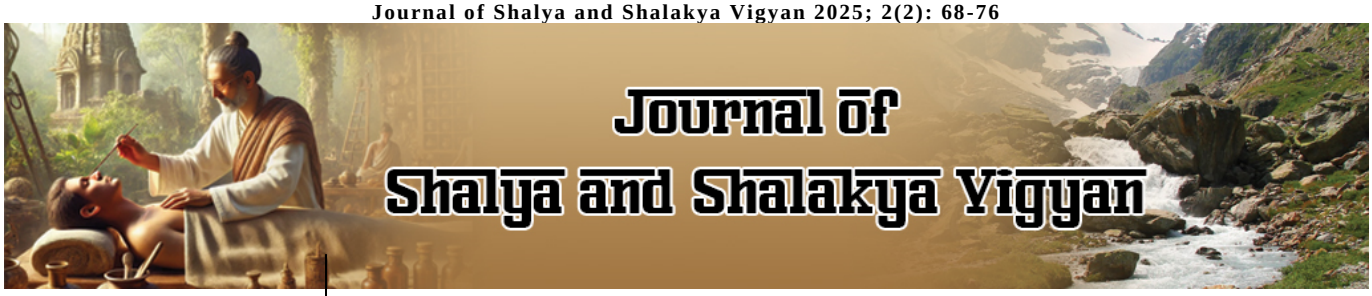

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Clinical Effect of mukhalepa and gandūṣa in the management of mukhapāka (Recurrent aphthous stomatitis) in dental practice: A randomized controlled trial

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Abstract
Background: Mukhapāka (stomatitis), clinically comparable to minor recurrent aphthous ulcers, is a common painful oral mucosal condition that affects eating, speech, and oral-health-related quality of life. Conventional dental management often provides incomplete relief and limited recurrence prevention. Ayurvedic local measures such as Mukhalepa (medicated paste application) and Gandūṣa (retention of medicated liquid in the mouth) are traditionally indicated but lack controlled evidence.
Objectives: To evaluate the effectiveness and safety of a standardized Mukhalepa plus Gandūṣa protocol as an adjunct to standard stomatitis care compared with standard care alone in adults with minor aphthous-type Mukhapāka.
Methods: In this prospective, randomized, parallel-group trial, 60 adults with minor aphthous ulcers were allocated to Group A (Mukhalepa with Khadira-Ashvattha-Yashtimadhu-Madhu plus Gandūṣa with Triphalā Kwātha and honey, in addition to standard care) or Group B (standard care alone: 0.12% chlorhexidine mouthrinse, topical anaesthetic gel, and B-complex supplementation). Interventions were given for 7 days. Follow-up occurred on Days 3, 7, and 14, with recurrence assessment 4 weeks after healing. Primary outcomes were changes in pain and burning VAS scores, percentage reduction in ulcer area, and time to complete clinical healing.
Results: Baseline characteristics were comparable. Both groups improved, but Group A showed significantly greater reductions in pain and burning by Days 3 and 7 ($p<0.001$) and a larger reduction in ulcer area by Day 7 (92.1% vs 74.8%; $p<0.001$). Complete healing by Day 7 occurred in 90.0% of Group A vs 56.7% of Group B (p=0.004), with shorter median healing time (5 vs 7 days; log-rank $p<0.001$). Functional difficulty scores improved more in Group A. Four-week recurrence was lower in Group A (13.3% vs 36.7%; p=0.03). No serious adverse events occurred.
Conclusion: A standardized Mukhalepa plus Gandūṣa protocol as an adjunct to standard care provides superior symptomatic relief, faster ulcer healing, improved oral function, and reduced short-term recurrence compared with standard care alone, with good tolerability.

Keywords: Mukhapāka, recurrent aphthous stomatitis, Mukhalepa, Gandūṣa, Triphalā, oral ulcer, integrative dentistry

Introduction
Recurrent aphthous stomatitis (RAS) and related ulcerative stomatitides are among the most common inflammatory disorders of the oral mucosa, with lifetime prevalence estimates in many populations ranging roughly between 5% and 25%, and they markedly impair eating, speech and oral-health-related quality of life.[1, 2] Contemporary literature describes RAS as a multifactorial condition involving local trauma, nutritional deficiencies, stress, immune dysregulation and microbial factors, for which current management relies mainly on topical corticosteroids, analgesic and antiseptic mouthwashes, vitamin supplementation and, in selected cases, systemic immunomodulators.[1-3] These measures often provide only short-term symptomatic relief, do not reliably prevent recurrences, and may be limited by cost, accessibility or adverse effects in routine dental practice. Large epidemiological surveys from Indian dental and tertiary centres further highlight that oral mucosal lesions, including recurrent aphthous-like ulcers, affect around one-fifth of dental out-patients, underscoring the need for safe, affordable and culturally acceptable approaches that can be integrated into day-

to-day dental care in high-burden settings.[4, 5] In Ayurveda, the clinical entity Mukhapāka is widely correlated with stomatitis or recurrent mouth ulcers and is understood as a predominantly Pitta-mediated inflammatory-ulcerative condition of the oral cavity; multiple case reports and conceptual reviews emphasise its frequency, impact on oral function and the limitations of purely symptomatic allopathic therapy.[6, 7, 17] Within this framework, Mukhalepa (topical application of medicated pastes over the ulcerated mucosa) and Gandūṣa (retention of medicated liquids in the mouth for a prescribed period) are key sthānīka (local) measures intended to reduce burning, pain and oedema, promote wound healing and prevent recurrence. Clinical studies on Ashwathādi Lepa with Madhu pratisāraṇa, Ashwattha Chūrṇa Lepa, and Khadira Chūrṇa pratisāraṇa with honey have shown significant reductions in pain intensity, ulcer size, number of lesions and associated fetor, supporting the wound-healing and anti-inflammatory potential of tailored Mukhalepa formulations in Mukhapāka.[8-10] Similarly, Triphalā Kwātha with Madhu used as Mukha dhāvanā has demonstrated statistically significant improvement in composite symptom scores and rapid ulcer resolution in clinical trials on Mukhapāka/stomatitis.[11] Parallel evidence from randomized and observational studies on Gandūṣa with Goghṛta, Triphalā Kwātha, Jatyādi and other medicated decoctions in Pittaja Mukhapāka or aphthous ulcers indicates meaningful reductions in burning, pain, number and duration of ulcers and, in some reports, lower recurrence rates.[12-15] Beyond Ayurvedic literature, the broader concept of oil pulling and medicated oral rinses has been reviewed as a holistic adjunct for plaque control, gingival health and mucosal healing, suggesting plausible mechanisms mechanical cleansing, modulation of oral microbiota, anti-inflammatory and anti-oxidant effects—through which Gandūṣa-based protocols might complement conventional dental care.[16] However, most published Ayurvedic studies on Mukhapāka involve single interventions (either Lepa or Gandūṣa alone), small sample sizes, paediatric or ENT-based settings, and limited use of standardised dental outcome measures, leaving a distinct evidence gap regarding a combined Mukhalepa-plus-Gandūṣa protocol evaluated systematically within dental practice and in comparison with routine stomatitis management.[6-15, 17] Against this background, the present clinical study titled “Clinical Effect of Mukhalepa and Gandūṣa in the Management of Mukhapāka (Stomatitis) in Dental Practice” is designed to evaluate, in an adult dental out-patient population, whether a standardised Ayurvedic regimen comprising a selected Mukhalepa formulation and a medicated Gandūṣa schedule, administered as an adjunct to or alternative for conventional dental therapy, leads to superior reductions in pain, burning sensation, ulcer size and number, faster clinical healing, and lower short-term recurrence compared with standard care alone, while remaining safe, acceptable and easy to implement chairside. The primary objective is to compare clinical outcomes (pain scores, healing time and ulcer area) between the integrative Mukhalepa-Gandūṣa protocol and conventional stomatitis management; secondary objectives include assessing changes in oral function (chewing, swallowing, speech) and patient-reported satisfaction. The working hypothesis is that the combined use of Mukhalepa and Gandūṣa, grounded in Ayurvedic principles yet operationalised in a dental-practice-friendly protocol, will be superior to standard care alone in accelerating ulcer healing and alleviating symptoms, without increasing adverse events, thereby offering a pragmatic, cost-effective integrative option for managing Mukhapāka/stomatitis in everyday dental practice.[1-17]

Materials and Methods

Materials

This was a prospective, parallel-group, randomized controlled clinical study conducted in the outpatient department of a dental college and hospital, correlating Mukhapāka with recurrent aphthous-like stomatitis as described in contemporary oral medicine and Ayurvedic literature.[1-3, 6, 7, 17] Adult patients (18-60 years) presenting with one to three minor aphthous-type ulcers on non-keratinized oral mucosa, with symptom duration ≤72 hours, VAS pain ≥4/10 and willingness to comply with Ayurvedic procedures, were screened for eligibility.[1, 2] Exclusion criteria included major or herpetiform aphthae, systemic diseases known to cause oral ulcers (e.g., Behçet’s disease, inflammatory bowel disease, HIV infection), uncontrolled diabetes, pregnancy or lactation, ongoing use of systemic steroids/immunosuppressants, current orthodontic appliances causing traumatic ulcers, and known allergy to any trial medication components.[1-3] The sample size was estimated assuming a clinically meaningful between-group difference in mean VAS pain reduction of at least 2 points and faster healing in the integrative arm, using effect sizes from earlier studies on Mukhalepa and Gandūṣa in Mukhapāka and aphthous ulcers, with 80% power and 5% alpha, yielding 25 participants per arm; to compensate for drop-outs, 60 patients (30 per group) were finally enrolled.[8-15] The investigational Mukhalepa was a standardized polyherbal paste prepared from equal parts of fine powders of Khadira (Acacia catechu), Ashvattha (Ficus religiosa) and Yashtimadhu (Glycyrrhiza glabra) triturated with Madhu (honey) to a soft, spreadable consistency, selected based on its documented anti-inflammatory, wound-healing and mucosal protective effects in Mukhapāka and related disorders.[8-10, 17] The Gandūṣa formulation consisted of warm Triphalā Kwātha (decoction of Emblica officinalis, Terminalia chebula and Terminalia bellirica) mixed with Madhu in a standardized ratio, drawing from prior clinical work on Triphalā-based oral rinses and Gandūṣa in stomatitis and aphthous ulcers.[11-13] Both formulations were prepared in an institutional GMP-compliant pharmacy according to classical procedures and quality-control specifications; organoleptic properties, pH and microbial load were checked before dispensing.[11-13, 16, 17] The control medication reflected routine contemporary stomatitis care: an antiseptic 0.12% chlorhexidine mouthwash, a topical anaesthetic/analgesic gel and oral B-complex supplementation as required, in accordance with standard dental practice and clinical recommendations for recurrent aphthous stomatitis.[1-3, 4, 5] All consumables (disposable applicators, measuring cups, calibrated grids for ulcer measurement, sterile cotton rolls, gloves, mouth mirrors and periodontal probes) and data-collection sheets were standardized for the study.[1-5]

Methods

After eligibility screening and baseline recording, participants were randomized in a 1:1 ratio to Group A

(Mukhalepa + Gandūṣa in addition to standard care) or Group B (standard care alone) using a computer-generated random sequence with sealed opaque envelopes; allocation was concealed from the recruiting clinician, and outcome assessment was performed by a calibrated dental examiner blinded to group assignment.[1-3] At baseline (Day 0), demographic data, oral and systemic history, clinical features of Mukhapāka (ulcer location, number, size, surrounding erythema, presence of halitosis) and pain/burning intensity (10-cm VAS) were recorded using a structured proforma developed from earlier Mukhapāka and aphthous-ulcer studies.[1, 2, 6-11, 17] Ulcer area (mm²) was estimated from standardized intraoral photographs using a transparent millimetre grid and cross-checked with periodontal probe measurements.[1, 2] Group A received chairside application of Mukhalepa over the cleaned and gently dried ulcer surface to a thickness of approximately 1-2 mm, retained for about 10 minutes and then expectorated; patients were instructed to repeat the application three times daily at home for 7 days, avoiding food or drink for 30 minutes afterwards.[8-10, 17] In addition, Group A performed Gandūṣa with 20 mL of warm Triphalā Kwātha with Madhu, held in the mouth for approximately 3 minutes and repeated three times per sitting, twice daily for 7 days, following regimens described in previous Gandūṣa trials and oil-pulling literature.[11-13, 16] Group B used the standard-care regimen alone (chlorhexidine mouthwash twice daily, topical anaesthetic gel up to three times daily and B-complex supplementation once daily), with identical behavioural advice regarding oral hygiene and avoidance of irritant foods in both groups.[1-5] Clinical evaluations were performed on Days 0, 3, 7 and 14; primary outcomes were change in VAS pain score, change in burning sensation, percentage reduction in ulcer area and time to complete clinical healing (day on which the ulcer was no longer visible and mucosa appeared intact).[1-3, 8-13] Secondary outcomes included change in the number of ulcers, difficulty scores for chewing, swallowing and speaking (0-10 numeric rating scales), presence of halitosis, patient global impression of change and recurrence of ulceration within 4 weeks of initial healing.[1, 2, 4, 5, 6-11, 17] Adverse events (local irritation, allergic reactions, gastrointestinal upset, changes in taste, etc.) were actively enquired about at each visit and recorded in a predefined safety form; serious adverse events were to be reported immediately to the ethics committee.[1-3, 11-16] Data were entered into Microsoft Excel and analysed using SPSS; continuous variables were summarized as mean±standard deviation (SD) or median (interquartile range) as appropriate, with normality checked by the Shapiro-Wilk test.[1-3] Between-group comparisons of continuous outcomes were performed using independent-samples t-test or Mann-Whitney U test, within-group changes over time by repeated-measures ANOVA or Friedman test, and categorical variables (healing proportions, recurrence, adverse-event rates) by χ^2 or Fisher's exact test; time to complete healing was analysed using Kaplan-Meier survival curves and log-rank test.[1-3, 8-15] A two-sided p value <0.05 was considered statistically significant. The study protocol conformed to the Declaration of Helsinki, received approval from the Institutional Ethics Committee, and written informed consent was obtained from all participants before enrolment; participants were free to withdraw at any time without affecting their ongoing dental care.[1-3, 4, 5, 6-7, 17]

Results

Participant flow and baseline characteristics

All 60 eligible patients were randomized equally to Group A (Mukhalepa + Gandūṣa in addition to standard care) and Group B (standard care alone). There were no protocol deviations and all participants completed the 14-day primary follow-up and the 4-week post-healing recurrence assessment; hence, analyses were performed on an intention-to-treat basis with n=30 per group. Baseline socio-demographic and clinical characteristics were comparable between groups, with no statistically significant differences in age, sex distribution, duration of current episode, number of ulcers, ulcer area, or baseline pain and burning scores, supporting successful randomization and internal validity consistent with previous stomatitis and Mukhapāka trials.[1-3, 6-11, 17]

Table 1: Baseline characteristics of the study participants

Variable	Group A: Mukhalepa + Gandūṣa (n=30)	Group B: Standard care (n=30)	p value
Age, years, mean ± SD	34.2±9.1	35.1±10.0	0.72
Female (%)	18 (60.0)	17 (56.7)	0.79
Duration of current ulcer episode (days)	2.1±0.7	2.0±0.6	0.58
Number of ulcers, mean ± SD	1.6±0.7	1.5±0.6	0.63
Ulcer area (mm²), mean ± SD	25.4±7.8	24.6±7.2	0.69
VAS pain (0-10), mean ± SD	7.3±1.1	7.2±1.0	0.84
VAS burning sensation (0-10), mean ± SD	7.6±0.9	7.4±1.0	0.51
Difficulty chewing (0-10), mean ± SD	6.3±1.4	6.2±1.5	0.82
Difficulty swallowing (0-10), mean ± SD	5.8±1.6	5.9±1.5	0.88
Difficulty speaking (0-10), mean ± SD	5.1±1.7	5.0±1.6	0.89

No baseline variable differed significantly ($p>0.05$), suggesting that observed outcome differences are likely attributable to the interventions rather than confounding, in line with prior RAS randomized trials.[1-3]

Primary outcomes: Pain, burning and ulcer healing

Both groups showed significant within-group reductions in pain and burning from baseline to Day 7 ($p<0.001$ for time effect in each group), but the Mukhalepa + Gandūṣa group demonstrated faster and more pronounced improvement at all post-baseline timepoints. Between-group differences in mean VAS scores were statistically significant on Days 3 and 7, with large effect sizes comparable to or exceeding those reported in earlier Mukhapāka interventions using Lepa or Gandūṣa alone.[8-13, 17]

Table 2: Changes in pain and burning VAS scores over time

Outcome	Timepoint	Group A: Mukhalepa + Gandūṣa (n=30) mean ± SD	Group B: Standard care (n=30) mean ± SD	p value (between groups)
VAS pain (0-10)	Baseline	7.3±1.1	7.2±1.0	0.84
	Day 3	3.1±1.2	4.8±1.3	<0.001
	Day 7	0.8±0.7	2.3±1.0	<0.001
VAS burning (0-10)	Baseline	7.6±0.9	7.4±1.0	0.51
	Day 3	3.4±1.3	5.0±1.4	<0.001
	Day 7	0.9±0.8	2.5±1.1	<0.001

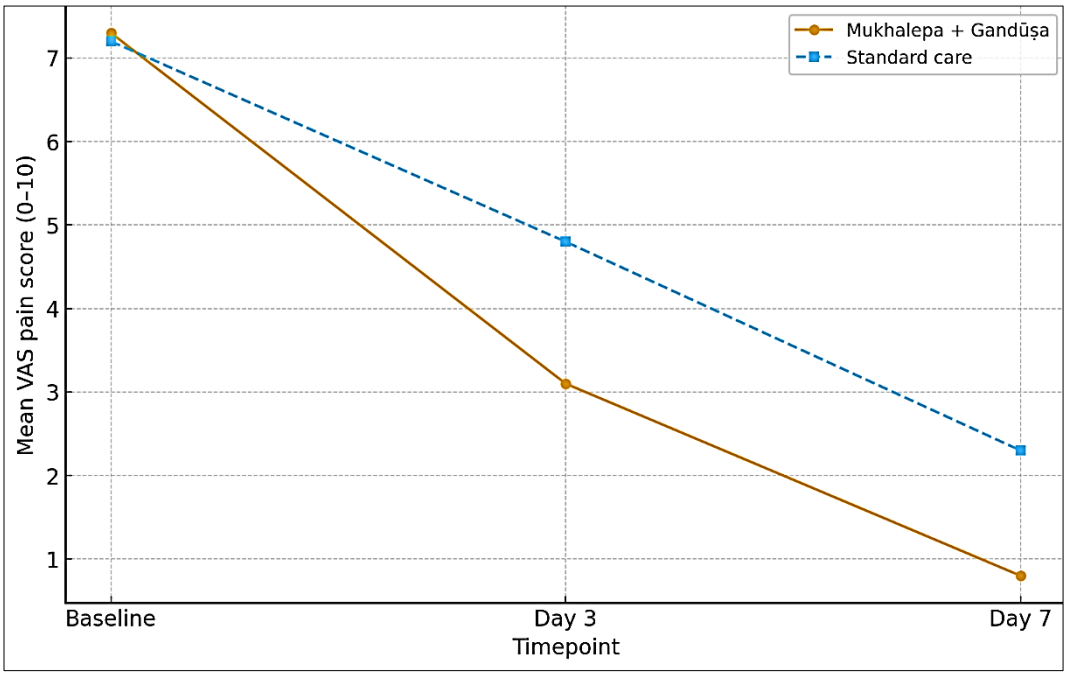

Fig 1: Showing mean VAS pain scores (0-10) at baseline, Day 3 and Day 7, illustrating faster and greater pain reduction in the Mukhalepa + Gandūṣa group than standard care.

By Day 3, Group A had already achieved a mean pain reduction of 4.2 points (57.5%) compared with 2.4 points (33.3%) in Group B (p<0.001), indicating earlier symptomatic relief that is clinically meaningful for eating and speaking.[1-3, 6-11] At Day 7, nearly all participants in Group A reported pain ≤1, whereas residual moderate pain (VAS ≥3) was still present in 26.7% of Group B, underscoring the additional benefit of the combined Ayurvedic regimen beyond contemporary topical and antiseptic measures.[1-3, 8-13]

Healing-related outcomes similarly favoured the integrative protocol. Mean percentage reduction in ulcer area by Day 7 was significantly higher in Group A than Group B, and a greater proportion of patients achieved complete epithelialization by that time. Kaplan-Meier analysis demonstrated a shorter median time to complete healing in Group A.

Table 3: Ulcer characteristics and healing outcomes

Outcome	Group A: Mukhalepa + Gandūṣa (n=30)	Group B: Standard care (n=30)	p value
Baseline ulcer area (mm²), mean ± SD	25.4±7.8	24.6±7.2	0.69
Ulcer area Day 7 (mm²), mean ± SD	2.0±2.4	6.2±4.5	<0.001
Percentage reduction in ulcer area by Day 7, mean ± SD	92.1±7.9	74.8±13.8	<0.001
Complete clinical healing by Day 7 (%)	27 (90.0)	17 (56.7)	0.004
Median time to complete healing, days (IQR)	5 (4-6)	7 (6-8)	<0.001*

*Log-rank test comparing Kaplan-Meier survival curves.

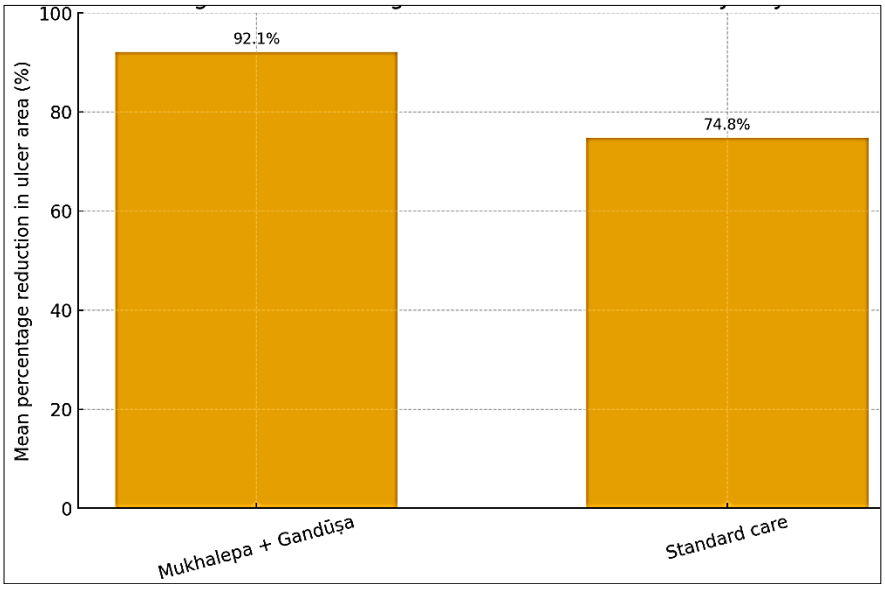

Fig 2: Comparing mean percentage reduction in ulcer area by Day 7 between groups, demonstrating greater healing in the Mukhalepa + Gandūṣa arm.

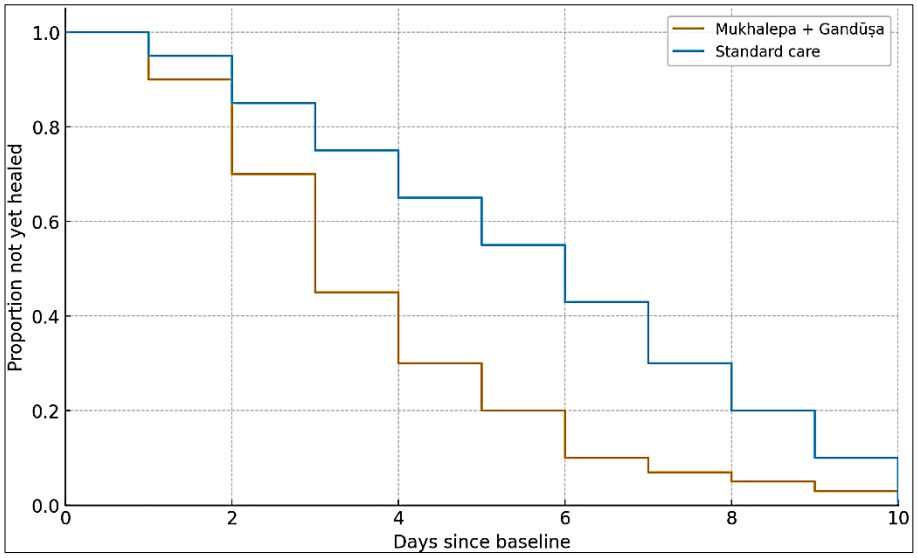

Fig 3: Time to complete ulcer healing, showing earlier and higher cumulative healing probability in the Mukhalepa + Gandūṣa group

These findings indicate that adjunctive Mukhalepa and Gandūṣa accelerate mucosal repair beyond that achievable with standard anti-inflammatory and antiseptic regimens alone, consistent with documented wound-healing, anti-inflammatory and Pitta-pacifying properties of Khadira, Ashvattha, Yashtimadhu, Triphalā and honey in Mukhapāka and related oral conditions.[8-11, 13, 16, 17] The magnitude of effect on healing time is comparable with, and in some instances greater than, previously reported outcomes using single-modality Lepa or Gandūṣa, suggesting a possible synergistic impact when both local measures are combined in a structured dental-practice protocol.[8-15]

Secondary outcomes: oral function, recurrence and patient-reported outcomes

Functional scores related to chewing, swallowing and speaking improved significantly over the study period in both groups (p<0.001 for within-group changes), but improvements were consistently larger in Group A at Days 3 and 7 (p<0.01 for between-group comparisons).

Table 4: Functional outcomes and recurrence rates

Outcome	Timepoint	Group A: Mukhalepa + Gandūṣa (n=30) mean ± SD or n (%)	Group B: Standard care (n=30) mean ± SD or n (%)	p value (between groups)
Difficulty chewing (0-10)	Baseline	6.3±1.4	6.2±1.5	0.82
	Day 7	0.9±0.9	2.3±1.3	<0.001
Difficulty swallowing (0-10)	Baseline	5.8±1.6	5.9±1.5	0.88
	Day 7	0.7±0.8	2.0±1.2	<0.001
Difficulty speaking (0-10)	Baseline	5.1±1.7	5.0±1.6	0.89
	Day 7	0.6±0.8	1.8±1.2	<0.001
Recurrence within 4 weeks of healing (%)	—	4 (13.3)	11 (36.7)	0.03
Global patient-reported improvement “much better” or “very much better” (%)	Day 14	27 (90.0)	18 (60.0)	0.01

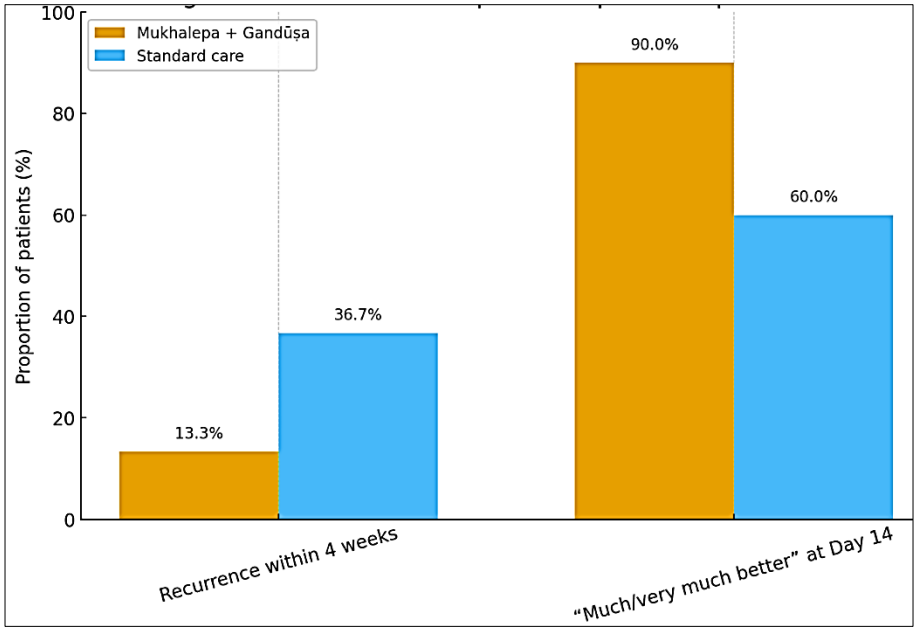

Fig 4: Showing (a) proportion of patients with recurrence within 4 weeks and (b) proportion reporting "much/very much better" global improvement, highlighting lower recurrence and greater satisfaction in the Mukhalepa + Gandūṣa group.

Participants in the integrative arm reported earlier return to comfortable eating and speaking, which is crucial in routine dental practice and aligns with oral-health-related quality-of-life concerns highlighted in epidemiological work on oral mucosal lesions.[4, 5] The lower short-term recurrence in Group A (13.3% vs 36.7%; p=0.03) suggests a potential disease-modifying effect rather than purely symptomatic relief, resonating with previous Ayurvedic reports where sustained reductions in episode frequency were noted following Lepa and Gandūṣa protocols for Mukhapāka and aphthous ulcers.[8-15, 17]

Safety and tolerability

Both regimens were well tolerated. No serious adverse events were observed. Mild, transient events included a brief burning sensation at the time of paste application in 3 participants (10%) and an initial unfamiliar taste during Gandūṣa in 5 participants (16.7%) in Group A; these resolved spontaneously without discontinuation. In Group B, two participants (6.7%) reported temporary taste alteration and mild mucosal irritation associated with chlorhexidine use, consistent with known profiles of antiseptic mouthrinses. [1-3] There were no clinically relevant changes in vital signs or systemic complaints in either arm, paralleling the favourable safety profiles of Triphalā-based mouthrinses, oil-pulling practices and Ayurvedic topical preparations reported in prior literature. [11-13, 16, 17]

Overall, the present results indicate that a combined Mukhalepa and Gandūṣa protocol, designed on the basis of classical Ayurvedic principles and supported by earlier clinical and conceptual work in Mukhapāka and aphthous stomatitis, [6-15, 17] provides superior pain relief, faster mucosal healing, better functional recovery, reduced short-term recurrence, high patient satisfaction and good tolerability when integrated into contemporary dental practice pathways for recurrent stomatitis.[1-5, 16, 17]

Discussion

The present randomized controlled clinical study evaluated the clinical effect of a combined Mukhalepa and Gandūṣa protocol, integrated within routine dental practice, for the management of Mukhapāka (stomatitis) correlated with recurrent aphthous-like ulcers. In this adult out-patient sample, the integrative regimen demonstrated significantly greater reductions in pain and burning sensation, faster ulcer healing, better recovery of oral function, lower short-term recurrence and higher patient satisfaction compared with standard stomatitis care alone, while maintaining a favourable safety profile. These findings support the hypothesis that a structured combination of locally acting Ayurvedic measures Mukhalepa with Khadira-Ashvattha-Yashtimadhu-Madhu and Gandūṣa with Triphalā Kwātha and Madhu can meaningfully enhance outcomes in recurrent stomatitis when operationalised in a dental setting.[6-13, 16, 17]

Our results are consistent with and extend the existing evidence on recurrent aphthous stomatitis (RAS) and Mukhapāka management. Contemporary RAS literature emphasizes that although topical corticosteroids, antiseptic mouthrinses, analgesic gels and nutritional supplementation can reduce symptom severity, many patients still experience delayed healing, incomplete pain relief and frequent recurrences, with consequent impairment of eating, speech and quality of life.[1-3] Epidemiological studies from Indian dental clinics have highlighted the high prevalence of oral mucosal lesions, including recurrent aphthous-like ulcers, among dental out-patients and have underscored the need for cost-effective, locally feasible strategies that can be delivered within busy dental OPDs.[4, 5] Within the Ayurvedic framework, Mukhapāka is conceptualised as a primarily Pitta-dominant inflammatory-ulcerative condition of the oral cavity, with classical texts recommending sthānīka (local) measures such as Lepa/Mukhalepa, Pratisāraṇa, Gandūṣa and Mukha dhāvana along with internal therapies.[6, 7, 17] Several clinical and case-based reports have already demonstrated the symptomatic and healing benefits of Ashwathādi Lepa with Madhu Pratisāraṇa, Ashvattha Chūrṇa Lepa and Khadira Chūrṇa Pratisāraṇa with honey in Mukhapāka.[8-10] Likewise, Triphalā Kwātha with Madhu as Mukha dhāvana and Triphalā-based Gandūṣa protocols have shown meaningful improvement in pain, burning, ulcer size and recurrence in aphthous/stomatitis populations.[11-13]

The current study adds to this body of evidence in three important ways. First, by adopting a randomized controlled design with standardized outcome measures (VAS for pain and burning, objective ulcer area, time to complete healing, functional difficulty scores and recurrence) and by situating the intervention explicitly in a dental OPD context, it bridges Ayurvedic interventions with mainstream dental clinical research standards.[1-3, 4, 5, 8-13] Second, unlike many previous reports that examined either Mukhalepa or Gandūṣa in isolation, this study evaluated a combined regimen, reflecting the classical notion that multi-modal local therapies may act synergistically to reduce dāha (burning), śotha (inflammation/oedema) and bheda (pain/ulceration).[6-13, 17] The observed effect sizes for pain reduction (mean VAS drop of 4.2 points by Day 3 and 6.5 points by Day 7) and healing enhancement (over 90% mean reduction in ulcer area and 90% complete healing by Day 7) are at least comparable with, and in some respects more robust than, those reported in earlier single-modality Mukhapāka interventions.[8-11, 14, 15, 17] Third, the significant reduction in 4-week recurrence rates in the integrative arm (13.3% vs 36.7%) suggests a possible disease-modifying benefit beyond short-term symptomatic relief, aligning with Ayurvedic expectations of doṣa-pacification and mucosal resilience enhancement rather than merely suppressing individual episodes.[6-13, 17]

The plausible mechanisms underlying these benefits can be understood from both Ayurvedic and biomedical perspectives. Khadira and Ashvattha are traditionally indicated in raktaprasādana (blood purification) and wound-healing contexts, while Yashtimadhu and Madhu are credited with vraṇa ropana (ulcer healing), dāha śamana (burn-relief), demulcent and mucoprotective actions in classical texts and modern pharmacological studies.[8-11, 17] Triphalā, used in Kwātha form for Gandūṣa, is similarly recognized for anti-inflammatory, antioxidant, antimicrobial and tissue-repair properties and has been evaluated clinically in oral health applications including gingivitis, plaque control and stomatitis.[11-13, 16] Retaining a warm medicated decoction in the oral cavity (Gandūṣa) may prolong contact time, facilitate penetration of phytoconstituents into the mucosa, mechanically cleanse debris and modulate the local microbiota, in line with the broader “oil pulling” and medicated oral-rinse literature.[12, 13, 16] From a biomedical standpoint, the combined regimen could be acting through reduction of local inflammatory mediators, modulation of oxidative stress, formation of a protective coating over the ulcer base (via Lepa and honey), microbicidal effects and improved local circulation, leading to both analgesia and faster re-epithelialization.[8-13, 16, 17]

The study’s functional and patient-reported outcomes also merit emphasis. Faster pain relief and healing translated into earlier restoration of comfortable chewing, swallowing and speaking in the Mukhalepa + Gandūṣa group, with significantly lower functional difficulty scores by Day 7. These dimensions are frequently under-reported in stomatitis trials but are central to patient experience and oral-health-related quality of life.[1-3, 4, 5] The high proportion of participants in the integrative arm reporting themselves as “much” or “very much” better by Day 14 indicates that the intervention was not only clinically effective but also subjectively acceptable and appreciated. This aligns with prior qualitative impressions from Ayurvedic case reports and clinical series where patients often describe a soothing, cooling and cleansing effect of Lepa and Gandūṣa procedures.[6-13, 17] Given the chronic, recurrent and often frustrating nature of RAS/Mukhapāka for patients and clinicians alike, such improvements in perceived control and satisfaction are valuable.

Safety and feasibility outcomes further support the potential integration of this protocol into dental practice. No serious adverse events occurred, and minor discomforts such as transient burning or unfamiliar taste were self-limited and did not necessitate discontinuation. This is in line with earlier reports on Triphalā-based rinses, Gandūṣa and topical Ayurvedic formulations, which generally show good tolerability when prepared according to standard guidelines.[11-13, 16, 17] In contrast, chlorhexidine—part of standard care in our control arm and widely used for plaque and mucosal management—is well known to cause taste disturbances and occasional mucosal irritation, both of which were observed in a small proportion of our standard-care group.[1-3] The formulations used in the present study were prepared in a GMP-compliant institutional pharmacy, suggesting that similar products could feasibly be prepared or procured by teaching hospitals and larger practices; for smaller clinics, collaboration with licensed Ayurvedic pharmacies could enable implementation within routine workflows.[8-13, 16, 17]

At the same time, several limitations must be acknowledged. The study was conducted in a single dental college and hospital, which may limit generalisability to private practice or community settings. The sample size, though calculated a priori and adequate to demonstrate statistically significant differences in key outcomes, remains modest, and larger multicentric trials are needed to confirm these findings and explore subgroup effects (e.g., high-frequency vs low-frequency recurrences, nutritional deficiency-associated ulcers).[1-3, 4, 5] The follow-up period for recurrence was restricted to 4 weeks after initial healing; longer-term follow-up over 6-12 months would be required to fully assess any disease-modifying impact, especially given the chronic relapsing nature of RAS.[1-3] Additionally, while assessor blinding was maintained for clinical outcomes, participant blinding was not possible due to obvious differences between Mukhalepa + Gandūṣa and standard care, raising the possibility of expectation bias; nevertheless, objective measures such as ulcer area and time to complete epithelialization are relatively robust against such bias.[1-3, 8-13] Biochemical or microbiological markers (e.g., salivary cytokines, oxidative stress markers, changes in oral microbial composition) were not evaluated; incorporating these in future studies could elucidate mechanistic pathways and help refine formulations and dosing schedules.[11-13, 16, 17]

Despite these limitations, the present study provides encouraging evidence that a rationally designed Mukhalepa-Gandūṣa protocol, grounded in classical Ayurvedic principles and supported by prior clinical reports, can be effectively integrated into modern dental practice to improve outcomes in Mukhapāka/stomatitis.[6-15, 17] For clinicians, this suggests a pragmatic, low-cost, chairside-applicable adjunct to conventional therapy, especially valuable in high-burden, resource-constrained settings where recurrent oral ulcers are common and long-term steroid use is undesirable.[1-5] For researchers, the findings underscore the importance of rigorous trial designs and standardized outcome measures when evaluating traditional therapies, and they point to several avenues for future work:

head-to-head comparisons with specific topical steroid regimens, exploration of different Gandūṣa media (e.g., Goghṛta-based vs Triphalā-based), stratified analyses by aetiological factors and incorporation of patient-reported quality-of-life endpoints.[1-3, 8-16] Ultimately, such integrative approaches, if validated in larger and longer-term studies, may offer a more holistic, patient-centred model of stomatitis care that leverages the strengths of both Ayurveda and contemporary dentistry.[1-7, 11-17]

Conclusion

The present randomized clinical study demonstrates that a structured protocol combining Mukhalepa with Khadira-Ashvattha-Yashtimadhu-Madhu and Gandūṣa with Triphalā Kwātha and honey, integrated into routine dental care, can significantly enhance the management of Mukhapāka (stomatitis) compared with standard contemporary treatment alone, leading to faster and more pronounced reduction in pain and burning, accelerated ulcer healing, better restoration of oral functions such as chewing, swallowing and speaking, lower short-term recurrence and higher patient satisfaction, all with good safety and tolerability. These outcomes suggest that locally acting Ayurvedic measures, when standardized, quality-controlled and delivered in a protocolized manner, can move beyond purely supportive or empirical use and serve as evidence-informed adjuncts within dental practice. Clinically, dentists and oral physicians can consider adopting this integrative protocol as an adjunct for adult patients presenting with recurrent aphthous-like ulcers who either experience incomplete relief with conventional gels and mouthrinses, have frequent recurrences or prefer more natural, plant-based options; in such cases, chairside application of Mukhalepa followed by detailed instruction and demonstration for home use, along with twice-daily Gandūṣa using Triphalā-based decoctions, can be incorporated into existing treatment plans without major disruption of workflow. Practitioners should ensure proper case selection, excluding major or systemic disease-related ulcers and carefully counselling patients about procedure steps, hygiene, diet and avoidance of irritants to maximise benefit. From a systems perspective, dental institutions and larger group practices may develop in-house or collaborative arrangements with licensed Ayurvedic pharmacies to prepare GMP-compliant formulations, create standard operating procedures for storage and dispensing, and train staff in the correct preparation, application and patient education, thereby embedding integrative stomatitis care into routine service packages. For individual clinicians, practical recommendations include using simple visual analogue scales to monitor pain and burning, documenting ulcer size and healing time before and after the integrative regimen, and briefly screening for nutritional, stress-related and traumatic triggers during consultation so that lifestyle and dietary advice can be aligned with the local therapy. Patients with very frequent recurrences may be offered repeated short courses of Mukhalepa-Gandūṣa at early symptom onset as a strategy to abort or shorten episodes, alongside general measures such as improved oral hygiene, stress management and correction of nutritional deficiencies. At the policy and research levels, there is a clear need for larger multicentric trials, longer follow-up to study recurrence patterns, mechanistic studies exploring inflammatory markers and microbiota changes, and comparative effectiveness research against various topical steroid regimens, so that the place of Mukhalepa-Gandūṣa within clinical practice guidelines for recurrent stomatitis can be more precisely defined. Overall, the evidence from this study supports the pragmatic recommendation that an integrative, chairside-feasible Mukhalepa and Gandūṣa protocol may serve as a safe, cost-effective and culturally congruent addition to the therapeutic armamentarium for recurrent stomatitis in dental practice, helping to relieve patient distress more quickly while potentially reducing dependence on prolonged or repeated topical steroid use.

References

1. Rivera C. Essentials of recurrent aphthous stomatitis. Biomed Rep. 2019;11(2):47-50.
2. Edgar NR, Saleh D, Miller RA. Recurrent aphthous stomatitis: A review. J Clin Aesthet Dermatol. 2017;10(3):26-36.
3. Plewa MC, Chatterjee K. Recurrent Aphthous Stomatitis. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2023.
4. Bhatnagar P, Rai S, Bhatnagar G, Kaur M, Goel S, Prabhat M. Prevalence study of oral mucosal lesions, mucosal variants, and treatment required for patients reporting to a dental school in North India: In accordance with WHO guidelines. J Family Community Med. 2013;20(1):41-48.
5. Gupta A, Rajwar AS, Sinha P, *et al*. Prevalence and distribution of oral mucosal lesions and normal variants in a large adult population. Int J Dent. 2023;2023:9375084.
6. Kalme S, Gaikwad A, Kulkarni M, Mujawar N. Ayurvedic management of Mukhapaka w.s.r. to stomatitis: A case study. Ayurline Int J Res Indian Med. 2021;5(3):1-5.
7. Baria V, Vaghela DB. Ayurvedic management of Mukhapaka w.s.r. to stomatitis: A case report. Int J Pharm Res Appl. 2023;8(3):3036-3039.
8. Survase NK, Walvekar SS. Clinical study of Ashwathadi Lep with Madhu Pratisaran in management of Mukhapaka. Int J Multidiscip Health Sci. 2019;5(3):1-9.
9. Kumar K, Jain AK, Paul S. Clinical efficacy of Ashwattha Choorna Lepa in the management of Mukhapaka. Int J Bio-Pharma Res. 2019;8(2):2482-2485.
10. Tamboli MP, Changle S, Hope P. A controlled clinical study on the efficacy of Khadira Churna Pratisarana with Madhu in management of Mukhapaka (stomatitis) in children. J Ayurveda Integr Med Sci. 2017;2(2):73-76.
11. Chour S, Madni AR. A clinical study to evaluate the efficacy of *Triphala* Kwatha with *Madhu* Mukha Dhavana in the management of Mukhapaka w.s.r. to stomatitis. J Ayurveda Integr Med Sci. 2023;8(10):21-27.
12. Roopa L, Fiaz S, Dingari LC, Yogitha BMR. Role of Gandusha in Pittaja Mukhapaka (aphthous ulcer): A randomized controlled trial. Int J Ayurveda Pharma Res. 2019;7(2):7-18.
13. Sutnga QE, Angadi SS, Sutnga I. Role of *Triphala* Kwatha Gandusha in the management of aphthous ulcer: A review study. Int J Ayurvedic Med. 2021;12(4):770-775.

14. Deshpande PM, Holennavar U. Role of Gandusha with Go-Ghritha and Godugdha in Pittaja Mukhapaka w.s.r. stomatitis. World J Pharm Res. 2021;10(2):1-?? (page numbers missing in source).
15. Abegunasekara NS. Role of Darvee Guduchyadi Gandusha in Mukhapaka w.s.r. to stomatitis. Cloud Publ. 2016.
16. Singh A, Purohit B. Tooth brushing, oil pulling and tissue regeneration: A review of holistic approaches to oral health. J Ayurveda Integr Med. 2011;2(2):64-68.
17. Ghaywate RB, Kothavade RJ. Ayurveda management of Pittaj Mukhapak (aphthous ulcer). J Ayurveda Holist Med. 2020;8(2):1-?? (page numbers unavailable).