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# Comparative Evaluation of Metformin Gel and Chlorhexidine Gel as Adjunct to Scaling and Root Planning in the Treatment of Chronic Periodontitis: A Clinical Study

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## Abstract

**Introduction:** Pyorrhoea is an inflammatory gum disease in which destruction of tooth supporting tissues that results ultimate tooth mobility and exfoliation. In local drug delivery (LDD), which includes the delivery of therapeutic agents like Irrigating systems, fibers, gels, strips, films, microparticles, nanoparticles and low dose antimicrobial agents via systemic and local route as an adjunct to mechanical therapy which has beneficial for periodontal therapy. **Aim:** To evaluate and compare the efficacy of subgingivally delivered 1% Metformin gel and Chlorhexidine gel as an adjunct to scaling and root planing in the management of patients with chronic periodontitis. **Materials and Method:** Twenty systemically healthy patients with the age group of 20-60 years irrespective of gender suffering from generalized chronic periodontitis were selected, in which fourty sites were randomized at split mouth level and divided into two groups: (Group A -SRP+1% Metformin gel and Group B - SRP+ 0.2% Chlorhexidine gel). Parameters such as, Plaque index (PI), Modified gingival index (MGI), Probing pocket depth (PPD), and Relative clinical attachment level (R-CAL) were measured at baseline and after 1 month and 3 months. The significance of difference within and between the groups was evaluated with paired and unpaired t-tests. **Result:** In our study, the mean Plaque index (PI), Modified gingival index (MGI), Probing pocket depth (PPD), and Relative clinical attachment level (R-CAL) showed a statistically significant difference from baseline to 1 month and 3 months ($p \leq 0.05$) in both Group A and Group B. But, Mean PPD reduction and mean R-CAL gain was found to be greater in Group-A than Group B at 1 month and 3 months. **Conclusion:** Both Metformin and 0.2% Chlorhexidine gel can be considered as effective as a LDD agent adjunct to scaling and root planning (SRP) in the management of chronic periodontitis. But, 1% Metformin gel was more effective as a LDD adjunct to SRP in curative of chronic periodontitis patient than Chlorhexidine gel (Cevitec gel).

**Keywords:** Periodontitis, Pocket depth, Subgingival, Metformin, Chlorhexidine, Local drug delivery.

## INTRODUCTION

The major cause of gum disease is bacterial growth, which occurs due to the accumulation of subgingival plaque. Periodontal bacteria release various enzymes like leucotoxins, collagenases, fibrinolysins and other proteases which triggered host immune response damage the periodontium [1, 2] The initial treatment of periodontitis involves scaling and root planing (SRP), mechanical debridement of tooth surfaces in conjunction with patient's proper plaque control. The aim of non-surgical periodontal therapy is to abolish the microflora from the tooth surface as well as from the adjacent soft tissues. However, the microbiota are not removed in certain inaccessible areas by conventional mechanical debridement [3].

So, various adjunctive treatments have been investigated and proposed adjunct to SRP. These include systemic and localized delivery of antibiotics, bisphosphonates etc. to reduce bacterial counts and improve clinical parameters such as probing depth reduction, gaining clinical attachment level through they reaches the base of periodontal pocket and is maintained for an adequate time to enhance antimicrobial effect in periodontitis [4-5]. Among all these, Goodson et al. in 1979 first developed the concept of LDD in the management of periodontitis [6]. Various drugs like Tetracyclines including doxycycline and minocycline, metronidazole, and Chlorhexidine (CHX), Metformin are used as a local drug delivery agent adjunct to SRP. And that way LDD is a minimal invasive treatment options for periodontal therapy and it requires less time compared to surgical treatment.

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Metformin (1,1-dimethylbiguanide) is one of the commonly used oral antihyperglycemic agents for the treatment of type 2 diabetes mellitus. They induce type I collagen formation & osteoblast cells to promote early bone formation [7]. Therefore 1% Metformin gel as an adjunct to SRP shown to diminish the PDL tissue damage indicating an osteomodulatory effect. Chlorhexidine (CHX) is one of the most effective topical agents which has been shown to be an effective agent to inhibit the plaque formation because it has long substantivity in the oral cavity due to its high affinity for hydroxyapatite and acidic salivary protein. The Cervitec gel is a Chlorhexidene gel, which is composed of 900 ppm Fluoride and 0.2% Chlorhexidine digluconate [8]. Therefore, the present study is undertaken to evaluate and compare the efficacy between 1% Metformin gel and Chlorhexidine gel which are used as a local drug delivery agent as an adjunct to scaling and root planing in chronic periodontitis.

The aim of this study was to evaluate and compare the efficacy of subgingivally delivered 1% Metformin gel and Chlorhexidine gel as an adjunct to scaling and root planing in the management of patients with chronic periodontitis.

The Objectives of this study were 1) To evaluate the efficacy of 1% Metformin gel ( in Group A).

2) To evaluate the efficacy of Chlorhexidine gel ( in Group B).3) To evaluate the changes in ancillary parameters [Plaque index (PI), Modified gingival index (MGI)] at baseline, one month and three months 4) To evaluate the changes in clinical parameters [Probing Pocket depth(PPD) and Relative clinical attachment level (R-CAL)] at baseline, one month and three months 5)To Compare the changes in clinical parameters[Probing Pocket depth(PPD) and Relative clinical attachment level (R-CAL)] between Group A and Group B

**MATERIAL AND METHOD**

**A. Type of Study:**

The study is a randomized, bilateral split mouth, 3 months clinical prospective study in which 40 sites from 20 subjects with chronic periodontitis, with the presence of at least two bilateral periodontal pockets with 5 to 7 mm probing depth were selected, with age ranging from 20 to 60 years irrespective of gender.

**Assortment of Subjects**:

The subjects were examined under the inclusion and exclusion criteria and they were selected for study, Subjects who agreed to participate in the study were asked to sign the written consent. The selection of patient, periodontal therapy and the maintenance treatment was done in the Department of Periodontology, Narsinhbhai Patel Dental College and Hospital, SPU, Visnagar.

**Inclusion Criteria:**

- Patients between 20 to 60 years of age
- Good general health
- Bilateral isolated sites with probing pocket depth 5 – 7 mm in chronic periodontitis patients.
- No history of gum therapy for the past 6 months.
- No history of use of antibiotics for the past 6 months

**Exclusion Criteria**

- Presence of vertical bone defect
- Habit of tobacco chewing and smoking
- History of systemic diseases
- Immunocompromised patients
- Pregnancy and lactation
- Aggressive periodontitis

**B. Study Design:**

Twenty systemically healthy patients with the age group of 20-60 years (both males and female) suffering from chronic periodontitis were selected amongst the patients visiting the department of Periodontology, Narsinhbhai Patel Dental College and Hospital, SPU, Visnagar. After scaling and root planing for each subject, two experimental sites were chosen that had probing depth 5 to 7 mm which located in symmetric quadrants, the two sites were randomized at split mouth level by a flip of a coin and divided into two groups:

The selected subjects were divided randomly in two parts:

**1. GROUP A:** 20 sites were treated with SRP followed by the placement of the 1% Metformin gel in the periodontal pocket (N-20)

**2. GROUP B:** 20 sites were treated with SRP followed by the placement of the Cevitec gel in the periodontal pocket. (N-20)

**METHODOLOGY**

Twenty patients, diagnosed with chronic periodontitis, aged between 20 and 60 years were enrolled in this study from the OPD of the Department of Periodontology, Narsinhbhai Patel Dental College and Hospital, SPU, Visnagar. Ancillary parameters namely plaque index (Turesky-Gilmore-Glickman modified Quigley-Hein plaque) and Modified Gingival index (Lobene et al, 1986) were recorded at baseline (before the SRP), 1 month and 3 months. Clinical parameters Probing pocket depth (PPD), and Relative clinical attachment level (R-CAL) were recorded at baseline,1 month and 3 months with the help of UNC-15 probe. Full mouth scaling and root planing was carried out and patients were recalled after 1 week for follow up. After follow up, the isolated sites with probing depth ranging between 5 to 7mm were selected and randomly allocated for local drug delivery with either 1% (w/v %) Metformin gel or 0.2% Chlorhexidine gel (Cevitec gel). In Group A Subgingival administration of 1% Metformin gel was placed at the base of pocket with a local anesthetic syringe provided with blunt sterile cannula till the pocket was completely filled, then Coe-pak was placed. In Group B Subgingival administration of Chlorhexidine gel was placed at the base of pocket with a local anesthetic syringe provided with blunt sterile cannula till the pocket was filled then Coe-pak was placed. Patients were informed to avoid chewing hard or sticky foods, brushing near the treated areas, or using any interdental aids for 1 week. No antibiotics and/or anti-inflammatory agents were prescribed after treatment. Patients recall after 1 week for the removal of Coe-pak. Adverse effects were noted at recall visits. Customized acrylic stents with vertical grooves were fabricated on the study cast for each patients, to standardize the position and angulation of UNC-15 probe. They were used to standardize the measurement of clinical parameters. Patients were recalled after 1 month and 3 months for recording of Ancillary parameter & Clinical parameters with customized acrylic stent.

**Statistical analysis**

The data of Clinical parameters were observed for 40 sites in 20 patients. The data was analysed using SPSS version 20.0, Descriptive statistics, Paired t test for intragroup comparison & ANOVA, unpaired t test for intergroup comparison was used. Comparison of different parameters of chronic periodontitis in Group A & B were done at baseline, after 1 month and 3 months and their mean scores were compared by applying the descriptive statistics and paired 't' test.

**RESULT**

All 20 patients completed the study. The treated sites were evaluated at baseline, 1 month and 3 months post-operatively. Satisfactory healing was observed. There was any side effect of drug was seen by the subjects. Out of 20 study subjects among Group B, 15 (75%) were male and 5 (25%) were female. Mean age of male and female among group B

were 45.80 ± 5.90 and 40.80 ± 5.45, Out of 20 study subjects among group A, 15 (75%) were male and 5 (25%) were female. Mean age was 44.55 ± 6.0 years for all study subjects, mean age of male and female among group A were 45.80 ± 5.90 and 40.80 ± 5.45. Overall mean age was 44.55. Statistically significant difference was present in mean plaque index scores and modified gingival index scores at 1 month and 3 months from baseline in both the groups as metformin shows a strong activity in reducing dental plaque against various periodontal pathogens.

Statistically, no significant difference was present in pocket depth between group B and group A at baseline. Statistically, significant difference was present in pocket depth between group A and group B at 1 month and 3 months. Mean pocket depth was less in Group A (3.90 ± 0.85 mm) at 1 month than Group B (4.65 ± 0.58 mm). Mean pocket depth was less in Group A (1.85 ± 0.58 mm) than Group B (3.65 ± 0.87 mm) at 3 months. (Table I) (Graph I) Statistically, no significant difference was present in Relative clinical Attachment Level between Group A and Group B at baseline. Statistically, significant difference was present in R-CAL between group A and group B at 1 month and 3months. Mean R-CAL was more in group B (6.95 ± 1.31 mm) than group A (5.80 ± 1.23 mm) at 1 month. Mean R-CAL was more in group B (4.40 ± 0.94 mm) than group A (3.95 ± 0.75 mm) at 3 months (Table II) (Graph II).

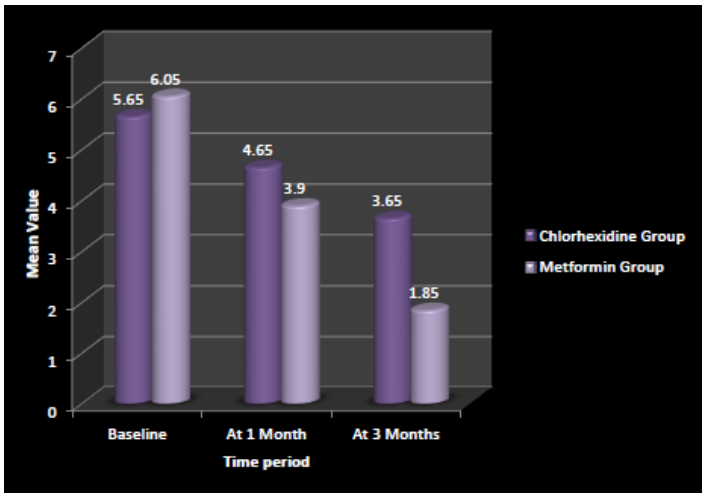
**Table 1:** Intergroup comparison of mean Pocket Depth

| Parameter | Duration | N | Group A | | Group B | | P value |
|---|---|---|---|---|---|---|---|
| | | | Mean | SD | Mean | SD | |
| PD | Baseline | 20 | 6.05 | 0.75 | 5.65 | 0.74 | >0.05" |
| | 1 months | 20 | 3.90 | 0.85 | 4.65 | 0.58 | < 0.05 |
| | 3 months | 20 | 1.85 | 0.58 | 3.65 | 0.87 | < 0.05 |

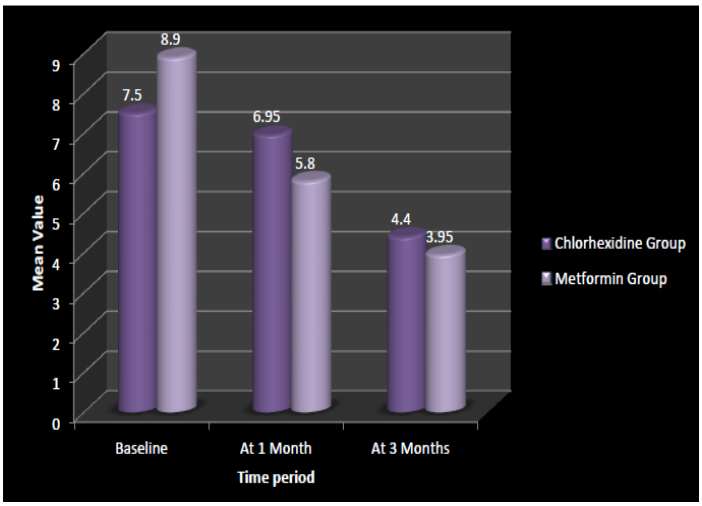
Level of Significance P ≤ 0.05, * Significant, ** Non Significan

**Table 2:** Intergroup comparison of mean Relative Clinical attachment Level :

| Parameter | Duration | N | Group A | | Group B | | P value |
|---|---|---|---|---|---|---|---|
| | | | Mean | SD | Mean | SD | |
| **PD** | Baseline | 20 | 8.90 | 1.51 | 7.50 | 1.39 | >0.05** |
| | 1 months | 20 | 5.80 | 1.23 | 6.95 | 1.31 | < 0.05* |
| | 3 months | 20 | 3.95 | 0.75 | 4.40 | 0.94 | < 0.05* |




**Graph I :** Intergroup comparison of mean Pocket Depth




**Graph II :** Intergroup comparison mean R-CAL

## DISCUSSION

Management of chronic periodontitis is routinely based on Surgical and Non-surgical therapies which reduces inflammation and improve health of periodontium. The different oral hydiene procedure & mechanical scaling and root planning are involved in Primary non-Surgical approach [9]. However, SRP is not found to be successful at all treated sites. So, to overcome these drawbacks, local drug delivery systems were developed, which were used in the present study.

Patient within the age range 25-60 years with pocket probing depth of 5-7 mm were selected. Patient who had undergone oral prophylaxis before six months were avoided, because of the proportion of coccoid cells increased as a result of SRP and was maintained throughout 25 weeks study Period [10].

Patients with history of local and/or systemic antibiotic therapy within last six months before baseline examination were excluded as according to Magnusson et al (1991) [11], more resistance should be expected in the microflora such individuals. Patient with good systemic health were selected. Patient with history of any Systemic disorder, immunosuppressive therapy were excluded as they may alter healing response of oral tissue. For e.g. diabetic patient, Cardiovascular disease etc (Mashimo et al, 1983) [12].

Hence, the aim of the present study was to evaluate and compare the efficacy of 1% Metformin gel and 0.2% chlorhexidine gel as a LDD agent adjunct to scaling and root planing in the treatment of chronic periodontitis. To the best of our knowledge, this is the first clinical study evaluating the comparison of these both gels used as a LDD agent adjunct to scaling and root planing.

The present study comprises two groups of treatment modalities and each group include 20 sites.

A total of 40 sites were selected from 20 patients in the age group of 20-60 years, with probing pocket depth of 5-7 mm and a mean age of both groups of female and male were 44.55

Oral hygiene maintains can be evaluated by using plaque index at every follow up. We can measure gingival status with help of modified gingival index in every follow up. Statistically, significant difference was present in change of mean plaque Index score from baseline to 3 months' time period in Group A and in Group B. In the present study, statistically no significant difference in mean plaque index was seen between both the groups A and B at baseline (≤ 0.05*), 1month (≤ 0.05*) and 3 months (≤ 0.05*). Statistically, significant difference was present in change of Modified Gingival Index score from baseline to 3 months' time period in Group A and in Group B. In the present study, statistically no significant difference in mean gingival index was seen between both the groups at baseline (P≤ 0.05*), 1 month (≤ 0.05*), and 3 months (≤ 0.05*).

The full mouth PI and MGI scores remained low throughout the study period. This reduction in scores could be attributed to the regular oral hygiene instructions given to the patients thereby enabling improved plaque control efficiency and better patient compliance.Till date no comparison studies between Metformin and Chlorhexidine as local drug delivery have been reported in literature, therefore a direct comparison with other studies is not possible. Similar results were obtained in the study done by Nishanth et al 2013 [13], He et al [14]. In the Present study, no significant difference was seen in mean pocket depth between Group A and Group B at baseline. Mean pocket depth was less in Group A (1.85 ± 0.58 mm) than Group B (3.65 ± 0.87 mm) at 3 months. In present study Statistically, significant difference was present in pocket depth between group A and group B at 1 month & 3 months (Table I) (Graph I).In the present study Mean Relative Clinical Attachment Level(R-CAL) was more in group B(6.95 ± 1.31 mm) than group A (5.80 ± 1.23 mm) at 1 month. Statistically, significant difference was present in R-CAL between Chlorhexidine (Group B) and Metformin (Group A) at 1 month. Mean R-CAL was more in Group B (4.40 ± 0.94 mm) than Group A (3.95 ± 0.75 mm) at 3 months. Statistically significant difference was present in R-CAL between Group A and Group B at 3 months (Table II) (Graph II). There is a significant reduction in the mean scores for CAL in both Groups. But the reduction is more significant in Group A than Group B. Thus, it shows that 1% metformin is more efficient in gaining the R-CAL. This result like the study which was done by Ida G. Kurian (2018) [15], in which mean Pocket depth (PD) reduction and mean CAL gain was found to be greater in MF groups than the placebo group at both 3 and 6 months. Pradeep et al & Mai et al. [16] suggested that the Metformin reduces receptor activator for nuclear factor-kB ligand (RANKL) & further inhibiting osteoclastic resorption and provokes osteoprotegerin expression in osteoblasts, and enhance osteogenic effect on osteoblasts. Chlorhexidine (CHX) is commonly used as mouth rinses being highly recommended as an adjunct to tooth brushing and for the control of dental plaque. It has considerable preventive action against plaque development; however, it appears less effective against established plaque by one of its cationic natures, and it could not penetrate subgingival plaque layers, No of activity of chlorhexidine could be compromised due to organic material present in (Robert and Addy) [17]. Therefore, the results from previous and present study shows the osteomodulatory effect of 1% Metformin gel and increase clinical parameter when used it was used as a LDD agent an adjunct to SRP in chronic periodontitis patients while comparing the Chlorhexidine gel (Cervitc).

## CONCLUSION

This is the first clinical study evaluating the comparison of Metformin and Chlorhexidine gel adjunct to scaling and root planing. mean value results from paired t test (Intra group) showed statistically significant difference in PI, MGI, PD, R-CAL in both the groups at baseline to one month and Three months postoperatively. The results from Un-paired t test (Inter group) showed no statistically significant difference in mean PI and MGI between both the groups at baseline, One month and three months postoperatively. But significant difference was found in mean Pocket depth (PD) and Relative clinical attachment level(R-CAL) ((p≤0.001) at 1 month and 3 months from baseline between both group A and group B. The efficacy of Metformin gel as adjunct to SRP is demonstrated by significant improvement in Clinical Parameters (PD, R-CAL) in Group A compared with (Group B). Both Metformin and 0.2% Chlorhexidine gel can be considered as a effective as LDD agent adjunct to scaling and root planing in the treatment of chronic periodontitis. But, 1% Metformin gel was more effective as a LDD adjunct to scaling and root planing in management of chronic periodontitis patient than Chlorhexidine gel (Cevitec gel).

**Conflict of Interest**

None declared.

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None declared.

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