# Evaluation of clinical efficacy of 0.2% chlorhexidine irrigation, 1.5% chlorhexidine gel and 2.5mg biodegradable chlorhexidine chip as an adjunct to scaling and root planing in the management of Chronic Periodontitis

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## Abstract

**Introduction:** Various chemotherapeutic agents can be administered subgingivally to enhance the efficacy of non-surgical therapy mechanical treatment. Chlorhexidine (CHX) is an effective antimicrobial agent and has been used as a topical antiseptic for over 30 years. The aim of the study was to evaluate and compare the clinical efficacy of various forms of local delivery of Chlorhexidine (CHX) i.e. 0.2% CHX irrigation, 1.5% CHX gel and 2.5mg biodegradable CHX chip as an adjunct to scaling and root planning in the management of Chronic Periodontitis.

**Materials and Method:** Forty sites from patients with Chronic Periodontitis and probing depth 5 to 7 mm were randomly divided into 4 groups. Group I (10 Sites): scaling and root planing (SRP) + subgingival irrigation with 0.2% Chlorhexidine; Group II (10 Sites): SRP + subgingival application of 1.5% Chlorhexidine gel (Chlo-Site); Group III (10 Sites): SRP + intrapocket administration of Chlorhexidine chip (Periocol-CG); Group IV (10 Sites): scaling and root planing only (control group). Improvement in periodontal health was assessed by the gingival index of Loe and Silness and plaque was assessed using the Turesky et al. modification of Quigley Hein Index at baseline, 1 month and 3 months. Pocket probing depth and clinical attachment level were also measured using customized acrylic stents.

**Results:** Significant clinical improvement was seen in all the groups from baseline to 3 months. Subgingival irrigation with 0.2% CHX xdid not provide any additional benefit over SRP alone in the improvement of clinical indices. Adjunctive use of 1.5% xanthan based CHX gel and CHX chip along with conventional nonsurgical therapy provided clinically favorable results in terms of reduction of pocket probing depth and clinical attachment level than SRP alone.

**Conclusion:** Based on the findings, it was concluded that 1.5% CHX gel and CHX chip provide significant results as compared to SRP alone. Subgingival irrigation with 0.2% CHX provides similar clinical benefits as mechanical debridement alone.

**Keywords:** 1.5% Chlorhexidine Gel; Chlorhexidine Chip; Subgingival Irrigation; Chronic Periodontitis

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## Introduction

Chronic Periodontitis is a disease attributable to multiple infectious agents and interconnected with cellular and humoral host immune responses. Progress in the understanding of pathogenesis has paved way for new approaches in the prevention, diagnosis and treatment of Chronic Periodontitis.

The aim of effective treatment of periodontal disease is to arrest the inflammatory disease process by removal of the subgingival biofilm and establish a local environment and microflora compatible with periodontal health. Non-surgical therapy includes both mechanical and chemotherapeutic approaches to minimize or eliminate the microbial biofilm. Chemotherapeutic approaches include both local and systemic administration of various antiseptics and antibiotic agents.

However, targeted delivery of therapeutic agents are fast gaining popularity as it reaches the base of the periodontal pocket and is maintained for an adequate time for the antimicrobial effect to occur. Local administration of antimicrobial drugs directly into the periodontal pocket has been accepted as a means of reducing systemic complications and targeting localized areas of periodontal destruction.[1] Several local drug delivery systems using antiseptics and antimicrobial have been developed and proven effective as an adjunct to scaling and root planing. These include application of the drug in the pocket via irrigating devices, gels, fibers or a chip form.

Among various chemical plaque control agents, chlorhexidine has proven to be the most effective, safe and clinically effective in reducing plaque and gingivitis and is accepted as the gold standard for the management of periodontal diseases.[2]

Chlorhexidine can be effectively used to lessen the biofilm burden when introduced in to the periodontal pockets, hence, resulting in improvement of the clinical parameters. It is well retained in the oral cavity, by reversible electrostatic binding to glycoproteins in the dental pellicle and by adsorption to teeth.[3] First sustained release dosage of chlorhexidine diacetate for topical use was developed by Friedman and Golomb in 1982[4]. In fact, Walsh et al, concluded that irrigation

with Chlorhexidine was more effective in reducing plaque vitality than rinsing with Chlorhexidine.[5] Recently, a new sustained release drug delivery Chlorhexidine gel (1.5%) and a controlled release 2.5mg Chlorhexidine chip have been developed which achieve high intrapocket concentration and significant reduction in the bacterial counts.

Chlo-site® (GHIMAS, Italy), is a xanthan based syringable gel system. The gel is a combination of two CHX formulations: 0.5% Chlorhexidine digluconate and 1.0% Chlorhexidine dihydrochloride incorporated in a saccharidic polymer, xanthan. The CHX xanthan based gel undergoes an imbibition process and is physically removed in 10-30 days. On the first day, Chlorhexidine digluconate is released and it achieves a concentration >100 µg/ml, which is maintained for an average of 6-9 days. Chlorhexidine dihydrochloride is released subsequently and maintains the bacteriostatic and bactericidal concentrations for at least 2 days, thus, preventing recolonization.[6]

PerioCol™-CG (Eucare pharmaceuticals (P) Ltd.) is a small, orange- brown rectangular chip. It is rounded at one end for easy insertion into periodontal pockets. Each chip contains approximately 2.5 mg of chlorhexidine gluconate in a biodegradable matrix of Type 1 collagen which is derived from fish sources. It releases chlorhexidine approximately 40-45% within 24h and afterwards in a linear fashion for 7-8 days. The release profile may be explained by initial burst effect due to diffusion of the drug from the chip followed by release of the drug due to enzymatic degradation.[7]

Thus, the present study was undertaken to compare the clinical effectiveness of three different modes of local delivery of chlorhexidine via pocket irrigation, chlorhexidine gel (CHLO-SITE) and chlorhexidine chip (PERIOCOL-CG) as an adjunct to scaling and root planing in the management of moderately deep periodontal pockets.

## Materials and Method

The study was conducted in the department of Periodontology and Oral Implantology, ITS Dental College, Ghaziabad. 40 patients diagnosed with Chronic Periodontitis in the age range of 30 to 50 years were selected from the outpatient department.

**Inclusion criteria**

- Subjects with Chronic Periodontitis with at least one site having 5-7mm of probing depth
- Subjects in age group of 30 to 50 years were selected

**Exclusion criteria**

- Subjects who had received any periodontal therapy in the last 6 months
- Subjects wearing removable or fixed partial dentures and undergoing orthodontic therapy
- Teeth with caries, restorations or endoperio lesions were not included in the study
- Subjects who had taken antibiotics, immunosuppressant or oral contraceptives in the last 6 months
- Subjects sensitive or allergic to Chlorhexidine
- Tobacco users
- Pregnant or lactating females
- Subjects unable to provide informed consent

Based on the selection criteria, 40 sites with probing depth 5 to 7 mm were selected for the study. All patients received standard periodontal therapy i.e. scaling and root planing in a single sitting using an ultrasonic scaler and Gracey curettes.

The selected 40 sites were further randomly divided into 4 groups and received the following treatment:
GROUP I (10 sites)
Scaling and root planing + subgingival irrigation with 0.2% Chlorhexidine
GROUP II (10 sites)
Scaling and root planing + subgingival application of 1.5% Chlorhexidine gel (CHLO-SITE)
GROUP III (10 sites)
Scaling and root planing + intrapocket administration of Chlorhexidine chip (PERIOCOL-CG)
GROUP IV (10 sites)
Scaling and root planing only (control group)

Clinical parameters were assessed using UNC 15 probe and a mouth mirror.
These included:

- Gingival index (Loe and Silness, 1963) [8]
- Plaque index (Turesky Gilmore Glickman modification of the Quigley Hein Plaque index, 1970)[9]

For recording periodontal parameters, customized acrylic stents were used to provide fixed reference point for measurements. These stents were fabricated on the patient's casts made from alginate impression of the upper and lower arches.
The following measurements were made:

- Relative attachment level (measured from a fixed point on the stent to the base of the pocket)
- Probing depth (measured from the gingival margin to the base of the pocket)

All the clinical measurements were made at baseline, 1 month and 3 months after the initial treatment.

**Statistical analysis:** Results were expressed as mean±standard deviation and SPSS (statistical package for social sciences) version 16.0 was used for statistical analysis. ANOVA (Analysis of Variance) test was used for calculating difference between more than two mean values. Post-Hoc Bonferroni test was used for multiple comparisons after the application of the ANOVA test

for comparison within the groups. The p-value was taken significant when less than 0.05 ($p<0.05$).

## Results

The present study was conducted to evaluate and compare the clinical efficacy of various forms of local drug delivery of CHX irrigation, CHX gel and CHX chip as an adjunct to SRP and SRP alone in the management of patients with Chronic Periodontitis. The study included 40 sites from 40 patients that included 22 males and 18 females in the age group of 30 to 50 years and clinically diagnosed with Chronic Periodontitis.

The evaluation was done by comparing the Gingival Index, Plaque Index, pocket probing depth and relative attachment level in four groups at baseline, 1 month and 3 months after the procedure.

Comparison of clinical findings in four groups at various time intervals has been shown in Table 1. At baseline, all clinical parameters did not show any significant intergroup difference. When intergroup comparisons were made, it was found that there was a statistically significant improvement in all clinical parameters from baseline to 3 months. On applying Post Hoc Bonferroni multiple comparison test, significant reduction of probing depth was seen in Group II and III as compared to control group at 1and 3 month time interval. ($p<0.05$)

Table 2 evaluates the comparison of change in clinical parameters in four groups at various time intervals. A reduction in plaque accumulation was seen in all groups from baseline to 3 months. However, this difference between the groups was not found to be statistically significant. When the reduction in gingival index was compared between groups, it was found that CHX chip was more effective in reducing gingival inflammation than control group from baseline to 3 months. ($p<0.05$).

Use of CHX gel and chip as adjuncts to SRP were also found to be statistically better in reduction of pocket probing depth and improvement in relative clinical attachment level from baseline to 3 months. However, Post Hoc Bonferroni multiple comparison tests showed that the difference between control and CHX irrigation groups was statistically insignificant from baseline to 3 months. Also, no significant difference in mean reduction of probing depth and relative attachment level was found in Group II and III from baseline to 3 months indicating comparable results.

**Table 1: Comparison of clinical parameters in four groups at baseline, 1 month and 3 months. (p <0.05 significant)**

| Group | Clinical parameters | Mean + SD | | | P value |
|---|---|---|---|---|---|
| | | Baseline | 1 Month | 3 Month | |
| Group I CHX Irrigation | PI | 2.40 ±0.52 | 1.50±0.53 | 1.60±0.52 | 0.000 |
| | GI | 1.90±0.32 | 1.50±0.53 | 1.60±0.52 | 0.000 |
| | PD | 6.20±0.63 | 5.40±0.52 | 5.70±0.48 | 0.000 |
| | RAL | 10.20±1.40 | 9.0±1.16 | 9.50±0.97 | 0.000 |
| Group II Chlosite | PI | 2.40±0.52 | 1.40±0.52 | 1.40±0.52 | 0.000 |
| | GI | 1.80±0.42 | 1.30±0.48 | 1.30±0.48 | 0.000 |
| | PD | 6.00±1.05 | 4.60±0.84 | 4.80±0.79 | 0.000 |
| | RAL | 10.1±1.20 | 8.7±1.06 | 8.7±0.68 | 0.000 |
| Group III Periocol CG | PI | 2.50±0.53 | 1.3±0.48 | 1.3±0.48 | 0.000 |
| | GI | 1.90±0.32 | 1.40±0.52 | 1.20±0.42 | 0.000 |
| | PD | 6.30±0.95 | 5.00±0.82 | 4.60±0.70 | 0.000 |
| | RAL | 10.30±1.06 | 9.10±0.74 | 8.40±1.08 | 0.000 |
| Group IV Control | PI | 2.30±0.82 | 1.50±0.53 | 1.83±0.42 | 0.000 |
| | GI | 1.90±0.32 | 1.70±0.48 | 1.80±0.42 | 0.000 |
| | PD | 6.20±0.42 | 5.90±0.57 | 5.80±0.42 | 0.000 |
| | RAL | 9.50±0.71 | 9.30±0.82 | 9.20±0.79 | 0.000 |

**Table 2: Comparison of change in clinical parameters in four groups groups at baseline, 1 month and 3 months. (* -p <0.05 significant)**

| Clinical Parameters | | Group I CHX Irrigation | Group II CHLOSITE | Group III PERIOCOL CG | Group IV Control | P value |
|---|---|---|---|---|---|---|
| GI | Baseline – 1 month | 0.40±0.52 | 0.50±0.53 | 0.50±0.53 | 0.20±0.42 | 0.5 |
| | Baseline – 3 months | 0.3±0.48 | 0.5±0.53 | 0.7±0.48 | 0.1±0.32 | 0.03* |
| | 1 month – 3months | -0.1±0.57 | 0.0±0.47 | 0.2±0.42 | -0.1±0.32 | 0.4 |
| PI | Baseline – 1 month | 0.9±0.88 | 1.0±0.82 | 1.2±0.83 | 0.8±0.92 | 0.7 |
| | Baseline – 3 months | 0.8±0.79 | 1.0±0.47 | 1.2±0.79 | 0.5±1.08 | 0.2 |

| | | | | | | |
|---|---|---|---|---|---|---|
| | 1 month – 3months | -0.1±0.74 | 0.0±0.67 | 0.0±0.67 | -0.3±0.82 | 0.7 |
| PD | Baseline – 1 month | 0.8±0.42 | 1.40±0.52 | 1.3±0.68 | 0.3±0.48 | 0.00* |
| | Baseline – 3 months | 0.5±0.53 | 1.20±0.63 | 1.7±0.68 | 0.4±0.52 | 0.00* |
| | 1 month – 3months | -0.3±0.68 | -0.2±0.63 | 0.4±0.52 | 0.1±0.32 | 0.03* |
| RAL | Baseline – 1 month | 1.20±0.63 | 1.40±0.52 | 1.2±0.63 | 0.20±0.42 | 0.00* |
| | Baseline – 3 months | 0.7±0.82 | 1.4±0.84 | 1.9±0.57 | 0.3±0.48 | 0.00* |
| | 1 month – 3months | -0.5±0.71 | 0.00±0.67 | 0.70±0.68 | 0.10±0.32 | 0.001* |

## Discussion

Success of periodontal therapy is aimed at eliminating pathogenic microorganisms found in dental plaque associated with the tooth surface and other niches in the oral cavity. However, very few patients are able to maintain periodontal health over a lifetime without regular dental care, which consists primarily of oral hygiene instructions and non-surgical therapy.[10] Since, most patients are not skilled in adequate plaque control, clinicians include local and systemic chemotherapeutic agents in their treatment regimen.

The present study was conducted to evaluate the clinical efficacy of administration of CHX in various forms i.e. irrigation, gel and chip form directly into periodontal pockets as adjuncts to SRP in the management of Chronic Periodontitis.

Clinical parameters were recorded at baseline, 1 month and 3 months. The 3 month interval was chosen because the effects of locally delivered Chlorhexidine are maintained for eleven weeks after administration and also 3 months corresponds to the typical recall interval for patients after periodontal treatment.[11,12,13]

In the present study, supragingival plaque decreased significantly from baseline in all the groups as a result of full mouth supragingival and subgingival scaling. The plaque scores were maintained at a low level throughout the study period, which indicate good oral hygiene maintenance by all the patients and successful motivation in supportive periodontal care.

Though the clinical parameters improved in all groups, we did not find any significant difference in the mean reduction between control and irrigation group. Subgingival irrigation with CHX resulted in less optimal results probably because of inability to reach biologically adequate concentration for sufficient time in periodontal pocket.[14] Therefore, research studies have focused on slow-releasing devices with higher substantivity to overcome these limitations of CHX irrigation.[15]

On clinical examination, Group II and III demonstrated a higher reduction in probing pocket depth (PPD) when compared to Group I and IV. In control group, the probing pocket depth reduced because of the beneficial effects of scaling and root planning and effective plaque control. In Group II and III, the probing pocket depths further reduced because of the placement of Chlosite and PerioCol TM-CG. This indicates that there was an enhanced benefit of chlorhexidine along with scaling and root planing alone.

On comparing the mean gain in clinical attachment level between the groups, the gain was higher in Group III. In Group IV, the improvement in clinical attachment level (CAL) could be due to higher baseline probing depth in the present study. According to Kaldahl, there was greater gain in clinical attachment level after scaling and root planing with PPD of >4 mm.[16] In Group III, the sites were treated by SRP followed by treatment of periodontal pockets with PerioCol TM-CG. With the additional placement of chlorhexidine chip, there was prolonged exposure of chlorhexidine in pocket environment for 6-9 days which gave long-lasting effects on microbiota. This would have brought about additional gain in the clinical attachment level in this group. These findings were similar to studies by Soskolne and Jeffcoat who also demonstrated gain in the clinical attachment level in test sites which were treated with the chlorhexidine chip.[17,18]

Enhanced improvement in clinical periodontal parameters should be attributed to CHX which is known to inhibit microbial proteases from potent periodontal pathogens, responsible for destruction of periodontal tissues during progression of periodontal diseases.[19] Puri et al, reported higher reduction in Porphyromonas gingivalis (Pg), Aggregatibacter actinomycetemcomitans (Aa), Prevotella intermedia (Pi) and Fusobacterium nucleatum (Fn) at sites treated with CHX chip.[20]

Also, prostaglandin E2 which is an immunoactive host produced agent and responsible for tissue damage is reduced by CHX thus accounting for improvement in periodontal health.[21] Grover et al also reported significant clinical attachment gain, reduction in bleeding index scores, probing pocket depth reduction and bone gain in sites treated biodegradable CHX chip.[22]

Similar results were reported by Paolantonio et al[23] and Gupta et al[24] who reported a significantly higher reduction in bleeding on probing, probing depth and clinical attachment level in sites treated with xanthan based CHX gel along with SRP than with SRP alone. Paolantonio et al[23] also reported reduction in total bacterial counts and GCF alkaline phosphatase activity at sites treated by CHX gel. Xanthan based CHX gel also reduced percentages of sites positive for the eight putative periodontopathic compared to SRP alone. Good effects of xanthan-based CHX gel is due to its

bio-adhesive capability by xanthan and slow release of CHX, which might help maintain acceptable oral hygiene in these patients. [14]

Thus, the results of the present study indicated that local subgingival application of CHX in the form of irrigation, gel and chip all produced significant clinical improvement in periodontal health. However, CHX gel and placement of CHX chip as an adjunct to SRP produced a statistically significant reduction in the probing depth and a gain in CAL at 1 month and 3 months from baseline when compared to SRP alone or the use of CHX irrigation. Further long term studies with larger sample size and multiple applications of these agents can be conducted to validate the results of the study.

## Conclusion

Based on the findings of the study, subgingival irrigation with CHX did not provide clinically significant benefits beyond that achieved with conventional SRP after a 3 month period. Adjunctive use of xanthan based CHX gel and CHX chip along with conventional nonsurgical therapy provide more favorable results in terms of reduction of pocket probing depth and clinical attachment level than SRP alone and thus can be recommended as a safe and effective chemotherapeutic agents in the management of patients with Chronic Periodontitis.

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