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A CLINICAL STUDY TO EVALUATE THE EFFECT OF SHIGRUADI ASCHYOTAN (EYE DROPS) IN THE MANAGEMENT OF KAPHAJA ABHISHYANDA W.S.R. TO SEASONAL ALLERGIC CONJUNCTIVITIS

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ABSTRACT

Background: Seasonal allergic conjunctivitis (SAC) presents predominantly with ocular itching, watering, redness and burning. The clinical features described for Kaphaja Abhishyanda in Ayurveda show substantial symptom-level correspondence with SAC. Aschyotana is described as an important Kriyakalpa for ocular disorders. The present study evaluated Shigruadi Aschyotan, a topical Ayurvedic eye-drop formulation, and compared its clinical outcomes with a standard comparator eye-drop combination. **Methods:** This simple randomized comparative clinical study was conducted in the P.G. Department of Shalakya Tantra, R.G.G.P.G. Ayurvedic College & Hospital, Paprola. Forty patients aged 10–70 years meeting the study criteria were enrolled and allocated into two groups of 20 each. Group I received Shigruadi Aschyotan and Group II received eye drops containing phenylephrine 0.12%, naphazoline hydrochloride 0.05%, menthol 0.005% and camphor 0.01%. Treatment was for 7 days with assessments on day 3, day 7 and follow-up after completion. Thirty-two patients completed treatment (16 in each group). Subjective and

objective parameters were scored and analysed using mean, SD, SE and paired Student's t-test. **Results:** In Group I, significant or highly significant improvement was documented for itching (65.21%), lacrimation (45.46%), discharge (50%), heaviness (57.13%), photophobia (53.85%), burning sensation (61.90%), redness/congestion (48.49%) and conjunctival hyperemia (60%); upper tarsal papillae showed 40% relief and was not statistically significant. Between-group comparison was statistically significant for itching, photophobia and burning sensation, while the remaining parameters did not show a statistically significant difference. Overall, 12.5% of Group I patients were markedly improved, 50% moderately improved and 37.5% mildly improved. **Conclusion:** Within the limits of this small, short-duration study, Shigruadi Aschyotan was associated with improvement in the evaluated clinical features of Kaphaja Abhishyanda/SAC, with no adverse effects reported in the dissertation. Larger studies with longer follow-up are required to establish the magnitude and durability of the observed effects.

KEYWORDS: Kaphaja Abhishyanda; Seasonal Allergic Conjunctivitis; Shigruadi Aschyotan; Aschyotana; Kriyakalpa; Ayurveda.

1. INTRODUCTION

Abhishyanda is described in Ayurvedic ophthalmology as a Sarvagata Netraroga, with classical descriptions covering multiple ocular structures. The dissertation notes that the symptoms of Kaphaja Abhishyanda—including itching, irritation/burning, lacrimation, congestion, lid swelling, sticky discharge and heaviness—can be clinically correlated with Seasonal Allergic Conjunctivitis. Aschyotana, the instillation of medicated drops, is presented as an important Kriyakalpa and as an early/local ocular therapeutic procedure in the classical literature.[1–4]

The selected formulation, Shigruadi Aschyotan, contains Shigru (Moringa oleifera), Madhu (honey), Saindhava (rock salt), Putiha (Mentha spicata) and Karpoor (Cinnamomum camphora), formulated as an eye-drop preparation. The formulation was selected because the individual ingredients are described in the thesis as having Chakshushya and/or Kapha-Vata-shamaka properties and because a classical reference was identified for its use in Abhishyanda.[5–8]

The present manuscript is an article-format conversion of the submitted dissertation. The numerical results, study design, formulation composition and conclusions are retained from

the dissertation rather than being recalculated or replaced with external data.

2. AIM AND OBJECTIVES

- To evaluate the effect of Shigruadi Aschyotan in the management of Kaphaja Abhishyanda w.s.r. to Seasonal Allergic Conjunctivitis.
- To compare the clinical efficacy of Shigruadi Aschyotan with a comparator eye-drop combination containing phenylephrine 0.12%, naphazoline hydrochloride 0.05%, menthol 0.005% and camphor 0.01%.
- To assess the clinical safety of Shigruadi Aschyotan.

3. MATERIALS AND METHODS

3.1 Study design and setting

A simple randomized comparative clinical study was conducted in the P.G. Department of Shalakya Tantra, Rajiv Gandhi Government Post Graduate Ayurvedic College and Hospital, Paprola, Kangra, Himachal Pradesh. The dissertation records Institutional Ethics Committee approval under letter no. Ayu/IEC/2024/1416 dated 29 October 2024 and clinical trial registration under CTRI/2025/03/081630.[9]

3.2 Participants

Forty patients fulfilling the inclusion criteria were enrolled. Eligible participants were willing to undergo the trial, diagnosed with Kaphaja Abhishyanda/SAC irrespective of sex, and aged 10–70 years. Patients unwilling to participate, those with blepharitis, trichiasis, dacryocystitis, corneal ulcer or trachoma, and those with specified systemic/metabolic disorders such as cardiovascular disease, diabetes or hypertension were excluded.

3.3 Randomization and interventions

Group	Participants enrolled	Intervention	Trial duration
Group I – Trial group	20	Shigruadi Aschyotan eye drops	7 days
Group II – Standard/comparator group	20	Phenylephrine 0.12% + Naphazoline HCl 0.05% + Menthol 0.005% + Camphor 0.01% eye drops	7 days

The dissertation specifies that follow-up assessments were performed on the 3rd day, 7th day and after completion of the 7-day trial. Patients were advised to use the exact amount of drops instructed and to avoid other medication during the trial except essential medication.

Written voluntary informed consent was obtained. The dissertation's procedural review notes that classical Aschyotana dose varies with indication and patient tolerance; therefore, this manuscript does not assign an additional fixed instillation dose beyond the documented study protocol.

3.4 Composition of Shigruadi Aschyotan

Ingredient	Botanical/Source	Part/form used	Composition in study formulation
Shigru	Moringa oleifera Lam.	Seeds; aqueous extract	0.5% w/v aqueous extract
Madhu	Honey	—	10% w/v
Saindhava	Rock salt	Powder	0.1% w/v
Putiha	Mentha spicata Linn.	Distillated extract of leaves	0.005% w/v aqueous extract*
Karpoor	Cinnamomum camphora Nees & Eberm.	Sublimated extract	0.01% w/v
Benzalkonium chloride	Preservative	—	0.01% w/v
Sterile aqueous base	—	—	Quantity sufficient

*The dissertation table labels this as an aqueous extract (A.E.). The formulation certificate reproduced in the dissertation should be consulted for manufacturing specifications and batch details.[5]

3.5 Preparation and pharmaceutical aspects

The dissertation records that the investigational eye drops were formulated/manufactured under an Ayurvedic pharmaceutical setup and supplied as a sterile eye-drop preparation. The formulation contains aqueous extract of Shigru, honey, rock salt, Putiha extract, camphor, benzalkonium chloride as preservative and sterile aqueous base q.s. The dissertation emphasizes filtration/aseptic handling for Aschyotana Drava and notes the advantage of a modern eye-drop formulation in minimizing dose variation and allowing aseptic packing.[5,10]

3.6 Outcome measures

Subjective parameters were graded for itching, lacrimation, mucus discharge, heaviness of lids, photophobia, burning sensation and redness/congestion. Objective parameters included conjunctival hyperemia and upper tarsal papillae. General eye examination and slit-lamp examination were used, with CBC, ESR and FBS recorded as investigational parameters. The scoring system used ordinal grades according to symptom severity.[11]

3.7 Statistical analysis

Data were summarized using mean, standard deviation and standard error. Paired Student's t-test was used for within-group analysis at $p<0.05$, $p<0.01$ and $p<0.001$ levels. The dissertation interpreted $p>0.05$ as insignificant, $p<0.05$/$p<0.01$ as significant and $p<0.001$ as highly significant. Overall response categories were defined as complete remission (100%), marked improvement (76–99%), moderate improvement (51–75%), mild improvement (26–50%) and unimproved (<25%).[11]

4. RESULTS

4.1 Participant flow

Study status	Group I	Group II	Total
Registered	20	20	40
Dropouts	4	4	8
Completed	16	16	32

The analysis of treatment effect was based on 32 completers (64 eyes), with 16 patients in each group. The dissertation reports that the largest age category among enrolled patients was 21–30 years (25%), followed by 10–20 years (20%) and 41–50 years (17.5%).

4.2 Within-group clinical response

Clinical feature	Group I BT	Group I AT	Relief	p value	Group II BT	Group II AT	Relief	p value
Itching	2.875	1.000	65.21%	<0.001	2.800	0.933	66.67%	<0.001
Lacrimation	2.200	1.200	45.46%	<0.05	2.000	0.889	55.55%	<0.05
Discharge	2.000	1.000	50.00%	<0.05	2.222	0.889	59.99%	<0.05
Heaviness	2.333	1.000	57.13%	<0.05	2.800	1.200	57.14%	<0.05
Photophobia	2.889	1.333	53.85%	<0.001	2.333	1.000	57.13%	<0.05
Burning sensation	3.000	1.143	61.90%	<0.001	3.385	1.077	68.18%	<0.001
Redness/congestion	2.357	1.214	48.49%	<0.001	2.571	0.857	66.66%	<0.001
Conjunctival hyperemia	2.500	1.000	60.00%	<0.05	2.000	1.000	50.00%	<0.001
Upper tarsal papillae	1.000	0.600	40.00%	>0.05	2.000	1.333	33.35%	>0.05

4.3 Inter-group comparison

Parameter	Group I relief	Group II relief	Difference	p value	Interpretation in thesis
Itching	65.21%	66.67%	1.46%	<0.05	Significant
Lacrimation	45.46%	55.55%	10.09%	>0.05	Not significant
Discharge	50.00%	59.99%	9.99%	>0.05	Not significant
Heaviness	57.13%	57.14%	0.01%	>0.05	Not significant
Photophobia	53.85%	57.13%	3.28%	<0.05	Significant
Burning sensation	61.90%	68.18%	6.28%	<0.05	Significant
Redness/congestion	48.49%	66.66%	18.17%	>0.05	Not significant

Conjunctival hyperemia	60.00%	50.00%	10.00%	>0.05	Not significant
Upper tarsal papillae	40.00%	33.35%	6.65%	>0.05	Not significant

4.4 Overall therapeutic response

Outcome category	Group I n (%)	Group II n (%)
Cured	0 (0%)	0 (0%)
Markedly improved	2 (12.5%)	3 (18.75%)
Moderately improved	8 (50.0%)	11 (68.75%)
Mildly improved	6 (37.5%)	2 (12.5%)
Unchanged	0 (0%)	0 (0%)

No participant was classified as cured or unchanged in either group among treatment completers. In Group I, half of the completers showed moderate improvement, while 37.5% showed mild improvement and 12.5% marked improvement.

5. DISCUSSION

The Ayurvedic framework in the dissertation identifies Kaphaja Abhishyanda through features such as Kandu (itching), Muhurmuhur Srava (lacrimation), Pichchila Srava (mucus discharge), Guruta (heaviness), Daha (burning), Prakasha Asahyata (photophobia) and Raga (redness/congestion). These were mapped to corresponding clinical manifestations of SAC. This symptom-level correlation formed the basis for the clinical model used in the trial.[1–4]

The trial formulation was selected on the basis of the classical indication of Shigruadi Aschyotan for Abhishyanda and the Ayurvedic properties attributed to its ingredients. The dissertation describes Shigru, Madhu, Saindhava, Putiha and Karpoor as contributing to Chakshushya and/or Kapha-Vata-shamaka actions. The formulation's combined profile was therefore considered relevant to the Kapha-dominant symptom complex.[5–8]

Within Group I, the largest recorded symptomatic improvements were in itching (65.21%), burning sensation (61.90%), conjunctival hyperemia (60%) and heaviness (57.13%). Upper tarsal papillae showed a smaller 40% improvement and did not reach statistical significance. These findings indicate that the response was not uniform across all clinical features and that structural/objective signs may require a longer observation period.

The inter-group analysis reported statistically significant differences for itching, photophobia and burning sensation, whereas the differences for lacrimation, discharge, heaviness, redness/congestion, conjunctival hyperemia and upper tarsal papillae were not statistically

significant. The dissertation therefore describes the clinical performance of Shigruadi Aschyotan as approaching that of the comparator regimen, while also acknowledging the limited sample size and short treatment period.

No adverse effects were reported after Shigruadi Aschyotan in the dissertation. However, this safety observation should be interpreted in the context of only 16 evaluable patients in the trial group and a short treatment duration; it does not establish long-term ocular safety.

6. Limitations

- Small sample size: 40 enrolled and 32 completed the intervention.
- Short treatment duration of 7 days with limited post-treatment observation.
- The study was conducted at a single Ayurvedic teaching hospital.
- The analysis relied mainly on clinical symptom and examination scores; the dissertation does not present a large-scale objective biomarker analysis.
- The study was designed around a symptom-based Ayurvedic correlation of Kaphaja Abhishyanda with SAC; these are not identical diagnostic labels in contemporary ophthalmology.

7. CONCLUSION

In this 7-day randomized comparative clinical study, Shigruadi Aschyotan was associated with statistically significant within-group improvement in several symptoms and signs of Kaphaja Abhishyanda w.s.r. to Seasonal Allergic Conjunctivitis. The most pronounced responses in the trial group were observed for itching, burning sensation, conjunctival hyperemia and heaviness, while upper tarsal papillae showed a non-significant response. Between-group differences were significant for itching, photophobia and burning sensation and non-significant for the other evaluated parameters. No adverse effects were reported in the dissertation. The findings support further evaluation of the formulation in larger, adequately powered and longer-duration clinical studies.

8. Declarations

Ethics approval: Institutional Ethics Committee, R.G.G.P.G. Ayurvedic College & Hospital, Paprola; letter no. Ayu/IEC/2024/1416 dated 29/10/2024.

Trial registration: CTRI/2025/03/081630.

Informed consent: Voluntary, signed and witnessed informed consent was obtained from participants.

Funding/support: The dissertation records pharmaceutical support/sponsorship for the investigational drug.

Conflict of interest: Not independently assessed in this article-format conversion; the original dissertation should be used for the authors' final declaration.

Data availability: Data are contained in the dissertation research records.

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