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A Randomized Controlled Clinical Trial To Evaluate The Efficacy Of Triphaladi Kashaya Gandusha And Tannic Acid–Choline Salicylate Gel Local Application In The Management Of Pittaj Mukhapaka

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ABSTRACT

Background: Pittaj Mukhapaka is a commonly encountered inflammatory and ulcerative condition of the oral cavity, characterized by burning sensation, pain, altered taste, and ulceration. Ayurveda describes it as a Pittaja Nanatmaja and Rakta Pradoshaja Vikara. Although several Ayurvedic formulations and local therapies have been studied for Mukhapaka, limited evidence exists comparing classical Ayurvedic Gandusha therapy with standard modern topical agents. **Objective:** To evaluate and compare the clinical efficacy of Triphaladi Kashaya Gandusha and Tannic Acid–Choline Salicylate Gel local application in the management of Pittaj Mukhapaka. **Methodology:** A randomized controlled clinical trial was conducted on 60 patients diagnosed with Pittaj Mukhapaka, divided equally into two groups. Group A received Triphaladi Kashaya Gandusha, while Group B received Tannic Acid–

Choline Salicylate Gel for 5 days. Assessment was done using subjective and objective parameters on Day 1, Day 3, and Day 5. Statistical analysis was performed using paired and unpaired tests. **Results:** - Both groups showed statistically significant improvement ($p < 0.05$) in all parameters. Group A demonstrated higher percentage relief in Asya Daha, Asya Ruja, Asya Vairasya, and number of Vrana compared to Group B. **Conclusion:** Triphaladi Kashaya Gandusha showed superior clinical efficacy compared to Tannic Acid–Choline Salicylate Gel in the management of Pittaj Mukhapaka, with no adverse effects observed.

KEYWORDS

Gandusha; Oral ulcers; Pittaj Mukhapaka; Triphaladi Kashaya.

1. INTRODUCTION

Oral health plays a pivotal role in maintaining overall well-being, nutrition, communication, and quality of life.[01] Diseases of the oral cavity, particularly inflammatory and ulcerative conditions, [02] significantly affect daily activities such as eating, speaking, and swallowing. Mukhapaka, correlated with stomatitis or recurrent aphthous ulcers, is one such frequently encountered disorder in clinical practice. [03]

According to Ayurvedic classics, Mukhapaka is classified under **Mukharoga**, described as a condition involving ulceration, pain, burning sensation, and inflammation of the oral mucosa.[04] Acharya Sushruta categorizes Mukhapaka as a **Rakta Pradoshaja Vikara**, while Vagbhata describes Pittaj Mukhapaka as a **Pittaja Nanatmaja Vikara**, emphasizing the predominant role of aggravated Pitta Dosha. [05]

The classical lakshanas of Pittaj Mukhapaka include: [06-08]

- Asya Daha (burning sensation)
- Asya Ruja (pain)
- Asya Vairasya (altered taste)
- Vrana (ulceration)

Modern medicine recognizes multiple etiological factors such as nutritional deficiencies, stress, immunological disturbances, trauma, microbial infection, and drug reactions. Conventional treatment primarily focuses on symptomatic relief using topical analgesics, anti- inflammatory agents, and antiseptics, which may not address the underlying pathology and may cause adverse effects on prolonged use.

Ayurveda offers a holistic approach through **Nidana Parivarjana**, **Shodhana**, and **Shamana** therapies. Among local therapies, **Gandusha** is considered highly effective for Mukharogas due to

prolonged contact of medicated liquids with oral mucosa. [09-10] Triphaladi Kashaya, possessing Pittashamaka, Vranashodhana, and Vranaropana properties, appears promising for Pittaj Mukhapaka but lacks sufficient comparative clinical evaluation.

2. Need of the Study

To scientifically validate Triphaladi Kashaya Gandusha and compare its efficacy with a standard modern topical therapy in Pittaj Mukhapaka.

3. MATERIALS AND METHODS

3.1 Study Design

- Randomized Controlled Clinical Trial
- Open-label, parallel-group study

3.2 Sample Size

- Total patients: 60
- Group A: 30 patients
- Group B: 30 patients

3.3 Selection Criteria

Inclusion Criteria

- Diagnosed cases of Pittaj Mukhapaka
- Age group 18–60 years
- Presence of oral ulcers with burning and pain

Exclusion Criteria

- Systemic illnesses (diabetes, malignancy)
- Immunocompromised conditions
- Pregnancy and lactation

3.4 Intervention [11,12,13]

Group	Intervention	Dose & Duration
A	Triphaladi Kashaya Gandusha [11]	Twice daily for 5 days
B	Tannic Acid + Choline Salicylate Gel [12,13]	Local application twice daily for 5 days

3.5

3.6 Assessment Criteria

Subjective Parameters

- Asya Daha
- Asya Ruja
- Asya Vairasya

Objective Parameter

- Number of Vrana

Scoring was done on a graded scale from 0–3.

4. STATISTICAL ANALYSIS

The collected data were subjected to systematic statistical evaluation to assess the efficacy of the interventions and to determine the significance of observed changes. Statistical analysis was carried out using standard biostatistical methods, ensuring objectivity and reliability of the study findings.

For within-group comparison, the paired t-test was employed. This test was used to evaluate the statistical significance of changes in clinical parameters before and after treatment within the same group (i.e., Day 1 vs Day 5). The paired t-test is appropriate in this context as the observations were obtained from the same subjects at different time points, thereby accounting for individual variability.

For between-group comparison, the unpaired t-test was applied. This test was used to compare the mean differences in outcome measures between Group A (Triphaladi Kashaya Gandusha) and Group B (Tannic Acid–Choline Salicylate Gel). The unpaired t-test is suitable for comparing two independent groups to determine whether the observed differences in treatment outcomes are statistically significant.

All statistical tests were conducted at a 5% level of significance, and a p-value less than 0.05 ($p < 0.05$) was considered statistically significant. This threshold indicates that there is less than a 5% probability that the observed differences occurred due to chance alone.

The results were expressed in terms of mean ± standard deviation (SD) to describe the central tendency and variability of the data. Additionally, percentage relief was calculated for each parameter to provide a clinically meaningful interpretation of therapeutic improvement. This dual representation of data facilitated both statistical and clinical evaluation of the treatment outcomes.

5. RESULTS

5.1 Overall Improvement

Improvement	Group A	Group B
Good	7 (23.3%)	3 (10%)
Moderate	21 (70%)	24 (80%)
Mild	2 (6.7%)	3 (10%)

5.2 Percentage Relief in Symptoms

Parameter	Group A (%)	Group B (%)
Asya Daha	69.41	60.00
Asya Ruja	70.00	63.01
Asya Vairasya	68.68	62.50
Number of Vrana	67.96	62.63

All parameters showed statistically significant improvement in both groups ($p < 0.05$), with Group A demonstrating better outcomes.

6. DISCUSSION

The present study demonstrates that both Triphaladi Kashaya Gandusha and Tannic Acid–Choline Salicylate Gel are effective in managing Pittaj Mukhapaka. However, the trial drug showed superior results in symptom relief and overall improvement.

The statistically significant reduction in Asya Daha and Asya Ruja in Group A may be attributed to the **Sheeta Virya**, **Pittashamaka**, and **Dahaprashamana** properties of Triphaladi Kashaya. Gandusha allows prolonged drug contact, enhancing absorption and local action.

Modern pharmacological activities such as antioxidant, anti-inflammatory, antimicrobial, and astringent effects of Triphala constituents support the observed results. In contrast, the control drug primarily provides symptomatic relief through prostaglandin inhibition and astringent action, without addressing the underlying doshic imbalance.

The unpaired t-test revealed that the difference between groups was statistically significant, indicating better efficacy of the Ayurvedic intervention.

7. CONCLUSION

Triphaladi Kashaya Gandusha is clinically and statistically more effective than Tannic Acid–Choline Salicylate Gel in the management of Pittaj Mukhapaka. The study validates the Ayurvedic approach as a safe, effective, and economical alternative. No adverse drug reactions were observed during the study.

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