

## A CLINICAL STUDY ON THE EFFECT OF GHRITKUMARYADI ASCHYOTAN (DROPS) IN THE MANAGEMENT OF SHUSHKAKSHIPAKA W.S.R. TO DRY EYE SYNDROME

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Received date: 30 April 2022

Revised date: 21 May 2022

Accepted date: 10 June 2022

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### ABSTRACT

*Shushkakshipaka* is mentioned in the classical literature of *Ayurveda* under *Sarvagata Netraroga*<sup>[1]</sup> i.e. affecting all parts of eye, very similar to Ocular surface disease i.e. Dry Eye Syndrome (DES) in modern ophthalmology. Eye health is a major victim of our evolving current lifestyle. Longer screen time, exposure to more technological devices and the ever growing pollution deteriorate our eye health. Dry eye syndrome(DES) is characterized by ocular irritation resulting from an alteration of the tear film.<sup>[2]</sup> In the present study 10 patients were selected randomly and treated with *Ghrithkumaryadi Aschyotan* (drops). The signs and symptoms were studied before and after treatment. Results of the study indicates significance of this drug as 10% of patients were cured, 50% were markedly improved, 30% were moderately improved and 10% of patients were mildly improved.

**KEYWORDS:** *Shushkakshipaka, Aushadha Sadhya, Ghrithkumaryadi Aschyotan, DES.*

### INTRODUCTION

The word '*Shushkakshipaka*' means eye wherein *Ashru* has been depleted or dried resulting in inflammation of the eye. In other words, inflammation in the eye due to decreased/depleted or dried *Ashru*.<sup>[3]</sup> Dry eye syndrome is a multifactorial disease of the ocular surface and tear film accompanied by increased osmolarity of the tear film and inflammation of the ocular surface.<sup>[4]</sup> Prevalence estimates of DES range from 5% to 34% in individuals over 50 years old.<sup>[5]</sup> *Acharya Sushruta* has described it as a *Vataja* disorder<sup>[6]</sup>, *Acharya Vagabhatta* describes it as a *Vata-Pittaja* disorder.<sup>[7]</sup>

*Shushkakshipaka* is a *Sarvagata, Sadhya* (curable disease) which is *Ashastrakruta*<sup>[8]</sup> (curable by drugs and no need for surgical intervention). *Acharya Sushruta* had given more importance to ophthalmology, as it is evident from the fact that the *Uttarantra* starts from eye diseases and out of 26 chapters of *Shalaky Tantra*, 19 are dedicated to *Netra Rogas*, which includes anatomy, classification, pathophysiology of eye diseases and their treatment.<sup>[9]</sup> *Ayurveda* has highlighted unique therapeutic procedures- *Netra Kriyakalpas* are among these procedures practiced in *Shalaky Tantra*.<sup>[10]</sup> These have

major role in overcoming of the disease and arresting its progression and overcoming the complications.

Hence the concept of *Aschyotan Kriya Kalpa* with *Ghrithkumaryadi Aschyotan* in the management of Dry Eye Syndrome has been taken. Therefore keeping in view the need of the time and gravity of the disease, present study was undertaken with topic entitled "A Clinical Study on the Effect of *Ghrithkumaryadi Aschyotan*(drops) in the Management of *Shushkakshipaka w.s.r. to Dry Eye Syndrome.*"

### AIMS AND OBJECTIVES

- To study conceptual resemblance between *Shushkakshipaka* and Dry Eye Syndrome (DES).
- To evaluate the effect of *Aschyotan Kriya Kalpa* with *Ghrithkumaryadi Aschyotan*(drops) on DES.
- To study the side effect of the drug, if any.
- To provide economic, safe and effective treatment.

### MATERIALS AND METHODS

**Study Design:** Open random comparative study.

### Selection of Patients

The patients presenting with clinical features of *Shushkakshipaka*/ DES were selected from *Shalakya Tantra* (Eye) O.P.D. of hospital affiliated to R.G.G.P.G. Ayu.College, Paprola (H.P.); irrespective of their sex, religion, occupation, education etc. A total of 10 patients were registered. Informed consent was taken from all.

### Inclusion Criteria

- i. Patients willing for trial.
- ii. Patients presenting with signs and symptoms of *Shushkakshipaka*/ DES will be taken into account irrespective of sex, caste and religion.
- iii. Age group above 20 years.

### Exclusion Criteria

- i. Patients not willing for trial.
- ii. Patients suffering from dry eye associated with other ocular disease (e.g. Squamous blepharitis, corneal ulcer, lagophthalmos, dacrocystitis, uveitis, any stage of glaucoma, allergic conjunctivitis) or systemic diseases.

### Investigational Criteria

Investigations were carried out in order to rule out any systemic disease- Complete blood picture (Hb gm%, TLC, DLC, ESR, FBS), Urine examination etc.

### Plan of Study

Clinical study was accomplished in three phases:

- i. Diagnostic Phase
- ii. Interventional Phase
- iii. Assessment Phase

### Diagnostic Phase

The diagnosis of selected patients was confirmed on the basis of positive signs (Conjunctival congestion, Mucin strands in tear film, marginal tear meniscus etc.) found during elaborative examination and specific clinical tests (Schirmer-1, TBUT and Ocular surface staining) of DES.

A special research proforma was prepared comprising of *Ayurvedic* and Modern parameters essential for diagnosis and assessment of Disease.

### Interventional Phase

*Ghririkumaryadi Aschyotan* (drops).

**Duration of Trial**- 30 days

**Dose** – 1-2 drops 4-6 times a day.

**Follow up** – Follow ups were done on 3<sup>rd</sup> day, 7<sup>th</sup> day, 14<sup>th</sup> day, 21<sup>st</sup> day, 28<sup>th</sup> day of trial.

And after 15 days of completion of trial for any complications and adverse effect of drug.

### Assessment Phase

**Clinical Assessment Criteria:** The clinical trial was assessed for its efficacy on the basis of following subjective and objective criteria.

### Subjective Criteria

#### 1. Foreign body sensation (*Gharsha*)

- 0 - No foreign body sensation
- 1 - Occasional foreign body sensation
- 2 - Frequent foreign body sensation
- 3 - Continuous foreign body sensation.

#### 2. Burning (*Ushadaha*)

- 0 - No burning sensation
- 1 - Mild burning sensation
- 2 - Moderate burning sensation
- 3 - Severe burning sensation

#### 3. Mucoïd discharges (*Updeha*)

- 0 - No mucoïd discharge
- 1 - Discharge not requiring mopping
- 2 - Discharges requiring intermittent mopping
- 3 - Discharges causing sticking of eyelashes

#### 4. Blurring of vision (*Avila-darshana*)

- 0 - No blurring
- 1 - Occasional blurring
- 2 - Frequent blurring
- 3 - Continuous blurring

#### 5. Dryness (*Vishushkatva*)

- 0 - No feeling of dryness
- 1 - Occasional feeling of dryness
- 2 - Frequent feeling of dryness
- 3 - Continuous feeling of dryness

#### 6. Pain (*Toda/Bheda/Shula*)

- 0 - No pain
- 1 - Not Continuous
- 2 - Continuous but not incapacitating normal routine activity
- 3 - Continuous throughout and incapacitating normal routine activity

#### 7. Photophobia (*Kunita-vartma*)

- 0 - No photophobia
- 1 - Photophobia only during exposure to sunlight.
- 2 - Frequent photophobia
- 3 - Continuous photophobia

#### 8. Itching (*Kandu*)

- 0 - No itching
- 1 - Occasional itching
- 2 - Frequent itching
- 3 - Continuous itching

#### 9. Redness (*Raga*)

- 0 - No redness
- 1 - Hyperaemia of exposed conjunctiva at nasal and temporal corners
- 2 - Diffuse hyperaemia of palpebral conjunctiva
- 3 - Diffuse palpebral and bulbar hyperaemia

#### 10. Crusting (*Daruna-ruksha vartma*)

- 0 - No crusting of lids

- 1 - Mild Crusting
- 2 - Moderate Crusting with inflammation
- 3 - Crusting with inflammation

#### 11. Eyelids stuck (*Kricchronmeela-neemeelnam*)

- 0 - No stucked eyelids
- 1 - Eyelids stuck on waking up occasionally
- 2 - Eyelids stuck on frequently
- 3 - Stickiness with difficulty to open the eye.

#### Objective Signs

##### 1. Debris/Mucin strands in tear film

- 0 - Absence of mucin debris and strands in the tear film
- 1 - Spotting of mucin debris and strands in the tear film on slit-lamp bicroscopy
- 2 - Spotting of mucin debris/strands in the tear film in diffuse illumination (torch light examination)
- 3 - Numerous spotting on naked eye

##### 2. Conjunctival congestion

- 0 - No congestion
- 1 - Mild congestion (Congestion with clear pattern of bloodvessels)
- 2 - Moderate congestion (Congestion with poorly visible pattern of blood vessels)
- 3 - Severe congestion (Congestion completely obscuring the pattern of blood vessels)

##### 3. Marginal tear meniscus

- 0 - Convex tear meniscus, height ~ 0.2 -0.4 mm height
- 1 - 0.2-0.3 mm height
- 2 - Concave tear meniscus, height 0.1-0.2 mm height
- 3 - Absent marginal tear strip

#### Objective clinical tests

##### 1. Schirmer- I test

- 0 - Schirmer strip wetting of >15mm in 5 minutes
- 1 - Schirmer strip wetting between 11-15 mm in 5 minutes
- 2 - Schirmer strip wetting between 6-10 mm in 5 minutes
- 3 - Schirmer strip wetting of < 5 mm in 5 minutes

#### 2. Tear Film Break Up Time

- 0 - The appearance of dry spot after 15 seconds
- 1 - The appearance of dry spot between 11-15 seconds
- 2 - The appearance of dry spot between 6-10 seconds
- 3 - The appearance of dry spot within 5 seconds

#### 3. Fluorescein Staining

- 0 - Staining Absent
- 1 - Staining <1/3 corneal epithelium
- 2 - Staining 1/2 corneal epithelium
- 3 - Staining >1/2 corneal epithelium

#### OVERALL EFFECT OF THERAPY

The assessment was done by adopting the following scoring pattern.

- **Cured:** 100 % relief in signs and symptoms.
- **Marked improvement:** 75% to 99% improvement in signs and symptoms was recorded as marked improvement.
- **Moderate improvement:** 50% to 74% improvement in signs and symptoms was considered as moderate improvement.
- **Mild improvement:** 25% to 49% improvement in signs and symptoms was considered as mild improvement.
- **Unchanged:** < 25% reduction in signs and symptoms was noted as unchanged.

#### DRUG REVIEW

Ingredients of the *Ghritkumaryadi Aschyotan*(drops) are- *Ghritkumari* (*Aloe vera*(Linn.)Burm f., *Madhu* and Glycerin.

References of *Ghritkumari* and *Madhu* being useful for curing eye diseases is available in various *Ayurvedic* texts.

*Ghritkumari*(*Bh.P.Ni Guduchi.Vr<sup>[11]</sup>*, *Kai.Ni. Aush.Vr<sup>[12]</sup>*) *Madhu* (*Bh.P.Ni.Madhu Vr<sup>[13]</sup>*, *Kai.Ni. Aush. Vr<sup>[14]</sup>*, *Su.S.Su<sup>[15]</sup>*)

Glycerin is added in this in this formulation to sustained and enhance the property of aloe vera (lubricant). So that it remain present in the eyes for longer time and become convenient to use.

Drug	Botanical Name	Family	Part Used	Proportion
<i>Ghritkumari</i>	<i>Aloevera</i> (Linn.)Burm f.	Liliaceae	<i>Patra majja</i> (Leaves Pulp)	10%
<i>Madhu</i>	Honey			3%
Glycerin				2%
Distilled water				Q.S.

#### Preparation of Eye Drops

As facility for the sterile manufacturing & packing of the eye drops is not available at Institue's pharmacy, preparation of the eye drops was done at Sricure Herbs India Pvt. Ltd. Panchkula, Haryana a GMP certified company, following full guidelines of the modern as well as *Ayurvedic* Formulary of India (AFI). The drug is

sponsored by the Search Orbis Pharmaceutical Mohali Punjab.

#### Statistical Analysis

The scoring of criteria of assessment was analysed statistically in terms of mean values of B.T. (Before Treatment), A.T. (After treatment), S.D.(Standard

Deviation), and S.E.(Standard Error). The effect of therapy was assessed by applying students paired t' test for comparing the before treatment and after treatment scores of assessment criteria. The results obtained were considered highly significant for  $p < 0.001$ , significant for  $p < 0.05$  and insignificant for  $p > 0.05$ .

## OBSERVATIONS

Maximum number of patients were of age group 41-60 years (65%), were females (55%), married (80%), Hindu (100%), residents of rural area (80%), matriculated (30%), belonged to middle class (65%), housewives (45%), were taking vegetarian diet (65%) *Vata-Pittaj prakriti* (60%), were consuming veg. diet (75%), addiction to tea, coffee was present in 45% and spent more than 2 hours in front of V.D.U (45%). Symptoms of DES were found in decreasing order of percentage as : FBS and Itching (95%), Dryness (75%), Redness and Burning sensation (70%), Transient blurring of vision (60%), Mucoïd Discharge (55%), Pain (50%) and Crusting, Eyelid Stuck (30%). In Objective Findings maximum number of patients were having Conjunctival Congestion (70%) followed by abnormal tear meniscus (55%), Mucin Strands/debris in tear film (40%). Clinical tests showed Schirmer -1 test positive in (100%) patients, T-BUT abnormality in (95%).

### Effect of Therapy

#### 1. Effect on Foreign Body Sensation

The initial mean score of Foreign body sensation was 1.20 which reduced to 0.00 after treatment. The study shows that percentage relief in foreign body sensation was 100%. Statistical analysis revealed that the improvement was highly significant ( $p < 0.001$ ).

#### 2. Effect on Burning sensation

The initial mean score was 1.10 which reduced to 0.10 after treatment. The study shows that percentage relief in foreign body sensation was 90.90%. Statistical analysis revealed that the improvement was highly significant ( $p < 0.001$ ).

#### 3. Effect on Mucous discharge

The initial mean score was 0.70 which reduced to 0.10 after treatment. The study shows that percentage relief in mucous discharge was 85.71%. Statistical analysis revealed that the improvement was statistically significant ( $p < 0.05$ ).

#### 4. Effect on Transient blurring

The initial mean score was 0.80 which reduced to 0.10 after treatment. The study shows that percentage relief in transient blurring was 87.50%. Statistical analysis revealed that the improvement was highly significant ( $p < 0.001$ ).

#### 5. Effect on Dryness

The initial mean score was 1.10 which reduced to 0.10 after treatment. The study shows that percentage relief in dryness was 90.90%. Statistical analysis revealed that the improvement was highly significant ( $p < 0.001$ ).

#### 6. Effect on Pain

The initial mean score was 0.70 which reduced to 0.10 after treatment. The study shows that percentage relief in

pain was 85.72%. Statistical analysis revealed that the improvement was statistically significant ( $p < 0.05$ ).

#### 7. Effect on Photophobia

The initial mean score was 0.40 which reduced to 0.10 after treatment. The study shows that percentage relief in pain was 75%. Statistical analysis revealed that the improvement was statistically insignificant ( $p > 0.05$ ).

#### 8. Effect on Itching

The initial mean score was 1.20 which reduced to 0.00 after treatment. The study shows that percentage relief in pain was 100%. Statistical analysis revealed that the improvement was highly significant ( $p < 0.001$ ).

#### 9. Effect on Redness

The initial mean score was 0.90 which reduced to 0.20 after treatment. The study shows that percentage relief in pain was 77.78%. Statistical analysis revealed that the improvement was highly significant ( $p < 0.001$ ).

#### 10. Effect on Crusting

The initial mean score was 0.40 which reduced to 0.10 after treatment. The study shows that percentage relief in pain was 75%. Statistical analysis revealed that the improvement was statistically significant ( $p < 0.05$ ).

#### 11. Effect on Eyelid stuck

The initial mean score was 0.30 which reduced to 0.10 after treatment. The study shows that percentage relief in pain was 66.67%. Statistical analysis revealed that the improvement was statistically insignificant ( $p > 0.05$ ).

#### 12. Effect on tear meniscus

The initial mean score was 0.80 which reduced to 0.40 after treatment. The study shows that percentage relief in pain was 50%. Statistical analysis revealed that the improvement was statistically significant ( $p < 0.05$ ).

#### 13. Effect on mucin strands

The initial mean score was 0.50 which reduced to 0.10 after treatment. The study shows that percentage relief in pain was 80%. Statistical analysis revealed that the improvement was statistically significant ( $p < 0.05$ ).

#### 14. Effect on conjunctival congestion

The initial mean score was 1.10 which reduced to 0.30 after treatment. The study shows that percentage relief in pain was 72.72%. Statistical analysis revealed that the improvement was statistically significant ( $p < 0.05$ ).

#### 15. Effect on schirmer-1

The initial mean score was 1.80 which reduced to 1.00 after treatment. The study shows that percentage relief in pain was 53.34%. Statistical analysis revealed that the improvement was statistically significant ( $p < 0.05$ ).

#### 16. Effect on T-BUT

The initial mean score was 1.30 which reduced to 0.70 after treatment. The study shows that percentage relief in pain was 46.15%. Statistical analysis revealed that the improvement was statistically significant ( $p < 0.05$ ).

Among 10 patients, 1 patient was cured, 5 patients were markedly improved, 3 patients were moderately improved, 1 patient was mildly improved.

## DISCUSSION

Amongst the various local and systemic preparations indicated for the disease *Ghritkumaryadi Aschyotan* was taken up for the trial. Drug chosen for the treatment are

having properties which pacifies *Vata, Pitta Doshas*. Contents of Drug are *Ghrithkumari* extract 10%, *Madhu* 3% and Glycerin 2%.

**PROPERTIES OF GHRITKUMARI:** *Ghrithkumari* as stated by *Acharyas* in classical texts acts as *Rasayan* for *Netra, Vishvatnashak, Pittrakt Shamak* properties<sup>[16]</sup> and *Sheet Veerya, Tikta* and *Madhur Rasa* pacifying the predominant *doshas* and the symptoms as blurred vision, burning sensation, redness, dryness of eyes, headache. *Rasayan*<sup>[17]</sup> (i.e. antioxidant) properties of *Ghrithkumari* helps in relieving the symptoms related to vision as it acts by providing strength to *Drishti*.

**PROPERTIES OF MADHU:** *Madhu* is also mentioned in classical texts as *Chakshushya, Vranshodhak, Ropak, Prasadak*<sup>[18]</sup>, having *Tridoshshamak* properties and *Madhur Rasa, Kashaya Anurasa, Laghu & Picchil Guna*<sup>[19]</sup> pacifying the predominant *doshas* and symptoms as redness, burning sensation and acts as eye tonic.

**PROPERTIES OF GLYCERIN:** Glycerin is used as a carrier for other medications as it does not make detrimental chemical interactions with other substances. It stays inert without changing the properties of whatever it is used with. It enhances the lubricant properties of lubricants for eyes and having capacity to absorb moisture and retaining it for a long. Also reduces evaporation.

## CONCLUSION

1. DES appears to be similar disease entity to the *Shushkakshipaka*. The etymology aetiology, pathogenesis and clinical features of both correlate immensely.
2. The drug *Ghrithkumaryadi Aschyotan*(drops) gives relieve in various symptoms of Dry Eye like Foreign body sensation, Burning Sensation, Dryness, Pain, Itching, Redness and Transient Blurring of vision.
3. *Ghrithkumaryadi Aschyotan*(drops) is effective in reliving subjective criteria of the disease and also has significant effect on objective clinical tests.
4. During the course of trial and after withdrawal no adverse effect were noted.

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