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# **Research Article**

# A CLINICAL STUDY ON EFFICACY OF *JIVANIYA GHRITAPANA* IN *SHUSHKAKSHIPAKA* (DRY EYE SYNDROME)

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Article info	ABSTRACT
Article History:	Dry eye syndrome is a disease commonly seen in all age groups with a greater ration in
Received: 27-05-2022	elderly population. Large scale studies have determined that increasing age, female sex,
Revised: 12-06-2022	and Asian race are all associated with higher DED prevalence. Their occurs tear deficiency
Accepted: 22-06-2022	and ocular surface disorders, which produces symptoms like discomfort, visual
<b>KEYWORDS:</b> Shushkakshipaka, Dry eye syndrome, Ghritapana.	disturbance and tear film instability. Clinically and etymologically, similar entity to Dry eye syndrome is <i>Shushkakshipaka</i> . In modern ophthalmology, conventional approach for Dry eye syndrome is lubricating eye drops which are not satisfactory. Ayurveda has a holistic approach to deal with this problem. This clinical study was done to evaluate the effect of <i>Jivaniya Ghritapana</i> in <i>Shushkakshipaka</i> (dry eye syndrome). An open clinical trial for 10 patients was planned. They were presenting with clinical features of <i>Shushkakshipaka</i> (dry eye syndrome). <i>Snehapana</i> was done in all patients with <i>Jivaniya</i> <i>Ghrita</i> . <b>Results</b> : On assessing the selected criteria, significant results were found in subjective parameters like <i>Rukshta</i> (feeling of dryness), <i>Gharshana</i> (gritty sensation), <i>Daruna vartmakshi</i> (hardness of eyelids), <i>Karachaunmilana</i> (difficulty in opening and closing of eyes), <i>Daha</i> (burning sensation) & intolerance to light. Significant result was found in all objective parameters. <b>Conclusion</b> : Thus we can conclude that, for successful treatment <i>Shushkakshipaka</i> (Dry Eye Syndrome), <i>Snehapana</i> can be advised in such patients.

#### **INTRODUCTION**

Dry eye is a multifactorial disease of the ocular surface characterized by a loss of homeostasis of the tear film, and accompanied by ocular symptoms, in which tear film instability, and hyperosmolarity, ocular surface inflammation and damage and neurosensory abnormalities play etiological roles<sup>[1]</sup>. Large scale studies have determined that increasing age, female sex, and Asian race are all associated with higher DED prevalence<sup>[2]</sup>. It is characterized by dryness, grittiness, blurring of vision, burning sensation, stinging sensation, mucoid discharge, photophobia, etc<sup>[3]</sup>.

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In Ayurvedic texts, clinical features of Shushkakshipaka can be remarkably correlated with characteristic features of dry eye syndrome. Shushkakshipaka is one among the Sarvagata, Sadhva Netra Roga. It is characterized<sup>[4]</sup> by *Vishushkta* (dryness), *Aavila* darshanam (blurred vision), Koonitam (narrowing of palpebral aperture), Daruna ruksha vartma (hardness and roughness of eyelids), Sudarunam yata pratibodhanam (difficulty in opening and closing of eve). Gharshana (gritty sensation), Paka (inflammation), Updehavata (stickiness), Toda-Bheda (pain sensation), *Sheetecha* (liking for cold)<sup>[5]</sup>, Sandahaytein (burning sensation)<sup>[6]</sup>. It is described as Vataja according to Acharya Sushruta<sup>[7]</sup>, Vata-pittaja according to Acharya Vagbhata<sup>[8]</sup>, and Vata-Raktaja netra vikara, according to Acharya Karala, Madhav. Many contributory factors affects the severity of dry eye syndrome. It may be anatomical features, autoimmune disease, environmental surroundings, contact lens use, unmodified life styles, hormonal

changes, chronic inflammation, infection, iatrogenic factors, such as medications or surgery.<sup>[9]</sup> With the advancing age, the increasing prevalence of the disease decreases the quality of life. In modern science, Dry eye syndrome is treated with artificial tears, ointments, gels, topical antibiotics, oral tetracycline, biological tear substitutes, etc<sup>[10]</sup>. Many researchers have been carried out, but the curative treatment of the disease is still not known. Only palliative measures are available, which is in the form of artificial tears solutions. Patient got dependent on it for lifelong. Later on these palliative measures also get fail, due to preservative induced damage to the corneal epithelium.

In Ayurveda, there are various treatment modalities for *Shushkakshipaka*. It includes both local as well as systemic measures. *Ghritapana* is indicated as a first line of treatment for *Shushkakshipaka* along with other topical regimes<sup>[11]</sup>. In *Shushkakshipaka*, lack of proper *Rasa dhatu* formation leads to depletion of *Ashru* (tears), therefore systemic administration of *Ghrita* is essential for normalization of *Rasa dhatu*. Hence the present study is done to evaluate the effect of *Jivaniya Ghritapana* in the management of *Shushkakshipaka* (dry eye syndrome).

# **AIMS AND OBJECTIVES**

To evaluate the effect of *Jivaniya Ghritapana* in *Shushakshipaka* (Dry Eye Syndrome).

# **MATERIAL AND METHODS**

**Selection of Patients:** Patients presenting with clinical features of *Shushkakshipaka*- Dry Eye Syndrome were selected from the OPD & IPD of P.G. Dept. of Shalakya Tantra, Rishikul Campus Haridwar. A total of 10 patients were registered irrespective of their sex, religion, occupation, education etc.

# Plan of the Study

- 1. Criteria for selection of patients
- 2. Criteria for diagnosis
- 3. Study design
- 4. Criteria for assessment.
- 5. Follow up study

# Criteria for Selection of Patients Inclusion Criteria

- Age 20-60 years
- Patients presenting with signs and symptoms suggestive of dry eye syndrome like irritation, foreign body sensation, feeling of dryness, itching, non-specific ocular discomfort and classical symptoms of *Shushkakshipaka*.
- Visual Acuity 6/6 (with or without glasses)
- Tear film break up time less than 10 second.
- Schirmer 1<sup>st</sup> test positive <15 mm
- Fluorescein staining positive.

# **Exclusion Criteria**

- Patients not willing to participate in the study.
- Systemic diseases DM, HTN, R.A.
- Patients having infective eye diseases corneal ulcer, trichiasis, dacryocystitis, acute conjunctivitis etc.
- Patients suffering from specific eye lid disorders like skin allergies, ectropion, entropion, lagophthalmos, etc.
- Patients having any fundus pathology like optic atrophy, retinal disorder, diabetic retinopathy, hypertensive retinopathy, papilledema, etc.

# Withdrawal Criteria

- Personal matters.
- Inter current illness.
- Cases complicated with superadded infections

# Criteria for Diagnosis

# Subjective Parameter

- *Rukshta* (feeling of dryness)
- Gharshana (gritty sensation)
- Aviladarshanam (blurring of vision)
- Darunvartmakshi (hardness of eyelids)
- *Karachaunmilana* (difficulty in opening and closing of eyes)
- *Daha* (burning sensation)
- Intolerance to light.

# **Objective** Parameter

- TBUT (Tear Film Break Up Time )
- Schirmer's 1<sup>st</sup> Test
- Fluorescein Staining

## **Functional Examination of Eyes**

External examination, visual acuity, slit lamp examination, fundoscopy.

# Investigations

- Blood sugar (fasting and PP)
- Erythrocyte sedimentation rate (ESR)
- Complete blood count
- Serum uric acid, Blood urea, Serum creatinine
- R.A factor
- Lipid profile test
- LFT

# Study Design

The method adopted in present study is open randomized clinical trial.

## Sampling

A total number of 10 patients with signs and symptoms of *Shushkakshipaka* (dry eye syndrome) was registered. Patients were advised *Snehapana* with *Jivaniya Ghrita* 15ml HS with milk for 28 days. Results of therapy were assessed on the basis of subjective & objective parameters.

Plan of Work: The study was carried out as follows. Proforma

On the basis of signs and symptoms of Shushkakshipaka and dry eye syndrome, especial proforma was prepared, to maintain the records of all **Criteria for Assessment** 

findings (before and after treatment) regarding the patients.

**Informed Consent:** The purpose of the study, nature of the study drugs, the procedures to be carried out and the potential risks and benefits were explained to the patients in detail. Thereafter their written consent was taken before starting the procedures.

Table 1: Subjective Parameters Were Assessed with the Help of Following Scoring Pattern							
	Rukshta (Feeling of dryness)	0- No Dryness					
		1- Occasional feeling of dryness					

	1- Occasional feeling of dryness
	1 Occasional lecting of all ylless
	2- Persistent does not disturb routine work
	3- Disturb routine work
Gharshan (Gritty sensation)	0- No Gritty sensation
	1- Occasional Gritty sensation
	2- Persistent does not disturb routine work
	3- Disturb routine work
Avildarshanam (Blurring of vision)	0- No Blurring of vision
	1- Occasional Blurring of vision
	2- Persistent does not disturb routine work
	3- Disturb routine work
Daruna vartmakshi (Hardness of	0- No Hardness of eyelids
eyelids)	1- Occasional hardness of eyelids
1.al	2- Persistent does not disturb routine work
me	3- Disturb routine work
Karachounmilana (Difficulty in	0- No difficulty in opening and closing of eye
opening and closing of eye)	1- Occasional difficulty in opening and
ITE	closing of eye
24.922	2- Persistent does not disturb routine work
	3- Disturb routine work
(Daha) Burning sensation	0- No burning sensation
	1- Mild burning sensation
	2- Persistent does not disturb routine work
	3- Disturb routine work
Intolerance to light	0- No Intolerance to light
1	1- Occasional intolerance to light
	<ol> <li>Persistent does not disturb routine work</li> <li>Disturb routine work</li> </ol>

## Table 2: Objective Parameters were Assessed with the Help of Following Scoring Pattern

TBUT Test (Tear Film	0- Normal >10 sec				
Break Up Time)	• Mild >8sec and $\leq$ 10 sec				
	2- Moderate >5sec and ≤ 8sec				
	3- Severe ≤ 5sec				
Schirmer 1 <sup>ST</sup> Test	0- Normal >15mm				
	- Mild >8mm and ≤15mm				
	2- Moderate >4mm and ≤8mm				
	3- Severe ≤4mm				
Fluorescein Staining	0- No staining of corneal epithelial surface				
	<ol> <li>Staining occupying ≤1/3 of corneal epithelial surface.</li> </ol>				
	2- Staining occupying >1/3 and $\leq 1/2$ of corneal epithelial surface				
	3- Staining occupying >1/2 of corneal epithelial surface.				

# **Statistical Analysis**

Wilcoxon's signed rank-Test (W-value) was applied to the statistical data

# **OBSERVATIONS AND RESULTS**

Out of all 10 patients registered for the present study maximum number of patients i.e. 60% belonged to 20-30 years Age group, 70% were Female, 90% were from Hindu religion, 50% were students, 50% were Post-graduated, 40% were from Upper middle class followed by 40% from Poor class. In terms of *Prakriti*, maximum patients i.e., 70% were having *Vataja-Pittaja prakriti*. In chronicity, 60% patients were having chronicity of less than one year.

Chief complaints reported were feeling of dryness 100% (R/E & L/E), gritty sensation 90% (R/E & L/E), blurring of vision 40% (R/E & L/E), hardness of eyelids 100% (R/E & L/E), difficulty in opening and closing of eye 90% (B/E), burning sensation 100% (B/E), intolerance to light 60% (B/E).

Objective parameters wise distribution showed Schirmer's  $1^{st}$  test reading 100 % (B/E), TBUT 100% (B/E), and Fluorescein staining 60% in RE and 70% in LE.

			(BT-A	T)	Follow up (AT-30 Day)					
Parameters	BT	AT	30 day Median	Wilcoxon Signed Rank W	P- value	% Effect	Result	Wilcoxon Signed Rank W	P- Value	Result
Feeling of dryness RE	2	1	1	2.889	< 0.05	66.66	Sig	1.727	>0.05	NS
Feeling of dryness LE	2	1	1	2.889	< 0.05	66.66	Sig	1.990	< 0.05	Sig
Gritty sensation RE	1.5	0	1	2.792	< 0.01	88.23	Sig	2.000	< 0.05	Sig
Gritty sensation LE	1.5	0	1	2.792	< 0.01	88.23	Sig	2.000	< 0.05	Sig
Blurring of vision RE	0	0	0	1.000	>0.05	25	NS	-	>0.05	NS
Blurring of vision LE	0	0	0	1.000	>0.05	25	NS	-	>0.05	NS
Hardness of eyelids RE	1	0.5	1 ]v	2.920	< 0.01	62.5	Sig	1.732	>0.05	NS
Hardness of eyelids LE	1	0	1 1	3.051	<0.01	68.75	Sig	2.000	<0.05	Sig
Difficulty in opening and closing of eyes RE	1	0	0.5	3.000	< 0.01	75	Sig	1.732	>0.05	NS
Difficulty in opening and closing of eyes LE	1	0	0.5	3.000	<0.01	75	Sig	1.732	>0.05	NS
Burning sensation RE	1	0	1	2.862	< 0.01	80	Sig	2.236	>0.05	NS
Burning sensation LE	1	0	1	2.862	< 0.01	80	Sig	2.449	>0.05	NS
Intolerance to light RE	1	0	0	1.985	< 0.05	58.33	Sig	1.000	>0.05	NS
Intolerance to light LE	1	0	0	1.985	< 0.05	58.33	Sig	1.000	>0.05	NS

## Table 3: Statistical Analysis Showing the Result on Subjective & Objective Parameters

 Table 4: Statistical Analysis Showing the Result of Therapy on Objective Parameters

Median				(BT-AT)				Follow up(AT-30 day)			
Objective Parameters	вт	АТ	30 day Median	Wilcoxon Sign Rank W	P- value	% Effect	Result	Wilcoxon Sign Rank W	P- value	Result	
Schirmer 1st test RE	2	AI 1	1.5	2.407	0.01	42.10	Sig	1.342	>0.05	Sig	
		1					0				
Schirmer 1st test LE	2.5	2	2	2.423	0.01	29.16	Sig	1.414	>0.05	NS	
Tear Film Break											
Time RE	2.5	2	2	2.423	0.01	30.43	Sig	1.342	>0.05	NS	
Tear Film Break											
Time LE	2.5	2	2	2.423	0.01	29.16	Sig	0.577	>0.05	NS	
Fluorescein stain RE	1	0	1	1.732	>0.05	37.5	NS	1.414	>0.05	NS	
Fluorescein stain LE	1	1	1	1.414	>0.05	18.18	NS	1.000	>0.05	NS	

## DISCUSSION

#### Effect of therapy

# Feeling of Dryness

Before treatment median score of dryness was 2 in right eye and 2 in left eye which after treatment reduced to 1 in both right and left eye with a relief of 66.66% in right eye and left eye which is statistically significant (P<0.05).

## **Gritty Sensation**

Before treatment median score of Gritty sensation was 1.5 in right eye and 1.5 in left eye which after treatment reduced to 0 in both right and left eye with a relief of 88.23% in right eye and left eye which is statistically significant (P<0.01).

## **Blurring of Vision**

Before treatment median score of blurring vision was 0 in right eye and 0 in left eye which after treatment remains 0 in both right and left eye. This way treatment provide 25% relief in right eye and left eye but it is statistically not significant (p>0.05). Blurring of vision was found only in 40% patients.

## **Hardness of Eyelids**

Before treatment median score of hardness of eyelids was 1 in right eye and 1 in left eye which after treatment reduced to 0.5 in right eye and 0 in left eye with a relief of 62.5% in right eye and 68.75% in left eye which is statistically significant (P<0.01).

## Difficulty in Opening and Closing of Eyes

Before treatment median score of Difficulty in opening and closing of eyes 1 in right eye and 1 in left eye which after treatment reduced to 0 in both right and left eye with a relief of 75% in right eye and left eye which is statistically significant (P<0.01).

## **Burning Sensation**

Before treatment median score of Burning sensation was 1 in right eye and 1 in left eye which after treatment reduced to 0 in both right and left eye with a relief of 80% in right eye and left eye which is statistically significant (P<0.01).

## **Intolerance to Light**

Before treatment median score of Intolerance to light was 1 in right eye and 1 in left eye which after treatment reduced to 0 in both right and left eye with a relief of 58.33% in right eye and left eye which is statistically significant (P<0.05).

## Schirmer's 1st test

Before treatment median score of Schirmer's  $1^{st}$  test was 2 in right eye and 2.5 in left eye which after treatment reduced to 1 in right eye and 2 in left eye with a relief of 42.10% in right eye and 29.16% in left eye which is statistically significant (P<0.05).

## Tear Film Break up Time

Before treatment median score of Tear Film Break Up Time was 2.5 in right eye and 2.5 in left eye which after treatment reduced to 2 in both right and left eye with a relief of 30.43% in right eye and 29.16% in left eye which is statistically significant (P<0.05).

## **Fluorescein Staining**

Before treatment median score of Fluorescein staining was 1 in right eye and 1 in left eye which after treatment reduced to 0 in right eye and remains 1 in left eye. This way treatment provide with a relief of 37.5% relief in right eye and 18.18% relief in left eye but it is not statistically significant (P>0.05).

## Probable Mode of Action of Jivaniya Ghritapana

The Jivaniya aushadhi present in Jivaniya Ghrita possess the property of Madhura rasa, Snigdha, Guru guna, Sheeta veerya, Madhura vipaka and having Vatapitta shamaka property predominantly<sup>[12]</sup>.

*Shushkakshipaka* is *Vata/Vata-Pitta* predominant condition where Ashru has been depleted due to the lack of proper *Rasa dhatu* formation. The contents<sup>[13]</sup> present in *Jivaniva Ghrita* (Vidarikanda<sup>[14]</sup>, Shatavari, Ashwagandha, Mudgaparni, Mashaparni, Jeevanti, Mulethi), Goghrita and Godugdha is having the properties like *Dhatu Vardhana*<sup>[15]</sup>, *Pushtivardhana*, Dhatu-Poshana,Dhatu-Prasadana, Agnibala vardhanam, etc. Hence for normalization of Rasa dhatu, systemic administration of medicated Ghrita is essential. After Pana, the Ghrita gets absorbed into the systemic circulation. Due to *Chakshushya* properties, it has an affinity towards ocular tissues and due to its lipid soluble property crosses blood ocular barriers. By active and passive transport the ingredients of the Ghrita crosses the cell membranes and reach the targeted tissue. The drug is having the properties like anti-inflammatory<sup>[16]</sup>, anti-bacterial<sup>[17]</sup>, antioxidant<sup>[18]</sup>, antimicrobial, rejuvenating and detoxifying property<sup>[19]</sup>, thereby correcting the abnormalities of ocular tissues, lubricating and rejuvenating it.

## CONCLUSION

*Jivaniya Ghritapana* has shown significant result in reduction of sign and symptoms of *Shushkakshipaka*. Oral administration of *Sneha Dravya* prevents further vitiation of *Vata*, provides proper nourishment and lubrication of ocular tissues. No adverse effect was observed during the study. However, study should be carried out in large number of sample and for longer duration to establish the efficacy of *Snehapana*. Thus, it can be concluded that *Snehapana*, as a systemic and holistic approach of Ayurvedic system of medicine provide significant relief in subjective and objective parameters of the disease *Shushkakshipaka* (dry eye syndrome)

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