

A CLINICAL STUDY ON THE ROLE OF TARPANA KRIYA KALPA WITH SHATAVAHADI GHRITA IN THE MANAGEMENT OF SHUSHKAKSHI-PAKA W.S.R. TO DRY EYE SYNDROME

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ABSTRACT-

Shushkakshi-paka(Dry Eye Syndrome) a common ophthalmic condition. 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. In this clinical trial, local therapy Tarpan Kriya Kalpa with Shatavahadi Ghrita has been selected for the clinical management of Dry Eye Syndrome. An open random comparative study was planned on 40 patients with clinical features of Shushkakshipaka. They were divided randomly into two therapeutic groups of 20 patients each, group A with Tarpana with Shatavahadi Ghrita Group B, Tarpana with Goghrita was done for 7 days. In comparative study over criteria's of assessment, no statistically significant difference was observed between two therapies except in symptom Foreign Body Sensation. . Though Group A fared far well on the basis of percentage relief.

KEY WORDS- Shushkakshi-paka, Dry Eye Syndrome, Tarpana, shatavahadi ghrita ,goghrita

INTRODUCTION-

Shushkakshipaka has an analogous term 'Dry Eye Syndrome' (DES) in modern literature. DES alone accounts for ¼ of ophthalmology clinic visits. *Shushkakshipaka* is a *Sarvagata roga*, i.e. affecting all parts of eye¹. It has been categorized as an *aushadha sadhya vyadhi* i.e. curable by medication. *Acharya Sushruta* and *Acharya Vagbhatta* have given the detailed description of this disease mentioning its causative *doshas*, clinical features and management. Now a days, use of computers, internet surfing, watching television, use of air conditioners, room heaters are the routine daily needs of a common man. People are facing more polluted, dusty, dry and hot environment, over use of vehicles and industrialization. Due to all these unhealthy surroundings, the organ of

body which is first and foremost at the risk is Eye. In the current scenario of ageing population and increasing environmental factors, the most prevalent eye disease is Dry Eye. The symptoms cause significant discomfort and substantially reduce the sufferer's quality of life. So the local therapy *Tarpan Kriya Kalpa* with *Shatavahadi Ghrita* has been selected for the clinical management of Dry Eye Syndrome which is described in *Ashtang Hridaya Uttar Sthana*.

AIMS AND OBJECTIVES

To evaluate the comparative effect of *Tarpana Kriya Kalpa* with *Shatavahadi Ghrita* & plain *Go-Ghrita* on DES.

MATERIAL AND METHODS:

Study Design: Open random comparative study.

Selection of Patients: The patients presenting with clinical features of *Shushkakshipaka/ DES* were selected from *Shalaky 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 40 of patients were registered. Approval from institutional ethical study was taken before commencing the trial. Patient information sheet was given to all the patients and Informed consent was taken from all.

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

Exclusion Criteria: Patients not willing for trial, Infective conjunctivitis / Keratitis, Disorders of lid globe apposition, Patients suffering from specific ocular / systemic disease.

Investigational Criteria: Investigations were carried out in order to rule out any systemic disease- Complete blood picture (Hb gm%, TLC, DLC, ESR, FBS), RA factor etc.

Sampling Technique: The selected patients were randomly divided into two groups A and B with 20 patients in each groups.

Plan of Study: Clinical study was accomplished in three phases i.e. Diagnostic Phase, Interventional Phase, 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: The study was intervened by treatment as follows: in group A *Tarpana karma with Shatavahadi Ghrita*, In Group B, *Tarpana karma with Go-Ghrita*

Duration of Trial- 7 days with follow up of 7 days after completion of trial.

Assessment Phase: Assessment was done on the basis of clinical improvement in signs and symptoms using a standardized grading scale during the study and scoring before and after the treatment.

Clinical Assessment Criteria:

The clinical trial was assessed for its efficacy on the basis of following subjective and objective criteria:-

Subjective Criteria: Foreign body sensation (*Gharsha*), Burning (*Ushadaha*), Mucoïd discharges (*Updeha*), Transient blurring of vision (*Aaviladarshana*), Dryness (*Vishushkatva*), Pain (*Toda/Bheda/Shula*), Photophobia (*Kunita-vartma*), Itching (*Kandu*), Redness (*Raga*), Crusting (*Darunaruksa vartma*), Eyelids stuck (*Kricchronmeela-neemeelnam*).

Objective Signs: Debris/Mucin strands in tear film, Conjunctival congestion, Marginal tear meniscus.

Objective clinical tests: Schirmer- I test, Tear Film Break Up Time, Fluorescein Staining: Rose Bengal Staining:

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 both the groups 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 $p < 0.001$ or < 0.01 , significant for $p < 0.05$ and insignificant for $p > 0.05$. For intergroup comparison unpaired t test was applied. Data obtained were considered highly significant for $p < 0.001$ or < 0.01 , significant for $p < 0.05$ and insignificant for $p > 0.05$. For intergroup comparison unpaired t test was applied.

Grading criteria of overall Effect Of Therapy:

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.

RESULT:

In the present study 40 patients were registered; of which 36 completed the trial. The clinical data and effect of therapy on 36 patients is presented below.

Effect of Therapy On Individual Criteria In Group A:

The efficacy of *Tarpana Karma* with *Shatavahadi Ghrita* was adjudged in 18 patients on the basis of assessment criteria's and results were derived after executing statistical analysis. Statistically Highly Significant relief ($p < 0.001, p < 0.01$) was found in FBS (%age relief=79.14%), Burning sensation (%age relief=75.77%), Mucous discharge (%age relief=62.4%), Transient blurring (%age relief=63.93%), Dryness (%age relief=80.81%), Pain (%age relief=78.94%), Photophobia (% relief=62.92%), Itching (%age relief=51.79%), Redness (% relief=65.46%), Conjunctival congestion (% relief=66.66%). Statistically Significant relief ($p < 0.05$) was found in Crusting (%age relief=56.41%)

Effect of Therapy In Group B:

The efficacy of *Tarpana karma* with *Go-Ghrita* was adjudged in 18 patients on various parameters of assessment criteria and results were derived after executing statistical analysis. Statistically Highly Significant relief ($p < 0.001, p < 0.01$) was found in FBS (%age relief=66.66%), Burning sensation (%age relief=66.91%), Dryness (%age relief=70.66%), Itching (%age relief=47.61%), Redness (% relief=59%), Conjunctival congestion (% relief=58.64%). Statistically Significant relief ($p < 0.05$) was found in Mucous Discharge (%age relief=45.90%), Transient Blurring (% relief=50.90%), Pain (% relief=60%), Photophobia (% relief=50.90%).

Intergroup Comparison (Group A Vs Group B):

Foreign body sensation symptom in Group A shows 12.48 % more relief than Group B; which is statistically significant. Intergroup comparison of Burning Sensation, Mucous Discharge, Transient Blurring, Dryness, Pain, Photophobia, Itching, Redness, Crusting, Eyelid Stuck, Tear Meniscus, Mucin Strands/Debris Conjunctival Congestion, Schirmer-1, T-BUT, Fluorescein Stain and Rose Bengal Stain were found statistically insignificant.

DISCUSSION

:In 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*. Eye is the site of *Aalochak Pitta* and the disease is concerned

with *Shukla* and *Krishnagata Mandala*, which are made up of *Rasa*, *Rakta* and *Mansa*. So the principle of treatment is *Vatapittaghna*, *Pittagnivardhak*, *Chakshushya*, *Balya*, *Jivaniya* and *Rasa*, *Rakta*, *Mansa dustihar*. The clinical trial drug "*Shatavahadi Ghrita*" possesses predominance of *Madhura Rasa*, *Snigdha Guna*, *Ushna 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. The *Ghrita* has the quality of trespassing into minute channels of the body. Hence, when applied in the eye, it enters deeper layers of *Dhatus* and cleanses every minute part of them. The lipophilic action of *Ghrita* facilitates the transportation of the drug to the target organ and finally reaching the cell, because the cell membrane also contains lipid. This lipophilic nature of *Ghrita* facilitates the entry of drug into the eyeball through the corneal surface since the corneal epithelium is permeable to lipid-soluble substances and lipid-soluble substances cross the corneal epithelium irrespective of their molecular size. *Ghrita* contains vitamin A, E, and β -carotene which are antioxidants and epithelio-protective thus preventing the ocular surface from oxidative injury. Moreover, *Ghrita* preparation used in *Akshi-Tarpana* is in the form of suspension containing different particles of the drugs and the particles do not leave the eye as quick as a solution. Tissue contact time and bioavailability is more and hence therapeutic concentration can be achieved by *Akshi-Tarpana*. *Go-Dugdha* is demulcent, thus maintain lubrication and nutrition. Moreover it contains anti-inflammatory substances. *Glycyrrhiza glabra* extract possess anti-inflammatory effect. It inhibits PGE₂, arachadonic acid release and suppresses dexamethasone-induced histamine release and mast cell degranulation. Its strong anti-inflammatory actions make Liquorice root an indispensable herbal remedy against autoimmune diseases in general. It can even be used as an eyebath in conjunctivitis and other inflammatory conditions of the eye surface. In ayurvedic text *Yashtimadhu* is described as *Chakshushya Dravya*. The wood of *C. deodara* also has potent anti-inflammatory & analgesic activity. *Nelumbo nucifera* has antioxidant activity may be due to the presence of phenolics, alkaloids, and saponins. A methanol rhizome extract possess anti-inflammatory action. The anti-inflammatory activity was comparable with that of phenylbutazone and dexamethasone.

That's why in India, eye infections have been treated with honey made from the lotus flowers. In *Bhava Prakash* Pinus roxburghii or *Sarala* has been described as good drug for eye disorders. Piper longum extracts and piperine possess inhibitory activities on prostaglandin and leukotrienes COX-1 inhibitory effect, as well as on NF-κB activation, and thus exhibit anti-inflammatory activity. Withania somnifera or *Ashwagandha* benefits anti-oxidant, immunomodulator & nervine tonic herb. It has some anti-inflammatory and analgesic effect also.

CONCLUSION:

DES appears to be similar disease entity to the *Shushkakshipaka*. The etymology aetiology pathogenesis and clinical features of both correlate immensely. *Tarpana Karma* with *Shatavahadi Ghrita* found effective in reliving subjective criteria of the disease whereas effect on objective clinical tests was not much satisfactory. *Tarpana* with plain *Go-Ghrita* is also effective in reliving symptoms of DES. But in comparative study over criteria's of assessment no statistically significant difference was observed between two therapies except in Foreign Body Sensation. Though, *Tarpana Karma* with *Shatavahadi Ghrita* fared far well on the basis of percentage relief. No adverse effects was seen in both groups.

TABLES:

Table No. 1: Contents of *Shatavahadi ghrita*

Kalka dravya

Name of Drug	Botanical name	Family	Part Used
<i>Shatpushpa</i>	<i>Anethum sowa</i> Kurz.	Umbelliferae	Fruit
<i>Kushta</i>	<i>Saussurea lappa</i> C.B. Clark.	Astraceae	Root
<i>Jatamansi</i>	<i>Nordostachys jatamansi</i> DC.	Valerianaceae	Root
<i>Yashimadhu</i>	<i>Glycyrrhiza glabra</i> Linn.	Legiminosae	Root
<i>Pundarika</i>	<i>Nelumbo nucifera</i> Gaertn.	Nymphaeaceae	All parts
<i>Sarala</i>	<i>Pinus roxburghii</i> Sargent.	Pinaceae	<i>Niryasa</i>
<i>Pippali</i>	<i>Piper longum</i> Linn.	Piperaceae	Fruit
<i>Devadaru</i>	<i>Cedrus deodara</i> (Roxb.) Loud.	Pinaceae	<i>Kanda Sara</i>
<i>Ashwagandha</i>	<i>Withania somnifera</i> (Linn) Dunal.	Solanaceae	Root

Sneh dravya : Cow's ghee-4 parts *Drava dravya* : Cow's milk - 8 parts of cow's ghee

Table No. 2: Effect of *Tarpana karmawith Shatavahadi Ghrita* on Assessment Criteria's in group A (18 patients)

Parameters	N	Mean Score		D	%age Relief	SD ±	SE±	T	P
		BT	AT						
FBS	18	2.11	0.44	1.67	79.14	0.686	0.162	10.308	<0.001
Burning Sensation	15	1.61	0.39	1.22	75.77	0.808	0.191	6.414	<0.001
Mucous Discharge	12	1.33	0.5	0.83	62.4	0.857	0.202	4.123	<0.001
Transient Blurring	11	0.61	0.22	0.39	63.93	0.502	0.118	3.289	<0.01
Dryness	16	1.72	0.33	1.39	80.81	0.850	0.200	6.934	<0.001
Pain	12	1.33	0.28	1.05	78.94	0.938	0.221	4.776	<0.001
Photophobia	16	0.89	0.33	0.56	62.92	0.511	0.121	4.610	<0.001
Itching	15	1.39	0.67	0.72	51.79	0.669	0.158	4.579	<0.001
Redness	18	1.94	0.67	1.27	65.46	0.575	0.135	9.436	<0.001
Crusting	7	0.39	0.17	0.22	56.41	0.428	0.101	2.204	<0.05
Eyelid Stuck	6	0.33	0.11	0.22	66.66	0.647	0.152	1.458	>0.05
Tear Meniscus	10	0.66	0.5	0.16	24.24	0.383	0.0904	1.844	>0.05

Mucin Debris	10	0.56	0.39	0.17	30.35	0.383	0.0904	1.844	>0.05
Conjunctival Congestion	17	1.5	0.5	1	66.66	0.485	0.114	8.746	<0.001
Schirmer- I	12	1.06	0.89	0.17	16.03	0.383	0.0904	1.844	>0.05
	10	0.77	0.61	0.16	20.77	0.383	0.0904	1.844	>0.05
Fluorescein Stain	6	0.5	0.39	0.11	22	0.323	0.0762	1.458	>0.05
Rose Bengal Stain	8	0.56	0.39	0.17	30.35	0.383	0.0904	1.844	>0.05

Table No.3:Effect of *Tarpana karmawithGo-Ghrita* on Assessment Criteria's in group B (18 patients)

Parameters	N	Mean		D	%age Relief	SD ±	SE±	T	P
		BT	AT						
FBS	17	1.5	0.5	1	66.66	0.686	0.162	6.185	<0.001
Burning Sensation	14	1.33	0.44	0.89	66.91	0.676	0.159	5.575	<0.001
Mucous Discharge	8	0.61	0.33	0.28	45.90	0.461	0.109	2.557	<0.05
Transient Blurring	10	0.55	0.27	0.28	50.90	0.461	0.109	2.557	<0.05
Dryness	15	1.5	0.44	1.06	70.66	0.725	0.171	6.174	<0.001
Pain	8	0.55	0.22	0.33	60	0.686	0.162	2.062	<0.05
Photophobia	10	0.55	0.27	0.28	50.90	0.461	0.109	2.557	<0.05
Itching	12	1.05	0.55	0.5	47.61	0.514	0.121	4.123	<0.001
Redness	17	1.61	0.66	0.95	59.00	0.725	0.171	5.524	<0.001
Crusting	6	0.33	0.16	0.17	51.51	0.083	0.0904	1.844	>0.05
Eyelid Stuck	4	0.22	0.11	0.11	50	0.323	0.0762	1.458	>0.05
Tear Meniscus	10	0.72	0.55	0.17	23.61	0.383	0.0904	1.844	>0.05
Mucin Debris	8	0.44	0.33	0.11	25	0.323	0.0762	1.458	>0.05
Conjunctival Congestion	17	1.33	0.55	0.78	58.64	0.428	0.101	7.714	<0.001
Schirmer- I	13	1.22	1.05	0.17	13.93	0.383	0.0904	1.844	>0.05
	10	0.72	0.55	0.17	23.61	0.383	0.0904	1.844	>0.05
Fluorescein Stain	7	0.38	0.33	0.05	13.15	0.236	0.0556	1.00	>0.05
Rose Bengal Stain	4	0.22	0.16	0.06	27.27	0.236	0.0556	1.00	>0.05

Table No.4:Comparison over individual criteria's of assessment

Parameters	Gr. A	Gr. B	% Relief diff.	S.D.	S.E.	T	P	Result
FBS	18	17	12.48	0.686	0.231	2.84	<0.01	S
Burning Sensation	15	14	8.86	0.747	0.277	1.19	>0.05	NS
Mucous Discharge	12	8	16.5	0.729	0.332	1.65	>0.05	NS
Transient Blurring	11	10	13.03	0.483	0.211	0.47	>0.05	NS
Dryness	16	15	10.15	0.792	0.284	1.19	>0.05	NS
Pain	12	8	18.94	0.849	0.387	1.85	>0.05	NS
Photophobia	16	10	12.02	0.492	0.198	1.36	>0.05	NS
Itching	15	12	4.18	0.606	0.234	0.93	>0.05	NS

Redness	18	17	6.46	0.652	0.220	1.45	>0.05	NS
Crusting	7	6	4.9	0.321	0.201	0.24	>0.05	NS
Eyelid stuck	6	4	16.66	0.548	0.353	0.31	>0.05	NS
Tear Meniscus	10	10	0.63	0.372	0.166	-0.06	>0.05	NS
Mucin debris	10	8	5.35	0.358	0.169	0.29	>0.05	NS
Conjunctival Congestion	17	17	8.02	0.457	0.156	1.40	>0.05	NS
Schirmer -1	12	13	2.1	0.383	0.153	-0.06	>0.05	NS
T-BUT	10	10	-2.84	0.383	0.171	0.00	>0.05	NS
Fluorescein Stain	6	7	8.85	0.278	0.154	0.38	>0.05	NS
Rose Bengal Stain	8	4	3.08	0.345	0.211	0.47	>0.05	NS

Table No. 5 : Overall Effect of Therapy In Group A

Result	No. Of Patients	Percentage
Cured	0	0
Markedly Improved	0	0
Moderately Improved	14	77.78
Mildly Improved	4	22.22
Unchanged	0	0

Table No. 6: Overall Effect of Therapy In Group B

Result	No. Of Patients	Percentage
Cured	0	0
Markedly Improved	0	0
Moderately Improved	5	27.78
Mildly Improved	13	72.22
Unchanged	0	0

Table No. 7: Comparison of Overall Effect of Therapy in Both Groups (36 patients)

Results	Group A (n=18)		Group B(n=18)	
	No. of Patients	%age	No. of Patients	%age
Cured	0	0	0	0
Markedly Improved	0	0	0	0
Moderately Improved	14	77.78	5	27.78
Mildly Improved	4	22.22	13	72.22
Unchanged	0	0	0	0

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