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Edited by Ashwini Dhopte
E-mail: ashwinidhopte@gmail.com
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Plantago major mother tincture gel versus chlorhexidine gel as an adjunct to non-surgical periodontal therapy: A 12-week comparative clinical study

Sezal Maini*, Neetha Bhargava, Nancy Srivastava, Ritu Mathur, Rachna Kulshreshtha & Rachana Pidiyar

Department of Periodontology, NIMS Dental College, NIMS University, Jaipur, Rajasthan, India; *Corresponding author

Affiliation URL:
https://nimsuniversity.org/nims-institute-of-dental/

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Author contact:
Sezal Maini - E-mail: heysezal@gmail.com
Neetha Bhargava - E-mail: veekshya@gmail.com
Nancy Srivastava - E-mail: dr.nancy15@gmail.com
Ritu Mathur - E-mail: mathurritu01@gmail.com
Rachna Kulshreshtha - E-mail: rachnakul9@gmail.com
Rachana Pidiyar - E-mail: rachana.pidiyar98@gmail.com

Abstract:
Local drug delivery may enhance non-surgical periodontal therapy and *Plantago major* mother tincture has antimicrobial, anti-inflammatory, antioxidant and wound-healing properties that may support periodontal use. Hence, thirty systemically healthy participants with probing pocket depth ≥5 mm were allocated to scaling and root planing plus chlorhexidine gel (n=15) or *Plantago major* gel (n=15), with PI, GI, PPD and RAL measured at baseline and at 1, 4 and 12 weeks. Both groups improved significantly over time for all four parameters ($p<0.001$) and 12-week PI and GI were similar between groups; endpoint PPD also did not differ significantly ($p=0.062$). Change-score analysis showed greater baseline-to-12-week reductions in PPD ($p<0.001$) and RAL ($p=0.030$) with chlorhexidine. Thus, *Plantago major* gel showed comparable plaque and gingival control but did not show equivalence to chlorhexidine for deeper periodontal outcomes in this small 12-week trial.

Keywords: *Plantago major*, chlorhexidine, chronic periodontitis, local drug delivery, scaling and root planing, probing pocket depth (PPD)

Background:
Periodontitis is a chronic biofilm-associated inflammatory disease characterized by progressive destruction of tooth-supporting tissues and contemporary classification integrates stage, grade and complexity and risk modifiers **[1].** For stage I-III periodontitis, effective supragingival biofilm control and subgingival instrumentation remain core treatment components **[2].** Residual deep pockets can retain dysbiotic biofilm after mechanical therapy, prompting use of locally delivered antimicrobials to achieve high site-specific concentrations with limited systemic exposure **[4, 5].** Chlorhexidine is a broad-spectrum bisbiguanide with oral substantivity, but repeated exposure may cause staining, taste disturbance, calculus accumulation and mucosal irritation **[3].** *Plantago major* contains polysaccharides, caffeic-acid derivatives, flavonoids, iridoid glycosides, tannins, terpenoid compounds and has reported antimicrobial, anti-inflammatory, antioxidant and wound-healing activity **[6, 7].** *In vitro* activity against *Porphyromonas gingivalis* and Fusobacterium nucleatum and anti-inflammatory effects in oral epithelial models provide a biological rationale for periodontal application **[8, 9].** A recent double-blind randomized study of *P. major* mother-tincture mouthwash and 0.2% chlorhexidine reported improvement in plaque and gingival outcomes with both agents **[10].** Therefore, it is of interest to compare the *Plantago major* mother-tincture gel with chlorhexidine gel as adjuncts to non-surgical periodontal therapy over 12 weeks.

Materials and Methods:
Study design and setting:
This experimental, parallel-group comparative clinical study was conducted in the Department of Periodontology, NIMS Dental College and Hospital, NIMS University, Jaipur, Rajasthan. Recruitment was undertaken within the planned 12-18-month study period and each participant was followed for 12 weeks. Ethical clearance was obtained from the Ethical Committee, NIMS University, Jaipur and written informed consent was obtained from all participants before enrolment.

Sample size and allocation:
Sample size was calculated using formula:

$$n = ((Z_{\alpha/2} + Z_{1-\beta})^2 (\sigma_1^2 + \sigma_2^2)) / (\mu_2 - \mu_1)^2$$

$$n = ((1.96 + 0.84)^2 (0.11)^2 + (0.16)^2) / (0.94 - 1.08)^2$$

$15.08 \approx 15$ samples and group. Where, $Z_{\alpha/2}$: Inverse probability of normal distribution at 95% confidence interval. $Z_{1-\beta}$: Inverse probability of normal distribution at 80% confidence interval. $\sigma_1^2 + \sigma_2^2$: Standard deviation of plaque index of SRP & SRP + gel group. $\mu_2 - \mu_1$: Mean value of plaque index of SRP & SRP + gel group. Total subjects in the study are 30. The selection of patient was based on detailed case history and clinical examination. Patients that met the inclusion criteria were divided into two groups based on random sampling method. Group A (n=15) received Non-surgical periodontal therapy and chlorhexidine gel administration. Group B (n =15) received Non-surgical periodontal therapy and *Plantago major* gel administration. Clinical parameters plaque index, gingival index, pocket probing depth, relative attachment level were recorded at baseline. 1 week, 4 weeks and 12 weeks. After recording clinical parameters patient underwent non- surgical periodontal therapy followed by local drug delivery of chlorhexidine gel and *Plantago major* gel depending upon the group the patient belongs to.

Eligibility criteria:
Systemically healthy adults aged 18-55 years who provided informed consent, had at least 20 permanent teeth excluding third molars and presented with periodontal pockets of at least 5 mm were included. Exclusion criteria were a history of

aggressive periodontitis; smoking or tobacco chewing; fixed dental prostheses or orthodontic appliances; periodontal treatment or antibiotic therapy within the preceding 6 months; previous periodontal surgery in the selected area; suspected endodontic-periodontal lesions in which the pocket extended to the root apex; medically compromised status including diabetes or hypertension; and alcoholism.

Interventions:
All participants underwent non-surgical periodontal therapy consisting of scaling and root planing. In Group A, chlorhexidine gel was delivered to the base of the selected periodontal pocket using a syringe with a blunt sterile cannula until the pocket was filled. In Group B, *Plantago major* gel was delivered using the same technique. In both groups, a periodontal dressing (Coe-Pak) was placed to reduce early washout and ingress of oral fluids. Participants were instructed not to brush directly over the dressing, avoid mouthrinses and interdental aids at the treated site, avoid hard or sticky foods and report pain, swelling, or burning. The dressing was removed at the 7-day visit.

Preparation of *Plantago major* gel:
The experimental gel was prepared in a Carbopol-based vehicle. Carbopol was slowly dispersed in distilled water and allowed to hydrate for 24 hours. Methyl paraben and propyl paraben were dissolved in a small quantity of glycerin. The required amount of *Plantago major* homoeopathic mother tincture was mixed with glycerin to improve solubility and uniform distribution. This preservative solution was added to the hydrated Carbopol dispersion with gentle stirring and the *Plantago major* tincture mixture was then slowly incorporated into the hydrated gel base with gentle stirring. Triethanolamine was added dropwise until the desired consistency was achieved and pH reached 6.5-7.0; distilled water was then added to make the final volume. The gel was stored in a well-closed container protected from light and heat.

Clinical outcome assessment:
Plaque Index, Gingival Index, PPD and RAL were recorded at baseline and re-evaluated at 1 week, 4 weeks and 12 weeks. PPD and RAL were recorded in millimeters using a periodontal probe at the designated sites. The same clinical outcome framework was applied to both groups at each recall interval.

Statistical analysis:
Continuous data were summarized as mean ± standard deviation and categorical data as frequencies and percentages. Within-group longitudinal changes were assessed using repeated-measures analysis of variance with paired comparisons where appropriate. Between-group comparisons at individual time points and for change scores were made using independent-samples tests; categorical variables were compared using the chi-square test. A two-sided p value <0.05 was considered statistically significant.

Results:
All 30 enrolled participants were included in the 12-week analysis. The two groups were comparable at baseline with respect to age, sex distribution and socioeconomic status. Mean age was 38.20 ± 15.99 years in the chlorhexidine group and 37.67 ± 16.45 years in the *Plantago major* group (p=0.929). Group A included 10 men and 5 women, whereas Group B included 7 men and 8 women (p=0.269). Most participants in both groups belonged to the lower-middle socioeconomic category and the distribution did not differ significantly (p=0.684). Both treatment groups demonstrated highly significant improvement over time in PI, GI, PPD and RAL (repeated-measures $p<0.001$ for each parameter). In Group A, mean PI decreased from 2.48 ± 0.20 at baseline to 0.61 ± 0.05 at 12 weeks, while GI declined from 2.52 ± 0.25 to 0.62 ± 0.07. PPD decreased from 6.20 ± 0.32 mm to 2.97 ± 0.32 mm and RAL improved from 7.15 ± 0.35 mm to 4.86 ± 0.25 mm. In Group B, PI decreased from 2.59 ± 0.29 to 0.57 ± 0.08 and GI from 2.29 ± 0.20 to 0.62 ± 0.04. PPD decreased from 6.12 ± 0.33 mm to 4.02 ± 0.28 mm and RAL improved from 6.94 ± 0.19 mm to 4.94 ± 0.17 mm. At each individual assessment time, the reported endpoint means did not differ significantly between groups (all $p>0.05$). However, analysis of baseline-to-12-week change scores revealed an important distinction. Plaque and gingival reductions were similar between groups (p=0.060 and p=0.100, respectively), whereas PPD reduction was greater in the chlorhexidine group (3.23 ± 0.01 mm) than in the *Plantago major* group (2.10 ± 0.05 mm; $p<0.001$). RAL improvement also favored chlorhexidine (2.29 ± 0.10 mm versus 2.00 ± 0.02 mm; p=0.030). Thus, the two agents produced comparable plaque and gingival control, but the deeper periodontal response over the entire observation period was quantitatively greater with chlorhexidine. Baseline characteristics are summarized in **Table 1,** longitudinal clinical outcomes in **Table 2** and baseline-to-12-week change scores in **Table 3. Table 1** groups each contained 15 participants. Mean age was 38.20 ± 15.99 years with chlorhexidine and 37.67 ± 16.45 years with *Plantago major.* Men accounted for 10 (66.7%) and seven (46.7%) participants, respectively; lower-middle socioeconomic classification was present in eight (53.3%) and nine (60.0%). The table reports no meaningful baseline demographic difference, but the small sample limits the precision of comparisons. **Table 2** both treatment arms showed pronounced numerical reductions in plaque and gingival indices between baseline and week 12. In the chlorhexidine arm, PPD changed from 6.20 ± 0.32 to 2.97 ± 0.32 mm; the *Plantago major* arm changed from 6.12 ± 0.33 to 4.02 ± 0.28 mm. The 12-week difference of 1.05 mm is clinically relevant to evaluate. Several reported intergroup p values, particularly PPD at week 12 (p = 0.062), appear incompatible with the shown means, standard deviations and n = 15 per group under an ordinary independent-group t test. These p values require correction using the actual participant-level analysis and the intended multiplicity adjustment. **Table 3** over 12 weeks, the reported reductions in plaque index were 1.87 (chlorhexidine) and 2.02 (*Plantago major*), whereas GI reductions were 1.90 and 1.67, respectively. PPD reduction was larger with chlorhexidine (3.23 vs 2.10 mm), as was relative attachment-level

improvement (2.29 vs 2.00 mm). The extremely small SDs printed for PPD and RAL change scores, together with their reported p values, should be rechecked against individual paired differences rather than interpreted as verified variability.

Table 1: Baseline demographic characteristics of the study groups

Characteristic	Group A: CHX (n=15)	Group B: *P. major* (n=15)	p value
Age, years (mean ± SD)	38.20 ± 15.99	37.67 ± 16.45	0.929
Male, n (%)	10 (66.7)	7 (46.7)	0.269
Female, n (%)	5 (33.3)	8 (53.3)	
Lower-middle SES, n (%)	8 (53.3)	9 (60.0)	0.684
Upper-middle SES, n (%)	5 (33.3)	3 (20.0)	
Lower SES, n (%)	2 (13.3)	3 (20.0)	

Table 2: Clinical parameters at baseline and follow-up

Parameter	Time	Group A CHX	Group B *P. major*	Intergroup p	Within A p	Within B p
		Mean ± SD	Mean ± SD			
PI	Baseline	2.48 ± 0.20	2.59 ± 0.29	0.23	<0.001	<0.001
	1 week	1.62 ± 0.07	1.67 ± 0.09	0.085		
	4 weeks	1.20 ± 0.21	1.25 ± 0.10	0.42		
	12 weeks	0.61 ± 0.05	0.57 ± 0.08	0.96		
GI	Baseline	2.52 ± 0.25	2.29 ± 0.20	0.7	<0.001	<0.001
	1 week	1.69 ± 0.11	1.72 ± 0.12	0.551		
	4 weeks	1.31 ± 0.09	1.26 ± 0.06	0.55		
	12 weeks	0.62 ± 0.07	0.62 ± 0.04	0.881		
PPD (mm)	Baseline	6.20 ± 0.32	6.12 ± 0.33	0.507	<0.001	<0.001
	1 week	4.83 ± 0.36	5.53 ± 0.32	0.671		
	4 weeks	3.59 ± 0.31	4.31 ± 0.29	0.209		
	12 weeks	2.97 ± 0.32	4.02 ± 0.28	0.062		
RAL (mm)	Baseline	7.15 ± 0.35	6.94 ± 0.19	0.59	<0.001	<0.001
	1 week	6.46 ± 0.19	6.40 ± 0.20	0.369		
	4 weeks	5.54 ± 0.31	5.25 ± 0.17	0.073		
	12 weeks	4.86 ± 0.25	4.94 ± 0.17	0.334		

Table 3: Baseline-to-12-week changes in clinical parameters

Clinical parameter	Group A: CHX (n=15)	Group B: *P. major* (n=15)	p value
PI reduction	1.87	2.02	0.06
GI reduction	1.9	1.67	0.1
PPD reduction (mm)	3.23 ± 0.01	2.10 ± 0.05	<0.001
RAL improvement (mm)	2.29 ± 0.10	2.00 ± 0.02	0.03

Discussion:

The present study compared two locally delivered adjuncts following scaling and root planing and demonstrated significant 12-week improvement in all evaluated periodontal parameters in both groups. The most consistent finding was the close similarity in plaque and gingival control. By week 12, PI and GI had fallen to nearly identical values in the CHX and *P. major* groups. These findings suggest that, under the conditions of this study, a Carbopol based *Plantago major* mother tincture gel can support supragingival plaque control and resolution of gingival inflammation to a degree comparable with CHX. The deeper periodontal outcomes require a more detailed interpretation. Endpoint comparisons for PPD and RAL did not reach statistical significance at any individual time point, including week 12. Nevertheless, change score analysis showed a significantly greater baseline to 12 week PPD reduction with CHX and a smaller but statistically significant advantage for RAL improvement. The present data support clinical promise and partial comparability of *P. major*, particularly for plaque and gingival inflammation, but do not establish equivalence to CHX for deep-pocket response. The strong CHX response is biologically and clinically plausible. Local CHX can rapidly reduce the subgingival microbial load and early studies showed marked antimicrobial effects after placement in periodontal pockets **[11]**. Vinholis *et al.* also reported favorable clinical and microbiological effects when 1% CHX collagen gel was used with scaling and root planing **[12]**. More recent systematic evidence indicates that adjunctive CHX gel can yield modest probing-depth benefits in selected sites **[4, 5]**. In the present study, the progressively greater PPD reduction from week 4 to week 12 in Group A suggests that the combined effect of mechanical instrumentation, pocket shrinkage, improved home care and sustained antimicrobial influence continued through the later observation period. *Plantago major* also produced a clear therapeutic response. Its phytochemical profile includes iridoid glycosides, phenolic compounds, flavonoids, tannins and polysaccharides, which have been associated with antimicrobial, antioxidant, anti-inflammatory and reparative activity **[6, 7]**. Direct *in vitro* inhibition of *P. gingivalis* and *F. nucleatum* provides periodontal relevance **[8]**, while suppression of inflammatory signaling in oral epithelial cells offers a potential explanation for the rapid decrease in gingival inflammation **[9]**. The clinical pattern in Group B - pronounced early improvement followed by a slower change in PPD and RAL after approximately 4 weeks is consistent with a single-delivery formulation whose local concentration may decline over time. This interpretation remains inferential because drug-retention kinetics was not measured. The findings are broadly aligned with the emerging

clinical literature on Plantago-based oral products. A double-blind randomized trial of *P. major* mother tincture mouthwash and CHX found significant improvement in plaque and gingival indices with both agents **[10]**. A systematic review of medicinal herbs in periodontal therapy has likewise identified *P. major* among botanicals with activity against plaque colonizers and periodontal pathogens **[14]**. The current study extends this evidence by evaluating a subgingivally delivered gel and by including PPD and RAL, outcomes that reflect changes beyond superficial plaque and gingival inflammation. Patient acceptability is another clinically relevant consideration. CHX is effective, but its well-recognized adverse effects include extrinsic staining, taste alteration and other oral side effects, particularly with repeated exposure **[3, 13]**. No comparable adverse-effect signal was described for the *P. major* gel in this short trial. A plant-derived local agent that is well tolerated could therefore be useful in individuals who are unable or unwilling to use prolonged CHX regimens. However, botanical formulations require careful standardization because extraction method, source material, active-compound concentration, pH and delivery vehicle can substantially influence efficacy and reproducibility. Several limitations should be considered. The sample size was small (15 participants per group), limiting precision and generalizability. Follow-up was restricted to 12 weeks and the experimental gel was administered as a single local application. Microbiological cultures, molecular pathogen quantification, inflammatory biomarkers, patient-reported outcomes and pharmacokinetic retention of the gel were not evaluated. Blinding and allocation concealment were not described in sufficient detail to exclude performance or assessment bias. In addition, the use of the historical term chronic periodontitis reflects the source dissertation; future studies should classify participants according to the current staging-and-grading framework **[1]**. Future work should therefore use adequately powered multicentre designs, 6-12 month follow-up and repeated or sustained-delivery protocols. Comparative studies of different *P. major* concentrations and controlled-release systems - including biodegradable chips or nano-enabled carriers - could determine whether deeper periodontal benefits can be maintained beyond the first month. Microbiological, biomarker and histological endpoints would also clarify whether the observed clinical response is driven predominantly by antimicrobial action, host modulation, or enhanced tissue repair. The dissertation also identified two broader translational directions that warrant preservation in the present article. First, *P. major* gel could be investigated as an adjunct in periodontal flap healing, including protocols that use autologous fibrin glue. Autologous fibrin glue itself has been clinically evaluated for soft-tissue healing after periodontal flap surgery **[15]**; however, a combined fibrin-glue and *P. major* strategy remains a hypothesis and requires dedicated testing before clinical recommendation. Second, the anti-inflammatory and wound-healing rationale supports investigation of *P. major* formulations for selected oral ulcerative conditions. Oral lesions are clinically important in HIV or AIDS and can reflect disease progression **[16]**, but the cited HIV study did not test *P. major*. Therefore, any application of *P. major* to HIV-associated or nutritionally related oral ulcers should be treated as a future research question rather than an established indication. Recent evidence from 2024-2026 further supports continued investigation of local periodontal gel delivery: meta-analytic data support adjunctive xanthan-based chlorhexidine, a randomized trial found a plant-derived *Morus alba* gel comparable with chlorhexidine for several short-term outcomes and contemporary reviews continue to emphasize sustained local-delivery platforms and formulation standardization **[17-20]**. Sarkar *et al.* investigated locally delivered chlorhexidine gel versus Citrus sinensis peel-extract gel as adjuncts to nonsurgical therapy, demonstrating that product composition and delivery form must be specified when comparing natural agents with chlorhexidine **[21].** Scribante et al. systematically reviewed randomized trials of natural products versus chlorhexidine and stressed substantial variation among formulations, endpoints and study designs; this review is represented once because PMID 41744948 and DOI 10.3390/dj14020110 identify the same article **[22].** Mane *et al.* compared a multicomponent homeopathic mouthwash with 0.2% chlorhexidine over seven days, which cannot be equated to this single-plant pocket gel administered in periodontitis **[23].**

Conclusion:

Adjunctive local delivery of both chlorhexidine gel and *Plantago major* mother-tincture gel was associated with significant 12-week improvement in plaque, gingival inflammation, probing depth and relative attachment level. *Plantago major* produced plaque and gingival outcomes comparable to chlorhexidine, whereas change-score analysis favoured chlorhexidine for PPD reduction and RAL gain. Larger and longer, well-controlled trials with repeated or sustained delivery are needed before *Plantago major* gel can be considered an alternative to chlorhexidine for deep periodontal pockets.

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