



## AN OPEN LABEL CLINICAL STUDY TO EVALUATE THE EFFICACY OF SEKA AND NASYA IN THE MANAGEMENT OF SHUSHKAKSHIPAKA W.S.R TO DRY EYES IN MENOPAUSAL WOMEN

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### ABSTRACT

Dry eye is a multifactorial ocular surface disease that causes ocular pain, discomfort and decreased visual acuity. It is more prevalent in the females and specifically in the menopausal and postmenopausal age group. This is believed to be due to the changes in balance of sex hormones. Sex hormones - Estrogen and Androgen. These hormones play an important role in the ocular surface function and homeostasis, during the whole life in both the sexes. Accomplished by estrogenic and androgenic receptors on the Cornea, Conjunctival epithelium and Meibomian glands it helps in production of tear film which includes aqueous, lipid, and mucin layer. Various mechanisms such as decrease in hormonal levels, shift in feedback mechanisms, and changes in receptor receptivity interplay to alter the ocular surface homeostasis and subsequently results in dry eye. On analysing through our science it can be emphasized that there is an involvement of *Vata dosha* and *Rasa dhatu dushti* during this stage in pathology. *Shushkakshipaka* which has metagorical features with Dry eyes of compendia also has *Vata* and *pitta* as Pathogenesis. Thus a clinical study was taken up to understand the *samprapti vighatana* of patients diagnosed with *Shushkakshipaka* during menopausal and post menopausal period and were subjected for *Prapundarikadi seka* for 7 days followed by *Shadbindu taila nasya* for 7 days. The outcome of the study revealed significant changes before and after the treatment, but long duration studies are needed to assess the sustained results.

**KEYWORDS:** Estrogen, Androgen, *Shushkakshipaka*, Dry eye, menopause, *samprapti vighatana*.

### INTRODUCTION

Dry eye is a common disease of the preocular tear film that results in damage to the ocular surface. It is also called as Keratoconjunctivitis sicca In Latin it means "dryness of the cornea and conjunctiva." Dry eye is more prevalent in the females, Mainly in the menopausal and postmenopausal.

Dry eye is due to low androgens and estrogen level because they stimulates meibomian gland to produce lipids which maintains the tear stability and prevents tear evaporation.<sup>[1]</sup>

Recent studies have suggested that androgen deficiency is the main cause for meibomian gland dysfunction, tear-film instability and evaporative dry eye.

On analysing through our science it can be emphasized that there is an involvement of *Vata dosha* and *Rasa dhathu* during this stage in pathology. *Shushkakshipaka*

which has features with Dry eyes of compendia also has *Vata* and *Pitta*<sup>[2,3]</sup> as Pathogenesis.

### OBJECTIVES OF THE STUDY

- ☉ To evaluate the efficacy of *Prapundarikadi kwatha seka*<sup>[4]</sup> followed by *Shadbindu taila nasya*<sup>[5]</sup> in the management of *Shushkakshipaka* w.s.r. to Dry eye in menopausal women.

### METHODOLOGY

#### STUDY DESIGN

- ☉ A single arm controlled open label observational study

#### SAMPLING TECHNIQUE

- ☉ The subjects who fulfilled the inclusion and exclusion criteria and complying with the informed consent (IC) were selected.

**SAMPLE SIZE**

- 10.

**DIAGNOSTIC CRITERIA**

- Patients with *lakshanas* of *Gharsha* (foreign body sensation in the eye), *Toda* (pricking pain), *Ruksha* (dryness), *Aveela darshana* (blurriness of eye), *Krichronmilanimilana* (painful blinking of eyes).
- Schirmer's Test less than normal reading, i.e., below 15 mm on the strip.
- Tear Film Break up time, with appearance of Dry spots below normal time of 15 sec.

**INCLUSION AND EXCLUSION CRITERIA****INCLUSION CRITERIA**

- Menopausal women with signs and symptoms of Dry eye.
- Clinical features in any stage of menopausal transition viz; Perimenopause, Menopause, Post menopause.

INTERVENTION	MEDICINE	DOSAGE	TIME	DURATION
<i>Seka</i>	<i>Prapoundarikadi kwata</i>	400 <i>matra kala</i>	Once a day in morning hours	7 days
<i>Nasya</i>	<i>Shadbindu taila</i>	6 <i>bindu</i> to each nostril	Once a day in morning hours	7 days

Including both the phases the total duration of the study was 30 days

**ASSESSMENT CRITERIA**

- The clinical findings were noted in specially prepared case proforma and assessment was done.
- Day 1-Before treatment (BT).
- Day 8- After *Seka* (AT1).
- Day 15- After *Nasya*(AT2).
- Day 30- At follow up (AF) on 15th day after the completion of treatment.
- The parameters considered for the study were scored from 0-3 for all the parameters for the purpose of statistical analysis and **paired t-Test** was applied to infer the results.

**GRADATION INDEX**

- Dryness of the Eyes:
- Foreign body sensation:
- Redness of the eyes:
- Pricking sensation of the eyes:
- Burning sensation of the eyes:
- Painful Blinking of the eyes:

SCORE	CRITERIA
0	Absence of symptom/Sign
1	Occasional/episodic, occurs under environmental stress
2	Frequent/episodic, with or without environmental stress
3	Constant without environmental stress

**EXCLUSION CRITERIA**

- Patients with history of any systemic disorder that interfere the course of the study.
- Associated with any other inflammatory and infective ocular conditions.

**DRUGS USED FOR Intervention**

- PRAPUNDARIKADI KWATA:** *Pundarika, Yashtimadhu, Lodhra, Erandamoola, Usheera, Rakta chandana, Daruharidra*
- SHADBINDU TAILA:** *Erandamoola, Saindhava, Tagara, Bhringaraja, Shatahva, Vidanga, Yashtimadu, Jeevanti, Rasna, Shunti, Ajapaya, Krishna tila taila*

**INTERVENTION**

- Two phases
- Treatment phase comprising of 15 days and
- Follow up phase comprising of 15 days.

**7. Schirmer's Test:**

SCORE	CRITERIA
0	> 15mm
1	≥10mm ≤ 15mm
2	≥ 5mm ≤ 10mm
3	< 5mm

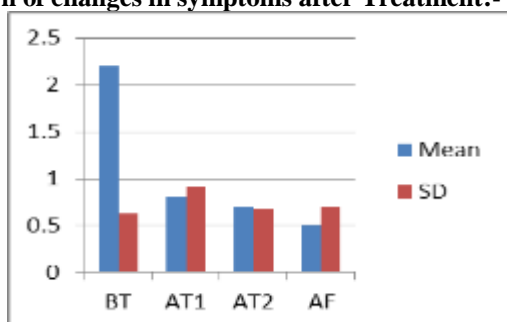
**8. Tear film break up time Test:**

SCORE	CRITERIA
0	> 15sec's
1	≥ 10sec & ≤ 15sec's
2	≥ 5sec & ≤ 10sec's
3	< 5sec's

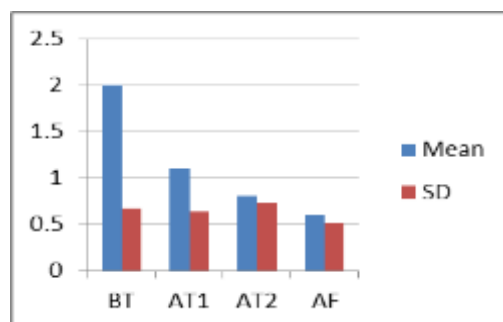
Statistical Analysis:-

Clinical features	Ass.	Mean	SD	t-Value	p-value	Remarks
Schirmer's Test	BT	2.2	0.632	-	-	-
	AT1	0.8	0.919	4.9	<0.001	HS
	AT2	0.7	0.675	6.72	<0.001	HS
	AF	0.5	0.699	7.81	<0.001	HS
Tear film breakup time	BT	2	0.667	-	-	-
	AT1	1.1	0.632	5.12	<0.001	HS
	AT2	0.8	0.738	7.27	<0.001	HS
	AF	0.6	0.516	8.16	<0.001	HS
Dryness	BT	2.5	0.527	-	-	-
	AT1	1	0.667	3.39	<0.001	HS
	AT2	0.2	0.707	4.25	<0.001	HS
	AF	0.3	0.675	3.99	<0.001	HS
Foreign body sensation of eye	BT	1.8	1.03	-	-	-
	AT1	0.8	0.52	4.61	<0.001	HS
	AT2	0.5	0.71	5.22	<0.001	HS
	AF	0.1	0.32	6.10	<0.001	HS
Redness	BT	1.5	0.707	-	-	-
	AT1	0.5	0.707	3.41	<0.01	HS
	AT2	0.2	0.422	3.96	<0.001	HS
	AF	0.1	0.316	4.08	<0.001	HS
Pricking sensation of eye	BT	1.5	0.707	-	-	-
	AT1	0.1	0.316	4.32	<0.001	HS
	AT2	0.2	0.422	5.06	<0.001	HS
	AF	0	0	5.99	<0.001	HS
Burning sensation of eye	BT	2.2	0.632	-	-	-
	AT1	0.6	0.699	4.76	<0.001	HS
	AT2	0.2	0.422	5.51	<0.001	HS
	AF	0	0	6.15	<0.001	HS
Painful blinking of eye	BT	1.1	0.568	-	-	-
	AT1	0.3	0.483	3.10	<0.01	HS
	AT2	0.2	0.422	4.19	<0.001	HS
	AF	0.1	0.316	4.85	<0.001	HS

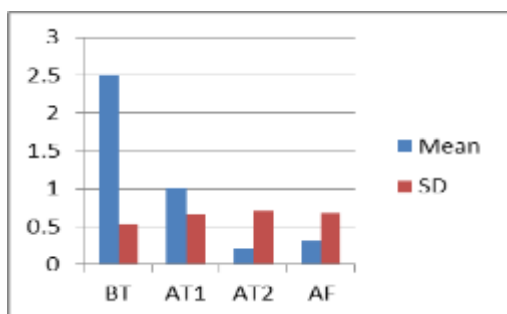
Pattern of changes in symptoms after Treatment:-



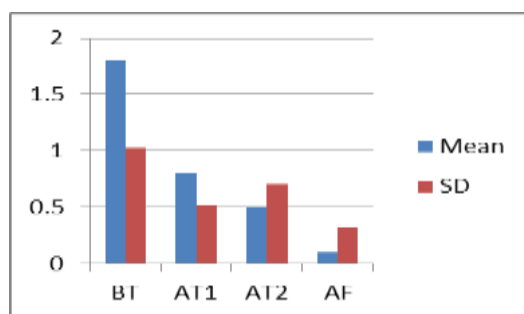
Effect of treatment on Dryness of eye



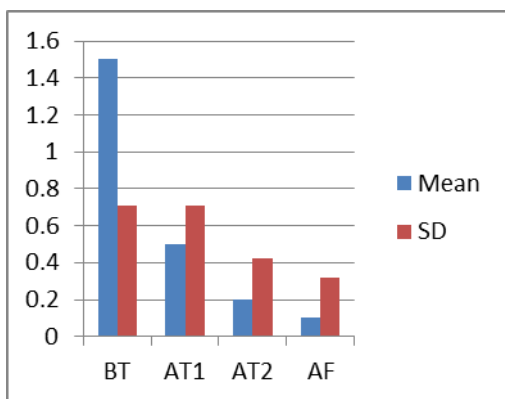
Effect of treatment on Tear film breakup time



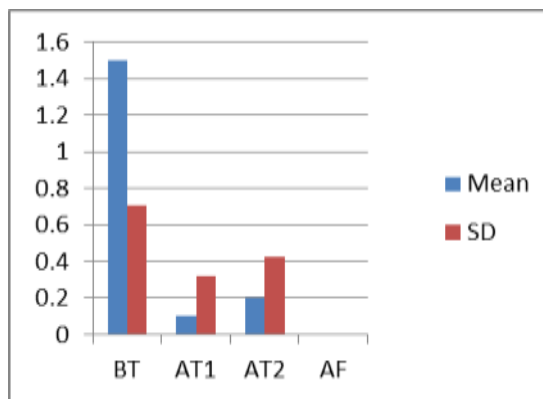
Effect of treatment on Dryness



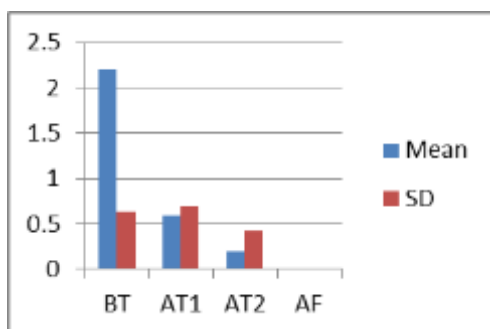
Effect of treatment on Foreign body sensation of eye



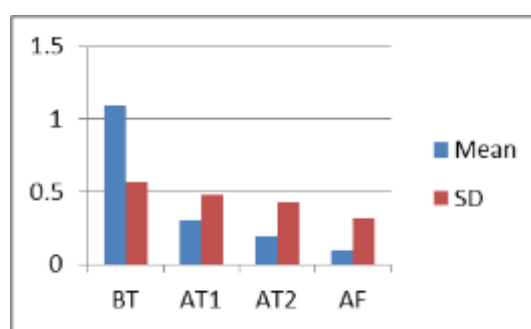
Effect of treatment on Redness



Effect of treatment on Pricking sensation of eye



Effect of treatment on Burning sensation of eye



Effect of treatment on Painful Blinking of eye

## DISCUSSION

In menopausal women *Vata vrudhhi* will take place which results in *agnimandhya* this leads to *rasa dhatu kshaya* which causes *Urdhvagamana* of *doshas* and gets *Sthana samshraya* in *netra*. Thus in this ailment we need *agni deepana* and *vatahara* line of treatment which results in *samprapti vighatana*.

*Seka* was done before the *Nasya* to get relief from *Ama lakshanas netra* (*Raga, Toda, Daruna*). As *shushruta* has mentioned the *pitta* present in the *twak* i.e. *bhrajakagni* will be ignited by *seka* and helps to remove the *amalakshana*.<sup>[6]</sup> Adding to this the *yogaratanakara* have emphasized *seka* as one of the main *kriyakalpa* among *shadvida pachana in netra roga*.<sup>[7]</sup> Thus *Prapundarikadi kwatha seka* was selected and done for 7 days as it possesses *vata piitahara* and *sarvakshi rogahara* properties.

The *snigdha guna* of *prapoundarika, erandamoola, yashtimadhu* and *daruharidra*, helped in reducing the *rukshata of netra*. After *seka* to prevent further complication, improve the glandular function and to combat *Vata, Nasya* with *Shadbindu taila* for 7 days was opted.

The drugs administrated through *nasya* will stimulate the higher centers of brain (hypothalamus) and helps to regulate the hormone synthesis.

*Shadbindu taila* used for *nasya* contains ingredients which has *katu, tikta, madhura, rasas* and it is having

*tridoshahara* property, especially which pacifies *Vata* and *Pitta*.

The *dravyas* like *tagara, jivanti, Saindhava* and *ajadugdha* of *shadbindu taila* has *snigdha guna* thus it helps to remove the *rukshata* of *netra*.<sup>[8]</sup>

*Shadbindu taila* helps to remove the obstruction in the lacrimal gland as it has *shunti* which Removes *sanga* of *srotas* by its *shodhana* property. *Saindhava* of *Shadbindu taila* stimulates blood circulation, facilitates cellular absorption. The base of *Shadbindu taila* i.e. *Krishna tila taila* has anti oxidative property and anti inflammatory action thus it helps to reduce the signs and symptoms of *shushkakshipaka*.

## CONCLUSION

According to Ayurveda, dry eye is not only an ocular surface disorder, but it is one of manifestation of the deranged metabolism of body tissues. *Ashru* (tear film) is the by-product of *Rasa, Meda,* and *Majja dhatu* and without normalizing them we cannot treat dry eye syndrome optimally.

In this clinical study with *Seka* and *Nasya*, ocular discomfort was relieved. Thus the holistic approach of *Ayurvedic* system of medicine provided both subjective and objective relief to the patients. For further management to prevent surgeries, secondary complications and to get relief for longer duration *bhrimhana* line of treatment has to be adopted like *Tarpana, Aschyotana* and *Grithapana*.

Adopting the regimen of *dincharya* mainly which has *chakshushya* properties like *shiro abhyanga*, *pada abhyanga*<sup>[9]</sup> in routine practice are beneficial.

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