

A Randomized Controlled Clinical Trial to Assess the Efficacy of Paya Sharkara Seka in Shushkakshipaka Special Reference to Dry Eye Syndrome

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ABSTRACT

Background: Shushkakshipaka, correlated with Dry Eye Syndrome, is a prevalent ocular surface disorder characterized by tear film instability, foreign body sensation, and ocular discomfort. Conventional therapy often yields transient relief.

Objective: To evaluate the clinical efficacy of Yashtimadhu Ksheerapaka Seka compared to artificial tear drops in managing Shushkakshipaka (Dry Eye) based on subjective and objective parameters.

Methodology: A randomized controlled clinical trial was conducted on 30 subjects diagnosed with Shushkakshipaka, divided into Group A (Yashtimadhu Ksheerapaka Seka) and Group B (artificial tear drops). Treatment was administered for 10 days with follow-up on day 21. Assessment included subjective symptom grading and objective tests—Schirmer's Test and Tear Film Break-Up Time (TBUT). Data were statistically analyzed using the Wilcoxon Signed-Rank Test and Mann-Whitney U Test.

Results: Group A showed highly significant improvement in symptoms: Rooksha ($Z = -3.49$, $p < 0.001$), Gharsha ($Z = -3.62$, $p < 0.001$), Toda ($Z = -2.97$, $p < 0.01$), and Daha ($Z = -3.28$, $p < 0.01$), compared to Group B. Objective scores also improved significantly in Group A: Schirmer's Test ($Z = -3.69$, $p < 0.001$; AF score: 2.6 ± 0.50) and TBUT ($Z = -3.69$, $p < 0.001$; AF score: 2.3 ± 0.44). Group B showed lower efficacy in both subjective (Rooksha: 1.7 ± 0.62 ; Gharsha: 1.5 ± 0.54) and objective outcomes (Schirmer's: 2.0 ± 0.55 ; TBUT: 1.8 ± 0.47). Overall, Group A demonstrated better therapeutic effect and sustained improvement.

Conclusion: Yashtimadhu Ksheerapaka Seka proved more effective than artificial tear drops in relieving symptoms and enhancing tear film parameters in Shushkakshipaka, confirming its clinical relevance and therapeutic superiority.

Keywords: Shushkakshipaka, Dry Eye Syndrome, Yashtimadhu Ksheerapaka Seka, Schirmer's Test, Tear Film Break-Up Time, Ayurvedic ophthalmology, Randomized controlled trial.

1. INTRODUCTION

Dry eye disease (DED) is a multifactorial ocular surface disorder characterized by discomfort, visual disturbance, and tear film instability, affecting millions globally [1]. In India, the prevalence ranges from 18.4% to 54.3%, making it a significant public health concern. Current treatment options, such as artificial tear substitutes and anti-inflammatory agents, often provide only temporary relief and fail to address underlying pathophysiological changes [2]. In Ayurvedic literature, DED closely resembles Shushkakshipaka, a Sarvagata Netra Roga associated with Vata and Pitta dosha vitiation [3]. Classical symptoms such as gharsha (foreign body sensation), rooksha (dryness), toda (pricking pain), and daha (burning sensation) correspond to modern clinical features of dry eye [4]. Among the traditional Ayurvedic ocular therapies (Kriyakalpa), Seka,

or therapeutic eye irrigation, has been advocated for its soothing and anti-inflammatory effects [5]. Yashtimadhu Ksheerapaka Seka, a formulation containing Glycyrrhiza glabra, Ksheera (milk), and Sharkara (sugar), is known for its Snigdha, Sheeta, and Pitta-Vata pacifying properties [6]. These attributes are beneficial in restoring tear film stability and reducing ocular surface inflammation. This study was designed to evaluate the efficacy of Yashtimadhu Ksheerapaka Seka compared to conventional artificial tear drops in the management of Shushkakshipaka (Dry Eye), using both subjective symptom scores and objective clinical assessments such as Schirmer's Test and Tear Film Break-Up Time [7].

2. MATERIAL AND METHOD

The selection of subjects for this clinical trial was based on both classical Ayurvedic diagnostic features and modern clinical parameters of Dry Eye Syndrome. Patients presenting with the classical lakshanas of Shushkakshipaka, as described in Ayurvedic texts, were included in the study. In addition, clinical features such as foreign body sensation, ocular dryness, pricking pain, and difficulty in opening and closing the eyelids were considered [8]. For objective diagnosis, Schirmer's test was used, and patients showing a reading of less than 15 mm were considered to have deficient tear secretion. Furthermore, the Tear Film Break-Up Time (TBUT) was assessed, and the appearance of dry spots within 10 seconds was considered indicative of an unstable tear film [9].

Inclusion criteria

The study included patients of either gender, aged between 18 to 70 years, who presented with classical lakshanas of Shushkakshipaka in accordance with Ayurvedic texts and clinical features consistent with Dry Eye Syndrome. Only those participants who fulfilled both the traditional and contemporary diagnostic criteria were enrolled in the study [10].

Exclusion criteria

Subjects with **congenital alacrimia**, impaired eyelid function, or conjunctival scarring disorders were excluded from the study. In addition, individuals with Dry Eye Syndrome secondary to systemic or autoimmune diseases were not considered for inclusion. Subjects with any other systemic illness that could potentially interfere with the study outcomes or treatment response were also excluded [11].

Intervention

Participants were randomly divided into two groups, Group A and Group B. Group A received Yashtimadhu Ksheerapaka Seka, a classical Ayurvedic procedure, wherein medicated decoction was poured over the closed eyes [12]. The procedure was carried out once daily for approximately 5–7 minutes, equivalent to 400 Matrakala, for a duration of 10 days. Group B, the control group, was administered artificial tear drops, with one drop instilled in each eye four times daily for the same period of 10 days. **Table 1** outlines the treatment protocol followed in each group [13]. The detailed treatment protocol for both Group A and Group B is summarized in Table 1.

Table 1: Treatment protocol for Group A and Group B

Group	Medicine	Treatment	Duration
A	Yashtimadhu Ksheerapaka	Seka for 400 Matrakala (5–7 minutes), once daily	10 days
B	Artificial Tear Drops	1 drop in each eye, 4 times daily	10 days

Duration of the study

The total duration of the study was 21 days, which included the treatment phase and a post-treatment follow-up period. Assessments were conducted at three time points: on Day 0 (Before Treatment - BT), on Day 11 (After Treatment - AT), and on Day 21 (After Follow-up - AF) [14].

Method of Preparation

The preparation of Yashtimadhu Ksheerapaka was carried out using the classical method described in Ayurvedic texts. The formulation included Yashtimadhu Kwatha Choorna (40 grams), Ksheera (milk) in the proportion of 320 ml, and Jala (water) in the proportion of 640 ml, maintaining a ratio of 1:8:32 respectively [15]. The ingredients were placed in a clean, sterile vessel and boiled over mandagni (mild heat) until the desired ksheeravashesha was achieved. Once the decoction was cooled to lukewarm temperature (sukhoshna), 5 grams of Sharkara (sugar) was added. The final preparation was filtered using a sterile cloth and used for the Seka procedure [16].

Subjective parameters

The therapeutic efficacy of the interventions was evaluated based on classical subjective parameters of Shushkakshipaka, which included Gharsha (foreign body sensation in eyes), Rooksha (feeling of dryness in eyes), Krichronmeelana (difficulty in opening and closing the eyelids), Toda (pricking pain), Avila Darshana (blurring of vision), and Daha (burning sensation).

Each of these symptoms was assessed using a four-point grading scale ranging from 0 (absence of symptom) to 3 (constant presence of symptom) [17]. The grading criteria for subjective symptoms and objective test parameters are presented in Table 2.

Objective parameters

In addition to subjective assessments, objective clinical tests were employed to evaluate the effectiveness of the treatments. These included Schirmer's test for tear secretion and Tear Film Break-Up Time (TBUT) for assessing tear film stability [18]. The results of both tests were categorized into four levels based on severity. The grading criteria for subjective symptoms and objective test parameters are presented in Table 2.

Table 2: Scoring system used for subjective and objective parameters [19]

Parameter	Score 0	Score 1	Score 2	Score 3
Gharsha (Foreign body sensation)	Absent	Occasionally present	Frequently present	Constantly present
Rooksha (Dryness)	Absent	Occasionally present	Frequently present	Constantly present
Krichronmeelana (Lid stiffness)	Absent	Occasionally present	Frequently present	Constantly present
Toda (Pricking pain)	Absent	Occasionally present	Frequently present	Constantly present
Avila Darshana (Blurring of vision)	Absent	Mild blurring	Moderate (episodic limiting activity)	Severe (constant limiting activity)
Daha (Burning sensation)	Absent	Occasionally present	Frequently present	Constantly present
Schirmer's Test (Tear secretion)	>15 mm	10–15 mm	5–10 mm	<5 mm
Tear Film Break-Up Time (TBUT)	>10 seconds	≤10 seconds	≤5 seconds	Immediate appearance of dry spots

Statistical Analysis

The collected data were subjected to appropriate non-parametric statistical analysis. Wilcoxon Signed-Rank Test was used for comparing pre-treatment and post-treatment values within each group (BT–AT and AT–AF). Mann–Whitney U Test was applied to determine statistical differences between the two groups. A p-value of <0.05 was considered statistically significant, while p-values of <0.01 and <0.001 were interpreted as highly significant [20].

3. RESULTS AND DISCUSSION

Effect on Gharsha (Foreign Body Sensation)

In Group A, there was a highly significant reduction in *gharsha* from BT to AT ($Z = -3.62$, $p < 0.001$), while Group B also showed a statistically significant reduction ($Z = -2.53$, $p < 0.05$). However, during follow-up, Group A maintained symptom reduction in 13 out of 15 subjects, while in Group B, 3 subjects experienced symptom recurrence. Between the groups, the difference at both AT and AF was statistically non-significant ($p > 0.05$), but the mean ranks favored Group A. The comparative effectiveness of treatments based on Z-values is illustrated in Figure 2. The **Effect on Effect on Gharsha** scores from baseline to post-treatment and follow-up is shown in Figure1. As shown in Table 3, Group A demonstrated a highly significant reduction in Gharsha ($Z = -3.62$, $p < 0.001$).

Table 3: Effect on Gharsha (Foreign Body Sensation)

Group	Stage	Z-value	p-value	Significance
A	BT–AT	-3.62	<0.001	Highly Significant
B	BT–AT	-2.53	<0.05	Significant
A vs B	AT	-0.54	>0.05	Not Significant

A vs B	AF	-1.32	>0.05	Not Significant
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Effect on Rooksha (Dryness of Eyes)

Group A exhibited highly significant improvement from BT to AT ($Z = -3.49$, $p < 0.001$) and sustained relief at follow-up ($Z = -2.23$, $p < 0.05$). Group B also showed significant results ($p < 0.05$), but the response was inferior in magnitude. Between-group comparison showed significant improvement in Group A over Group B both at AT ($p < 0.05$) and AF ($p < 0.001$). The comparative effectiveness of treatments based on Z-values is illustrated in Figure 2 and The progression of Rooksha (dryness) scores from baseline to post-treatment and follow-up is shown in Figure 1 and The effectiveness of Yashtimadhu Ksheerapaka Seka on ocular dryness is evident in Table 4, showing a significant reduction in Rooksha scores. This supports the **kledakara and lubricating action of Yashtimadhu Ksheerapaka**, which provided more durable relief compared to artificial tears.

Table 4: Effect on Rooksha (Dryness of Eyes)

Group	Stage	Z-value	p-value	Significance
A	BT-AT	-3.49	<0.001	Highly Significant
A	AT-AF	-2.23	<0.05	Significant
B	BT-AT	-2.64	<0.05	Significant
B	AT-AF	-2.44	<0.05	Significant
A vs B	AT	-2.23	<0.05	Significant
A vs B	AF	-3.87	<0.001	Highly Significant

Effect on Toda (Pricking Pain)

Group A showed a highly significant reduction in pricking pain ($Z = -2.97$, $p < 0.01$), while Group B had only significant improvement ($Z = -2.53$, $p < 0.05$). Between-group comparison revealed statistically better results for Group A at AT ($p < 0.001$) and AF ($p < 0.05$). The comparative effectiveness of treatments based on Z-values is illustrated in Figure 2. The **Effect on Toda (Pricking Pain)** scores from baseline to post-treatment and follow-up is shown in Figure 1 and Table 5 illustrates a marked improvement in Toda (pricking pain), with Group A achieving statistically superior outcomes. The **anti-nociceptive and anti-inflammatory actions** of Glycyrrhiza glabra flavonoids likely contributed to this superior relief in Group A.

Table 5: Effect on Toda (Pricking Pain)

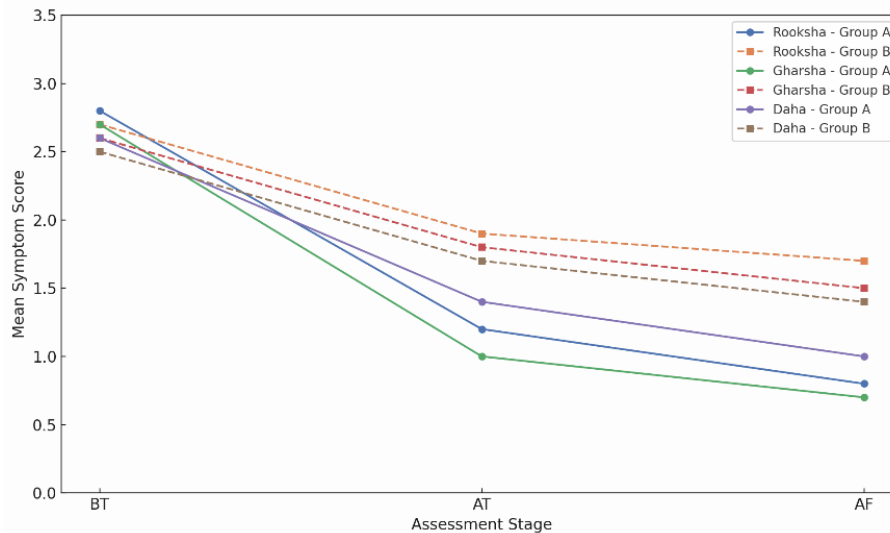
Group	Stage	Z-value	p-value	Significance
A	BT-AT	-2.97	<0.01	Highly Significant
B	BT-AT	-2.53	<0.05	Significant
A vs B	AT	-3.50	<0.001	Highly Significant
A vs B	AF	-2.42	<0.05	Significant

Effect on Daha (Burning Sensation)

Both groups showed highly significant intra-group reduction in burning sensation (Group A: $Z = -3.28$, $p < 0.01$; Group B: $Z = -3.20$, $p < 0.01$). However, the difference between groups was statistically non-significant at both AT and AF. Although both groups improved, the **mild cooling effect of Yashtimadhu and milk** appeared to provide longer relief, though statistical significance was not achieved. The comparative effectiveness of treatments based on Z-values is illustrated in Figure 2 and The **Effect on Daha (Burning Sensation)** scores from baseline to post-treatment and follow-up is shown in Figure 1 and Burning sensation (Daha) was reduced significantly in both groups; however, sustained relief was more evident in Group A, as depicted in Table 6.

Table 6: Effect on Daha (Burning Sensation)

Group	Stage	Z-value	p-value	Significance
A	BT–AT	-3.28	<0.01	Highly Significant
B	BT–AT	-3.20	<0.01	Highly Significant
A vs B	AT	-0.10	>0.05	Not Significant
A vs B	AF	-0.77	>0.05	Not Significant

**Figure 1: Symptom score progression across BT, AT, and AF in Group A and Group B for Rooksha, Gharsha, and Daha.****Effect on Schirmer's Test (Tear Secretion)**

Group A demonstrated highly significant improvement in tear secretion ($Z = -3.69$, $p < 0.001$), while Group B showed significant improvement ($Z = -3.00$, $p < 0.01$). Between-group comparison showed better results in Group A at both AT ($p < 0.05$) and AF ($p < 0.01$). The comparative effectiveness of treatments based on Z-values is illustrated in Figure 2. The findings suggest that **Yashtimadhu Ksheerapaka Seka effectively stimulates lacrimal gland function**, improving natural tear production. Objective assessment using Schirmer's Test (Table 7) revealed highly significant tear production improvement in Group A compared to Group B.

Table 7: Effect on Schirmer's Test

Group	Stage	Z-value	p-value	Significance
A	BT–AT	-3.69	<0.001	Highly Significant
A	AT–AF	-2.23	<0.05	Significant
B	BT–AT	-3.00	<0.01	Highly Significant
B	AT–AF	-1.41	>0.05	Not Significant
A vs B	AT	-2.53	<0.05	Significant
A vs B	AF	-3.45	<0.01	Highly Significant

Effect on Tear Film Break-Up Time (TBUT)

Group A showed highly significant improvement from BT to AT ($Z = -3.69$, $p < 0.001$), and significant retention of tear film stability at follow-up ($Z = -2.44$, $p < 0.05$). Group B also showed improvement ($Z = -3.05$, $p < 0.01$), but inter-group

comparison remained statistically non-significant. The comparative effectiveness of treatments based on Z-values is illustrated in Figure 2 and Figure 3 give Progression of objective parameter scores (Schirmer's Test and TBUT) in Group A and Group B at BT, AT, and AF. Group A shows a more consistent and sustained improvement. Improvements in tear film stability assessed by TBUT are shown in Table 8, highlighting the superior efficacy of Group A.

Table 8: Effect on Tear Film Break-Up Time

Group	Stage	Z-value	p-value	Significance
A	BT–AT	-3.69	<0.001	Highly Significant
A	AT–AF	-2.44	<0.05	Significant
B	BT–AT	-3.05	<0.01	Highly Significant
A vs B	AT	-0.86	>0.05	Not Significant
A vs B	AF	-0.35	>0.05	Not Significant

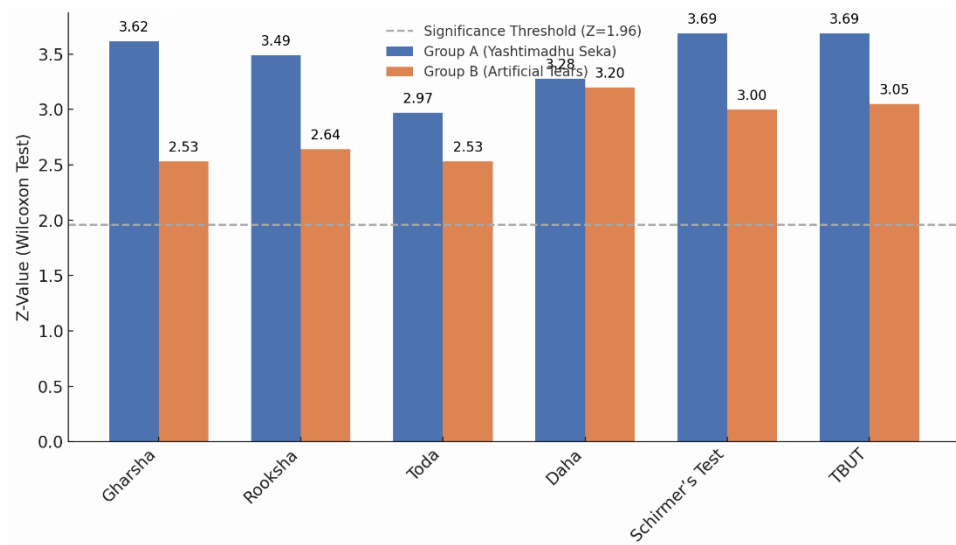
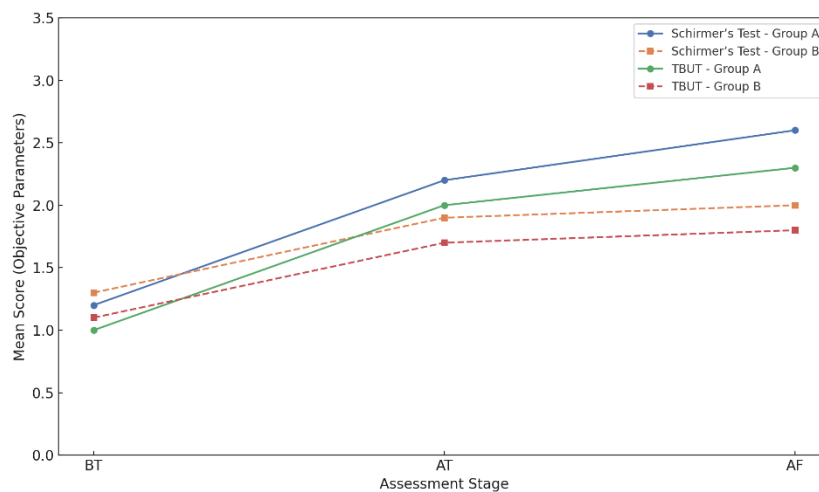


Figure 2. Comparative Z-values showing treatment efficacy in Group A and Group B across key clinical parameters. $Z > 1.96$ denotes statistically significant change ($p < 0.05$).



Figures 3: Progression of objective parameter scores (Schirmer's Test and TBUT) in Group A and Group B at BT, AT, and AF.

4. CONCLUSION

The findings of this clinical study demonstrate that Yashtimadhu Ksheerapaka Seka is a significantly effective therapeutic modality in the management of Shushkakshipaka (Dry Eye Syndrome) when compared to conventional artificial tear therapy. The intervention led to a statistically significant improvement in both subjective symptoms, such as rooksha (dryness), gharsha (foreign body sensation), toda (pricking pain), and daha (burning sensation), and objective parameters, including Schirmer's test and Tear Film Break-Up Time (TBUT). Patients treated with Yashtimadhu Ksheerapaka Seka not only experienced faster symptomatic relief but also showed sustained therapeutic outcomes during the follow-up period, indicating a longer-lasting effect. The formulation, with its Snigdha (unctuous), Sheeta (cooling), and Madhura (sweet) properties, contributed to Vata-Pitta pacification and improved ocular surface lubrication and healing. These results suggest that Ayurvedic ocular therapy like Seka, using pharmacologically active and safe herbal preparations such as Yashtimadhu, offers a holistic and integrative alternative to synthetic tear substitutes. Moreover, the trial supports the classical Ayurvedic understanding of Shushkakshipaka and validates traditional interventions through modern scientific methodology.

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Conflict of Interest

The authors declare that there is no conflict of interest associated with this research work.

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