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A Comparative Clinical Study In The Management Of *Vataja Oshtharoga* With Respect To Chapped Lips By *Navaneet Madhu Lepa* And *Puran Ghruta Lepa*.

[1]Dr. Nutan Sawant, [2]Dr. Chandana Virkar,Dr. Nilima Amruthe,Dr. Sandeep darunde, Dr. Sukhada Kulkarni,Dr. Sanika Virkar

[1]PG Scholar, [2]HOD and professor, [3]Associate professor,[4]Associate professor,[5]Assistant professor,

[1]Department of shalakya tantra,

[1]PDEA`S College of Ayurveda and Research Centre Nigdi, Pune,India.

Abstract:

Background and objective:

Vataja Oshthaprakop, correlated with chapped lips, is a common *mukharoga* characterised by roughness, dryness, fissuring, discoloration, and pain of the lips, primarily due to *vata* vitiation and environmental factors such as dehydration and extreme temperatures.[1] Modern management largely depends on synthetic lip balms, which offer mainly symptomatic and temporary relief. Ayurveda describes various local measures like *lepa, sneha,* and *swedana*, and *Harit Samhita* specifically mentions *Navaneet–Madhu lepa* for *oshtharoga*.[2] *Vataj oshtharoga* w.r.t. chapped lips is a disease of *mukharoga*, is one of the commonest problem in tropical country the prevalence of chapped lips is remarkable. *Vataja oshtharoga* is present with symptoms like *karkasha, parusha, ruksha, krushna, dalyate paripatyate* etc.[3]

In Ayurveda, research has been done and *vataj oshtharoga* is compared with chapped lips. Chapped lips resulting from dry and cracked skin of lips.

Method:

The present randomized controlled clinical trial was undertaken to evaluate and compare the efficacy of *Navaneet–Madhu lepa* and *Puran Ghrita lepa* in *Vataja Oshthaprakop*. Sixty-eight patients fulfilling diagnostic criteria were randomly allocated into two groups: Group A received *Navaneet–Madhu lepa* and Group B received *Puran Ghrita lepa*, both applied twice daily for 7 days.Subjective parameters (*karkasha, parushata, sthabdhata, krushnavarna, tivraruja, dalyate, paripatyate*) and objective moisture/oil values by moisture meter were assessed on Day 0 and Day 7, and analysed using appropriate statistical tests.

Result:

Both groups showed statistically significant improvement in roughness, dryness, colour change and moisture parameters ($p < 0.05$), with comparable efficacy between *Navaneet–Madhu* and *Puran Ghrita*.No adverse effects were reported.The findings suggest that both formulations are safe, effective, economical, and easily applicable options for *Vataja Oshthaprakop*, with *Navaneet–Madhu lepa* being especially suitable as a natural lip-balm–like formulation for contemporary use.

Interpretation and conclusion:

Both groups showed clinically and statistically significant reduction in key *Vataja Oshthaprakop* symptoms from Day 0 to Day 7.

The mean rank values indicated a consistent downward trend in severity grades with continued treatment over 7 days in both arms, signifying progressive restoration of lip smoothness and colour.

Mean moisture percentage increased from 30.92 ± 3.38 at Day 0 to 42.50 ± 3.55 at Day 7, with a mean difference of −11.58 and t = −22.77 ($p < 0.001$), showing highly significant improvement in hydration. Mean oil percentage rose modestly from 24.79 ± 1.86 to 25.57 ± 2.05, with $p < 0.001$, suggesting a mild but significant increase in surface lipid content.

KEYWORDS
Vataja Oshthaprakop, chapped lips, *Navaneet, Madhu lepa*, *Puran Ghrita lepa*, *Shalakyatantra*.

INTRODUCTION

Vataja Oshtharoga, one of the 65 *mukharogas* described in Ayurveda, primarily affects the lips and presents with roughness, dryness, stiffness, blackish discoloration, severe pain, cracking, and desquamation. Classical texts by *Sushruta, Vagbhata*, and *Yogaratnakara* classify *oshtharoga* based on *dosha* predominance and describe *Vataja Oshtharoga* as a *sadhya* condition when treated appropriately.[4]

Clinically, *Vataja Oshthaprakop* closely resembles chapped or fissured lips in modern medicine, characterized by dryness, scaling, fissuring, and erythema due to low humidity, wind, sun exposure, dehydration, and habitual lip licking. The lips' thin skin and lack of sebaceous and sweat glands predispose them to rapid dehydration, resulting in xerocheilosis. [5,6]

Conventional management with petrolatum- or wax-based lip balms provides only temporary relief without addressing the underlying *dosha* imbalance. Although Ayurveda describes several internal and external therapies for *oshtharoga*, many are time-consuming and less acceptable to modern patients. *Harit Samhita* recommends *Navaneet–Madhu lepa*, while *Puran Ghrita* is known for its *vata-pitta shamaka, snigdha*, and *ropana* properties beneficial in dry and chronic conditions. Despite their theoretical benefits, no controlled clinical study had previously compared these two interventions. [7-18]

Therefore, the present randomized controlled clinical trial was undertaken to compare the efficacy and safety of *Navaneet–Madhu lepa* and *Puran Ghrita lepa* in *Vataja Oshthaprakop* using subjective assessment and objective moisture-meter readings.

Need of the Study

Vataja Oshtharoga, caused by the aggravation of Vata dosha, is a commonly occurring condition affecting individuals of all age groups and closely correlates with chapped lips (cheilitis simplex) in modern medicine. Its incidence is increasing due to factors such as inadequate hydration, habitual lip licking, and exposure to extreme environmental conditions. Although the reported prevalence is approximately 0.74%, the condition often causes significant discomfort and affects quality of life.

Classical Ayurvedic texts describe Vataja Oshtharoga in detail and recommend snigdha and vātahara therapies, including Navaneeta–Madhu lepa and Purāṇa Ghṛta lepa. Contemporary treatments provide only symptomatic relief and may have limitations with long-term use. Therefore, the present study is undertaken to evaluate the therapeutic efficacy of Navaneeta–Madhu lepa and Purāṇa Ghṛta lepa in the management of Vataja Oshtharoga (chapped lips).

OBJECTIVE OF THE STUDY

- To study the efficacy of *navaneet* and *madhu lepa* twice a day given for 7 days in *vataj oshthaprakop.*
- To observe the adverse effect of *navaneet* and *madhu lepa* if any.

MATERIAL AND METHODOLOGY

This was a randomized controlled, double-arm clinical trial conducted to evaluate the Efficacy of Navaneet and Madhu Lepa with Puran Ghrita Lepa in Vataja Oshthaprakop (Chapped Lips).

Sample selection:

The subjects were selected incidentally and randomly placed into two groups.

Sample

A total of 66 patients were enrolled and allocated into two groups, 33 subjects in each.
Group A (*Navaneet–Madhu lepa*) application on lips twicw a day for 7 days.
Group B (*Puran Ghrita lepa*) application on lips twicw a day for 7 days.

Study design:

Randomised controlled clinical trial.

Inclusion criteria

- Age 18–60 years, irrespective of sex, religion, and socio-economic status.
- Presence of minimum three signs and symptoms of *Vataja Oshthaprakop* as per classical description.
- Willingness to give written informed consent and comply with trial protocol.

Exclusion and withdrawal criteria

- Patients with mucocele, severe pathological dry lip, lip tumours, carcinoma, active herpes labialis, or systemic diseases severely affecting lip integrity were excluded.
- Subjects developing serious adverse events, marked worsening of symptoms, or unwilling to continue treatment were withdrawn and offered appropriate care.

Diagnostic criteria:

Patients were diagnosed as *Vataja Oshthaprakop* if they exhibited at least three of the following cardinal features described in Ayurvedic literature as a subjective parameter [19]

Karkasha – roughness of lips

Grade: 0 No *Karkashta* (smooth surface)

Grade: 1 Roughness of the surface of *oshtha* is not visible by naked eye but can be felt by touching by finger.

Grade: 2 Roughness of surface of *oshtha* is visible by naked eye and can be felt by finger but not hurts the finger.

Grade: 3 Roughness of surface of *oshtha* with fissures is visible by naked eye, can be felt by finger not hurts the finger.

Grade: 4 Roughness of surface of *oshtha* with fissures is visible by naked eye, can be felt by finger and hurts the finger.

Parushta – dryness

Grade: 0 No dryness (moist)

Grade: 1 Mild dryness. No need of lubrication.

Grade: 2 Needs lubrication once or twice a day.

Grade: 3 No benefit with frequent lubrication

Sthabdhata – restricted movement (Immobile)

Grade: 0 Lip movement not restricted.

Grade: 1 Difficulty in lip movement.

Grade: 2 Lip movement is totally restricted.

Grade: 3 No lip movement.

Krushnavarni – blackish or dark discoloration

Grade: 0 No change in colour.

Grade: 1 Dark than normal colour.

Grade: 2 Darker but not complete black.

Grade: 3 Blackish in colour.

Tivraruja – severe pain

Grade: 0 No pain.

Grade: 1 Pain while movement.

Grade: 2 Continuous pain.

Grade: 3 Discomfort for pain, patient have to take analgesics

Dalyate – Cracked lip

Grade: 0 No crack.

Grade: 1 Single crack.

Grade: 2 Multiple crack.

Grade: 3 Multiple deep cracks (bleeding).

Paripatyate – desquamation

Grade: 0 No desquamation.

Grade: 1 Superficial desquamation of epithelium which looks like soft white scales.

Grade: 2 Deep desquamation of epithelium which looks like hard white scales and ready to bleed.

Grade: 3 Deep desquamation with bleeding.

Objective parameters- based on percentage of moisture meter

Normal moisture range was taken as 16–22% and moist skin as 23–33%; normal oil 23–33% and oily 34–63% as per device norms.[20]

Interventions

- Group A – *Navaneet–Madhu lepa*:

Fresh *Navaneet* (white butter) and *Madhu* (honey) were combined in a standardised proportion to prepare a soft *lepa* suitable for lip application, following classical guidance from *Harit Samhita* and pharmaceutically acceptable conditions.[21]

Patients were instructed to apply an appropriate quantity with cleaned index finger on the lips twice daily (morning and night) for 7 days, after washing hands and lips, and to leave it in place for absorption.

- Group B – *Puran Ghrita lepa:* [22]

One-year-old Go-ghrita (*Puran Ghrita*) fulfilling Ayurvedic and contemporary quality parameters was used as lepa.[23]

Application schedule and instructions were identical to Group A: twice daily for 7 days over the lips.

No other topical lip products or systemic drugs specifically targeting lips were permitted during the trial period.

STATISTICAL TESTS

Data were analysed using appropriate parametric and non-parametric tests.

- Paired t-test was used for within-group comparison of moisture and oil values between Day 0 and Day 7.
- Wilcoxon signed-rank test and related non-parametric methods were used for ordinal symptom scores over time.
- Inter-group comparisons were done by suitable tests (e.g., Mann–Whitney or unpaired t-test) to examine differences between Group A and Group B.
- A p-value < 0.05 was considered statistically significant.

Results

Baseline characteristics

A total of 68 patients were enrolled; after accounting for two withdrawals, 66 patients (33 in each group) completed the trial.Both groups were comparable in terms of age, sex distribution, and baseline symptom scores, indicating successful randomization.

Table showing test results of subjective parameter:

	GROUP A			GROUP B		
	Mean rank	Sum of ranks	P - values	Mean rank	Sum of ranks	P - values
Karkasha	17.00	561.00	0.000	17.00	561.00	0.000
Parusha	17.00	561.00	0.000	17.00	561.00	0.000
Stabdha	0.000	0.000	1.000	0.000	0.000	1.000
Krushna	13.50	351.00	0.000	12.50	300.00	0.000
Trivraruja	0.000	0.000	1.000	0.000	0.000	1.000
Dalyate	1.50	3.00	0.157	4.000	28.00	0.000
Paripatyate	0.000	0.000	1.000	0.000	0.000	1.000

	Mean rank		Sum of ranks		P – value
	Group A	Group B	Group A	Group B	
Karkasha	33.50	33.50	1105.50	1105.50	1.000
Parusha	33.50	33.50	1105.50	1105.50	1.000
Stabdha	33.50	33.50	1105.50	1105.50	1.000
Krushna	34.50	32.50	1138.50	1072.50	0.569
Trivraruja	33.50	33.50	1105.50	1105.50	1.000
Dalyate	31.00	36.00	1023.00	1188.00	0.075
Paripatyate	33.50	33.50	1105.50	1105.50	1.000

Table showing test results of Objective parameter:

	Group A				Group B			
	Mean	SD	SE Mean	P - value	Mean	SD	SE Mean	P - value
Moisture meter moist	-11.5787	2.92080	0.50845	0.000	10.19656	3.17420	0.55256	0.000
Moisture meter oil	-0.78030	0.80214	0.13963	0.000	0.98939	1.54565	0.26906	0.000

Symptomatic improvement

Both groups showed clinically and statistically significant reduction in key *Vataja Oshthaprakop* symptoms from Day 0 to Day 7.

- *Karkasha* (roughness), *Parushta* (dryness) and *Krushnavarna* (blackish discoloration) scores decreased significantly in both Group A and Group B ($p < 0.05$).
- *Dalyate* (cracked lips) and *Paripatyate* (desquamation) also reduced, though some parameters such as *Sthabdhata* and *Tivraruja* did not show statistically significant change in all comparisons.

The mean rank values indicated a consistent downward trend in severity grades with continued treatment over 7 days in both arms, signifying progressive restoration of lip smoothness and colour.

Moisture-meter findings

In Group A (*Navaneet–Madhu*):

- Mean moisture percentage increased from 30.92 ± 3.38 at Day 0 to 42.50 ± 3.55 at Day 7, with a mean difference of −11.58 and $t = -22.77$ ($p < 0.001$), showing highly significant improvement in hydration.
- Mean oil percentage rose modestly from 24.79 ± 1.86 to 25.57 ± 2.05, with $p < 0.001$, suggesting a mild but significant increase in surface lipid content.

Similar statistically significant improvements were recorded in Group B *Puran Ghrita*, with moisture and oil parameters moving towards the normal/moist ranges, reflecting restored barrier function of the vermilion.

Inter-group comparison

When Group A and Group B were compared, there was no significant difference in the magnitude of change for major factors such as *Karkasha, Parushta, Krushnavarna*, and overall moisture improvement; thus, the alternate hypothesis that *Navaneet–Madhu lepa* is as effective as *Puran Ghrita lepa* could not be rejected.For several parameters (e.g., *Sthabdhata, Tivraruja, Dalyate, Paripatyate*), the pattern of change was similar, indicating near-equivalent clinical outcomes.

Patient images

Before treatment

After treatment

Discussion

The study shows that both *Navaneet–Madhu lepa* and *Puran Ghrita lepa* provide significant relief in *Vataja Oshthaprakop*, a *vata*-predominant *mukharoga* affecting the lips and comparable to chapped lips in modern terms. By restoring *snigdhata*, colour, and mobility of the *oshtha*, both therapies effectively address the core pathology.

Navaneet, with its *sheeta, atisnigdha*, *vata-shamaka* and *varnya* properties, improves lubrication, suppleness, and lip colour, while *Madhu* enhances penetration and promotes rapid healing through its *vrana-shodhana* and *ropana* actions. Their combination offers both emollient and humectant effects, reflected in improved moisture-meter readings and reduced cracking and roughness.

Puran Ghrita, a *vata-pitta shamaka* and *vrana-ropaka sneha*, shows strong affinity for epithelial tissues, improving hydration, elasticity, and deeper nourishment of the lips. Comparable clinical and objective outcomes in both groups indicate that *Navaneet–Madhu lepa* is as effective as *Puran Ghrita lepa* in managing *Vataja Oshthaprakop*.

From a modern perspective, both act as natural occlusive-emollient systems that reduce transepidermal water loss and enhance barrier function. *Navaneet–Madhu lepa* also offers practical advantages, as it can be easily developed into a cosmetically acceptable, low-cost lip-balm-like formulation. The absence of adverse effects confirms the safety of both therapies for mild to moderate cases.

Conclusion

The randomized controlled clinical trial establishes that both *Navaneet–Madhu lepa* and *Puran Ghrita lepa* are safe and effective in the management of *Vataja Oshthaprakop* (chapped lips), producing significant improvement in roughness, dryness, and discolouration and objective moisture parameters within 7 days of twice-daily application. Statistical analysis indicates no meaningful difference in overall therapeutic response between the two groups, thereby validating the alternate hypothesis that *Navaneet–Madhu lepa* is as effective as *Puran Ghrita lepa* in this condition.

Given its *atisnigdha, vatashamaka* and *ropana* properties, simple preparation, low cost and high patient acceptability, *Navaneet–Madhu lepa* emerges as a promising Ayurvedic, lip-balm–type local therapy for chapped lips in everyday practice.Further multi-centre studies with larger sample sizes and longer follow-up would help confirm long-term benefits and recurrence patterns.

FURTHER SCOPE FOR STUDY

The present study had limitations due to short time duration, small sample size, and limited drug dose. A similar study with a larger sample size and longer duration could lead to more effective results in preventing chapped lips.

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