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A CLINICAL STUDY TO EVALUATE THE EFFECT OF MAHOSHADH SARPI ANJANA IN THE MANAGEMENT OF SHUSHKAKSHIPAKA W.S.R. TO DRY EYE SYNDROME

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ABSTRACT

Context: Eyes are the gateways of external world, visual defects tantamount to the obliteration of the world. Shushkakshipaka is a Sarvgata roga, i.e. affecting all parts of eye. It has been categorized as an aushadha sadhya vyadhi i.e. curable by medication. Shushkakshipaka has an analogous term 'Dry Eye Syndrome' (DES) in modern literature. DES has caught the fancy of ophthalmologist today as it alone accounts for ¼ of ophthalmology clinic visits. DES is a highly prevalent (3.5-33% across different population) yet largely undiagnosed condition that can substantially affect the quality of life. If untreated DES can lead to visual morbidity. Despite the magnitude of problem no definitive cure is available for DES and palliative measures are inadequate too; with symptoms often improving without

achievement of cure causing frustration on the part of patient and physician. Thus the present study was undertaken to find a better solution of the Problem. **Aims & Objectives:** 1) To study conceptual resemblance between *Shushkakshipaka* and Dry Eye Syndrome (DES). 2) To evaluate the effect of *Mahoshadh Sarpi Anjana* on DES and *Shushkakshipaka*. **Material and Method:** 15 patients presenting with clinical features of *Shushkakshipaka*/DES were

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selected from *Shalakya Tantra* (Eye) O.P.D. of hospital affiliated to R.G.G.P.G. *Ayu*. College, Paprola (H.P.) In this study *Mahoshadh Sarpi Anjana* was given for L.A. twice a day for 15 days. **Results:** 30.77% patients were Markedly Improved, 69.23% were Moderately Improved.

KEYWORDS: Shushkakshipaka, Dry Eye Syndrome, Mahoshadh Sarpi Anjana.

INTRODUCTION

Shalakya Tantra holds a prime position among the eight specialties of Ayureda (Ashtanga Ayurveda). Shalkya Tantra encompasses in itself Otorhino-laryngiology and disease of head besides Ophthalmology. Amongst them ophthalmology is most important; as eyes are the gateways of external world, visual defects tantamount to the obliteration of the world. As mentioned by Acharya Charak as: Sarvendriyanam Chakshu Pradhanam. Acharya Sushruta has described 76 eye disease with their treatment both in medicinal and surgical way. Acharya Sushruta and Acharya Vagbhatta have given the detailed description of this disease mentioning its causative doshas, clinical features and management. Shushkakshipaka is one of the Vataja (Sushruta), Vata-pittaja (Vagbhat) Sarvgata Sadhya Netra Vikar. [1] The characteristic features of Shushkakshipaka mentioned by different Acharays in different texts are as^[2]- Koonitam (Narrowing of palpebral aperture), Daruna (hardness of eyelid), Avildarshanam (blurred vision), Sudarunam Yata Pratibodhanam (difficulty to open and close lids), Toda- Bheda (pain sensation), Updehavata (stickiness), Vishushkta (Dryness), Gharsha (foreign body sensation), Paka (inflammation), Sheetechha and Sandahaytein (Burning sensation). Shushkakshipaka has an analogous term 'Dry Eye Syndrome' (DES) in modern literature. Dry Eye Syndrome' (DES) defined as^[3] "A multifactorial disease of the tears and ocular surface that results in symptoms of discomfort, visual disturbance and tear film instability with potential damage to the ocular surface. It is accompanied by increased osmolarity of the tear film and inflammation of the ocular surface." If untreated DES can lead to visual morbidity. It may compromise the result of corneal, cataract and refractive surgery and successful contact lens fitting. While Modern ophthalmology is struggling to find a definite cure for DES Ayurvedic texts have given an elaborated account of Shushkakshipaka management. In lieu of above facts it was tempting to evaluate the effectiveness of in formulations mentioned classical Avurvedic texts for the Shushkakshipaka/DES; thus re-establishing the ancient therapy by means of thorough and intensive research.

MATERIALS AND METHODS

Aims and Objectives

- 1. To study conceptual resemblance between *Shushkakshipaka* and Dry Eye Syndrome (DES).
- 2. To evaluate the effect of Mahoshadh Sarpi Anjana on DES and Shushkakshipaka.

STUDY DESIGN: Open Ramdom Clinical Study.

Selection of Patients

15 Patients were selected randomly 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 etc. informed consent was taken from all.

Ethical committee ref. no- R.G.G.P.G. Ayu. College, Paprola (H.P.)/23.03.2011/Sr. No.-32

INCLUSION CRITERIA

- 1. Patients willing for trial.
- 2. Patients presenting with signs and symptoms of *Shushkakshipaka* and Dry eye syndrome and 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.

INVESTIGATIONS

Complete blood picture (Hb gm%, TLC, DLC, ESR, FBS), RA factor etc. to rule out any systemic disease.

PROCEDURE

Mahoshadh Sarpi Anjana for local application, twice in a day, was given to patients.

Study duration- 15 days therapy.

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CLINICAL ASSESSMENT

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
- 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
- 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

- O 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)
- Severe congestion (Congestion completely obscuring the pattern of blood vessels)

3. Marginal tear meniscus

- O Convex tear meniscus, height ~ 1mm
- Concave tear meniscus, height < 0.5 mm
- 2 Absent marginal tear strip

Objective clinical tests: Following system of grading was used for recording clinical tests readings.

1. Schirmer- I test

- O Schirmer strip wetting of >15mm <30 mm in 5 minutes
- 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

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

3. Fluorescein Staining

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

4. Rose Bengal Staining

- 0 Staining Absent
- Fine punctuate staining in interpalpebral area

- 2 Moderate staining of entire exposed part
- 3 Conjunctival and corneal staining

RESULTS AND DISCUSSION

Maximum number of patients in present study belonged to age group 41-60 years followed by 21-40 age group. In present study, 56.67% patients were females and 43.33% patients were males. In present study, 93.37% patients were Hindu and 03.33% patients were Sikh. In present study maximum number of patients were married (83.33%). Maximum number of patients in present study were secondary educated (33.33%) followed by post graduates (20%). Maximum number of patients were housewives (43.33%) followed by students and office Emp (14% each). 83.33% patients belonged to middle class followed by lower class(10%). In the present study, maximum number of patients (56.67%) were residents of urban area. Maximum number of patients were on mixed diet with minimal /no fats (33.33%) followed by patients on vegetarian diet with minimal/no fats (30%). Majority of patients were having normal appetite(86.67%). Majority of patients (63.33%) were having regular bowel habits followed by constipated (20%) and irregular bowel habits (13.33%%). In the present study 73.34% of patients having normal micturition while 13.33% were having either polyuria or burning micturition. In the present study 63.33% patients were having no addiction while 13.66% patients each were smoker and alcoholic. 50% were of Vata-Pittaja prakriti followed by Vata-Kaphaja prakriti (30%). Maximum number of patients spent >2 hours in front of VDU(46.66%) followed by 30% patients who spent 0-1 hour.

Symptoms of DES were found in decreasing order of percentage as: FBS (83.33%), Mucoid discharge(76.67%), Photophobia(66.67%), Transient Blurring of vision (63.33%), Itching (70.00%), Burning sensation (60.00%), Dryness (56.33%), Redness (53.33%), Eyelid stuck (43.33%), Pain (40.00%), Crusting (23.33%). In **objective** findings maximum number of patients were having Mucin Strands/debris in tear film(86.67%) followed by Conjunctival congestion (63.33%) and abnormal Tear meniscus (53.33%). **Clinical Tests** showed T-BUT abnormality in 93.33%, Schirmer-1 test positive in 63.33%, Fluorescein staining in 36.67% and Rose Bengal Staining in 20.00%.

Table no. 1: Effect of Therapy.

S. n.	Parameters	n	Mean		D	%age	CD .	SE:	4	
			BT	AT	D	Relief	SD ±	SE±	t	p
1.	FBS	13	3.69	.31	3.38	91.60	2.063	.572	5.92	< 0.001
2.	Burning Sensation	13	1.69	.15	1.54	91.11	1.854	.514	2.99	< 0.05
3.	Mucous Discharge	13	3.23	.46	2.77	85.76	1.739	.482	5.74	< 0.001
4.	Transient Blurring	13	2.15	.46	1.69	78.60	1.377	.382	4.43	< 0.01
5.	Dryness	13	2.77	.46	2.31	83.39	2.562	.711	3.25	< 0.01
6.	Pain	13	1.38	.46	.92	66.67	1.320	.366	2.52	< 0.05
7.	Photophobia	13	1.38	.46	.92	66.67	1.038	.288	3.21	< 0.01
8.	Itching	13	3.38	.62	2.77	81.95	1.922	.533	5.20	< 0.001
9.	Redness	13	1.23	.46	.77	62.60	1.536	.426	1.81	>0.05
10.	Crusting	13	.15	.00	.15	100.0	.555	.154	1.00	>0.05
11.	Eyelid Stuck	13	.92	.00	.92	100.0	1.038	.288	3.21	< 0.01
12.	Tear Meniscus	13	1.62	.54	1.08	66.67	1.382	.383	2.81	< 0.05
13.	Mucin Debris	13	1.92	.00	1.92	100.0	.8623	.239	8.04	< 0.001
14.	Conjunctival Congestion	13	1.69	.62	1.08	63.90	1.038	.288	3.74	< 0.01
15.	Schirmer- I	13	3.92	2.46	1.46	37.24	1.391	.386	3.79	< 0.01
16.	T-BUT	13	4.23	3.31	0.92	21.75	1.038	.288	3.21	< 0.01
17.	Fluorescein Stain	13	.85	.00	.85	100.0	1.519	.421	2.01	>0.05
18.	Rose Bengal Stain	13	.46	.00	.46	100.0	1.198	.332	1.38	>0.05

Analysis of above table gives the following points

Statistically Highly Significant relief (p<0.001,p<0.01) was found in FBS (%age relief=91.60%), Mucous Discharge(%age relief=85.76%), Itching (%age relief= 81.95%), Mucin debris (%age relief=66.67%), Schirmer-1 test (%age relief= 37.24%), TBUT (%age relief=21.75%), Transient Blurring (%age relief=78.60%), Dryness (%age relief=83.39%), Photophobia(%age relief=66.67%), Eyelid Stuck (%age relief=100%), Conjunctival Congestion(%age relief=63.90%).

Statistically Significant relief (p<0.05) was found in Burning Sensation (%age relief=91.11%), Pain(%age relief=66.67%), Tear Meniscus(%age relief=66.67%).

Statistically Insignificant relief (p>0.05) was found in Redness (%age relief= 62.60%), Crusting(%age relief=100%), Fluorescein Stain(%age relief=100%), Rose Bengal Stain(%age relief=100%)

Probable Mode of action of Mahoshadh Sarpi Anjana (Ayurvedic view)

The probable mode of action of drug can be understood as given below

a. On Dosha Dushti

There is Vata–Pitta pradhana Dosha dushti in Shushkakshipaka and Mahoshadh Sarpi Anjana is Vata-Pitta shamka too because it has Madhura Rasa, Madhura Vipaka, Sheeta virya which pacify Vata-Pitta. Snigdha Guna counters the Ruksha guna of Vata, Guru guna is Vata shamka, Sheeta Guna pacifies Pitta by countering the Ushna guna while Mridu guna is Vata-Pitta Shamka. Moreover Ghrita pacifies Vata by Sneha guna and Pitta due to its Madhura-Sheeta-Manda guna and is classified as the best Vata-Pitta prashmana^[4]. Go-Dugdha is Vata-Pitta shamka too.

b. On Dhatu Dushti

There is Rasa, Rakta, Meda and Majja dushti in Shushkakshipaka which is the by the drug as follows:-

On Rasa, Meda, Majja Dushti (Kshya)

This drug is having properties like Dhatu Vardhna (Building), Dhatu poshana i.e. preenan (Nourshing) and Dhatu prasadana i.e. jeevniya (maintaining in health). Madhura rasa is 'sarva dhatu vardhaka' (rasa.... shukravardhana and balya,sandhankara),preenan and jeevniya. Sheet virya is having Prasadana and Jeevniya properties. Guru guna is dhatu vardhaka.

Moreover, **Ghrita** is beneficial for maintaining Rasa Dhatu^[5]. It alleviates Meda dhatu dushti as it is Kapha–meda vivardhana^[6]. Further it possess Rasayana and Ojovardhaka properties thus having Dhatuvardhaka effect. **Go-Dugdha** has a wide range of action on Dhatus (Sarvadhatuka Karma). It is Rasyana thus forming the Prashasta Dhatus^[7]. It is Balya accounting for its Dhatuvardhana (Building) property; and its Preenan and sandhaniya karma results in Dhatuposhana (nourishing). Indu has described it as '**Saumya Dhatu Vardhaka'**, and Rasa, Meda and Majja are Saumya dhatu^[8]. It is considered as 'Pravara Jeevniya' (Vitaliser) thus maintaining the vitality of Dhatus. So it can alleviate the Dhatu Dushti.

On Rakta dushti (Vridhhi): As Rakta is sadharmi with Pitta so Pitta pacifying properties of Drug alleviates Rakta Dushti.

C. On Netra

Madhura rasa is Indriyaprasadna. Go-Ghrita, Go-dugdha possess Chakshushya properties thus keeping the eye healthy. Tejobalkara property of Go-Ghrita gives strength to Alochaka Pitta which maintains normal functioning of Netra. Moreover as stated by Acharya Vagbhatta, Purana Ghrita alleviates eye disorders. Further Go-Dugdha gives relief in eye disease including burning sensation as stated by Acharya Kashyapa.

D. On Vyadhi lakshana

It provides symptomatic relief as under

- **1. Dahprashamna** Madhura rasa, Sheeta virya, Mridu guna and Nirvapanam (coolant) karma Go-ghrita and Go-Dugdha
- **2. Vishushktanashan**-Kledana(hydration) by Sheeta virya and snigdha guna; Go-dugdha is dhatu mala kledkara too.
- 3. Shoola-prashmana- Go-ghrita, Shunthi
- 4. Gharsha nashka-Snigdha and Pichhila guna.

This is a Raskriyanjana of Prasadana type due to Madhura rasa and prabhuta sneha thus having special Snehana properties.

Probable Mode of action of drug (Modern View)

Shunthi directly attack the core mechanism of DES comprising of Ocular surface inflammation and Tear glands derangement. Firstly, it inhibits the prostaglandin release (dose dependent) possessing great Anti-inflammatory property thus subsiding ocular surface inflammation.

Secondly, it has stimulant effect on mucous membranes thus probably increasing the mucin glycocalyx secretion. Thirdly, it is Glandular Stimulant so probably enhancing the secretion lacrimal and meibomian glands. Besides it is antibacterial, stimulant, rubefecient and analgesic so working on symptomtology of DES.

Go-Dugdha is demulcent and nutrient thus maintain lubrication and nutrition. Moreover it contains anti-inflammatory substances.

Ghrita contains vitamin A, E, and β -carotene which are antioxidants thus preventing the ocular surface from oxidative injury. Vitamin A which is epithelio-protective and whose deficiency is a major etiological factor is present in *Ghrita*. Moreover *Ghrita* has nutritive

property and some researchers have showed the presence of Omega-3 fatty acids in *Ghrita* whose deficiency is a risk factor for DES.

Mechanism of action (Modern View)

Digestion, absorption and delivery to a target organ system are crucial in obtaining the maximum benefit from any formulation. All *anjanas* have good bioavailability as they remain in contact of cells for longer time. This *raskriyanjana* having thick consistency has even more bioavailability and efficacy. This is further facilitated by *Ghrita*, since active ingredients of drugs are mixed with *Ghrita* and they are easily absorbed. Lipophilic action of *Ghrita* facilitates transportation to the target organ and final delivery inside the cell, because cell membrane is also formed of lipids. The drug enters the eyeball passing through conjunctiva and cornea. Mucous membrane of conjunctiva is a good absorbing surface. *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. Also instillation of this *anjana* which is rich in lipids forms a uniform layer on ocular surface which reduces excessive evaporation of tears thus preventing EDE.

CONCLUSION

- 1. The disease *Shushkakshipaka* results either due to altered coherence of tears with ocular surface or deficiency of *vaypata ashru*.
- 2. DES appears to be similar disease entity to the *Shushkakshipaka*. The etymology aetiology pathogenesis and clinical features of both correlate immensely.
- 3. *Anjanas* in ointment forms are easy to apply and have more bioavailability and enhanced shelf life without the untoward effects of preservatives.
- 4. *Mahoshadha Sarpi Anjana* showed statistically significant result on subjective and objective parameters except Redness, Crusting, Fluorescein Stain & Rose Bengal Stain.

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