Evaluation of the efficacy of subgingival irrigation in patients with moderate-to-severe chronic periodontitis otherwise indicated for periodontal flap surgeries

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Abstract:
Background: In certain medically and physically compromised; and terminally ill patients, periodontal surgery may not be feasible. They need special attention and assistance for their daily plaque control regimens for the management and maintenance of periodontal conditions. Subgingival irrigation home care devices with antiplaque agents may serve as useful tools in such specific patient populations. Aims: The aim of this study was to evaluate the efficacy of sub-gingival irrigation in patients with moderate-to-severe chronic periodontitis otherwise indicated for periodontal flap surgeries. Settings and Design: Randomized comparative parallel group interventional clinical trial. Materials and Methods: Forty adults with moderate-to-severe periodontitis, divided inot Group A and B, were subjected to the use of subgingival home irrigations using 0.06% chlorhexidine (CHX) and mouth-rinsing with 15 ml of 0.12% CHX twice daily, respectively after Phase I therapy. Clinical parameters, i.e., gingival index, oral hygiene index simplified, and bleeding on probing scores were assessed at baseline, 2 weeks, 4 weeks, 8 weeks, and 12 weeks’ postphase I therapy, whereas clinical attachment level (CAL), probing depth (PD), and stain assessment at baseline and 12 weeks following Phase I therapy. Statistical Analysis Used: Statistical Package for Social Sciences (SPSS Inc., Chicago, IL, USA version 15.0 for Windows). Results: A statistically significant difference was seen with the use of 0.06% CHX irrigations in PD (P = 0.004) and CAL (P = 0.002) as compared to the use of mouth rinsing with 0.12% CHX. Similar differences were observed in both intensity (P = 0.014) and area (P = 0.034) of lingual surface staining with greater staining with CHX mouth rinsing. Conclusion: The adjunctive use of subgingival home irrigations using 0.06% CHX has a promising potential to maintain the oral health and results in lesser staining compared to CHX mouth rinsing. The regimen may further obviate the need of periodontal surgery in medically compromised subjects. Key words: Antiplaque, chlorhexidine, gingivitis, mouth rinsing, periodontitis, staining, subgingival home irrigation

INTRODUCTION

Periodontitis is a chronic and progressive inflammatory disease predominantly caused by interplay of microorganisms and host immune response.¹ These microorganisms are found associated with the periodontal tissues as a host-associated biofilm; dental plaque which is a complex community of microorganisms, highly resistant to breakdown, and antimicrobial action as compared to bacteria in a planktonic state.² Despite the paradigm shift which places immense importance to the immune response in fighting periodontal infections, removal of dental plaque still remains the prime requisite in maintaining periodontal health. Periodontal therapy since times immemorial has aimed at reducing the bacterial load and minimizing further plaque accumulation by creating easily cleansable environments.³ Brushing, flossing, and use of inter-dental aids have been the traditionally established methods of plaque disruption and have shown excellent results.⁴ However, there are certain conditions in which their range of use exhibits limitations, such as the presence of deep pockets, furcation areas, and distal molar areas. Moreover, their use warrants

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high levels of constant supervision and patient motivation and is a tedious process entailing great thoroughness and dexterity. Several chemotherapeutic agents dispensed as mouth rinses, sprays and gels have been serving as adjuncts to mechanical means to enhance antimicrobial and anti-plaque effects.\(^6,7\) However, they have shown a minimal zone of activity and limited penetrability in the presence of moderate-to-severe periodontitis with deep pockets.\(^8\) Irrigation devices have been researched and have shown promise in facilitating oral health maintenance and also serve as vehicles for various antimicrobial agents. Supra and subgingival irrigations have been found to be very effective in diluting and removing bacterial toxins, interfering with maturation of plaque and the removal of unattached plaque leading to suppression of periodontal infection.\(^9\) They have also been found to down modulate the levels of pro-inflammatory mediators in the gingival crevicular fluid thereby inhibiting the periodontal pathogens located within the pocket.\(^10\) Studies have shown that daily oral irrigations are very effective in suppressing periodontal pathogens located within the deepened crevice and have demonstrated a significant reduction in bleeding, gingivitis, and probing depths (PDs).\(^11,12\)

Moderate-to-severe periodontitis cases often have deep periodontal pockets that make the need for surgical treatment imperative. However, any form of surgical intervention is definitely laced with anxiety and concern of the patient with many refusing to come for recall. This could be attributed to the painless nature of the disease which is why the patient’s perception of the severity of the disease and its consequences are often ill conceived and hence he is often reluctant to surgical interventions. Another group of patients who need an effective and long-term treatment strategy include the medically compromised, who due to their ailing health may be unable to undergo surgeries and need assistance even in their daily plaque control regimens. These patients may benefit from the use of irrigations to maintain their periodontal health.

However, no study has been done so far that can objectively look at some alternative therapy that could be prescribed to these patients, so that they are able to maintain their active disease free state for a longer duration of time and may either be able to avoid surgery completely or at least delay the surgery for a foreseeable future.

Chlorhexidine (CHX), a well-known anti-plaque agent, has been extensively researched and found to show excellent results as an anti-plaque agent thereby improving oral health status.\(^13\)

It is hypothesized that the use of sub-gingival home irrigations with 0.06% CHX, twice daily as an adjunct to routine unsupervised home care after Phase I therapy shall help in maintaining the active disease free state in patients of moderate-to-severe chronic periodontitis who are otherwise indicated for periodontal flap surgeries for the 3-month follow-up period. The results of this study shall be of particular relevance in the third world countries wherein chronic periodontitis is vastly prevalent and the access to specialist care is very minimal and unaffordable to the majority of population.

The present study was designed with the aim of evaluating the efficacy of adjunctive use of sub-gingival home irrigations using 0.06% CHX vis-a-vis mouth-rinsing with 0.12% CHX on gingival and periodontal health status in cases of moderate-to-severe chronic periodontitis indicated for periodontal flap surgery. The effect of CHX in staining of teeth by both the administered techniques was also assessed.

**MATERIALS AND METHODS**

**Study population**

This study was a randomized controlled clinical trial in which 40 medically healthy adults male and female controls with moderate-to-severe periodontitis were enrolled from the outpatient department of the Department of Periodontics, Department of Periodontology, Dr. HS Judge Institute of Dental Sciences, Punjab University, Chandigarh, India, dental institute over 2 years of duration. The study was approved by the institutional ethical committee and informed consent was obtained from each patient after appropriately explaining the research protocol to them prior to the study. Systemically, healthy controls with no underlying medical conditions and suffering from moderate to severe periodontitis were selected. Inclusion criteria for periodontal disease were ≥2 inter-proximal sites with clinical attachment level (CAL) ≥4 mm (not on the same tooth) or ≥2 inter-proximal sites with PD ≥5 mm (not on the same tooth) who were indicated for periodontal flap surgery but were not willing to undergo the same immediately. Patients selected had not taken any antibiotic in the past 1 month and were able to maintain good oral hygiene. Patients with known history of allergies especially to CHX, those in the need of prophylactic antibiotic coverage to prevent infective endocarditis, pregnant or lactating women, smokers and alcoholics were all selectively excluded from the study.

The patients enrolled in the study were subjected to Phase I therapy comprising scaling and root planning and oral hygiene instructions. On completion of Phase I therapy, the selected patients were randomized into two Groups A and B using computer generated random numbers. Group A patients were prescribed the use of subgingival home irrigations (Water flosser-ultra, from Water Pik, Inc., USA) using 0.06% CHX twice daily (treatment option 1) and Group B patients were prescribed mouth-rinsing with 15 ml of 0.12% CHX twice daily (treatment option 2) at an interval of 10 min after the brushing after breakfast and dinner. Six milliliter of commercially available 6% CHX (Neelkanth, s chlorhexidine gluconate solution 6%, from Neelkanth Ortho Dent (p) Ltd., Jodhpur, India) concentrate solution was diluted with 600 ml of water in the home irrigation to achieve 0.06% CHX solution. The study was carried out over a period of 3 months with evaluations of clinical parameters, i.e., gingival index (GI), oral hygiene index simplified (OHIS), and bleeding on probing scores (BOP) at baseline, 2 weeks, 4 weeks, and 12 weeks’ post-Phase I therapy and PD, CAL and stain assessment at baseline and 12 weeks following Phase I therapy. GI by Loe and Silness, OHIS by Greene and Vermillion were used and for BOP scores the percentage of bleeding sites out of the total number of experimental sites was calculated for each treatment group. PD and CAL were ascertained on 6 sites per tooth. Stain assessment including intensity and area scores on both buccal and lingual surfaces was done using a modification of Loe & Silness index.\(^14\) All measurements were carried out by a single
examiner, who was calibrated and blinded to the allotment of the treatment options rendered.

Group A patients were taught the use of water irrigation device using the subgingival tip with 600 ml of 0.06% CHX so as to be able to perform home irrigations appropriately. The other group of patients was prescribed the use of mouthrinse containing 15 ml of 0.12% CHX; to be swished for 60 s twice daily. The patients were followed up and re-assessed at 2 weeks, 4 weeks and 12 weeks’ post-Phase I therapy.

At the follow-up visits, if the individual showed any further breakdown of the periodontal attachment apparatus, evidenced by increase in probing attachment levels ≥2 mm, the patients were immediately emphasized the need for periodontal surgery and were exited from the study.

Statistical analysis

The statistical analysis was carried out using Statistical Package for Social Sciences (SPSS Inc., Chicago, IL, USA version 15.0 for Windows). In this study for the sample size enrolled, the power of the correlations came out to be 90% at 95% confidence interval. All quantitative variables were estimated using measures of central location (mean, median) and measures of dispersion (standard deviation). One sample Kolmogorov–Smirnov test was used for the detection of normality of distribution of data. Since the data were normally distributed, hence, Independent t-test was applied for testing statistical difference in the age and Chi-square tests for gender assessment. Intragroup analysis for study parameters was carried using paired t-tests, whereas for inter group comparative analysis independent t-tests was applied. ANOVA was utilized for the comparative assessment of multiple variables. All statistical tests were two-sided and performed at a significance level of α = 0.05.

RESULTS

A total of 40 patients were enrolled for the study and the mean age group of patients on sub-gingival irrigations with 0.06% CHX was 41.80 ± 12.56 years and those on mouth rinsing was 43.07 ± 9.46 years with no statistical difference between them (P = 0.78). Similarly, the study was equally matched between the two treatment options for gender (P = 0.63). In the present study, four patients were exited, either due to continuing attachment loss or due to failure to comply or return for appropriate follow-up. The mean values of all the clinical parameters at all points in time have been tabulated [Table 1].

On assessing the effect of therapy on the clinical parameters, i.e., GI, BOP and OHIS, statistically significant results were seen from baseline to 2 weeks, baseline to 4 weeks, and from baseline to 12 weeks [Table 2].

Regarding the parameters of PD and CAL, results revealed statistically significant reduction in PD and gain in CAL with both treatment options from baseline to 12 weeks’ post-Phase I treatment (P < 0.001) [Table 2].

The results of two-way ANOVA showed that on comparing the various clinical parameters following the use of the two treatment options; changes in GI, OHIS, and BOP scores over the span of the study showed no significant difference between the two treatment options. However, statistically significant difference was seen with the use of 0.06% CHX irrigations in PD and CAL as compared to the use of mouth rinsing with 0.12% CHX [Table 1].

The assessment of staining was done on both buccal and lingual surfaces with regards intensity and area of staining, and the results revealed that with subgingival irrigations no significant difference in staining was seen between buccal and lingual surfaces. However, with CHX mouthrinsing, statistically significant results were seen for staining regarding both intensity and area with significantly greater staining on lingual surfaces as compared to buccal being evident. On analyzing the difference of staining between the two treatment options no significant difference in staining was seen between CHX mouth rinsing and irrigations on the buccal surface, however, statistically significant difference in both intensity and area was seen on the lingual surfaces with greater staining being present with CHX mouth rinsing [Table 3].

DISCUSSION

The overwhelming challenge for successful periodontal therapy will always remain dependent on patient compliance to regular professional and home care. Patients with medical compromises, those who refuse or delay treatment, or those who present with other limitations may be unable to undergo recommended procedures required to establish a completely healthy periodontium. In those situations, appropriate therapy to establish the best possible periodontal health is the imminent need of the hour.

CHX a well-established anti-plaque agent has been found to be very useful in minimizing the effects of gingival inflammation.

Table 1: Evaluation of the clinical parameters pertaining to the two Groups over the entire span (multiple time periods) of the study

| Parameter       | Group A (subgingival home irrigations with 0.06% chlorhexidine twice daily) | Group B (mouthrinsing with 0.12% chlorhexidine twice daily) | P
|----------------|--------------------------------------------------------------------------------|-----------------------------------------------------------------|------|
|                | Pre | 2 weeks | 4 weeks | 12 weeks | Pre | 2 weeks | 4 weeks | 12 weeks | Group A versus Group B |
| GI             | 1.69±0.18 | 0.67±0.39 | 0.41±0.42 | 0.49±0.47 | 1.62±0.25 | 0.97±0.37 | 0.55±0.29 | 0.51±0.42 | 0.209 (NS) |
| OHIS           | 2.53±0.58 | 0.35±0.49 | 0.16±0.22 | 0.32±0.39 | 3.04±0.56 | 0.22±0.22 | 0.20±0.22 | 0.24±0.31 | 0.307 (NS) |
| BOP            | 68.24±28.89 | 18.57±12.23 | 29.57±29.71 | 18.58±20.76 | 70.45±22.49 | 24.34±11.16 | 31.54±20.87 | 17.96±11.87 | 0.582 (NS) |
| PD             | 3.2±1.31 | 2.23±0.8 | 3.38±0.99 | 2.81±0.99 | 3.55±1.12 | 3±1.11 | 0.004* |
| CAL            | 2.96±1.47 | 1.9±0.94 | 3.38±0.99 | 2.81±0.99 | 3.55±1.12 | 3±1.11 | 0.002* |

*The value of P is considered significant <0.05. GI – Gingival index; OHIS – Oral hygiene index simplified; BOP – Bleeding on probing scores; PD – Probing depth; CAL – Clinical attachment level; SD – Standard deviation; NS – Nonsignificant; P – P-value or probability value
Table 2: Effect of treatment on clinical parameters at multiple time intervals

| Group | Treatment | Pre-2 weeks | Pre-4 weeks | Pre-12 weeks | 2-4 weeks | 2-12 weeks | 4-12 weeks | Percentage reduction (baseline- 12 weeks) |
|-------|-----------|-------------|-------------|--------------|-----------|-----------|-----------|--------------------------------------|
| Group A (sub-gingival home irrigations with 0.06% chlorhexidine twice daily) | GI | <0.001** | <0.001** | <0.001** | 0.730 | 1.000 | 1.000 | 71.9 |
| | OHIS | <0.001** | <0.001** | <0.001** | 1.000 | 1.000 | 1.000 | 86.1 |
| | BOP | <0.001** | 0.006* | <0.001** | 1.000 | 1.000 | 1.000 | 74.9 |
| | PD | - | - | <0.001** | - | - | - | 29.7 |
| | CAL | - | - | 0.001** | - | - | - | 32.3 |
| Group B (mouth rinsing with 0.12% chlorhexidine twice daily) | GI | <0.001** | <0.001** | <0.001** | 0.11* | 0.004* | 1.000 | 67.9 |
| | OHIS | <0.001** | <0.001** | <0.001** | 1.000 | 1.000 | 1.000 | 91.9 |
| | BOP | <0.001** | <0.001** | <0.001** | 1.000 | 1.000 | 0.262 | 73.8 |
| | PD | - | - | <0.001** | - | - | - | 18.4 |
| | CAL | - | - | <0.001** | - | - | - | 16.6 |

The value of P is considered significant <0.05 and highly significant <0.01, **Highly significant, *Significant. GI – Gingival index; OHIS – Oral hygiene index simplified; BOP – Bleeding on probing scores; PD – Probing depth; CAL – Clinical attachment level

Table 3: Assessment of staining on various surfaces from baseline to 12 weeks’ postprophylaxis

| Percentage difference in staining | T/T option | Staining assessment buccal surfaces of teeth | Staining assessment lingual surfaces of teeth | Buccal surfaces versus lingual surfaces P |
|----------------------------------|------------|------------------------------------------|------------------------------------------|----------------------------------------|
|                                  | Intensity  | Area                                     | Intensity  | Area                                      |                                        |
| Group A (sub-gingival home irrigations with 0.06% chlorhexidine twice daily) | 0.59±0.47 | 0.48±0.43 | 0.69±0.68 | 0.44±0.54 | 0.624 |
| Group B (mouth rinsing with 0.12% chlorhexidine twice daily) | 1.06±0.62 | 0.81±0.67 | 1.43±0.67 | 1.12±0.83 | 0.014* |
| P (Group A vs. Group B) | 0.055 | 0.188 | 0.014* | 0.034* |                            |

The value of P is considered statistically significant <0.05. P – P-value or probability value

It has been used in various forms and at varying concentrations and has been shown to be most efficacious in reducing supragingival plaque and gingivitis as compared with other anti-microbial agents with minimal adverse reactions.[13,16] Oral irrigation with 0.0075% CHX was found to be better in reducing gingival inflammation as compared to 0.12% CHX mouthwash.[12] In the present study, a 0.06% CHX was used for subgingival irrigations and compared to mouth rinsing with 0.12% CHX. Since staining is an important side effect of CHX use, its presence was identified and quantified and significant difference in both intensity and area was seen between the two groups on the lingual surface with greater staining seen with mouth rinsing with 0.12% CHX.

Regarding the clinical parameters, subgingival irrigations with CHX resulted in significant improvements in various clinical parameters of gingival health such as GI, OHIS, and BOP scores. However, there was no statistical difference when compared to CHX mouth rinsing regarding these scores indicating it to be equally efficacious. This could possibly be explained by the superficial sub-gingival penetration of oral rinses as well leading to an equally efficacious response by the marginal tissues. Studies by Flemming et al.[11] have similarly shown no significant difference in the improvement of GI scores when comparing CHX irrigations with CHX rinsing and water irrigation.

On assessing the PD and CAL, significant reductions were observed from baseline with the use of both the treatment options, but sub-gingival irrigations resulted in statistically significant reductions as compared to mouth-rinsing. Hence, superior results in periodontal health status were achieved with the use of subgingival irrigations. Studies by Lang and Ramseier-Grossmann found that a total dose of 80 mg was the minimal required for supra-gingival irrigation with CHX, however, in the present protocol, 600 ml of 0.06% of CHX resulted in a total dose of 72 mg in a twice daily home care regimen and was found to be equally efficacious in minimizing the clinical parameters.[18]

The use of 0.06% CHX for supragingival irrigation has produced promising results which prompted us to use this concentration in subgingival areas. Marked reduction in clinical parameters such as GI, PI, BOP, and PD were seen in patients of gingivitis placed on a regime of 0.06% CHX supra-gingival irrigations as compared to plain water irrigations, mouthrinsing with 0.12% CHX or traditional brushing with a fluoride dentifrice.[11]

This therapeutic technique has been shown to exhibit superior levels of penetration into the crevicular space thereby helping to flush out the bacterial toxins as well as disrupt the unattached plaque in the subgingival environment. A pulsating stream of water that incorporates a compression and inter-pulse decompression phase facilitates displacement of food debris and bacteria from inter-dental spaces and plaque-retentive areas. Rinsing with antiseptics has been shown to reach only up to 4% the depth of the gingival sulcus as against 90% achievable through subgingival irrigations especially in pockets with depth ≥6 mm.[18,19,20] Numerous studies have shown a reduction in the levels of periodontopathogens in the sulcular microenvironment with both supra and subgingival irrigations.[21,22] Studies have shown an incremental beneficial effect on the marginal and subgingival microflora of patients
irrigating supra-gingivally at home daily with 0.06% CHX.[24] These results too were superior to mouthrinsing with 0.12% CHX. Hence, it was hypothesized that subgingival irrigations would possibly achieve higher and more sustained levels of therapeutic agents in deep pockets of patients with moderate-to-severe periodontitis based on which this study was designed.

Enhanced benefits of sub-gingival irrigations have been achieved by administering this regime in conjunction with professional scaling and root planing as compared to its use as a sole agent[25] and hence to accrue this advantage, this regime was prescribed following Phase I therapy in the present study.

Home irrigations therefore hold a valid premise for plaque control due to their ability to dilute and remove bacterial toxins, interfere with plaque maturation as well as removal of unattached plaque mass. They are thus very useful in controlling gingivitis, especially in those patients who do not or cannot perform adequate inter-proximal hygiene. Moreover, routinely prescribed mouthrinses have been found to be effective in a minimal zone of the gingival tissues and the need for this more effective plaque control methodology should be explored. This treatment modality may especially be useful as an alternative to surgery in the medically compromised patients with severe periodontitis, in patients of refractory periodontitis and in those with difficult to maintain areas such as fixed prosthesis, orthodontic appliances, and inaccessible embrasure spaces. Hence, the ability to maintain deep pockets free from micro-organisms through the use of water irrigation devices would minimize the need for open flap debridement procedures. Exploring the role of sub-gingival irrigations using antisepsics in the treatment of moderate-to-severe chronic periodontitis patients who are otherwise indicated for flap surgeries would open new avenues for nonsurgical periodontal therapy.

CONCLUSION AND CLINICAL IMPLICATIONS

Within the limitations, the findings from the study reveal that the adjunctive use of subgingival home irrigations using 0.06% CHX has a promising potential to maintain the oral health by controlling active periodontal inflammation and may further obviate the need of periodontal surgery for longer periods. This is of particular significance to the patient groups such as aged and medically compromised patients for whom surgical interventions cannot be opted. Further, well-designed and controlled studies with larger subject samples should be carried out to ascertain the findings and explore the long-term utility of the adjunctive use of home irrigation devices with antimicrobials, in the context of patient centered objectives including long-term cost-effectiveness of the maintenance therapy.

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Conflicts of interest
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