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Clinical study to assess the efficacy of *Keshanjana* and *Netra Parisheka* in the management of *Shushkakshipaka* (dry eye syndrome)

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Abstract

Background: Dry eye syndrome (DES) is a common ophthalmic problem predominantly affecting middle-aged and elderly people. It is a disease of deficient or deranged tears and ocular surface disorder producing symptoms of discomfort, visual disturbance, and tears film instability. *Shushkakshipaka,* an etymologically and clinically similar entity to DES, is defined in Ayurveda as the disease affecting all parts of the eye characterized by *Paka* (inflammation) due to *Shuskatva* (dryness) caused by altered coherence of *Ashru* (tears) with ocular surface or due to lack of *Ashru*. **Aim:** To compare the effect of *Keshanjana* and *Netra Parisheka* in *Shushkakshipaka* with artificial tear drops (carboxy methyl cellulose [CMC]). **Materials and Methods:** To search a safe, potent and cost-effective Ayurvedic treatment for DES, a randomized comparative clinical trial was conducted on 32 patients. Patients were divided in two groups 15 in group I and 17 in group II. Group I treated with artificial tear drop four times a day for topical use and group II treated with combination therapy of *Keshanjana* applied topically once a day and *Netra Prisheka* was done thrice a day. **Results:** The effect of Ayurvedic management was found to be equivalent to the standard therapy, although the trial drugs provided more relief in foreign body sensation, burning sensation, dryness, pain, photophobia, itching, crusting, stuck eyelids, tear meniscus, conjunctival congestion, Schirmer I test, and tear film break-up time (TUBT). The standard therapy provided more relief than trial drugs in mucous discharges, transiently blurred vision, redness, and the presence of mucin debris in tear film. **Conclusion:** *Keshanjana* and *Netra Parisheka* can be used as a potent, safe and cost-effective treatment to ameliorate the symptoms of DES.

Key words: Carboxy methyl cellulose, dry eye syndrome, *Keshanjana*, *Netra Parisheka*, *Shushkakshipaka*

Introduction

Dry eye syndrome (DES) is one of the most common problems observed in ophthalmic practice although often overlooked as a possible cause of patient's misery. The disease acquired tremendous significance in this era of commercialization due to changes in lifestyle, stress, indiscriminate use of topical ocular drugs, preservative induced damage, laser surgeries, and occupations requiring extended periods of attention (visual display terminal syndrome) besides the hazardous effects of certain systemic drugs. Studies show its prevalence ranging from 14.6% to 28%.[1-5] Incidence increases linearly with advancing age.

Dry eye is defined as "a multifactorial disease of the tears and ocular surface that results in symptoms of discomfort, visual disturbance, and tears 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".[6] *Shushkakshipaka*, an etymologically similar entity, has been described in Ayurvedic texts whose etio-pathogenesis and clinical features of dryness and inflammation of the ocular surface remarkably correlate with that of DES. *Shushkakshipaka* is a *Sarvagata Roga*, that is, disease affecting all parts of the eye; a *Vataja* or *Vata-Pittaja/Vata-Raktaja* curable disease.[7] While the description in Sushruta Samhita demarcates the early stage, Vagbhatta Samhitas give details of a fully-fledged picture including *Paka* (inflammatory) stage of the disease.[8-10]

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Dry eye can be classified into two types, evaporative (tear sufficient), and tear deficient. In tear deficient dry eyes, there is disorder of lacrimal gland to secrete or transfer fluid to the conjunctival sac. In tear sufficient (evaporative) dry eyes, there is increased evaporation of tear fluid from the ocular surface.

The spectrum of complaints found in dry eye in order of frequency includes foreign body sensation (gritty feeling), excessive secretion, burning, redness, photophobia, blurred vision, itching, and pain. Patients with severe filamentary keratitis may complain of severe pain brought on by blinking. Surprisingly, patients seldom complain that their eyes are dry, although some may report a lack of emotional tears or a deficient response to irritation stimuli.[11] There may be crusting of eyelids and sticking, which is commonly seen in the morning on waking up. Nonspecific symptoms include headache, heaviness of eyes, or tiredness.[12] Patients can have considerable discomfort with this affliction, which can interfere with normal daily functioning.

Signs of dry eye include tear film abnormalities like an increase in mucous strands and debris in early stage of the disease. The marginal tear meniscus is found to be concave, small, and in severe cases, it may be absent altogether. In normal eyes, the meniscus is convex and about 1 mm high at lower lid margin.[11] Less than 0.5 mm meniscus height is indicative of tear deficiency.[11] Corneal abnormalities are observed in moderate to severe cases, e.g. punctate epitheliopathy involving the inferior cornea,[11] filamentary keratopathy, and mucous plaques. Conjunctival congestion, corneal surface irregularities, blink disorders, and associated blepharitis may also be observed.

Despite a number of researches being carried out, no curative treatment for DES has been achieved. Only palliative measures in the form of tear replacement therapy with a variety of artificial tear solutions are available which are to be used for lifelong by the patients, further burdening them financially. Palliative measures also fail to alleviate the symptoms later on due to preservative induced damage to the epithelial lining and basic secretors.

Ayurvedic texts enlist a number of treatment modalities for treatment of the disease, including both localized and systemic measures. In view of the magnitude of the problem, this study was undertaken to achieve cost-effective treatment modalities of Ayurveda in treating this chronic ailment. Among the various preparations indicated for *Shushkakshipaka*, *Keshanjana* is described as the best *Anjana*.[13] Therefore, this *Rasakriya Anjana* (ointment) along with *Netra Parisheka* (ocular irrigation) with cow milk and *Saindhava Lavana* was evaluated and compared with artificial eye drops (carboxy methyl cellulose [CMC]) in prescribed doses for amelioration of symptoms and improvement in signs and clinical tests.

Materials and Methods

A prospective comparative clinical study was designed and conducted with following specifications:

Selection of patients

Patients were selected from the Shalakya Tantra (eye unit) Out Patient Department of the Rajiv Gandhi Govt. Post Graduate Ayurveda College and Hospital, Paprola, HP. A total of 32 patients were registered for the present study. The clinical study was in accordance with the ethical standards of the Institutional Ethics Committee (IEC) and with the Helsinki Declaration.

Inclusion criteria

All patients presenting with signs and symptoms of *Shushkakshipaka* (DES) and at least one positive specific test were taken into this study:

Symptoms

1. *Gharsha* (foreign body sensation), 2. *Samdahana* (burning), 3. *Upadeha* (mucous discharges), 4. *Aavila Darshana* (transient blurring of vision), 5. *Vishushkatva* (dryness), 6. *Toda*, *Bheda*, *Shula* (pain), 7. *Kunita Vartma* (narrowing of the palpabral aperture due to photophobia, etc.), 8. *Toda* (itching), 9. Redness, 10. *Daruna Ruksha Vartma* (crusting of lids) and 11. *Kricchronmeelana* (eyelid stuck).

Signs

1. Debris/mucin strands in tear film, 2. Conjunctival congestion, 3. Marginal tear meniscus.

Clinical tests

- Schirmer - I test
- Tear film break-up time.

Exclusion criteria

- Patients presenting with Dry eye complicated with infective conjunctivitis/keratitis
- Patients presenting with disorders of lid-globe apposition
- Patients suffering from specific ocular or systemic diseases.

Trial drug

Keshanjana was prepared by rubbing human scalp hairs with *Go-Ghrita* on mirror followed by *Massi* preparation in *Mallaka Samputa*. *Massi* was further triturated with *Go-Ghrita* in a ratio of 5:95 in *Lauh Khalva* (iron pestle mortar) to achieve a very fine particulate matter containing *Rasakriya Anjana* (eye ointment). Prepared *Anjana* was stored in a sterile vessel and further filled up in collapsible plastic vials. The *Anjana*, being indicated in a predominantly *Vataja* condition and conforming to *Ropana Anjana* characteristics, was applied in lower fornices of the eyes of the patients at evening time (*Sayahne Vataje*).[14] Concurrently, lukewarm cow milk admixed with a bit of *Saindhava Lavana* was applied thrice a day in the form of continuous irrigation for 15–16 min each session (*Ropanasya Shadvakshatani*).[15]

Grouping and posology

The diagnosed patients, who fulfilled the inclusion criteria, were divided into the two groups by random sampling technique:

Group I

In this group, 15 patients were registered. They were treated with artificial tear drops (CMC) four times a day for topical use for 15 days.

Group II

17 patients of this group were treated with the trial drugs combination of *Keshanjana* applied topically once a day (in the evening)[16] and *Netra Parisheka* applied 3 times a day for 15 days.

Follow-up

After completion of the therapy, the patients were followed up for further 1-month at the interval of 15 days to see for any untoward effects.

Assessment criteria

Grading and scoring system was adopted for assessing each clinical feature before the commencement of trial and after the completion of the trial.

Observations

Demographic data have been presented for 32 patients, while clinical data and observations were made on 31 patients (i.e. 15 in Group I and 16 in Group II) who completed the trial.

Demographic profile

In the present study, maximum number of patients were of age group 41–60 years (46.88%), were females (59.38%), married (93.75%), Hindu (100%), residents of rural area (87.5%), illiterate (43.75%), belonged to middle class (68.75%), housewives (53.12%), and enjoyed mixed diet (59.38%). Majority of the patients were having no addiction (56.25%) and spent up to 1 h in front of television or computer monitor (31.25%).

Majority of the patients had *Vata-Pittaja Prakriti* (59.38%), with *Avara Dehabala* (50%), had *Samaagni* (59.38%) and medium appetite (84.37%).

Clinical profile

Maximum numbers of patients were suffering from dry eye symptoms for 6 months or less (31.25%). Symptoms of dry eye were found in decreasing order of percentage as: Foreign body sensation (65.63%), itching (53.13%), redness and mucous discharges (43.75% each), pain (34.38%), transient blurring of vision (25%), burning sensation and crusting of lids (21.88% each), dryness and stuck eyelids (18.75% each), and photophobia (12.5%). Conjunctival congestion was observed in the maximum number of patients (93.75%) followed by mucin debris and strands in tear film (90.63%). Tear meniscus was found abnormal in 75% of the patients. Tear film break-up time was subnormal in 96.88%, and Schirmer strip wetting was less than normal in 84.38% of the patients. The incidence of clinical signs, symptoms, and positive specific tests are depicted in Chart no. 1.

Results

Effect of therapy in Group I

In Foreign body sensation, mucous discharges, itching, and redness the relief percentages observed were 85.2%, 87.6%, 75%, and 73.9% in that order. Mucin debris/strands reduced by 95.03% and conjunctival congestion subsided by 78.27%. The effects were statistically highly significant ($P < 0.001$). In transient blurring of vision, the percentage of relief was 87.5%, which was significant statistically ($P < 0.01$). In burning sensation and in pain, the percentage of relief were 62.4% and 70.1%, respectively, and in TBUT the relief observed was 19.98%, which were statistically significant ($P < 0.05$). In the dryness, photophobia, crusting, and sticking of eyelids the relief percentages observed were 53.2%, 75%, 66.7%, and 33.3% in that order. Tear meniscus showed 23.03% relief and Schirmer I test showed relief by 6.87%, respectively. The effects were statistically insignificant ($P > 0.05$) [Table 1].

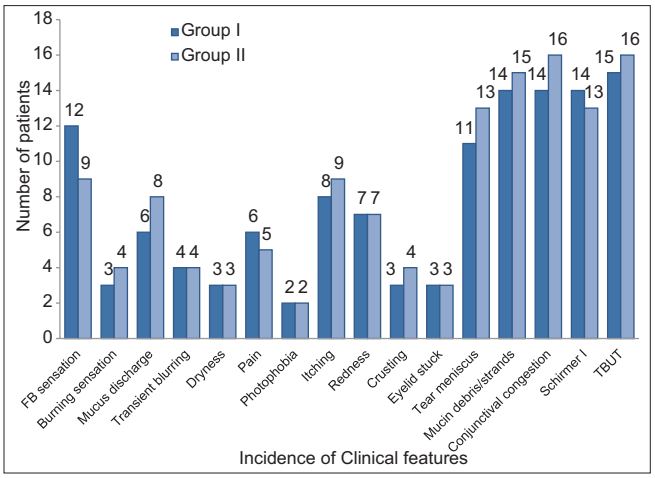

Chart 1: Incidence of clinical features of dry eye syndrome in Groups I and II

Effect of therapy in Group II

In foreign body sensation, mucous discharges; itching, redness, and crusting the relief percentages observed were 95.5%, 69.2%, 95.1%, 69.3%, and 90%, respectively. In mucin debris/strands relief of 91.13% was observed and in conjunctival congestion the relief was 87.68%. The effects were statistically highly significant ($P < 0.001$). In pain, tear meniscus and TBUT; the relief percentages observed were 100%, 38.67%, and 29.7% in that order, which were statistically significant ($P < 0.01$). In Burning sensation, 100% relief was observed which was significant statistically ($P < 0.05$). In the transient blurring, dryness, photophobia, and stuck eyelids, observed relief percentages were 75%, 87.6%, 83.3%, and 100%, respectively, whereas relief percentage in Schirmer I test was found to be 12.9%, which were statistically insignificant ($P > 0.05$) [Table 2].

Inter group comparison

In a comparative study over criteria of assessment, statistically insignificant difference ($P > 0.05$) was observed between the two therapies except in burning sensation ($P < 0.05$) on which the trial group showed 37.6% more relief than the standard group [Table 3]. The effect of Ayurvedic treatment was found to be equivalent to the standard therapy of tear supplementation (CMC eye drops) in terms of statistical significance, although the trial drugs provided more relief in foreign body sensation (10.3%), burning sensation (37.6%), dryness (34.4%), pain (29.9%), photophobia (8.3%), itching (20.1%), crusting (23.3%), stuck eyelids (66.7%), tear meniscus (15.64%), conjunctival congestion (9.41%), Schirmer I test (6.03%), and TBUT (9.73%) in terms of relief percentage difference. The standard therapy provided more relief than trial drug in mucous discharges (18.4%), transiently blurred vision (12.5%), redness (4.6%), and the presence of mucin debris in tear film (3.9%).

After completion of the trial also, the results were sustained for a long time in trial group patients who came for follow-up. No adverse effects of both the therapies came into light during or after the course of the trial.

Table 1: Effect of therapy in Group I (standard group)

Clinical features	*n*	Mean value		d	Percentage of relief	SD±	SE±	*t*	*P*
		BT	AT						
FB sensation	12	2.25	0.33	1.92	85.2	0.515	0.149	12.9	<0.001
Burning sensation	3	1.33	0.5	0.83	62.4	0.289	0.166	4.99	<0.05
Mucus discharge	6	1.33	0.17	1.16	87.6	0.408	0.167	7	<0.001
Transient blurring	4	1	0.125	0.875	87.5	0.25	0.125	7	<0.01
Dryness	3	2.5	1.17	1.33	53.2	1.115	0.666	1.99	>0.05
Pain	6	1.67	0.5	1.17	70.1	0.753	0.307	3.8	<0.05
Photophobia	2	1	0.25	0.75	75	0.354	0.25	3	>0.05
Itching	8	2	0.5	1.5	75	0.756	0.267	5.61	<0.001
Redness	7	1.64	0.43	1.21	73.9	0.567	0.214	5.67	<0.001
Crusting	3	1	0.33	0.67	66.7	0.577	0.333	2	>0.05
Eyelid stuck	3	1	0.67	0.33	33.3	0.577	0.333	1	>0.05
Tear meniscus	11	1.18	0.91	0.27	23.03	0.467	0.141	1.93	>0.05
Mucin debris/strands	14	1.43	0.07	1.36	95.03	0.497	0.133	10.2	<0.001
Conjunctival congestion	14	1.64	0.36	1.28	78.27	0.726	0.194	6.63	<0.001
Schirmer I	14	2.07	1.93	0.14	6.87	0.363	0.097	1.472	>0.05
TBUT	15	1.67	1.33	0.34	19.98	0.488	0.126	2.643	<0.05

FB: Foreign body, TBUT: Tear film break up time, SD: Standard deviation, SE: Standard error, BT: Before treatment, AT: After treatment

Table 2: Effect of therapy in Group II (trial group)

Clinical features	*n*	Mean value		d	Percentage of relief	SD±	SE±	*t*	*P*
		BT	AT						
FB sensation	9	2.44	0.11	2.33	95.5	0.707	0.236	9.89	<0.001
Burning sensation	4	2.13	0	2.13	100	0.854	0.427	4.98	<0.05
Mucus discharge	8	1.63	0.5	1.13	69.2	0.353	0.125	9.01	<0.001
Transient blurring	4	1	0.25	0.75	75	0.5	0.25	3	>0.05
Dryness	3	2.67	0.33	2.34	87.6	1.155	0.667	3.5	>0.05
Pain	5	1.8	0	1.8	100	0.837	0.374	4.81	<0.01
Photophobia	2	1.5	0.25	1.25	83.3	0.354	0.25	5	>0.05
Itching	9	2.28	0.11	2.17	95.1	0.612	0.204	10.62	<0.001
Redness	7	1.86	0.57	1.29	69.3	0.488	0.184	6.97	<0.001
Crusting	4	1.25	0.13	1.12	90	0.25	0.125	9	<0.001
Eyelid stuck	3	1.33	0	1.33	100	0.577	0.333	3.99	>0.05
Tear meniscus	13	1.19	0.73	0.46	38.67	0.519	0.144	3.2	<0.01
Mucin debris/strands	15	1.5	0.13	1.37	91.13	0.611	0.158	8.67	<0.001
Conjunctival congestion	16	2.03	0.25	1.78	87.68	0.657	0.164	10.84	<0.001
Schirmer I	13	2.38	2.08	0.3	12.9	0.522	0.145	2.125	>0.05
TBUT	16	2	1.41	0.59	29.7	0.612	0.153	3.882	<0.01

FB: Foreign body, TBUT: Tear film break up time, SD: Standard deviation, SE: Standard error, BT: Before treatment, AT: After treatment

Discussion

There is ample description of *Sushkakshipaka* in *Ayurvedic* literature. It has been described as a *Vata* or *Vata-Pittaja* eye disorder affecting all parts of the eye which is curable by medical means. It is clear from the etymological derivation of the *Sushkakhipaka* that the disease can occur in two ways, viz., either by absent or decreased secretion of tears or their altered coherence with the ocular surface resulting in *Paka* (inflammation) of the *Netra*. Similar classification of dry eye in two broad categories of tear deficient and tear sufficient dry eye is in vogue in modern ophthalmological literature. Whereas the abstraction of tear is described vividly in modern literature, it is not so in texts of Ayurveda. To ascertain the Ayurvedic concept of fluids which bathe the ocular surface, a thorough search was done which yielded that though no structure was linked with the formation of *Ashru* in Ayurveda, the ancient sages knew the importance of tear fluid very well and drainage pathway of lacrimal system was known to them. It was concluded from the evidences scattered in Ayurvedic literature that *Ashru* is derived from the *Rasa Dhatu*, and its functions in the eye are similar to that of *Rasa Dhatu* in the body. It restores the wear and tear and provides nutrition to the outer tunics. It lubricates the eye and keeps the eye wet.[17]

Table 3: Intergroup comparison of Group I and Group II

Clinical features	Group I (in percentage)	Group II (in percentage)	Relief difference	SE±	*t*	*P*
FB sensation	85.2	95.5	10.3	0.278	1.49	>0.05
Burning sensation	62.4	100	37.6	0.458	2.83	<0.05
Mucus discharge	87.6	69.2	18.4	0.208	0.2	>0.05
Transient blurring	87.5	75	12.5	0.576	0.217	>0.05
Dryness	53.2	87.6	34.4	0.943	1.061	>0.05
Pain	70.1	100	29.9	0.484	1.308	>0.05
Photophobia	75	83.3	8.3	0.354	1.412	>0.05
Itching	75	95.1	20.1	0.336	1.985	>0.05
Redness	73.9	69.3	4.6	0.283	0.255	>0.05
Crusting	66.7	90	23.3	0.356	1.278	>0.05
Eyelid stuck	33.3	100	66.7	0.471	2.123	>0.05
Tear meniscus	23.03	38.67	15.64	0.201	0.94	>0.05
Mucin debris/strands	95.03	91.13	3.9	0.206	0.044	>0.05
Conjunctival congestion	78.27	87.68	9.41	0.254	1.945	>0.05
Schirmer I	6.87	12.9	6.03	0.174	0.947	>0.05
TBUT	19.98	29.7	9.72	0.198	1.318	>0.05

FB: Foreign body, TBUT: Tear film break up time, SE: Standard error

Ashru can be broadly divided into 3 categories of *Vyapta Ashru*, *Ashru Vega*, and *Ashru Srava*. Another ocular secretion *Netra Vita* is also inherently concerned with the stability of the *Ashru* on the ocular surface.

A number of treatment modalities has been described in Ayurveda for the management of *Sushkakshipaka*. It not only includes localized measures, but also systemic use of drugs has also been indicated. This variety of treatment modalities points toward the diverse pathology of the disease.

Clinical profile

Majority of the patients were in the age group 41–60 years followed by age group of 60 years and above indicating decline in tear production with age. Majority of patients were housewives of postmenopausal age reflecting toward role of hormonal changes in the causation of DES. Most of the patients registered in this study were Hindu of rural habitat signifying predominance of this community in the area where the trial was conducted. Most of the patients were having *Vata-Pittaja Prakriti* and as the disease is *Vata-Pitta* dominating, the person with similar *Prakriti* is more prone to develop this disease. Thus, the disease was a challenge to treat due to the similarity in *Kala* (age group affected), *Prakriti* (*Vata-Pittaja Prakriti* of the patients) and *Dosha* (*Vata-Pittaja* disease) besides being of *Dvidoshaja* nature.[18] Maximum number of patients had *Avara Dehabala* followed closely by *Madhyam Dehabala*. It can be ascribed to the age (middle and old age) group affected by this disease in which *Pitta* and *Vata* show their predominance, respectively.

As CMC does not alter the mechanism of tear secretions and merely provide lubrication, the results in the standard group confirm to the properties of tear substitutes.

Owing to *Rasakriya* (ointment) form of trial drug, transient blurring, and stuck eyelids are a natural consequence of drug application. Trial drugs appear to improve tear film stability more than enhancing tear secretions as evident from statistical analysis.

Conclusions

The effect of Ayurvedic treatment was found to be equivalent to standard therapy of tear supplementation (CMC eye drops), although *Keshanjana* and *Netra Parisheka* provided more relief in certain symptoms like foreign body sensation, burning sensation, etc., This Ayurvedic management can be used as a potent, safe and cost-effective treatment to ameliorate the symptoms of DES. However, to substantiate the effect of *Keshanjana* and *Parisheka*, further elaborative studies are required.

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हिन्दी सारांश

शुष्काक्षिपाक (ड्राई आई सिन्ड्रोम) में केशांजन एवम् परिषेक का चिकित्सापरक अध्ययन

प्रभाकर वर्धन, करतारसिंह धीमान

शुष्काक्षिपाक (ड्राई आई सिन्ड्रोम) मध्मम एवम् वृद्धावस्था की एक सामान्य नेत्र व्याधि है जिसकी सन्तोषजनक चिकित्सा वर्तमान में उपलब्ध नही है। अष्टांग ह्रदय में वर्णित केशांजन एवम् सुश्रुत संहिता में वर्णित एक परिषेक योग के चिकित्सापरक अध्ययन में इन योगों के प्रभाव की कार्बोक्सी मिथाईल सैलुलोज नेत्र बिन्दु के प्रभाव के साथ तुलना करने पर सार्थकता परीक्षण में दोनों चिकित्साएं समान प्रभावी पायी गयी तथापि आयुर्वेदीय चिकित्सा प्रतिशतता के आधार पर अधिक लाभकारी देखी गई। अध्ययन अवधि में दोनों चिकित्साओं का कोई भी दुष्परिणाम नही पाया गया।