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A CLINICAL STUDY ON THE ROLE OF TARPANA KRIYAKALPA WITH YASHTIMADHU GHRITA IN THE MANAGEMENT OF SHUSHKAKSHIPAKA W.S.R. TO DRY EYE SYNDROME

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ABSTRACT
The diseases of the eye are much more important than any other physical disability since the loss of vision completely disables the patient. The most disastrous result of ocular disease is blindness. *Shushkakshipaka* is mentioned in the classical literature of *Ayurveda* under *Sarvgata Netraroga*, i.e. affecting all parts of eye, very similar to Ocular surface disease i.e, Dry Eye Syndrome (DES) in modern ophthalmology. It has been categorized as an *Aushadha sadhya. Acharya Sushruta* and *Acharya Vagbhatta* have given the detailed description of this disease mentioning its causative *Doshas*, clinical features and management. *Ayurveda* has highlighted unique therapeutic procedures- *Netra Kriyakalpas* are among these procedures practiced in *Shalakya Tantra*. These have major role in overcoming of the disease and arresting its progression and overcoming the complications.Here the concept of *Tarpan Kriya Kalpa* with *Yashtimadhu Ghrita* in the management of Dry Eye Syndrome has been taken from the *Ashtang Hridaya Uttar Sthana*. 15 patients with clinical features of *Shushkakshipaka*/DES and with at least 1 positive clinical test for DES were included in study. A significant relief was found in various sign and symptoms of DES.

KEYWORDS: *Sarvagata Netra Roga, Shushkakshipaka, Netra Kriyakalpas,* Dry Eye Syndrome (DES).

INTRODUCTION
The main goal of *Ayurveda* is to provide healthy life to individuals along with prevention and cure of disease. Persons desirous of long life, which is the means for achieving *Dharma* (righteousness), *Artha* (wealth) and *Sukha* (happiness) should have utmost faith in the principles of *Ayurveda*. *Shushkakshipaka* is mentioned in classical literature of Ayurveda under *Sarvagata Netra Rogas,*[1] the Diseases affecting all parts of the eye. It is *Vataja* disease according to *Acharya Sushruta,*[2] *Vata–Pittaja* vitiated condition by *Acharya Vagbhatt.*[3] and *Vata–Raktaja* according to *Karala*. By analyzing these different opinions it is clear that vitiation of *Vata, Pitta, Rakta* play the major role in the disease pathology.

The disease affecting all parts of the eye characterised by *Paka* (inflammation) of the *Akshi* due to *Sushkata* (dryness) caused by altered coherence of *Ashru* with ocular surface or lack of *Ashru.*

यत् कूणितं दारुणरुक्षवर्त्म विलोकने चाविलदर्शनं यत्।
सुदारुणं यत् प्रतिबोधने च षुष्काक्षिपाकोपहतं तदक्षि ।[4]

The pathogenesis is same as that of general eye diseases as mentioned in *Su. Ut. 1/20* and *As. Hr. Ut. 8/1,2*. Foods and habits which are harmful to eyes i.e. *Achaksusya Aahara Vihara* vitiate the *doshas* which propagate through the channels *(Sira)* towards head (the *Uttamanga*) and enter the parts of the eye to produce ailment.[5] Its description is very much similar to the disease 'Dry Eye Syndrome' described in modern literature.

'Dry eye is a multifactorial disease of the ocular surface characterized by a loss of homeostasis of 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'.[6]

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 Role of Tarpana Kriyakalpa with Yashtimadhu Ghrita in the Management of Shushkakshipaka w.s.r. to Dry Eye Syndrome''*

AIMS AND OBJECTIVES

1. To study conceptual resemblance between *Shushkakshipaka* and Dry Eye Syndrome (DES).
2. To evaluate the comparative effect of *Tarpana Kriya Kalpa* with *Yashtimadhu Ghrita* on DES.
3. To study the side/toxic effect of the drug, if any.
4. To standardize the preparation of *Yashtimadhu Ghrita*.
5. To provide cheap, safe and effective treatment.

MATERIALS AND METHODS

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 15 of patients were registered. Informed consent was taken from all.

Inclusion Criteria

1. Patients willing for trial.
2. Patients presenting with signs and symptoms of *Shushkakshipaka/* DES with at least 1 positive diagnostic test.

Exclusion Criteria

1. Patients not willing for trial.
2. Infective conjunctivitis / Keratitis.
3. Disorders of lid globe apposition.
4. Patients suffering from specific ocular / systemic disease.

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. Mucoid discharges (*Updeha*)
0 - No mucoid discharge
1 - Discharge not requiring mopping
2 - Discharges requiring intermittent mopping
3 - Discharges causing sticking of eyelashes

4. Transient blurring of vision (*Aavila-darshana*)
0 - No blurring
1 - Transient 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 - Mild pain
2 - Moderate pain
3 - Severe pain

7. Photophobia (*Kunita-vartma*)
0 - No photophobia
1 - Photophobia only during exposure to sunlight.
2 - 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 - Crusting of eyelids

11. Eyelids stuck (*Kricchronmeela-neemeelnam*)
0 - No stucked eyelids
1 - Eyelids stuck on waking up

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 bimicroscopy
2 - Spotting of mucin debris/strands in the tear film in diffuse illumination (torch light examination)

2. Conjunctival congestion
0 - No congestion
1 - Mild congestion (Congestion with clear pattern of blood vessels)
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 ~ 1mm
1 - Concave tear meniscus, height <0.5 mm
2 - 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 11-15sceonds
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

4. Rose Bengal Staining:

0 - Staining Absent
1 - Fine punctate staining in interpalpebral area
2 - Moderate staining of entire exposed part
3 - Severe confluent staining on exposed bulbar conjunctiva & blotchy confluent staining on cornea

Criteria For Over All Assessment

The assessment was done by adopting the following scoring pattern

- **Cured:** 100 % relief in signs and symptoms.
- **Marked improvement:** More than 75% improvement in signs and symptoms was recorded as marked improvement.
- **Moderate improvement:** 51% to 75% improvement in signs and symptoms was considered as moderate improvement.
- **Mild improvement:** 26% to 50% improvement in signs and symptoms was considered as mild improvement.
- **Unchanged:** Up to 25% reduction in signs and symptoms was noted as unchanged.

DRUG REVIEW

Yashtimadhu Ghrita

षुष्काक्षिपाके हविषः पानमक्ष्णोष्च तर्पणम्।
घृतेन जीवनीयेन नस्यं तैलेन वाऽणुना।
परिषेको हितश्चात्र पयः कोष्णं ससैन्धवम्। (अ0 ह. उ. स्थान–16/28)[7]

Table Presentation of Pharmacodynamic Properties of *Yashtimadhu Ghrita*.

Drug name	Rasa						Guna					Virya		Vipaka			Dosha Karma		
	M	*A*	*L*	*K*	*T*	*K.S*	*L*	*G*	*R*	*T*	*S*	*S*	*U*	*M*	*A*	*K*	*V*	*P*	*K*
Yashtimadhu[8]	+	-	-	-	-	-	-	+	-	-	+	+	-	+	-	-	+	+	-
Ghrita[9]	+	-	-	-	-	-	-	+	-	-	+	+	-	+	-	-	+	+	-

Method of preparation

Fresh well identified raw material of herbal drug was taken and dried properly.Firstly *Yavakutta* (coarse powder) of *Yashtimadhu* has been done. Then this coarse powder has been mixed with 8 times water and kept for one night. Then *Ghrita Paak* has been done with *Yashtimadu Kalka* for next three days on *Madhyam Agni*. *Sneha Dravya* should be four times more than *Kalka Dravyas* and *Drava Dravyas* should be four times more than *Sneha Dravyas*. *Yashtimadhu Kalka* : G*hrita* : water was 1:4:16.All the active principle of *Dravya* gets inculated in *Ghrita*.After filtering it will be preserved.

GROUPING

15 patients with clinical features of *Shushkakshipaka*/DES and at least 1 positive clinical test for DES were included in study from the *Netra Roga* OPD of *Shalakya Tantra* Deptt. R.G.G.P.G. Ayu. Hospital, Paprola, Distt. Kangra (H.P.), and treated in single trial group**.**

Drug Dose, Formulation and Schedule

Drug: *Yashtimadhu Ghrita.*
Mode of administration: *Tarpan Kriya Kalpa.*
Duration: 7 days.
Follow up: 7 days after the completion of trial.

STATISTICAL ANALYSIS

The information regarding demographic data was given in percentage. 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 in the group 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 <0.001or <0.01, significant for p<0.05 and insignificant for p >0.05.

OBSERVATION

In the present study maximum numbers of patients (40%) were in the age group of 61 and above, followed by 41-60 age group (33.33%) and 21-41 age group (20%). Majority of patients in this study were females (66.66%) as compared to males (33.33%). Most of patients registered were Hindus (100%) Majority of patients were married (80%) followed by (20%) of unmarried patients. The educational status of the present series reveals that 26.66% were graduate 26.66% patients were having higher secondary education, 13.33% patients were having secondary education, 13.33% were primary educated and 20% of the patients were illiterate. On considering the nature of occupation it was observed that maximum number of patient were housewife (33.33%). In this study most of the patients belonged to

middle economical class (53.33%), followed by lower economic class (33.33%) and High economic status (13.33%). 86.66% patients were residents of rural area. Maximum number of patients were on mixed type of diet (53.33) followed by patients taking vegetarian diet 46.66%.Majority of patients were having normal appetite (80%) as compared to reduced appetite (20%). 26.66% patients were addicted to smoking/tobacco and 26.66% to alcohol while 40% patients were not having any addiction. In the present study maximum number of patients were of *Vata-Pittaja Prakriti* (60%) followed by *Vata -Kaphaja Prakriti*(20%) and *Pitta-Kaphaja Prakriti* (20%). As the disease is *Vata-Pitta* dominating, the person with similar *prakriti* are more prone to develop disease. 46.66% of patients were spending more than 2 hours in front of V.D.U. These activities require constant staring which reduces blink rate significantly. In the present study, incidence of symptoms was found in following orders: FBS (93.33%), Burning sensation (80%), Mucoid Discharge (46.66%), Transient blurring of Vision (53.33%), Dryness (73.33%), Pain (60%), Photophobia (46.66%), Itching (60%), Redness (40%), Crusting (33.33%), Eyelid stuck (20%) patients. Tear meniscus was abnormal in 66.66%, Mucus strands/ debris was observed in 46.66% and Conjunctival congestion was noticed in 66.66% patients. Schirmer-1 test positive in 73.33%, T-BUT abnormality in 53.33%, Fluorescein staining in 40% and Rose Bengal staining in 26.66%.

Effect of therapy

Effect of *Tarpana karma* with *Yashtimadhu Ghrita* on Assessment Criteria's in 15 patients)

Parameters	N	Mean Score		D	%age Relief	SD ±	SE±	T	P
		BT	AT						
FBS	14	2.53	0.53	2.00	79.05	0.65	0.169	11.83	<0.001
Burning Sensation	12	1.80	0.40	1.40	77.77	0.828	0.214	6.54	<0.001
Mucous Discharge	7	0.73	0.26	0.46	62.75	0.516	0.133	3.50	<0.05
Transient Blurring	8	0.53	0.20	0.33	62.26	0.48	0.126	2.64	<0.05
Dryness	11	1.80	0.40	1.40	77.77	0.986	0.254	5.501	<0.001
Pain	9	1.40	0.40	1.00	71.42	0.92	0.23	4.18	<0.001
Photophobia	7	0.73	0.26	0.46	63.01	0.51	0.133	3.50	<0.05
Itching	9	1.26	0.40	0.86	68.25	0.834	0.215	4.02	<0.001
Redness	6	0.93	0.33	0.60	64.51	0.91	0.235	2.553	<0.001
Crusting	5	0.33	0.20	0.13	39.39	0.352	0.090	1.46	>0.05
Eyelid Stuck	3	0.20	0.13	0.06	30.00	0.258	0.066	1.00	>0.05
Tear Meniscus	10	1.06	0.86	0.20	18.86	0.414	0.107	1.871	>0.05
Mucin Debris	7	0.66	0.46	0.20	30.30	0.41	0.107	1.87	>0.05
Conjunctival Congestion	10	1.33	0.40	0.93	69.92	0.79	0.206	4.52	<0.001
Schirmer- I	11	1.73	1.26	0.46	26.58	0.51	0.133	3.50	<0.05
	11	1.40	0.73	0.66	47.14	0.724	0.187	3.56	<0.05
Fluorescein Stain	6	0.80	0.60	0.20	25	0.41	0.107	1.87	>0.05
Rose Bengal Stain	4	0.40	0.26	0.13	32.50	0.352	0.090	1.468	>0.05

1. **F.B.S. -** The initial mean score of FBS was 2.53 which reduced to 0.53 after treatment. The study shows that percentage relief in foreign body sensation was 79.05%. Statistical analysis revealed that the improvement was highly significant (p <0.01).
2. **Burning sensation-** The study shows that initially burning sensation was present in 80% of cases. The mean score was 1.80 which became 0.40 after the treatment. The Relief in burning sensation was 77.77 %. Statistical analysis revealed that the improvement was highly significant (p <0.01).
3. **Mucous discharge-** The mean score of 0.73 before treatment became 0.26 after treatment. Relief in mucous discharge was 62.75%. Statistical analysis revealed that the improvement was statistically significant (p<0.05).
4. **Transient blurring**- The study shows that initially transient blurring was present in 53.33% of cases. The initial mean score was 0.53 which reduced to 0.20 after the treatment. Relief in transient blurring was 62.75%. Statistical analysis revealed that the improvement was statistically significant (p<0.05).
5. **Dryness**- Initially dryness was present in 73.33% of patients. The mean score of 1.80 before treatment became 0.40 after treatment. Relief in dryness was 77.77%. Statistical analysis revealed that the improvement was highly significant (p <0.01).
6. **Pain**- The study shows that initially pain was present in 60.00% of cases. The mean score was 1.40 which reduced to 0.40 after the treatment. Relief in transient blurring was 71.42%. Statistical analysis revealed that the improvement was highly significant (p <0.01).
7. **Photophobia**- The mean score of 0.73 before treatment became 0.26 after treatment. Relief in photophobia was 63.01%. Statistical analysis revealed that the improvement was statistically significant (p<0.05).

8. **Itching-** The initial mean score of itching was 21.26 which reduced to 0.40 after treatment. The study shows that percentage relief in foreign body sensation was 68.25%. Statistical analysis revealed that the improvement was highly significant (p <0.01).
9. **Redness**- The mean score of 0.93 before treatment became 0.33 after treatment. Relief in redness was 64.51%. Statistical analysis revealed that the improvement was statistically significant (p<0.05).
10. **Crusting**- The study shows that initially crusting was present in 33.33% of cases. The mean score was 0.33 which reduced to 0.20 after the treatment. Improvement in crusting was 39.39%. Statistical analysis revealed that the improvement was insignificant statistically (p>0.05).
11. **Eyelid stuck**- The mean score of 0.20 before treatment became 0.13 after treatment. Relief in the symptom was 30.00%. Statistical analysis revealed that the improvement was insignificant statistically (p>0.05).
12. **Effect on tear meniscus –** The mean score of 1.06 before treatment became 0.86 after treatment. Effect on tear meniscus was 18.86%. Statistical analysis revealed that the improvement was insignificant statistically (p>0.05).
13. **Effect on mucin strands**- The initial mean score of mucin strands was 0.66 which reduced to 0.46 after treatment. The study shows that percentage relief in foreign body sensation was 30.30%. Statistical analysis revealed that the improvement was insignificant statistically (p>0.05).
14. **Effect on conjunctival congestion**- The study shows that initially conjunctival congestion was present in 66.66% of cases. The mean score was 1.33 which reduced to 0.40 after the treatment. Relief in the symptom was 69.92%. Statistical analysis revealed that the improvement was highly significant (p <0.01).
15. **Effect on schirmer-1**- The initial mean score of schirmer-1 was 1.73 which reduced to 0.46 after treatment. The study shows that percentage improvement was 69.92%. Statistical analysis revealed that the improvement was significant statistically (p<0.05).
16. **Effect on T-BUT**- The mean score of 1.40 before treatment became 0.73 after treatment. Effect on T-BUT was 47.14%. Statistical analysis revealed that the improvement was significant statistically (p<0.05).
17. **Effect on Fluorescein stain**- Initially fluorescein stain was present in 40.00% of patients. The mean score of 0.80 before treatment became 0.60 after treatment. Improvement in the symptom was 25.00%. Statistical analysis revealed that the improvement was insignificant statistically (p >0.05).
18. **Effect on Rose-Bengal stain**- The mean score of 0.40 before treatment became 0.26 after treatment. Effect on Rose-Bengal staining was 32.50%. Statistical analysis revealed that the improvement was insignificant statistically (p>0.05).

Overall effect of therapy

- No patients were completely cured.
- 1 (6.66%) patient was markedly improved.
- 12 patients (80%) were moderately improved.
- 2 patients 13.53%were mildly improved.

DISCUSSION

Shushkakshipaka a well-known disease of eye which comes under *Sarvagata Netra Roga*. Eyes are one of the most powerful tool that anyone can have hence all efforts should be made to protect the eyes. Dry Eye Syndrome a common ophthalmic condition, it is a chronic ocular pathology that manifests as a plethora of symptoms such as burning, photophobia, tearing, and grittiness. Patients with DES experience difficulties in daily routine activities thus compromising their quality of life. Due to its variegated aetiology, multifactorial pathophysiology, lack of gold standard diagnostic procedure and absence of any curative modality it presents a great challenge to physician's skills. Thus making it a highly prevalent yet largely undiagnosed condition. Though perceived by many, as just little more than ocular irritation it results in considerable ocular discomfort resulting in frequent clinic visits and can result in visual morbidity if left untreated. In *Shushkakshipaka* i.e. Dry Eye Syndrome, patients are having complaints of ocular irritation, foreign body sensation, burning sensation, a stringy mucous discharge, transient blurring of vision, itching, tired and heavy feeling, redness, pain and dryness. By all these symptoms, we can say that, there is predominance of *Vata* and *Pitta Dosha*. On the bases of *Shrotodushti Lakshana* it can be concluded that *Shushkakshipaka* is originated by *Sang* type of *Shrodushti.* Treatment wise it is a *Aushadha Sadhya Sarvagata Vayadhi.* In this disease *Vitiated Doshas* i.e. *Vata and Pitta* affect *Rasa, Rakta Dhatu* and *Ashru* and *Akshi Sneha* hence the treatment should be *Vata Pitta shamaka and Rasa, Rakta Dhatu Prasadana* along with *Sneha Vardhana* effect. Many systemic and local therapeutic applications have been mentioned in *Ayurvedic* classics for the treatment of *Shushkakshipaka*[1111]. Among these *Yashtimadhu Ghrita* been selected in this study. The clinical trial drug "*Yashtimadhu Ghrita*" possesses predominance of *Madhura Rasa, Guru and Snigdha Guna, Sheeta Virya* and *Madhura Vipaka*. So the trial drug is *Vatapitta Shamaka* by virtue of its *Rasa, Guna and Vipaka*; and hence it disintegrates the pathology of the disease "*Sushkakshipaka"* which is *Vataj/Vata-Pittaj* in its manifestation.

CONCLUSION

The study was aimed with the objectives of study of *Shushkakshipaka* in context of Dry Eye, evaluation of effect and the side effects of the drug. In the present research work on the basis of facts, observation and result of drug and clinical studies, it can be concluded that The disease *Shushkakshipaka* results either due to

altered coherence of tears with ocular surface or deficiency of *Vaypata Ashru*. DES appears to be similar disease entity to the *Shushkakshipaka*. The etymology aetiology pathogenesis and clinical features of both correlate immensely. *Tarpana Karma* with *Yashtimadhu Ghrita* is effective in reliving subjective criteria of the disease whereas effect on objective clinical tests was not much satisfactory. Mild irritation was noticed on instillation of *Yashtimadhu Ghrita.* No adverse effects of therapy came into light during the course of trial.

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