Embilca officinalis Irrigation as an Adjunct to Scaling and Root Planing: A Randomized Controlled Clinical Trial

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Embelica officinalis Irrigation as an Adjunct to Scaling and Root Planing: A Randomized Controlled Clinical Trial

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ABSTRACT

Objective: To evaluate the effect of 10% Embelia officinalis irrigation, which has anti-inflammatory, antioxidative, and antimicrobial activities, adjunctive to scaling and root planing (SRP) for treatment of chronic periodontitis.

Methods: Sixty-six patients were randomly assigned to the negative control group (SRP+saline irrigation; n=22), positive control group (SRP+chlorhexidine irrigation; n=22), and test group (SRP+10% E. officinalis irrigation; n=22). Plaque index (PI), gingival index (GI), probing pocket depth (PPD), clinical attachment level (CAL), and sulcus bleeding index (SBI) were monitored ≤3 months post-therapy.

Results: There were significantly greater reductions in the mean PI, PPD, and SBI but a greater mean CAL at 3 months post-therapy in the test group than in the negative control (p<0.05). Compared with the positive control, the test group demonstrated greater reduction in SBI but comparable improvements in PI, GI, CAL, deep pockets (PPD≥5–6 mm, ≥7 mm), and sites with CAL ≥6 mm at 3 months post-therapy (p>0.05) but less reduction in the mean PPD (p<0.05).

Conclusions: E. officinalis 10% irrigant adjunctive to SRP improved periodontal healing without side effects and may be an alternative to chlorhexidine for chronic periodontitis treatment.

Keywords: chlorhexidine; chronic periodontitis; Embelia officinalis; root planing

INTRODUCTION

Bacterial plaque is the principal etiological factor in the initiation of inflammatory periodontal diseases, and the destructive host responses triggered by microbial pathogens exaggerate the already existing condition, which results in connective tissue loss characterizing the inflammatory periodontal diseases.¹ The key element in periodontal therapy is to achieve significant reduction or eradication of suspected periodontal pathogens and modulation of destructive host responses.

Chlorhexidine has been extensively used as an adjunct to conventional mechanical treatment for chronic periodontitis. Its use, however, is limited by various side effects, including development of resistance, decrease in salivary secretions, acceleration in calculus accumulation, altered taste perception, and teeth staining. Researchers are increasingly turning their attention to phyto-therapeutic agents and looking for new leads to develop better drugs against multidrug-resistant microbial strains. Bacteria are less likely to develop resistance to these natural substances, which should be safer for patients and cause fewer side effects.²

Embelica officinalis Gaertn. (E. officinalis) (a.k.a. Phyllanthus emblica Linn.) belongs to the family Euphorbiaceae. All parts of the plant are useful in treating various ailments, but the fruit is of immense value in various traditional systems of medicine because it possesses a wide array of activities, such as antibacterial, anti-inflammatory, analgesic, antioxidant, immunomodulatory, antibacterial, antipyretic, anti-diabetic, hypolipidemic, cardioprotective, and...
also ameliorate acute and chronic
irrigant was prepared by dissolving
mineralogy, zinc, chromium, copper, and gallic acid. The
sustained-release gel with nonsurgical
mainly to flavonoids, phenols, saponins, and tannins. Saponins and tannins have been proven to have potent antimicrobial properties. Phenolic compounds of E. officinalis also ameliorate acute and chronic inflammation because of their modulatory action on free radicals and by affecting the cyclooxygenase (COX) pathway, specifically prostaglandins. In a clinical randomized controlled trial, Grover et al. recently demonstrated that adjunctive use of E. officinalis sustained-release gel in the management of chronic periodontitis and to compare it with that of 0.2% chlorhexidine and 0.9% saline solution adjuncts to SRP.

**METHODS**

This study was conducted in the Department of Periodontics and Oral Implantology, Post Graduate Institute of Dental Sciences (PGIDS), Rohtak, in collaboration with the College of Pharmacy and Department of Microbiology, Post Graduate Institute of Medical Sciences (PGIMS), Rohtak. This study was designed according to the ethical standards outlined in the 1964 Declaration of Helsinki, as revised in 2008. The study was approved by the Institutional Review Board, PGIDS, Rohtak (PGIDS/2013/IERC/87) and ethical committee of PGIDS, Rohtak.

**Study population**

The study patients were selected from systemically healthy individuals attending the regular outpatient Department of Periodontics and Oral Implantology, PGIDS, Rohtak. The inclusion criteria were systemically healthy patients with chronic periodontitis, age ≥30 years, and ≥20 teeth. The exclusion criteria were the presence of systemic illnesses that affect the outcome of periodontal therapy, such as diabetes mellitus; immunocompromised states; history of periodontal therapy in the preceding 6 months; prior use of antibiotics or anti-inflammatory drugs within the last 6 months; allergy to chlorhexidine; aggressive periodontitis; pregnancy or lactating women; smokers (current/former); and alcohol or drug abuse. Prior written informed consent was obtained from each patient after explaining the procedure in detail along with the advantages and disadvantages in the patient’s own language.

This study was a single-center, double-blind, randomized controlled clinical trial. Sixty-six patients diagnosed as having chronic periodontitis were enrolled in the study by one investigator (SG) and randomly allocated by using a computer-generated table to the test group (SRP+10% E. officinalis irrigation), positive control group (SRP+0.2% chlorhexidine irrigation), and negative control group (SRP+0.9% saline irrigation) by another investigator (ST).

**Periodontal examination**

After inclusion in the study, all patients underwent a full-mouth periodontal examination in a standardized manner that used a mouth mirror, tweezers, a Williams probe (Hu-Friedy, Chicago, IL, USA), and an explorer. The following parameters were considered: primary outcome variables, including probing depth (PD) and clinical attachment level (CAL); and secondary outcome variables, including plaque index (PI), gingival index (GI), and sulcus bleeding index (SBI). Each tooth was assessed at four sites (mesiobuccal, midbuccal, distobuccal, and midlingual) for PI and GI and at six sites (mesiobuccal, midbuccal, distobuccal, mesiolingual, midlingual, and distolingual) for PD, CAL, and SBI during the periodontal examination. Intra-examiner reproducibility was determined for 10% of the patients to rule out any variability in the measurements. Each participant was assessed twice, and measurements were repeated within 2 days. The reproducibility of the data collection was determined for each site. Repeated measurements were recorded with >90% accuracy, and the k values ranged from 0.82 to 0.86.

**Preparation of E. officinalis extract**

The authenticated E. officinalis fruits (herbal garden, College of Pharmacy, PGIMS, Rohtak) were collected, washed, and shade dried at room temperature. E. officinalis extract was prepared by using the methodology according to Kokate as described in our previous study (Grover et al.), and a 10% concentration of E. officinalis extract was finalized for subgingival irrigation in the present study also.

E. officinalis irrigant was prepared by dissolving weighed E. officinalis extract (20g) in 200mL of distilled water. The pH of the resultant solution was 2.5. Sodium hydroxide buffer (Titan Biotech Limited, Bhiwadi, India) was added to adjust the pH to neutral. The pH was measured by using a pH meter (Thermo Electron Corporation, Beverly, MA, USA).

**Periodontal treatment**

The patients received nonsurgical treatment in the form of full-mouth supragingival and subgingival
SRP in two sessions using manual instruments and an ultrasonic scaler (Suprasson® P5 Booster; Satelec, a Division of A-tec, Newberg, OR, USA) by one investigator (SG). A single application of subgingival irrigation with 0.9% saline, 0.2% chlorhexidine, or 10% \textit{E. officinalis} irrigant was given to each patient in the negative control group, positive control group, and test group, respectively, on the day of completion of SRP by another investigator (ST). The subgingival irrigation was accomplished by applying 5mL of irrigant in both arches by using a syringe and blunted needle. The patients were instructed to use only mechanical techniques to clean teeth during the study period, and mouthwashes and/or antimicrobials were not prescribed. All periodontal parameters were recorded at baseline and after 2 and 3 months of follow-up by a single periodontist (SG).

Statistical analysis
Assuming a fairly normal distribution of the samples, a minimum sample of 18 patients per group was required to detect a clinically significant difference in PPD and CAL with effect size (d)=1 (a difference in CAL or PPD of 1 mm with a standard deviation of 1 between two

### Table 1. Demographic data and periodontal parameters at baseline.

<table>
<thead>
<tr>
<th>Parameters</th>
<th>Negative control group (n=20)</th>
<th>Positive control group (n=20)</th>
<th>Test group (n=20)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>Mean±SD 38.65±8.165</td>
<td>Mean±SD 38.20±5.996</td>
<td>Mean±SD 38.05±6.832</td>
<td>0.85</td>
</tr>
<tr>
<td></td>
<td>Minimum 30</td>
<td>Minimum 30</td>
<td>Minimum 30</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Maximum 58</td>
<td>Maximum 52</td>
<td>Maximum 56</td>
<td></td>
</tr>
<tr>
<td>Sex</td>
<td>Male n=11 (Mean age=37.86±6.38)</td>
<td>Male n=9 (Mean age=39.57±7.53)</td>
<td>Male n=9 (Mean age=37.0±5.802)</td>
<td>0.92</td>
</tr>
<tr>
<td></td>
<td>Female n=9 (Mean age=42.57±9.83)</td>
<td>Female n=11 (Mean age=40.28±2.98)</td>
<td>Female n=11 (Mean age=40.14±9.459)</td>
<td>0.64</td>
</tr>
<tr>
<td></td>
<td>Minimum 30</td>
<td>Minimum 30</td>
<td>Minimum 30</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Maximum 52</td>
<td>Maximum 55</td>
<td>Maximum 56</td>
<td></td>
</tr>
</tbody>
</table>

$p<0.05$ indicates significance (by Kruskal–Wallis analysis); \textsuperscript{1} Negative control group: SRP + subgingival saline irrigation; Positive control group: SRP + subgingival chlorhexidine irrigation; Test group: SRP + subgingival \textit{E. officinalis} irrigation
To further compensate for dropouts, 22 patients were assigned to each group. The distribution of the data for all parameters was analyzed by performing the Kolmogorov-Smirnov test. For non-normal distribution of data, differences among the test, positive control, and negative control groups at baseline were analyzed by using the Kruskal-Wallis test. The comparison of periodontal parameters between baseline, 2 months, and 3 months within a group were analyzed by using the Friedman test followed by the Wilcoxon signed-rank test. Differences between the groups for improvements in parameters were assessed by using the Kruskal-Wallis test followed by the Mann-Whitney U test. All statistical analyses were two tailed with a threshold for significance of $p<0.05$ and were calculated by using standard statistical software (SPSS, v.21.0 for Windows; IBM, Chicago, IL, USA).

**RESULTS**

Sixty-six patients participated in the study. Out of these, 60 patients completed both follow-ups at 2 and 3 months posttreatment (Figure 1). No adverse effect was observed during or after the treatment with *E. officinalis* extract irrigation. Healing was uneventful.

Table 1 highlights the demographic and baseline clinical characteristics of the study groups. There were no statistically significant differences between the ages and sex distributions between the two groups ($p>0.05$). Statistically insignificant differences in whole-mouth PI, GI, PPD, CAL, and SBI were found among the groups at baseline ($p>0.05$).

Table 2 shows that there were statistically significant improvements in all clinical parameters from baseline to 2 and 3 months post-therapy in all test and control groups ($p<0.05$).

Table 3 shows the intergroup comparisons among the clinical parameters at all time points posttreatment. PI: The test group showed reductions in plaque scores at 3 months post-therapy similar to those in the negative and positive control groups. GI: Similar reductions at all time points were observed among the test group and
positive and negative control groups. PPD: Compared with the negative control group, the test group showed statistically significant reductions at 2 and 3 months post-therapy. Similar reductions were observed at 2 months post-therapy in the test and positive control groups, whereas the positive control group showed a statistically significant reduction after 3 months. CAL: Compared with the negative control group, the test group showed statistically significant gains at 2 and 3 months post-therapy. The test group and positive control group exhibited similar CAL gains at 2 and 3 months posttreatment. The positive control group showed greater reductions than those in the negative control group after 3 months. SBI: The test group showed significantly greater reductions in SBI than those in the positive and negative control groups at 2 and 3 months for respective treatments.

Table 4 shows that the test group and positive control group had statistically significant greater reductions in the number of sites with moderately deep pockets (PPD of 5–6mm) than those in the negative control after 2 and 3 months of therapy \((p<0.05)\), whereas the test group exhibited greater reduction in the moderately deep pockets than that in the positive control group. The test group and positive control group showed statistically significant greater reductions in the sites with CAL \( \geq 6\) mm than those in the negative control group after 2 and 3 months of therapy \((p<0.05)\), whereas the test and positive control groups exhibited similar reductions \((p>0.05)\).

DISCUSSION

*E. officinalis* Geartn. is arguably one of the most important plants in traditional systems of medicine. Various parts of the plant, particularly the fruit, possess a number of compounds (phenolic compounds, saponins, tannins, and flavonoids) with varied medicinal properties that may be beneficial in the treatment of various chronic diseases, such as periodontitis. The *E. officinalis* extract used in this study has been generally recognized as safe for its intended use by the U.S. Food and Drug Administration as per 21 CFR 170.36 (2009).

When compared with the saline irrigation group, the *E. officinalis* irrigation group showed greater reductions in PPDs, SBIs, % of deep pockets with PPD=5–6mm, % of sites with CAL \( \geq 6\) mm, and % of sites with SBI than those in the negative control group.
Table 4. Intergroup comparison of percentage improvements (Δ) in the number of moderately deep (PPD=5-6mm) and deep pockets (PD>7mm) and in the number of sites with CAL ≥6mm, pre- and post-therapy (Mean±SD) between the positive control group, test group, and negative control group.

<table>
<thead>
<tr>
<th>Period</th>
<th>Parameters</th>
<th>Positive control group</th>
<th>Test group</th>
<th>P-value</th>
<th>Negative control group</th>
<th>P-value</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline to 2</td>
<td>ΔPPD=5–6</td>
<td>60.787±34.067</td>
<td>40.046±40.357</td>
<td>0.05*</td>
<td>0.04*</td>
<td>0.00*</td>
<td>0.16</td>
</tr>
<tr>
<td>months</td>
<td>mm.</td>
<td>45.26±48.458</td>
<td>45.26±48.458</td>
<td>0.90</td>
<td>40.046±40.357</td>
<td>0.86</td>
<td>0.96</td>
</tr>
<tr>
<td></td>
<td>ΔCAL≥6</td>
<td>54.507±38.878</td>
<td>60.145±32.008</td>
<td>0.56</td>
<td>31.244±29.816</td>
<td>0.00*</td>
<td>0.09</td>
</tr>
<tr>
<td></td>
<td>mm.</td>
<td>89.734±19.552</td>
<td>91.93±18.573</td>
<td>0.52</td>
<td>63.706±29.442</td>
<td>0.00*</td>
<td>0.00*</td>
</tr>
<tr>
<td></td>
<td>ΔPPD=5–6</td>
<td>57.712±49.133</td>
<td>48.375±49.936</td>
<td>0.56</td>
<td>62.483±38.249</td>
<td>0.30</td>
<td>0.75</td>
</tr>
<tr>
<td>months</td>
<td>mm.</td>
<td>70.203±36.642</td>
<td>75.376±21.674</td>
<td>1.00</td>
<td>45.198±33.216</td>
<td>0.00*</td>
<td>0.03*</td>
</tr>
<tr>
<td>2–3 months</td>
<td>ΔPPD=5–6</td>
<td>66.877±42.180</td>
<td>52.64±44.323</td>
<td>0.46</td>
<td>37.95±34.444</td>
<td>0.46</td>
<td>0.04*</td>
</tr>
<tr>
<td></td>
<td>mm.</td>
<td>16.183±35.564</td>
<td>6.33±20.798</td>
<td>0.56</td>
<td>29.33±28.374</td>
<td>0.00*</td>
<td>0.06</td>
</tr>
<tr>
<td></td>
<td>ΔCAL≥6</td>
<td>37.789±41.01</td>
<td>30.665±26.058</td>
<td>0.90</td>
<td>27.873±29.709</td>
<td>0.56</td>
<td>0.90</td>
</tr>
</tbody>
</table>

*p<0.05 indicates significance (by Mann–Whitney U test analysis); p¹=Positive control and test groups.; p²=Negative control and test groups; p³=Positive control and negative control groups.

and CAL ≥6mm and significant gain in CALs at both 2 and 3 months post-therapy. There were nonsignificant differences in the PIs and GI scores after 3 months of post-therapy between the E. officinalis irrigation group and saline group. Improvements in periodontal primary outcome parameters suggest the role of possible diverse biological activities of E. officinalis, such as antimicrobial, anti-inflammatory, antioxidant, immunomodulatory, and antiresorptive properties.

Compared with the chlorhexidine irrigation group, the E. officinalis irrigation group showed similar reductions in PIs and gingival inflammation and increases in CALs at all time points. Regarding PPDs, there was an insignificant difference in improvements within the first 2 months post-therapy, but a statistically significant difference in PPDs was observed between baseline and 3 months for chlorhexidine. The nonsignificant improvement in PPD in the first 2 months might be a result of the cytotoxic and inhibitory effect of chlorhexidine on the fibroblasts in early stages of healing, which could delay subsequent fibroblast attachment and thus regeneration of the periodontium.

With respect to the SBI and moderately deep pockets, the E. officinalis group showed better improvements than did the chlorhexidine group after 2 and 3 months post-therapy, which suggested anti-inflammatory and antimicrobial effects of E. officinalis irrigant.

A comparison showed that improvements in PI and PPD were greater in the positive control group than in the negative control group at all time points, and increases in CALs and reduction in moderately deep pockets were also more evident in the positive control group after 3 months of post-therapy. Our results are consistent with those in studies by Wesley et al. and Gottumukkala et al. in which they stated that chlorhexidine had a significantly greater effect on microbiological parameters and PPD at test sites than that of saline. Additional improvements in clinical parameters in the test group might be possible because of the various beneficial properties of E. officinalis extract.

The antimicrobial activity of E. officinalis has been observed in studies to be active against a range of bacteria. According to an in vitro study conducted by Hasan S et al., E. officinalis fruit inhibited virulence factors of Streptococcus mutans, sucrose-dependent and sucrose-independent glass surface adherence, biofilm formation by S. mutans and biofilm architecture. Ni et al. observed that E. officinalis, through the presence of pyrogallol and its analogs, can antagonize bacterial quorum sensing in Vibrio harveyi.

The spectrum of anti-inflammatory activity of E. officinalis against a variety of irritants in experimental rat models has been evaluated and found to be effective in most of these models. The mechanism of anti-inflammatory activity was suggested to be similar to nonsteroidal anti-inflammatory drugs rather than to steroidal drugs and credited possibly to its action on inflammatory mediators through the COX pathway, especially prostaglandins. The reduction...
in the modified SBI values in the present study may support the anti-inflammatory role of *E. officinalis* irrigant. Recently, a randomized controlled trial demonstrated antiplaque and antigingivitis activity of 10% triphala (*Terminalia bellirica*, *Terminalia chebula*, and *E. officinalis*) similar to that of chlorhexidine in school children, which further supported the results of the present study.25

The antioxidant properties of *E. officinalis* extract have been studied by Scartezzini *et al.*, and they suggested that ascorbic acid (0.4% w/w) is present in the fruit accounts for approximately 45-70% of the antioxidant activity.26

An *in vitro* study to demonstrate antiresorptive activity was conducted by Penolazzi *et al.*, and the results demonstrated that *E. officinalis* extracts act by interfering with NF-KB activity, a transcription factor involved in osteoclast biology, and thus induce osteoclast apoptosis.29 The immunostimulatory activity of the *E. officinalis* extract has also been validated by many studies and has been shown to enhance natural killer cell activity.27 One study reported that a triphala

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**Figure 1.** Flow chart of patients through the study
preparation containing *E. officinalis* as one of its components caused a 76.6% reduction in MMP-9 in adult periodontitis patients.\(^2\)

Very few studies have reported the clinical effects of *E. officinalis* formulations on oral diseases. Alam *et al.* conducted a study on humans to compare the efficacy of a mouth rinse containing *E. officinalis* extract 20mg/mL and Glycrrhiza glabra 20mg/mL (HMR), a herbal toothpaste gel containing *E. officinalis* extract 20mg/mL and *G. glabra* 20mg/mL (HTG), and a chlorhexidine mouth rinse on cariogenic microorganisms (*S. mutans* and *Lactobacilli* species) and showed that HTG was effective for a longer duration than those of HMR and chlorhexidine mouth rinse.\(^2\) Grover *et al.* investigated the effect of subgingival application of indigenously prepared 10% *E. officinalis* (Amla) sustained-release gel in deep pockets adjunctive to SRP on chronic periodontitis in their randomized clinical trial and found that the gel may be beneficial in reducing inflammation and periodontal destruction.\(^2\) However, they had not compared the clinical efficacy of *E. officinalis* with chlorhexidine. In the present study, irrigation with 10% *E. officinalis* was performed as an adjunct to SRP, and its effectiveness was compared with that of chlorhexidine. The results of this study showed that significantly greater reduction in inflammation and improved periodontal healing in deep pockets was achieved by using *E. officinalis* than by using chlorhexidine, whereas improvement in other periodontal parameters was comparable in the test and positive control groups in patients with chronic periodontitis.

Our study design had the following strengths: the strict inclusion and exclusion criteria and the exclusion of smokers to evacuate the effect of smoking on periodontal treatment outcomes. However, there were also some study limitations: the bioactive components present in *E. officinalis* extract were not studied; none of the biochemical markers were assessed either in serum or gingival crevicular fluid; the substantivity of the test irrigant could not be evaluated; and only a single concentration of *E. officinalis* irrigant was used in the study.

**CONCLUSION**

To summarize, *E. officinalis* fruit (hydroalcoholic) extract-based irrigant effectively improved periodontal parameters associated with periodontal healing in the treatment of chronic periodontitis when used as an adjunct to conventional mechanical therapy and may provide an alternative to chlorhexidine in nonsurgical periodontal therapy. Future longitudinal multicentered studies with different concentrations of *E. officinalis* subgingival irrigations are required to validate these results.

**ACKNOWLEDGMENT**

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**CONFLICT OF INTEREST**

The authors declare that there were no conflicts of interest related to this study.

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