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Clinical Evaluation of Gairikadi Pratisarana in Vataja Oshthaprakopa: An Exploratory Clinical Study

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Abstract: *Background: Vataja Oshthaprakopa is an Ayurvedic clinical entity characterized by lip dryness, roughness, fissuring, and discoloration. This study explored the clinical changes observed following the topical application of Gairikadi Pratisarana. Methods: This single-arm exploratory study enrolled patients aged 18–60 years presenting with at least three defined signs or symptoms. Gairikadi Pratisarana was topically applied to the lips twice daily for seven consecutive days. Clinical symptom scoring, Visual Analogue Scale (VAS) for pain, and objective digital moisture-meter readings were evaluated at baseline (Day 0), Day 4, and Day 8. Results: Out of 55 enrolled participants, 51 completed the trial protocol. Significant improvements were observed in recorded clinical features and digital moisture-meter measurements over the treatment period. Conclusion: Topical application of Gairikadi Pratisarana showed favorable changes in lip moisture and symptom scores over seven days. Given the single-arm design and short follow-up duration, these findings are preliminary and warrant confirmation through adequately powered, controlled clinical trials.*

Keywords: *Gairikadi Pratisarana; Vataja Oshthaprakopa; Ayurveda; Cheilitis; Exploratory clinical study.*

I. INTRODUCTION

The lips are continuously exposed to environmental stressors and prone to scaling, dryness, fissuring, and discomfort. While "cheilitis" serves as a broad modern umbrella term for inflammatory lip disorders, classical Ayurvedic texts classify localized lip pathology under Oshtharoga.

Vataja Oshthaprakopa is specifically characterized by Karkashata (roughness), Parushata (dryness), Sthabdhata (stiffness), Krishnavarni (dark or blackish discoloration), Tivraruja (pain), Dalan (cracking), and Paripatana (peeling). Pratisarana denotes localized topical application accompanied by gentle massage.

The test formulation, Gairikadi Pratisarana, incorporates traditional lipid bases and active ingredients (taila, ghrita, Sarjarasa, Siktha, guda, saindhava, and Gairika). Although previous studies have explored other Ayurvedic topical preparations for similar symptoms, clinical data documenting the outcomes of Gairikadi Pratisarana remain limited. This study aims to systematically document clinical changes following its administration.

Aims and Objectives

- Aim: To evaluate clinical changes in Vataja Oshthaprakopa following the local application of Gairikadi Pratisarana for seven days.

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- Primary Objective: To assess alterations in scored clinical features between baseline and follow-up intervals.
- Secondary Objectives: To monitor changes in digital moisture-meter values and document any reported adverse effects.

II. MATERIALS AND METHODS

Research Design and Setting

This was an exploratory clinical study conducted within the outpatient department of Shalakya Tantra at the institutional hospital. The evaluation followed a single-arm prospective observational framework.

Participant Selection Criteria

- Inclusion Criteria: Patients aged 18 to 60 years of either gender presenting with at least three diagnostic features of Vataja Oshthaprakopa (Karkashata, Parushata, Sthabdhata, Krishnavarni, Tivraruja, Dalan, or Paripatana).
- Exclusion Criteria: Individuals presenting with lip mucoceles, severe deep-seated pathology, malignancies (tumors/carcinomas), traumatic fissures, or recent history of perioral surgery.
- Withdrawal Criteria: Occurrence of severe local adverse events (e.g., acute burning, allergic rashes, marked swelling), patient non-compliance, or voluntary withdrawal.

Intervention Protocol

Gairikadi Pratisarana was topically administered twice daily for seven days. Participants were instructed to clean the lips, apply a sufficient quantity of the formulation with a clean fingertip utilizing gentle rubbing (Pratisarana), and allow it to remain for absorption.

The standard preparation utilized Taila (200 mL), Ghrita (200 mL), Sarjarasa (80 g), Siktha (80 g), Guda (20 g), Saindhava (40 g), and Gairika (8 g). Preparation method: Taila and ghrita were melted together, combined with the remaining finely powdered/prepared ingredients, mixed thoroughly, filtered through a clean cloth, and stored in sterile containers.

Outcome Measures and Evaluation Intervals

Assessments were conducted on Day 0 (Baseline), Day 4, and Day 8. Subjective parameters (roughness, dryness, stiffness, discoloration, cracking, and peeling) were graded using validated ordinal scales, pain was quantified via a Visual Analogue Scale (VAS), and objective hydration levels were recorded using a digital moisture meter.

Statistical Analysis

Data were compiled into a master sheet. Within-group analyses across observation points were performed using paired t-tests, with statistical significance set at $p < 0.05$. Analyses reflect data collected from the completer population (N = 51).

Results

A total of 55 patients were enrolled, of whom 4 discontinued follow-up, resulting in 51 participants who successfully completed the 7-day trial protocol.

Clinical Parameter Improvements

Statistically significant reductions were observed across almost all evaluated symptom scores and pain scales alongside marked increases in skin hydration values by Day 8.

Clinical Parameter	Baseline (Mean ± SD)	Day 4 (Mean ± SD)	Day 8 (Mean ± SD)	p-value
Roughness (Karkashata)	2.15 ± 0.49	1.24 ± 0.43	0.49 ± 0.50	<0.001
Dryness (Parushata)	2.87 ± 0.34	1.55 ± 0.50	0.53 ± 0.54	<0.001
Blackish Discoloration	0.58 ± 0.88	0.49 ± 0.77	0.27 ± 0.49	<0.001

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Cracking (Dalan)	1.25 ± 1.11	0.71 ± 0.71	0.20 ± 0.40	<0.001
Peeling (Paripatana)	1.07 ± 1.05	0.67 ± 0.70	0.22 ± 0.42	<0.001
Pain (VAS)	0.36 ± 0.93	0.24 ± 0.69	0.05 ± 0.23	0.007
Moisture-Meter Reading	17.49 ± 2.66	38.71 ± 4.96	59.53 ± 8.81	<0.001

(Note: Stiffness scores remained constant at baseline and follow-up intervals in this cohort).

Overall Therapeutic Response (N = 51 completers analyzed)

- Complete Relief (100%): 8 participants (15.7%)
- Marked Relief (≥75% to <100%): 26 participants (51.0%)
- Moderate Relief (≥50% to <75%): 16 participants (31.4%)
- Mild Relief (>0% to <50%): 1 participant (1.9%)

Discussion

The findings indicate favorable changes in clinical parameters associated with Vataja Oshthaprakopa following seven days of localized Gairikadi Pratisarana treatment. Substantial reductions were recorded in primary indicators such as Parushata (dryness) and Karkashata (roughness), supported by quantitative increases in skin hydration measurements.

Ayurvedically, the formulation's unctuous components (taila and ghrita) provide local snigdha properties that pacify aggravated Vata dosha, counteracting local roughness and cracking. However, because this study lacked a concurrent control group, natural resolution trends or placebo effects cannot be completely isolated. Limitations include the single-arm design, short observation window, and absence of long-term post-treatment tracking. Future research should incorporate randomized controlled formats and extended follow-up parameters to validate comparative efficacy.

IV. CONCLUSION

Local application of Gairikadi Pratisarana demonstrated positive improvements in symptom severity scores and moisture metrics among patients with Vataja Oshthaprakopa. These preliminary outcomes encourage further rigorous, controlled clinical investigations.

Declarations

Ethical Approval: Approved by the Institutional Ethics Committee of PDEA's College of Ayurved and Research Centre, Nigdi, Pune (Approval No: PDEA/ACRC/IEC/2023-24/018). Written informed consent was obtained from all participants prior to enrollment.

Conflict of Interest: The authors declare no competing financial interests.

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