

EVALUATION OF KHADIRADI VATI AND MEDICATED MOUTHWASH (TRIPHALA KWATHA GANDUSHA) IN CHRONIC PERIODONTITIS: A RANDOMIZED ACTIVE-CONTROLLED CLINICAL TRIAL

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ABSTRACT

Background: 0.2% Chlorhexidine (CHX) gluconate remains the gold-standard adjunctive mouthwash for chronic periodontitis, but its long-term use is limited by extrinsic dental staining, taste alteration, and mucosal side effects. Khadira (Acacia catechu) and Triphala are classically described in Shalakya Tantra as possessing Kashaya (astringent) and Raktastambhaka (hemostatic) properties relevant to periodontal disease. **Objective:** To compare the clinical, microbiological, and safety outcomes of Triphala Kwatha Gandusha combined with Khadiradi Vati against 0.2% CHX mouthwash in patients with chronic periodontitis. **Methods:** In this randomized, active-controlled, examiner-blinded, parallel-group trial,⁸⁰ participants with localized or generalized chronic periodontitis were allocated to Triphala Kwatha Gandusha (15 mL, twice daily) plus Khadiradi Vati (chewed slowly, twice daily), or 0.2% CHX mouthwash (15 mL, twice daily), for 30 days. **Outcomes** - Plaque Index (PI), Gingival Index (GI), Probing Pocket Depth (PPD), Clinical Attachment Loss (CAL), subgingival anaerobic CFU counts, adverse events, and patient compliance - were assessed at baseline, Day 15, and Day 30. **Results:** Seventy-six participants (38 per arm) completed the trial. Both groups showed highly significant intra-group improvement in PI, GI, PPD, and CAL by Day 30 (all $p \leq 0.05$; $p = 0.041$), and higher patient compliance (94.7% vs. 68.4%; $p < 0.01$). **Conclusion:** Triphala Kwatha Gandusha combined with Khadiradi Vati achieved clinical and microbiological outcomes comparable to 0.2% CHX in chronic periodontitis, while essentially eliminating CHX's characteristic staining and taste-alteration side effects and yielding substantially higher patient compliance, supporting its consideration as a well-tolerated alternative for extended periodontal maintenance therapy.

Keywords: Khadiradi Vati, Triphala Kwatha Gandusha, Chronic Periodontitis, Chlorhexidine, Plaque Index, Gingival Index, Probing Pocket Depth, Clinical Attachment Loss, Subgingival Microflora, Shalakya Tantra

1. INTRODUCTION

Chronic periodontitis is a biofilm-driven inflammatory disease of the periodontium, sustained by obligate anaerobes such as Porphyromonas gingivalis, and 0.2% Chlorhexidine (CHX) gluconate mouthwash remains the pharmacological gold standard for adjunctive plaque control; however, its well-documented side-effect profile - extrinsic dental staining, taste alteration, and mucosal desquamation with prolonged use - limits its acceptability for the extended maintenance therapy that chronic periodontitis often requires.¹

Classical Shalakya Tantra describes disorders of the Danta and Danta-Mula (teeth and gingiva) in terms recognizably continuous with periodontal disease, and identifies Khadira (Acacia catechu) and Triphala as dravyas of pronounced Kashaya Rasa (astringent taste), valued for their Raktastambhaka (hemostatic) and tissue-tightening (Stambhana) action on inflamed gingival tissue.²

Khadiradi Vati is a classical formulation built around Khadira and indicated specifically for oral and dental conditions in traditional formularies.³ while Triphala - the combination of Amalaki, Bibhitaki, and Haritaki - has separately accumulated a modern pharmacological literature documenting antimicrobial, antioxidant, and anti-inflammatory activity, including prior studies of Triphala mouthwash showing measurable reductions in plaque and gingival indices.⁴

No prior trial has evaluated the specific combination of Triphala Kwatha Gandusha and Khadiradi Vati against 0.2% CHX as an active comparator using a combined clinical, microbiological, and

safety-and-compliance framework. This trial was designed to test whether this Ayurvedic regimen achieves clinical and microbiological outcomes comparable to CHX while avoiding its characteristic side effects.

2. MATERIALS AND METHODS

2.1 STUDY DESIGN AND SETTING

This was a randomized, active-controlled, examiner-blinded, parallel-group clinical trial conducted over 30 days at National Institute of Ayurveda Hospital, Jaipur, India. The study was approved by the Institutional Ethics Committee IEC/NIA/2025/ST-042 and registered with the Clinical Trials Registry - India (CTRI) under registration number CTRI/2025/04/086115. Written informed consent was obtained from all participants prior to enrollment.

2.2 PARTICIPANTS

Adults diagnosed with localized or generalized chronic periodontitis per standard periodontal disease classification criteria⁵ were eligible. Exclusion criteria included antibiotic use within 3 months prior to enrollment, uncontrolled systemic disease affecting periodontal status, pregnancy or lactation, and known hypersensitivity to Chlorhexidine or to any constituent of the Ayurvedic formulations.

2.3 RANDOMIZATION AND BLINDING

Eligible participants were allocated in a 1:1 ratio to the Ayurvedic trial regimen or the CHX control using a computer-generated

randomization sequence, with allocation concealment maintained through sequentially numbered, opaque, sealed envelopes. Because the trial and control interventions differ inherently in appearance, taste, and mode of administration (a chewable tablet plus decoction gargle versus a mouthwash solution), full participant blinding was not feasible; the trial was therefore examiner-blinded, with all clinical periodontal measurements (PI, GI, PPD, CAL) recorded by an assessor kept unaware of group allocation.

2.4 INTERVENTIONS

The trial group received Triphala Kwatha Gandusha (15 mL of medicated decoction, gargled for 5 minutes, twice daily) together with Khadiradi Vati tablets (chewed slowly, twice daily), prepared under standardized conditions consistent with contemporary pharmacopoeial quality-control recommendations.³ The control group received 0.2% Chlorhexidine gluconate mouthwash (15 mL, twice daily).¹ Both regimens were continued for 30 consecutive days without adjunctive mechanical debridement beyond routine oral hygiene instruction common to both arms.

2.5 OUTCOME MEASURES

Primary clinical outcomes - Plaque Index (PI), Gingival Index (GI), Probing Pocket Depth (PPD), and Clinical Attachment Loss (CAL) - were assessed at baseline, Day 15, and Day 30 using standard periodontal indices.⁶ Subgingival plaque samples were cultured under anaerobic conditions to quantify total anaerobic colony-forming units (CFU/mL), with particular attention to periodontopathic species such as *Porphyromonas gingivalis*.⁷ Adverse events (extrinsic dental staining, dysgeusia, mucosal desquamation) and patient compliance were recorded at each follow-up visit.

2.6 STATISTICAL ANALYSIS

Continuous variables are expressed as mean $\pm$ standard deviation. Intra-group change from baseline to Day 30 was assessed using paired t-tests; between-group comparisons of continuous and categorical outcomes were assessed using independent t-tests and chi-square tests, respectively. A two-tailed p-value < 0.05 was considered statistically significant. No formal non-inferiority margin was pre-specified; comparability between arms is inferred from the similar magnitude of intra-group change and non-significant between-group p-values, a limitation discussed below.

3. RESULTS

3.1 STUDY DESIGN AND PARTICIPANT BASELINE

Eighty participants with chronic periodontitis were randomized.⁴⁰ to the Ayurvedic trial regimen and 40 to the CHX control. Seventy-six participants (38 per arm) completed the 30-day trial. Baseline periodontal parameters and demographic characteristics were statistically comparable between groups ($p > 0.05$ for all comparisons), supporting the validity of subsequent between-group comparisons.

3.2 PRIMARY CLINICAL PERIODONTAL PARAMETERS

Both the Ayurvedic regimen and the CHX control produced highly significant reductions in periodontal inflammation and plaque accumulation by Day 30 (Table 1).

Table 1. Primary clinical periodontal parameters at baseline and Day 30, by group.

Clinical Insight: While both groups effectively controlled plaque (PI), the Ayurvedic group showed a marginally greater reduction in the Gingival Index. This is clinically attributed to the pronounced

Kashaya (astringent) and Raktastambhaka (hemostatic) properties of Khadira and Triphala, which promote rapid gingival tissue tightening and capillary constriction.

3.3 MICROBIOLOGICAL ANALYSIS (SUBGINGIVAL FLORA)

Subgingival plaque samples were cultured to evaluate antimicrobial efficacy against the obligate anaerobes associated with chronic periodontitis (Table 2).

Table 2. Total subgingival anaerobic colony-forming units (CFU/mL), baseline versus Day 30, by group.

The antimicrobial action of CHX was numerically greater in absolute reduction; however, the between-group difference in CFU/mL at Day 30 was not statistically significant ($p = 0.114$).

3.4 ADVERSE EVENTS, COMPLIANCE, AND SIDE EFFECTS

The most significant divergence between the two interventions occurred in the side-effect profile, with direct implications for patient compliance (Table 3).

Table 3. Adverse events and patient compliance by group.

Translational Takeaway: The Khadiradi Vati and Triphala Gandusha combination delivered clinical and microbiological benefits comparable to 0.2% Chlorhexidine while essentially eliminating the brown dental staining and taste alteration that characteristically limit prolonged CHX use, corresponding to substantially higher patient compliance.

4. DISCUSSION

This trial found that a combined regimen of Triphala Kwatha Gandusha and Khadiradi Vati produced clinical and microbiological improvements in chronic periodontitis closely comparable to 0.2% CHX, the pharmacological gold standard, across all four primary periodontal indices and subgingival anaerobic CFU counts. The marginally greater reduction in Gingival Index in the Ayurvedic arm is mechanistically consistent with the classically described Kashaya-Rasa and Raktastambhaka action of Khadira and Triphala on inflamed, vascularized gingival tissue, and is paralleled by a modern pharmacological literature documenting antimicrobial and anti-inflammatory activity for both agents.

Acacia catechu, the primary constituent of Khadiradi Vati, contains catechins and related tannins with documented antibacterial activity against gram-negative anaerobes.⁸ while Triphala's polyphenolic constituents have been separately reported to exert anti-biofilm and anti-inflammatory effects relevant to periodontal pathogens.⁹ together offering a plausible pharmacological basis for the clinical and microbiological findings observed here.

The most clinically consequential finding of this trial, however, is not the comparative efficacy data but the safety and compliance data: the near-total absence of dental staining, dysgeusia, and mucosal desquamation in the Ayurvedic arm, against substantial rates of all three in the CHX arm, corresponded to markedly higher patient-reported compliance. Because chronic periodontitis typically requires extended maintenance therapy, and CHX use is conventionally restricted to short courses precisely because of these side effects, a regimen with comparable efficacy and a substantially better tolerability profile has plausible relevance for longer-term adjunctive use, pending confirmation in larger trials.

This study has important limitations. Full participant blinding was not achievable given the inherently different modality of the two interventions, introducing potential for reporting bias in subjective outcomes such as compliance and taste-related adverse events; the

examiner-blind design mitigates but does not eliminate this concern for the objectively measured clinical indices. No non-inferiority margin was pre-specified, so the comparability described here rests on similar magnitude of intra-group change and non-significant between-group differences rather than formal non-inferiority testing, and should be interpreted accordingly. The 30-day duration is adequate to demonstrate short-term efficacy and tolerability but cannot address longer-term periodontal maintenance, recurrence, or durability of the microbiological effect, and compliance was assessed by self-report rather than an objective adherence measure.

5. CONCLUSION

Triphala Kwatha Gandusha combined with Khadiradi Vati achieved clinical and microbiological outcomes comparable to 0.2% Chlorhexidine in the management of chronic periodontitis, while essentially eliminating the dental staining and taste-alteration side effects that limit prolonged CHX use and corresponding to substantially higher patient compliance. These findings support further evaluation of this Ayurvedic regimen, in an adequately powered trial with a pre-specified non-inferiority margin and longer follow-up, as a well-tolerated alternative for extended periodontal maintenance therapy.

6. DECLARATIONS

- * Clinical Parameter | Group | Baseline (Mean +/- SD) | Day 30 (Mean +/- SD) | p-value (Intra-group)
- * Plaque Index (PI) | Trial (Ayurveda) | 2.34 +/- 0.42 | 0.88 +/- 0.25 | p < 0.001
- * Plaque Index (PI) | Control (CHX) | 2.31 +/- 0.38 | 0.82 +/- 0.21 | p < 0.001
- * Gingival Index (GI) | Trial (Ayurveda) | 2.15 +/- 0.35 | 0.65 +/- 0.18 | p < 0.001
- * Gingival Index (GI) | Control (CHX) | 2.12 +/- 0.32 | 0.72 +/- 0.20 | p < 0.001
- * Probing Pocket Depth (PPD) | Trial (Ayurveda) | 4.85 +/- 0.60 mm | 3.42 +/- 0.45 mm | p < 0.001
- * Probing Pocket Depth (PPD) | Control (CHX) | 4.90 +/- 0.55 mm | 3.45 +/- 0.48 mm | p < 0.001
- * Clinical Attachment Loss (CAL) | Trial (Ayurveda) | 3.75 +/- 0.50 mm | 3.55 +/- 0.40 mm | p = 0.042
- * Clinical Attachment Loss (CAL) | Control (CHX) | 3.72 +/- 0.48 mm | 3.52 +/- 0.42 mm | p = 0.045
- * Group | Baseline CFU/mL | Day 30 CFU/mL | % Reduction | p-value
- * Trial (Ayurveda) | 4.8 x 10⁵ | 1.2 x 10⁵ | 75% | p < 0.001
- * Control (CHX) | 4.9 x 10⁵ | 0.9 x 10⁵ | 81% | p < 0.001
- * Adverse Event / Outcome | Trial Group (Ayurveda) | Control Group (CHX) | p-value (between groups)
- * Extrinsic Dental Staining | 0% (0/38) | 57.8% (22/38) | p < 0.001
- * Alteration of Taste (Dysgeusia) | 2.6% (1/38) | 42.1% (16/38) | p < 0.001
- * Mucosal Desquamation | 0% (0/38) | 10.5% (4/38) | p = 0.041
- * Excellent Patient Compliance | 94.7% | 68.4% | p < 0.01

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