

TOPICAL CHEMOTHERAPEUTIC ADJUNCTS IN NON-SURGICAL PERIODONTAL THERAPY – A RANDOMISED CONTROLLED DOUBLE BLINDED TRIAL.

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Abstract

Introduction: Topical chemotherapeutic agents used in treatment of chronic periodontitis are antimicrobial agents which help in plaque control. The present study evaluates the efficacy of ornidazole gel with gold standard chlorhexidine gel when used as adjunct to scaling and root planing.

Material and Methods: 90 patients diagnosed as chronic periodontitis, having pocket depth ≥ 3 mm and in good systemic health were selected by systematic sampling method and divided in 3 groups. In all 3 groups scaling and root planing was done. In group A, Ornidazole gel application was done while in Group B Chlorhexidine gel application was done while Group C was control group. Plaque Index (PI) and Gingival Index (GI) were recorded at baseline, 1 and 3 months while Probing pocket depth (PPD) and Clinical attachment level (CAL) were recorded at baseline and 3 months.

Results: PI and GI showed significant reduction in all three groups after 1 and 3 months compared to baseline. On inter group comparison, both PI and GI showed no significant difference in reduction of scores after 1 month and 3 months ($p > 0.05$). PPD and CAL values showed statistically significant reduction after 3 months when compared to baseline values. The intergroup comparison revealed statistically significant reduction in group A and B compared to control group C ($p < 0.05$).

Conclusion: Ornidazole showed comparable efficacy as Chlorhexidine when used as adjunct to scaling and root planing for treatment of chronic periodontitis.

Introduction:

Periodontal disease is a major global dental problem induced by bacterial plaque. These are chronic disorders affecting most of the people. Periodontitis manifests as inflammation of the gingival and the deeper periodontal tissues which may result into loss of supporting structures of tooth and finally the tooth. The disease affects the gingiva causing gingivitis which may or may not progress into periodontitis. As Bacterial plaque is considered as the main etiological factor for initiation of disease, plaque control remains the ultimate focus for maintaining the periodontal health. Various treatment modalities have been attempted to control the plaque. Although, mechanical debridement with oral prophylaxis is till date the gold standard, still many antimicrobial agents have been used to prevent the plaque accumulation and disease progression.¹

Chemotherapeutic agents such as tetracycline, minocycline, doxycycline, ornidazole, chlorhexidine etc. are available in the form of gels, paste, films, strips, and fibers.²⁻⁶ These can be used for mouth rinsing, irrigation, systemic administration or local applications.⁷

Chlorhexidine is considered as gold standard in chemical plaque control due to its substantivity and has been used effectively in treatment of gingivitis over last 4 decades. But due to its adverse effects such as staining of teeth,

desquamation, altered taste and mucosal burning, other active ingredients have also been investigated as an alternative for this agent.⁸

One such agent is Nitroimidazole group of compounds. It acts by inhibiting DNA synthesis. It works on the principle that inactive form passively diffuses into cells where it is activated by chemical reduction. The nitro group gets reduced to anionic radicles which causes oxidation of DNA leading to strand breakage and cell death.

Hence, it has both anti-microbial and mutagenic effect. This effect is primarily seen on obligate gram negative anaerobes like *P. Gingivalis*, *P. Intermedia*, *Fusobacterium*, *Selenomonas sputigena*, *Bacteroides Forsythus* and the gram-positive anaerobes like *Peptostreptococcus*, and *C. Rectus* which are implicated in periodontal disease. Ornidazole and metronidazole are two such drugs belonging to nitroimidazole group.⁹

Ornidazole and chlorhexidine both have a broad-spectrum antimicrobial activity of which chlorhexidine is more active against gram positive bacteria. It is bacteriostatic at lower concentration and bactericidal at higher concentration. The actual level at which the activity is bacteriostatic or bactericidal vary between species. On the other hand, Ornidazole is bactericidal even at lower concentration and is

active against anaerobic bacteria, which are responsible for periodontal disease.^{8,9}

Ornidazole is used for the treatment of anaerobic infections and has better antibacterial properties. Till date, there is no study comparing Chlorhexidine gel and Ornidazole gel topical application in patients with chronic periodontitis. In the present study, the effect of topical application of the Chlorhexidine gel and Ornidazole gel have been evaluated as an adjunct to scaling and root planing over period of three months in patients with chronic periodontitis.

Materials and method

A total of 90 patients for this study were randomly selected by a systematic sampling method in which every 5th subject was selected and recruited alternatively in each group from the outpatient department of Periodontics, Nair Hospital Dental College whose written consent and audio visual consent was taken prior to the study and if the patient was willing to discontinue the treatment procedure during the study, he or she was allowed to do so.

The study number is **EC/PG-10/PERIO/2015**

Armamentarium

Mouth mirror, University of North Carolina-15(UNC-15) probe, Syringe, Local anaesthesia: 2% lignocaine Hydrochloride (HCl) with adrenaline (1:100,000), Ultrasonic scaler, Curettes, Ornidazole gel (ClorniTM), Chlorhexidine gel (HexigelTM).

Study design

The chronic periodontitis patients having probing pocket depth ≥ 3 mm were randomly divided into Group A, Group B, and Group C by a systematic sampling method in which every 5th subject was selected and recruited alternatively in each group as follows:

- Group A: Scaling and Root planing, followed by application of Ornidazole gel.
- Group B: Scaling and Root planing, followed by application of Chlorhexidine gel.
- Group C: Scaling and Root planing alone.

The patients following Phase I therapy were given oral hygiene instructions and taught Bass method of tooth brushing.

Clinical parameters:

The following clinical parameters were recorded at baseline (day zero), 1 month and 3 months. The patients were advised to apply the gel for 14 days post phase I therapy.

- Plaque Index (P.I.) (TURESKEY-GILMORE-GLICKMAN MODIFICATION OF QUIGLEY HEIN¹⁰).
- Gingival Index (G.I.) (LOE & SILNESS¹¹).

The following parameters were recorded at baseline (day zero), and 3 months.

- Probing Pocket Depth (PPD).

4. Clinical Attachment Level (CAL).

Procedure:

Following initial examination and treatment planning, the selected subjects underwent thorough scaling and root planing (SRP) with or without local anaesthesia. If local anaesthesia was required, then working site was infiltrated with 1ml of anaesthetic solution with/without adrenaline (1:200000). If any trauma from occlusion (TFO) was detected, it was relieved. A detailed instructions regarding self-performed plaque control measures was given. The patients were instructed to take a pea sized amount of gel on finger and apply to the gingiva twice daily and leave it for 10 minutes on affected area for 14 days of post phase I therapy, whereas Group C was used as a control group and only Scaling and Root Planing was done with or without local anaesthesia. The clinical parameters were evaluated at baseline, after 1 month and 3 months and Probing Pocket Depth and Clinical Attachment Level was evaluated at baseline and at the end of 3 months.

Inclusion criteria

- Age group between 25-55 years
- Patients having chronic periodontitis that is periodontal pocket or loss of clinical attachment.
- Patients in good systemic health
- Patients having probing pocket depths of ≥ 3 mm.
- Patients who have not received any type of periodontal therapy in the past 6 months.

Exclusion criteria

- Patients suffering from any systemic diseases like bleeding disorder, diabetes mellitus and thyroid disorders.
- Patients with a known history of allergy to ornidazole or chlorhexidine.
- Patients showing unacceptable oral hygiene compliance during/after the phase I therapy.
- Patients taking any drug known to cause gingival enlargement.
- Pregnant and/or lactating mothers.
- Patient on anticoagulant therapy and immunosuppressive drugs like corticosteroids.

Observations and results

The present study evaluated and compared the clinical efficacy of Ornidazole Gel and Chlorhexidine Gel as an adjunct to scaling and root planing in chronic periodontitis patients.

The study consisted of 90 (51 males and 39 females) patients in the age group of 25 – 55 years having mean age of 34.82 years who were divided into three groups. Group A consisted 30 (15 males and 15 females) patients, Group B consisted 30 (21 males and 9 females) patients and Group C consisted 30 (15 males and 15 females) patients. Patients

were randomly selected by a systematic sampling method in which every 5th subject was selected and recruited alternatively in each group from the outpatient department of Periodontics.

- a) Group A: Scaling and Root planing, followed by application of Ornidazole gel.
- b) Group B: Scaling and Root planing, followed by application of Chlorhexidine gel.
- c) Group C: Scaling and Root planing alone.

All patients were compliant. The overall results including baseline recordings with final outcomes are displayed in the form of tables and graphs for all the parameters.

Effect of Ornidazole on Plaque Index (P.I)

Table 1: Plaque Index (P.I.): Data Summary (Group A)

| | MEAN | SD | P* | POST-HOC TEST** VALUE |
|-------------|--------|--------|-------|--------------------------|
| PI BASELINE | 3.5097 | .96937 | <0.01 | BL>1MONTH>3MONTH |
| 1 MONTH | 2.1907 | .84029 | | |
| 3 MONTH | 1.4793 | .58949 | | |

Effect of Chlorhexidine on Plaque Index (P.I)

Table 2: Plaque Index (P.I.): Data Summary (Group B)

| | MEAN | SD | P* | POST-HOC TEST** VALUE |
|-------------|--------|--------|-------|--------------------------|
| PI BASELINE | 3.9240 | .89910 | <0.01 | BL>1MONTH>3MONTH |
| 1 MONTH | 2.5030 | .74073 | | |
| 3 MONTH | 1.7207 | .54261 | | |

Effect of Scaling and Root Planing on Plaque Index (P.I)

Table 3: Plaque Index (P.I.): Data Summary (Group C)

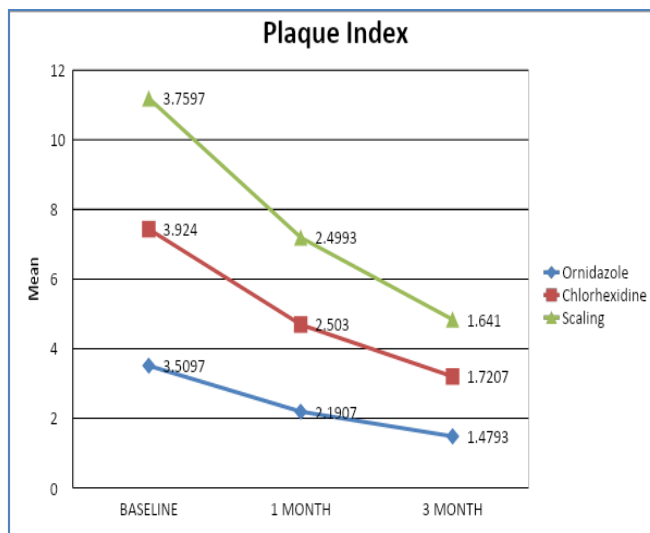
| | MEAN | SD | P* | POST-HOC TEST** VALUE |
|-------------|--------|--------|-------|--------------------------|
| PI BASELINE | 3.7597 | .75247 | <0.01 | BL>1MONTH>3MONTH |
| 1 MONTH | 2.4993 | .71713 | | |
| 3 MONTH | 1.6410 | .51541 | | |

Table 4: Comparison of mean Plaque Index between Study groups (Group A, Group B and Group C)

| | N | Mean | Std. Deviation | P* | POST-HOC TEST** |
|----------------------------------|----|--------|----------------|------|-----------------|
| PI(BL) Ornidazole (Group A) | 30 | 3.5097 | .96937 | | |
| Chlorhexidine (Group B) | 30 | 3.9240 | .89910 | 0.19 | A=B=C |
| Scaling & Root Planing (Group C) | 30 | 3.7597 | .75247 | | |
| Total | 90 | 3.7311 | .88512 | | |

| | | | | | | |
|-------------|----------------------------------|----|--------|--------|------|-------|
| PI(1 MONTH) | Ornidazole (Group A) | 30 | 2.1907 | .84029 | 0.20 | A=B=C |
| | Chlorhexidine (Group B) | 30 | 2.5030 | .74073 | | |
| | Scaling & Root Planing (Group C) | 30 | 2.4993 | .71713 | | |
| | Total | 90 | 2.3977 | .77337 | | |

| | N | Mean | Std. Deviation | P* | POST-HOC TEST** | |
|--------------|----------------------------------|------|----------------|--------|-----------------|-------|
| PI(3 MONTHS) | Ornidazole (Group A) | 30 | 1.4793 | .58949 | 0.22 | A=B=C |
| | Chlorhexidine (Group B) | 30 | 1.7207 | .54261 | | |
| | Scaling & Root Planing (Group C) | 30 | 1.6410 | .51541 | | |
| | Total | 90 | 1.6137 | .55310 | | |



Graph 1: Comparison of mean Plaque Index between Study groups (Group A, Group B and Group C)

A, Group B and Group C)

Since the Plaque Indices were observed repeatedly at three time points, repeated measures statistical analysis was done. The parametric tests (post – hoc test, ANOVA for three or more groups) were chosen for statistical analysis. There was a significant decrease in the plaque index between baseline, 1 month and 3rd month in all the experimental groups. The P value was <0.05 for all the three experimental groups. (Table 1, Table 2 and Table 3). (Table 4 and Graph 1) show inter-group comparison of the mean plaque index. One-way ANOVA test & Post-hoc Tukey’s test showed no significant difference between three groups (p>0.05).

Effect of Ornidazole on Gingival Index (G.I)

Table 5: Gingival Index (G.I): Data Summary (Group A)

| | | MEAN | SD | P* | POST-HOC TEST** VALUE |
|----|----------|--------|--------|-------|--------------------------|
| GI | BASELINE | 1.6497 | .16849 | <0.01 | BL>1MONTH>3MONTH |
| | 1 MONTH | .7830 | .30427 | | |
| | 3 MONTH | .3650 | .23627 | | |

Effect of Chlorhexidine on Gingival Index (G.I)

Table 6: Gingival Index (G.I): Data Summary (Group B)

| | | MEAN | SD | P* | POST-HOC TEST** VALUE |
|----|----------|--------|--------|-------|--------------------------|
| GI | BASELINE | 1.6867 | .34895 | <0.01 | BL>1MONTH>3MONTH |
| | 1 MONTH | .7394 | .34638 | | |
| | 3 MONTH | .3077 | .18243 | | |

Effect of Scaling on Gingival Index (G.I)

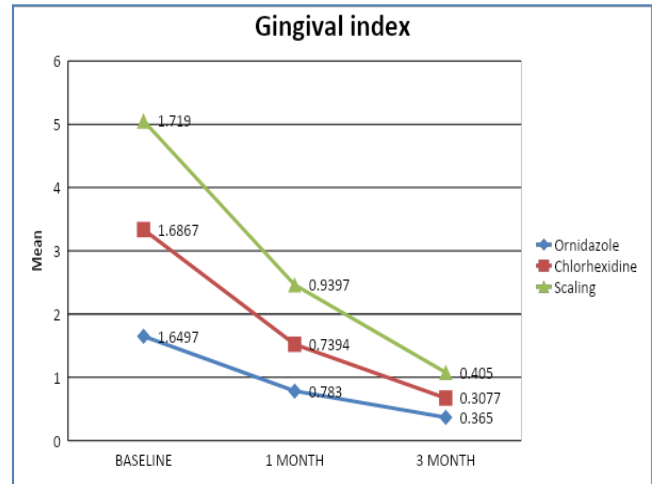
Table 7: GINGIVAL Index (G.I): Data Summary (Group C)

| | | MEAN | SD | P* | POST-HOC TEST** VALUE |
|----|----------|--------|--------|-------|--------------------------|
| GI | BASELINE | 1.7190 | .12896 | <0.01 | BL>1MONTH>3MONTH |
| | 1 MONTH | .9397 | .30487 | | |
| | 3 MONTH | .4050 | .22342 | | |

Table 8: Comparison of mean Gingival Index between Study groups (Group A, Group B and Group C)

| | | N | Mean | Std. Deviation | P* | POST-HOC TEST** |
|---------|----------------------------------|----|--------|----------------|------|-----------------|
| GI(BL) | Ornidazole (Group A) | 30 | 1.6497 | .16849 | 0.52 | A=B=C |
| | Chlorhexidine (Group B) | 30 | 1.6867 | .34895 | | |
| | Scaling & Root Planing (Group C) | 30 | 1.7190 | .12896 | | |
| | Total | 90 | 1.6851 | .23486 | | |
| GI(1 M) | Ornidazole (Group A) | 30 | .7830 | .30427 | 0.04 | (A=B)<C |
| | Chlorhexidine (Group B) | 30 | .7394 | .34638 | | |
| | Scaling & Root Planing (Group C) | 30 | .9397 | .30487 | | |
| | Total | 90 | .8207 | .32715 | | |
| GI(3 M) | Ornidazole (Group A) | 30 | .3650 | .23627 | | |
| | Chlorhexidine (Group B) | 30 | .3077 | .18243 | | |
| | Scaling & Root Planing (Group C) | 30 | .4050 | .22342 | | |
| | Total | 90 | .3592 | .21659 | | |

| | | | MEAN | SD | P* | POST-HOC TEST** |
|--------|----------------------------------|----|-------|--------|------|-----------------|
| GI(3M) | Ornidazole (Group A) | 30 | .3650 | .23627 | 0.21 | A=B=C |
| | Chlorhexidine (Group B) | 30 | .3077 | .18243 | | |
| | Scaling & Root Planing (Group C) | 30 | .4050 | .22342 | | |
| | Total | 90 | .3592 | .21659 | | |



graph 2: Comparison of mean Gingival Index between Study groups (Group A, Group B and Group C)

Since the gingival Indices were observed repeatedly at three time points, repeated measures statistical analysis was done. The parametric tests (post – hoc test, ANOVA for three or more groups) were chosen for statistical analysis. There was a significant decrease in the gingival index between baseline, 1 month and 3rd month in all the experimental groups. The P value was <0.05 for all the three experimental groups. (Table 5, Table 6 and Table 7). (Table 8 and Graph 2) show inter-group comparison of the mean gingival index. One-way ANOVA test & Post-hoc Tukey’s test showed no significant difference between three groups (p>0.05).

Effect of Ornidazole on Probing Pocket Depth

Table 9: Probing Pocket Depth (PPD): Data Summary (Group A)

| | | MEAN | SD | P* VALUE | POST-HOC TEST** |
|-----|----------|--------|--------|----------|-----------------|
| PPD | BASELINE | 3.3117 | .29446 | <0.01 | |
| | 3 MONTH | .8863 | .83733 | | |

Effect of Ornidazole on Probing Pocket Depth

Table 10: Probing Pocket Depth (PPD): Data Summary (Group B)

| | | MEAN | SD | P* VALUE | POST-HOC TEST** |
|-----|----------|--------|--------|----------|-----------------|
| PPD | BASELINE | 3.3390 | .52420 | <0.01 | |
| | 3 MONTH | .6113 | .93461 | | |

Effect of Ornidazole on Probing Pocket Depth

Table 11: Probing Pocket Depth (PPD): Data Summary (Group C)

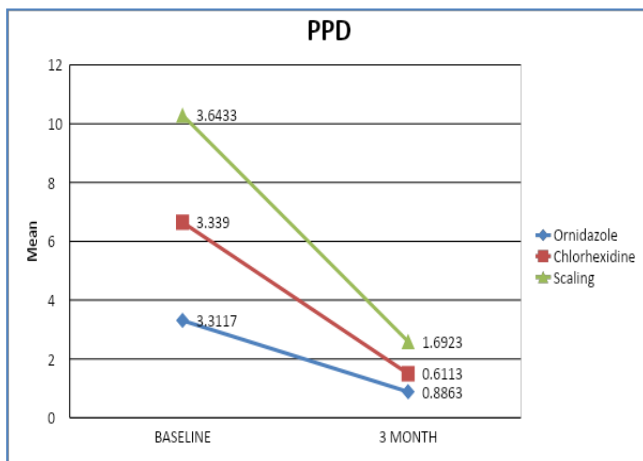
| | | MEAN | SD | P* VALUE | POST-HOC TEST** |
|-----|----------|--------|--------|----------|-----------------|
| PPD | BASELINE | 3.3390 | .52420 | <0.01 | |
| | 3 MONTH | .6113 | .93461 | | |

| | MEAN | SD | P* | POST-HOC |
|--------------|--------|--------|-----------------|----------|
| | | | VALUE | TEST** |
| PPD BASELINE | 3.6433 | .98357 | <0.01 | |
| 3 MONTH | 1.6923 | 1.2790 | | |

Table 12: Comparison of mean Probing Pocket Depth between Study groups (Group A, Group B and Group C)

| | N | Mean | Std. Deviation | P* | POST-HOC TEST** |
|----------------------------------|----|--------|----------------|------|-----------------|
| PPD(bl) Ornidazole (Group A) | 30 | 3.3117 | .29446 | 0.10 | A=B=C |
| Chlorhexidine (Group B) | 30 | 3.3390 | .52420 | | |
| Scaling & Root Planing (Group C) | 30 | 3.6433 | .98357 | | |
| Total | 90 | 3.4313 | .67518 | | |

| | N | Mean | Std. Deviation | P* | POST-HOC TEST** |
|----------------------------------|----|--------|----------------|--------------|-----------------|
| PPD(3m) Ornidazole (Group A) | 30 | .8863 | .83733 | 0.025 | (A=B)<C |
| Chlorhexidine (Group B) | 30 | .6113 | .93461 | | |
| Scaling & Root planing (Group C) | 30 | 1.6923 | 1.2790 | | |
| Total | 90 | .8652 | .98470 | | |



GRAPH 3: Comparison of mean Probing Pocket Depth between Study groups (Group A, Group B and Group C)

Since the probing pocket depth was observed repeatedly at two time points, repeated measures statistical analysis was done. The parametric tests (post – hoc test, ANOVA for three or more groups) were chosen for statistical analysis. There was a significant decrease in the probing pocket depth between baseline and 3rd month in all the experimental groups. The P value was <0.05 for all the three experimental groups. (Table 9, Table 10 and Table 11).

(Table 12 and Graph 3) show inter-group comparison of the mean probing pocket depth. One-way ANOVA test showed significant difference between three groups (p<0.05). Post-hoc Tukey’s test showed that scaling group had significantly higher mean probing pocket depth score as compared to ornidazole & chlorhexidine group (p<0.05).

Effect of Ornidazole on Clinical Attachment Level (CAL)

Table 13: Clinical Attachment Level (CAL): Data Summary (Group A)

| | MEAN | SD | P* VALUE | POST-HOC TEST** |
|--------------|--------|--------|-----------------|-----------------|
| CAL BASELINE | 3.3070 | .62574 | <0.01 | |
| 3 MONTH | 2.6723 | .53178 | | |

Effect of Chlorhexidine on Clinical Attachment Level (CAL)

Table 14: Clinical Attachment Level (CAL): Data Summary (Group B)

| | MEAN | SD | P* VALUE | POST-HOC TEST** |
|--------------|--------|--------|-----------------|-----------------|
| CAL BASELINE | 3.0310 | .63309 | <0.01 | |
| 3 MONTH | 2.5087 | .53644 | | |

Effect of Scaling on Clinical Attachment Level (CAL)

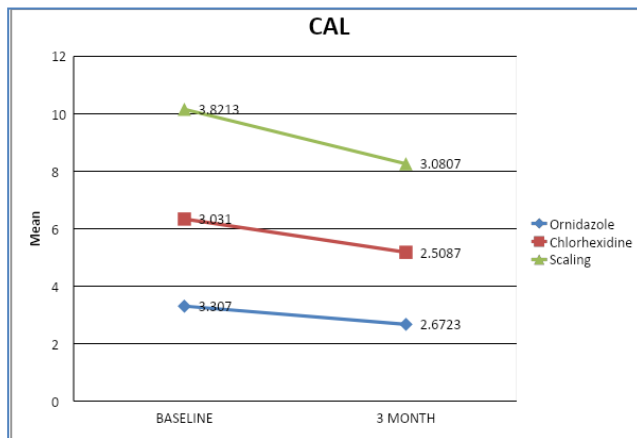
Table 15: Clinical Attachment Level (CAL): Data Summary (Group C)

| | MEAN | SD | P* | POST-HOC |
|--------------|--------|---------|-----------------|----------|
| | | | VALUE | TEST** |
| CAL BASELINE | 3.8213 | 1.37379 | <0.01 | |
| 3 MONTH | 3.0807 | 1.00188 | | |

Table 16: Comparison of mean Clinical Attachment Level (CAL) between Study groups (Group A, Group B and Group C)

| | N | Mean | Std. Deviation | P* | POST-HOC TEST** |
|----------------------------------|----|--------|----------------|--------------|-----------------|
| CAL(BL) Ornidazole (Group A) | 30 | 3.3070 | .62574 | 0.006 | (A=B)<C |
| Chlorhexidine (Group B) | 30 | 3.0310 | .63309 | | |
| Scaling & Root planing (Group C) | 30 | 3.8213 | 1.37379 | | |
| Total | 90 | 3.3864 | .99076 | | |

| | N | Mean | Std. Deviation | P* VALUE | POST-HOC TEST** |
|----------------------------------|----|--------|----------------|--------------|-----------------|
| CAL (3M) Ornidazole (Group A) | 30 | 2.6723 | .53178 | 0.009 | (A=B)<C |
| Chlorhexidine (Group B) | 30 | 2.5087 | .53644 | | |
| Scaling & Root Planing (Group C) | 30 | 3.0807 | 1.00188 | | |
| Total | 90 | 2.7539 | .75597 | | |



Graph 4: Comparison of mean Clinical Attachment Level (CAL) between Study groups (Group A, Group B and Group C)

Since the clinical attachment level were observed repeatedly at two time points, repeated measures statistical analysis was done. The parametric tests (post – hoc test, ANOVA for three or more groups) were chosen for statistical analysis. There was a significant decrease in the clinical attachment level between baseline and 3rd month in all the experimental groups. The P value was <0.05 for all the three experimental groups. (Table 13, Table 14 and Table 15). (Table 16 and Graph 4) show inter-group comparison of the mean clinical attachment level. One-way ANOVA test showed significant difference between three groups ($p < 0.05$). Post-hoc Tukey's test showed that scaling group had significantly higher mean clinical attachment level score as compared to ornidazole & chlorhexidine group ($p < 0.05$).

Discussion

The present clinical study evaluates and compare the efficacy of Ornidazole Gel with Chlorhexidine Gel as an adjunct to scaling in chronic periodontitis patients.

Periodontal disease is a host-derived inflammatory disease and multifactorial in origin. Treatment of periodontal disease is routinely based on mechanical debridement of the tooth surface and appropriate and meticulous maintenance of oral hygiene. As an adjunctive approach, systemic or local administration of antimicrobials is used because of the microbial etiology of periodontitis. Topical administration of antibacterial agents in the form of mouthwashes, dentifrice or gels can be used effectively in controlling supra-gingival plaque formation.¹²

To the best of our knowledge, no comparative evaluation has been done to check the efficacy of Ornidazole Gel with Chlorhexidine Gel as an adjunct to scaling in chronic periodontitis patients. The purpose of this study is to compare Ornidazole Gel with Chlorhexidine Gel as an adjunct to scaling in chronic periodontitis patients.

Patients with good systemic health and no contraindications to periodontal therapy were selected, since patients suffering from systemic diseases like uncontrolled diabetes mellitus or

patients on immunosuppressive therapy, almost always show poor response to the periodontal therapy.¹³

Hormonal fluctuations in the female patient may alter the status of periodontal health and affect the treatment outcome. The most pronounced periodontal changes occur during pregnancy and lactation. Treatment considerations for pregnant patients with periodontal disease may include deferral of periodontal therapy until after parturition.¹⁴ Hence, pregnant and lactating females were excluded from the study.

Smoking status has repeatedly shown to detrimentally affect the clinical outcomes of different periodontal procedures. In study of patients with untreated advanced periodontal disease Renvert *et al.* (1998)¹⁵ concluded that non-surgical therapy resulted in significantly lesser mean reduction in pocket depth and bleeding on probing in smokers than in non-smokers when evaluated six months after the therapy.

In the present study the chronic periodontitis patients having probing pocket depth ≥ 3 mm were randomly divided into Group A, Group B, and Group C by a systematic sampling method in which every 5th subject was selected and recruited alternatively in each group as follows:

- Group A: Scaling and Root planing, followed by application of Ornidazole gel.
- Group B: Scaling and Root planing, followed by application of Chlorhexidine gel.
- Group C: Scaling and Root planing alone.

All the patients following Phase I therapy were given oral hygiene instructions and taught Bass method of tooth brushing with standard toothpaste and soft toothbrush.

Clinical parameters like plaque index, gingival index, probing pocket depth and clinical attachment level were evaluated.

Clinical parameters

Plaque index (Turesky S. Gilmore N.D. and Glickman I. modification of Quigley-Hein in 1970)¹⁰ indicates the oral hygiene maintained by patient and is important because it can influence the periodontal outcome. Plaque scores were evaluated at baseline, 1, 3 months post phase I therapy.

Experimental Group A

The mean plaque index score for patients in group A at baseline was 3.50 ± 0.97 which was reduced to 2.19 ± 0.84 at 1 month from baseline, 1.48 ± 0.59 at 3 months from baseline. There was statistically significant difference between baseline, 1 month & 3 months follow-up ($p < 0.05$). Post-hoc Tukey's test showed significant reduction in plaque index score from baseline to 3 months follow-up ($p < 0.05$). (Table 1)

Experimental Group B

The mean plaque index score for patient in group B was 3.92 ± 0.90 at baseline, 2.50 ± 0.74 at 1 month, 1.72 ± 0.54 at end of 3 months. There was statistically significant

difference between baseline, 1 month & 3 months follow-up ($p < 0.05$). Post-hoc Tukey's test showed significant reduction in plaque index score from baseline to 3 months follow-up ($p < 0.05$). (Table 2)

Experimental Group C

The mean plaque index score for patient in group C group was 3.76 ± 0.75 at baseline, 2.50 ± 0.72 at 1 month, 1.64 ± 0.52 at end of 3 months. There was statistically significant difference between baseline, 1 month & 3 months follow-up ($p < 0.05$). Post-hoc Tukey's test showed significant reduction in plaque index score from baseline to 3 months follow-up ($p < 0.05$). (Table 3)

Comparison between the groups

When results of three groups were compared, no statistically significant difference was observed. (Table 4 and Graph 1) Thus, it can be concluded that in three groups, statistically significant reduction in plaque index was observed from the baseline to 3 months within the groups. However, there was no statistically significant difference observed when the three groups were compared with each other. This demonstrates that all the treatment modalities result in comparable reduction in the plaque scores of the patients.

A general trend of progressive decline in plaque index scores over the duration of the study was seen. This could be due to the repeated reinforcement of oral hygiene habits in recall visits and overall general improvement in periodontal parameters. Similar trend in reduction of the plaque index was observed in a study conducted by Mirzadeh *et al.* (2014)¹⁶

Gingival Index (GI) (Loe & Silness 1963)¹¹ is considered to be a true reflection of gingival status in health and disease. It is simple, easy and reproducible index and is used commonly in clinical periodontal research studies. Gingival index scores were evaluated at baseline, 1, and 3 months post-phase I therapy.

Experimental Group A

The mean gingival index score for patients in the group A was 1.64 ± 0.17 at baseline, 0.78 ± 0.30 at 1 month and 0.37 ± 0.24 at end of 3 months. There was statistically significant difference between baseline, 1 month & 3 months follow-up ($p < 0.05$). Post-hoc Tukey's test showed significant reduction in plaque index score from baseline to 3 months follow-up ($p < 0.05$). (Table 5)

Experimental Group B

The mean gingival index score for patient in the group B group was 1.69 ± 0.35 at baseline, 0.74 ± 0.35 at 1 month and 0.31 ± 0.18 at end of 3 months. There was statistically significant difference between baseline, 1 month & 3 months follow-up ($p < 0.05$). Post-hoc Tukey's test showed significant reduction in plaque index score from baseline to 3 months follow-up ($p < 0.05$). (Table 6)

Experimental Group C

The mean gingival index score for patient in the group C group was 1.72 ± 0.13 at baseline, 0.94 ± 0.30 at 1 month and 0.41 ± 0.22 at end of 3 months. There was statistically significant difference between baseline, 1 month & 3 months follow-up ($p < 0.05$). Post-hoc Tukey's test showed significant reduction in plaque index score from baseline to 3 months follow-up ($p < 0.05$). (Table 7)

Comparison between the groups

When results of all the groups were compared, after 1 month no statistically significant difference was observed between groups A and B, but both the groups had significant reduction in gingival index score when compared to group C. (Table 8 and Graph 2)

After 3 months no statistically significant difference was seen when all three groups were compared.

Thus it can be said that in all groups, statistically significant reduction in gingival index was observed from the baseline to 3 months within the groups. After 1 month both group A and group B had statistically significant reduction in gingival index as compared to group C. This demonstrates the efficacy of ornidazole gel and chlorhexidine gel when used as adjunct to scaling and root planing. This finding are similar to studies done by Roopa *et al.* (2016)¹⁷ and Loe H and Schiott C.R. (1970)¹⁸. However, there was no statistically significant difference observed when all the groups were compared to each other after 3 months. This finding are similar to studies done by Mishra *et al.* (2015)¹⁹. This demonstrates that all three treatment modalities result in comparable reduction in the gingival index scores of the patients.

A general trend of progressive decline in gingival index scores over the duration of the study was seen. As with plaque index, this could also be due to the repeated reinforcement of oral hygiene habits in recall visits and overall general improvement in periodontal parameters.

Probing pocket depth

Periodontal pocket is considered as pathognomic sign of periodontal disease, whereas the probing pocket depth is considered as the yardstick for evaluating the success of periodontal therapy. It is the distance between the gingival margin to the probe tip during periodontal probing. It becomes an important variable to be measured for the long-term maintenance of periodontal health.

Experimental Group A

The mean probing pocket depth (in mm) for patient in the group A was 3.31 ± 0.29 at baseline and 0.89 ± 0.84 at 3 months respectively, and the difference was found to be statistically significant. ($P < 0.05$) (Table 9)

Experimental Group B

The mean probing pocket depth (in mm) for patient in the Group B group was 3.34 ± 0.52 at baseline and 0.61 ± 0.93 at 3 months respectively, and the difference was found to be statistically significant. ($P < 0.05$) (Table 10)

Experimental Group C

The mean probing pocket depth (in mm) for patient in the Group C group was 3.64 ± 0.98 at baseline and 1.69 ± 1.27 at 3 months respectively, and the difference was found to be statistically significant. ($P < 0.05$) (Table 11)

Comparison between the Groups

When results of all the groups were compared, after 3 months no statistically significant difference was observed between group A and B, but both the groups had The mean patient Clinical Attachment Level (in mm) in Group A was 3.30 ± 0.63 at baseline and 2.67 ± 0.53 at 3 months respectively and the difference was found to be statistically significant. ($P < 0.05$) (Table 13)

Experimental Group B

The mean patient Clinical Attachment Level (in mm) in group B group was 3.03 statistically significant reduction in probing pocket depth score when compared to group C. (Table 12 and Graph 3) This findings are similar to the study done by Kinane et al. (1999)²⁰.

The primary reason for reduction in probing pocket depth after the treatment can be attributed to the reduction in inflammation and shrinkage of pocket wall. It can also occur due to combination of gain in clinical attachment as well as because of post treatment gingival recession. It has been reported that plaque removal by scaling and root planing decreases as pocket depth increases (Waerhaug 1978).²¹

Clinical attachment level

Clinical attachment level is widely accepted as one of the primary clinical end point of periodontal therapy. It is the distance between the cemento-enamel junction of tooth to the probe tip during periodontal probing. (Caton and Greenstein 1994).²²

Experimental Group A

The mean patient Clinical Attachment Level (in mm) in group B group was 3.03 ± 0.63 at baseline and 2.51 ± 0.54 at 3 months respectively and the difference was found to be statistically significant. ($P < 0.05$) (Table 14)

Experimental Group C

The mean patient Clinical Attachment Level (in mm) in group C group was 3.82 ± 1.37 at baseline and 3.08 ± 1.00 at 3 months respectively and the difference was found to be statistically significant. ($P < 0.05$) (Table 15)

Comparison between the groups

When results of all the groups was compared after 3 months no statistically significant difference was observed between group A and B, but both the groups had statistically significant reduction in clinical attachment level score when compared to group C. (Table 16 & Graph 4)

Thus it can be said that in all groups, statistically significant reduction in CAL was observed from the baseline to 3 months within the groups. After 3 months both group A and

group B had statistically significant reduction in clinical attachment level as compared to group C. This demonstrates the efficacy of ornidazole gel and chlorhexidine gel when used as adjunct to scaling and root planing.

Limitation of the present study:

At the end of the study, it has been observed that there have been certain aspects, which demand more detailed observation and elucidation of data and facts.

- A larger sample size would have been preferable with a more long-term follow up.
- An evaluation of microbiological parameters should have been carried out to know the minimal inhibitory concentration of the periodontal pathogens.
- Paired or split mouth design would have excluded the influence of patients' specific characteristics and facilitated the interpretation of the study by minimizing the effects of inter-patient variability.
- Among the patients enrolled in the study, not all patient were regular for follow-up. There were dropouts which were accounted for my enrolling new patients.

Conclusion

The Clinical evaluation was suggestive of the fact that both Ornidazole gel and Chlorhexidine gel were biocompatible with the tissues. They did not cause any biological complications and therefore could be safely used. The plaque and gingival index decreased in all the three groups when compared within the groups. This indicates an overall improvement in oral hygiene status of patients. The reduction in gingival index score was statistically significant after topical application of both Ornidazole gel and Chlorhexidine gel as compared to scaling and root planing alone when evaluated after 1 month. The Gingival Index values after 3 months were comparable for all the groups. This demonstrates the efficacy of adjunctive use of both the gels over scaling and root planing with respect to initial healing after 1 month. Reduction in probing pocket depth and gain in clinical attachment levels were significant within the groups from baseline to 3 months. When comparison was made between the groups with respect to the reduction in PPD and CAL values, the reduction observed in group A and B was statistically non-significant. When groups A and B were compared with group C there was statistically significant reduction in group A and B than group C after 3 months. It can be concluded that the Adjunctive use of Ornidazole and Chlorhexidine caused improvement in clinical parameters. Long term evaluation of the sites is recommended to evaluate the sustainability of the results.

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