked to accommodative or binocular vision stress, and external symptoms linked to dry eye.(3) While, doing this type of work, individuals tend to stare continuously at the screen, without blinking, which along with the effect of light rays leads to dry eyes. Increased computer work hours, reduced blinking and effect of light rays and radiation has contributed to raise number of cases of dry eye.(4)

Irritation of eyes, foreign body sensation, itching, ocular discomfort, feeling of dryness is the symptoms of dry eye. Signs of dry eye syndrome are as follows; presence of mucus in the tear film, conjunctival xerosis, lusterless ocular surface, reduced or absent marginal tear strip and corneal changes in the form of punctate epithelial erosions and filaments. (5)

Dry eye syndrome can be clinically correlated to *Shushkaakshipaka* explained in major texts of

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Ayurveda. It is classified under *Sadhya Sarvagata Netraroga* caused due to vitiation of *Rakta Dhatu* and *Vata Dosha* according to Acharya Sushruta and aggravated *Vata-Pitta Dosha* according to Acharya Vaghbhat.*(*6,7) Commentator Arunadatta has explained *Shushkaakshipaka* as *kricchonmilana* and dryness of eyes in his commentary on *Ashtanga Hridaya.(*8)

Use of ocular surface lubricants, computer glasses, and counseling for cautious use of digital gadgets are the only remedial measures available in the domain of modern ophthalmology. In contemporary treatments, Hydroxypropyl Methylcellulose (HPMC) eye drops or ointment is commonly used as surface lubricant. At times preservatives from the ointment can cause allergic reactions.(9) As preservative free lubricants are expensive; patients are hesitant to use this option for lifetime as it becomes a costly matter. Moreover, it does not correct the underlying pathology which makes patient dependent on surface lubricant for lifetime.

Ayurvedic treatment of *Shushkaakshipaka* includes *Dugdha siddha Snehapana, Nasya, Tarpana,Parisheka, Aashchyotana,* etc. Acharya Vagbhat has indicated cooling and rejuvenating therapies for eyes affected by bright light, high voltage electric spark, and heat exposure, phenomenon also like etiopathology of dry eye. So, *Amalaki Ghrita Aashchyotana* was selected for dry eye treatment.(10)

The present clinical study was conducted to compare the clinical efficacy of *Amalaki Ghrita Aashchyotana* with Hydroxypropyl Methylcellulose (HPMC) eye ointment as a surface lubricant in dry eye syndrome with special reference to *Shushkaakshipaka.*

Materials and Methods

Study Sites, IEC approval and CTRI registration of the study

The study was conducted in OPD and IPD of department of Shalakya Tantra, D. Y. Ayurvedic Hospital, Nerul, Navi Mumbai, Maharashtra state. Approval was obtained from the institutional ethics committee (IEC) of D. Y. Patil Deemed to be University School of Ayurveda, Nerul, Navi Mumbai.

Study Design

The study was an open labeled, comparative, randomized, prospective clinical study where patients in trial group were given *Amalaki Ghrita Aashchyotana* for consecutive 90 days while patients in the control group were given local application of HPMC eye ointment for consecutive 90 days.

Sample Size

The total sample size in the study was 60 patients. Total 60 patients of Dry eye syndrome were randomly selected randomly irrespective of, sex, religion, education, and occupation etc., and categorized into 2 groups, each comprising 30 patients each. All 60 subjects completed the study and there were no drop outs.

Inclusion & Exclusion Criteria

Inclusion Criteria

Patients between 18 and 75 years of age who were computer users having minimum 2 hours of exposure to desktop, laptop, or both with minimum 1 year exposure to any type of above-mentioned devices and having a minimum of three symptoms of dry eye syndrome such as eye strain, dry eyes, blurred vision, redness, burning eyes, excessive tears, double vision, headache, glare sensitivity, fatigue, neck, shoulder and back pain. Patients who were ready to give consent and abide to the study protocol were enrolled in the study.

Exclusion Criteria

Patients of age below 18 years or above 75 years, not willing for registration, having symptoms due to direct physiological effects of substance (e.g., drug sensitivity, medication), also patients suffering from infectious conditions of the eye like conjunctivitis, scleritis, uveitis, glaucoma, stye, blepharitis, etc. were excluded from the study. Patients having any fundus pathology like optic atrophy, diabetic retinopathy, hypertensive retinopathy, papilledema, etc. were also excluded.

Study Product, dosage, and duration

Amalaki Siddha Ghrita was prepared in the department of Rasashastra and Bhaishajya-Kalpana, D Y. Patil School of Ayurveda, Nerul, Navi Mumbai. *Amalaki Ghrita* was prepared according to *Sharangdhara Samhita*. *Amalaki Kalka* & *Swaras* was taken 1 part, *ghrita* was taken 4 parts and water was taken 16 parts. *Ghrita siddhi* method was followed for the preparation.

Hydroxypropyl Methylcellulose (HPMC) eye ointment was obtained from the local pharmacy.

Intervention

The 30 patients enrolled in trial group were given *Amalaki Ghrita Ashchyotana* locally once daily at evening for continuous 90 days. The 30 patients enrolled in control group were given Hydroxypropyl Methylcellulose (HPMC) eye ointment local application once daily at night for continuous 90 days.

Ashchyotana Procedure

The patient should be comfortably lying down in supine position, in *Kriyakalpa* theatre. The eye is opened by stretching and pressing *Apangapradesa* (lateral end). From the right hand, *Amalaki Ghrita* is instilled into open eye. These drugs can be held, either in a conch shell, small vessels or in a piece of cotton. *Amalaki Ghrita* fallen on the eye from a height of two *Anguli*. The *Ghrita* should fall on the eye, should be wiped out with a piece of cotton or soft cloth immediately (within one or two min.).

Follow up

Follow up was carried out on Day 0, Day 15, Day 30, Day 60 and after completion of treatment i. e. day 90.

A. Aqueous extracts derived from	Weight in mg					
	F1	F2	F3	F4	F5	F6
Withania somnifera	3	3.5	3.5	4	3	3
Asparagus racemosus	2	2.5	2.5	4	2	2
Vitis Vinifera	2.5	3	3.5	4	2.5	2.5
Boerhaavia diffusa	2	2.5	3	3	2	2
Pueraria tuberosa	2	2.5	3	3	2	2
Ecliptaalba (L.) Hassk	2	2.5	3	3	2	2
Mucuna pruriens	2	2.5	3	3	2	2
Phyllanthus emblica	2	2.5	3	3	2	2
Triticum aestivum L	2	2.5	2.5	3	2	2
Rubia cordifolia	1	1	1	1	1	1.5
Aloe barbadensis miller	1	1.5	1.5	3	1	1
Dioscorea bulbifera	1	1	1	1	1	1.5
Glycine max	1	1.5	2	2.5	1	1
Tinospora cordifolia	1	1.5	2	2.5	1	1
Fenugreek	1	1.5	1.5	2	1	1
Hemidesmus indicus	0.5	1	1.5	2	0.5	0.5
Chlorophytum borivilianum	0.5	1	1	1.5	0.5	0.5
Chickpea	0.5	1	1.5	2	0.5	0.5
common sunflower	0.5	1	1	1.5	0.5	0.5
Phaselous vulgaris	0.5	1	1	1.5	0.2	0.5
Flax	0.15	1	1	1.5	0.15	0.5
Trapa natans	0.15	0.15	0.15	0.15	0.15	0.65
Terminalia chebula	0.5	1	1.5	2	0.5	0.5
B. Fruit juices are derived from:						
Carica papaya	0.01	0.51	0.51	1.01	1.51	1.51
Ananas comosus	0.01	0.51	1.01	1.01	1.51	1.51
Punica granatum	0.01	0.01	0.51	1.01	1.51	1.51
C. Powders used						
Ashphaltum	0.5	1	1	1.5	0.5	0.5
D. Liquids liquid						
Syzygium aromaticum	2	2	2	2	2	2
Sugar syrup base	Q.S.	Q.S.	Q.S.	Q.S.	Q.S.	Q.S.
Excipients	Q.S.	Q.S.	Q.S.	Q.S.	Q.S.	Q.S.

Criteria for assessment

The drugs were given to the patients for procedure to perform on their own at home after proper demonstration at the study centre on day 1 and asked to do it for 3 months and the changes in subjective and objective parameters were recorded during every visit. Total effect of therapy in each patient was evaluated after completion of treatment. It was assessed by adopting suitable scoring methods and objective parameters by using appropriate clinical tools.

Subjective Criteria

Dry eye, Blurred vision, Dizziness / Nausea, Headache, Redness, burning sensation, Eye strain, change in color perception, slow refocusing and fatigue were the subjective criteria for clinical assessment. Each criterion had grading as absent – 0, mild – 1, moderate – 2 and severe – 3.

Objective Criteria

Schirmer's test and Tear film break-up time (TBUT) test were the objective criteria for clinical assessment.

i. Schirmer's test: Schirmer's test determines tear production, and whether the eye produces enough tears to keep it moist. A small strip of filter paper is inserted inside the lower eyelid of each eye and the eyes are closed for 5 minutes. The paper is then removed and the length of paper that is moist is measured. A young person normally moistens 15 mm of the paper. The shorter the length of moist paper, the drier the eyes. A positive change score indicates improvement.(11)

ii. Tear film break-up time (TBUT) test: The time required for dry spots to appear on the corneal surface after blinking. Sodium fluorescein dye is added to the eye and the tear film is observed under a slit lamp while the patient avoids blinking until tiny dry spots develop. The longer it takes, the more stable the tear film. A short tear breakup time is a sign of a poor tear film. Generally, >10 seconds is thought to be normal, 5 to 10 seconds marginal, and <5 seconds low (with high likelihood of dry eye symptoms), i. e., a shorter time indicates greater eye dryness. A positive change score indicates improvement.(12)

Plan for Statistical Analysis

The study data generated and collected was put to statistical analysis to reach the final results and conclusions. The demographic data were presented in tables and graphs. The data obtained in the studies were subjected to tests of significance. The data on discrete variables have been represented as n (%) and Median (Range). The data on continuous variables have been represented as Mean ± SD. GraphPad InStat Version 4.0 (www.graphpad.com) software was used for statistical analysis of data. P value < 0.05 was considered statistically significant. The paired t test or Wilcoxon matched-pairs signed-ranks test were applied for intra-group comparison whereas Unpaired t test or Mann – Whitney test were applied for inter-group comparison.

Observations and Results

Thirty patients enrolled in trial group received *Amalaki Ghrita Aashchyotana* for 90 days and 30 patients enrolled in control group were given HPMC eye ointment for local application for 90 days. All patients from both the groups completed the treatment.

The average age of patients in Group A and Group B were 32.83 ± 8.28 years and 34.63 ± 8.97 years with no statistically significant difference (p = 0.4119). There were 18 males and 12 females in trial group whereas 17 males and 13 females were enrolled in control group with no statistically significant difference between number of males and females. Out of 60 patients, maximum number of patients, i. e. 32 (53.33%) patients had *Vata – Pitta Prakriti*, 08 (13.33%) patients had *Kapha – Pitta Prakriti*, 07 (11.67%) patients had *Vata Pradhana Prakriti*, 03 (05%) patients had *Pitta Pradhana* and *Kapha Pradhana Prakriti* each whereas 07 (11.67%) patients had *Vata – Kapha Pradhana Prakriti*.

Clinical Assessment:

a) **Assessment by Schirmer's test:** In Group A, the mean Schirmer's test value before treatment (Day 0) was 1.67 ± 0.48 which got changed to 0.17 ± 0.38 with statistically significant difference (p < 0.0001). In Group B, the mean Schirmer's test value before treatment (Day 0) was 1.83 ± 0.38 which got changed to 0.07 ± 0.325 with statistically significant difference (p < 0.0001). On comparison between two groups, the difference in mean Schirmer's test was found to be insignificant (p > 0.05).

b) **Assessment of Tear film break-up time (TBUT):** In Group A, the mean Tear film break-up time (TBUT) value before treatment (Day 0) was 1.57 ± 0.50 which got changed to 0.17 ± 0.38 with statistically significant difference (p < 0.0001). In Group B, the mean TBUT) value before treatment (Day 0) was 1.83 ± 0.38 which got changed to 0.07 ± 0.25 with statistically significant difference (p < 0.0001). On comparison between two groups, the difference in mean Tear film break-up time (TBUT) was found to be insignificant (p > 0.05).

c) **Assessment of Dry Eye Score:** In Group A, the median dry eye score before treatment (Day 0) was 02 (01 – 02) which got changed to 00 (00 – 01) with statistically significant difference (p < 0.0001). In Group B, median dry eye score before treatment (Day 0) was 02 (01 – 02) which got changed to 00 (00 – 01) with statistically significant difference (p < 0.0001). On comparison between two groups, the difference in median dry eye score was found to be insignificant (p > 0.05).

d) **Assessment of Blurred Vision:** In Group A, the median blurred vision score before treatment (Day 0) was 02 (01 – 02) which got changed to 00 (00 – 01) with statistically significant difference (p < 0.0001). In Group B, median blurred vision score before treatment (Day 0) was 02 (01 – 02) which got changed to 00 (00 – 01) with statistically significant difference (p < 0.0001). On comparison between two groups, the difference in median blurred vision score was found to be insignificant (p > 0.05).

e) **Assessment of Dizziness / Nausea:** In Group A, the median dizziness / nausea score before treatment (Day 0) was 02 (01 – 02) which got changed to 00 (00 – 01) with statistically significant difference (p < 0.0001). In Group B, median dizziness / nausea score before treatment (Day 0) was 02 (01 – 02) which got changed to 00 (00 – 01) with statistically significant difference (p < 0.0001). On comparison between two groups, the difference in median dizziness / nausea score was found to be insignificant (p > 0.05).

f) **Assessment of Headache:** In Group A, the median headache score before treatment (Day 0) was 02 (01 – 02) which got changed to 00 (00 – 01) with statistically significant difference (p < 0.0001). In Group B, median headache score before treatment (Day 0) was 02 (01 – 02) which got changed to 00 (00 – 01) with statistically significant difference (p < 0.0001). On comparison between two groups, the difference in median headache score was found to be insignificant (p > 0.05).

g) **Assessment of Redness of eyes:** In Group A, the median redness of eyes score before treatment (Day 0) was 02 (01 – 02) which got changed to 00 (00 – 01) with statistically significant difference (p < 0.0001). In Group B, median redness of eyes score before treatment (Day 0) was 02 (01 – 02) which got changed to 00 (00 – 01) with statistically significant difference (p < 0.0001). On comparison between two groups, the difference in median redness of eyes score was found to be insignificant (p > 0.05).

h) **Assessment of Eye strain:** In Group A, the median eye strain score before treatment (Day 0) was 02 (01 – 02) which got changed to 00 (00 – 01) with statistically significant difference (p < 0.0001). In

Group B, median eye strain score before treatment (Day 0) was 02 (01 – 02) which got changed to 00 (00 – 01) with statistically significant difference ($p < 0.0001$). On comparison between two groups, the difference in median eye strain score was found to be insignificant ($p > 0.05$).

i) **Assessment of change in color perception:** In Group A, the median change in color perception score before treatment (Day 0) was 02 (01 – 02) which got changed to 00 (00 – 01) with statistically significant difference ($p < 0.0001$). In Group B, median change in color perception score before treatment (Day 0) was 02 (01 – 02) which got changed to 00 (00 – 01) with statistically significant difference ($p < 0.0001$). On comparison between two groups, the difference in median change in color perception score was found to be insignificant ($p > 0.05$).

j) **Assessment of slow refocusing:** In Group A, the median slow refocusing score before treatment (Day 0) was 02 (01 – 02) which got changed to 00 (00 – 01) with statistically significant difference ($p < 0.0001$). In Group B, median slow refocusing score before treatment (Day 0) was 02 (01 – 02) which got changed to 00 (00 – 01) with statistically significant difference ($p < 0.0001$). On comparison between two groups, the difference in median slow refocusing score was found to be insignificant ($p > 0.05$).

k) **Assessment of burning sensation:** In Group A, the median burning sensation score before treatment (Day 0) was 02 (01 – 02) which got changed to 00 (00 – 01) with statistically significant difference ($p < 0.0001$). In Group B, median burning sensation score before treatment (Day 0) was 02 (01 – 02) which got changed to 00 (00 – 01) with statistically significant difference ($p < 0.0001$). On comparison between two groups, the difference in median burning sensation score was found to be insignificant ($p > 0.05$).

l) **Assessment of excessive fatigue:** In Group A, the median excessive fatigue score before treatment (Day 0) was 02 (01 – 02) which got changed to 00 (00 – 01) with statistically significant difference ($p < 0.0001$). In Group B, median excessive fatigue score before treatment (Day 0) was 02 (01 – 02) which got changed to 00 (00 – 01) with statistically significant difference ($p < 0.0001$). On comparison between two groups, the difference in median excessive fatigue score was found to be insignificant ($p > 0.05$).

Both the groups exhibited efficacy of respective treatments on intra-group comparison of all objectives as well as subjective parameters. This signifies that both the treatments were effective. The inter-group comparison was not statistically significant in any of the parameters. It shows that both the treatments were equivalent. The null hypothesis of no significant difference is to be accepted. Overall assessment in both groups showed > 90% improvement in subjective as well as objective criteria.

No adverse events were observed during or after the completion of study in any of the groups which indicates that both the treatments were safe.

Discussion

Increased computer work hours, reduced blinking and effect of light rays and radiation has contributed to a raised number of cases of dry eye. Dry eyes are one of the most common causes of chronic low-grade burning, irritation, and discomfort of the eyes. It is caused due to disturbance in the tear film function owing to change in lipid, water, or mucin component of the tears.(13) It is now recognized that dry eye syndrome results from an underlying cytokine and receptor mediated inflammatory process affecting the lacrimal glands.(14) Inflammation, in turn, can either decrease tear production or alter the contents of the tear film and disrupt homeostasis at the ocular surface, leading to dry eye syndrome.(15) These findings have redirected treatment efforts towards more targeted therapies aimed at resolving the underlying inflammation.

Shushkaakshipaka means inflammation of the eye due to decreased / dried *Ashru.* Signs and symptoms of *Shushkaakshipaka* are as described by Acharya Sushruta are dryness of eyes, stiffness and dryness of eyelids, contraction and blurred vision. Additional symptoms like pricking sensation in eyes, burning sensation, sticking of lids, liking towards cold, pain and pus formation are mentioned by Acharya Vagbhat.

In contemporary treatments of Dry eye syndrome, HPMC eye drop or ointment is commonly used as surface lubricant but it does not correct the underlying pathology and makes patients dependent on surface lubricant for lifetime. Anti-inflammatory/ immunomodulatory treatments are now becoming standard therapy for moderate to severe dry eye syndrome. Contemporary tear substitutes stimulate the cell surface glycoproteins that maintain ocular hydration and mucoadhesive property due to lipid content in it. It slows the evaporation of the tear film, thus resolves the condition which leads to dry eye.(16)

The study consisted of 60 patients in two groups, 30 patients in each, of age 16 to 75 years irrespective of genders, religion, etc. having minimum three symptoms of *Shushkaakshipaka* (Dry eye syndrome) and with minimum two hours every day for continuous one year exposure to desktop, laptop or both. Thirty patients enrolled in trial group received *Amalaki Ghrita Aashchyotana* for 90 days and 30 patients enrolled in control group were given HPMC eye ointment for local application for 90 days.

Maximum number of patients (i. e. 43.33% of total patients) was from age group of 31- 40 years followed by number of patients (38.33%) in the 20-30 years of age group. This indicates that occurrence of this disease is considerably high in the young age group

(20 – 40 years of age). According to Ayurveda, this stage of life is considered as *Taruna Vayo Awastha* in which predominance of *Pitta Dosha* is seen. Total 35 males and 25 females enrolled in the present study indicate male predominance in dry eye syndrome. The *Sharira – Prakriti* wise distribution of patients reaffirms the role of *Pitta and Vata Dosha* as part of pathogenesis in *Shushkakshipaka.*

On treatment of *Amalaki Ghrita Aashchyotana* in trial group and HPMC eye ointment in control group for 90 days showed significant difference in all objectives as well as subjective parameters on intra-group comparison. Overall assessment in both groups in terms of percentage improvement in subjective and objective criteria showed comparable results. This signifies that both treatments were efficacious in dry eye symptoms. The statistically insignificant inter-group comparison shows that both the treatments were equivalent. No adverse events during or after the completion of study in any of the groups indicated that both the treatments were safe.

Amalaki Ghrita alleviates *Vata* and *Pitta Dosha* responsible for the pathogenesis of *Shushkaakshipaka*. Due to S*nigdha and Sheeta* attributes, it can also act as a lubricant. Thus, *Amalaki Ghrita Aashchyotana* can act as a surface lubricant which breaks the pathology of dry eye syndrome with reference to *Shushkaakshipaka*. *Ghrita* is lipophilic in nature which facilitates absorption through corneal epithelium. Mucin layer which is present in tear film allows the *Ghrita* to spread over the ocular surface.(17,18) *Amalaki Ghrita* is *Rasayana* formulation which can strengthen the eyes along with relief from dry eye syndrome. Moreover, *Ghrita Kalpana* has a shelf life of one year without any preservative.19 Thus; it has an advantage over HPMC ointment used currently. As *Amalaki* is *chakshashya* and *Sheeta* and *Ghrita* is a *Snigdha* so combination of both in the form of *Amalaki Ghrita Aaschyotana* was selected for dry eye treatment.

This approach provides long lasting relief to the patients with moderate-to-severe dry eye symptoms. Lipid based drugs are a very less explored area in the domain of research regarding Dry eye syndrome. Hence, preparation and usage of *Amalaki Ghrita* in the present study can help as a guide for future research in Ayurvedic as well as modern ophthalmology.

Conclusion

From the results of the present study, it can be inferred that *Amalaki Ghrita Aashchyotana* is equally efficient as HPMC eye ointment. *Amalaki* being *Chakshushya*, use of *Amalaki Ghrita Aashchyotana* in Dry eye syndrome, has more advantage over HPMC ointment, as it also can help to improve visual acuity.

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