



Research Article

A CLINICAL STUDY ON EFFICACY OF JEEVANTYAADI GHRIT IN SUSHKAKSHIPAAKA (DRY EYE)

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ABSTRACT

Dry eye also known as keratoconjunctivitis sicca or xerophthalmia, is a multi-factorial disease that results in discomfort, visual disturbance and tear film instability with potential damage to the ocular surface on progress of the disease, if proper step(s) are not adopted for prevention or management from the beginning of the disease. Dry eye is accompanied by increased osmolarity of the tear film and inflammation of the ocular surface. It is a commonest ocular disorder especially among the elderly because of reduction in tear film secretion. As far as the prevailing practices available for dry eye are concerned, no specific treatment is effective addressing the symptoms visualized in dry eye. The condition dry eye can be well compared to *Sushkakshipaaka* (*Sushka*=Dry, *Akshi*=Eye, *Paaka*=inflammation) explained in Ayurveda owing to its simulating clinical features and pathogenesis. Various regulated principles of management are in place addressing the above clinical complications by reaching the target tissues and receptors for enriching the ocular surface, and thus extending milestone in recovering from dry eye symptoms. Thus patients (n=10) registered with dry eye in outpatients department of Shalakyta tantra of Shri Kalabyraveshwara Ayurveda Medical College Hospital and Research Centre Bangalore, were taken up for the study and treated with *Jeevantyadi ghrita tarpana* five days of two sittings with an interval of ten days. There was no drops outs and treatment event was successful.

KEYWORDS: *Dry eye, Tarpana, Jeevantyadi ghrita*

INTRODUCTION

Dry eye also known as *keratoconjunctivitis sicca* is the most frequent condition we come across in our clinical Ophthalmology^[1] It is a multifactorial disorder of the tears and ocular surface^[2], characterized by chronic dryness of the cornea and conjunctiva caused by unstable tear film^[3]. Although the condition is more common among the elderly due to the general aging, there is an increase in prevalence of dry eye in recent years irrespective of the age. Approximately 8% of the world population is suffering with dry eye, of which 78% are women. A number of contributory factors affect the severity of dry eye syndrome, including autoimmune disease, anatomical features, environmental surroundings, contact lens use, unmodified life styles, hormonal changes, chronic inflammation, infections, and iatrogenic factors, such as medications or

surgery^[6]. Dry eye disease can hinder the performance of activities of daily living and is associated with an overall decrease in quality of life^[7]. The condition is characterized by feeling of dryness, foreign body sensation, pain, redness, burning or stinging, light sensitivity, grittiness and itchiness in the eyes with a greater risk of depression and anxiety^[8,9] due to negative impact on the quality of life.

Among many eye diseases, which have been described by the ancient classics of *Ayurveda*, the clinical features of *Shushkakshipaka* are having similarities with dry eye. *Shushkakshipaka* is one among *Sarvagata netra rogas* mentioned by Sushruta as well as Vagbhata under *Sadhya vyadhis*, caused due to affliction of *Vata* and *Pitta Doshas* having symptoms of *Gharsha* (foreign

body sensation), *Toda* (pricking pain), *Bheda* (pain), *Upadeha* (stingy mucous discharge), *Krichronmeelanimeelana* (difficult in opening and closing eye lids), *Vishushkata* (dryness), *Rooksha daruna vartmakshi* (dryness - painful of the eyelids)^[10,11].

Preservative-free tear substitutes is the first step in medical management of dry eye^[12], which increases humidity and improves lubrication at the ocular surface^[13]. Temporary symptomatic relief can be obtained by these modalities of modern treatment, but there is no satisfactory treatment of dry eye at present. The common ingredients recommended in daily practices includes cellulose derivatives, carbomers, mucolytic, and contact lens etc., have proven limited therapeutic actions for long term use. The preservative present in these formulations may lead to further aggravation of the condition on prolonged usage. In these situations researchers always try to find out drug or procedure to get respite the conditions which are having nil or least adverse effects.

The promotion of the visual acuity was considered as one of the priorities in the branch of *Shalakyas* of *Ayurveda*. Sushruta, the father of ancient Indian surgery, recommended '*Kriyakalpa*' for the management of *Shushkakshipaka*, along with other forms of treatment. Some of the proven principles of management procedures and medicaments include intake of medicated clarified ghee (*Ghritapaana*), nourishing eye bath therapy (*Tarpana*), processed liquid instillation through nostrils by drops or powders (*Nasya*), eye bath therapy (*Pariseka*), application of medicated paste on eye lids (*Bidalaka*) and collyrium (*Anjana*).

The procedure *Tarpana karma* taken up for the study has been indicated in several eye diseases by various acharyas. The word "*Tarpana*" is derived from root '*trup*' that means to become satisfied. *Tarpana* with *Jeevantlyaadi ghrita* was selected for the present study which is beneficial in reducing the features of *Shushkakshipaka* (Dry Eye Syndrome). According to *Acharya Charaka*, *Ghrita* is effective in subsiding *Pittaja* & *Vataja* disorders; and improve *Dhatus* and *ojas*^[14]. According to *Acharya Sushruta* along with above said properties it provides strength to

the eye sight^[15]. *Acharya Bhavaprakash* has also described *Ghrita* as *Rasayana*, good for the eyes & protects body from various diseases^[16]. The present formulation was selected due to its *Tridoshashamaka* properties, *Madhura Vipaka* and *potentialities* like *Chakshushya*, *Rasayana*, *Brimhana* & *Balya* which will strengthen the ocular surface & improve the vision.

AIMS AND OBJECTIVES

1. To evaluate the efficacy of *Jeevantlyaadi ghrita* in the management of dry eye.
2. To assess the *Tarpana* effect in the management of dry eye.

MATERIALS AND METHODS

This study was cleared by the institutional ethical committee of SKAMCH & RC Bangalore. Written consent was taken from each patient willing to participate before the start of the study. Patients were free to withdraw their name from the study at any time without giving for any reason thereof.

The diagnosis of dry eye - *Sushkakshipaaka* was done on both the modern and *Ayurvedic* basis. For this purpose a special research proforma was prepared as per the modern and *Ayurvedic* view. The patients of after taking ophthalmic and systemic history, the best corrected vision was recorded in the case sheet as per the protocol. Later Schirmer's test was performed to know the dryness of the eye. Routine blood, fasting blood sugar and serum cholesterol profile were completed to rule out the associated pathology if any.

(i) About the medicaments

Jeevantlyaadi ghrita was selected for the present study which is specially mentioned by *Sushruta acharya* in context of *Shushkakshipaka chikitsa*^[17]. *Jeevantlyaadi ghrita* used in this study was purchased from approved *Ayurvedic* pharmacy, manufactured by *Pentacare Ayurpharma Bangalore*. The ingredients of *Jeevantlyaadi ghrita* are *Jeevanti* (*Leptadenia reticulata* W & A.), *Padmaka* (*Nelumbo nucifera* Gaertn.), *Ashwagandha* (*Withania somnifera* Linn Dunal.), *Pippali* (*Piper longum* Linn.), *Lodhra* (*Symplocos Racemosus* Roxb.), *Saindhava Lavana* (*NaCl*), *Shatahva* (*Anethum sowa* Roxb. Ex Flem.), *Madhuyashti* (*Glycyrrhiza glabra* Linn.), *Draksha* (*Vitis vinifera* Linn.), *Sita* (*Cynodon*

Dactylon (Linn), *Devadaru* (*Cedrus deodara* Roxb. Lowd.), *Haritaki* (*Terminalia chebula* Retz.), *Vibhitaki* (*Terminalia bellirica* Gaertn Roxb.), *Amalaki* (*Phyllanthus emblica* Linn.), *Goghrita* (*Butyrum deparatu*), *Godugdha* (Cow milk). This drug contains *Madhura Rasa*, *Laghu Guna*, *Sheeta Veerya*, *Madhura Vipaka*. The *Jeevantlyaadi ghrita* was prepared by classical method of *Ghrita paaka*.

(ii) *Tarpana*

It can be done either in early morning or evening; only after the digestion of any food taken previously. The patient is asked to lie down on his back, in a chamber free from direct sun rays, wind and dust, and is given mild fomentation with a cotton soaked in lukewarm water, then the eyes are encircled with firm, compact wall made up of paste of powdered *Maasha* pulse (black gram). The height of this wall should be two *Angula*. The patient is asked to close the eyes and over the closed eyes, liquefied *Ghrita* is poured very

slowly till the entire eyelashes are covered with *Ghrita*. Patient is instructed to blink slowly (*Unmesha* & *Nimesha*) during the procedure. After retaining for the stipulated time, the liquid is drained out through the hole made near the outer canthus and the eye is irrigated by lukewarm water fomentation (*S.S.Ut. 18/10-11*).

Study design

Open label clinical trial was conducted on 10 patients fulfilling the criteria for the diagnosis of the disease dry eye – *Sushkakshipaaka* in the present study. The patients were selected from the outpatient department of *Shalaky Tantra* of Shri Kalabyraveshwara Ayurveda Medical College Hospital and Research Centre Bangalore.

Selection of patients: 10 no. of patients of age group 30-60 years were selected after obtaining the informed consent. Sampling was done based on inclusion and exclusion criteria (Table 1).

Table 1: Inclusion and exclusion criteria

| Inclusion criteria | Exclusion criteria |
|---|---|
| <ul style="list-style-type: none"> • Friction / Feeling of dirt in the eyes (<i>Gharsha</i>) • Burning sensation (<i>Daha</i>) • Difficulty in opening and closing of eye lids (<i>Krichronmeelanimeelana</i>) • Dryness - Painful of lid and eye (<i>Rooksha daruna vartmakshi</i>) • Schirmer's Test | <ul style="list-style-type: none"> • Injuries- <i>Abhighataja netra roga</i> • Systemic disorders like RA, Systemic leucosis erythematus (SLE) and Sjögren's Syndrome • Patients who are using drugs like antihistamines, decongestants, hormonal therapy, antidepressants, dermatologic medications, antipsychotic medications and chemotherapy medications • Congenital Alacremia • Associated with any inflammatory and infective ocular conditions and other conditions like glaucoma, |

Treatment regime

The study was intervened by the treatment with *Jeevantlyaadi ghrita tarpana* as per the posology mentioned. Later the patients were advised to follow the *Pathyaahara* as noted in the protocol as endorsed in classics.

Dose & duration

40gms per day once a daily for 8-10 minutes for a five day regimen. Patients are again advised for continuing the five days *Tarpana* once more after a ten days gap.

Follow up

Ten days after second courses of *Tarpana* to measure visual acuity.

Duration of study: Thirty days.

Criteria for Assessment

The assessment was done on improvement in signs & symptoms with the help of suitable scoring method ranging from 0 - 3.

Gradation of results were assessed as follows:

- Cured: 100% relief in signs and symptoms and no recurrence during follow up study.
- Marked Improvement: More than 75% improvement in signs and symptoms.
- Moderate Improvement: 51-75% improvement in signs and symptoms.
- Mild Improvement: 26-50% improvement in signs and symptoms.
- Unchanged: Up to 25% reduction in signs and symptoms.

OBSERVATIONS AND RESULTS

The graphic data in relation to sex, age, occupation and socioeconomic status on various parameters are presented in table no.2

Table 2: Sex, age, occupation and socioeconomic status

| Variables | Age groups | | | Total | |
|----------------------|--------------|---------|---------|---------|---------|
| | 30-40yr | 41-50yr | 51-60yr | | |
| Gender | Male | 1 (10%) | 2 (20%) | 1 (10%) | 4 (40%) |
| | Female | 2 (20%) | 2 (20%) | 2 (20%) | 6 (60%) |
| Socioeconomic status | Lower class | 1 (10%) | 2 (20%) | 1 (10%) | 4 (40%) |
| | Middle class | 1 (10%) | 0 (0%) | 2 (20%) | 3 (30%) |
| | Higher class | 2 (20%) | 1 (10%) | 0 (0%) | 3 (30%) |
| Occupation | Homemaker | 0 (0%) | 1 (0%) | 1 (10%) | 2 (20%) |
| | Red collar | 1 (0%) | 0 (0%) | 1 (10%) | 2 (20%) |
| | White collar | 3 (30%) | 2 (20%) | 1 (10%) | 6 (60%) |

Total 10 subjects were registered for the present study, among them 60% of the study population were females, 40% were belongs to lower socioeconomic status and 60% of patients were White collar.

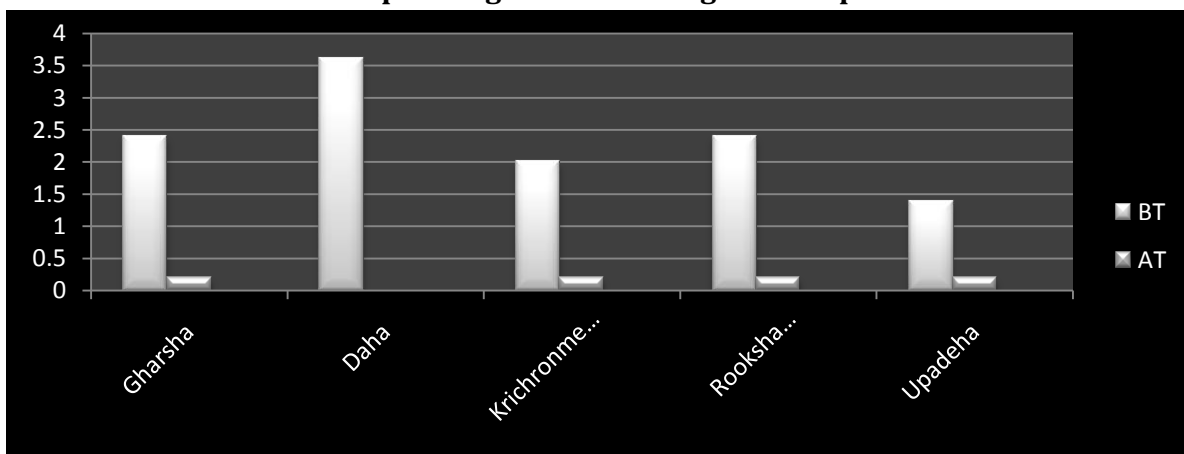
The friction (*Gharsha*) between palpebral and bulbar conjunctiva which was uncomfortable prior to treatment (mean=2.4) has resulted in extending comfort (mean=0.2), burning sensation (*Daha*) which was before treatment (mean=2.6) has resulted in extending comfort (mean=0.0), Difficulty in opening and closing of eye lids (*Krichronmeelanimeelana*) which was before treatment (mean=2.0) has resulted in

extending comfort (mean=0.2), Dryness - Painful of lid and eye (*Rooksha daruna vartmakshi*) which was before treatment (mean=2.0) has resulted in extending comfort (mean=0.2) and Stingy mucous discharge (*Upadeha*) which was before treatment (BT) (mean=1.4) has resulted in extending comfort after treatment (AT) (mean=0.2). The parameters selected for clinical significance before and after treatment are summarized in table no.3. In all the 10 patients, marked improvement was observed, with highly significant and significant 'p' values (p<0.001). (Graph-1).

Table 3: The parameters for clinical significance

| Parameters | Before treatment | After treatment |
|---|------------------|-----------------|
| <i>Gharsha</i> (Friction) | 2.4 | 0.2 |
| <i>Daha</i> (Burning sensation) | 2.6 | 0.0 |
| <i>Krichronmeelanimeelana</i> (Difficulty in opening and closing of eye lids) | 2.0 | 0.2 |
| <i>Rooksha daruna vartmakshi</i> (Dryness - Painful of lid and eye) | 2.4 | 0.2 |
| <i>Upadeha</i> (Stingy mucous discharge) | 1.4 | 0.2 |

Graph-1: significant and significant 'p' values



DISCUSSION

Dry eye is a disorder of the tear film due to tear deficiency or excessive tear evaporation which causes damage to the interpalpebral ocular surface and is associated with symptoms of ocular discomfort. The most common symptoms are irritation, a foreign body sensation, burning, excessive secretion, redness, photophobia, blurred vision, itching, pain and inability to tear in response to irritation or emotions. There may be crusting of eyelids and sticking. The condition of eye in which *Paaka* associated with *Sushkata* is known as *Shushkakshipaka* (Dry Inflammation of Eye) [18].

Shushkakshipaka is a disorder of the eye characterized by *Gharsha* (foreign body sensation), *Toda* (pricking pain), *Upadeha* (stingy mucous discharge), *Rooksha daruna Vartmakshi* (dryness - painful of the eye lids), *krichra unmeelanimeelana* (difficulty in closing and opening of eye lids), *Sushkata* (dryness), *Shoola* (pain). The vitiated *Vata* and *Pitta doshas* passing through *sira's* gets accumulated in the parts of the eye like *Vartma*, *Sandhis*, *Shukla Mandala*, *Krishna Mandala*, *Drusti Mandala* and manifests the disease *Shushkakshipaka* [19,20].

Jeevantlyaadi ghrita has cow's ghee, a animal fat is abundant in saturated fatty acids. Ghee contains approximately 8% lower saturated fatty acids which make it easily digestible. The digestibility coefficient or rate of absorption is 96% which is better than other animal and vegetable fats. Cow's ghee (*Goghrita*) contains carotene in the amount of 3.2 – 7.4 µg/g, vitamin - A in the amount of 19 – 34 I.U./g and Tocopherol (vitamin E) in the amount of 26 – 48 µg in it, all of which are beneficial for eyes. It also contains vitamin D and K. It is beneficial because of the combination present in *Jeevantlyaadi ghrita Vatashamaka*, *Pitashamaka*, *Kaphashamaka gunas* by virtue of its implied *Rasa*, *Guna*, *Virya* & *Vipaka*. Hence, the overall effect of the formulation (*Jeevantlyaadi ghrita*) is *tridhoshamaka* & thus it help to pacify *Sushkakshipaaka*, which is *Vata pradhana Tridoshaja* in its manifestation.

Digestion, absorption and delivery to a target organ system are crucial in obtaining the maximum benefit from any formulation.

This is facilitated by *Ghrita*, since active ingredients of drugs are mixed with *Ghrita* and they are easily absorbed. Lipophilic action of *Ghrita* facilitates transportation to a target organ and final delivery inside the cell, because cell membrane also contains lipid. This lipophilic nature of *Ghrita* facilitates entry of drug in eyeball through corneal surface since corneal epithelium is also permeable to lipid soluble substances and lipid soluble substances cross corneal epithelium irrespective of their molecular size. Moreover, *ghrita* preparation used in *tarpana* is in the form of suspension containing different particles of the drugs and the particles do not leave the eye as quick as solution. Tissue contact time and bio availability is more, and hence therapeutic concentration can be achieved.

CONCLUSION

The main object of dry eye therapy is to preserve the already existing tears or reduction of normal tear drainage or both. By *Tarpana* procedure the lipophilic nature of the *Ghritha* enters inside the cells of eye, helps to maintain the normalcy of the ocular tissues by reducing the dryness of eye. The drug *Jeevantlyaadi ghrita* contains *Madhura rasa*, *Laghu Guna*, *Sheeta Veerya*, *Madhura Vipaka* by virtue of these properties it helps to lubricate the target tissues. *Chakshushya* and *Brimhana* properties of the drug improve the acuity of vision. In nutshell the present study has established the fact that, *Jeevantlyaadi ghrita Tarpana* in dry eye - *Sushkakshipaaka* has obtained the best results without any adverse effects.

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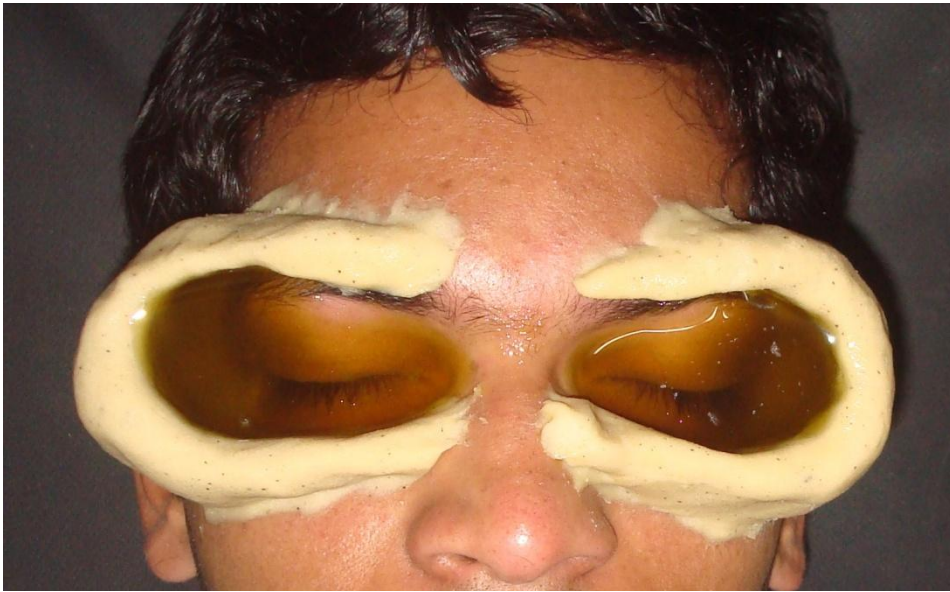
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PROCEDURE PICTURES



Picture 1. Tarpana with Jeevanti ghrita, male



Picture 2. Tarpana with Jeevanti ghrita, female