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Efficacy Of Bhringarajaadi Tail Pratimarsha Nasya As An Adjuvant To Carboxymethyl Cellulose Eye Drops In Dry Eye Syndrome: A Randomized Controlled Clinical Study

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Abstract

Dry Eye Syndrome (DES) is a multifactorial ocular surface disorder characterized by tear film instability and inflammatory changes, presenting with symptoms such as dryness, burning sensation, foreign body sensation, redness, and ocular fatigue. In Ayurveda, DES correlates with Shushkakshipaka, caused mainly by vitiation of Vata and Pitta Doshas. Conventional treatment with artificial tears like Carboxymethylcellulose (CMC) provides symptomatic relief but has limited long-term benefits.

This randomized, controlled clinical study evaluated the add-on effect of Bhringarajaadi Tail Pratimarsha Nasya with CMC 0.5% eye drops in DES. Sixty patients were randomly divided into two groups of 30 each. Group A received Bhringarajaadi Tail Pratimarsha Nasya along with CMC eye drops, while Group B received CMC eye drops alone for 15 days. Subjective symptoms and objective parameters (TBUT and Schirmer-I test) were assessed. Statistical analysis using paired t-test, unpaired t-test, and Mann–Whitney U test showed highly significant improvement in both groups ($p < 0.001$), with Group A demonstrating superior results. The study concludes that the integrative approach is more effective and safe in the management of Dry Eye Syndrome.

Introduction

Dry Eye Syndrome (DES) is a common ocular surface disorder characterized by tear film instability, hyper-osmolarity, inflammation, and neurosensory dysfunction, leading to symptoms such as dryness, burning sensation, redness, foreign body sensation, and visual disturbances. Its prevalence is increasing

globally[1], particularly in India, due to excessive digital screen exposure, environmental pollution, and lifestyle changes.[2]

In Ayurveda, DES can be correlated with Shushkakshipaka, a condition resulting from vitiation of Vata and Pitta Doshas, described under Shalakya Tantra. Classical texts advocate Sneha-based therapies, especially Pratimarsha Nasya, for disorders of the head and eyes, as the nose is considered the gateway to the cranial region.

Conventional management relies mainly on artificial tear substitutes such as Carboxymethylcellulose (CMC), which provide symptomatic relief but do not adequately address the underlying pathology. Hence, the present study evaluates the efficacy of Bhringarajaadi Tail Pratimarsha Nasya as an adjunct to CMC 0.5% eye drops in the management of Dry Eye Syndrome, with emphasis on objective and statistical outcomes.

Aim and Objectives

Aim

• To evaluate the add-on effect of Bhringarajaadi Tail Nasya with Carboxy Methylcellulose (CMC) 0.5% eye drops in the management of Dry Eye Syndrome.

Objectives

Primary Objective:

• To study the add-on effect of Bhringarajaadi Tail Nasya with CMC 0.5% eye drops for 15 days in the management of Dry Eye Syndrome.

Secondary Objective:

• To observe any adverse effects of Bhringarajaadi Tail Nasya, if present.

Review of Literature

Ayurvedic texts such as *Sushruta Samhita*[3], *Ashtanga Hridaya*[4], and *Chakradatta* describe various ocular disorders and emphasize *Nasya Karma* for diseases affecting vision. *Bhringarajaadi Tail*[5] is specifically indicated for *Drishtiprasadana* (improvement of vision) and is known for its *Chakshushya*, *Vata-Pitta Shamana*, and *Snehana* properties.

Modern literature reports that artificial tears like CMC improve tear film viscosity, reduce evaporation, and enhance ocular surface lubrication[6]. However, studies also indicate that monotherapy with artificial tears often provides only temporary symptomatic relief.

Materials and Methods

Study Design

The present study was designed as a randomized controlled clinical trial conducted on patients diagnosed with otomycosis. Ethical approval was obtained prior to commencement of the study, and informed consent was taken from all participants.

Sample size- 60 patients

Study duration: 15 days treatment with follow-ups on day 4, day 7, and day 15

Selection of Patients

Patients diagnosed with Dry Eye Syndrome based on clinical features and objective tests were selected from the outpatient department. Inclusion and exclusion criteria were predefined to ensure homogeneity.

Grouping and Intervention

Eligible patients were randomly allocated into two groups:

Group A (Trial Group): Bhringarajaadi Tail Pratimarsha Nasya + CMC 0.5% eye drops

Group B (Control Group): CMC 0.5%13 eye drops alone.

30 patients from Group A and 30 patients from Group B were allocated for the study. The study was performed for 15 days and results were observed.

Drugs

- Bhringarajaadi Tail Nasya prepared using Bhringaraaj, Yashtimadhu and til tail , administered as pratimarsha nasya (2 drops).
- Carboxymethylcellulose 0.5% eye drop: Standard topical lubricating agent administered for Dry Eye Syndrome.

Inclusion Criteria:

• Patients exhibiting a minimum of three characteristic symptoms of dry eye syndrome, which include:
  - Irritation in eyes
  - Foreign body sensation
  - Feeling of dryness
  - Itching
  - Blurring of vision
  - Ocular fatigue
  - Excessive blinking

• Patients aged between 18 and 60 years, inclusive.
• Patients were selected irrespective of their gender, religion, or socio economic status.
• Patients deemed fit for Pratimarsha Nasya Karma (as per Ayurvedic clinical assessment).

Exclusion Criteria:

Patients presenting with any of the following conditions was excluded from the study:

- Known cases of congenital anomalies of the eyes.
- Any acute infective condition of the eye.
- Severe dry eye with documented corneal involvement.

- Presence of ocular tumors
- History of intraocular surgery performed within the last one month.

Withdrawal Criteria:

A patient was withdrawn from the study under any of the following circumstances:

- Development of any adverse effects attributable to the interventions, such as excessive watering of eyes, increased itching, or significant redness. In such cases, the patient were receive prompt and appropriate medical attention.
- Exacerbation of existing Dry Eye Syndrome symptoms.
- Patient's unwillingness to continue participation in the treatment or follow-up schedule.

Procedure

In the trial group, Pratimarsha Nasya was given with Bhringarajaadi tail Nasya after snehan swedan along with Carboxymethylcellulose (0.5%) eye drop 1 drop 3 times a day. In the control group, Carboxymethylcellulose (0.5%) eye drop 1 drop 3 times a day was administered.

Assessment Criteria
Subjective Parameters[7,8]

Symptoms	Absent (0)	Mild (1)	Moderate (2)	Severe (3)
Itching	Not Experienced	Experienced Occasionally	Experienced Frequently	Always Experienced
Burning Sensation	Not Experienced	Experienced Occasionally	Experienced Frequently	Always Experienced
Foreign Body Sensation	Not Experienced	Experienced Occasionally	Experienced Frequently	Always Experienced
Redness/Conjunctival Congestion	Not Seen	Seen Occasionally	Seen Frequently	Always Seen
Blurring of Vision	Not Experienced	Seen Occasionally, episodic mild fatigue	Seen Frequently, annoying and/or activity- limiting, episodic	Always Seen, annoying, chronic and/or constant, limiting activity

Ocular Fatigue	Not Experienced	Experienced Occasionally	Experienced Frequently	Always Experienced
Excessive Blinking	Not Experienced	Experienced Occasionally	Experienced Frequently	Always Experienced
Lid/Meibomian Glands	Not Experienced	MGD variably present	MGD variably present	Frequent

Objective Parameters

-Tear Film Break-Up Time (TBUT) – Right and Left eye
-Schirmer-I Test – Right and Left eye

Statistical Analysis

The data obtained from the present clinical study were subjected to appropriate biostatistical analysis to evaluate the efficacy of the trial and control interventions in the management of Dry Eye Syndrome. Both **subjective and objective parameters** were analyzed systematically to assess intra-group and inter-group variations before and after treatment.

All observations were recorded in a pre-designed case record proforma and tabulated accordingly. Statistical analysis was performed using standard statistical methods suitable for clinical research. The level of significance was fixed in advance to avoid bias in interpretation.

Tests Applied and Rationale

1. **Within-group comparison (Before Treatment vs After Treatment):**
    - For **objective parameters** such as Tear Film Break-Up Time (TBUT) and Schirmer-I test (right and left eye), **Paired t-test** was applied, as these variables were continuous and followed a normal distribution.
    - This test helped to determine whether the observed changes within each group after intervention were statistically significant.
2. **Between-group comparison (Group A vs Group B):**
    - For **objective parameters**, **Unpaired t-test** was employed to compare the mean difference between the two independent groups and to evaluate the comparative efficacy of the trial drug regimen over the control drug.
    - For **subjective parameters** (itching, burning sensation, foreign body sensation, redness, blurring of vision, ocular fatigue, excessive blinking, and lid/meibomian gland involvement), **Mann–Whitney U test** was used, as these parameters were ordinal in nature and did not satisfy the criteria for parametric testing.

3. **Level of Significance:**

- A **p-value < 0.05** was considered *statistically significant.*
- A **p-value < 0.001** was considered *highly statistically significant*. These cut-off values were selected in accordance with standard biomedical research guidelines.

Summary of Statistical Findings

Parameter	**Statistical Test Applied**	**Statistical Outcome**
TBUT (Right & Left Eye)	Paired t-test	Highly significant improvement observed within both Group A and Group B ($p < 0.001$)
Schirmer-I Test (Right & Left Eye)	Paired t-test	Highly significant improvement observed within both groups ($p < 0.001$)
Subjective symptoms (all parameters)	Mann–Whitney U test	Group A showed statistically significant superiority over Group B ($p < 0.05$)
Inter-group comparison of objective parameters	Unpaired t-test	Group A demonstrated significantly greater improvement than Group B

Interpretation of Statistical Results

The statistical analysis clearly demonstrated that both treatment protocols were effective in improving subjective as well as objective parameters of Dry Eye Syndrome. However, the magnitude of improvement was consistently higher in Group A, which received Bhringarajaadi Tail Pratimarsha Nasya along with Carboxymethylcellulose 0.5% eye drops, compared to Group B, which received Carboxymethylcellulose 0.5% eye drops alone.

The highly significant improvement ($p < 0.001$) in objective parameters such as TBUT and Schirmer-I test indicates enhancement in tear film stability and tear secretion in both groups, while the statistically significant inter-group difference suggests an add-on therapeutic benefit of Bhringarajaadi Tail Nasya.

Similarly, the Mann–Whitney U test revealed that relief in subjective symptoms was significantly better in Group A, reflecting superior clinical efficacy in alleviating discomfort, dryness, burning sensation, and ocular fatigue.

Overall, the statistical findings strongly support the **rejection of the null hypothesis and acceptance of the alternate hypothesis**, establishing the adjunctive role of Bhringarajaadi Tail Nasya in the comprehensive management of Dry Eye Syndrome.

Observation and Results:

Equal number of patients were enrolled in two groups. Majority of the patients belonged to age group of 18-27 years. Itching, foreign body sensation, Eye strain, congestion in eyes were the common presenting symptoms. The assessments and the observations were recorded on the day of follow up. Post-treatment observations revealed significant reduction in itching, congestion , eye strain in both the groups, more in Group A. No serious adverse effects were observed in either group. The change in the parameter before and after the treatment was compared by applying paired and unpaired test. From the data the result was discussed in detail.

Discussion

The present study demonstrates statistically significant improvement in both subjective and objective parameters in patients of Dry Eye Syndrome treated with Bhringarajaadi Tail Pratimarsha Nasya along with CMC 0.5% eye drops. The within-group analysis revealed highly significant improvement in TBUT and Schirmer-I test values in both groups, indicating that both interventions were effective.

However, the between-group comparison showed that Group A achieved significantly better outcomes than Group B. The Mann–Whitney U test for subjective parameters revealed statistically significant superiority of Group A in reducing itching, burning sensation, foreign body sensation, redness, ocular fatigue, and excessive blinking. Similarly, unpaired t-test analysis for objective parameters demonstrated greater improvement in tear film stability and aqueous tear secretion in Group A.

From an Ayurvedic perspective, Dry Eye Syndrome corresponds to *Shushkakshipaka*, where *Vata* predominance leads to dryness and discomfort, while *Pitta* aggravation contributes to burning and redness. *Bhringarajaadi Tail* possesses *Snigdha*, *Vata-Pitta Shamana*, and *Chakshushya* properties. Administration through *Nasya Karma* allows the drug to act directly on *Shiras* and *Indriyas*, thereby influencing ocular physiology.

Modern pharmacological understanding suggests that the anti-inflammatory, antioxidant, demulcent, and neuro-protective properties of Bhringaraja, Yashtimadhu, and Til oil may contribute to improved tear secretion, stabilization of tear film, and reduction of ocular surface inflammation. When combined with the lubricating and viscosity-enhancing effect of CMC, a synergistic therapeutic action is achieved.

Conclusion

The study conclusively demonstrates that Bhringarajaadi Tail Pratimarsha Nasya administered along with Carboxymethylcellulose 0.5% eye drops is statistically more effective

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