



## Research Article

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### A CLINICAL STUDY ON THE ROLE OF TARPANA KRIYA KALPA WITH SHATAVAHADI GHRITA IN THE MANAGEMENT OF SHUSHKAKSHI-PAKA WITH SPECIAL REFERENCE TO DRY EYE SYNDROME

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#### ABSTRACT

*Shushkakshi-paka* (Dry Eye Syndrome) a common ophthalmic condition. Due to its variegated etiology, multifactorial pathophysiology, lack of gold standard diagnostic procedure and absence of any curative modality, it presents as a great challenge to physician's skills. In this clinical trial, local therapy *Tarpana 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* and divided randomly into two therapeutic groups of 20 patients each. In group A, *Tarpana* with *Shatavahadi Ghrita* and in Group B, *Tarpana* with *Goghrita* was done for 7 days. In comparative study over criteria 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.

**Keywords:** *Shushkakshi-paka*, Dry Eye Syndrome, *Tarpana*, *Shatavahadi Ghrita*, *Goghrita*.

#### INTRODUCTION

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. Ayurveda describes a similar condition called *Shushkakshipaka*, which matches etymological<sup>1</sup> derivation and clinical picture<sup>2</sup> mentioned in the classical literature of Ayurveda under *Sarvagata Netraroga* (diseases affecting all parts of the eye). It has been categorized as an *aushadha sadhya vyadhi* i.e. curable by medication. *Acharya Sushruta*<sup>3</sup> and *Acharya Vagbhatta* have given the detailed description of this disease mentioning its causative *doshas*, clinical features and management<sup>4</sup>. So the local therapy *Tarpana Kriya Kalpa* with *Shatavahadi Ghrita* has been selected for the clinical management of Dry Eye Syndrome which is described in *Ashtang Hridaya Uttar Sthana*<sup>5</sup>.

**Aims and Objectives:** To evaluate the comparative effect of *Tarpana Kriya Kalpa* with *Shatavahadi Ghrita* & plain *Goghrita* on Dry Eye Syndrome.

#### MATERIAL AND METHODS

**Study Design:** Open random comparative study.

**Selection of Patients:** The patients presenting with clinical features of *Shushkakshipaka*/Dry Eye Syndrome 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 committee was taken before commencing the trial (IEC/2013/360). 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* / Dry Eye Syndrome 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 group.

**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 Dry Eye Syndrome. A special research performa 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* and 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*), Mucoid discharges (*Updeha*), Transient blurring of vision (*Aavila-darshana*), Dryness (*Vishushkatva*), Pain (*Toda/Bheda/Shula*), Photophobia (*Kunita-varmta*), Itching (*Kandu*), Redness (*Raga*), Crusting (*Daruna-ruksha varmta*), 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 analyzed 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 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 for 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.

Moderate improvement: 51% to 75% improvement in signs and symptoms.

Mild improvement: 26% to 50% improvement in signs and symptoms.

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 and results were derived after executing statistical analysis. Statistically highly significant relief (p<0.001, p<0.01) was found in FBS (% relief=79.14%), Burning sensation (% relief=75.77%), Mucous discharge (% relief=62.4%), Transient blurring (% relief= 63.93%), Dryness (% relief=80.81%), Pain (% relief= 78.94%), Photophobia (% relief=62.92%), Itching (% relief=51.79%), Redness (% relief=65.46), Conjunctival congestion (% relief=66.66%). Statistically Significant relief (p<0.05) was found in Crusting (% relief=56.41%)

#### Effect Of Therapy In Group B

The efficacy of *Tarpana karma* with *Goghrita* 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 (% relief=66.66%), Burning sensation (% relief=66.91%), Dryness (% relief=70.66%), Itching (% relief=47.61%), Redness (% relief =59%), Conjunctival congestion (% relief=58.64%). Statistically significant relief (p<0.05) was found in Mucous Discharge (% 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.

Table 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>Yashtimadhu</i> | <i>Glycyrrhiza glabra</i> Linn.         | Leguminosae   | 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:** *Goghrita*-4 parts **Drava dravya:** *Godugdha* - 8 parts of *Goghrita*

**Table 2: Effect of Tarpana karma with Shatavahadi Ghrita on Assessment Criteria's in group A (18 patients)**

| Parameters              | N  | Mean Score |      | D    | % 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  |

BT: Before Treatment, AT: After Treatment

**Table 3: Effect of Tarpana karma with Go-Ghrita on Assessment Criteria's in group B (18 patients)**

| Parameters              | N  | Mean |      | D    | % 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  |

BT: Before Treatment, AT: After Treatment

**Table 4: Comparison over individual criterions 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 -I             | 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 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 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 7: Comparison of Overall Effect of Therapy in Both Groups (36 patients)

| Results             | Group A (n=18)  |       | Group B(n=18)   |       |
|---------------------|-----------------|-------|-----------------|-------|
|                     | No. of Patients | %     | No. of Patients | %     |
| 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     |

## DISCUSSION

Causative factors of *Shushkakshipaka* include dietary, regimental, psychological and traumatic causes which are specifically *achakshushya* and *pittanusari*. *Doorekshanata* (distant gazing for long time) cause *kriya-atiyogjanya vata* vitiation caused increased ocular surface exposure in upgaze. *Sukshma nireekshana* especially working on computers causes *kriya-atiyoga* resulting in reduced blinking a predisposing factor for DES. *Raja-dhoom nisevana* a consequence of pollution is considered harmful for eyes. *Abhighata* in form of chemical and thermal burns or lid deformities lead to dry eyes. *Ushana-abhitaptaysa jala praveshata*, *Ati maithuna*, *Ritu viparayayata* and psychological factors like *kopa*, *klesha* etc are prevalent in modern lifestyle. These *nidanas* are either *Vata* or *Pitta prakopka* or *Vata-pitta prakopka*, thus causative factors for dry eye<sup>4</sup>. 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*, hence it disintegrates the pathology of the disease “*Sushkakshipaka*”, which is *Vataj/Vata-Pittaj* in its manifestation. *Goghrita* is lipophilic in nature, which facilitates absorption of drugs through corneal epithelium<sup>11</sup>. *Go-Dugdha* is demulcent, thus maintain lubrication and nutrition. *Glycyrrhiza glabra* extract possess anti-inflammatory effect<sup>7</sup>. 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*<sup>6</sup>. The wood of *C.deodara* also has potent anti-inflammatory & analgesic activity<sup>8</sup>. *Nelumbo nucifera* has antioxidant activity may be due to the presence of phenolics, alkaloids, and saponins<sup>9</sup>. *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<sup>10</sup>. In the present study, maximum number of patients (57.50%) were in the age group of 41-60 Incidence of DES increase with age Majority of patients in this study were females (60%) as compared to males (40%). Exposure to dust and smoke (*Rajo dhoom nisevana*) also predisposes them to DES. Moreover increased T.V. watching and poor nutrition also make them susceptible.

## CONCLUSION

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

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